

PETITION FORM FOR SUBSTANTIAL AMENDMENT TO CLINICAL TRIAL PROTOCOL



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

Document Identification
(For use by the receiving agency)

1	Clinical Trial Specific Dossier Process Number	2	Office Hours
<i>Company Data</i>			
3	Applicant	4	Authorization / Registration Number
5	Manufacturer	6	Authorization / Registration Number
<i>Clinical Protocol Data</i>			
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 Amendment Substantial : a) Changing the primary objective of the clinical protocol? b) Change in primary outcomes? c) Use of a new parameter to measure the primary outcome? d) Removal of the Independent Data Monitoring Committee initially planned for the study? e) Change in sample size calculation not foreseen for the study? f) Sample size reduction due to interim analysis planned in the study? g) Shifting statistical analysis to primary outcomes? h) Changes related to dosage that are not provided for in the protocol? i) Extension or continuation of 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? 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? k) Inclusion of new route of administration? l) Expansion of use? m) Others, at the sponsor's discretion (including justifications).	a) () Yes () No b) () Yes () No c) () Yes () No d) () Yes () No e) () Yes () No f) () Yes () No g) () Yes () No h) () Yes () No i) () Yes () No j) () Yes () No k) () Yes () No l) () Yes () No m) () Yes () No	
13	Provide the version and date of the last amendment approved by Anvisa		Version: Date: Office Hours: