PMOS Information

Title	Prospective, non-interventional observation study for the use of palivizumab in high-risk children in Germany- SYNAGIS
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Joint PASS	N/A
Research Question and Objectives	The objectives of this post-marketing surveillance of Synagis® were: • To determine Synagis® usage patterns in infants under risk for RSV • To determine RSV hospitalization rates among Synagis® infants • To determine compliance rates among parents of Synagis® infants • To determine Synagis® usage in the German healthcare system • To understand demographics of Synagis® infants • To further evaluate the impact of risk factors
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Marketing Authorisation Holder(s)

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1.0 Abstract

Title

Prospective, non-interventional observation study for the use of palivizumab in high-risk children in Germany – SYNAGIS

Keywords

Palivizumab, respiratory syncytial virus, high-risk children, hospitalization rate, Germany

Rationale and Background

Respiratory syncytial virus (RSV) is the most common cause of childhood acute lower respiratory tract infections, and a major cause of admission to pediatric hospitals. The clinical spectrum of RSV-related respiratory diseases is broad and ranges from self-limiting upper airway infections to severe lower respiratory tract infections (LRTI) that may require admission to intensive care unit (ICU). RSV ranks among the top causes of death in childhood from acute LRTI. In Germany, RSV's high contagiosity and its effective mode of transmission results in very high numbers of infected individuals during RSV season, which usually occurs in the cold months between autumn and spring.

Palivizumab (Synagis®), a humanized monoclonal antibody against an epitope of RSV envelope fusion protein, has been granted European approval since 1999 for the prevention of serious LRTI in children at high risk for serious RSV disease.

The SYNAGIS Registry was carried out in order to gather comprehensive real-world data on the use of palivizumab in high-risk children. This registry was designed as a post-marketing observational study, and conducted from 2002-2016 with the aim of collecting data on palivizumab administration, the risk factors for a complicated RSV disease, frequency of hospitalizations, and drug adherence. In the course of the years, the registry was amended several times in order to acknowledge changes such as the expansion of the palivizumab label or new scientific information on risk factors for severe LRTI. A detailed overview of the changes is listed in the Appendix.

Research Question and Objectives

The objectives of this post-marketing surveillance of Synagis® were

- To determine Synagis® usage patterns in infants under risk for RSV
- To determine RSV hospitalization rates among Synagis® infants
- To determine compliance rates among parents of Synagis® infants
- To determine Synagis® usage in the German healthcare system
- To understand demographics of Synagis® infants
- To further evaluate the impact of risk factors

Study Design

This post-marketing observational study (PMOS) was conducted in a prospective, single-arm, multicenter format in Germany according to the amended protocol dated April 2006.

Setting

This post-marketing observational study was conducted in Germany. Primary care pediatricians from hospital outpatient facilities and neonatologists from inpatient facilities were invited to participate in this study and enrolled subjects into the registry at their discretion.

Subjects and Study Size, Including Dropouts

Eligible subjects were infants and children, in whom the attending neonatologist or pediatrician decided to use palivizumab prophylaxis to prevent serious disease due to RSV infection during the current RSV season. These were to be treated according to the German summary of product characteristics (SPC) “Fachinformation” for Synagis®.

Summarized over all seasons, data from 30804 subjects was entered into the registry. Of these, 29468 were considered for analysis since they were verifiably treated with Synagis® according to the SPC.

Variables and Data Sources

All study data (baseline characteristics, risk factors, immunoprophylaxis administration) were to be reported on paper-based case report forms (CRF, 2002/03 – 2007/08) or electronic case report forms (eCRF, 2008/09 – 2015/16): Hospitalization details were to be detailed on occurrence on separate hospitalization forms (2002/03 – 2007/08) or within the eCRF system (2008/09 – 2015/16).

Results

In total, 142723 injections of palivizumab were documented in 29468 evaluable subjects during the observational period. Results of the German SYNAGIS Registry were subdivided into three parts due to procedural changes including changes in the methods of study data reporting during the conduct of the study: (i) seasons 2002/03 – 2006/07, (ii) 2007/08 and 2008/09, and (iii) 2009/10 – 2015/16. Mean age of subjects upon start of immunoprophylaxis with palivizumab was between 4.3 and 5.9 months; there was a slight male preponderance in study participants (53.8%-55.1% males). Median number of palivizumab administrations for all study periods was 5 (range: 1-12). A high proportion of subjects received more than 5 palivizumab injections during the corresponding RSV season (35%-45%).

On the assumption that no multiple RSV-related hospitalization occurred per infant, the RSV-related hospitalization rates were 0.7%-1.6% (according to discharge diagnosis of the treating physician). These rates are still inside the expected margins derived from prospectively randomized trials [1-3].

The decisions of the participating physicians to administer palivizumab prophylaxis to an individual patient were based on underlying risk factors [4], and on the official German recommendations for passive immunization against RSV in neonates: Most evaluable subjects were prematurely born, with a median gestational age at birth between 29 and 32 weeks. A significant proportion (18.9%-42.6%) had CLD (BPD). Medical treatment of CLD in the 6 months preceding the first administration of palivizumab was documented from 2008/09 in 12.5%-14.7% of subjects per study period.

Between 25.2% and 34.9% of subjects were diagnosed with CHD. Hemodynamically significant congenital heart disease (hsCHD) was added to the list of recommended indications for palivizumab in Germany in 2004. Starting in 2008/09, the investigators could indicate whether hsCHD was the main reason for prophylaxis; this was documented in 13%-14.1% of subjects. The overall hospitalization rate for subjects passively immunized with palivizumab and CHD in the German SYNAGIS Registry

2009-2016 was 3.4% (n = 118); the corresponding average number of RSV-related hospitalizations in subjects with CHD diagnosis was 0.8% (n = 26).

The overall compliance/adherence of the parents of evaluable subjects with the palivizumab administration regimen [5, 6] was good in 91.1 – 93.5% of cases (documented per injection commencing in 2008/09 and documented per infant from 2002/03 to 2007/08).

Safety information was documented in the CRFs and by means of separate adverse event reporting forms. Detailed information on adverse events (terms, serious criteria, outcome etc.) were not included in the study database, but were still captured and processed by AbbVie pharmacovigilance. Most frequent events were infections of the respiratory system. Review of the safety data indicates that the majority of the SAEs were not unexpected for the pediatric patients with significant medical conditions (i.e., prematurity, bronchopulmonary dysplasia/chronic lung disease, or CHD) indicated for palivizumab.

Discussion

This report on the results of the German SYNAGIS Registry comprises one of the largest prospectively documented datasets on children receiving at least one dose of palivizumab during the corresponding RSV season. Notwithstanding, not all infants and children who received palivizumab prophylaxis against LRTI RSV-infection during the observational period could be included in this registry. Therefore, the results presented in this report cannot be used to calculate the real number of subjects on palivizumab prophylaxis in Germany.

The results of the German SYNAGIS Registry confirm the effectiveness of palivizumab prophylaxis in concordance with published reports from other palivizumab registries (recently reviewed by Paes et al. [7]). Despite the lack of comprehensive safety reporting during this registry, the good adherence rates suggest a favorable tolerability profile of palivizumab.

Marketing Authorisation Holder(s)

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2.0 List of Abbreviations

AAP	American Academy of Pediatrics
ADR	Adverse Drug Reaction
AE	Adverse Event
BPD	Bronchopulmonary Dysplasia
CHD	Congenital Heart Defect
CI	Confidence Interval
CLD	Chronic Lung Disease
CRO	Contract Research Organization
DGPI	German society of Pediatric Infectious Diseases
DGPK	German Society of Pediatric Cardiology
DS	Down syndrome
eCRF	Electronic Case Report Form
EMEA	European Agency for the Evaluation of Medicinal Products
EMA	European Medicines Agency
EVP	Evaluable Population
GA	Gestational Age
[redacted]	[redacted]
GNPI	German Society of Neonatal and Pediatric Intensive Care Medicine
HmPV	Human Metapneumovirus
hsCHD	Hemodynamically significant Congenital Heart Disease
ICD-9 CM	International Classification of Diseases, 9th Revision, Clinical Modification
ICU	Intensive Care Unit
IMBEI	Institute for Medical Biostatistics, Epidemiology and Informatics
IQR	Interquartile Range
LOCF	Last-Observation-Carried-Forward
LRTI	Lower Respiratory Tract Infection
LSLV	Last Subject Last Visit
MedDRA	Medical Dictionary for Regulatory Activities
NEP	Non-Evaluable Population
NMI	Neuromuscular Impairment
PB	Premature Birth
PK	Pharmacokinetics
PMOS	Post-Marketing Observational Study
PV	Pharmacovigilance
RIH	Hospitalizations for Respiratory-related Illness
RNA	Ribonucleic Acid
RSV	Respiratory Syncytial Virus

RTI	Respiratory Tract Infection
RT-PCR	Reverse-Transcriptase Polymerase Chain Reaction
SAE	Serious Adverse Event
SADR	Serious Adverse Drug Reaction
SAP	Statistical Analysis Plan
SD	Standard Deviation
SOP	Standard Operating Procedures
SPC	Summary of Product Characteristics
TO	Treatment with Oxygen at home

3.0 Investigators

A list of participating investigators can be found in the Appendix A2.3.

4.0 Other Responsible Parties

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5.0 Milestones

Milestone	Planned Date	Actual Date	Comments
Start of Data Collection:	N/A	1 Sep 2002	Information contained in Insights2: 21 Nov 2007
End of Data Collection	31 Jul 2016	31 July 2016	In accordance with local requirements (LSLV of 31-July-2016)
Final Report of Study Results	31 Jan 2017	31 Jan 2017	Based on the LSLV of 31-July-2016, the deadline for submission to the EMA is 31-January-2017

6.0 Rationale and Background

Virology of RSV and modes of transmission

Respiratory Syncytial Virus (RSV), an enveloped, nonsegmented single negative-strand RNA virus, belongs to the family of *Paramyxoviridae*, genus *Pneumovirus*. RSV infects cells in the ciliated epithelium in the upper and lower respiratory tract, and type I pneumocytes in the alveoli [8, 9]. Its envelope contains three major proteins, of which the G protein is responsible for attachment of the virus to cell receptors in the ciliated outer surface of the respiratory epithelium. The F (fusion) protein is involved in fusion of the virus and cell membranes virus internalization into the epithelial cell, which is necessary to start the intracellular cycle of viral replication. Two distinct RSV subtypes (A and B) have been described; in addition, a growing number of genotypes have been defined based on genetic modifications of the G Protein.

RSV can be transmitted via direct or indirect contact and via droplets. The virus is capable of surviving on the hands of e.g., children, their caregivers or healthcare workers for approximately one hour, and for up to 4 hours on inanimate surfaces, fomites, and medical equipment such as stethoscopes [10-13]. RSV's high contagiosity and its effective mode of transmission result in very high number of infected individuals during RSV season, and explain its pre-eminent role in nosocomial outbreaks of respiratory tract infections [14-21].

Epidemiology

Globally, RSV is the most common cause of childhood acute LRTI, and a major cause of admission to pediatric hospitals. Mortality data from a recently published systematic literature review [22] reveal that RSV ranks third among the top causes of death in childhood from acute lower respiratory tract infection, after pneumococcal and *Haemophilus influenzae* type b pneumonia[1].

Stockman et al. [23] recently published the results of a retrospective analysis of hospital discharges for LRTI in children younger than 5 years of age from the National Hospital Discharge Survey 1997-2006. The final data elucidated that RSV-related hospitalizations accounted for 24% of an estimated total of 5.5 million LRTI-related hospitalizations in this age group during the 10 study years. The RSV-related hospitalization rate in infants younger than 1 year of age was 26.0 per 1000, with no significant differences between study years. The hospitalization rate was highest among infants younger than 3 months

[1]In Germany, the majority of cases concerning these two bacterial pathogens are preventable by active immunization.

(48.9 per 1000), followed by infants 3 to 5 months of age (28.4 per 1,000), and again considerably lower among those older than 1 year (1.8 per 1000). In a prospective, population-based surveillance study of acute respiratory infections among children under 5 years of age in three U.S. counties [24], 18% of 5,067 enrolled children had RSV infections. In those acute respiratory infections occurring from November through April, RSV was associated with 20% of hospitalizations, 18% of emergency department visits, and 15% of office visits. RSV is the most relevant viral pathogen responsible for respiratory tract infections (RTI) in neonates, infants and toddlers up to the age of 24 months [8, 24, 25]. During the first 12 months of life and until 24 months of age, 70% and 98% of all children have experienced at least one RSV-infection [26]. RSV infection does not result in long-term sustained protection, neither on a humoral (specific neutralizing antibodies) nor on a cellular level of acquired specific immunity (mediated by e.g., TCD3/CD8 positive cytotoxic T-cells). Thus, RSV reinfections may occur throughout life [27] but tend to present with a milder clinical course.

Clinical spectrum of RSV disease, treatment, active immunization

The clinical spectrum of RSV related respiratory disease is very broad. It ranges from self-limiting upper airway infections (common cold, sometimes complicated by acute otitis media, sinusitis or bronchitis) in otherwise healthy children and adults, croup syndrome in toddlers [9, 28], to severe LRTIs that may be associated with apnea-bradycardia syndrome in premature infants [29]. LRTIs (bronchiolitis, pneumonia, acute respiratory failure) predominantly occur in infants, yet also in severely immunocompromised people of all ages and in the frail elderly.

Children with severe RSV LRTI present with tachypnea, fever, hypoxemia [30-33] and airway obstruction (air trapping and prolonged expiration with or without audible wheezing).

Besides supportive and symptomatic care, there is still no causal treatment available to shorten the clinical course of RSV disease in hospitalized children [34-36]. In addition, no safe and effective RSV vaccine has been licensed for active immunization in infants yet. In the absence of effective active immunization against RSV infection, population level approaches to prevent severe RSV LRTI should continue to focus on reducing prenatal and environmental risk factors including prematurity, smoking and improving hygiene practices [37].

In addition to the burden of disease associated with acute illness, severe RSV-infection in early infancy may cause a protracted clinical syndrome of recurrent wheezing and airway hyper-responsiveness/reactivity in older children [3, 38-40].

Risk factors for a complicated clinical course

Most children admitted to the hospital with acute RSV LRTI are otherwise healthy infants and children, of which about 1% have to be hospitalized during their first RSV infection [41]. Notwithstanding, several risk factors for a complicated course of RSV infection have been published; many of which have only been identified recently [42-45].

Prematurely born infants (including late preterms), in particular those with a very low birthweight (< 1500 g) and a gestational age below 32 weeks with or without bronchopulmonary dysplasia (chronic lung disease of prematurity) face an increased risk of rehospitalization due to RSV-infection during the first 2 years of life [46-55].

An increased risk of RSV related complications has also been confirmed for children with congenital heart disease (CHD) [2, 56-58], severe neurological impairment or severe neuromuscular disorders [59-62], certain congenital malformations/syndromes [50, 63], and – most recently – patients with Down syndrome (trisomy 21) [62, 64-70]. Infants with a preexisting pulmonary disease such as cystic fibrosis [62], infants after surgical correction of an congenital diaphragmatic hernia [71, 72] or those who are mechanically ventilated due to other reasons [73], have an increased risk of complicated RSV disease [74, 75].

Additional risk factors leading to a significant higher risk of RSV-related hospitalization in infants are of male gender, attending day care, having older siblings, household tobacco smoke exposure [76, 77], (family) history of atopy, no breastfeeding, and living in a crowded home environment [44, 78-81].

Chu et al. [82] investigated the epidemiology and the molecular epidemiology of RSV transmission in childcare and the impact of RSV disease in a community-based daycare population during three winter seasons. RSV was detected in 59 (11%) of respiratory illnesses. Compared to RSV-negative illnesses, RSV-positive illnesses were associated with longer symptom duration and increased frequency of health care visits.

Palivizumab

Palivizumab[2] is a neutralizing humanized monoclonal antibody specific for antigenic site II on the RSV fusion glycoprotein [83]. The efficacy of palivizumab to reduce the risk of RSV related hospitalizations has been confirmed in three prospective, randomized placebo-controlled trials involving premature infants with or without bronchopulmonary

[2] Synagis®; formerly licensed by Abbott Laboratories Limited, United Kingdom, actually licensed by Medimmune / AbbVie)

dysplasia (chronic lung disease of prematurity) [1, 3] and children with congenital heart disease [2].

The standard dose of palivizumab prophylaxis is 15 mg/kg administered by intramuscular injection once a month. Body weight-based dosing of 15 mg/kg yields similar palivizumab concentrations in children of different gestational and postnatal ages [84]. Pharmacokinetic (PK) simulations demonstrated that there was little difference in palivizumab PK between healthy term and premature infants. PK simulations also demonstrated that the 5 monthly palivizumab doses of 15 mg/kg, consistent with the label and studied in two randomized clinical trials, provided greater and more prolonged palivizumab exposure than an abbreviated dosing regimen of 3 monthly doses, as recommended in the latest update of the American Academy of Pediatrics recommendation [85].

The objective of the IMpact Trial [1] was to determine the safety and efficacy of prophylaxis with palivizumab in reducing the incidence of hospitalization due to RSV infection in high-risk subjects. This randomized, double blind, placebo-controlled trial was conducted at 139 centers in the United States, United Kingdom, and Canada. During the 1996 to 1997 RSV seasons, 1502 subjects with prematurity (less than or equal to 35 weeks of gestational age) or BPD were randomized to receive 5 injections of either palivizumab (15 mg/kg) or an equivalent volume of placebo by intramuscular injection every 30 days. The primary endpoint was hospitalization with confirmed RSV infection. Subjects were followed up for 150 days (until 30 days from the last injection). Those with hospitalization as a result of RSV infection were evaluated for total number of days in the hospital, total days with increased supplemental oxygen, total days with moderate or severe LRTI illness, and incidence and total days of intensive care and mechanical ventilation. The incidence of hospitalization for respiratory illness not caused by RSV, and the incidence of otitis media were also evaluated. The placebo and palivizumab groups were balanced at entry for demographics and RSV risk factors. Ninety-nine percent of subjects in both groups completed the study and approximately 93% received all five scheduled injections. Results showed that palivizumab prophylaxis resulted in a 55% reduction in hospitalization as a result of RSV (10.6% placebo vs 4.8% palivizumab, $P = 0.00004$). Subjects with prematurity but without BPD had a 78% reduction in RSV hospitalization (8.1% vs 1.8%); subjects with BPD had a 39% reduction (12.8% vs 7.9%). When gender, entry age, entry weight, BPD, and gestational age were included in a logistic regression model, the effect of prophylaxis with palivizumab remained statistically significant. The palivizumab group had proportionally fewer total RSV hospital days, fewer RSV hospital days with increased oxygen, fewer RSV hospital days with a moderate/severe lower respiratory tract illness, and a lower incidence of intensive care unit (ICU) admission. Palivizumab was safe and well tolerated. The number needed to treat to prevent one RSV-related hospitalization in premature subjects was 17.

Feltes et al. [2] evaluated the safety, tolerance, and efficacy of palivizumab in subjects with hemodynamically significant CHD. This randomized, double-blind, placebo-controlled trial included 1,287 subjects with CHD randomly assigned 1:1 to receive 5 monthly intramuscular injections of 15 mg/kg palivizumab or placebo. Subjects were followed up for 150 days. The primary efficacy end point was antigen-confirmed RSV hospitalization. Palivizumab recipients had a 45% relative reduction in RSV hospitalizations (P = 0.003), a 56% reduction in total days of RSV hospitalization per 100 subjects (P = 0.003), and a 73% reduction in total RSV hospital days with increased supplemental oxygen per 100 subjects (P = 0.014). Adverse events were similar in the treatment groups; no child had discontinued the drug for a related adverse event. Serious adverse events occurred in 55.4% of palivizumab recipients and 63.1% of placebo recipients (P < 0.005); none were related to palivizumab. The rates of cardiac surgeries performed earlier than planned were similar in the treatment groups.

In the double-blind, placebo-controlled MAKI trial, Blanken et al. [3] randomly assigned 429 otherwise healthy preterm subjects born at a gestational age of 33 to 35 weeks to receive either monthly palivizumab injections (214 subjects) or placebo (215 subjects) during the RSV season. The pre-specified primary outcome was the total number of parent-reported wheezing days in the first year of life. Rehospitalization rates and medically attended RSV-infections without hospitalization were secondary outcomes. Nasopharyngeal swabs were taken by parents or caregivers during 30% of all respiratory episodes for viral analysis (real time RT-PCR, designed to detect 16 different pathogens). Palivizumab treatment resulted in a relative reduction of 61% (95% confidence interval, 56 to 65) in the total number of wheezing days during the first year of life (930 of 53,075 days in the RSV-prevention group [1.8%] vs. 2309 of 51726 days [4.5%] in the placebo group). During this time, the proportion of subjects with recurrent wheeze was by 10% lower in subjects treated with palivizumab (11% vs. 21%, P = 0.01). The authors hypothesize that RSV primarily causes direct pulmonary epithelial damage and local immunologic alterations in the lungs, leading to long-term airway hyper-responsiveness and wheezing. Regarding RSV-related rehospitalization rates, palivizumab prophylaxis significantly reduced the number of rehospitalization in otherwise healthy preterm subjects born at a gestational age of 33 to 35 weeks (0.9% vs. 5.2%, P = 0.01; relative risk reduction 82%; absolute risk reduction: 4.2% number needed to treat: 24) [3].

Andabaka et al. [86] have recently published a Cochrane Meta-analysis to assess the effectiveness and safety of palivizumab prophylaxis compared with placebo, or another type of prophylaxis, in reducing the risk of complications (hospitalization due to RSV infection) in high-risk subjects to assess the cost-effectiveness (or cost-utility) of palivizumab prophylaxis compared to no prophylaxis in subjects in different risk groups. This meta-analysis included data from randomized trails, in which palivizumab was compared to motavizumab [87, 88], an investigational monoclonal antibody directed

against RSV [89-91]. Of the seven available RCTs, three compared palivizumab with a placebo in 2831 subjects, and four compared palivizumab with motavizumab in 8265 subjects. Palivizumab prophylaxis was associated with a statistically significant reduction in RSV hospitalizations (RR 0.49, 95% CI 0.37 to 0.64) when compared to placebo. When compared to motavizumab, palivizumab recipients showed a non-significant increase in the risk of RSV hospitalizations (RR 1.36, 95% CI 0.97 to 1.90). In both cases, the proportion of subjects with any AE or any AE related to the study drug was similar between the two groups. In the meantime, the drug manufacturer MedImmune Inc. (Gaithersburg, USA) has discontinued the development of motavizumab use for prophylaxis due to an increased risk of skin reactions compared with palivizumab [37].

Rehospitalization despite palivizumab prophylaxis

If plasma levels of neutralizing antibodies are sufficient [84, 92, 93], palivizumab will display a virus neutralizing capacity in vivo, but its administration does not protect the infant from RSV transmission to (and infection of) the upper airways. The concentration of antibodies of IgG type is much lower in the mucosal secretions of the upper airways (nasopharynx), where specific humoral immunity predominantly relies on secretory immunoglobulins (IgA). Although palivizumab reduces the risk of severe lower airway RSV disease, a definite proportion of all infants and children eventually experience an RSV-infection despite previous passive immunization [1-3].

Forbes et al. [93] recently have demonstrated that the palivizumab level has a clinical relevance, and adherence to timely monthly dosing may confer additional protection among high-risk subjects receiving palivizumab. The authors performed a post hoc analysis of a previous randomized, placebo-controlled trial that evaluated the relationship between serum palivizumab levels at the time of RSVH and disease severity. Pediatric ICU admission was the primary severity marker. Mean palivizumab levels were lower in ICU-admitted subjects (n = 11/48; palivizumab level 47.2 µg/mL) vs. non-ICU subjects (n = 37/48; 98.7 µg/mL; $P < 0.0001$); there were no statistically significant differences in other variables examined. In multivariate analyses, palivizumab level was the only independent predictor of ICU admission ($P = 0.009$). Palivizumab levels also correlated with the duration of RSV hospitalization and ICU stay, supplemental oxygen use and its duration, as well as mechanical ventilation use and its duration ($P < 0.05$). Higher palivizumab levels were associated with decreased disease severity in high-risk subjects.

Impact of palivizumab on pediatric intensive care admissions for RSV infection

Since the children eligible for palivizumab, in whom palivizumab prophylaxis is recommended by national guidelines, comprise only a very small proportion of all

children in any birth cohort, it is not expected, that palivizumab prophylaxis will substantially reduce the overall number of pediatric ICU admissions due to severe RSV-infection [62]. In 85% of all these admissions, the patient does not show any of the confirmed risk factors of complicated RSV disease [44, 62, 94-96].

Safety

Palivizumab administration has been associated with a very low rate of serious adverse events [97] and is regarded as safe even in subjects who receive this monoclonal antibody in two subsequent RSV seasons [85] although studies investigating the latter issue are still limited [98, 99].

No significant differences were observed in the IMpact study [1] in reported adverse events between the two groups (palivizumab vs. placebo). Few subjects discontinued injections for related adverse events in the palivizumab arm (0.3%). Reactions at the site of injection were uncommon (1.8% placebo vs 2.7% palivizumab); the most frequent reaction was mild and transient erythema. Mild or moderate elevations of aspartate aminotransferase occurred in 1.6% of placebo recipients and 3.6% of palivizumab recipients; for alanine aminotransferase these percentages were 2.0% and 2.3%, respectively. Hepatic and renal adverse events related to the study drug were similar in the two groups. Most AEs related to palivizumab are local reactions at the injection site. The incidence of allergic exanthema/rash after palivizumab injection has been observed with an incidence of 0.016% [100]. In 2002, the U.S.-American Federal Drug Administration (FDA) published an alert on palivizumab safety: Post licensure, information based on four seasons of worldwide post-marketing experience representing over 400,000 subjects and 2,000,000 doses administered have been reviewed, and a total of 2 subjects with anaphylaxis have been reported. Both subjects made a full recovery with appropriate therapy.' (available online[3]). In response, the warnings section of the updated Synagis® label/product information leaflet has been changed by the manufacturer MedImmune, Inc. to provide clarification on the risk of anaphylaxis.

In the interim report on the results of palivizumab prophylaxis in Germany 2002-2007, Simon et al. [101] came to the conclusion, that in the context of 49608 evaluable administrations, the risk of an SAE considered possibly or probably related to the administration of palivizumab by the attending physicians (n = 10) was approximately 0.2 per 1000 administrations. The SAEs probably or possibly related to the administration of palivizumab (n = 10) were skin rash (n = 1), dyspnoea/cyanosis with or without fever

[3] *http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm155089.htm*

(n = 4), thrombocytopenia with petechiae (n = 1), osteomyelitis of the distal femur epiphysis (n = 1), seizure (n = 1), transient unresponsiveness (n = 1), fever, restlessness, and feeding difficulties (n = 1).

Chen et al. [102] recently reported on SAEs in the Canadian Registry of Children Receiving palivizumab (CARESS) for RSV Prevention. As mentioned above, this registry follows a strategy of active surveillance utilizing trained site-specific research nurses. This increases the probability of complete SAE reporting compared to strategies which rely on voluntary SAE reports of the attending physicians. In total, 13025 subjects received 57392 palivizumab injections in the years 2008 to 2013. Hospitalizations for respiratory-related illness (RIH) were reported in 915 subjects, and SAEs other than RIH were reported in 52 subjects. Of these, 6 (0.05%) subjects had a total of 14 hypersensitivity reactions that were deemed possibly or probably related to palivizumab (incidence: 2.8 per 10000 patient-months). The SAEs of 42 subjects were assessed as not related to palivizumab. SAEs in the remaining 4 subjects were not classifiable as their records were incomplete. There were no significant demographic predictors of SAE occurrence. The authors conclude that under active surveillance, a small proportion of subjects in the CARESS registry experienced SAEs that had a potential relationship with palivizumab and these appeared to be unpredictable in terms of onset. Since a significant proportion of all subjects eligible for palivizumab prophylaxis have severe underlying diseases or comorbidities, it is expected that some of them will die due to genuine complications of their underlying disease or due to other reasons during the time period, when palivizumab is administered [103]. In the Feltes study investigating palivizumab use in CHD [2] twenty-one subjects (3.3%) in the palivizumab group and 27 (4.2%) in the placebo group died; no deaths were attributed to palivizumab.

Palivizumab-resistant RSV mutants

The efficacy of palivizumab may be decreased in subjects infected with a virus isolate in which the antigenic epitopes on the G protein are modified due to genetic alteration (palivizumab resistant mutants) [104]. Adams et al. [105] isolated palivizumab-resistant RSV from an infant treated with palivizumab. A stable mutation at codon 276 led to a nearly complete resistance to palivizumab. Additional studies revealed a second mutation at codon 272. Further passage of the virus led to a complete loss of binding of palivizumab. Zhu et al. [106] found palivizumab-resistant mutants in 5% of all subjects, who had been allocated to the group of palivizumab failures. The fitness of these RSV variants was impaired, compared to wild-type RSV. Until today, no increase in palivizumab-resistant RSV-mutants has been reported during more than 15 years of palivizumab use in medical practice but ongoing surveillance is necessary [104, 106].

Palivizumab use in Germany

Palivizumab (Synagis®, Abbott Laboratories Limited, United Kingdom), a humanized monoclonal antibody directed to an epitope of the F-protein of RSV [100], was approved by the European Medicines Evaluation Agency (EMEA) in August 1999. Relying on the results of the IMpact trial [1], palivizumab was approved for the prevention of serious LRTI requiring hospitalization caused by RSV in children at high risk for RSV. Initially, the product labelling indicated that children born at ≤ 35 weeks of gestation who were < 6 months of age at the onset of the RSV season and children < 2 years of age who required treatment for BPD within the last 6 months were eligible for passive immunization with palivizumab [107]. In 2003, Feltes et al. [2] proved a significant benefit of palivizumab prophylaxis as well in children with hemodynamically relevant CHD. Accordingly, EMEA expanded the palivizumab label to include use in children < 2 years of age and with hemodynamically significant CHD. In general, the DGPI (German Society of Pediatric Infectious Diseases) recommendations for palivizumab use were more restrictive than the recommendations of the American Academy of Pediatrics [108] particularly considering the use of palivizumab in preterm infants with a gestational age > 32 weeks without BPD.

The current Consensus statement of the DGPI, the German Society of Pediatric Cardiology (DGPK), the German Society of Pediatric Pulmonology (DPP) and the German Society of Neonatology and Pediatric Intensive Care Medicine (GNPI) Medical Association of Outpatient Pediatricians (bvkj), and the National Organization “The Premature Infant” (2012) [109] specifies the following recommendations: Children with high risk should receive palivizumab prophylaxis; children with intermediate risk may receive palivizumab prophylaxis.

Risk categories have been specified as follows:

- Children with high-risk to experience a complicated course of RSV-infection (e.g. hospitalization)
  - Age ≤ 24 months at the onset of the RSV season, who have been treated in the previous 6 month with supplementary oxygen due to bronchopulmonary dysplasia or any other severe impairment in respiratory capacity.
  - Age ≤ 12 months at the onset of the RSV season, with haemodynamically relevant congenital heart disease (in particular, CHD which needs surgical or medical intervention, with pulmonary hypertonia, hyperperfusion of the lungs or cyanosis and/or severe cardiac insufficiency under pharmacologic treatment)

- Children with intermediate-risk to experience a complicated course of RSV-infection (e.g. hospitalization)

- Age ≤ 12 months at the onset of the RSV season, born prematurely with a gestational age ≤ 28 + 6 weeks.
- Age ≤ 6 months at the onset of the RSV season, born prematurely with a gestational age from 29 + 0 to 35 + 6 weeks and at least two of the following risk factors

  a) First discharge from the neonatology unit during or at the onset of the RSV season;

  b) Day care or siblings in day care;

  c) Severe neurological impairment.
- Age ≤ 12 months at the onset of the RSV season, with other underlying disease and severely impaired respiratory capacity (protracted oxygen supplementation) e.g. neuromuscular impairment, trisomy 21, diaphragmatic hernia or severe immunodeficiency.

- Age > 12 to ≤ 24 months at the onset of the RSV season, with haemodynamically relevant congenital heart disease (in particular, CHD which needs surgical or medical intervention, with pulmonary hypertonia, hyperperfusion of the lungs or cyanosis and/or severe cardiac insufficiency under pharmacologic treatment)

Notably, the administration of palivizumab to high-risk inpatients to avoid nosocomial RSV infection has never been part of these recommendations. With respect to the costs of palivizumab administration in Germany, palivizumab prophylaxis for children who match the inclusion criteria of the official recommendations is covered by supplemental agreements with the health insurance companies.

As real-life data may differ sharply from data gathered in the artificial setting of a prospective controlled randomized trial [100, 110, 111] additional comprehensive data from prospective non-interventional observational studies of palivizumab use in high-risk patients are warranted, and strongly requested by neonatologists and pediatric infectious disease specialists. The SYNAGIS Registry was carried out in order to minimize this knowledge gap. This registry was designed as a post-marketing observational study, and conducted from 2002-2016 with the aim of collecting data on palivizumab administration, the risk factors for a complicated RSV disease, frequency of hospitalizations, and drug adherence. In the course of the years, the registry was amended several times in order to acknowledge changes such as the expansion of the palivizumab label or new scientific information on risk factors for severe LRTIs. A detailed overview of the changes is listed in Annex A2.1.2 and A2.1.4.

7.0 Research Questions and Objectives

The objectives of this registry, initiated and conducted by the license holder (Abbott GmbH, Wiesbaden, Germany until Nov 1, 2012; then AbbVie Deutschland GmbH & Co. KG, Wiesbaden, Germany), were to provide consistent prospectively collected data on

- Demographic characteristics (gestational age, birth weight, age at first palivizumab injection, comorbidities) of infants and children in Germany who receive at least one injection of palivizumab during the RSV season (observation period September 01 to June 30)
- Distribution of previously defined risk factors for a complicated course of RSV-infection
- Primary indication for palivizumab use
- Setting of the first palivizumab administration (in hospital or in the outpatient clinics/pediatric office)
- Recommendation for palivizumab prophylaxis by the attending neonatologist
- Schedule of palivizumab administration
- Number of palivizumab injections per patient and RSV season
- Compliance/attendance of the parents/caregivers to the palivizumab administration schedule
- Frequency of rehospitalization (for any reason and RSV-related hospitalizations).
- Causal relationship between RSV infection and hospitalization (reason of hospitalization, respiratory tract infection, diagnostic confirmation of RSV infection)
- Nosocomial RSV infection (symptomatic $\geq$ 5 days after hospital admission)
- Mechanically ventilated at the onset of the RSV infection due to other reason
- Clinical course in hospitalized infants and children (oxygen supplementation, number of days in ICU, days of mechanical ventilation)
- Outcome death related or unrelated to the RSV infection
- Serious adverse events related to palivizumab administration reported to/ stored in a separate database, evaluated by drug safety personnel of the manufacturer (Abbott GmbH, Wiesbaden, Germany until Nov 1, 2012; than AbbVie Deutschland GmbH & Co. KG, Wiesbaden, Germany).

8.0 Amendments and Updates

Not applicable

9.0 Research Methods

The German Synagis® Registry comprises a series of post-marketing observational (non-interventional) studies performed by the license holder of palivizumab (Abbott GmbH, Wiesbaden, Germany until Nov 1, 2012; than AbbVie Deutschland GmbH & Co. KG, Wiesbaden, Germany) between 2002 and 2016.

9.1 Study Design

This post-marketing observational study (PMOS) was conducted in a prospective, single-arm, multicenter format in Germany according to the protocol dated April 2006.

It was planned to enroll approximately 1000 subjects per RSV season. Preterm subjects and subjects born with hemodynamically significant congenital heart diseases who were treated with palivizumab (SYNAGIS®) according to the local product label and prescription guidelines were eligible for participation. Each subject included in this study was observed during his/her palivizumab treatment during the prevailing RSV season (since 2009, until June 30 of the corresponding RSV season). Administrations and hospitalizations were documented on an ongoing basis. Data was documented on case report forms for documentation either on paper (until 2002/03 – 2007/08) or in a protected internet-based data entry system (eCRF, 2008/09 – 2015/16). All data were entered into the registry database as reported by the participating physicians.

Baseline documentations included socio-demographic factors, perinatal history and risk factors. Information about palivizumab administrations was recorded on an ongoing basis. Information about occurring hospitalizations was entered on a separate hospitalization form either on paper-based forms or within the eCRF system.

Study objectives were addressed by means of descriptive analyses of CRF items and hospitalization forms.

9.2 Settings

Primary care pediatricians from hospital outpatient facilities and neonatologists from inpatient facilities were invited to participate in this post-marketing observational study and enrolled subjects into the registry at their discretion.

According to the requirements for non-interventional or observational studies, no diagnostic or monitoring procedures were applied to the subjects included in the study other than those which would ordinarily be applied in the course of the individual therapeutic strategy. Only data which were part of routine medical care were collected.

The assignment of a subject to palivizumab prophylaxis was done before subject enrolment in the study. The prescription of palivizumab was clearly separated from the decision to include the subject in this study. No additional procedures (other than the standard of care) were applied to the subjects. AbbVie was not involved in the product supply since the drug was used according to the approved marketing label and prescribed by the physician under the usual and customary practice of a physician prescription.

The attending neonatologist (inpatients) or primary care pediatrician (outpatients) was responsible for administering prophylaxis with palivizumab according to approved standards of administration and monitoring. The Synagis® summary of product characteristics ("Fachinformation") recommends 5 monthly administrations of palivizumab at a dose of 15 mg/kg of body weight administered as an intramuscular injection during the current RSV season. To include as many evaluable subjects (EVP) as possible, it was intended to collect data from all subjects who received palivizumab between 01 September and June 30 during the corresponding RSV season.

The registry was conducted in Germany for the entire study duration (2002 – 2016). In the seasons 2002/03 and 2003/04, the registry was also conducted in Italy. In the seasons 2004/05 and 2005/06, the registry was also conducted in Portugal. To focus on the long-term description of palivizumab use and its effectiveness over the years in the course of the entire registry, result presentation in this report is restricted to the German SYNAGIS registry. Results of the Italian and Portuguese registries can be found in the corresponding study reports (Annex 1).

Before the practical implementation of the protected internet data-entry platform, the medical advisor of the study (Prof. Dr. med. [redacted] obtained approval for the study by the Ethics Committee of the Medical Faculty University of Bonn, Germany (Reference No. 132/08). This approval was extended to July 2012 on 09 September 2010.

After a change of his affiliation to the [redacted], approval for the study was obtained by the Ethics Committee of the Medical Association of the Saarland (Ärztekammer des Saarlandes) on 13 April 2013 (Reference No. Ha89/13). This approval was extended to July 2016.

9.3 Subjects

Eligible subjects were infants and children, for whom the attending neonatologists or pediatricians decided to prescribe palivizumab prophylaxis to prevent RSV infection during the current RSV season.

In particular, these were subjects for whom the following inclusion- and exclusion criteria were specified in the PMOS protocol.

Inclusion criteria:

The inclusion criteria were as stated in the German summary of product characteristics (SPC) "Fachinformation" for Synagis® (Appendix I):

- Subjects born at 35 weeks of gestation or less and less than 6 months of age at the onset of the RSV season.
- Subjects less than 2 years of age and requiring treatment for bronchopulmonary dysplasia (BPD resp. chronic lung disease (CLD)) within the last 6 months.
- Subjects less than 2 years of age and with hemodynamically significant congenital heart disease (hsCHD).

Exclusion criteria:

The exclusion criteria were as stated in the German summary of product characteristics (SPC) "Fachinformation" for Synagis® (Appendix I):

- Subjects with known hypersensitivity to palivizumab or any component of the formulation, or other humanized monoclonal antibodies.

A prerequisite for study participation was that the parents or the legal guardians gave written informed consent for the participation of their child/children in the study.

During the whole observational period (2002 – 2016) the parents or legal guardians gave their informed consent for data to be recorded on the CRF and to be analyzed for scientific purposes. This analysis met the recommendations of the EMEA for investigations of post license use and drug safety alerts by the manufacturer. The anonymity of all participants was maintained throughout the study. This registry was conducted according to the current regulations for PMOS in Germany.

9.4 Variables

For seasons 2002/03 to 2007/08, the data collection was conducted by a paper-based CRF. For seasons 2008/09 to 2015/16, an eCRF system was used. Both the paper-based CRFs and the eCRF system were subject to changes during the whole time of the registry. Changes were generally implemented at the start of a season. In Annex 2.1, detailed information about the used CRFs and corresponding changes over time is given. In the following, details of the latest paper-CRF version of season 2007/08 and the latest eCRF version of season 2015/16 is displayed. An overview of all CRF items of the two seasons is given in Table 9.4-1. An 'X' in column 2015/16 or 2007/08 indicates whether the item was applied in the corresponding season. In some cases, items for a specific topic (e.g. smoking) were changed between CRF versions (e.g. eCRF: number of smokers in household; paper-CRF: occurrence of smoking in household), but for analysis information was reduced to the same form (e.g. presence of smoking).

The CRF was generally subdivided into four sections: Two sections covered baseline characteristics with subject data and information about RSV risk factors. In a further section, immunoprophylaxis details were to be specified. For this, some basic information was requested and additionally, administered palivizumab injections were documented on an ongoing basis. At last, hospitalization details had to be specified on occurrence.

For the assessment of safety, different types of adverse events (AEs) were reported in the CRF. For seasons 2002/03 until season 2007/08, the occurrence of at least one ADR could be documented per subject – summarized for the whole observational period of one season. For season 2008/09 until season 2011/12, the occurrence of at least one serious ADR (SADR) and/or at least one acute ADR could be reported for each documented palivizumab administration. For these seasons (season 2002/03 until 2011/12), the requested events were reported to the AbbVie Germany pharmacovigilance (PV) department on separate reporting forms. Contents of this AE form were not included in the study database.

From season 2012/13 on, the AE reporting to PV was included into the eCRF. Any type of AE was documented. Detailed information about AEs were not included in the study database, but redirected to the AbbVie PV department.

Table 9.4-1: Overview of paper-CRF items for season 2007/08 and eCRF items for season 2015/16

	2015/16	2007/08	Comment
Subject data			
Initials	X	X	
Date of birth	X	X	
Birth weight (g)	X	X	
Gestational age	X	X	Paper-CRF: only for premature births
Multiple birth	X	X	
Gender	X	X	
Any chronic disease	X	–	
∟ If yes: Date of indication	X	–	
Comment (open text field)	X	–	
Informed consent available	X	–	
Date of informed consent	X	–	
RSV risk factors			
Any risk factors	X	–	
Premature birth	–	X	eCRF: calculable from gestational age
Chronic lung disease (CLD)	X	X	
CLD therapy with medication/oxygen	X	X	
Treatment with oxygen at home	X	–	
Family history of asthma	X	X	
Immunodeficiency	X	X	
∟ If yes: Diagnosis	–	X	
Down syndrome	X	–	
Congenital heart defect	X	X	
∟ If yes: Cyanotic, acyanotic, unknown	–	X	
∟ If yes: Pulmonary hypoperfusion	–	X	
∟ If yes: Diagnosis (open text field)	–	X	
Cyanotic heart defect	X	–	
ICD-10 Diagnosis	X	–	
Family history of atopy	X	–	
Family history of allergic rhinitis	–	X	
Family history of allergic eczema	–	X	
Neuromuscular impairment	X	–	
Serious neurological disease	X	–	
Attending daycare	X	X	

	2015/16	2007/08	Comment
Siblings in kindergarten or school	X	–	
Other subjects (< 12 years) in household	–	X	
∟ If yes: Number of siblings	–	X	
Low social status	X	–	
Crowded living conditions	X	–	
Exposition to air pollution	X	–	
Number of smokers in household	X	–	
Smoking in household	–	X	The term family is used in study protocol and analysis.
Breast feeding ≤ 2 months	X	–	
Hospital discharge during RSV season	X	–	
Other risk factors (open text field)	X	X	
Other CLD (open text field)	X	–	
Immunoprophylaxis			
Reason for immunoprophylaxis	X		
Location of first palivizumab injection	X	X	Paper-CRF: immunoprophylaxis started in clinic
Recommendation by neonatologist	X	X	
Date of first palivizumab injection	X	–	
Age at start of prophylaxis	–	X	
Immunoprophylaxis in last season	X	X	
Immunoprophylaxis plan created	X	–	
Occurrence of any adverse drug reaction in season	–	X	eCRF: occurrence of adverse events are specified per palivizumab injection
Cooperation of parents (very good; good; moderate; bad; very bad)	–	X	
For each palivizumab injection (1-10):			
∟ Date of palivizumab injection	X	X	
∟ Weight (g/kg)	X	X	
∟ Dosage (ml)	X	X	eCRF: specified either for ready-to-use solution or powder
∟ RSV-Hospitalization	–	X	
∟ Occurrence of adverse events until palivizumab injection	X	–	
∟ Comment	X	–	
Hospitalization form			
Reason for hospitalization	X	–	

	2015/16	2007/08	Comment
Hospital	X	–	
Date of hospitalization	X	X	
Date of discharge	X	X	
Respiratory tract infection	X	–	
Nosocomial infection	X	–	
Causal relationship to palivizumab	X	–	
Main diagnosis at discharge	X	–	eCRF: single choice of pre-specified categories
Diagnosis at discharge:			Paper-CRF: For each of the following diagnoses, it has to be specified, whether it is applicable.
∟ Bronchiolitis (yes; no; unknown)	–	X	
∟ RSV-Bronchiolitis (yes; no; unknown)	–	X	
∟ Viral-Pneunomia (yes; no; unknown)	–	X	
∟ RSV-Pneunomia (yes; no; unknown)	–	X	
∟ RSV-Infection (yes; no; unknown)	–	X	
∟ Other (yes; no; unknown)	–	X	
RSV-Test	X	X	
∟ If yes: Result	X	X	eCRF: specified as causality of RSV
Number of days in intensive care unit (ICU)	X	–	
Admission to ICU (yes; no; unknown)	–	X	
∟ If yes: Number of days in ICU	–	X	
O2 dependency (yes; no; unknown)	X	X	eCRF: both for respiratory tract infection and for other reasons
∟ If yes: Number of days with supplementary oxygen	–	X	
Number of days with mechanical ventilation	X	–	
Mechanical ventilation (yes; no; unknown)	–	X	
∟ If yes: Number of days with mechanical ventilation	–	X	
Death	X	–	
Death with causal relationship to RSV	X	–	

9.5 Data Sources and Measurement

All subject data, medical history, procedures and findings were entered into the paper-based CRF (2002/03 – 2007/08) or into the protected internet-based data entry platform (eCRF, 2008/09 – 2015/16) by the attending physician or by instructed medical personnel.

On occurrence of a hospitalization, the physician was asked to complete a separate RSV hospitalization form for each hospitalization (2002/03 – 2007/08) or to fill in a form within the eCRF system (2008/09 – 2015/16). Information about the hospitalization was based on the medical hospitalization report.

9.6 Bias

The prescription of palivizumab (SYNAGIS®) was to be clearly separated from the decision to include the subject in the study. No additional procedures – other than the standard of care – were to be applied to the subjects. Once a decision had been made between the physician and the parents/legal guardian to use palivizumab (Synagis®) as prophylaxis for severe RSV, the parents/legal guardians were offered to enroll their child/children in this PMOS.

Due to the pure observational character of this study the risk for selection bias was minimized.

All therapeutic decisions, including decisions for hospitalizing or monitoring a subject at a pediatric ICU, were completely at the discretion of the attending physicians; thus participation in the registry did not influence any decision regarding medical treatment of the included subjects.

9.7 Study Size

A registry intends to collect data from all subjects with a particular characteristic – in our case, subjects receiving palivizumab immunoprophylaxis. Hence, sample size calculations were not required. However, it was expected that approximately 1000 subjects per season would have been enrolled.

9.8 Data Transformation

Section 9.4 gives an overview of the data collected in this study. In almost all cases, statistical analysis is based on the raw data format, so that data transformations were not

necessary. In few other cases, derivations were applied, but these were based on basic groupings. These included the following transformations:

- Subjects with any hospitalization (≥ 1 hospitalization form available)
- Hospitalizations that are characterized as RSV-associated by discharge diagnosis and RSV test positive (yes, no)
- Subjects with any RSV-associated hospitalization (≥ 1 hospitalization for which an RSV association is documented)
- Subjects with any immunoprophylaxis (≥ 1 injection of palivizumab)
- Subjects with > 5 injections of palivizumab
- Injections of palivizumab per calendar month
- Gestational age (GA) in groups:
  - premature birth (≤ 35 weeks GA), non-premature birth (> 35 weeks GA)
  - refined categories: < 29 weeks GA, 29 – < 33 weeks GA, 33 – ≤ 35 weeks GA, > 35 weeks GA
- Birth weight in groups: normal birth weight (2500 – 3200 g), low birth weight (1500 – 2499 g), very low birth weight (1000 – 1499 g) and extremely low birth weight (< 1000 g)
- Admission to ICU at hospitalization (yes, no); yes corresponds to ≥ 1 day in ICU, no corresponds to 0 days in ICU.
- Mechanical ventilation at hospitalization (yes, no); yes corresponds to ≥ 1 day of mechanical ventilation, no corresponds to 0 days of mechanical ventilation.

9.9 Statistical Methods

9.9.1 Main Summary Measures

Statistical analyses were carried out by means of the SAS® package (version 8.2) for seasons 2002/03 until 2008/09 and by means of IBM-SPSS (version 23) for seasons 2009/10 until 2015/16.

Quantitative data (e.g. birth weight) were analyzed by the statistical parameters valid N, missing N, mean, standard deviation (SD), minimum (0%), lower quartile (25%), median (50%), upper quartile (75%), and maximum (100%).

Qualitative data (e.g., gender) were presented by means of (absolute and relative) frequency distributions. If applicable, two methods were followed for calculation of percentages. The first method considers missing data as a separate group, which results in the same sample size for all parameters. The second method of calculation is based on the valid data per parameter, excluding subjects with missing values (“valid data analysis”).

Accordingly, this results in different sample sizes. In general, description of results within the report was based on the "valid data analysis".

9.9.2 Main Statistical Methods

Analysis population

The following analysis populations were defined:

- **Evaluable population (EVP)**: For the analysis of each season, all subjects with palivizumab treatment in the corresponding season were considered. i.e. subjects with first palivizumab injection between 01 September (starting year) and 31 May (subsequent year). Furthermore, subjects should have been younger than 2 years at start of immunoprophylaxis.
- **Non-evaluable population (NEP)**: All selected subjects not belonging to EVP.

Generally, data analysis was based on the EVP.

General methods

Mainly descriptive analyses have been performed, based on the general methodology described in Section 9.9.1.

For the eCRF-based registry, hospitalization characteristics were analyzed separately for the following subgroups: (1) Hospitalizations directly allocated to the category "associated with RSV infection" and (2) hospitalizations not allocated to the category "associated with RSV infection".

9.9.3 Missing Values

This study is based on an initial documentation visit where subject data, risk factors and basic data about the immunoprophylaxis were collected. No further documentation visits were scheduled, but the physician was asked to document any application of immunoprophylaxis (date, dose, weight of subject, occurrence of hospitalization and adverse drug reactions) during the season. Hospitalization forms were asked to be filled in upon occurrence of hospitalization. Data was analyzed on an available data basis. Imputation methods for missing data like last-observation-carried-forward (LOCF) were not applicable due to the study design.

To obtain an estimate of the primary endpoint "RSV hospitalization rate", it was assumed that the percentage of hospitalizations with positive RSV test result was the same for hospitalizations with and without available RSV information. Using this adjusted estimate

of the total number of hospitalizations with positive RSV test, an estimate of the RSV hospitalization rate was calculated adjusted for missing RSV information.

A missing day of a date (either not require or missing) was substituted by the 15th calendar day of the respective month. Should this result in a non-plausible negative difference to another date, the 1st of the respective month was chosen.

9.9.4 Sensitivity Analyses

No sensitivity analyses were conducted.

9.9.5 Amendments to the Statistical Analysis Plan

For the analysis of registry 2002/03 until 2008/09, no statistical analysis plans were provided. The statistical analysis plan for seasons 2009/10 – 2015/16 was adhered to.

9.9.6 Quality Control

In general, the physicians were responsible for the validity of all data collected at a site.

Data management and quality control for the paper-based register of the seasons 2002/03 to 2007/08 was conducted by a CRO [redacted], Germany). The CRFs were forwarded to [redacted] for constitution of the database. Data from the CRFs were entered into an Oracle™ database using Clintrial™ (V4.4). An independent second data entry was performed in order to ensure the quality of data entry. Plausibility checks were performed according to a validation plan using Clintrial/SAS™ (V8.2). No queries to the sites were made; however, self-evident documentation errors were corrected. For instance, all injections of palivizumab that were not given in the season of interest were removed from the database. Data were integrated in a common database (SAS) using mapping rules which serves as the source database for statistical analysis.

Starting from the season 2008/09, physicians entered the required information into an eCRF. Subject characteristics as well as immunoprophylaxis details and hospitalization information were to be documented in an ASP.NET web application implemented by the provider [redacted] ([redacted], Germany) who also hosted the database. During data entry, the eCRF system automatically conducted checks: for missing mandatory data, and checks for implausible values. In addition, the medical advisor of the registry was principally enabled to send case related queries to participating physicians, e.g. to

elucidate inconsistent data concerning the reason for hospitalization. Further data cleaning was based on self-evident corrections conducted in preparation for statistical analysis (see below).

The German Synagis® Registry has never included or supported an on-site data monitoring.

Statistical analysis for seasons 2002/03 to 2008/09 was conducted by [redacted] and statistical analysis for seasons 2009/10 to 2015/16 was conducted by [redacted] Prof. Dr. [redacted]). Selected additional analyses were implemented by [redacted], Germany). For the conduct of all analyses, the standard operating procedures (SOPs) of the respective companies/institutes applied.

This clinical study report was prepared according to the SOPs of [redacted]

10.0 Results

Each result section is divided in three parts in order to account for specific features of different phases of the registry:

- Registry 02/03 – 06/07
- Registry 07/08 and registry 08/09
- Registry 09/10 – 15/16

Data collection for registry 02/03 – 06/07 was conducted by use of paper-based CRFs and hospitalization forms. Corresponding results have already been published [112] and are hence depicted together in one subsection.

Registry 07/08 and registry 08/09 are considered transitional years in the process of switching the type of data collection to an eCRF system. Therefore, though data collection of registry 07/08 was still paper-based, it was not included in the original publication. Hence, results are displayed in a separate section of this report. In season 08/09 the mode of data collection was switched from paper-based CRFs to an eCRF system. However, several physicians still used the paper-based CRFs for documentation. In order to use all documentations and lose as few data as possible, results for 08/09 are based on a combination of paper-based CRF and eCRF data. Hence, it was decided to keep the results for 08/09 separate from the depiction of the homogenous, eCRF-based results of the following seasons.

Data collection for registry 09/10 – 15/16 was implemented by an eCRF system. Corresponding results are therefore depicted together in one subsection.

In accordance with the displayed registry part, the analysis populations (defined in Section 9.9.2) are named EVP 02/03 – 06/07, EVP 07/08, EVP 08/09 and EVP 09/10 – 15/16.

10.1 Participants

10.1.1 Registry 02/03 – 06/07

During the 5 RSV seasons between 01 September 2002 and 31 May 2007, 10 686 documented subjects received at least one injection of palivizumab. The numbers of subjects evaluable in each RSV season are summarized in Table 10.1-1. The number of enrolled subjects increased from 928 in season 2002/03 to 3358 in season 2006/07. The non-evaluable population comprised approximately 2% of the total enrolled population (238 of 10924 subjects). For these non-evaluable subjects, either the first palivizumab administration was not performed between 01 September and 31 May (205 subjects) or

the subject's age was more than 24 months at the first administration (37 subjects), see Annex A2.2.1, Table 1.4.

The number of participating centers (i.e., hospitals or private practices where palivizumab was administered) increased over time, from 483 in the 2002/03 season to 1354 in the 2006/07 season (Table 10.1-1). Although a large percentage of centers enrolled only one subject (Annex A2.2.1, Table 1.1.1), the average enrolment was 2.5 subjects/center. Enrolment was relatively stable after the 2004/05 season (2002/03 season, 1.9 subjects/center; 2006/07 season, 2.5 subjects/center). The center with the greatest number of subjects enrolled 28 subjects in 2004/05 and 27 subjects in 2005/06. The next highest enrolment was 17 subjects at one center.

Table 10.1-1: Number of enrolled and evaluable subjects for registry 02/03 – 06/07

	02/03	**03/04**	**04/05**	**05/06**	**06/07**	**All**
Subjects total	928	1346	2269	3023	3358	10924
Evaluable subjects (EVP)	853	1287	2208	3000	3338	10686
Non-evaluable subjects	75	59	61	23	20	238
Centers*	483	352	949	1299	1354	4437

Source: Annex A2.2.1, Tables 1.3, 1.1.1
*Number of centers identifiable by ZIP-Code

A total of 49780 administrations were documented for the 10686 subjects from 2002 to 2007, with an average of 4.7 administrations per subject per season. 35% of subjects received more than 5 monthly injections (3734 subjects).

Table 10.1-2: Number of palivizumab injections – EVP 02/03 – 06/07

		02/03	03/04	04/05	05/06	06/07	All
Subjects with any immunoprophylaxis		853	1287	2208	3000	3338	10686
Number of palivizumab injections per subject	Mean	4.4	4.4	4.6	4.6	4.9	4.7
	SD	1.6	1.7	1.8	1.8	1.9	1.8
	Minimum	1	1	1	1	1	1
	Median	5	5	5	5	5	5
	Maximum	8	9	9	10	12	12
Subjects with more than 5 injections of palivizumab	n	211	352	770	1033	1368	3734
	%	24.7	27.4	34.9	34.4	41.0	34.9
Total number of documented injections of palivizumab		3747	5712	10129	13900	16292	49780

Source: Annex A2.2.1, Tables 4.5.1, Annex A2.2.4, Table 2.1

10.1.2 Registry 07/08 and 08/09

In season 2007/08, 3805 subjects received at least one injection of palivizumab (Table 10.1-3). The non-evaluable population comprised less than 0.5% of the total enrolled population (13 of 3818 subjects). For all of these non-evaluable subjects, the subject's age was more than 24 months at the first administration (regarding administrations at or after 1 September 2007) or the year of birth was after 2008, see Annex A2.2.2, Table 1.4. The number of participating centers was 1539. This corresponds to an average enrolment of 2.5 subjects/center. There were 4 centers with a maximum number of 13 subjects each (Annex A2.2.2, Table 1.1.1).

In season 2008/09, 2248 subjects received at least one injection of palivizumab (Table 10.1-3). For 12 subjects age was more than 24 months at the first administration (regarding administrations at or after 1 September 2008), see Annex A2.2.3, Table 1.4. These were excluded from the evaluable population. The number of participating centers was 676. This corresponds to an average enrolment of 3.3 subjects/center. The center with the greatest number of subjects enrolled 29 subjects. The next highest enrolment was 15 subjects at one center (Annex A2.2.3, Table 1.1).

Table 10.1-3: Number of enrolled and evaluable subjects for registry EVP 07/08 and 08/09

	07/08	08/09
Subjects total	3818	2260
Evaluable subjects	3805	2248
Non-evaluable subjects	13	12
Centers*	1539	676

Source: Annex A2.2.2, Tables 1.1.1, 1.3 and Annex A2.2.3, Tables 1.1, 1.3
*Number of centers identifiable by ZIP-Code

A total of 18332 administrations were documented for the 3805 subjects of season 2007/08, with an average of 4.8 administrations per subject (Table 10.1-4). 41.1% of subjects received more than 5 monthly injections (1562 subjects). For season 2008/09, 11039 administrations were documented for 2248 subjects. This corresponds to an average of 4.9 administrations per subject. 44.2% of subjects received more than 5 monthly injections (998 subjects).

Table 10.1-4: Number of palivizumab injections – EVP 07/08 and 08/09

		07/08	08/09
Subjects with any immunoprophylaxis		3805	2248
Number of palivizumab injections per subject	Mean	4.8	4.9
	SD	1.9	2.0
	Minimum	1	1
	Median	5	5
	Maximum	9	11
Subjects with more than 5 injections of palivizumab	n	1562	993
	%	41.1	44.2
Total number of documented injections of palivizumab		18332	11039

Source: Annex A2.2.2, Table 4.5.1, Annex A2.2.3, Table 4.7.1, Annex A2.2.4, Tables 2.2, 2.3

Most of the subjects (1505 subjects, 66.9%) received prophylaxis because they were born prematurely (≤ 35 weeks GA), followed by 318 subjects with hsCHD (14.1%) and 310 subjects with CLD (13.8%), see Table 10.1-5.

Table 10.1-5: Main reason for immunoprophylaxis – EVP 08/09

	n	%
Premature birth (≤ 35 weeks GA)	1505	66.9
CLD[a]	310	13.8
hsCHD[b]	318	14.1
NMI[c]	14	0.6
Mucoviscidosis	4	0.2
Other	90	4.0
Unknown	7	0.3
Total	2248	100.0

Source: Annex A2.2.3, Table 4.1.1.1
[a]Chronic lung disease, [b]hemodynamically significant congenital heart disease, [c]Neuromuscular impairment

10.1.3 Registry 09/10 – 15/16

During the 7 RSV seasons between 01 September 2009 and 31 May 2016, 13802 documented subjects received at least one injection of palivizumab. The numbers of subjects evaluable in each RSV season are summarized in Table 10.1-6. The number of enrolled subjects decreased from 2158 in season 2009/10 to 1757 in season 2015/16. The non-evaluable population comprised less than 1% of the total enrolled population (91 of 13802 subjects). For these non-evaluable subjects, either the first injection of palivizumab was not performed between 01 September and 31 May (29 subjects), the subject's age was higher than 24 months at the first administration (49 subjects), or no immunoprophylaxis were documented at all (13 subjects), see Annex A2.2.5, p. 4.

In the following, only results of subjects are depicted who received their first immunoprophylaxis in the corresponding season (EVP with first RSV registry).

The number of participating centers (i.e., hospitals or private practices where palivizumab was administered) decreased over time, from 617 in the 2009/10 season to 363 in the 2015/16 season (Table 10.1-6). In total, 1005 different centers participated in seasons 2009/10 to 2015/16. The average enrolment was 13.7 subjects/center.

Table 10.1-6: Number of enrolled and evaluable subjects for registry 09/10 – 15/16

	09/10	**10/11**	**11/12**	**12/13**	**13/14**	**14/15**	**15/16**	**All**
Subjects total	2158	1994	2092	2100	1923	1778	1757	13802
Non-evaluable subjects	25	25	6	7	13	9	6	91
Evaluable subjects (EVP)	2133	1969	2086	2093	1910	1769	1751	13711
EVP with first RSV registry	2133	1812	1911	1926	1759	1602	1586	12729
EVP with first RSV registry and Down syndrome	25	25	41	38	39	47	34	249
Centers (EVP with first RSV registry)	617	523	501	503	436	401	363	1005*

Source: Annex A2.2.5, p. 4, p. 14
*Centers who participated in more than one season are counted only once

A total of 63572 injections of palivizumab were documented for the 12729 subjects from 2009 to 2016, with an average of 5.0 injections of palivizumab per subject per season (Table 10.1-7). 45.4% of subjects received more than 5 monthly injections (5773 subjects). For an overview of administrations per month see Figure 1. Most of the subjects started prophylaxis in October (4116 subjects), whereas the most injections of palivizumab were administered in January, February and March (> 10400 injections). The primary reason for immunoprophylaxis with palivizumab for most of the subjects was premature birth (73.9%, Table 10.1-8 and Figure 2).

Table 10.1-7: Number of injections of palivizumab – EVP 09/10 – 15/16

N	12729
Mean	5.0
SD	2.0
Minimum	1
Median	5
Maximum	10
Subjects with > 5 injections of palivizumab	5773 (45.4%)
Number of injections of palivizumab	63572

Source: Annex A2.2.5, p. 17

Figure 1: Number of injections of palivizumab per month

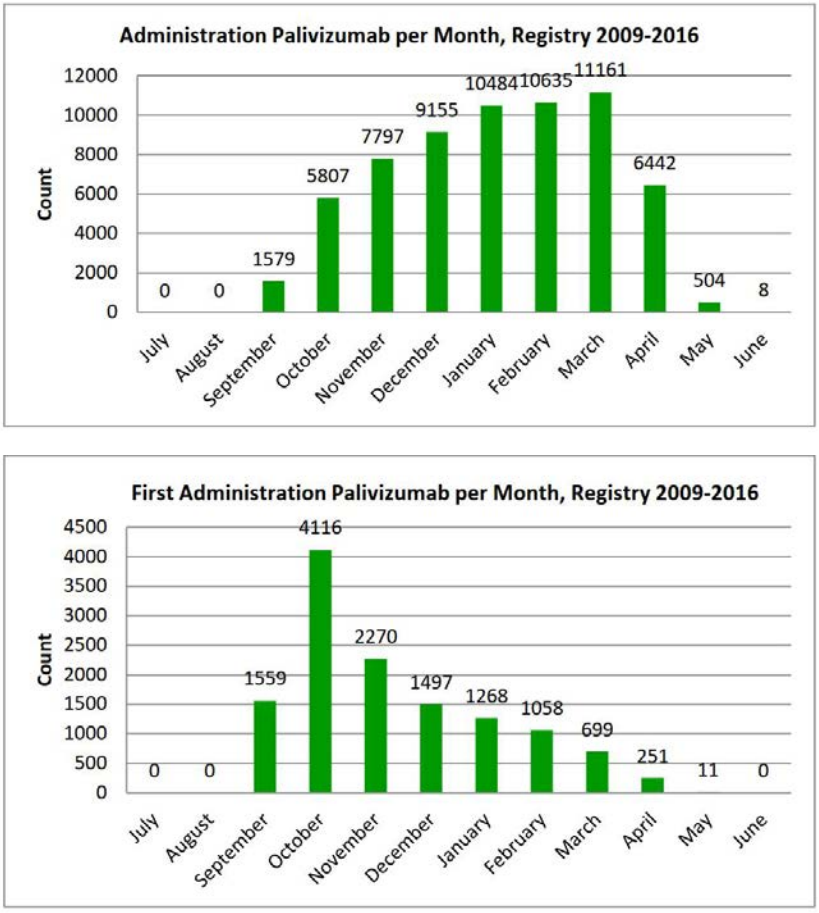

Figure 2: Main reason for immunoprophylaxis

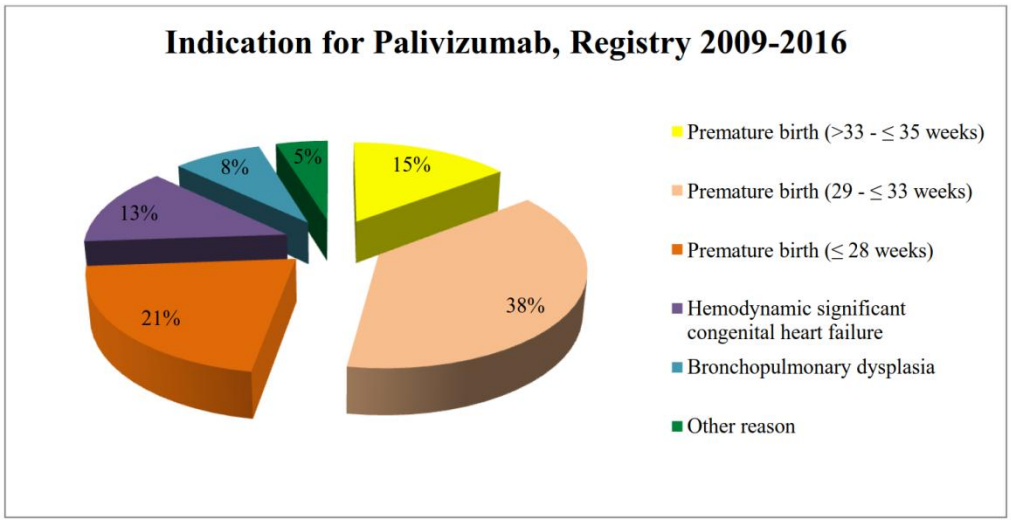

Table 10.1-8: Main reason for immunoprophylaxis – EVP 09/10 – 15/16

	n	%
Premature birth (≤ 28 weeks GA)	1868	14.7
Premature birth (29 - ≤ 33 weeks GA)	4826	37.9
Premature birth (> 33 - ≤ 35 weeks GA)	2707	21.3
CLD[a]	1681	13.2
hsCHD[b]	1038	8.2
Other	609	4.8
Total	12729	100.0

Source: Annex A2.2.5, Addendum, p. 6
[a]Chronic lung disease, [b]hemodynamically significant congenital heart disease

10.2 Descriptive Data

10.2.1 Registry 02/03 – 06/07

Characteristics of the evaluable population are summarized in Table 10.2-1 and Table 10.2-2. Overall, 53.8% of subjects were male (5716 subjects). Most of the subjects were premature, i.e. born ≤ 35 weeks of gestational age (8467 subjects, 94.6%). The median gestational age at birth was 29 weeks. 31.1% of subjects had an extremely low birth weight (< 1000 g), the median birth weight was 1350 g.

Table 10.2-1: Baseline characteristics (qualitative variables) – EVP 02/03 – 06/07

		N	N	%
Sex	Female	10617	4901	46.2
	Male		5716	53.8
Gestational age (weeks)	< 29	8948	3582	40.0
	29 – < 33		3385	37.8
	33– ≤ 35		1500	16.8
	> 35		481	5.4
Birth weight	< 1000 g	10448	3280	31.4
	1000 – < 1499 g		2782	26.6
	1500 – < 1999 g		1788	17.1
	≥ 2000 g		2595	24.8

Source: Annex A2.2.1, Tables 2.1.2, 2.2.2.2, 2.3.2.2

Table 10.2-2: Baseline characteristics (quantitative variables) – EVP 02/03 – 06/07

	Gestational age (weeks)	Birth weight (g)	Age at start of immunopro-phylaxis (months)
N	8947	10448	10059
Missing	1739	238	627
Mean	29.7	1566	5.2
SD	3.5	837	4.0
Minimum	20	320	0.0
25%-Quantile	27	930	2.5
Median	29	1350	4.0
75%-Quantile	32	1990	6.5
Maximum	41	6620	30.0

Source: Annex A2.2.1, Tables 2.3.1, 4.4.1, Annex A2.2.4, Table 3.1

Characteristics of immunoprophylaxis are summarized in Table 10.2-3. Parental adherence to the passive immunoprophylaxis schedule was evaluable in 10304 cases (missing data for 4%) and was rated as very good or good for 91.1%, moderate for 5.5%, and bad/very bad for 3.4%. Prophylaxis was started in the hospital in 15.6% of the evaluable population (1645 subjects). The corresponding rate of 'first prophylactic injection in the hospital' decreased from 26.4% in 2002/03 to 13.3% in 2006/07 (Annex A2.2.1, Table 4.2.1). 18.1% of subjects received immunoprophylaxis in the previous season. Median age at the start of the palivizumab prophylaxis was 4.0 months (Table 10.2-2). The parents of 56.3% of all subjects received a distinct recommendation from the neonatologists in the hospital to start the passive prophylaxis schedule under the supervision of their primary care pediatrician.

Table 10.2-3: Immunoprophylaxis with palivizumab – EVP 02/03 – 06/07

		N	n	%
Immunoprophylaxis with palivizumab in previous season		9637	1743	18.1
Immunoprophylaxis with palivizumab started in clinic		10544	1645	15.6
Recommendation by neonatologist		9475	5335	56.3
Cooperation of parents	Very good/good	10304	9383	91.1
	Moderate		567	5.5
	Bad/very bad		354	3.4

Source: Annex A2.2.1, Tables 4.1.2, 4.2.2, 4.3.2, 7.2

Risk factors for all evaluable subjects are summarized in Table 10.2-4. Several risk factors were assessed from 2003 onwards, so that results do not incorporate data of the 2002 cohort. For the evaluable population from 2002 to 2007, 40.0% of all subjects were extremely premature (born ≤ 29 weeks of gestational age, 3582 subjects) and 26.7% were multiple-birth siblings (2607 subjects). In total, 42.6% (4179 subjects) had a diagnosis of CLD and 31.3% (3001 subjects) had a diagnosis of CHD. In 4.8% (430 subjects), the attending physician classified the subject as immunodeficient without further specification. Other extrinsic risk factors were present that are associated with a higher risk for a severe RSV infection: 17.7% (1422 subjects) were exposed to smoking in the family, 2.5% (240 subjects) attended daycare and in 46.0% of cases (4440 subjects) other children (< 12 years of age) lived in the same household. Family history of asthma was present in 10.4% (823 subjects), of allergic rhinitis in 15.8% (1234 subjects), and of allergic eczema in 9.2% (713 subjects).

Table 10.2-4: Risk factors at baseline – EVP 02/03 – 06/07

	N	n	%
Premature birth (< 29 weeks GA)	8948	3582	40.0
Premature birth (≤ 35 weeks GA)	8948	8467	94.6
Multiple births*	9752	2607	26.7
CHD[a]*	9588	3001	31.3
Smoking in the family*	8043	1422	17.7
Family history of asthma*	7877	823	10.4
Family history of allergic rhinitis*	7819	1234	15.8
Family history of allergic eczema*	7751	713	9.2
CLD[b]	9805	4179	42.6
Immunodeficiency*	8875	430	4.8
Attending daycare*	9722	240	2.5
Other children (< 12 years) in household*	9662	4440	46.0

Source: Annex A2.2.1, Tables 2.2.2.2, 3.2.1.2, 3.3.1.2, 3.4.1.2, 3.5.2, 3.6.2, 3.7.1.2, 3.8.2, 3.9.2, 3.10.2, 3.11.2
*Based on all informative cases from 2003 on
[a]Congenital heart disease, [b]Chronic lung disease

10.2.2 Registry 07/08 and 08/09

Characteristics of the evaluable population are summarized in Table 10.2-5, Table 10.2-6 and Table 10.2-7. In season 2007/08, 54.1% of subjects were male (2051 subjects) and in season 2008/09, 54.7% of subjects were male (1229 subjects). Most of the subjects were premature, i.e. born ≤ 35 weeks of gestational age (in season 2007/08: 2912 subjects, 94.7%; in season 2008/09: 1873 subjects, 83.3%). The median gestational age at birth was 30 weeks for season 2007/08 and 31 weeks for season 2008/09. 29.6% of subjects had an extremely low birth weight (< 1000 g) in season 2007/08 and the median birth weight was 1420 g. In season 2008/09, 26.5% of subjects had an extremely low birth weight. The median birth weight for this cohort was 1494 g.

Table 10.2-5: Baseline characteristics (qualitative variables) – EVP 07/08 and 08/09

		07/08			08/09		
		N	**N**	**%**	**N**	**n**	**%**
Sex	Female	3788	1737	45.9	2248	1019	45.3
	Male		2051	54.1		1229	54.7
Gestational age (weeks)	< 29	3076	1173	38.1	2248	694	30.9
	29 – < 33		1161	37.7		705	31.4
	33– ≤ 35		578	18.8		474	21.1
	> 35		164	5.3		375	16.7
Birth weight	< 1000 g	3720	1101	29.6	2248	595	26.5
	1000 – < 1499 g		965	25.9		538	23.9
	1500 – < 1999 g		659	17.7		424	18.9
	≥ 2000 g		995	26.7		691	30.7

Source: Annex A2.2.2, Tables 2.1.2, 2.2.2.2, 2.3.2.2 and Annex A2.2.3, Tables 2.1, 2.2.2.1, 2.3.2

Table 10.2-6: Baseline characteristics (quantitative variables) – EVP 07/08

	Gestational age (weeks)	**Birth weight (g)**	**Age at start of immunopro-phylaxis (months)**
N	3076	3720	3578
Missing	729	85	227
Mean	29.9	1623	5.0
SD	3.6	863	4.0
Minimum	22	300	0.0
25%-Quantile	27	960	2.3
Median	30	1420	3.8
75%-Quantile	32	2070	6.3
Maximum	42	5110	32.5

Source: Annex A2.2.2, Tables 2.2.1, 2.3.1, 4.4.1

Table 10.2-7: Baseline characteristics (quantitative variables) – EVP 08/09

	Gestational age (weeks)	**Birth weight (g)**	**Age at start of immunopro-phylaxis (months)**
N	2248	2248	2248
Missing	0	0	0
Mean	31.2	1690	5.9
SD	4.5	858	4.9
Minimum	23	350	0.2
25%-Quantile	28	990	2.4
Median	31	1494	4.2
75%-Quantile	34	2200	7.5
Maximum	42	4900	25.0

Source: Annex A2.2.3, Tables 2.2.1, 2.3.1, 4.5.1

Characteristics of immunoprophylaxis are summarized in Table 10.2-8. Parental adherence was very good/good for 91.2%, moderate for 6.0%, and bad/very bad for 2.8% in season 2007/08. In season 2008/09, parental adherence was very good/good for 92.2%, moderate for 6.2%, and bad/very bad for 1.6%. Prophylaxis was started in the hospital in 13.9% in season 2007/08 and 17.4% in season 2008/09. Median age at the start of the palivizumab prophylaxis was 3.8 months in season 2007/08 (Table 10.2-6) and 4.2 months in season 2008/09 (Table 10.2-7). The parents of 55.9% of all subjects in season 2007/08 and of 64.3% of all subjects in season 2008/09 received a distinct recommendation from the neonatologists in the hospital to start the passive prophylaxis schedule under the supervision of their primary care pediatrician.

Table 10.2-8: Immunoprophylaxis with palivizumab – EVP 07/08 and 08/09

		07/08			08/09		
		N	**n**	**%**	**N**	**n**	**%**
Immunoprophylaxis with palivizumab in previous season		3720	673	18.1	2248	333	14.8
Immunoprophylaxis with palivizumab started in clinic		3745	519	13.9	1798	313	17.4
Recommendation by neonatologist		3635	2033	55.9	1851	1191	64.3
Cooperation of parents	Very good/good	3663	3340	91.2	8868*	8175	92.2
	Moderate		221	6.0		550	6.2
	Bad/very bad		102	2.8		143	1.6

Source: Annex A2.2.2, Tables 4.1.2, 4.2.2, 4.3.2, 7.2 and Annex A2.2.3, Tables 4.2, 4.3.2, 4.4.1.2, 8.2
*Cooperation of parents is evaluated per injection in registry 08/09. Categories for cooperation ratings were changed to good, satisfying, bad.

Risk factors for all evaluable subjects of season 2007/08 are summarized in Table 10.2-9. 38.1% of all subjects were extremely premature, i.e. born ≤ 29 weeks of gestational age (1173 subjects) and 24.4% were multiple-birth siblings (922 subjects). In total, 38.0% (1330 subjects) had a diagnosis of CLD and 34.9% (1283 subjects) had a diagnosis of CHD. In 4.9% (167 subjects), the attending physician classified the subject as immunodeficient. Other extrinsic risk factors were present that are associated with a higher risk for a severe RSV infection: 15.9% (482 subjects) were exposed to smoking in the family, 2.9% (109 subjects) attended daycare and in 45.1% of cases (1682 subjects) other children (< 12 years of age) lived in the same household. Family history of asthma was present in 10.3% (304 subjects), of allergic rhinitis in 15.4% (450 subjects), and of allergic eczema in 8.5% (245 subjects).

Table 10.2-9: Risk factors at baseline – EVP 07/08

	N	n	%
Premature birth (< 29 weeks GA)	3076	1173	38.1
Premature birth (≤ 35 weeks GA)	3076	2912	94.7
Multiple births	3771	922	24.4
CHD[a]	3677	1283	34.9
Smoking in the family	3031	482	15.9
Family history of asthma	2956	304	10.3
Family history of allergic rhinitis	2920	450	15.4
Family history of allergic eczema	2889	245	8.5
CLD[b]	3501	1330	38.0
Immunodeficiency	3428	167	4.9
Attending daycare	3745	109	2.9
Other children (< 12 years) in household	3728	1682	45.1

Source: Annex A2.2.2, Tables 2.2.2.2, 3.2.1.2, 3.3.1.2, 3.4.1.2, 3.5.2, 3.6.2, 3.7.1.2, 3.8.2, 3.9.2, 3.10.2, 3.11.2
[a]Congenital heart disease, [b]Chronic lung disease

Risk factors for all evaluable subjects of season 2008/09 are summarized in Table 10.2-10. 30.9% of all subjects were extremely premature (694 subjects) and 29.5% were multiple-birth siblings (632 subjects). In total, 26.0% (584 subjects) had a diagnosis of CLD, 12.5 (281 subjects) received CLD therapy and 5.9% (133 subjects) were treated with oxygen at home. 25.2% (567 subjects) had a diagnosis of CHD and 5.5% (123 subjects) had a cyanotic heart defect. In 1.3% (30 subjects), the attending physician classified the subject as immunodeficient. 5.3% (120 subjects) had a diagnosis of NMI. Other extrinsic risk factors were present that are associated with a higher risk for a severe RSV infection: 15.4% (346 subjects) were exposed to smoking in the family, 3.3% (74 subjects) attended daycare and in 49.6% of cases (1115 subjects) other children (< 12 years of age) lived in the same household. A family history of atopy was present in 15.4% (346 subjects).

Table 10.2-10: Risk factors at baseline – EVP 08/09

	N	N	%
Premature birth (< 29 weeks GA)	2248	694	30.9
Premature birth (≤ 35 weeks GA)	2248	1873	83.3
Multiple births	2141	632	29.5
CHD[a]	2248	567	25.2
Cyanotic heart defect	2248	123	5.5
CLD[b]	2248	584	26.0
CLD therapy	2248	281	12.5
Treatment with oxygen at home	2248	133	5.9
NMI[c]	2248	120	5.3
Immunodeficiency	2248	30	1.3
Family history of atopy	2248	346	15.4
Smoking in the family	2248	400	17.8
Attending daycare	2248	74	3.3
Other children (< 12 years) in household	2248	1115	49.6

Source: Annex A2.2.3, Tables 2.2.2.1, 3.1
[a]Congenital heart disease, [b]Chronic lung disease, [c]Neuromuscular impairment

10.2.3 Registry 09/10 – 15/16

Characteristics of the evaluable population are summarized in Table 10.2-11 and Table 10.2-12. 55.1% of all subjects were male (7013 subjects). Most of the subjects were premature, i.e. born ≤ 35 weeks of gestational age (9981 subjects, 78.4%). The median gestational age at birth was 32 weeks. 23.1% of subjects had an extremely low birth weight (< 1000 g), the median birth weight was 1605 g.

Table 10.2-11: Baseline characteristics (qualitative variables) – EVP 09/10 – 15/16

		N	n	%
Sex	Female	12720	5707	44.9
	Male		7013	55.1
Gestational age (weeks)	< 29	12729	3514	27.6
	29 – < 33		4033	31.7
	33– < 35		2434	19.1
	≥ 35		2748	21.6
Birth weight	< 1000 g	12729	2946	23.1
	1000 – 1499 g		3063	24.1
	1500 – 1999 g		2590	20.3
	≥ 2000 g		4130	32.4

Source: Annex A2.2.5, p. 14 and p. 15

Table 10.2-12: Baseline characteristics (quantitative variables) – EVP 09/10 – 15/16

	Gestational age (weeks)	Birth weight (g)	Age at start of immunoprophylaxis (months)
N	12729	12729	12729
Missing	0	0	0
Mean	31.5	1730	4.3
SD	4.3	840	3.6
Minimum	22	330	0.0
25%-Quantile	28	1070	1.8
Median	32	1605	3.2
75%-Quantile	34	2230	5.5
Maximum	42	6160	26.2

Source: Annex A2.2.5, p. 15 and p. 18 and corresponding correction

Characteristics of immunoprophylaxis with palivizumab are summarized in Table 10.2-13. Parental adherence to the passive immunoprophylaxis schedule was rated as good for 93.5%, satisfying for 5.4%, and bad for 1.0%. Prophylaxis was started in the hospital in 24.6% of the evaluable population (3127 subjects). The corresponding rate of 'first prophylactic injection in the hospital' increased from 18% in 2009/10 to 29% in 2015/16 (Figure 1). Median age of subjects at the start of the palivizumab prophylaxis was 3.2 months (Table 10.2-2).

