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	2023-504863-17-00
Title of clinical trial	A Multicenter, Open-Label, Single-Arm, Phase 3, Long-Term Extension Study to Evaluate Continuous Safety and Efficacy of BIIB059 (Litifilimab) in Adult Participants With Active Subacute Cutaneous Lupus Erythematosus and/or Chronic Cutaneous Lupus Erythematosus With or Without Systemic Manifestations and Refractory and/or Intolerant to Antimalarial Therapy (AMETHYST LTE)
Name of site, city	SOS Malattie rare dermatologiche - Ospedale Piero Palagi, Viale Michelangiolo n. 41 – 50122 Firenze (FI), Italy Azienda USL Toscana Centro
Name of principal investigator	Alice Verdelli
Planned number of trial participants at the site	About 3 patients

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 BIIB059 (litifilimab) as 1.5 mL liquid in a prefilled syringe that delivers 225 mg of litifilimab. Study drug will be provided in quantities sufficient to accommodate study design.

The receipt of the study treatment will take place through the pharmacy of the healthcare facility and, subsequently 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.

Sudy Treatment will be stored as specified by the sponsor and in accordance with applicable regulatory requirements and in accordance with the approved protocol (Litifilimab is to be protected from light and stored at 2°C to 8°C in a secure location at the study site with limited access).

The Investigator, the trial staff are responsible for clinical supplies accountability, reconciliation, and record maintenance (ie, receipt, reconciliation, and final disposition records). The Investigator will maintain accurate records of receipt of all study drug, including dates of receipt. In addition, accurate records will be kept regarding when and how much study drug is dispensed and used by each patient in the study.

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.

Patients will be instructed to return the used and unused medication to the study site at the next study visit. Used and unused medication will be stored for final accountability.

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 rare dermatologiche
- SOS Farmacia Ospedaliera Firenze II – Santa Maria Nuova (IMP 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 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
- 12-Lead ECG
- Equipment for signal vitals measurements: personal-weighing scale, altimeter, saturimeter, cardiofrequency meter and blood pressure measurement equipment

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:

- calibrated minimum/maximum thermometers for IP temperature monitoring

Sponsor will provide through loan contract tablets for subject electronic clinical outcome assessment (eCOA). Sponsor will provide lab kits for the tests requested per protocol and samples will be shipped and analysed through the Central Laboratory. Central laboratory will provide Sediplast® Autozero Westergren for erythrocyte sedimentation rate to be performed locally.

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

All trial procedures described in the Protocol will be conducted at the site.

Participants will have up to 27 visits during the LTE treatment period:
• 8 visits for treatment administration with site visit assessments (Day 1, Week 12, 24, 36, 52, 64, 76, and 88)
• 18 visits for treatment administration without visit assessments (Week 4, 8, 16, 20, 28, 32, 40, 44, 48, 56, 60, 68, 72, 80, 84, 92, 96, and 100)
• 1 visit for site visit assessments without treatment administration (Week 104).

During the Safety Follow-Up (SFU) period, visits will be conducted 4, 8, 12, 16, 20, and 24 weeks after the last study visit (Week 104 or ET). The SFU visits are telephone contacts, except for SFU Week 12 and SFU Week 24, which are site visits.

Study assessments conducted at each visit are listed in the Schedule of Activities.

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: Dr.ssa Alice Verdelli
- 3 Sub-investigator: Prof.ssa Marzia Caproni, Dr. Alberto Corrà, Dr.ssa Lavinia Quintarelli
- 3 Resident
- 2 Study Coordinator
- 1 Pharmacist: receipt, transit of the IMP
- 2 Biologists: samples management for central laboratory
- 1 Study Nurse: blood draws

The skills of the staff involved are adequate for conducting the study.

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
21.07.2023 13:13:48 GMT+00:00

Date:

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