BRAZIL CLINICAL TRIAL END DATE FORM –

Version 3

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

1- Clinical Trial End Date in Brazil*:____/_____/____

2. Information about the center of the last participant and investigator

Name of the research center where the last participant's last visit occurred clinical trial in Brazil or other definition of the sponsor, expressly determined in the specific protocol of the clinical trial:	Name of the principal investigator of this center

3. Research centers that completed clinical trials in Brazil:

Name of the Center	Researcher Number of	Trial Participants Clinical no Brazil	Number of Trial Participants Clinicians who completed the study	Total number of Trial Participants Clinical removed from the study	Number of Trial Participants Clinical withdrawn for safety reasons

4. In the case of multinational studies, has the study already been completed in the other countries participating in the clinical trial? ÿ Yes ÿ No

5. Countries where the clinical trial has not yet been completed (if applicable):

6. The clinical trial was completed ahead of schedule: ÿ Yes ÿ No
If so:
6.1 Justify:

_____
_____
_____

6.2 Present an assessment of the impact of completing the clinical trial ahead of schedule in relation to the outcome assessment and the overall benefit-risk assessment of the trial.
experimental drug:

_____

_____

_____

_____

6.3 In the event of termination earlier than expected, for safety reasons, inform how the clinical trial participants will be monitored:

_____

_____

_____

_____

- The form must be sent to Anvisa within **30 business days** of the Clinical Trial End Date in Brazil.

- We assume full civil and criminal responsibility for the information provided here.

_____

Legal Representative (Signature and Stamp)

* Clinical Trial End Date in Brazil: corresponds to the date of the last visit of the last clinical trial participant in Brazil or another definition by the sponsor, expressly determined in the specific clinical trial protocol.