

# Site Suitability Template

- This form may be used by Sponsors of clinical trials as part of the application dossier. This is not a mandatory form and different national arrangements may be in place which should be confirmed prior to submission.
- 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 <sup>1</sup> , unique identification number of the site	
Name of principal investigator	
Planned number of trial participants at the site	

Section 2
a) Please provide a <u>comprehensive</u> written statement on the suitability of the site adapted to the nature and use of the investigational medicinal product.

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<sup>1</sup> This request is only applicable in those countries where sites are identified with a unique identification number. This helps identifying the specific site.

Click or tap here to enter text.
b) Please describe <u>in detail</u> the suitability of the facilities
Click or tap here to enter text.
c) Please describe <u>accurately</u> the suitability of the 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.
Click or tap here to enter text.
e) Please provide a <u>detailed</u> description of Human Resources arrangements and expertise at the site
Click or tap here to enter text.
Section 3
<p>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.</p> <p>Issued by:</p> <p>Name: Click here to enter text.</p> <p>Position: Click here to enter text.</p> <p>On behalf of the site/organisation</p> <p>Date: Click here to enter a date.</p> <p>Please ensure that you have consulted with any national guidelines before submitting this form</p>

NB : The CTR does not require signing individual documents in the clinical trial application – a request for signature could however be subject to national legislation.