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	2023-510422-32-00
Title of clinical trial	A Phase III, Multicentre, Randomised, Double-Blind Study to Assess the Safety and Efficacy of Emactuzumab vs. Placebo in Subjects with Tenosynovial Giant Cell Tumour
Name of site, city	Azienda USL Toscana Centro – Nuovo Ospedale Santo Stefano Via Suor Niccolina Infermiera 20/22, 59100 Prato
If applicable1, unique identification number of the site	N/A
Name of principal investigator	Dottor 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: **Emactuzumab** is a recombinant, humanised mAb directed against the human CSF-1R molecule and will be presented as a sterile, colourless concentrate for infusion, in a single-use vial. Drug supplies must be stored at 2-8°C and protected from direct sunlight. Route of Administration: intravenous infusion

Study population: patients with tenosynovial giant cell tumours (TGCT), selected on the basis of the inclusion and exclusion criteria described in the study Protocol.

Study design: randomised, double-blind, placebo-controlled, parallel-group, multicentre study of emactuzumab in adult subjects aged ≥18 years with TGCT.

IMP management details: IMP will be provided by the Sponsor and will be received and stored by the local Pharmacy (SOC Farmacia Ospedaliera Santo Stefano), while the management, handling and assignment will be under the responsibility of the SOC Oncologia Prato, which appears to be equipped with all the requirements needs 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.

Site declares that:

1. The personnel involved (principal investigator and collaborators) are competent and suitable in the treatment of TGCT disease and for the conduction of the study;
2. The Operating Units where the study is carried out are appropriate:
3. The Unit has the necessary time and resources to carry out the study accordingly to protocol requirements;
4. The study will be conducted according to the study protocol, in accordance with the principles of Good Clinical Practice, and in compliance with current regulations.
5. The local Pharmacy is able to receive the IMP. Any investigational drug will be stored separately from the other drugs accordingly to the regulatory mandate.
6. The site has documented experience with clinical trials.

b) Please describe in detail the suitability of the facilities

Referring to this clinical trial, this 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.

The Site has a dedicated area and trained personnel for the processing, storage and shipment of samples to the centralised laboratory to perform analysis listed in the Protocol.

In particular, the following facilities will be involved:

- Primary Research Location: SOC Oncologia Medica Prato
- SOC Farmacia Ospedaliera Santo Stefano

- SOS Patologia Clinica Santo Stefano
- SOC Radiologia Santo Stefano
- SOC Cardiologia Santo Stefano

As per protocol indication and ordinary clinical practice, the Site works in collaboration with a specialized orthopedic Unit of Azienda Ospedaliera Universitaria Careggi, "SOD Ortopedia oncologica e ricostruttiva" . This Unit is a regional referee centre for sarcomas and soft tissue tumors.

c) Please describe accurately the suitability of the equipment

The following equipment will be used in the study:

- Computer for data uploading;
- Weight scale;
- Height scale
- Oral/timpanic thermometer;
- Sphygmomanometer;
- 12 lead ECG machine;
- MRI 1.5-3T scanner;
- Ambient temperature centrifuge;
- Freezer -20°C and thermometer
- Freezer -70°C/-80°C and thermometerFridge 2-8°C for IMP storage
- Fridge store sample 4° (used if sample delivery is delayed) ;
- Min/Max thermometers (for fridges)
- Infusion Pump

The equipment present at the site is subject to ordinary maintenance by the Clinical Engineering Department. Maintenance documentation is available upon request if needed.

All above equipment which it is not available at site will be provided by Sponsor that will be stored and used as per contract and relative manuals.

Moreover, the Sponsor will provide all sites with the following equipment for carrying out the study:

- iPAD (medidata);
- iPhone/s (Medidata) as back up device
- Apple iPad (ATOM)
- IMP temperature monitor for drug shipment;
- Tripod Mount;
- Filming Kit;
- Digital goniometer;
- Finger goniometer;
- Drv erase marker,
- eREQ scanner

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

The following procedures will be conducted at site:
Informed Consent, Inclusion/Exclusion Criteria, Demographics and Medical History, Concomitant Medications, ECG, Physical Examination, Vital Signs, Height, Weight, Haematology, Serum Biochemistry Urinalysis, Pregnancy Test, Tanner Stage (for adolescents), Emactuzumab ADA, PK Sampling, Tumour Evaluation, PROMIS-PF TGCT Scale, Check subject has access to NRS "Worst Pain" and NRS "Worst Stiffness" eDiary, NRS "Worst Pain", SF-12 v2 NRS "Worst Stiffness" Goniometry, PGI of Change and Severity, EQ-5D-5L, Health Economics, Subject Interview, IMP Randomisation, IMP Infusion, Adverse Event Evaluation

The complete list of procedures that will be conducted at site is reported in the Protocol, in Table 1.3 "Schedule of activities" (SoA), page 16 and subsequent, and section 8. "Study Assessments and Procedures".

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

The site has qualified and trained medical and technical staff with experience in conducting clinical trials according to the GCP.

The following study staff will be involved: Oncologists, Datamanagers ,Pharmacists, Nurses, orthopedics, cardiologists, radiologists.

Other figures involved in the trial, also by occasion, such as the dermatologist, performs the procedures requested by the study protocol as part of clinical practice and it is not possible to identify a single person for each study procedure since the staff of these departments work on shift.

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: Dr Alessandro Sergi

Position: Director Staff Direzione Sanitaria – Azienda USL Toscana Centro

ALESSANDRO SERGI
Regione Toscana/01386030488
19.09.2024 08:47:48 GMT+00:00

On behalf of the site/organisation

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.