الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Regulations and Requirements for Conducting Clinical Trials on Drugs

Version 4.0

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Saudi Food & Drug Authority

Drug Sector

For Inquiries *Via email: CEC@sfda.gov.sa*

Via phone: 19999

For Comments Drug.Comments@sfda.gov.sa

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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

Version	Author	Date	Comments
1.0	Executive Directorate of Products Evaluation	08 July 2015	Final
1.1	Executive Directorate of Products Evaluation	27 October 2016	Update
2	Executive Directorate of Products Evaluation	15 June 2021	Update
2.1	Executive Directorate of Benefits and risks Evaluation	30 November 2021	Update
2.2	Executive Directorate of Benefits and risks Evaluation	30 October 2022	Update
2.3	Executive Directorate of Benefits and risks Evaluation	24 November 2022	Update
3.0	Executive Directorate of Benefits and risks Evaluation	5 January 2025	Update
4.0	Executive Directorate of Benefits and risks Evaluation	10 May 2026	(Next page shows the updated details)

What is New in version no. 4.0?

The following table shows the update to the previous version:

Section	Description of change
Definitions	**Update:** Revised all definitions to match local and global standards. **Add:** New terms added such as Biosimilar and Referenced Regulatory Authority (RRA) and Post-Trial Access Program (PTAP).
Clinical trial phases	**Update:** Revised the section for additional clarity on the different phases, and guidance on submissions, waves and timelines.
Import license	**Add:** For site activation import license is allowed
Reliance pathway	**Add:** New section on reliance pathway for clinical trials.
Non-supported studies	**Add:** New section added for PI initiated trials
Post-Clinical Trial Access Program	**Add:** New section to describe the program.
Annex	**Form added:** Request cover letter **Table added:** Table 3: Phase IV amendments **Table update:** Table 1, Table 2 and Table 3 **Form update:** Form 5 Reliance **Form added:** Post-Trial Access Program Clearance Request

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DEFINITIONS

Authority: The Saudi Food and Drug Authority.

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: Individual, company, institute, establishment or organization which take the responsibilities of starting, managing and financing the clinical trial.

CRO: It is the individual or institution who/which the trial sponsor contract with to perform some or all of the trial's responsibilities.

Saudi Clinical Trials Registry (SCTR): It is an electronic system with electronic database which includes an official records of all drugs clinical studies in Saudi Arabia to ensure that all received information are accurate and completed along with publishing selected information about the clinical trials-which is globally agreed-on for public view.

Institutional Review Board (IRB): An independent body (a review board or a committee, institutional, regional, national or supranational) constituted of medical professionals and non-medical members whose responsibility it is to ensure the protection of the rights, safety and well-being of human participants involved in a trial and to provide public assurance of that protection by, among other things, reviewing and approving/providing favorable opinion on the trial protocol, the suitability of the investigator(s), the facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial participants. The legal status, composition, function, operations and regulatory requirements pertaining to IRBs/IECs may differ among countries but should allow the IRB/IEC to act in agreement with GCP as described in this guideline.

Good Clinical Practices (GCP): It is an international guideline to control the design, carry out (conducting), monitor, and review of clinical trial to ensure the quality and accuracy of it. In addition of protecting the safety, rights, and confidentiality of the participants data.

Good Laboratory Practice (GLP): It is a quality framework to ensure the quality, integrity, and reliability of nonclinical data

Clinical trial site: The location(s) where trial-related activities are conducted and/or coordinated under the investigator's/institution's oversight.

Phase IV studies: Studies conducted on pharmaceutical products that is registered at the Saudi Food and Drug Authority in order to collect more information about the product's safety and efficacy.

Phase I studies: Clinical studies conducted on human for the first time to test the safety of the product. Usually, trials in this phase are conducted on healthy participants/volunteers.

Phase II-III studies: Clinical studies conducted on patients to test product's safety and efficacy.

Bioequivalence studies: A comparability study between two pharmaceutical products which are conducted to determine if the studied product falls within an acceptable limit of statistical difference in terms of bioavailability levels with the comparable product.

Biopharmaceutical product: Biological Product mainly based on biotechnology-derived proteins, mostly for recombinant DNA-derived versions. Other terms biological medicinal product or biologic.

Biosimilar: a biopharmaceutical product highly similar to an already approved RP in terms of quality characteristics including structural and functional attributes and has no clinically meaningful differences.

Investigational Product (IP)

- A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.
- Investigational products should be considered synonymous with drugs, medicines, medicinal products, vaccines and biological products.

Referenced Regulatory Authority (RRA): *current approved list*

1. United States Food and Drug Administration -US FDA.
2. European Medicines Agency- EMA.
3. United Kingdom's Medicines and Healthcare products Regulatory Agency- MHRA
4. Swiss Agency for Therapeutic Products (Swissmedic)

Substantial Amendment: An adjustment to the protocol, on how to manage the study or any other supported documents that could affect the participant or the scientific value of this study, or the safety, efficacy and quality of the tested product.

Non-Substantial Amendment: An adjustment to the protocol (or any trial related document), on

how to manage the study or any other supported documents in a way that doesn't affect the participant or the scientific value of this study, or the safety, quality and efficacy of the tested product.

Suspected Unexpected Serious Adverse Reaction: It is the serious adverse reaction (side effect) which is suspected to be related to research drug and its nature or seriousness not aligned with the information that mentioned in the investigator brochure.

The applicant: The researcher, study sponsor or the contract research organization (CRO).

