# 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 | 2023-508507-20-00 |
| Title of clinical trial | A Phase 3, multicenter, double-blind, randomized, placebo-controlled study of ivosidenib in participants ≥18 years of age with locally advanced or metastatic conventional chondrosarcoma with an IDH1 mutation, untreated or previously treated with 1 systemic treatment regimen (CHONQUER study) |
| Name of site, city | Department of Oncology - Hospital of Prato, Azienda USL Toscana Centro<br><br>Via Suor Niccolina Infermiera, 20 - 59100 PRATO |
| If applicable[1], unique identification number of the site | ITA-003 |
| Name of principal investigator | Giacomo Giulio BALDI |
| Planned number of trial participants at the site | 2 |

[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. |
| IMP used in the clinical trial: Ivosidenib (also known as S95031, AG-120, and AGI-16678) is an oral, selective, potent inhibitor of the IDH1-mutated protein. Somatic mutations in IDH1 occur in solid tumors (eg, cholangiocarcinoma, chondrosarcoma) and hematologic malignancies (eg, acute myeloid leukemia). Ivosidenib will be provided as 250 mg tablets to be administered orally at a dose of 500 mg QD.<br><br>Study population: patients ≥18 years of age with locally advanced or metastatic conventional chondrosarcoma with an IDH1 mutation untreated or previously treated with 1 systemic treatment regimen.<br><br>Study design: Phase 3, multicenter, double-blind, randomized, placebo-controlled study. Participants will be randomized 1:1 to ivosidenib or a matched placebo control, with randomization stratified by grade (Grade 1 versus 2 versus 3), and locally advanced versus metastatic disease.<br><br>IMP management details: IMP will be provided by the Sponsor. The packaging and labelling are in accordance with the national legal requirements. The IMP will be received and stored by the Hospital Pharmacy (SOC Farmacia Ospedaliera Santo Stefano), while the management, storage and assignment will be under the responsibility of the Department of Oncology, Hospital of Prato which has all the equipment required by the protocol as detailed in the subsequent sections of this form. Study drug must be kept in an appropriate, limited-access, secure place until it is used or returned to the sponsor or designee for destruction. Study drug must be stored under the conditions specified on the label and in the Investigator Brochure.<br><br>Characteristics in favour of the suitability of the trial Site for IMP: The Site Department of Oncology, Hospital of Prato is suitable for conducting the Clinical Trial, particularly the Site has the equipment, processes, and qualified personnel for the proper management of IMP as described in the subsequent sections of this document. |
| b) Please describe in detail the suitability of the facilities |
| Referring to this clinical trial, this trial Site has all the structural and organizational requirements needed to the management of the Protocol and it is able to grant the conduction of the clinical trial in accordance with the Good Clinical Practice (GCP) and the current legislation. |
| c) Please describe accurately the suitability of the equipment |
| Equipment at the trial Site:<br><br>Bone scan or Positron Emission Tomography (PET) scan, Computed Tomography (CT) or Magnetic Resonance Imaging (MRI), XRay equipment, 12-lead electrocardiogram (ECG), Echocardiography (ECHO), refrigerated centrifuge, equipment for paraffin embedding, temperature-controlled refrigerator, temperature-controlled -80 +/- 10 Celsius Freezer.<br><br>Characteristics in favour of the suitability of the equipment: the Site has the appropriate protocol- |

required equipment to conduct the Study. All equipment is fit for use and maintained to continue to be fit for use with by authorized technicians. After the evaluation of the procedures required by the Protocol, I consider the equipment suitable to the conduction of this Trial.

d) Please provide a detailed description of all trial procedures which will take place at the site.

After the review of all the assessments, procedures, collection of biological samples foreseen in this Clinical Trial included in the Investigational Schedule of the Protocol, all the study procedures will be conducted at the site in the manner described in the Protocol.

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

Principal Investigator and investigators.

All investigators and physicians of the investigating team will have completed regulatory training according to recommendations.

Members of the investigating team include Principal Investigator, Sub-Investigators, Study Coordinators, Study Nurses and Study Pharmacists, who are required to have knowledge of the trial protocol, the investigator's brochure and/or other trial-related specifications to execute assigned activities and/or to assess diagnostic findings correctly and in accordance to GCP standard.

Members of the investigating team have been informed about their involvement in the study and have expressed their agreement in this regard. Principal Investigator and research personnel have the necessary training in good-clinical practice (GCP).

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

On behalf of the site/organisation

PIERO LUIGI PERRUCCIO
Regione Toscana/01386030488
08.01.2024 10:21:23 GMT+00:00

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.