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	2024-511879-16-00
Title of clinical trial	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Efficacy and Safety Study of Povorcitinib in Participants With Prurigo Nodularis
Name of site, city	Azienda USL Toscana Centro – Ospedale Piero Palagi, Firenze
If applicable[1], unique identification number of the site	NA
Name of principal investigator	Nicola Pimpinelli
Planned number of trial participants at the site	3

[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 meets the requirements, appropriate storage conditions and equipment necessary for carrying out all study procedures provided for in the clinical trial protocol.

The site qualifies for the phase 3 study with the Investigational Product (IP) Povorcitinib, sponsored by Incyte Corporation, in particular:

1.study personnel (Principal Investigator and Sub-investigators) is competent & suitable;

2.the Unit where the study will be carried out is appropriate;

3.the site is equipped with all the necessary facilities for conducting the study and for the management of enrolled patients;

4.has time and tools necessary to carry out the study;

5.the receipt of the IP or other product used for the study will take place through the Pharmacy Unit of the hospital and the study drug will be stored separately from other drugs according to Good Clinical Practice.

IP must be stored at 15°C-30°C °C. The minimal acceptable criteria for IP temperature monitoring are:

- Storage facility has a functional, currently calibrated temperature monitoring device that displays the current min/max temperatures in the storage area.
- Temperature is checked at least once daily, Monday-Friday by study staff and the readings are recorded at least once daily on a temperature log.

A direct print out of the daily temperature monitoring is used as record. In case of excursion, site staff delegated for the study will contact the site monitor immediately and provide information required for Sponsor assessment.

b) Please describe in detail the suitability of the facilities

The Clinical Unit and the personnel associated with it have gained experience over the years in the management of clinical trials.

After evaluating the procedures and requirements required by the protocol, the site declares that it has the spaces and facilities necessary to conduct the study

- Availability of clinical offices (e.g., treatment/examination rooms)

- Availability of equipment to perform the protocol required tests and assessments (e.g., weight scales, centrifuge, blood pressure monitors and appropriately sized cuffs, etc.)
- IP receipt, storage and dispensing areas, including required temperature controls, and recording devices (min/max thermometer)
- Adequate storage space in a secured, locked area that is separate from other drug supplies, in a temperature-monitored space (min/max thermometer/temperature recording device present and temperature logs/records maintained).
- Laboratory specimen collection, handling, and storage areas, including site access to a centrifuge, -20/70ºC freezer for specimen storage that has a min/max thermometer for temperature monitoring, access to dry ice for frozen samples.
- Calibration records for all applicable equipment (e.g., weight scales, centrifuge, blood pressure monitors, min/max thermometers, etc.)
- Appropriate access to electronic source data if medical records are retained electronically on site.
- Electronic Data Management/CRA capabilities, including internet access for EDC, ECG machine, and other applicable study systems.

The facilities involved in this trial are:

-SOC Dermatologia I e II Piero Palagi – Azienda USL Toscana Centro

-SOS Farmacia Ospedaliera Firenze I – Santa Maria Nuova (IMPs reception, qualitative- quantitative control of the shipment, registration and transport to the Site);

-Laboratorio di Immunologia Cutanea c/O Ospedale Palagi (samples management for central laboratory shipment and local if required)

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

Site equipment is confirmed as available for study purposes at site and will be used according to study protocol, such as:

- Refrigerated centrifuge or Regular centrifuge (if not available at site, Sponsor will provide refrigerated centrifuge as free loan for use)
- ECG (if not available at site, Sponsor will provide as free loan for use)
- Freezer -20 or Freezer -70 (if not available at site, Sponsor will provide Freezer -70 as free loan for use)
- Incubator (if not available at site, Sponsor will provide as free loan for use)
- Thermometer Min/Max for IP Storage (if not available at site, Sponsor will provide as free loan for use)
- Thermometer Min/Max for Freezer Sample Storage (if not available at site, Sponsor will provide as free loan for use)
- Weight and Height Scale (if not available at site, Sponsor will provide as free loan for use)

- Emergency kit
- Laboratory kits supplied by central labs
- Access to dry ice for frozen samples
- Computer connected to the internet (site will need this for EDC, eCOA and Suvoda)

The site will receive additional devices in loan for use (eCOA devices, handheld eDiaries and site tablet). Any equipment that will be provided by the Sponsor will be stored and used as per contract and relative manuals.

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

The following procedure will be performed at site:

- Obtain informed consent
- Verify inclusion and exclusion criteria
- Obtain medical history
- Verify prior and concomitant medication
- Perform comprehensive physical examination
- Height and weight
- Vital signs
- 12-lead electrocardiogram
- Efficacy assessments - GA-CPG-S, IGA-CPG-A and PAS
- Patient-Reported Outcomes assessments - Itch NRS, Skin Pain NRS, DLQI, PGIC, EQ-5D-5L, FACIT-F, PROMIS sleep scales, WPAI-GH,
- Clinical laboratory tests – blood and urinalysis
- Serum pregnancy (females of childbearing potential only)
- Pharmacokinetic sampling (blood)
- Pharmacodynamic and biomarkers sampling (blood)
- Adverse Event Assessment
- Randomize subjects
- Dispense IMP

For details regarding assessments and procedures requested by the study please refer to the trial flowchart reported in the study protocol- Table 3.

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

The PI has conducted 3 dermatology studies in the past. Current GCP training available.

The site has access to the patient pool to comply with recruitment expectations.

The site has adequate facilities & equipment.

The site is adequately staffed:

- 5 physicians with experience in conducting dermatology studies will be delegated. Current GCP training available for all physicians.
- 1 study coordinator who is GCP and IATA trained.
- 1 Study nurse who is GCP trained.
- 1 pharmacist who is GCP trained.

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: 23/07/2024

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.

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