Protocol: A document that describes the objective(s), design, methodology, statistical considerations and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the guideline, the term "protocol" refers to protocol and protocol amendments.

Post-Trial Access Program (PTAP): It is a program that supports medication access for participant patients after the completion of clinical trial conduction in Saudi Arabia.

REGULATIONS AND REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS

1. According to the Saudi Food and Drug Authority law which was issued on 25/1/1428 H by Royal decree (M/6), and its implemented regulation that issued by the authority's (SFDA's) board of directors, with a decision number (7-7-1428) dated 25/7/1429 H. in addition to the authority's number (3476), which dated 13/2/1431 H, all clinical studies should be registered at SFDA through the Saudi Clinical Trial Registry system (SCTR) , noting that the act of registering a clinical trial in the system is distinct from, and does not signify, the SFDA approval of the trial. For more information about the registration process, you can check the registration guideline through the following link: https://sctr.sfda.gov.sa/Guidance.aspx
2. The following regulations, memos and guidelines must be obligated:

    - Guideline for Good Clinical Practice.
    - Law of ethics of research on living creatures and its implemented regulation, which issued on 14/9/1431 H by Royal decree number (M/59).
    - The memo number (15421) and (15482) dated on 13/5/1434H in regard to the registration of local institutional review boards (IRBs).

3. The applicant must have an official presence or a legal representative within the Kingdom of Saudi Arabia, with their presence being accompanied by official documentation of representation and authorization from the competent authority, in addition to carrying out all regulatory tasks related to the clinical study for which they have been authorized.
4. Applicants who can submit an application are classified as follow:

    - Governmental Sectors sponsored clinical trial: The applicant will be the research center, hospital, CRO or principal investigator who is authorized by the sponsor.
    - Private Sector sponsored clinical trial: The sponsor institution or the CRO.
    - Unsponsored clinical trial: The applicant will be the principal investigator or the CRO.

5. According to the memo number (9699) which was issued on 23/4/1432H, the applicant must pay the financial fees of evaluating the clinical trial file, which equals 15.000 Saudi Riyals. However, any clinical trial which is either sponsored by Governmental Sectors, unsponsored trials that submitted by researchers, or considered a Phase IV study can be exempted from paying the finical fees.
6. Phase IV studies:

    A. The applicant should notify and obtain the SFDA's response/acknowledgment by registering the Phase IV trial at the SCTR and sending the requirements in (Table 1) to the Clinical Trials Department (ct.submit@sfda.gov.sa) within 20 working days after

obtaining local IRB approval. The authority has the right to suspend the trial if it is not classified as a phase IV study.

B. For post-approval requests, the applicant should notify the SFDA by submitting the requirements in (Table 3) to the email ct.submit@sfda.gov.sa.

C. It is mandatory to obtain SFDA approval before conducting clinical trials on registered drugs, which are not phase IV trials and considered as early phase trials, such as trials under the following criteria:

- New indication or off-label use
- Change of dosage regimen or route of administration.
- Change in dosage form.

D. Non-interventional phase IV trials which aim to gather information about the safety of registered products or registry observational studies, the applicant should adhere to the Good Pharmacovigilance Guideline (GVP). Studies exempted from registration at the SCTR include survey, questionnaire (e.g., satisfaction, awareness, etc.). Risk minimization studies and Effectiveness of Implemented Risk Minimization Measures studies (RIMS) must be consulted by the Drug Safety and Risk Management Department at DS@sfda.gov.sa

7. Clinical trials in phase I, II, III:

A. It is mandatory to obtain SFDA approval before conducting clinical trials, in accordance with the requirements in (Table 1). The clinical trial will not be registered if it was started without the authority's approval.

B. For clinical trial applications, a letter must be submitted to the authority in Arabic, accompanied by a "Cover letter for the application" as per Form No. (2) found in the annexes.

C. The applicant must annually submit a progress report on the ongoing trials by completing the Progress Report (Form No. 1) and submit it to the clinical trials department through the email ct.submit@sfda.gov.sa. The report must be submitted after obtaining the approval by one year. However, in case the trial duration is less than one year, the applicant must submit the progress report after half the study duration have passed. In addition, the delegation log for each trial site and proof of adequate GCP training for all research team must be submitted.

D. Clinical trials amendments:

- In case of non-substantial amendments, the SFDA should be notified via the annual progress report. Non-substantial amendments examples include, but not limited to, patients facing materials, health diaries and questionnaires.

- In case of substantial amendments, it is mandatory to obtain SFDA approval/ acknowledgment before implementing any amendments, in accordance with the requirements in (Table 2) and (Table 3). Substantial amendments examples include, but not limited to, Protocol, Investigator's brochure, and Informed Consent Form.
- If there is any risk or harm to study participants, the amendment must be put into effect without delay, and the authority shall be informed of the amendment immediately through the following email address: ct.submit@sfda.gov.sa.
- Upon the exposure of any trial participant to a hazard or harm, the applicant is authorized to implement the necessary amendment immediately. Concurrently, the applicant must provide immediate formal notification, including the IRB notification, via email to ct.submit@sfda.gov.sa.
- The applicant must adhere to the requirements in (Table 2) if the amendment includes changing the principal investigator, the addition or the closure of a clinical trial site.
- Request change must be accompanied by a letter to the authority written in Arabic, together with a 'cover letter for the application' (Form No. 2 in the annexes) as part of the amendments package. The SFDA recommends consolidating all amendments into a single submission to prevent fragmented or piecemeal submissions.

