الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Research and Investigational Drugs (RAID) Designation

Version 1.0

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Saudi Food & Drug Authority

Drug Sector

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Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document Control

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Glossary

RAID	Research and Investigational drugs, including biologics, that are used in a clinical investigation and not yet authorized by SFDA The name "R**ā'i**d رائد" reflects the essence of pioneering, symbolizing innovation and development of investigational drugs, particularly those with clinical studies conducted within Saudi Arabia.
RAID designation Application	It is an application submitted to obtain the Saudi Food and Drug Authority (SFDA) designation for RAID to enable access to incentives when conducting research and developing (R&D) in Saudi Arabia, including running Clinical trials. RAID designation aims to expedite the development and review of investigational drugs.
Clinical Trials	Any interventional investigation in human participants intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s); and/or to identify any adverse reactions to an investigational product(s); and/or to study absorption, distribution, metabolism and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.
Sponsor	An individual, company, institution or organization that takes responsibility for the initiation, management and arrangement of the financing of a clinical trial. A clinical trial may have one or several sponsors.
Saudi Clinical Trials Registry (SCTR)	It is an electronic system with electronic database which includes an official record of all drugs clinical studies in Saudi Arabia to ensure that all received information are accurate and completed along with publishing the minimum amount of information about the clinical trials, which is globally agreed, so it can be viewed by public.
Biologics	Medicinal products derived from a variety of natural sources or produced by biotechnology methods and other cutting-edge technologies. They include a wide range of products such as vaccines, blood and blood components, allergenic, advanced therapy medicinal products (ATMPs), recombinant proteins and biosimilar.

Drug	An article intended for use in the diagnosis, cure mitigation, treatment, or prevention of disease and which is intended to affect the structure or function of the body.
Common Technical Document (CTD)	An international harmonized format for submissions for approval of pharmaceuticals. The CTD provides a standardization of the presentation of the content.
Phase I studies	early clinical studies, especially for the initial administration of an investigational product to humans. These studies may be conducted in healthy volunteer participants or in a selected population of patients who have the condition or the disease, depending on drug properties and the objectives of the development programme.
Phase II-III studies	clinical pharmacology and dose, exploratory and confirmatory studies are conducted to further evaluate both the safety and efficacy of the drug

1. INTRODUCTION

The Research and Investigational Drugs (RAID) designation is one of the Saudi Food and Drug Authority (SFDA) designation programs that promote conducting Research and Development (R&D) in Saudi Arabia. It aims to accelerate the development and regulatory review of drugs and biologics, expediting the availability of promising new therapies in Saudi Arabia.

The purpose of this guidance is to outline the procedures and requirements for submitting a RAID designation application and to encourage the development of innovative products for effective treatment in Saudi Arabia.

1.1. Importance of Research and Innovation in Saudi Arabia

Research and Development (R&D) in the pharmaceutical sector plays a pivotal role in advancing public health, driving innovation, and strengthening national drug security. In Saudi Arabia, R&D is essential in supporting the Kingdom's vision for a knowledge-based economy and self-sufficiency in high-value healthcare products. By fostering scientific discovery and accelerating the development of new therapies, pharmaceutical R&D enables the creation of tailored, effective treatments that address both local and global health priorities. It also supports the growth of the biotechnology ecosystem, attracts strategic investment, and positions the Kingdom as a regional hub for pharmaceutical innovation. The RAID program has been launched to promote the R&D ecosystem by providing regulatory frameworks that support innovation, facilitating clinical trials, and promoting collaboration between academic institutions, industry, and government bodies. Through RAID, the SFDA ensures that promising research can be efficiently translated into safe, effective, and accessible medical products

1.2. Scope

This guidance applies to applicants seeking SFDA designation for investigational products that are under development, have not yet been authorized for marketing by any other regulatory authority globally, and are intended for future submission as a Marketing Authorization Application (MAA) to the SFDA. Designation applications may be submitted during any clinical phase (Phase I, II, or III) of drug development.

1.3. Criteria for RAID designation

For an application to be eligible for RAID designation, it must meet all of the following criteria:

1. The product is under development and has not yet been authorized for marketing by any other regulatory authority globally.
2. The product should aim to address an unmet medical need or provide a meaningful therapeutic or scientific value compared with available treatment options, based on the scientific or clinical evidence available at the time of submission
3. A clinical trial for the investigational product must be intended and committed to be conducted in Saudi Arabia.

