Site Suitability Template

* For Belgium, this form is a mandatory document
* 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. The template has then been endorsed by the Belgian National Contact Point and the Clinical trial College Board to comply with Regulation (EU) No. 746/2017 on in vitro diagnostic medical devices, as well as Regulation (EU) No. 745/2017 on medical devices.

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| Section 1 |
| Title of clinical investigation or performance study |  |
| Name of site[[1]](#footnote-1), city | Cliniques universitaires Saint-Luc (CUSL), Brussels |
| If applicable, unique identification number of the site[[2]](#footnote-2) | Belgian hospital approval number : 403 |
| Name of principal investigator |  |
| Planned number of study participants at the site |  |

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| Section 2 |
| 1. *Please provide a comprehensive written statement on the suitability of the site adapted to the nature and use of the (in vitro diagnostic) medical device.*
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| Based on the nature and use of the (in vitro diagnostic) medical device, the human resources, equipment and facilities are of sufficient quality and adequacy to conduct the investigation undertaken at site.The device will be stored at the pharmacy/ the xx department/ the laboratory in good conditions with controlled storage facilities and a secure area, in accordance with protocol requirements.The pharmacy/ the xx department/ the laboratory of the Cliniques universitaires Saint-Luc is well-equipped and has all necessary material to conduct the name of the study study as per protocol requirements. The pharmacy department has a dedicated pharmacist for materiovigilance. Human resources is adequate and available to conduct the study.  |
| 1. *Please describe in detail the suitability of the facilities*
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| Cliniques universitaires Saint-Luc have all equipment, facilities and human resources to conduct the name of the study study as per protocol requirements. Site has :* name of departments/units involved in the study, radiology department, pathology department, pharmacy department, …
* inpatient units, consultation rooms, and day hospitalization
* storage areas for study materials (investigator binders, laboratory KITs, facilities for laboratory sample preparation) and offices dedicated to clinical research staff with computer, telephone, fax, printer and internet access
* adequate storage areas for the study drug, with secure, limited access and temperature control.
* room for CRAs to carry out monitoring visits, with access to an internet connection

Site is adequate and well equipped to perform all procedures required by the protocol.  |
| 1. *Please describe accurately the suitability of the equipment*
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| The equipment required at the center is calibrated, checked, maintained and documented:- a weigh scale ; - a height gauge ; - an automated blood pressure and pulse measurement device; - thermometers; - 12-electrode ECG; - cardiac ultrasound; - other ultrasound;- magnetic resonance imaging;- CT scanner;- PET scanner;- Muga scan;- Scintigraphy;- ophthalmology equipment for examination : list of equipment or examination- pneumology equipment for examination : list of equipment or examination- a local laboratory; - emergency equipment; - surgery rooms;- a temperature-controlled refrigerator at 4°C; - a temperature-controlled freezer at -20°C ± 5°C; - a temperature-controlled freezer at -80°C; - a temperature-controlled centrifuge;- a room temperature centrifuge. |
| 1. *Please provide a detailed description of all trial procedures which will take place at the site.*
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| All study procedures can be performed at site: * Collect of ICF
* Follow-up of the patients by the investigator (PI and sub) and study coordinator
* Procedures regarding the use of the device
* All procedures detailed in protocol : list of procedures according to the protocol (cfr flowchart).
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| 1. *Please provide a detailed description of Human Resources arrangements and expertise at the site*
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| The PI has sufficient human resources (including back-ups) in order to conduct the investigation effectively:* PI: name of the PI
* Sub-investigators: Number
* Study-coordinators/study-nurses and Back-up: Number

The work of study coordinators is taken over by nurses and scientists to cover all the aspects of the study.* Pharmacists for clinical research: 4
* Pharmacist for materiovigilance : 1

All our study staff is qualified to conduct the study, and have the appropriate training and experience to carry out the tasks assigned to them within the framework of the study. All the staff involved in clinical research is GCP (Transcelerate) certified since less than 3 years. People involved in samples management and shipping are IATA certified (less than 2 years)The site and the principal investigator have a good potential for eligible patients and have extensive experience in clinical investigations.The principal investigator, name, MD, PhD has more than xx years experience inspeciality clinical investigations and with the use of the type of the device. The CUSL has a university emergency and ICU department being able to follow the safety issues.The radiology department also has radiologists trained in interventional radiology.The laboratory is accredited by BELAC and Sciensano. The internal biobank is accredited by the FAHMP.All the hospital department including radiology, laboratory, pharmacy are working on a 24/24 hours -7/7 days basis.One-day clinic and hospitalization units are available with experienced staff in clinical research.The CUSL Clinical Trial Center is managing centrally the submissions preparation, the contracts, the initial and continuous training of the study coordinators, the quality management system for clinical researchThe Cliniques universitaires Saint Luc are AAHRPP accredited since 2015 (renewed in 2023 for 5 more years).The EMR (EPIC) used as source data is built to track and follow research patients, to allow specific accesses and to protect data. |

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| Section 3 |
| In authorising this document, I confirm that the site has the facilities and equipment to be able to conduct the study and has suitable arrangements in place to ensure that all investigators and other individuals involved in conducting the study have the suitable qualifications, expertise and training in relation to their role in the study, in compliance with EU Regulation 745/2017 and/or with EU Regulation 746/2017, and all conditions identified, which might influence the impartiality of any investigators, were addressed.Issued by:Name: Jean-Pascal MachielsPosition: Medical directorOn behalf of the site/organisation[[3]](#footnote-3) Cliniques universitaires Saint-Luc (CUSL)Date[[4]](#footnote-4): Signature: Please ensure that you have consulted with any national guidelines before submitting this form |

*PI signature for acknowledgement (CuSL requirement)*

*Name :*

*Date :*

*Signature :*

1. For BE: If it does not concern a healthcare institution, mention the name of the Private organisation. [↑](#footnote-ref-1)
2. For BE: Mention the “Erkenningsnummer van het ziekenhuis” / “Numéro d'agrément de l’hôpital” as given in the list of the [FPS Public Health (belgium.be)](https://www.health.belgium.be/en/node/25589) and which are registered in CTIS. If the CEO of different hospital sites is the same, the sites can be listed in one statement. [↑](#footnote-ref-2)
3. For BE: The person signing the document is authorised to sign on behalf of the site/organisation. [↑](#footnote-ref-3)
4. The CTR does not require signing individual documents in the clinical trial application – a request for signature could however be subject to national legislation. For Belgium, this document must be signed in the clinical trial application. [↑](#footnote-ref-4)