E. Phase I trials:

Phase I trials must be conducted in an SFDA accredited phase I unit. In addition, the applicant must adhere to (Guideline on strategies to identify and mitigate risks for first-in human and early clinical trials with investigational products).

8. Bioequivalence and biosimilar:

A. Having the authority's approval is essential before conducting bioequivalence or biosimilar studies, in accordance with the requirements in (Table 1).

B. Bioequivalence studies must be conducted in centers that are licensed either by SFDA or local authority or Gulf Health Council. (Refer to Bioequivalence guideline).

9. Importing Drugs/Study Materials Related to Clinical Trials:

A. According to the import and export procedures guideline, it is mandatory to obtain import license for drugs or study materials/supplies that related to clinical trials from drug's importing license department at the operation sector. (Refer to Procedures of Importing and Exporting). Submission using "Release Form of Drug Material (s) for Clinical Trials" (refer to annexes).

B. For site activation and study preparation process, while parallel submission of release form (import license) for materials, supplies, and kits related to the submitted (under review) clinical trials is acceptable for release, no investigational products will be released before full approval of study conduction.

10. Exporting Clinical Trial Bio-samples:

A. The applicant must adhere to the regulations of the Research Ethics Code on Living Creatures, issued by Royal decree no. M/59 on 14/9/1431 H, which regulates bio-sample exportation.

B. The applicant must provide the SFDA with a copy of the local IRB exportation permission.

11. Clinical Trials safety reporting:

A. It is mandatory to inform the SFDA immediately about any suspected unexpected serious adverse reactions (SUSAR) for both local and global cases of ongoing trials in Saudi Arabia on "Form No. 2" as soon as possible, no later than 15 days followed by the follow-up report as soon as possible. If the SUSAR is fatal or life threating, SFDA must be informed as soon as possible, no later than seven days in accordance with the ICH-E2A guideline, with a follow-up report succeeding it within 8 days.

B. SUSARs should be reported through the National Pharmacovigilance Center via email (icsr.drug@sfda.gov.sa). It is necessary to provide the SCTR number and the e-mail must be titled as "SUSAR Case."

C. The applicant must send SUSARs in (XML) format in addition to complete the Council for International Organizations of Medical Sciences (CIOMS) Form. It is adequate to send the report to the attached form 2, when submitted by the researcher.

D. Clinical trials related local SUSARs/Adverse Events are anticipated for all clinical trials registered in the SCTR platform and only approved by the SFDA for conduction in Saudi, and should be reported to Clinical Trials Department via Email (Ct.submit@sfda.gov.sa). Reported SUSARs for investigational products (pre and post authorization) per protocol only. Periodic line listing is acceptable for foreign SUSARs.

E. The applicant must annually submit the development safety update report (DSUR) in accordance with the ICH-E2A guideline to the authority with the SCTR number. If the full DSUR is not available, an executive summary shall be submitted with justification.

12. Completion, Termination, or Suspension of Clinical Trials:

A. The SFDA has the right to temporarily suspend the clinical trial in order to protect human participants in case of the following:

- Non-compliance with Good Clinical Practice.
- Safety concerns affecting participants.
- Non-compliance with SFDA regulations and requirements.

While the clinical trial is temporarily suspended, the SFDA will launch an investigation. Once the investigation is complete, the SFDA will decide one of the

following:

1. Lift the suspension.
2. Terminate the study.

B. The applicant must inform the SFDA within 60 days with a proof of IRB approval to completing, terminating or suspending the clinical trials. Include proof of destruction and/or drug accountability log. In addition, it is mandatory to submit the final clinical trial report within one year of the end of the trial in accordance to ICH-E3 guidelines.

13. The Qualifications of the Clinical Trial Research Team.

To ensure the safety of clinical trial subjects, all members of the research team must provide proof of adequate training in GCP. It is mandatory that the latest training was completed no longer than three years ago. In addition, follow local regulations applies to the investigators.

14. Study Monitoring:

The applicant must provide SFDA with a clinical trial monitoring plan that comply with the Good Clinical Practices (GCP) guideline. Moreover, curriculum vitae and a GCP certificate must be provided for the monitor of the study. Monitor must not be part of the research team of the trial.

15. Timeframes for responding to applicant requests after completing all the required documents are:

- 10 working days for phase IV trials.
- 15 working days for bioequivalence studies.
- 30 working days for phase III trials.
- 40 working days for phase II trials.
- 60 working days for phase I trials.
- 60 working days for biological products studies at any phase, products including vaccines, gene therapy, stem cells and biosimilars.

A. Acceptance of an application is contingent upon the complete and accurate submission of all required documentation (Table-2). However, parallel submission is allowed as clinical trial applications may enter the evaluation phase pending the subsequent provision of Institutional Review Board (IRB) approval and/or a Clinical Trial Agreement (CTA). Processing timeframes mentioned above are calculated after successful administrative validation through the assessment period ending at decision of trial conduction.

B. The applicant will be notified if there are any missing documents, deficiencies or comments related to the trial application. Upon such notification, the review timeline shall

be suspended, and the time taken by the applicant to respond shall not be counted within the specified review period. The applicant is required to address all identified requirements and submit a complete response within the allowable response period, taking into consideration the requirement to provide all requested documents within 60 days. Failure to do so may result in rejection of the application, and a new application should be submitted.