The RAID designation is voluntary; however, applicants must submit a well-justified request demonstrating that the application meets all eligibility criteria for RAID designation.

1.4.Related documents

This document should be read in conjunction with the following documents:

- SFDA Regulations and Requirements for Conducting Clinical Trials on Drugs.
- SFDA Procedures for Importation and Exportation of Pharmaceutical Products.
- SFDA Clearance Conditions and Requirements.
- Guideline for Good Clinical Practice.
- Guideline on strategies to identify and mitigate risks for first-in human and early clinical trials with investigational medicinal products.
- General Considerations for Preclinical Studies Submissions.
- Guidelines for Chemical and Pharmaceutical Quality Documentation of Small Molecules Investigational Product in Clinical Trials. (draft)
- Guideline on Submission of Chemistry, Manufacturing, and Control (CMC) Information for Cell-based Clinical Trial Applications.
- Guidance on Submission of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Clinical Trial Applications. (draft)
- International Council for Harmonization (ICH) relevant guidance documents.
- Contract Research Organization Guideline.

2. Incentives and Benefits of RAID Designation

The following incentives aim to strengthen collaboration between the SFDA and applicants, encourage the conduct of clinical studies within Saudi Arabia, facilitate the expedited introduction of innovative products to the Saudi market, and deliver tangible benefits to patients and society. Receiving the RAID designation entitles the product to various incentives and benefits to support its development and review:

- **SFDA dedicated contact point**: assigning a product manager who will coordinate the support offered throughout the RAID application.
- **Pre-designation meeting:** an introductory meeting held with a multidisciplinary group of experts from the SFDA, during which preliminary scientific and regulatory guidance is provided regarding RAID designation requirements.
- **Scientific guidance**: Scientific advice and regulatory support to help applicants align their development strategies with SFDA requirements. Furthermore, there are opportunities for frequent interactions, including meetings throughout product development, with the SFDA and relevant stakeholders for a designated product.
- **Pricing rules**: the SFDA will provide support in the pricing procedures of the investigational product. This will include approving meeting requests and providing consultations on pricing rules, conducting parallel reviews with the registration review, and initiating early discussions with applicants regarding pricing.
- **Guidance on regulatory pathways**: SFDA will further support the development through the potential for expediting assessment at the time of an application for marketing authorization (MAA), a drug that has been granted RAID designation is eligible for:
    - Priority Review of the MAA.
    - Rolling submission of MAA as SFDA may consider reviewing portions of a MAA before the sponsor submits the complete application.
    - Further support and incentives may be granted for RAID-designated products, such as the product may be eligible for conditional approval if supported by clinical data.

3. Pre-designation Meeting

The SFDA provides support to sponsors planning to submit a RAID designation application

through optional pre-designation meetings. The primary purpose of this meeting is to obtain the SFDA's preliminary assessment and feedback on a planned RAID designation application, especially when a sponsor's inquiries are not fully addressed by guidance documents and other publicly available resources. The pre-designation meeting will also effectively assist sponsors in preparing to submit complete RAID designation applications.

3.1.Meeting request

The SFDA encourages sponsors to request a pre-designation meeting. The request for a pre-designation meeting must be submitted using the request form available in Appendix 1. The form includes the following information and supporting documents:

- Description of the product (information on the product and its stage of development).
- A proposed agenda (a list of specific questions to be addressed, such as those relating to preclinical, clinical, quality, and manufacturing requirements), including estimated duration needed for the discussion of each agenda item.
- Relevant details of the proposed clinical trials to be conducted and supporting documentation, which should be sufficiently extensive to provide the necessary background information.
- A list of planned attendees from the sponsor's organization, including their names and titles, if applicable.
- Proposed meeting dates and times.

If the submitted documents are insufficient when a request is made, SFDA may request additional data or clarification of the submitted information.

3.2.Process for pre-designation meeting

1. **Submission**: Submit a request for a pre-designation meeting, accompanied by a complete meeting request form and supporting documentation via email (Designation.Drug@sfda.gov.sa). It is recommended to submit the request at least one month prior to the proposed meeting date to manage timeframes and resources.
2. **SFDA response to the Meeting Request**: Upon receiving the pre-designation meeting request, the SFDA validates and reviews the request, and then responds within 30 working days:

- **If the request meets all requirements,** it will proceed to the next step.
- **If any deficiencies are identified**, the SFDA will notify the applicant of the required corrections. The applicant must address the deficiencies and resubmit the application form through the assigned email within 60 working days.

