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	2023-509088-26-00
Title of clinical trial	Single arm phase II study of ctDNA-guided encorafenib plus cetuximab retreatment in patients with *BRAFV600E* mutated mCRC
Name of site, city	Nuovo Ospedale Santo Stefano, Prato
~~If applicable[1], unique identification number of the site~~	
Name of principal investigator	Dr.ssa Samantha Di Donato
Planned number of trial participants at the site	1

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

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 site appears to be suitable for conducting the Trial, in detail it has the equipment, processes, and qualified personnel for the correct management of the IMP. Encorafenib (tablet 75 mg) will be supplied by Pierre Fabre while cetuximab (5 mg/mL solution for infusion) will be provided by Merck.
b) Please describe in detail the suitability of the facilities
The selected site provides an appropriate environment in which to conduct this trial proposal due to its current availability of physician oncologists, specialists and residents, and personnel with recognized experience in promoting and conducting sponsored clinical trials and translational cancer research of the colon rectal cancer. Staff have prior experience with some study drugs and with their class. In particular, the following facilities will be involved: SOS Patologia clinica Santo Stefano SOC Radiologia Santo Stefano SOC Anatomia patologica Empoli e Prato SOC Farmacia ospedaliera Santo Stefano Study-required clinical laboratory analysis will be carried out by a central laboratory. Site has dedicated area and trained personnel for the processing, storage and shipment of samples to the centralised laboratory to perform the relevant analysis listed in the Protocol.
c) Please describe accurately the suitability of the equipment
The following equipment is available at the site to conduct the Bricket study: - CT scan/MRI for radiologic images - freezer 80°C and freezer 20°C for blood samples storage before sending to central lab - centrifuge for blood samples processing before sending to central lab - refrigerator with temperature monitoring for IP storage. - infusion pump for IP administration - computer and internet connection for the eCRF's compilation All biomedical equipments required for conducting the study are available at the site and they are object to periodic maintenance and calibration.

d) Please provide a detailed description of all trial procedures which will take place at the site.
All procedures are described in the section "Tabulated overview " of the Study Protocol: -Informed Consent -Complete medical history -Inclusion/Exclusion Criteria Checked -Tumor imaging (total-body CT or abdomen MRI + chest CT) -12-lead ECG -ECOG PS -Physical examination -blood examination -Collection of an archival treatment-naïve FFPE tissue sample for translational analyses -Collection of blood sample for centralized cf-DNA analysis -Collection of plasma samples for translational analyses -Collection of blood samples for translational analyses -Collection of a CD-ROM copy of CT scan -PROs questionnaires -Adverse events and toxicity -Survival follow up
e) Please provide a detailed description of Human Resources arrangements and expertise at the site
Qualified personnel with previous clinical research experience are available at the site (PI, Sub-I, study coordinator, study nurses, pharmacist). They are qualified to perform their duties in accordance with the study protocol, ICH/GCP and applicable regulatory requirements.
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: Piero Luigi Perruccio

Position: Direttore SOS Etica e Cura – Task Force Sperimentazione Clinica, Azienda USL Toscana Centro

PIERO LUIGI PERRUCCIO
Regione Toscana/01386030488
12.02.2024 14:37:10
GMT+00:00

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