الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Regulations and Requirements for Conducting Clinical Trials on Drugs

Version 3.0

Date of issue	08 July 2015
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Regulations and Requirements for Conducting Clinical Trials on Drugs

Version 3.0

Saudi Food & Drug Authority

Drug Sector

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Please visit SFDA's website at
https://www.sfda.gov.sa/en/regulations?tags=2

for the latest update

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 (Next page shows the updated details)

What is New in version no. 3.0?

The following table shows the update to the previous version:

Section	Description of change
Regulations and Requirements for Conducting Clinical Trials - Phase IV studies.	**Delete:** Concerning phase IV trials on unregistered direct purchased drugs, the researcher must adhere to memo E/1811 16/1/1436 H.
Regulations and Requirements for Conducting Clinical Trials - Early phases trials (phase I, II, III).	**Update:** The applicant must submit the progress report after half the study duration have passed in case the trial duration is less than one year.
Regulations and Requirements for Conducting Clinical Trials - Reporting Clinical Trials Adverse Drug Reactions.	**Add:** SUSAR for local cases and global cases for trials ongoing in Saudi Arabia
Regulations and Requirements for Conducting Clinical Trials – The timeline to respond after completing all the required documents.	**Update:** - The time taken to respond to SFDA will not be considered within the specified timeline. - The application will be rejected if the applicant failed to provide the requirements.
Regulations and Requirements for Conducting Clinical Trials – Clinical Trials in Special cases (a)	**Update:** Trials on drugs related to national initiatives from SFDA and related bodies.
Regulations and Requirements for Conducting Clinical Trials – Clinical Trials in Special cases (b)	**Delete:** - Response timeline do not exceed 15 working days. - Study documents must be submitted through an appointment via the Saudi Clinical Trial Registry (SCTR). **Add:** - Applications will be given priority in appointments via the electronic system for clinical trials.
Regulations and Requirements for Conducting Clinical Trials – the electronic submission of the trial documents.	**Delete:** - Submitting the trial documents electronically in a CD. - Attending the scheduled meeting at the Saudi Clinical Trial Registry (SCTR). **Add:**

	- Submitting the trial documents electronically via SFDA Cloud service. - Requesting the SFDA Cloud link to upload the documents.
Annex - Table 1: Clinical Trial Requirements	**Update and Add:** - Including in Arabic-Headed Letter the list of submitted documents and the needed scientific advice. - Statistical Analysis Plan (SAP) or reference to the plan. - Certificate of Analysis for the Study Drug and Placebo. - Valid GMP Certificate from the country of origin. - A letter to state the availability of Delegation log. - Fill Form No.5. - Providing pre-clinical documents as full study reports.
Email address	**Update email for submission of clinical trials and amendments**
Annex - (Form No. 5)	**Form added**

TABLE OF CONTENT

DEFINITIONS:

Authority: The Saudi Food and Drug Authority.

Clinical Trials: Each research (study) that concerns with collecting and analyzing information, which related to volunteers and patients to reach general knowledge that could be applied on other patients according to the mechanism of diseases occurrence, diagnosis, its spreading or treatment.

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 the minimum amount of information about the clinical trials , which is globally agreed, so it can be viewed by the public.

Institutional Review Board (IRB): It is the research licensing committee which is formed (established) according to the living creatures ethics law and its implementing regulation.

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.

Clinical trial site: Any institution that licensed to provide health care services and/or conducting the clinical trials.

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

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

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

Bioequivalence studies: Studies which are conducted to determine any statistical differences in the bioavailability levels between two pharmaceutical products.

Non-Substantial Amendment: An adjustment to the protocol, 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.

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, 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 describing the objectives, design, methodology, statistical considerations, and procedure for organizing clinical trials.

REGULATIONS AND REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS

1. According to the Saudi Food and Drug Authority law which 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 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), Knowing that the registration of a clinical trial (registering the trial in the system) does not mean the approval of the trial. For more information about the registration process, you can check the registration guideline through this 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. Applicant who can submit an application:

    - Clinical trial sponsored by the Governmental Sectors: The applicant will be the research center, hospital, CRO or principal investigator who is authorized by the sponsor.
    - Clinical trial sponsored by the private Sector: 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 issued on 23/4/1432H, the applicant must pay the financial fees of evaluating the clinical trial file, which equals 15,000 Saudi Riyals. The clinical trials which are sponsored by Governmental Sectors, unsponsored trials that submitted by researchers and the Phase IV studies will be excluded from the finical fees.
6. Phase IV studies:

A. The applicant can start the clinical trial after obtaining local IRB approval. They should notify the SFDA by registering the 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. When changing or adding a clinical trial site, the applicant should notify the SFDA by sending the IRB approval and the researcher obligation form (Form 4) 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 for:

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

D. Concerning the non-interventional phase IV trials which aim to gather information about the safety of registered products, the applicant should adhere to the Good Pharmacovigilance Guideline (GVP).

