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RESOLUTION OF THE COLLEGIATE BOARD - RDC NO. 601, OF FEBRUARY 9, 2022

Provides for the simplified analysis, on an exceptional and transient basis, of petitions for Consent in the Clinical Research Process, DDCM Modifications, Substantial Amendment to the Clinical Protocol and Consent in the Clinical Drug Development Dossier (DDCM) Process referring to the Experimental Drug Dossier due to the public health emergency of national importance resulting from the new coronavirus (SARS-CoV-2) outbreak.

The Collegiate Board of the National Health Surveillance Agency, in use of the powers conferred on it by art. 15, III and IV, allied to art. 7, III and IV of Law No. 9,782, of January 26th, 1999, and to art. 187, VI, § 1 of the Internal Regulations approved by the Collegiate Board Resolution - RDC No. 585, of December 10th, 2021, resolves to adopt the following Resolution, as resolved at a meeting held on February 9th, 2022, and I, Chief Executive Officer, determine its publication.

Art. 1 This Resolution provides for the simplified analysis, on an exceptional and temporary basis, within the Coordination of Clinical Research in Drugs and Biological Products (COPEC) scope, of the following petitions:

I- Consent in the Clinical Research Process;

II - DDCM Modification - Inclusion of Clinical Trial Protocol not provided for in the initial development plan, except for prophylactic vaccines;

III - DDCM Modification - Alteration that potentially impacts the quality or safety of the investigational product;

IV - Substantial Amendment to the Clinical Protocol; and

V - Consent in the Clinical Drug Development Dossier (DDCM) Process, referring to the Experimental Drug Dossier.

Art. 2 The documents required in art. 38, items VII and VIII; in art. 43, items I and III; and in art. 46, of the Collegiate Board Resolution - RDC No. 9, of February 20, 2015, linked to the petitions listed in art. 1 of this Resolution may be analyzed in a simplified way, provided that they have been approved:

I- by regulatory authority of at least one founding member country (Founding Regulatory Members) or a permanent member country (Standing Regulatory Members) of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH); or

II- by the UK regulatory authority (Medicines and Healthcare products Regulatory Agency - MHRA).

§1 The clinical protocol or substantial amendment linked to the petitions listed in items I, II and IV of art. 1 of this Resolution must be identical to those approved by the regulatory authorities mentioned in the caput items of this article.

§2 The investigational product/experimental drug referred to in the petitions listed in items III and V of art. 1 of this Resolution must be identical to those approved by the regulatory authorities mentioned in the caput items of this article.

§3 The manufacturing process of the investigational product/experimental drug referred to in the petitions listed in items III and V of art. 1 of this Resolution must comply with the guidelines and principles described in the current ICH guides, as applicable, according to the clinical development phase.

§4 The petitions listed in item V of art. 1 of this Resolution may be analyzed in a simplified way in cases of DDCMs of experimental drugs registered by the regulatory authorities mentioned in the caput items of this article.

Art. 3 To prove the conditions established in art. 2 of this Resolution, an official document issued by the corresponding regulatory authority and a declaration of compliance with the criteria described in said provision must be presented, as per Annex I.

Sole paragraph. In the absence of the official document, justification must be presented demonstrating that the petition was approved, or authorized, considering the non-objection mechanism used by some regulatory authorities.

Art. 4 They must be submitted to ANVISA, for each petition listed in art. 1 of this Resolution, all documents required in the Collegiate Board Resolution - RDC No. 9, of February 20th, 2015

Sole paragraph. For the simplified analysis purposes dealt with in this Resolution, the following documents will be considered:

I - in the petitions listed in items I, II, and IV of art. 1 of this Resolution: Clinical Trial Submission Form (FAEC).

II - in the petitions described in items III and V of art. 1 of this Resolution:

a) results of stability studies under accelerated and long-term conditions that support the proposed shelf-life for the investigational drug and, when applicable, for the placebo and modified comparator, when the storage recommendation is at room temperature (between 15 and 30°C);

b) experimental drug label template for DDCM petitions; and

c) placebo quality dossier, when the petition to be analyzed falls within the provisions of §4 of art. 2 of this Resolution.

Art. 5 The documents described in caput of art. 4 of this Resolution must be submitted before the petition technical analysis start to be classified in the criteria of this Resolution, through a secondary petition with a specific subject code established by Anvisa.

§ 1 If the criteria of this Resolution are met, the secondary petition status will be updated to "Agreed" and the simplified analysis will be carried out.

§ 2 In the event of non-compliance with this Resolution criteria, the secondary petition status will be updated to "Not Agreed" and a full analysis of all documents linked to the petition will be carried out.

§3 In the event of §2 of this article, a letter will be sent to the company with the respective justification.

Art. 6 At any time, upon justification, all documents required by the Collegiate Board Resolution - RDC No. 9, of February 20th, 2015 may be fully analyzed by the technical area decision, regardless of whether they were included in this Resolution.

Art. 7 Without prejudice to the criteria fulfillment for prioritizing the petitions analysis, provided for in specific rules, Anvisa will create specific queues for the allocation and petitions analysis that fall under the terms of this Resolution.

Art. 8 The provisions of this Resolution apply to petitions submitted before or during the term of this Resolution and which are awaiting the technical analysis start.

Art. 9 This Resolution validity will automatically cease after 120 (one hundred and twenty) days from the entry into force of the Ministry of Health act that recognizes that the Public Health emergency of National Importance declared by Ordinance No. 188/GM/MS on February 4th, 2020.

Art. 10 This Resolution takes effect on the date of its publication.

ANTONIO BARRA TORRES

Chief Executive Officer

ANNEX I

Declaration form on compliance with the criteria described in art. 2 of the Collegiate Board Resolution - RDC No. 601, of February 9th, 2022.

I. ( ) Substantial Amendment to the Clinical Protocol, File No. (enter the amendment file number).

II. ( ) DDCM Modification - Inclusion of Clinical Trial Protocol not provided for in the initial development plan.

III. (_____) Consent in the Clinical Research Process (DEECs provided for in the Development Plan previously approved by COPEC).

IV. (_) Analysis of the Clinical Drug Development Dossier (DDCM) petition or,

V. ( ) Substantial modification of the investigational drug quality, modified active comparator or placebo, File No. _____ [enter the modification file number].

According to the provisions of the Collegiate Board Resolution - RDC No. 601, of February 9th, 2022, I DECLARE that:

1. The clinical protocol or substantial amendment [enter protocol code, version and date] has been authorized in the following country(ies): [cite at least one country that meets the criteria described in art. 2]

2. The clinical protocol or substantial amendment [enter protocol code, version and date] submitted to Anvisa is identical to the one approved by the regulatory authorities of any of the countries that meet the criteria described in item I, art. 2.

3. The investigational drug _____ [enter the drug name/code] to be administered in the clinical trial(s) to be conducted in Brazil is identical to the one administered in the clinical trials listed in item 1.

4. The investigational drug to be administered in the clinical trial(s) to be conducted in Brazil is registered at: _____ [at least one country listed in art. 2].

5. Substantial quality modifications of the investigational drug, active comparator or placebo, are the same as those approved in the following country(ies): [at least one country listed in art. 2].

6. The investigational drug manufacturing process [enter the drug name/code] meets the guidelines and principles of the ICH guides, at the clinical development stage.

I assume civilly and criminally, full responsibility for the information provided here.

_____

Sponsor's Legal Representative