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	2023-505841-22-00
Title of clinical trial	TAK-279-3001: A Phase 3, Randomized, Multicenter, Double-Blind, Placebo- and Active Comparator-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of TAK 279 in Subjects With Moderate-to-Severe Plaque Psoriasis
Name of site, city	Azienda USL Toscana Centro - Firenze Dept. of Medical Specialties – SOS Malattie Cutanee Croniche e Terapie Biologiche
If applicable[1], unique identification number of the site	NA
Name of principal investigator	Francesca Prignano
Planned number of trial participants at the site	Approximately 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.
In this study, the interventions include: □ Study drug: TAK-279 tablet or matching placebo tablet. □ Other products required for the study: Over-encapsulated apremilast (30, 20, and 10 mg titrated) or matching placebo capsules. Sponsor will provide all study drugs. The receipt of the drugs 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, 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.
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: - SOS Malattie cutanee croniche e terapie biologiche, where subjects will be visited and treated. - 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) 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
In this clinical trial the following equipment will be used and it's available at our site: - Freezer -20/-80°C with temperature monitoring

-Refrigerated/ambient centrifuge

- Weight scale

- Sphygmomanometer

-Stadiometer

- Body thermometer

- X-ray scanner

For clinical equipments regular maintenance is done.

Following equipment must be provided on loan by the sponsor to the center:

- Incubator for TB QuantiFERON test

- Min/Max Thermometer for IP monitoring

- ECG machine

- tablets and smartphones with SIM cards.

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 Schedule of Activities Table 1.a; please refer to the appendix for further information):

Screening Period:

The screening period will be a maximum of 35 days and no fewer than 7 days (to collect PSSD scores prior to Day 1 and calculate a weekly average baseline score). Key activities during screening include collection of PSSD, PASI, sPGA, and BSA, collection of ECG, and collection of serum blood samples. Consenting subjects will be screened for eligibility in a clinical setting before randomization.

Randomization and Stratification Factors:

If subjects meet the study's eligibility criteria, they will be randomized in a 3:1:1 ratio on Day 1 to receive either TAK-279, placebo, or apremilast.

Treatment Period:

Subjects will be dosed with blinded study drug (either TAK-279, placebo, or apremilast) on Day 1. Blinded study drug will be administered on site during site visits on Day 1, at Weeks 1, 2, 4 and every 4 weeks thereafter until Week 48. Subjects will self-administer twice daily through Week 52. The end-of-study safety visit take place approximately 4 weeks after last dose. Efficacy will be assessed using PASI, 5-point sPGA, and percentage BSA involvement. For subjects with scalp psoriasis at Day 1, 5-point ssPGA will be assessed

during the study period. For subjects with nail psoriasis at Day 1, NAPSI will be assessed during the study period. For subjects with hands and/or feet psoriasis involvement at Day 1, PGA of the hands and/or feet will be assessed during the study period. Patient-reported outcome assessments will include: DLQI, EQ-5D-5L, SF-36v2, and WPAI-PSO. Patient-reported psoriasis symptoms and signs will be evaluated using the daily PSSD. Safety will be assessed by collecting TEAEs, including AESIs; recording vital signs; performing complete and targeted physical examinations; and evaluating ECG and clinical laboratory results. Signs of depression and suicidal ideation and behavior will be monitored with the 8-item Patient Health Questionnaire (PHQ-8) and Columbia-Suicide Severity Rating Scale (C-SSRS), respectively.

Safety Follow-Up:

The treatment period will be followed by an on-site EOS 4-week safety follow-up visit.

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

- 2 Sub-investigators: Dr. Elia Rosi, Dr. ssa Scandagli Ilaria

- 3 Residents: drssa Prisca Guerra, drssa Giulia Nunziati, dr Gianmarco Silvi

- 1 Study Coordinator

- 1 Pharmacist: receipt, transit of the Study Drugs

- 2 Biologists: samples management for central laboratory

- 1 Study Nurse: blood draws

The radiology and cardiology staff perform the procedures requested by the study protocol as part of clinical practice and it is not possible to identify a single person for each study procedure since both of the staff of these department work on shift. Both of the staff of these department can be involved in the required study procedure

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

Date:

PIERO LUIGI PERRUCCIO
Regione Toscana/01386030488
19.10.2023 10:58:58 GMT+00:00

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.