

## Universität Regensburg Site Suitability Template<sup>1</sup>

This template may be used by sponsors of clinical trials as part of the application dossier. A separate document should be completed and submitted for each site.

This template has been developed and endorsed by the EU Clinical Trials Expert Group to comply with Regulation (EU) No. 536/2014 Clinical Trials on Medicinal Products for Human Use. However, this template is also relevant under Directive 2001/20/EC and may be used in advance of the regulation applying.

This template was modified by more detailed specifications and help texts by the Arbeitskreis Medizinischer Ethik-Kommissionen in Deutschland in joint agreement with the Platform of the Austrian Ethics Committees.

Protocol title:

Protocol Code:

EU trial number:

Trial site name and address:

Principal (or single) investigator: Title, name, contact details

**Please provide a written statement on the suitability of the site adapted to the nature and use of the investigational medicinal product.**

The trial site appears to be suitable for this trial according to the following description.

**Please describe the suitability of the facilities**

**Spatial / apparatus equipment testing laboratory / premises equipment:**

- For clinics: Number of beds, treatment rooms
- For medical offices: Number of consulting rooms, waiting rooms, treatment rooms, approx. total area, monitoring facilities

Pharmacy / study medication:

- Who is responsible for the study medication and drug accountability?
- Address, person responsible

Clinical chemistry / laboratory:

- Which laboratory do you commission as standard for your studies?
- Address, person responsible

Source documents:

- In what form are the source documents (patient records) kept?
- Where are they kept?

Availability of emergency care

- Equipment at the trial site, connection to an emergency centre must be indicated

<sup>1</sup> Basierend auf der AKEK Sitzung am 01.10.2021

**Subjects / patient treatment at the trial site**

Treatment focus of the trial site:

Average number of patients treated per year in the trial indication:

Planned number of subjects / patients for inclusion in the above-mentioned clinical trial:

Number of clinical trials currently in progress:

Number of currently running clinical trials with the same trial indication:

How are trials with the same indication with comparable inclusion and exclusion criteria and overlapping recruitment periods handled.

**Quality assurance at the trial site**

Please confirm that SOPs are used including process descriptions of the investigator-specific tasks (guidance, required information provision, staff selection, substitution, monitoring) and archiving of study documents.

**Please describe the suitability of the equipment**

Equipment at the trial site, connection to an emergency centre to be indicated

ECG, X-ray/MRI equipment, temperature-controlled refrigerator, temperature-controlled- 20° freezer, centrifuge, computer, fax, Internet connection, e-mail, lockable cabinets, any other trial specific equipment, external service providers have to be indicated

**Please provide a description of all trial procedures which will take place at the site.**

Remark: Please describe at which parts of the trial site which procedures will take place.

**Please provide a description of human resources arrangements and expertise at the site**

Please note that the information must be valid for the duration of the present clinical trial - even in the event of a change of personnel. The following text explains the individual points; the necessary information is to be entered in the forms provided in appendices 1 and 2.

**Principal investigator and investigators**

- Proof of qualification for examiners and deputies
- Current (not older than 1 year), professional CV (1-2 pages) with the following information: Name, business address, current activity, professional career, specialist doctor, additional qualifications, date and signature
- Information on clinical trials already carried out according to EU Regulation 2014/536 / AMG with patient recruitment (see **Appendix 1**): Areas of indication, phases of clinical trials, own function, period of participation
- Evidence of advanced training on general principles and rules of clinical trials, in particular EU Regulation 536/2014, AMG and ICH-GCP guidelines. Here, the requirements according to the curricular advanced training (cf. requirements according to the applicable curricular advanced training as published by the German Medical Association in Deutsches Ärzteblatt and their website).

- Any conditions, such as economic interests and institutional affiliations, that might influence the impartiality of the investigators

**Investigation team**

Please provide the description of the qualification requirements of the investigational team according to **Appendix 2**.

