

Arbeitskreis Medizinischer Ethik-Kommissionen

in der Bundesrepublik Deutschland e.V.

Site Suitability Template (CTR)

- This form is based on the EU template site suitability statement, Version 3.0. It includes further help texts and specifications to ease the application process.
- To minimise the number of Request For Information (RFIs) that could be raised during the process and possible rejection, kindly provide detailed and informative responses to each and every question at the best of your knowledge.
- When completing this form, any national guidelines should also be referred to with regards to which sections must be completed. Where no national guidelines exist, the form should be completed in full.
- Where information which is requested in this form is provided elsewhere in the application dossier, the document can just be referenced rather than repeating the information.
- A separate document should be completed and submitted for each site.
- By using this template, the CTR Annex I requirement N.67. is fulfilled.

This template has been endorsed by the EU Clinical Trials Coordination and Advisory Group to comply with Regulation (EU) No. 536/2014 Clinical Trials on Medicinal Products for Human Use.

Section 1	
EU trial number	
Title of clinical trial	
Name of site, city	
If applicable[1], unique identification number of the site	
Name of principal investigator	
Planned number of trial participants at the site	

[1] This request is only applicable in those countries where sites are identified with a unique identification number. This helps identifying the specific site. In Germany this field can be left empty.

Section 2

a) Please provide a comprehensive 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.[2]

b) Please describe in detail the suitability of the facilities

Spatial / Apparatus Equipment Testing Laboratory / Premises equipment:

- Does the facility have
  - Inpatient facilities Yes ☐ No ☐
  - Outpatient rooms Yes ☐ No ☐
  - Immediate access to ICU Yes ☐ No ☐
  - Emergency equipment is available and appropriate processes are established 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

Treatment focus of the trial site: Click or tap here to enter text.

Average number of patients treated per year in the trial indication: Click or tap here to enter text.

Planned number of subjects / patients for inclusion in the above-mentioned clinical trial (please provide a yearly average for > 1 year trials): Click or tap here to enter text.

[2] Please amend this text if needed.

Are procedures established in case clinical trials with similar inclusion and exclusion criteria are conducted with overlapping recruitment periods?

Yes ☐ No ☐

If no, please provide further information:

Click or tap here to enter text.

Quality assurance at the trial site

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 ☐

If no, please provide further information:

Click or tap here to enter text.

c) Please describe <u>accurately</u> the suitability of the equipment

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)

Click or tap here to enter text.

d) Please provide a <u>detailed</u> description of all trial procedures which will take place at the site.

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.

Click or tap here to enter text.

e) Please provide a detailed description of Human Resources arrangements and expertise at the site

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.

Investigating team

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

Composition of the investigating team and professional qualifications of its members:

- How many physicians are required at minimum in the investigating team?

Click or tap here to enter text.

- How many non-physician members are required at minimum in the investigating team?

Click or tap here to enter text.

Section 3

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 by the principal 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.

Please ensure that you have consulted with any national guidelines before submitting this form.

NB: The CTR does not require signing individual documents in the clinical trial application.

Appendix
Title of the trial: xxx
Protocol code number: xxx
EU ID: 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 section I § 1 of the "Richtlinie zur Bewertung der Qualifikation von Prüfern, Hauptprüfern, Leitern und Mitgliedern eines Prüfungsteams durch Ethik-Kommissionen"[3]

☐ Yes ☐ No (in this case please describe the regulatory training in detail)

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.

[3] Richtlinie zur Bewertung der Qualifikation von Prüfern, Hauptprüfern, Leitern und ärztlichen Mitgliedern von Prüfungsteams durch Ethik-Kommissionen (Veröffentlichungsdatum: 11.07.2025)

Function	**Coding (Example) *** *To be adapted to the particular clinical trial.*	**required qualification**	*Please replace the notes written in italics defining the minimum criteria independent of person according to the particular clinical trial.*
a: Investigator **(in the case of a personal exchange introducing new investigators into the team)**	**1-15**	**(1) Profession**	*Licensed physician*
		(2) Details of the clinical experience	*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)*
		(3) Study-specific information	*Study-specific requirements are to be defined (e. g. compulsory participation in study-specific training modules):* _____

Function	**Coding***	**required qualification**	*Please replace the notes written in italics according to the particular clinical trial.*
	1-15	(1) Profession	*Licensed physician*

b. Member of the investigating team **(full delegation)**		(2) Details of the clinical experience	*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)*
		(3) Study-specific information	*Study-specific requirements are to be defined (e. g. compulsory participation in study-specific training modules):* _____

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

Function	Coding*	required qualification	*Please replace the notes written in italics according to the particular clinical trial.*
d. Non-medical scientific member of the investigating team *(e.g. psychologist, possibly not applicable, to be adapted to the specific study)*	1, 8-10, 12	(1) Scientific (technical) university degree	*Requirements for the type of degree are to be specified*
		(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.*

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

* Coding of the delegation list (the assignment suggested in the table is for orientation purposes and should be adapted to the specific clinical trial):

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:_____