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 |  |
| If applicable, unique identification number of the site[[2]](#footnote-2) |  |
| 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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| Click or tap here to enter text.  |
| 1. Please describe in detail the suitability of the facilities
 |
| Click or tap here to enter text. |
| 1. Please describe accurately the suitability of the equipment
 |
| Click or tap here to enter text. |
| 1. Please provide a detailed description of all study procedures which will take place at the site.
 |
| Click or tap here to enter text. |
| 1. Please provide a detailed description of Human Resources arrangements and expertise at the site
 |
| Click or tap here to enter text. |
| 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: Click here to enter text.Position: Click here to enter text.On behalf of the site/organisation[[3]](#footnote-3)Date[[4]](#footnote-4): Click here to enter a date.Signature: Please ensure that you have consulted with any national guidelines before submitting this form. |

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) . 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 IVDR 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 performance study application. [↑](#footnote-ref-4)