Clinical research platform for molecular testing, treatment and outcome of patients with Multiple Myeloma
(Myeloma Registry Platform; MYRIAM)
Steering Board

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<tr>
<th>Name</th>
<th>Role</th>
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<tr>
<td>John Smith</td>
<td>Project Lead</td>
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<td>Steve Johnson</td>
<td>Clinical Lead</td>
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<td>David Kim</td>
<td>Finance</td>
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<td>Marketing</td>
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<td>Customer</td>
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### Addresses and responsibilities

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# Table of contents

Steering Board ...................................................................................................................... II
Addresses and responsibilities ..............................................................................................III
Table of contents.................................................................................................................. IV
List of abbreviations .............................................................................................................. V
Project plan summary ............................................................................................................ 1
1. Background .................................................................................................................. 3
   1.1. Epidemiology ......................................................................................................... 3
   1.2. Treatment ............................................................................................................... 3
   1.3. Quality of life ....................................................................................................... 3
   1.4. Molecular testing ................................................................................................. 3
2. Study rationale and purpose ......................................................................................... 4
3. Objectives .................................................................................................................... 4
4. Project design .............................................................................................................. 5
   4.1. Description of project design ................................................................................ 5
   4.2. Timetable .............................................................................................................. 5
   4.3. Patient-Reported Outcomes – PRO satellite ......................................................... 6
   4.4. Decentralized biobank satellite .......................................................................... 6
5. Recruitment .................................................................................................................. 7
   5.1. Inclusion criteria ................................................................................................... 7
   5.2. Exclusion criteria ................................................................................................ 7
6. Study variables ............................................................................................................. 8
   6.1. Data collected in the electronic Case Report Form (eCRF) .................................... 8
   6.2. Patient-reported outcomes measures ................................................................... 8
   6.2.1. General health-related quality of life in patients with MM: ................................ 8
   6.2.2. Brief Pain Inventory (BPI) - short form ............................................................. 8
   6.2.3. Vaccinations .................................................................................................. 9
   6.3. Data source and data collection in the eCRF ........................................................ 9
   6.4. Data collection PROs .......................................................................................... 9
   6.5. Database management and quality control .......................................................... 9
   6.6. Quality assurance site visits .............................................................................. 9
7. Statistical methods and data analysis ..........................................................................10
8. Study management and administrative procedures .....................................................10
   8.1. Review by Ethics Committee ..............................................................................10
   8.2. Data confidentiality ..............................................................................................10
   8.3. Patient informed consent procedures ..................................................................10
   8.4. Withdrawal of informed consent ........................................................................11
   8.5. Discontinuation of the study ................................................................................11
   8.6. Publication of study results ................................................................................11
   8.7. Confidentiality of study documents and patient records ......................................11
9. References....................................................................................................................11
List of abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DKFZ</td>
<td>German Cancer Research Center [Deutsches Krebsforschungzentrum]</td>
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<td>ECOG</td>
<td>Eastern Cooperative Oncology Group</td>
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<tr>
<td>edc</td>
<td>Electronic data capture</td>
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<tr>
<td>EMA</td>
<td>European Medicines Agency</td>
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<tr>
<td>EORTC</td>
<td>European Organization for Research and Treatment of Cancer</td>
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<tr>
<td>FACT</td>
<td>Functional Assessment of Cancer Therapy</td>
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<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
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<tr>
<td>FPI</td>
<td>First patient in</td>
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<td>G</td>
<td>General</td>
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<td>HRQOL</td>
<td>Health-related quality of life</td>
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<td>IMiDs</td>
<td>immunomodulatory drugs</td>
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<td>LPI</td>
<td>Last patient in</td>
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<td>LPO</td>
<td>Last patient out</td>
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<td>MP</td>
<td>Monitoring plan</td>
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<tr>
<td>PRO</td>
<td>Patient-reported outcome</td>
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<tr>
<td>QLQ</td>
<td>Quality of Life Questionnaire</td>
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<td>QoL</td>
<td>Quality of Life</td>
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<td>RKI</td>
<td>Robert Koch Institute</td>
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# Project plan summary

