Investigational Drug Development Plan (PDME)

(according to paragraph III of Art. 28 of DRC No 945/2024)

1. API or active substance

Provide a brief description of the API or active substance. For example: name of the API, physical-chemical and biological characteristics.

2. Category of investigational drug

Inform whether the medicine is synthetic, biological, specific, dynamized, medicinal gas, phytotherapeutic or radiopharmaceutical

3. Therapeutic class

Inform the therapeutic class of the medicine

4. Presentation of the experimental drug

Pharmaceutical form	Concentration	Route of administration

Inform the pharmaceutical form, concentration, studied and intended administration routes.
If there is more than one type of presentation, add new lines.

5. Mechanism of action

Briefly state the mechanism of action and explain whether the mechanism is innovative.

6. Indications to be studied

Report the therapeutic indications of the experimental drug that have been studied and those that are intended to be evaluated in this clinical development.

7. Overall objectives and planned duration of clinical development

Report the overall objectives of clinical development and submit a technical justification for the clinical development of this medicine.
Provide the expected duration of development. For example: The estimated duration of clinical development is expected to be 2028.

In this section, you can also inform whether the medicine has already been forwarded to the Anvisa registration area and for which indications/ pharmaceutical forms/ populations.

In this section, you can also inform whether the experimental drug has already been submitted for registration in other countries and is awaiting a response from other agencies. In this case, inform for which indications/ pharmaceutical forms/ populations the registration was submitted.

8. Clinical trials

8.1. List of completed, ongoing and planned clinical trials

Protocol	Status	Start (month and year)	End (month and year)	Phase	Quantity of participants	Brazil's participation
ABC123	*Completed*	*01/2023*	*12/2023*	*1*	*75*	*No*
DEF456	*In progress*	*03/2024*	*05/2025*	*2*	*120*	*No*
GHI789	*In progress (Planned in Brazil)*	*12/2024*	*12/2026*	*3*	*680*	*Try*
JKL123	*Planned*	*01/2025*	*01/2027*	*3*	*870*	*Try*
MNO456	*Planned*	*03/2025*	*12/2025*	*2*	*200*	*Try*

Filling:

- ***Protocol:*** *enter the protocol code*
- ***Status:*** *inform whether the study has been completed, is in progress or is planned.*
  If the clinical trial is underway worldwide, but will still be submitted in Brazil, include the observation that it is planned in Brazil (as per the example of the GHI789 protocol)
- ***Start:*** *inform the date the study was started. If it is a planned study, set the start date for the clinical trial*
- ***End:*** *inform the date on which the study was completed. If it is a planned study, set the forecast for the end of the clinical trial*
- ***Phase:*** *inform whether it is phase 1, 2, 3, etc.*
- ***Number of participants:*** *Enter how many participants were/ will be included in the study*
- ***Participation of Brazil:*** *inform whether the study was/ is being/ will be conducted in Brazil*

8.2. Status of clinical development worldwide

8.2.1. Countries where clinical development was submitted

Country	Submitted clinical trial(s)
AAAAA	*ABC123* *DEF456* *GHI789*
BBBBB	*DEF456*
3000	*GHI789* *JKL123* *MNO456*
DDDDD	*ABC123* *JKL123* *MNO456*

Filling:

- ***Country:** inform the country where the clinical development was submitted*
- ***Submitted clinical trial:** inform the protocol code for the clinical trials that were submitted in the country.*

8.2.2. Regulatory and ethical approval status

Inform whether in any country clinical development has been approved with reservations, rejected, interrupted or cancelled by regulatory or ethical authorities.
Provide justifications or clarifications for each of these cases.