Figure 3: Location of first administration

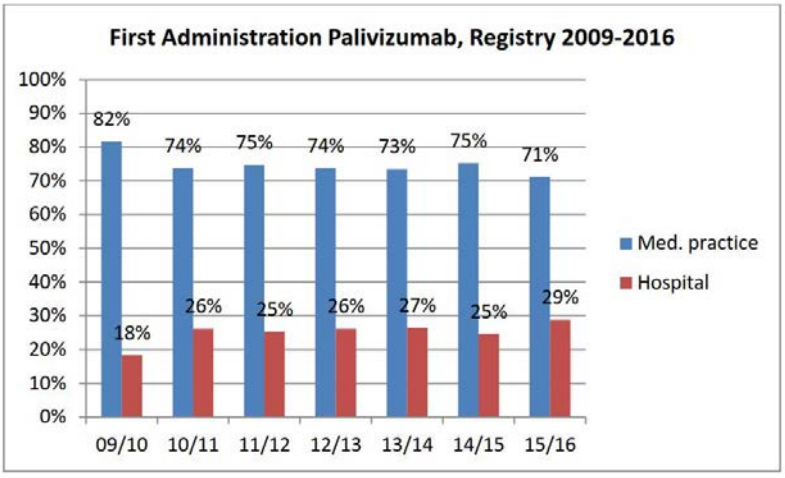

Table 10.2-13: Immunoprophylaxis with palivizumab – EVP 09/10 – 15/16

		N	n	%
Immunoprophylaxis with palivizumab started in clinic		12729	3127	24.6
Immunoprophylaxis with palivizumab started in medical practice		12729	9406	73.9
Cooperation of parents	Good	54968*	51408	93.5
	Satisfying		2985	5.4
	Bad		575	1.0

Source: Annex A2.2.5, p.17
* Number of injections of palivizumab

Risk factors for all evaluable subjects of seasons 2009 to 2016 are summarized in Table 10.2-14. 84.7% of all subjects were born premature (10784 subjects) and 31.2% had multiple-birth siblings (3793 subjects). In total, 18.9% (2346 subjects) had a diagnosis of

CLD and 14.7 (1803 subjects) received CLD therapy, while 6.1% (763 subjects) were treated with oxygen at home. 27.3% (3430 subjects) had a diagnosis of CHD and 6.3% (784 subjects) had a cyanotic heart defect. In 1.4% (171 subjects), the attending physician classified the subject as immunodeficient. 9.3% (786 subjects) had a diagnosis of NMI and 5.1% (428 subjects) had a serious neurological disease. 2.0% of subjects (249 subjects) were diagnosed with Down syndrome. The following other extrinsic risk factors were present that are associated with a higher risk for a severe RSV infection: 32.2% (2037 subjects) were exposed to smoking in the family, 45.5% (4899 subjects) had siblings in kindergarten or school and 24.5% (2592 subjects) lived in crowded living conditions. Only 2.9% (361 subjects) attended daycare. About half of all subjects (50.8%, 5794 subjects) were breast fed for $\leq$ 2 months.

Table 10.2-14: Risk factors at baseline – EVP 09/10 – 15/16

	N	n	%
Premature birth (< 36 weeks GA)	12729	10784	84.7
Multiple births	12147	3793	31.2
Chronic lung disease (CLD)	12422	2346	18.9
CLD therapy	12291	1803	14.7
Treatment with oxygen at home	12490	763	6.1
Congenital heart disease (CHD)	12544	3430	27.3
Cyanotic heart defect	12363	784	6.3
Immunodeficiency	12271	171	1.4
Down syndrome (Trisomy 21)	12729	249	2.0
Neuromuscular impairment (NMI)	8435	786	9.3
Serious neurological disease	8393	428	5.1
NMI positive*	12185	1181	9.7
Smoking in the family	6332	2037	32.2
Family history of asthma	10589	1128	10.7
Family history of atopy	10606	2039	19.2
Attending daycare	12389	361	2.9
Siblings in kindergarten or school	10767	4899	45.5
Low social status	11915	2258	19.0
Crowded living conditions	10575	2592	24.5
Exposition to air pollution	10960	1710	15.6
Breast feeding ≤ 2 months	11417	5794	50.8

Source: Annex A2.2.5, p. 16
*Neuromuscular impairment positive or serious neuromuscular disease positive

10.3 Outcome Data

The main outcome data for the SYNAGIS registry is the occurrence of RSV hospitalizations for all evaluable subjects. The number of evaluable subjects is already described in Table 10.1-1, Table 10.1-3 and Table 10.1-6. The number of RSV hospitalizations is *per se* the main outcome and is displayed in the following sections.

10.4 Main Results

10.4.1 Registry 02/03 – 06/07

Hospitalization due to RSV was documented on a separate hospitalization form. In addition, in the CRF, the occurrence of hospitalizations was reported for each Synagis® administration.

The total number of documented hospitalizations was calculated from both sources: For each subject the maximum number of documented hospitalizations was used. That is, if more forms were available than number of hospitalizations reported in the CRF, the number of forms determined the number of hospitalizations for this subject – and vice versa. Because all participating physicians were clearly and repeatedly instructed to report any hospitalization, subjects with missing data on the presence/absence of hospitalizations were counted as “no hospitalization”.

In Table 10.4-1 and Table 10.4-2 an overview of documented hospitalizations and concerned subjects is given. In total, 495 hospitalizations for 451 subjects (4.2%) were documented. Of these, 334 hospitalizations of 324 subjects (3.0% of all subjects) were documented on hospitalization forms. There was a discrepancy between documentations on hospitalization form and CRF: For 134 subjects (1.3%) more hospitalizations were reported in the CRF than forms were present; in 90 subjects (0.8%) more forms were present than hospitalizations were documented in the CRF.

Table 10.4-1: Overview of hospitalizations per season (EVP 02/03 – 06/07)

Hospitalizations	02/03*	03/04	04/05	05/06	06/07	All
Documentation via CRF and/or form	82	64	87	123	139	495
Documentation via form	–	57	74	107	96	334
Missing forms for documented hospitalizations on CRF	82	7	13	16	43	161
Documentation via form, but not on CRF	–	18	16	23	36	93

Source: Annex A2.2.4, Tables 1.1-4, 1.2-4, 1.3-4, 1.4-4, 1.5-4
*Form not available in season 02/03

Table 10.4-2: Overview of subjects with hospitalizations per season (EVP 02/03 – 06/07)

Subjects with	02/03* (N = 853)	03/04 (N = 1287)	04/05 (N = 2208)	05/06 (N = 3000)	06/07 (N = 3338)	All (N = 10686)
Subjects with any hospitalization (documentation via CRF and/or form)	82 (9.6%)	58 (4.5%)	84 (3.8%)	115 (3.8%)	112 (3.4%)	451 (4.2%)
Subjects with hospitalization (documentation via form)	–	54 (4.2%)	74 (3.4%)	103 (3.4%)	93 (2.8%)	324 (3.0%)
Subjects with missing forms for hospitalization	82 (9.6%)	7 (0.5%)	11 (0.5%)	13 (0.4%)	21 (0.6%)	134 (1.3%)
Subjects with hospitalization documented on form, but not on CRF	–	16 (1.2%)	16 (0.7%)	23 (0.8%)	35 (1.0%)	90 (0.8%)

Source: Annex A2.2.4, Tables 1.1-4, 1.2-4, 1.3-4, 1.4-4, 1.5-4
*Form not available in season 02/03

In the following, description of analyses is based on the information on hospitalizations documented on forms. Hence, analyses are based on the 334 documented hospitalizations.

In 46.1% (154 hospitalizations), the hospitalization was allocated to 'RSV associated' according to diagnosis at hospital discharge (Table 10.4-3). In 145 of 'RSV associated' hospitalizations (43.4%), this was confirmed by a positive RSV test result. In total, an RSV test was performed for 211 hospitalizations (63.2%).

Of all documented hospitalizations with RSV tests result, 73.9% yielded a 'positive' result (156 of 211). Predicting RSV test outcomes for hospitalizations with missing RSV information, 73.9% of all hospitalizations with no available RSV test result (123

hospitalizations) would have yielded a positive RSV result (91 additional hospitalizations). Following this scenario, 247 hospitalizations would eventually have yielded a positive RSV test result with an overall RSV-related hospitalization rate of 2.5% (= 247/9833).

Table 10.4-3: Overview of RSV information for hospitalizations (EVP 02/03 – 06/07)

	n	%*
Hospitalizations allocated to 'RSV associated[a]	154	46.1
Hospitalizations allocated to 'RSV associated[a] with RSV test performed	145	43.4
Hospitalizations allocated to 'RSV associated[a] with RSV test result positive	145	43.4
Hospitalizations allocated to 'RSV associated[a] with RSV test result negative or RSV test not performed	9	2.7
Hospitalizations with no RSV test performed[b]	123	36.8
Hospitalizations with RSV test performed	211	63.2
Hospitalizations with RSV test positive	156	46.7
Hospitalizations with RSV test negative	55	16.5

Source: Annex A2.2.1, Table 5.3.3.1
[a]According to diagnosis at hospital discharge
[b]Missing and unknown RSV result
*N=334 (total number of hospitalizations documented on forms). For season 02/03 no forms were available.

In Table 10.4-4 the effectiveness of RSV prophylaxis is depicted. For this, the rate of subjects with at least one hospitalization that is allocated to 'RSV associated' was calculated. For seasons 2003 – 2007, 152 subjects with RSV-associated hospitalizations were reported. This corresponds to a rate of 1.5%. Additionally, the rate of subjects with at least one hospitalization with positive RSV test is depicted. For seasons 2003 – 2007, 154 subjects had at least one hospitalization with positive RSV test. This corresponds to a rate of 1.6%. The average number of RSV-associated hospitalizations for all evaluable subjects in seasons 2003 – 2007 was 0.016, the average number of hospitalizations with positive RSV test for all evaluable subjects in seasons 2003 – 2007 was 0.016, as well.

Table 10.4-4: Rate of hospitalizations on total population (EVP 02/03 – 06/07)

Subjects with at least one	**03/04 (N = 1287)**	**04/05 (N = 2208)**	**05/06 (N = 3000)**	**06/07 (N = 3338)**	**2003 –2007 (N = 9833)**
RSV associated hospitalization [a]	20 (1.6%)	33 (1.5%)	45 (1.5%)	54 (1.7%)	152 (1.5%)
Hospitalization with positive RSV test	21 (1.6%)	34 (1.5%)	42 (1.4%)	57 (1.7%)	154 (1.6%)

Source: Annex A2.2.7, Tables 1.1, 1.2
Forms with corresponding information not available in season 02/03
[a]According to diagnosis at hospital discharge

The following diagnoses were associated with an RSV infection by the physician at discharge of the subject (Table 10.4-5): RSV-Bronchiolitis (99 hospitalizations, 29.6%), RSV pneumonia (44 hospitalizations, 13.2%) and RSV infection (49 hospitalizations, 14.7%).

Table 10.4-5: Diagnosis documented at hospital discharge – EVP 02/03 – 06/07

	n	**%***
Bronchiolitis	67	20.1
RSV-Bronchiolitis	99	29.6
Pneumonia (Viral pneumonia)	26	7.8
RSV-Pneumonia	44	13.2
RSV-Infection	49	14.7
Other	134	40.1
Any RSV diagnosis	154	46.1

Source: Annex A2.2.1, Tables 5.1.1, 5.1.2, 5.1.3, 5.1.4, 5.1.5, 5.1.6, 5.1.7
*Multiple entries for discharge diagnosis were possible (334 = 100.0%).
In Season 02/03 no distinction between infection types were made.

Regarding all documented cases of hospitalization, in 33.2% (111 hospitalizations) admission to ICU care was required with a median duration of 8 days, in 53.0% (177 hospitalizations) supplemental oxygen was given with a median duration of 5 days, and in 13.2% (44 hospitalizations) mechanical ventilation was applied with a median duration of 6 days (Table 10.4-6 and Table 10.4-7). Documented treatment interventions for the 145 subjects with RSV-related complications were ICU admission in 32.4% (47 hospitalizations), supplemental oxygen in 64.1% (93 hospitalizations), and mechanical ventilation in 9.7% (14 hospitalizations).

Table 10.4-6: Presence of complications at hospitalization – EVP 02/03 – 06/07

	Hospitalization (N = 334)		Hospitalization with confirmed RSV diagnosis (N = 145)	
	n	%*	n	%*
ICU admission	111	33.2	47	32.4
O_2 dependency	177	53.0	93	64.1
Mechanical ventilation	44	13.2	14	9.7

Source: Annex A2.2.1, Tables 5.4.1, 5.5.1, 5.6.1, 9.3, 9.4, 9.5
*Multiple entries for complications were possible (N accounts for 100.0%).
In Season 02/03 no complications were evaluated.

Table 10.4-7: Duration (days) of complications at hospitalization – EVP 02/03 – 06/07

	ICU	O_2 dependency	Mechanical ventilation
N	85	134	35
Mean	14.7	7.1	9.9
SD	18.9	8.1	10.7
Minimum	1	0	1
25%-Quantile	3	2	3
Median	8	5	6
75%-Quantile	15	8	10
Maximum	103	43	45

Source: Annex A2.2.1, Tables 5.4.2, 5.5.2, 5.6.2
In Season 02/03 no complications were evaluated

10.4.2 Registry 07/08 and 08/09

10.4.2.1 Registry 07/08

Information on hospitalizations of season 07/08 was recorded in the same way as in the previous seasons (see Section 10.4.1).

In Table 10.4-8 an overview of documented hospitalizations and concerned subjects is given. In total, 149 hospitalizations for 125 subjects (3.3%) were documented. Of these, 121 hospitalizations of 107 subjects (2.8%) were documented on hospitalization forms. As before, there was a discrepancy between documentations on hospitalization form and CRF: For 23 subjects (0.6%) more hospitalizations were reported in the CRF than forms were present; in 25 subjects (0.7%) more forms were present than hospitalizations were documented in the CRF.

In the following, description of analyses is based on the information on hospitalizations documented on forms. Hence, analyses are based on the 121 documented hospitalizations.

Table 10.4-8: Overview of hospitalizations and subjects with hospitalization (EVP 07/08)

	Hospitalizations	**Subjects with hospitalizations (N = 3805)**
Documentation via CRF and/or form	149	125 (3.3%)
Documentation via form	121	107 (2.8%)
Missing forms for documented hospitalizations on CRF	31	23 (0.6%)
Documentation via form, but not on CRF	31	25 (0.7%)

Source: Annex A2.2.4, Table 1.6-4

In 47.1% (57 hospitalizations), the hospitalization was allocated to 'RSV associated' according to diagnosis at hospital discharge (Table 10.4-9). In 50 of 'RSV associated' hospitalizations (41.3%), this was confirmed by a positive RSV test result. In total, an RSV test was performed for 78 hospitalizations (64.5%).

Of all documented hospitalizations with RSV test result, 66.7% yielded a 'positive' result (52 of 78). Predicting RSV test results for hospitalizations with missing information, 66.7% of all hospitalizations with no available RSV test result (43 hospitalizations) would have yielded a positive RSV result (29 additional hospitalizations). Following this scenario, 81 hospitalizations would eventually have yielded a positive RSV test result with an overall RSV-related hospitalization rate of 2.1% (= 81/3805).

For evaluating the effectiveness of RSV prophylaxis, the rate of subjects with at least one RSV-associated hospitalizations was calculated (Annex 2.2.7, Tables 1.1, 1.2). 56 subjects had at least one 'RSV-associated' hospitalization. This corresponds to a rate of 1.5%. The percentage of subjects with at least one hospitalization with positive RSV test was 1.3% (51 subjects). For 3805 evaluable subjects, 57 RSV-associated hospitalizations and 52 hospitalizations with a positive RSV test result were documented. This corresponds to an average number of RSV-associated hospitalizations of 0.015. The average number of hospitalizations with positive RSV test was 0.014.

Table 10.4-9: Overview of RSV information for hospitalizations (EVP 07/08)

	n	%*
Hospitalizations allocated to 'RSV associated'[a]	57	47.1
Hospitalizations allocated to 'RSV associated' [a] with RSV test performed	51	42.1
Hospitalizations allocated to 'RSV associated' [a] with RSV test result positive	50	41.3
Hospitalizations allocated to 'RSV associated' [a] with RSV test result negative or RSV test not performed	7	5.8
Hospitalizations with no RSV test performed[b]	43	35.5
Hospitalizations with RSV test performed	78	64.5
Hospitalizations with RSV test positive	52	43.0
Hospitalizations with RSV test negative	26	21.5

Source: Annex A2.2.2, Table 5.3.3
[a]According to diagnosis at hospital discharge
[b]Unknown RSV result
*N=121 (total number of hospitalizations documented on forms)

The following diagnoses that are associated with an RSV infection were documented by the physician at discharge of the subject (Table 10.4-10): RSV-Bronchiolitis (34 hospitalizations, 28.1%), RSV pneumonia (14 hospitalizations, 11.6%) and RSV infection (26 hospitalizations, 21.5%).

Table 10.4-10: Diagnosis documented at hospital discharge – EVP 07/08

	n	%*
Bronchiolitis	18	14.9
RSV-Bronchiolitis	34	28.1
Pneumonia (Viral pneumonia)	12	9.9
RSV-Pneumonia	14	11.6
RSV-Infection	26	21.5
Other	70	57.9
Any RSV diagnosis	57	47.1

Source: Annex A2.2.2, Tables 5.1.1, 5.1.2, 5.1.3, 5.1.4, 5.1.5, 5.1.6
*Multiple entries for discharge diagnosis were possible (121 = 100.0%).

Regarding all documented cases of hospitalization, in 24.0% (29 hospitalizations) admission to ICU was required with a median duration of 9 days, in 44.6% (54 hospitalizations) supplemental oxygen was given with a median duration of 5 days, and in

9.1% (11 hospitalizations) mechanical ventilation was applied with a median duration of 9 days (Table 10.4-11 and Table 10.4-12).

Table 10.4-11: Presence of complications at hospitalization – EVP 07/08

	Hospitalization (N = 121)	
	n	%*
ICU admission	29	24.0
O_2 dependency	54	44.6
Mechanical ventilation	11	9.1

Source: Annex A2.2.2, Tables 5.4.1, 5.5.1, 5.6.1
*Multiple entries for complications were possible (121=100.0%).

Table 10.4-12: Duration (days) of complications at hospitalization – EVP 07/08

	ICU	O_2 dependency	Mechanical ventilation
N	21	38	7
Mean	10.9	9.7	8.1
SD	9.1	18.8	7.0
Minimum	1	1	1
25%-Quantile	4	3	1
Median	9	5	9
75%-Quantile	14	9	11
Maximum	38	115	21

Source: Annex A2.2.2, Tables 5.4.2, 5.5.2, 5.6.2

10.4.2.2 Registry 08/09

In the season 2008/09, the eCRF system for data collection was introduced. Hospitalization due to RSV infection was documented on a separate hospitalization form in the eCRF. In addition, the occurrence of hospitalization was documented for each palivizumab injection.

In Table 10.4-13 an overview of documented hospitalizations and concerned subjects is given. In total, 119 hospitalizations for 104 subjects (4.6%) were documented. Of these, 92 hospitalizations of 79 subjects (3.5%) were documented on the separate hospitalization form. As before, there was a discrepancy between documentations on form and on the immunoprophylaxis documentation sheet: A hospitalization was mentioned in 25 subjects (1.1%) on the immunoprophylaxis documentation sheet, but further documentation on the

form was not available; for none of the subjects information was missing on the immunoprophylaxis documentation sheet when information on the form was documented.

In the following, description of analyses is based on the information on hospitalizations documented on forms. Thereof, 2 hospitalizations were not considered within the original analysis tables. Hence, analyses are based on the 90 documented hospitalizations.

Table 10.4-13: Overview of hospitalizations and subjects with hospitalization (EVP 08/09)

	Hospitalizations	**Subjects with hospitalizations (N = 2248)**
Documentation on immunization prophylaxis sheet and/or form	119	104 (4.6)
Documentation via form	92	79 (3.5)
Missing forms for documented hospitalizations on immunoprophylaxis sheet	27	25 (1.1)
Documentation via form, but not on immunoprophylaxis sheet	0	0 (0.0)

Source: Annex A2.2.3, Table 5.1.1.3

For 18 hospitalizations documented on the hospitalization form (20.0%), a causal relationship to RSV was specified (Table 10.4-14). This corresponds to an average number of RSV-associated hospitalizations of 0.008 concerning all 2248 evaluable subjects. On the assumption that no multiple RSV-associated hospitalization occurred per subject, 0.008 (i.e. 0.8%) is the proportion of subjects with an RSV-associated hospitalization.

For 44 hospitalizations (48.9%) an RSV test was performed. In 17 cases (18.9%), a causal relationship with RSV was confirmed by a positive RSV test. Of all documented hospitalizations with RSV tests result, 40.9% yielded a ‘positive’ result (18 of 44). This corresponds to an average number of hospitalizations with positive RSV test result of 0.008 concerning all 2248 evaluable subjects. On the assumption that no multiple RSV-associated hospitalization occurred per subject, 0.008 (i.e. 0.8%) is the proportion of subjects with a hospitalization with positive RSV test result.

Predicting RSV test results for hospitalizations with missing information, 40.9% of all hospitalizations with not available RSV test result (46 hospitalizations) would have yielded a positive RSV result (19 additional hospitalizations). Following this scenario, 37

hospitalizations would eventually have yielded a positive RSV test result with an overall predicted RSV-related hospitalization rate of 1.6% (37/2248).

Table 10.4-14: Overview of RSV information for hospitalizations (EVP 08/09)

	n	%*
Hospitalizations with causal relationship to RSV	18	20.0
Hospitalizations allocated to 'RSV associated' [a] with RSV test performed	17	18.9
Hospitalizations allocated to 'RSV associated' [a] with RSV test result positive	17	18.9
Hospitalizations allocated to 'RSV associated' [a] with RSV test result negative or RSV test not performed	0	0.0
Hospitalizations with no RSV test performed[b]	46	51.1
Hospitalizations with RSV test performed	44	48.9
Hospitalizations with RSV test positive	18	20.0
Hospitalizations with RSV test negative	26	28.9

Source: Annex A2.2.3, Tables 5.3, 5.4.1, 5.4.3
*N=90 (total number of hospitalizations documented)
[a]Evaluated with a causal relationship to RSV
[b]Missing information or not assessable

In season 08/09, the physician had the opportunity to specify a primary diagnosis at hospital discharge (see Table 10.4-15). In 24 hospitalizations (26.7%), bronchitis was diagnosed. In 25 hospitalizations (27.8%), pneumonia was diagnosed. 18 were confirmed by chest radiography (20.0% of all hospitalizations). Bronchiolitis, acute respiratory failure and apnoe-bradycardia syndrome occurred in less than 5 hospitalizations each. Note that in 33 cases (36.7%), the physician did not specify a primary discharge diagnosis.

Table 10.4-15: Diagnosis documented at hospital discharge – EVP 08/09

	n	%*
Bronchitis	24	26.7
Bronchiolitis	4	4.4
Pneumonia (clinical diagnosis)	7	7.8
Pneumonia (confirmed by chest radiography)	18	20.0
Acute respiratory failure	3	3.3
Apnoe-bradycardia syndrome	1	1.1
Not specified	33	36.7

Source: Annex A2.2.3, Table 5.5.1
*N=90 (total number of hospitalizations)

Regarding all documented cases of hospitalization, in 24.4% (22 hospitalizations) admission to ICU was required with a median duration of 10 days (Table 10.4-16 and Table 10.4-17). In 46.7% (42 hospitalizations) supplemental oxygen was given – in 34 of these cases this was due to a respiratory infection. In 8.9% (8 hospitalizations) mechanical ventilation was applied with a median duration of 3.5 days. A nosocomial infection occurred in 11 hospitalizations (12.2%). No deaths associated with RSV infection were reported.

Table 10.4-16: Presence of complications at hospitalization – EVP 08/09

	Hospitalization (N = 90)	
	n	%*
Nosocomial infection	11	12.2
ICU admission**	22	24.4
O_2 dependency because of respiratory infection	34	37.8
O_2 dependency because of other reasons	8	8.9
Mechanical ventilation***	8	8.9
Death associated with RSV infection	0	–

Source: Annex A2.2.3, Tables 5.2, 5.6, 5.7, 5.8, 5.9, 5.10
*Multiple entries for complications were possible (90=100.0%).
**Days in ICU > 0
***Days of mechanical ventilation > 0

Table 10.4-17: Duration (days) of complications at hospitalization – EVP 08/09

	ICU	Mechanical ventilation
N	22	8
Mean	11.5	4.9
SD	13.5	4.9
Minimum	1	1
25%-Quantile	3	1
Median	10	3.5
75%-Quantile	14	8
Maximum	64	13

Source: Annex A2.2.4, Tables 2.4, 2.5

10.4.3 Registry 09/10 – 15/16

For the seasons 09/10 and 15/16, analysis of hospitalization numbers and characteristics were solely based on the documentations made on the eCRF hospitalization form. Additionally, the analysis was restricted to subjects that were enrolled into the registry in this season for the first time.

In Table 10.1-1 an overview of all documented hospitalizations and hospitalizations of subjects that were newly enrolled is given. In total, 488 hospitalizations were documented, 448 of which were from newly enrolled subjects. The number of hospitalizations ranged from 47 to 97 and 43 to 88 over the seasons, respectively.

Table 10.4-18: Overview of hospitalizations per season (EVP 09/10 – 15/16)

Hospitalizations	09/10	10/11	11/12	12/13	13/14	14/15	15/16	Total
Total	84	97	65	62	47	66	67	488
Only subjects with first RSV registry	84	88	59	54	43	60	60	448

Source: Annex A2.2.5, p. 18

An overview of hospitalization characteristics and concerned subject groups is displayed in Table 10.4-19. The 448 hospitalizations were observed in 345 newly enrolled subjects (2.7%). Hence, 1.3 hospitalizations per subject were reported. 78.8% of concerned subjects were born prematurely (272 subjects), 34.2% of subjects had CHD (118 subjects), 40.3% had CLD (139 subjects) and 4.1% had Down syndrome (14 subjects). In 49.8% of hospitalizations overall, it was reported that an RSV test was performed (223 hospitalizations). For 17.2% a positive RSV test result was reported (77 hospitalizations).

The average number of RSV-related hospitalizations for all evaluable subjects was 0.007 (= 92/12729). On the assumption that no multiple RSV-related hospitalization occurred per subject, 0.007 (i.e. 0.7%) is the proportion of subjects with an RSV-related hospitalization. The average number of hospitalizations with a positive RSV test result for all evaluable subjects was 0.006 (= 77/12729). On the assumption that no multiple hospitalization with positive RSV test occurred per subject, 0.006 (i.e. 0.6%) is the proportion of subjects with a hospitalization with positive RSV test.

Of all documented hospitalizations with available RSV tests result (77 positive plus 145 negative tests), 34.7% yielded a 'positive' result (77 of 222).

Predicting RSV test results, 34.7% of all hospitalizations with not available RSV test result (226 hospitalizations) would have yielded a positive RSV result (79 additional hospitalizations). Following this scenario, 156 hospitalizations would eventually have yielded a positive RSV test result with an overall predicted RSV-related hospitalization rate of 1.2% (= 156/12729).

No data cleaning using case related queries was performed; in this regard, some inconsistencies could not be resolved such as:

- Missing values regarding the results of performed RSV testing (20 hospitalizations; 10 of these cases were allocated to the category 'probably or confirmed RSV associated hospitalization');
- Hospitalization allocated to the category 'probably or confirmed RSV associated' but 'RSV test result negative' ticked by the documenting physician (1 hospitalization);
- Hospitalization with no information about whether a RSV test was performed, but allocated to the category 'probably or confirmed RSV associated' (12 hospitalizations);
- Hospitalization with RSV test result positive or negative, but no information whether test was performed (19 hospitalizations);

Eventually, we decided to differentiate the following groups for analysis of further hospitalization characteristics:

Group 1: Hospitalization directly allocated to the category 'associated with RSV infection' (92 hospitalizations; line 3 and line 4 of Table 10.4-19)

Group 2: Hospitalizations not allocated to 'associated with RSV infection' (n=356)

Group 3: Subjects without hospitalization during the corresponding RSV season (12384 subjects)

These values sum up to more than the 1279 evaluable subjects / cases since some subjects experienced more than one hospitalization (RSV associated or not) during the corresponding RSV season.

Subject characteristics of groups can be found in Appendix A2.2.5, p. 22.

Table 10.4-19: Overview of RSV information for hospitalizations (EVP 09/10 – 15/16)

	n (% of N[a])	PB[b] (% of n)	CHD[c] (% of n)	CLD[d] (% of n)	CLDT[e] (% of n)	TO[f] (% of n)	DS[g] (% of n)
Hospitalizations total	448 (3.5)	355 (79.2)	164 (36.6)	197 (44.0%)	151 (33.7)	86 (19.2)	22 (4.9)
Subjects with hospitalization	345 (2.7)	272 (78.8)	118 (34.2)	139 (40.3)	106 (30.7)	62 (18.0)	14 (4.1)
Hospitalizations assessed as RSV associated by the physician (confirmed or probably)	88 (0.7)	76 (86.4)	24 (27.3)	38 (43.2)	28 (31.8)	15 (17.0)	3 (3.4)
Hospitalizations assessed as RSV associated by the physician, but RSV test result negative or RSV test not performed	4 (0.03)	4 (100.0)	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hospitalizations with RSV test performed	223 (1.8)	183 (82.1)	73 (32.7)	96 (43.0)	76 (34.1)	39 (17.5)	13 (5.8)
Hospitalizations with RSV test positive	77 (0.6)	65 (84.4)	26 (33.8)	34 (44.2)	24 (31.2)	15 (19.5)	4 (5.2)
Hospitalizations with RSV test negative	145 (1.1)	119 (82.1)	46 (31.7)	64 (44.1)	54 (37.2)	27 (18.6)	9 (6.2)

Source: Annex A2.2.5, p. 20 and p. 33
[a] N = 12729
[b] PB = Premature birth
[c] CHD = Congenital heart disease
[d] CLD = Chronic lung disease
[e] CLDT = Chronic lung disease therapy
[f] TO = Treatment with oxygen at home
[g] DS = Down syndrome

In the following, hospitalization characteristics are displayed separately for hospitalizations that are associated with RSV infection (group 1) and for hospitalizations that are not associated with RSV infection (group 2), see Table 10.4-20 and Table 10.4-21. For hospitalizations associated with RSV infection (n = 92; allocated to the categories 'probably or confirmed RSV-associated hospitalization' by the attending physician) the rate of oxygen administration because of respiratory infection was higher than for those not associated with RSV: 60.9% in comparison to 36.1%. In

hospitalizations not associated with RSV, complications occurred more frequently and had a longer duration. Specifically, admission to ICU was necessary in 18.2% of cases (median duration of 4 days) and mechanical ventilation in 11.9% of cases (median duration of 4.5 days). In hospitalizations associated with RSV, admission to ICU was necessary in 16.9% of cases (median duration of 3 days) and mechanical ventilation in 8.0% of cases (median duration of 2.5 days). No deaths associated with RSV infection occurred in either group.

Table 10.4-20: Characteristics of hospitalizations – EVP 09/10 – 15/16

	Group 1: Associated with RSV infection[a] (N = 92)			**Group 2: Not associated with RSV infection[b] (N =356)**		
	N	**n**	**%**	**N**	**n**	**%**
Nosocomial infection	85	3	3.5	293	12	4.1
Oxygen because of respiratory infection	92	56	60.9	352	127	36.1
Oxygen because of other reasons	92	2	2.2	347	33	9.5
ICU admission (> 0 days)	83	14	16.9	308	56	18.2
Mechanical ventilation (> 0 days)	75	6	8.0	286	34	11.9
Death	91	0	0.0	353	9	2.5
Death associated with RSV infection	68	0	0.0	255	0	0.0

Source: Annex A2.2.5, p. 21
[a] Hospitalizations associated with RSV infection by physician's rating (sure, confirmed or probably)
[b] Hospitalizations not associated with RSV infection by physician's rating

Table 10.4-21: Duration (days) of ICU treatment and mechanical ventilation – EVP 09/10 – 15/16

	ICU		**Mechanical ventilation**	
	Group 1[a]	**Group 2[b]**	**Group 1[a]**	**Group 2[b]**
N	14	56	6	34
Mean	6.2	7.9	6.3	7.4
SD	6.3	8.2	6.8	8.3
Minimum	2	1	1	1
Median	3	4	2.5	4.5
Maximum	23	33	16	37

Source: Annex A2.2.5, p. 21
[a] Hospitalizations associated with RSV infection by physician's rating (sure, confirmed or probably)
[b] Hospitalizations not associated with RSV infection by physician's rating

The main diagnosis documented at hospital discharge differed between groups, as well (Table 10.4-22). For hospitalizations that are not associated with RSV, the majority of physicians indicated bronchitis (52.3%) as the final diagnosis, followed by pneumonia

(38.6%). For hospitalizations associated with RSV, the most often reported final diagnosis was bronchiolitis (37.6%), followed by pneumonia (32.9%) and bronchitis (28.2%).

Table 10.4-22: Diagnosis documented at hospital discharge – EVP 09/10 – 15/16

	Group 1[a] (N = 85)		**Group 2[b] (N = 220)**	
	n	**%**	**N**	**%**
Bronchitis	24	28.2	115	52.3
Bronchiolitis	32	37.6	15	6.8
Pneumonia (clinical diagnosis)	9	10.6	27	12.3
Pneumonia (chest radiography)	19	22.4	58	26.4
Acute respiratory failure	1	1.2	3	1.4
Apnoea-bradycardia syndrome	0	0.0	2	0.9

Source: Annex A2.2.5, p. 21
[a] Hospitalizations associated with RSV infection by physician's rating (sure, confirmed or probably)
[b] Hospitalizations not associated with RSV infection by physician's rating

10.5 Other Analyses

No other analyses were planned for this study.

10.6 Adverse Events and Adverse Reactions

For a comprehensive safety analysis that includes all AEs that are reported to AbbVie PV and that covers large parts of the registry, an export from the database was provided by AbbVie Pharmacovigilance, which is based exclusively on data of the study database (see also Section 9.4). For preparation of this report, the AEs were coded by means of the Medical Dictionary for Regulatory Activities (MedDRA dictionary, version 19.1).

In Table 10.6-1 and Table 10.6-2, the provided information of the PV database is depicted. Seasons were derived upon the PV Awareness date. Start of each season was on 1 September of the corresponding season. The number of reported AEs was higher than average for season 08/09 (12.4% of AEs), season 10/11 (15.5% of AEs) and season 14/15 (11.9% of AEs), whereas the share of reported AEs of the remaining seasons on all reported AEs was equal or below 10.6%. The majority of AEs was categorized as serious (95.5% of all reported events).

The number of ADRs that had been reported in the CRF for seasons 02/03 until 07/08 can be found in Annex A2.2.1, Table 6 and Annex A2.2.2, Table 6.

Table 10.6-1: AEs per season

Season	Total	
	n	%
2006/07	20	1.8
2007/08	101	8.9
2008/09	141	12.4
2009/10	93	8.2
2010/11	176	15.5
2011/12	120	10.6
2012/13	100	8.8
2013/14	79	7.0
2014/15	135	11.9
2015/16	110	9.7
2016/17[a]	60	5.3
All	1135	100.0

Source: Annex A2.2.6, Table 1.1 and 1.3
[a]reported after study end

Table 10.6-2: Seriousness of AEs per season

Season	Seriousness				Total	
	Serious		Non-serious			
	n	%	n	%	n	%
2006/07	16	80.0	4	20.0	20	100.0
2007/08	86	85.1	15	14.9	101	100.0
2008/09	135	95.7	6	4.3	141	100.0
2009/10	93	100.0	0	0.0	93	100.0
2010/11	172	97.7	4	2.3	176	100.0
2011/12	112	93.3	8	6.7	120	100.0
2012/13	97	97.0	3	3.0	100	100.0
2013/14	72	91.1	7	8.9	79	100.0
2014/15	134	99.3	1	0.7	135	100.0
2015/16	107	97.3	3	2.7	110	100.0
2016/17[a]	60	100.0	0	0.0	60	100.0
All	1084	95.5	51	4.5	1135	100.0

Source: Annex A2.2.6, Table 1.1 and 1.3
[a]reported after study end

In Table 10.6-3 and Table 10.6-4 the frequency of SAEs by the most frequent system organ classes (SOCs) respectively preferred terms (PTs) are displayed.

The most frequent SOC was *infection and infestations* (57.0% of SAEs). 13.8% of SAEs were *surgical and medical procedure* and 10.5% of SAEs were *respiratory, thoracic and mediastinal disorders*. All other SOCs occurred in less than 6.0% of SAEs.

The most frequent PT was *bronchitis* (12.2% of SAEs). 10.7% of SAEs were *pneumonia*, 8.2%. The next frequent PTs were RSV infections: *respiratory syncytial virus bronchiolitis* (8.2%), *pneumonia respiratory syncytial viral* (5.0%), *respiratory syncytial virus infection* (4.2%) and *respiratory syncytial virus bronchitis* (3.0%). All other PTs occurred in 3.0% of SAEs or less.

A complete analysis of all terms for SAEs as well as AEs can be found in Appendix A2.2.6 Tables 1.4 – 1.9.

Table 10.6-3: Serious adverse events in total and by SOC

System Organ Class (SOC)	SAEs n	SAEs %*
Any	1084	100.0
Infections and infestations	618	57.0
Surgical and medical procedures	150	13.8
Respiratory, thoracic and mediastinal disorders	114	10.5
General disorders and administration site conditions	64	5.9
Investigations	26	2.4
Metabolism and nutrition disorders	25	2.3
Cardiac disorders	19	1.8
Gastrointestinal disorders	18	1.7
Nervous system disorders	17	1.6

*Multiple entries with the same SOC within one patient were counted only once
Table sorted in descending order by overall frequency, only events with frequency > 1.0% are displayed
Source: Annex A2.2.6, Table 1.7

Table 10.6-4: Serious adverse events in total and by PT

Preferred Term (PT)	SAEs n	SAEs %*
Any	1084	100.0
Bronchitis	132	12.2
Hospitalization[a]	121	11.2
Pneumonia	116	10.7
Respiratory syncytial virus bronchiolitis	89	8.2
Pneumonia respiratory syncytial viral	54	5.0
Respiratory syncytial virus infection	45	4.2
Respiratory syncytial virus bronchitis	33	3.0
Bronchiolitis	32	3.0
Pyrexia	25	2.3
Respiratory tract infection	20	1.8
Dyspnoea	19	1.8
Respiratory failure	19	1.8
Pneumonia viral	18	1.7
Cough	17	1.6
Upper respiratory tract infection	13	1.2
Respiratory disorder	13	1.2
Death	12	1.1
General physical health deterioration	12	1.1

*Multiple entries with the same PT within one patient were counted only once
[a] Hospitalization is by definition a serious criterion and not an event term. Therefore, the term hospitalization was only coded if no other event term was documented in the reporting form, or if the event was assessed as “non-serious” or as “no case”.
Table sorted in descending order by overall frequency, only events with frequency > 1.0% are displayed
Source: Annex A2.2.6, Table 1.8

11.0 Discussion

11.1 Key Results

Results of the German SYNAGIS Registry were subdivided into three parts due to procedural changes including changes in the methods of study data reporting during the conduct of the study: (i) seasons 2002/03 – 2006/07, (ii) 2007/08 and 2008/09, and (iii) 2009/10 – 2015/16. This report on the results of the German SYNAGIS Registry comprises one of the largest prospectively documented datasets on subjects receiving at least one dose of palivizumab during the corresponding RSV season [7]. In total, 142723 injections were documented in 29468 evaluable subjects during the observational period. Mean age of subjects upon start of immunoprophylaxis with palivizumab% was between 4.3 and 5.9 months; there was a slight male preponderance in study participants (53.8%-55.1% males). Median number of palivizumab injections per subject for all study periods throughout the study was 5 (range: 1-12).

Effectiveness data of palivizumab prophylaxis are in concordance with published reports from other palivizumab registries (recently reviewed by Paes et al. [7]): Data within this registry revealed RSV-related hospitalization rates of 0.7% – 1.6% (evaluated by the mean number of RSV-associated hospitalizations). Extrapolating the rates of RSV tests to unknown RSV test results by basing them on the average number of hospitalizations with proven RSV infection yielded effectiveness rates of 1.2 – 2.5%. Both margins are still inside the expected margins derived from prospectively randomized trials [1-3].

The decisions of the participating physicians to administer palivizumab prophylaxis to an individual patient were based on underlying risk factors [4], and on the official German recommendations for passive immunization against RSV in neonates: Most evaluable subjects were prematurely born, with a median gestational age at birth between 29 and 32 weeks. A significant proportion (18.9% – 42.6%) had CLD (BPD). Medical treatment of CLD in the 6 months preceding the first administration of palivizumab was documented from 2008/09 in 12.5%-14.7% of subjects per study period.

Between 25.2% and 34.9% of subjects were diagnosed with CHD. Hemodynamically significant congenital heart disease (hsCHD) was added to the list of recommended indications for palivizumab in Germany in 2004 as per an official DGPK statement [113]. Starting in 2008/09, the investigators could indicate whether hsCHD was the main reason for prophylaxis; this was documented in 13%-14.1% of subjects per study period. The overall hospitalization rate for subjects passively immunized with palivizumab for CHD in the German SYNAGIS Registry 2009-2016 was 3.4% (n = 118); the corresponding average number of RSV-related hospitalizations in subjects with CHD diagnosis was 0.8% (n = 26).

Of all evaluable subjects, 13.9 – 24.6% started the palivizumab passive immunization schedule in the hospital (before discharge). Interestingly, this proportion increased from 2002 to 2016 from 15.6% to 24.6%. A plausible explanation for this observation may be the introduction of an official reimbursement for palivizumab prophylaxis in hospitalized subjects since 2008 ('Zusatzentgelt').

The data from the German SYNAGIS Registry describe significant morbidity in subjects who underwent an RSV-related hospitalization despite palivizumab prophylaxis. Documented treatment interventions for the subjects with RSV-related complications were as follows:[4]

- In 2002-2007, during RSV-related hospitalizations, ICU admission took place in 32.4%, supplemental oxygen administration in 64.1%, and mechanical ventilation in 9.7%;
- In 2009-2016, during RSV-related hospitalizations, ICU admission took place in 16.9% (median duration of 3 days), supplemental oxygen administration in 60.9%, and mechanical ventilation in 8.0% (median duration of 2.5 days).

Interestingly, during hospitalizations not associated with RSV from 2009-2016, the rates of treatment interventions were of similar magnitudes: intensive care monitoring was performed in 18.2%, and mechanical ventilation in 11.9%; however, supplemental oxygen was administered markedly less often (36.1%) than in RSV-related hospitalizations.

Safety information was documented in the CRFs and by means of separate adverse event reporting forms. Detailed information on adverse events (terms, serious criteria, outcome etc.) were not included in the study database, but were still captured and processed by AbbVie pharmacovigilance. Overall, 839 adverse events were reported. The number of reported AEs were higher than average for season 08/09 (15.1% of AEs) and season 10/11 (19.0% of AEs). Of note, the overwhelming majority of AEs was categorized as serious (95.8% of all reported events), which may be due to a potential underreporting of non-serious events. Most frequent events were infections of the respiratory system. As causality information was not provided, further interpretation regarding the safety profile of palivizumab could not be performed. However, review of the safety data indicates that the majority of the SAEs were not unexpected for the pediatric patients with significant medical conditions (i.e., prematurity, bronchopulmonary dysplasia/chronic lung disease, or CHD) indicated for palivizumab.

[4] The results from October 2007-May 2009 do not allow a separate analysis of intensive care monitoring for subjects with RSV-related hospitalization.

11.2 Limitations

Data of an observational study are inherently of a lower evidence level than in a clinical trial. Although all therapeutic decisions were completely at the discretion of the participating physicians, and participation in the registry was not supposed to influence any decision regarding medical treatment of the included subjects, selection bias cannot be ruled out entirely. Moreover, in this observational study, no active on-site data monitoring had been performed. Thus, the validity of the primary data mainly depends on correct reporting by the physicians.

11.3 Interpretation

The results of the German Palivizumab Registry confirm the effectiveness of palivizumab prophylaxis in concordance with published reports from other palivizumab registries (recently reviewed by Paes et al. [7]). Additionally, in a study using the U.S.-American The Kids' Inpatient Database, Doucette et al. [114] recently confirmed, that RSV hospitalization rates declined among subjects with CLD by 47.0% and and among higher-risk CHD subjects by 49.7% between 1997 and 2012, coincident with widespread RSV immunoprophylaxis use in these populations.

Much higher RSV-related rehospitalization rates in subjects with CHD (overall incidence 9.6%) than those documented in the German SYNAGIS Registry have been published by Resch et al. in their prospective analysis of RSV related hospitalizations in Graz (Austria) between 2004 and 2008 [115]. Importantly, palivizumab effectiveness in this population was not an endpoint of that study (personal communication of Prof. [redacted] with Prof. [redacted], December 09, 2016), and the authors identified a documented recommendation for palivizumab in only 27.2% of the clinical records of subjects with hsCHD.

Children with CHD are most likely to be eligible for palivizumab prophylaxis if suffering from hsCHD during the first year of life [116]. Chang et al. recently investigated the impact of palivizumab on RSV-hospitalizations in subjects with hsCHD in California [117]. Statewide hospital discharge data from years 2000-2002 (pre-AAP [American Academy of Pediatrics] policy revision) were compared to those from the years 2004-2006 (post-AAP policy revision). Hospitalizations due to RSV bronchiolitis in children < 2 years of age were identified by ICD-9 CM (International Classification of Diseases, Ninth Revision, Clinical Modification) codes, and children with CHD/hsCHD were identified by their concomitant diagnoses. The overall rate of RSV-hospitalizations was 71 per 10000 subjects < 2 years of age. Of all RSV-hospitalizations, 3.0% were among subjects with CHD, and 0.50% among subjects with hsCHD. In 2000-02, hsCHD subjects accounted for 0.56% of RSV-hospitalizations, compared to 0.46% RSV-hospitalizations

in 2004-2006. After 2003, a 19% reduction in RSV hospitalizations among hsCHD subjects was observed. This 19% decrease in RSV-hospitalizations equated to seven fewer hospitalizations (76 hospital days) per year among hsCHD subjects or 29 hospitalizations over fours RSV seasons (N = 1287, 639 of which in the palivizumab group). The authors concluded that the impact on RSV hospitalizations in California among hsCHD patients since 2003 has been limited. As a most likely explanation, the authors postulate low adherence, yet several limitations of the study must also be taken into account.

As pointed out above, the administration of palivizumab in hospitalized high-risk patients to prevent nosocomial RSV-infection [124, 125] has never been addressed in German recommendations for palivizumab use. Recently, a proposal of the German Society of Virology [119, 126] argued for this practice, referring to some reports in which palivizumab has been used to contain outbreaks, e.g. in neonatal ICUs [20, 127-130].

Until today, no active monitoring / home care programs for RSV prophylaxis, such as the Syncare® program in Ireland and in The Netherlands [132] or the CARESS Registry in Canada [7] have been implemented in Germany. Whether or not a patient receives palivizumab prophylaxis is completely left at the discretion of the attending neonatologist or pediatrician. Nonetheless, in the German SYNAGIS Registry the overall compliance/adherence of the parents of evaluable subjects with the palivizumab administration regimen [5, 6] was 91.1 – 93.5% of cases (documented per injection commencing in 2008/09 and documented per infant from 2002/03 to 2007/08). High adherence was reported perhaps since most parents do not have to drive very long distances to their medical provider, and German pediatricians try to accommodate and facilitate separate appointments for high-risk subjects in order to avoid exposure to respiratory pathogens in the waiting area of their office. The high level of adherence may be as well reflected by the high proportion of subjects, who have received more than 5 palivizumab injections during the corresponding RSV season (35% - 45%). The results from 2009-2016 confirm that most physicians started palivizumab administration in September or October. At this early time point, the decision for immunoprophylaxis (with palivizumab) may not have been based on the time course of the corresponding RSV-season in the particular geographical region where the patient lives [119]. Although there have been some attempts to publish actual RSV activities related to different geographical regions in Germany (http://rvdev.medical-dpc.com/), this important information is often incomplete or entirely unavailable for the physician. Reasons for the high rate of subjects receiving more than 5 injections may be diverse, including an extended RSV season requiring longer prophylaxis.

Importantly, after repeated injections a sustained increase in serum palivizumab can be measured shown to be protective [120] and which is maintained for 4 weeks after the last injection [85, 121]. This argumentation (together with cost issues) has been considered in the recommendations of the AAP in 2014 [85]. However, other authors have argued

against a shorter administration schedule and discussed the rationale for full-season dosing for passive antibody prophylaxis of respiratory syncytial virus due to significant decline in serum concentrations [122]. In fact, the number of publications confirming the safety of a shorter administration schedule (only 3 or 4 monthly injections depending on the risk profile of the patient) is still very limited [123].

Gestational age threshold for palivizumab in moderate-to-late preterm infants (gestational age at birth 32-35 weeks) is still under debate [50, 133], but such restrictive schedules of palivizumab administration may increase the burden of RSV-infections in high-risk subjects attending public healthcare facilities [134]. In addition, there may be a higher risk of long term respiratory morbidity (such as recurrent wheezing) in preterm subjects born at 32-35 weeks [52] who do not receive palivizumab prophylaxis and experience a severe RSV infection during infancy [3, 135, 136].

In the German SYNAGIS Registry, nasal swabs to detect or exclude an RSV infection were not consistently performed on hospital admission in all evaluable subjects during the observation period. Indeed, an RSV test was documented only in 48.9% – 64.5% of all hospitalizations. Diagnostic testing for RSV infection in infants and children, who are hospitalized despite palivizumab prophylaxis, is of particular importance to allocate the hospitalization to the categories “RSV-related” or “Not-RSV-related” and to identify “palivizumab failures” (RSV-related hospitalization despite a correct passive immunization schedule). Sullivan et al. [137] reported on 23 subjects who received palivizumab for the 2013-2014 bronchiolitis season. Among those subjects, there were 10 admissions for bronchiolitis, in 8 of which affected subjects had been receiving palivizumab (35%). In none was the swab positive for RSV, 3 were positive for rhinovirus and in the remainder, no virus was identified. Despite an admission rate of 43% (10/23) subjects with bronchiolitis in this high-risk group, in none of the subjects was an RSV infection detected by the molecular test. On the other hand, routine RSV testing on admission for surveillance purposes (e.g., in a patient scheduled for elective cardiac surgery) may yield a positive result in an asymptomatic child [138]. It is known that asymptomatic prolonged shedding of the virus after cessation of clinical symptoms may follow an RSV infection in the recent medical history. In these cases, RSV is not causally related to the current hospitalization [139]. Therefore, RSV test results, albeit highly useful, must be interpreted in the context of the overall clinical picture.

Simon et al. [16, 59, 73, 140] performed a prospective multicenter study to investigate risk factors and clinical course of patients hospitalized with RSV infection in German hospitals (DSM RSV Paed Study). This study covered six consecutive RSV seasons (1999-2005); the surveillance took place in 14 pediatric hospitals in Germany. Of the 1568 prospectively documented RSV infections resulting in hospitalization, 26% (n = 406) were observed in preterms [vs. 1162 subjects born at term (74%)] and 3% (n = 50) had chronic lung disease (CLD), of which 49 had received treatment in the last 6 months

('CLD plus'). The attributable mortality was 0.2% (n = 2) in the subjects born at term group vs. 1.2% (n = 5) in the preterm group (p = 0.015). The corresponding results for community-acquired (n = 1,478) and nosocomially acquired RSV infection (n = 90) were 0.4% and 1.1%, respectively [16]. The attributable mortality was significantly higher in subjects with preexisting neuromuscular impairment (5.5% vs. 0.2%; P < 0.001). The highest attributable mortality was documented in subjects, who had been mechanically ventilated for other reasons before the RSV infection (n = 3 of 20; 15%) [73].

Egglestone et al. [141] described the clinical course of subjects admitted to a pediatric intensive care unit (ICU) due to LRTI caused by either RSV or human metapneumovirus (HmPV). Of all subjects hospitalized with RSV infection during the study period 14.4% required pediatric intensive care; 107 of the ICU admissions were infected with RSV (median age 1.5 years, interquartile range, IQR; 0.36 to 3.0). Thirty-eight percent had at least one comorbidity such as prematurity (28%) or congenital heart disease (10%). The proportion of subjects who needed mechanical ventilation was 35%; 34% received non-invasive positive pressure ventilator support. The median duration of mechanical ventilation was 7 days (IQR 4-9 days); the median ICU length of stay was 7 days (IQR 5-11 days). In 29%, the attending physicians suspected or confirmed a bacterial coinfection, two subjects died (attributable mortality 1.9%).

11.4 Generalisability

This is the biggest data set to date on subjects receiving palivizumab prophylaxis Germany. Notwithstanding, not all subjects who received palivizumab prophylaxis against LRTI RSV-infection during the observational period could be included in this registry. Therefore, the results presented in this report cannot be used to calculate the real number of subjects on palivizumab prophylaxis in Germany. The discrepancy in numbers becomes evident when looking at, for example, the number of premature subjects with a birthweight below 1,500 g is relatively constant with 8,500 per year (including at about 3,500 subjects with extremely low birth weight below 1,000 g) [142]. The prevalence of hemodynamically significant CHD (before cardiosurgical correction) comprises at least 3000 newborns per year[5] . To our knowledge, no other data source to calculate the real number of subjects receiving palivizumab in Germany has been published yet. In this regard, we do not know whether the results are representative for all subjects, who have received palivizumab as prophylaxis against LRT RSV-infection during the observation period of this study.

[5] http://www.kompetenznetz-ahf.de/

12.0 Other Information

Not applicable.

13.0 Conclusion

- The German SYNAGIS Registry comprises the largest dataset on subjects receiving palivizumab for prophylaxis of RSV in Germany.
- Mean rates of RSV-related hospitalizations in subjects receiving palivizumab ranged between 0.7%-2.5% (evaluated by different methods). Effectiveness data are in accordance with published reports from other palivizumab registries.
- Median number of immunizations was in all seasons 5 (range: 1-12). A fairly large percentage (35%-45%) of subjects received more than 5 palivizumab injections.
- Over the years, an increasing rate of subjects starting the immunization regimen in the hospital was observed (13.9%-24.6%).
- Most subjects who received palivizumab were prematurely born. A significant proportion was diagnosed with CLD/BPD (18.9%-42.6%), and CHD (25.2%-34.9%).
- Most frequently reported SAEs during the study were infections of the respiratory system. No new safety signals were identified.
- Compliance among parents of subjects receiving palivizumab was good in the large majority of subjects (91.1%-93.5%).

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AbbVie Inc. (AbbVie)

Post Marketing Observational Study

Protocol (P10-410)

SYNAGIS® registration – GERM 06-01

Final Report

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Appendices

Annex 1. List of Stand-Alone Documents

Number	Document Reference Number	Date	Title
1	–	April 2006	PMOS study protocol
2	–	17 July 2006	Annual report: Global Synagis Registry 2002/2003
3	–	17 July 2006	Annual report: Global Synagis Registry 2003/2004
4	–	17 July 2006	Annual report: Global Synagis Registry 2004/2005
5	–	15 June 2008	Annual report: Global Synagis Registry 2005/2006
6	–	16 June 2008	Annual report: Global Synagis Registry 2006/2007
7	–	15 August 2010	Annual report: Global Synagis Registry 2007/2008
8	–	05 April 2011	Annual report: Global Synagis Registry 2008/2009
9	–	27 September 2016	Statistical analysis plan (2009/10 – 2015/16)

Annex 2. Additional Information

A2.1 CRF

A2.1.1 Paper-based CRF 2007/08

Dokumentationsbogen

Name des Arztes: ⌊_____⌋

Arztnummer (AIS+): ⌊_____⌋

Mitarbeiterstempel/Gebietsnummer

Arzt-Stempel/Unterschrift/Datum

A) Patientendaten:

1. Pat.-Initialen: ⌊__⌋
2. Geb.-Datum: ⌊__⌋⌊__⌋⌊____⌋ (Monat / Jahr)
3. Geb.-Gewicht: ⌊____⌋ (Gramm)
4. Geschlecht: w ☐ m ☐
5. Alter zu Beginn der RSV-Prophylaxe (Startimmunisierung):
   ⌊__⌋ Monate und ⌊__⌋ Wochen

B) RSV-Risikofaktoren

1. Frühgeburt: nein ☐ ja ☐ wenn ja: Gestationsalter: ⌊__⌋ Wochen
2. BPD: nein ☐ ja ☐
3. Angeb. Herzfehler: nein ☐ ja ☐ unbekannt ☐
   wenn ja: zyanotisch ☐ azyanotisch ☐ unbekannt ☐
   mit Malperfusion der Lunge nein ☐ ja ☐ unbekannt ☐
   Diagnose: _____ unbekannt ☐
4. Mehrlingsgeburt: nein ☐ ja ☐ wenn ja: wie viele? ⌊__⌋
5. Immundefekte: nein ☐ ja ☐ unbekannt ☐
   Diagnose: _____
6. Besucht das Kind eine Kindertageseinrichtung? nein ☐ ja ☐ unbekannt ☐
7. Leben andere Kinder unter 12 Jahren im Haushalt? nein ☐ ja ☐ unbekannt ☐
   wenn ja: wie viele? ⌊__⌋
8. Rauchen in der Umgebung des Kindes: nein ☐ ja ☐ unbekannt ☐
9. Leidet/litt eines der Familienmitglieder an:
   a) Asthma nein ☐ ja ☐ unbekannt ☐
   b) Allergischer Rhinitis nein ☐ ja ☐ unbekannt ☐
   c) Allergischem Ekzem nein ☐ ja ☐ unbekannt ☐
10. Weitere Grund- und Begleiterkrankungen:

_____

Dokumentationsbogen

C) Immunisierungsdaten:

1. Hat das Kind in der vergangenen Saison Synagis™ erhalten?
   nein ☐ ja ☐ unbekannt ☐
2. Wurde die Startimmunisierung in der jetzigen Saison in der Klinik durchgeführt?
   nein ☐ ja ☐
3. Wurde eine Palivizumab-Prophylaxe von der Klinik empfohlen?
   nein ☐ ja ☐
4. Angaben zur RSV-Prophylaxe mit Synagis™ beim Pädiater:

	Datum (TT/MM/JJ)	**Gewicht (kg)**	**Dosierung (mg)**	**Hospitalisierung mit RSV-Infektion***
1.	⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋⌊⌋	nein ☐ ja ☐
2.	⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋⌊⌋	nein ☐ ja ☐
3.	⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋⌊⌋	nein ☐ ja ☐
4.	⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋⌊⌋	nein ☐ ja ☐
5.	⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋⌊⌋	nein ☐ ja ☐
6.	⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋⌊⌋	nein ☐ ja ☐
7.	⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋⌊⌋	nein ☐ ja ☐
8.	⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋⌊⌋	nein ☐ ja ☐
9.	⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋⌊⌋	nein ☐ ja ☐
10.	⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋⌊⌋	⌊⌋⌊⌋⌊⌋	nein ☐ ja ☐

* Wenn das Kind seit der letzten Immunisierung mit einer RSV-Infektion hospitalisiert wurde, füllen Sie bitte ein Extraformblatt für jede RSV-Hospitalisierung aus.

5. Traten Nebenwirkungen auf? nein ☐ ja* ☐
   * Falls ja, bitte im separaten, vollständig ausgefüllten Formblatt „Bericht über unerwünschte Arzneimittelwirkungen“ dokumentieren und Formblatt mit den zugehörigen Dokumentationsbögen einreichen! Bei schwerwiegenden unerwünschten Arzneimittelwirkungen bitte zusätzlich das Formblatt „Bericht über unerwünschte Arzneimittelwirkungen (BfArM-Meldebogen)“ ausfüllen und beide vollständig ausgefüllten Formulare innerhalb von 24 Stunden an Fax (06122) 58-16 28 senden.
6. Wie beurteilen Sie die Kooperation der Eltern bzgl. der Einhaltung der Immunisierungstermine?
   sehr gut ☐ gut ☐ mäßig ☐ schlecht ☐ sehr schlecht ☐

RSV-Hospitalisierungs-formblatt

Name des Arztes:

Arztnummer (AIS+):

Arzt-Stempel/Unterschrift/Datum

Bitte beantworten Sie die folgenden Fragen zu der jeweiligen RSV-Hospitalisierung:

(Bitte beachten: Für jede Hospitalisierung ein Extra-Formblatt!)

1. Datum der stationären Aufnahme:

2. Entlassungsdatum:

3. Welche der folgenden Entlassungsdiagnosen wurden angegeben?

Bronchiolitis	nein ☐	ja ☐	unbekannt ☐
RSV-Bronchiolitis	nein ☐	ja ☐	unbekannt ☐
Virale Pneumonie	nein ☐	ja ☐	unbekannt ☐
RSV-Pneumonie	nein ☐	ja ☐	unbekannt ☐
RSV-Infektion	nein ☐	ja ☐	unbekannt ☐
Andere	nein ☐	ja ☐	_____

4. Wurde ein RSV-Test während des stationären Aufenthaltes durchgeführt? nein ☐ ja ☐ unbekannt ☐

   Wenn ja, wie lauteten die Ergebnisse? negativ ☐ positiv ☐

5. Wurde das Kind auf die Intensivstation aufgenommen?

   nein ☐ unbekannt ☐

   ja ☐, bitte Gesamtzahl der Tage auf der Intensivstation angeben: _____ Tage

6. Benötigte das Kind während des stationären Aufenthalts eine Sauerstoffgabe?

   nein ☐ unbekannt ☐

   ja ☐, bitte Gesamtzahl der Tage mit zusätzlichem Sauerstoff angeben: _____ Tage

7. Wurde das Kind während des stationären Aufenthalts mechanisch beatmet?

   nein ☐ unbekannt ☐

   ja ☐, bitte Gesamtzahl der Tage mit mechanischer Ventilation angeben: _____ Tage

A2.1.2 Change history of paper-based CRFs 2002/03 – 2007/08

Table 1: Overview of paper-based CRF items and changes from 02/03 to 07/08

	02/03*	03/04	04/05	05/06	06/07	07/08
Patient data						
Initials	X	X	X	X	X	X
Date of birth (month; year)	X[a]	X[a]	X	X	X	X
Birth weight (g)	X	X	X	X	X	X
Gender (male; female)	X	X	X	X	X	X
Age at start of prophylaxis (in months and weeks)	X	X	X	X	X	X
Maternity clinic (open text field)	X	–	–	–	–	–
RSV risc factors						
Premature birth (yes; no)	–	X	X	X	X	X
∟ If yes: Gestagional age (weeks)	X	X	X	X	X	X
Chronic lung disease (yes; no)	X	X	X	X	X	X
Congenital heart malformation (yes; no; unknown)	–	X	X	X	X	X
∟ If yes: Cyanotic, acyanotic, unknown	–	X	X	X	X	X
∟ If yes: Pulmonary hypoperfusion (yes, no, unknown)	–	X	X	X	X	X
∟ If yes: Diagnosis (open text field; unknown)	–	X	X	X	X	X
Multiple birth (yes, no)	–	X	X	X	X	X
∟ If yes: Number of multiple birth siblings	–	X	X	X	X	X
Immuno-deficiency (yes, no, unknown)	–	X	X	X	X	X
∟ If yes: Diagnosis (open text field)	–	X	X	X	X	X
Attending daycare (yes, no unknown)	–	X	X	X	X	X
Other children (< 12 years) in houshold (yes; no; unknown)	–	X	X	X	X	X
∟ If yes: Number of siblings	–	X	X	X	X	X
Smoking[b] in surrounding[c] b (yes; no; unknown)	–	X	X	X	X	X
Family history of asthma (yes; no; unknown)	–	X	X	X	X	X
Family history of allergic rhinitis (yes; no; unknown)	–	X	X	X	X	X
Family history of allergic eczema (yes; no; unknown)	–	X	X	X	X	X
Other (open text field)	X	X	X	X	X	X
Immunizations						
Immunizations in last season (yes; no; unknown)	–	X	X	X	X	X
Immunization started in clinic (yes; no)	X	X	X	X	X	X
Recommendation by neonatologist (yes; no)	–	X	X	X	X	X
Occurrence of adverse drug reaction (yes; no)	X	X	X	X	X	X

	02/03*	03/04	04/05	05/06	06/07	07/08
Cooperation of parents (very good; good; moderate; bad; very bad)	X	X	X	X	X	X
For each immunization (1-10):						
∟ Date of immunization	X	X	X	X	X	X
∟ Weight (kg)	X	X	X	X	X	X
∟ Dosage (mg)	X	X	X	X	X	X
∟ RSV-Hospitalisation (yes; no)	–	X	X	X	X	X
∟ Tolerability (very good; good; moderate; bad)	X	–	–	–	–	–
Any hospitalization with respiratory infection in season	X	–	–	–	–	–
Hospitalization form						
Date of hospitalization	–	X	X	X	X	X
Date of discharge	–	X	X	X	X	X
Diagnosis at discharge:						
∟ Bronchiolitis (yes; no; unknown)	–	X	X	X	X	X
∟ RSV-Bronchiolitis (yes; no; unknown)	–	X	X	X	X	X
∟ Viral-Pneunomia (yes; no; unknown)	–	X	X	X	X	X
∟ RSV-Pneunomia (yes; no; unknown)	–	X	X	X	X	X
∟ RSV-Infection (yes; no; unknown)	–	X	X	X	X	X
∟ Other (yes; no; unknown)	–	X	X	X	X	X
RSV-Test (yes; no; unknown)	–	X	X	X	X	X
∟ If yes: Result (negative; positive)	–	X[d]	X[d]	X	X	X
Intensive care (yes; no; unknown)	–	X	X	X	X	X
∟ If yes: Number of days with intensive care	–	X	X	X	X	X
O2 dependency (yes; no; unknown)	–	X	X	X	X	X
∟ If yes: Number of days with supplementary oxygen	–	X	X	X	X	X
Mechanical ventilation (yes; no; unknown)	–	X	X	X	X	X
∟ If yes: Number of days with mechanical ventilation	–	X	X	X	X	X

*In 02/03, the CRF was fundamentally different to the other seasons (see separate listing).
[a]Additional field day in 02/03 and 03/04
[b]Was 'Tabacco consumption' in 03/04
[c]In research plan and analysis the term 'family' is used
[d]In 03/04 and 04/05 the additional category 'unknown' was presented

Specifics of the 02/03 CRF:

- Birth date is specified as day, month, year
- Gender is specified in an box as ‘m’ or ‘w’
- For age at start of immunization, only months had to be documented
- Gestational age at birth was to be documented for all infants (not only those who were born prematurely)
- Dosage of SYNAGIS® was to be documented in ml instead of mg
- Cooperation of parents was assessed via a 6-point rating scale ranging from 1 = very good to 6 = bad.
- Occurrence of adverse drug reactions was assessed as an open text field.
- Additional items:
  - Upper respiratory tract infection in season (yes, no)
    - Start date (day, month, year)
    - Duration (days)
  - Lower respiratory tract infection in season (yes, no)
    - Start date (day, month, year)
    - Duration (days)
- Documentation of any hospitalization of respiratory infection between first prophylaxis and 30 days after last prophylaxis (yes, no)
  - If yes: RSV-Test (yes, no)
    - If yes: Result (positive, negative)

A2.1.3 eCRF 2015/2016

[redacted]

Synagis®-Patientenregister

eCRF

Saison 2015-2016

Autor	[redacted]
Datum	06. Dezember 2016
Beauftragt durch	[redacted]

[redacted]

Inhaltsverzeichnis

[redacted]

1 eCRF

[redacted]

1.2 Menüleiste

[redacted]

1.2.1 Patient

[redacted]

1.2.2 Saison

[redacted]

1.2.3 AE/ SAE Historie

[redacted]

[redacted]

1.2.4 **Service**

1.2.5 **Berichte**

1.2.6 **Kalender**

1.2.7 **Hilfe**

[redacted]

1.3 Patient

1.3.1 **Neu - Patient anlegen**

Schreib-Modus

[redacted]

1.3.2 **Basisdaten**

[redacted]

[redacted]

1.3.3 **Patientendaten**

Ansicht-Modus

[redacted]

1.3.4 **Immunisierungen**

Ansicht-Modus

[redacted]

Schreib-Modus

[redacted]

[redacted]

1.4 Risikofaktoren

[redacted]

[redacted]

1.5 Hospitalisierung

Ansicht-Modus

Schreib-Modus

[redacted]

1.6 Saison abschließen

[redacted]

[redacted]

[redacted]

1.7 AE/ SAE Historie

1.7.1 Übersicht

[redacted]

1.7.2 Unerwünschtes Ereignis auswählen

[redacted]

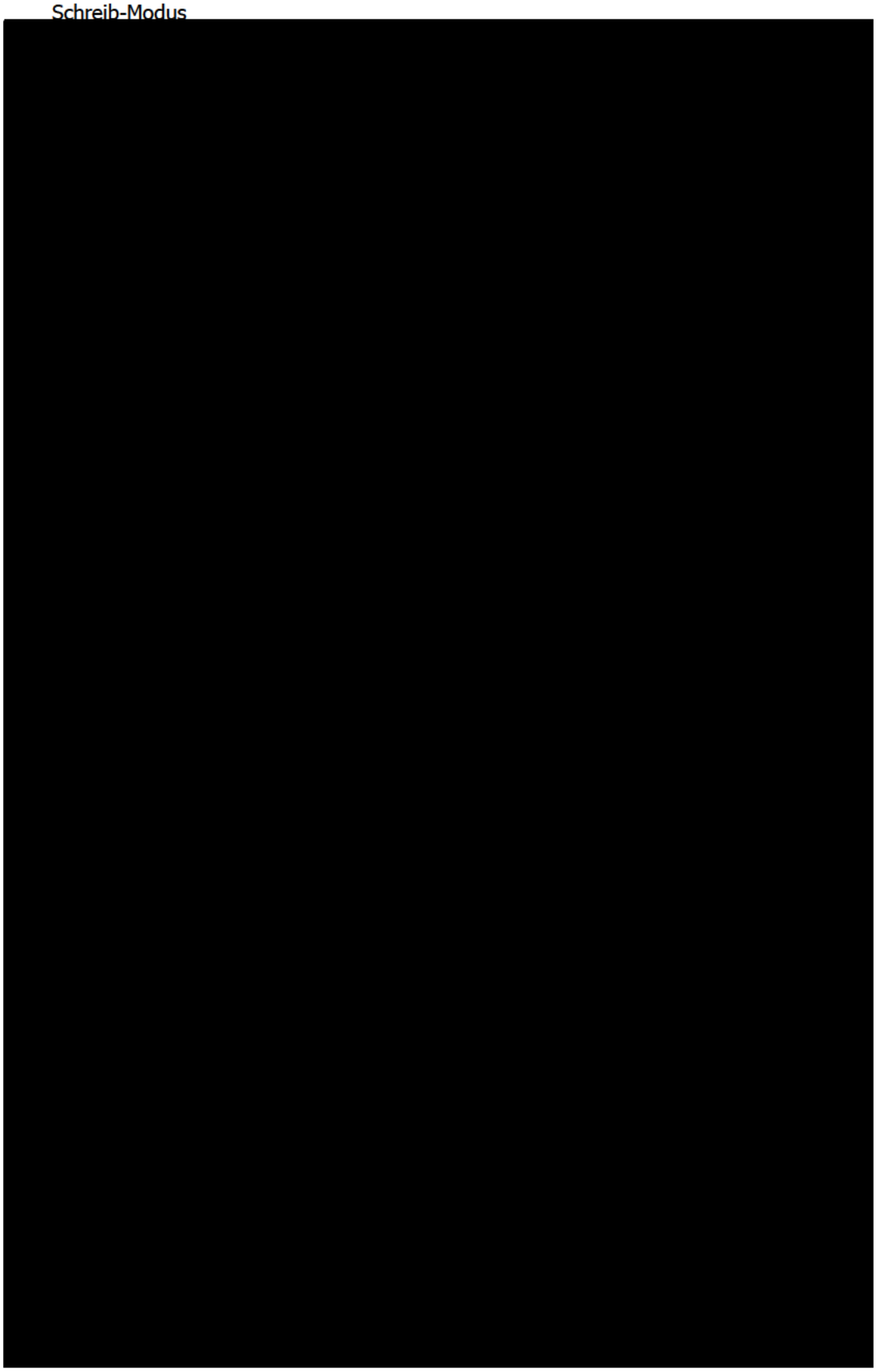
1.7.3 Ereignis melden

[redacted]

[redacted]

1.7.4 **Ereignis dokumentieren**

Schreib-Modus



[redacted]

1.8 Service

[redacted]

[redacted]

1.9 Berichte

1.9.1 **Patientenakte**

Übersicht

[redacted]

[redacted]

PDF

[redacted]

[redacted]

1.10 Kalender

1.10.1 Kalender


[redacted]

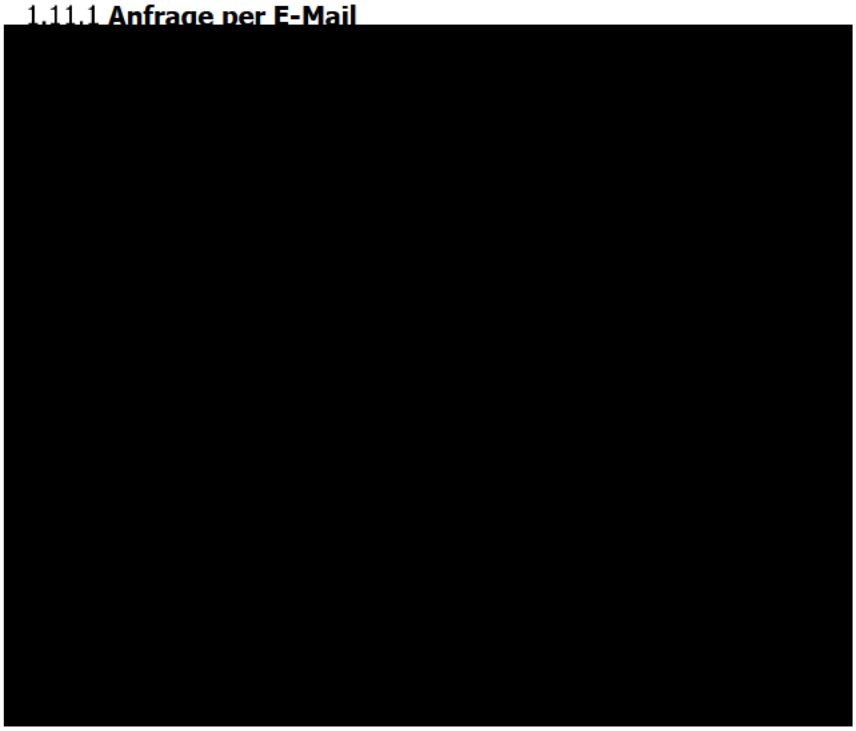
[redacted]

1.10.2 **Terminliste**

[redacted]

1.11 Hilfe

1.11.1 Anfrage per E-Mail



[redacted]

1.11.2 **Support**

[redacted]

A2.1.3 eCRF 2015/2016

A2.1.4 Change history of eCRF 2008/09 – 2015/16

Season	Domain	Changes, modifications, extensions
[redacted]		
14/15	Remuneration process	Reorganization of the import process
14/15	Hospitalizations	Preface: After adaptation of the hospitalization process in the last season in consultation with the study management and the medical director, a status can be established that makes it impossible for the user to conclude a patient record for the study: - Upon study completion, hospitalizations earlier than 4 weeks before the first administration of Synagis or later than 4 weeks after the last administration of Synagis are queried. If such a hospitalization is found, the user is requested to remove it, as it is not, by definition, associated with Synagis. - The "Respiratory disease" or "Other cause" qualification immediately leads to an SAE being triggered, and the underlying hospitalization can no longer be edited or deleted. - There is now a qualification of the cause (respiratory disease, planned elective surgery, other cause). - Until the end of the season, [redacted] will manually set the completion status in such cases provided that no further validation parameters are violated. For this purpose, [redacted] is to collect the study management's consent via email.
14/15	Hospitalizations	Changes to the validation for hospitalization admission - When calling up the hospitalization, check whether immunizations are already present; if not, note: "Please record the immunizations first." -> Cancel the action - Generally, hospitalizations are only recorded during the following period (range): after the first immunization or up to 6 weeks after the last administration of Synagis - Consequently, as per the previous item, the date of admission is between 01 Sep and 30 Jun (plus x, depending on the last immunization) of the current season - Upon completion: If the admission date is "Out of Range" the doctor is notified that the hospitalization will be deleted, and an email is sent to Pharmacovigilance and the Medical Director that the hospitalization was deleted - All adverse events before administration of Synagis are irrelevant, but all events after administration of Synagis are important for Pharmacovigilance: This means that the

Season	Domain	Changes, modifications, extensions
		term "6 weeks after the last administration of Synagis" is removed. - Should a message to Pharmacovigilance be invalid because the doctor changed the event date of hospitalization or an adverse event to a date before the first immunization, the message is deleted, and a notification is forwarded to Pharmacovigilance and the Medical Director. "The SAE with the ID xxx dated xxx has been deleted because the event occurred before the date of the first immunization."
14/15	Hospitalizations	- Additional field "Causal relationship with Synagis® immunization" - Extension of "Causal relationship with RSV infection" by "Probable," i.e. Yes, No, Probable - "RSV test" mandatory field - Max. date limited to season (or date)
14/15	Immunizations	Implementation of additional note: "Please make sure to complete the data entry after entering the last immunization."
14/15	Management tool	Implementation of the Patient Code for the search for queries by Medical Director Prof. [redacted]
14/15	SAE management	- Data fields are removed from the system and locked for overwriting - Should the fields be empty, the doctor is permitted to edit them - Event Start and End mandatory field - Duration of days is calculated - Event Start after start of treatment is validated - The age is generated automatically via the system - Age in months and weeks is changed to months and days
14/15	SAE management	- Medical Director Prof. [redacted] removed from the distribution list - SAE report for the doctor to save and to print - Email address of Pharmacovigilance changed - Lock mechanism of SAE on immunization - SAE text report revised (office name, office ID, office contact details additionally recorded) - With each hospitalization that takes place after the first immunization an SAE/AE report is sent to Pharmacovigilance - Weight at the time of the event changed from kg to g
14/15	Season completion	Automated email sent as reminder for the doctors to enter data
14/15	Wording	"Please make sure to complete the season after entering the last immunization." reworded to "Please complete the season after entering the last immunization. Delete the immunizations that have not taken place from the list."
14/15	Validations	- Weight at the time of the immunization: Lower limit (1.000 g), upper limit (15.000 g) - Birth weight: Lower limit (350 g), upper limit (reserved)
14/15	Patient summary	Matrix for visits including status flag implemented

Season	Domain	Changes, modifications, extensions
14/15	Wording	- "Complete" renamed to "Season completion" - "Entry complete" renamed to "Data entry in this form is complete"
13/14	General	Conversion from Abbott to AbbVie - Logo, texts, reports, service documents, administrative templates, user accounts
13/14	Menu navigation	Introduction of status icon and status bar
13/14	SAE management	Introduction of monthly reconciliation reports to AbbVie Pharmacovigilance
13/14	Season completion	- At completion, the number of non-completed patients are shown to the study doctor - Causal relationship with administration of Synagis®
12/13	ADM module	A further report for the field force with contact details of all doctors who were called upon during the previous seasons
12/13	Menu navigation	Add season The selection of the season is limited to the current season
12/13	Menu navigation	All non-completed patients from the previous seasons will be blocked for the new season so that no more data can be entered here
12/13	Menu navigation	Set up patient - The season selection is removed - The season is always the current season
12/13	Patient summary	The doctor is notified that he entered data for a patient during the previous season, but did not complete it properly and can no longer edit it
12/13	SAE management	- The "Adverse events" report form is no longer sent by fax to Pharmacovigilance, but is automatically sent by email to the study management and [redacted] from Abbott Pharmacovigilance at [redacted] upon saving the documentation, regardless of whether it is a serious or a non-serious adverse event. - "Document event" is expanded so that all the information for the report form can be generated from the database. - The email notification for AEs and hospitalizations to Pharmacovigilance is expanded such that all information from the report form is included. - The doctor's office stamp and signature are no longer necessary. - When saving the documentation, a message opens with the following text: "If you have any further documentation regarding the adverse event, please fax it to Abbott Pharmacovigilance under the fax number [redacted] " - For this fax, a cover page for printing will be provided to the doctor. The cover page is provided as a blank PDF in the menu. - The heading of the AE form "If the event meets one of the following criteria, it is considered to be serious." is omitted. - Analogous to the report to Pharmacovigilance, the SAE report is provided to the study management and the Medical Director without personal data. - Overview of the adverse events for the study management and the Medical Director
12/13	Validations	The validation of the lower limit for the birth weight is modified. An entry of less than 500 g generates a note, but saving is still permitted.
11/12	Hospitalizations	When entering the hospitalization, the SAE form opens automatically

Season	Domain	Changes, modifications, extensions
11/12	Immunizations	Current weight: Selection kg or g, validation is adjusted accordingly
11/12	Immunizations	Weight at immunization: Entry of 12-20 kg is possible, but will be questioned
11/12	Immunizations	Cause for immunization: "Premature birth of less than/equal to 35 weeks GA" split into: - "Premature birth of less than 29 weeks GA" - "Premature birth of 29-35 weeks GA"
11/12	Immunizations	Change of final validation: It is checked whether immunizations have been entered; otherwise, completion is not possible
11/12	Contact information	Preliminary form for checking the contact information of the doctor at the first login in the current season
11/12	Management tool	Further report for study management with the following items - Current season, split up into the individual months with comparison to previous season - Contract concluded - Offices registered (unlocked) - Patients completed - Participation completed - Offices registered and no children documented - Documented children (by x doctors)
11/12	Menu navigation	Patient filter extended by selection item "current season"
11/12	Patient summary	- Matrix with overview of all registered patients - Display of the treatment status - Shortcut to the corresponding visits - Review of previous season(s)
11/12	Risk factors	Further risk factors: - Down syndrome - Severe neurological disorder - Siblings in preschool
11/12	Risk factors	Deleted: - Neuromuscular disease
11/12	Risk factors	All risk factors will be mandatory fields
11/12	SAE management	- Notification on the procedure when an event occurs - Documentation of the events directly in the system - Output of the AE form to fill out - Automated email with all information to Abbott Pharmacovigilance - Including immunization data, end of therapy and treatment status
10/11	Hospitalizations	In the case of "Causal relationship with RSV" a check box Yes/No is implemented as a mandatory field

Season	Domain	Changes, modifications, extensions
10/11	Hospitalizations	In the case of "Microbiologically confirmed" a check box Yes/No is implemented as a mandatory field If Yes, a selection box with the following selection options becomes available: - Not assessable - RSV negative - RSV positive
10/11	Hospitalizations	On completion, only hospitalizations are permitted in which the admission date is after the first administration of Synagis or up to 4 weeks after the last administration of Synagis. The doctor receives a notification in this regard. If the doctor has to delete the re-hospitalization from the system, the Medical Director receives a notification of the cancellation.
10/11	Immunizations	The upper limit of the weight at the time of immunization is increased to 12 kg. The following query is then made: "You have entered a body weight of more than 12 kg. Is this correct?"
10/11	Immunizations	The units mL and mg can be selected at dosage.
10/11	Calendars	The calendar is expanded. The doctor can have a list of all immunization dates generated, chronologically sorted for the current season.
10/11	Menu navigation	The order of the main navigation (crossbar) is changed to make it clearer which data fields must be edited by the doctor: - Patient - Risk factors - Hospitalization - Season - Completion - Empty - Empty - Documents - Reports - Calendar - Help
10/11	Menu navigation	The menu item "Transfer to current season" is also listed under "Patient"
10/11	Menu navigation	After the basic data of the patient have been created, the doctor is automatically led to the risk factors. A notification is displayed that the doctor can now enter the risk factors.
10/11	Risk factors	Under risk factors, Yes and No check boxes are implemented
10/11	Risk factors	If something has been entered under "Other risk factors," this item will be classified as a risk factor in the future
09/10	General	Transfer of the Synagis patient register to the [redacted] portal
09/10	User management	The blank data sheet for the access data is attached to the Synagis folder and is no longer sent by [redacted]
09/10	Remuneration process	Within the completion process, a further step is included at the beginning which displays an information text. The information makes it clear to the user that after completion, no further data of the season (immunizations, hospitalizations, risk factors) can be edited. The user can only end this process if it is absolutely certain that no further data can be entered.
09/10	Remuneration process	The export routine, which contains the immunization data, is modified. Only 3 flags will be included per record (primary, subsequent, final immunization)
09/10	Remuneration process	The flag "Delete" is omitted. If data are deleted that have already been remunerated, this must be handled manually.
09/10	Remuneration process	Exporting generates 2 lists. One list contains the current visits to be remunerated, another contains all visits (cumulative). Only completed cases are transferred to the remuneration list.