C. The wave count refers to the total number of complete review cycles between the SFDA and the applicant. Each wave consists of the SFDA's regulatory review, the issuance of comments or deficiencies or decision, to the applicant. The applicant is recommended to utilize less than three rounds for the entire application that is under evaluation. Each submission by the applicant in response to SFDA comments shall be counted as one review round, regardless of whether the response is complete or partial. Incomplete, fragmented, or piecemeal submissions shall not extend the review process. The applicant must consolidate all responses, revisions, and supporting documents into a single, complete submission for each review round.

16. Reliance Pathway

The Reliance Pathway allows applicants to leverage a prior approval from a Referenced Regulatory Authority (RRA) to expedite the SFDA's review process. Applicants must submit the RRA's approval documents, which will be validated by SFDA Clinical Trials Department to determine if the application is qualified for the Reliance Pathway or must follow the regular assessment pathway.

A. Application Process:

- Complete Form 5: Application for Reliance Pathway.
- Mandatory documents listed in Table 1: “Clinical Trials Requirements” must be submitted in addition to form 5.
- Include global supportive documents with the initial submission.

B. Global Supportive Documents:

- RRA Approval Letter: The official study approval letter from the RRA.
- IRB Approval Letter: The official approval letter from the local Institutional Review Board (IRB) or Ethics Committee (EC) in the country of the reference RRA.
- Assessment Report (if available): Study assessment report from the RRA.
- Scientific advice from the RRA (if available)

Note:

- The SFDA accepts at least one complete set of documents for the clinical trial application of the RRA to process as reliance.
- To expedite processing, ensure Form 5 is completed accurately and that all submitted study documents are the latest versions as approved by the RRA.
- Incomplete information in Form 5 or missing documents affects processing timeframe and may result in the application being routed to the regular pathway.

17. Non-Commercial Studies (PI initiated):

Clinical trials application on SFDA registered drug can be submitted and processed via parallel submission without requirements no. (6, 7, 13, 14, 25) in (Table 1). However, for unregistered products the applicant must submit all required documents when applicable.

18. Clinical Trials in Special cases

A. The SFDA has the right to take the appropriate measures regarding regulatory requirements and applications review priority in the following cases:

- Pandemics, epidemics, and national emergencies declared by Ministry of Health and Public Health Authority.
- Trials on drugs submitted for registration purposes with no alternative treatment in Saudi Arabia.
- Trials on drugs related to national initiatives from SFDA and related bodies.

B. Special cases request is processed according to the following criteria:

- Priority for application in submissions.
- Priority review.
- Priority regulatory consultation meetings.
- Pandemics, epidemics and national emergencies declared by Ministry of Health and Public Health Authority: applications will be exempted from the following requirements no. (2-8-9-10-11-15-16-17-18-19-20) in (Table 1) during initial submission. Parallel submission is allowed with commitment to complete the remaining requirements during the application review period.

19. The applicant must submit the trial documents electronically via SFDA cloud service, organized in folders in accordance with (Table 1) on the day of the booked appointment via the electronic system. Moreover, the applicant can request the SFDA cloud link via email (ct.submit@sfda.gov.sa) in case a link was not received. Applicant is requested to ensure that the content format is in the requested order, can be searched and copied, and not pictures.

Failure to do that will result in delaying the processing of the application. Any use of Artificial Intelligence (AI) in the clinical trial related documents, should be declared by the applicant upon submission.

20. Post-Clinical Trial Access Program

Post-clinical trial drug access program (PTAP) refers to the program that ensures continued supply of an investigational product to participants in a SFDA approved clinical trial. This program is different than the special access program (SAP) (refer to SAP guideline).

A. Eligibility Criteria: Patients who participated in a clinical trial and benefited from the treatment. Continued access programs allow them to keep receiving the investigational product once the study concludes.

B. PTAP may be structured in the following way:

- Participant/s can continue receiving the investigational product in approved clinical trials where both the patient and the investigator are aware of the treatment is being administered.
- Informed consent form of the enrolled participant's must be available during GCP inspection.
- Monitoring: Some clinical trials offer continued access to the treatment with follow-up visits to monitor safety and efficacy of the investigational product.
- The following requirements must be submitted for PTAP within 60 days prior to the closure of the original clinical trial.

C. Requirements of PTAP application process:

- Cover letter written in Arabic directed to Clinical Trial Department at SFDA
- Completed and signed Post-Trial Access Program Clearance Request form (refer to annexes).
- Updated and signed Informed Consent Form readily available during GCP inspection visits. The ICF must be provided in a language the patient understands, which may be Arabic, English, or both. It must include information of the treating physician and/or the principal investigator including direct contact number.

ANNEXES

Form (2) Request Cover Letter MUST BE ALL FILLED AND SUBMITTED WITH EACH REQUEST			
Letter Number	*(Applicant reference number)*	Date:	
Study Title			
SCTR Number			
Study Sponsor			
CRO (if applicable)			
Clinical Trial status at SFDA	☐ New application ☐ Under review ☐ Approved ☐ Terminated ☐ Completed ☐ Suspended ☐ Rejected		
Request Type (select all applies)	☐ Initial submission ☐ Deficiencies responses ☐ Adding site ☐ Amendment ☐ Change PI ☐ Close out ☐ Termination ☐ Cancelation	☐ Appeal ☐ Protocol deviation ☐ Safety reporting ☐ Annual progress report ☐ Final study report ☐ Compassionate use/SAP ☐ Notification/ Update ☐ Other…….	
Amendments (select all applies)	☐ Protocol *(specify below if clinical or non-clinical data change)* ☐ IB ☐ Quality related (IMPD) ☐ GMP related ☐ ICF ☐ Other……. ☐ Clinical data update ☐ Non-Clinical data update, specify type of amendment and the reason of change *(see below)*	☐ Change of indication ☐ Change in route of administration ☐ Change in dosage or dose regimen ☐ New drug formulation ☐ Addition of a vulnerable population (e.g., pediatric, pregnant women, etc.) ☐ Introduction of a combination therapy ☐ Significant change in patient population ☐ Discovery of new safety concerns ☐ Other substantial amendments where a bridging non-clinical data is available	