3. **Meeting Scheduled**: the SFDA product manager will notify the applicant via email with details on meeting arrangements (a mutually acceptable time and date), the format of the meeting (in person face-to-face meeting or virtual meeting).
    - In general, meetings will be organized within 20 working days from the end of the previous step.
4. **During the meeting:**
    - The meeting will be chaired by SFDA staff, and its duration will be determined based on the meeting agenda.
    - Only the materials that have been included in the request form should be presented at the time of the meeting (if important new information becomes available, send an email with updates to the SFDA at least 5 working days before the meeting).
5. **After the meeting**
    - The applicant is requested to record the meeting minutes and send them as a Word document to the SFDA within 10 working days following the meeting for agreement.
    - The SFDA may comment on the recorded minutes if necessary, and the final version will be returned to the applicant within 10 working days. If no comments are raised, the SFDA will acknowledge the meeting record within 10 working days of receiving the meeting minutes.

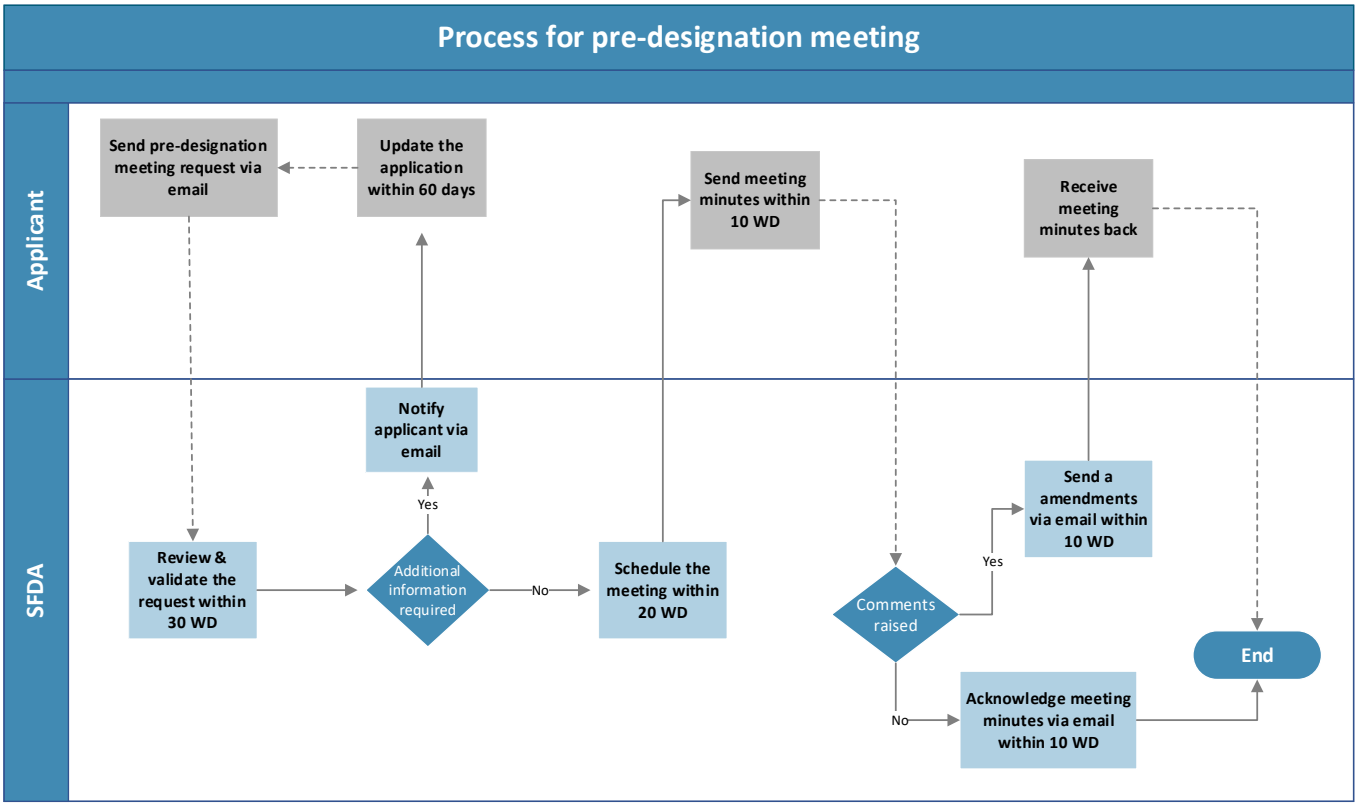

Figure 1: Flowchart for the pre-designation meeting request. WD: working day.

