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.

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 |  |
| Name of principal investigator |  |
| Planned number of trial participants at the site |  |

|  |
| --- |
| Section 2 |
| 1. Please provide a comprehensive written statement on the suitability of the site adapted to the nature and use of the investigational medicinal product.
 |
| The Azienda USL di Bologna is suitable for the nature and use of the experimental medicinal product and for carrying out clinical trials, according to the provisions of the Italian Ministerial Decree ." DM 19 marzo 1998 “Riconoscimento della idoneità dei centri per la sperimentazione clinica dei medicinali.”  |
| 1. Please describe in detail the suitability of the facilities
 |
| According to the protocol, the facilities involved are the follows: • inserire il centro in italiano• Il Dipartimento Farmaceutico Interaziendale• Il Laboratorio Unico MetropolitanoThese are facilities that are part of the Azienda USL di Bologna, therefore suitable for carrying out the proposed study according to the specifications of point a) Section 2.*If applicable**(c) Facilities cooperating with the experimental center outside the Azienda USL di Bologna.**•* *•* *For the facilities in point c) refer to the specific site suitability for External Facilities issued by the relevant Legal Managers.* |
| 1. Please describe accurately the suitability of the equipment
 |
| All electromedical equipment/ devices and facilities required for conducting the studyare available at the clinical center or will be provided on loan for useby the promoter upon execution of an appropriate contractIn particular, the following are available at the center:- ....... The UOC Ingegneria Clinica of Azienda USL Bologna is responsible for the matenance and calibration of all equipment in the Azienda USL of Bologna (scheduled preventive maintenance, corrective or breakdown maintenance, periodic safety checks, periodic functionality checks) |
| 1. Please provide a detailed description of all trial procedures which will take place at the site.

All procedures will be carried out at the *….. inserire nome del sito di sperimentazione* …. in which the clinical centre is based with a timeline in accordance to the study flowchart in the version approved by the relevant regulatory bodies. (See flowchart inside the protocol) |
| *Refer to the part of the protocol that lists the procedures* |
| 1. Please provide a detailed description of Human Resources arrangements and expertise at the site
 |
| The experimental center in which the study will be conducted has appropriately trained personnel with proven experience in clinical research, being specifically equipped with:---- |
| 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:Name: Click here to enter text.Position: Click here to enter text.On behalf of the site/organisation Date[[1]](#endnote-2): Click here to enter a date.Please ensure that you have consulted with any national guidelines before submitting this form |

1. The CTR does not require signing individual documents in the clinical trial application – a request for signature could however be subject to national legislation. [↑](#endnote-ref-2)