*EU regulation 536/2014 Annex I N. 67 - A duly justified written statement on the suitability of the clinical trial sites adapted to the nature and use of the investigational medicinal product and including a description of the suitability of facilities, equipment, human resources and description of expertise, issued by the head of the clinic/institution at the clinical trial site or by some other responsible person, according to the system in the Member State concerned, shall be submitted.*

***Statement of CEO/person acting on behalf of CEO or responsible person authorized to represent the clinical trial site***

**Concerning**

**Name of Institution[[1]](#footnote-1):**

**Recognition number of the Institution[[2]](#footnote-2) (if applicable):**

**List of site locations (name and address[[3]](#footnote-3)) where participants will be treated:**

**PI:**

**CTC name and internal number (if applicable):**

**Sponsor:**

**Title:**

**EU CT number:**

**I hereby confirm that the clinical trial (see details above) may be carried out at our Institution taking into account internal procedures of the Institution and the confirmation of the following elements:**

A copy of the feasibility report[[4]](#footnote-4) by the sponsor comprising study specific requirements is attached to this document.

* This Institution has all the facilities and equipment to conduct the clinical trial.
* This Institution has suitable human resources and warrants 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.
* The Institution will participate in the negotiation of an agreement (or legal contract) that describes the mutual legally enforceable obligations between the Sponsor(s), the CRO or its/their representatives and the Principal Investigator (when applicable) with regard to financial provisions and other contractual and legally required elements that matter between legal entities. The Institution will make the necessary arrangements to make sure that the interventions that are not considered standard of care and are paid by the clinical trial budget, are not charged to the participant or the health insurance.

**Declaration of the Principal Investigator (PI):**

* As PI I declare I have read the protocol and all related documentation as part of the application dossier, I have no ethical or scientific objections and I, together with my study staff, can perform the study in accordance with the protocol. All necessary precautions are taken at the study site to protect the safety of the study participants. I confirm that I reasonably expect to be able to include the estimated number of participants based on a review of my patient charts and experience and considering the methodological and ethical aspects of the trial.
* I confirm study participants will be correctly informed about the standard of care (and what will be charged to the participant and their health insurance) and what interventions/examinations are extra for the trial (always paid by the clinical trial budget).
* I confirm that any actual or potential conflicts of interest which might influence the impartiality of any investigator will be properly addressed.
* I confirm that all study staff members, including those that are self-employed or directly employed by myself, will have the suitable qualifications, expertise and training in relation to their role in the clinical trial, in compliance with EU Regulation 536/2014.

Signature of PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name PI:

Date Signature PI**:** (dd/mm/yyyy)

**Signature CEO/person acting on behalf of CEO of the Institution/responsible person authorized to represent the clinical trial site** : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Print Name CEO**:

**Date Signature CEO:** (dd/mm/yyyy)

1. When it concerns a healthcare institution, use the name of the organisation - not the name of the site (in Dutch: campus; in French: site) - as given in the list of the Federal Public Service ( <https://www.health.belgium.be/nl/gezondheid/organisatie-van-de-gezondheidszorg/delen-van-gezondheidsgegevens/gezondheidszorginstellingen> ). If it doesn’t concern a healthcare institution, mention the name of the Private organisation. [↑](#footnote-ref-1)
2. If applicable: Mention the “Erkenningsnummer van het ziekenhuis” / “Numéro d'agrément de l’hôpital”. [↑](#footnote-ref-2)
3. When it concerns a healthcare institution, mention the name(s) and addresse(s)of the site(s) (in Dutch: campus; in French: site) - as given in the list of the Federal Public Service ( <https://www.health.belgium.be/nl/gezondheid/organisatie-van-de-gezondheidszorg/delen-van-gezondheidsgegevens/gezondheidszorginstellingen> ) - and ensure this list corresponds to the list of site locations in CTIS. [↑](#footnote-ref-3)
4. If a feasibility report is not available, a description of the study-specific requirements regarding facilities, equipment and availability of staff should be attached to this document. This document should also contain the planned number of patients to be recruited and the envisioned timelines and is to be prepared by the sponsor. [↑](#footnote-ref-4)