7. Early phases trials (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. 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 training in GCP for all research team must be submitted.

C. Clinical trials amendments:

- In case of non-substantial amendments, the SFDA should be notified via the annual progress report.
- In case of substantial amendments, it is mandatory to obtain SFDA approval before implementing any amendments, in accordance with the requirements in Table 2.
- The applicant can apply (Implement) amendment immediately if the participants exposed to hazardous or harm during the trial, and inform the authority immediately by sending an 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.

D. Phase I trials:

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

8. Bioequivalence Studies:

A. Having the authority's approval is essential before conducting the bioequivalence studies, in accordance with the requirements in table 1.
B. The bioequivalence studies must be conducted in centers that are licensed by SFDA or the authority or Gulf Health Council.

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

According to the import and export procedures guideline which is published in the SFDA's website, it is mandatory to obtain an importation license for drugs or study materials that related to clinical trials from drug's importing license department at the operation sector.

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. Reporting Clinical Trials Adverse Drug Reactions:

A. It is mandatory to inform the SFDA immediately about any suspected unexpected serious adverse reactions (SUSAR) for local cases and global cases for trials ongoing 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. It is mandatory to inform the SFDA of any SUSAR that occurs internationally to an investigational drug involved in ongoing clinical trials in Saudi Arabia as soon as possible by adopting the same procedures that mentioned above.
C. 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 subject must be "SUSAR Case."

D. The applicant must send SUSARs in (XML) format in addition to completing the (CIOMS) Form. It is adequate to send the report to the attached form 2, if it will be received from the researcher.
E. The applicant must annually send a development safety update report (DSUR) to the authority with the SCTR number.

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 subjects 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. In addition, it is mandatory to submit the final clinical trial report within one year of the end of the trial in accordance with 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.

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 the study.

15. The period (timeline) needed to respond to the 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 and the biological products studies (vaccines, gene therapy, stem cells and biosimilars).

The applicant will be notified if there are any missing documents, deficiencies or comments related to the trial file, and the timelines stated above will be stopped from the date of notifying the applicant, so the time taken to respond to SFDA will not be considered within the specified timeline, taking into consideration the need to provide requirements within 90 days. The application will be rejected if the applicant failed to provide these requirements during this period, and a new application should be submitted

16. 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:

- Applications will be given priority in submissions.
- Priority review.
- Priority regulatory consultation meetings.
- Pandemics, epidemics and national emergencies declared by Ministry of Health and Public Health Authority: Parallel submission is acceptable without requirements no. (2-8-9-10-11-15-16-17-18-19-20) in Table no. (1) during initial submission, with commitment to completing the remaining requirements during the application review period.

17. The applicant must submit the trial documents electronically via SFDA cloud service organized in folders in accordance with table 1 in the same 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. Furthermore, ensuring that its contents can be copied, searched and are not in image format.

ANNEXES

Table 1: Clinical Trial Requirements

Documents	Phase I / II / III	Phase IV	BE
1. Arabic-Headed Letter to SFDA Drug Clinical Trials Department. (Including SCTR registration number, list of the submitted document and if the applicant is seeking for scientific advice)	√		√
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 Medicinal Product Dossier (According to EMA Requirements)	√		
8. Case Report Form	√		√
9. Labeling of the Study Drug, Placebo, Comparator	√		√
10. Clinical Trial Agreement	√		√
11. Financial Disclosure of Principal Investigator (Form No. 3)	√		√
12. Confidentiality Agreement	√		√
13. Certificate of Analysis for the Study Drug and Placebo	√		√
14. Valid GMP Certificate for Study drug and Placebo from the country of origin (To be specified according to the Table 1-a)	√		√
15. Participants' Insurance	√		√
16. CVs of Principal Investigator (Signed and dated) and research team.	√		√
17. GCP Certificate of research team.	√		√
18. Delegation log (if not available, provide a letter to state when it will be finalized)	√		√
19. Statement of Investigator (Form No. 4)	√	√	√
20. Monitoring Plan and CV, GCP Certificate for monitor	√		√
21. CV and conflict of interest agreement for the Independent Data Monitoring Committee (IDMC) (if applicable)	√		
22. Delegation/Authorization Letter for CRO (if applicable)	√	√	√
23. Biobatch (expected production size)			√
24. Fill Form No.5.	√	√	√
25. Pre-Clinical Studies reports (according to Table 1-b)	√		

