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	2023-505928-59-00
Title of clinical trial	A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato-DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients With Previously Untreated Triple-Negative or Hormone Receptor-low/HER2-negative Breast Cancer (D926QC00001; TROPION-Breast04)
Name of site, city	Azienda USL Toscana Centro - SOC Oncologia Medica Empoli - Ospedale San Giuseppe - viale Giovanni Boccaccio 16 - Empoli (Firenze)
Name of principal investigator	Drssa Francesca Martella
Planned number of trial participants at the site	8

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 is suitable for carrying out the study as it possesses all the structural and technical/organizational measures necessary for conducting the study:

1. the personnel involved (principal investigator and collaborators) is competent and suitable;
2. the Operating Unit where the study takes place is appropriate;
3. the site is equipped with all the facilities necessary for conducting the study, including a laboratory dedicated to the management of biological samples and a pharmacy dedicated to the management of the experimental drug;
4. the site has the time and means necessary to carry out the study;
5. the investigational medicinal product or other product (if any) used for the study will be received through the pharmacy of the site and, subsequently, the medicinal product itself will be stored at the experimental site separately from the other drugs

b) Please describe in detail the suitability of the facilities

The Operating Unit/Department identified for the study conduction meets the structural and organizational requirements for the study conduction according to the Protocol, and is able to guarantee the study conduction according to the Good Clinical Practice (GCP) and the current legislation.

Other Operating Units/Departments involved:

- Laboratory Medicine Unit – SOS Patologia Clinica San Giuseppe
- Pharmacy Unit – SOS Farmacia Ospedaliera Empoli
- Radiology Unit – SOC Radiologia San Giuseppe
- Cardiology Unit – SOC Cardiologia San Giuseppe
- Surgery Unit – SOC Chirurgia senologica

c) Please describe accurately the suitability of the equipment

The Operating Unit/Department owns the appropriate and suitable equipment to conduct the study in an adequate and safe way, according to the Protocol.

List of the equipment used for the study:

- Physical examination room;
- Facility/Room to collect biologic samples;
- Restricted and secure area to store IMP and to store study documents (ISF, PSF);
- Storage Room for ancillary supply (sharps container, cooler bags and cooler packs)
- Access to a computer and internet connection;
- Adequate space to receive monitoring visits;
- Body size measuring device;

- Emergency equipment (e.g.: crash car, emergency medication) or rapid access to emergency room;
- 12-Lead Electrocardiogram (ECG) machine;
- Thermometers for body temperature (axillary, oral, or tympanic), digital or analogic;
- Access to X-Ray/CT scan facilities;
- Access to biopsy laboratory (if central lab will not be used) and pathologist review for sample interpretation and report (if central lab will not be used);
- Centrifuge (regular and/or refrigerated);
- Freezer (-20°C, -70°C or -80°C) with calibrated thermometer to monitor temperature;
- Refrigerator 2°C – 8°C, with restricted access to study team;
- Thermometer to monitor refrigerator temperature (Max/Min or continuous monitoring)

In addition, the sponsor will provide the following equipment, certified according to current regulations, on loan for use:

- Smartphone for diary and patient questionnaires completion

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

The study will be conducted according to the study protocol (Schedule of Activities section), in accordance with the principles of Good Clinical Practice and in compliance with current regulations.

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

All personnel who will be involved in the clinical trial, under the supervision of the principal investigator, are appropriately qualified to conduct the clinical trial in accordance with applicable regulations and requirements and shall undergo periodic trainings on study procedures.

The following professional figures are available and will be involved in conducting the study:

- Principale Investigator
- N. 4 Sub-investigators
- Pharmacist
- Study Coordinator
- Nurse

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: The Legal Representative's delegate, endowed with the necessary powers

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[i]:

PIERO LUIGI
PERRUCCIO
Regione
Toscana/01386030488
19.10.2023 10:59:57
GMT+00:00

Digital Signature:

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

[i] The CTR does not require signing individual documents in the clinical trial application – a request for signature could however be subject to national legislation.