PETITION FORM FOR SUBSTANTIAL AMENDMENT TO PROTOCOL CLINICAL TRIAL

National Health Surveillance Agency
Clinical Research
Substantial Amendment to Test Protocol Petition Form
Clinical

Document Identification
(For use by the receiving agency)

1	Trial Specific Dossier Process Number Clinical	2	Office Hours

Company Data

3	Applicant	4	Authorization/Registration Number
5	Manufacturer	6	Authorization/Registration Number

Clinical Protocol Data

7	Petition Subject (codes and description)	8	Generating Fact (datavisa)
9	Clinical Trial Protocol Title and Code	10	Protocol No. (Version and date)
		11	Test Phase I ( ) II ( ) III ( ) IV ( )

12	**Reasons for Substantial Amendment:**	
	a) Change in the primary objective of the clinical protocol?	a) ( ) Yes ( ) No
	b) Change in primary outcomes?	b) ( ) Yes ( ) No
	c) Use of a new parameter to measure the primary outcome?	c) ( ) Yes ( ) No
	d) Removal of the Independent Data Monitoring Committee initially planned for the study?	d) ( ) Yes ( ) No
	e) Change in the sample size calculation not foreseen for the study?	e) ( ) Yes ( ) No
	f) Reduction in sample size due to interim analysis planned in study?	f) ( ) Yes ( ) No
	g) Change of statistical analysis for primary outcomes?	g) ( ) Yes ( ) No
	h) Changes related to dosage, which are not provided for in the protocol?	h) ( ) Yes ( ) No
	i) Extension or continuation of the clinical research with removal of the control arm or active arm, crossing between arms (cross-over), changing the blinding of the study or including new participants?	i) ( ) Yes ( ) No
	j) Major modifications related to adaptive studies, such as modification/exclusion/ addition of treatment arms, alteration of outcomes, modification of dose and/ or duration of treatment or adaptation of randomization schemes?	j) ( ) Yes ( ) No
	k) Inclusion of a new route of administration?	k) ( ) Yes ( ) No
	l) Expansion of use?	l) ( ) Yes ( ) No
	m) Others, at the sponsor's discretion (including justifications).	m) ( ) Yes ( ) No

13	**Provide the version and date of the last amendment approved by Anvisa**	Version: Data: Office Hours: