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	2024-511025-63-00
Title of clinical trial	EASi-KIDNEY™ (Studies of Heart & Kidney Protection with BI 690517 in combination with empagliflozin)
Name of site, city	Azienda USL Toscana Centro – Ospedale Santo Stefano -Prato
If applicable[1], unique identification number of the site	
Name of principal investigator	Dr Gesualdo Campolo
Planned number of trial participants at the site	It is a competitive trial, we have committed ourselves to randomize at least 25 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*.
The Site is suitable for the nature and use of the experimental medicinal product and for

[1] This request is only applicable in those countries where sites are identified with a unique identification number. This helps identifying the specific site.

carrying out clinical trials, according to the current legislations.
In this trial the study drug is BI 690517 10mg once daily (oral administration).
Study drug will be shipped to the Pharmacy of the Site upon indication of the Sponsor.
Patients enrolled in the study will also receive Empagliflozin (during run-in and follow-up)
Empagliflozin is a non-investigational medicinal product having been licensed in Italy for use in CKD.
Empagliflozin will be shipped to the Pharmacy of the Site upon indication of the Sponsor.
During the study run-in phase, patients will assume (oral administration) placebo film-coated tablet of study drug ("BI 690517") once daily (single-blind) and Empagliflozin. From randomization patients will take study drug (BI 690517 10mg film-coated tablet) once daily versus matching placebo film-coated tablet once daily (double-blind) for oral administration and Empagliflozin.

Both Study drug (BI 690517) and Empagliflozin must be stored as per label storage condition statement: no specific storage conditions expected for Italy (expect 2-30°C which will be the general storage range).

Management: Study drug (BI 690517) and Empagliflozin will be received and checked by the Pharmacy of the site; the management, storage and assignment to patients will be done by investigators: please refer to section c) for details.
Site staff details: the Medical Staff is experienced in managing, assigning and instructing patients for oral medications, please refer to section e) for details.
Facilities/Equipment details: the Trial site has the facilities required by the protocol in terms of dedicated spaces and equipment. For study drug (BI 690517) and Empagliflozin management the site staff has dedicated environment with limited access to delegated study staff.

After the evaluation of the eligibility criteria and study procedures required by the Protocol, we states that the site is suitable to take part in this Trial.

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

The facilities involved in this trial are:
- Primary Research Location: SOC Nefrologia Santo Stefano
-Pharmacy: SOC Farmacia Ospedaliera Santo Stefano
- Analysis Laboratory: SOS Patologia Clinica Santo Stefano

The Trial site has all structural and organizational requirements needed to the management of the Protocol ensuring the conduction of the trial in accordance with Good Clinical Practice and current legislation.

c) Please describe <u>accurately</u> the suitability of the equipment

After the evaluation of the Protocol procedures it is confirmed that the Site has the appropriate protocol required equipment to conduct the Study.
The Sponsor will provide the kits for samples to be sent to central Lab for evaluation.

d) Please provide a <u>detailed</u> description of all trial procedures which will take place at the site
After the review of all study procedures included in the Protocol, it is confirmed that all the Study procedures will be conducted at site in accordance to the study flowchart in the version approved by the relevant regulatory bodies.
e) Please provide a <u>detailed</u> description of Human Resources arrangements and expertise at the site
All personnel that will be involved in the trial under the supervision of the Principal Investigator is properly qualified to conduct Clinical Trial according to applicable regulations and undergoes initial and periodic training on study procedures. Properly qualified site personnel is available at the site and the following professional roles will be involved: 2 Nephrologists, 1 Nurse, 1 Pharmacist. It should be noted that the dedicated staff per function has been indicated basing on availability at the time of completing this form: it may change when the site will be activated. However the site guarantees the presence of required staff for proper conduction of the Trial.

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: Alessandro Sergi. Position: Director Staff Direzione Sanitaria – Azienda USL Toscana Centro ALESSANDRO SERGI Regione Toscana/01386030488 24.04.2024 11:47:27 GMT+00:00 On behalf of the site/organisation Date: _____ Please ensure that you have consulted with any national guidelines be ng 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.