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Clinical research platform for molecular testing, treatment and outcome of patients with Multiple Myeloma (Myeloma Registry Platform; MYRIAM)</th>
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<tbody>
<tr>
<td>Study Type</td>
<td>National, observational, prospective, longitudinal, multicenter cohort study (tumor registry platform)</td>
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<tr>
<td>Population</td>
<td>Adult patients with multiple myeloma (MM) requiring systemic treatment</td>
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<tr>
<td>Study treatment and follow-up</td>
<td>Physician’s choice according to patient’s needs. Routine care as per site standard.</td>
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<tr>
<td>Number of patients, number/specification of sites</td>
<td>2,000 patients with MM, treated at up to 150 study sites (hematologists, hospital-based and office-based). 1,000 of these patients will participate in the patient-reported outcomes (PRO) survey.</td>
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<tr>
<td>Purpose and rationale</td>
<td>It is estimated that 6,800 people are diagnosed with MM and approximately 3,800 people die from the disease in Germany each year. MM is not curable with current standard treatments. Nevertheless, with the introduction of novel agents, such as the proteasome inhibitors bortezomib, carfilzomib, ixazomib, the immunomodulatory drugs (IMiDs) thalidomide, lenalidomide, pomalidomide, and the monoclonal antibody elotuzumab targeting the glycoprotein SLAMF7/CS1, treatment of patients with MM has changed significantly over the last years. Efficacy of novel agents is established based on randomized controlled trials (RCTs), which have to recruit a selected patient population to ensure a high degree of internal validity. Real-world data from cohort studies (such as tumor registries) provide deep insight into real-life treatment of patients in routine practice where patients’ sociodemographic and medical characteristics often differ from those treated in RCTs. The purpose of the project is to set up a national, prospective, longitudinal, multicenter cohort study with associated satellites, a tumor registry platform, to document uniform data on characteristics, molecular diagnostics, treatment and course of disease, to collect patient-reported outcomes and to establish a decentralized biobank for patients with MM.</td>
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<tr>
<td>Objectives</td>
<td>• To describe treatment reality especially with regards to sequential treatments applied in real-life practice in Germany.</td>
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<td></td>
<td>• To describe real-life patient characteristics and comorbidities.</td>
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<td></td>
<td>• To describe physician-reported factors affecting treatment decision making.</td>
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<td></td>
<td>• To assess effectiveness of systemic treatments (response rate, progression-free survival, overall survival).</td>
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<td></td>
<td>• To identify characteristics affecting prognosis.</td>
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<td></td>
<td>• PRO satellite: To evaluate health-related quality of life in patients with MM.</td>
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<td></td>
<td>• Biobank satellite: To establish a decentralized biobank for future translational research projects.</td>
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### Inclusion criteria
- MM requiring systemic first- (cohort 1) or second-line (cohort 2) treatment
- Age ≥ 18 years
- Written informed consent
  - Patients not participating in the PRO satellite: signing of informed consent not later than four weeks after start of respective treatment, and not more than eight weeks before the start of respective systemic treatment
  - Patients participating in the PRO satellite: signing of informed consent and completion of baseline questionnaire before, but not more than eight weeks before the start of respective systemic treatment
- Sufficient German language skills for participation in the PRO satellite

### Exclusion criteria
- No systemic therapy for myeloma
- Patients already enrolled in studies that prohibit any participation in other studies

### Data collection
Data are collected from medical files and patient’s records and transferred into an electronic documentation system (edc).
Baseline (demographic, clinical, tumor) characteristics, treatment decision making, cytogenetics / molecular testing, all systemic treatment including details such as bisphosphonate therapy, key data on stem-cell transplantations, surgery, radiotherapy and specified supportive therapies including prophylaxis of thromboembolism where applicable, outcome (response, progression, survival), course of disease, incidence of secondary neoplasia.

### Patient-reported outcomes
Patient-reported outcomes (“MyLife”) will be assessed using the specific, validated questionnaires addressing general health-related quality of life in patients with Myeloma: EORTC QLQ-C30 core questionnaire, plus EORTC QLQ-MY20, the myeloma specific module and the Brief Pain Inventory (BPI)
PROs will be assessed at the time of recruitment, every 3 months for the first 24 months and every 6 months thereafter, for a maximum of 5 years altogether.

