

Applications for clinical trial per annum

Applications 2022

Product group	Phase I	Phase II	Phase III	Phase IV
Allergens	0	3	6	0
Blood products	0	0	3	0
Fusion protein	6	4	5	1
Gene therapeutics/ GMO	14	13	8	1
Coagulation factors	0	1	5	0
Immunoglobulins, normal	5	1	2	0
Immunoglobulins, special	0	0	0	0
Vaccines	6	8	12	1
Monoclonal antibodies	55	97	129	4
Somatic cell therapeutics	6	8	4	1
Tumour vaccines / peptides	3	2	1	0

Applications 2021

Product group	Phase I	Phase II	Phase III	Phase IV
Allergens	0	2	1	0
Blood products	0	1	3	0
Fusion protein	2	8	12	0
Gene therapeutics/ GMO	16	9	13	0
Coagulation factors	0	0	2	0
Immunoglobulins, normal	2	1	2	0
Immunoglobulins, special	0	1	0	0
Vaccines	4	15	7	7
Monoclonal antibodies	30	102	123	11
Somatic cell therapeutics	4	4	0	1
Tumour vaccines / peptides	2	3	2	0

Distribution of application numbers for approval of clinical trials in 2021, broken down into clinical trial phases and product groups.

Applications 2020

Product group	Phase I	Phase II	Phase III	Phase IV
Allergens	1	3	3	0
Blood products	1	7	0	0
Fusion protein	4	4	1	0

Gene therapeutics/ GMO	15	16	12	0
Coagulation factors	0	1	3	0
Immunoglobulins, normal	4	1	2	0
Immunoglobulins, special	0	0	0	0
Vaccines	4	2	6	1
Monoclonal antibodies	59	86	134	9
Somatic cell therapeutics	7	6	4	1
Tumour vaccines / peptides	3	5	1	0

Distribution of application numbers for approval of clinical trials in 2020, broken down into clinical trial phases and product groups.

Applications 2019

Product group	Phase I	Phase II	Phase III	Phase IV
Allergens	1	2	2	0
Blood products	0	1	1	0
Fusion protein	2	2	2	0
Gene therapeutics/ GMO	16	11	4	0
Coagulation factors	0	1	3	1
Immunoglobulins, normal	1	2	1	0
Immunoglobulins, special	0	0	0	0
Vaccines	0	2	3	0
Monoclonal antibodies	43	93	92	13
Somatic cell therapeutics	2	6	7	0
Tumour vaccines / peptides	1	2	0	0

Distribution of application numbers for approval of clinical trials in 2019, broken down into clinical trial phases and product groups.

Applications 2018

Product group	Phase I	Phase II	Phase III	Phase IV
Allergens	1	2	3	0
Blood products	0	1	5	0
Fusion protein	2	4	2	0
Gene therapeutics/ GMO	12	15	9	1
Coagulation factors	1	1	6	0
Immunoglobulins, normal	1	0	1	0
Immunoglobulins, special	0	0	0	0
Vaccines	2	3	4	0
Monoclonal antibodies	26	120	103	7

Somatic cell therapeutics	6	4	3	1
Tumour vaccines / peptides	2	1	0	0

Distribution of application numbers for approval of clinical trials in 2018, broken down into clinical trial phases and product groups.

Applications 2017

Product group	Phase I	Phase II	Phase III	Phase IV
Allergens	1	6	4	0
Blood products	1	1	2	2
Fusion protein	5	5	3	0
Gene therapeutics / GMO	12	9	9	0
Coagulation factors	0	0	4	2
Immunoglobulins, normal	0	1	2	0
Immunoglobulins, special	0	0	0	0
Vaccines	2	2	3	1
Monoclonal antibodies	43	86	98	7
Somatic cell therapeutics	4	5	5	0
Tumour vaccines / peptides	5	2	0	0

Distribution of application numbers for approval of clinical trials in 2017, broken down into clinical trial phases and product groups.

