الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Regulations & Requirements for Conducting Clinical Trials on Drugs

Version 1.0

Date issued	08/07/2015
Date of implementation	08/07/2015

[SFDA Regulations & Requirements for Conducting Clinical Trials on Drugs]

Version 1.0

Drug Sector

Saudi Food & Drug Authority

Kingdom of Saudi Arabia

Please visit SFDA's website at http://www.sfda.gov.sa/En/Drug for the latest update

For Inquiries: Ct.drug@sfda.gov.sa

For Comments or Suggestions: Drug.Comments@sfda.gov.sa

Document Control

Version	Date	Author(s)	Comments
1.0	08/07/2015	Clinical Trials Department	Final

SFDA Regulations & Requirements for Conducting Clinical Trials on Drugs

1. According to Memo number (1794), issued on 20/1/1432 H, all clinical trials involving drugs, must be registered with the Clinical Trials Department/Drug Sector/SFDA by the researcher, the sponsor or the Contract Research Organisation (CRO) through the Saudi Clinical Trials Registry (SCTR), **knowing that the registration of a clinical trial does not indicate approval**. The registration processes should be in accordance with the SCTR guidance available at: https://sctr.sfda.gov.sa/Guidance.aspx .

2. The researcher, sponsor and CRO must adhere to the regulations of Research Ethics Code on Living Creatures issued by Royal decree number (M/59) on 14/9/1431 H.

3. It is mandatory to adhere to SFDA memo (E/15481 and E/15482) 13/5/1434 H in regards to the registration of local Institutional Review Boards (IRBs).

4. The researcher, sponsor and CRO must adhere to Good Clinical Practice (GCP) in accordance with the (ICH-E6) guideline.

5. According to the memo (E/9699) 23/4/1432 H, the sponsor or CRO must pay 15,000 Saudi Riyals for each submitted trial as an evaluation fee for the clinical trial, excluding phase IV from such fees.

6. Phase IV Trials:
   Clinical trials that are conducted on registered drugs at the SFDA to gather more data about the drug.

   A. The researcher, sponsor and CRO can start the clinical trial after obtaining local IRB approval. The SFDA should be notified by

registering the trial at the SCTR and sending the requirements in Table (1) to the Clinical Trials Department e-mail: ct.drug@sfda.gov.sa, within 20 working days after obtaining local IRB approval.

B. In the case of changing or adding a clinical trial site, the researcher, sponsor or CRO should notify the SFDA by sending the IRB approval via e-mail to the Clinical Trials Department.

C. It is mandatory to obtain SFDA approval before conducting clinical trials (on registered drugs), which are not phase IV trials, such as:

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

D. Concerning phase IV trials on unregistered direct purchased drugs, the researcher must adhere to memo (E/1811) 16/1/1436 H.

7. Phase II and III Trials:

A. It is mandatory to obtain SFDA approval before conducting phase II and III clinical trials, in accordance with the requirements in Table (1).

B. The researcher, sponsor or CRO must submit a progress report on the ongoing trials annually.

C. Clinical Trials Amendments:

- In case of non-substantial amendments, the SFDA should be notified through the annual progress report.

- In case of substantial amendment, it is mandatory to obtain SFDA approval before implementing any amendments, in accordance with the requirements in Table (2).

- In the case of urgent safety measures needed to be taken to protect trial subjects from immediate hazards, the SFDA allows such actions to be taken without prior approval. However, the SFDA must be notified as soon as possible.

- If the amendment contains changes or addition of a clinical trial site, the researcher, sponsor or CRO must adhere to the requirements in Table (2).

8. Importing Drugs/Study Materials Related to Clinical Trials:
   It is mandatory to obtain an importation license for the investigational drugs or study materials from the Importation Department at the drug sector of SFDA, in accordance to "Regulations and Requirements for Importing and Clearance of Medications and Medical Supplies for Clinical Trials" which published on the SFDA website.

9. Exporting Clinical Trial Bio-Samples:

   A. The researcher, sponsor and CRO must adhere to the regulation of Research Ethics Code on Living Creatures issued by Royal decree number (M/59) on 14/9/1431 H, which regulates bio-sample exportation.

   B. The researcher, sponsor or CRO must provide the SFDA with a copy of the local IRB exportation permission.

10. Clinical Trials Adverse Drug Reactions Reporting:
    A. It is mandatory to inform SFDA immediately about any Suspected Unexpected Serious Adverse Reactions (SUSAR) (**The form attached below**) as soon as possible, no later than 15 days. If the SUSAR is fatal or life threating, SFDA must be informed as soon as possible, no later than seven days in accordance with (ICH-E2A) guideline.

    B. It is mandatory to inform SFDA of any SUSAR that occurs internationally to an investigational drug involved in ongoing clinical trials in Saudi Arabia as soon as possible, within the same time limits.

    C. SUSAR should be reported through the National Pharmacovigilance Center via e-mail: npc.drug@sfda.gov.sa. The e-mail subject must be entitled "SUSAR Case".

    D. The sponsor or CRO must send SUSARs in (XML) format besides completing the (CIOMS-1) form (Attached below). In contrast, researchers may be exempted from reporting in (XML) format.

    E. The researcher, sponsor or CRO must send a Development Safety Update Report (DSUR) to the Clinical Trials Department /SFDA annually, in accordance with (ICH-E2F) guideline.

11. Completion, Termination or Suspension of Clinical Trials:
    The researcher, sponsor or CRO should inform SFDA within a maximum of 60 days with the need to attach proof of IRB notification. In addition to that, it is mandatory to submit the final report from the trial within one year from the end of the trial, in accordance with (ICH-E3) guidelines.

12. The Qualifications of the Clinical Trial Research Team:
    To ensure the safety of clinical trial subjects, the research team must provide proof of adequate training in GCP. It is important that the latest training must not exceed two years.

13. The period (timeline) needed to respond to the researcher, sponsor or CRO requests after completing all the required documents are:
    - 10 working days (maximum) for phase IV trials.
    - 30 working days (maximum) for phase III trials.
    - 60 working days (maximum) for phase II trials.

Table 1: Clinical Trial Requirements

Documents	Phase II / III	Phase IV
1. Arabic Headed Letter to the SFDA Including SCTR Registration No.	√	
2. IRB Approval.	√	√
3. Informed Consent Form (Arabic & English)	√	√
4. Trial Protocol.	√	√
5. Investigator Brochure.	√	
6. Case Report Form	√	
7. Labeling of the Study Drug.	√	
8. Clinical Trial Agreement.	√	
9. Financial Disclosure of Principal Investigator.	√	
10. Confidentiality Agreement.	√	
11. Certificate of Analysis for the Study Drug.	√	
12. GMP Certificate.	√	
13. Subjects Insurance	√	
14. Delegation/Authorisation Letter for CRO (if applicable)	√	√
15. CVs of Principal Investigator & Coordinator.	√	
16. Documents must be submitted as hard/soft copies	√	

Table 2: Amendment/Adding Site Requirements (Phase II & III)

Documents	Amendment	Adding Site
Arabic Headed letter to SFDA Including SCTR Registration No	√	√
Confidentiality Agreement		√
IRB Approval	√	√
Financial Disclosure of Principal Investigator		√
Clinical Trial Agreement		√
CVs of Principal Investigator & Coordinator (if applicable).		√
Summary of the Proposed Amendment	√	
List of Modified Documents (identity, version, date)	√	
Amendment Track of Changes	√	
Supportive Information (if applicable)	√	

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

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	