4. Research and Investigational Drugs (RAID) Designation Application

4.1. Requirements and format for RAID designation application

Applicants seeking a RAID designation shall submit a completed RAID designation application form (see Appendix 2), with supporting documents indicating how the product fulfils the criteria for designation.

The application format must be well prepared in a modular format consistent with the electronic Common Technical Document (eCTD) to facilitate the preparation of future MAA submission . refer to Appendix 3 for eCTD modules and requirements.

4.2. Application process

- **Step 1: Submission**
  - A formal request for RAID designation must be submitted through email (Designation.Drug@sfda.gov.sa), accompanied by the designation application form and details showing that the product is within the scope of the eligibility criteria and satisfies the requirements.
  - Additionally, the application file and supporting documentation must be in the electronic Common Technical Document (eCTD) format and submitted to the SFDA on electronic media (i.e. CD) to the Drug Sector.

- **Step 2: Validation of the application**
  - Following the submission, the application will be validated, and notification via email will be given within 15 working days regarding whether the RAID designation application is within the scope and that the format and content are adequate to support the evaluation of the request.
  - If validation issues are raised, the SFDA will notify the applicant via email to address the deficiencies and resubmit the updated application within 90 days.
    - Applicants are allowed to request by email for a timeframe extension to address deficiencies if needed.

- **Step 3: Evaluation**
  - Once validated, the application will undergo evaluation by multidisciplinary specialist evaluation areas across the SFDA for 40 working days.
  - If deficiencies, comments, or additional information related to the application file are raised during the evaluation, the applicant will be notified via email to address them and update the application within 90 days.
  - Applicants are allowed to request a timeframe extension by email to address deficiencies if needed.

- **Step 4: SFDA Decision on Designation**
  - Once the evaluation is complete, and based on the adequacy of the preliminary quality data related to manufacturing and controls, as well as the availability of preclinical or clinical data depending on the intended phase of submission, the SFDA will issue a final decision letter through Designation.Drug@sfda.gov.sa within 5 working days.
  - If the application meets all requirements, the application will be granted the RAID designation.
  - If the application does not meet all requirements, the application will be rejected.
    - The applicant has the right to appeal against the decision in accordance with the Policy of Appeal to Drug Sector Decisions.

Following the decision to grant the RAID designation, the applicant shall submit a Clinical Trial Application (CTAp) via the Saudi Clinical Trial Registry (SCTR) and submit the application through the Saudi Drug Registration (SDR) system to facilitate the future MAA submission. Both submissions shall be submitted within 6 months from the date of the designation decision.