<table>
<tr><td>Safety reporting</td><td>☐ DSUR
☐ Local SUSAR
☐ Global SUSAR</td></tr>
<tr><td>Substantial amendments</td><td>Complete amendment package shall be submitted at once and must include all applicable supporting documents including, but not limited to, the institutional review board (IRB) approval (s). Incomplete amendment submissions will not be processed. Parallel or staged submissions of amendment documents are not permitted.</td></tr>
<tr><td>Non-substantial amendments</td><td>Non-substantial amendments are considered modifications that do not require prior SFDA approval or a formal response, as outlined under the non-substantial amendment provision of this document.</td></tr>
<tr><td>Declaration</td><td>- A signed declaration by the applicant confirming that all information and documents submitted to the SFDA are correct and accurate.
- Providing inaccurate or misleading information may result in rejection of the application or regulatory action in accordance with applicable laws and regulations.

By signing below;

1. I hereby acknowledge that I have read and understood the information enclosed in this form and agree to it is terms and conditions.
2. I commit to immediately notify SFDA if the status of the trial has been changed e.g.: the trial has been suspended for safety reasons during SFDA submission period.

<table><tr><td colspan="2">Name:</td></tr><tr><td>Signature:</td><td>Date:</td></tr></table></td></tr>
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Table 1: Clinical Trial Requirements

1-A	Documents at submission	Phase I/II/III	Phase IV	BE/BS
1.	Arabic-Headed Letter to SFDA- Drug- Clinical Trials Department including Form 2 to indicate SCTR registration number, list of the submitted documents, etc	√	√	√
2.	IRB Approval (Including list of reviewed documents, version and dates for each document)	√	√	√
3.	Informed Consent Form (Arabic and English)	√	√	√
4.	Trial Protocol(s) (latest and all previous versions/ amendments) according to SFDA Guideline for Good Clinical Practice (GCP)	√	√	√
5.	Statistical Analysis Plan (SAP) (if not available, provide a letter to state when it will be finalized)	√		√
6.	Investigator Brochure according to Guideline for Good Clinical Practice (GCP)	√		√
7.	Investigational Product Dossier (According to EMA Requirements)	√		
8.	Certificate of Analysis for the Study Drug and Placebo	√		
9.	Labeling of the Study Drug, Placebo, Comparator	√		√
10.	Financial Disclosure of Principal Investigator (Form No. 3)	√		√
11.	Certificate of Analysis for the Study Drug and Placebo	√		√
12.	Valid GMP Certificate for Study drug and Placebo from the country of origin (To be specified according to the Table C)	√		√
13.	Participants' Insurance	√		√
14.	CVs of Principal Investigator (Signed and dated)	√		√
15.	GCP Certificate of Principal Investigator	√		√
16.	Statement of Investigator (Form No. 4)	√	√	√
17.	Monitoring Plan and CV, GCP Certificate for monitor	√		√
18.	Delegation/Authorization Letter for CRO (if applicable)	√	√	√
*	Pre-Clinical Studies reports for phase I clinical trials and upon request (according to Table D)	√		
*	Form No.5. and global supportive documents	√		√

1-B	Additional documents must be available at GCP inspection visit	Phase I/II/III	Phase IV	BE/BS
1.	Case Report Form	√		√

2.	Clinical Trial Agreement (CTA), or commitment form	√		√
3.	Confidentiality Agreement	√		√
4.	Delegation log	√		√
5.	CV and conflict of interest agreement for the Independent Data Monitoring Committee (IDMC) (if applicable)	√		
6.	GCP Certificate of research team.	√		√

Table 1-C:

No.	Company Name	Activities
1		Manufacturing of the drug substance
2		Manufacturing of the finish products
3		Primary and/or secondary packaging
4		Batch release
5		Quality control
..		…….

Table 1-D:

The following preclinical documents need to be provided as full study reports*:

	Provided	Not applicable/Not provided *(justification is mandatory)*	
1. Nonclinical Overview			
- Non-clinical overview	☐	☐	
2. Nonclinical Study Reports			
2.1 Pharmacology			
2.1.1 Primary pharmacodynamics	☐	☐	
2.1.2 Secondary pharmacodynamics	☐	☐	
2.1.3 Safety pharmacology	☐	☐	
2.1.4 Pharmacodynamic drug interactions	☐	☐	
2.2 Pharmacokinetics			
2.2.1 Analytical Methods and Validation	☐	☐	

Reports			
2.2.2 Absorption	☐	☐	
2.2.3 Distribution	☐	☐	
2.2.4 Metabolism	☐	☐	
2.2.5 Excretion	☐	☐	
2.2.6 Pharmacokinetic drug interactions	☐	☐	
2.2.7 Other pharmacokinetic studies	☐	☐	
2.3 Toxicology			
2.3.1 Single-dose toxicity	☐	☐	
2.3.2 Repeat dose toxicity.	☐	☐	
2.3.3 Genotoxicity 2.3.3.1 In vitro 2.3.3.2 In vivo	☐	☐	
2.3.4 Carcinogenicity	☐	☐	
2.3.4.1 Long-term studies	☐	☐	
2.3.4.2 Short- or medium-term studies	☐	☐	
2.3.4.3 Other studies	☐	☐	
2.3.5 Reproductive and developmental toxicity	☐	☐	
2.3.5.1 Fertility and early embryonic development	☐	☐	
2.3.5.2 Embryo-fetal development	☐	☐	
2.3.5.3 Prenatal and postnatal development, including maternal function	☐	☐	
2.3.5.4 Studies in which the offspring (juvenile animals) are dosed and/or further evaluated	☐	☐	
2.3.6 Local Tolerance	☐	☐	
2.3.7 Other toxicity studies, if available	☐	☐	
2.4 Literature References	☐	☐	