Applications 2016

Product group	Phase I	Phase II	Phase III	Phase IV
Allergens	3	4	5	0
Blood products	0	1	1	1
Fusion protein	2	5	0	0
Gene therapeutics / GMO	4	10	4	0
Coagulation factors	5	1	3	0
Immunoglobulins, normal	0	2	7	0
Immunoglobulins, special	0	0	0	0
Vaccines	5	2	7	1
Monoclonal antibodies	32	96	107	11
Somatic cell therapeutics	2	3	6	0
Tumour vaccines / peptides	2	7	1	0

Distribution of the number of applications for approval of clinical trials in 2016, broken down by stages of the clinical trial and product groups.

Applications 2015

Product group	Phase I	Phase II	Phase III	Phase IV
Allergens	0	2	6	0
Blood products	0	1	2	0
Fusion protein	3	1	6	0
Gene therapeutics / GMO	5	8	5	0
Coagulation factors	1	1	7	1
Immunoglobulins, normal	0	3	1	0
Immunoglobulins, special	0	0	0	0
Vaccines	4	2	3	1
Monoclonal antibodies	32	93	109	4
Somatic cell therapeutics	5	8	4	2
Tumour vaccines / peptides	1	6	0	0

Distribution of the number of applications for approval of clinical trials in 2015 broken down by phase of the clinical trial and product groups.

Applications 2014

Product group	Phase I	Phase II	Phase III	Phase IV
Allergens	0	4	2	1
Blood products	1	1	2	2
Fusion protein	0	9	2	0
Gene therapeutics / GMO	4	3	1	0
Coagulation factors	1	0	9	2
Immunoglobulins, normal	0	0	4	0
Immunoglobulins, special	0	0	0	0
Vaccines	2	3	6	1
Monoclonal antibodies	33	55	85	11
Somatic cell therapeutics	4	5	4	0
Tumour vaccines / peptides	3	3	4	0

Distribution of the number of applications for approval of clinical trials in 2014, broken down by phases of the clinical trial and product groups.

Applications 2013

Product group	Phase I	Phase II	Phase III	Phase IV
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Allergens	1	6	1	0
Blood products	0	1	4	0
Fusion protein	3	3	0	1
Gene therapeutics / GMO	1	1	1	0
Coagulation factors	1	1	3	0
Immunoglobulins, normal	0	1	3	0
Immunoglobulins, special	0	0	0	0
Vaccines	3	3	14	3
Monoclonal antibodies	24	69	64	4
Somatic cell therapeutics	2	4	7	0
Tumour vaccines / peptides	6	7	3	0

Distribution of application numbers for 2013 clinical trial approval broken down into clinical trial phases and product groups.

Applications 2012

Product group	Phase I	Phase II	Phase III	Phase IV
Allergens	0	11	3	0
Blood products	2	2	2	0
Fusion protein	0	2	0	0
Gene therapeutics / GMO	4	2	0	0
Coagulation factors	2	6	6	1
Immunoglobulins, normal	0	0	4	0
Immunoglobulins, special	0	0	0	0
Vaccines	1	5	9	0
Monoclonal antibodies	23	72	71	5
Somatic cell therapeutics	2	9	4	0
Tumour vaccines / peptides	2	9	1	0

Distribution of application numbers for 2012 clinical trials approval by phase of clinical trial and product groups.

Applications 2011

Product group	Phase I	Phase II	Phase III	Phase IV
Allergens	0	5	4	0
Blood products	1	1	1	2
Fusion protein	0	0	0	0
Gene therapeutics / GMO	4	2	3	0
Coagulation factors	2	4	17	0
Immunoglobulins, normal	0	1	4	0

Immunoglobulins, special	0	0	0	0
Vaccines	1	5	12	5
Monoclonal antibodies	30	88	60	6
Somatic cell therapeutics	3	2	5	0
Tumour vaccines / peptides	6	5	1	0

Distribution of the number of applications for approval of clinical trials in 2011, broken down by phases of the clinical trial and product groups.