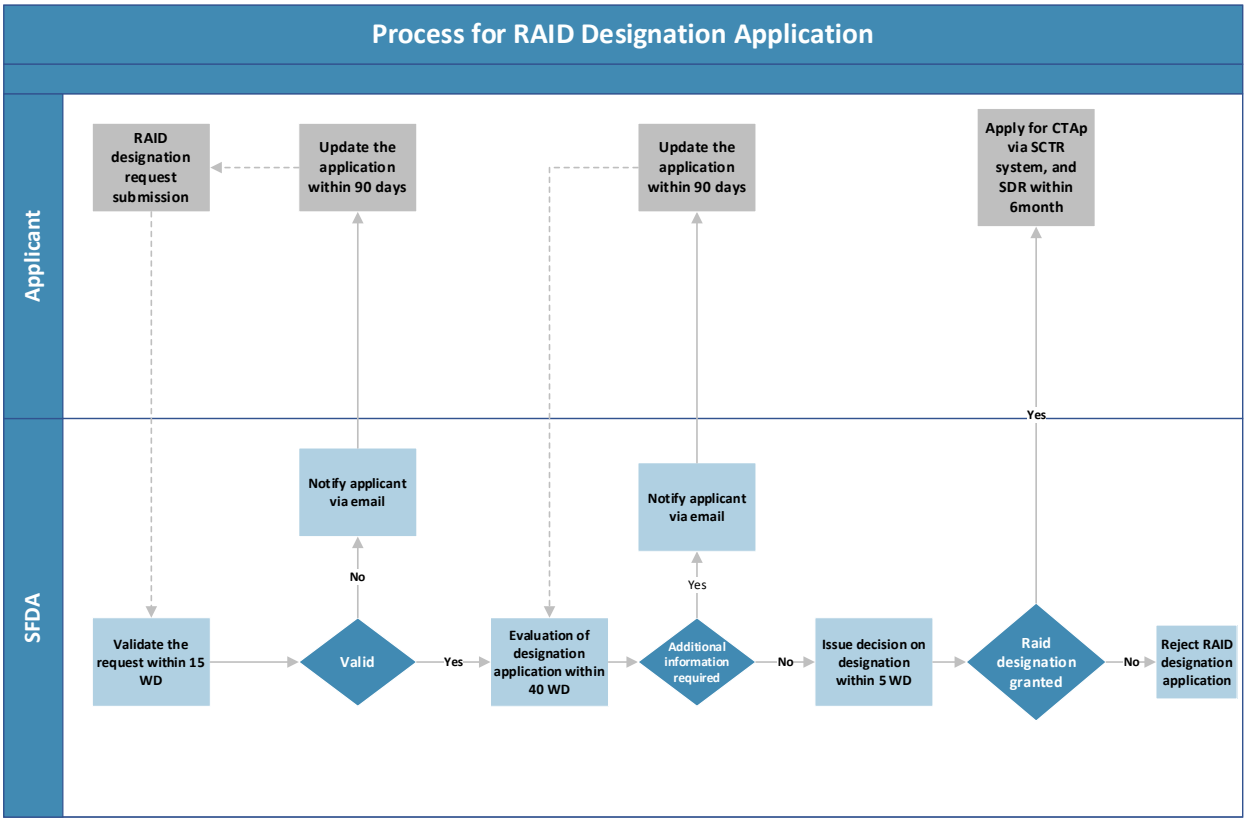

Figure 2: Application for RAID designation flowchart.

WD: Working Day, CTAp: Clinical Trial Application, SCTR: Saudi Clinical Trial Registry System, SDR: Saudi Drug Registration system**.**

5. Guidance on Regulatory Pathways

- RAID designated drug under development should be submitted to a Marketing Authorization Application (MAA) after completion of the clinical trial. The pharmaceutical company can submit the MAA to the SFDA in accordance with the SFDA regulations for drug approval.
- To take full advantage of other tools supporting early patient access to therapy, including the Breakthrough Medicine Program, a further application can be submitted by the end of Phase II or at any time after if the criteria are fulfilled.

Appendix 1: Pre-designation meeting:

Section A: Meeting Request Information	
Meeting Objectives	Please state the specific objectives of the meeting briefly (e.g., clarify study designs, discuss CMC concerns, address regulatory questions).
Agenda	Propose a preliminary meeting agenda.
List of Attendees	Names and titles.
Proposed Meeting Dates	Provide at least three preferred dates (submission must be at least one month in advance).
Meeting Format	○ In person face-to-face ○ Virtual
List of Requested SFDA Participants	○ Quality ○ Pre-clinical ○ Clinical ○ Regulatory affairs
Section B: Applicant &innovative product Information	
Applicant	Name: Address:
Marketing Authorization Holder	Name: Address:
Contact Person	Name: Title: Phone Number: Email Address:
SCTR Number	If applicable
Name of Drug	Include all available names: Trade, Chemical, or Code
Route of Administration	
innovative product Type	○ Biologic (Specify) ○ New chemical
SRA innovative product Status	Clinical and regulatory status of innovative product in SRA
Phase of Clinical Investigation to Be Conducted	○ Phase I trials ○ Phase II trials ○ Phase III trials ○ Other
Description and Composition of innovative product	
Mechanism of Action	
Proposed Indication	
Dosing Regimen, Including Concentration, Amount Dosed, And Frequency and Duration of Dosing If Known	
Manufacturing Sites of Drug	