### Decentralized biobank
All patients will be asked to give consent for their tumor sample to be used for future investigational translational research. If the patient agrees, the sample’s identification number will be documented together with contact details of the local pathology where the tumor sample is stored.

### Statistics
Descriptive analyses will be performed annually.

### Planned Timelines
- First Patient In (FPI/FPFV): Q3 / 2017
- Last Patient In (LPI): Q3 / 2019 (cohort 2)
  Q3 / 2021 (cohort 1)
- Last Patient Out (LPO): Q3 / 2026
- Additional follow-up (survival): 12 months after LPO
- Last Patient Out (LPO-FU): Q3 / 2027

### Contact details
Sponsor: iOMEDICO AG, Hanferstr. 28, 79108 Freiburg, Germany
1. Background

1.1. Epidemiology

Multiple myeloma (MM; International Classification of Disease C.90.0) is a frequent hematological B-cell malignancy characterized by the proliferation and expansion of abnormal monoclonal plasma cells and their infiltration of the bone marrow (1,2). Amongst hematological malignancies MM represents the third most common cancer after non-Hodgkin’s lymphoma (NHL) and leukemia. It is estimated that 6,800 people are diagnosed with MM and approximately 3,800 people die from the disease in Germany each year (3).

1.2. Treatment

MM is not curable with current therapies. For younger patients (< 70 years) and for the physically fit elderly, guidelines currently suggest induction therapy followed by high-dose chemotherapy with autologous peripheral blood stem cell transplantation (autoPBSCT) as first choice of treatment. Combination chemotherapy is the recommended treatment option in the presence of comorbidity, or disability and frailty that make high-dose chemotherapy intolerable (4–7).

With the introduction of novel agents - such as the proteasome inhibitors bortezomib, carfilzomib and ixazomib, the immunomodulatory drugs (IMiDs) thalidomide, lenalidomide and pomalidomide, and the monoclonal antibody elotuzumab targeting the glycoprotein SLAMF7/CS1 - treatment of patients with MM has changed significantly over the last years (5, 8–12).

Few data are available on diagnostics, treatment and outcome in routine practice. In Germany, ambulatory oncology care is delivered by both, office-based and clinic-based hematologists. The Tumor Registry Multiple Myeloma by German office-based hematologists prospectively collected data on 500 patients starting systemic treatment for MM between 2009 and 2011 in 106 sites in Germany. Patients are followed for 5 years. First data on non-transplant patients showed that bortezomib-based regimens dominate the first- and second-line treatment (13). Data on transplant patients or from the clinic-based setting have not been published to date.

1.3. Quality of life

MM is often associated with severe and distressing symptoms such as pain and fatigue resulting in impaired quality of life (QoL, 13). Patient-reported outcomes (PRO) addressing health-related quality of life and symptoms are increasingly used in clinical trials to complement objective measurement parameters such as response and survival with subjective perceptions from the patient’s perspective. Data on PROs in routine practice are rare.

1.4. Molecular testing

Several chromosomal anomalies with prognostic significance have been identified for MM. For example, immunoglobulin heavy chain locus (IgH) translocations like t(4;14), t(14;16), t(14;20) and genomic imbalances like non-hyperdiploidity, 1q gains and 17p deletions are associated with unfavorable prognosis, whereas the translocation t(11;14) is associated with a favorable or no significant impact on prognosis (15,16). So far, no biomarkers predictive for
the response to therapeutic targets have been identified. However, the relevance of several biomarkers (e.g. cereblon, the CRBN gene) is being investigated (5,17,18).

2. Study rationale and purpose

Efficacy of novel agents is established based on randomized controlled trials (RCTs), which have to recruit a selected patient population to ensure a high degree of internal validity. Real-world data from cohort studies (such as tumor registries) provide deep insight into real-life treatment of patients in routine practice where patients' sociodemographic and medical characteristics often differ from those treated in RCTs.