Season	Domain	Changes, modifications, extensions
09/10	Hospitalizations	Additional fields - Death causally related to RSV infection - Re-hospitalized children (RSV negative)
09/10	Hospitalizations	In the case of re-hospitalization, an inquiry starts to determine whether a serious adverse event is present.
09/10	Immunizations	Establishment of the immunization scheduler (After creating the first immunization with date, the system provides the doctor with an appointment list until the end of May)
09/10	Immunizations	It is investigated whether there are immunization records that have the same date within a process
09/10	Management tool	Development of a sponsor module for study management, regional director and field force
09/10	Menu navigation	The "Release" menu item will no longer release the process as before to allow further data input. Instead, a notification is displayed that re-release for data input can only be carried out by the technical support of HSD. The contact data of HSD are shown at this point.
09/10	Menu navigation	The data from basic data and risk factors are combined
09/10	Menu navigation	Season: the first season is season 08/09
09/10	Menu navigation	Logout: will only be possible through the lettering in the future, not through the entire bar
09/10	Mandatory fields	Completing patients: - Basic data on the patient (birthday, birth weight, gestational week, gender) - Immunization data with weight
09/10	Risk factors	Additional field - No risk factors Further risk factors: - Discharge during RSV season - Born within the period from 10 weeks before to 10 weeks after the start of the RSV season - Preschool- or school-aged siblings - Daycare exposure - Crowded living conditions - Low social status - Exposure to airborne toxins including tobacco smoke - Male gender - Low birth weight (< 10th percentile) - Multiple birth - Breastfeeding for ≤ 2 months - Family history of asthma - Family history of atopy

Season	Domain	Changes, modifications, extensions
09/10	Risk factors	Involvement of the risk factors in the completion process to get users to enter these factors
09/10	SAE management	No more automated emails will be sent after consultation with Abbott Pharmacovigilance. It is solely the responsibility of the doctor to send the appropriate fax to the department.
09/10	SAE management	Filing the additional sheet on serious adverse events and the adverse events report form as a writable version
09/10	SAE management	An automated email with the note "Side effect" and the AE form (but not the SAE form) goes to the responsible PMOS team
09/10	SAE management	When SN or AN is clicked, a message appears stating that the incident must be reported via fax to Pharmacovigilance
09/10	SAE management	When reporting side effects, the accuracy is questioned via a notification
09/10	Service	A table of contents for the printable documents on the website is available at any time
09/10	Validations	Set up patient The set up of existing patients will be prevented in the future. The patient's first name, last name and birthday is checked and a corresponding message is issued.
09/10	Validations	- Date of immunization after date of birth - Date of immunization within the season - Weight at immunization 2-15 kg - Immunization dose 20-200 mL - Gestational age extended to 23-42 weeks - Lower limit of birth weight reduced from 1500 g to 500 g
09/10	Other	Indication that the entry of initials is possible
09/10	Other	Removed from the system: - The target date, since most data are entered retrospectively - The Synagis passport, because it was not really used
09/10	Wording	- "Patient information" renamed to "Informed consent" - "Hospitalization" renamed to "Hospitalization due to respiratory infections" - "Actual date" renamed to "Date of immunization" - "Documents" renamed to "Service"
08/09	General	Programming "Tip of the day"
08/09	Birth weight	Plausibility check for the birth weight. To date, the value range for entry is limited. From now on, a notification is only issued if the limits are violated.
08/09	Remuneration process	Programming the remuneration interface
08/09	Remuneration process	Remuneration takes place after each case is finalized
08/09	Remuneration process	The prerequisites for payment of the compensation for expenses are checked (minimum degree of completion, mandatory fields)
08/09	Remuneration	[redacted] generates a record per immunization with

A2.2 Source tables

A2.2.1 Source tables 2002/03 – 2006/07

Tables Behind Text

Table of contents for tables behind text

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Tab 1.1.1: Patient distribution
by center size
center identifiable

	Number of patients/center																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	27	28	all
Germany																		
2002	252	126	62	24	7	3	4	3		1		1						483
2003	185	91	35	24	5	8	1	1	1	1								352
2004	412	233	142	70	38	20	8	9	3	7	4		1	1			1	949
2005	558	322	188	107	57	27	16	9	4	4	4		1	1		1		1299
2006	541	350	186	101	76	46	20	15	9	1	3	3	1		2			1354
all	1948	1122	613	326	183	104	49	37	17	14	11	4	3	2	2	1	1	4437

Tab 1.1.2: Patient distribution
by center size
center not identifiable

	Center status			
	center identifiable	ZIP-code missing	ZIP-code present, doc. name missing	all
Germany				
2002	913	14	1	928
2003	675	670	1	1346
2004	2218	51		2269
2005	2999	22	2	3023
2006	3322	33	3	3358
all	10127	790	7	10924

	Number of patients in region											
	0	1	2	3	4	5	6	7	8	9	missing	all
Germany												
2002	184	107	17	55	168	144	79	32	39	89	14	928
2003	114	123	36	55	86	51	64	27	21	99	670	1346
2004	447	320	57	176	231	293	200	124	105	265	51	2269
2005	567	395	164	248	322	332	241	157	216	359	22	3023
2006	562	496	153	381	370	330	253	200	255	325	33	3358
all	1874	1441	427	915	1177	1150	837	540	636	1137	790	10924

Tab 1.3: Patient distribution
by evaluablity

	Number of patients		
	EVP	NEP	all
Germany			
2002	853	75	928
2003	1287	59	1346
2004	2208	61	2269
2005	3000	23	3023
2006	3338	20	3358
all	10686	238	10924

Analysis population: EVP=evaluable population, NEP=non-evaluable population

	Number of patients with reason (1)			
	1	2	3	all
Germany				
2002	72	4		75
2003	55	7		59
2004	53	9		61
2005	16	6	1	23
2006	9	11		20
all	205	37	1	238

(1) Reason 1: first immunization not between 01-SEP and 31-MAY of the respective season
Reason 2: date of birth prior to 01-SEP-2001
Reason 3: Insufficient data

Tab 2.1.1: Patient characteristics
sex
including missing
evaluable population (EVP)

	Sex						all	
	missing		male		female			
	n	%	n	%	n	%	n	%
Germany								
2002	38	4.5	441	51.7	374	43.8	853	100.0
2003	3	0.2	690	53.6	594	46.2	1287	100.0
2004	11	0.5	1209	54.8	988	44.7	2208	100.0
2005	6	0.2	1593	53.1	1401	46.7	3000	100.0
2006	11	0.3	1783	53.4	1544	46.3	3338	100.0
all	69	0.6	5716	53.5	4901	45.9	10686	100.0

Tab 2.1.2: Patient characteristics
sex
excluding missing
evaluable population (EVP)

	Sex					
	male		female		all	
	n	%	n	%	n	%
Germany						
2002	441	54.1	374	45.9	815	100.0
2003	690	53.7	594	46.3	1284	100.0
2004	1209	55.0	988	45.0	2197	100.0
2005	1593	53.2	1401	46.8	2994	100.0
2006	1783	53.6	1544	46.4	3327	100.0
all	5716	53.8	4901	46.2	10617	100.0

Tab 2.2.1: Patient characteristics
gestational age [weeks]
statistics
evaluable population (EVP)

		n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2002	22	831	29.49	3.69	27.00	29.00	32.00	22.0	41.0
	2003	152	1135	29.38	3.42	27.00	29.00	32.00	20.0	41.0
	2004	337	1871	29.71	3.53	27.00	29.00	32.00	22.0	41.0
	2005	544	2456	29.75	3.55	27.00	30.00	32.00	13.0	41.0
	2006	683	2655	29.80	3.49	27.00	30.00	32.00	22.0	40.0
	all	1738	8948	29.69	3.53	27.00	29.00	32.00	13.0	41.0

Tab 2.2.2.1: Patient characteristics
gestational age [weeks]
classification
including missing
evaluable population (EVP)

	Gestational age												all	
	missing		<25 weeks		25-<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002	22	2.6	47	5.5	315	36.9	293	34.3	128	15.0	48	5.6	853	100.0
2003	152	11.8	79	6.1	429	33.3	407	31.6	174	13.5	46	3.6	1287	100.0
2004	337	15.3	119	5.4	618	28.0	716	32.4	316	14.3	102	4.6	2208	100.0
2005	544	18.1	148	4.9	810	27.0	947	31.6	413	13.8	138	4.6	3000	100.0
2006	683	20.5	134	4.0	883	26.5	1022	30.6	469	14.1	147	4.4	3338	100.0
all	1738	16.3	527	4.9	3055	28.6	3385	31.7	1500	14.0	481	4.5	10686	100.0

Tab 2.2.2.2: Patient characteristics
gestational age [weeks]
classification
excluding missing
evaluable population (EVP)

	Gestational age										all	
	<25 weeks		25-<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%	n	%
Germany												
2002	47	5.7	315	37.9	293	35.3	128	15.4	48	5.8	831	100.0
2003	79	7.0	429	37.8	407	35.9	174	15.3	46	4.1	1135	100.0
2004	119	6.4	618	33.0	716	38.3	316	16.9	102	5.5	1871	100.0
2005	148	6.0	810	33.0	947	38.6	413	16.8	138	5.6	2456	100.0
2006	134	5.0	883	33.3	1022	38.5	469	17.7	147	5.5	2655	100.0
all	527	5.9	3055	34.1	3385	37.8	1500	16.8	481	5.4	8948	100.0

Tab 2.2.2.3: Patient characteristics
gestational age [weeks]
classification
frequencies by weeks (25-28)
evaluable population (EVP)

	Gestational age								all	
	25		26		27		28			
	n	%	n	%	n	%	n	%	n	%
Germany										
2002	70	22.2	73	23.2	88	27.9	84	26.7	315	100.0
2003	65	15.2	96	22.4	137	31.9	131	30.5	429	100.0
2004	119	19.3	146	23.6	164	26.5	189	30.6	618	100.0
2005	160	19.8	183	22.6	233	28.8	234	28.9	810	100.0
2006	166	18.8	224	25.4	259	29.3	234	26.5	883	100.0
all	580	19.0	722	23.6	881	28.8	872	28.5	3055	100.0

Tab 2.2.3.1: Patient characteristics 1
gestational age [weeks]
classification by risk of premature birth
including missing
evaluable population (EVP)

Premature birth		Gestational age												all	
		missing		<25 weeks		25-<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany															
2002															
	missing	20	2.9	40	5.9	244	35.8	225	33.0	107	15.7	45	6.6	681	100.0
	no	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	yes	2	1.2	7	4.1	71	41.3	68	39.5	21	12.2	3	1.7	172	100.0
	all	22	2.6	47	5.5	315	36.9	293	34.3	128	15.0	48	5.6	853	100.0
2003															
	missing	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	100.0
	no	79	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	79	100.0
	yes	69	5.7	79	6.6	429	35.6	407	33.8	174	14.5	46	3.8	1204	100.0
	all	152	11.8	79	6.1	429	33.3	407	31.6	174	13.5	46	3.6	1287	100.0
2004															
	missing	12	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	12	100.0
	no	214	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	214	100.0
	yes	111	5.6	119	6.0	618	31.2	716	36.1	316	15.9	102	5.1	1982	100.0
	all	337	15.3	119	5.4	618	28.0	716	32.4	316	14.3	102	4.6	2208	100.0
2005															
	missing	9	90.0	0	0.0	0	0.0	0	0.0	0	0.0	1	10.0	10	100.0
	no	350	97.0	0	0.0	0	0.0	0	0.0	0	0.0	11	3.0	361	100.0
	yes	185	7.0	148	5.6	810	30.8	947	36.0	413	15.7	126	4.8	2629	100.0
	all	544	18.1	148	4.9	810	27.0	947	31.6	413	13.8	138	4.6	3000	100.0
2006															
	missing	13	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	13	100.0
	no	445	97.6	0	0.0	0	0.0	0	0.0	0	0.0	11	2.4	456	100.0
	yes	225	7.8	134	4.7	883	30.8	1022	35.6	469	16.3	136	4.7	2869	100.0
	all	683	20.5	134	4.0	883	26.5	1022	30.6	469	14.1	147	4.4	3338	100.0
all															
	missing	58	8.1	40	5.6	244	33.9	225	31.3	107	14.9	46	6.4	720	100.0
	no	1088	98.0	0	0.0	0	0.0	0	0.0	0	0.0	22	2.0	1110	100.0
	yes	592	6.7	487	5.5	2811	31.7	3160	35.7	1393	15.7	413	4.7	8856	100.0

(Continued)

Tab 2.2.3.1: Patient characteristics
gestational age [weeks]
classification by risk of premature birth
including missing
evaluable population (EVP)

Premature birth	Gestational age												all	
	missing		<25 weeks		25-<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
all														
all	1738	16.3	527	4.9	3055	28.6	3385	31.7	1500	14.0	481	4.5	10686	100.0

Tab 2.2.3.2: Patient characteristics 1
gestational age [weeks]
classification by risk of premature birth
excluding missing
evaluable population (EVP)

Premature birth		Gestational age										all	
		<25 weeks		25-<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
		n	%	n	%	n	%	n	%	n	%	n	%
Germany													
2002													
	no	0	0	0	0	0	0	0	0	0	0	0	0
	yes	7	4.1	71	41.8	68	40.0	21	12.4	3	1.8	170	100.0
	all	7	4.1	71	41.8	68	40.0	21	12.4	3	1.8	170	100.0
2003													
	no	0	0	0	0	0	0	0	0	0	0	0	0
	yes	79	7.0	429	37.8	407	35.9	174	15.3	46	4.1	1135	100.0
	all	79	7.0	429	37.8	407	35.9	174	15.3	46	4.1	1135	100.0
2004													
	no	0	0	0	0	0	0	0	0	0	0	0	0
	yes	119	6.4	618	33.0	716	38.3	316	16.9	102	5.5	1871	100.0
	all	119	6.4	618	33.0	716	38.3	316	16.9	102	5.5	1871	100.0
2005													
	no	0	0.0	0	0.0	0	0.0	0	0.0	11	100.0	11	100.0
	yes	148	6.1	810	33.1	947	38.7	413	16.9	126	5.2	2444	100.0
	all	148	6.0	810	33.0	947	38.6	413	16.8	137	5.6	2455	100.0
2006													
	no	0	0.0	0	0.0	0	0.0	0	0.0	11	100.0	11	100.0
	yes	134	5.1	883	33.4	1022	38.7	469	17.7	136	5.1	2644	100.0
	all	134	5.0	883	33.3	1022	38.5	469	17.7	147	5.5	2655	100.0
all													
	no	0	0.0	0	0.0	0	0.0	0	0.0	22	100.0	22	100.0
	yes	487	5.9	2811	34.0	3160	38.2	1393	16.9	413	5.0	8264	100.0
	all	487	5.9	2811	33.9	3160	38.1	1393	16.8	435	5.2	8286	100.0

Tab 2.2.4.1: Patient characteristics
gestational age [weeks]
classification by risk of BPD
including missing
evaluable population (EVP)

BPD		Gestational age												all	
		missing		<25 weeks		25-<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany															
2002															
	missing	4	4.4	4	4.4	23	25.6	30	33.3	19	21.1	10	11.1	90	100.0
	no	10	2.9	7	2.1	93	27.4	124	36.6	84	24.8	21	6.2	339	100.0
	yes	8	1.9	36	8.5	199	46.9	139	32.8	25	5.9	17	4.0	424	100.0
	all	22	2.6	47	5.5	315	36.9	293	34.3	128	15.0	48	5.6	853	100.0
2003															
	missing	19	20.2	5	5.3	26	27.7	22	23.4	20	21.3	2	2.1	94	100.0
	no	83	13.9	11	1.8	123	20.7	230	38.7	118	19.8	30	5.0	595	100.0
	yes	50	8.4	63	10.5	280	46.8	155	25.9	36	6.0	14	2.3	598	100.0
	all	152	11.8	79	6.1	429	33.3	407	31.6	174	13.5	46	3.6	1287	100.0
2004															
	missing	52	31.7	2	1.2	40	24.4	34	20.7	23	14.0	13	7.9	164	100.0
	no	217	18.0	20	1.7	209	17.3	463	38.4	226	18.8	70	5.8	1205	100.0
	yes	68	8.1	97	11.6	369	44.0	219	26.1	67	8.0	19	2.3	839	100.0
	all	337	15.3	119	5.4	618	28.0	716	32.4	316	14.3	102	4.6	2208	100.0
2005															
	missing	56	23.1	9	3.7	51	21.1	63	26.0	38	15.7	25	10.3	242	100.0
	no	368	22.6	19	1.2	282	17.4	575	35.4	283	17.4	98	6.0	1625	100.0
	yes	120	10.6	120	10.6	477	42.1	309	27.3	92	8.1	15	1.3	1133	100.0
	all	544	18.1	148	4.9	810	27.0	947	31.6	413	13.8	138	4.6	3000	100.0
2006															
	missing	92	31.6	8	2.7	69	23.7	61	21.0	38	13.1	23	7.9	291	100.0
	no	437	23.5	20	1.1	308	16.5	663	35.6	336	18.0	98	5.3	1862	100.0
	yes	154	13.0	106	8.9	506	42.7	298	25.1	95	8.0	26	2.2	1185	100.0
	all	683	20.5	134	4.0	883	26.5	1022	30.6	469	14.1	147	4.4	3338	100.0
all															
	missing	223	25.3	28	3.2	209	23.7	210	23.8	138	15.7	73	8.3	881	100.0
	no	1115	19.8	77	1.4	1015	18.0	2055	36.5	1047	18.6	317	5.6	5626	100.0
	yes	400	9.6	422	10.1	1831	43.8	1120	26.8	315	7.5	91	2.2	4179	100.0

(Continued)

Tab 2.2.4.1: Patient characteristics
gestational age [weeks]
classification by risk of BPD
including missing
evaluable population (EVP)

BPD	Gestational age												all	
	missing		<25 weeks		25-<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
all														
all	1738	16.3	527	4.9	3055	28.6	3385	31.7	1500	14.0	481	4.5	10686	100.0

Tab 2.2.4.2: Patient characteristics 1
gestational age [weeks]
classification by risk of BPD
excluding missing
evaluable population (EVP)

BPD		Gestational age										all	
		<25 weeks		25-<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
		n	%	n	%	n	%	n	%	n	%	n	%
Germany													
2002													
	no	7	2.1	93	28.3	124	37.7	84	25.5	21	6.4	329	100.0
	yes	36	8.7	199	47.8	139	33.4	25	6.0	17	4.1	416	100.0
	all	43	5.8	292	39.2	263	35.3	109	14.6	38	5.1	745	100.0
2003													
	no	11	2.1	123	24.0	230	44.9	118	23.0	30	5.9	512	100.0
	yes	63	11.5	280	51.1	155	28.3	36	6.6	14	2.6	548	100.0
	all	74	7.0	403	38.0	385	36.3	154	14.5	44	4.2	1060	100.0
2004													
	no	20	2.0	209	21.2	463	46.9	226	22.9	70	7.1	988	100.0
	yes	97	12.6	369	47.9	219	28.4	67	8.7	19	2.5	771	100.0
	all	117	6.7	578	32.9	682	38.8	293	16.7	89	5.1	1759	100.0
2005													
	no	19	1.5	282	22.4	575	45.7	283	22.5	98	7.8	1257	100.0
	yes	120	11.8	477	47.1	309	30.5	92	9.1	15	1.5	1013	100.0
	all	139	6.1	759	33.4	884	38.9	375	16.5	113	5.0	2270	100.0
2006													
	no	20	1.4	308	21.6	663	46.5	336	23.6	98	6.9	1425	100.0
	yes	106	10.3	506	49.1	298	28.9	95	9.2	26	2.5	1031	100.0
	all	126	5.1	814	33.1	961	39.1	431	17.5	124	5.0	2456	100.0
all													
	no	77	1.7	1015	22.5	2055	45.6	1047	23.2	317	7.0	4511	100.0
	yes	422	11.2	1831	48.5	1120	29.6	315	8.3	91	2.4	3779	100.0
	all	499	6.0	2846	34.3	3175	38.3	1362	16.4	408	4.9	8290	100.0

Tab 2.2.5.1: Patient characteristics
gestational age [weeks]
classification by risk of CHD
including missing
evaluable population (EVP)

CHD		Gestational age												all	
		missing		<25 weeks		25-<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany															
2002															
	missing	21	2.7	45	5.7	291	36.9	275	34.9	117	14.8	39	4.9	788	100.0
	no	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	yes	1	1.5	2	3.1	24	36.9	18	27.7	11	16.9	9	13.8	65	100.0
	unknown	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	all	22	2.6	47	5.5	315	36.9	293	34.3	128	15.0	48	5.6	853	100.0
2003															
	missing	5	29.4	1	5.9	6	35.3	2	11.8	3	17.6	0	0.0	17	100.0
	no	76	8.1	59	6.3	320	34.0	327	34.8	133	14.1	25	2.7	940	100.0
	yes	70	21.9	18	5.6	101	31.6	75	23.4	35	10.9	21	6.6	320	100.0
	unknown	1	10.0	1	10.0	2	20.0	3	30.0	3	30.0	0	0.0	10	100.0
	all	152	11.8	79	6.1	429	33.3	407	31.6	174	13.5	46	3.6	1287	100.0
2004															
	missing	5	15.2	2	6.1	12	36.4	10	30.3	3	9.1	1	3.0	33	100.0
	no	134	8.7	77	5.0	453	29.3	583	37.8	248	16.1	49	3.2	1544	100.0
	yes	198	31.7	40	6.4	150	24.0	120	19.2	64	10.3	52	8.3	624	100.0
	unknown	0	0.0	0	0.0	3	42.9	3	42.9	1	14.3	0	0.0	7	100.0
	all	337	15.3	119	5.4	618	28.0	716	32.4	316	14.3	102	4.6	2208	100.0
2005															
	missing	15	23.1	2	3.1	23	35.4	14	21.5	8	12.3	3	4.6	65	100.0
	no	178	9.1	94	4.8	572	29.2	745	38.1	318	16.2	50	2.6	1957	100.0
	yes	350	36.4	52	5.4	210	21.8	183	19.0	83	8.6	84	8.7	962	100.0
	unknown	1	6.3	0	0.0	5	31.3	5	31.3	4	25.0	1	6.3	16	100.0
	all	544	18.1	148	4.9	810	27.0	947	31.6	413	13.8	138	4.6	3000	100.0
2006															
	missing	15	17.6	1	1.2	30	35.3	29	34.1	8	9.4	2	2.4	85	100.0
	no	244	11.4	90	4.2	622	29.0	783	36.5	353	16.4	54	2.5	2146	100.0
	yes	421	38.4	42	3.8	228	20.8	209	19.1	105	9.6	90	8.2	1095	100.0
	unknown	3	25.0	1	8.3	3	25.0	1	8.3	3	25.0	1	8.3	12	100.0

(Continued)

Tab 2.2.5.1: Patient characteristics
gestational age [weeks]
classification by risk of CHD
including missing
evaluable population (EVP)

CHD		Gestational age												all	
		missing		<25 weeks		25-<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany															
2006															
	all	683	20.5	134	4.0	883	26.5	1022	30.6	469	14.1	147	4.4	3338	100.0
all															
	missing	61	6.2	51	5.2	362	36.6	330	33.4	139	14.1	45	4.6	988	100.0
	no	632	9.6	320	4.9	1967	29.9	2438	37.0	1052	16.0	178	2.7	6587	100.0
	yes	1040	33.9	154	5.0	713	23.3	605	19.7	298	9.7	256	8.3	3066	100.0
	unknown	5	11.1	2	4.4	13	28.9	12	26.7	11	24.4	2	4.4	45	100.0
	all	1738	16.3	527	4.9	3055	28.6	3385	31.7	1500	14.0	481	4.5	10686	100.0

CHD		Gestational age										all	
		<25 weeks		25-<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
		n	%	n	%	n	%	n	%	n	%	n	%
Germany													
2002													
	no	0	0	0	0	0	0	0	0	0	0	0	0
	yes	2	3.1	24	37.5	18	28.1	11	17.2	9	14.1	64	100.0
	unknown	0	0	0	0	0	0	0	0	0	0	0	0
	all	2	3.1	24	37.5	18	28.1	11	17.2	9	14.1	64	100.0
2003													
	no	59	6.8	320	37.0	327	37.8	133	15.4	25	2.9	864	100.0
	yes	18	7.2	101	40.4	75	30.0	35	14.0	21	8.4	250	100.0
	unknown	1	11.1	2	22.2	3	33.3	3	33.3	0	0.0	9	100.0
	all	78	6.9	423	37.7	405	36.1	171	15.2	46	4.1	1123	100.0
2004													
	no	77	5.5	453	32.1	583	41.3	248	17.6	49	3.5	1410	100.0
	yes	40	9.4	150	35.2	120	28.2	64	15.0	52	12.2	426	100.0
	unknown	0	0.0	3	42.9	3	42.9	1	14.3	0	0.0	7	100.0
	all	117	6.3	606	32.9	706	38.3	313	17.0	101	5.5	1843	100.0
2005													
	no	94	5.3	572	32.2	745	41.9	318	17.9	50	2.8	1779	100.0
	yes	52	8.5	210	34.3	183	29.9	83	13.6	84	13.7	612	100.0
	unknown	0	0.0	5	33.3	5	33.3	4	26.7	1	6.7	15	100.0
	all	146	6.1	787	32.7	933	38.8	405	16.8	135	5.6	2406	100.0
2006													
	no	90	4.7	622	32.7	783	41.2	353	18.6	54	2.8	1902	100.0
	yes	42	6.2	228	33.8	209	31.0	105	15.6	90	13.4	674	100.0
	unknown	1	11.1	3	33.3	1	11.1	3	33.3	1	11.1	9	100.0
	all	133	5.1	853	33.0	993	38.4	461	17.8	145	5.6	2585	100.0
all													
	no	320	5.4	1967	33.0	2438	40.9	1052	17.7	178	3.0	5955	100.0
	yes	154	7.6	713	35.2	605	29.9	298	14.7	256	12.6	2026	100.0
	unknown	2	5.0	13	32.5	12	30.0	11	27.5	2	5.0	40	100.0

(Continued)

Tab 2.2.5.2: Patient characteristics 2
gestational age [weeks]
classification by risk of CHD
excluding missing
evaluable population (EVP)

CHD	Gestational age										all	
	<25 weeks		25-<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%	n	%
Germany												
all												
all	476	5.9	2693	33.6	3055	38.1	1361	17.0	436	5.4	8021	100.0

Tab 2.3.1: Patient characteristics
birth weight [g]
statistics
evaluable population (EVP)

		n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2002	17	836	1347.6	659.4	847.5	1177.5	1692.5	410	4720
	2003	23	1264	1436.4	763.4	877.0	1225.0	1820.0	355	5350
	2004	38	2170	1565.6	827.6	940.0	1380.0	1990.0	340	6620
	2005	65	2935	1598.9	858.3	950.0	1390.0	2010.0	340	4630
	2006	95	3243	1643.7	876.7	950.0	1410.0	2135.0	320	4909
	all	238	10448	1566.1	837.2	930.0	1350.0	1990.0	320	6620

Tab 2.3.2.1: Patient characteristics
birth weight [g]
classification
including missing
evaluable population (EVP)

	Birth weight														all	
	missing		<750 g		750-999 g		1000-1499 g		1500-1999 g		2000-2499 g		>2499 g			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																
2002	17	2.0	134	15.7	189	22.2	225	26.4	161	18.9	72	8.4	55	6.4	853	100.0
2003	23	1.8	185	14.4	274	21.3	346	26.9	214	16.6	111	8.6	134	10.4	1287	100.0
2004	38	1.7	274	12.4	391	17.7	587	26.6	379	17.2	248	11.2	291	13.2	2208	100.0
2005	65	2.2	404	13.5	470	15.7	809	27.0	505	16.8	278	9.3	469	15.6	3000	100.0
2006	95	2.8	410	12.3	552	16.5	815	24.4	529	15.8	392	11.7	545	16.3	3338	100.0
all	238	2.2	1407	13.2	1876	17.6	2782	26.0	1788	16.7	1101	10.3	1494	14.0	10686	100.0

Tab 2.3.2.2: Patient characteristics
birth weight [g]
classification
excluding missing
evaluable population (EVP)

	Birth weight												all	
	<750 g		750-999 g		1000-1499 g		1500-1999 g		2000-2499 g		>2499 g			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002	134	16.0	189	22.6	225	26.9	161	19.3	72	8.6	55	6.6	836	100.0
2003	185	14.6	274	21.7	346	27.4	214	16.9	111	8.8	134	10.6	1264	100.0
2004	274	12.6	391	18.0	587	27.1	379	17.5	248	11.4	291	13.4	2170	100.0
2005	404	13.8	470	16.0	809	27.6	505	17.2	278	9.5	469	16.0	2935	100.0
2006	410	12.6	552	17.0	815	25.1	529	16.3	392	12.1	545	16.8	3243	100.0
all	1407	13.5	1876	18.0	2782	26.6	1788	17.1	1101	10.5	1494	14.3	10448	100.0

Tab 2.3.3: Patient characteristics 1
birth weight [g]
correlation birth weight vs. gestational age
evaluable population (EVP)

Country	Year	Birth weight	Gestational age												all	
			missing		<25 weeks		25-<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
			n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																
	2002															
		missing	1	4.5	1	2.1	5	1.6	2	0.7	4	3.1	4	8.3	17	2.0
		<750 g	1	4.5	37	78.7	91	28.9	5	1.7	0	0.0	0	0.0	134	15.7
		750-999 g	6	27.3	6	12.8	136	43.2	41	14.0	0	0.0	0	0.0	189	22.2
		1000-1499 g	7	31.8	3	6.4	81	25.7	124	42.3	7	5.5	3	6.3	225	26.4
		1500-1999 g	2	9.1	0	0.0	2	0.6	100	34.1	54	42.2	3	6.3	161	18.9
		2000-2499 g	0	0.0	0	0.0	0	0.0	18	6.1	43	33.6	11	22.9	72	8.4
		>2499 g	5	22.7	0	0.0	0	0.0	3	1.0	20	15.6	27	56.3	55	6.4
		all	22	100.0	47	100.0	315	100.0	293	100.0	128	100.0	48	100.0	853	100.0
	2003															
		missing	9	5.9	1	1.3	5	1.2	7	1.7	0	0.0	1	2.2	23	1.8
		<750 g	10	6.6	59	74.7	102	23.8	13	3.2	1	0.6	0	0.0	185	14.4
		750-999 g	14	9.2	18	22.8	189	44.1	53	13.0	0	0.0	0	0.0	274	21.3
		1000-1499 g	17	11.2	1	1.3	128	29.8	176	43.2	23	13.2	1	2.2	346	26.9
		1500-1999 g	17	11.2	0	0.0	4	0.9	134	32.9	50	28.7	9	19.6	214	16.6
		2000-2499 g	11	7.2	0	0.0	0	0.0	22	5.4	67	38.5	11	23.9	111	8.6
		>2499 g	74	48.7	0	0.0	1	0.2	2	0.5	33	19.0	24	52.2	134	10.4
		all	152	100.0	79	100.0	429	100.0	407	100.0	174	100.0	46	100.0	1287	100.0
	2004															
		missing	14	4.2	0	0.0	8	1.3	8	1.1	6	1.9	2	2.0	38	1.7
		<750 g	11	3.3	94	79.0	150	24.3	18	2.5	0	0.0	1	1.0	274	12.4
		750-999 g	24	7.1	23	19.3	268	43.4	74	10.3	1	0.3	1	1.0	391	17.7
		1000-1499 g	34	10.1	2	1.7	185	29.9	328	45.8	35	11.1	3	2.9	587	26.6
		1500-1999 g	27	8.0	0	0.0	3	0.5	237	33.1	101	32.0	11	10.8	379	17.2
		2000-2499 g	39	11.6	0	0.0	2	0.3	47	6.6	126	39.9	34	33.3	248	11.2
		>2499 g	188	55.8	0	0.0	2	0.3	4	0.6	47	14.9	50	49.0	291	13.2
		all	337	100.0	119	100.0	618	100.0	716	100.0	316	100.0	102	100.0	2208	100.0
	2005															
		missing	28	5.1	1	0.7	8	1.0	14	1.5	7	1.7	7	5.1	65	2.2
		<750 g	31	5.7	122	82.4	229	28.3	21	2.2	1	0.2	0	0.0	404	13.5

(Continued)

Country	Year	Birth weight	Gestational age												all	
			missing		<25 weeks		25-<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
			n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																
	2005															
		750-999 g	42	7.7	22	14.9	334	41.2	71	7.5	1	0.2	0	0.0	470	15.7
		1000-1499 g	57	10.5	2	1.4	228	28.1	482	50.9	38	9.2	2	1.4	809	27.0
		1500-1999 g	32	5.9	0	0.0	6	0.7	307	32.4	140	33.9	20	14.5	505	16.8
		2000-2499 g	25	4.6	1	0.7	4	0.5	46	4.9	168	40.7	34	24.6	278	9.3
		>2499 g	329	60.5	0	0.0	1	0.1	6	0.6	58	14.0	75	54.3	469	15.6
		all	544	100.0	148	100.0	810	100.0	947	100.0	413	100.0	138	100.0	3000	100.0
	2006															
		missing	45	6.6	1	0.7	12	1.4	24	2.3	6	1.3	7	4.8	95	2.8
		<750 g	43	6.3	119	88.8	218	24.7	30	2.9	0	0.0	0	0.0	410	12.3
		750-999 g	33	4.8	13	9.7	406	46.0	99	9.7	1	0.2	0	0.0	552	16.5
		1000-1499 g	56	8.2	0	0.0	236	26.7	481	47.1	39	8.3	3	2.0	815	24.4
		1500-1999 g	36	5.3	0	0.0	7	0.8	317	31.0	151	32.2	18	12.2	529	15.8
		2000-2499 g	71	10.4	0	0.0	1	0.1	66	6.5	202	43.1	52	35.4	392	11.7
		>2499 g	399	58.4	1	0.7	3	0.3	5	0.5	70	14.9	67	45.6	545	16.3
		all	683	100.0	134	100.0	883	100.0	1022	100.0	469	100.0	147	100.0	3338	100.0
	all															
		missing	97	5.6	4	0.8	38	1.2	55	1.6	23	1.5	21	4.4	238	2.2
		<750 g	96	5.5	431	81.8	790	25.9	87	2.6	2	0.1	1	0.2	1407	13.2
		750-999 g	119	6.8	82	15.6	1333	43.6	338	10.0	3	0.2	1	0.2	1876	17.6
		1000-1499 g	171	9.8	8	1.5	858	28.1	1591	47.0	142	9.5	12	2.5	2782	26.0
		1500-1999 g	114	6.6	0	0.0	22	0.7	1095	32.3	496	33.1	61	12.7	1788	16.7
		2000-2499 g	146	8.4	1	0.2	7	0.2	199	5.9	606	40.4	142	29.5	1101	10.3
		>2499 g	995	57.2	1	0.2	7	0.2	20	0.6	228	15.2	243	50.5	1494	14.0
		all	1738	100.0	527	100.0	3055	100.0	3385	100.0	1500	100.0	481	100.0	10686	100.0

Tab 2.4: Patient characteristics
children born in summer/winter

evaluable population (EVP)

	Born in						all	
	Missing		Summer		Winter			
	n	%	n	%	n	%	n	%
Germany								
2002	3	0.4	425	49.8	425	49.8	853	100.0
2003	0	0	667	51.8	620	48.2	1287	100.0
2004	1295	58.7	464	21.0	449	20.3	2208	100.0
2005	12	0.4	1339	44.6	1649	55.0	3000	100.0
2006	17	0.5	1591	47.7	1730	51.8	3338	100.0
all	1327	12.4	4486	42.0	4873	45.6	10686	100.0

Tab 3.1.1: Risks
premature birth
all cases (including missing)
evaluable population (EVP)

	Premature birth						all	
	missing		no		yes			
	n	%	n	%	n	%	n	%
Germany								
2002	681	79.8	0	0.0	172	20.2	853	100.0
2003	4	0.3	79	6.1	1204	93.6	1287	100.0
2004	12	0.5	214	9.7	1982	89.8	2208	100.0
2005	10	0.3	361	12.0	2629	87.6	3000	100.0
2006	13	0.4	456	13.7	2869	85.9	3338	100.0
all	720	6.7	1110	10.4	8856	82.9	10686	100.0

Tab 3.1.2: Risks
premature birth
all informative cases from 2003 on
evaluable population (EVP)

	Premature birth					
	no		yes		all	
	n	%	n	%	n	%
Germany						
2003	79	6.2	1204	93.8	1283	100.0
2004	214	9.7	1982	90.3	2196	100.0
2005	361	12.1	2629	87.9	2990	100.0
2006	456	13.7	2869	86.3	3325	100.0
all	1110	11.3	8684	88.7	9794	100.0

Tab 3.2.1.1: Risks
BPD
prevalences
including missing
evaluable population (EVP)

	BPD						all	
	missing		no		yes			
	n	%	n	%	n	%	n	%
Germany								
2002	90	10.6	339	39.7	424	49.7	853	100.0
2003	94	7.3	595	46.2	598	46.5	1287	100.0
2004	164	7.4	1205	54.6	839	38.0	2208	100.0
2005	242	8.1	1625	54.2	1133	37.8	3000	100.0
2006	291	8.7	1862	55.8	1185	35.5	3338	100.0
all	881	8.2	5626	52.6	4179	39.1	10686	100.0

Tab 3.2.1.2: Risks
BPD
prevalences
excluding missing
evaluable population (EVP)

	BPD					
	no		yes		all	
	n	%	n	%	n	%
Germany						
2002	339	44.4	424	55.6	763	100.0
2003	595	49.9	598	50.1	1193	100.0
2004	1205	59.0	839	41.0	2044	100.0
2005	1625	58.9	1133	41.1	2758	100.0
2006	1862	61.1	1185	38.9	3047	100.0
all	5626	57.4	4179	42.6	9805	100.0

Tab 3.2.2.1: Risks
BPD
stratified by birth in season*
including missing
evaluable population (EVP)

		BPD							
		missing		no		yes		all	
		n	%	n	%	n	%	n	%
Germany									
2002									
	no	17	10.3	42	25.5	106	64.2	165	100.0
	yes	73	10.6	297	43.2	318	46.2	688	100.0
2003									
	no	13	5.0	63	24.4	182	70.5	258	100.0
	yes	81	7.9	532	51.7	416	40.4	1029	100.0
2004									
	no	40	7.6	224	42.5	263	49.9	527	100.0
	yes	124	7.4	981	58.4	576	34.3	1681	100.0
2005									
	no	44	8.4	191	36.4	290	55.2	525	100.0
	yes	198	8.0	1434	57.9	843	34.1	2475	100.0
2006									
	no	45	7.2	228	36.5	352	56.3	625	100.0
	yes	246	9.1	1634	60.2	833	30.7	2713	100.0
all									
	no	159	7.6	748	35.6	1193	56.8	2100	100.0
	yes	722	8.4	4878	56.8	2986	34.8	8586	100.0

* birth in season is yes if date of birth is >= 01MAR02, 01MAR03, 01MAR04 acc. to season

Tab 3.2.2.2: Risks
BPD
stratified by birth in season*
excluding missing
evaluable population (EVP)

		BPD					
		no		yes		all	
		n	%	n	%	n	%
Germany							
2002							
	no	42	28.4	106	71.6	148	100.0
	yes	297	48.3	318	51.7	615	100.0
2003							
	no	63	25.7	182	74.3	245	100.0
	yes	532	56.1	416	43.9	948	100.0
2004							
	no	224	46.0	263	54.0	487	100.0
	yes	981	63.0	576	37.0	1557	100.0
2005							
	no	191	39.7	290	60.3	481	100.0
	yes	1434	63.0	843	37.0	2277	100.0
2006							
	no	228	39.3	352	60.7	580	100.0
	yes	1634	66.2	833	33.8	2467	100.0
all							
	no	748	38.5	1193	61.5	1941	100.0
	yes	4878	62.0	2986	38.0	7864	100.0

* birth in season is yes if date of birth is >= 01MAR02, 01MAR03, 01MAR04 acc. to season

Tab 3.3.1.1: Risks
congenital heart misformation
number of patients
all cases (including missing)
evaluable population (EVP)

	Congenital heart misformation									
	missing		no		yes		not examined/unknown		all	
	n	%	n	%	n	%	n	%	n	%
Germany										
2002	788	92.4	0	0.0	65	7.6	0	0.0	853	100.0
2003	17	1.3	940	73.0	320	24.9	10	0.8	1287	100.0
2004	33	1.5	1544	69.9	624	28.3	7	0.3	2208	100.0
2005	65	2.2	1957	65.2	962	32.1	16	0.5	3000	100.0
2006	85	2.5	2146	64.3	1095	32.8	12	0.4	3338	100.0
all	988	9.2	6587	61.6	3066	28.7	45	0.4	10686	100.0

Tab 3.3.1.2: Risks
congenital heart misformation
number of patients
all informative cases from 2003 on
evaluable population (EVP)

	Congenital heart misformation					
	no		yes		all	
	n	%	n	%	n	%
Germany						
2003	940	74.6	320	25.4	1260	100.0
2004	1544	71.2	624	28.8	2168	100.0
2005	1957	67.0	962	33.0	2919	100.0
2006	2146	66.2	1095	33.8	3241	100.0
all	6587	68.7	3001	31.3	9588	100.0

Tab 3.3.2: Risks
congenital heart misformation
details for patients with congenital heart missformation=yes
evaluable population (EVP)

Country	Lung malperfusion	Type								all	
		missing		cyanotic		acyanotic		unknown			
		n	%	n	%	n	%	n	%	n	%
Germany											
2002											
	missing	65	100.0	0	0.0	0	0.0	0	0.0	65	100.0
	no	0	0	0	0	0	0	0	0	0	0
	yes	0	0	0	0	0	0	0	0	0	0
	not examined/unknown	0	0	0	0	0	0	0	0	0	0
2003											
	missing	10	25.6	8	20.5	19	48.7	2	5.1	39	100.0
	no	7	4.1	15	8.8	141	82.9	7	4.1	170	100.0
	yes	3	3.4	49	55.7	32	36.4	4	4.5	88	100.0
	not examined/unknown	0	0.0	7	30.4	13	56.5	3	13.0	23	100.0
2004											
	missing	44	35.5	14	11.3	64	51.6	2	1.6	124	100.0
	no	8	3.2	29	11.6	204	81.9	8	3.2	249	100.0
	yes	7	3.4	124	59.9	76	36.7	0	0.0	207	100.0
	not examined/unknown	2	4.5	13	29.5	22	50.0	7	15.9	44	100.0
2005											
	missing	73	28.4	65	25.3	108	42.0	11	4.3	257	100.0
	no	6	1.6	33	8.8	329	88.2	5	1.3	373	100.0
	yes	5	1.9	149	57.5	96	37.1	9	3.5	259	100.0
	not examined/unknown	1	1.4	23	31.5	32	43.8	17	23.3	73	100.0
2006											
	missing	121	42.9	54	19.1	88	31.2	19	6.7	282	100.0
	no	12	2.8	54	12.8	350	82.7	7	1.7	423	100.0
	yes	6	2.0	179	60.9	105	35.7	4	1.4	294	100.0
	not examined/unknown	2	2.1	18	18.8	52	54.2	24	25.0	96	100.0
all											
	missing	313	40.8	141	18.4	279	36.4	34	4.4	767	100.0
	no	33	2.7	131	10.8	1024	84.3	27	2.2	1215	100.0
	yes	21	2.5	501	59.1	309	36.4	17	2.0	848	100.0
	not examined/unknown	5	2.1	61	25.8	119	50.4	51	21.6	236	100.0

Tab 3.4.1.1: Risks
multiple birth
yes/no
all cases (including missing)
evaluable population (EVP)

	Multiple birth						all	
	missing		no		yes			
	n	%	n	%	n	%	n	%
Germany								
2002	783	91.8	0	0.0	70	8.2	853	100.0
2003	4	0.3	891	69.2	392	30.5	1287	100.0
2004	18	0.8	1561	70.7	629	28.5	2208	100.0
2005	26	0.9	2224	74.1	750	25.0	3000	100.0
2006	33	1.0	2469	74.0	836	25.0	3338	100.0
all	864	8.1	7145	66.9	2677	25.1	10686	100.0

Tab 3.4.1.2: Risks
multiple birth
yes/no
all informative cases from 2003 on
evaluable population (EVP)

	Multiple birth					
	no		yes		all	
	n	%	n	%	n	%
Germany						
2003	891	69.4	392	30.6	1283	100.0
2004	1561	71.3	629	28.7	2190	100.0
2005	2224	74.8	750	25.2	2974	100.0
2006	2469	74.7	836	25.3	3305	100.0
all	7145	73.3	2607	26.7	9752	100.0

Tab 3.4.2: Risks
multiple birth
number of children
evaluable population (EVP)

	Multiple birth													
	missing		1		2		3		4		5		all	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002	853	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	853	100.0
2003	935	72.6	6	0.5	299	23.2	45	3.5	2	0.2	0	0.0	1287	100.0
2004	1604	72.6	15	0.7	488	22.1	89	4.0	8	0.4	4	0.2	2208	100.0
2005	2295	76.5	13	0.4	572	19.1	111	3.7	9	0.3	0	0.0	3000	100.0
2006	2557	76.6	30	0.9	669	20.0	78	2.3	4	0.1	0	0.0	3338	100.0
all	8244	77.1	64	0.6	2028	19.0	323	3.0	23	0.2	4	0.0	10686	100.0

Tab 3.5.1: Risks
immuno deficiency
all cases (including missing)
evaluable population (EVP)

	Immuno deficiency									
	missing		no		yes		not examined/unknown		all	
	n	%	n	%	n	%	n	%	n	%
Germany										
2002	851	99.8	0	0.0	2	0.2	0	0.0	853	100.0
2003	35	2.7	1088	84.5	57	4.4	107	8.3	1287	100.0
2004	60	2.7	1918	86.9	68	3.1	162	7.3	2208	100.0
2005	120	4.0	2560	85.3	159	5.3	161	5.4	3000	100.0
2006	131	3.9	2879	86.2	146	4.4	182	5.5	3338	100.0
all	1197	11.2	8445	79.0	432	4.0	612	5.7	10686	100.0

Tab 3.5.2: Risks
immuno deficiency
all informative cases from 2003 on
evaluable population (EVP)

	Immuno deficiency					
	no		yes		all	
	n	%	n	%	n	%
Germany						
2003	1088	95.0	57	5.0	1145	100.0
2004	1918	96.6	68	3.4	1986	100.0
2005	2560	94.2	159	5.8	2719	100.0
2006	2879	95.2	146	4.8	3025	100.0
all	8445	95.2	430	4.8	8875	100.0

Tab 3.6.1: Risks
attending daycare
all cases (including missing)
evaluable population (EVP)

	Attending daycare									
	missing		no		yes		not examined/unknown		all	
	n	%	n	%	n	%	n	%	n	%
Germany										
2002	853	100.0	0	0.0	0	0.0	0	0.0	853	100.0
2003	4	0.3	1264	98.2	15	1.2	4	0.3	1287	100.0
2004	7	0.3	2140	96.9	55	2.5	6	0.3	2208	100.0
2005	26	0.9	2892	96.4	68	2.3	14	0.5	3000	100.0
2006	32	1.0	3186	95.4	102	3.1	18	0.5	3338	100.0
all	922	8.6	9482	88.7	240	2.2	42	0.4	10686	100.0

Tab 3.6.2: Risks
attending daycare
all informative cases from 2003 on
evaluable population (EVP)

	Attending daycare					
	no		yes		all	
	n	%	n	%	n	%
Germany						
2003	1264	98.8	15	1.2	1279	100.0
2004	2140	97.5	55	2.5	2195	100.0
2005	2892	97.7	68	2.3	2960	100.0
2006	3186	96.9	102	3.1	3288	100.0
all	9482	97.5	240	2.5	9722	100.0

Tab 3.7.1.1: Risks
children <12 years in household
yes/no
all cases (including missing)
evaluable population (EVP)

	Children <12 years in household									
	missing		no		yes		not examined/unknown		all	
	n	%	n	%	n	%	n	%	n	%
Germany										
2002	853	100.0	0	0.0	0	0.0	0	0.0	853	100.0
2003	4	0.3	714	55.5	556	43.2	13	1.0	1287	100.0
2004	11	0.5	1173	53.1	1002	45.4	22	1.0	2208	100.0
2005	29	1.0	1565	52.2	1383	46.1	23	0.8	3000	100.0
2006	27	0.8	1770	53.0	1499	44.9	42	1.3	3338	100.0
all	924	8.6	5222	48.9	4440	41.5	100	0.9	10686	100.0

Tab 3.7.1.2: Risks
children <12 years in household
yes/no
all informative cases from 2003 on
evaluable population (EVP)

	Children <12 years in household					
	no		yes		all	
	n	%	n	%	n	%
Germany						
2003	714	56.2	556	43.8	1270	100.0
2004	1173	53.9	1002	46.1	2175	100.0
2005	1565	53.1	1383	46.9	2948	100.0
2006	1770	54.1	1499	45.9	3269	100.0
all	5222	54.0	4440	46.0	9662	100.0

Tab 3.7.2: Risks
children <12 years in household
number of children
evaluable population (EVP)

	Children <12 years in household													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002	853	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2003	740	57.5	5	0.4	367	28.5	119	9.2	34	2.6	13	1.0	6	0.5
2004	1240	56.2	1	0.0	675	30.6	215	9.7	49	2.2	11	0.5	7	0.3
2005	1663	55.4	2	0.1	889	29.6	295	9.8	97	3.2	28	0.9	18	0.6
2006	1915	57.4	4	0.1	982	29.4	319	9.6	76	2.3	25	0.7	10	0.3
all	6411	60.0	12	0.1	2913	27.3	948	8.9	256	2.4	77	0.7	41	0.4

(Continued)

	Children <12 years in household								all	
	6		7		8		12			
	n	%	n	%	n	%	n	%	n	%
Germany										
2002	0	0.0	0	0.0	0	0.0	0	0.0	853	100.0
2003	2	0.2	1	0.1	0	0.0	0	0.0	1287	100.0
2004	5	0.2	4	0.2	1	0.0	0	0.0	2208	100.0
2005	4	0.1	4	0.1	0	0.0	0	0.0	3000	100.0
2006	3	0.1	2	0.1	1	0.0	1	0.0	3338	100.0
all	14	0.1	11	0.1	2	0.0	1	0.0	10686	100.0

Tab 3.8.1: Risks
smoking in the family
all cases (including missing)
evaluable population (EVP)

	Smoking in the family									
	missing		no		yes		not examined/unknown		all	
	n	%	n	%	n	%	n	%	n	%
Germany										
2002	831	97.4	0	0.0	22	2.6	0	0.0	853	100.0
2003	31	2.4	861	66.9	217	16.9	178	13.8	1287	100.0
2004	46	2.1	1485	67.3	337	15.3	340	15.4	2208	100.0
2005	104	3.5	2039	68.0	411	13.7	446	14.9	3000	100.0
2006	116	3.5	2236	67.0	457	13.7	529	15.8	3338	100.0
all	1128	10.6	6621	62.0	1444	13.5	1493	14.0	10686	100.0

Tab 3.8.2: Risks
smoking in the family
all informative cases from 2003 on
evaluable population (EVP)

	Smoking in the family					
	no		yes		all	
	n	%	n	%	n	%
Germany						
2003	861	79.9	217	20.1	1078	100.0
2004	1485	81.5	337	18.5	1822	100.0
2005	2039	83.2	411	16.8	2450	100.0
2006	2236	83.0	457	17.0	2693	100.0
all	6621	82.3	1422	17.7	8043	100.0

Tab 3.9.1: Risks
familiy history: asthma
all cases (including missing)
evaluable population (EVP)

	Familiy history: asthma									
	missing		no		yes		not examined/unknown		all	
	n	%	n	%	n	%	n	%	n	%
Germany										
2002	848	99.4	0	0.0	5	0.6	0	0.0	853	100.0
2003	44	3.4	950	73.8	114	8.9	179	13.9	1287	100.0
2004	87	3.9	1572	71.2	190	8.6	359	16.3	2208	100.0
2005	87	2.9	2169	72.3	251	8.4	493	16.4	3000	100.0
2006	120	3.6	2363	70.8	268	8.0	587	17.6	3338	100.0
all	1186	11.1	7054	66.0	828	7.7	1618	15.1	10686	100.0

Tab 3.9.2: Risks
familiy history: asthma
all informative cases from 2003 on
evaluable population (EVP)

	Familiy history: asthma					
	no		yes		all	
	n	%	n	%	n	%
Germany						
2003	950	89.3	114	10.7	1064	100.0
2004	1572	89.2	190	10.8	1762	100.0
2005	2169	89.6	251	10.4	2420	100.0
2006	2363	89.8	268	10.2	2631	100.0
all	7054	89.6	823	10.4	7877	100.0

Tab 3.10.1: Risks
familiy history: allergic rhinitis
all cases (including missing)
evaluable population (EVP)

	Familiy history: allergic rhinitis									
	missing		no		yes		not examined/unknown		all	
	n	%	n	%	n	%	n	%	n	%
Germany										
2002	853	100.0	0	0.0	0	0.0	0	0.0	853	100.0
2003	44	3.4	900	69.9	159	12.4	184	14.3	1287	100.0
2004	78	3.5	1452	65.8	296	13.4	382	17.3	2208	100.0
2005	85	2.8	2001	66.7	402	13.4	512	17.1	3000	100.0
2006	116	3.5	2232	66.9	377	11.3	613	18.4	3338	100.0
all	1176	11.0	6585	61.6	1234	11.5	1691	15.8	10686	100.0

Tab 3.10.2: Risks
familiy history: allergic rhinitis
all informative cases from 2003 on
evaluable population (EVP)

		Familiy history: allergic rhinitis					
		no		yes		all	
		n	%	n	%	n	%
Germany							
	2003	900	85.0	159	15.0	1059	100.0
	2004	1452	83.1	296	16.9	1748	100.0
	2005	2001	83.3	402	16.7	2403	100.0
	2006	2232	85.6	377	14.4	2609	100.0
	all	6585	84.2	1234	15.8	7819	100.0

Tab 3.11.1: Risks
familiy history: allergic eczema
all cases (including missing)
evaluable population (EVP)

		Familiy history: allergic eczema									
		missing		no		yes		not examined/unknown		all	
		n	%	n	%	n	%	n	%	n	%
Germany											
	2002	853	100.0	0	0.0	0	0.0	0	0.0	853	100.0
	2003	44	3.4	954	74.1	106	8.2	183	14.2	1287	100.0
	2004	93	4.2	1563	70.8	173	7.8	379	17.2	2208	100.0
	2005	89	3.0	2168	72.3	211	7.0	532	17.7	3000	100.0
	2006	141	4.2	2353	70.5	223	6.7	621	18.6	3338	100.0
	all	1220	11.4	7038	65.9	713	6.7	1715	16.0	10686	100.0

Tab 3.11.2: Risks
familiy history: allergic eczema
all informative cases from 2003 on
evaluable population (EVP)

	Familiy history: allergic eczema					
	no		yes		all	
	n	%	n	%	n	%
Germany						
2003	954	90.0	106	10.0	1060	100.0
2004	1563	90.0	173	10.0	1736	100.0
2005	2168	91.1	211	8.9	2379	100.0
2006	2353	91.3	223	8.7	2576	100.0
all	7038	90.8	713	9.2	7751	100.0

Tab 3.12.1: Risks
other reasons
all cases (including missing)
evaluable population (EVP)

		Other reasons						all	
		missing		no		yes			
		n	%	n	%	n	%	n	%
Germany									
	2002	844	98.9	0	0.0	9	1.1	853	100.0
	2003	682	53.0	0	0.0	605	47.0	1287	100.0
	2004	1213	54.9	0	0.0	995	45.1	2208	100.0
	2005	1850	61.7	0	0.0	1150	38.3	3000	100.0
	2006	2042	61.2	0	0.0	1296	38.8	3338	100.0
	all	6631	62.1	0	0.0	4055	37.9	10686	100.0

Tab 3.12.2: Risks
other reasons
all informative cases from 2003 on
evaluable population (EVP)

		Other reasons			
		yes		all	
		n	%	n	%
Germany					
	2003	605	100.0	605	100.0
	2004	995	100.0	995	100.0
	2005	1150	100.0	1150	100.0
	2006	1296	100.0	1296	100.0
	all	4046	100.0	4046	100.0

Tab 4.1.1: Immunization
RSV prophylaxis in the last season
including missing
evaluable population (EVP)

	RSV prophylaxis in the last season									
	missing		no		yes		unknown		all	
	n	%	n	%	n	%	n	%	n	%
Germany										
2002	853	100.0	0	0.0	0	0.0	0	0.0	853	100.0
2003	33	2.6	1054	81.9	196	15.2	4	0.3	1287	100.0
2004	48	2.2	1821	82.5	332	15.0	7	0.3	2208	100.0
2005	55	1.8	2357	78.6	564	18.8	24	0.8	3000	100.0
2006	60	1.8	2618	78.4	651	19.5	9	0.3	3338	100.0
all	1049	9.8	7850	73.5	1743	16.3	44	0.4	10686	100.0

Tab 4.1.2: Immunization
RSV prophylaxis in the last season
excluding missing
evaluable population (EVP)

	RSV prophylaxis in the last season						all	
	no		yes		unknown			
	n	%	n	%	n	%	n	%
Germany								
2003	1054	84.1	196	15.6	4	0.3	1254	100.0
2004	1821	84.3	332	15.4	7	0.3	2160	100.0
2005	2357	80.0	564	19.2	24	0.8	2945	100.0
2006	2618	79.9	651	19.9	9	0.3	3278	100.0
all	7850	81.5	1743	18.1	44	0.5	9637	100.0

Tab 4.2.1: Immunization
location
including missing
evaluable population (EVP)

	Immunization started in clinic						all	
	missing		no		yes			
	n	%	n	%	n	%	n	%
Germany								
2002	0	0.0	628	73.6	225	26.4	853	100.0
2003	21	1.6	1036	80.5	230	17.9	1287	100.0
2004	32	1.4	1873	84.8	303	13.7	2208	100.0
2005	44	1.5	2506	83.5	450	15.0	3000	100.0
2006	45	1.3	2856	85.6	437	13.1	3338	100.0
all	142	1.3	8899	83.3	1645	15.4	10686	100.0

Tab 4.2.2: Immunization
location
excluding missing
evaluable population (EVP)

	Immunization started in clinic					
	no		yes		all	
	n	%	n	%	n	%
Germany						
2002	628	73.6	225	26.4	853	100.0
2003	1036	81.8	230	18.2	1266	100.0
2004	1873	86.1	303	13.9	2176	100.0
2005	2506	84.8	450	15.2	2956	100.0
2006	2856	86.7	437	13.3	3293	100.0
all	8899	84.4	1645	15.6	10544	100.0

Tab 4.3.1: Immunization recommendation including missing evaluable population (EVP)

	Recommendation from clinic						all	
	missing		no		yes			
	n	%	n	%	n	%	n	%
Germany								
2002	853	100.0	0	0.0	0	0.0	853	100.0
2003	48	3.7	526	40.9	713	55.4	1287	100.0
2004	87	3.9	961	43.5	1160	52.5	2208	100.0
2005	100	3.3	1223	40.8	1677	55.9	3000	100.0
2006	123	3.7	1430	42.8	1785	53.5	3338	100.0
all	1211	11.3	4140	38.7	5335	49.9	10686	100.0

Tab 4.3.2: Immunization recommendation excluding missing evaluable population (EVP)

	Recommendation from clinic					
	no		yes		all	
	n	%	n	%	n	%
Germany						
2003	526	42.5	713	57.5	1239	100.0
2004	961	45.3	1160	54.7	2121	100.0
2005	1223	42.2	1677	57.8	2900	100.0
2006	1430	44.5	1785	55.5	3215	100.0
all	4140	43.7	5335	56.3	9475	100.0

Tab 4.4.1: Immunization
age at start of RSV prophylaxis [months]
all patients
evaluable population (EVP)

		n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2002	41	812	4.846	3.606	2.000	4.000	6.000	1.00	27.00
	2003	69	1218	5.120	3.670	2.750	4.000	6.250	0.00	25.00
	2004	130	2078	5.260	3.856	2.750	4.250	6.750	0.25	27.00
	2005	195	2805	5.340	4.131	2.500	4.000	6.750	0.25	24.00
	2006	192	3146	5.235	4.114	2.500	4.000	6.500	0.25	30.00
	all	627	10059	5.224	3.977	2.500	4.000	6.500	0.00	30.00

Tab 4.4.2.1: Immunization
age at start of RSV prophylaxis [months]
age < 12 months
by risk of BPD
evaluable population (EVP)

		BPD	n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2002	missing	5	83	3.759	2.254	2.000	3.000	5.000	1.00	10.00
		no	12	320	3.916	2.351	2.000	3.000	5.000	1.00	11.00
		yes	24	363	4.577	2.427	3.000	4.000	6.000	1.00	11.00
	2003	missing	4	85	3.959	1.754	2.750	3.750	5.000	1.50	9.00
		no	26	552	3.926	2.261	2.250	3.500	5.000	0.00	11.75
		yes	39	506	5.030	2.465	3.250	4.500	6.500	0.50	11.75
	2004	missing	19	137	4.651	2.371	3.000	4.250	6.500	0.50	11.75
		no	54	1097	4.029	2.277	2.250	3.500	5.250	0.50	11.75
		yes	57	692	5.039	2.581	3.000	4.500	6.875	0.25	11.75
	2005	missing	37	193	4.422	2.554	2.500	4.000	6.000	0.75	11.75
		no	88	1459	4.079	2.475	2.250	3.500	5.250	0.25	11.75
		yes	70	942	5.011	2.755	3.000	4.500	6.750	0.25	11.75
	2006	missing	35	243	4.329	2.556	2.500	4.000	5.750	0.25	11.75
		no	88	1668	3.924	2.442	2.000	3.250	5.250	0.25	11.75
		yes	69	981	4.950	2.708	3.000	4.500	6.750	0.25	11.75
	all	missing	100	741	4.307	2.418	2.500	4.000	5.750	0.25	11.75
		no	268	5096	3.991	2.392	2.000	3.500	5.250	0.00	11.75
		yes	259	3484	4.957	2.636	3.000	4.500	6.750	0.25	11.75

Tab 4.4.2.2: Immunization
age at start of RSV prophylaxis [months]
age < 12 months
by risk of CHD
evaluable population (EVP)

		CHD	n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2002	missing	38	712	4.220	2.397	2.000	4.000	6.000	1.00	11.00
		yes	3	54	4.111	2.455	2.000	4.000	6.000	1.00	11.00
	2003	missing	2	14	4.018	2.454	3.000	3.125	4.750	1.50	11.50
		no	49	847	4.317	2.327	2.500	3.750	5.500	0.00	11.75
		yes	18	273	4.784	2.527	2.750	4.500	6.250	0.75	11.75
		unknown	0	9	3.306	1.919	1.750	2.500	5.500	1.25	6.00
	2004	missing	9	23	4.413	2.083	2.750	4.500	5.500	1.50	10.25
		no	78	1387	4.332	2.379	2.500	4.000	5.750	0.25	11.75
		yes	43	509	4.712	2.611	2.750	4.250	6.250	0.50	11.75
		unknown	0	7	5.036	2.347	3.500	5.000	7.250	1.50	8.00
	2005	missing	16	46	4.582	2.734	2.500	4.000	5.750	1.00	11.75
		no	109	1722	4.328	2.522	2.500	3.750	5.750	0.25	11.75
		yes	64	816	4.660	2.786	2.500	4.000	6.500	0.25	11.75
		unknown	6	10	5.975	3.796	2.750	4.375	10.000	2.00	11.50
	2006	missing	12	66	3.890	1.934	2.500	3.625	5.000	1.00	9.50
		no	113	1907	4.246	2.543	2.250	3.750	5.750	0.25	11.75
		yes	66	909	4.460	2.711	2.250	3.750	6.000	0.25	11.75
		unknown	1	10	4.475	2.936	1.750	4.375	6.000	1.25	10.50
	all	missing	77	861	4.216	2.376	2.000	4.000	5.500	1.00	11.75
		no	349	5863	4.301	2.468	2.500	3.750	5.750	0.00	11.75
		yes	194	2561	4.601	2.693	2.500	4.000	6.250	0.25	11.75
		unknown	7	36	4.708	2.951	2.125	3.750	6.250	1.25	11.50

Tab 4.4.3.1: Immunization
age at start of RSV prophylaxis [months]
age >= 12 months
by risk of BPD
evaluable population (EVP)

		BPD	n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2002	missing	0	2	14.000	2.828	12.000	14.000	16.000	12.00	16.00
		no	0	7	14.286	2.059	12.000	14.000	15.000	12.00	18.00
		yes	0	37	15.676	4.314	12.000	14.000	18.000	12.00	27.00
	2003	missing	0	5	13.350	2.748	12.000	12.000	12.500	12.00	18.25
		no	0	17	15.706	2.533	13.750	16.000	17.000	12.00	21.25
		yes	0	53	16.123	3.240	14.000	15.250	18.000	12.00	25.00
	2004	missing	0	8	16.125	3.386	13.125	16.000	18.375	12.00	22.00
		no	0	54	15.194	3.021	12.750	14.375	17.750	12.00	27.00
		yes	0	90	15.969	3.210	13.000	15.625	18.250	12.00	26.50
	2005	missing	0	12	17.188	3.177	14.625	16.125	19.750	13.00	23.00
		no	0	78	16.189	3.192	13.500	15.375	19.000	12.00	23.50
		yes	0	121	16.401	3.395	13.000	16.000	19.750	12.00	24.00
	2006	missing	0	13	14.615	2.380	12.750	14.000	16.500	12.00	19.75
		no	0	106	15.790	3.424	13.250	15.000	17.500	12.00	29.00
		yes	0	135	15.946	3.481	13.000	15.000	18.500	12.00	30.00
	all	missing	0	40	15.500	3.091	12.750	15.250	17.625	12.00	23.00
		no	0	262	15.740	3.201	13.250	15.000	17.750	12.00	29.00
		yes	0	436	16.076	3.445	13.000	15.375	18.500	12.00	30.00

Tab 4.4.3.2: Immunization
age at start of RSV prophylaxis [months]
age >= 12 months
by risk of CHD
evaluable population (EVP)

		CHD	n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2002	missing	0	38	15.816	4.197	12.000	15.000	18.000	12.00	27.00
		yes	0	8	13.375	1.996	12.000	13.000	13.500	12.00	18.00
	2003	missing	0	1	18.250		18.250	18.250	18.250	18.25	18.25
		no	0	44	16.080	2.704	14.000	16.000	18.000	12.00	22.00
		yes	0	29	15.466	3.704	13.000	14.250	16.250	12.00	25.00
		unknown	0	1	14.000		14.000	14.000	14.000	14.00	14.00
	2004	missing	0	1	15.000		15.000	15.000	15.000	15.00	15.00
		no	0	79	15.839	3.185	13.000	15.500	18.000	12.00	26.50
		yes	0	72	15.563	3.157	13.000	14.500	18.000	12.00	27.00
	2005	missing	0	3	17.750	3.500	13.750	19.250	20.250	13.75	20.25
		no	0	126	16.583	3.548	13.000	16.125	20.000	12.00	24.00
		yes	0	82	15.985	2.872	13.500	15.250	18.000	12.00	23.00
	2006	missing	0	7	19.607	3.452	17.250	18.250	23.000	14.75	23.75
		no	0	126	15.601	3.291	13.000	14.750	17.750	12.00	25.75
		yes	0	120	15.767	3.404	13.250	15.000	17.500	12.00	30.00
		unknown	0	1	21.500		21.500	21.500	21.500	21.50	21.50
	all	missing	0	50	16.495	4.148	13.000	15.000	19.250	12.00	27.00
		no	0	375	16.037	3.310	13.000	15.500	18.500	12.00	26.50
		yes	0	311	15.687	3.223	13.000	15.000	17.750	12.00	30.00
		unknown	0	2	17.750	5.303	14.000	17.750	21.500	14.00	21.50

Tab 4.5.1: Immunization
administrations
total number
evaluable population (EVP)

	1		2		3		4		5		6		7		8		9	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																		
2002	40	4.7	76	8.9	127	14.9	146	17.1	253	29.7	160	18.8	43	5.0	8	0.9	0	0.0
2003	80	6.2	106	8.2	185	14.4	222	17.2	342	26.6	227	17.6	96	7.5	28	2.2	1	0.1
2004	118	5.3	240	10.9	266	12.0	333	15.1	481	21.8	461	20.9	248	11.2	55	2.5	6	0.3
2005	143	4.8	285	9.5	382	12.7	537	17.9	620	20.7	584	19.5	316	10.5	121	4.0	11	0.4
2006	167	5.0	273	8.2	365	10.9	484	14.5	681	20.4	695	20.8	458	13.7	178	5.3	31	0.9
all	548	5.1	980	9.2	1325	12.4	1722	16.1	2377	22.2	2127	19.9	1161	10.9	390	3.6	49	0.5

	10		11		12		all	
	n	%	n	%	n	%	n	%
Germany								
2002	0	0.0	0	0.0	0	0.0	853	100.0
2003	0	0.0	0	0.0	0	0.0	1287	100.0
2004	0	0.0	0	0.0	0	0.0	2208	100.0
2005	1	0.0	0	0.0	0	0.0	3000	100.0
2006	3	0.1	2	0.1	1	0.0	3338	100.0
all	4	0.0	2	0.0	1	0.0	10686	100.0

Tab 4.5.2: Immunization
administrations
total number of documented administrations (with/without gaps)
evaluable population (EVP)

	Number of documented administrations (excl. gaps)	Number of documented administrations (incl. gaps)
Germany		
2002	3699	3747
2003	5707	5712
2004	10118	10129
2005	13847	13900
2006	16237	16292
all	49608	49780

Tab 4.6.1: Immunization 1
total number of follow-up administrations by month of first administration
including missing
evaluable population (EVP)

Month of first admin	0		1		2		3		4		5		6		7		8	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																		
2002																		
missing	0	0.0	4	12.9	5	16.1	4	12.9	8	25.8	6	19.4	2	6.5	2	6.5	0	0.0
September	0	0.0	0	0.0	0	0.0	4	6.2	12	18.5	27	41.5	18	27.7	4	6.2	0	0.0
October	2	0.9	1	0.4	13	5.6	22	9.4	83	35.6	88	37.8	22	9.4	2	0.9	0	0.0
November	9	3.6	15	6.0	21	8.4	60	24.0	107	42.8	37	14.8	1	0.4	0	0.0	0	0.0
December	2	1.7	6	5.1	29	24.6	39	33.1	40	33.9	2	1.7	0	0.0	0	0.0	0	0.0
January	4	5.6	17	23.9	32	45.1	16	22.5	2	2.8	0	0.0	0	0.0	0	0.0	0	0.0
February	3	5.7	22	41.5	26	49.1	1	1.9	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0
March	14	58.3	10	41.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
April	6	75.0	2	25.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
May	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
all	40	4.7	77	9.0	126	14.8	146	17.1	253	29.7	160	18.8	43	5.0	8	0.9	0	0.0
2003																		
missing	0	0.0	1	8.3	4	33.3	1	8.3	0	0.0	3	25.0	2	16.7	1	8.3	0	0.0
September	1	1.0	3	2.9	6	5.7	6	5.7	19	18.1	34	32.4	22	21.0	13	12.4	1	1.0
October	12	3.0	10	2.5	21	5.2	29	7.1	126	31.0	131	32.3	70	17.2	7	1.7	0	0.0
November	7	2.0	22	6.4	30	8.7	77	22.4	147	42.7	54	15.7	7	2.0	0	0.0	0	0.0
December	10	5.2	8	4.1	47	24.2	80	41.2	46	23.7	3	1.5	0	0.0	0	0.0	0	0.0
January	4	4.5	12	13.6	47	53.4	19	21.6	5	5.7	0	0.0	1	1.1	0	0.0	0	0.0
February	8	12.5	22	34.4	29	45.3	5	7.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
March	24	42.1	25	43.9	6	10.5	1	1.8	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0
April	13	81.3	3	18.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
May	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	80	6.2	106	8.2	190	14.8	218	16.9	344	26.7	225	17.5	102	7.9	21	1.6	1	0.1
2004																		
missing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
September	2	0.7	7	2.4	11	3.8	18	6.3	38	13.2	62	21.5	99	34.4	45	15.6	6	2.1
October	17	2.1	18	2.3	33	4.2	77	9.7	195	24.7	300	37.9	141	17.8	10	1.3	0	0.0
November	8	1.7	25	5.4	41	8.8	103	22.1	188	40.3	94	20.1	8	1.7	0	0.0	0	0.0
December	11	4.5	21	8.6	50	20.5	102	41.8	56	23.0	4	1.6	0	0.0	0	0.0	0	0.0
January	11	6.3	36	20.5	92	52.3	32	18.2	5	2.8	0	0.0	0	0.0	0	0.0	0	0.0
February	19	14.1	81	60.0	34	25.2	1	0.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

(Continued)

Tab 4.6.1: Immunization 2
total number of follow-up administrations by month of first administration
including missing
evaluable population (EVP)

Month of first admin	0		1		2		3		4		5		6		7		8	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																		
2004																		
March	32	38.6	49	59.0	2	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
April	18	75.0	4	16.7	2	8.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
May	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
all	118	5.3	241	10.9	265	12.0	333	15.1	482	21.8	460	20.8	248	11.2	55	2.5	6	0.3
2005																		
missing	0	0.0	3	9.7	2	6.5	10	32.3	5	16.1	5	16.1	5	16.1	1	3.2	0	0.0
September	2	0.5	6	1.6	8	2.1	13	3.5	43	11.5	78	20.9	118	31.6	96	25.7	10	2.7
October	6	0.7	22	2.6	32	3.8	72	8.6	182	21.6	325	38.6	177	21.0	23	2.7	1	0.1
November	17	2.5	21	3.1	55	8.1	147	21.8	261	38.7	159	23.6	14	2.1	1	0.1	0	0.0
December	11	2.6	24	5.8	76	18.2	168	40.3	119	28.5	17	4.1	2	0.5	0	0.0	0	0.0
January	12	4.4	34	12.5	101	37.0	117	42.9	9	3.3	0	0.0	0	0.0	0	0.0	0	0.0
February	17	8.6	75	38.1	94	47.7	11	5.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
March	36	25.7	90	64.3	14	10.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
April	37	78.7	10	21.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
May	5	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	143	4.8	285	9.5	382	12.7	538	17.9	619	20.6	584	19.5	316	10.5	121	4.0	11	0.4
2006																		
missing	0	0.0	1	3.8	1	3.8	1	3.8	2	7.7	5	19.2	4	15.4	5	19.2	2	7.7
September	6	1.3	4	0.9	7	1.6	19	4.2	47	10.5	87	19.4	125	27.9	124	27.7	29	6.5
October	17	1.5	22	1.9	34	2.9	72	6.2	239	20.5	419	36.0	312	26.8	49	4.2	0	0.0
November	22	3.2	24	3.4	45	6.5	134	19.3	283	40.7	170	24.4	17	2.4	0	0.0	1	0.1
December	10	2.8	20	5.6	61	17.1	153	43.0	101	28.4	11	3.1	0	0.0	0	0.0	0	0.0
January	13	5.3	27	11.1	97	39.9	94	38.7	11	4.5	1	0.4	0	0.0	0	0.0	0	0.0
February	20	9.1	78	35.6	111	50.7	10	4.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
March	54	34.8	92	59.4	9	5.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
April	23	79.3	6	20.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
May	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	167	5.0	274	8.2	365	10.9	483	14.5	683	20.5	693	20.8	458	13.7	178	5.3	32	1.0
all																		
missing	0	0.0	9	9.0	12	12.0	16	16.0	15	15.0	19	19.0	13	13.0	9	9.0	2	2.0
September	11	0.9	20	1.6	32	2.5	60	4.7	159	12.4	288	22.5	382	29.8	282	22.0	46	3.6

(Continued)

Tab 4.6.1: Immunization
total number of follow-up administrations by month of first administration
including missing
evaluable population (EVP)

Month of first admin	0		1		2		3		4		5		6		7		8	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																		
all																		
October	54	1.6	73	2.1	133	3.9	272	7.9	825	24.0	1263	36.8	722	21.0	91	2.6	1	0.0
November	63	2.6	107	4.4	192	7.9	521	21.4	986	40.5	514	21.1	47	1.9	1	0.0	1	0.0
December	44	3.3	79	5.9	263	19.8	542	40.8	362	27.2	37	2.8	2	0.2	0	0.0	0	0.0
January	44	5.2	126	14.8	369	43.4	278	32.7	32	3.8	1	0.1	1	0.1	0	0.0	0	0.0
February	67	10.0	278	41.6	294	44.0	28	4.2	1	0.1	0	0.0	0	0.0	0	0.0	0	0.0
March	160	34.9	266	58.0	31	6.8	1	0.2	1	0.2	0	0.0	0	0.0	0	0.0	0	0.0
April	97	78.2	25	20.2	2	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
May	8	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	548	5.1	983	9.2	1328	12.4	1718	16.1	2381	22.3	2122	19.9	1167	10.9	383	3.6	50	0.5

(Continued)

Tab 4.6.1: Immunization
total number of follow-up administrations by month of first administration
including missing
evaluable population (EVP)

Month of first admin	9		10		11		all	
	n	%	n	%	n	%	n	%
Germany								
2002								
missing	0	0.0	0	0.0	0	0.0	31	100.0
September	0	0.0	0	0.0	0	0.0	65	100.0
October	0	0.0	0	0.0	0	0.0	233	100.0
November	0	0.0	0	0.0	0	0.0	250	100.0
December	0	0.0	0	0.0	0	0.0	118	100.0
January	0	0.0	0	0.0	0	0.0	71	100.0
February	0	0.0	0	0.0	0	0.0	53	100.0
March	0	0.0	0	0.0	0	0.0	24	100.0
April	0	0.0	0	0.0	0	0.0	8	100.0
May	0	0	0	0	0	0	0	0
all	0	0.0	0	0.0	0	0.0	853	100.0
2003								
missing	0	0.0	0	0.0	0	0.0	12	100.0
September	0	0.0	0	0.0	0	0.0	105	100.0
October	0	0.0	0	0.0	0	0.0	406	100.0
November	0	0.0	0	0.0	0	0.0	344	100.0
December	0	0.0	0	0.0	0	0.0	194	100.0
January	0	0.0	0	0.0	0	0.0	88	100.0
February	0	0.0	0	0.0	0	0.0	64	100.0
March	0	0.0	0	0.0	0	0.0	57	100.0
April	0	0.0	0	0.0	0	0.0	16	100.0
May	0	0.0	0	0.0	0	0.0	1	100.0
all	0	0.0	0	0.0	0	0.0	1287	100.0
2004								
missing	0	0	0	0	0	0	0	0
September	0	0.0	0	0.0	0	0.0	288	100.0
October	0	0.0	0	0.0	0	0.0	791	100.0
November	0	0.0	0	0.0	0	0.0	467	100.0
December	0	0.0	0	0.0	0	0.0	244	100.0
January	0	0.0	0	0.0	0	0.0	176	100.0
February	0	0.0	0	0.0	0	0.0	135	100.0

(Continued)

Tab 4.6.1: Immunization
total number of follow-up administrations by month of first administration
including missing
evaluable population (EVP)

Month of first admin	9		10		11		all	
	n	%	n	%	n	%	n	%
Germany								
2004								
March	0	0.0	0	0.0	0	0.0	83	100.0
April	0	0.0	0	0.0	0	0.0	24	100.0
May	0	0	0	0	0	0	0	0
all	0	0.0	0	0.0	0	0.0	2208	100.0
2005								
missing	0	0.0	0	0.0	0	0.0	31	100.0
September	0	0.0	0	0.0	0	0.0	374	100.0
October	1	0.1	0	0.0	0	0.0	841	100.0
November	0	0.0	0	0.0	0	0.0	675	100.0
December	0	0.0	0	0.0	0	0.0	417	100.0
January	0	0.0	0	0.0	0	0.0	273	100.0
February	0	0.0	0	0.0	0	0.0	197	100.0
March	0	0.0	0	0.0	0	0.0	140	100.0
April	0	0.0	0	0.0	0	0.0	47	100.0
May	0	0.0	0	0.0	0	0.0	5	100.0
all	1	0.0	0	0.0	0	0.0	3000	100.0
2006								
missing	2	7.7	2	7.7	1	3.8	26	100.0
September	0	0.0	0	0.0	0	0.0	448	100.0
October	0	0.0	0	0.0	0	0.0	1164	100.0
November	0	0.0	0	0.0	0	0.0	696	100.0
December	0	0.0	0	0.0	0	0.0	356	100.0
January	0	0.0	0	0.0	0	0.0	243	100.0
February	0	0.0	0	0.0	0	0.0	219	100.0
March	0	0.0	0	0.0	0	0.0	155	100.0
April	0	0.0	0	0.0	0	0.0	29	100.0
May	0	0.0	0	0.0	0	0.0	2	100.0
all	2	0.1	2	0.1	1	0.0	3338	100.0
all								
missing	2	2.0	2	2.0	1	1.0	100	100.0
September	0	0.0	0	0.0	0	0.0	1280	100.0

(Continued)

Tab 4.6.1: Immunization
total number of follow-up administrations by month of first administration
including missing
evaluable population (EVP)

Month of first admin	9		10		11		all	
	n	%	n	%	n	%	n	%
Germany								
all								
October	1	0.0	0	0.0	0	0.0	3435	100.0
November	0	0.0	0	0.0	0	0.0	2432	100.0
December	0	0.0	0	0.0	0	0.0	1329	100.0
January	0	0.0	0	0.0	0	0.0	851	100.0
February	0	0.0	0	0.0	0	0.0	668	100.0
March	0	0.0	0	0.0	0	0.0	459	100.0
April	0	0.0	0	0.0	0	0.0	124	100.0
May	0	0.0	0	0.0	0	0.0	8	100.0
all	3	0.0	2	0.0	1	0.0	10686	100.0

Tab 4.6.2: Immunization
total number of follow-up administrations by month of first administration
excluding missing
evaluable population (EVP)

Month of first admin	0		1		2		3		4		5		6		7		8	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																		
2002																		
September	0	0.0	0	0.0	0	0.0	4	6.2	12	18.5	27	41.5	18	27.7	4	6.2	0	0.0
October	2	0.9	1	0.4	13	5.6	22	9.4	83	35.6	88	37.8	22	9.4	2	0.9	0	0.0
November	9	3.6	15	6.0	21	8.4	60	24.0	107	42.8	37	14.8	1	0.4	0	0.0	0	0.0
December	2	1.7	6	5.1	29	24.6	39	33.1	40	33.9	2	1.7	0	0.0	0	0.0	0	0.0
January	4	5.6	17	23.9	32	45.1	16	22.5	2	2.8	0	0.0	0	0.0	0	0.0	0	0.0
February	3	5.7	22	41.5	26	49.1	1	1.9	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0
March	14	58.3	10	41.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
April	6	75.0	2	25.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
May	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
all	40	4.9	73	8.9	121	14.7	142	17.3	245	29.8	154	18.7	41	5.0	6	0.7	0	0.0
2003																		
September	1	1.0	3	2.9	6	5.7	6	5.7	19	18.1	34	32.4	22	21.0	13	12.4	1	1.0
October	12	3.0	10	2.5	21	5.2	29	7.1	126	31.0	131	32.3	70	17.2	7	1.7	0	0.0
November	7	2.0	22	6.4	30	8.7	77	22.4	147	42.7	54	15.7	7	2.0	0	0.0	0	0.0
December	10	5.2	8	4.1	47	24.2	80	41.2	46	23.7	3	1.5	0	0.0	0	0.0	0	0.0
January	4	4.5	12	13.6	47	53.4	19	21.6	5	5.7	0	0.0	1	1.1	0	0.0	0	0.0
February	8	12.5	22	34.4	29	45.3	5	7.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
March	24	42.1	25	43.9	6	10.5	1	1.8	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0
April	13	81.3	3	18.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
May	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	80	6.3	105	8.2	186	14.6	217	17.0	344	27.0	222	17.4	100	7.8	20	1.6	1	0.1
2004																		
September	2	0.7	7	2.4	11	3.8	18	6.3	38	13.2	62	21.5	99	34.4	45	15.6	6	2.1
October	17	2.1	18	2.3	33	4.2	77	9.7	195	24.7	300	37.9	141	17.8	10	1.3	0	0.0
November	8	1.7	25	5.4	41	8.8	103	22.1	188	40.3	94	20.1	8	1.7	0	0.0	0	0.0
December	11	4.5	21	8.6	50	20.5	102	41.8	56	23.0	4	1.6	0	0.0	0	0.0	0	0.0
January	11	6.3	36	20.5	92	52.3	32	18.2	5	2.8	0	0.0	0	0.0	0	0.0	0	0.0
February	19	14.1	81	60.0	34	25.2	1	0.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
March	32	38.6	49	59.0	2	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
April	18	75.0	4	16.7	2	8.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
May	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

