CLINICAL TRIAL SUBMISSION FORM (CTR) – Version 5

National Health Surveillance Agency
Clinical Trial Submission Form (CTF) – Version 5

Document Identification

(For use by the receiving agency)

1	Applicant's Name/Company Name	2	CNPJ
3	Municipality / City	4	UF
		5	Country
6	Name / Company name of the Sponsor	7	Sponsor's CNPJ, if applicable
8	Sponsor Municipality/City	9	Sponsor's State
		10	Sponsor Country

11

Does this form refer to any changes to previously submitted information?
☐No
☐Yes

↳ If so, does the change refer to

☐Change in Medicines and Products to be imported for conducting the clinical trial
☐Inclusion of Clinical Trial Centers
☐Exclusion of Clinical Trial Centers
☐Change of Principal Investigator
☐Change of ORPC or delegated activities
☐Others
↳ Which ones?

Information Related to the Investigational Drug			
12	Name of the active pharmaceutical ingredient or active substance	13	Business name, if applicable
14	Pharmaceutical form	15	Route of Administration
16	Storage conditions	17	Expiration date
18	Presentation of the medicine (concentration/pharmaceutical form/primary and secondary packaging/quantity or volume per packaging)		
19	**Is the investigational medicinal product(s) identical to the authorized DDCM or the already approved substantial modification?** ☐Not applicable ☐Yes. Case Number(s):_____ ☐No ↳If not, are there any modifications to the product under investigation, relating to the experimental drug to be used in this protocol, that have not yet been completed by Copec ? ☐Yes – Case number: _____ ☐No – Justification for using the experimental drug other than that previously approved by Copec:_____		
20	Drug approved in Brazil ☐No ☐Yes ↳If so, registration number	21	Medicine approved in the world ☐No ☐Yes ↳Countries where the drug is approved

Information Related to the Comparator Drug (Active or Placebo)			
22	Name of the active pharmaceutical ingredient or active substance	23	Business name, if applicable
24	Pharmaceutical form	25	Route of Administration
26	Storage conditions	27	Expiration date
28	Presentation of the medicine (concentration/pharmaceutical form/primary and secondary packaging/quantity or volume per packaging)		
29	Therapeutic Class (ATC Code) / Category		
30	Drug approved in Brazil ☐No ☐Yes ↳ If yes, registration number:	31	Medicine approved in the world ☐No ☐Yes

Clinical Trial Related Information			
32	Clinical Protocol Title	33	Clinical Protocol Number/Code

<table>
<tr><td>34</td><td>Clinical Protocol Phase
☐I ☐II ☐III ☐IV
☐Other:</td><td>35</td><td>Clinical Protocol Version and Date</td></tr>
<tr><td>36</td><td colspan="3">Controlled Studies
☐Placebo
If yes, is there exclusive use of placebo in the study? ☐No ☐Yes

☐Active comparator
☐Others:</td></tr>
<tr><td>37</td><td colspan="3">Conditions to be studied

<table><tr><th>All ICD-10s under investigation</th><th>Clinical Indication to be researched</th><th>Treatment or therapy now available in Brazil</th></tr><tr><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>38</td><td colspan="3">The study is:
☐Strictly National

☐Foreign Cooperation

Countries where the proposed clinical trial is planned to be conducted</td></tr>
<tr><td>39</td><td colspan="3">Has the clinical trial already started in any country?
☐No
☐Yes
↳ If so, in which country(ies):</td></tr>
<tr><td>40</td><td colspan="3">electronic clinical trials registry database</td></tr>
<tr><td>41</td><td colspan="3">Study population

☐Children under 12 years of age. Please indicate the age range:
☐Teenagers
☐Adults
☐Over 65 years old
☐Pregnant women
☐Lactating women</td></tr>
</table>

42	Type of clinical trial risk category (according to Article 3 of IN 338/2024): ☐ **Low risk** Subcategory: ☐a. Medicine used as registered in Brazil or by AREE, without substantial modifications. ☐b. New therapeutic indication and/or target population and/or dosage regimen, supported by robust evidence from scientific literature based on meta-analyses, systematic reviews of scientific articles published in indexed journals containing information on the safety and efficacy of the drug or API. ☐c. Fixed-dose combinations (FDA) with registered active pharmaceutical ingredients (APIs) already used concomitantly in medical practice, for the same claimed indication, target population and dosage regimen (without clinically significant pharmacokinetic and/or pharmacodynamic interaction). ☐ **Moderate risk** Subcategory: ☐a. New therapeutic indication and/or target population and/or dosage regimen. ☐b. New Pharmaceutical Form and/or concentration. ☐c. New route of administration. ☐d. Biosimilar Products ☐e. Drug registered in Brazil or by AREE, modified for use in clinical trials. ☐f. Fixed-dose combinations (FDA) with registered APIs already used concomitantly in medical practice, for the same claimed indication, target population and dosage regimen (with clinically significant pharmacokinetic and/or pharmacodynamic interaction). ☐ **High risk** Subcategory: ☐a. New medicines; ☐b. Fixed dose combinations (FDC) with one or more unregistered APIs ☐c. Association of registered APIs considering new therapeutic indication
43	Is it a complex clinical trial (as per item VIII of Article 3 of IN 338/2024)? ☐No ☐Yes. Select the type of clinical trial: ☐a. Trials that study multiple therapies or multiple indications in a single clinical trial, called master protocols (in English, Basket trials , Umbrella trials , Platform trials); ☐b. New adaptive trial designs that allow planned changes to the study protocol to occur at pre -specified times during the life cycle of a trial; ☐c. Phase 1 clinical trials, in which the experimental drug is being used for the first time in humans (First In Human - FIH); ☐d. Phase 1, 2 and 3 clinical trials integrated into a single protocol; ☐e. Clinical trials containing interim analyses; ☐f. Pragmatic clinical trials or those containing real-world data (RWD); ☐g. Clinical trials involving vulnerable populations such as pediatric, pregnant and lactating women.

44. Medicines and Products to be imported for conducting the clinical trial				
Products with their respective presentations	**Route of administration**	**Conditions Storage**	**Expiration Date**	**Controlled**
				☐YES ☐NO
				☐YES ☐NO
				☐YES ☐NO

				☐YES ☐NO

45. Information on all Clinical Trial Centers					
Clinical Trial Center Number	**Clinical Trial Center**	**City and Federative Unit**	**CNES**	**Institution management email**	**Number of Participants in the center**
1					
2					
3					
4					

46. Information on all respective principal investigators				
Clinical Trial Center Number	**Researcher**	**CPF**	**Investigator's Email**	**Date of birth**
1				
2				
3				
4				

* The information regarding the investigators requested above must be completed in accordance with the corresponding number of the clinical trial center provided in the previous table, since the investigator is responsible for conducting the clinical trial at the center.

47. Information on the Clinical Research Representative Organizations (CRROs) participating in the clinical trial contracted for Brazil	
Name of ORPC	**Delegated activities in the clinical trial**

Disclaimer

We assume full civil and criminal responsibility for the information provided here (including the quality of the product(s) to be used in the clinical trial presented herein).

_____ _____

Legal Representative Responsible Pharmacist
(Signature and Stamp) (Signature and Stamp)