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	2022-500273-14-00
Title of clinical trial	A Phase 2b/3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Combined Dose-Finding and Cardiovascular Outcome Study to Investigate the Efficacy and Safety of CSL300 (Clazakizumab) in Subjects with End Stage Kidney Disease Undergoing Dialysis - CSL300_2301
Name of site, city	Azienda USL Toscana Centro – Ospedale Santo Stefano - Prato
Name of principal investigator	Gesualdo Campolo
Planned number of trial participants at the site	10

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:

CSL300, solution for injection. CSL300 is a genetically engineered humanized mAb directed against the human cytokine IL-6. Route of Administration: Intravenous bolus

Study population: Subjects with end stage Kidney Disease undergoing dialysis, selected on the basis of the inclusion and exclusion criteria described in the study Protocol.

Study design: A Phase 2b/3, multicenter, randomized, double-Blind, placebo-controlled. Two randomized clinical studies will be conducted in one protocol: a Part 1 (phase 2b) dose-finding study and a Part 2 (pivotal phase 3) study to demonstrate a reduction in the risk of CV events.

IMP management details:
IMP will be provided by the Sponsor in supply of single-use vials for IV bolus. The packaging and labelling are in accordance with ICH GMP, Good Clinical Practice (GCP) guidelines, and national legal requirements
The IMP will be received and stored by SOC Farmacia Ospedaliera Santo Stefano, while the management, storage and assignment will be under the responsibility of the SOC Nefrologia e dialisi Prato which appears to be equipped with 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.

Characteristics in favour of the suitability of the Trial site for IMP:
The SOC Nefrologia e dialisi Prato is suitable for conducting the Clinical Trial, particularly the Trial sites has the equipment, processes, and qualified personnel for the proper management of IMP.

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

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 Schedule of Activities (SOA) 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

All personnel that will be involved in the Clinical Trial under the supervision of the Principal Investigator is properly qualified to conduct the Clinical Trial according to applicable regulations and requirements, and undergo periodic training on study procedures.

Properly qualified site personnel with previous experience in clinical research is available at the site and for this Clinical Trial the following professional roles will be involved: Principal Investigator, 1 Sub Investigator, 2 Pharmacist.

It should be noted that the number of dedicated staff per function has been calculated based on

availability at the time of filling this form out and therefore it may change when the site will be activated.

However, the site guarantees the presence of at least one dedicated figure.

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

Date[i]: Click here to enter a date.

PIERO LUIGI PERRUCCIO
Regione Toscana/01386030488
15.09.2023 08:52:59 GMT+00:00

Please ensure that you have consulted with any national guidelines before submitting this form

[i] The CTR does not require signing individual documents in the clinical trial application – a request for signature could however be subject to national legislation.