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	2024-516646-19-00
Title of clinical trial	COLchicine and non-enteric coated aspirin in the Cardiovascular Outcomes Trial of patients with Type 2 Diabetes (COLCOT-T2D)
Name of site, city	SOS Diabetologia San Giovanni Di Dio Azienda USL Toscana Centro
If applicable[1], unique identification number of the site	
Name of principal investigator	Drssa Cristiana Maria Baggiore
Planned number of trial participants at the site	It is a competitive trial, we have committed ourselves to randomize at least 5 patients

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.***

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

The Site 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.”
In this trial the study drug is Colchicine 0.5 mg once daily, and/or non-enteric coated aspirin 40 mg twice daily, or matching placebos (oral administration).
Study drug will be shipped to the Pharmacy of the Site upon indication of the Sponsor.

Management: Study drug will be received and checked by the Hospital Pharmacy; the management, storage and assignment to patients will be done by investigators: please refer to section c) for details.
Site staff details: the Medical Staff is experienced in managing, assigning and instructing patients for oral medications, please refer to section e) for details.
Facilities/Equipment details: The Trial site has the facilities required by the protocol in terms of dedicated spaces and equipment. For study drug the site staff has dedicated environment with limited access to delegated study staff.
After the evaluation of the eligibility criteria and study procedures required by the Protocol, Principal Investigator states that the site is suitable to take part in this Trial.

b) Please describe <u>in detail</u> the suitability of the facilities

The facilities involved in this trial are:

- SOS Diabetologia San Giovanni Di Dio;
- SOS Farmacia Ospedaliera San Giovanni Di Dio

The Trial site has all structural and organizational requirements needed to the management of the Protocol ensuring the conduction of the trial in accordance with Good Clinical Practice and current legislation.

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

After the evaluation of the Protocol procedures it is confirmed that the Site has the appropriate protocol required equipment to conduct the Study.

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

After the review of all study procedures included in the Protocol, it is confirmed that all the Study procedures will be conducted at site in accordance to the study flowchart in the version approved by the relevant regulatory bodies.

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

All personnel that will be involved in the trial under the supervision of the Principal Investigator is properly qualified to conduct Clinical Trial according to applicable regulations and undergoes initial and periodic training on study procedures.
Properly qualified site personnel are available at the site and the following professional roles will be involved:
N° 3 Diabetologists,

N°1 Pharmacist
It should be noted that the dedicated staff per function has been indicated basing on availability at the time of completing this form: it may change when the site will be activated. However, the site guarantees the presence of required staff for proper conduction of the Trial.

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: Ing Valerio Mari
Position: Direttore Generale Azienda USL Toscana Centro
Date: 01/08/2024

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 – a request for signature could however be subject to national legislation.