* Please be aware that the preclinical requirements may differ depending on the type of pharmaceutical product. Consult the appropriate local and ICH guideline(s) for more details on the relevant preclinical data requirements. This section is mandatory if "not applicable/not provided" box was checked.

Table 2: Amendment, Adding Site and New Investigator Requirements (Phases I, II & III)

Documents	Amendment	Adding Site / New Investigator	Close out	Termination
1. Arabic-Headed Letter to SFDA- Drug- Clinical Trials Department including Form 2 to indicate SCTR registration number, list of the submitted documents, etc	√	√	√	√
2. IRB Approval (Including list of reviewed documents, version and dates for each document)	√	√	√	√
3. Confidentiality Agreement		√		
4. Financial Disclosure of Principal Investigator (Form No. 3)		√		
5. Clinical Trial Agreement		√		
6. CVs of Principal Investigator, Co-investigator(s) and Coordinator (if applicable)		√		
7. GCP Certificate of research team		√		
8. Statement of Investigator (Form No. 4)	√	√		
9. Summary of the Proposed Amendment	√			
10. Tabulated summary of the proposed change and the reason/rational	√			
11. Amendment Track of Changes	√			
12. List of Modified Documents (version, date)	√			
13. Proof of destruction or methods of dealing with remains			√	√
14. Delegation log		√		
15. Progress report or final report	√		√	√
16. Supporting Information (if applicable)	√			
17. Form 5. (for reliance approved trials)	√			

Table 3: Amendment, Adding Site and New Investigator Requirements (Phase IV)

Documents	Amendment	Adding Site /New Investigator	Close out	Termination
1. Arabic-Headed Letter to SFDA- Drug- Clinical Trials Department including Form 2 to indicate SCTR registration number, list of the submitted documents, etc	√	√	√	√
2. Statement of Investigator (Form No. 4)	√	√		
3. Summary of the Proposed Amendment	√			
4. Amendment Track of Changes	√			
5. List of Modified Documents (version, date)	√			
6. Proof of destruction			√	√
Progress report or final report	√		√	√
7. Supporting Information (if applicable)	√			

Annual Progress Report to SFDA

(This report should be completed by an authorized personal)

Soft copy of the form can be found under the drug sector portal in "Forms Section"

1. Details of sponsor

Name of Sponsor / CRO:	
Address:	
City:	
Contact Person:	
Contact number:	

2. Details of study

Study title:	
Protocol number:	
Product class	☐Biological ☐Innovative ☐Generic
Current study status:	☐Completed ☐Terminated ☐Ongoing ☐other: please specify:
SCTR number (if applicable):	

3. Start and Completion dates

Has the study started in Saudi Arabia?	**Yes / No**
If yes, what was the actual start date in Saudi Arabia?	
If no, what are the reasons for not starting the study in Saudi Arabia? What is the expected start date?	
Has the study completed?	**Yes / No**
If no, what is the expected completion date?	

If you do not expect the study to be completed, give reason(s)	

4. Investigational site information

4.1 Number of sites / participants

Total number of participants Globally (if applicable):	
Total number of participants in Saudi Arabia:	
Number of sites proposed in original application:	
Number of sites recruited to date:	
Do you plan to increase the total number of sites proposed for the study?	**Yes / No**

4.2 Site details

Name of site: Name of principle investigator: Number of participants on this site:
Number of withdrawals from trial to date due to: (a) withdrawal of consent: _____ (b) loss to follow-up: _____ (c) death (where not the primary outcome): _____ Total study withdrawals: _____
Number of treatment failures to date (prior to reaching primary outcome) due to: (a) adverse events: _____ (b) lack of efficacy: _____ Total treatment failures: _____

**(For 4.2 fill each site of the study separately)*

4.3 Recruitment

Have there been any serious difficulties in recruitir participants?	**Yes / No**
If yes, give details:	
Do you plan to increase the planned recruitment of participants into the study?	**Yes / No**

5. Safety reports

Have there been any Suspected Unexpected Serious Adverse Reactions (SUSARs) in this trial in Saudi Arabia?	**Yes / No**
Have these SUSARs been notified to SFDA within 7 or 15 days in accordance with SFDA Regulations and Requirements for Conducting Clinical Trials on Drugs? If no, please arrange urgently and give reasons for late notification.	**Yes / No**
Has DSUR been submitted?	**Yes / No / Not yet due**
When is the next DSUR due?	

6. Amendments

Have any substantial amendments been made to the trial?	**Yes / No**
If yes, please give the date and amendment number for each substantial amendment made.	

7. Serious deviations of the protocol or Good Clinical Practice

Have any serious deviations of the protocol or GCP occurred in relation to this trial?	**Yes / No**
If yes, please give the date of each notification to the SFDA. Please provide the IRB/EC with a copy of each notification for information (unless previously notified).	