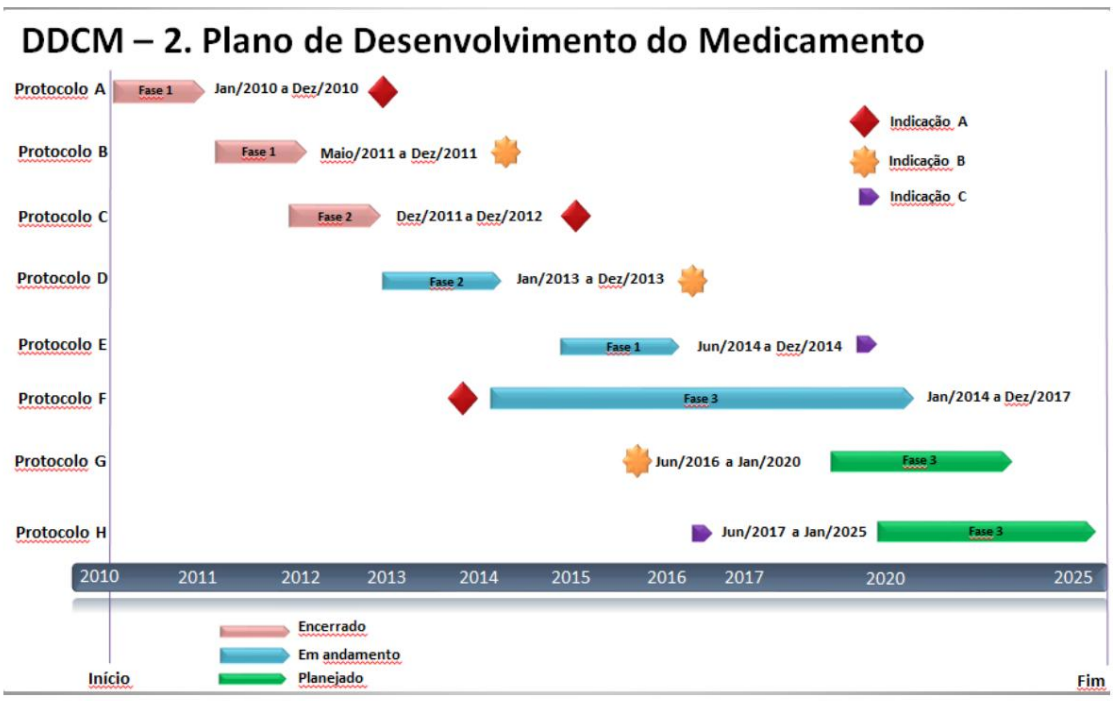
8.2.3 Scientific advisory opinions from any foreign regulatory authority, if any, on clinical development;

Indicate whether scientific advisory opinions have been received on clinical development in any country. If so, attach the opinion.

If the scientific advisory opinion is specific to a single clinical trial, include this information in the respective DEEC (as per item "d" of section VI of Art. 28 of RDC 945/2024).

9. Timeline with all clinical trials of the drug development.

Example:



GENERAL OBSERVATIONS:

ÿ The plan must preferably be written in Portuguese.

ÿ For each new plan update, change the document version, highlight the changes made and send a change control history.

ÿ The results of clinical trials should not be included in this document.

results should be presented in the Investigator's Brochure.

ÿ The development plan is the first technical document to be analyzed, as it provides an overview of the DDCM. Therefore, the more complete and clear the document is, the faster the analysis of the DDCM as a whole will be. Other documents can be referenced in this document, however, the brief description of each item facilitates the analysis, as it allows for a quick verification of the clinical development of the drug.

ÿ It is clarified that Anvisa understands that the Development Plan is a dynamic document, which may be changed throughout the clinical development. However, such information is still essential for the initial analysis of the DDCM and understanding the general idea of the development of the experimental drug.

CHANGE HISTORY

Version	Date	Main changes
1	2017	Original document
2	12/19/2024	Adjustments to meet the requirements of RDC 945/2024
3	12/23/2024	Inclusion of item 8.2.3 to meet the requirement of item “e” of paragraph III of Art. 28 of RDC 945/2024.
3	12/23/2024	Inclusion of change history