Tab 4.6.2: Immunization 2
total number of follow-up administrations by month of first administration
excluding missing
evaluable population (EVP)

Month of first admin	0		1		2		3		4		5		6		7		8	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																		
2004																		
all	118	5.3	241	10.9	265	12.0	333	15.1	482	21.8	460	20.8	248	11.2	55	2.5	6	0.3
2005																		
September	2	0.5	6	1.6	8	2.1	13	3.5	43	11.5	78	20.9	118	31.6	96	25.7	10	2.7
October	6	0.7	22	2.6	32	3.8	72	8.6	182	21.6	325	38.6	177	21.0	23	2.7	1	0.1
November	17	2.5	21	3.1	55	8.1	147	21.8	261	38.7	159	23.6	14	2.1	1	0.1	0	0.0
December	11	2.6	24	5.8	76	18.2	168	40.3	119	28.5	17	4.1	2	0.5	0	0.0	0	0.0
January	12	4.4	34	12.5	101	37.0	117	42.9	9	3.3	0	0.0	0	0.0	0	0.0	0	0.0
February	17	8.6	75	38.1	94	47.7	11	5.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
March	36	25.7	90	64.3	14	10.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
April	37	78.7	10	21.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
May	5	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	143	4.8	282	9.5	380	12.8	528	17.8	614	20.7	579	19.5	311	10.5	120	4.0	11	0.4
2006																		
September	6	1.3	4	0.9	7	1.6	19	4.2	47	10.5	87	19.4	125	27.9	124	27.7	29	6.5
October	17	1.5	22	1.9	34	2.9	72	6.2	239	20.5	419	36.0	312	26.8	49	4.2	0	0.0
November	22	3.2	24	3.4	45	6.5	134	19.3	283	40.7	170	24.4	17	2.4	0	0.0	1	0.1
December	10	2.8	20	5.6	61	17.1	153	43.0	101	28.4	11	3.1	0	0.0	0	0.0	0	0.0
January	13	5.3	27	11.1	97	39.9	94	38.7	11	4.5	1	0.4	0	0.0	0	0.0	0	0.0
February	20	9.1	78	35.6	111	50.7	10	4.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
March	54	34.8	92	59.4	9	5.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
April	23	79.3	6	20.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
May	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	167	5.0	273	8.2	364	11.0	482	14.6	681	20.6	688	20.8	454	13.7	173	5.2	30	0.9
all																		
September	11	0.9	20	1.6	32	2.5	60	4.7	159	12.4	288	22.5	382	29.8	282	22.0	46	3.6
October	54	1.6	73	2.1	133	3.9	272	7.9	825	24.0	1263	36.8	722	21.0	91	2.6	1	0.0
November	63	2.6	107	4.4	192	7.9	521	21.4	986	40.5	514	21.1	47	1.9	1	0.0	1	0.0
December	44	3.3	79	5.9	263	19.8	542	40.8	362	27.2	37	2.8	2	0.2	0	0.0	0	0.0
January	44	5.2	126	14.8	369	43.4	278	32.7	32	3.8	1	0.1	1	0.1	0	0.0	0	0.0
February	67	10.0	278	41.6	294	44.0	28	4.2	1	0.1	0	0.0	0	0.0	0	0.0	0	0.0
March	160	34.9	266	58.0	31	6.8	1	0.2	1	0.2	0	0.0	0	0.0	0	0.0	0	0.0

(Continued)

Tab 4.6.2: Immunization
total number of follow-up administrations by month of first administration
excluding missing
evaluable population (EVP)

Month of first admin	0		1		2		3		4		5		6		7		8	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																		
all																		
April	97	78.2	25	20.2	2	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
May	8	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	548	5.2	974	9.2	1316	12.4	1702	16.1	2366	22.4	2103	19.9	1154	10.9	374	3.5	48	0.5

(Continued)

Tab 4.6.2: Immunization
total number of follow-up administrations by month of first administration
excluding missing
evaluable population (EVP)

Month of first admin	9		all	
	n	%	n	%
Germany				
2002				
September	0	0.0	65	100.0
October	0	0.0	233	100.0
November	0	0.0	250	100.0
December	0	0.0	118	100.0
January	0	0.0	71	100.0
February	0	0.0	53	100.0
March	0	0.0	24	100.0
April	0	0.0	8	100.0
May	0	0	0	0
all	0	0.0	822	100.0
2003				
September	0	0.0	105	100.0
October	0	0.0	406	100.0
November	0	0.0	344	100.0
December	0	0.0	194	100.0
January	0	0.0	88	100.0
February	0	0.0	64	100.0
March	0	0.0	57	100.0
April	0	0.0	16	100.0
May	0	0.0	1	100.0
all	0	0.0	1275	100.0
2004				
September	0	0.0	288	100.0
October	0	0.0	791	100.0
November	0	0.0	467	100.0
December	0	0.0	244	100.0
January	0	0.0	176	100.0
February	0	0.0	135	100.0
March	0	0.0	83	100.0
April	0	0.0	24	100.0
May	0	0	0	0

(Continued)

Tab 4.6.2: Immunization
total number of follow-up administrations by month of first administration
excluding missing
evaluable population (EVP)

Month of first admin	9		all	
	n	%	n	%
Germany				
2004				
all	0	0.0	2208	100.0
2005				
September	0	0.0	374	100.0
October	1	0.1	841	100.0
November	0	0.0	675	100.0
December	0	0.0	417	100.0
January	0	0.0	273	100.0
February	0	0.0	197	100.0
March	0	0.0	140	100.0
April	0	0.0	47	100.0
May	0	0.0	5	100.0
all	1	0.0	2969	100.0
2006				
September	0	0.0	448	100.0
October	0	0.0	1164	100.0
November	0	0.0	696	100.0
December	0	0.0	356	100.0
January	0	0.0	243	100.0
February	0	0.0	219	100.0
March	0	0.0	155	100.0
April	0	0.0	29	100.0
May	0	0.0	2	100.0
all	0	0.0	3312	100.0
all				
September	0	0.0	1280	100.0
October	1	0.0	3435	100.0
November	0	0.0	2432	100.0
December	0	0.0	1329	100.0
January	0	0.0	851	100.0
February	0	0.0	668	100.0
March	0	0.0	459	100.0

(Continued)

Tab 4.6.2: Immunization
total number of follow-up administrations by month of first administration
excluding missing
evaluable population (EVP)

Month of first admin	9		all	
	n	%	n	%
Germany				
all				
April	0	0.0	124	100.0
May	0	0.0	8	100.0
all	1	0.0	10586	100.0

Tab 4.7: Immunization 1
total number of administrations grouped by children born in summer/winter
evaluable population (EVP)

Country/year/born in summer/winter	Total number of administrations														
	1		2		3		4		5		6		7		8
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n
Germany															
2002															
Missing	0	0	0	0	1	33.3	1	33.3	0	0	0	0	1	33.3	0
Summer	12	2.8	17	4.0	40	9.4	70	16.5	153	36.0	95	22.4	33	7.8	5
Winter	28	6.6	59	13.9	86	20.2	75	17.6	100	23.5	65	15.3	9	2.1	3
all	40	4.7	76	8.9	127	14.9	146	17.1	253	29.7	160	18.8	43	5.0	8
2003															
Summer	23	3.4	36	5.4	57	8.5	111	16.6	211	31.6	148	22.2	60	9.0	20
Winter	57	9.2	70	11.3	128	20.6	111	17.9	131	21.1	79	12.7	36	5.8	8
all	80	6.2	106	8.2	185	14.4	222	17.2	342	26.6	227	17.6	96	7.5	28
2004															
Missing	79	6.1	145	11.2	155	12.0	206	15.9	270	20.8	260	20.1	151	11.7	24
Summer	11	2.4	17	3.7	47	10.1	57	12.3	123	26.5	121	26.1	67	14.4	20
Winter	28	6.2	78	17.4	64	14.3	70	15.6	88	19.6	80	17.8	30	6.7	11
all	118	5.3	240	10.9	266	12.0	333	15.1	481	21.8	461	20.9	248	11.2	55
2005															
Missing	2	16.7	0	0	2	16.7	1	8.3	5	41.7	1	8.3	0	0	1
Summer	34	2.5	67	5.0	113	8.4	217	16.2	302	22.6	332	24.8	196	14.6	71
Winter	107	6.5	218	13.2	267	16.2	319	19.3	313	19.0	251	15.2	120	7.3	49
all	143	4.8	285	9.5	382	12.7	537	17.9	620	20.7	584	19.5	316	10.5	121
2006															
Missing	1	5.9	1	5.9	2	11.8	2	11.8	2	11.8	5	29.4	3	17.6	1
Summer	45	2.8	46	2.9	92	5.8	199	12.5	379	23.8	430	27.0	277	17.4	107
Winter	121	7.0	226	13.1	271	15.7	283	16.4	300	17.3	260	15.0	178	10.3	70
all	167	5.0	273	8.2	365	10.9	484	14.5	681	20.4	695	20.8	458	13.7	178
all															
Missing	82	6.2	146	11.0	160	12.1	210	15.8	277	20.9	266	20.0	155	11.7	26
Summer	125	2.8	183	4.1	349	7.8	654	14.6	1168	26.0	1126	25.1	633	14.1	223
Winter	341	7.0	651	13.4	816	16.7	858	17.6	932	19.1	735	15.1	373	7.7	141
all	548	5.1	980	9.2	1325	12.4	1722	16.1	2377	22.2	2127	19.9	1161	10.9	390

(Continued)

Tab 4.7: Immunization
total number of administrations grouped by children born in summer/winter
evaluable population (EVP)

Country/year/born in summer/winter	Total number of administrations										
	8	9		10		11		12		all	
	%	n	%	n	%	n	%	n	%	n	%
Germany											
2002											
Missing	0	0	0	0	0	0	0	0	0	3	100.0
Summer	1.2	0	0	0	0	0	0	0	0	425	100.0
Winter	0.7	0	0	0	0	0	0	0	0	425	100.0
all	0.9	0	0	0	0	0	0	0	0	853	100.0
2003											
Summer	3.0	1	0.1	0	0	0	0	0	0	667	100.0
Winter	1.3	0	0	0	0	0	0	0	0	620	100.0
all	2.2	1	0.1	0	0	0	0	0	0	1287	100.0
2004											
Missing	1.9	5	0.4	0	0	0	0	0	0	1295	100.0
Summer	4.3	1	0.2	0	0	0	0	0	0	464	100.0
Winter	2.4	0	0	0	0	0	0	0	0	449	100.0
all	2.5	6	0.3	0	0	0	0	0	0	2208	100.0
2005											
Missing	8.3	0	0	0	0	0	0	0	0	12	100.0
Summer	5.3	6	0.4	1	0.1	0	0	0	0	1339	100.0
Winter	3.0	5	0.3	0	0	0	0	0	0	1649	100.0
all	4.0	11	0.4	1	0.0	0	0	0	0	3000	100.0
2006											
Missing	5.9	0	0	0	0	0	0	0	0	17	100.0
Summer	6.7	15	0.9	0	0	1	0.1	0	0	1591	100.0
Winter	4.0	16	0.9	3	0.2	1	0.1	1	0.1	1730	100.0
all	5.3	31	0.9	3	0.1	2	0.1	1	0.0	3338	100.0
all											
Missing	2.0	5	0.4	0	0	0	0	0	0	1327	100.0
Summer	5.0	23	0.5	1	0.0	1	0.0	0	0	4486	100.0
Winter	2.9	21	0.4	3	0.1	1	0.0	1	0.0	4873	100.0
all	3.6	49	0.5	4	0.0	2	0.0	1	0.0	10686	100.0

Tab 4.8: Immunization
weight change relative to birth weigth and trt admin
evaluable population (EVP)

Survey year=2002

Country/year-/month after DOB	Weight diff. [kg]																	
	missing		-2.2 - <0		0-< 5		5-< 6		6-< 7		7-< 8		8-< 9		9-<10		10-<15	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																		
missing	4	33.3			8	66.7												
0-< 1	4	28.6	1	7.1	9	64.3												
1-< 2	18	17.3			85	81.7			1	1.0								
2-< 3	25	10.7	1	0.4	203	87.1			1	0.4	2	0.9	1	0.4				
3-< 4	23	6.6			319	91.7	3	0.9	1	0.3	1	0.3	1	0.3				
4-< 5	19	4.5			393	92.7	7	1.7	3	0.7	1	0.2	1	0.2				
5-< 6	16	3.8			336	80.8	50	12.0	11	2.6	2	0.5	1	0.2				
6-< 7	15	3.8			263	65.9	86	21.6	30	7.5	3	0.8	2	0.5				
7-< 8	17	4.7			174	48.2	112	31.0	44	12.2	14	3.9						
8-< 9	16	5.2			117	38.4	92	30.2	58	19.0	20	6.6	2	0.7				
9-<10	8	3.5			63	27.5	71	31.0	50	21.8	33	14.4	4	1.7				
10-<11	10	5.8			34	19.9	44	25.7	47	27.5	30	17.5	6	3.5				
11-<12	6	4.2			22	15.3	42	29.2	37	25.7	28	19.4	9	6.3				
12-<13	6	5.0			15	12.6	32	26.9	31	26.1	23	19.3	10	8.4	2	1.7		
13-<14	6	7.9			5	6.6	14	18.4	28	36.8	14	18.4	8	10.5	1	1.3		
14-<15	5	7.9			4	6.3	17	27.0	14	22.2	16	25.4	6	9.5	1	1.6		
15-<16	2	4.2					10	20.8	13	27.1	17	35.4	4	8.3	2	4.2		
16-<17	4	9.1			2	4.5	6	13.6	15	34.1	12	27.3	4	9.1	1	2.3		
17-<18	4	10.5					5	13.2	11	28.9	13	34.2	5	13.2				
18-<19	2	7.1					2	7.1	11	39.3	7	25.0	6	21.4				
19-<20	2	9.1					1	4.5	4	18.2	7	31.8	5	22.7	3	13.6		
20-<21							3	14.3	4	19.0	5	23.8	4	19.0	4	19.0	1	4.8
21-<22	2	9.5					2	9.5	3	14.3	6	28.6	4	19.0	3	14.3	1	4.8
22-<23							1	7.1	3	21.4	1	7.1	6	42.9	2	14.3	1	7.1
23-<24	1	6.7							4	26.7	2	13.3	5	33.3	2	13.3	1	6.7
24-<25									3	23.1	3	23.1	1	7.7	5	38.5	1	7.7
25-<32	2	11.8									8	47.1			4	23.5	3	17.6
all	217	5.9	2	0.1	2052	55.5	600	16.2	427	11.5	268	7.2	95	2.6	30	0.8	8	0.2

Tab 4.8: Immunization
weight change relative to birth weigth and trt admin
evaluable population (EVP)

Survey year=2002

Country/year-/month after DOB	all	
	n	%
Germany		
missing	12	100.0
0-< 1	14	100.0
1-< 2	104	100.0
2-< 3	233	100.0
3-< 4	348	100.0
4-< 5	424	100.0
5-< 6	416	100.0
6-< 7	399	100.0
7-< 8	361	100.0
8-< 9	305	100.0
9-<10	229	100.0
10-<11	171	100.0
11-<12	144	100.0
12-<13	119	100.0
13-<14	76	100.0
14-<15	63	100.0
15-<16	48	100.0
16-<17	44	100.0
17-<18	38	100.0
18-<19	28	100.0
19-<20	22	100.0
20-<21	21	100.0
21-<22	21	100.0
22-<23	14	100.0
23-<24	15	100.0
24-<25	13	100.0
25-<32	17	100.0
all	3699	100.0

Tab 4.8: Immunization
weight change relative to birth weigth and trt admin
evaluable population (EVP)

Survey year=2003

Country/year-/month after DOB	Weight diff. [kg]																	
	missing		-2.2 - <0		0-< 5		5-< 6		6-< 7		7-< 8		8-< 9		9-<10		10-<15	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																		
missing	51	86.4			8	13.6												
0-< 1			1	7.1	13	92.9												
1-< 2	14	10.4			120	89.6												
2-< 3	27	9.0			272	91.0												
3-< 4	29	5.8			467	94.2												
4-< 5	32	5.4			541	92.0	15	2.6										
5-< 6	34	5.3			527	82.6	63	9.9	14	2.2								
6-< 7	26	4.3			402	66.2	148	24.4	29	4.8	2	0.3						
7-< 8	27	5.0			274	51.1	164	30.6	61	11.4	10	1.9						
8-< 9	33	7.0			161	34.3	162	34.5	85	18.1	27	5.7	2	0.4				
9-<10	25	6.4			77	19.7	143	36.7	95	24.4	37	9.5	13	3.3				
10-<11	27	8.7			48	15.5	91	29.4	89	28.8	41	13.3	13	4.2				
11-<12	19	8.0			39	16.5	59	24.9	77	32.5	31	13.1	10	4.2	2	0.8		
12-<13	11	6.9			20	12.6	33	20.8	58	36.5	26	16.4	8	5.0	3	1.9		
13-<14	11	8.9			15	12.2	16	13.0	39	31.7	28	22.8	10	8.1	4	3.3		
14-<15	8	7.4			12	11.1	15	13.9	23	21.3	30	27.8	12	11.1	4	3.7	4	3.7
15-<16	6	7.4			7	8.6	14	17.3	11	13.6	21	25.9	13	16.0	7	8.6	2	2.5
16-<17	3	4.7			5	7.8	15	23.4	8	12.5	15	23.4	10	15.6	6	9.4	2	3.1
17-<18	3	4.8			3	4.8	8	12.9	9	14.5	19	30.6	14	22.6	5	8.1	1	1.6
18-<19	2	3.2			4	6.5	6	9.7	10	16.1	15	24.2	16	25.8	7	11.3	2	3.2
19-<20	3	5.3			1	1.8	6	10.5	12	21.1	11	19.3	14	24.6	6	10.5	4	7.0
20-<21	4	8.9			4	8.9	3	6.7	7	15.6	8	17.8	12	26.7	4	8.9	3	6.7
21-<22	3	7.5			3	7.5	3	7.5	4	10.0	10	25.0	6	15.0	8	20.0	3	7.5
22-<23	2	5.7			3	8.6	2	5.7	6	17.1	8	22.9	7	20.0	5	14.3	2	5.7
23-<24	1	3.7			1	3.7	3	11.1	6	22.2	5	18.5	5	18.5	3	11.1	3	11.1
24-<25	2	10.5			1	5.3	1	5.3	2	10.5	5	26.3	1	5.3	3	15.8	4	21.1
25-<32	4	8.3					1	2.1	4	8.3	10	20.8	8	16.7	11	22.9	10	20.8
all	407	7.1	1	0.0	3028	53.1	971	17.0	649	11.4	359	6.3	174	3.0	78	1.4	40	0.7

Tab 4.8: Immunization
weight change relative to birth weigth and trt admin
evaluable population (EVP)

Survey year=2003

Country/year-/month after DOB	all	
	n	%
Germany		
missing	59	100.0
0-< 1	14	100.0
1-< 2	134	100.0
2-< 3	299	100.0
3-< 4	496	100.0
4-< 5	588	100.0
5-< 6	638	100.0
6-< 7	607	100.0
7-< 8	536	100.0
8-< 9	470	100.0
9-<10	390	100.0
10-<11	309	100.0
11-<12	237	100.0
12-<13	159	100.0
13-<14	123	100.0
14-<15	108	100.0
15-<16	81	100.0
16-<17	64	100.0
17-<18	62	100.0
18-<19	62	100.0
19-<20	57	100.0
20-<21	45	100.0
21-<22	40	100.0
22-<23	35	100.0
23-<24	27	100.0
24-<25	19	100.0
25-<32	48	100.0
all	5707	100.0

Tab 4.8: Immunization
weight change relative to birth weigth and trt admin
evaluable population (EVP)

Survey year=2004

Country/year-/month after DOB	Weight diff. [kg]																	
	missing		-2.2 - <0		0-< 5		5-< 6		6-< 7		7-< 8		8-< 9		9-<10		10-<15	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																		
missing	249	4.3	6	0.1	3032	51.8	1106	18.9	743	12.7	420	7.2	219	3.7	61	1.0	20	0.3
before	3	18.8			9	56.3	3	18.8	1	6.3								
0-< 1					10	90.9											1	9.1
1-< 2	3	3.4	2	2.3	80	90.9	1	1.1	1	1.1	1	1.1						
2-< 3	8	3.9			194	95.1	1	0.5			1	0.5						
3-< 4	11	3.4			300	94.0	6	1.9	1	0.3	1	0.3						
4-< 5	7	1.8			360	94.0	11	2.9	5	1.3								
5-< 6	13	3.1			349	82.7	48	11.4	11	2.6			1	0.2				
6-< 7	11	2.5			300	67.6	99	22.3	32	7.2	1	0.2					1	0.2
7-< 8	19	4.5			194	46.4	158	37.8	40	9.6	7	1.7						
8-< 9	16	4.2			107	28.2	150	39.5	82	21.6	23	6.1	2	0.5				
9-<10	16	4.9			76	23.1	110	33.4	79	24.0	39	11.9	7	2.1	2	0.6		
10-<11	11	4.1			50	18.6	72	26.8	78	29.0	53	19.7	5	1.9				
11-<12	12	5.6			31	14.4	59	27.4	58	27.0	45	20.9	10	4.7				
12-<13	10	6.1			18	10.9	36	21.8	46	27.9	38	23.0	16	9.7	1	0.6		
13-<14	12	10.4			12	10.4	26	22.6	27	23.5	22	19.1	12	10.4	4	3.5		
14-<15	9	10.8			5	6.0	23	27.7	18	21.7	15	18.1	11	13.3	2	2.4		
15-<16	3	4.5			5	7.6	12	18.2	17	25.8	14	21.2	11	16.7	3	4.5	1	1.5
16-<17	5	8.5			3	5.1	9	15.3	11	18.6	14	23.7	13	22.0	3	5.1	1	1.7
17-<18	2	3.6			1	1.8	7	12.7	14	25.5	14	25.5	10	18.2	4	7.3	3	5.5
18-<19	4	8.9			2	4.4	11	24.4	8	17.8	9	20.0	7	15.6	3	6.7	1	2.2
19-<20	2	4.3			1	2.1	4	8.5	12	25.5	12	25.5	10	21.3	5	10.6	1	2.1
20-<21	2	5.6					5	13.9	5	13.9	9	25.0	8	22.2	6	16.7	1	2.8
21-<22	2	7.1					2	7.1	8	28.6	5	17.9	7	25.0	3	10.7	1	3.6
22-<23	1	4.5					3	13.6	4	18.2	5	22.7	4	18.2	5	22.7		
23-<24	2	13.3							3	20.0	4	26.7	3	20.0	2	13.3	1	6.7
24-<25	1	10.0							1	10.0	2	20.0	1	10.0	4	40.0	1	10.0
25-<32									2	11.1	3	16.7	8	44.4	4	22.2	1	5.6
all	434	4.3	8	0.1	5139	50.8	1962	19.4	1307	12.9	757	7.5	365	3.6	112	1.1	34	0.3

Tab 4.8: Immunization
weight change relative to birth weigth and trt admin
evaluable population (EVP)

Survey year=2004

Country/year-/month after DOB	all	
	n	%
Germany		
missing	5856	100.0
before	16	100.0
0-< 1	11	100.0
1-< 2	88	100.0
2-< 3	204	100.0
3-< 4	319	100.0
4-< 5	383	100.0
5-< 6	422	100.0
6-< 7	444	100.0
7-< 8	418	100.0
8-< 9	380	100.0
9-<10	329	100.0
10-<11	269	100.0
11-<12	215	100.0
12-<13	165	100.0
13-<14	115	100.0
14-<15	83	100.0
15-<16	66	100.0
16-<17	59	100.0
17-<18	55	100.0
18-<19	45	100.0
19-<20	47	100.0
20-<21	36	100.0
21-<22	28	100.0
22-<23	22	100.0
23-<24	15	100.0
24-<25	10	100.0
25-<32	18	100.0
all	10118	100.0

Tab 4.8: Immunization
weight change relative to birth weigth and trt admin
evaluable population (EVP)

Survey year=2005

Country/year-/month after DOB	Weight diff. [kg]																	
	missing		-2.2 - <0		0-< 5		5-< 6		6-< 7		7-< 8		8-< 9		9-<10		10-<15	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																		
missing	15	27.3			26	47.3	7	12.7	1	1.8	3	5.5	2	3.6	1	1.8		
before					21	70.0	4	13.3	4	13.3	1	3.3						
0-< 1	1	4.5	4	18.2	13	59.1	1	4.5	1	4.5	2	9.1						
1-< 2	8	4.5	7	4.0	156	88.6			2	1.1	2	1.1	1	0.6				
2-< 3	19	3.1	1	0.2	577	95.5	1	0.2	3	0.5	2	0.3			1	0.2		
3-< 4	22	2.2	2	0.2	959	96.9	1	0.1	2	0.2	3	0.3					1	0.1
4-< 5	31	2.5	1	0.1	1206	95.9	16	1.3			4	0.3						
5-< 6	43	3.1			1222	88.9	92	6.7	13	0.9	4	0.3						
6-< 7	45	3.2			1057	75.8	241	17.3	48	3.4	4	0.3						
7-< 8	33	2.7			715	57.8	362	29.2	103	8.3	23	1.9	2	0.2				
8-< 9	43	4.0			440	40.5	386	35.5	160	14.7	49	4.5	7	0.6	1	0.1		
9-<10	33	3.5			280	30.0	351	37.7	186	20.0	70	7.5	12	1.3				
10-<11	26	3.3			181	23.2	269	34.5	207	26.5	75	9.6	20	2.6	2	0.3		
11-<12	15	2.3			131	20.0	192	29.4	186	28.4	89	13.6	36	5.5	5	0.8		
12-<13	17	2.9			93	16.0	143	24.7	183	31.6	100	17.2	35	6.0	9	1.6		
13-<14	14	3.1			52	11.7	106	23.8	141	31.6	87	19.5	33	7.4	13	2.9		
14-<15	19	5.3			33	9.2	60	16.8	101	28.2	98	27.4	36	10.1	10	2.8	1	0.3
15-<16	20	6.8			19	6.4	57	19.3	78	26.4	70	23.6	41	13.9	11	3.7		
16-<17	18	7.5			14	5.8	32	13.3	65	27.0	59	24.5	32	13.3	18	7.5	3	1.2
17-<18	14	6.3			12	5.4	32	14.3	53	23.7	54	24.1	44	19.6	12	5.4	3	1.3
18-<19	13	6.9			5	2.7	22	11.7	49	26.1	50	26.6	27	14.4	14	7.4	8	4.3
19-<20	18	11.0			4	2.5	20	12.3	38	23.3	39	23.9	24	14.7	14	8.6	6	3.7
20-<21	19	11.0			7	4.1	16	9.3	36	20.9	41	23.8	29	16.9	15	8.7	9	5.2
21-<22	17	11.5			8	5.4	12	8.1	27	18.2	34	23.0	28	18.9	14	9.5	8	5.4
22-<23	13	9.4			3	2.2	6	4.3	26	18.8	24	17.4	30	21.7	23	16.7	13	9.4
23-<24	7	7.7			2	2.2	7	7.7	14	15.4	13	14.3	20	22.0	22	24.2	6	6.6
24-<25	9	11.0			2	2.4	9	11.0	7	8.5	11	13.4	16	19.5	18	22.0	10	12.2
25-<32	16	12.7					10	7.9	11	8.7	18	14.3	30	23.8	15	11.9	26	20.6
all	548	4.0	15	0.1	7238	52.3	2455	17.7	1745	12.6	1029	7.4	505	3.6	218	1.6	94	0.7

Tab 4.8: Immunization
weight change relative to birth weigth and trt admin
evaluable population (EVP)

Survey year=2005

Country/year-/month after DOB	all	
	n	%
Germany		
missing	55	100.0
before	30	100.0
0-< 1	22	100.0
1-< 2	176	100.0
2-< 3	604	100.0
3-< 4	990	100.0
4-< 5	1258	100.0
5-< 6	1374	100.0
6-< 7	1395	100.0
7-< 8	1238	100.0
8-< 9	1086	100.0
9-<10	932	100.0
10-<11	780	100.0
11-<12	654	100.0
12-<13	580	100.0
13-<14	446	100.0
14-<15	358	100.0
15-<16	296	100.0
16-<17	241	100.0
17-<18	224	100.0
18-<19	188	100.0
19-<20	163	100.0
20-<21	172	100.0
21-<22	148	100.0
22-<23	138	100.0
23-<24	91	100.0
24-<25	82	100.0
25-<32	126	100.0
all	13847	100.0

Tab 4.8: Immunization
weight change relative to birth weigth and trt admin
evaluable population (EVP)

Survey year=2006

Country/year-/month after DOB	Weight diff. [kg]																	
	missing		-2.2 - <0		0-< 5		5-< 6		6-< 7		7-< 8		8-< 9		9-<10		10-<15	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																		
missing	55	43.0			34	26.6	19	14.8	13	10.2	7	5.5						
0-< 1			4	16.7	20	83.3												
1-< 2	7	2.8	13	5.2	230	91.6					1	0.4						
2-< 3	36	5.1	2	0.3	670	94.1	3	0.4			1	0.1						
3-< 4	54	4.8			1058	94.6	4	0.4	2	0.2								
4-< 5	55	3.9			1314	94.3	23	1.7					1	0.1				
5-< 6	54	3.5			1343	88.0	110	7.2	16	1.0	2	0.1	2	0.1				
6-< 7	47	3.1			1101	73.0	288	19.1	63	4.2	9	0.6			1	0.1		
7-< 8	48	3.3			760	52.0	478	32.7	153	10.5	20	1.4	3	0.2				
8-< 9	56	4.2			504	38.0	458	34.6	238	18.0	60	4.5	8	0.6	1	0.1		
9-<10	43	3.8			307	27.4	378	33.7	275	24.5	99	8.8	18	1.6	1	0.1		
10-<11	41	4.4	2	0.2	193	20.5	277	29.4	271	28.8	120	12.7	37	3.9	1	0.1		
11-<12	39	4.8	1	0.1	134	16.6	226	28.0	230	28.5	126	15.6	42	5.2	6	0.7	2	0.2
12-<13	23	3.7			98	15.8	156	25.2	174	28.1	115	18.5	43	6.9	11	1.8		
13-<14	26	4.6			76	13.5	119	21.2	157	28.0	108	19.3	56	10.0	16	2.9	3	0.5
14-<15	17	3.9			44	10.2	83	19.2	117	27.1	104	24.1	47	10.9	16	3.7	4	0.9
15-<16	27	7.1			39	10.3	60	15.8	87	23.0	97	25.6	44	11.6	22	5.8	3	0.8
16-<17	21	6.8			27	8.7	41	13.2	73	23.5	80	25.7	39	12.5	20	6.4	10	3.2
17-<18	23	7.9			17	5.8	33	11.3	65	22.3	68	23.4	51	17.5	19	6.5	15	5.2
18-<19	17	6.8			16	6.4	28	11.2	43	17.2	49	19.6	56	22.4	25	10.0	16	6.4
19-<20	25	10.7			11	4.7	23	9.9	42	18.0	51	21.9	41	17.6	27	11.6	13	5.6
20-<21	17	9.0			9	4.8	19	10.1	34	18.0	46	24.3	29	15.3	29	15.3	6	3.2
21-<22	16	9.9			7	4.3	10	6.2	27	16.7	37	22.8	33	20.4	21	13.0	11	6.8
22-<23	14	9.9			7	4.9	9	6.3	17	12.0	38	26.8	27	19.0	20	14.1	10	7.0
23-<24	11	9.9			3	2.7	14	12.6	11	9.9	25	22.5	23	20.7	11	9.9	13	11.7
24-<25	8	9.4			1	1.2	8	9.4	10	11.8	18	21.2	22	25.9	8	9.4	10	11.8
25-<32	22	14.4			3	2.0	13	8.5	18	11.8	24	15.7	39	25.5	24	15.7	10	6.5
all	802	4.9	22	0.1	8026	49.4	2880	17.7	2136	13.2	1305	8.0	661	4.1	279	1.7	126	0.8

Tab 4.8: Immunization
weight change relative to birth weigth and trt admin
evaluable population (EVP)

Survey year=2006

Country/year-/month after DOB	all	
	n	%
Germany		
missing	128	100.0
0-< 1	24	100.0
1-< 2	251	100.0
2-< 3	712	100.0
3-< 4	1118	100.0
4-< 5	1393	100.0
5-< 6	1527	100.0
6-< 7	1509	100.0
7-< 8	1462	100.0
8-< 9	1325	100.0
9-<10	1121	100.0
10-<11	942	100.0
11-<12	806	100.0
12-<13	620	100.0
13-<14	561	100.0
14-<15	432	100.0
15-<16	379	100.0
16-<17	311	100.0
17-<18	291	100.0
18-<19	250	100.0
19-<20	233	100.0
20-<21	189	100.0
21-<22	162	100.0
22-<23	142	100.0
23-<24	111	100.0
24-<25	85	100.0
25-<32	153	100.0
all	16237	100.0

Tab 4.8: Immunization
weight change relative to birth weigth and trt admin
evaluable population (EVP)

Survey year=all

Country/year-/month after DOB	Weight diff. [kg]																	
	missing		-2.2 - <0		0-< 5		5-< 6		6-< 7		7-< 8		8-< 9		9-<10		10-<15	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																		
missing	374	6.1	6	0.1	3108	50.9	1132	18.5	757	12.4	430	7.0	221	3.6	62	1.0	20	0.3
before	3	6.5			30	65.2	7	15.2	5	10.9	1	2.2						
0-< 1	5	5.9	10	11.8	65	76.5	1	1.2	1	1.2	2	2.4					1	1.2
1-< 2	50	6.6	22	2.9	671	89.1	1	0.1	4	0.5	4	0.5	1	0.1				
2-< 3	115	5.6	4	0.2	1916	93.4	5	0.2	4	0.2	6	0.3	1	0.0	1	0.0		
3-< 4	139	4.2	2	0.1	3103	94.9	14	0.4	6	0.2	5	0.2	1	0.0			1	0.0
4-< 5	144	3.6	1	0.0	3814	94.3	72	1.8	8	0.2	5	0.1	2	0.0				
5-< 6	160	3.7			3777	86.3	363	8.3	65	1.5	8	0.2	4	0.1				
6-< 7	144	3.3			3123	71.7	862	19.8	202	4.6	19	0.4	2	0.0	1	0.0	1	0.0
7-< 8	144	3.6			2117	52.7	1274	31.7	401	10.0	74	1.8	5	0.1				
8-< 9	164	4.6			1329	37.3	1248	35.0	623	17.5	179	5.0	21	0.6	2	0.1		
9-<10	125	4.2			803	26.8	1053	35.1	685	22.8	278	9.3	54	1.8	3	0.1		
10-<11	115	4.7	2	0.1	506	20.5	753	30.5	692	28.0	319	12.9	81	3.3	3	0.1		
11-<12	91	4.4	1	0.0	357	17.4	578	28.1	588	28.6	319	15.5	107	5.2	13	0.6	2	0.1
12-<13	67	4.1			244	14.9	400	24.3	492	29.9	302	18.4	112	6.8	26	1.6		
13-<14	69	5.2			160	12.1	281	21.3	392	29.7	259	19.6	119	9.0	38	2.9	3	0.2
14-<15	58	5.6			98	9.4	198	19.0	273	26.1	263	25.2	112	10.7	33	3.2	9	0.9
15-<16	58	6.7			70	8.0	153	17.6	206	23.7	219	25.2	113	13.0	45	5.2	6	0.7
16-<17	51	7.1			51	7.1	103	14.3	172	23.9	180	25.0	98	13.6	48	6.7	16	2.2
17-<18	46	6.9			33	4.9	85	12.7	152	22.7	168	25.1	124	18.5	40	6.0	22	3.3
18-<19	38	6.6			27	4.7	69	12.0	121	21.1	130	22.7	112	19.5	49	8.6	27	4.7
19-<20	50	9.6			17	3.3	54	10.3	108	20.7	120	23.0	94	18.0	55	10.5	24	4.6
20-<21	42	9.1			20	4.3	46	9.9	86	18.6	109	23.5	82	17.7	58	12.5	20	4.3
21-<22	40	10.0			18	4.5	29	7.3	69	17.3	92	23.1	78	19.5	49	12.3	24	6.0
22-<23	30	8.5			13	3.7	21	6.0	56	16.0	76	21.7	74	21.1	55	15.7	26	7.4
23-<24	22	8.5			6	2.3	24	9.3	38	14.7	49	18.9	56	21.6	40	15.4	24	9.3
24-<25	20	9.6			4	1.9	18	8.6	23	11.0	39	18.7	41	19.6	38	18.2	26	12.4
25-<32	44	12.2			3	0.8	24	6.6	35	9.7	63	17.4	85	23.5	58	16.0	50	13.8
all	2408	4.9	48	0.1	25483	51.4	8868	17.9	6264	12.6	3718	7.5	1800	3.6	717	1.4	302	0.6

Tab 4.8: Immunization
weight change relative to birth weigth and trt admin
evaluable population (EVP)

Survey year=all

Country/year-/month after DOB	all	
	n	%
Germany		
missing	6110	100.0
before	46	100.0
0-< 1	85	100.0
1-< 2	753	100.0
2-< 3	2052	100.0
3-< 4	3271	100.0
4-< 5	4046	100.0
5-< 6	4377	100.0
6-< 7	4354	100.0
7-< 8	4015	100.0
8-< 9	3566	100.0
9-<10	3001	100.0
10-<11	2471	100.0
11-<12	2056	100.0
12-<13	1643	100.0
13-<14	1321	100.0
14-<15	1044	100.0
15-<16	870	100.0
16-<17	719	100.0
17-<18	670	100.0
18-<19	573	100.0
19-<20	522	100.0
20-<21	463	100.0
21-<22	399	100.0
22-<23	351	100.0
23-<24	259	100.0
24-<25	209	100.0
25-<32	362	100.0
all	49608	100.0

Tab 5.1.1: Complications
infections (since 2003)
Bronchiolitis**
evaluable population (EVP)

Country	year	hosp. form	missing		no		yes		unknown		all	
			n	%	n	%	n	%	n	%	n	%
Germany												
	2003											
		no	1233	100.0	0	0.0	0	0.0	0	0.0	1233	100.0
		yes	22	38.6	18	31.6	17	29.8	0	0.0	57	100.0
		all	1255	97.3	18	1.4	17	1.3	0	0.0	1290	100.0
	2004											
		no	2134	100.0	0	0.0	0	0.0	0	0.0	2134	100.0
		yes	28	37.8	28	37.8	17	23.0	1	1.4	74	100.0
		all	2162	97.9	28	1.3	17	0.8	1	0.0	2208	100.0
	2005											
		no	2897	100.0	0	0.0	0	0.0	0	0.0	2897	100.0
		yes	47	43.9	38	35.5	21	19.6	1	0.9	107	100.0
		all	2944	98.0	38	1.3	21	0.7	1	0.0	3004	100.0
	2006											
		no	3245	100.0	0	0.0	0	0.0	0	0.0	3245	100.0
		yes	61	63.5	23	24.0	12	12.5	0	0.0	96	100.0
		all	3306	99.0	23	0.7	12	0.4	0	0.0	3341	100.0
	all											
		no	9509	100.0	0	0.0	0	0.0	0	0.0	9509	100.0
		yes	158	47.3	107	32.0	67	20.1	2	0.6	334	100.0
		all	9667	98.2	107	1.1	67	0.7	2	0.0	9843	100.0

** In Season 2002/03 no distinction between infection types were made
More than one hospitalization can occur, therefore multiple infections are possible

Tab 5.1.2: Complications
infections (since 2003)
RSV-Bronchiolitis**
evaluable population (EVP)

Country	year	hosp. form	missing		no		yes		unknown		all	
			n	%	n	%	n	%	n	%	n	%
Germany												
	2003											
		no	1233	100.0	0	0.0	0	0.0	0	0.0	1233	100.0
		yes	28	49.1	16	28.1	10	17.5	3	5.3	57	100.0
		all	1261	97.8	16	1.2	10	0.8	3	0.2	1290	100.0
	2004											
		no	2134	100.0	0	0.0	0	0.0	0	0.0	2134	100.0
		yes	25	33.8	24	32.4	22	29.7	3	4.1	74	100.0
		all	2159	97.8	24	1.1	22	1.0	3	0.1	2208	100.0
	2005											
		no	2897	100.0	0	0.0	0	0.0	0	0.0	2897	100.0
		yes	38	35.5	36	33.6	30	28.0	3	2.8	107	100.0
		all	2935	97.7	36	1.2	30	1.0	3	0.1	3004	100.0
	2006											
		no	3245	100.0	0	0.0	0	0.0	0	0.0	3245	100.0
		yes	38	39.6	21	21.9	37	38.5	0	0.0	96	100.0
		all	3283	98.3	21	0.6	37	1.1	0	0.0	3341	100.0
	all											
		no	9509	100.0	0	0.0	0	0.0	0	0.0	9509	100.0
		yes	129	38.6	97	29.0	99	29.6	9	2.7	334	100.0
		all	9638	97.9	97	1.0	99	1.0	9	0.1	9843	100.0

** In Season 2002/03 no distinction between infection types were made
More than one hospitalization can occur, therefore multiple infections are possible

Tab 5.1.3: Complications
infections (since 2003)
Vir. pneumonia**
evaluable population (EVP)

Country	year	hosp. form	missing		no		yes		unknown		all	
			n	%	n	%	n	%	n	%	n	%
Germany												
	2003											
		no	1233	100.0	0	0.0	0	0.0	0	0.0	1233	100.0
		yes	30	52.6	18	31.6	7	12.3	2	3.5	57	100.0
		all	1263	97.9	18	1.4	7	0.5	2	0.2	1290	100.0
	2004											
		no	2134	100.0	0	0.0	0	0.0	0	0.0	2134	100.0
		yes	38	51.4	28	37.8	5	6.8	3	4.1	74	100.0
		all	2172	98.4	28	1.3	5	0.2	3	0.1	2208	100.0
	2005											
		no	2897	100.0	0	0.0	0	0.0	0	0.0	2897	100.0
		yes	56	52.3	41	38.3	8	7.5	2	1.9	107	100.0
		all	2953	98.3	41	1.4	8	0.3	2	0.1	3004	100.0
	2006											
		no	3245	100.0	0	0.0	0	0.0	0	0.0	3245	100.0
		yes	62	64.6	27	28.1	6	6.3	1	1.0	96	100.0
		all	3307	99.0	27	0.8	6	0.2	1	0.0	3341	100.0
	all											
		no	9509	100.0	0	0.0	0	0.0	0	0.0	9509	100.0
		yes	186	55.7	114	34.1	26	7.8	8	2.4	334	100.0
		all	9695	98.5	114	1.2	26	0.3	8	0.1	9843	100.0

** In Season 2002/03 no distinction between infection types were made
More than one hospitalization can occur, therefore multiple infections are possible

Tab 5.1.4: Complications
infections (since 2003)
RSV-pneumonia**
evaluable population (EVP)

Country	year	hosp. form	missing		no		yes		unknown		all	
			n	%	n	%	n	%	n	%	n	%
Germany												
	2003											
		no	1233	100.0	0	0.0	0	0.0	0	0.0	1233	100.0
		yes	33	57.9	14	24.6	8	14.0	2	3.5	57	100.0
		all	1266	98.1	14	1.1	8	0.6	2	0.2	1290	100.0
	2004											
		no	2134	100.0	0	0.0	0	0.0	0	0.0	2134	100.0
		yes	33	44.6	32	43.2	7	9.5	2	2.7	74	100.0
		all	2167	98.1	32	1.4	7	0.3	2	0.1	2208	100.0
	2005											
		no	2897	100.0	0	0.0	0	0.0	0	0.0	2897	100.0
		yes	56	52.3	41	38.3	10	9.3	0	0.0	107	100.0
		all	2953	98.3	41	1.4	10	0.3	0	0.0	3004	100.0
	2006											
		no	3245	100.0	0	0.0	0	0.0	0	0.0	3245	100.0
		yes	52	54.2	24	25.0	19	19.8	1	1.0	96	100.0
		all	3297	98.7	24	0.7	19	0.6	1	0.0	3341	100.0
	all											
		no	9509	100.0	0	0.0	0	0.0	0	0.0	9509	100.0
		yes	174	52.1	111	33.2	44	13.2	5	1.5	334	100.0
		all	9683	98.4	111	1.1	44	0.4	5	0.1	9843	100.0

** In Season 2002/03 no distinction between infection types were made
More than one hospitalization can occur, therefore multiple infections are possible

Tab 5.1.5: Complications
infections (since 2003)
RSV-infection**
evaluable population (EVP)

Country	year	hosp. form	missing		no		yes		unknown		all	
			n	%	n	%	n	%	n	%	n	%
Germany												
	2003											
		no	1233	100.0	0	0.0	0	0.0	0	0.0	1233	100.0
		yes	34	59.6	11	19.3	8	14.0	4	7.0	57	100.0
		all	1267	98.2	11	0.9	8	0.6	4	0.3	1290	100.0
	2004											
		no	2134	100.0	0	0.0	0	0.0	0	0.0	2134	100.0
		yes	34	45.9	24	32.4	13	17.6	3	4.1	74	100.0
		all	2168	98.2	24	1.1	13	0.6	3	0.1	2208	100.0
	2005											
		no	2897	100.0	0	0.0	0	0.0	0	0.0	2897	100.0
		yes	58	54.2	38	35.5	11	10.3	0	0.0	107	100.0
		all	2955	98.4	38	1.3	11	0.4	0	0.0	3004	100.0
	2006											
		no	3245	100.0	0	0.0	0	0.0	0	0.0	3245	100.0
		yes	60	62.5	19	19.8	17	17.7	0	0.0	96	100.0
		all	3305	98.9	19	0.6	17	0.5	0	0.0	3341	100.0
	all											
		no	9509	100.0	0	0.0	0	0.0	0	0.0	9509	100.0
		yes	186	55.7	92	27.5	49	14.7	7	2.1	334	100.0
		all	9695	98.5	92	0.9	49	0.5	7	0.1	9843	100.0

** In Season 2002/03 no distinction between infection types were made
More than one hospitalization can occur, therefore multiple infections are possible

Tab 5.1.6: Complications
infections (since 2003)
Other**
evaluable population (EVP)

Country	year	hosp. form	missing		no		yes		all	
			n	%	n	%	n	%	n	%
Germany										
	2003									
		no	1233	100.0	0	0.0	0	0.0	1233	100.0
		yes	26	45.6	5	8.8	26	45.6	57	100.0
		all	1259	97.6	5	0.4	26	2.0	1290	100.0
	2004									
		no	2134	100.0	0	0.0	0	0.0	2134	100.0
		yes	31	41.9	19	25.7	24	32.4	74	100.0
		all	2165	98.1	19	0.9	24	1.1	2208	100.0
	2005									
		no	2897	100.0	0	0.0	0	0.0	2897	100.0
		yes	44	41.1	11	10.3	52	48.6	107	100.0
		all	2941	97.9	11	0.4	52	1.7	3004	100.0
	2006									
		no	3245	100.0	0	0.0	0	0.0	3245	100.0
		yes	52	54.2	12	12.5	32	33.3	96	100.0
		all	3297	98.7	12	0.4	32	1.0	3341	100.0
	all									
		no	9509	100.0	0	0.0	0	0.0	9509	100.0
		yes	153	45.8	47	14.1	134	40.1	334	100.0
		all	9662	98.2	47	0.5	134	1.4	9843	100.0

** In Season 2002/03 no distinction between infection types were made
More than one hospitalization can occur, therefore multiple infections are possible

Tab 5.1.7: Complications
infections (since 2003)
Any RSV diagnosis**
evaluable population (EVP)

Country	year	hosp. form	missing		no		yes		unknown		all	
			n	%	n	%	n	%	n	%	n	%
Germany												
	2003											
		no	1233	100.0	0	0.0	0	0.0	0	0.0	1233	100.0
		yes	24	42.1	9	15.8	20	35.1	4	7.0	57	100.0
		all	1257	97.4	9	0.7	20	1.6	4	0.3	1290	100.0
	2004											
		no	2134	100.0	0	0.0	0	0.0	0	0.0	2134	100.0
		yes	18	24.3	20	27.0	33	44.6	3	4.1	74	100.0
		all	2152	97.5	20	0.9	33	1.5	3	0.1	2208	100.0
	2005											
		no	2897	100.0	0	0.0	0	0.0	0	0.0	2897	100.0
		yes	32	29.9	30	28.0	45	42.1	0	0.0	107	100.0
		all	2929	97.5	30	1.0	45	1.5	0	0.0	3004	100.0
	2006											
		no	3245	100.0	0	0.0	0	0.0	0	0.0	3245	100.0
		yes	27	28.1	13	13.5	56	58.3	0	0.0	96	100.0
		all	3272	97.9	13	0.4	56	1.7	0	0.0	3341	100.0
	all											
		no	9509	100.0	0	0.0	0	0.0	0	0.0	9509	100.0
		yes	101	30.2	72	21.6	154	46.1	7	2.1	334	100.0
		all	9610	97.6	72	0.7	154	1.6	7	0.1	9843	100.0

** In Season 2002/03 no distinction between infection types were made
More than one hospitalization can occur, therefore multiple infections are possible

Tab 5.2.1: Complications
hospitalization
general overview (CRF or forms)
evaluable population (EVP)

	Number of hospitalizations/patient												
	missing		0		1		2		3		4		5
	n	%	n	%	n	%	n	%	n	%	n	%	n
Germany													
2002	104	12.2	667	78.2	82	9.6	0	0.0	0	0.0	0	0.0	0
2003	41	3.2	1200	93.2	42	3.3	3	0.2	1	0.1	0	0.0	0
2004	77	3.5	2063	93.4	65	2.9	3	0.1	0	0.0	0	0.0	0
2005	131	4.4	2775	92.5	90	3.0	3	0.1	0	0.0	1	0.0	0
2006	144	4.3	3109	93.1	75	2.2	6	0.2	0	0.0	0	0.0	2
all	497	4.7	9814	91.8	354	3.3	15	0.1	1	0.0	1	0.0	2

(Continued)

	Number of hospitalizations/patient					all	
	5	6		8			
	%	n	%	n	%	n	%
Germany							
2002	0.0	0	0.0	0	0.0	853	100.0
2003	0.0	0	0.0	0	0.0	1287	100.0
2004	0.0	0	0.0	0	0.0	2208	100.0
2005	0.0	0	0.0	0	0.0	3000	100.0
2006	0.1	1	0.0	1	0.0	3338	100.0
all	0.0	1	0.0	1	0.0	10686	100.0

Tab 5.2.2: Complications
hospitalization
hospitalization forms overview
evaluable population (EVP)

		Number of hospitalization forms							
		1		2		3		all	
		n	%	n	%	n	%	n	%
Country	Survey year								
Germany	2003	52	8.0	1	0.2	1	0.2	54	8.3
	2004	74	11.4	0	0.0	0	0.0	74	11.4
	2005	100	15.4	2	0.3	1	0.2	103	15.9
	2006	90	13.9	3	0.5	0	0.0	93	14.4
	all	316	48.8	6	0.9	2	0.3	324	50.0

In Season 2002/2003 no hospitalization forms existed

Tab 5.2.3: Complications
hospitalization
cross-tabulation of hospitalization (CRF vs. hospitalization form)
evaluable population (EVP)

Country	Hosp. form existing	Number of hospitalizations=yes											
		0		1		2		4		5		6	
		n	%	n	%	n	%	n	%	n	%	n	%
Germany													
	2002												
	no	771	90.4	82	9.6	0	0.0	0	0.0	0	0.0	0	0.0
	yes	0	0	0	0	0	0	0	0	0	0	0	0
	2003												
	no	1229	99.7	4	0.3	0	0.0	0	0.0	0	0.0	0	0.0
	yes	15	27.8	36	66.7	3	5.6	0	0.0	0	0.0	0	0.0
	2004												
	no	2124	99.5	8	0.4	2	0.1	0	0.0	0	0.0	0	0.0
	yes	16	21.6	57	77.0	1	1.4	0	0.0	0	0.0	0	0.0
	2005												
	no	2885	99.6	11	0.4	0	0.0	1	0.0	0	0.0	0	0.0
	yes	21	20.4	79	76.7	3	2.9	0	0.0	0	0.0	0	0.0
	2006												
	no	3226	99.4	13	0.4	2	0.1	0	0.0	2	0.1	1	0.0
	yes	35	37.6	54	58.1	4	4.3	0	0.0	0	0.0	0	0.0
	all												
	no	10235	98.8	118	1.1	4	0.0	1	0.0	2	0.0	1	0.0
	yes	87	26.9	226	69.8	11	3.4	0	0.0	0	0.0	0	0.0

(Continued)

Tab 5.2.3: Complications
hospitalization
cross-tabulation of hospitalization (CRF vs. hospitalization form)
evaluable population (EVP)

Country	Hosp. form existing	Number of hospitalizations=yes			
		8		all	
		n	%	n	%
Germany					
2002					
	no	0	0.0	853	100.0
	yes	0	0	0	0
2003					
	no	0	0.0	1233	100.0
	yes	0	0.0	54	100.0
2004					
	no	0	0.0	2134	100.0
	yes	0	0.0	74	100.0
2005					
	no	0	0.0	2897	100.0
	yes	0	0.0	103	100.0
2006					
	no	1	0.0	3245	100.0
	yes	0	0.0	93	100.0
all					
	no	1	0.0	10362	100.0
	yes	0	0.0	324	100.0

Tab 5.3.1: Complications
RSV-test
including missing
evaluable population (EVP)

Country	year	hosp. form	RSV-test									
			missing		negative		positive		unknown		all	
			n	%	n	%	n	%	n	%	n	%
Germany												
	2002											
		no	819	96.0	16	1.9	18	2.1	0	0.0	853	100.0
		yes	0	0	0	0	0	0	0	0	0	0
		all	819	96.0	16	1.9	18	2.1	0	0.0	853	100.0
	2003											
		no	1233	100.0	0	0.0	0	0.0	0	0.0	1233	100.0
		yes	22	38.6	12	21.1	21	36.8	2	3.5	57	100.0
		all	1255	97.3	12	0.9	21	1.6	2	0.2	1290	100.0
	2004											
		no	2134	100.0	0	0.0	0	0.0	0	0.0	2134	100.0
		yes	26	35.1	12	16.2	34	45.9	2	2.7	74	100.0
		all	2160	97.8	12	0.5	34	1.5	2	0.1	2208	100.0
	2005											
		no	2897	100.0	0	0.0	0	0.0	0	0.0	2897	100.0
		yes	48	44.9	17	15.9	42	39.3	0	0.0	107	100.0
		all	2945	98.0	17	0.6	42	1.4	0	0.0	3004	100.0
	2006											
		no	3245	100.0	0	0.0	0	0.0	0	0.0	3245	100.0
		yes	23	24.0	14	14.6	59	61.5	0	0.0	96	100.0
		all	3268	97.8	14	0.4	59	1.8	0	0.0	3341	100.0
	all											
		no	10328	99.7	16	0.2	18	0.2	0	0.0	10362	100.0
		yes	119	35.6	55	16.5	156	46.7	4	1.2	334	100.0
		all	10447	97.7	71	0.7	174	1.6	4	0.0	10696	100.0

Tab 5.3.2: Complications
RSV-test
excluding missing
evaluable population (EVP)

Country	year	hosp. form	RSV-test					
			negative		positive		all	
			n	%	n	%	n	%
Germany								
	2002							
		no	16	47.1	18	52.9	34	100.0
		yes	0	0	0	0	0	0
		all	16	47.1	18	52.9	34	100.0
	2003							
		no	0	0	0	0	0	0
		yes	12	36.4	21	63.6	33	100.0
		all	12	36.4	21	63.6	33	100.0
	2004							
		no	0	0	0	0	0	0
		yes	12	26.1	34	73.9	46	100.0
		all	12	26.1	34	73.9	46	100.0
	2005							
		no	0	0	0	0	0	0
		yes	17	28.8	42	71.2	59	100.0
		all	17	28.8	42	71.2	59	100.0
	2006							
		no	0	0	0	0	0	0
		yes	14	19.2	59	80.8	73	100.0
		all	14	19.2	59	80.8	73	100.0
	all							
		no	16	47.1	18	52.9	34	100.0
		yes	55	26.1	156	73.9	211	100.0
		all	71	29.0	174	71.0	245	100.0

Tab 5.3.3.1: Complications
RSV-test
any RSV diagnosis (by hosp. form exist) vs. result of RSV test
including missing
evaluable population (EVP)

Country	year	hosp. form	any RSV diag.	RSV-test								all	
				missing		negative		positive		unknown			
				n	%	n	%	n	%	n	%	n	%
Germany													
	2002												
		no											
			missing	819	96.0	16	1.9	18	2.1	0	0.0	853	100.0
			no	0	0	0	0	0	0	0	0	0	0
			yes	0	0	0	0	0	0	0	0	0	0
			unknown	0	0	0	0	0	0	0	0	0	0
			all	819	96.0	16	1.9	18	2.1	0	0.0	853	100.0
		yes											
			missing	0	0	0	0	0	0	0	0	0	0
			no	0	0	0	0	0	0	0	0	0	0
			yes	0	0	0	0	0	0	0	0	0	0
			unknown	0	0	0	0	0	0	0	0	0	0
			all	0	0	0	0	0	0	0	0	0	0
		all											
			missing	819	96.0	16	1.9	18	2.1	0	0.0	853	100.0
			no	0	0	0	0	0	0	0	0	0	0
			yes	0	0	0	0	0	0	0	0	0	0
			unknown	0	0	0	0	0	0	0	0	0	0
			all	819	96.0	16	1.9	18	2.1	0	0.0	853	100.0
	2003												
		no											
			missing	1233	100.0	0	0.0	0	0.0	0	0.0	1233	100.0
			no	0	0	0	0	0	0	0	0	0	0
			yes	0	0	0	0	0	0	0	0	0	0
			unknown	0	0	0	0	0	0	0	0	0	0
			all	1233	100.0	0	0.0	0	0.0	0	0.0	1233	100.0
		yes											
			missing	13	54.2	10	41.7	1	4.2	0	0.0	24	100.0
			no	6	66.7	1	11.1	0	0.0	2	22.2	9	100.0

(Continued)

Tab 5.3.3.1: Complications
RSV-test
any RSV diagnosis (by hosp. form exist) vs. result of RSV test
including missing
evaluable population (EVP)

Country	year	hosp. form	any RSV diag.	RSV-test								all	
				missing		negative		positive		unknown			
				n	%	n	%	n	%	n	%	n	%
Germany													
	2003												
		yes											
			yes	0	0.0	0	0.0	20	100.0	0	0.0	20	100.0
			unknown	3	75.0	1	25.0	0	0.0	0	0.0	4	100.0
			all	22	38.6	12	21.1	21	36.8	2	3.5	57	100.0
		all											
			missing	1246	99.1	10	0.8	1	0.1	0	0.0	1257	100.0
			no	6	66.7	1	11.1	0	0.0	2	22.2	9	100.0
			yes	0	0.0	0	0.0	20	100.0	0	0.0	20	100.0
			unknown	3	75.0	1	25.0	0	0.0	0	0.0	4	100.0
			all	1255	97.3	12	0.9	21	1.6	2	0.2	1290	100.0
	2004												
		no											
			missing	2134	100.0	0	0.0	0	0.0	0	0.0	2134	100.0
			no	0	0	0	0	0	0	0	0	0	0
			yes	0	0	0	0	0	0	0	0	0	0
			unknown	0	0	0	0	0	0	0	0	0	0
			all	2134	100.0	0	0.0	0	0.0	0	0.0	2134	100.0
		yes											
			missing	10	55.6	6	33.3	2	11.1	0	0.0	18	100.0
			no	13	65.0	6	30.0	1	5.0	0	0.0	20	100.0
			yes	2	6.1	0	0.0	31	93.9	0	0.0	33	100.0
			unknown	1	33.3	0	0.0	0	0.0	2	66.7	3	100.0
			all	26	35.1	12	16.2	34	45.9	2	2.7	74	100.0
		all											
			missing	2144	99.6	6	0.3	2	0.1	0	0.0	2152	100.0
			no	13	65.0	6	30.0	1	5.0	0	0.0	20	100.0
			yes	2	6.1	0	0.0	31	93.9	0	0.0	33	100.0
			unknown	1	33.3	0	0.0	0	0.0	2	66.7	3	100.0

(Continued)

Tab 5.3.3.1: Complications
RSV-test
any RSV diagnosis (by hosp. form exist) vs. result of RSV test
including missing
evaluable population (EVP)

Country	year	hosp. form	any RSV diag.	RSV-test								all	
				missing		negative		positive		unknown			
				n	%	n	%	n	%	n	%	n	%
Germany													
	2004												
		all											
			all	2160	97.8	12	0.5	34	1.5	2	0.1	2208	100.0
	2005												
		no											
			missing	2897	100.0	0	0.0	0	0.0	0	0.0	2897	100.0
			no	0	0	0	0	0	0	0	0	0	0
			yes	0	0	0	0	0	0	0	0	0	0
			unknown	0	0	0	0	0	0	0	0	0	0
			all	2897	100.0	0	0.0	0	0.0	0	0.0	2897	100.0
		yes											
			missing	23	71.9	7	21.9	2	6.3	0	0.0	32	100.0
			no	20	66.7	10	33.3	0	0.0	0	0.0	30	100.0
			yes	5	11.1	0	0.0	40	88.9	0	0.0	45	100.0
			unknown	0	0	0	0	0	0	0	0	0	0
			all	48	44.9	17	15.9	42	39.3	0	0.0	107	100.0
		all											
			missing	2920	99.7	7	0.2	2	0.1	0	0.0	2929	100.0
			no	20	66.7	10	33.3	0	0.0	0	0.0	30	100.0
			yes	5	11.1	0	0.0	40	88.9	0	0.0	45	100.0
			unknown	0	0	0	0	0	0	0	0	0	0
			all	2945	98.0	17	0.6	42	1.4	0	0.0	3004	100.0
	2006												
		no											
			missing	3245	100.0	0	0.0	0	0.0	0	0.0	3245	100.0
			no	0	0	0	0	0	0	0	0	0	0
			yes	0	0	0	0	0	0	0	0	0	0
			unknown	0	0	0	0	0	0	0	0	0	0
			all	3245	100.0	0	0.0	0	0.0	0	0.0	3245	100.0

(Continued)

Tab 5.3.3.1: Complications
RSV-test
any RSV diagnosis (by hosp. form exist) vs. result of RSV test
including missing
evaluable population (EVP)

Country	year	hosp. form	any RSV diag.	RSV-test									
				missing		negative		positive		unknown		all	
				n	%	n	%	n	%	n	%	n	%
Germany													
	2006												
		yes											
			missing	14	51.9	9	33.3	4	14.8	0	0.0	27	100.0
			no	7	53.8	5	38.5	1	7.7	0	0.0	13	100.0
			yes	2	3.6	0	0.0	54	96.4	0	0.0	56	100.0
			unknown	0	0	0	0	0	0	0	0	0	0
			all	23	24.0	14	14.6	59	61.5	0	0.0	96	100.0
		all											
			missing	3259	99.6	9	0.3	4	0.1	0	0.0	3272	100.0
			no	7	53.8	5	38.5	1	7.7	0	0.0	13	100.0
			yes	2	3.6	0	0.0	54	96.4	0	0.0	56	100.0
			unknown	0	0	0	0	0	0	0	0	0	0
			all	3268	97.8	14	0.4	59	1.8	0	0.0	3341	100.0
	all												
		no											
			missing	10328	99.7	16	0.2	18	0.2	0	0.0	10362	100.0
			no	0	0	0	0	0	0	0	0	0	0
			yes	0	0	0	0	0	0	0	0	0	0
			unknown	0	0	0	0	0	0	0	0	0	0
			all	10328	99.7	16	0.2	18	0.2	0	0.0	10362	100.0
		yes											
			missing	60	59.4	32	31.7	9	8.9	0	0.0	101	100.0
			no	46	63.9	22	30.6	2	2.8	2	2.8	72	100.0
			yes	9	5.8	0	0.0	145	94.2	0	0.0	154	100.0
			unknown	4	57.1	1	14.3	0	0.0	2	28.6	7	100.0
			all	119	35.6	55	16.5	156	46.7	4	1.2	334	100.0
		all											
			missing	10388	99.3	48	0.5	27	0.3	0	0.0	10463	100.0
			no	46	63.9	22	30.6	2	2.8	2	2.8	72	100.0

(Continued)

Tab 5.3.3.1: Complications
RSV-test
any RSV diagnosis (by hosp. form exist) vs. result of RSV test
including missing
evaluable population (EVP)

Country	year	hosp. form	any RSV diag.	RSV-test									
				missing		negative		positive		unknown		all	
				n	%	n	%	n	%	n	%	n	%
Germany													
	all												
		all											
			yes	9	5.8	0	0.0	145	94.2	0	0.0	154	100.0
			unknown	4	57.1	1	14.3	0	0.0	2	28.6	7	100.0
			all	10447	97.7	71	0.7	174	1.6	4	0.0	10696	100.0

Tab 5.3.3.2: Complications
RSV-test
any RSV diagnosis (by hosp. form exist) vs. result of RSV test
excluding missing
evaluable population (EVP)

Country	year	hosp. form	any RSV diag.	RSV-test							
				negative		positive		unknown		all	
				n	%	n	%	n	%	n	%
Germany											
	2003										
		yes									
			no	1	33.3	0	0.0	2	66.7	3	100.0
			yes	0	0.0	20	100.0	0	0.0	20	100.0
			unknown	1	100.0	0	0.0	0	0.0	1	100.0
			all	2	8.3	20	83.3	2	8.3	24	100.0
		all									
			no	1	33.3	0	0.0	2	66.7	3	100.0
			yes	0	0.0	20	100.0	0	0.0	20	100.0
			unknown	1	100.0	0	0.0	0	0.0	1	100.0
			all	2	8.3	20	83.3	2	8.3	24	100.0
	2004										
		yes									
			no	6	85.7	1	14.3	0	0.0	7	100.0
			yes	0	0.0	31	100.0	0	0.0	31	100.0
			unknown	0	0.0	0	0.0	2	100.0	2	100.0
			all	6	15.0	32	80.0	2	5.0	40	100.0
		all									
			no	6	85.7	1	14.3	0	0.0	7	100.0
			yes	0	0.0	31	100.0	0	0.0	31	100.0
			unknown	0	0.0	0	0.0	2	100.0	2	100.0
			all	6	15.0	32	80.0	2	5.0	40	100.0
	2005										
		yes									
			no	10	100.0	0	0.0	0	0.0	10	100.0
			yes	0	0.0	40	100.0	0	0.0	40	100.0
			unknown	0	0	0	0	0	0	0	0
			all	10	20.0	40	80.0	0	0.0	50	100.0

(Continued)

Tab 5.3.3.2: Complications
RSV-test
any RSV diagnosis (by hosp. form exist) vs. result of RSV test
excluding missing
evaluable population (EVP)

Country	year	hosp. form	any RSV diag.	RSV-test						all	
				negative		positive		unknown			
				n	%	n	%	n	%	n	%
Germany											
	2005										
		all									
			no	10	100.0	0	0.0	0	0.0	10	100.0
			yes	0	0.0	40	100.0	0	0.0	40	100.0
			unknown	0	0	0	0	0	0	0	0
			all	10	20.0	40	80.0	0	0.0	50	100.0
	2006										
		yes									
			no	5	83.3	1	16.7	0	0.0	6	100.0
			yes	0	0.0	54	100.0	0	0.0	54	100.0
			unknown	0	0	0	0	0	0	0	0
			all	5	8.3	55	91.7	0	0.0	60	100.0
		all									
			no	5	83.3	1	16.7	0	0.0	6	100.0
			yes	0	0.0	54	100.0	0	0.0	54	100.0
			unknown	0	0	0	0	0	0	0	0
			all	5	8.3	55	91.7	0	0.0	60	100.0
	all										
		yes									
			no	22	84.6	2	7.7	2	7.7	26	100.0
			yes	0	0.0	145	100.0	0	0.0	145	100.0
			unknown	1	33.3	0	0.0	2	66.7	3	100.0
			all	23	13.2	147	84.5	4	2.3	174	100.0
		all									
			no	22	84.6	2	7.7	2	7.7	26	100.0
			yes	0	0.0	145	100.0	0	0.0	145	100.0
			unknown	1	33.3	0	0.0	2	66.7	3	100.0
			all	23	13.2	147	84.5	4	2.3	174	100.0

Tab 5.4.1: Complications
intensive care (since 2003)
no/yes/unknown
evaluable population (EVP)

Country	year	hosp. form	intensive care									
			missing		no		yes		not examined/unknown		all	
			n	%	n	%	n	%	n	%	n	%
Germany												
	2003											
		no	1233	100.0	0	0.0	0	0.0	0	0.0	1233	100.0
		yes	1	1.8	29	50.9	24	42.1	3	5.3	57	100.0
		all	1234	95.7	29	2.2	24	1.9	3	0.2	1290	100.0
	2004											
		no	2134	100.0	0	0.0	0	0.0	0	0.0	2134	100.0
		yes	4	5.4	42	56.8	23	31.1	5	6.8	74	100.0
		all	2138	96.8	42	1.9	23	1.0	5	0.2	2208	100.0
	2005											
		no	2897	100.0	0	0.0	0	0.0	0	0.0	2897	100.0
		yes	2	1.9	69	64.5	28	26.2	8	7.5	107	100.0
		all	2899	96.5	69	2.3	28	0.9	8	0.3	3004	100.0
	2006											
		no	3245	100.0	0	0.0	0	0.0	0	0.0	3245	100.0
		yes	1	1.0	50	52.1	36	37.5	9	9.4	96	100.0
		all	3246	97.2	50	1.5	36	1.1	9	0.3	3341	100.0
	all											
		no	9509	100.0	0	0.0	0	0.0	0	0.0	9509	100.0
		yes	8	2.4	190	56.9	111	33.2	25	7.5	334	100.0
		all	9517	96.7	190	1.9	111	1.1	25	0.3	9843	100.0

Tab 5.4.2: Complications
intensive care (since 2003)
duration (days)
evaluable population (EVP)

		n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2003	1268	22	17.82	21.40	6.00	11.50	26.00	1.0	99.0
	2004	2190	18	15.50	16.02	4.00	9.00	22.00	1.0	60.0
	2005	2984	20	15.25	23.27	3.50	7.00	16.50	1.0	103.0
	2006	3316	25	11.08	14.77	2.00	6.00	10.00	1.0	60.0
	all	9758	85	14.74	18.92	3.00	8.00	15.00	1.0	103.0

Tab 5.5.1: Complications
oxygen needed (since 2003)
no/yes/unknown
evaluable population (EVP)

Country	year	hosp. form	oxygen needed									
			missing		no		yes		not examined/unknown		all	
			n	%	n	%	n	%	n	%	n	%
Germany												
	2003											
		no	1233	100.0	0	0.0	0	0.0	0	0.0	1233	100.0
		yes	0	0.0	19	33.3	34	59.6	4	7.0	57	100.0
		all	1233	95.6	19	1.5	34	2.6	4	0.3	1290	100.0
	2004											
		no	2134	100.0	0	0.0	0	0.0	0	0.0	2134	100.0
		yes	4	5.4	32	43.2	34	45.9	4	5.4	74	100.0
		all	2138	96.8	32	1.4	34	1.5	4	0.2	2208	100.0
	2005											
		no	2897	100.0	0	0.0	0	0.0	0	0.0	2897	100.0
		yes	1	0.9	42	39.3	54	50.5	10	9.3	107	100.0
		all	2898	96.5	42	1.4	54	1.8	10	0.3	3004	100.0
	2006											
		no	3245	100.0	0	0.0	0	0.0	0	0.0	3245	100.0
		yes	2	2.1	36	37.5	55	57.3	3	3.1	96	100.0
		all	3247	97.2	36	1.1	55	1.6	3	0.1	3341	100.0
	all											
		no	9509	100.0	0	0.0	0	0.0	0	0.0	9509	100.0
		yes	7	2.1	129	38.6	177	53.0	21	6.3	334	100.0
		all	9516	96.7	129	1.3	177	1.8	21	0.2	9843	100.0

Tab 5.5.2: Complications
oxygen needed (since 2003)
duration (days)
evaluable population (EVP)

		n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2003	1260	30	8.37	8.73	3.00	5.00	10.00	1.0	30.0
	2004	2182	26	7.69	8.57	2.00	6.50	8.00	1.0	40.0
	2005	2963	41	6.37	7.39	2.00	4.00	7.00	1.0	39.0
	2006	3304	37	6.51	8.02	2.00	4.00	7.00	0.0	43.0
	all	9709	134	7.11	8.06	2.00	5.00	8.00	0.0	43.0

Tab 5.6.1: Complications
mechanical respiration (since 2003)
no/yes/unknown
evaluable population (EVP)

Country	year	hosp. form	mechanical respiratory									
			missing		no		yes		not examined/unknown		all	
			n	%	n	%	n	%	n	%	n	%
Germany												
	2003											
		no	1233	100.0	0	0.0	0	0.0	0	0.0	1233	100.0
		yes	0	0.0	43	75.4	11	19.3	3	5.3	57	100.0
		all	1233	95.6	43	3.3	11	0.9	3	0.2	1290	100.0
	2004											
		no	2134	100.0	0	0.0	0	0.0	0	0.0	2134	100.0
		yes	4	5.4	59	79.7	9	12.2	2	2.7	74	100.0
		all	2138	96.8	59	2.7	9	0.4	2	0.1	2208	100.0
	2005											
		no	2897	100.0	0	0.0	0	0.0	0	0.0	2897	100.0
		yes	2	1.9	89	83.2	16	15.0	0	0.0	107	100.0
		all	2899	96.5	89	3.0	16	0.5	0	0.0	3004	100.0
	2006											
		no	3245	100.0	0	0.0	0	0.0	0	0.0	3245	100.0
		yes	2	2.1	83	86.5	8	8.3	3	3.1	96	100.0
		all	3247	97.2	83	2.5	8	0.2	3	0.1	3341	100.0
	all											
		no	9509	100.0	0	0.0	0	0.0	0	0.0	9509	100.0
		yes	8	2.4	274	82.0	44	13.2	8	2.4	334	100.0
		all	9517	96.7	274	2.8	44	0.4	8	0.1	9843	100.0

Tab 5.6.2: Complications
mechanical respiration (since 2003)
duration (days)
evaluable population (EVP)

		n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2003	1282	8	11.75	9.48	5.00	10.00	16.00	1.0	31.0
	2004	2200	8	9.63	10.51	4.00	6.50	9.00	3.0	35.0
	2005	2993	11	7.64	9.58	2.00	3.00	10.00	2.0	32.0
	2006	3333	8	11.38	14.52	2.50	6.00	13.50	2.0	45.0
	all	9808	35	9.89	10.71	3.00	6.00	10.00	1.0	45.0

Tab 6: Occurrence of ADR
evaluable population (EVP)

	Occurrence of ADR							
	missing		no		yes		all	
	n	%	n	%	n	%	n	%
Germany								
2002	65	7.6	779	91.3	9	1.1	853	100.0
2003	37	2.9	1235	96.0	15	1.2	1287	100.0
2004	56	2.5	2140	96.9	12	0.5	2208	100.0
2005	121	4.0	2865	95.5	14	0.5	3000	100.0
2006	132	4.0	3192	95.6	14	0.4	3338	100.0
all	411	3.8	10211	95.6	64	0.6	10686	100.0

Tab 7.1: Cooperation of parents
including missing
evaluable population (EVP)

	Cooperation of parents												all	
	missing		very good		good		moderate		bad		very bad			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002	82	9.6	586	68.7	111	13.0	33	3.9	17	2.0	24	2.8	853	100.0
2003	18	1.4	919	71.4	251	19.5	62	4.8	21	1.6	16	1.2	1287	100.0
2004	44	2.0	1547	70.1	391	17.7	139	6.3	56	2.5	31	1.4	2208	100.0
2005	111	3.7	2112	70.4	535	17.8	148	4.9	62	2.1	32	1.1	3000	100.0
2006	127	3.8	2320	69.5	611	18.3	185	5.5	68	2.0	27	0.8	3338	100.0
all	382	3.6	7484	70.0	1899	17.8	567	5.3	224	2.1	130	1.2	10686	100.0

Tab 7.2: Cooperation of parents
excluding missing
evaluable population (EVP)

	Cooperation of parents											
	very good		good		moderate		bad		very bad		all	
	n	%	n	%	n	%	n	%	n	%	n	%
Germany												
2002	586	76.0	111	14.4	33	4.3	17	2.2	24	3.1	771	100.0
2003	919	72.4	251	19.8	62	4.9	21	1.7	16	1.3	1269	100.0
2004	1547	71.5	391	18.1	139	6.4	56	2.6	31	1.4	2164	100.0
2005	2112	73.1	535	18.5	148	5.1	62	2.1	32	1.1	2889	100.0
2006	2320	72.3	611	19.0	185	5.8	68	2.1	27	0.8	3211	100.0
all	7484	72.6	1899	18.4	567	5.5	224	2.2	130	1.3	10304	100.0

Tab 8.1.1: Subgroup analyses for hospitalization
by premature birth
including missing
evaluable population (EVP)

Premature birth	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002														
missing	89	13.1	526	77.2	66	9.7	0	0.0	0	0.0	0	0.0	0	0.0
no	0	0	0	0	0	0	0	0	0	0	0	0	0	0
yes	15	8.7	141	82.0	16	9.3	0	0.0	0	0.0	0	0.0	0	0.0
all	104	12.2	667	78.2	82	9.6	0	0.0	0	0.0	0	0.0	0	0.0
2003														
missing	0	0.0	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
no	1	1.3	75	94.9	2	2.5	1	1.3	0	0.0	0	0.0	0	0.0
yes	40	3.3	1121	93.1	40	3.3	2	0.2	1	0.1	0	0.0	0	0.0
all	41	3.2	1200	93.2	42	3.3	3	0.2	1	0.1	0	0.0	0	0.0
2004														
missing	2	16.7	10	83.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
no	6	2.8	200	93.5	7	3.3	1	0.5	0	0.0	0	0.0	0	0.0
yes	69	3.5	1853	93.5	58	2.9	2	0.1	0	0.0	0	0.0	0	0.0
all	77	3.5	2063	93.4	65	2.9	3	0.1	0	0.0	0	0.0	0	0.0
2005														
missing	0	0.0	10	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
no	16	4.4	335	92.8	10	2.8	0	0.0	0	0.0	0	0.0	0	0.0
yes	115	4.4	2430	92.4	80	3.0	3	0.1	0	0.0	1	0.0	0	0.0
all	131	4.4	2775	92.5	90	3.0	3	0.1	0	0.0	1	0.0	0	0.0
2006														
missing	2	15.4	11	84.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
no	17	3.7	430	94.3	9	2.0	0	0.0	0	0.0	0	0.0	0	0.0
yes	125	4.4	2668	93.0	66	2.3	6	0.2	0	0.0	0	0.0	2	0.1
all	144	4.3	3109	93.1	75	2.2	6	0.2	0	0.0	0	0.0	2	0.1
all														
missing	93	12.9	561	77.9	66	9.2	0	0.0	0	0.0	0	0.0	0	0.0
no	40	3.6	1040	93.7	28	2.5	2	0.2	0	0.0	0	0.0	0	0.0
yes	364	4.1	8213	92.7	260	2.9	13	0.1	1	0.0	1	0.0	2	0.0
all	497	4.7	9814	91.8	354	3.3	15	0.1	1	0.0	1	0.0	2	0.0

(Continued)

Tab 8.1.1: Subgroup analyses for hospitalization
by premature birth
including missing
evaluable population (EVP)

Premature birth	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
2002						
missing	0	0.0	0	0.0	681	100.0
no	0	0	0	0	0	0
yes	0	0.0	0	0.0	172	100.0
all	0	0.0	0	0.0	853	100.0
2003						
missing	0	0.0	0	0.0	4	100.0
no	0	0.0	0	0.0	79	100.0
yes	0	0.0	0	0.0	1204	100.0
all	0	0.0	0	0.0	1287	100.0
2004						
missing	0	0.0	0	0.0	12	100.0
no	0	0.0	0	0.0	214	100.0
yes	0	0.0	0	0.0	1982	100.0
all	0	0.0	0	0.0	2208	100.0
2005						
missing	0	0.0	0	0.0	10	100.0
no	0	0.0	0	0.0	361	100.0
yes	0	0.0	0	0.0	2629	100.0
all	0	0.0	0	0.0	3000	100.0
2006						
missing	0	0.0	0	0.0	13	100.0
no	0	0.0	0	0.0	456	100.0
yes	1	0.0	1	0.0	2869	100.0
all	1	0.0	1	0.0	3338	100.0
all						
missing	0	0.0	0	0.0	720	100.0
no	0	0.0	0	0.0	1110	100.0
yes	1	0.0	1	0.0	8856	100.0

(Continued)

Tab 8.1.1: Subgroup analyses for hospitalization
by premature birth
including missing
evaluable population (EVP)

Premature birth	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
all						
all	1	0.0	1	0.0	10686	100.0

Tab 8.1.2: Subgroup analyses for hospitalization
by premature birth
excluding missing
evaluable population (EVP)

Premature birth	Number of hospitalizations/patient													
	0		1		2		3		4		5		6	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002														
no	0	0	0	0	0	0	0	0	0	0	0	0	0	0
yes	141	89.8	16	10.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	141	89.8	16	10.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2003														
no	75	96.2	2	2.6	1	1.3	0	0.0	0	0.0	0	0.0	0	0.0
yes	1121	96.3	40	3.4	2	0.2	1	0.1	0	0.0	0	0.0	0	0.0
all	1196	96.3	42	3.4	3	0.2	1	0.1	0	0.0	0	0.0	0	0.0
2004														
no	200	96.2	7	3.4	1	0.5	0	0.0	0	0.0	0	0.0	0	0.0
yes	1853	96.9	58	3.0	2	0.1	0	0.0	0	0.0	0	0.0	0	0.0
all	2053	96.8	65	3.1	3	0.1	0	0.0	0	0.0	0	0.0	0	0.0
2005														
no	335	97.1	10	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
yes	2430	96.7	80	3.2	3	0.1	0	0.0	1	0.0	0	0.0	0	0.0
all	2765	96.7	90	3.1	3	0.1	0	0.0	1	0.0	0	0.0	0	0.0
2006														
no	430	97.9	9	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
yes	2668	97.2	66	2.4	6	0.2	0	0.0	0	0.0	2	0.1	1	0.0
all	3098	97.3	75	2.4	6	0.2	0	0.0	0	0.0	2	0.1	1	0.0
all														
no	1040	97.2	28	2.6	2	0.2	0	0.0	0	0.0	0	0.0	0	0.0
yes	8213	96.7	260	3.1	13	0.2	1	0.0	1	0.0	2	0.0	1	0.0
all	9253	96.8	288	3.0	15	0.2	1	0.0	1	0.0	2	0.0	1	0.0

(Continued)

Tab 8.1.2: Subgroup analyses for hospitalization
by premature birth
excluding missing
evaluable population (EVP)

Premature birth	Number of hospitaliza-tions/patie-nt			
	8		all	
	n	%	n	%
Germany				
2002				
no	0	0	0	0
yes	0	0.0	157	100.0
all	0	0.0	157	100.0
2003				
no	0	0.0	78	100.0
yes	0	0.0	1164	100.0
all	0	0.0	1242	100.0
2004				
no	0	0.0	208	100.0
yes	0	0.0	1913	100.0
all	0	0.0	2121	100.0
2005				
no	0	0.0	345	100.0
yes	0	0.0	2514	100.0
all	0	0.0	2859	100.0
2006				
no	0	0.0	439	100.0
yes	1	0.0	2744	100.0
all	1	0.0	3183	100.0
all				
no	0	0.0	1070	100.0
yes	1	0.0	8492	100.0
all	1	0.0	9562	100.0

Tab 8.2.1: Subgroup analyses for hospitalization
by BPD
including missing
evaluable population (EVP)