The purpose of the project is to set up a national, prospective, longitudinal, multicenter cohort study with associated satellites, a tumor registry platform, to document uniform data on characteristics, molecular diagnostics, treatment and course of disease, collect patient-reported outcomes and establish a decentralized biobank for patients with MM in Germany.

The project will reveal how German patients are treated in routine practice over the entire course of disease. It will identify factors that influence treatment decision making, and will show if and how the choice of treatment changes over time. The project will be an important tool to provide real world evidence as it assesses the effectiveness of different treatments for Myeloma in unselected patients. The data shall be used to assess the current state of care and to develop recommendations concerning topics that could be improved. Patient-reported outcomes will be used to assess quality of life, symptom burden and state of care in real-life patients. The decentralized biobank will set up a national basis for future translational projects on molecular alterations.

3. Objectives

To assess treatment and outcome of patients with multiple myeloma requiring treatment, in particular:

1. To describe treatment reality especially with regards to sequential treatments applied in real-life practice in Germany.
2. To describe real-life patient characteristics and comorbidities.
3. To describe physician-reported factors affecting treatment decision making.
4. To assess effectiveness of systemic treatments (response rate, progression-free survival, overall survival).
5. To identify characteristics affecting prognosis.
6. PRO satellite “MyLife”: To evaluate health-related quality of life in patients with MM.
7. Biobank satellite: To establish a decentralized biobank for future translational research projects.
4. Project design

4.1. Description of project design

The Myeloma Registry Platform is a national, prospective, longitudinal, multicenter cohort study with associated satellites, a tumor registry platform.

1,500 patients with previously untreated multiple myeloma will be recruited at the start of first-line treatment (cohort 1) and 500 patients with previously systemically treated multiple myeloma will be recruited at the start of second-line treatment (cohort 2) in up to 150 study sites (clinics, outpatient centers) in Germany. Treatment and course of disease for each patient will be observed and documented for five years.

After informed consent is obtained, data on patients’ demographic and clinical (tumor) characteristics and on molecular testing will be documented. Patients will be treated according to their physician’s choice based on patients’ individual needs and schedules. During the five year observation and documentation period, data on all treatments, course of disease and outcome will be updated at least every six months. In addition, updated survival data will be collected 12 months after last patient out (LPO).

4.2. Timetable

Planned First Patient In (FPI)  
Planned Last Patient In (LPI) cohort 2  
Planned Last Patient In (LPI) cohort 1  
Planned Last Patient Out (LPO)  
Planned Last Patient Out (follow-up survival)  

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
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<tbody>
<tr>
<td>Planned First Patient In (FPI)</td>
<td>Q3/2017</td>
</tr>
<tr>
<td>Planned Last Patient In (LPI) cohort 2</td>
<td>Q3/2019</td>
</tr>
<tr>
<td>Planned Last Patient In (LPI) cohort 1</td>
<td>Q3/2021</td>
</tr>
<tr>
<td>Planned Last Patient Out (LPO)</td>
<td>Q3/2026</td>
</tr>
<tr>
<td>Planned Last Patient Out (follow-up survival)</td>
<td>Q3/2027</td>
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Figure 1: Project timetable
4.3. **Patient-Reported Outcomes – PRO satellite “MyLife”**

1,000 patients will be asked to complete the first PRO assessment at time of recruitment, before start of respective systemic treatment (before or at first day of systemic treatment). Afterwards, patients will receive PRO questionnaires every three months until month 24 and thereafter every six months for a maximum of five years.

*Figure 2: PRO assessment “MyLife”: timetable*

4.4. **Decentralized biobank satellite**

All patients will be asked to give consent for their tumor sample to be used for future investigational translational research. If the patient agrees, the sample’s identification number will be documented together with contact details of the local pathology where the tumor sample is stored.

For future translational research projects, tissue samples will be collected from local pathologists/molecular geneticists, shipped to a central pathology and analyzed for specific biomarkers. Translational research projects will be described in detail in independent research proposals.

*Figure 3: Decentralized biobank*
5. Recruitment

Study sites are asked to enroll all patients that meet the inclusion criteria consecutively without selecting by any means. Patients receive oral and written information about the study and are asked to give written informed consent in duplicate (one copy for the participant, one for the recruiting physician).