8. Other issues

Are there any other developments in the trial that you wis to report to the SFDA?	**Yes / No**
Are there any ethical issues on which further advice is required? *If yes to either, please attach separate statement with details.*	**Yes / No**

9. Declaration

Name and title of authorized person:	
Signature:	
Date of submission:	

Form no. 2

CIOMS FORM (SUSAR REPORT)

Soft copy of the form can be found under the drug sector portal in "Forms Section"

SUSPECT ADVERSE REACTION REPORT	

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE Years	3. SEX	4-6 REACTION ONSET Day	Month	Year	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
										☐ PATIENT DIED ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ LIFE THREATENING
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)										

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
17. INDICATION(S) FOR USE		☐ YES ☐ NO ☐ NA
18. THERAPY DATES (from/to)	19. THERAPY DURATION	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER		
	24b. MFR CONTROL NO.	
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL	
DATE OF THIS REPORT	25a. REPORT TYPE ☐ INITIAL ☐ FOLLOWUP	

7+13. DESCRIBE REACTION(S) (continuation): (additional information can be added)

Form no. 3

Soft copy of the form can be found under the drug sector portal in “Forms Section"

Kingdom of Saudi Arabia
Saudi Food & Drug Authority

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

Disclosure: Financial Interests and Arrangements of Clinical Investigators Form

TO BE COMPLETED BY APPLICANT

Study title:	
Protocol number:	Study sponsor:
Investigator/Sub-investigator name:	Study site:

Please indicate by marking YES or NO below if any of the finical interests or arrangements applies to you, your spouse, dependent children, or any combination.

YES / NO

Are you, your spouse or any dependent children an employee of study sponsor?

☐ ☐ Any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study.

☐ ☐ Any significant payments of other sorts made from the sponsor of the covered study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria.

☐ ☐ Any proprietary interest in the product tested in the covered study held by the clinical investigator, his spouse or any of his dependent children.

☐ ☐ Any significant equity interest held by the clinical investigator, his spouse or any of his dependent children in the sponsor of the covered study.

For each YES response above, please provide detailed information disclosing the nature of the financial arrangement, including total value amount:

_____

_____

_____

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_____

_____

By signing this form, 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 on this form during the course of the study.

Name:	
Signature:	Date:

Form no. 4

Soft copy of the form can be found under the drug sector portal in "Forms Section"

Statement of Investigator

بسم الله الرحمن الرحيم

Kingdom of Saudi Arabia
Saudi Food & Drug Authority

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

NAME AND ADDRESS OF INVESTIGATOR			
Name of Principal Investigator			
Address		Saudi Commission for Health Specialties No.	
City	Qualified Area(s) of Specialty	Telephone No.	Email

EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED *(Select **one** of the following.)*

☐ Curriculum Vitae ☐ Other Statement of Qualifications

Do the Investigator have GCP certification?
☐Yes ☐No
IF yes, attach your certification.

NAME OF TRIAL SITE			
Name of Hospital, or Other Research Facility			
Address		City	
Telephone No.			

NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY (In Case of Central Lab)			
Name of Clinical Laboratory Facility			
Address			
City	Province/Region	Country	Postal Code

NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES)	
Name of IRB	
Address	Registration No. at NCBE

Details of Study

Study Title	Protocol No.
	SCTR No.
	Version No.

COMMITMENTS

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and institutional review board (IRB) review and SFDA regulations are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirement. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with GCP E6 and to make those records available for inspection in accordance with GCP E6.

I will ensure that an IRB that complies with the requirements of National Committee of Bioethics (NCBE) will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in Regulations and Requirements for Conducting Clinical Trials on Drugs.

NOTE: INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE SFDA.

DATE *(mm/dd/yyyy)*	**SIGNATURE OF INVESTIGATOR**

Reliance (Form no.5)					
Study Title					
SCTR Number					
Product Scientific name					
Product class	☐ Biological ☐ Innovative ☐ Generic				
Study Sponsor					
Protocol Number		Version		Date	
Investigator Brochure (IB)	*(Product/s name)*	Version		Date	
Investigational Product Dossier (IPD)	*(Product/s name)*	Version		Date	
Is the submitted study approved in RRA?	☐ No ☐Yes; ☐ FDA. Registration/Identifier number: ☐ EMA. Registration/Identifier number: ☐ MHRA. Registration/Identifier number: ☐ Swissmedic. Registration/Identifier number:				
Are the versions and dates of the submitted study documents identical the documents approved by the RRA?	☐ No ☐ Yes				
Has the submitted study application been rejected, suspended or put on hold due to any safety reason anywhere?	☐ No ☐ Yes. More details are required:				
Has there been modification on the protocol of this study based on recommendations from other regulatory authorities?	☐ No ☐ Yes. More details are required:				

Is the IP registered in the RRA?	☐ No ☐ Yes; ☐ FDA. Registration number: ☐ EMA. Registration number: ☐ MHRA. Registration/Identifier number: ☐ Swissmedic. Registration/Identifier number:
Is the quality data (including manufacturing site, manufacturing process, and product quality) for the submitted clinical trial identical to the most updated quality data approved by the RRA	☐ Yes ☐ No. More details are required:
KSA registration status of the IP	☐ No ☐ Yes, registration number: ☐ Under registration, application number:
Is the IP involved in other clinical trial(s) submitted previously at SFDA	☐ No ☐ Yes. SCTR number: Status:
Will this submission be included as a part of a dossier for a market authorization submission at SFDA?	☐ No ☐ Yes. More details are required:
Is the IP considered an advanced medicinal product (cell and gene therapy)?	☐ No ☐ Yes. Please specify the type
Is the IP considered a cell, tissue or plasma related product?	☐ No ☐ Yes
Is the IP considered a first in class novel medicinal product?	☐ No ☐ Yes. More details are required:
Are the participants considered a special population? (e.g., Pediatric, Renal or Hepatic dysfunction)	☐ No ☐ Yes. Please specify the type