BPD	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002														
missing	22	24.4	61	67.8	7	7.8	0	0.0	0	0.0	0	0.0	0	0.0
no	41	12.1	274	80.8	24	7.1	0	0.0	0	0.0	0	0.0	0	0.0
yes	41	9.7	332	78.3	51	12.0	0	0.0	0	0.0	0	0.0	0	0.0
all	104	12.2	667	78.2	82	9.6	0	0.0	0	0.0	0	0.0	0	0.0
2003														
missing	10	10.6	80	85.1	3	3.2	1	1.1	0	0.0	0	0.0	0	0.0
no	19	3.2	562	94.5	14	2.4	0	0.0	0	0.0	0	0.0	0	0.0
yes	12	2.0	558	93.3	25	4.2	2	0.3	1	0.2	0	0.0	0	0.0
all	41	3.2	1200	93.2	42	3.3	3	0.2	1	0.1	0	0.0	0	0.0
2004														
missing	23	14.0	137	83.5	4	2.4	0	0.0	0	0.0	0	0.0	0	0.0
no	32	2.7	1146	95.1	26	2.2	1	0.1	0	0.0	0	0.0	0	0.0
yes	22	2.6	780	93.0	35	4.2	2	0.2	0	0.0	0	0.0	0	0.0
all	77	3.5	2063	93.4	65	2.9	3	0.1	0	0.0	0	0.0	0	0.0
2005														
missing	23	9.5	213	88.0	4	1.7	1	0.4	0	0.0	1	0.4	0	0.0
no	72	4.4	1500	92.3	52	3.2	1	0.1	0	0.0	0	0.0	0	0.0
yes	36	3.2	1062	93.7	34	3.0	1	0.1	0	0.0	0	0.0	0	0.0
all	131	4.4	2775	92.5	90	3.0	3	0.1	0	0.0	1	0.0	0	0.0
2006														
missing	28	9.6	253	86.9	10	3.4	0	0.0	0	0.0	0	0.0	0	0.0
no	75	4.0	1749	93.9	36	1.9	1	0.1	0	0.0	0	0.0	1	0.1
yes	41	3.5	1107	93.4	29	2.4	5	0.4	0	0.0	0	0.0	1	0.1
all	144	4.3	3109	93.1	75	2.2	6	0.2	0	0.0	0	0.0	2	0.1
all														
missing	106	12.0	744	84.4	28	3.2	2	0.2	0	0.0	1	0.1	0	0.0
no	239	4.2	5231	93.0	152	2.7	3	0.1	0	0.0	0	0.0	1	0.0
yes	152	3.6	3839	91.9	174	4.2	10	0.2	1	0.0	0	0.0	1	0.0
all	497	4.7	9814	91.8	354	3.3	15	0.1	1	0.0	1	0.0	2	0.0

(Continued)

Tab 8.2.1: Subgroup analyses for hospitalization
by BPD
including missing
evaluable population (EVP)

BPD	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
2002						
missing	0	0.0	0	0.0	90	100.0
no	0	0.0	0	0.0	339	100.0
yes	0	0.0	0	0.0	424	100.0
all	0	0.0	0	0.0	853	100.0
2003						
missing	0	0.0	0	0.0	94	100.0
no	0	0.0	0	0.0	595	100.0
yes	0	0.0	0	0.0	598	100.0
all	0	0.0	0	0.0	1287	100.0
2004						
missing	0	0.0	0	0.0	164	100.0
no	0	0.0	0	0.0	1205	100.0
yes	0	0.0	0	0.0	839	100.0
all	0	0.0	0	0.0	2208	100.0
2005						
missing	0	0.0	0	0.0	242	100.0
no	0	0.0	0	0.0	1625	100.0
yes	0	0.0	0	0.0	1133	100.0
all	0	0.0	0	0.0	3000	100.0
2006						
missing	0	0.0	0	0.0	291	100.0
no	0	0.0	0	0.0	1862	100.0
yes	1	0.1	1	0.1	1185	100.0
all	1	0.0	1	0.0	3338	100.0
all						
missing	0	0.0	0	0.0	881	100.0
no	0	0.0	0	0.0	5626	100.0
yes	1	0.0	1	0.0	4179	100.0

(Continued)

Tab 8.2.1: Subgroup analyses for hospitalization
by BPD
including missing
evaluable population (EVP)

BPD	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
all						
all	1	0.0	1	0.0	10686	100.0

BPD	Number of hospitalizations/patient													
	0		1		2		3		5		6		8	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002														
no	274	91.9	24	8.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
yes	332	86.7	51	13.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	606	89.0	75	11.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2003														
no	562	97.6	14	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
yes	558	95.2	25	4.3	2	0.3	1	0.2	0	0.0	0	0.0	0	0.0
all	1120	96.4	39	3.4	2	0.2	1	0.1	0	0.0	0	0.0	0	0.0
2004														
no	1146	97.7	26	2.2	1	0.1	0	0.0	0	0.0	0	0.0	0	0.0
yes	780	95.5	35	4.3	2	0.2	0	0.0	0	0.0	0	0.0	0	0.0
all	1926	96.8	61	3.1	3	0.2	0	0.0	0	0.0	0	0.0	0	0.0
2005														
no	1500	96.6	52	3.3	1	0.1	0	0.0	0	0.0	0	0.0	0	0.0
yes	1062	96.8	34	3.1	1	0.1	0	0.0	0	0.0	0	0.0	0	0.0
all	2562	96.7	86	3.2	2	0.1	0	0.0	0	0.0	0	0.0	0	0.0
2006														
no	1749	97.9	36	2.0	1	0.1	0	0.0	1	0.1	0	0.0	0	0.0
yes	1107	96.8	29	2.5	5	0.4	0	0.0	1	0.1	1	0.1	1	0.1
all	2856	97.4	65	2.2	6	0.2	0	0.0	2	0.1	1	0.0	1	0.0
all														
no	5231	97.1	152	2.8	3	0.1	0	0.0	1	0.0	0	0.0	0	0.0
yes	3839	95.3	174	4.3	10	0.2	1	0.0	1	0.0	1	0.0	1	0.0
all	9070	96.3	326	3.5	13	0.1	1	0.0	2	0.0	1	0.0	1	0.0

(Continued)

Tab 8.2.2: Subgroup analyses for hospitalization
by BPD
excluding missing
evaluable population (EVP)

BPD	all	
	n	%
Germany		
2002		
no	298	100.0
yes	383	100.0
all	681	100.0
2003		
no	576	100.0
yes	586	100.0
all	1162	100.0
2004		
no	1173	100.0
yes	817	100.0
all	1990	100.0
2005		
no	1553	100.0
yes	1097	100.0
all	2650	100.0
2006		
no	1787	100.0
yes	1144	100.0
all	2931	100.0
all		
no	5387	100.0
yes	4027	100.0
all	9414	100.0

Tab 8.3.1: Subgroup analyses for hospitalization
by congenital heart misformation
including missing
evaluable population (EVP)

Congenital heart misformation	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002														
missing	95	12.1	619	78.6	74	9.4	0	0.0	0	0.0	0	0.0	0	0.0
no	0	0	0	0	0	0	0	0	0	0	0	0	0	0
yes	9	13.8	48	73.8	8	12.3	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	0	0	0	0	0	0	0	0	0	0	0	0	0	0
all	104	12.2	667	78.2	82	9.6	0	0.0	0	0.0	0	0.0	0	0.0
2003														
missing	3	17.6	14	82.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
no	28	3.0	881	93.7	29	3.1	1	0.1	1	0.1	0	0.0	0	0.0
yes	8	2.5	297	92.8	13	4.1	2	0.6	0	0.0	0	0.0	0	0.0
not examined/unknown	2	20.0	8	80.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	41	3.2	1200	93.2	42	3.3	3	0.2	1	0.1	0	0.0	0	0.0
2004														
missing	9	27.3	24	72.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
no	54	3.5	1443	93.5	45	2.9	2	0.1	0	0.0	0	0.0	0	0.0
yes	14	2.2	591	94.7	18	2.9	1	0.2	0	0.0	0	0.0	0	0.0
not examined/unknown	0	0.0	5	71.4	2	28.6	0	0.0	0	0.0	0	0.0	0	0.0
all	77	3.5	2063	93.4	65	2.9	3	0.1	0	0.0	0	0.0	0	0.0
2005														
missing	6	9.2	59	90.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
no	84	4.3	1807	92.3	63	3.2	3	0.2	0	0.0	0	0.0	0	0.0
yes	40	4.2	895	93.0	26	2.7	0	0.0	0	0.0	1	0.1	0	0.0
not examined/unknown	1	6.3	14	87.5	1	6.3	0	0.0	0	0.0	0	0.0	0	0.0
all	131	4.4	2775	92.5	90	3.0	3	0.1	0	0.0	1	0.0	0	0.0
2006														
missing	7	8.2	75	88.2	2	2.4	1	1.2	0	0.0	0	0.0	0	0.0
no	80	3.7	2009	93.6	49	2.3	4	0.2	0	0.0	0	0.0	2	0.1
yes	56	5.1	1014	92.6	24	2.2	1	0.1	0	0.0	0	0.0	0	0.0
not examined/unknown	1	8.3	11	91.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	144	4.3	3109	93.1	75	2.2	6	0.2	0	0.0	0	0.0	2	0.1

(Continued)

Tab 8.3.1: Subgroup analyses for hospitalization
by congenital heart misformation
including missing
evaluable population (EVP)

Congenital heart misformation	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
all														
missing	120	12.1	791	80.1	76	7.7	1	0.1	0	0.0	0	0.0	0	0.0
no	246	3.7	6140	93.2	186	2.8	10	0.2	1	0.0	0	0.0	2	0.0
yes	127	4.1	2845	92.8	89	2.9	4	0.1	0	0.0	1	0.0	0	0.0
not examined/unknown	4	8.9	38	84.4	3	6.7	0	0.0	0	0.0	0	0.0	0	0.0
all	497	4.7	9814	91.8	354	3.3	15	0.1	1	0.0	1	0.0	2	0.0

(Continued)

Tab 8.3.1: Subgroup analyses for hospitalization
by congenital heart misformation
including missing
evaluable population (EVP)

Congenital heart misformation	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
2002						
missing	0	0.0	0	0.0	788	100.0
no	0	0	0	0	0	0
yes	0	0.0	0	0.0	65	100.0
not examined/unknown	0	0	0	0	0	0
all	0	0.0	0	0.0	853	100.0
2003						
missing	0	0.0	0	0.0	17	100.0
no	0	0.0	0	0.0	940	100.0
yes	0	0.0	0	0.0	320	100.0
not examined/unknown	0	0.0	0	0.0	10	100.0
all	0	0.0	0	0.0	1287	100.0
2004						
missing	0	0.0	0	0.0	33	100.0
no	0	0.0	0	0.0	1544	100.0
yes	0	0.0	0	0.0	624	100.0
not examined/unknown	0	0.0	0	0.0	7	100.0
all	0	0.0	0	0.0	2208	100.0
2005						
missing	0	0.0	0	0.0	65	100.0
no	0	0.0	0	0.0	1957	100.0
yes	0	0.0	0	0.0	962	100.0
not examined/unknown	0	0.0	0	0.0	16	100.0
all	0	0.0	0	0.0	3000	100.0
2006						
missing	0	0.0	0	0.0	85	100.0
no	1	0.0	1	0.0	2146	100.0
yes	0	0.0	0	0.0	1095	100.0
not examined/unknown	0	0.0	0	0.0	12	100.0

(Continued)

Tab 8.3.1: Subgroup analyses for hospitalization
by congenital heart misformation
including missing
evaluable population (EVP)

Congenital heart misformation	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
2006						
all	1	0.0	1	0.0	3338	100.0
all						
missing	0	0.0	0	0.0	988	100.0
no	1	0.0	1	0.0	6587	100.0
yes	0	0.0	0	0.0	3066	100.0
not examined/unknown	0	0.0	0	0.0	45	100.0
all	1	0.0	1	0.0	10686	100.0

Tab 8.3.2: Subgroup analyses for hospitalization
by congenital heart misformation
excluding missing
evaluable population (EVP)

Congenital heart misformation	Number of hospitalizations/patient													
	0		1		2		3		4		5		6	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002														
no	0	0	0	0	0	0	0	0	0	0	0	0	0	0
yes	48	85.7	8	14.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	0	0	0	0	0	0	0	0	0	0	0	0	0	0
all	48	85.7	8	14.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2003														
no	881	96.6	29	3.2	1	0.1	1	0.1	0	0.0	0	0.0	0	0.0
yes	297	95.2	13	4.2	2	0.6	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	8	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	1186	96.3	42	3.4	3	0.2	1	0.1	0	0.0	0	0.0	0	0.0
2004														
no	1443	96.8	45	3.0	2	0.1	0	0.0	0	0.0	0	0.0	0	0.0
yes	591	96.9	18	3.0	1	0.2	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	5	71.4	2	28.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	2039	96.8	65	3.1	3	0.1	0	0.0	0	0.0	0	0.0	0	0.0
2005														
no	1807	96.5	63	3.4	3	0.2	0	0.0	0	0.0	0	0.0	0	0.0
yes	895	97.1	26	2.8	0	0.0	0	0.0	1	0.1	0	0.0	0	0.0
not examined/unknown	14	93.3	1	6.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	2716	96.7	90	3.2	3	0.1	0	0.0	1	0.0	0	0.0	0	0.0
2006														
no	2009	97.2	49	2.4	4	0.2	0	0.0	0	0.0	2	0.1	1	0.0
yes	1014	97.6	24	2.3	1	0.1	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	11	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	3034	97.4	73	2.3	5	0.2	0	0.0	0	0.0	2	0.1	1	0.0
all														
no	6140	96.8	186	2.9	10	0.2	1	0.0	0	0.0	2	0.0	1	0.0
yes	2845	96.8	89	3.0	4	0.1	0	0.0	1	0.0	0	0.0	0	0.0
not examined/unknown	38	92.7	3	7.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	9023	96.8	278	3.0	14	0.2	1	0.0	1	0.0	2	0.0	1	0.0

(Continued)

Tab 8.3.2: Subgroup analyses for hospitalization
by congenital heart misformation
excluding missing
evaluable population (EVP)

Congenital heart misformation	Number of hospitalizations/patient			
	8		all	
	n	%	n	%
Germany				
2002				
no	0	0	0	0
yes	0	0.0	56	100.0
not examined/unknown	0	0	0	0
all	0	0.0	56	100.0
2003				
no	0	0.0	912	100.0
yes	0	0.0	312	100.0
not examined/unknown	0	0.0	8	100.0
all	0	0.0	1232	100.0
2004				
no	0	0.0	1490	100.0
yes	0	0.0	610	100.0
not examined/unknown	0	0.0	7	100.0
all	0	0.0	2107	100.0
2005				
no	0	0.0	1873	100.0
yes	0	0.0	922	100.0
not examined/unknown	0	0.0	15	100.0
all	0	0.0	2810	100.0
2006				
no	1	0.0	2066	100.0
yes	0	0.0	1039	100.0
not examined/unknown	0	0.0	11	100.0
all	1	0.0	3116	100.0
all				
no	1	0.0	6341	100.0

(Continued)

Tab 8.3.2: Subgroup analyses for hospitalization
by congenital heart misformation
excluding missing
evaluable population (EVP)

Congenital heart misformation	Number of hospitalizations/patient			
	8		all	
	n	%	n	%
Germany				
all				
yes	0	0.0	2939	100.0
not examined/unknown	0	0.0	41	100.0
all	1	0.0	9321	100.0

Tab 8.4.1: Subgroup analyses for hospitalization
by multiple birth
including missing
evaluable population (EVP)

Multiple birth	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002														
missing	95	12.1	611	78.0	77	9.8	0	0.0	0	0.0	0	0.0	0	0.0
no	0	0	0	0	0	0	0	0	0	0	0	0	0	0
yes	9	12.9	56	80.0	5	7.1	0	0.0	0	0.0	0	0.0	0	0.0
all	104	12.2	667	78.2	82	9.6	0	0.0	0	0.0	0	0.0	0	0.0
2003														
missing	0	0.0	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
no	18	2.0	842	94.5	28	3.1	2	0.2	1	0.1	0	0.0	0	0.0
yes	23	5.9	354	90.3	14	3.6	1	0.3	0	0.0	0	0.0	0	0.0
all	41	3.2	1200	93.2	42	3.3	3	0.2	1	0.1	0	0.0	0	0.0
2004														
missing	1	5.6	16	88.9	1	5.6	0	0.0	0	0.0	0	0.0	0	0.0
no	47	3.0	1455	93.2	56	3.6	3	0.2	0	0.0	0	0.0	0	0.0
yes	29	4.6	592	94.1	8	1.3	0	0.0	0	0.0	0	0.0	0	0.0
all	77	3.5	2063	93.4	65	2.9	3	0.1	0	0.0	0	0.0	0	0.0
2005														
missing	1	3.8	25	96.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
no	96	4.3	2060	92.6	65	2.9	2	0.1	0	0.0	1	0.0	0	0.0
yes	34	4.5	690	92.0	25	3.3	1	0.1	0	0.0	0	0.0	0	0.0
all	131	4.4	2775	92.5	90	3.0	3	0.1	0	0.0	1	0.0	0	0.0
2006														
missing	3	9.1	29	87.9	0	0.0	0	0.0	0	0.0	0	0.0	1	3.0
no	109	4.4	2301	93.2	51	2.1	5	0.2	0	0.0	0	0.0	1	0.0
yes	32	3.8	779	93.2	24	2.9	1	0.1	0	0.0	0	0.0	0	0.0
all	144	4.3	3109	93.1	75	2.2	6	0.2	0	0.0	0	0.0	2	0.1
all														
missing	100	11.6	685	79.3	78	9.0	0	0.0	0	0.0	0	0.0	1	0.1
no	270	3.8	6658	93.2	200	2.8	12	0.2	1	0.0	1	0.0	1	0.0
yes	127	4.7	2471	92.3	76	2.8	3	0.1	0	0.0	0	0.0	0	0.0
all	497	4.7	9814	91.8	354	3.3	15	0.1	1	0.0	1	0.0	2	0.0

(Continued)

Tab 8.4.1: Subgroup analyses for hospitalization
by multiple birth
including missing
evaluable population (EVP)

Multiple birth	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
2002						
missing	0	0.0	0	0.0	783	100.0
no	0	0	0	0	0	0
yes	0	0.0	0	0.0	70	100.0
all	0	0.0	0	0.0	853	100.0
2003						
missing	0	0.0	0	0.0	4	100.0
no	0	0.0	0	0.0	891	100.0
yes	0	0.0	0	0.0	392	100.0
all	0	0.0	0	0.0	1287	100.0
2004						
missing	0	0.0	0	0.0	18	100.0
no	0	0.0	0	0.0	1561	100.0
yes	0	0.0	0	0.0	629	100.0
all	0	0.0	0	0.0	2208	100.0
2005						
missing	0	0.0	0	0.0	26	100.0
no	0	0.0	0	0.0	2224	100.0
yes	0	0.0	0	0.0	750	100.0
all	0	0.0	0	0.0	3000	100.0
2006						
missing	0	0.0	0	0.0	33	100.0
no	1	0.0	1	0.0	2469	100.0
yes	0	0.0	0	0.0	836	100.0
all	1	0.0	1	0.0	3338	100.0
all						
missing	0	0.0	0	0.0	864	100.0
no	1	0.0	1	0.0	7145	100.0
yes	0	0.0	0	0.0	2677	100.0

(Continued)

Tab 8.4.1: Subgroup analyses for hospitalization
by multiple birth
including missing
evaluable population (EVP)

Multiple birth	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
all						
all	1	0.0	1	0.0	10686	100.0

Tab 8.4.2: Subgroup analyses for hospitalization
by multiple birth
excluding missing
evaluable population (EVP)

Multiple birth	Number of hospitalizations/patient													
	0		1		2		3		4		5		6	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002														
no	0	0	0	0	0	0	0	0	0	0	0	0	0	0
yes	56	91.8	5	8.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	56	91.8	5	8.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2003														
no	842	96.4	28	3.2	2	0.2	1	0.1	0	0.0	0	0.0	0	0.0
yes	354	95.9	14	3.8	1	0.3	0	0.0	0	0.0	0	0.0	0	0.0
all	1196	96.3	42	3.4	3	0.2	1	0.1	0	0.0	0	0.0	0	0.0
2004														
no	1455	96.1	56	3.7	3	0.2	0	0.0	0	0.0	0	0.0	0	0.0
yes	592	98.7	8	1.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	2047	96.8	64	3.0	3	0.1	0	0.0	0	0.0	0	0.0	0	0.0
2005														
no	2060	96.8	65	3.1	2	0.1	0	0.0	1	0.0	0	0.0	0	0.0
yes	690	96.4	25	3.5	1	0.1	0	0.0	0	0.0	0	0.0	0	0.0
all	2750	96.7	90	3.2	3	0.1	0	0.0	1	0.0	0	0.0	0	0.0
2006														
no	2301	97.5	51	2.2	5	0.2	0	0.0	0	0.0	1	0.0	1	0.0
yes	779	96.9	24	3.0	1	0.1	0	0.0	0	0.0	0	0.0	0	0.0
all	3080	97.3	75	2.4	6	0.2	0	0.0	0	0.0	1	0.0	1	0.0
all														
no	6658	96.8	200	2.9	12	0.2	1	0.0	1	0.0	1	0.0	1	0.0
yes	2471	96.9	76	3.0	3	0.1	0	0.0	0	0.0	0	0.0	0	0.0
all	9129	96.9	276	2.9	15	0.2	1	0.0	1	0.0	1	0.0	1	0.0

(Continued)

Tab 8.4.2: Subgroup analyses for hospitalization
by multiple birth
excluding missing
evaluable population (EVP)

Multiple birth	Number of hospitalizations/patient			
	8		all	
	n	%	n	%
Germany				
2002				
no	0	0	0	0
yes	0	0.0	61	100.0
all	0	0.0	61	100.0
2003				
no	0	0.0	873	100.0
yes	0	0.0	369	100.0
all	0	0.0	1242	100.0
2004				
no	0	0.0	1514	100.0
yes	0	0.0	600	100.0
all	0	0.0	2114	100.0
2005				
no	0	0.0	2128	100.0
yes	0	0.0	716	100.0
all	0	0.0	2844	100.0
2006				
no	1	0.0	2360	100.0
yes	0	0.0	804	100.0
all	1	0.0	3164	100.0
all				
no	1	0.0	6875	100.0
yes	0	0.0	2550	100.0
all	1	0.0	9425	100.0

Tab 8.5.1: Subgroup analyses for hospitalization
by immuno deficiency
including missing
evaluable population (EVP)

Immuno deficiency	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002														
missing	104	12.2	665	78.1	82	9.6	0	0.0	0	0.0	0	0.0	0	0.0
no	0	0	0	0	0	0	0	0	0	0	0	0	0	0
yes	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	0	0	0	0	0	0	0	0	0	0	0	0	0	0
all	104	12.2	667	78.2	82	9.6	0	0.0	0	0.0	0	0.0	0	0.0
2003														
missing	5	14.3	30	85.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
no	31	2.8	1015	93.3	39	3.6	2	0.2	1	0.1	0	0.0	0	0.0
yes	0	0.0	55	96.5	1	1.8	1	1.8	0	0.0	0	0.0	0	0.0
not examined/unknown	5	4.7	100	93.5	2	1.9	0	0.0	0	0.0	0	0.0	0	0.0
all	41	3.2	1200	93.2	42	3.3	3	0.2	1	0.1	0	0.0	0	0.0
2004														
missing	11	18.3	45	75.0	3	5.0	1	1.7	0	0.0	0	0.0	0	0.0
no	62	3.2	1797	93.7	57	3.0	2	0.1	0	0.0	0	0.0	0	0.0
yes	2	2.9	63	92.6	3	4.4	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	2	1.2	158	97.5	2	1.2	0	0.0	0	0.0	0	0.0	0	0.0
all	77	3.5	2063	93.4	65	2.9	3	0.1	0	0.0	0	0.0	0	0.0
2005														
missing	12	10.0	105	87.5	3	2.5	0	0.0	0	0.0	0	0.0	0	0.0
no	112	4.4	2372	92.7	72	2.8	3	0.1	0	0.0	1	0.0	0	0.0
yes	6	3.8	148	93.1	5	3.1	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	1	0.6	150	93.2	10	6.2	0	0.0	0	0.0	0	0.0	0	0.0
all	131	4.4	2775	92.5	90	3.0	3	0.1	0	0.0	1	0.0	0	0.0
2006														
missing	23	17.6	102	77.9	6	4.6	0	0.0	0	0.0	0	0.0	0	0.0
no	105	3.6	2704	93.9	62	2.2	5	0.2	0	0.0	0	0.0	1	0.0
yes	10	6.8	133	91.1	3	2.1	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	6	3.3	170	93.4	4	2.2	1	0.5	0	0.0	0	0.0	1	0.5
all	144	4.3	3109	93.1	75	2.2	6	0.2	0	0.0	0	0.0	2	0.1

(Continued)

Immuno deficiency	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
all														
missing	155	12.9	947	79.1	94	7.9	1	0.1	0	0.0	0	0.0	0	0.0
no	310	3.7	7888	93.4	230	2.7	12	0.1	1	0.0	1	0.0	1	0.0
yes	18	4.2	401	92.8	12	2.8	1	0.2	0	0.0	0	0.0	0	0.0
not examined/unknown	14	2.3	578	94.4	18	2.9	1	0.2	0	0.0	0	0.0	1	0.2
all	497	4.7	9814	91.8	354	3.3	15	0.1	1	0.0	1	0.0	2	0.0

(Continued)

Tab 8.5.1: Subgroup analyses for hospitalization
by immuno deficiency
including missing
evaluable population (EVP)

Immuno deficiency	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
2002						
missing	0	0.0	0	0.0	851	100.0
no	0	0	0	0	0	0
yes	0	0.0	0	0.0	2	100.0
not examined/unknown	0	0	0	0	0	0
all	0	0.0	0	0.0	853	100.0
2003						
missing	0	0.0	0	0.0	35	100.0
no	0	0.0	0	0.0	1088	100.0
yes	0	0.0	0	0.0	57	100.0
not examined/unknown	0	0.0	0	0.0	107	100.0
all	0	0.0	0	0.0	1287	100.0
2004						
missing	0	0.0	0	0.0	60	100.0
no	0	0.0	0	0.0	1918	100.0
yes	0	0.0	0	0.0	68	100.0
not examined/unknown	0	0.0	0	0.0	162	100.0
all	0	0.0	0	0.0	2208	100.0
2005						
missing	0	0.0	0	0.0	120	100.0
no	0	0.0	0	0.0	2560	100.0
yes	0	0.0	0	0.0	159	100.0
not examined/unknown	0	0.0	0	0.0	161	100.0
all	0	0.0	0	0.0	3000	100.0
2006						
missing	0	0.0	0	0.0	131	100.0
no	1	0.0	1	0.0	2879	100.0
yes	0	0.0	0	0.0	146	100.0
not examined/unknown	0	0.0	0	0.0	182	100.0

(Continued)

Tab 8.5.1: Subgroup analyses for hospitalization
by immuno deficiency
including missing
evaluable population (EVP)

Immuno deficiency	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
2006						
all	1	0.0	1	0.0	3338	100.0
all						
missing	0	0.0	0	0.0	1197	100.0
no	1	0.0	1	0.0	8445	100.0
yes	0	0.0	0	0.0	432	100.0
not examined/unknown	0	0.0	0	0.0	612	100.0
all	1	0.0	1	0.0	10686	100.0

Tab 8.5.2: Subgroup analyses for hospitalization
by immuno deficiency
excluding missing
evaluable population (EVP)

Immuno deficiency	Number of hospitalizations/patient													
	0		1		2		3		4		5		6	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002														
no	0	0	0	0	0	0	0	0	0	0	0	0	0	0
yes	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	0	0	0	0	0	0	0	0	0	0	0	0	0	0
all	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2003														
no	1015	96.0	39	3.7	2	0.2	1	0.1	0	0.0	0	0.0	0	0.0
yes	55	96.5	1	1.8	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	100	98.0	2	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	1170	96.2	42	3.5	3	0.2	1	0.1	0	0.0	0	0.0	0	0.0
2004														
no	1797	96.8	57	3.1	2	0.1	0	0.0	0	0.0	0	0.0	0	0.0
yes	63	95.5	3	4.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	158	98.8	2	1.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	2018	96.9	62	3.0	2	0.1	0	0.0	0	0.0	0	0.0	0	0.0
2005														
no	2372	96.9	72	2.9	3	0.1	0	0.0	1	0.0	0	0.0	0	0.0
yes	148	96.7	5	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	150	93.8	10	6.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	2670	96.7	87	3.2	3	0.1	0	0.0	1	0.0	0	0.0	0	0.0
2006														
no	2704	97.5	62	2.2	5	0.2	0	0.0	0	0.0	1	0.0	1	0.0
yes	133	97.8	3	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	170	96.6	4	2.3	1	0.6	0	0.0	0	0.0	1	0.6	0	0.0
all	3007	97.4	69	2.2	6	0.2	0	0.0	0	0.0	2	0.1	1	0.0
all														
no	7888	97.0	230	2.8	12	0.1	1	0.0	1	0.0	1	0.0	1	0.0
yes	401	96.9	12	2.9	1	0.2	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	578	96.7	18	3.0	1	0.2	0	0.0	0	0.0	1	0.2	0	0.0
all	8867	96.9	260	2.8	14	0.2	1	0.0	1	0.0	2	0.0	1	0.0

(Continued)

Tab 8.5.2: Subgroup analyses for hospitalization
by immuno deficiency
excluding missing
evaluable population (EVP)

Immuno deficiency	Number of hospitalizations/patient			
	8		all	
	n	%	n	%
Germany				
2002				
no	0	0	0	0
yes	0	0.0	2	100.0
not examined/unknown	0	0	0	0
all	0	0.0	2	100.0
2003				
no	0	0.0	1057	100.0
yes	0	0.0	57	100.0
not examined/unknown	0	0.0	102	100.0
all	0	0.0	1216	100.0
2004				
no	0	0.0	1856	100.0
yes	0	0.0	66	100.0
not examined/unknown	0	0.0	160	100.0
all	0	0.0	2082	100.0
2005				
no	0	0.0	2448	100.0
yes	0	0.0	153	100.0
not examined/unknown	0	0.0	160	100.0
all	0	0.0	2761	100.0
2006				
no	1	0.0	2774	100.0
yes	0	0.0	136	100.0
not examined/unknown	0	0.0	176	100.0
all	1	0.0	3086	100.0
all				
no	1	0.0	8135	100.0

(Continued)

Tab 8.5.2: Subgroup analyses for hospitalization
by immuno deficiency
excluding missing
evaluable population (EVP)

Immuno deficiency	Number of hospitalizations/patient			
	8		all	
	n	%	n	%
Germany				
all				
yes	0	0.0	414	100.0
not examined/unknown	0	0.0	598	100.0
all	1	0.0	9147	100.0

Tab 8.6.1: Subgroup analyses for hospitalization
by attending daycare
including missing
evaluable population (EVP)

Attending daycare	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002														
missing	104	12.2	667	78.2	82	9.6	0	0.0	0	0.0	0	0.0	0	0.0
no	0	0	0	0	0	0	0	0	0	0	0	0	0	0
yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
not examined/unknown	0	0	0	0	0	0	0	0	0	0	0	0	0	0
all	104	12.2	667	78.2	82	9.6	0	0.0	0	0.0	0	0.0	0	0.0
2003														
missing	2	50.0	2	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
no	38	3.0	1180	93.4	42	3.3	3	0.2	1	0.1	0	0.0	0	0.0
yes	1	6.7	14	93.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	0	0.0	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	41	3.2	1200	93.2	42	3.3	3	0.2	1	0.1	0	0.0	0	0.0
2004														
missing	0	0.0	7	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
no	75	3.5	2000	93.5	62	2.9	3	0.1	0	0.0	0	0.0	0	0.0
yes	2	3.6	50	90.9	3	5.5	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	0	0.0	6	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	77	3.5	2063	93.4	65	2.9	3	0.1	0	0.0	0	0.0	0	0.0
2005														
missing	2	7.7	24	92.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
no	125	4.3	2676	92.5	87	3.0	3	0.1	0	0.0	1	0.0	0	0.0
yes	3	4.4	63	92.6	2	2.9	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	1	7.1	12	85.7	1	7.1	0	0.0	0	0.0	0	0.0	0	0.0
all	131	4.4	2775	92.5	90	3.0	3	0.1	0	0.0	1	0.0	0	0.0
2006														
missing	3	9.4	29	90.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
no	126	4.0	2981	93.6	70	2.2	6	0.2	0	0.0	0	0.0	2	0.1
yes	8	7.8	89	87.3	4	3.9	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	7	38.9	10	55.6	1	5.6	0	0.0	0	0.0	0	0.0	0	0.0
all	144	4.3	3109	93.1	75	2.2	6	0.2	0	0.0	0	0.0	2	0.1

(Continued)

Tab 8.6.1: Subgroup analyses for hospitalization
by attending daycare
including missing
evaluable population (EVP)

Attending daycare	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
all														
missing	111	12.0	729	79.1	82	8.9	0	0.0	0	0.0	0	0.0	0	0.0
no	364	3.8	8837	93.2	261	2.8	15	0.2	1	0.0	1	0.0	2	0.0
yes	14	5.8	216	90.0	9	3.8	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	8	19.0	32	76.2	2	4.8	0	0.0	0	0.0	0	0.0	0	0.0
all	497	4.7	9814	91.8	354	3.3	15	0.1	1	0.0	1	0.0	2	0.0

(Continued)

Tab 8.6.1: Subgroup analyses for hospitalization
by attending daycare
including missing
evaluable population (EVP)

Attending daycare	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
2002						
missing	0	0.0	0	0.0	853	100.0
no	0	0	0	0	0	0
yes	0	0	0	0	0	0
not examined/unknown	0	0	0	0	0	0
all	0	0.0	0	0.0	853	100.0
2003						
missing	0	0.0	0	0.0	4	100.0
no	0	0.0	0	0.0	1264	100.0
yes	0	0.0	0	0.0	15	100.0
not examined/unknown	0	0.0	0	0.0	4	100.0
all	0	0.0	0	0.0	1287	100.0
2004						
missing	0	0.0	0	0.0	7	100.0
no	0	0.0	0	0.0	2140	100.0
yes	0	0.0	0	0.0	55	100.0
not examined/unknown	0	0.0	0	0.0	6	100.0
all	0	0.0	0	0.0	2208	100.0
2005						
missing	0	0.0	0	0.0	26	100.0
no	0	0.0	0	0.0	2892	100.0
yes	0	0.0	0	0.0	68	100.0
not examined/unknown	0	0.0	0	0.0	14	100.0
all	0	0.0	0	0.0	3000	100.0
2006						
missing	0	0.0	0	0.0	32	100.0
no	0	0.0	1	0.0	3186	100.0
yes	1	1.0	0	0.0	102	100.0
not examined/unknown	0	0.0	0	0.0	18	100.0

(Continued)

Tab 8.6.1: Subgroup analyses for hospitalization
by attending daycare
including missing
evaluable population (EVP)

Attending daycare	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
2006						
all	1	0.0	1	0.0	3338	100.0
all						
missing	0	0.0	0	0.0	922	100.0
no	0	0.0	1	0.0	9482	100.0
yes	1	0.4	0	0.0	240	100.0
not examined/unknown	0	0.0	0	0.0	42	100.0
all	1	0.0	1	0.0	10686	100.0

Tab 8.6.2: Subgroup analyses for hospitalization
by attending daycare
excluding missing
evaluable population (EVP)

Attending daycare	Number of hospitalizations/patient													
	0		1		2		3		4		5		6	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2003														
no	1180	96.2	42	3.4	3	0.2	1	0.1	0	0.0	0	0.0	0	0.0
yes	14	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	1198	96.3	42	3.4	3	0.2	1	0.1	0	0.0	0	0.0	0	0.0
2004														
no	2000	96.9	62	3.0	3	0.1	0	0.0	0	0.0	0	0.0	0	0.0
yes	50	94.3	3	5.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	6	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	2056	96.8	65	3.1	3	0.1	0	0.0	0	0.0	0	0.0	0	0.0
2005														
no	2676	96.7	87	3.1	3	0.1	0	0.0	1	0.0	0	0.0	0	0.0
yes	63	96.9	2	3.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	12	92.3	1	7.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	2751	96.7	90	3.2	3	0.1	0	0.0	1	0.0	0	0.0	0	0.0
2006														
no	2981	97.4	70	2.3	6	0.2	0	0.0	0	0.0	2	0.1	0	0.0
yes	89	94.7	4	4.3	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
not examined/unknown	10	90.9	1	9.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	3080	97.3	75	2.4	6	0.2	0	0.0	0	0.0	2	0.1	1	0.0
all														
no	8837	96.9	261	2.9	15	0.2	1	0.0	1	0.0	2	0.0	0	0.0
yes	216	95.6	9	4.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.4
not examined/unknown	32	94.1	2	5.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	9085	96.9	272	2.9	15	0.2	1	0.0	1	0.0	2	0.0	1	0.0

(Continued)

Tab 8.6.2: Subgroup analyses for hospitalization
by attending daycare
excluding missing
evaluable population (EVP)

Attending daycare	Number of hospitalizations/patient: 8		all	
	n	%	n	%
Germany				
2003				
no	0	0.0	1226	100.0
yes	0	0.0	14	100.0
not examined/unknown	0	0.0	4	100.0
all	0	0.0	1244	100.0
2004				
no	0	0.0	2065	100.0
yes	0	0.0	53	100.0
not examined/unknown	0	0.0	6	100.0
all	0	0.0	2124	100.0
2005				
no	0	0.0	2767	100.0
yes	0	0.0	65	100.0
not examined/unknown	0	0.0	13	100.0
all	0	0.0	2845	100.0
2006				
no	1	0.0	3060	100.0
yes	0	0.0	94	100.0
not examined/unknown	0	0.0	11	100.0
all	1	0.0	3165	100.0
all				
no	1	0.0	9118	100.0
yes	0	0.0	226	100.0
not examined/unknown	0	0.0	34	100.0
all	1	0.0	9378	100.0

Children <12 years in household	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002														
missing	104	12.2	667	78.2	82	9.6	0	0.0	0	0.0	0	0.0	0	0.0
no	0	0	0	0	0	0	0	0	0	0	0	0	0	0
yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
not examined/unknown	0	0	0	0	0	0	0	0	0	0	0	0	0	0
all	104	12.2	667	78.2	82	9.6	0	0.0	0	0.0	0	0.0	0	0.0
2003														
missing	0	0.0	3	75.0	1	25.0	0	0.0	0	0.0	0	0.0	0	0.0
no	16	2.2	683	95.7	13	1.8	1	0.1	1	0.1	0	0.0	0	0.0
yes	25	4.5	501	90.1	28	5.0	2	0.4	0	0.0	0	0.0	0	0.0
not examined/unknown	0	0.0	13	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	41	3.2	1200	93.2	42	3.3	3	0.2	1	0.1	0	0.0	0	0.0
2004														
missing	0	0.0	11	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
no	45	3.8	1103	94.0	24	2.0	1	0.1	0	0.0	0	0.0	0	0.0
yes	31	3.1	929	92.7	40	4.0	2	0.2	0	0.0	0	0.0	0	0.0
not examined/unknown	1	4.5	20	90.9	1	4.5	0	0.0	0	0.0	0	0.0	0	0.0
all	77	3.5	2063	93.4	65	2.9	3	0.1	0	0.0	0	0.0	0	0.0
2005														
missing	3	10.3	26	89.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
no	75	4.8	1456	93.0	30	1.9	3	0.2	0	0.0	1	0.1	0	0.0
yes	49	3.5	1274	92.1	60	4.3	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	4	17.4	19	82.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	131	4.4	2775	92.5	90	3.0	3	0.1	0	0.0	1	0.0	0	0.0
2006														
missing	2	7.4	25	92.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
no	67	3.8	1669	94.3	29	1.6	2	0.1	0	0.0	0	0.0	2	0.1
yes	73	4.9	1375	91.7	46	3.1	4	0.3	0	0.0	0	0.0	0	0.0
not examined/unknown	2	4.8	40	95.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	144	4.3	3109	93.1	75	2.2	6	0.2	0	0.0	0	0.0	2	0.1

(Continued)

Tab 8.7.1: Subgroup analyses for hospitalization
by children <12 years in household
including missing
evaluable population (EVP)

Children <12 years in household	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
all														
missing	109	11.8	732	79.2	83	9.0	0	0.0	0	0.0	0	0.0	0	0.0
no	203	3.9	4911	94.0	96	1.8	7	0.1	1	0.0	1	0.0	2	0.0
yes	178	4.0	4079	91.9	174	3.9	8	0.2	0	0.0	0	0.0	0	0.0
not examined/unknown	7	7.0	92	92.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0
all	497	4.7	9814	91.8	354	3.3	15	0.1	1	0.0	1	0.0	2	0.0

(Continued)

Tab 8.7.1: Subgroup analyses for hospitalization
by children <12 years in household
including missing
evaluable population (EVP)

Children <12 years in household	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
2002						
missing	0	0.0	0	0.0	853	100.0
no	0	0	0	0	0	0
yes	0	0	0	0	0	0
not examined/unknown	0	0	0	0	0	0
all	0	0.0	0	0.0	853	100.0
2003						
missing	0	0.0	0	0.0	4	100.0
no	0	0.0	0	0.0	714	100.0
yes	0	0.0	0	0.0	556	100.0
not examined/unknown	0	0.0	0	0.0	13	100.0
all	0	0.0	0	0.0	1287	100.0
2004						
missing	0	0.0	0	0.0	11	100.0
no	0	0.0	0	0.0	1173	100.0
yes	0	0.0	0	0.0	1002	100.0
not examined/unknown	0	0.0	0	0.0	22	100.0
all	0	0.0	0	0.0	2208	100.0
2005						
missing	0	0.0	0	0.0	29	100.0
no	0	0.0	0	0.0	1565	100.0
yes	0	0.0	0	0.0	1383	100.0
not examined/unknown	0	0.0	0	0.0	23	100.0
all	0	0.0	0	0.0	3000	100.0
2006						
missing	0	0.0	0	0.0	27	100.0
no	0	0.0	1	0.1	1770	100.0
yes	1	0.1	0	0.0	1499	100.0
not examined/unknown	0	0.0	0	0.0	42	100.0

(Continued)

Tab 8.7.1: Subgroup analyses for hospitalization
by children <12 years in household
including missing
evaluable population (EVP)

Children <12 years in household	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
2006						
all	1	0.0	1	0.0	3338	100.0
all						
missing	0	0.0	0	0.0	924	100.0
no	0	0.0	1	0.0	5222	100.0
yes	1	0.0	0	0.0	4440	100.0
not examined/unknown	0	0.0	0	0.0	100	100.0
all	1	0.0	1	0.0	10686	100.0

Tab 8.7.2: Subgroup analyses for hospitalization
by children <12 years in household
excluding missing
evaluable population (EVP)

Children <12 years in household	Number of hospitalizations/patient													
	0		1		2		3		4		5		6	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2003														
no	683	97.9	13	1.9	1	0.1	1	0.1	0	0.0	0	0.0	0	0.0
yes	501	94.4	28	5.3	2	0.4	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	13	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	1197	96.4	41	3.3	3	0.2	1	0.1	0	0.0	0	0.0	0	0.0
2004														
no	1103	97.8	24	2.1	1	0.1	0	0.0	0	0.0	0	0.0	0	0.0
yes	929	95.7	40	4.1	2	0.2	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	20	95.2	1	4.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	2052	96.8	65	3.1	3	0.1	0	0.0	0	0.0	0	0.0	0	0.0
2005														
no	1456	97.7	30	2.0	3	0.2	0	0.0	1	0.1	0	0.0	0	0.0
yes	1274	95.5	60	4.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	19	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	2749	96.7	90	3.2	3	0.1	0	0.0	1	0.0	0	0.0	0	0.0
2006														
no	1669	98.0	29	1.7	2	0.1	0	0.0	0	0.0	2	0.1	0	0.0
yes	1375	96.4	46	3.2	4	0.3	0	0.0	0	0.0	0	0.0	1	0.1
not examined/unknown	40	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	3084	97.3	75	2.4	6	0.2	0	0.0	0	0.0	2	0.1	1	0.0
all														
no	4911	97.8	96	1.9	7	0.1	1	0.0	1	0.0	2	0.0	0	0.0
yes	4079	95.7	174	4.1	8	0.2	0	0.0	0	0.0	0	0.0	1	0.0
not examined/unknown	92	98.9	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	9082	96.9	271	2.9	15	0.2	1	0.0	1	0.0	2	0.0	1	0.0

(Continued)

Tab 8.7.2: Subgroup analyses for hospitalization
by children <12 years in household
excluding missing
evaluable population (EVP)

Children <12 years in household	Number of hospitalizations/patient			
	8		all	
	n	%	n	%
Germany				
2003				
no	0	0.0	698	100.0
yes	0	0.0	531	100.0
not examined/unknown	0	0.0	13	100.0
all	0	0.0	1242	100.0
2004				
no	0	0.0	1128	100.0
yes	0	0.0	971	100.0
not examined/unknown	0	0.0	21	100.0
all	0	0.0	2120	100.0
2005				
no	0	0.0	1490	100.0
yes	0	0.0	1334	100.0
not examined/unknown	0	0.0	19	100.0
all	0	0.0	2843	100.0
2006				
no	1	0.1	1703	100.0
yes	0	0.0	1426	100.0
not examined/unknown	0	0.0	40	100.0
all	1	0.0	3169	100.0
all				
no	1	0.0	5019	100.0
yes	0	0.0	4262	100.0
not examined/unknown	0	0.0	93	100.0
all	1	0.0	9374	100.0

Tab 8.8.1: Subgroup analyses for hospitalization
by smoking in the family
including missing
evaluable population (EVP)

Smoking in the family	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002														
missing	104	12.5	647	77.9	80	9.6	0	0.0	0	0.0	0	0.0	0	0.0
no	0	0	0	0	0	0	0	0	0	0	0	0	0	0
yes	0	0.0	20	90.9	2	9.1	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	0	0	0	0	0	0	0	0	0	0	0	0	0	0
all	104	12.2	667	78.2	82	9.6	0	0.0	0	0.0	0	0.0	0	0.0
2003														
missing	3	9.7	28	90.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
no	26	3.0	799	92.8	32	3.7	3	0.3	1	0.1	0	0.0	0	0.0
yes	5	2.3	205	94.5	7	3.2	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	7	3.9	168	94.4	3	1.7	0	0.0	0	0.0	0	0.0	0	0.0
all	41	3.2	1200	93.2	42	3.3	3	0.2	1	0.1	0	0.0	0	0.0
2004														
missing	1	2.2	44	95.7	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0
no	47	3.2	1394	93.9	43	2.9	1	0.1	0	0.0	0	0.0	0	0.0
yes	14	4.2	309	91.7	12	3.6	2	0.6	0	0.0	0	0.0	0	0.0
not examined/unknown	15	4.4	316	92.9	9	2.6	0	0.0	0	0.0	0	0.0	0	0.0
all	77	3.5	2063	93.4	65	2.9	3	0.1	0	0.0	0	0.0	0	0.0
2005														
missing	11	10.6	90	86.5	3	2.9	0	0.0	0	0.0	0	0.0	0	0.0
no	78	3.8	1899	93.1	60	2.9	2	0.1	0	0.0	0	0.0	0	0.0
yes	17	4.1	379	92.2	14	3.4	0	0.0	0	0.0	1	0.2	0	0.0
not examined/unknown	25	5.6	407	91.3	13	2.9	1	0.2	0	0.0	0	0.0	0	0.0
all	131	4.4	2775	92.5	90	3.0	3	0.1	0	0.0	1	0.0	0	0.0
2006														
missing	15	12.9	100	86.2	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0
no	78	3.5	2109	94.3	45	2.0	2	0.1	0	0.0	0	0.0	1	0.0
yes	19	4.2	420	91.9	15	3.3	2	0.4	0	0.0	0	0.0	0	0.0
not examined/unknown	32	6.0	480	90.7	14	2.6	2	0.4	0	0.0	0	0.0	1	0.2
all	144	4.3	3109	93.1	75	2.2	6	0.2	0	0.0	0	0.0	2	0.1

(Continued)

Tab 8.8.1: Subgroup analyses for hospitalization
by smoking in the family
including missing
evaluable population (EVP)

Smoking in the family	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
all														
missing	134	11.9	909	80.6	85	7.5	0	0.0	0	0.0	0	0.0	0	0.0
no	229	3.5	6201	93.7	180	2.7	8	0.1	1	0.0	0	0.0	1	0.0
yes	55	3.8	1333	92.3	50	3.5	4	0.3	0	0.0	1	0.1	0	0.0
not examined/unknown	79	5.3	1371	91.8	39	2.6	3	0.2	0	0.0	0	0.0	1	0.1
all	497	4.7	9814	91.8	354	3.3	15	0.1	1	0.0	1	0.0	2	0.0

(Continued)

Tab 8.8.1: Subgroup analyses for hospitalization
by smoking in the family
including missing
evaluable population (EVP)

Smoking in the family	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
2002						
missing	0	0.0	0	0.0	831	100.0
no	0	0	0	0	0	0
yes	0	0.0	0	0.0	22	100.0
not examined/unknown	0	0	0	0	0	0
all	0	0.0	0	0.0	853	100.0
2003						
missing	0	0.0	0	0.0	31	100.0
no	0	0.0	0	0.0	861	100.0
yes	0	0.0	0	0.0	217	100.0
not examined/unknown	0	0.0	0	0.0	178	100.0
all	0	0.0	0	0.0	1287	100.0
2004						
missing	0	0.0	0	0.0	46	100.0
no	0	0.0	0	0.0	1485	100.0
yes	0	0.0	0	0.0	337	100.0
not examined/unknown	0	0.0	0	0.0	340	100.0
all	0	0.0	0	0.0	2208	100.0
2005						
missing	0	0.0	0	0.0	104	100.0
no	0	0.0	0	0.0	2039	100.0
yes	0	0.0	0	0.0	411	100.0
not examined/unknown	0	0.0	0	0.0	446	100.0
all	0	0.0	0	0.0	3000	100.0
2006						
missing	0	0.0	0	0.0	116	100.0
no	0	0.0	1	0.0	2236	100.0
yes	1	0.2	0	0.0	457	100.0
not examined/unknown	0	0.0	0	0.0	529	100.0

(Continued)

Tab 8.8.1: Subgroup analyses for hospitalization
by smoking in the family
including missing
evaluable population (EVP)

Smoking in the family	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
2006						
all	1	0.0	1	0.0	3338	100.0
all						
missing	0	0.0	0	0.0	1128	100.0
no	0	0.0	1	0.0	6621	100.0
yes	1	0.1	0	0.0	1444	100.0
not examined/unknown	0	0.0	0	0.0	1493	100.0
all	1	0.0	1	0.0	10686	100.0

Tab 8.8.2: Subgroup analyses for hospitalization
by smoking in the family
excluding missing
evaluable population (EVP)

Smoking in the family	Number of hospitalizations/patient													
	0		1		2		3		4		5		6	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002														
no	0	0	0	0	0	0	0	0	0	0	0	0	0	0
yes	20	90.9	2	9.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	0	0	0	0	0	0	0	0	0	0	0	0	0	0
all	20	90.9	2	9.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2003														
no	799	95.7	32	3.8	3	0.4	1	0.1	0	0.0	0	0.0	0	0.0
yes	205	96.7	7	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	168	98.2	3	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	1172	96.2	42	3.4	3	0.2	1	0.1	0	0.0	0	0.0	0	0.0
2004														
no	1394	96.9	43	3.0	1	0.1	0	0.0	0	0.0	0	0.0	0	0.0
yes	309	95.7	12	3.7	2	0.6	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	316	97.2	9	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	2019	96.8	64	3.1	3	0.1	0	0.0	0	0.0	0	0.0	0	0.0
2005														
no	1899	96.8	60	3.1	2	0.1	0	0.0	0	0.0	0	0.0	0	0.0
yes	379	96.2	14	3.6	0	0.0	0	0.0	1	0.3	0	0.0	0	0.0
not examined/unknown	407	96.7	13	3.1	1	0.2	0	0.0	0	0.0	0	0.0	0	0.0
all	2685	96.7	87	3.1	3	0.1	0	0.0	1	0.0	0	0.0	0	0.0
2006														
no	2109	97.7	45	2.1	2	0.1	0	0.0	0	0.0	1	0.0	0	0.0
yes	420	95.9	15	3.4	2	0.5	0	0.0	0	0.0	0	0.0	1	0.2
not examined/unknown	480	96.6	14	2.8	2	0.4	0	0.0	0	0.0	1	0.2	0	0.0
all	3009	97.3	74	2.4	6	0.2	0	0.0	0	0.0	2	0.1	1	0.0
all														
no	6201	97.0	180	2.8	8	0.1	1	0.0	0	0.0	1	0.0	0	0.0
yes	1333	96.0	50	3.6	4	0.3	0	0.0	1	0.1	0	0.0	1	0.1
not examined/unknown	1371	97.0	39	2.8	3	0.2	0	0.0	0	0.0	1	0.1	0	0.0
all	8905	96.8	269	2.9	15	0.2	1	0.0	1	0.0	2	0.0	1	0.0

(Continued)

Tab 8.8.2: Subgroup analyses for hospitalization
by smoking in the family
excluding missing
evaluable population (EVP)

Smoking in the family	Number of hospitalizations/patient			
	8		all	
	n	%	n	%
Germany				
2002				
no	0	0	0	0
yes	0	0.0	22	100.0
not examined/unknown	0	0	0	0
all	0	0.0	22	100.0
2003				
no	0	0.0	835	100.0
yes	0	0.0	212	100.0
not examined/unknown	0	0.0	171	100.0
all	0	0.0	1218	100.0
2004				
no	0	0.0	1438	100.0
yes	0	0.0	323	100.0
not examined/unknown	0	0.0	325	100.0
all	0	0.0	2086	100.0
2005				
no	0	0.0	1961	100.0
yes	0	0.0	394	100.0
not examined/unknown	0	0.0	421	100.0
all	0	0.0	2776	100.0
2006				
no	1	0.0	2158	100.0
yes	0	0.0	438	100.0
not examined/unknown	0	0.0	497	100.0
all	1	0.0	3093	100.0
all				
no	1	0.0	6392	100.0

(Continued)

Tab 8.8.2: Subgroup analyses for hospitalization
by smoking in the family
excluding missing
evaluable population (EVP)

Smoking in the family	Number of hospitalizations/patient			
	8		all	
	n	%	n	%
Germany				
all				
yes	0	0.0	1389	100.0
not examined/unknown	0	0.0	1414	100.0
all	1	0.0	9195	100.0

Tab 8.9.1: Subgroup analyses for hospitalization
by familiy history: asthma
including missing
evaluable population (EVP)

Familiy history: asthma	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002														
missing	104	12.3	663	78.2	81	9.6	0	0.0	0	0.0	0	0.0	0	0.0
no	0	0	0	0	0	0	0	0	0	0	0	0	0	0
yes	0	0.0	4	80.0	1	20.0	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	0	0	0	0	0	0	0	0	0	0	0	0	0	0
all	104	12.2	667	78.2	82	9.6	0	0.0	0	0.0	0	0.0	0	0.0
2003														
missing	3	6.8	39	88.6	2	4.5	0	0.0	0	0.0	0	0.0	0	0.0
no	25	2.6	890	93.7	31	3.3	3	0.3	1	0.1	0	0.0	0	0.0
yes	3	2.6	107	93.9	4	3.5	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	10	5.6	164	91.6	5	2.8	0	0.0	0	0.0	0	0.0	0	0.0
all	41	3.2	1200	93.2	42	3.3	3	0.2	1	0.1	0	0.0	0	0.0
2004														
missing	5	5.7	81	93.1	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0
no	52	3.3	1475	93.8	43	2.7	2	0.1	0	0.0	0	0.0	0	0.0
yes	5	2.6	173	91.1	12	6.3	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	15	4.2	334	93.0	10	2.8	0	0.0	0	0.0	0	0.0	0	0.0
all	77	3.5	2063	93.4	65	2.9	3	0.1	0	0.0	0	0.0	0	0.0
2005														
missing	4	4.6	79	90.8	4	4.6	0	0.0	0	0.0	0	0.0	0	0.0
no	91	4.2	2012	92.8	63	2.9	2	0.1	0	0.0	1	0.0	0	0.0
yes	8	3.2	235	93.6	8	3.2	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	28	5.7	449	91.1	15	3.0	1	0.2	0	0.0	0	0.0	0	0.0
all	131	4.4	2775	92.5	90	3.0	3	0.1	0	0.0	1	0.0	0	0.0
2006														
missing	12	10.0	106	88.3	2	1.7	0	0.0	0	0.0	0	0.0	0	0.0
no	78	3.3	2229	94.3	50	2.1	3	0.1	0	0.0	0	0.0	2	0.1
yes	10	3.7	248	92.5	8	3.0	1	0.4	0	0.0	0	0.0	0	0.0
not examined/unknown	44	7.5	526	89.6	15	2.6	2	0.3	0	0.0	0	0.0	0	0.0
all	144	4.3	3109	93.1	75	2.2	6	0.2	0	0.0	0	0.0	2	0.1

(Continued)

Tab 8.9.1: Subgroup analyses for hospitalization
by familiy history: asthma
including missing
evaluable population (EVP)

Familiy history: asthma	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
all														
missing	128	10.8	968	81.6	89	7.5	1	0.1	0	0.0	0	0.0	0	0.0
no	246	3.5	6606	93.6	187	2.7	10	0.1	1	0.0	1	0.0	2	0.0
yes	26	3.1	767	92.6	33	4.0	1	0.1	0	0.0	0	0.0	0	0.0
not examined/unknown	97	6.0	1473	91.0	45	2.8	3	0.2	0	0.0	0	0.0	0	0.0
all	497	4.7	9814	91.8	354	3.3	15	0.1	1	0.0	1	0.0	2	0.0

(Continued)

Tab 8.9.1: Subgroup analyses for hospitalization
by familiy history: asthma
including missing
evaluable population (EVP)

Familiy history: asthma	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
2002						
missing	0	0.0	0	0.0	848	100.0
no	0	0	0	0	0	0
yes	0	0.0	0	0.0	5	100.0
not examined/unknown	0	0	0	0	0	0
all	0	0.0	0	0.0	853	100.0
2003						
missing	0	0.0	0	0.0	44	100.0
no	0	0.0	0	0.0	950	100.0
yes	0	0.0	0	0.0	114	100.0
not examined/unknown	0	0.0	0	0.0	179	100.0
all	0	0.0	0	0.0	1287	100.0
2004						
missing	0	0.0	0	0.0	87	100.0
no	0	0.0	0	0.0	1572	100.0
yes	0	0.0	0	0.0	190	100.0
not examined/unknown	0	0.0	0	0.0	359	100.0
all	0	0.0	0	0.0	2208	100.0
2005						
missing	0	0.0	0	0.0	87	100.0
no	0	0.0	0	0.0	2169	100.0
yes	0	0.0	0	0.0	251	100.0
not examined/unknown	0	0.0	0	0.0	493	100.0
all	0	0.0	0	0.0	3000	100.0
2006						
missing	0	0.0	0	0.0	120	100.0
no	0	0.0	1	0.0	2363	100.0
yes	1	0.4	0	0.0	268	100.0
not examined/unknown	0	0.0	0	0.0	587	100.0

(Continued)

Tab 8.9.1: Subgroup analyses for hospitalization
by familiy history: asthma
including missing
evaluable population (EVP)

Familiy history: asthma	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
2006						
all	1	0.0	1	0.0	3338	100.0
all						
missing	0	0.0	0	0.0	1186	100.0
no	0	0.0	1	0.0	7054	100.0
yes	1	0.1	0	0.0	828	100.0
not examined/unknown	0	0.0	0	0.0	1618	100.0
all	1	0.0	1	0.0	10686	100.0

Tab 8.9.2: Subgroup analyses for hospitalization
by familiy history: asthma
excluding missing
evaluable population (EVP)

Familiy history: asthma	Number of hospitalizations/patient													
	0		1		2		3		4		5		6	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002														
no	0	0	0	0	0	0	0	0	0	0	0	0	0	0
yes	4	80.0	1	20.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	0	0	0	0	0	0	0	0	0	0	0	0	0	0
all	4	80.0	1	20.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2003														
no	890	96.2	31	3.4	3	0.3	1	0.1	0	0.0	0	0.0	0	0.0
yes	107	96.4	4	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	164	97.0	5	3.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	1161	96.3	40	3.3	3	0.2	1	0.1	0	0.0	0	0.0	0	0.0
2004														
no	1475	97.0	43	2.8	2	0.1	0	0.0	0	0.0	0	0.0	0	0.0
yes	173	93.5	12	6.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	334	97.1	10	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	1982	96.7	65	3.2	2	0.1	0	0.0	0	0.0	0	0.0	0	0.0
2005														
no	2012	96.8	63	3.0	2	0.1	0	0.0	1	0.0	0	0.0	0	0.0
yes	235	96.7	8	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	449	96.6	15	3.2	1	0.2	0	0.0	0	0.0	0	0.0	0	0.0
all	2696	96.8	86	3.1	3	0.1	0	0.0	1	0.0	0	0.0	0	0.0
2006														
no	2229	97.5	50	2.2	3	0.1	0	0.0	0	0.0	2	0.1	0	0.0
yes	248	96.1	8	3.1	1	0.4	0	0.0	0	0.0	0	0.0	1	0.4
not examined/unknown	526	96.9	15	2.8	2	0.4	0	0.0	0	0.0	0	0.0	0	0.0
all	3003	97.3	73	2.4	6	0.2	0	0.0	0	0.0	2	0.1	1	0.0
all														
no	6606	97.0	187	2.7	10	0.1	1	0.0	1	0.0	2	0.0	0	0.0
yes	767	95.6	33	4.1	1	0.1	0	0.0	0	0.0	0	0.0	1	0.1
not examined/unknown	1473	96.8	45	3.0	3	0.2	0	0.0	0	0.0	0	0.0	0	0.0
all	8846	96.9	265	2.9	14	0.2	1	0.0	1	0.0	2	0.0	1	0.0

(Continued)

Tab 8.9.2: Subgroup analyses for hospitalization
by familiy history: asthma
excluding missing
evaluable population (EVP)

Familiy history: asthma	Number of hospitalizations/patient			
	8		all	
	n	%	n	%
Germany				
2002				
no	0	0	0	0
yes	0	0.0	5	100.0
not examined/unknown	0	0	0	0
all	0	0.0	5	100.0
2003				
no	0	0.0	925	100.0
yes	0	0.0	111	100.0
not examined/unknown	0	0.0	169	100.0
all	0	0.0	1205	100.0
2004				
no	0	0.0	1520	100.0
yes	0	0.0	185	100.0
not examined/unknown	0	0.0	344	100.0
all	0	0.0	2049	100.0
2005				
no	0	0.0	2078	100.0
yes	0	0.0	243	100.0
not examined/unknown	0	0.0	465	100.0
all	0	0.0	2786	100.0
2006				
no	1	0.0	2285	100.0
yes	0	0.0	258	100.0
not examined/unknown	0	0.0	543	100.0
all	1	0.0	3086	100.0
all				
no	1	0.0	6808	100.0

(Continued)

Tab 8.9.2: Subgroup analyses for hospitalization
by familiy history: asthma
excluding missing
evaluable population (EVP)

Familiy history: asthma	Number of hospitalizations/patient			
	8		all	
	n	%	n	%
Germany				
all				
yes	0	0.0	802	100.0
not examined/unknown	0	0.0	1521	100.0
all	1	0.0	9131	100.0

Tab 8.10.1: Subgroup analyses for hospitalization
by familiy history: allergic rhinitis
including missing
evaluable population (EVP)

Familiy history: allergic rhinitis	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002														
missing	104	12.2	667	78.2	82	9.6	0	0.0	0	0.0	0	0.0	0	0.0
no	0	0	0	0	0	0	0	0	0	0	0	0	0	0
yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
not examined/unknown	0	0	0	0	0	0	0	0	0	0	0	0	0	0
all	104	12.2	667	78.2	82	9.6	0	0.0	0	0.0	0	0.0	0	0.0
2003														
missing	4	9.1	38	86.4	2	4.5	0	0.0	0	0.0	0	0.0	0	0.0
no	25	2.8	841	93.4	31	3.4	2	0.2	1	0.1	0	0.0	0	0.0
yes	4	2.5	150	94.3	4	2.5	1	0.6	0	0.0	0	0.0	0	0.0
not examined/unknown	8	4.3	171	92.9	5	2.7	0	0.0	0	0.0	0	0.0	0	0.0
all	41	3.2	1200	93.2	42	3.3	3	0.2	1	0.1	0	0.0	0	0.0
2004														
missing	4	5.1	73	93.6	0	0.0	1	1.3	0	0.0	0	0.0	0	0.0
no	53	3.7	1356	93.4	41	2.8	2	0.1	0	0.0	0	0.0	0	0.0
yes	5	1.7	278	93.9	13	4.4	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	15	3.9	356	93.2	11	2.9	0	0.0	0	0.0	0	0.0	0	0.0
all	77	3.5	2063	93.4	65	2.9	3	0.1	0	0.0	0	0.0	0	0.0
2005														
missing	5	5.9	77	90.6	3	3.5	0	0.0	0	0.0	0	0.0	0	0.0
no	83	4.1	1851	92.5	64	3.2	2	0.1	0	0.0	1	0.0	0	0.0
yes	13	3.2	383	95.3	6	1.5	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	30	5.9	464	90.6	17	3.3	1	0.2	0	0.0	0	0.0	0	0.0
all	131	4.4	2775	92.5	90	3.0	3	0.1	0	0.0	1	0.0	0	0.0
2006														
missing	14	12.1	100	86.2	2	1.7	0	0.0	0	0.0	0	0.0	0	0.0
no	67	3.0	2115	94.8	44	2.0	3	0.1	0	0.0	0	0.0	2	0.1
yes	22	5.8	340	90.2	14	3.7	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	41	6.7	554	90.4	15	2.4	3	0.5	0	0.0	0	0.0	0	0.0
all	144	4.3	3109	93.1	75	2.2	6	0.2	0	0.0	0	0.0	2	0.1

(Continued)

Tab 8.10.1: Subgroup analyses for hospitalization
by familiy history: allergic rhinitis
including missing
evaluable population (EVP)

Familiy history: allergic rhinitis	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
all														
missing	131	11.1	955	81.2	89	7.6	1	0.1	0	0.0	0	0.0	0	0.0
no	228	3.5	6163	93.6	180	2.7	9	0.1	1	0.0	1	0.0	2	0.0
yes	44	3.6	1151	93.3	37	3.0	1	0.1	0	0.0	0	0.0	0	0.0
not examined/unknown	94	5.6	1545	91.4	48	2.8	4	0.2	0	0.0	0	0.0	0	0.0
all	497	4.7	9814	91.8	354	3.3	15	0.1	1	0.0	1	0.0	2	0.0

(Continued)

Tab 8.10.1: Subgroup analyses for hospitalization
by familiy history: allergic rhinitis
including missing
evaluable population (EVP)

Familiy history: allergic rhinitis	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
2002						
missing	0	0.0	0	0.0	853	100.0
no	0	0	0	0	0	0
yes	0	0	0	0	0	0
not examined/unknown	0	0	0	0	0	0
all	0	0.0	0	0.0	853	100.0
2003						
missing	0	0.0	0	0.0	44	100.0
no	0	0.0	0	0.0	900	100.0
yes	0	0.0	0	0.0	159	100.0
not examined/unknown	0	0.0	0	0.0	184	100.0
all	0	0.0	0	0.0	1287	100.0
2004						
missing	0	0.0	0	0.0	78	100.0
no	0	0.0	0	0.0	1452	100.0
yes	0	0.0	0	0.0	296	100.0
not examined/unknown	0	0.0	0	0.0	382	100.0
all	0	0.0	0	0.0	2208	100.0
2005						
missing	0	0.0	0	0.0	85	100.0
no	0	0.0	0	0.0	2001	100.0
yes	0	0.0	0	0.0	402	100.0
not examined/unknown	0	0.0	0	0.0	512	100.0
all	0	0.0	0	0.0	3000	100.0
2006						
missing	0	0.0	0	0.0	116	100.0
no	0	0.0	1	0.0	2232	100.0
yes	1	0.3	0	0.0	377	100.0
not examined/unknown	0	0.0	0	0.0	613	100.0

(Continued)

Tab 8.10.1: Subgroup analyses for hospitalization
by familiy history: allergic rhinitis
including missing
evaluable population (EVP)

Familiy history: allergic rhinitis	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
2006						
all	1	0.0	1	0.0	3338	100.0
all						
missing	0	0.0	0	0.0	1176	100.0
no	0	0.0	1	0.0	6585	100.0
yes	1	0.1	0	0.0	1234	100.0
not examined/unknown	0	0.0	0	0.0	1691	100.0
all	1	0.0	1	0.0	10686	100.0

Tab 8.10.2: Subgroup analyses for hospitalization
by familiy history: allergic rhinitis
excluding missing
evaluable population (EVP)

Familiy history: allergic rhinitis	Number of hospitalizations/patient													
	0		1		2		3		4		5		6	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2003														
no	841	96.1	31	3.5	2	0.2	1	0.1	0	0.0	0	0.0	0	0.0
yes	150	96.8	4	2.6	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	171	97.2	5	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	1162	96.4	40	3.3	3	0.2	1	0.1	0	0.0	0	0.0	0	0.0
2004														
no	1356	96.9	41	2.9	2	0.1	0	0.0	0	0.0	0	0.0	0	0.0
yes	278	95.5	13	4.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	356	97.0	11	3.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	1990	96.7	65	3.2	2	0.1	0	0.0	0	0.0	0	0.0	0	0.0
2005														
no	1851	96.5	64	3.3	2	0.1	0	0.0	1	0.1	0	0.0	0	0.0
yes	383	98.5	6	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	464	96.3	17	3.5	1	0.2	0	0.0	0	0.0	0	0.0	0	0.0
all	2698	96.7	87	3.1	3	0.1	0	0.0	1	0.0	0	0.0	0	0.0
2006														
no	2115	97.7	44	2.0	3	0.1	0	0.0	0	0.0	2	0.1	0	0.0
yes	340	95.8	14	3.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.3
not examined/unknown	554	96.9	15	2.6	3	0.5	0	0.0	0	0.0	0	0.0	0	0.0
all	3009	97.3	73	2.4	6	0.2	0	0.0	0	0.0	2	0.1	1	0.0
all														
no	6163	96.9	180	2.8	9	0.1	1	0.0	1	0.0	2	0.0	0	0.0
yes	1151	96.7	37	3.1	1	0.1	0	0.0	0	0.0	0	0.0	1	0.1
not examined/unknown	1545	96.7	48	3.0	4	0.3	0	0.0	0	0.0	0	0.0	0	0.0
all	8859	96.9	265	2.9	14	0.2	1	0.0	1	0.0	2	0.0	1	0.0

(Continued)

Tab 8.10.2: Subgroup analyses for hospitalization
by familiy history: allergic rhinitis
excluding missing
evaluable population (EVP)

Familiy history: allergic rhinitis	Number of hospitalizations/patient			
	8		all	
	n	%	n	%
Germany				
2003				
no	0	0.0	875	100.0
yes	0	0.0	155	100.0
not examined/unknown	0	0.0	176	100.0
all	0	0.0	1206	100.0
2004				
no	0	0.0	1399	100.0
yes	0	0.0	291	100.0
not examined/unknown	0	0.0	367	100.0
all	0	0.0	2057	100.0
2005				
no	0	0.0	1918	100.0
yes	0	0.0	389	100.0
not examined/unknown	0	0.0	482	100.0
all	0	0.0	2789	100.0
2006				
no	1	0.0	2165	100.0
yes	0	0.0	355	100.0
not examined/unknown	0	0.0	572	100.0
all	1	0.0	3092	100.0
all				
no	1	0.0	6357	100.0
yes	0	0.0	1190	100.0
not examined/unknown	0	0.0	1597	100.0
all	1	0.0	9144	100.0

Tab 8.11.1: Subgroup analyses for hospitalization
by familiy history: allergic eczema
including missing
evaluable population (EVP)

Familiy history: allergic eczema	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2002														
missing	104	12.2	667	78.2	82	9.6	0	0.0	0	0.0	0	0.0	0	0.0
no	0	0	0	0	0	0	0	0	0	0	0	0	0	0
yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
not examined/unknown	0	0	0	0	0	0	0	0	0	0	0	0	0	0
all	104	12.2	667	78.2	82	9.6	0	0.0	0	0.0	0	0.0	0	0.0
2003														
missing	4	9.1	39	88.6	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0
no	25	2.6	894	93.7	32	3.4	3	0.3	0	0.0	0	0.0	0	0.0
yes	2	1.9	99	93.4	4	3.8	0	0.0	1	0.9	0	0.0	0	0.0
not examined/unknown	10	5.5	168	91.8	5	2.7	0	0.0	0	0.0	0	0.0	0	0.0
all	41	3.2	1200	93.2	42	3.3	3	0.2	1	0.1	0	0.0	0	0.0
2004														
missing	5	5.4	87	93.5	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0
no	49	3.1	1469	94.0	43	2.8	2	0.1	0	0.0	0	0.0	0	0.0
yes	8	4.6	156	90.2	9	5.2	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	15	4.0	351	92.6	13	3.4	0	0.0	0	0.0	0	0.0	0	0.0
all	77	3.5	2063	93.4	65	2.9	3	0.1	0	0.0	0	0.0	0	0.0
2005														
missing	5	5.6	81	91.0	3	3.4	0	0.0	0	0.0	0	0.0	0	0.0
no	90	4.2	2013	92.9	63	2.9	2	0.1	0	0.0	0	0.0	0	0.0
yes	5	2.4	199	94.3	6	2.8	0	0.0	0	0.0	1	0.5	0	0.0
not examined/unknown	31	5.8	482	90.6	18	3.4	1	0.2	0	0.0	0	0.0	0	0.0
all	131	4.4	2775	92.5	90	3.0	3	0.1	0	0.0	1	0.0	0	0.0
2006														
missing	14	9.9	124	87.9	3	2.1	0	0.0	0	0.0	0	0.0	0	0.0
no	82	3.5	2215	94.1	50	2.1	3	0.1	0	0.0	0	0.0	2	0.1
yes	5	2.2	210	94.2	7	3.1	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	43	6.9	560	90.2	15	2.4	3	0.5	0	0.0	0	0.0	0	0.0
all	144	4.3	3109	93.1	75	2.2	6	0.2	0	0.0	0	0.0	2	0.1

(Continued)

Tab 8.11.1: Subgroup analyses for hospitalization
by familiy history: allergic eczema
including missing
evaluable population (EVP)

Familiy history: allergic eczema	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
all														
missing	132	10.8	998	81.8	89	7.3	1	0.1	0	0.0	0	0.0	0	0.0
no	246	3.5	6591	93.6	188	2.7	10	0.1	0	0.0	0	0.0	2	0.0
yes	20	2.8	664	93.1	26	3.6	0	0.0	1	0.1	1	0.1	0	0.0
not examined/unknown	99	5.8	1561	91.0	51	3.0	4	0.2	0	0.0	0	0.0	0	0.0
all	497	4.7	9814	91.8	354	3.3	15	0.1	1	0.0	1	0.0	2	0.0

(Continued)

Tab 8.11.1: Subgroup analyses for hospitalization
by familiy history: allergic eczema
including missing
evaluable population (EVP)

Familiy history: allergic eczema	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
2002						
missing	0	0.0	0	0.0	853	100.0
no	0	0	0	0	0	0
yes	0	0	0	0	0	0
not examined/unknown	0	0	0	0	0	0
all	0	0.0	0	0.0	853	100.0
2003						
missing	0	0.0	0	0.0	44	100.0
no	0	0.0	0	0.0	954	100.0
yes	0	0.0	0	0.0	106	100.0
not examined/unknown	0	0.0	0	0.0	183	100.0
all	0	0.0	0	0.0	1287	100.0
2004						
missing	0	0.0	0	0.0	93	100.0
no	0	0.0	0	0.0	1563	100.0
yes	0	0.0	0	0.0	173	100.0
not examined/unknown	0	0.0	0	0.0	379	100.0
all	0	0.0	0	0.0	2208	100.0
2005						
missing	0	0.0	0	0.0	89	100.0
no	0	0.0	0	0.0	2168	100.0
yes	0	0.0	0	0.0	211	100.0
not examined/unknown	0	0.0	0	0.0	532	100.0
all	0	0.0	0	0.0	3000	100.0
2006						
missing	0	0.0	0	0.0	141	100.0
no	0	0.0	1	0.0	2353	100.0
yes	1	0.4	0	0.0	223	100.0
not examined/unknown	0	0.0	0	0.0	621	100.0

(Continued)

Tab 8.11.1: Subgroup analyses for hospitalization
by familiy history: allergic eczema
including missing
evaluable population (EVP)

Familiy history: allergic eczema	Number of hospitalizations/patient					
	6		8		all	
	n	%	n	%	n	%
Germany						
2006						
all	1	0.0	1	0.0	3338	100.0
all						
missing	0	0.0	0	0.0	1220	100.0
no	0	0.0	1	0.0	7038	100.0
yes	1	0.1	0	0.0	713	100.0
not examined/unknown	0	0.0	0	0.0	1715	100.0
all	1	0.0	1	0.0	10686	100.0

Tab 8.11.2: Subgroup analyses for hospitalization
by familiy history: allergic eczema
excluding missing
evaluable population (EVP)

Familiy history: allergic eczema	Number of hospitalizations/patient													
	0		1		2		3		4		5		6	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2003														
no	894	96.2	32	3.4	3	0.3	0	0.0	0	0.0	0	0.0	0	0.0
yes	99	95.2	4	3.8	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0
not examined/unknown	168	97.1	5	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	1161	96.3	41	3.4	3	0.2	1	0.1	0	0.0	0	0.0	0	0.0
2004														
no	1469	97.0	43	2.8	2	0.1	0	0.0	0	0.0	0	0.0	0	0.0
yes	156	94.5	9	5.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	351	96.4	13	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	1976	96.7	65	3.2	2	0.1	0	0.0	0	0.0	0	0.0	0	0.0
2005														
no	2013	96.9	63	3.0	2	0.1	0	0.0	0	0.0	0	0.0	0	0.0
yes	199	96.6	6	2.9	0	0.0	0	0.0	1	0.5	0	0.0	0	0.0
not examined/unknown	482	96.2	18	3.6	1	0.2	0	0.0	0	0.0	0	0.0	0	0.0
all	2694	96.7	87	3.1	3	0.1	0	0.0	1	0.0	0	0.0	0	0.0
2006														
no	2215	97.5	50	2.2	3	0.1	0	0.0	0	0.0	2	0.1	0	0.0
yes	210	96.3	7	3.2	0	0.0	0	0.0	0	0.0	0	0.0	1	0.5
not examined/unknown	560	96.9	15	2.6	3	0.5	0	0.0	0	0.0	0	0.0	0	0.0
all	2985	97.3	72	2.3	6	0.2	0	0.0	0	0.0	2	0.1	1	0.0
all														
no	6591	97.0	188	2.8	10	0.1	0	0.0	0	0.0	2	0.0	0	0.0
yes	664	95.8	26	3.8	0	0.0	1	0.1	1	0.1	0	0.0	1	0.1
not examined/unknown	1561	96.6	51	3.2	4	0.2	0	0.0	0	0.0	0	0.0	0	0.0
all	8816	96.9	265	2.9	14	0.2	1	0.0	1	0.0	2	0.0	1	0.0

(Continued)

Tab 8.11.2: Subgroup analyses for hospitalization
by familiy history: allergic eczema
excluding missing
evaluable population (EVP)

Familiy history: allergic eczema	Number of hospitalizations/patient			
	8		all	
	n	%	n	%
Germany				
2003				
no	0	0.0	929	100.0
yes	0	0.0	104	100.0
not examined/unknown	0	0.0	173	100.0
all	0	0.0	1206	100.0
2004				
no	0	0.0	1514	100.0
yes	0	0.0	165	100.0
not examined/unknown	0	0.0	364	100.0
all	0	0.0	2043	100.0
2005				
no	0	0.0	2078	100.0
yes	0	0.0	206	100.0
not examined/unknown	0	0.0	501	100.0
all	0	0.0	2785	100.0
2006				
no	1	0.0	2271	100.0
yes	0	0.0	218	100.0
not examined/unknown	0	0.0	578	100.0
all	1	0.0	3067	100.0
all				
no	1	0.0	6792	100.0
yes	0	0.0	693	100.0
not examined/unknown	0	0.0	1616	100.0
all	1	0.0	9101	100.0

Tab 9.1: Subgroup analyses for RSV complications
by premature birth and BPD
evaluable population (EVP)

Country	year	hosp. form	any RSV diag.	RSV test	Premature birth	BPD						all	
						missing		no		yes			
						n	%	n	%	n	%	n	%
Germany													
	all												
		yes											
			yes										
				positive									
					no	1	5.6	14	77.8	3	16.7	18	100.0
					yes	8	6.3	58	45.7	61	48.0	127	100.0
					all	9	6.2	72	49.7	64	44.1	145	100.0

Tab 9.2: Subgroup analyses for RSV complications
by cong. heart misfor.
evaluable population (EVP)

Country	year	hosp. form	any RSV diag.	RSV test	Cong. heart misfor.	n	%
Germany							
	all						
		yes					
			yes				
				positive			
					missing	4	100.0
					no	101	100.0
					yes	38	100.0
					not examined/unknown	2	100.0
					all	145	100.0

Tab 9.3: Subgroup analyses for RSV complications
by intensive care
evaluable population (EVP)

Country	year	hosp. form	any RSV diag.	RSV test	Intensive care	n	%
Germany							
	all						
		yes					
			yes				
				positive			
					missing	1	100.0
					no	81	100.0
					yes	47	100.0
					not examined/unknown	16	100.0
					all	145	100.0

Tab 9.4: Subgroup analyses for RSV complications
by supplementary oxygen
evaluable population (EVP)

Country	year	hosp. form	any RSV diag.	RSV test	Supplementary oxygen	n	%
Germany							
	all						
		yes					
			yes				
				positive			
					missing	1	100.0
					no	42	100.0
					yes	93	100.0
					not examined/unknown	9	100.0
					all	145	100.0

Tab 9.5: Subgroup analyses for RSV complications
by mechanical vetilation
evaluable population (EVP)

Country	year	hosp. form	any RSV diag.	RSV test	Mechanical vetilation	n	%
Germany							
	all						
		yes					
			yes				
				positive			
					missing	3	100.0
					no	126	100.0
					yes	14	100.0
					not examined/unknown	2	100.0
					all	145	100.0

A2.2.2 Source tables 2007/08

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Tab 1.1.1: Patient distribution
by center size
center identifiable

	Number of patients/center													
	1	2	3	4	5	6	7	8	9	10	11	12	13	all
Germany 2007	575	413	235	147	70	38	26	19	3	1	5	3	4	1539

Tab 1.1.2: Patient distribution
by center size
center not identifiable

	Center status			
	center identifiable	ZIP-code missing	ZIP-code present, doc. name missing	all
Germany 2007	3786	27	5	3818

Tab 1.2: Patient distribution
by region (first character)

	Number of patients in region																	
	0		1		2		3		4		5		6		7		8	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2007	698	18.28	518	13.57	213	5.58	412	10.79	393	10.29	398	10.42	326	8.54	180	4.71	239	6.26

(Continued)

	Number of patients in region				all	
	9		missing			
	n	%	n	%	n	%
Germany 2007	414	10.84	27	0.71	3818	100.00

Tab 1.3: Patient distribution
by evaluablity

	Number of patients		
	EVP	NEP	all
Germany 2007	3805	13	3818

Analysis population: EVP=evaluable population, NEP=non-evaluable population

Tab 1.4: Patient distribution
reasons for non-evaluability

	Number of patients with reason (1)	
	2	all
Germany 2007	13	13

(1) Reason 1: first Immunization not between 01-SEP and 31-MAY of the respective season
Reason 2: date of birth prior to 01-SEP-2005 or after 2008
Reason 3: Insufficient data

Tab 2.1.1: Patient characteristics
sex
including missing
evaluable population (EVP)

	Sex						all	
	missing		male		female			
	n	%	n	%	n	%	n	%
Germany								
2007	17	0.4	2051	53.9	1737	45.7	3805	100.0

Tab 2.1.2: Patient characteristics
sex
excluding missing
evaluable population (EVP)

	Sex					
	male		female		all	
	n	%	n	%	n	%
Germany						
2007	2051	54.1	1737	45.9	3788	100.0

Tab 2.2.1: Patient characteristics
gestational age [weeks]
statistics
evaluable population (EVP)

		n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2007	729	3076	29.87	3.62	27.00	30.00	32.00	22.0	42.0

Tab 2.2.2.1: Patient characteristics
gestational age [weeks]
classification
including missing
evaluable population (EVP)

	Gestational age										all	
	missing		<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2007	729	19.2	1173	30.8	1161	30.5	578	15.2	164	4.3	3805	100.0

Tab 2.2.2.2: Patient characteristics
gestational age [weeks]
classification
excluding missing
evaluable population (EVP)