Substance and Product	
Section C: Information Package	
Pre-clinical	Provide sufficient nonclinical information to support proceeding to clinical trials
Clinical	Therapeutic area and indications proposed preclinical data supporting movements to clinical phase. if available, scientific advice received from other regulatory authorities
CMC	Summary of related quality data
Section D: A List of Proposed Questions	
For each question there should be a brief explanation of the context and purpose of the question.	
Declaration :I confirm that all information provided is, to the best of my knowledge and belief, true, correct and complete. Furthermore, I will notify SFDA with any updates/change on the provided information immediately.	
Name	Insert the name of the person submitting the request
Title	Insert title of the person submitting the request
Signature	Insert signature
Date	insert date of submission

Appendix 2: RAID designation application form

Section I: Drug Information	
Applicant	Name: Address:
Marketing Authorization Holder/ Study Sponsor	Name: Address:
Authorized Contact Person	Name: Title: Phone Number: Email Address:
Drug Type	○ Biologic (Specify) ○ New chemical (Specify)
Name of Drug	Include all available names: Trade, Chemical, or Code
ATC code	
Strength(s)	
Dosage Form(s)	
Route(s) of Administration	
Mechanism of Action	
Proposed Indication	
Dosing Regimen, Including Concentration, Amount Dosed, And Frequency and Duration of Dosing If Known	
Drug Substance Manufacturer(s)	
Drug Product Manufacturer(s)	
Description and Composition of Drug Product	
Storage Condition(s)	
Shelf life	
Current global regulatory status including: - **Application in other global expedited pathways (e.g. PRIME, BTD)** - **Compassionate/specials usage** - **Pending and refused marketing authorization applications** - **Granted marketing authorizations**	
Is the drug not authorized or under registration in Saudi Arabia?	○ Yes (with evidence) ○ No
Is the drug innovative with novel mechanism of action?	○ Yes (with evidence) ○ No

Local & International Patent Information	
Is this indication for a rare disease (prevalence 5 in 10,000 individuals in Saudi Arabia)?	○ Yes (with evidence) ○ No
Does this product have an SFDA Orphan Designation for this indication?	○ Yes (with evidence) ○ No
Proposed MAA pathway	
Section II: Clinical Trial Information	
SCTR Number	
Study Title	
Protocol Number	
Study site(s)	
Phase of Clinical trial to be conducted	○ Phase I trials ○ Phase II trials ○ Phase III trials ○ Other
SRA Clinical stages of development including: - **Clinical trial phase** - **Global clinical trial registration number, if any (e.g. EudraCT, ClinicalTrial.gov)**	Clinical and regulatory status of innovative product in SRA
Section III: Data package (eCTD)	
Sequence No.	

Appendix 3: Contents of RAID designation application in accordance with eCTD Format

Sponsors shall compile all necessary information and documentation required for the RAID designation application, Including manufacturing and process control information, preclinical data, clinical trial protocols, and safety monitoring plans. The submission shall be prepared according to SFDA regulations and guidance documents in the eCTD format, and any information not available at the time of submission should be incorporated into the relevant eCTD modules once available.

Module	Contents of submission
Module 1	Administrative information about the proposed trial should include: - Cover letter - Payment bill - RAID designation application form - All requirements set out in SFDA Regulations and Requirements for Conducting Clinical Trials on Drugs should be submitted in additional data section. - scientific advice by other regulators - Information on the experts (clinical, preclinical and quality)
Module 2	Contains summaries about the drug to be used in the proposed trial
Module 3	Contains supporting quality information in accordance with the applicable SFDA requirements in the following guidelines: - Guidelines for Chemical and Pharmaceutical Quality Documentation of Small Molecules Investigational Product in Clinical Trials. - Guidance on Submission of Chemistry, Manufacturing, and Control (CMC) Information for Cell-based Clinical Trial Applications - Guidance on Submission of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Clinical Trial Applications
Module 4	Preclinical data in accordance with the General Considerations for Preclinical Studies Submissions.
Module 5	Clinical data requirements: - Tabular listing of all studies related to the innovative product - Clinical Study Report (CSR) for completed trials, or Interim analysis if available. - Protocols of completed studies. - Current protocol including details of statistical analysis including all previous versions