Global Supportive Documents
The following supportive documents need to be submitted at the initial submission under "Supportive Documents": 1. RRA Approval Letter: The official study approval letter from the RRA. 2. IRB Approval Letter: The official approval letter from the local Institutional Review Board (IRB) or Ethics Committee (EC) in the country of the RRA 3. Assessment Report (if available): Study assessment report from the RRA. 4. Scientific advice from the RRA or Q&A document (if available) NB. Completing this form and submitting the above documents in addition to the latest versions (as submitted to RRA) of the study documents at the initial submission package supports expediting the processing of your application.
Terms and Conditions
1. Providing inaccurate or misleading information may result in application rejection or even a legal action by SFDA. 2. Filling out this form does not bind the SFDA to any commitment. 3. The application processing timelines may be affected by the information provided in this form.
Commitments
By signing below; 3. I hereby acknowledge that I have read and understood the information enclosed in this form and agree to it is terms and conditions. 4. I commit to immediately notify SFDA if the status of the trial has been changed e.g.: the trial has been suspended for safety reasons during SFDA submission period. 5. I confirm that all information provided is, to the best of my knowledge and belief, accurate, correct and complete. Furthermore, I will notify SFDA of any updates/changes to the provided information on this form during the course of the study.

Name:	
Signature:	Date:

Release Form of Drug/Material (s) for Clinical Trials Use

To Be Completed By The Authorized Person

Study title			
Sponsor		**CRO (if applicable)**	
SCTR number		**Total number of study site(s) within KSA**	
Study planned starting date		**Study planned ending date**	
Total planed number of study subject (s) within KSA		**Total number of study recruited subject (s) within KSA**	

- **Please fill-in the following applicable table (s) according to your request:**

Table 1: Study drug (s) under investigation

No.	Study site (s)	Storage location	No. of current recruited subject (s)	Study Drug (s) under Investigation				
				Drug (name)	Drug (Expiry date)	Dose (unit) *	Quantity (unit)	Total previous released quantity (unit)**
1								
2								
3								

Table 2: Study comparator (s)

No.	Study site (s)	Storage location	No. of current recruited subject (s)	Study Comparator				
				Drug (name)	Drug (Expiry date)	Dose (unit) *	Quantity (unit)	Total previous released quantity (unit)**
1								
2								
3								

Table 3: Study material (s)

No.	Study site (s)	Storage location	No. of current recruited subject (s)	Study Material (s)			
				Item (name)	Item (Expiry date if applicable)	Quantity (unit)	Total previous released quantity (unit)**
1							
2							
3							

- **Please check the following according to the last clearance request status if applicable** (check more than one if needed):

☐ **Released** ☐ **Not Released** ☐ **Utilized** ☐ **Not Utilized** ☐ **Expired**

☐ **Other:** _____

I am the applicant agree to abide by all rules of Saudi Food and Drug Authority, and I pledge to use the above drug/material (s) for clinical trials purposes only.

Applicant name _____ **Applicant occupation** _____ **Signature** _____ **Date** _____

*If there are more than one dosage strength, each dose should be completed separately.

**All previous released quantities not the last release request.

Form. 6 (Post-Trial Access Program Clearance Request)

Section A: Principal Investigator Information	
Principal Investigator Name:	
Principal Investigator ID:	Principal Investigator SCFHS Licensing:
Hospital Name:	
Province:	City:
Contact Person: (If other than physician)	
Principal Investigator Telephone: Extension:	Principal Investigator Mobile:
Contact Telephone: Extension:	Contact Mobile:
Treating Physician's/Principal Investigator Email Address:	Contact's Email Address:
SECTION B: Drug and Manufacturer Information	
Trade Name:	Other Name:
Manufacturer:	Sponsor: (If Applicable)
Route Of Administration: ORAL ☐ I.V. ☐ I.M. ☐ TOPICAL ☐ S.C. ☐ I.T. ☐ OTHER ☐	
Dosage Form: Tab ☐ Cap ☐ Liquid ☐ Powder ☐ Cream ☐ Oint ☐ Patch ☐ Other:	
Section C: Investigational product quantity	
Please specify the **exact amount** of drug requested (e.g., number of tabs, vials, units, etc.) for the anticipated participant patients>	**Total:**

Accountability log and/or dispensing log must be available at GCP visits to track dispensing and disposal
Section D: Clinical Trial Enrollment
Title of the clinical trial enrolled: SCTR no.: Site: Close out Date:
Section F: Applicant attestation
I, the physician/principal investigator, am accessing this non-marketed drug for treatment of a patient under my care in accordance with the Saudi Food and Drug Authority regulations.
I, the physician/principal investigator, agree to provide the progress report and a report on the results of the use of the drug including information on adverse drug reactions and, on request, to account for quantities of the drug received.
I, the physician/principal investigator, agree that all information provided in this form are correct and I am aware that any modifications or changes made on this form after issuing of SFDA decision will reject/cancel the request and I will be subjected to legal action by SFDA.

Treating physician signature (if provided):	**Date:**
Principal investigator signature:	**Date:**
Sponsor signature:	**Date:**