

# Site Suitability Template

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:**

- Does the facility have
- Inpatient facilities Yes/No
- Ambulance rooms Yes/No
- Immediate access to ICU Yes/No

Pharmacy / study medication:

Is clarified who is responsible for the study medication and drug accountability?  
Yes/No

Clinical chemistry / laboratory:

- Is clarified who is responsible for processing of the samples for clinical chemical analysis Yes/No

Source documents:

- Are the source documents kept safe and does the investigator have access to the source documents at any time (also after the end of trial)? Yes/No

**Please provide additional information on the facility if needed for the specific trial.**

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

<p>Treatment focus of the trial site:</p> <p>Average number of patients treated per year in the trial indication:</p> <p>Planned number of subjects / patients for inclusion in the above-mentioned clinical trial (please provide a yearly average for &gt; 1 year trials):</p> <p>Are procedures established in case clinical trials with similar inclusion and exclusion criteria are conducted with overlapping recruitment periods? Yes/No</p> <p><b>Quality assurance at the trial site</b></p> <p>Please confirm that SOPs are in place including process descriptions of the investigator-specific tasks (informed consent, staff selection, archiving of study documents, etc.). Yes/No</p>
<p><b>Please describe the suitability of the equipment</b></p>
<p>Equipment at the trial site</p> <p>Please provide information which equipment needed for the trial is available at the trial site (e. g. ECG, X-ray/MRI equipment, temperature-controlled refrigerator, temperature-controlled -20° freezer, centrifuge, any other trial specific equipment)</p>
<p><b>Please provide a description of all trial procedures which will take place at the site</b></p>
<p>This information is only required if only a subset of tasks are performed at a trial site. Please describe which study specific tasks will be performed that this site and which tasks will be performed at a different site and how the collaboration is organized.</p>
<p><b>Please provide a description of Human Resources arrangements and expertise at the site</b></p>
<p>Please note that the information must be valid for the whole 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.</p> <p><b>Principal Investigator and investigators</b></p> <ul style="list-style-type: none"> <li>- Proof of qualification for investigators. Note: In contrast to the former AMG/GCP Regulation, the AMG/CTR does not stipulate an official deputy (“Stellvertreter”). However, it is strongly recommended to appoint <i>at least one</i> suitably qualified person who can replace the principal investigator at any time.</li> <li>- 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. The use of the Investigator Curriculum Vitae template according to EudraLex - Volume 10 - Clinical trials guidelines is strongly encouraged.</li> <li>- If such information is not included in the CV please list separately: Information on clinical trials already carried out according to EU Regulation 2014/536 / AMG with patient recruitment (see <b>Appendix 1</b>): areas of indication, phases of clinical trials, own function, period of participation.</li> </ul>

- Evidence (certificates) 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. The use of the Declaration of interest template according to EudraLex - Volume 10 - Clinical trials guidelines is strongly encouraged.

### **Investigation team**

As principal investigator, 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
- How many physicians are required at minimum in the investigating team?
- What professional qualifications do you require for those physicians in your team, which will decide on a subject's inclusion in the trial?
- What professional qualifications do you require (at minimum) of the non-medical members of your investigational team?
- Training 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) (certificates need be provided for the (principal) investigator, only).

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 authorising 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 principle investigator:

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

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

On behalf of the site/organisation

**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 (principal) 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/EU DAMED-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  
Protocol code number: xxx  
EudraCT number: xxx

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

All investigators and physicians of the investigating team will have completed regulatory training according to "Recommendations"<sup>2</sup> Yes/No

Members of the investigating team are typically individuals, who are required to have knowledge of the trial protocol, the investigator's brochure and/or other trial-related specifications to execute assigned activities and/or to assess diagnostic findings correctly and in accordance to GCP standard. Persons, who execute daily medical routine measures (e.g. measurement of blood pressure; standard diagnostic investigations); are not necessarily required to be members of the investigating team.

Function	Coding (Example) *	required qualification	<i>Please adapt the notes written in italics according to the particular study number.</i>
<b>a: Investigator (in the case of a personal exchange introducing new investigators into the team)</b>	1-15	<b>(1) Profession</b>	<i>Licensed physician</i>
		<b>(2) Details of the clinical experience</b>	<i>2 years of clinical experience in the indication under investigation (Please adapt to the trial accordingly to maintain the "Facharztstandard" and explain if less experience is regarded as sufficient)</i>
		<b>(3) Study-specific information</b>	<i>Study-specific requirements are to be defined (e. g. compulsory participation in study-specific training modules):</i>  _____

<sup>2</sup> Empfehlungen zur Bewertung der Qualifikation von Prüfern/Hauptprüfern sowie Mitgliedern eines Prüfungsteams/einer Prüfergruppe (gemäß Verordnung [EU] Nr. 536/2014 bzw. Verordnung [EU] Nr. 2017/745 und 2017/746 i. V. m. d. Medizinprodukte-Durchführungsgesetz [MPDG]) durch Ethik-Kommissionen von Bundesärztekammer und Arbeitskreis Medizinischer Ethik-Kommissionen (DOI: 10.3238/arztbl.2022.Empfehlungen\_AMG\_MPG\_2022)

<b>Function</b>	<b>Coding*</b>	<b>required qualification</b>	<i>Please replace the notes written in italics according to the examination.</i>
<b>b. Member of the investigating team (full delegation)</b>	1-15	(1) Profession	Licensed physician
		(2) Details of the clinical experience	<i>2 years of clinical experience in the indication under investigation (Please adapt to the trial accordingly to maintain the "Facharztstandard" and explain if less experience is regarded as sufficient)</i>
		(3) Study-specific information	Study-specific requirements are to be defined (e. g. compulsory participation in study-specific training modules):  _____

<b>Function</b>	<b>Coding*</b>	<b>required qualification</b>	<i>Please replace the notes written in italics according to the examination.</i>
<b>c. Member of the investigating team (Restricted delegation)</b>  <i>Depending on the tasks to be performed, further requirement profiles may have to be differentiated and defined.</i>	1,5,6-10, 12, 13	(1) Profession	<i>Requirements for the type of degree are to be specified, usually these members of the investigational team will have to be physicians</i>
		(2) Details of the clinical experience	Details of the <b>clinical</b> experience in the indication under investigation <i>or with regard to the specific study tasks</i>  _____

<b>Function</b>	<b>Coding*</b>	<b>required qualification</b>	<i>Please replace the notes written in italics according to the examination.</i>
<b>d. Non-medical scientific member of the investigating team</b>  <i>(e.g. psychologist, possibly not applicable, to be adapted to the specific study)</i>	1, 8-10, 12	(1) Scientific (technical) university degree	<i>Requirements for the type of degree are to be specified</i>
		(2) Details of the clinical experience	Clinical experience and knowledge (if applicable; define minimum experience with reference to the tasks to be assumed; define duration in years).  Define here additional study-specific necessary experience and knowledge.



<b>Function</b>	<b>Coding*</b>	<b>required qualification</b>	<i>Please replace the notes written in italics according to the examination.</i>
<b>e. Non-medical member of the investigating team (study assistance, study nurses)</b>	1, 7, 9, 12	(1) Vocational training	<i>Define the necessary training/experience here (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 -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: \_\_\_\_\_