CLINICAL TRIAL SUBMISSION FORM (FAEC) – Version 4

National Health Surveillance Agency
Clinical Trial Submission Form (FAEC) – Version 4

Document Identification
(For use by the receiving agency)

1	Name / Company name	2	CNPJ
3	Municipality/City	4	UF
		5	Country
6	Sponsor's name/business name	7	Sponsor's CNPJ, if applicable
8	Municipality/City of Sponsor	9	Requestor's email
		10	Sponsor Country
11	Name of the active pharmaceutical ingredient/active substance of the experimental medicine and/or product codes under development	12	Brand/Complement, if applicable
13	Presentation of the medicine (concentration/pharmaceutical form/primary and secondary packaging/quantity or volume per packaging)	14	Route of Administration
15	Storage conditions	16	Expiration date

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Does this petition correspond to a specific dossier to be submitted after approval/authorization by the DDCM?
ÿNão
ÿSim

ÿIf so, inform the file number of the most recent petition* referring to the Development Plan that contains information about this clinical trial

* For example, the initial submission of the DDCM itself, Compliance with requirements with updating the plan, Inclusion of a Clinical Trial Protocol not foreseen in the Initial Development Plan, Safety Update Report for the Development of the Experimental Medicine

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Does this form refer to any changes to previously sent information?
ÿNão
ÿSim

ÿIf so, the change refers to
ÿChange in Medicines and Products to be imported to conduct the clinical trial
ÿInclusion of Clinical Trial Centers
ÿExclusion of Clinical Trial Centers
ÿChange of Principal Investigator
ÿAlteração de ORPC
ÿOutras
ÿQuais?

Information Related to the Investigational Drug

19	**Is the investigational drug(s) identical to the authorized DDCM or already approved substantial modification?** ÿ Not applicable ÿYes. File number(s):_____ ÿNão ÿIf not, is there any substantial quality change regarding the experimental medicine to be used in this protocol, which has not yet been completed by Copec? ÿYes – File number: ÿNo – Justification for using the experimental medicine other than what was previously approved _____ by Copec:_____
20	Therapeutic Class (ATC Code) / category

21	Medicine approved in Brazil ÿNão ÿSim ÿIn positive case, registration number	22	Medicine approved in the world ÿNão ÿSim ÿCountries where the medicine is approved
23	Name of the active pharmaceutical ingredient or active substance	24	Brand/Complement, if applicable
25	Pharmaceutical form	26	Route of Administration
27	Presentation of the medicine (concentration/pharmaceutical form/primary and secondary packaging/quantity or volume per packaging)		
28	Storage conditions	29	Expiration date

30	Form No 31	Pharmaceutical form 32	Compose before the formula 33	Code DCB/DCI/CAS RN 34	Tip O 35	Concentra dog Quantity e/ Volume 36	Demonstration Unit Formula

Information Related to the Comparator Drug (Active or Placebo)

37	Therapeutic Class (ATC Code) / category		
38	Medicine approved in Brazil ÿNão ÿSim ÿIn positive case, registration number:	39	Medicine approved in the world ÿNão ÿSim
40	Name of the active pharmaceutical ingredient or active substance	41	Brand/Complement, if applicable
42	Pharmaceutical form	43	Route of Administration
44	Storage conditions	45	Expiration date
46	Presentation of the medicine (concentration/pharmaceutical form/primary and secondary packaging/quantity or volume per packaging)		

47	Form No	48	Pharmaceutical form	49	Formula components	50	Code DCB/DCI /CAS RN	51	Tip O	52	Concentration Quantity/Volume	53	Unity of Demonstration of Formula

Clinical Trial Related Information

54	Clinical trial characteristics ÿRandomizado ÿAberto ÿSimple Blind ÿDouble Blind ÿParallel groups ÿCross groups ÿOutros:	55	Controlled Studies ÿPlacebo ÿActive comparator ÿOutros:
56	All ICD-10 under investigation		
57	Countries where the proposed clinical trial is planned to be conducted		
58	Has the clinical trial already started in any country? ÿNo ÿYes ÿIf so, in which country(ies):		

59	Record number(s) in electronic clinical trial registration database		
60	Population under study ÿUnder 12 years old ÿOver 65 years old ÿÍndios ÿWomen of childbearing age (exclusively) ÿPatients with special needs ÿNot applicable		
61	The study is: ÿStrictly National ÿForeign Cooperation		
62	Is there exclusive use of placebo in the study? ÿNo ÿSim		
63	Clinical indication to be researched		
64	Treatment or therapy already available in Brazil for the indication being researched		
65	Was there a prior meeting with Anvisa about this DEEC? ÿNo ÿYes. Dates:_____ (Attach the meeting minutes to the process)		
66	Title of the Clinical Protocol	67	Clinical Protocol number/code
68	Clinical Protocol Phase ÿI ÿII ÿIII ÿIV ÿOutra:	69	Version and Date of the Clinical Protocol

70. Medicines and Products to be imported to conduct the clinical trial				
Products with their respective presentations	**Route of administration**	**Conditions of storage**	**Expiration date**	**Controlled**
				ÿSIM ÿNÃO
				ÿSIM ÿNÃO
				ÿSIM ÿNÃO
				ÿSIM ÿNÃO

71. Information about all Clinical Trial Centers					
Test Center Number Clinical	**Center Clinical trial**	**Unit Federative**	**CNES**	**Email from the institution's management**	**Number of Participants at the center**
1					
2					
3					
4					

72. Information about all respective principal investigators					
Number of Center Rehearsal Clinical	**Investigator**	**CPF**	**Email from Investigator**	**Training Academic**	**On the Birth**
1					
2					
3					
4					

* The information regarding researchers requested above must be filled in according to the corresponding number of the clinical trial center informed in the previous table, since the investigator is responsible for conducting the clinical trial at the center.

73. Information about Clinical Research Representative Organizations (CRORs) participating in the clinical trial contracted for Brazil	
ORPC name	**Activities delegated in the clinical trial**

Statement of responsibility

We assume civilly and criminally full responsibility for the information provided here (including the Description of the Formula Components and the Presentations described in this form, as well as the quality of the product(s) to be used in the clinical trial presented here).

Legal Representative
(Signature and Stamp)

Pharmacist responsible
(Signature and Stamp)