Site Suitability

- 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	2023-506620-87-00
Title of clinical trial	IMPlementing geriatric assessment for dose Optimization of CDK 4/6-inhibitors in older bReasT cAncer patieNTs – a pragmatic randomized-controlled trial
Name of site, city	SOC Oncologia Medica, Azienda USL Toscana Centro, Prato
Name of principal investigator	Prof. Laura Biganzoli
Planned number of trial participants at the site	20

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 study site fulfills the following obligations and are, therefore, considered suitable for participating in the trial: 1. The site is treating breast cancer patients who are potentially eligible for the trial.

2. The study site.is suitable for conducting the Clinical Trial, particularly the Trial sites has the equipment, processes, and qualified personnel to use the investigational medicinal product dossier. The Trial site is a reference center for the pathology under study (breast cancer) and it has the requirement to exercise healthcare activities in accordance with the National legislation and in compliance with current regulations on hygiene, health and safety.
3. The study site has breast oncologists with clinical experience in treating older patients with breast cancer treated with CDK 4/6-inhibitors and experience in participating as investigators to clinical trials.
4. The study site has routines on how to follow patients treated with CDK 4/6-inhibitors to capture and treat potential side effects.
5. The study site has procedures on how to keep their healthcare professionals updated related to Good Clinical Practice principles.
6. The study site is equipped with necessary tools for diagnosis, treatment, and follow-up of patients with breast cancer.

b) Please describe <u>in detail</u> the suitability of the facilities and equipment

1. Examination rooms for patients under treatment.

2. Examination rooms for acute patient visits due to side effects.

3. Laboratories for blood analyses and radiological examinations as a part of follow-up or in case of emergency.

c) Please provide a <u>detailed</u> description of all trial procedures which will take place at the site.

1. Patient recruitment

2. Treatment initiation and follow-up (as in normal care)

3. Assessment of potential side effects and adequate treatment (as in normal care)

4. Sending questionnaires for patient-reported outcome measures (PROMs) for participants choosing paper PROMs instead of electronic.

d) Please provide a <u>detailed</u> description of Human Resources arrangements and expertise at the site

All personnel that will be involved in the Clinical Trial under the supervision of the Principal Investigator is properly qualified to conduct the Clinical Trial according to applicable regulations and requirements, and undergo periodic training on study procedures.

Properly qualified site personnel (with previous experience in treating patients using CDK 4/6-inhibitors and in clinical research) is available at the site. For this Clinical Trial the following professional roles will be involved:

Principal Investigator,

2 SubInvestigators,

1 Study Coordinator/Data Manager,

1 Pharmacist,

1 Nurse,

1 Geriatrician.

It should be noted that the number of dedicated staff per function has been calculated based on availability at the time of filling this form out and therefore it may change when the site will be activated.

However, the site guarantees the presence of at least one dedicated figure.

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: Piero Luigi Perruccio

Position: Direttore SOS Etica e Cura –Task Force Sperimentazione Clinica, Azienda USL Toscana Centro

On behalf of the site/organisation

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Regione Toscana/01386030488
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GMT+00:00

Date[i]: Click here to enter a date.

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.