- Composition of the investigating team and professional qualifications of its members
- What is the minimum number of other members of the investigating team?
- How many (sub-)investigators and physicians are members of the investigating team?
- What professional qualifications do you require of the physicians in your review panel with regard to the review indication?
- What professional qualifications do you require (at minimum) of the non-medical members of your investigational team? Remark: In general, at least one of the investigators should have the same qualification as the principal investigator.
- Please explain which trial-related tasks you delegate and which qualifications you require in each case.
- Experience of the members of the investigating team with the conduct of clinical trials
- Please state in each case whether and what experience with regard to the conduct of clinical trials is required of the medical and non-medical members of your trial team for this clinical trial.
- Which training certificates on the European Regulation 536/2014, the AMG, the GCP Regulation and the ICH GCP Guideline do you require for members of the trial team; here, the requirements according to the curricular training courses and the "Recommendations" (cf. announcement of the German Medical Association in the German Medical Journal of 07.10.2016 and 25.01.2019).

With regard to the statutory tasks of the investigator according to Art. 2 para. 15 2014/536/EU, it is recommended to establish SOPs (Standard Operating Procedures).

In authorizing this document, I confirm that the site has the facilities and equipment to be able to conduct the clinical trial and has suitable arrangements in place to ensure that all investigators and other individuals involved in conducting the trial have the suitable qualifications, expertise and training in relation to their role in the clinical trial, in compliance with EU Regulation 536/2014, and all conditions identified, which might influence the impartiality of any investigators, were addressed.

Issued by the principal investigator:

Name: [Click here to enter text.](#)

Position: [Click here to enter text.](#)

On behalf of the site/organization Date:

[Click here to enter a date.](#)

**Appendix 1**

## Experience in conducting clinical trials with medicinal products or medical devices<sup>1</sup>

**Name of the investigator:**

**Office address:**

Indication	Phase (trials with med. prod.) Type of trial (med. dev.)	Function (Coordinating investigator / Principal investigator / investigator medical member of the investigating team)	Period of Participation	EudraCT-Number	Participation in Initiation meetings (yes / no)

<sup>1</sup> Only clinical trials in which patients/test persons have been recruited are to be reported. Definition of clinical trials according to Art. 2 para. 2 EU-VO 2014/536 or § 4 Abs. 23 AMG.

## Appendix 2

Title of the trial: xxx Proto-  
col code number: xxxEU trial  
number: xxx

### Information on the required qualification of the members of the investigating team

Function	Coding*	Required qualification	<i>Please replace the notes written in italics according to the examination.</i>
<b>Investigator (full delegation including deputy of the PI)</b>	1-15	(1) Profession	Licensed physician
		(2) Details of the clinical experience	Details of the clinical experience in the indication under investigation ( <i>Minimum experience in the indication to be tested, if applicable also specific medical experience and knowledge, indicate duration of the corresponding medical activity in years or specialist title</i> ):  _____
		(3) Information on regulatory knowledge	Completed basic course, if necessary, refresher/update course according to "Recommendations" <sup>2</sup> <i>Requirements for the acquisition of regulatory knowledge are to be stated:</i>  _____

<sup>2</sup> Empfehlungen zur Bewertung der Qualifikation von Prüfern und Stellvertretern sowie zur Bewertung der Auswahlkriterien von ärztlichen Mitgliedern einer Prüfgruppe (gemäß Arzneimittelgesetz, Verordnung (EU) Nr. 536/2014, Medizinproduktegesetz) durch Ethik-Kommissionen von Bundesärztekammer und Arbeitskreis Medizinischer Ethik-Kommissionen (DOI: 10.3238/arztbl.2019.Empfehlungen\_AMG\_MPG\_2019)

		<p>(4) Information on experience in the conduct of clinical trials</p>	<p>Requirements for experience in the conduct of clinical trials</p> <p><i>The minimum experience required shall be indicated (e.g. by stating the number or total duration of clinical trials participated in so far). If no previous experience in conducting clinical trials is required, this shall be stated:</i></p> <p>Number:</p> <p>or</p> <p>Total duration:</p>
		<p>(5) Study-specific information</p>	<p>Study-specific requirements are to be defined (e. g. compulsory participation in study-specific training modules):</p> <p>_____</p>