	Gestational age								all	
	<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%
Germany 2007	1173	38.1	1161	37.7	578	18.8	164	5.3	3076	100.0

Tab 2.2.2.3: Patient characteristics
gestational age [weeks]
classification
frequencies by weeks (25-28)
evaluable population (EVP)

	Gestational age								all	
	25		26		27		28			
	n	%	n	%	n	%	n	%	n	%
Germany 2007	182	18.5	254	25.8	246	25.0	302	30.7	984	100.0

Tab 2.2.3.1: Patient characteristics
gestational age [weeks]
classification by risk of premature birth
including missing
evaluable population (EVP)

Premature birth	Gestational age										all	
	missing		<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%	n	%
Germany												
2007												
missing	23	100.0	0	0.0	0	0.0	0	0.0	0	0.0	23	100.0
no	468	94.7	0	0.0	0	0.0	0	0.0	26	5.3	494	100.0
yes	238	7.2	1173	35.7	1161	35.3	578	17.6	138	4.2	3288	100.0
all	729	19.2	1173	30.8	1161	30.5	578	15.2	164	4.3	3805	100.0

Tab 2.2.3.2: Patient characteristics
gestational age [weeks]
classification by risk of premature birth
excluding missing
evaluable population (EVP)

Premature birth	Gestational age								all	
	<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%
Germany										
2007										
no	0	0.0	0	0.0	0	0.0	26	0.8	26	0.8
yes	1173	38.1	1161	37.7	578	18.8	138	4.5	3050	99.2
all	1173	38.1	1161	37.7	578	18.8	164	5.3	3076	100.0

Tab 2.2.4.1: Patient characteristics
gestational age [weeks]
classification by risk of BPD
including missing
evaluable population (EVP)

BPD		Gestational age										all	
		missing		<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
		n	%	n	%	n	%	n	%	n	%	n	%
Germany													
2007													
	missing	95	31.3	71	23.4	81	26.6	47	15.5	10	3.3	304	100.0
	no	482	22.2	390	18.0	764	35.2	415	19.1	120	5.5	2171	100.0
	yes	152	11.4	712	53.5	316	23.8	116	8.7	34	2.6	1330	100.0
	all	729	19.2	1173	30.8	1161	30.5	578	15.2	164	4.3	3805	100.0

Tab 2.2.4.2: Patient characteristics
gestational age [weeks]
classification by risk of BPD
excluding missing
evaluable population (EVP)

BPD		Gestational age								all	
		<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
		n	%	n	%	n	%	n	%	n	%
Germany											
2007											
	no	390	13.6	764	26.6	415	14.5	120	4.2	1689	58.9
	yes	712	24.8	316	11.0	116	4.0	34	1.2	1178	41.1
	all	1102	38.4	1080	37.7	531	18.5	154	5.4	2867	100.0

Tab 2.2.5.1: Patient characteristics
gestational age [weeks]
classification by risk of CHD
including missing
evaluable population (EVP)

CHD	Gestational age										all	
	missing		<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%	n	%
Germany												
2007												
missing	23	21.5	33	30.8	33	30.8	16	15.0	2	1.9	107	100.0
no	227	9.5	826	34.5	874	36.5	418	17.5	49	2.0	2394	100.0
yes	475	37.0	305	23.8	250	19.5	140	10.9	113	8.8	1283	100.0
unknown	4	19.0	9	42.9	4	19.0	4	19.0	0	0.0	21	100.0
all	729	19.2	1173	30.8	1161	30.5	578	15.2	164	4.3	3805	100.0

Tab 2.2.5.2: Patient characteristics
gestational age [weeks]
classification by risk of CHD
excluding missing
evaluable population (EVP)

CHD	Gestational age								all	
	<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%
Germany										
2007										
no	826	27.6	874	29.2	418	14.0	49	1.6	2167	72.4
yes	305	10.2	250	8.4	140	4.7	113	3.8	808	27.0
unknown	9	0.3	4	0.1	4	0.1	0	0.0	17	0.6
all	1140	38.1	1128	37.7	562	18.8	162	5.4	2992	100.0

Tab 2.3.1: Patient characteristics
birth weight [g]
statistics
evaluable population (EVP)

		n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2007	85	3720	1623.2	863.6	960.0	1420.0	2070.0	300	5110

Tab 2.3.2.1: Patient characteristics
birth weight [g]
classification
including missing
evaluable population (EVP)

	Birth weight														all	
	missing		<750 g		750-999 g		1000-1499 g		1500-1999 g		2000-2499 g		>2499 g			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2007	85	2.2	465	12.2	636	16.7	965	25.4	659	17.3	395	10.4	600	15.8	3805	100.0

Tab 2.3.2.2: Patient characteristics
birth weight [g]
classification
excluding missing
evaluable population (EVP)

	Birth weight												all	
	<750 g		750-999 g		1000-1499 g		1500-1999 g		2000-2499 g		>2499 g			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2007	465	12.5	636	17.1	965	25.9	659	17.7	395	10.6	600	16.1	3720	100.0

Tab 2.3.3: Patient characteristics
birth weight [g]
correlation birth weight vs. gestational age
evaluable population (EVP)

Country	Year	Birth weight	Gestational age										all	
			missing		<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
			n	%	n	%	n	%	n	%	n	%	n	%
Germany	2007													
		missing	34	4.7	12	1.0	19	1.6	16	2.8	4	2.4	85	2.2
		<750 g	43	5.9	402	34.3	19	1.6	1	0.2	0	0.0	465	12.2
		750-999 g	58	8.0	462	39.4	111	9.6	5	0.9	0	0.0	636	16.7
		1000-1499 g	65	8.9	274	23.4	575	49.5	50	8.7	1	0.6	965	25.4
		1500-1999 g	49	6.7	17	1.4	369	31.8	201	34.8	23	14.0	659	17.3
		2000-2499 g	44	6.0	2	0.2	61	5.3	250	43.3	38	23.2	395	10.4
		>2499 g	436	59.8	4	0.3	7	0.6	55	9.5	98	59.8	600	15.8
		all	729	100.0	1173	100.0	1161	100.0	578	100.0	164	100.0	3805	100.0

Tab 2.4: Patient characteristics
children born in summer/winter

evaluable population (EVP)

	Born in						all	
	Missing		Summer		Winter			
	n	%	n	%	n	%	n	%
Germany 2007	8	0.2	1804	47.4	1993	52.4	3805	100.0

Tab 3.1.1: Risks
premature birth
all cases (including missing)
evaluable population (EVP)

	Premature birth						all	
	missing		no		yes			
	n	%	n	%	n	%	n	%
Germany 2007	23	0.6	494	13.0	3288	86.4	3805	100.0

Tab 3.1.2: Risks
premature birth
all informative cases
evaluable population (EVP)

	Premature birth					
	no		yes		all	
	n	%	n	%	n	%
Germany 2007	494	13.1	3288	86.9	3782	100.0

Tab 3.2.1.1: Risks
BPD
prevalences
including missing
evaluable population (EVP)

	BPD						all	
	missing		no		yes			
	n	%	n	%	n	%	n	%
Germany 2007	304	8.0	2171	57.1	1330	35.0	3805	100.0

Tab 3.2.1.2: Risks
BPD
prevalences
excluding missing
evaluable population (EVP)

	BPD					
	no		yes		all	
	n	%	n	%	n	%
Germany 2007	2171	62.0	1330	38.0	3501	100.0

Tab 3.2.2.1: Risks
BPD
stratified by birth in season
including missing
evaluable population (EVP)

	BPD						all	
	missing		no		yes			
	n	%	n	%	n	%	n	%
Germany								
2007								
no	51	8.3	248	40.5	313	51.1	612	100.0
yes	253	7.9	1923	60.2	1017	31.9	3193	100.0

Tab 3.2.2.2: Risks
BPD
stratified by birth in season
excluding missing
evaluable population (EVP)

	BPD					
	no		yes		all	
	n	%	n	%	n	%
Germany						
2007						
no	248	44.2	313	55.8	561	100.0
yes	1923	65.4	1017	34.6	2940	100.0

Tab 3.3.1.1: Risks
congenital heart misformation
number of patients
all cases (including missing)
evaluable population (EVP)

	Congenital heart misformation									
	missing		no		yes		not examined/unknown		all	
	n	%	n	%	n	%	n	%	n	%
Germany 2007	107	2.8	2394	62.9	1283	33.7	21	0.6	3805	100.0

Tab 3.3.1.2: Risks
congenital heart misformation
number of patients
all informative cases
evaluable population (EVP)

	Congenital heart misformation					
	no		yes		all	
	n	%	n	%	n	%
Germany 2007	2394	65.1	1283	34.9	3677	100.0

Tab 3.3.2.1: Risks
congenital heart misformation
details for patients with congenital heart misformation=yes
all cases (including missing)
evaluable population (EVP)

Country	Lung malperfusion	Type								all	
		missing		cyanotic		acyanotic		unknown			
		n	%	n	%	n	%	n	%	n	%
Germany											
2007											
	missing	133	36.5	91	25.0	130	35.7	10	2.7	364	100.0
	no	17	3.5	51	10.6	396	82.7	15	3.1	479	100.0
	yes	9	2.5	211	59.3	130	36.5	6	1.7	356	100.0
	not examined/unknown	2	2.4	23	27.4	49	58.3	10	11.9	84	100.0
all		161	12.5	376	29.3	705	54.9	41	3.2	1283	100.0

Tab 3.3.2.2: Risks
congenital heart misformation
details for patients with congenital heart misformation=yes
all informative cases
evaluable population (EVP)

Country	Lung malperfusion	Type					
		cyanotic		acyanotic		all	
		n	%	n	%	n	%
Germany							
2007							
	no	51	11.4	396	88.6	447	100.0
	yes	211	61.9	130	38.1	341	100.0
all		262	33.2	526	66.8	788	100.0

Tab 3.4.1.1: Risks
multiple birth
yes/no
all cases (including missing)
evaluable population (EVP)

	Multiple birth							
	missing		no		yes		all	
	n	%	n	%	n	%	n	%
Germany 2007	34	0.9	2849	74.9	922	24.2	3805	100.0

Tab 3.4.1.2: Risks
multiple birth
yes/no
all informative cases
evaluable population (EVP)

	Multiple birth					
	no		yes		all	
	n	%	n	%	n	%
Germany 2007	2849	75.6	922	24.4	3771	100.0

Tab 3.4.2: Risks
multiple birth
number of children
evaluable population (EVP)

	Multiple birth										all	
	missing		1		2		3		4			
	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2007	2942	77.3	21	0.6	730	19.2	111	2.9	1	0.0	3805	100.0

Tab 3.5.1: Risks
immuno deficiency
all cases (including missing)
evaluable population (EVP)

	Immuno deficiency									
	missing		no		yes		not examined/unknown		all	
	n	%	n	%	n	%	n	%	n	%
Germany 2007	172	4.5	3261	85.7	167	4.4	205	5.4	3805	100.0

Tab 3.5.2: Risks
immuno deficiency
all informative cases
evaluable population (EVP)

	Immuno deficiency					
	no		yes		all	
	n	%	n	%	n	%
Germany 2007	3261	95.1	167	4.9	3428	100.0

Tab 3.6.1: Risks
attending daycare
all cases (including missing)
evaluable population (EVP)

	Attending daycare									
	missing		no		yes		not examined/unknown		all	
	n	%	n	%	n	%	n	%	n	%
Germany 2007	38	1.0	3636	95.6	109	2.9	22	0.6	3805	100.0

Tab 3.6.2: Risks
attending daycare
all informative cases
evaluable population (EVP)

	Attending daycare					
	no		yes		all	
	n	%	n	%	n	%
Germany 2007	3636	97.1	109	2.9	3745	100.0

Tab 3.7.1.1: Risks
children <12 years in household
yes/no
all cases (including missing)
evaluable population (EVP)

	Children <12 years in household									
	missing		no		yes		not examined/unknown		all	
	n	%	n	%	n	%	n	%	n	%
Germany 2007	22	0.6	2046	53.8	1682	44.2	55	1.4	3805	100.0

Tab 3.7.1.2: Risks
children <12 years in household
yes/no
all informative cases
evaluable population (EVP)

	Children <12 years in household					
	no		yes		all	
	n	%	n	%	n	%
Germany 2007	2046	54.9	1682	45.1	3728	100.0

Tab 3.7.2: Risks
children <12 years in household
number of children
evaluable population (EVP)

	Children <12 years in household													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2007	2187	57.5	6	0.2	1041	27.4	390	10.2	99	2.6	50	1.3	17	0.4

(Continued)

	Children <12 years in household												all	
	6		7		8		9		10		15			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2007	5	0.1	2	0.1	5	0.1	1	0.0	1	0.0	1	0.0	3805	100.0

Tab 3.8.1: Risks
smoking in the family
all cases (including missing)
evaluable population (EVP)

	Smoking in the family									
	missing		no		yes		not examined/unknown		all	
	n	%	n	%	n	%	n	%	n	%
Germany 2007	130	3.4	2549	67.0	482	12.7	644	16.9	3805	100.0

Tab 3.8.2: Risks
smoking in the family
all informative cases
evaluable population (EVP)

	Smoking in the family					
	no		yes		all	
	n	%	n	%	n	%
Germany 2007	2549	84.1	482	15.9	3031	100.0

Tab 3.9.1: Risks
family history: asthma
all cases (including missing)
evaluable population (EVP)

	Family history: asthma									
	missing		no		yes		not examined/unknown		all	
	n	%	n	%	n	%	n	%	n	%
Germany 2007	89	2.3	2652	69.7	304	8.0	760	20.0	3805	100.0

Tab 3.9.2: Risks
family history: asthma
all informative cases
evaluable population (EVP)

	Family history: asthma					
	no		yes		all	
	n	%	n	%	n	%
Germany 2007	2652	89.7	304	10.3	2956	100.0

Tab 3.10.1: Risks
family history: allergic rhinitis
all cases (including missing)
evaluable population (EVP)

	Family history: allergic rhinitis								all	
	missing		no		yes		not examined/unknown			
	n	%	n	%	n	%	n	%	n	%
Germany 2007	97	2.5	2470	64.9	450	11.8	788	20.7	3805	100.0

Tab 3.10.2: Risks
family history: allergic rhinitis
all informative cases
evaluable population (EVP)

	Family history: allergic rhinitis					
	no		yes		all	
	n	%	n	%	n	%
Germany 2007	2470	84.6	450	15.4	2920	100.0

Tab 3.11.1: Risks
family history: allergic eczema
all cases (including missing)
evaluable population (EVP)

	Family history: allergic eczema									
	missing		no		yes		not examined/unknown		all	
	n	%	n	%	n	%	n	%	n	%
Germany 2007	100	2.6	2644	69.5	245	6.4	816	21.4	3805	100.0

Tab 3.11.2: Risks
family history: allergic eczema
all informative cases
evaluable population (EVP)

	Family history: allergic eczema					
	no		yes		all	
	n	%	n	%	n	%
Germany 2007	2644	91.5	245	8.5	2889	100.0

Tab 3.12.1: Risks
other reasons
all cases (including missing)
evaluable population (EVP)

	Other reasons						all	
	missing		no		yes			
	n	%	n	%	n	%	n	%
Germany 2007	2392	62.9	0	0.0	1413	37.1	3805	100.0

Tab 3.12.2: Risks
other reasons
all informative cases
evaluable population (EVP)

	Other reasons			
	yes		all	
	n	%	n	%
Germany 2007	1413	100.0	1413	100.0

Tab 4.1.1: Immunization
RSV prophylaxis in the last season
including missing
evaluable population (EVP)

	RSV prophylaxis in the last season									
	missing		no		yes		unknown		all	
	n	%	n	%	n	%	n	%	n	%
Germany 2007	85	2.2	3023	79.4	673	17.7	24	0.6	3805	100.0

Tab 4.1.2: Immunization
RSV prophylaxis in the last season
excluding missing
evaluable population (EVP)

	RSV prophylaxis in the last season						all	
	no		yes		unknown			
	n	%	n	%	n	%	n	%
Germany 2007	3023	81.3	673	18.1	24	0.6	3720	100.0

Tab 4.2.1: Immunization
location
including missing
evaluable population (EVP)

	Immunization started in clinic							
	missing		no		yes		all	
	n	%	n	%	n	%	n	%
Germany 2007	60	1.6	3226	84.8	519	13.6	3805	100.0

Tab 4.2.2: Immunization
location
excluding missing
evaluable population (EVP)

	Immunization started in clinic					
	no		yes		all	
	n	%	n	%	n	%
Germany 2007	3226	86.1	519	13.9	3745	100.0

Tab 4.3.1: Immunization recommendation including missing evaluable population (EVP)

	Recommendation from clinic							
	missing		no		yes		all	
	n	%	n	%	n	%	n	%
Germany 2007	170	4.5	1602	42.1	2033	53.4	3805	100.0

Tab 4.3.2: Immunization recommendation excluding missing evaluable population (EVP)

	Recommendation from clinic					
	no		yes		all	
	n	%	n	%	n	%
Germany 2007	1602	44.1	2033	55.9	3635	100.0

Tab 4.4.1: Immunization
age at start of RSV prophylaxis [months]
all patients
evaluable population (EVP)

		n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2007	227	3578	4.974	4.004	2.250	3.750	6.250	0.00	32.50

Tab 4.4.2.1: Immunization
age at start of RSV prophylaxis [months]
age < 12 months
by risk of BPD
evaluable population (EVP)

		BPD	n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2007	missing	32	266	3.929	2.384	2.000	3.250	5.000	0.50	11.75
		no	101	1965	3.821	2.404	2.000	3.250	5.250	0.25	11.75
		yes	94	1117	4.885	2.679	2.750	4.250	6.750	0.00	11.75

Tab 4.4.2.2: Immunization
age at start of RSV prophylaxis [months]
age < 12 months
by risk of CHD
evaluable population (EVP)

		CHD	n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2007	missing	12	93	4.204	2.468	2.500	3.750	5.000	0.75	11.50
		no	133	2151	4.101	2.469	2.250	3.500	5.500	0.00	11.75
		yes	81	1085	4.357	2.700	2.250	3.750	6.000	0.25	11.75
		unknown	1	19	3.658	1.819	2.000	4.000	5.500	1.00	6.25

Tab 4.4.3.1: Immunization
age at start of RSV prophylaxis [months]
age >= 12 months
by risk of BPD
evaluable population (EVP)

		BPD	n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2007	missing	0	6	18.250	7.802	12.000	15.750	21.500	12.00	32.50
		no	0	105	16.710	3.760	13.750	16.000	18.250	12.00	27.00
		yes	0	119	16.181	3.351	13.500	15.500	18.000	12.00	28.00

Tab 4.4.3.2: Immunization
age at start of RSV prophylaxis [months]
age >= 12 months
by risk of CHD
evaluable population (EVP)

		CHD	n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2007	missing	0	2	17.000	6.364	12.500	17.000	21.500	12.50	21.50
		no	0	110	16.143	3.531	13.500	15.500	18.000	12.00	27.00
		yes	0	117	16.741	3.821	13.750	16.000	18.500	12.00	32.50
		unknown	0	1	21.000		21.000	21.000	21.000	21.00	21.00

Tab 4.5.1: Immunization
administrations
total number
evaluable population (EVP)

	1		2		3		4		5		6		7		8		9		all	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2007	214	5.6	308	8.1	452	11.9	527	13.9	742	19.5	830	21.8	521	13.7	198	5.2	13	0.3	3805	100.0

Tab 4.5.2: Immunization
administrations
total number of documented administrations (with/without gaps)
evaluable population (EVP)

	Number of documented administrations (excl. gaps)	Number of documented administrations (incl. gaps)
Germany		
2007	18318	18332

Tab 4.6.1: Immunization
total number of follow-up administrations by month of first administration
including missing
evaluable population (EVP)

Month of first admin	0		1		2		3		4		5		6		7		8		all	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																				
2007																				
missing	0	0.0	0	0.0	0	0.0	3	33.3	3	33.3	2	22.2	0	0.0	1	11.1	0	0.0	9	100.0
September	6	1.2	11	2.2	14	2.8	16	3.2	52	10.4	103	20.7	147	29.5	136	27.3	13	2.6	498	100.0
October	34	2.5	27	2.0	53	3.9	88	6.5	242	17.9	499	37.0	345	25.6	61	4.5	0	0.0	1349	100.0
November	21	2.8	22	2.9	61	8.0	134	17.7	287	37.9	204	26.9	29	3.8	0	0.0	0	0.0	758	100.0
December	14	3.5	17	4.3	55	13.9	150	37.9	139	35.1	21	5.3	0	0.0	0	0.0	0	0.0	396	100.0
January	13	4.0	35	10.9	128	39.9	126	39.3	19	5.9	0	0.0	0	0.0	0	0.0	0	0.0	321	100.0
February	17	7.1	89	37.2	123	51.5	9	3.8	1	0.4	0	0.0	0	0.0	0	0.0	0	0.0	239	100.0
March	35	25.2	86	61.9	18	12.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	139	100.0
April	69	75.8	22	24.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	91	100.0
May	5	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	100.0
all	214	5.6	309	8.1	452	11.9	526	13.8	743	19.5	829	21.8	521	13.7	198	5.2	13	0.3	3805	100.0

Tab 4.6.2: Immunization
total number of follow-up administrations by month of first administration
excluding missing
evaluable population (EVP)

Month of first admin	0		1		2		3		4		5		6		7		8		all	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																				
2007																				
September	6	1.2	11	2.2	14	2.8	16	3.2	52	10.4	103	20.7	147	29.5	136	27.3	13	2.6	498	100.0
October	34	2.5	27	2.0	53	3.9	88	6.5	242	17.9	499	37.0	345	25.6	61	4.5	0	0.0	1349	100.0
November	21	2.8	22	2.9	61	8.0	134	17.7	287	37.9	204	26.9	29	3.8	0	0.0	0	0.0	758	100.0
December	14	3.5	17	4.3	55	13.9	150	37.9	139	35.1	21	5.3	0	0.0	0	0.0	0	0.0	396	100.0
January	13	4.0	35	10.9	128	39.9	126	39.3	19	5.9	0	0.0	0	0.0	0	0.0	0	0.0	321	100.0
February	17	7.1	89	37.2	123	51.5	9	3.8	1	0.4	0	0.0	0	0.0	0	0.0	0	0.0	239	100.0
March	35	25.2	86	61.9	18	12.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	139	100.0
April	69	75.8	22	24.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	91	100.0
May	5	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	100.0
all	214	5.6	309	8.1	452	11.9	523	13.8	740	19.5	827	21.8	521	13.7	197	5.2	13	0.3	3796	100.0

Tab 4.7: Immunization
total number of administrations grouped by children born in summer/winter
evaluable population (EVP)

Country/year/born in summer/winter	Total number of administrations																	
	1		2		3		4		5		6		7		8		9	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																		
2007																		
Missing	1	12.5	0	0	1	12.5	0	0	3	37.5	2	25.0	0	0	1	12.5	0	0
Summer	43	2.4	65	3.6	130	7.2	207	11.5	391	21.7	503	27.9	324	18.0	133	7.4	8	0.4
Winter	170	8.5	243	12.2	321	16.1	320	16.1	348	17.5	325	16.3	197	9.9	64	3.2	5	0.3
all	214	5.6	308	8.1	452	11.9	527	13.9	742	19.5	830	21.8	521	13.7	198	5.2	13	0.3

(Continued)

Country/year/born in summer/winter	all	
	n	%
Germany		
2007		
Missing	8	100.0
Summer	1804	100.0
Winter	1993	100.0
all	3805	100.0

Tab 4.8: Immunization
weight change relative to birth weight and trt admin
evaluable population (EVP)

Survey year=2007

Country/year-/month after DOB	Weight diff. [kg]																	
	missing		-2.2 - <0		0-< 5		5-< 6		6-< 7		7-< 8		8-< 9		9-<10		10-<15	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																		
missing	26	50.0			8	15.4	4	7.7	7	13.5	5	9.6	2	3.8				
0-< 1	3	12.0	3	12.0	19	76.0												
1-< 2	13	4.2	6	2.0	288	93.8												
2-< 3	40	4.5	6	0.7	850	94.8	1	0.1										
3-< 4	52	3.8	4	0.3	1299	95.2	8	0.6			1	0.1						
4-< 5	52	3.2	1	0.1	1527	93.9	38	2.3	7	0.4			1	0.1			1	0.1
5-< 6	65	3.6			1554	87.1	143	8.0	18	1.0	1	0.1	1	0.1			2	0.1
6-< 7	54	3.0			1276	70.8	384	21.3	76	4.2	9	0.5	2	0.1			1	0.1
7-< 8	62	3.7			876	52.0	518	30.8	189	11.2	33	2.0	4	0.2			1	0.1
8-< 9	67	4.5			552	36.9	485	32.4	306	20.5	71	4.7	12	0.8	1	0.1	1	0.1
9-<10	50	3.8			380	28.9	361	27.4	352	26.7	146	11.1	25	1.9	2	0.2	1	0.1
10-<11	47	4.3			247	22.5	284	25.9	288	26.2	180	16.4	46	4.2	4	0.4	2	0.2
11-<12	48	5.3			163	18.0	226	24.9	231	25.5	169	18.6	56	6.2	13	1.4	1	0.1
12-<13	32	4.6			94	13.4	159	22.6	190	27.0	141	20.1	72	10.2	10	1.4	5	0.7
13-<14	32	5.7			69	12.2	120	21.3	136	24.1	111	19.7	71	12.6	21	3.7	4	0.7
14-<15	30	6.8			49	11.0	81	18.2	102	23.0	92	20.7	69	15.5	16	3.6	5	1.1
15-<16	29	8.0			35	9.6	58	15.9	78	21.4	96	26.4	42	11.5	21	5.8	5	1.4
16-<17	18	5.9			26	8.6	51	16.8	66	21.8	70	23.1	41	13.5	26	8.6	5	1.7
17-<18	22	8.5			17	6.5	33	12.7	49	18.8	70	26.9	40	15.4	22	8.5	7	2.7
18-<19	16	7.3			15	6.8	26	11.8	50	22.7	46	20.9	36	16.4	26	11.8	5	2.3
19-<20	18	9.0			13	6.5	23	11.4	44	21.9	41	20.4	35	17.4	17	8.5	10	5.0
20-<21	16	8.8			10	5.5	14	7.7	29	16.0	45	24.9	38	21.0	17	9.4	12	6.6
21-<22	11	6.4			6	3.5	19	11.0	25	14.5	39	22.5	35	20.2	22	12.7	16	9.2
22-<23	14	9.3			6	4.0	17	11.3	25	16.6	38	25.2	27	17.9	14	9.3	10	6.6
23-<24	7	5.9			3	2.5	18	15.3	14	11.9	27	22.9	22	18.6	19	16.1	8	6.8
24-<25	8	8.2			1	1.0	9	9.3	17	17.5	19	19.6	22	22.7	12	12.4	9	9.3
25-<32	15	8.3			2	1.1	20	11.0	30	16.6	28	15.5	38	21.0	24	13.3	24	13.3
all	847	4.6	20	0.1	9385	51.2	3100	16.9	2329	12.7	1478	8.1	737	4.0	287	1.6	135	0.7

Tab 4.8: Immunization
weight change relative to birth weight and trt admin
evaluable population (EVP)

Survey year=2007

Country/year-/month after DOB	all	
	n	%
Germany		
missing	52	100.0
0-< 1	25	100.0
1-< 2	307	100.0
2-< 3	897	100.0
3-< 4	1364	100.0
4-< 5	1627	100.0
5-< 6	1784	100.0
6-< 7	1802	100.0
7-< 8	1683	100.0
8-< 9	1495	100.0
9-<10	1317	100.0
10-<11	1098	100.0
11-<12	907	100.0
12-<13	703	100.0
13-<14	564	100.0
14-<15	444	100.0
15-<16	364	100.0
16-<17	303	100.0
17-<18	260	100.0
18-<19	220	100.0
19-<20	201	100.0
20-<21	181	100.0
21-<22	173	100.0
22-<23	151	100.0
23-<24	118	100.0
24-<25	97	100.0
25-<32	181	100.0
all	18318	100.0

Tab 5.1.1: Complications
infections
Bronchiolitis
evaluable population (EVP)

Country	year	hosp. form	missing		no		yes		unknown		all	
			n	%	n	%	n	%	n	%	n	%
Germany												
	2007											
		no	3698	100.0	0	0.0	0	0.0	0	0.0	3698	100.0
		yes	63	52.1	37	30.6	18	14.9	3	2.5	121	100.0
		all	3761	98.5	37	1.0	18	0.5	3	0.1	3819	100.0

More than one hospitalization can occur, therefore multiple infections are possible

Tab 5.1.2: Complications
infections
RSV-Bronchiolitis
evaluable population (EVP)

Country	year	hosp. form	missing		no		yes		unknown		all	
			n	%	n	%	n	%	n	%	n	%
Germany												
	2007											
		no	3698	100.0	0	0.0	0	0.0	0	0.0	3698	100.0
		yes	50	41.3	34	28.1	34	28.1	3	2.5	121	100.0
		all	3748	98.1	34	0.9	34	0.9	3	0.1	3819	100.0

More than one hospitalization can occur, therefore multiple infections are possible

Tab 5.1.3: Complications
infections
Vir. pneumonia
evaluable population (EVP)

Country	year	hosp. form	missing		no		yes		unknown		all	
			n	%	n	%	n	%	n	%	n	%
Germany												
	2007											
		no	3698	100.0	0	0.0	0	0.0	0	0.0	3698	100.0
		yes	68	56.2	37	30.6	12	9.9	4	3.3	121	100.0
		all	3766	98.6	37	1.0	12	0.3	4	0.1	3819	100.0

More than one hospitalization can occur, therefore multiple infections are possible

Tab 5.1.4: Complications
infections
RSV-pneumonia
evaluable population (EVP)

Country	year	hosp. form	missing		no		yes		unknown		all	
			n	%	n	%	n	%	n	%	n	%
Germany												
	2007											
		no	3698	100.0	0	0.0	0	0.0	0	0.0	3698	100.0
		yes	63	52.1	39	32.2	14	11.6	5	4.1	121	100.0
		all	3761	98.5	39	1.0	14	0.4	5	0.1	3819	100.0

More than one hospitalization can occur, therefore multiple infections are possible

Tab 5.1.5: Complications
infections
RSV-infection
evaluable population (EVP)

Country	year	hosp. form	missing		no		yes		unknown		all	
			n	%	n	%	n	%	n	%	n	%
Germany												
	2007											
		no	3698	100.0	0	0.0	0	0.0	0	0.0	3698	100.0
		yes	55	45.5	35	28.9	26	21.5	5	4.1	121	100.0
		all	3753	98.3	35	0.9	26	0.7	5	0.1	3819	100.0

More than one hospitalization can occur, therefore multiple infections are possible

Tab 5.1.6: Complications
infections
Other
evaluable population (EVP)

Country	year	hosp. form	missing		no		yes		all	
			n	%	n	%	n	%	n	%
Germany										
	2007									
		no	3698	100.0	0	0.0	0	0.0	3698	100.0
		yes	37	30.6	14	11.6	70	57.9	121	100.0
		all	3735	97.8	14	0.4	70	1.8	3819	100.0

More than one hospitalization can occur, therefore multiple infections are possible

Tab 5.1.7: Complications
infections
Any RSV diagnosis
evaluable population (EVP)

Country	year	hosp. form	missing		no		yes		unknown		all	
			n	%	n	%	n	%	n	%	n	%
Germany												
	2007											
		no	3698	100.0	0	0.0	0	0.0	0	0.0	3698	100.0
		yes	37	30.6	23	19.0	57	47.1	4	3.3	121	100.0
		all	3735	97.8	23	0.6	57	1.5	4	0.1	3819	100.0

More than one hospitalization can occur, therefore multiple infections are possible

Tab 5.2.1: Complications
hospitalization
general overview (CRF or forms)
evaluable population (EVP)

	Number of hospitalizations/patient												
	missing		0		1		2		3		4		5
	n	%	n	%	n	%	n	%	n	%	n	%	n
Germany 2007	218	5.7	3478	91.4	101	2.7	2	0.1	3	0.1	2	0.1	1

(Continued)

	Number of hospitalizations/patient		
	5	all	
	%	n	%
Germany 2007	0.0	3805	100.0

Tab 5.2.2: Complications
hospitalization
hospitalization forms overview
evaluable population (EVP)

		Number of hospitalization forms						all	
		1		2		3			
		n	%	n	%	n	%	n	%
Country	Survey year								
Germany	2007	98	91.6	4	3.7	5	4.7	107	100.0

In Season 2002/2003 no hospitalization forms existed

Tab 5.2.3: Complications
hospitalization
cross-tabulation of hospitalization (CRF vs. hospitalization form)
evaluable population (EVP)

Country	Hosp. form existing	Number of hospitalizations=yes											
		0		1		2		3		4		5	
		n	%	n	%	n	%	n	%	n	%	n	%
Germany													
	2007												
	no	3680	99.5	16	0.4	0	0.0	1	0.0	0	0.0	1	0.0
	yes	21	19.6	81	75.7	1	0.9	2	1.9	2	1.9	0	0.0
all		3701	97.3	97	2.5	1	0.0	3	0.1	2	0.1	1	0.0

(Continued)

Tab 5.2.3: Complications
hospitalization
cross-tabulation of hospitalization (CRF vs. hospitalization form)
evaluable population (EVP)

Country	Hosp. form existing	all	
		n	%
Germany			
	2007		
	no	3698	100.0
	yes	107	100.0
all		3805	100.0

Tab 5.3.1: Complications
RSV-test
including missing
evaluable population (EVP)

Country	year	hosp. form	RSV-test							
			missing		negative		positive		all	
			n	%	n	%	n	%	n	%
Germany										
	2007									
		no	3698	100.0	0	0.0	0	0.0	3698	100.0
		yes	43	35.5	26	21.5	52	43.0	121	100.0
		all	3741	98.0	26	0.7	52	1.4	3819	100.0

Tab 5.3.2: Complications
RSV-test
excluding missing
evaluable population (EVP)

Country	year	hosp. form	RSV-test					
			negative		positive		all	
			n	%	n	%	n	%
Germany								
	2007							
		yes	26	33.3	52	66.7	78	100.0
		all	26	33.3	52	66.7	78	100.0

Tab 5.3.3: Complications
RSV-test
any RSV diagnosis (by hosp. form exist) vs. result of RSV test
evaluable population (EVP)

Country	year	hosp. form	any RSV diag.	RSV-test						all	
				missing		negative		positive			
				n	%	n	%	n	%	n	%
Germany											
	2007										
		no									
			missing	3698	100.0	0	0.0	0	0.0	3698	100.0
			no	0	0	0	0	0	0	0	0
			yes	0	0	0	0	0	0	0	0
			unknown	0	0	0	0	0	0	0	0
			all	3698	100.0	0	0.0	0	0.0	3698	100.0
		yes									
			missing	22	59.5	13	35.1	2	5.4	37	100.0
			no	11	47.8	12	52.2	0	0.0	23	100.0
			yes	6	10.5	1	1.8	50	87.7	57	100.0
			unknown	4	100.0	0	0.0	0	0.0	4	100.0
			all	43	35.5	26	21.5	52	43.0	121	100.0
		all									
			missing	3720	99.6	13	0.3	2	0.1	3735	100.0
			no	11	47.8	12	52.2	0	0.0	23	100.0
			yes	6	10.5	1	1.8	50	87.7	57	100.0
			unknown	4	100.0	0	0.0	0	0.0	4	100.0
			all	3741	98.0	26	0.7	52	1.4	3819	100.0

Tab 5.4.1: Complications
intensive care
no/yes/unknown
evaluable population (EVP)

Country	year	hosp. form	intensive care									
			missing		no		yes		not examined/unknown		all	
			n	%	n	%	n	%	n	%	n	%
Germany												
	2007											
		no	3698	100.0	0	0.0	0	0.0	0	0.0	3698	100.0
		yes	1	0.8	78	64.5	29	24.0	13	10.7	121	100.0
		all	3699	96.9	78	2.0	29	0.8	13	0.3	3819	100.0

Tab 5.4.2: Complications
intensive care
duration (days)
evaluable population (EVP)

		n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2007	3798	21	10.90	9.09	4.00	9.00	14.00	1.0	38.0

Tab 5.5.1: Complications
oxygen needed
no/yes/unknown
evaluable population (EVP)

Country	year	hosp. form	oxygen needed									
			missing		no		yes		not examined/unknown		all	
			n	%	n	%	n	%	n	%	n	%
Germany												
	2007											
		no	3698	100.0	0	0.0	0	0.0	0	0.0	3698	100.0
		yes	2	1.7	51	42.1	54	44.6	14	11.6	121	100.0
		all	3700	96.9	51	1.3	54	1.4	14	0.4	3819	100.0

Tab 5.5.2: Complications
oxygen needed
duration (days)
evaluable population (EVP)

		n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2007	3781	38	9.66	18.78	3.00	5.00	9.00	1.0	115.0

Tab 5.6.1: Complications
mechanical respiration
no/yes/unknown
evaluable population (EVP)

Country	year	hosp. form	mechanical respiratory									
			missing		no		yes		not examined/unknown		all	
			n	%	n	%	n	%	n	%	n	%
Germany												
	2007											
		no	3698	100.0	0	0.0	0	0.0	0	0.0	3698	100.0
		yes	2	1.7	99	81.8	11	9.1	9	7.4	121	100.0
		all	3700	96.9	99	2.6	11	0.3	9	0.2	3819	100.0

Tab 5.6.2: Complications
mechanical respiration
duration (days)
evaluable population (EVP)

		n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2007	3812	7	8.14	7.03	1.00	9.00	11.00	1.0	21.0

Tab 6: Occurrence of ADR
evaluable population (EVP)

	Occurrence of ADR							
	missing		no		yes		all	
	n	%	n	%	n	%	n	%
Germany 2007	149	3.9	3642	95.7	14	0.4	3805	100.0

Tab 7.1: Cooperation of parents
including missing
evaluable population (EVP)

	Cooperation of parents													
	missing		very good		good		moderate		bad		very bad		all	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2007	142	3.7	2637	69.3	703	18.5	221	5.8	72	1.9	30	0.8	3805	100.0

Tab 7.2: Cooperation of parents
excluding missing
evaluable population (EVP)

	Cooperation of parents										all	
	very good		good		moderate		bad		very bad			
	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2007	2637	72.0	703	19.2	221	6.0	72	2.0	30	0.8	3663	100.0

Tab 8.1.1: Subgroup analyses for hospitalization
by premature birth
including missing
evaluable population (EVP)

Premature birth	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
missing	5	21.7	18	78.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
no	38	7.7	444	89.9	11	2.2	0	0.0	1	0.2	0	0.0	0	0.0
yes	175	5.3	3016	91.7	90	2.7	2	0.1	2	0.1	2	0.1	1	0.0
all	218	5.7	3478	91.4	101	2.7	2	0.1	3	0.1	2	0.1	1	0.0

(Continued)

Tab 8.1.1: Subgroup analyses for hospitalization
by premature birth
including missing
evaluable population (EVP)

Premature birth	all	
	n	%
Germany		
2007		
missing	23	100.0
no	494	100.0
yes	3288	100.0
all	3805	100.0

Tab 8.1.2: Subgroup analyses for hospitalization
by premature birth
excluding missing
evaluable population (EVP)

Premature birth	Number of hospitalizations/patient												all	
	0		1		2		3		4		5			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
no	444	97.4	11	2.4	0	0.0	1	0.2	0	0.0	0	0.0	456	100.0
yes	3016	96.9	90	2.9	2	0.1	2	0.1	2	0.1	1	0.0	3113	100.0
all	3460	96.9	101	2.8	2	0.1	3	0.1	2	0.1	1	0.0	3569	100.0

Tab 8.2.1: Subgroup analyses for hospitalization
by BPD
including missing
evaluable population (EVP)

BPD	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
missing	38	12.5	262	86.2	4	1.3	0	0.0	0	0.0	0	0.0	0	0.0
no	115	5.3	2015	92.8	38	1.8	1	0.0	2	0.1	0	0.0	0	0.0
yes	65	4.9	1201	90.3	59	4.4	1	0.1	1	0.1	2	0.2	1	0.1
all	218	5.7	3478	91.4	101	2.7	2	0.1	3	0.1	2	0.1	1	0.0

(Continued)

Tab 8.2.1: Subgroup analyses for hospitalization
by BPD
including missing
evaluable population (EVP)

BPD	all	
	n	%
Germany		
2007		
missing	304	100.0
no	2171	100.0
yes	1330	100.0
all	3805	100.0

Tab 8.2.2: Subgroup analyses for hospitalization
by BPD
excluding missing
evaluable population (EVP)

BPD	Number of hospitalizations/patient												all	
	0		1		2		3		4		5			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
no	2015	98.0	38	1.8	1	0.0	2	0.1	0	0.0	0	0.0	2056	100.0
yes	1201	94.9	59	4.7	1	0.1	1	0.1	2	0.2	1	0.1	1265	100.0
all	3216	96.8	97	2.9	2	0.1	3	0.1	2	0.1	1	0.0	3321	100.0

Tab 8.3.1: Subgroup analyses for hospitalization
by congenital heart misformation
including missing
evaluable population (EVP)

Congenital heart misformation	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
missing	27	25.2	78	72.9	2	1.9	0	0.0	0	0.0	0	0.0	0	0.0
no	126	5.3	2199	91.9	64	2.7	2	0.1	1	0.0	2	0.1	0	0.0
yes	62	4.8	1183	92.2	35	2.7	0	0.0	2	0.2	0	0.0	1	0.1
not examined/unknown	3	14.3	18	85.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
all	218	5.7	3478	91.4	101	2.7	2	0.1	3	0.1	2	0.1	1	0.0

(Continued)

Tab 8.3.1: Subgroup analyses for hospitalization
by congenital heart misformation
including missing
evaluable population (EVP)

Congenital heart misformation	all	
	n	%
Germany		
2007		
missing	107	100.0
no	2394	100.0
yes	1283	100.0
not examined/unknown	21	100.0
all	3805	100.0

Tab 8.3.2: Subgroup analyses for hospitalization
by congenital heart misformation
excluding missing
evaluable population (EVP)

Congenital heart misformation	Number of hospitalizations/patient												all	
	0		1		2		3		4		5			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
no	2199	97.0	64	2.8	2	0.1	1	0.0	2	0.1	0	0.0	2268	100.0
yes	1183	96.9	35	2.9	0	0.0	2	0.2	0	0.0	1	0.1	1221	100.0
not examined/unknown	18	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	18	100.0
all	3400	96.9	99	2.8	2	0.1	3	0.1	2	0.1	1	0.0	3507	100.0

Tab 8.4.1: Subgroup analyses for hospitalization
by multiple birth
including missing
evaluable population (EVP)

Multiple birth	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
missing	2	5.9	31	91.2	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0
no	165	5.8	2593	91.0	87	3.1	2	0.1	2	0.1	0	0.0	0	0.0
yes	51	5.5	854	92.6	13	1.4	0	0.0	1	0.1	2	0.2	1	0.1
all	218	5.7	3478	91.4	101	2.7	2	0.1	3	0.1	2	0.1	1	0.0

(Continued)

Tab 8.4.1: Subgroup analyses for hospitalization
by multiple birth
including missing
evaluable population (EVP)

Multiple birth	all	
	n	%
Germany		
2007		
missing	34	100.0
no	2849	100.0
yes	922	100.0
all	3805	100.0

Tab 8.4.2: Subgroup analyses for hospitalization
by multiple birth
excluding missing
evaluable population (EVP)

Multiple birth	Number of hospitalizations/patient													
	0		1		2		3		4		5		all	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
no	2593	96.6	87	3.2	2	0.1	2	0.1	0	0.0	0	0.0	2684	100.0
yes	854	98.0	13	1.5	0	0.0	1	0.1	2	0.2	1	0.1	871	100.0
all	3447	97.0	100	2.8	2	0.1	3	0.1	2	0.1	1	0.0	3555	100.0

Tab 8.5.1: Subgroup analyses for hospitalization
by immuno deficiency
including missing
evaluable population (EVP)

Immuno deficiency	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
missing	42	24.4	127	73.8	3	1.7	0	0.0	0	0.0	0	0.0	0	0.0
no	157	4.8	3013	92.4	86	2.6	2	0.1	1	0.0	2	0.1	0	0.0
yes	9	5.4	151	90.4	4	2.4	0	0.0	2	1.2	0	0.0	1	0.6
not examined/unknown	10	4.9	187	91.2	8	3.9	0	0.0	0	0.0	0	0.0	0	0.0
all	218	5.7	3478	91.4	101	2.7	2	0.1	3	0.1	2	0.1	1	0.0

(Continued)

Tab 8.5.1: Subgroup analyses for hospitalization
by immuno deficiency
including missing
evaluable population (EVP)

Immuno deficiency	all	
	n	%
Germany		
2007		
missing	172	100.0
no	3261	100.0
yes	167	100.0
not examined/unknown	205	100.0
all	3805	100.0

Tab 8.5.2: Subgroup analyses for hospitalization
by immuno deficiency
excluding missing
evaluable population (EVP)

Immuno deficiency	Number of hospitalizations/patient												all	
	0		1		2		3		4		5			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
no	3013	97.1	86	2.8	2	0.1	1	0.0	2	0.1	0	0.0	3104	100.0
yes	151	95.6	4	2.5	0	0.0	2	1.3	0	0.0	1	0.6	158	100.0
not examined/unknown	187	95.9	8	4.1	0	0.0	0	0.0	0	0.0	0	0.0	195	100.0
all	3351	96.9	98	2.8	2	0.1	3	0.1	2	0.1	1	0.0	3457	100.0

Tab 8.6.1: Subgroup analyses for hospitalization
by attending daycare
including missing
evaluable population (EVP)

Attending daycare	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
missing	15	39.5	22	57.9	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0
no	192	5.3	3340	91.9	97	2.7	2	0.1	2	0.1	2	0.1	1	0.0
yes	4	3.7	102	93.6	3	2.8	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	7	31.8	14	63.6	1	4.5	0	0.0	0	0.0	0	0.0	0	0.0
all	218	5.7	3478	91.4	101	2.7	2	0.1	3	0.1	2	0.1	1	0.0

(Continued)

Tab 8.6.1: Subgroup analyses for hospitalization
by attending daycare
including missing
evaluable population (EVP)

Attending daycare	all	
	n	%
Germany		
2007		
missing	38	100.0
no	3636	100.0
yes	109	100.0
not examined/unknown	22	100.0
all	3805	100.0

Tab 8.6.2: Subgroup analyses for hospitalization
by attending daycare
excluding missing
evaluable population (EVP)

Attending daycare	Number of hospitalizations/patient												all	
	0		1		2		3		4		5			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
no	3340	97.0	97	2.8	2	0.1	2	0.1	2	0.1	1	0.0	3444	100.0
yes	102	97.1	3	2.9	0	0.0	0	0.0	0	0.0	0	0.0	105	100.0
not examined/unknown	14	93.3	1	6.7	0	0.0	0	0.0	0	0.0	0	0.0	15	100.0
all	3456	97.0	101	2.8	2	0.1	2	0.1	2	0.1	1	0.0	3564	100.0

Tab 8.7.1: Subgroup analyses for hospitalization
by children <12 years in household
including missing
evaluable population (EVP)

Children <12 years in household	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
missing	6	27.3	15	68.2	0	0.0	0	0.0	1	4.5	0	0.0	0	0.0
no	100	4.9	1902	93.0	42	2.1	1	0.0	1	0.0	0	0.0	0	0.0
yes	106	6.3	1513	90.0	58	3.4	1	0.1	1	0.1	2	0.1	1	0.1
not examined/unknown	6	10.9	48	87.3	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0
all	218	5.7	3478	91.4	101	2.7	2	0.1	3	0.1	2	0.1	1	0.0

(Continued)

Tab 8.7.1: Subgroup analyses for hospitalization
by children <12 years in household
including missing
evaluable population (EVP)

Children <12 years in household	all	
	n	%
Germany		
2007		
missing	22	100.0
no	2046	100.0
yes	1682	100.0
not examined/unknown	55	100.0
all	3805	100.0

Tab 8.7.2: Subgroup analyses for hospitalization
by children <12 years in household
excluding missing
evaluable population (EVP)

Children <12 years in household	Number of hospitalizations/patient												all	
	0		1		2		3		4		5			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
no	1902	97.7	42	2.2	1	0.1	1	0.1	0	0.0	0	0.0	1946	100.0
yes	1513	96.0	58	3.7	1	0.1	1	0.1	2	0.1	1	0.1	1576	100.0
not examined/unknown	48	98.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	49	100.0
all	3463	97.0	101	2.8	2	0.1	2	0.1	2	0.1	1	0.0	3571	100.0

Tab 8.8.1: Subgroup analyses for hospitalization
by smoking in the family
including missing
evaluable population (EVP)

Smoking in the family	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
missing	24	18.5	105	80.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0
no	121	4.7	2353	92.3	68	2.7	2	0.1	2	0.1	2	0.1	1	0.0
yes	15	3.1	453	94.0	14	2.9	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	58	9.0	567	88.0	18	2.8	0	0.0	1	0.2	0	0.0	0	0.0
all	218	5.7	3478	91.4	101	2.7	2	0.1	3	0.1	2	0.1	1	0.0

(Continued)

Tab 8.8.1: Subgroup analyses for hospitalization
by smoking in the family
including missing
evaluable population (EVP)

Smoking in the family	all	
	n	%
Germany		
2007		
missing	130	100.0
no	2549	100.0
yes	482	100.0
not examined/unknown	644	100.0
all	3805	100.0

Tab 8.8.2: Subgroup analyses for hospitalization
by smoking in the family
excluding missing
evaluable population (EVP)

Smoking in the family	Number of hospitalizations/patient												all	
	0		1		2		3		4		5			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
no	2353	96.9	68	2.8	2	0.1	2	0.1	2	0.1	1	0.0	2428	100.0
yes	453	97.0	14	3.0	0	0.0	0	0.0	0	0.0	0	0.0	467	100.0
not examined/unknown	567	96.8	18	3.1	0	0.0	1	0.2	0	0.0	0	0.0	586	100.0
all	3373	96.9	100	2.9	2	0.1	3	0.1	2	0.1	1	0.0	3481	100.0

Tab 8.9.1: Subgroup analyses for hospitalization
by family history: asthma
including missing
evaluable population (EVP)

Family history: asthma	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
missing	17	19.1	71	79.8	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0
no	129	4.9	2443	92.1	73	2.8	2	0.1	2	0.1	2	0.1	1	0.0
yes	15	4.9	282	92.8	7	2.3	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	57	7.5	682	89.7	20	2.6	0	0.0	1	0.1	0	0.0	0	0.0
all	218	5.7	3478	91.4	101	2.7	2	0.1	3	0.1	2	0.1	1	0.0

(Continued)

Tab 8.9.1: Subgroup analyses for hospitalization
by family history: asthma
including missing
evaluable population (EVP)

Family history: asthma	all	
	n	%
Germany		
2007		
missing	89	100.0
no	2652	100.0
yes	304	100.0
not examined/unknown	760	100.0
all	3805	100.0

Tab 8.9.2: Subgroup analyses for hospitalization
by family history: asthma
excluding missing
evaluable population (EVP)

Family history: asthma	Number of hospitalizations/patient												all	
	0		1		2		3		4		5			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
no	2443	96.8	73	2.9	2	0.1	2	0.1	2	0.1	1	0.0	2523	100.0
yes	282	97.6	7	2.4	0	0.0	0	0.0	0	0.0	0	0.0	289	100.0
not examined/unknown	682	97.0	20	2.8	0	0.0	1	0.1	0	0.0	0	0.0	703	100.0
all	3407	96.9	100	2.8	2	0.1	3	0.1	2	0.1	1	0.0	3515	100.0

Tab 8.10.1: Subgroup analyses for hospitalization
by family history: allergic rhinitis
including missing
evaluable population (EVP)

Family history: allergic rhinitis	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
missing	17	17.5	78	80.4	2	2.1	0	0.0	0	0.0	0	0.0	0	0.0
no	127	5.1	2266	91.7	71	2.9	2	0.1	1	0.0	2	0.1	1	0.0
yes	20	4.4	421	93.6	8	1.8	0	0.0	1	0.2	0	0.0	0	0.0
not examined/unknown	54	6.9	713	90.5	20	2.5	0	0.0	1	0.1	0	0.0	0	0.0
all	218	5.7	3478	91.4	101	2.7	2	0.1	3	0.1	2	0.1	1	0.0

(Continued)

Tab 8.10.1: Subgroup analyses for hospitalization
by family history: allergic rhinitis
including missing
evaluable population (EVP)

Family history: allergic rhinitis	all	
	n	%
Germany		
2007		
missing	97	100.0
no	2470	100.0
yes	450	100.0
not examined/unknown	788	100.0
all	3805	100.0

Tab 8.10.2: Subgroup analyses for hospitalization
by family history: allergic rhinitis
excluding missing
evaluable population (EVP)

Family history: allergic rhinitis	Number of hospitalizations/patient												all	
	0		1		2		3		4		5			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
no	2266	96.7	71	3.0	2	0.1	1	0.0	2	0.1	1	0.0	2343	100.0
yes	421	97.9	8	1.9	0	0.0	1	0.2	0	0.0	0	0.0	430	100.0
not examined/unknown	713	97.1	20	2.7	0	0.0	1	0.1	0	0.0	0	0.0	734	100.0
all	3400	96.9	99	2.8	2	0.1	3	0.1	2	0.1	1	0.0	3507	100.0

Tab 8.11.1: Subgroup analyses for hospitalization
by family history: allergic eczema
including missing
evaluable population (EVP)

Family history: allergic eczema	Number of hospitalizations/patient													
	missing		0		1		2		3		4		5	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
missing	19	19.0	79	79.0	2	2.0	0	0.0	0	0.0	0	0.0	0	0.0
no	132	5.0	2429	91.9	76	2.9	2	0.1	2	0.1	2	0.1	1	0.0
yes	12	4.9	229	93.5	4	1.6	0	0.0	0	0.0	0	0.0	0	0.0
not examined/unknown	55	6.7	741	90.8	19	2.3	0	0.0	1	0.1	0	0.0	0	0.0
all	218	5.7	3478	91.4	101	2.7	2	0.1	3	0.1	2	0.1	1	0.0

(Continued)

Tab 8.11.1: Subgroup analyses for hospitalization
by family history: allergic eczema
including missing
evaluable population (EVP)

Family history: allergic eczema	all	
	n	%
Germany		
2007		
missing	100	100.0
no	2644	100.0
yes	245	100.0
not examined/unknown	816	100.0
all	3805	100.0

Tab 8.11.2: Subgroup analyses for hospitalization
by family history: allergic eczema
excluding missing
evaluable population (EVP)

Family history: allergic eczema	Number of hospitalizations/patient												all	
	0		1		2		3		4		5			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany														
2007														
no	2429	96.7	76	3.0	2	0.1	2	0.1	2	0.1	1	0.0	2512	100.0
yes	229	98.3	4	1.7	0	0.0	0	0.0	0	0.0	0	0.0	233	100.0
not examined/unknown	741	97.4	19	2.5	0	0.0	1	0.1	0	0.0	0	0.0	761	100.0
all	3399	96.9	99	2.8	2	0.1	3	0.1	2	0.1	1	0.0	3506	100.0

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Tab 1.1: Patient distribution
by center size

	Number of patients/center																
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	29	all
Germany 2008	161	145	112	97	64	32	28	16	6	2	4	5	1	1	1	1	676

Tab 1.2: Patient distribution
by region (first character)

	Number of patients in region																	
	0		1		2		3		4		5		6		7		8	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2008	386	17.08	388	17.17	109	4.82	206	9.12	319	14.12	237	10.49	158	6.99	115	5.09	121	5.35

(Continued)

	Number of patients in region		all	
	9			
	n	%	n	%
Germany 2008	221	9.78	2260	100.00

Tab 1.3: Patient distribution
by evaluablity

	Number of patients		
	EVP	NEP	all
Germany 2008	2248	12	2260

Analysis population: EVP=evaluable population, NEP=non-evaluable population

Tab 1.4: Patient distribution
reasons for non-evaluability

	Number of patients with reason (1)	
	1	all
Germany 2008	12	12

(1) Reason 1: date of birth prior to 01-SEP-2006
Reason 2: Insufficient data

Tab 2.1: Patient characteristics
sex
evaluable population (EVP)

	Sex					
	male		female		all	
	n	%	n	%	n	%
Germany						
2008	1229	54.7	1019	45.3	2248	100.0

Tab 2.2.1: Patient characteristics
gestational age [weeks]
statistics
evaluable population (EVP)

		n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2008	0	2248	31.23	4.47	28.00	31.00	34.00	23.0	42.0

Tab 2.2.2.1: Patient characteristics
gestational age [weeks]
classification
all cases
evaluable population (EVP)

	Gestational age								all	
	<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%
Germany 2008	694	30.9	705	31.4	474	21.1	375	16.7	2248	100.0

Tab 2.2.2.2: Patient characteristics
gestational age [weeks]
classification
frequencies by weeks
evaluable population (EVP)

	Gestational age															
	23		24		25		26		27		28		29		30	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2008	35	1.6	82	3.6	114	5.1	136	6.0	151	6.7	176	7.8	177	7.9	141	6.3

(Continued)

Tab 2.2.2.2: Patient characteristics
gestational age [weeks]
classification
frequencies by weeks
evaluable population (EVP)

	Gestational age															
	31		32		33		34		35		36		37		38	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2008	179	8.0	208	9.3	178	7.9	199	8.9	97	4.3	49	2.2	52	2.3	81	3.6

(Continued)

Tab 2.2.2.2: Patient characteristics
gestational age [weeks]
classification
frequencies by weeks
evaluable population (EVP)

	Gestational age								all	
	39		40		41		42			
	n	%	n	%	n	%	n	%	n	%
Germany 2008	75	3.3	86	3.8	27	1.2	5	0.2	2248	100.0

Tab 2.2.3.1: Patient characteristics
gestational age [weeks]
classification by risk of premature birth
all cases
evaluable population (EVP)

Premature birth	Gestational age								all	
	<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
no	0	0.0	0	0.0	0	0.0	375	16.7	375	16.7
yes	694	30.9	705	31.4	474	21.1	0	0.0	1873	83.3
all	694	30.9	705	31.4	474	21.1	375	16.7	2248	100.0

Tab 2.2.3.2: Patient characteristics
gestational age [weeks]
classification by risk of premature birth
all informative cases
evaluable population (EVP)

Premature birth	Gestational age								all	
	<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
no	0	0.0	0	0.0	0	0.0	375	100.0	375	100.0
yes	694	37.1	705	37.6	474	25.3	0	0.0	1873	100.0
all	694	30.9	705	31.4	474	21.1	375	16.7	2248	100.0

Tab 2.2.4.1: Patient characteristics
gestational age [weeks]
classification by risk of CLD
all cases
evaluable population (EVP)

CLD	Gestational age								all	
	<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
not ticked	381	16.9	572	25.4	400	17.8	311	13.8	1664	74.0
yes	313	13.9	133	5.9	74	3.3	64	2.8	584	26.0
all	694	30.9	705	31.4	474	21.1	375	16.7	2248	100.0

Tab 2.2.4.2: Patient characteristics
gestational age [weeks]
classification by risk of CLD
all informative cases
evaluable population (EVP)

CLD	Gestational age								all	
	<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
yes	313	53.6	133	22.8	74	12.7	64	11.0	584	100.0
all	313	53.6	133	22.8	74	12.7	64	11.0	584	100.0

Tab 2.2.5.1: Patient characteristics
gestational age [weeks]
classification by risk of CHD
all cases
evaluable population (EVP)

CHD	Gestational age								all	
	<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
not ticked	564	25.1	595	26.5	410	18.2	112	5.0	1681	74.8
yes	130	5.8	110	4.9	64	2.8	263	11.7	567	25.2
all	694	30.9	705	31.4	474	21.1	375	16.7	2248	100.0

Tab 2.2.5.2: Patient characteristics
gestational age [weeks]
classification by risk of CHD
all informative cases
evaluable population (EVP)

CHD	Gestational age								all	
	<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
yes	130	22.9	110	19.4	64	11.3	263	46.4	567	100.0
all	130	22.9	110	19.4	64	11.3	263	46.4	567	100.0

Tab 2.2.6.1: Patient characteristics
gestational age [weeks]
classification by risk of CHD (ICD-10 criteria)
all cases
evaluable population (EVP)

CHD (ICD-10 criteria)	Gestational age								all	
	<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
Angeb. Fehlb. der Herzhöhlen, nicht näher bez.	0	0.0	0	0.0	0	0.0	2	0.1	2	0.1
Angeb. Fehlb. der Pulmonal- und der Trikuspidalklappe	0	0.0	0	0.0	0	0.0	3	0.1	3	0.1
Angeb. Fehlb. der Trikuspidalklappe, nicht näher bez.	0	0.0	0	0.0	0	0.0	1	0.0	1	0.0
Angeb. Fehlb. der großen Arterien, nicht näher bez.	0	0.0	1	0.0	0	0.0	3	0.1	4	0.2
Angeb. Fehlb. des Herzens, nicht näher bez.	0	0.0	0	0.0	0	0.0	1	0.0	1	0.0
Angeb. Fehlbildungen der Herzhöhlen	1	0.0	0	0.0	1	0.0	7	0.3	9	0.4
Angeb. Fehlbildungen der Herzhöhlen, Sonstige	0	0.0	0	0.0	0	0.0	1	0.0	1	0.0
Angeb. Fehlbildungen der Herzsepten	0	0.0	1	0.0	0	0.0	1	0.0	2	0.1
Angeborene Aortenklappeninsuffizienz	0	0.0	0	0.0	1	0.0	2	0.1	3	0.1
Angeborene Aortenklappenstenose	0	0.0	0	0.0	1	0.0	7	0.3	8	0.4
Angeborene Fehlbildungen der großen Arterien	0	0.0	1	0.0	0	0.0	0	0.0	1	0.0

(Continued)

Tab 2.2.6.1: Patient characteristics
gestational age [weeks]
classification by risk of CHD (ICD-10 criteria)
all cases
evaluable population (EVP)

CHD (ICD-10 criteria)	Gestational age								all	
	<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
Angeborene Mitralklappeninsuffizienz	2	0.1	0	0.0	0	0.0	1	0.0	3	0.1
Angeborene Mitralklappenstenose	0	0.0	0	0.0	0	0.0	1	0.0	1	0.0
Angeborene Pulmonalklappenstenose	2	0.1	6	0.3	0	0.0	2	0.1	10	0.4
Angeborene Stenose der V. cava	0	0.0	0	0.0	1	0.0	0	0.0	1	0.0
Angeborene Trikuspidalklappenstenose	0	0.0	0	0.0	1	0.0	1	0.0	2	0.1
Aortopulmonaler Septumdefekt	1	0.0	1	0.0	0	0.0	1	0.0	3	0.1
Atresie der A. pulmonalis	0	0.0	0	0.0	0	0.0	3	0.1	3	0.1
Cor triatriatum	0	0.0	0	0.0	0	0.0	1	0.0	1	0.0
Defekt des Vorhof- und Kammerseptums	2	0.1	0	0.0	6	0.3	13	0.6	21	0.9
Diskordante atrioventrikuläre Verbindung	1	0.0	0	0.0	0	0.0	3	0.1	4	0.2
Diskordante ventrikuloarterielle Verbindung	0	0.0	0	0.0	0	0.0	14	0.6	14	0.6
Doppeleinstromventrikel	0	0.0	0	0.0	0	0.0	4	0.2	4	0.2
Ebstein-Anomalie	0	0.0	0	0.0	0	0.0	2	0.1	2	0.1
Fallot-Tetralogie	0	0.0	1	0.0	3	0.1	22	1.0	26	1.2

(Continued)

Tab 2.2.6.1: Patient characteristics
gestational age [weeks]
classification by risk of CHD (ICD-10 criteria)
all cases
evaluable population (EVP)

CHD (ICD-10 criteria)	Gestational age								all	
	<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
Fehleinmündung der Lungenvenen, nicht näher bez.	0	0.0	0	0.0	0	0.0	2	0.1	2	0.1
Hypoplastisches Linksherzsyndrom	0	0.0	0	0.0	1	0.0	23	1.0	24	1.1
Hypoplastisches Rechtsherzsyndrom	0	0.0	0	0.0	0	0.0	7	0.3	7	0.3
Infundibuläre Pulmonalstenose	2	0.1	1	0.0	2	0.1	1	0.0	6	0.3
Koarktation der Aorta	1	0.0	0	0.0	1	0.0	5	0.2	7	0.3
Linker Doppelausstromventrikel	0	0.0	0	0.0	0	0.0	1	0.0	1	0.0
Offener Ductus arteriosus	43	1.9	25	1.1	5	0.2	2	0.1	75	3.3
Partielle Fehleinmündung der Lungenvenen	1	0.0	0	0.0	0	0.0	0	0.0	1	0.0
Persistenz der linken V. cava superior	0	0.0	1	0.0	0	0.0	3	0.1	4	0.2
Pulmonalklappenatresie	0	0.0	0	0.0	1	0.0	5	0.2	6	0.3
Rechter Doppelausstromventrikel	0	0.0	0	0.0	0	0.0	9	0.4	9	0.4
Sonst. angeb. Fehlb.der Aorten- und Mitralklappe	0	0.0	0	0.0	0	0.0	1	0.0	1	0.0
Sonstige angeb. Fehlb. der A. pulmonalis	1	0.0	0	0.0	0	0.0	0	0.0	1	0.0
Sonstige angeb. Fehlb. der Pulmonalklappe	0	0.0	0	0.0	0	0.0	1	0.0	1	0.0

(Continued)

Tab 2.2.6.1: Patient characteristics
gestational age [weeks]
classification by risk of CHD (ICD-10 criteria)
all cases
evaluable population (EVP)

CHD (ICD-10 criteria)	Gestational age								all	
	<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
Sonstige angeb. Fehlb. der Trikuspidalklappe	1	0.0	0	0.0	0	0.0	3	0.1	4	0.2
Sonstige angeb. Fehlbild. der großen Arterien	0	0.0	0	0.0	0	0.0	2	0.1	2	0.1
Sonstige angeb. Fehlbildungen der Herzsepten	3	0.1	0	0.0	0	0.0	0	0.0	3	0.1
Sonstige angeborene Fehlbildungen der Aorta	0	0.0	0	0.0	0	0.0	7	0.3	7	0.3
Sonstige näher bez.angeb. Fehlb. des Herzens	0	0.0	0	0.0	0	0.0	1	0.0	1	0.0
Stenose der A. pulmonalis	7	0.3	6	0.3	2	0.1	1	0.0	16	0.7
Stenose der Aorta	0	0.0	0	0.0	1	0.0	3	0.1	4	0.2
Totale Fehleinmündung der Lungenvenen	0	0.0	0	0.0	0	0.0	1	0.0	1	0.0
Truncus arteriosus communis	0	0.0	1	0.0	0	0.0	3	0.1	4	0.2
Ventrikelseptumdefekt	8	0.4	13	0.6	12	0.5	40	1.8	73	3.2
Vorhofisomerismus	0	0.0	0	0.0	0	0.0	1	0.0	1	0.0
Vorhofseptumdefekt	36	1.6	34	1.5	18	0.8	11	0.5	99	4.4
unbekannt	582	25.9	613	27.3	417	18.5	146	6.5	1758	78.2
all	694	30.9	705	31.4	474	21.1	375	16.7	2248	100.0

Tab 2.2.6.2: Patient characteristics
gestational age [weeks]
classification by risk of CHD (ICD-10 criteria)
all informative cases
evaluable population (EVP)

CHD (ICD-10 criteria)	Gestational age								all	
	<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
Angeb. Fehlb. der Herzhöhlen, nicht näher bez.	0	0.0	0	0.0	0	0.0	2	100.0	2	100.0
Angeb. Fehlb. der Pulmonal- und der Trikuspidalklappe	0	0.0	0	0.0	0	0.0	3	100.0	3	100.0
Angeb. Fehlb. der Trikuspidalklappe, nicht näher bez.	0	0.0	0	0.0	0	0.0	1	100.0	1	100.0
Angeb. Fehlb. der großen Arterien, nicht näher bez.	0	0.0	1	25.0	0	0.0	3	75.0	4	100.0
Angeb. Fehlb. des Herzens, nicht näher bez.	0	0.0	0	0.0	0	0.0	1	100.0	1	100.0
Angeb. Fehlbildungen der Herzhöhlen	1	11.1	0	0.0	1	11.1	7	77.8	9	100.0
Angeb. Fehlbildungen der Herzhöhlen, Sonstige	0	0.0	0	0.0	0	0.0	1	100.0	1	100.0
Angeb. Fehlbildungen der Herzsepten	0	0.0	1	50.0	0	0.0	1	50.0	2	100.0
Angeborene Aortenklappeninsuffizienz	0	0.0	0	0.0	1	33.3	2	66.7	3	100.0
Angeborene Aortenklappenstenose	0	0.0	0	0.0	1	12.5	7	87.5	8	100.0
Angeborene Fehlbildungen der großen Arterien	0	0.0	1	100.0	0	0.0	0	0.0	1	100.0

(Continued)

Tab 2.2.6.2: Patient characteristics
gestational age [weeks]
classification by risk of CHD (ICD-10 criteria)
all informative cases
evaluable population (EVP)

CHD (ICD-10 criteria)	Gestational age								all	
	<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
Angeborene Mitralklappeninsuffizienz	2	66.7	0	0.0	0	0.0	1	33.3	3	100.0
Angeborene Mitralklappenstenose	0	0.0	0	0.0	0	0.0	1	100.0	1	100.0
Angeborene Pulmonalklappenstenose	2	20.0	6	60.0	0	0.0	2	20.0	10	100.0
Angeborene Stenose der V. cava	0	0.0	0	0.0	1	100.0	0	0.0	1	100.0
Angeborene Trikuspidalklappenstenose	0	0.0	0	0.0	1	50.0	1	50.0	2	100.0
Aortopulmonaler Septumdefekt	1	33.3	1	33.3	0	0.0	1	33.3	3	100.0
Atresie der A. pulmonalis	0	0.0	0	0.0	0	0.0	3	100.0	3	100.0
Cor triatriatum	0	0.0	0	0.0	0	0.0	1	100.0	1	100.0
Defekt des Vorhof- und Kammerseptums	2	9.5	0	0.0	6	28.6	13	61.9	21	100.0
Diskordante atrioventrikuläre Verbindung	1	25.0	0	0.0	0	0.0	3	75.0	4	100.0
Diskordante ventrikuloarterielle Verbindung	0	0.0	0	0.0	0	0.0	14	100.0	14	100.0
Doppeleinstromventrikel	0	0.0	0	0.0	0	0.0	4	100.0	4	100.0
Ebstein-Anomalie	0	0.0	0	0.0	0	0.0	2	100.0	2	100.0
Fallot-Tetralogie	0	0.0	1	3.8	3	11.5	22	84.6	26	100.0

(Continued)

Tab 2.2.6.2: Patient characteristics
gestational age [weeks]
classification by risk of CHD (ICD-10 criteria)
all informative cases
evaluable population (EVP)

CHD (ICD-10 criteria)	Gestational age								all	
	<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
Fehleinmündung der Lungenvenen, nicht näher bez.	0	0.0	0	0.0	0	0.0	2	100.0	2	100.0
Hypoplastisches Linksherzsyndrom	0	0.0	0	0.0	1	4.2	23	95.8	24	100.0
Hypoplastisches Rechtsherzsyndrom	0	0.0	0	0.0	0	0.0	7	100.0	7	100.0
Infundibuläre Pulmonalstenose	2	33.3	1	16.7	2	33.3	1	16.7	6	100.0
Koarktation der Aorta	1	14.3	0	0.0	1	14.3	5	71.4	7	100.0
Linker Doppelausstromventrikel	0	0.0	0	0.0	0	0.0	1	100.0	1	100.0
Offener Ductus arteriosus	43	57.3	25	33.3	5	6.7	2	2.7	75	100.0
Partielle Fehleinmündung der Lungenvenen	1	100.0	0	0.0	0	0.0	0	0.0	1	100.0
Persistenz der linken V. cava superior	0	0.0	1	25.0	0	0.0	3	75.0	4	100.0
Pulmonalklappenatresie	0	0.0	0	0.0	1	16.7	5	83.3	6	100.0
Rechter Doppelausstromventrikel	0	0.0	0	0.0	0	0.0	9	100.0	9	100.0
Sonst. angeb. Fehlb.der Aorten- und Mitralklappe	0	0.0	0	0.0	0	0.0	1	100.0	1	100.0
Sonstige angeb. Fehlb. der A. pulmonalis	1	100.0	0	0.0	0	0.0	0	0.0	1	100.0
Sonstige angeb. Fehlb. der Pulmonalklappe	0	0.0	0	0.0	0	0.0	1	100.0	1	100.0

(Continued)

Tab 2.2.6.2: Patient characteristics
gestational age [weeks]
classification by risk of CHD (ICD-10 criteria)
all informative cases
evaluable population (EVP)

CHD (ICD-10 criteria)	Gestational age								all	
	<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
Sonstige angeb. Fehlb. der Trikuspidalklappe	1	25.0	0	0.0	0	0.0	3	75.0	4	100.0
Sonstige angeb. Fehlbild. der großen Arterien	0	0.0	0	0.0	0	0.0	2	100.0	2	100.0
Sonstige angeb. Fehlbildungen der Herzsepten	3	100.0	0	0.0	0	0.0	0	0.0	3	100.0
Sonstige angeborene Fehlbildungen der Aorta	0	0.0	0	0.0	0	0.0	7	100.0	7	100.0
Sonstige näher bez.angeb. Fehlb. des Herzens	0	0.0	0	0.0	0	0.0	1	100.0	1	100.0
Stenose der A. pulmonalis	7	43.8	6	37.5	2	12.5	1	6.3	16	100.0
Stenose der Aorta	0	0.0	0	0.0	1	25.0	3	75.0	4	100.0
Totale Fehleinmündung der Lungenvenen	0	0.0	0	0.0	0	0.0	1	100.0	1	100.0
Truncus arteriosus communis	0	0.0	1	25.0	0	0.0	3	75.0	4	100.0
Ventrikelseptumdefekt	8	11.0	13	17.8	12	16.4	40	54.8	73	100.0
Vorhofisomerismus	0	0.0	0	0.0	0	0.0	1	100.0	1	100.0
Vorhofseptumdefekt	36	36.4	34	34.3	18	18.2	11	11.1	99	100.0
all	112	22.9	92	18.8	57	11.6	229	46.7	490	100.0

Tab 2.2.7.1: Patient characteristics
gestational age [weeks]
classification by risk of cyan. vitium
all cases
evaluable population (EVP)

Cyan. vitium	Gestational age								all	
	<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
not ticked	692	30.8	701	31.2	468	20.8	264	11.7	2125	94.5
yes	2	0.1	4	0.2	6	0.3	111	4.9	123	5.5
all	694	30.9	705	31.4	474	21.1	375	16.7	2248	100.0

Tab 2.2.7.2: Patient characteristics
gestational age [weeks]
classification by risk of cyan. vitium
all informative cases
evaluable population (EVP)

Cyan. vitium	Gestational age								all	
	<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
yes	2	1.6	4	3.3	6	4.9	111	90.2	123	100.0
all	2	1.6	4	3.3	6	4.9	111	90.2	123	100.0

Tab 2.3.1: Patient characteristics
birth weight [g]
statistics
evaluable population (EVP)

		n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2008	0	2248	1690.7	858.5	990.0	1494.0	2200.0	350	4900

Tab 2.3.2: Patient characteristics
birth weight [g]
classification
all cases
evaluable population (EVP)

	Birth weight													
	<750 g		750-999 g		1000-1499 g		1500-1999 g		2000-2499 g		>2499 g		all	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2008	281	12.5	314	14.0	538	23.9	424	18.9	288	12.8	403	17.9	2248	100.0

Tab 2.3.3: Patient characteristics
birth weight [g]
correlation birth weight vs. gestational age
evaluable population (EVP)

Country	Year	Birth weight	Gestational age								all	
			<29 weeks		29-<33 weeks		33-35 weeks		>35 weeks			
			n	%	n	%	n	%	n	%	n	%
Germany												
	2008											
		<750 g	264	38.0	16	2.3	1	0.2	0	0.0	281	12.5
		750-999 g	247	35.6	65	9.2	2	0.4	0	0.0	314	14.0
		1000-1499 g	177	25.5	321	45.5	36	7.6	4	1.1	538	23.9
		1500-1999 g	4	0.6	253	35.9	158	33.3	9	2.4	424	18.9
		2000-2499 g	0	0.0	44	6.2	206	43.5	38	10.1	288	12.8
		>2499 g	2	0.3	6	0.9	71	15.0	324	86.4	403	17.9
		all	694	100.0	705	100.0	474	100.0	375	100.0	2248	100.0

Tab 2.4: Patient characteristics
children born in summer/winter
evaluable population (EVP)

	Born in				all	
	Summer		Winter			
	n	%	n	%	n	%
Germany						
2008	1055	46.9	1193	53.1	2248	100.0

Tab 3.1: Risks
Overview
all cases
evaluable population (EVP)

Country Year Riskfactor	Result						all	
	unknown		no/not ticked		yes			
	n	%	n	%	n	%	n	%
Germany								
2008								
CLD	0	0.0	1664	74.0	584	26.0	2248	100.0
CLD treated with oxygen/medication	0	0.0	1967	87.5	281	12.5	2248	100.0
add. children < 12 years	0	0.0	1133	50.4	1115	49.6	2248	100.0
attending daycare	0	0.0	2174	96.7	74	3.3	2248	100.0
congenital heart misformation	0	0.0	1681	74.8	567	25.2	2248	100.0
cyan.vitium	0	0.0	2125	94.5	123	5.5	2248	100.0
family history pos. for atopy	0	0.0	1902	84.6	346	15.4	2248	100.0
immuno deficiency	0	0.0	2218	98.7	30	1.3	2248	100.0
multiple birth	107	4.8	1509	67.1	632	28.1	2248	100.0
neuromuscular impairment	0	0.0	2128	94.7	120	5.3	2248	100.0
other chron lung disease	0	0.0	1775	79.0	473	21.0	2248	100.0
other risk factor	0	0.0	1970	87.6	278	12.4	2248	100.0
oxygen at home	0	0.0	2115	94.1	133	5.9	2248	100.0
premat. birth	0	0.0	375	16.7	1873	83.3	2248	100.0
smoking at home	0	0.0	1848	82.2	400	17.8	2248	100.0

Tab 3.2: Risks
premature birth
all cases
evaluable population (EVP)

	Premature birth					
	no		yes		all	
	n	%	n	%	n	%
Germany 2008	375	16.7	1873	83.3	2248	100.0

Tab 3.3.1: Risks
CLD
prevalences
all cases
evaluable population (EVP)

	CLD					
	not ticked		yes		all	
	n	%	n	%	n	%
Germany 2008	1664	74.0	584	26.0	2248	100.0

Tab 3.3.2: Risks
CLD
stratified by birth in season
all cases
evaluable population (EVP)

	CLD					
	not ticked		yes		all	
	n	%	n	%	n	%
Germany						
2008						
no	217	54.1	184	45.9	401	100.0
yes	1447	78.3	400	21.7	1847	100.0

Tab 3.4: Risks
congenital heart misformation
all cases
evaluable population (EVP)

	Congenital heart misformation					
	not ticked		yes		all	
	n	%	n	%	n	%
Germany 2008	1681	74.8	567	25.2	2248	100.0

Tab 3.5.1.1: Risks
multiple birth
yes/no
all cases
evaluable population (EVP)

	Multiple birth						all	
	unknown		no		yes			
	n	%	n	%	n	%	n	%
Germany 2008	107	4.8	1509	67.1	632	28.1	2248	100.0

Tab 3.5.1.2: Risks
multiple birth
yes/no
all informative cases
evaluable population (EVP)

	Multiple birth					
	no		yes		all	
	n	%	n	%	n	%
Germany 2008	1509	70.5	632	29.5	2141	100.0

Tab 3.5.2: Risks
multiple birth
number of children
evaluable population (EVP)

	Multiple birth														all	
	unknown		single child		twin		triplet		quadruplet		quintuplet		sextuplet			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2008	107	4.8	1509	67.1	562	25.0	69	3.1	1	0.0	0	0.0	0	0.0	2248	100.0

Tab 3.6: Risks
immuno deficiency
all cases
evaluable population (EVP)

	Immuno deficiency					
	not ticked		yes		all	
	n	%	n	%	n	%
Germany 2008	2218	98.7	30	1.3	2248	100.0

Tab 3.7: Risks
attending daycare
all cases
evaluable population (EVP)

	Attending daycare					
	not ticked		yes		all	
	n	%	n	%	n	%
Germany 2008	2174	96.7	74	3.3	2248	100.0

Tab 3.8.1: Risks
children <12 years in household
yes/no
all cases
evaluable population (EVP)

	Children <12 years in household					
	not ticked		yes		all	
	n	%	n	%	n	%
Germany 2008	1133	50.4	1115	49.6	2248	100.0

Tab 3.8.2: Risks
children <12 years in household
number of children
evaluable population (EVP)

	Children <12 years in household													
	0		1		2		3		4		5		6	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2008	1133	50.4	498	22.2	398	17.7	131	5.8	57	2.5	17	0.8	5	0.2

(Continued)

	Children <12 years in household						all	
	7		8		15			
	n	%	n	%	n	%	n	%
Germany 2008	5	0.2	2	0.1	2	0.1	2248	100.0

0 and missing are not distinguishable

Tab 3.9.1: Risks
smoking in the family
all cases
evaluable population (EVP)

	Smoking in the family					
	not ticked		yes		all	
	n	%	n	%	n	%
Germany 2008	1848	82.2	400	17.8	2248	100.0

0 and missing are not distinguishable

Tab 3.9.2: Risks
smoking in the family
number of smokers
evaluable population (EVP)

	Smoking in the family										all	
	0		1		2		3		4			
	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2008	1848	82.2	280	12.5	116	5.2	3	0.1	1	0.0	2248	100.0

0 and missing are not distinguishable

Tab 3.10: Risks
treatment CLD with medication/oxygen
all cases
evaluable population (EVP)

	Treatment CLD with medication/oxygen					
	not ticked		yes		all	
	n	%	n	%	n	%
Germany 2008	1967	87.5	281	12.5	2248	100.0

0 and missing are not distinguishable

Tab 3.11: Risks
treatment with oxygen at home
all cases
evaluable population (EVP)

	Treatment with oxygen at home					
	not ticked		yes		all	
	n	%	n	%	n	%
Germany 2008	2115	94.1	133	5.9	2248	100.0

0 and missing are not distinguishable

Tab 3.12: Risks
neuromuscular impairment (NMI)
all cases
evaluable population (EVP)

	Neuromuscular impairment (NMI)					
	not ticked		yes		all	
	n	%	n	%	n	%
Germany 2008	2128	94.7	120	5.3	2248	100.0

Tab 3.13: Risks
family history pos. for atopy
all cases
evaluable population (EVP)

	Family history pos. for atopy					
	not ticked		yes		all	
	n	%	n	%	n	%
Germany 2008	1902	84.6	346	15.4	2248	100.0

Tab 3.14: Risks
other risk factors
all cases
evaluable population (EVP)

	Other risk factors					
	not ticked		yes		all	
	n	%	n	%	n	%
Germany 2008	1970	87.6	278	12.4	2248	100.0

0 and missing are not distinguishable

Tab 3.15: Risks
other chron lung diseases
all cases
evaluable population (EVP)

	Other chron lung diseases					
	not ticked		yes		all	
	n	%	n	%	n	%
Germany 2008	1775	79.0	473	21.0	2248	100.0

0 and missing are not distinguishable

Tab 4.1.1.1: Immunization
Reason
Overview
all cases
evaluable population (EVP)

	Reason for immunization															
	unknown		premature birth <=35weeks		BPD		CHD (haemodyna-m. sign)		NMI		Mucoviscid-osis		other		all	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2008	7	0.3	1505	66.9	310	13.8	318	14.1	14	0.6	4	0.2	90	4.0	2248	100.0

Tab 4.1.1.2: Immunization
Reason
Overview
all informative cases
evaluable population (EVP)

	Reason for immunization										all	
	premature birth <=35weeks		BPD		CHD (haemodynam. sign)		NMI		Mucoviscido-sis			
	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2008	1505	70.0	310	14.4	318	14.8	14	0.7	4	0.2	2151	100.0

Tab 4.1.2.1: Immunization
Reason
Subanalysis for children 33-35weeks
all cases
evaluable population (EVP)