Applications 2010

Product group	Phase I	Phase II	Phase III	Phase IV
Allergens	1	3	2	0
Blood products	1	3	3	0
Fusion protein	0	1	2	0
Gene therapeutics / GMO	1	2	1	0
Coagulation factors	7	1	7	0
Immunoglobulins, normal	0	1	2	0
Immunoglobulins, special	0	0	0	0
Vaccines	4	9	19	1
Monoclonal antibodies	13	70	63	8
Somatic cell therapeutics	1	3	7	0
Tumour vaccines / peptides	5	4	2	0

Distribution of application numbers for approval of clinical trials in 2010, broken down into clinical trial phases and product groups.

Applications 2009

Product group	Phase I	Phase II	Phase III	Phase IV
Allergens	0	5	4	2
Blood products	0	3	5	1
Fusion protein	0	0	2	0
Gene therapeutics / GMO	1	1	1	0
Coagulation factors	4	3	6	4
Immunoglobulins, normal	1	0	2	0
Immunoglobulins, special	0	1	0	0
Vaccines	6	4	21	3
Monoclonal antibodies	12	56	47	3
Somatic cell therapeutics	2	3	8	0
Tumour vaccines / peptides	4	3	1	0

Distribution of application numbers for approval of clinical trials in 2009, broken down into clinical trial phases and product groups.

Applications 2008

Product group	Phase I	Phase II	Phase III	Phase IV
Allergens	2	4	6	0
Blood products	0	2	3	0
Gene therapeutics / GMO	1	4	1	0
Coagulation factors	1	2	2	0
Immunoglobulins, normal	1	2	1	0
Immunoglobulins, special	0	1	0	0
Vaccines	7	6	17	3
Monoclonal antibodies	16	57	42	7
Somatic cell therapeutics	5	5	5	0
Tumour vaccines / peptides	1	7	2	0

Distribution of the number of applications for approval of clinical trials in 2008, broken down into phases of the clinical trial and product groups.

Applications 2007

Product group	Phase I	Phase II	Phase III	Phase IV
Allergens	0	11	5	0
Blood products	1	0	0	0
Gene therapeutics / GMO	3	2	3	0
Coagulation factors	3	5	4	1
Immunoglobulins, normal	0	3	3	0
Immunoglobulins, special	0	0	0	0
Vaccines	3	6	23	6
Monoclonal antibodies	12	55	39	4
Somatic cell therapeutics	1	4	4	0
Tumour vaccines / peptides	4	3	2	0

Distribution of application numbers for 2007 clinical trial approval broken down into phases of clinical trial and product groups.

Applications 2006

Product group	Phase I	Phase II	Phase III	Phase IV
Allergens	3	1	15	0
Blood products	0	1	2	1
Gene therapeutics / GMO	5	1	1	0
Coagulation factors	0	1	0	1
Immunoglobulins, normal	1	0	2	1
Immunoglobulins, special	0	0	3	0
Vaccines	5	8	18	5
Monoclonal antibodies	9	41	43	2
Somatic cell therapeutics	2	3	1	0
Tumour vaccines / peptides	2	3	1	0

Distribution of application numbers for approval of clinical trials in 2006, broken down into clinical trial phases and product groups.

Applications 2005

Product group	Phase I	Phase II	Phase III	Phase IV
Allergens	4	1	8	1
Blood products	0	4	2	1
Gene therapeutics / GMO	1	3	2	0
Coagulation factors	4	0	5	1
Immunoglobulins, normal	1	0	1	1
Immunoglobulins, special	0	0	1	0
Vaccines	2	5	18	7
Monoclonal antibodies	7	28	37	3
Somatic cell therapeutics	3	3	0	0
Tumour vaccines / peptides	2	2	0	0

Distribution of application numbers for approval of clinical trials in 2005 broken down by stages of clinical trial and product groups.

Applications 2004

(August 2004 - 31.12.2004)

Product group	Phase I	Phase II	Phase III	Phase IV
Allergens	1	1	2	0
Coagulation factors	1	0	0	0
Immunoglobulins, normal	0	0	1	0
Vaccines	2	0	2	1
Monoclonal antibodies	4	3	5	0

Tumour vaccines / peptides	2	0	0	0
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Distribution of application numbers for 2004 clinical trial approval broken down into phases of clinical trial and product groups.