Function	Coding*	Required Qualification	<i>Please replace the notes written in italics according to the examination.</i>
<p><b>(Sub-) Investigator</b></p> <p><b>Restricted delegation</b></p> <p><i>Depending on the tasks to be performed, further requirement profiles may have to be differentiated and defined. For example, a radiotherapist performs radiation but does not prescribe chemotherapy.</i></p>	<p>1,5,6-10, 12, 13</p>	<p>(1) Profession</p>	<p><i>Requirements for the type of degree are to be specified, usually these members of the investigational team will have to be physicians</i></p>
		<p>(2) Details of the clinical experience</p>	<p>Details of the clinical experience in the indication under investigation (<i>Minimum experience in the indication to be tested, if applicable also specific medical experience and knowledge; indicate duration of the corresponding medical activity in years or specialist title</i>):</p> <p>_____</p>
		<p>(3) Information on regulatory knowledge</p>	<p>Completed basic course, if necessary, refresher/update course according to "Recommendations"<sup>3</sup></p> <p><i>Requirements for the acquisition of regulatory knowledge are to be stated:</i></p> <p>_____</p>
		<p>(4) Information on experience in the conduct of clinical trials</p>	<p>Requirements for experience in the conduct of clinical trials</p> <p><i>The minimum experience required shall be indicated (e.g. by stating the number or total duration of clinical trials participated in so far). If no</i></p>

<sup>3</sup> Empfehlungen zur Bewertung der Qualifikation von Prüfern und Stellvertretern sowie zur Bewertung der Auswahlkriterien von ärztlichen Mitgliedern einer Prüfgruppe (gemäß Arzneimittelgesetz, Verordnung (EU) Nr. 536/2014, Medizinproduktegesetz) durch Ethik-Kommissionen von Bundesärztekammer und Arbeitskreis Medizinischer Ethik-Kommissionen (DOI: 10.3238/arztbl.2019.Empfehlungen\_AMG\_MPG\_2019)



			<p><i>previous experience in conducting clinical trials is required, this shall be stated:</i></p> <p>Number:</p> <p><i>or</i></p> <p>Total duration:</p>
		<p>(5) Study-specific information</p>	<p>Study-specific requirements are to be defined (<i>e. g. compulsory participation in study-specific training modules</i>):</p> <p>_____</p>

Function	Coding*	Required Qualification	<i>Please replace the notes written in italics according to the examination.</i>
<p><b>Non-medical scientific member of the investigating team</b></p> <p><i>Possibly not applicable, to be adapted to the specific study.</i></p>	<p>1, 8-10, 12</p>	<p>(1) Scientific (technical) university degree</p>	<p><i>Requirements for the type of degree are to be specified</i></p>
		<p>(2) Details of the clinical experience</p>	<p>Clinical experience and knowledge (if applicable; define minimum experience with reference to the tasks to be assumed; define duration in years)</p> <p>Define additional study-specific necessary experience and knowledge:</p>
		<p>(3) Information on regulatory knowledge</p>	<p><i>Requirements for the acquisition of regulatory knowledge are to be defined (e.g. basic course or other training):</i></p> <p>_____</p>
		<p>(4) Information on experience in the conduct of clinical trials</p>	<p>Study-specific requirements have to be defined (e.g. mandatory participation in study-specific training modules).</p>

Function	Coding*	Required Qualification	<i>Please replace the notes written in italics according to the examination.</i>
<b>Non-medical scientific member of the investigating team</b> <b>(study assistance, study nurses)</b>	1, 7, 9, 12	(1) Vocational training	<i>Define the necessary training/experience (e.g. nursing exam or medical assistant profession):</i>  _____
		(2) Information on required knowledge and skills	<i>Define regulatory as well as additional study-specific necessary knowledge</i>

\* Coding of the delegation list (to be adapted to the specific study; the assignment suggested in the table is for orientation purposes and can also be adapted to the specific study): \_\_\_\_\_

- 1 Recruitment
- 2 Informing and obtaining consent from the data subject
- 3 Assessment of inclusion/exclusion criteria
- 4 Treatment decisions
- 5 Taking the medical history
- 6 Physical examination
- 7 Distribution of study medication
- 8 Conducting study-related examinations
- 9 Drug accountability
- 10 Completion of CRFs/SAEs
- 11 Assessment/evaluation of SAEs/AEs
- 12 Processing of queries
- 13 ISF management incl. preparation of missing document notes
- 14 Other: e.g. evaluation according to RECIST (to be indicated in the table under proof of qualification: Specialist in radiology and at least 6 months' experience in evaluation according to RECIST).
- 15 Other: \_\_\_\_\_

The guidance, necessary information provision, selection and monitoring of the members of the review panel as well as final signature of the CRF cannot be delegated but are to be carried out only by the principal investigator.