Table 1-a:

No.	Company Name	Activities
1	X *(To be filled by applicant)*	Manufacturing of the drug substance
2	X *(To be filled by applicant)*	Manufacturing of the finish products
3	X *(To be filled by applicant)*	Primary and/or secondary packaging
4	X *(To be filled by applicant)*	Batch release
5	X *(To be filled by applicant)*	Quality control
..	…….	…….

Table 1-b:

The following pre-clinical documents need to be provided as full study reports*:

Documents	Phase I / II / III
Pharmacology Studies	
Primary Pharmacodynamics	Phase I / II / III
Secondary Pharmacodynamics	Phase I / II / III
Safety Pharmacology	Phase I / II / III
Pharmacodynamic Drug Interactions	Phase I / II / III
Pharmacokinetic Studies	
Pharmacokinetic Drug Interactions (e.g. metabolic and plasma protein binding data).	Phase I / II / III
Absorption, Distribution, Metabolism, and Excretion	Phase I/II/III
Toxicokinetics	Phase I / II / III
Toxicology Studies	
Single dose Toxicity	Phase I / II / III
Repeat dose Toxicity	Phase I / II / III
Genotoxicity	Phase II / III
Carcinogenicity (if applicable)	Phase III
Reproductive and Developmental Toxicity	Phase III

Local Tolerance (if applicable)	Phase I / II / III
Other toxicity studies, if applicable (e.g. immunotoxicity, photosensitivity antigenicity, impurities, dependence/abuse liability, etc.).	Phase III
Literature References (if applicable)	Phase I / II / III

* 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**.**

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 SCTR Registration No.	√	√	√	√
2. IRB Approval (Including list of reviewed documents, version and dates for each documents)	√	√	√	√
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. Amendment Track of Changes	√			
11. List of Modified Documents (version, date)	√			
12. Proof of destruction			√	√
13. Delegation log		√		
14. Progress report or final report	√		√	√
15. Supporting Information (if applicable)	√			

Form no. 1

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:	
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

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

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 sites of the study separately)*

4.3

Have there been any serious difficulties in recruiting 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			2a. AG Years	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	☐ 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 REINTRO- DUCTION? ☐ YES ☐ NO ☐ NA
17. INDICATION(S) FOR USE		
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"

بسم الله الرحمن الرحيم

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 has GCP certification
☐ Yes ☐ No
IF Yes, attached 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 STUD` (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**

Form no.5						
Study Title						
SCTR Number						
Study Sponsor						
Protocol Number		Version		Date		
Investigator Brochure (IB)		Version		Date		
Investigational Medicinal Product Dossier (IMPD)		Version		Date		

Is the submitted study approved in FDA or EMA	□ No □ Yes; □ FDA. Registration/Identifier number: □ EMA. Registration/Identifier number:
Are the versions and dates of the submitted study documents the same as the documents approved by any FDA or EMA	□ 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 IMP registered in FDA or EMA	□ No □ Yes; □ FDA. Registration number: □ EMA. Registration 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 FDA or EMA	□ Yes □ No. More details are required:
KSA registration status of the IMP	□ No □ Yes, registration number: □ Under registration, application number:
Is the IMP involved in other clinical trial(s) submitted previously at SFDA	□ No □ Yes. SCTR number:
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 IMP considered an advanced medicinal product (cell and gene therapy)?	□ No □ Yes
Is the IMP considered a first in class novel medicinal product?	□ No □ Yes. More details are required:

Supportive Documents

The following supportive documents need to be submitted at the initial submission under "Supportive Documents":

1. Official study approval letter(s) of the SRA(s) (the list of reviewed documents with versions and dates should be included in the letter).
2. One or more official study approval letter(s) of the local IRB(s) in countries of the above SRA(s) (the list of reviewed documents with versions and dates should be included in the letter).
3. Full study assessment report(s) by the FDA or EMA (if applicable).

NB. Completing this form and submitting the above documents in addition to the latest versions (as submitted to FDA or EMA) of the study documents at the initial submission package may support 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;

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.
3. 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: