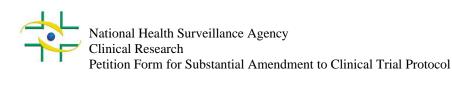
PETITION FORM FOR SUBSTANTIAL AMENDMENT TO CLINICAL TRIAL PROTOCOL



(For use by the receiving

Document Identification

				agency)	
1	Clinical Trial Specific Dossier Process Number	2	Office Hours		
Compa	ny Data				
3	Applicant 4 Authoriza		ion / Registration Number		
5	Manufacturer		Authorization / Registration Number		
Clinica	l Protocol Data				
7	Petition Subject (codes and description)	8	Generating Fact (datavisa)		
9	Clinical Trial Protocol Title and Code	10	Protocol No	Protocol No. (Version and date)	
		11	Test Phase I () II () III	E() IV()	
12	 a) Changing the primary objective of the clinical p b) Change in primary outcomes? c) Use of a new parameter to measure the primary d) Removal of the Independent Data Monitoring planned for the study? e) Change in sample size calculation not foreseen if f) Sample size reduction due to interim analysis pl g) Shifting statistical analysis to primary outcomes h) Changes related to dosage that are not provided i) Extension or continuation of clinical research control arm or active arm, crossing between changing the blinding of the study or including if j) Major modifications related to adaptive modification/exclusion/addition of treatment outcomes, modification schemes? k) Inclusion of new route of administration? l) Expansion of use? m) Others, at the sponsor's discretion (including justice) 	s for Amendment Substantial : a) (hanging the primary objective of the clinical protocol? b) (a) (b) a) Changing the primary outcomes? b) (c) (c) (c) b) Change in primary outcomes? (c) (c) (c) c) Use of a new parameter to measure the primary outcome? (c) (c) d) Removal of the Independent Data Monitoring Committee initially planned for the study? (c) (c) e) Change in sample size calculation not foreseen for the study? (c) (c) (c) Sample size reduction due to interim analysis planned in the study? (f) (c) (c) Shifting statistical analysis to primary outcomes? (f) (c) (d) 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? (i) (i) 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 new route of administration? (j) (j) Expansion of use? (j) (j) (n) Others, at the sponsor's discretion (i			
13	Provide the version and date of the last amendment approved by Anvisa			Version: Date: Office Hours:	