Patient’s recruitment is completed by:

- Collecting written informed consent
- Registering patient in the electronic data capture system
- If patient participates in PRO satellite: Reporting the contact details (name, address) through the report form in the electronic system

The investigator or designee must ensure that only eligible patients are recruited into the project.

5.1. Inclusion criteria

Patient who meet all of the following criteria are eligible for the project:

- MM requiring systemic first- (cohort 1) or second-line (cohort 2) treatment
- Age ≥ 18 years
- Written informed consent
  - Patients not participating in the PRO satellite: signing of informed consent not later than four weeks after start of respective systemic treatment, and not more than eight weeks before the start of respective systemic treatment
  - Patients participating in the PRO satellite: signing of informed consent and completion of baseline questionnaire before, but not more than eight weeks before the start of respective systemic treatment
- Sufficient German language skills for participation in the PRO satellite

5.2. Exclusion criteria

- No systemic therapy for myeloma
- Patients already enrolled in a study that prohibit any participation in other studies

![Figure 4: Time frame for inclusion](image)
6. Study variables

6.1. Data collected in the electronic Case Report Form (eCRF)

- Baseline demographic and clinical characteristics, including comorbidities
- Baseline tumor characteristics
- Baseline prognostic parameters relevant for the revised Myeloma Comorbidity Index (R-MCI) (19,20)
- Details on molecular testing
- Treatment decision making
- First systemic therapy including details (e.g. on stem-cell transplants)
- Subsequent lines of treatment (up to four lines after inclusion) including details
- Key data on radiotherapies, surgeries and specified supportive therapies
- Key data on occurrence of secondary malignancies and infections requiring (application of) iv-antibiotics
- Outcome (response, progression, survival) as assessed by local study site
- If patients consent to cede their tumor biopsy samples to future translational research: Details on the sample (sample number, contact details of local pathology)

<table>
<thead>
<tr>
<th>Table 1: Documentation schedule</th>
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<tr>
<td><strong>Time</strong></td>
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<tr>
<td>Inclusion</td>
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<tr>
<td>Throughout the project*</td>
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<tr>
<td>End of documentation</td>
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</table>

* Update at least every six months.

6.2. Patient-reported outcomes measures (“MyLife”)

PRO will be assessed using the following questionnaires:

6.2.1. General health-related quality of life in patients with MM:

- EORTC QLQ-C30
  The EORTC QLQ-C30, version 3.0, is a questionnaire developed to assess the quality of life of cancer patients, covering 5 QoL domains (Global Health Status, Physical Functioning, Emotional Functioning, Fatigue, Pain)
- EORTC QLQ-MY20, the MM-specific module

6.2.2. Brief Pain Inventory (BPI) - short form

The BPI is a 15-item questionnaire to assess the severity of pain and the impact of pain on daily functions.
6.2.3. Vaccinations

Patients will be asked to list vaccinations received.

6.3. Data source and data collection in the eCRF

All data collected in this project will be transferred from patients’ medical records to a secure web-based electronic case report form (eCRF) by the physician or trained study nurses.

iOMEDICO provides the iOstudy office edc software for the period of the study. iOstudy office edc is a field-tested and validated system. The eCRF is built using fully validated secure software that conforms to 21 CFR Part 11 requirements. Automatic validation programs check for data discrepancies in the eCRF and allow modification or verification of the entered data by designated study site staff.

The Principal Investigator is responsible for assuring that the data entered into the eCRF is complete, accurate, and that entry and updates are performed in a timely manner.

6.4. Data collection PROs

After signing informed consent, patients will receive the baseline questionnaire at the study site together with a prepaid, labelled return-envelope for mailing to iOMEDICO, where questionnaire data will be collected and analyzed.

Patient contact details (name, address) will be reported by study site personnel to the iOMEDICO Site Management Organization (iOMEDICO SMO) through a secure, web-based reporting tool. For subsequent points of time during the project, questionnaires are sent to the patient by mail by the iOMEDICO SMO. Patient contact details received by iOMEDICO SMO are strictly separated from data received and handled by iOMEDICO where the management of the project takes place and patients’ medical and questionnaire data are collected pseudonymized. Data are stored in separate databases on separate servers, and iOMEDICO SMO staff has no access to iOMEDICO databases and vice versa. The entire process has been reviewed and approved by an independent data protection registrar.

