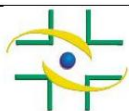


BRAZIL CLINICAL TRIAL START DATE FORM – Version 3



National Health Surveillance Agency
Brazil Clinical Trial Start Date Form – Version 3

1- Clinical Trial Start Date in Brazil*: ____/____/____

Date of first center initiation visit:

Date of signing of the first TCLE:

Date of first screening:

Date of first randomization:

2. Information about the 1st center and researcher

Name of the research center where the first clinical trial participant in Brazil was enrolled	Name of the principal investigator of this center

3. Research centers that have already included clinical trial participants in Brazil:

Name of the Center	Researcher	Number of Participants Clinical Trial included

4. Countries where the clinical trial has already started:

Country	Number of Participants Clinical Trial included	**Clinical trial start date in the country

5. Has the study ever been interrupted (in any country) due to security issues?

☐ Yes ☐ No

5.1 If so, describe the reasons for the interruption.

6. Is proof of registration of the clinical trial, in the same version of the clinical protocol submitted to Anvisa, in the registration database of the International Clinical Trials Registration Platform/World Health Organization (ICTRP/WHO) or others recognized by the International Committee of Medical Journals Editors (ICMJE) and the World Health Organization (WHO) being sent in this petition?

☐ Try

☐ No (it was sent in the DEEC petition previously)

6.1 Provide the registration number(s) in the electronic clinical trials registration database :_____.

- This form must be sent to Anvisa within **30 business days** after the start date of the Clinical Trial in Brazil.
- We assume full civil and criminal responsibility for the information provided here.

Legal Representative (Signature and Stamp)

* Clinical Trial Start Date in Brazil:

the first act of recruitment in Brazil of a potential participant for a specific clinical trial, unless otherwise defined in the protocol. The first act of recruitment refers to the date of signing of the TCLE of the first potential participant recruited in Brazil, unless otherwise defined in the protocol.

** Clinical Trial Start Date in the country: the first act of recruitment of a potential participant for a specific clinical trial, unless otherwise defined in the protocol. The first act of recruitment refers to the date of signing of the ICF of the first potential participant recruited in the country, unless otherwise defined in the protocol.