	Reason for immunization														all	
	unknown		premature birth <=35weeks		BPD		CHD (haemodyn-am. sign)		NMI		Mucovisci-dosis		other			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																
2008																
<25 weeks	0	0.0	78	66.7	36	30.8	1	0.9	1	0.9	0	0.0	1	0.9	117	100.0
25-<29 weeks	0	0.0	412	71.4	153	26.5	4	0.7	2	0.3	0	0.0	6	1.0	577	100.0
29-<33 weeks	0	0.0	615	87.2	64	9.1	14	2.0	0	0.0	1	0.1	11	1.6	705	100.0
33-35 weeks	0	0.0	400	84.4	31	6.5	29	6.1	3	0.6	1	0.2	10	2.1	474	100.0
>35 weeks	7	1.9	0	0.0	26	6.9	270	72.0	8	2.1	2	0.5	62	16.5	375	100.0
all	7	0.3	1505	66.9	310	13.8	318	14.1	14	0.6	4	0.2	90	4.0	2248	100.0

Tab 4.1.2.2: Immunization
Reason
Subanalysis for children 33-35weeks
all informative cases
evaluable population (EVP)

	Reason for immunization											
	premature birth <=35weeks		BPD		CHD (haemodyn-am. sign)		NMI		Mucovisci-dosis		all	
	n	%	n	%	n	%	n	%	n	%	n	%
Germany												
2008												
<25 weeks	78	67.2	36	31.0	1	0.9	1	0.9	0	0.0	116	100.0
25-<29 weeks	412	72.2	153	26.8	4	0.7	2	0.4	0	0.0	571	100.0
29-<33 weeks	615	88.6	64	9.2	14	2.0	0	0.0	1	0.1	694	100.0
33-35 weeks	400	86.2	31	6.7	29	6.3	3	0.6	1	0.2	464	100.0
>35 weeks	0	0.0	26	8.5	270	88.2	8	2.6	2	0.7	306	100.0
all	1505	70.0	310	14.4	318	14.8	14	0.7	4	0.2	2151	100.0

Tab 4.1.3.1: Immunization
Reason
Subanalysis for children with CLD
all cases
evaluable population (EVP)

	Reason for immunization														all	
	unknown		premature birth <=35weeks		BPD		CHD (haemodyna-m. sign)		NMI		Mucoviscid-osis		other			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																
2008																
not ticked	7	0.4	1239	74.5	58	3.5	287	17.2	6	0.4	2	0.1	65	3.9	1664	100.0
yes	0	0.0	266	45.5	252	43.2	31	5.3	8	1.4	2	0.3	25	4.3	584	100.0
all	7	0.3	1505	66.9	310	13.8	318	14.1	14	0.6	4	0.2	90	4.0	2248	100.0

Tab 4.1.3.2: Immunization
Reason
Subanalysis for children with CLD
all informative cases
evaluable population (EVP)

	Reason for immunization											
	premature birth <=35weeks		BPD		CHD (haemodyna-m. sign)		NMI		Mucoviscid-osis		all	
	n	%	n	%	n	%	n	%	n	%	n	%
Germany												
2008												
yes	266	47.6	252	45.1	31	5.5	8	1.4	2	0.4	559	100.0
all	266	47.6	252	45.1	31	5.5	8	1.4	2	0.4	559	100.0

Tab 4.1.4.1: Immunization
Reason
Subanalysis for children with CHD
all cases
evaluable population (EVP)

	Reason for immunization														all	
	unknown		premature birth <=35weeks		BPD		CHD (haemodyna-m. sign)		NMI		Mucoviscid-osis		other			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																
2008																
not ticked	6	0.4	1300	77.3	257	15.3	36	2.1	12	0.7	3	0.2	67	4.0	1681	100.0
yes	1	0.2	205	36.2	53	9.3	282	49.7	2	0.4	1	0.2	23	4.1	567	100.0
all	7	0.3	1505	66.9	310	13.8	318	14.1	14	0.6	4	0.2	90	4.0	2248	100.0

Tab 4.1.4.2: Immunization
Reason
Subanalysis for children with CHD
all informative cases
evaluable population (EVP)

	Reason for immunization											
	premature birth <=35weeks		BPD		CHD (haemodyna-m. sign)		NMI		Mucoviscid-osis		all	
	n	%	n	%	n	%	n	%	n	%	n	%
Germany												
2008												
yes	205	37.8	53	9.8	282	51.9	2	0.4	1	0.2	543	100.0
all	205	37.8	53	9.8	282	51.9	2	0.4	1	0.2	543	100.0

Tab 4.2: Immunization
RSV prophylaxis in the last season
all cases
evaluable population (EVP)

	RSV prophylaxis in the last season					
	not ticked		yes		all	
	n	%	n	%	n	%
Germany						
2008	1915	85.2	333	14.8	2248	100.0

Tab 4.3.1: Immunization
location
all cases
evaluable population (EVP)

	Immunization start in									
	unknown		med. practice		hospital		other		all	
	n	%	n	%	n	%	n	%	n	%
Germany 2008	446	19.8	1485	66.1	313	13.9	4	0.2	2248	100.0

Tab 4.3.2: Immunization
location
all informative cases
evaluable population (EVP)

	Immunization started in clinic					
	med. practice		hospital		all	
	n	%	n	%	n	%
Germany 2008	1485	82.6	313	17.4	1798	100.0

Tab 4.4.1.1: Immunization recommendation overview all cases evaluable population (EVP)

	Recommendation from								all	
	unknown		paediatrician		hospital		other			
	n	%	n	%	n	%	n	%	n	%
Germany 2008	368	16.4	660	29.4	1191	53.0	29	1.3	2248	100.0

Tab 4.4.1.2: Immunization recommendation overview all informative cases evaluable population (EVP)

	Recommendation from					
	paediatrician		hospital		all	
	n	%	n	%	n	%
Germany 2008	660	35.7	1191	64.3	1851	100.0

Tab 4.4.2.1: Immunization recommendation
Subanalysis for patients with 1st immun. in paediatric practice
all cases
evaluable population (EVP)

Country	Year	1st immun.	Recommendation from								all	
			unknown		paediatrician		hospital		other			
			n	%	n	%	n	%	n	%	n	%
Germany												
	2008											
		unknown	349	78.3	34	7.6	58	13.0	5	1.1	446	100.0
		med. practice	15	1.0	342	23.0	1108	74.6	20	1.3	1485	100.0
		hospital	3	1.0	283	90.4	24	7.7	3	1.0	313	100.0
		other	1	25.0	1	25.0	1	25.0	1	25.0	4	100.0

Tab 4.4.2.2: Immunization recommendation
Subanalysis for patients with 1st immun. in paediatric practice
all informative cases
evaluable population (EVP)

Country	Year	1st immun.	Recommendation from				all	
			paediatrician		hospital			
			n	%	n	%	n	%
Germany								
	2008							
		med. practice	342	23.6	1108	76.4	1450	100.0
		hospital	283	92.2	24	7.8	307	100.0

Tab 4.4.3.1: Immunization recommendation by age at start of RSV prophylaxis [months] all cases evaluable population (EVP)

Country	Year	Age[month]	Recommendation from								all	
			unknown		paediatrician		hospital		other			
			n	%	n	%	n	%	n	%	n	%
Germany												
	2008											
		0	1	8.3	4	33.3	7	58.3	0	0.0	12	100.0
		1	35	18.7	32	17.1	117	62.6	3	1.6	187	100.0
		2	58	15.4	104	27.7	211	56.1	3	0.8	376	100.0
		3	58	16.5	109	31.1	181	51.6	3	0.9	351	100.0
		4	36	14.3	77	30.7	134	53.4	4	1.6	251	100.0
		5	44	20.4	64	29.6	105	48.6	3	1.4	216	100.0
		6	33	19.2	45	26.2	94	54.7	0	0.0	172	100.0
		7	23	19.3	30	25.2	64	53.8	2	1.7	119	100.0
		8	16	18.0	24	27.0	48	53.9	1	1.1	89	100.0
		9	7	11.7	23	38.3	29	48.3	1	1.7	60	100.0
		10	7	12.1	22	37.9	26	44.8	3	5.2	58	100.0
		11	8	16.3	20	40.8	21	42.9	0	0.0	49	100.0
		12	4	9.8	17	41.5	20	48.8	0	0.0	41	100.0
		13	4	9.1	18	40.9	22	50.0	0	0.0	44	100.0
		14	3	8.8	15	44.1	15	44.1	1	2.9	34	100.0
		15	8	23.5	8	23.5	17	50.0	1	2.9	34	100.0
		16	5	17.9	10	35.7	11	39.3	2	7.1	28	100.0
		17	1	4.3	11	47.8	11	47.8	0	0.0	23	100.0
		18	2	10.0	4	20.0	14	70.0	0	0.0	20	100.0
		19	2	11.1	5	27.8	11	61.1	0	0.0	18	100.0
		20	3	18.8	6	37.5	7	43.8	0	0.0	16	100.0
		21	6	26.1	5	21.7	11	47.8	1	4.3	23	100.0
		22	0	0.0	0	0.0	7	100.0	0	0.0	7	100.0
		23	3	21.4	6	42.9	4	28.6	1	7.1	14	100.0
		24	1	25.0	1	25.0	2	50.0	0	0.0	4	100.0
		25	0	0.0	0	0.0	2	100.0	0	0.0	2	100.0

Tab 4.4.3.2: Immunization recommendation by age at start of RSV prophylaxis [months] all informative cases evaluable population (EVP)

Country	Year	Age[month]	Recommendation from					
			paediatrician		hospital		all	
			n	%	n	%	n	%
Germany								
	2008							
		0	4	36.4	7	63.6	11	100.0
		1	32	21.5	117	78.5	149	100.0
		2	104	33.0	211	67.0	315	100.0
		3	109	37.6	181	62.4	290	100.0
		4	77	36.5	134	63.5	211	100.0
		5	64	37.9	105	62.1	169	100.0
		6	45	32.4	94	67.6	139	100.0
		7	30	31.9	64	68.1	94	100.0
		8	24	33.3	48	66.7	72	100.0
		9	23	44.2	29	55.8	52	100.0
		10	22	45.8	26	54.2	48	100.0
		11	20	48.8	21	51.2	41	100.0
		12	17	45.9	20	54.1	37	100.0
		13	18	45.0	22	55.0	40	100.0
		14	15	50.0	15	50.0	30	100.0
		15	8	32.0	17	68.0	25	100.0
		16	10	47.6	11	52.4	21	100.0
		17	11	50.0	11	50.0	22	100.0
		18	4	22.2	14	77.8	18	100.0
		19	5	31.3	11	68.8	16	100.0
		20	6	46.2	7	53.8	13	100.0
		21	5	31.3	11	68.8	16	100.0
		22	0	0.0	7	100.0	7	100.0
		23	6	60.0	4	40.0	10	100.0
		24	1	33.3	2	66.7	3	100.0
		25	0	0.0	2	100.0	2	100.0

Tab 4.5.1: Immunization
age at start of RSV prophylaxis [months]
all patients
evaluable population (EVP)

		n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2008	0	2248	5.898	4.932	2.433	4.233	7.517	0.20	25.00

Tab 4.5.2.1: Immunization
age at start of RSV prophylaxis [months]
age < 12 months
by risk of CLD
evaluable population (EVP)

		CLD	n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2008	not ticked	0	1506	3.978	2.510	2.000	3.333	5.400	0.20	11.93
		yes	0	458	5.572	2.915	3.200	5.083	7.667	0.40	11.97

Tab 4.5.2.2: Immunization
age at start of RSV prophylaxis [months]
age < 12 months
by risk of CHD
evaluable population (EVP)

		CHD	n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2008	not ticked	0	1516	4.246	2.597	2.217	3.567	5.700	0.20	11.97
		yes	0	448	4.702	2.979	2.250	3.983	6.900	0.23	11.90

Tab 4.5.3.1: Immunization
age at start of RSV prophylaxis [months]
age >= 12 months
by risk of CLD
evaluable population (EVP)

		CLD	n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2008	not ticked	0	158	16.415	3.205	13.767	15.467	18.800	12.07	25.00
		yes	0	126	16.834	3.504	13.433	16.350	19.600	12.07	24.90

Tab 4.5.3.2: Immunization
age at start of RSV prophylaxis [months]
age >= 12 months
by risk of CHD
evaluable population (EVP)

		CHD	n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2008	not ticked	0	165	16.584	3.224	13.867	15.867	19.000	12.07	25.00
		yes	0	119	16.624	3.512	13.500	15.767	19.467	12.13	24.90

Tab 4.6: Immunization
Frequency of age at start of RSV prophylaxis [months]
evaluable population (EVP)

	0		1		2		3		4		5		6		7		8		9	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2008	12	0.5	187	8.3	376	16.7	351	15.6	251	11.2	216	9.6	172	7.7	119	5.3	89	4.0	60	2.7

	10		11		12		13		14		15		16		17		18		19	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2008	58	2.6	49	2.2	41	1.8	44	2.0	34	1.5	34	1.5	28	1.2	23	1.0	20	0.9	18	0.8

	20		21		22		23		24		25		all	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2008	16	0.7	23	1.0	7	0.3	14	0.6	4	0.2	2	0.1	2248	100.0

Tab 4.7.1: Immunization
administrations
total number
evaluable population (EVP)

	1		2		3		4		5		6		7		8		9		10	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2008	126	5.6	200	8.9	251	11.2	299	13.3	379	16.9	474	21.1	385	17.1	98	4.4	20	0.9	10	0.4

	11		all	
	n	%	n	%
Germany 2008	6	0.3	2248	100.0

Tab 4.7.2: Immunization
administrations
total number categorized into <5 vs >= 5 administrations
evaluable population (EVP)

	<5		>=5		all	
	n	%	n	%	n	%
Germany						
2008	876	39.0	1372	61.0	2248	100.0

Tab 4.7.3: Immunization
administrations
time between successive administrations
evaluable population (EVP)

	<= 13days		14-20days		21-35days		36-50days		50-100days		>100days		all	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany 2008	18	0.2	64	0.7	7539	85.8	871	9.9	216	2.5	83	0.9	8791	100.0

Tab 4.7.4: Immunization administrations outside original definition of season evaluable population (EVP)

	before 01SEP2008		between 01SEP2008 and 31May2009		after 31May2009		all	
	n	%	n	%	n	%	n	%
Germany 2008	51	0.5	10918	98.9	70	0.6	11039	100.0

Tab 4.8: Immunization
total number of follow-up administrations by month and year of first administration
all cases
evaluable population (EVP)

Month + year of 1st admin	0		1		2		3		4		5		6		7		8		9	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																				
2008																				
NOV07	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0
JAN08	0	0.0	0	0.0	2	28.6	1	14.3	0	0.0	0	0.0	3	42.9	0	0.0	1	14.3	0	0.0
FEB08	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	50.0	1	50.0	0	0.0	0	0.0	0	0.0
MAR08	1	25.0	0	0.0	0	0.0	0	0.0	1	25.0	0	0.0	0	0.0	1	25.0	1	25.0	0	0.0
APR08	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	50.0	1	50.0	0	0.0	0	0.0	0	0.0
AUG08	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	6	37.5	4	25.0
SEP08	9	2.8	5	1.6	2	0.6	18	5.7	26	8.2	37	11.7	123	38.9	79	25.0	12	3.8	5	1.6
OCT08	12	1.5	13	1.6	17	2.1	44	5.5	136	17.1	314	39.5	241	30.3	18	2.3	0	0.0	0	0.0
NOV08	8	2.1	20	5.2	27	7.1	64	16.8	139	36.5	108	28.3	15	3.9	0	0.0	0	0.0	0	0.0
DEC08	3	1.4	8	3.6	25	11.3	103	46.4	71	32.0	11	5.0	1	0.5	0	0.0	0	0.0	0	0.0
JAN09	13	6.2	32	15.3	92	44.0	65	31.1	6	2.9	1	0.5	0	0.0	0	0.0	0	0.0	0	0.0
FEB09	9	6.1	56	37.8	79	53.4	4	2.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
MAR09	39	36.1	62	57.4	7	6.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
APR09	28	87.5	4	12.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
MAY09	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
OCT09	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0
all	126	5.6	200	8.9	251	11.2	299	13.3	379	16.9	474	21.1	385	17.1	98	4.4	20	0.9	10	0.4

(Continued)

Tab 4.8: Immunization
total number of follow-up administrations by month and year of first administration
all cases
evaluable population (EVP)

Month + year of 1st admin	10		all	
	n	%	n	%
Germany				
2008				
NOV07	0	0.0	1	100.0
JAN08	0	0.0	7	100.0
FEB08	0	0.0	2	100.0
MAR08	0	0.0	4	100.0
APR08	0	0.0	2	100.0
AUG08	6	37.5	16	100.0
SEP08	0	0.0	316	100.0
OCT08	0	0.0	795	100.0
NOV08	0	0.0	381	100.0
DEC08	0	0.0	222	100.0
JAN09	0	0.0	209	100.0
FEB09	0	0.0	148	100.0
MAR09	0	0.0	108	100.0
APR09	0	0.0	32	100.0
MAY09	0	0.0	3	100.0
OCT09	0	0.0	2	100.0
all	6	0.3	2248	100.0

Tab 4.9: Immunization
Dose
evaluable population (EVP)

		RSV-Number	n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2008	1	7	2241	79.356	33.504	50.000	74.000	100.000	5.00	200.00
		2	5	2117	90.182	31.190	66.000	90.000	100.000	4.00	200.00
		3	5	1917	99.800	28.373	80.000	100.000	110.000	4.00	200.00
		4	4	1667	107.115	27.036	91.000	100.000	120.000	6.00	220.00
		5	0	1372	113.656	27.042	100.000	104.000	130.000	15.00	250.00
		6	0	993	119.543	27.318	100.000	113.000	141.000	5.00	250.00
		7	0	519	124.171	29.279	100.000	120.000	150.000	50.00	250.00
		8	0	134	134.568	36.144	100.000	132.000	150.000	62.00	250.00
		9	0	36	149.556	47.648	117.500	150.000	200.000	11.00	250.00
		10	0	16	178.125	31.458	150.000	175.000	200.000	150.00	250.00
		11	0	6	175.000	27.386	150.000	175.000	200.000	150.00	200.00

Tab 4.10: Immunization
total number of administrations grouped by children born in summer/winter
evaluable population (EVP)

Country/year/born in summer/winter	Total number of administrations																	
	1		2		3		4		5		6		7		8		9	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																		
2008																		
Summer	33	3.1	49	4.6	60	5.7	120	11.4	197	18.7	281	26.6	238	22.6	65	6.2	6	0.6
Winter	93	7.8	151	12.7	191	16.0	179	15.0	182	15.3	193	16.2	147	12.3	33	2.8	14	1.2
all	126	5.6	200	8.9	251	11.2	299	13.3	379	16.9	474	21.1	385	17.1	98	4.4	20	0.9

(Continued)

Country/year/born in summer/winter	Total number of administrations					
	10		11		all	
	n	%	n	%	n	%
Germany						
2008						
Summer	1	0.1	5	0.5	1055	100.0
Winter	9	0.8	1	0.1	1193	100.0
all	10	0.4	6	0.3	2248	100.0

Tab 4.11: Immunization
weight change relative to birth weight and age (months)
evaluable population (EVP)

Country/year-/month after DOB	Weight diff. [kg]																	
	missing		-2.2 - <0		0-< 5		5-< 6		6-< 7		7-< 8		8-< 9		9-<10		10-<15	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany																		
2008																		
0-< 1			3	4.9	58	95.1												
1-< 2			1	0.2	408	99.5			1	0.2								
2-< 3	1	0.1	2	0.3	722	99.4			1	0.1								
3-< 4	1	0.1	1	0.1	917	99.1	4	0.4	2	0.2								
4-< 5					935	94.2	50	5.0	5	0.5	2	0.2	1	0.1				
5-< 6					862	82.8	147	14.1	24	2.3	7	0.7	1	0.1				
6-< 7					630	63.5	272	27.4	76	7.7	13	1.3	1	0.1				
7-< 8					415	45.8	330	36.4	138	15.2	18	2.0	6	0.7				
8-< 9					262	31.2	321	38.3	195	23.2	52	6.2	8	1.0	1	0.1		
9-<10					166	24.3	229	33.5	198	28.9	76	11.1	12	1.8	2	0.3	1	0.1
10-<11					94	16.9	155	27.9	188	33.8	93	16.7	20	3.6	3	0.5	3	0.5
11-<12					50	11.4	101	23.1	149	34.0	98	22.4	28	6.4	7	1.6	5	1.1
12-<13					52	14.5	75	20.9	117	32.7	74	20.7	31	8.7	8	2.2	1	0.3
13-<14					38	12.4	65	21.2	82	26.7	74	24.1	39	12.7	7	2.3	2	0.7
14-<15					34	12.7	40	14.9	81	30.2	62	23.1	37	13.8	13	4.9	1	0.4
15-<16					25	10.3	28	11.6	74	30.6	64	26.4	27	11.2	20	8.3	4	1.7
16-<17					22	10.9	28	13.9	49	24.4	53	26.4	27	13.4	18	9.0	4	2.0
17-<18					10	5.6	18	10.1	50	27.9	44	24.6	31	17.3	18	10.1	8	4.5
18-<19					13	8.0	17	10.4	35	21.5	49	30.1	29	17.8	13	8.0	7	4.3
19-<20					5	3.8	16	12.1	23	17.4	43	32.6	24	18.2	16	12.1	5	3.8
20-<21					6	4.3	10	7.2	32	23.2	34	24.6	28	20.3	25	18.1	3	2.2
21-<22					6	5.9	9	8.8	20	19.6	21	20.6	22	21.6	18	17.6	6	5.9
22-<23					3	3.2	8	8.5	15	16.0	20	21.3	22	23.4	18	19.1	8	8.5
23-<24					2	2.4	9	10.7	17	20.2	9	10.7	22	26.2	14	16.7	11	13.1
24-<25					1	1.3	5	6.7	15	20.0	13	17.3	18	24.0	8	10.7	15	20.0
25-<32							5	4.1	28	23.0	17	13.9	24	19.7	18	14.8	30	24.6
>32											2	100.0						
all	2	0.0	7	0.1	5736	52.0	1942	17.6	1615	14.6	938	8.5	458	4.1	227	2.1	114	1.0

Tab 4.11: Immunization
weight change relative to birth weight and age (months)
evaluable population (EVP)

Country/year-/month after DOB	all	
	n	%
Germany		
2008		
0-< 1	61	100.0
1-< 2	410	100.0
2-< 3	726	100.0
3-< 4	925	100.0
4-< 5	993	100.0
5-< 6	1041	100.0
6-< 7	992	100.0
7-< 8	907	100.0
8-< 9	839	100.0
9-<10	684	100.0
10-<11	556	100.0
11-<12	438	100.0
12-<13	358	100.0
13-<14	307	100.0
14-<15	268	100.0
15-<16	242	100.0
16-<17	201	100.0
17-<18	179	100.0
18-<19	163	100.0
19-<20	132	100.0
20-<21	138	100.0
21-<22	102	100.0
22-<23	94	100.0
23-<24	84	100.0
24-<25	75	100.0
25-<32	122	100.0
>32	2	100.0
all	11039	100.0

Tab 5.1.1.1: Complications
hospitalization
general overview
(CRF or forms)
evaluable population (EVP)

	Number of hospitalizations/patient									
	0		1		2		3		all	
	n	%	n	%	n	%	n	%	n	%
Germany 2008	2144	95.4	93	4.1	7	0.3	4	0.2	2248	100.0

Tab 5.1.1.2: Complications
hospitalization
general overview
hospitalization forms overview
evaluable population (EVP)

		Number of hospitalization forms							
		1		2		3		all	
		n	%	n	%	n	%	n	%
Country	Survey year								
Germany	2008	71	89.9	5	6.3	3	3.8	79	100.0

Tab 5.1.1.3: Complications
hospitalization
general overview
cross-tabulation of hospitalization (CRF vs. hospitalization form)
evaluable population (EVP)

Country	Hosp. form existing	Number of hospitalizations=yes								all	
		0		1		2		3			
		n	%	n	%	n	%	n	%	n	%
Germany											
	2008										
	no	2144	98.8	23	1.1	2	0.1	0	0.0	2169	100.0
	yes	0	0.0	70	88.6	5	6.3	4	5.1	79	100.0
all		2144	95.4	93	4.1	7	0.3	4	0.2	2248	100.0

Tab 5.1.2: Complications
hospitalization
time [days] from 1st admin. for patients with causal relationship to RSV-Infection and RSV=pos
evaluable population (EVP)

		n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2008	0	17	70.1	68.4	16.0	31.0	103.0	5	201

Tab 5.1.3: Complications
hospitalization
time [days] from most recent admin. for patients with causal relationship to RSV-Infection and RSV=pos
evaluable population (EVP)

		n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2008	0	17	20.4	8.8	12.0	19.0	26.0	5	34

Tab 5.1.4: Complications
hospitalization
duration
evaluable population (EVP)

		n miss	n	mean	std dev	25% quartile	median	75% quartile	minimum	maximum
Germany	2008	2	88	11.9	16.0	4.0	7.0	13.0	1	111

Tab 5.2: Complications
Nosocomial infection
all cases
evaluable population (EVP)

Country	year	NI					
		not ticked		yes		all	
		n	%	n	%	n	%
Germany	2008	79	87.8	11	12.2	90	100.0

Tab 5.3: Complications
causal relationship to RSV
all cases
evaluable population (EVP)

Country	year	Causal relationship to RSV					
		not ticked		yes		all	
		n	%	n	%	n	%
Germany	2008	72	80.0	18	20.0	90	100.0

Tab 5.4.1: Complications
RSV-Result (microbiolog. proved)
all cases
evaluable population (EVP)

Country	year	RSV-Result								all	
		unknown		RSV-positive		RSV-negative		not assessable			
		n	%	n	%	n	%	n	%	n	%
Germany	2008	42	46.7	18	20.0	26	28.9	4	4.4	90	100.0

Tab 5.4.2: Complications
RSV-Result (microbiolog. proved)
all informative cases
evaluable population (EVP)

Country	year	RSV-Result					
		RSV-positive		RSV-negative		all	
		n	%	n	%	n	%
Germany	2008	18	40.9	26	59.1	44	100.0

Tab 5.4.3: Complications
RSV-Result (microbiolog. proved)
by causal relationship to RSV
all informative cases
evaluable population (EVP)

Country year	Causality to RSV	RSV-Result					
		RSV-positive		RSV-negative		all	
		n	%	n	%	n	%
Germany							
2008							
	not ticked	1	3.7	26	96.3	27	100.0
	yes	17	100.0	0	0.0	17	100.0

Tab 5.5.1: Complications
Epicrit. diagnosis
all cases
evaluable population (EVP)

Country	year	Epicrit. diagnosis														all	
		unknown		bronchitis		bronchioli-tis		pneumonia (clin)		pneumonia (rad)		acute lung failure		A-B-Syndrome			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany	2008	33	36.7	24	26.7	4	4.4	7	7.8	18	20.0	3	3.3	1	1.1	90	100.0

Tab 5.5.2: Complications
Epicrit. diagnosis
all informative cases
evaluable population (EVP)

Country	year	Epicrit. diagnosis												all	
		bronchitis		bronchioli-tis		pneumonia (clin)		pneumonia (rad)		acute lung failure		A-B-Syndrome			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany	2008	24	42.1	4	7.0	7	12.3	18	31.6	3	5.3	1	1.8	57	100.0

Tab 5.6: Complications
intensive care [days]
all cases
evaluable population (EVP)

Country	year	intensive care [days]																	
		0		1		2		3		5		6		7		10		11	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany	2008	68	75.6	2	2.2	2	2.2	3	3.3	1	1.1	1	1.1	1	1.1	4	4.4	1	1.1

(Continued)

0 days and missing entries are not distinguishable

Tab 5.6: Complications
intensive care [days]
all cases
evaluable population (EVP)

Country	year	intensive care [days]										all	
		14		17		23		24		64			
		n	%	n	%	n	%	n	%	n	%	n	%
Germany	2008	3	3.3	1	1.1	1	1.1	1	1.1	1	1.1	90	100.0

0 days and missing entries are not distinguishable

Tab 5.7: Complications
mechanical ventilation [days]
all cases
evaluable population (EVP)

Country	year	mechanical ventilation [days]												all	
		0		1		3		4		12		13			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%
Germany	2008	82	91.1	3	3.3	1	1.1	2	2.2	1	1.1	1	1.1	90	100.0

0 days and missing entries are not distinguishable

Tab 5.8: Complications
oxygen due to RSV
all cases
evaluable population (EVP)

Country	year	Oxygen due to RSV					
		not ticked		yes		all	
		n	%	n	%	n	%
Germany	2008	56	62.2	34	37.8	90	100.0

Tab 5.9: Complications
oxygen due to other reason
all cases
evaluable population (EVP)

Country	year	Oxygen due to other reason					
		not ticked		yes		all	
		n	%	n	%	n	%
Germany	2008	82	91.1	8	8.9	90	100.0

Tab 5.10: Complications
death directly or indirectly associated with RSV-Infection
all cases
evaluable population (EVP)

Country	year	death directly or indirectly associated with RSV-Infection			
		not ticked		all	
		n	%	n	%
Germany	2008	90	100.0	90	100.0

Tab 6: Occurrence of serious adverse events (SAE)
all cases
evaluable population (EVP)

Country	Season	Immun. number	Occurrence of SAE					
			not ticked		yes		all	
			n	%	n	%	n	%
Germany								
	2008							
		1	2242	99.7	6	0.3	2248	100.0
		2	2119	99.9	3	0.1	2122	100.0
		3	1920	99.9	2	0.1	1922	100.0
		4	1668	99.8	3	0.2	1671	100.0
		5	1369	99.8	3	0.2	1372	100.0
		6	991	99.8	2	0.2	993	100.0
		7	519	100.0	0	0.0	519	100.0
		8	134	100.0	0	0.0	134	100.0
		9	36	100.0	0	0.0	36	100.0
		10	16	100.0	0	0.0	16	100.0
		11	6	100.0	0	0.0	6	100.0
		all	11020	99.8	19	0.2	11039	100.0

Tab 7: Occurrence of acute adverse events
all cases
evaluable population (EVP)

Country	Season	Immun. number	Occurrence of acute adverse events					
			not ticked		yes		all	
			n	%	n	%	n	%
Germany								
	2008							
		1	2246	99.9	2	0.1	2248	100.0
		2	2121	100.0	1	0.0	2122	100.0
		3	1917	99.7	5	0.3	1922	100.0
		4	1669	99.9	2	0.1	1671	100.0
		5	1371	99.9	1	0.1	1372	100.0
		6	992	99.9	1	0.1	993	100.0
		7	519	100.0	0	0.0	519	100.0
		8	134	100.0	0	0.0	134	100.0
		9	36	100.0	0	0.0	36	100.0
		10	16	100.0	0	0.0	16	100.0
		11	6	100.0	0	0.0	6	100.0
		all	11027	99.9	12	0.1	11039	100.0

Tab 8.1: Cooperation of parents
all cases
evaluable population (EVP)

Country	Season	Immun. number	Cooperation of parents								all	
			unknown		good		bad		satisfying			
			n	%	n	%	n	%	n	%	n	%
Germany												
	2008											
		1	382	17.0	1697	75.5	37	1.6	132	5.9	2248	100.0
		2	402	18.9	1565	73.8	28	1.3	127	6.0	2122	100.0
		3	406	21.1	1402	72.9	26	1.4	88	4.6	1922	100.0
		4	341	20.4	1225	73.3	26	1.6	79	4.7	1671	100.0
		5	293	21.4	1000	72.9	16	1.2	63	4.6	1372	100.0
		6	209	21.0	750	75.5	4	0.4	30	3.0	993	100.0
		7	117	22.5	383	73.8	2	0.4	17	3.3	519	100.0
		8	20	14.9	103	76.9	2	1.5	9	6.7	134	100.0
		9	1	2.8	32	88.9	2	5.6	1	2.8	36	100.0
		10	0	0.0	13	81.3	0	0.0	3	18.8	16	100.0
		11	0	0.0	5	83.3	0	0.0	1	16.7	6	100.0
		all	2171	19.7	8175	74.1	143	1.3	550	5.0	11039	100.0

Tab 8.2: Cooperation of parents
all informative cases
evaluable population (EVP)

Country	Season	Immun. number	Cooperation of parents						all	
			good		bad		satisfying			
			n	%	n	%	n	%	n	%
Germany										
	2008									
		1	1697	90.9	37	2.0	132	7.1	1866	100.0
		2	1565	91.0	28	1.6	127	7.4	1720	100.0
		3	1402	92.5	26	1.7	88	5.8	1516	100.0
		4	1225	92.1	26	2.0	79	5.9	1330	100.0
		5	1000	92.7	16	1.5	63	5.8	1079	100.0
		6	750	95.7	4	0.5	30	3.8	784	100.0
		7	383	95.3	2	0.5	17	4.2	402	100.0
		8	103	90.4	2	1.8	9	7.9	114	100.0
		9	32	91.4	2	5.7	1	2.9	35	100.0
		10	13	81.3	0	0.0	3	18.8	16	100.0
		11	5	83.3	0	0.0	1	16.7	6	100.0
		all	8175	92.2	143	1.6	550	6.2	8868	100.0

Tab 9.1: Subgroup analyses for hospitalization
by CLD
all cases
evaluable population (EVP)

CLD	Number of hospitalizations/patient									
	0		1		2		3		all	
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
not ticked	1619	97.3	40	2.4	4	0.2	1	0.1	1664	100.0
yes	550	94.2	31	5.3	1	0.2	2	0.3	584	100.0
all	2169	96.5	71	3.2	5	0.2	3	0.1	2248	100.0

Tab 9.2: Subgroup analyses for hospitalization
by CLD treated with oxygen/medication
all cases
evaluable population (EVP)

CLD treated with oxygen/medication	Number of hospitalizations/patient								all	
	0		1		2		3			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
not ticked	1915	97.4	47	2.4	4	0.2	1	0.1	1967	100.0
yes	254	90.4	24	8.5	1	0.4	2	0.7	281	100.0
all	2169	96.5	71	3.2	5	0.2	3	0.1	2248	100.0

Tab 9.3: Subgroup analyses for hospitalization
by children <12 years
all cases
evaluable population (EVP)

Children <12 years	Number of hospitalizations/patient								all	
	0		1		2		3			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
not ticked	1105	97.5	26	2.3	0	0.0	2	0.2	1133	100.0
yes	1064	95.4	45	4.0	5	0.4	1	0.1	1115	100.0
all	2169	96.5	71	3.2	5	0.2	3	0.1	2248	100.0

Tab 9.4: Subgroup analyses for hospitalization
by attending daycare
all cases
evaluable population (EVP)

Attending daycare	Number of hospitalizations/patient									
	0		1		2		3		all	
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
not ticked	2098	96.5	68	3.1	5	0.2	3	0.1	2174	100.0
yes	71	95.9	3	4.1	0	0.0	0	0.0	74	100.0
all	2169	96.5	71	3.2	5	0.2	3	0.1	2248	100.0

Tab 9.5: Subgroup analyses for hospitalization
by congenital heart misformation
all cases
evaluable population (EVP)

Congenital heart misformation	Number of hospitalizations/patient								all	
	0		1		2		3			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
not ticked	1632	97.1	44	2.6	3	0.2	2	0.1	1681	100.0
yes	537	94.7	27	4.8	2	0.4	1	0.2	567	100.0
all	2169	96.5	71	3.2	5	0.2	3	0.1	2248	100.0

Tab 9.6: Subgroup analyses for hospitalization
by cyan. vitium
all cases
evaluable population (EVP)

Cyan. vitium	Number of hospitalizations/patient									
	0		1		2		3		all	
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
not ticked	2057	96.8	60	2.8	5	0.2	3	0.1	2125	100.0
yes	112	91.1	11	8.9	0	0.0	0	0.0	123	100.0
all	2169	96.5	71	3.2	5	0.2	3	0.1	2248	100.0

Tab 9.7: Subgroup analyses for hospitalization
by family history pos. for atopy
all cases
evaluable population (EVP)

Family history pos. for atopy	Number of hospitalizations/patient								all	
	0		1		2		3			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
not ticked	1839	96.7	57	3.0	4	0.2	2	0.1	1902	100.0
yes	330	95.4	14	4.0	1	0.3	1	0.3	346	100.0
all	2169	96.5	71	3.2	5	0.2	3	0.1	2248	100.0

Tab 9.8: Subgroup analyses for hospitalization
by immuno deficiency
all cases
evaluable population (EVP)

Immuno deficiency	Number of hospitalizations/patient									
	0		1		2		3		all	
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
not ticked	2139	96.4	71	3.2	5	0.2	3	0.1	2218	100.0
yes	30	100.0	0	0.0	0	0.0	0	0.0	30	100.0
all	2169	96.5	71	3.2	5	0.2	3	0.1	2248	100.0

Tab 9.9: Subgroup analyses for hospitalization
by multiple birth
all cases
evaluable population (EVP)

Multiple birth	Number of hospitalizations/patient									
	0		1		2		3		all	
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
unknown	104	97.2	3	2.8	0	0.0	0	0.0	107	100.0
no	1452	96.2	49	3.2	5	0.3	3	0.2	1509	100.0
yes	613	97.0	19	3.0	0	0.0	0	0.0	632	100.0
all	2169	96.5	71	3.2	5	0.2	3	0.1	2248	100.0

Tab 9.10: Subgroup analyses for hospitalization
by neuromuscular impairment
all cases
evaluable population (EVP)

Neuromuscular impairment	Number of hospitalizations/patient								all	
	0		1		2		3			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
not ticked	2062	96.9	59	2.8	5	0.2	2	0.1	2128	100.0
yes	107	89.2	12	10.0	0	0.0	1	0.8	120	100.0
all	2169	96.5	71	3.2	5	0.2	3	0.1	2248	100.0

Tab 9.11: Subgroup analyses for hospitalization
by other chron lung disease
all cases
evaluable population (EVP)

Other chron lung disease	Number of hospitalizations/patient									
	0		1		2		3		all	
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
not ticked	1711	96.4	58	3.3	3	0.2	3	0.2	1775	100.0
yes	458	96.8	13	2.7	2	0.4	0	0.0	473	100.0
all	2169	96.5	71	3.2	5	0.2	3	0.1	2248	100.0

Tab 9.12: Subgroup analyses for hospitalization
by other risk factor
all cases
evaluable population (EVP)

Other risk factor	Number of hospitalizations/patient								all	
	0		1		2		3			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
not ticked	1903	96.6	59	3.0	5	0.3	3	0.2	1970	100.0
yes	266	95.7	12	4.3	0	0.0	0	0.0	278	100.0
all	2169	96.5	71	3.2	5	0.2	3	0.1	2248	100.0

Tab 9.13: Subgroup analyses for hospitalization
by oxygen at home
all cases
evaluable population (EVP)

Oxygen at home	Number of hospitalizations/patient								all	
	0		1		2		3			
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
not ticked	2052	97.0	58	2.7	4	0.2	1	0.0	2115	100.0
yes	117	88.0	13	9.8	1	0.8	2	1.5	133	100.0
all	2169	96.5	71	3.2	5	0.2	3	0.1	2248	100.0

Tab 9.14: Subgroup analyses for hospitalization
by premat. infant
all cases
evaluable population (EVP)

Premat. infant	Number of hospitalizations/patient									
	0		1		2		3		all	
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
no	360	96.0	13	3.5	2	0.5	0	0.0	375	100.0
yes	1809	96.6	58	3.1	3	0.2	3	0.2	1873	100.0
all	2169	96.5	71	3.2	5	0.2	3	0.1	2248	100.0

Tab 9.15: Subgroup analyses for hospitalization
by smoking at home
all cases
evaluable population (EVP)

Smoking at home	Number of hospitalizations/patient									
	0		1		2		3		all	
	n	%	n	%	n	%	n	%	n	%
Germany										
2008										
not ticked	1787	96.7	55	3.0	4	0.2	2	0.1	1848	100.0
yes	382	95.5	16	4.0	1	0.3	1	0.3	400	100.0
all	2169	96.5	71	3.2	5	0.2	3	0.1	2248	100.0

A2.2.4 Additional analyses for 2002/03 – 2008/09

Table 1.1 - Number of hospitalization forms by number of hospitalizations documented in CRF
Year: 2002

	Number of hospitalizations in CRF								
Number of hospitalization forms	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
no 0	771	82	0	0	0	0	0	0	0

Table 1.2 - Number of hospitalization forms by number of hospitalizations documented in CRF
Year: 2003

	Number of hospitalizations in CRF								
Number of hospitalization forms	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
no 0	1229	4	0	0	0	0	0	0	0
yes 1	14	35	3	0	0	0	0	0	0
yes 2	0	1	0	0	0	0	0	0	0
yes 3	1	0	0	0	0	0	0	0	0

Table 1.3 - Number of hospitalization forms by number of hospitalizations documented in CRF
Year: 2004

	Number of hospitalizations in CRF								
Number of hospitalization forms	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
no 0	2124	8	2	0	0	0	0	0	0
yes 1	16	57	1	0	0	0	0	0	0

Table 1.4 - Number of hospitalization forms by number of hospitalizations documented in CRF
Year: 2005

	Number of hospitalizations in CRF								
Number of hospitalization forms	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
no 0	2885	11	0	0	1	0	0	0	0
yes 1	21	78	1	0	0	0	0	0	0
yes 2	0	1	1	0	0	0	0	0	0
yes 3	0	0	1	0	0	0	0	0	0

Table 1.5 - Number of hospitalization forms by number of hospitalizations documented in CRF
Year: 2006

	Number of hospitalizations in CRF								
Number of hospitalization forms	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
no 0	3226	13	2	0	0	2	1	0	1
yes 1	34	54	2	0	0	0	0	0	0
yes 2	1	0	2	0	0	0	0	0	0

Table 1.6 - Number of hospitalization forms by number of hospitalizations documented in CRF
Year: 2007

	Number of hospitalizations in CRF								
Number of hospitalization forms	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
no 0	3680	16	0	1	0	1	0	0	0
yes 1	18	77	1	2	0	0	0	0	0
yes 2	1	3	0	0	0	0	0	0	0
yes 3	2	1	0	0	2	0	0	0	0

Table 1.7 - Number of hospitalization forms by number of hospitalizations documented in CRF
Year: 2008

	Number of hospitalizations in CRF								
Number of hospitalization forms	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
no 0	2144	22	1	0	0	0	0	0	0
yes 1	0	71	1	1	0	0	0	0	0
yes 2	0	0	5	0	0	0	0	0	0
yes 3	0	0	0	3	0	0	0	0	0

Table 2.1 - Immunization administrations 2002-2006 (Quantitative results)
Basis: tabsyg02_03_04_05_06a.pdf
Table: 4.5.1

	N	Missing	Mean	SD	Min	25%-Q	Median	75%-Q	Max
2002	853	0	4.4	1.6	1.0	3.0	5.0	5.0	8.0
2003	1287	0	4.4	1.7	1.0	3.0	5.0	6.0	9.0
2004	2208	0	4.6	1.8	1.0	3.0	5.0	6.0	9.0
2005	3000	0	4.6	1.8	1.0	3.0	5.0	6.0	10.0
2006	3338	0	4.9	1.9	1.0	4.0	5.0	6.0	12.0
all	10686	0	4.7	1.8	1.0	3.0	5.0	6.0	12.0

Table 2.2 - Immunization administrations 2007 (Quantitative results)
Basis: tabsyg07a_de.pdf
Table: 4.5.1

	N	Missing	Mean	SD	Min	25%-Q	Median	75%-Q	Max
2007	3805	0	4.8	1.9	1.0	3.0	5.0	6.0	9.0

Table 2.3 - Immunization administrations 2008 (Quantitative results)
Basis: tabsyg08a_de_final.pdf
Table: 4.7.1

	N	Missing	Mean	SD	Min	25%-Q	Median	75%-Q	Max
2008	2248	0	4.9	2.0	1.0	3.0	5.0	6.0	11.0

Table 2.4 - Complications - intensive care [days] 2008 (Quantitative results)
Basis: tabsyg08a_de_final.pdf
Table: 5.6

	N	Missing	Mean	SD	Min	25%-Q	Median	75%-Q	Max
2008	22	0	11.5	13.5	1.0	3.0	10.0	14.0	64.0

Table 2.5 - Complications - mechanical ventilation [days] 2008 (Quantitative results)
Basis: tabsyg08a_de_final.pdf
Table: 5.7

	N	Missing	Mean	SD	Min	25%-Q	Median	75%-Q	Max
2008	8	0	4.9	4.9	1.0	1.0	3.5	8.0	13.0

Table 3.1 - Patient characteristics - gestational age [weeks] without outliers
Basis: tabsyg02_03_04_05_06a.pdf
Table: 2.2.1

	N	Missing	Mean	SD	Min	25%-Q	Median	75%-Q	Max
2002	831	22	29.49	3.69	22.00	27.00	29.00	32.00	41.00
2003	1135	152	29.38	3.42	20.00	27.00	29.00	32.00	41.00
2004	1871	337	29.71	3.53	22.00	27.00	29.00	32.00	41.00
2005	2455	545	29.76	3.54	22.00	27.00	30.00	32.00	41.00
2006	2655	683	29.80	3.49	22.00	27.00	30.00	32.00	40.00
all	8947	1739	29.69	3.52	20.00	27.00	29.00	32.00	41.00

A2.2.5 Source tables 2009/10 – 2015/16

Synagis Report

28. October 2016

Report No. SYNAGIS-02-2016 GW

Analysis:

- Synagis Registry 2015-2016 (year 2015/16)
- Synagis Registry 2009-2016 (years 2009/10 - 2015/16)

ANALYSIS SYNAGIS, 28. OCT. 2016

CONTENTS

STUDY POPULATIONS

Number of subjects and disposition

	2009-2010	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016
Patients total	2158	1994	2092	2100	1923	1778	1757
Excluded because of date of birth*	9	6	3	6	10	9	6
Excluded because of date of first immunization**	12	11	3	1	2	-	-
Excluded because of missing immunization	4	8	-	-	1	-	-
Evaluable patients	**2133**	**1969**	**2086**	**2093**	**1910**	**1769**	**1751**
Participating centers/ paediatric offices	**617**	**523**	**501**	**503**	**436**	**403**	**375**

* Date of birth before the 1st of September, more than 2 years before the start of the correspoding RSV season (age > 24 months)
** First immunization not administered between the September 1st and the May 31st

STUDY POPULATIONS WITH DOWN SYNDROME (TRISOMY 21)

Number of patients with Down syndrome

Registry	Down syndrome total	Thereof no premature birth (<36 weeks)	Thereof no chronic lung disease	Thereof no congenital heart malformation	Without these three risk factors
2009-2010	25	19	22	11	**8**
2010-2011	26	18	23	3	**1**
2011-2012	46	29	38	7	**2**
2012-2013	47	36	36	3	**2**
2013-2014	48	38	35	2	**0**
2014-2015	61	45	54	7	**2**
2015-2016	44	32	35	5	**3**
2009-2016	297	217	243	38	**18**

PLAUSIBILITY CHECKS

- **Hospitalization**
  - 8x: delete because last immunization has been admistered more than 5 weeks before hospitalization (PatID [redacted] time 102 days, PatID [redacted] time 57 days, PatID [redacted] time 45 days, PatID [redacted] time 43 days, PatID [redacted] time 40 days, PatID [redacted] time 59 days, PatID [redacted] time 36 days, PatID [redacted] time 41 days
  - 1x correct duration of mechanical ventilation in days (PatID [redacted] original -19, corrected 19)

BASELINE CHARACTERISTICS

Sex

		Frequency	Percent
Valid	female	815	46.5
	male	936	53.5
	Total	1751	100.0

Gestational age (weeks)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	< 29	456	26.0	26.0	26.0
	29-<33	568	32.4	32.4	58.5
	33-<35	338	19.3	19.3	77.8
	≥35	389	22.2	22.2	100.0
	Total	1751	100.0	100.0	

Birth weight

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	< 1000 g	399	22.8	22.8	22.8
	1000-1499 g	418	23.9	23.9	46.7
	1500-1999 g	353	20.2	20.2	66.8
	≥2000 g	581	33.2	33.2	100.0
	Total	1751	100.0	100.0	

Descriptive Statistics

		Gestational age (weeks)	Birth weight
N	Valid	1751	1751
	Missing	0	0
Mean		31.54	1755.69
Median		32	1625
Std. Deviation		4.33	858.94
Minimum		22	353
Maximum		42	4830
Percentile	25	28	1090
	50	32	1625
	75	34	2280

Table: Risk factors (N=total information. n=number of children with risk factors)

Risik factors	N	n	in %
Premature birth (<36 weeks)	1751	1467	83.8
Multiple births	1648	557	33.8
Siblings in kinder garden or school age	1644	636	38.7
Congenital heart malformation	1715	542	31.6
Smoking in the family[+]	965	311	32.2
Family history of asthma	1511	103	6.8
Family history of atopy	1491	251	16.8
Chronic lung disease (CLD)[#]	1697	311	18.3
CLD therapy	1655	254	15.3
Treatment with oxygen at home	1689	136	8.1
Immuno-deficiency	1648	27	1.6
Down syndrome (trisomy 21)	1724	44	2.6
Cyanotic vitium	1667	130	7.8
Neuromuscular impairment	1650	189	11.5
Serious neuromuscular disease	1659	101	6.1
NMI positive*	1635	222	13.6
Attending daytime care	1646	94	5.7
Low social status	1590	335	21.1
Crowded living condition	1358	421	31.0
Exposition to air pollution	1513	238	15.7
Breast feeding <=2 month	1502	853	56.8

[+]"Smoking in the family" is defined as yes, if variable "AnzahlRaucher" in dataset is greater than 0.
"Smoking in the family" is defined as no, if variable "AnzahlRaucher" in dataset is equal to 0.
#This item refers to "bronchopulmonary dysplasia" (BPD)
*Neuromuscular impairment positive or serious neuromuscular disease positive

Descriptive Statistics: Number of immunizations

N = Number of children	1751
Mean*	5.21
Median*	6
Std. Deviation	1.995
Minimum*	1
Maximum*	9
Patients with more than 5 immunizations (number)	912
Patients with more than 5 immunizations (percentage)	52.1%
Immunizations altogether (total number of documented immunization cycles oder courses)	9123

* Number of immunizations per child and season

Number of immunizations

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	67	3.8	3.8	3.8
	2	166	9.5	9.5	13.3
	3	168	9.6	9.6	22.9
	4	195	11.1	11.1	34.0
	5	243	13.9	13.9	47.9
	6	360	20.6	20.6	68.5
	7	370	21.1	21.1	89.6
	8	163	9.3	9.3	98.9
	9	19	1.1	1.1	100.0
	Total	1751	100.0	100.0	

Cooperation of the parents / caregivers with the immunization schedule

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	good	7140	78.3	93.2	93.2
	satisfying	425	4.7	5.5	98.7
	bad	98	1.1	1.3	100.0
	Total	7663	84.0	100.0	
Missing	System	1460	16.0		
Total		9123	100.0		

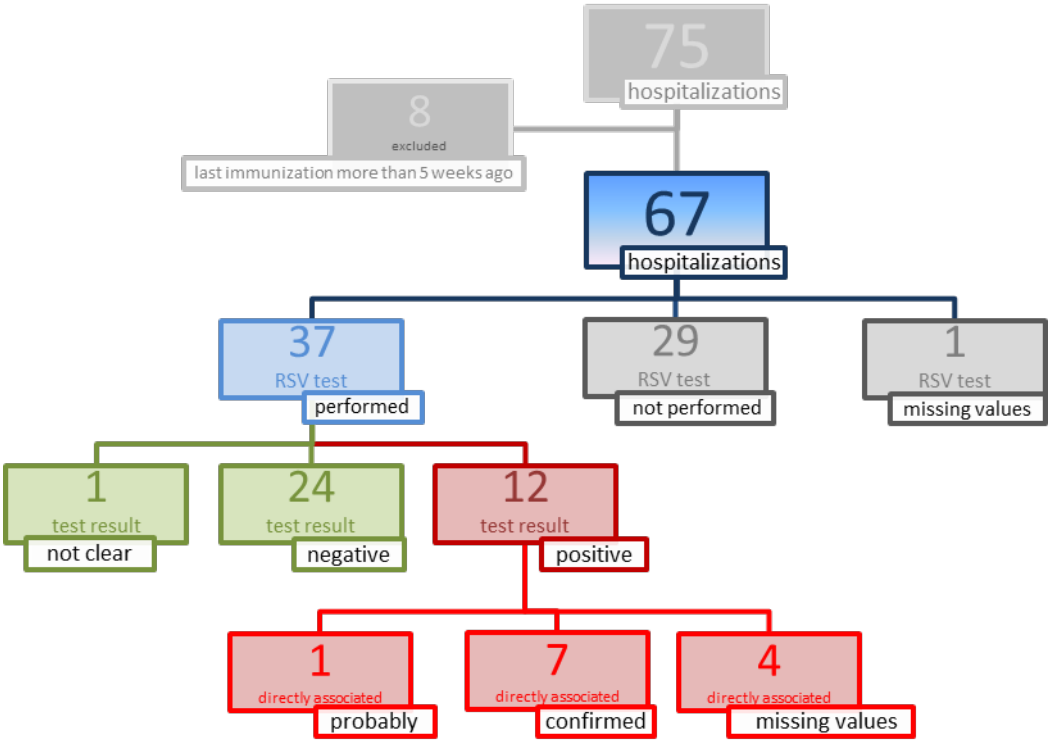
Location of Synagis first immunzation

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	unknown	34	1.9	1.9	1.9
	med. practice	1225	70.0	70.0	71.9
	hospital	492	28.1	28.1	100.0
	Total	1751	100.0	100.0	

Age at start of immunization

N	Valid			1751
	Missing			0
		days	weeks	months
Mean		151	21.6	5.0
Median		98	14.0	3.2
Std. Deviation		145	20.7	4.8
Minimum		0	0	0
Maximum		759	108.4	24.9
Percentile	25	52	7.4	1.7
	50	98	14.0	3.2
	75	198	28.3	6.5

Flow chart of hospitalized children



	n (% of N=1751)	Premature birth (% of n)	Congenital heart malformation (% of n)	Chronic lung disease (% of n)	CLD therapy (% of n)	Treatment with oxygen at home (% of n)
Hospitalizations total	67 (3.8)	51 (76.1)	36 (53.7)	31 (46.3)	20 (29.9)	13 (19.4)
Patients with hospitalization	47 (2.7)	35 (74.5)	22 (46.8)	19 (40.4)	12 (25.5)	9 (19.1)
Hospitalizations allocated to ‚RSV associated' by the documenting physician (confirmed and probably)	8 (0.5)	8 (100)	4 (50.0)	5 (62.5)	4 (50.0)	2 (25.0)
Hospitalizations allocated to ‚RSV associated' by the documenting physician but test result negative or RSV test not performed	0	-	-	-	-	-
Hospitalizations with RSV test performed	37 (2.1)	29 (78.4)	20 (54.1)	19 (51.4)	15 (40.5)	10 (27.0)
Hospitalizations with RSV test positive	12 (0.7)	11 (91.7)	6 (50.0)	7 (58.3)	5 (41.7)	4 (33.3)
Hospitalizations with RSV test negative	24 (1.4)	18 (75.0)	13 (54.2)	11 (45.8)	10 (41.7)	6 (25.0)
Hospitalizations with RSV test no informative result	1 (0.1)	0 (0)	1 (100)	1 (100)	0 (0)	0 (0)

	n	in % of N=1751	in % of all immunizations =9123
Adverse events total	86	4.9	0.94
Patients with adverse events	58	3.1	0.59

Severity of the documented adverse events

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	not severe	5	5.8	9.1	9.1
	mild	9	10.5	16.4	25.5
	moderate	21	24.4	38.2	63.6
	severe (SAE)	20	23.3	36.4	100.0
	Total	55	64.0	100.0	
Missing	System	31	36.0		
Total		86	100.0		

Associated with immunization

		Frequency	Percent
Valid	unknown	76	88.4
	reliable	7	8.1
	possible	3	3.5
	Total	86	100.0

Severity with reliable or possible association

		Frequency	Percent
Valid	not severe	1	10.0
	mild	2	20.0
	moderate	3	30.0
	severe (SAE)	2	20.0
	Total	8	80.0
Missing	System	2	20.0
Total		10	100.0

SEPARATE ANALYSIS

Classification of patients into 3 groups (several hospitalzations per patient allowed)

Group 1: 12 hospitalizations directly allocated to the category "associated with RSV infection" (denominated as confirmed or probable per physician or positive RSV test)

Group 2: 55 hospitalizations not allocated to "associated with RSV infection" or RSV test negative

Group 3: 1704 patients without hospitalization during the corresponding RSV season

HOSPITALIZATIONS

N=total hospitlizations. n= hospitalizations with particular characteristics

Group	1			2		
	N	n	in %	N	n	in %
Respiratory infection	12	12	100.0	54	33	61.1
Nosocomial infection	11	0	0	23	0	0
Oxygen because of respiratory infection	12	7	58.3	55	21	38.2
Oxygen because of other reasons	10	0	0	55	3	5.5
Intensive care*	11	0	0	54	8	14.8
Mechanical ventilation**	11	2	18.2	55	6	10.9
Death	12	0	0	55	0	0
Death associated with RSV infection						

* days of intensive care > 0

** days of mechanical ventilation > 0

	Duration of intensive care (days)		Duration of mechanical ventilation (days)	
	Group 1	Group 2	Group 1	Group 2
N	0	8	2	6
Mean		7.9	5.5	15.8
Median		4.5	5.5	14.5
Std. Deviation		6.5	6.4	12.2
Minimum		2	1	1
Maximum		19	10	37

Epicrit diagnosis

	Group 1 (N=12)		Group 2 (N=48)	
	n	in %	n	in %
Bronchitis	3	25	19	39.6
Bronchiolitis	5	41.7	1	2.1
Pneumonia (clinical diagnosis)	1	8.3	0	0
Pneumonia (confirmed by chest radiography)	2	16.7	5	10.4
Acute respiratory failure	0	0	1	2.1
Unknown	1	8.3	22	45.8

BASELINE CHARACTERISTICS

Group 1 and 2: N= total hospitlizations. n= hospitalizations with particular characteristics
Groupe 3: N=total patients without hospitalization. n=patients with particular characteristics

Group	1			2			3		
	N	n	in %	N	n	in %	N	n	in %
Sex female	12	9	75.0	55	24	43.6	1704	790	46.4
male		3	25.0		31	56.4		914	53.6
Gestational < 29	12	8	66.7	55	18	32.7	1704	438	25.7
age (weeks) 29-<33		3	25.0		11	20.0		557	32.7
33-<35		0	0.0		7	12.7		334	19.6
≥35		1	8.3		19	34.5		375	22.0
Birth weight < 1000 g	12	8	66.7	55	18	32.7	1704	381	22.4
1000-1499 g		2	16.7		8	14.5		411	24.1
1500-1999 g		1	8.3		3	5.5		349	20.5
≥2000 g		1	8.3		26	47.3		563	33.0
Premature birth (<36 weeks)	12	11	91.7	55	40	72.7	1704	1432	84.0
Multiple births	12	4	33.3	51	8	15.7	1605	547	34.1
Siblings in kindergarten or school	12	4	33.3	51	19	37.3	1599	619	38.7
Congenital heart malformation	12	6	50.0	55	30	54.5	1668	520	31.2
Smoking in the family[+]	8	1	12.5	40	9	22.5	932	306	32.8
Family history of asthma	11	0	0.0	52	2	3.8	1466	101	6.9
Family history of atopy	8	2	25.0	47	6	12.8	1450	245	16.9
Chronic lung disease (CLD)#	12	7	58.3	55	24	43.6	1650	292	17.7
CLD therapy	12	5	41.7	52	15	28.8	1609	242	15.0
Treatment with oxygen at home	12	4	33.3	55	9	16.4	1642	127	7.7
Immuno-deficiency	11	0	0.0	49	3	6.1	1604	25	1.6
Down syndrome (Trisomy 21)	12	0	0.0	55	5	9.1	1677	41	2.4
Cyanotic vitium cordis	12	0	0.0	55	9	16.4	1620	125	7.7
Neuromuscular impairment	12	1	8.3	55	26	47.3	1603	173	10.8
Serious neuromuscular disease	10	1	10.0	50	5	10.0	1615	98	6.1
NMI positive*	10	1	10.0	53	27	50.9	1590	205	12.9
Attending day care	12	2	16.7	54	4	7.4	1600	91	5.7
Low social status	11	3	27.3	53	10	18.9	1545	326	21.1
Crowded living condition	9	1	11.1	45	11	24.4	1318	412	31.3
Exposition to air pollution	12	2	16.7	49	8	16.3	1469	233	15.9
Breast feeding ≤ 2month	12	5	41.7	52	34	65.4	1458	829	56.9

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"Smoking in the family" is defined as no, if variable "AnzahlRaucher" in dataset is equal to 0.
#This item refers to "bronchopulmonary dysplasia" (BPD)
*Neuromuscular impairment positive or serious neuromuscular disease positive

STUDY POPULATIONS

Only the first registration is analysed.

	Patients total	Down syndrome total	Thereof patients with first RSV-registry	Thereof patients with Down syndrome (Trisomie 21)	Participating centers / paediatric offices
2009-2010	2133	25	2133	25	617
2010-2011	1969	26	1812	25	523
2011-2012	2086	46	1911	41	501
2012-2013	2093	47	1926	38	503
2013-2014	1910	48	1759	39	436
2014-2015	1769	61	1602	47	401
2015-2016	1751	44	1586	34	363
Summarized	*13711*	*297*	*12729*	*249*	*3344*
Total 2009-2016			**12729**	**249**	**1005***

*Number of pairwise different participating centers / paediatric offices

BASELINE CHARACTERISTICS

Sex

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	female	5707	44.8	44.9	44.9
	male	7013	55.1	55.1	100.0
	Total	12720	99.9	100.0	
Missing	System	9	0.1		
Total		12729	100.0		

Gestational age (weeks)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	< 29	3514	27.6	27.6	27.6
	29-<33	4033	31.7	31.7	59.3
	33-<35	2434	19.1	19.1	78.4
	≥35	2748	21.6	21.6	100.0
	Total	12729	100.0	100.0	

Birth weight

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	< 1000 g	2946	23.1	23.1	23.1
	1000-1499 g	3063	24.1	24.1	47.2
	1500-1999 g	2590	20.3	20.3	67.6
	≥2000 g	4130	32.4	32.4	100.0
	Total	12729	100.0	100.0	

Descriptive Statistics

		Gestational age (weeks)	Birth weight
N	Valid	12729	12729
	Missing	0	0
Mean		31.5	1729.8
Median		32	1605
Std. Deviation		4.30	840.23
Minimum		10	330
Maximum		42	6160
Percentile	25	28	1070
	50	32	1605
	75	34	2230

RISK FACTORS

Table: Risk factors (N=total information. n=number of children with risk factors)

Risk factors	N	n	in %
Premature birth (<36 weeks)	12729	10784	84.72
Multiple births	12147	3793	31.23
Siblings in kindergarten or school	10767	4899	45.50
Congenital heart malformation	12544	3430	27.34
Smoking in the family[+]	6332	2037	32.17
Family history of asthma	10589	1128	10.65
Family history of atopy	10606	2039	19.22
Chronic lung disease (CLD)#	12422	2346	18.89
CLD therapy	12291	1803	14.67
Treatment with oxygen at home	12490	763	6.11
Immuno-deficiency	12271	171	1.39
Down syndrome (Trisomy 21)°	12729	249	1.96
Cyanotic vitium cordis	12363	784	6.34
Neuromuscular impairment	8435	786	9.32
Serious neuromuscular disease	8393	428	5.10
NMI positive*	12185	1181	9.69
Attending day care	12389	361	2.91
Low social status	11915	2258	18.95
Crowded living condition	10575	2592	24.51
Exposition to air pollution	10960	1710	15.60
Breast feeding ≤ 2month	11417	5794	50.75

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"Smoking in the family" is defined as no, if variable "AnzahlRaucher" in dataset is equal to 0.
#This item refers to "bronchopulmonary dysplasia" (BPD).
°N=Number of patients in total with first RSV immunization. n=Number of patients with down syndrome (respective variable value = 1 (registry 2011-2012 to 2015-2016) or extracted from physician comments contained in datasets (registry 2009-2010 and 2010-2011).
*Neuromuscular impairment positive or serious neuromuscular disease positive.

Descriptive Statistics: Number of immunizations

N = Number of children	12729
Mean*	4.99
Median*	5
Std. Deviation	2.0
Minimum*	1
Maximum*	10
Patients with more than 5 immunizations (number)	5773
Patients with more than 5 immunizations (percentage)	45.4%
Immunizations altogether (total number of documented immunization cycles oder courses)	63572

* Number of immunizations per child with first season

Number of immunizations

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	585	4.6	4.6	4.6
	2	1200	9.4	9.4	14.0
	3	1479	11.6	11.6	25.6
	4	1570	12.3	12.3	38.0
	5	2122	16.7	16.7	54.6
	6	2518	19.8	19.8	74.4
	7	2084	16.4	16.4	90.8
	8	993	7.8	7.8	98.6
	9	160	1.3	1.3	99.9
	10	18	0.1	0.1	100.0
	Total	12729	100.0	100.0	

Cooperation of the parents / caregivers with the immunization schedule

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	good	51408	80.9	93.5	93.5
	satisfying	2985	4.7	5.4	99.0
	bad	575	0.9	1.0	100.0
	Total	54968	86.5	100.0	
Missing	System	8604	13.5		
Total		63572	100.0		

Location of Synagis first immunzation

		Frequency	Percent
Valid	unknown	196	1.5
	med. practice	9406	73.9
	hospital	3127	24.6
	Total	12729	100.0

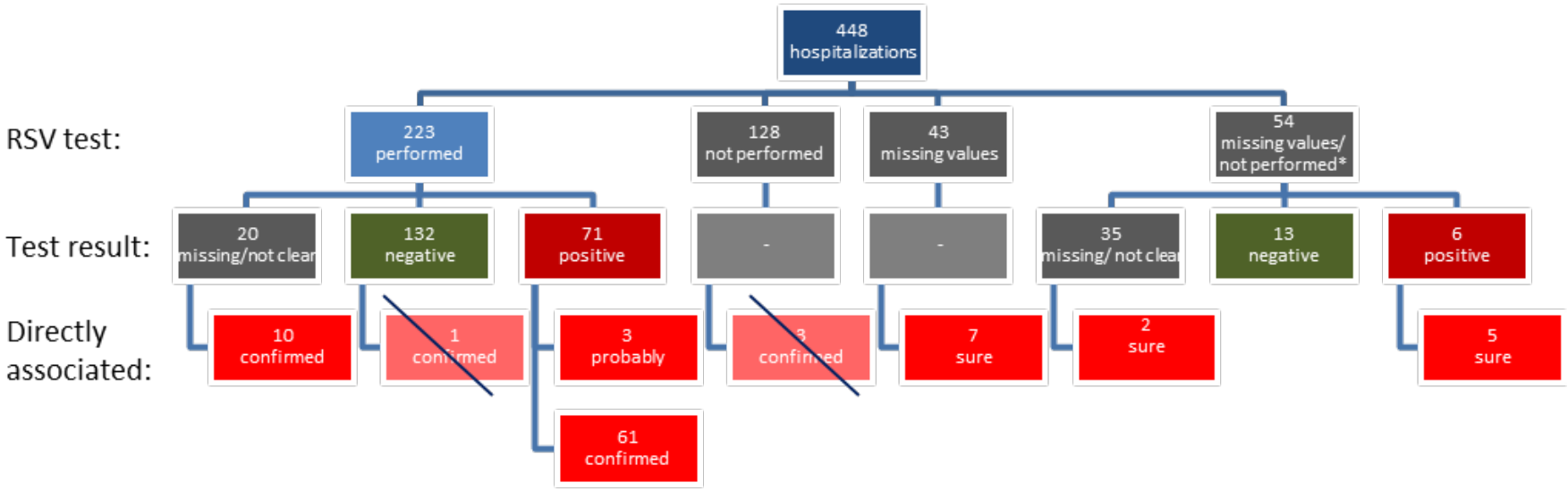
Age at start of immunization

N				
	Valid	12729		
	Missing	0		
		days	weeks	months
Mean		130	18.6	4.3
Median		97	13.9	3.2
Std. Deviation		111	15.9	3.6
Minimum		0	0	0
Maximum		800	114.3	26.2
Percentile	25	55	7.9	1.8
	50	97	13.9	3.2
	75	169	24.1	5.5

HOSPITALIZATIONS

	Hospitalizations total	**Hospitalizations only patients with first RSV-Registry**
2009-2010	84	**84**
2010-2011	97	**88**
2011-2012	65	**59**
2012-2013	62	**54**
2013-2014	47	**43**
2014-2015	66	**60**
2015-2016	67	**60**
2009-2016	488	**448**

Flow chart of hospitalized children



*no differentiation in 09/10

	n (% of N=12729)	Premature birth (% of n)	Congenital heart malformation (% of n)	Chronic lung disease (% of n)	CLD therapy (% of n)	Treatment with oxygen at home (% of n)
Hospitalizations total	448 (3.5)	355 (79.2)	164 (36.6)	197 (44.0)	151 (33.7)	86 (19.2)
Patients with hospitalization	345 (2.7)	272 (78.8)	118 (34.2)	139 (40.3)	106 (30.7)	62 (18.0)
Hospitalizations allocated to ‚RSV associated' by the documenting physician (confirmed and probably)*	88 (0.7)	76 (86.4)	24 (27.3)	38 (43.2)	28 (31.8)	15 (17.0)
Hospitalizations allocated to ‚RSV associated' by the documenting physician but test result negative or RSV test not performed**	4 (0.03)	4 (100)	2 (50)	0 (0)	0 (0)	0 (0)
Hospitalizations with RSV test performed	223 (1.8)	183 (82.1)	73 (32.7)	96 (43.0)	76 (34.1)	39 (17.5)
Hospitalizations with RSV test positive	77 (0.6)	65 (84.4)	26 (33.8)	34 (44.2)	24 (31.2)	15 (19.5)
Hospitalizations with RSV test negative	145 (1.1)	119 (82.1)	46 (31.7)	64 (44.1)	54 (37.2)	27 (18.6)

*Without hospitalizations with test result negative or RSV test not performed (crossed-out in the flow chart above).
**Crossed-out in the flow chart above.

SEPARATE ANALYSIS

Classification of patients into 3 groups (several hospitalzations per patient allowed)

Group 1: 92 hospitalizations directly allocated to the category "associated with RSV infection" (denominated as confirmed or probable per physician or positive RSV test)

Group 2: 356 hospitalizations not allocated to "associated with RSV infection" or RSV test negative

Group 3: 12384 patients without hospitalization during the corresponding RSV season

HOSPITALIZATIONS

N=total hospitlizations. n= hospitalizations with particular characteristics

Group	1			2		
	N	n	in %	N	n	in %
Nosocomial infection	85	3	3.5	293	12	4.1
Oxygen because of respiratory infection	92	56	60.9	352	127	36.1
Oxygen because of other reasons	92	2	2.2	347	33	9.5
Intensive care*	83	14	16.9	308	56	18.2
Mechanical ventilation**	75	6	8.0	286	34	11.9
Death	91	0	0	353	9	2.5
Death associated with RSV infection	68	0	0	255	0	0

* days of intensive care > 0

** days of mechanical ventilation > 0

	Duration of intensive care (days)		Duration of mechanical ventilation (days)	
	Group 1	Group 2	Group 1	Group 2
N	14	56	6	34
Mean	6.2	7.9	6.3	7.4
Median	3	4	2.5	4.5
Std. Deviation	6.3	8.2	6.8	8.3
Minimum	2	1	1	1
Maximum	23	33	16	37

Epicrit diagnosis

	Group 1 (N=85)		Group 2 (N=220)	
	n	in %	n	in %
Bronchitis	24	28.2	115	52.3
Bronchiolitis	32	37.6	15	6.8
Pneumonia (clinical diagnosis)	9	10.6	27	12.3
Pneumonia (confirmed by chest radiography)	19	22.4	58	26.4
Acute respiratory failure	1	1.2	3	1.4
Apnoea-bradycardia Syndrome	0	0	2	0.9

BASELINE CHARACTERISTICS

Group 1 and 2: N= total hospitlizations. n= hospitalizations with particular characteristics
Groupe 3: N=total patients without hospitalization. n=patients with particular characteristics

Group		1			2			3		
		N	n	in %	N	n	in %	N	n	in %
Sex	female	92	37	40.2	356	126	35.4	12375	5576	45.1
	male		55	59.8		230	64.6		6799	54.9
Gestational age (weeks)	< 29	92	40	43.5	356	141	39.6	12384	3378	27.3
	29-<33		23	25.0		93	26.1		3944	31.8
	33-<35		15	16.3		26	7.3		2400	19.4
	≥35		14	15.2		96	27.0		2662	21.5
Birth weight	< 1000 g	92	37	40.2	356	132	37.1	12384	2819	22.8
	1000-1499 g		15	16.3		73	20.5		2998	24.2
	1500-1999 g		18	19.6		41	11.5		2544	20.5
	≥2000 g		22	23.9		110	30.9		4023	32.5
Premature birth (<36 weeks)		92	80	87.0	356	275	77.2	12384	10512	84.9
Multiple births		82	27	32.9	333	66	19.8	11553	3716	32.2
Siblings in kindergarten or school		84	57	67.9	323	186	57.6	10457	4718	45.1
Congenital heart malformation		92	26	28.3	354	138	39.0	12201	3312	27.1
Smoking in the family[+]		54	23	42.6	206	80	38.8	6138	1964	32.0
Family history of asthma		72	6	8.3	312	36	11.5	10293	1097	10.7
Family history of atopy		70	16	22.9	302	63	20.9	10318	1979	19.2
Chronic lung disease (CLD)#		89	38	42.7	350	159	45.4	12085	2207	18.3
CLD therapy		90	28	31.1	349	123	35.2	11953	1697	14.2
Treatment with oxygen at home		92	15	16.3	354	71	20.1	12147	701	5.8
Immuno-deficiency		92	2	2.2	337	9	2.7	11937	166	1.4
Down syndrome (Trisomy 21)		92	3	3.3	356	19	5.3	12360	235	1.9
Cyanotic vitium cordis		90	4	4.4	353	32	9.1	12023	758	6.3
Neuromuscular impairment		56	12	21.4	215	61	28.4	8234	739	9.0
Serious neuromuscular disease		54	6	11.1	208	22	10.6	8197	408	5.0
NMI positive*		88	17	19.3	348	103	29.6	11849	1100	9.3
Attending day care		91	1	1.1	352	14	4.0	12049	349	2.9
Low social status		88	25	28.4	341	89	26.1	11585	2172	18.7
Crowded living condition		80	25	31.3	308	87	28.2	10273	2506	24.4
Exposition to air pollution		82	23	28.0	313	78	24.9	10655	1641	15.4
Breast feeding ≤ 2month		81	47	58.0	328	194	59.1	11101	5614	50.6

[+]"Smoking in the family" is defined as yes, if variable "AnzahlRaucher" in dataset is greater than 0.
"Smoking in the family" is defined as no, if variable "AnzahlRaucher" in dataset is equal to 0.
*Neuromuscular impairment positive or serious neuromuscular disease positive
#This item refers to "bronchopulmonary dysplasia" (BPD)

SEPARATE ANALYSIS WITH AND WITHOUT DOWN SYNDROME

STUDY POPULATIONS

	Only patients with first RSV-registry			Patients total		
	All	Patients without Down syndrome (Trisomy 21)	Patients with Down syndrome (Trisomy 21)	All	Patients without Down syndrome (Trisomy 21)	Patients with Down syndrome (Trisomy 21)
2009-2010	2133	2108	25	2133	2108	25
2010-2011	1812	1787	25	1969	1943	26
2011-2012	1911	1870	41	2086	2040	46
2012-2013	1926	1888	38	2093	2046	47
2013-2014	1759	1720	39	1910	1862	48
2014-2015	1602	1555	47	1769	1708	61
2015-2016	1586	1552	34	1751	1707	44
2009-2016	12729	**12480**	**249**	13711	13414	297

PATIENTS WITHOUT DOWN SYNDROME

Sex

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	female	5590	44.8	44.8	44.8
	male	6881	55.1	55.2	100.0
	Total	12471	99.9	100.0	
Missing	System	9	0.1		
Total		12480	100.0		

Gestational age (weeks)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	< 29	3509	28.1	28.1	28.1
	29-<33	4005	32.1	32.1	60.2
	33-<35	2409	19.3	19.3	79.5
	≥35	2557	20.5	20.5	100.0
	Total	12480	100.0	100.0	

Birth weight

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	< 1000 g	2941	23.6	23.6	23.6
	1000-1499 g	3044	24.4	24.4	48.0
	1500-1999 g	2556	20.5	20.5	68.4
	≥2000 g	3939	31.6	31.6	100.0
	Total	12480	100.0	100.0	

Descriptive Statistics

		Gestational age (weeks)	Birth weight
N	Valid	12480	12480
	Missing	0	0
Mean		31.37	1711.96
Median		31	1590
Std. Deviation		4.26	831.74
Minimum		10	330
Maximum		42	6160
Percentile	25	28	1055
	50	31	1590
	75	34	2200

RISIK FACTORS

Table: Risk factors (N=total information. n=number of children with risk factors)

Risk factors	N	n	in %
Premature birth (<36 weeks)	12480	10716	85.9
Multiple births	11651	3774	32.4
Siblings in kindergarten or school	10535	4760	45.2
Congenital heart malformation	12296	3219	26.2
Smoking in the family[+]	6209	2007	32.3
Family history of asthma	10389	1121	10.8
Family history of atopy	10407	2018	19.4
Chronic lung disease (CLD)#	12180	2313	19.0
CLD therapy	12060	1773	14.7
Treatment with oxygen at home	12251	739	6.0
Immuno-deficiency	12040	145	1.2
Down syndrome (Trisomy 21)	12456	0	0.0
Cyanotic vitium cordis	12130	728	6.0
Neuromuscular impairment	8255	717	8.7
Serious neuromuscular disease	8212	401	4.9
NMI positive*	11956	1091	9.1
Attending day care	12148	350	2.9
Low social status	11681	2221	19.0
Crowded living condition	10373	2546	24.5
Exposition to air pollution	10756	1691	15.7
Breast feeding ≤ 2month	11198	5695	50.9

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"Smoking in the family" is defined as no, if variable "AnzahlRaucher" in dataset is equal to 0.
*Neuromuscular impairment positive or serious neuromuscular disease positive
#This item refers to "bronchopulmonary dysplasia" (BPD)

Descriptive Statistics: Number of immunizations

N = Number of children	12480
Mean*	5.0
Median*	5
Std. Deviation	2.0
Minimum*	1
Maximum*	10
Patients with more than 5 immunizations (number)	5669
Patients with more than 5 immunizations (percentage)	45.4%
Immunizations altogether (total number of documented immunization cycles oder courses)	62381

* Number of immunizations per child with first season

Number of immunizations

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	571	4.6	4.6	4.6
	2	1175	9.4	9.4	14.0
	3	1446	11.6	11.6	25.6
	4	1537	12.3	12.3	37.9
	5	2082	16.7	16.7	54.6
	6	2468	19.8	19.8	74.4
	7	2047	16.4	16.4	90.8
	8	977	7.8	7.8	98.6
	9	159	1.3	1.3	99.9
	10	18	0.1	0.1	100.0
	Total	12480	100.0	100.0	

Cooperation of the parents / caregivers with the immunization schedule

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	good	50447	80.9	93.5	93.5
	satisfying	2948	4.7	5.5	99.0
	bad	563	0.9	1.0	100.0
	Total	53958	86.5	100.0	
Missing	System	8423	13.5		
Total		62381	100.0		

Location of Synagis first immunzation

		Frequency	Percent
Valid	unknown	190	1.5
	med. practice	9215	73.8
	hospital	3075	24.6
	Total	12480	100.0

Age at start of immunization

N	Valid	12480	
	Missing	0	

		days	weeks	months
Mean		130	18.6	4.3
Median		97	13.9	3.2
Std. Deviation		110	15.7	3.6
Minimum		0	0.0	0.0
Maximum		800	114.3	26.2
Percentile	25	55	7.9	1.8
	50	97	13.9	3.2
	75	168	24.0	5.5

	Hospitalizations total	Hospitalizations with first RSV-registry	**Thereof hospitalizations without Down syndrome**
2009-2010	84	84	**84**
2010-2011	97	88	**86**
2011-2012	65	59	**54**
2012-2013	62	54	**50**
2013-2014	47	43	**43**
2014-2015	66	60	**53**
2015-2016	67	60	**56**
2009-2016	488	448	**426**

	n (% of N=12480)	Premature birth (% of n)	Congenital heart malformation (% of n)	Chronic lung disease (% of n)	CLD therapy (% of n)	Treatment with oxygen at home (% of n)
Hospitalizations total	426 (3.4)	348 (81.7)	144 (33.8)	194 (45.5)	146 (34.3)	85 (20.0)
Patients with hospitalization	331 (2.7)	268 (81.0)	105 (31.7)	138 (41.7)	104 (31.4)	61 (18.4)
Hospitalizations directly associated with RSV infection (sure and probably)*	85 (0.7)	76 (89.4)	21 (24.7)	38 (44.7)	28 (32.9)	15 (17.6)
Hospitalizations allocated to ‚RSV associated' by the documenting physician but test result negative or RSV test not performed	4 (0.03)	4 (100)	2 (50)	0 (0)	0 (0)	0 (0)
Hospitalizations with realized RSV test	210 (1.7)	180 (85.7)	60 (28.6)	94 (44.8)	73 (34.8)	38 (18.1)
Hospitalizations with RSV test positive	73 (0.6)	65 (89.0)	22 (30.1)	34 (46.6)	24 (32.9)	15 (20.5)
Hospitalizations with RSV test negative	136 (1.1)	116 (85.3)	37 (27.2)	62 (45.6)	51 (37.5)	26 (19.1)

*Without hospitalizations with test result negative or RSV test not performed.

