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	2023-505061-82-00
Title of clinical trial	A Phase 3 randomized, placebo-controlled, double-blind program to evaluate efficacy and safety of upadacitinib in adult and adolescent subjects with severe alopecia areata
Name of site, city	SOS Malattie Cutanee Croniche e Terapie Biologiche – Presidio Ospedaliero Piero Palagi - Azienda USL Toscana Centro
Name of principal investigator	Francesca Prignano
Planned number of trial participants at the site	4

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.
Sponsor will provide Upadacitinib in tablets with two different dosages (15 and 30 mg) and matching placebo. Upadacitinib and matching placebo will be packaged in kits with quantities sufficient to accommodate study design.

The receipt of the IMPs (Upadacitinib and matching placebo) used for the study will take place through the pharmacy of the healthcare facility and, subsequently, the IMPs will be stored at the experimental site separately from the other drugs according to standard procedures, in accordance with the principles of Good Clinical Practice.

IMPs will be stored as specified by the sponsor (stored between 15° to 25°C) and in accordance with applicable regulatory requirements and in accordance with the approved protocol.

The investigator and/or a pharmacist or other appropriate person designated by the investigator will maintain records of product delivery to the trial site, site inventory, use by each subject, and return to the sponsor or alternative disposal of unused products. These records should include dates, quantities, lot/serial numbers, expiration dates, and unique code numbers assigned to the investigational products and investigational subjects. Investigators will maintain records that adequately document that subjects were provided the doses specified by the protocol and reconcile all investigational products received from the sponsor.

The investigator, or a person designated by the investigator, will explain the correct use of the investigational products to each subject and will check, at intervals appropriate for the trial, that each subject is following the instructions properly.

The investigator will promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational products.

b) Please describe <u>in detail</u> 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.

The facilities involved in this trial are:

- SOS Malattie cutanee croniche e terapie biologiche
- SOS Farmacia Ospedaliera Firenze II – 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)
- SOS Cardiologia Santa Maria Nuova e Palagi (ECG at screening to be performed locally)
- SOS Radiologia Santa Maria Nuova e Palagi (chest x-ray management to be performed locally)

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.

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

In this clinical trial the following equipment will be used and it's available at our site:

- centrifuge,
- -20°C freezer,

- -80°C freezer,
- 2/8°C refrigerator
- ECG
- Equipment for signal vitals measurements: personal-weighing scale, altimeter, saturimeter, cardiofrequency meter and blood pressure measurement equipment
- Chest X-Ray

Clinical equipment is calibrated and regular maintenance is done.

In this clinical trial the following equipment are not available and will be provided by the sponsor:

- incubator for QuantiFERON Test (Sponsor will provide through loan contract),
- calibrated minimum/maximum thermometers for IP temperature monitoring

Sponsor will provide through loan contract a tablet for subject questionnaire completion and equipment needed for scalp photographs. Sponsor will provide lab kits for the tests requested per protocol and samples will be shipped and analysed through the Central Laboratory.

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

At the site the following trial procedures will take place (as described in the appendix D Activity Schedule of the protocol; please refer to the appendix for further information):

- Discussion with the potential subjects about the trial design, procedures, and the related benefit risk ratio
- Informed consent, eligibility criteria review and collection and review of all data related to the subject medical/surgical History
- tanner stage assessment in case of adolescents
- SALT and Alopecia areata disease evaluation
- Adverse event and concomitant medications assessment
- Physical Exam, vital signs and Urine pregnancy tests
- ECG (at screening visit)
- Chest X-Ray (local exam requested per protocol in case of positive TB test or an increased risk to have TB)
- Tuberculosis (TB) evaluation (through TB risk questionnaire and depending on the result of Quantiferon TB test)
- Study Drug administration
- Electronic questionnaires to be completed by subject during the study visits.
- Blood samples draws and urine collection (blood samples for HIV, HBV, HCV, TBC tests, haematology, chemistry, urinalysis etc). Central laboratory will be used for tests.
- photographs of scalp, nails, and beard of the disease area(s) to ensure consistent visual representation of the disease.

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

The site staff that will be involved in the trial include adequately trained personnel with proven experience in clinical research:

- Principal Investigator: Prof.ssa Francesca Prignano

- 1 Sub-investigator: Dr. Elia Rosi
- 3 Resident
- 2 Study Coordinator
- 1 Pharmacist: receipt, transit of the IMPs
- 2 Biologists: samples management for central laboratory
- 1 Radiologist: chest x-ray management to be performed locally
- 1 Cardiologist: ECG to be performed locally at screening
- 1 Study Nurse: blood draws

The skills of the staff involved are adequate for conducting the study. Adequate resources are also confirmed for the blind study staff. All trial staff will be trained on the blinding procedures.

Investigators are qualified by education, training and experience to assume responsibility for the proper conduct of the trial, meet all qualifications specified by applicable regulatory requirements. All investigators are trained and comply with ICH E6 (R2) Good clinical practice.

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 Piero Luigi Perruccio

Position: Direttore SOS Etica e Cura - Task Force aziendale sperimentazione clinica – Azienda USL Toscana Centro

On behalf of the site/organisation

PIERO LUIGI PERRUCCIO
Regione Toscana/01386030488
14.07.2023 10:30:24 GMT+00:00

Date:

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