6.5. Database management and quality control

Automatic checks for plausibility and completeness of documented data are implemented in the electronic data capture system iOstudy office edc. In addition, key data will be randomly and regularly checked by data managers. In case of discrepancies or missing values, study sites will be contacted. Designated site staff is required to respond promptly to enquiries and to make any necessary changes to the data. Study sites will be visited by clinical monitors to check informed consents and samples of key data.

6.6. Quality assurance site visits

Throughout the study, quality assurance monitoring will be performed by clinical monitor assigned by iOMEDICO according to iOMEDICO’s standard operating procedures (SOP). The project-specific monitoring activities are described in more detail in the monitoring plan (MP).

By participating in the project the investigator agrees to project-related monitoring and is responsible for ensuring time and resources to provide access to source data and project-
related documents to the monitor, as well as availability of the study personnel responsible for documentation at the time of the monitoring visit.

The investigator must maintain source documents for each patient in the project, consisting of case and visit notes (hospital or clinic medical records) containing demographic and medical information, and the results of assessments. All information recorded in the eCRF must be traceable to source documents in the patient's file.

7. Statistical methods and data analysis

Annual interim analyses will be performed. Interim reports will cover descriptive data on real-life treatment including outcome, patient and tumor characteristics, molecular testing and PROs. Exploratory analyses will be performed on selected hypotheses.

Categorical variables will be presented as relative frequencies, continuous variables with mean and standard deviation or median and 25th and 75th percentiles. Time to event variables, such as progression-free and overall survival will be analyzed using the Kaplan-Meier method. If required, multivariate regression models will be applied for exploratory analyses.

PROs will be evaluated according to the respective questionnaire manuals.

The registry analysis plan indicates which specific analyses will be performed at which time point.

8. Study management and administrative procedures

8.1. Review by Ethics Committee

The project will be reviewed by the Ethics Committee of the Landesärztekammer Baden-Württemberg.

8.2. Data confidentiality

Information on study patients will be kept confidential and managed under the applicable laws and regulations.

The data collection system for this platform uses built-in security features to encrypt all data for transmission in both directions, preventing unauthorized access to confidential participant information. Access to the system will be controlled by a sequence of individually assigned user identification codes and passwords, made available only to authorized personnel.

8.3. Patient informed consent procedures

The investigator is responsible to fully provide patients with in-depth oral and written information about the project. If the patient understands the information and is willing to participate in the project an informed consent form will be signed. No patient data should be documented before the informed consent form has been signed. The informed consent form will be dated and signed in duplicate by both parties: the investigator that has provided the information and the patient. Each party will receive one set of the patient information and the signed consent form.
Consent for the decentralized clinically biobank is not mandatory to participate in the project.

8.4. Withdrawal of informed consent

At any time throughout the study patients can withdraw consent without giving reasons. In case of withdrawal of consent, data documentation and further mailing of questionnaires ends and patient’s contact data are deleted. If applicable, any bone marrow biopsy sample and extramedullary myeloma biopsy sample provided for future translational research will not be used for further projects. Data received and documented until this point of time will remain in the study, unless the patient requests complete deletion of data. Data published prior to the withdrawal of consent will remain part of the respective publication.

8.5. Discontinuation of the study

The sponsor reserves the right to discontinue this study under the conditions specified in the agreement.

8.6. Publication of study results

The study will be registered in a public trial registry (clinicaltrials.gov). Various publications concerning key results are planned during the course of the project.

8.7. Confidentiality of study documents and patient records

The investigator must ensure pseudonymity of the patients. Patients must not be identified by names in any documents submitted to the sponsor or entered into the eCRF. The signed patient informed consent must be kept strictly confidential at the study site.

In order to mail questionnaires to patients directly, patient identification (name and address) is reported from site personnel to iOMEDICO SMO. The patient identification is strictly separated, both in terms of database and personnel with access rights from iOMEDICO receiving the patients’ medical and questionnaire data (see section 6.4, page 9).

9. References


