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.
- 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.

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.

Section 1
a) Please provide a written statement on the suitability of the site adapted to the nature and use of the investigational medicinal product.
Click or tap here to enter text.
b) Please describe the suitability of the facilities
Click or tap here to enter text.
c) Please describe the suitability of the equipment
Click or tap here to enter text.
d) Please provide a description of all trial procedures which will take place at the site.
Click or tap here to enter text.
e) Please provide a description of Human Resources arrangements and expertise at the site

Click or tap here to enter text.

Section 2

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:

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