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	2023-510339-12-00
Title of clinical trial	A phase III study to assess efficacy and safety of N-Acetyl-GED-0507-34-LEVO gel 5%, applied once daily for 12 weeks in patients with acne vulgaris (GEDACNE-1)
Name of site, city	SOC Dermatologia I Ospedale Piero Palagi – Azienda USL Toscana Centro Viale Michelangiolo, 41 – 50122 Florence
If applicable[1], unique identification number of the site	**N.A.**
Name of principal investigator	Prof. Nicola Pimpinelli
Planned number of trial participants at the site	about 5

Section 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.

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 to accomplish the health-related activities according to the national laws and abides by the current legislation on hygiene/health and safety for all the activities that are herein carried on.

The site qualifies for the phase 3 study with the investigational medical product (IMPs) N-Acetyl-GED-0507-34-LEVO gel 5% and N-Acetyl-GED-0507-34-Levo corresponding vehicle, sponsored by PPM Services S.A., 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 IMP 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.

The N-Acetyl-GED-0507-34-LEVO gel 5%, as well as the corresponding vehicle gel, will be supplied as gel for topical use in a 35 g Aluminium tubes by the Sponsor.

Two type of kits will be supplied: a face kit and a face + trunk kit.

Each kit has to be stored at Below 30°C, as mentioned in the study protocol.

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.

The facilities involved in this trial are:

-SOC Dermatologia I

-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);

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 accurately 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:

-Centrifuge (not refrigerated)

-Fridge for sample storage +4°C

-T logger Fridge for sample storage

-T Logger room temperature

-Sphygmomanometer

Clinical equipment is calibrated, and regular maintenance is done.

The site will receive additional devices in loan for use (Stadiometer, Thermometer and Body balance). 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:

-Collection of Informed consent, Demography, Medical history, Physical examination/ Vital signs, Prior medications, Body weight

-Blood sample collection

-UPT pregnancy test (if applicable)

-Evaluation of Investigator's Global Assessment (IGA), Physician Global Assessment (PGA), lesion count, local tolerability, overall application site irritation

-Randomization

-IMP and diary dispensation/return/accountability

-Adverse events and concomitant medication intake monitoring

-Collection of Dermatology Life Quality Index (DLQI) (age 17 and older)/Children's Dermatology Life Quality Index (C-DLQI)

-Scar evaluation, face only

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

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

All personnel who will be involved in the study are adequately trained and have proven experience in clinical research:

- Principal Investigator: Prof. Nicola Pimpinelli

- Nr. 5 Sub I
- Nr. 1 Study Nurse
- Nr. 1 Pharmacist
- Nr. 1 Study Coordinator
- Nr. 1 Biologist

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.

ALESSANDRO SERGI
Regione
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10.04.2024 11:01:04
GMT+00:00

Issued by:

Name: dr Alessandro Sergi

Position: Director Staff Direzione Sanitaria – Azienda USL T

On behalf of the site/organisation

Date: Click here to enter a 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.