Sex

		Frequency	Percent
Valid	female	117	47.0
	male	132	53.0
	Total	249	100.0

Gestational age (weeks)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	< 29	5	2.0	2.0	2.0
	29-<33	28	11.2	11.2	13.3
	33-<35	25	10.0	10.0	23.3
	≥35	191	76.7	76.7	100.0
	Total	249	100.0	100.0	

Birth weight

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	< 1000 g	5	2.0	2.0	2.0
	1000-1499 g	19	7.6	7.6	9.6
	1500-1999 g	34	13.7	13.7	23.3
	≥2000 g	191	76.7	76.7	100.0
	Total	249	100.0	100.0	

Descriptive Statistics

		Gestational age (weeks)	Birth weight
N	Valid	249	249
	Missing	0	0
Mean		36.44	2625.15
Median		37	2750
Std. Deviation		3.26	776.33
Minimum		23	600
Maximum		42	4320
Percentile	25	35	2048
	50	37	2750
	75	38	3185

Table: Risk factors (N=total information. n=number of children with risk factors)

Risk factors	N	n	in %
Premature birth (<36 weeks)	249	68	27.3
Multiple births	218	19	8.7
Siblings in kindergarten or school	232	139	59.9
Congenital heart malformation	248	211	85.1
Smoking in the family[+]	123	30	24.4
Family history of asthma	200	7	3.5
Family history of atopy	199	21	10.6
Chronic lung disease (CLD)#	242	33	13.6
CLD therapy	231	30	13.0
Treatment with oxygen at home	239	24	10.0
Immuno-deficiency	231	26	11.3
Down syndrome (Trisomy 21)	249	249	100.0
Cyanotic vitium cordis	233	56	24.0
Neuromuscular impairment	180	69	38.3
Serious neuromuscular disease	181	27	14.9
NMI positive*	229	90	39.3
Attending day care	241	11	4.6
Low social status	234	37	15.8
Crowded living condition	202	46	22.8
Exposition to air pollution	204	19	9.3
Breast feeding ≤ 2month	219	99	45.2

[+]"Smoking in the family" is defined as yes, if variable "AnzahlRaucher" in dataset is greater than 0.
"Smoking in the family" is defined as no, if variable "AnzahlRaucher" in dataset is equal to 0.
*Neuromuscular impairment positive or serious neuromuscular disease positive
#This item refers to "bronchopulmonary dysplasia" (BPD)

Descriptive Statistics: Number of immunizations

N = Number of children	249
Mean*	4.78
Median*	5
Std. Deviation	1.97
Minimum*	1
Maximum*	9
Patients with more than 5 immunizations (number)	104
Patients with more than 5 immunizations (percentage)	41.8%
Immunizations altogether (total number of documented immunization cycles oder courses)	1191

* Number of immunizations per child with first season

Number of immunizations

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	14	5.6	5.6	5.6
	2	25	10.0	10.0	15.7
	3	33	13.3	13.3	28.9
	4	33	13.3	13.3	42.2
	5	40	16.1	16.1	58.2
	6	50	20.1	20.1	78.3
	7	37	14.9	14.9	93.2
	8	16	6.4	6.4	99.6
	9	1	0.4	0.4	100.0
	Total	249	100.0	100.0	

Cooperation of the parents / caregivers with the immunization schedule

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	good	961	80.7	95.1	95.1
	satisfying	37	3.1	3.7	98.8
	bad	12	1.0	1.2	100.0
	Total	1010	84.8	100.0	
Missing	System	181	15.2		
Total		1191	100.0		

Location of Synagis first immunzation

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	unknown	6	2.4	2.6	2.6
	med. practice	191	76.7	75.3	77.9
	hospital	52	20.9	22.1	100.0
	Total	249	100.0	100.0	

Age at start of immunization

N	Valid	249	
	Missing	0	

		days	weeks	months
Mean		160	22.9	5.2
Median		104	14.9	3.4
Std. Deviation		150	21.4	4.9
Minimum		2	0.3	0.1
Maximum		786	112.3	25.8
Percentile	25	52	7.4	1.7
	50	104	14.9	3.4
	75	231	33.0	7.6

	Hospitalizations total	Hospitalizations with first RSV-registry	**Thereof hospitalizations with Down syndrome**
2009-2010	84	84	**0**
2010-2011	97	88	**2**
2011-2012	65	59	**5**
2012-2013	62	54	**4**
2013-2014	47	43	**0**
2014-2015	66	60	**7**
2015-2016	67	60	**4**
2009-2016	488	448	**22**

	n (% of N=249)	Premature birth (% of n)	Congenital heart malformation (% of n)	Chronic lung disease (% of n)	CLD therapy (% of n)	Treatment with oxygen at home (% of n)
Hospitalizations total	22 (8.8)	7 (31.8)	20 (90.9)	3 (13.6)	5 (22.7)	1 (4.5)
Patients with hospitalization	14 (5.6)	4 (28.6)	13 (92.9)	1 (7.1)	2 (14.3)	1 (7.1)
Hospitalizations directly associated with RSV infection (sure and probably)	3 (1.2)	0 (0)	3 (100)	0 (0)	0 (0)	0 (0)
Hospitalizations allocated to ‚RSV associated' by the documenting physician but test result negative or RSV test not performed	0	-	-	-	-	-
Hospitalizations with realized RSV test	13 (5.2)	3 (23.1)	13 (100)	2 (15.4)	3 (23.1)	1 (7.7)
Hospitalizations with RSV test positive	4 (1.6)	0 (0)	4 (100)	0 (0)	0 (0)	0 (0)
Hospitalizations with RSV test negative	9 (3.6)	3 (33.3)	9 (100)	2 (22.2)	3 (33.3)	1 (11.1)

Synagis Registry 2009-2016

		Hospitalizations							
		no		yes				95% confidence interval	
		total	in %	total	in %	p-value	OR	Lower	Upper
Down syndrome (Trisomy 21)	no	12149	97.3%	331	2.7%	0.005	2.187	1.261	3.791
	yes	235	94.4%	14	5.6%				
Premature birth (<36 weeks)	no	1872	96.2%	73	3.8%	0.002	0.664	0.510	0.863
	yes	10512	97.5%	272	2.5%				
Congenital heart malformation	no	8889	97.5%	225	2.5%	0.003	1.408	1.122	1.765
	yes	3312	96.6%	118	3.4%				

		Hospitalizations directly associated with RSV infection (sure and probably)							
		no		yes				95% confidence interval	
		total	in %	total	in %	p-value	OR	Lower	Upper
Down syndrome (Trisomy 21)	no	12364	99.3%	84	0.7%	0.316	1.810	0.568	5.765
	yes	244	98.8%	3	1.2%				
Premature birth (<36 weeks)	no	1923	99.4%	12	0.6%	0.706	1.125	0.610	2.073
	yes	10685	99.3%	75	0.7%				
Congenital heart malformation	no	9033	99.3%	63	0.7%	0.950	1.015	0.633	1.627
	yes	3390	99.3%	24	0.7%				

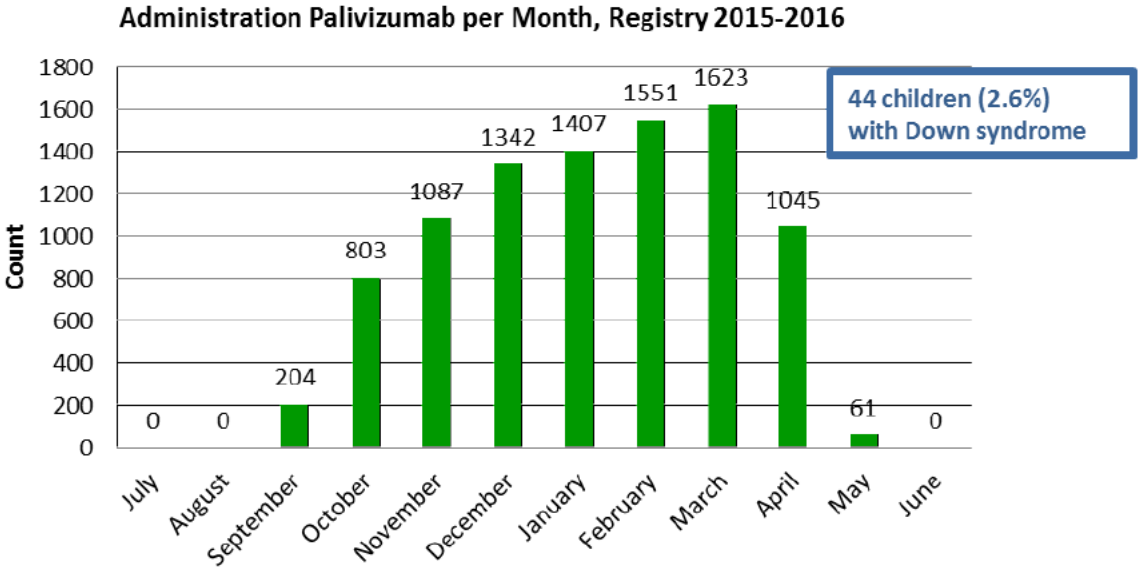
Synagis Registry 2009-2016

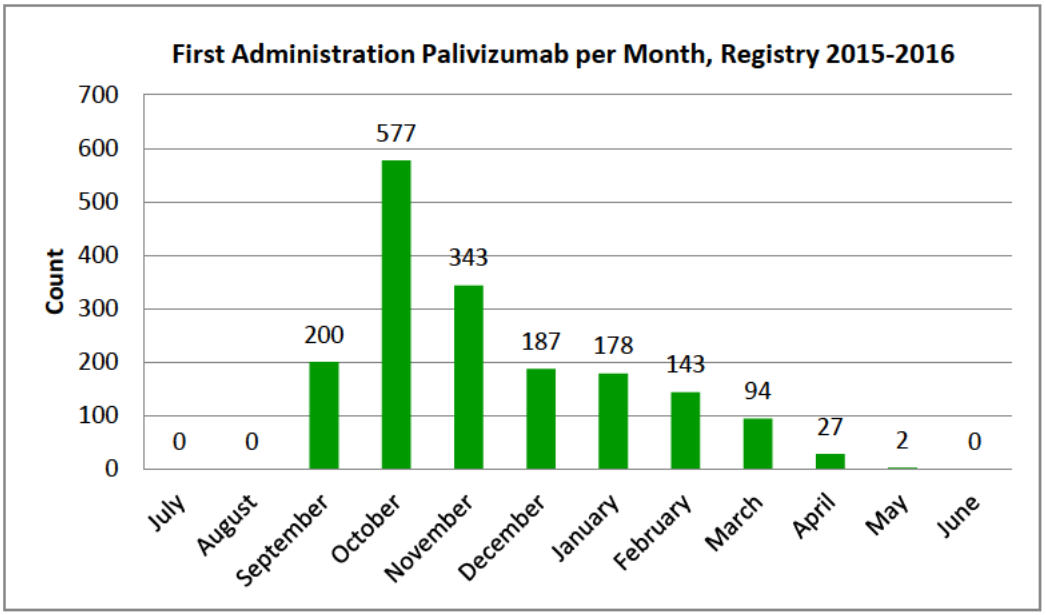
		Hospitalizations							
		no		yes				95% confidence interval	
		total	in %	total	in %	p-value	OR	Lower	Upper
Down syndrome (Trisomy 21)	no	12149	97.3%	331	2.7%	1.000	1.305	0.030	9.247
	yes	235	94.4%	14	5.6%				
Premature birth (<36 weeks)	no	1872	96.2%	73	3.8%	0.049	0.574	0.350	0.998
	yes	10512	97.5%	272	2.5%				
Congenital heart malformation	no	8889	97.5%	225	2.5%	0.606	0.832	0.466	1.545
	yes	3312	96.6%	118	3.4%				
Down syndrome by premature birth	no	12320	97.3%	341	2.7%	1.000	1.940	0.000	75.678
	yes	64	94.1%	4	5.9%				
Down syndrome by congenital heart malformation	no	12185	97.3%	332	2.7%	1.000	1.265	0.140	62.516
	yes	198	93.8%	13	6.2%				
Premature birth by congenital heart malformation	no	10320	97.4%	279	2.6%	0.187	1.614	0.804	3.127
	yes	1889	96.7%	64	3.3%				
Down syndrome by premature birth by congenital heart malformation	no	12338	97.3%	341	2.7%	1.000	0.713	0.018	+ ∞
	yes	46	92.0%	4	8.0%				

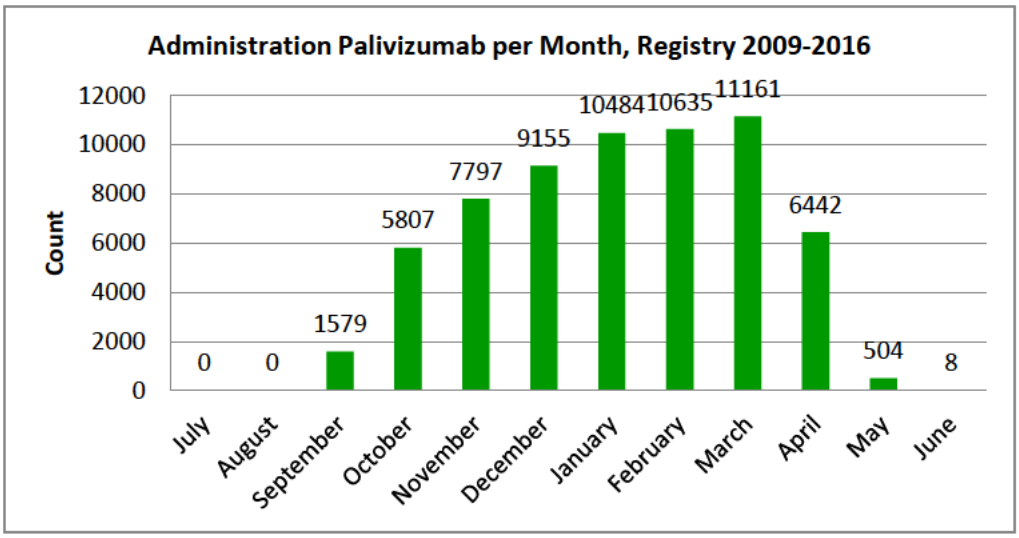
GRAPHICS

ADMINISTRATION OF PALIVIZUMAB

REGISTRY 2015-2016






Administration Palivizumab per Month, Registry 2009-2016
Count
12000
10000
8000
6000
4000
2000
0
0
0
1579
5807
7797
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6442
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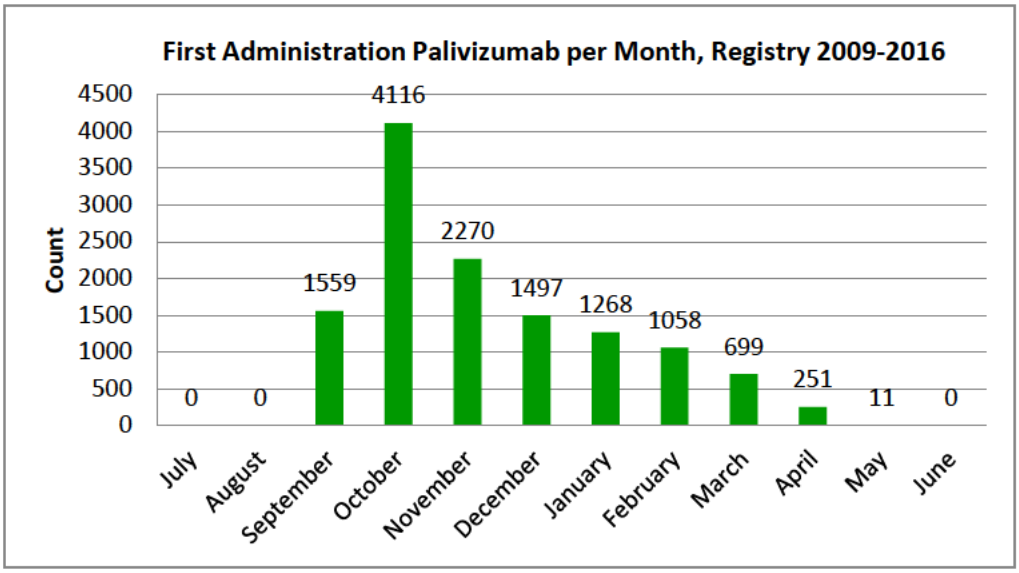
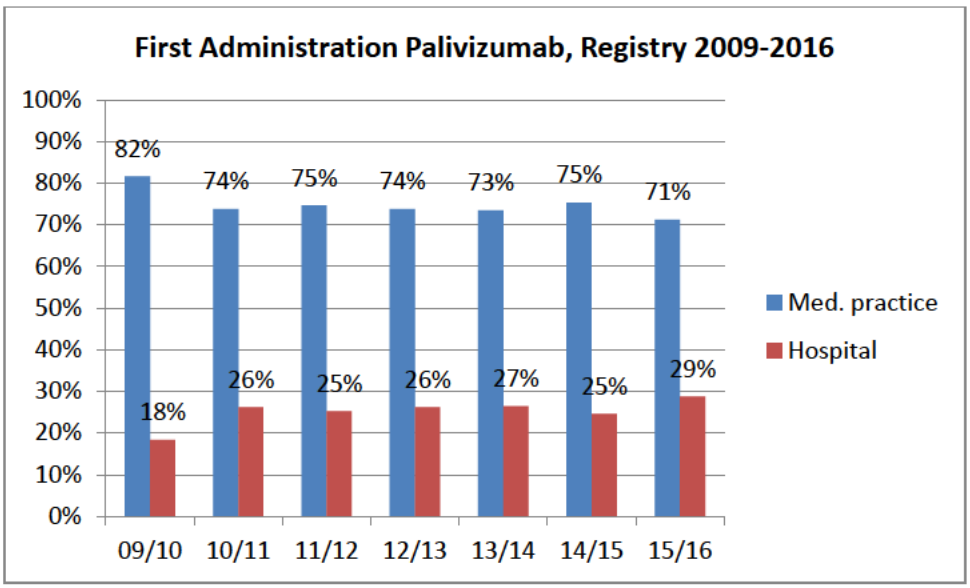
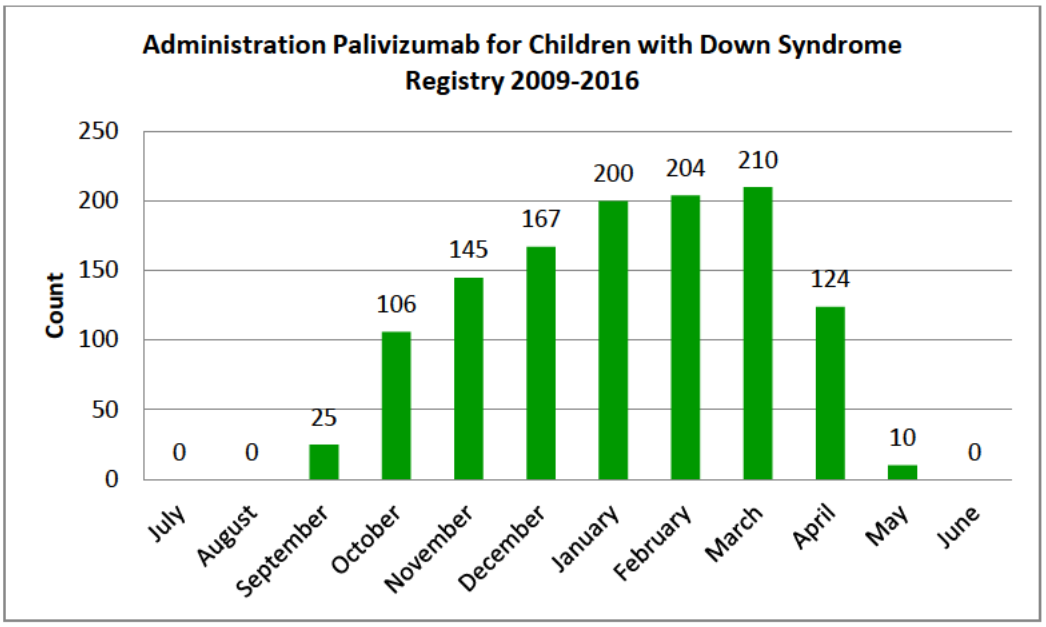
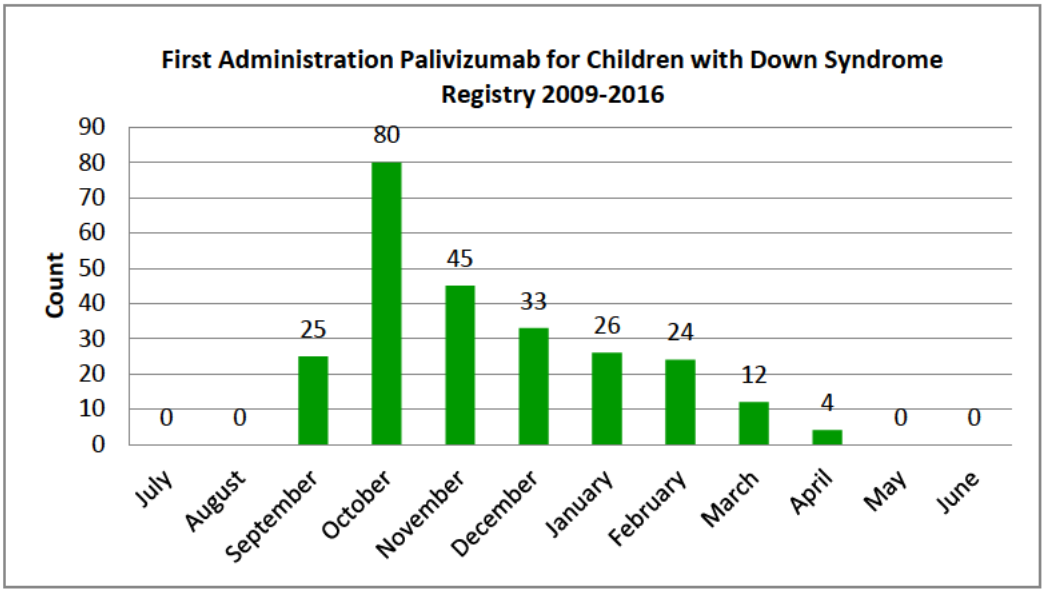
September
October
November
December
January
February
March
April
May
June


First Administration Palivizumab per Month, Registry 2009-2016
Count
4500
4000
3500
3000
2500
2000
1500
1000
500
0
0
0
1559
4116
2270
1497
1268
1058
699
251
11
0
July
August
September
October
November
December
January
February
March
April
May
June

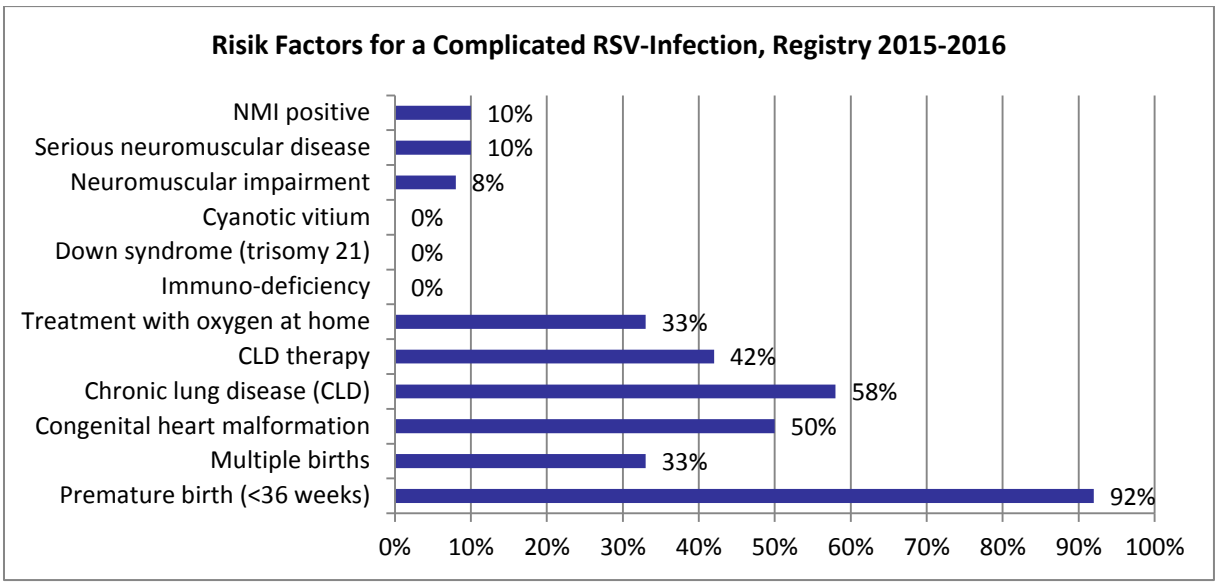

First Administration Palivizumab, Registry 2009-2016
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
82%
18%
74%
26%
75%
25%
74%
26%
73%
27%
75%
25%
71%
29%
09/10
10/11
11/12
12/13
13/14
14/15
15/16
Med. practice
Hospital

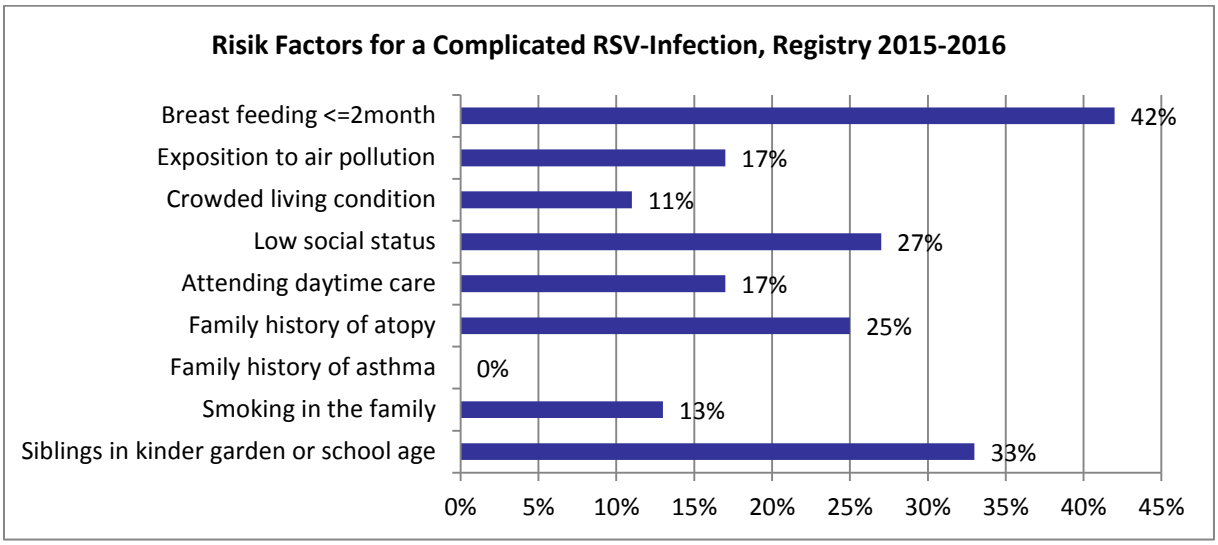

Administration Palivizumab for Children with Down Syndrome Registry 2009-2016
Count
250
200
150
100
50
0
0
0
25
106
145
167
200
204
210
124
10
0
July
August
September
October
November
December
January
February
March
April
May
June


First Administration Palivizumab for Children with Down Syndrome Registry 2009-2016
Count
90
80
70
60
50
40
30
20
10
0
0
0
25
80
45
33
26
24
12
4
0
0
July
August
September
October
November
December
January
February
March
April
May
June

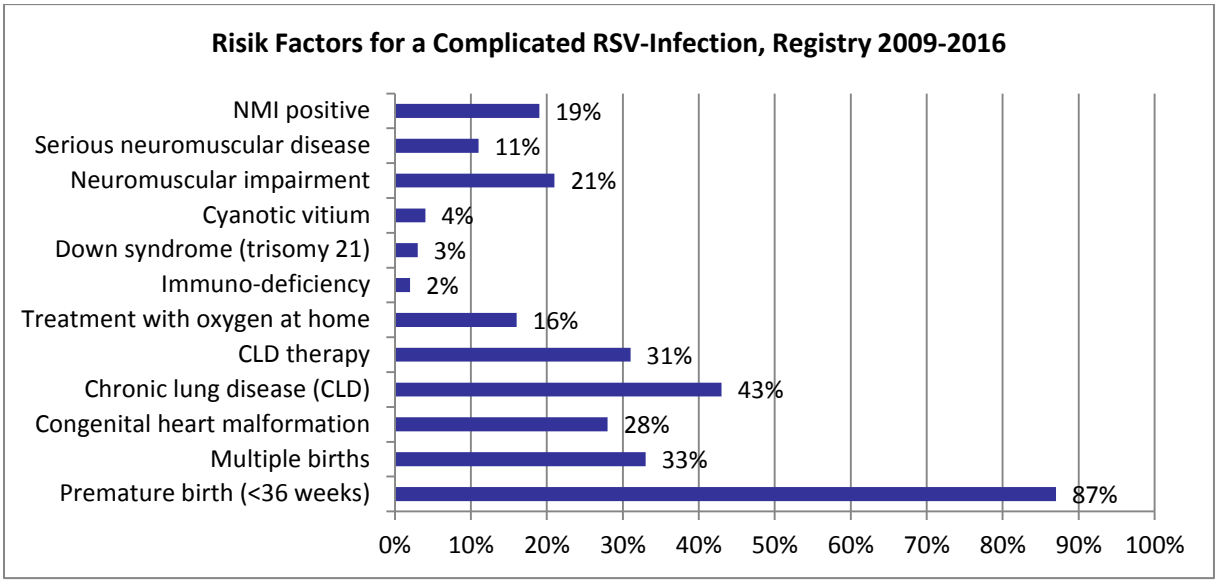
REGISTRY 2015-2016

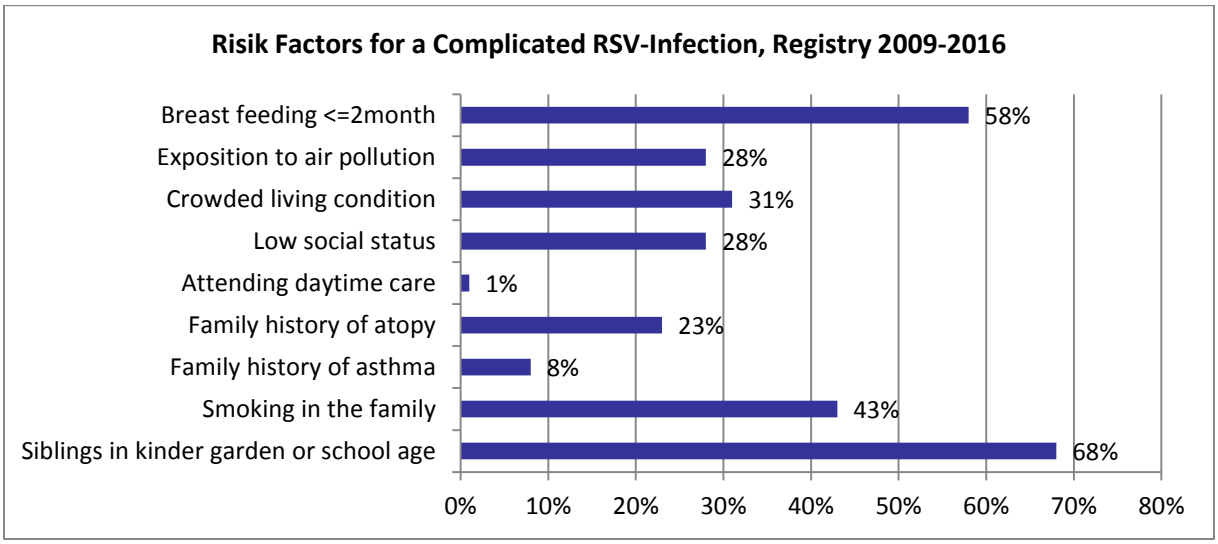
Complicated RSV infections are identical to group 1 in Separate Analysis (page 12):
12 hospitalizations directly associated with RSV infection.



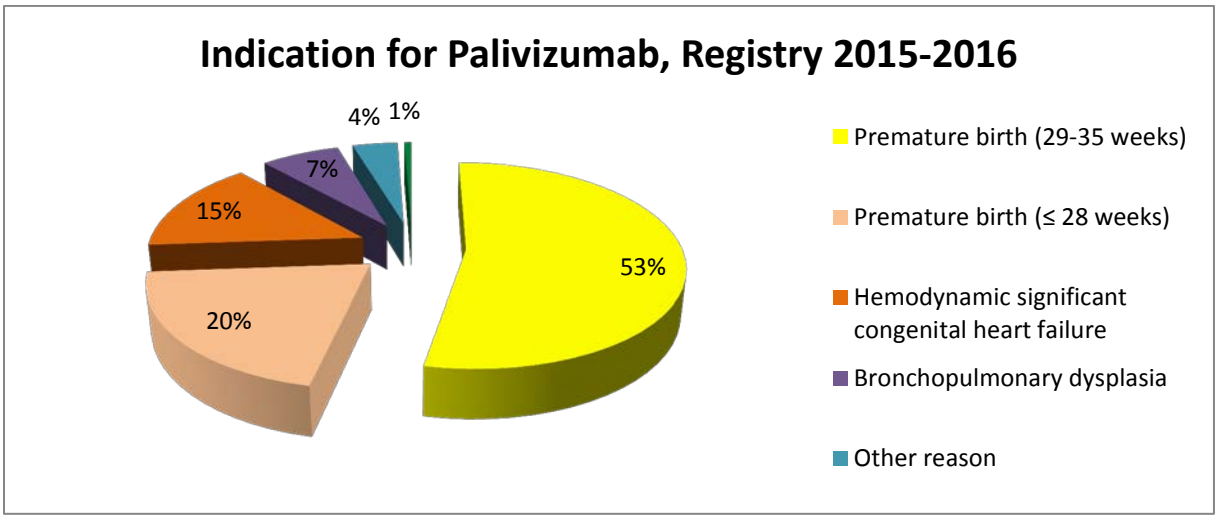


Complicated RSV infections are identical to group 1 in Separate Analysis (page 21): 92 hospitalizations directly associated with RSV infection.





REGISTRY 2015-2016



REGISTRY 2009–2016

As background for Registry 2009-2016 considering indication for Palivizumab the following categories are given:

Registry 2009-2010

- Bronchopulmonary dysplasia
- Hemodynamic significant congenital heart failure
- Other reason
- Premature birth (≤ 35 weeks)
- Neuromuscular diseases

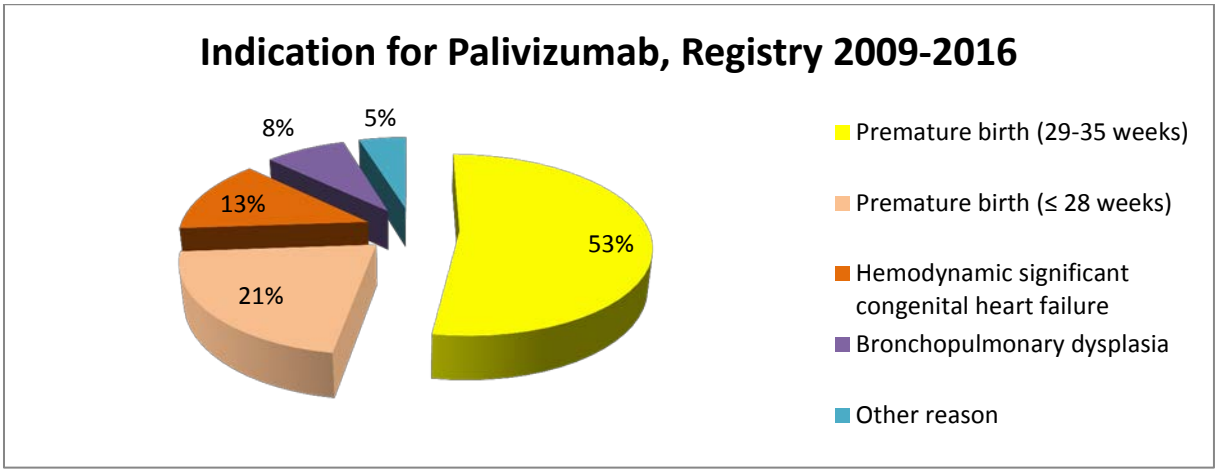
Registry 2010-2011

- Unknown
- Bronchopulmonary dysplasia
- Hemodynamic significant congenital heart failure
- Other reason
- Premature birth (≤ 35 weeks)
- Neuromuscular diseases

Registries 2011-2016

- Unknown
- Bronchopulmonary dysplasia
- Hemodynamic significant congenital heart failure
- Other reason
- Premature birth (≤ 28 weeks)
- Premature birth (29-35 weeks)

For the following summarizing figure of Registries 2009-2016, premature birth (≤ 35 weeks) from Registry 09/10 and 10/11 was split into “Premature birth (≤ 28 weeks)” and “Premature birth (29-35 weeks)”. 15 patients with “Neuromuscular diseases” from Registry 09/10 and 14 patients with “Neuromuscular diseases” from Registry 10/11 were counted as “Other reason” in the summarizing figure. From Registry season 2010/11 on indication category “unknown” was counted as “Other reason”.



APPENDIX

Data were obtained on 19.09.2016 via email from [redacted] as Excel-file [redacted]".
Data magement and data analysis are due to the statistical software package IBM-SPSS version 23.
Statistical study report is written in Microsoft Word 2010 as specified in Statistical Analysis Plan SYNAGIS-01-2016 GW.
Graphical presentations are due to Microsoft Excel 2010.

[redacted]

KORRIGIERTE TABELLEN

Korrektur: PatID 830043804 aus Welle 2014-15 mit Schwangerschaftswoche 10 bei einem Geburtsgewicht von 800g wurde korrigiert auf SSW=26.

SYNAGIS REGISTRY 2009-2016

Geänderte Tabelle von Seite 15:

Descriptive Statistics

		Gestational age (weeks)	Birth weight
N	Valid	12729	12729
	Missing	0	0
Mean		31.5	1729.8
Median		32	1605
Std. Deviation		4.30	840.23
Minimum		22	330
Maximum		42	6160
Percentile	25	28	1070
	50	32	1605
	75	34	2230

PATIENTS WITHOUT DOWN SYNDROME

Geänderte Tabelle von Seite 23:

Descriptive Statistics

		Gestational age (weeks)	Birth weight
N	Valid	12480	12480
	Missing	0	0
Mean		31.37	1711.96
Median		31	1590
Std. Deviation		4.26	831.74
Minimum		22	330
Maximum		42	6160
Percentile	25	28	1055
	50	31	1590
	75	34	2200

Addendum

Zusatzanalyse
according to inquiry email (10. January 2017)

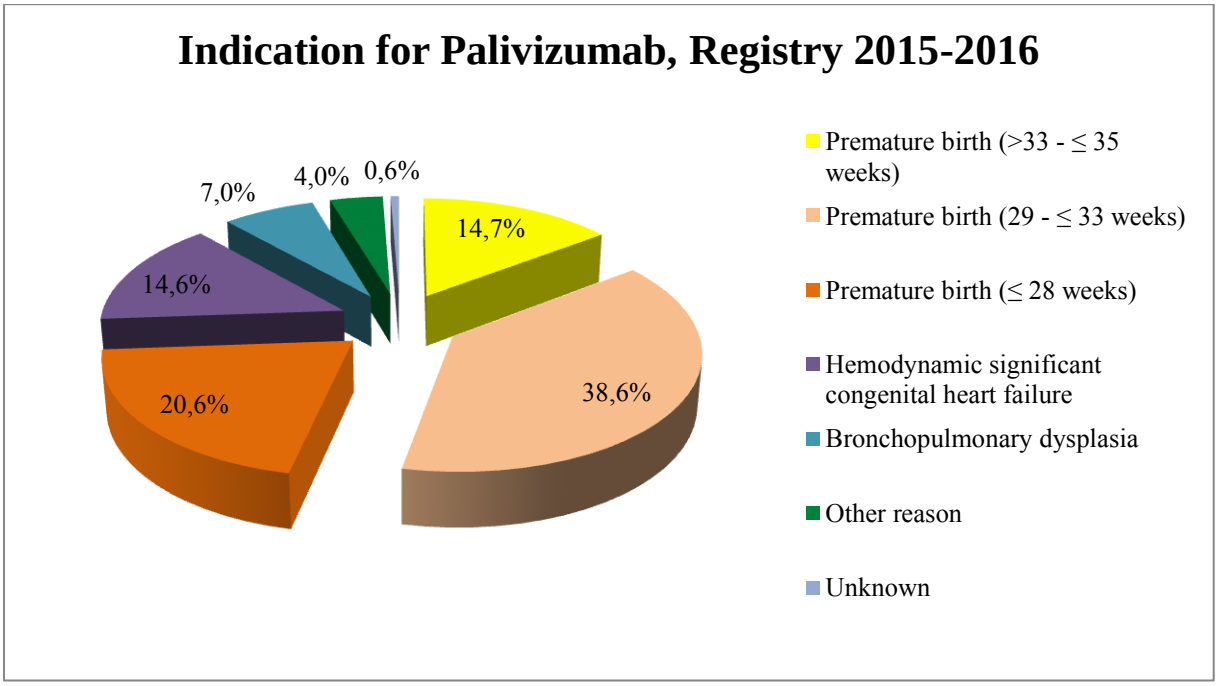
16. January 2017

Analysis:

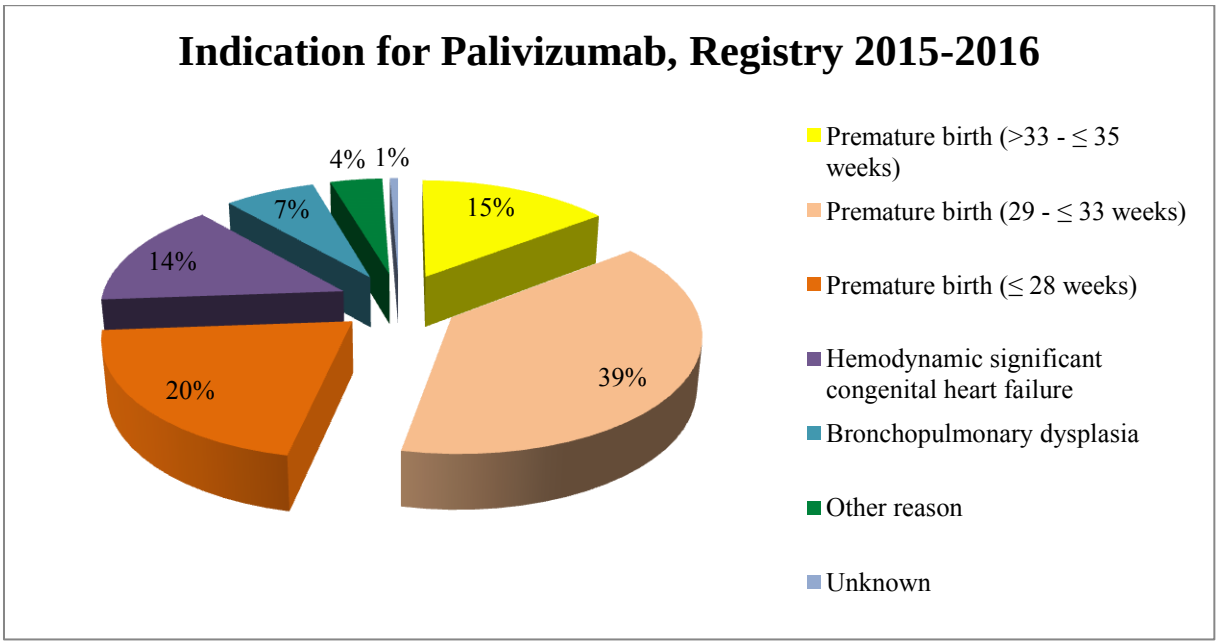
- Synagis Registry 2015-2016 (year 2015/16)
- Synagis Registry 2009-2016 (years 2009/10 - 2015/16)

Indications for Palivizumab

Registry 2015-2016



Relative frequencies rounded to 1 position after decimal point.



Relative frequencies rounded without decimal place.

Figures above are based on the following absolute and relative frequencies:

	Frequency	Percent
Premature birth (>33 - ≤ 35 weeks)	257	14,7
Premature birth (29 - ≤ 33 weeks)	676	38,6
Premature birth (≤ 28 weeks)	360	20,6
Hemodynamic significant congenital heart failure	255	14,6
Bronchopulmonary dysplasia	122	7,0
Other reason	70	4,0
Unknown	11	0,6
Total	1751	100,0

Calculation of Figure „Indication for Palivizumab, Registry 2015-2016" in Synagis Report from 28. October 2016, Report No. SYNAGIS-02-2016 GW, page 41, is based on variable "IndikationID" in [redacted] database. However, this variable codes only one category indicating premature birth 29-35 weeks without distinction between 29 - ≤ 33 weeks and >33 - ≤ 35 weeks. Thus patients with category "premature birth 29-35 weeks" in variable "IndikationID" were selected resulting in a total number of 933 patients. Based on this filtering database variable "Schwangerschaftswoche " = "Gestational age (weeks)" was used for additional stratification according to the following assignment:

Gestational age (weeks)	
	Frequency
23	1
24	1
25	2
26	1
27	7
28	8
29	122
30	111
31	138
32	143
33	142
34	164
35	90
36	1
37	1
39	1
Total	933

=> 676 with Indication „Premature birth (29 - ≤33 weeks)"

=> 257 with Indication „Premature birth (>33 - ≤35 weeks)"

Registry 2009-2016

As background for Registry 2009-2016 considering indication for Palivizumab the following categories are given:

Registry 2009-2010

- Bronchopulmonary dysplasia
- Hemodynamic significant congenital heart failure
- Other reason
- Premature birth (≤ 35 weeks)
- Neuromuscular diseases

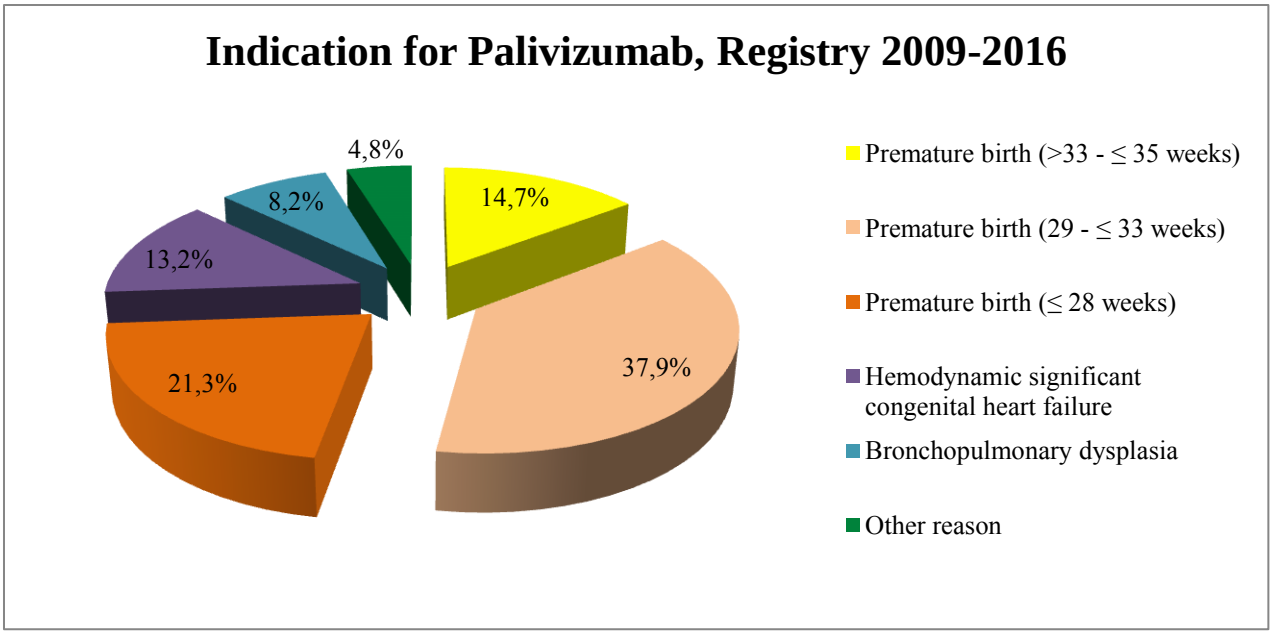
Registry 2010-2011

- Unknown
- Bronchopulmonary dysplasia
- Hemodynamic significant congenital heart failure
- Other reason
- Premature birth (≤ 35 weeks)
- Neuromuscular diseases

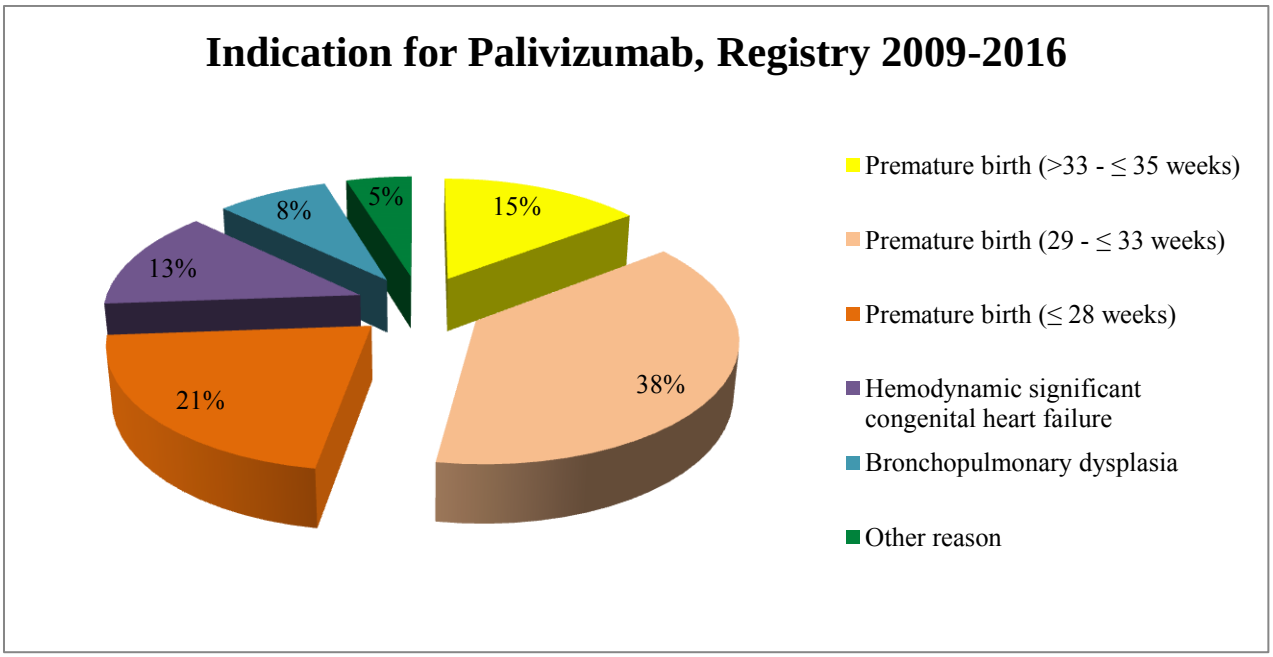
Registries 2011-2016

- Unknown
- Bronchopulmonary dysplasia
- Hemodynamic significant congenital heart failure
- Other reason
- Premature birth (≤ 28 weeks)
- Premature birth (29-35 weeks)

For the following summarizing figure of Registries 2009-2016, premature birth (≤ 35 weeks) from Registry 09/10 and 10/11 was split into “Premature birth (≤ 28 weeks)” and “Premature birth (29-35 weeks)”. 15 patients with “Neuromuscular diseases” from Registry 09/10 and 14 patients with “Neuromuscular diseases” from Registry 10/11 were counted as “Other reason” in the summarizing figure. From Registry season 2010/11 on indication category “unknown” was counted as “Other reason”.



Relative frequencies rounded to 1 position after decimal point.



Relative frequencies rounded without decimal place.

Figures on previous page are based on the following absolute and relative frequencies:

	Frequency	Percent
Premature birth (>33 - ≤ 35 weeks)	1868	14,7%
Premature birth (29 - ≤ 33 weeks)	4826	37,9%
Premature birth (≤ 28 weeks)	2707	21,3%
Hemodynamic significant congenital heart failure	1681	13,2%
Bronchopulmonary dysplasia	1038	8,2%
Unknown	609	4,8%
Total	12729	100,0%

Calculation of Figure „Indication for Palivizumab, Registry 2009-2016" in Synagis Report from 28. October 2016, Report No. SYNAGIS-02-2016 GW, page 42, is based on variable "IndikationID" in [redacted] database. However, this variable codes only one category indicating premature birth 29-35 weeks without distinction between 29 - ≤ 33 weeks and >33 - ≤ 35 weeks. Thus patients with category "premature birth 29-35 weeks" in variable "IndikationID" were selected resulting in a total number of 6694 patients. Based on this filtering database variable "Schwangerschaftswoche " = "Gestational age (weeks)" was used for additional stratification according to the following assignment:

Gestational age (weeks)

	Frequency
10	1
23	4
24	6
25	12
26	11
27	17
28	86
29	775
30	746
31	964
32	1156
33	1048
34	1180
35	674
36	10
37	2
38	1
39	1
Total	6694

=> 4826 with Indication „Premature birth (29 - ≤33 weeks)"

=> 1868 with Indication „Premature birth (>33 - ≤35 weeks)"

A2.2.6 Safety analysis

Table 1.1 - Number of adverse events - Total

Total	n	%
serious	1084	95.5
non-serious	51	4.5
Total	1135	100.0

Table 1.2 - Number of adverse events - by year

Year	Seriousness				Total	
	serious		non-serious			
	n	%	n	%	n	%
2006	1	100.0	0	0.0	1	100.0
2007	87	92.6	7	7.4	94	100.0
2008	125	88.0	17	12.0	142	100.0
2009	24	96.0	1	4.0	25	100.0
2010	93	98.9	1	1.1	94	100.0
2011	173	98.3	3	1.7	176	100.0
2012	112	93.3	8	6.7	120	100.0
2013	98	95.1	5	4.9	103	100.0
2014	74	93.7	5	6.3	79	100.0
2015	132	99.2	1	0.8	133	100.0
2016	165	98.2	3	1.8	168	100.0

Table 1.3 - Number of adverse events - by season [01SEPyyyy - 30AUGyyyy+1]

Season	Seriousness				Total	
	serious		non-serious			
	n	%	n	%	n	%
2006/2007	16	80.0	4	20.0	20	100.0
2007/2008	86	85.1	15	14.9	101	100.0
2008/2009	135	95.7	6	4.3	141	100.0
2009/2010	93	100.0	0	0.0	93	100.0
2010/2011	172	97.7	4	2.3	176	100.0
2011/2012	112	93.3	8	6.7	120	100.0
2012/2013	97	97.0	3	3.0	100	100.0
2013/2014	72	91.1	7	8.9	79	100.0
2014/2015	134	99.3	1	0.7	135	100.0
2015/2016	107	97.3	3	2.7	110	100.0
2016/2017	60	100.0	0	0.0	60	100.0

Table 1.4 - Number of adverse events - by System organ class (SOC)

Total	n	%
General disorders and administration site conditions	15	29.4
Infections and infestations	11	21.6
Psychiatric disorders	5	9.8
Skin and subcutaneous tissue disorders	4	7.8
Gastrointestinal disorders	4	7.8
Metabolism and nutrition disorders	3	5.9
Cardiac disorders	2	3.9
Respiratory, thoracic and mediastinal disorders	2	3.9
Injury, poisoning and procedural complications	2	3.9
Surgical and medical procedures	1	2.0
Congenital, familial and genetic disorders	1	2.0
Blood and lymphatic system disorders	1	2.0
Total	51	100.0

Table 1.5 - Number of adverse events - by Preferred term (PT)

Total	n	%
Pyrexia	6	11.8
Rash	3	5.9
Diarrhoea	3	5.9
Bronchitis	3	5.9
Respiratory syncytial virus infection	3	5.9
Restlessness	2	3.9
Adverse drug reaction	2	3.9
Peripheral swelling	1	2.0
Administration site reaction	1	2.0
Decreased appetite	1	2.0
Erythema	1	2.0
Diet refusal	1	2.0
Cyanosis	1	2.0
Bronchial obstruction	1	2.0
Dyspnoea	1	2.0
Feeding disorder	1	2.0
Screaming	1	2.0
Viral infection	1	2.0

(Continued)

Table 1.5 - Number of adverse events - by Preferred term (PT)

Total	n	%
Upper respiratory tract infection	1	2.0
Brucellosis	1	2.0
Overdose	1	2.0
Cardiovascular disorder	1	2.0
Hospitalisation	1	2.0
Confusional state	1	2.0
Personality change	1	2.0
Vomiting	1	2.0
Infection	1	2.0
Respiratory syncytial virus bronchitis	1	2.0
Vaccination site reaction	1	2.0
Heart disease congenital	1	2.0
Thrombocytopenia	1	2.0
Drug ineffective	1	2.0
Adverse event	1	2.0
No adverse event	1	2.0
Vaccination complication	1	2.0

(Continued)

Table 1.5 - Number of adverse events - by Preferred term (PT)

Total	n	%
Irritability postvaccinal	1	2.0
Total	51	100.0

Table 1.6 - Number of adverse events - by System organ class (SOC) and Preferred term (PT)

		n	%
SOC	**PT**		
General disorders and administration site conditions	**Pyrexia**	6	11.8
	Adverse drug reaction	2	3.9
	Administration site reaction	1	2.0
	Adverse event	1	2.0
	Drug ineffective	1	2.0
	Irritability postvaccinal	1	2.0
	No adverse event	1	2.0
	Peripheral swelling	1	2.0
	Vaccination site reaction	1	2.0
Infections and infestations	**Bronchitis**	3	5.9
	Respiratory syncytial virus infection	3	5.9
	Brucellosis	1	2.0
	Infection	1	2.0
	Respiratory syncytial virus bronchitis	1	2.0
	Upper respiratory tract infection	1	2.0
	Viral infection	1	2.0

(Continued)

Table 1.6 - Number of adverse events - by System organ class (SOC) and Preferred term (PT)

		n	%
SOC	**PT**		
Psychiatric disorders	**Restlessness**	2	3.9
	Confusional state	1	2.0
	Personality change	1	2.0
	Screaming	1	2.0
Gastrointestinal disorders	**Diarrhoea**	3	5.9
	Vomiting	1	2.0
Skin and subcutaneous tissue disorders	**Rash**	3	5.9
	Erythema	1	2.0
Metabolism and nutrition disorders	**Decreased appetite**	1	2.0
	Diet refusal	1	2.0
	Feeding disorder	1	2.0
Cardiac disorders	**Cardiovascular disorder**	1	2.0
	Cyanosis	1	2.0
Injury, poisoning and procedural complications	**Overdose**	1	2.0
	Vaccination complication	1	2.0

(Continued)

Table 1.6 - Number of adverse events - by System organ class (SOC) and Preferred term (PT)

		n	%
SOC	**PT**		
Respiratory, thoracic and mediastinal disorders	**Bronchial obstruction**	1	2.0
	Dyspnoea	1	2.0
Blood and lymphatic system disorders	**Thrombocytopenia**	1	2.0
Congenital, familial and genetic disorders	**Heart disease congenital**	1	2.0
Surgical and medical procedures	**Hospitalisation**	1	2.0

Table 1.7 - Number of serious adverse events - by System organ class (SOC)

Total	n	%
Infections and infestations	618	57.0
Surgical and medical procedures	150	13.8
Respiratory, thoracic and mediastinal disorders	114	10.5
General disorders and administration site conditions	64	5.9
Investigations	26	2.4
Metabolism and nutrition disorders	25	2.3
Cardiac disorders	19	1.8
Gastrointestinal disorders	18	1.7
Nervous system disorders	17	1.6
Congenital, familial and genetic disorders	8	0.7
Blood and lymphatic system disorders	6	0.6
Psychiatric disorders	5	0.5
Skin and subcutaneous tissue disorders	4	0.4
Pregnancy, puerperium and perinatal conditions	2	0.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.2
Injury, poisoning and procedural complications	2	0.2
Musculoskeletal and connective tissue disorders	1	0.1
Renal and urinary disorders	1	0.1

(Continued)

Table 1.7 - Number of serious adverse events - by System organ class (SOC)

Total	n	%
Immune system disorders	1	0.1
Vascular disorders	1	0.1
Total	1084	100.0

Table 1.8 - Number of serious adverse events - by Preferred term (PT)

Total	n	%
Bronchitis	132	12.2
Hospitalisation	121	11.2
Pneumonia	116	10.7
Respiratory syncytial virus bronchiolitis	89	8.2
Pneumonia respiratory syncytial viral	54	5.0
Respiratory syncytial virus infection	45	4.2
Respiratory syncytial virus bronchitis	33	3.0
Bronchiolitis	32	3.0
Pyrexia	25	2.3
Respiratory tract infection	20	1.8
Dyspnoea	19	1.8
Respiratory failure	19	1.8
Pneumonia viral	18	1.7
Cough	17	1.6
Upper respiratory tract infection	13	1.2
Respiratory disorder	13	1.2
Death	12	1.1
General physical health deterioration	12	1.1

(Continued)

Table 1.8 - Number of serious adverse events - by Preferred term (PT)

Total	n	%
Oxygen supplementation	10	0.9
Apnoea	9	0.8
Oxygen saturation decreased	9	0.8
Respiratory syncytial virus test positive	8	0.7
Cardiac operation	8	0.7
Nasopharyngitis	8	0.7
Gastroenteritis	7	0.6
Fluid intake reduced	7	0.6
Vomiting	6	0.6
Adverse drug reaction	6	0.6
Febrile convulsion	6	0.6
Respiratory tract infection viral	6	0.6
Diet refusal	6	0.6
Seizure	5	0.5
Viral infection	5	0.5
Acute respiratory failure	5	0.5
Cyanosis	4	0.4
Restlessness	4	0.4

(Continued)

Table 1.8 - Number of serious adverse events - by Preferred term (PT)

Total	n	%
Failure to thrive	4	0.4
Pseudocroup	4	0.4
Influenza	4	0.4
Dehydration	3	0.3
Leukocytosis	3	0.3
Obstructive airways disorder	3	0.3
Otitis media	3	0.3
Hydrocephalus	3	0.3
Bradycardia	3	0.3
Gastroenteritis norovirus	3	0.3
Infantile apnoea	3	0.3
Diarrhoea	3	0.3
Hernia repair	3	0.3
Conjunctivitis	3	0.3
Infection	3	0.3
Irregular breathing	3	0.3
Weight decreased	3	0.3
Osteomyelitis	2	0.2

(Continued)

Table 1.8 - Number of serious adverse events - by Preferred term (PT)

Total	n	%
Tachypnoea	2	0.2
No adverse event	2	0.2
Adverse event	2	0.2
Cardiac disorder	2	0.2
Aspiration	2	0.2
Gastroenteritis rotavirus	2	0.2
Cardiac arrest	2	0.2
Heart disease congenital	2	0.2
Malnutrition	2	0.2
Hypoxia	2	0.2
Hypercapnia	2	0.2
Malaise	2	0.2
Cardiac failure	2	0.2
Infantile spasms	2	0.2
Adenoviral upper respiratory infection	2	0.2
Rash	2	0.2
Elective procedure	2	0.2
Bronchial hyperreactivity	2	0.2

(Continued)

Table 1.8 - Number of serious adverse events - by Preferred term (PT)

Total	n	%
Apathy	1	0.1
Decreased appetite	1	0.1
Diaphragmatic hernia	1	0.1
Arthritis	1	0.1
Altered state of consciousness	1	0.1
Renal disorder	1	0.1
Pulmonary valve repair	1	0.1
Body temperature increased	1	0.1
Neonatal disorder	1	0.1
Acute respiratory distress syndrome	1	0.1
Poor weight gain neonatal	1	0.1
Bronchial obstruction	1	0.1
Wolf-Hirschhorn syndrome	1	0.1
Necrotising colitis	1	0.1
Enterostomy	1	0.1
Intestinal obstruction	1	0.1
Sepsis	1	0.1
Bronchopulmonary dysplasia	1	0.1

(Continued)

Table 1.8 - Number of serious adverse events - by Preferred term (PT)

Total	n	%
Breath sounds abnormal	1	0.1
Rales	1	0.1
Hyperhidrosis	1	0.1
Laryngeal stenosis	1	0.1
Hypothermia	1	0.1
Exanthema subitum	1	0.1
Pulmonary hypertension	1	0.1
Restrictive cardiomyopathy	1	0.1
Plastic surgery of the lips and mouth	1	0.1
Myocarditis	1	0.1
Right ventricular dysfunction	1	0.1
Antimicrobial susceptibility test resistant	1	0.1
Leukopenia	1	0.1
Thrombocytopenia	1	0.1
Cellulitis	1	0.1
Cardiovascular insufficiency	1	0.1
Hypoplastic left heart syndrome	1	0.1
Congenital central hypoventilation syndrome	1	0.1

(Continued)

Table 1.8 - Number of serious adverse events - by Preferred term (PT)

Total	n	%
Bronchitis viral	1	0.1
Histiocytosis	1	0.1
Myelitis	1	0.1
Aortic valve stenosis	1	0.1
Atrial septal defect	1	0.1
Pneumonia aspiration	1	0.1
Immunisation	1	0.1
Haemangioma	1	0.1
Staphylococcus test positive	1	0.1
Iron deficiency anaemia	1	0.1
Lissencephaly	1	0.1
Catheterisation cardiac	1	0.1
Umbilical hernia	1	0.1
Lower limb fracture	1	0.1
Anaphylactic reaction	1	0.1
Ileostomy closure	1	0.1
Superinfection bacterial	1	0.1
Pneumonia bacterial	1	0.1

(Continued)

Table 1.8 - Number of serious adverse events - by Preferred term (PT)

Total	n	%
Cardiac death	1	0.1
Oedema	1	0.1
Asthma	1	0.1
Gastrooesophageal reflux disease	1	0.1
Pneumonia escherichia	1	0.1
Lactose intolerance	1	0.1
Aortic stenosis	1	0.1
Cardiopulmonary failure	1	0.1
Pharyngeal reconstruction	1	0.1
Fallot's tetralogy	1	0.1
Influenza virus test positive	1	0.1
Pneumonia influenzal	1	0.1
Sleep apnoea syndrome	1	0.1
Haematochezia	1	0.1
Flatulence	1	0.1
Eczema infantile	1	0.1
Staphylococcal infection	1	0.1
Infective pericardial effusion	1	0.1

(Continued)

Table 1.8 - Number of serious adverse events - by Preferred term (PT)

Total	n	%
Inguinal hernia	1	0.1
Abdominal pain	1	0.1
Neonatal hypoxia	1	0.1
Metabolic acidosis	1	0.1
Apparent life threatening event	1	0.1
Device related sepsis	1	0.1
Respiratory distress	1	0.1
Injection related reaction	1	0.1
Laryngotracheitis obstructive	1	0.1
Pertussis	1	0.1
Bronchitis chronic	1	0.1
Total	1084	100.0

Table 1.9 - Number of serious adverse events - by System organ class (SOC) and Preferred term (PT)

		n	%
SOC	**PT**		
Infections and infestations	**Bronchitis**	132	12.2
	Pneumonia	116	10.7
	Respiratory syncytial virus bronchiolitis	89	8.2
	Pneumonia respiratory syncytial viral	54	5.0
	Respiratory syncytial virus infection	45	4.2
	Respiratory syncytial virus bronchitis	33	3.0
	Bronchiolitis	32	3.0
	Respiratory tract infection	20	1.8
	Pneumonia viral	18	1.7
	Upper respiratory tract infection	13	1.2
	Nasopharyngitis	8	0.7
	Gastroenteritis	7	0.6
	Respiratory tract infection viral	6	0.6
	Viral infection	5	0.5
	Influenza	4	0.4
	Pseudocroup	4	0.4
	Conjunctivitis	3	0.3

(Continued)

Table 1.9 - Number of serious adverse events - by System organ class (SOC) and Preferred term (PT)

		n	%
SOC	**PT**		
Infections and infestations	**Gastroenteritis norovirus**	3	0.3
	Infection	3	0.3
	Otitis media	3	0.3
	Adenoviral upper respiratory infection	2	0.2
	Gastroenteritis rotavirus	2	0.2
	Osteomyelitis	2	0.2
	Bronchitis viral	1	0.1
	Cellulitis	1	0.1
	Device related sepsis	1	0.1
	Exanthema subitum	1	0.1
	Infective pericardial effusion	1	0.1
	Laryngotracheitis obstructive	1	0.1
	Myelitis	1	0.1
	Pertussis	1	0.1
	Pneumonia bacterial	1	0.1
	Pneumonia escherichia	1	0.1
	Pneumonia influenzal	1	0.1

(Continued)

Table 1.9 - Number of serious adverse events - by System organ class (SOC) and Preferred term (PT)

		n	%
SOC	**PT**		
Infections and infestations	**Sepsis**	1	0.1
	Staphylococcal infection	1	0.1
	Superinfection bacterial	1	0.1
Surgical and medical procedures	**Hospitalisation**	121	11.2
	Oxygen supplementation	10	0.9
	Cardiac operation	8	0.7
	Hernia repair	3	0.3
	Elective procedure	2	0.2
	Enterostomy	1	0.1
	Ileostomy closure	1	0.1
	Immunisation	1	0.1
	Pharyngeal reconstruction	1	0.1
	Plastic surgery of the lips and mouth	1	0.1
	Pulmonary valve repair	1	0.1

(Continued)

Table 1.9 - Number of serious adverse events - by System organ class (SOC) and Preferred term (PT)

		n	%
SOC	**PT**		
Respiratory, thoracic and mediastinal disorders	**Dyspnoea**	19	1.8
	Respiratory failure	19	1.8
	Cough	17	1.6
	Respiratory disorder	13	1.2
	Apnoea	9	0.8
	Acute respiratory failure	5	0.5
	Infantile apnoea	3	0.3
	Irregular breathing	3	0.3
	Obstructive airways disorder	3	0.3
	Aspiration	2	0.2
	Bronchial hyperreactivity	2	0.2
	Hypercapnia	2	0.2
	Hypoxia	2	0.2
	Tachypnoea	2	0.2
	Acute respiratory distress syndrome	1	0.1
	Apparent life threatening event	1	0.1
	Asthma	1	0.1

(Continued)

Table 1.9 - Number of serious adverse events - by System organ class (SOC) and Preferred term (PT)

		n	%
SOC	**PT**		
Respiratory, thoracic and mediastinal disorders	**Bronchial obstruction**	1	0.1
	Bronchitis chronic	1	0.1
	Bronchopulmonary dysplasia	1	0.1
	Laryngeal stenosis	1	0.1
	Neonatal hypoxia	1	0.1
	Pneumonia aspiration	1	0.1
	Pulmonary hypertension	1	0.1
	Rales	1	0.1
	Respiratory distress	1	0.1
	Sleep apnoea syndrome	1	0.1
General disorders and administration site conditions	**Pyrexia**	25	2.3
	Death	12	1.1
	General physical health deterioration	12	1.1
	Adverse drug reaction	6	0.6
	Adverse event	2	0.2
	Malaise	2	0.2
	No adverse event	2	0.2

(Continued)

Table 1.9 - Number of serious adverse events - by System organ class (SOC) and Preferred term (PT)

		n	%
SOC	**PT**		
General disorders and administration site conditions	**Cardiac death**	1	0.1
	Hypothermia	1	0.1
	Oedema	1	0.1
Investigations	**Oxygen saturation decreased**	9	0.8
	Respiratory syncytial virus test positive	8	0.7
	Weight decreased	3	0.3
	Antimicrobial susceptibility test resistant	1	0.1
	Body temperature increased	1	0.1
	Breath sounds abnormal	1	0.1
	Catheterisation cardiac	1	0.1
	Influenza virus test positive	1	0.1
	Staphylococcus test positive	1	0.1
Metabolism and nutrition disorders	**Diet refusal**	7	0.6
	Fluid intake reduced	7	0.6
	Failure to thrive	4	0.4
	Dehydration	3	0.3
	Malnutrition	2	0.2

(Continued)

Table 1.9 - Number of serious adverse events - by System organ class (SOC) and Preferred term (PT)

		n	%
SOC	**PT**		
Metabolism and nutrition disorders	**Decreased appetite**	1	0.1
	Lactose intolerance	1	0.1
	Metabolic acidosis	1	0.1
Cardiac disorders	**Cyanosis**	4	0.4
	Bradycardia	3	0.3
	Cardiac arrest	2	0.2
	Cardiac disorder	2	0.2
	Cardiac failure	2	0.2
	Aortic valve stenosis	1	0.1
	Cardiopulmonary failure	1	0.1
	Cardiovascular insufficiency	1	0.1
	Myocarditis	1	0.1
	Restrictive cardiomyopathy	1	0.1
	Right ventricular dysfunction	1	0.1

(Continued)

Table 1.9 - Number of serious adverse events - by System organ class (SOC) and Preferred term (PT)

		n	%
SOC	**PT**		
Gastrointestinal disorders	**Vomiting**	5	0.5
	Diarrhoea	3	0.3
	Abdominal pain	1	0.1
	Diaphragmatic hernia	1	0.1
	Flatulence	1	0.1
	Gastrooesophageal reflux disease	1	0.1
	Haematochezia	1	0.1
	Inguinal hernia	1	0.1
	Intestinal obstruction	1	0.1
	Necrotising colitis	1	0.1
	Umbilical hernia	1	0.1
Nervous system disorders	**Febrile convulsion**	6	0.6
	Seizure	5	0.5
	Hydrocephalus	3	0.3
	Infantile spasms	2	0.2
	Altered state of consciousness	1	0.1

(Continued)

Table 1.9 - Number of serious adverse events - by System organ class (SOC) and Preferred term (PT)

		n	%
SOC	**PT**		
Congenital, familial and genetic disorders	**Heart disease congenital**	2	0.2
	Atrial septal defect	1	0.1
	Congenital central hypoventilation syndrome	1	0.1
	Fallot's tetralogy	1	0.1
	Hypoplastic left heart syndrome	1	0.1
	Lissencephaly	1	0.1
	Wolf-Hirschhorn syndrome	1	0.1
Blood and lymphatic system disorders	**Leukocytosis**	3	0.3
	Iron deficiency anaemia	1	0.1
	Leukopenia	1	0.1
	Thrombocytopenia	1	0.1
Psychiatric disorders	**Restlessness**	4	0.4
	Apathy	1	0.1
Skin and subcutaneous tissue disorders	**Rash**	2	0.2
	Eczema infantile	1	0.1
	Hyperhidrosis	1	0.1

(Continued)

Table 1.9 - Number of serious adverse events - by System organ class (SOC) and Preferred term (PT)

		n	%
SOC	**PT**		
Injury, poisoning and procedural complications	**Injection related reaction**	1	0.1
	Lower limb fracture	1	0.1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**Haemangioma**	1	0.1
	Histiocytosis	1	0.1
Pregnancy, puerperium and perinatal conditions	**Neonatal disorder**	1	0.1
	Poor weight gain neonatal	1	0.1
Immune system disorders	**Anaphylactic reaction**	1	0.1
Musculoskeletal and connective tissue disorders	**Arthritis**	1	0.1
Renal and urinary disorders	**Renal disorder**	1	0.1
Vascular disorders	**Aortic stenosis**	1	0.1

A2.2.7 Additional analyses for hospitalization rates

Table 1.1 - Number of patients with any RSV diagnosis

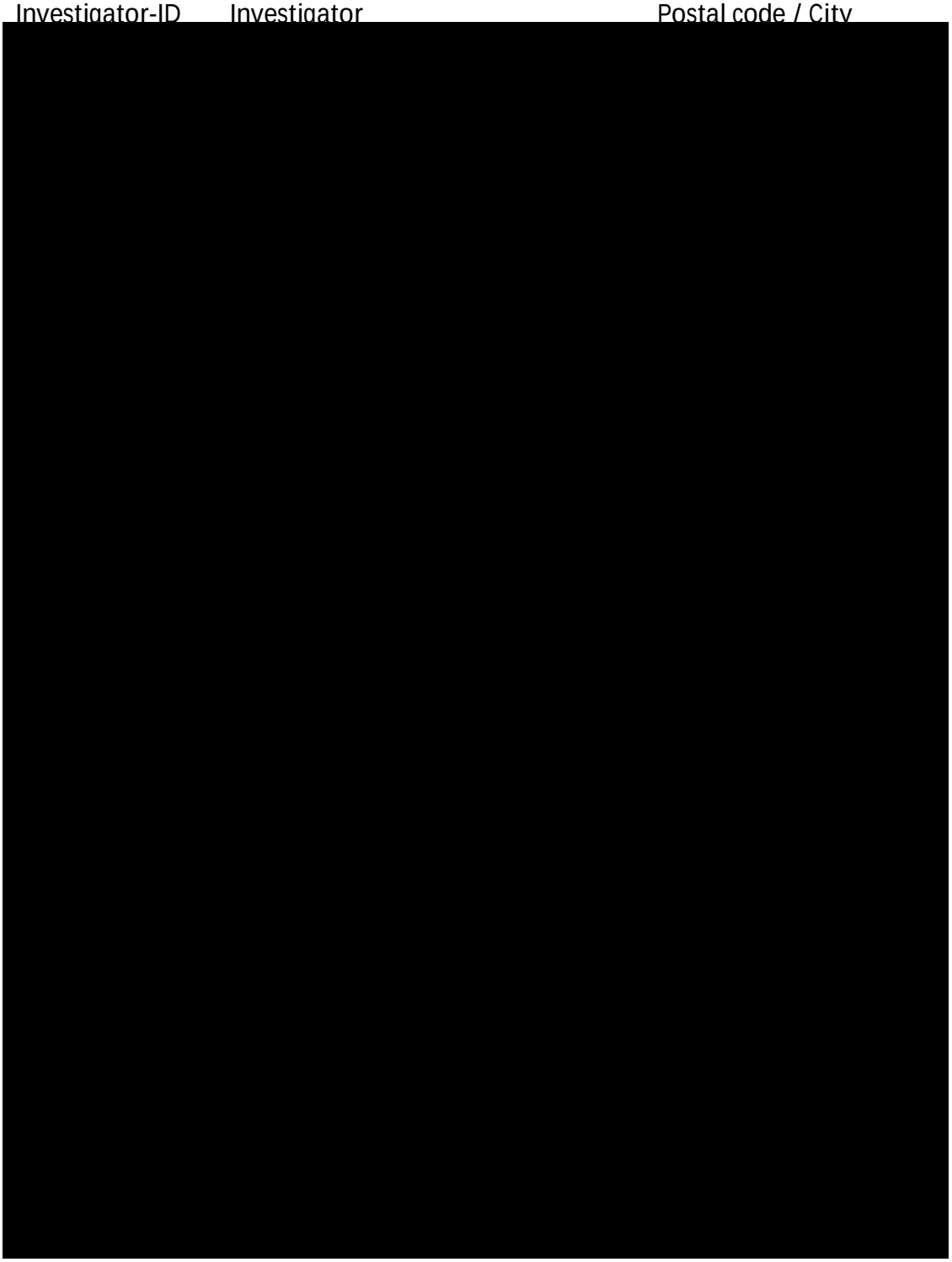
		Patients with any RSV diagnosis	
Year	**N**	**n**	**%**
2003	1287	20	1.6
2004	2208	33	1.5
2005	3000	45	1.5
2006	3338	54	1.6
2007	3805	56	1.5
Total	13638	208	1.5

Table 1.2 - Number of patients with a positive RSV-test result

		Patients with a positive RSV-test result	
Year	**N**	**n**	**%**
2002	853	18	2.1
2003	1287	21	1.6
2004	2208	34	1.5
2005	3000	42	1.4
2006	3338	57	1.7
2007	3805	51	1.3
2008	2248	18	0.8
2009	2145	15	0.7
Total	18884	256	1.4

A2.3 List of participating investigators

Investigator-ID Investigator Postal code / City



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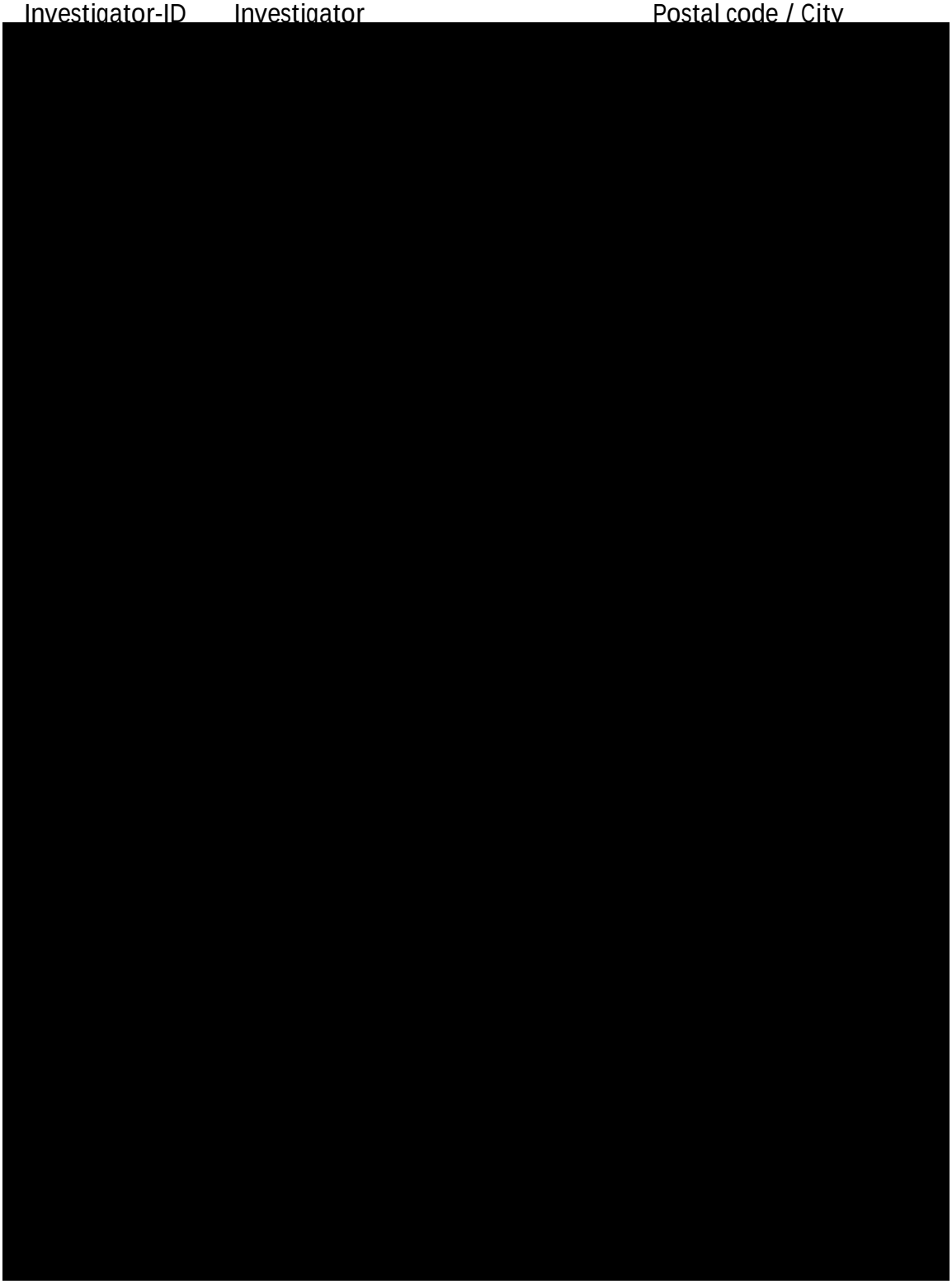

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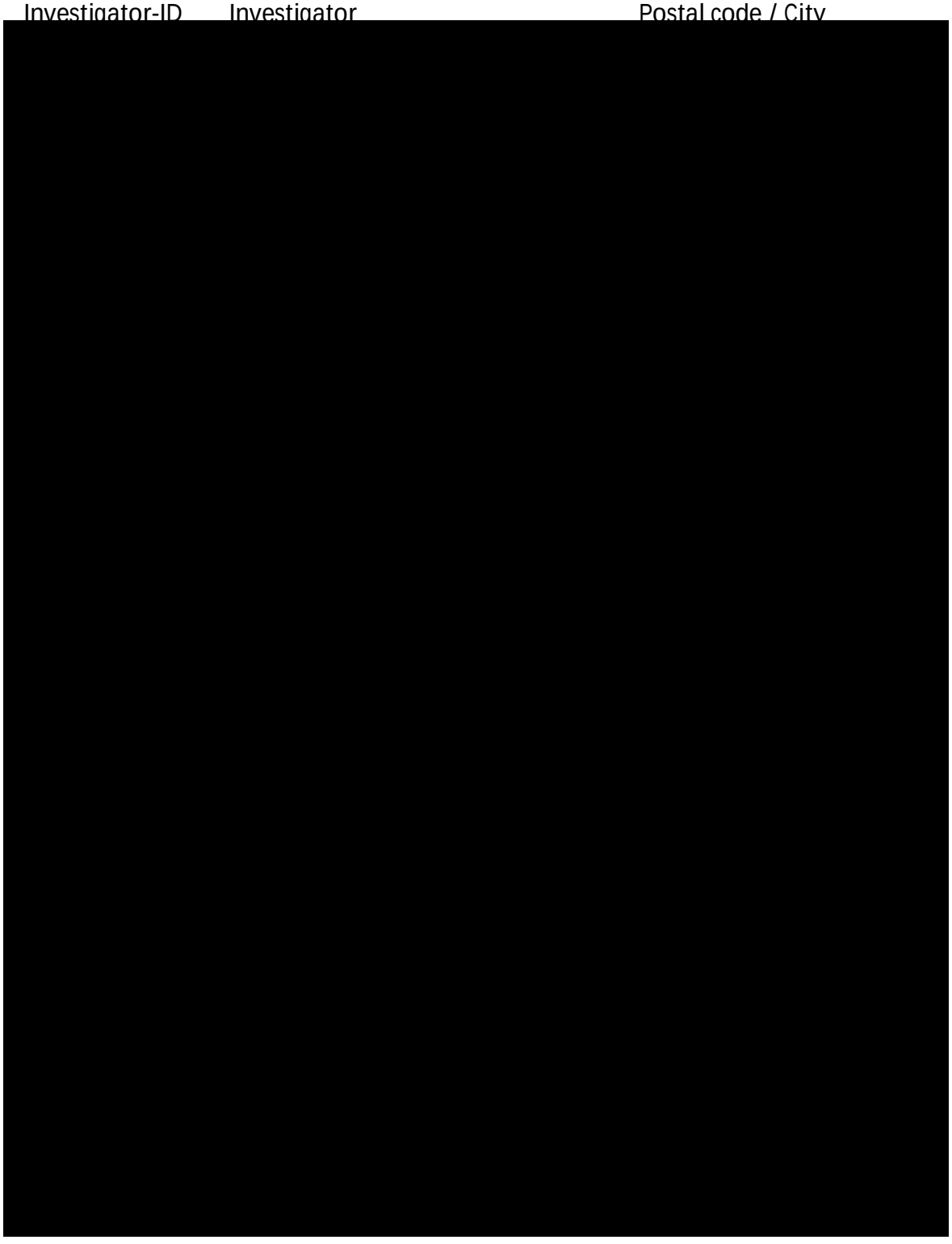

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