Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Saudi Food & Drug Authority

Guidance for Investor to Obtain a Clinical Trials Centers License

Version No. 3 - 1442 AH

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Chapter I: Introduction:

The Fifth Article of the Saudi Food And Drug Authority System issued by Royal Decree No. M/6 dated 25/1/1428 AH designated the centers for the follow-up of clinical trials within the Included facilities under the SFDA Supervision .

Investor Definition:

An individual or group of individuals (company) who wishes to establish clinical trials centers and performs one or all of the following activities on behalf of the trial sponsor: Follow up the application for approval of the clinical trial with SFDA, follow up the implementation of the trial with the agency executing, collect all the results of the trial and analyze them.

Chapter II: Field and Scope of Application

This guidance shall apply to the investor who wishes to obtain clinical trial centers after fulfilling all the documents and requirements of the concerned government entities, which are as follows:

Saudi Food & Drug Authority	Ministry of Investment	Saudi Arabian General Investment Authority

The Center's sub-commercial register in case of multiple branches or the main register

Chapter III: How to Submit a license Request for (new) clinical trial center.

Registration in the electronic system of the Saudi Food & Drug Authority (GHAD) for the purpose of obtaining a license.
Issuing the license fees if approved by the Licensing Department.
Establishments at the Saudi Food and Drug Authority.
Obtaining a license from the Saudi Food and Drug Authority.
Conduct an on-site inspection.

Expected duration for obtaining a license

Reviewing the establishment's application within two working days → Issuing of a clinical trial center license within one working day → Inspection of the establishment after issuing the license

Procedure for applying for licensing (new) clinical trials centers

Obtaining an investment license and commercial register

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Applying for the issuance of the license and pay the fees

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Obtaining a license for the Clinical trials Follow-up Center

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Conduct an on-site inspection

Chapter IV: Conditions and documents for obtaining a license

- Appointing a manager of the establishment, provided that the manager shall be a full-time Saudi and holds a bachelor's degree in one of the health or scientific disciplines.
- Appointing a responsible for clinical trial who shall meet the following conditions:
- To be full-time and hold an appropriate academic qualification of not less than a bachelor's degree.
- Experience in the same field of at least three years.
- The Center shall have a special seal.
- Finishing furnishing and equipping the Center with the necessary.
- Providing appropriate sources of information.
- **Placing an external panel for the Center that shall show the following**
  - The trade name of the Center is mentioned in the license.
  - Working hours.
  - Telephone and fax No.
  - * E-mail
- **The following shall be adhered to:**
  - Good foundations for practicing clinical trials issued by SFDA
  - No clinical trials without SFDA approval shall be verified.
  - The obligations agreed upon with the sponsor of the trials and stipulated in the contract between them shall not be deviated.
  - Appointing a trained and qualified employee and organize continuous training programs to develop their skills.
  - Documenting the duties and tasks of the Center in writing in each clinical trials with the trial sponsor.
  - Verifying that the responsibilities transferred to the Center from the sponsoring company are carried out effectively and efficiently.

- Providing training programs for agency employees executing clinical trials that suit the conducted clinical trials, provided that it includes the foundations of good practice for clinical trials.
- Archiving all documents and correspondence related to the duties and tasks assigned to the Center in accordance with written work procedures, and maintaining the confidentiality and privacy of information.
- Commitment to the law of ethics of scientific research on living creatures.

Documents:

- A copy of the lease contract or title deed of the establishment.
- A clear and accurate computer sketch of the location of the establishment to be established showing the name of the city, the name of the neighborhood, the names of the streets, and the names of the establishments adjacent to the location, and the phone numbers of the applicant shall be written on the sketch.
- a copy of the Center's sub-commercial register in case of multiple branches or the main register
- A copy of the foreign investment license (for foreigners).
- A copy of the national ID of the establishment manager.
- A copy of the academic certificate of the establishment manager.
- A copy of the national ID/Resident of the clinical trial responsible.
- A copy of the CV, certificates and experiences of the person responsible for clinical trials (shall be certified by the Kingdom's embassy for foreigners).
- A list of the Center's work procedures.
- Special undertakings for establishment manager and clinical trials responsible.

Chapter V: Mechanism for renewing the license to practice the activity

- Access the e-services portal of the SFDA through the link.
- Issuing the fees for the license to practice the activity in case of the approval of the Inspection Department at the SFDA.
- Obtaining a license to practice the activity by the SFDA.
- Visit the establishment by SFDA inspectors to ensure that the Clinical trials Follow-up Center applies the technical requirements.

Chapter VI

License Duration and Fees

License Duration	fees
Years 5	SFDA receives a fee of (5,000 riyals) for the services it provides in the field of follow-up clinical trials

Chapter VII: Violations and Penalties

The committees formed in accordance with the Private Health Institutions Law issued by Royal Decree No. M/40 dated 03/11/1423 AH, defined the violations of this law:

- Warning
- A fine of SAR 100,000 .

- Close the establishment for a period of no more than 60 days
  License revocation
- The a fine and suspension penalties can be issued together, and the Penalties Committee, consisting of relevant authorities, may review the cases and approve penalties according to the requirements of the violation.

The Executive Regulations of the Pharmaceutical Establishments and Products Law No. M/108 dated 26 /1/1442 AH may be reviewed using the following link:

Chapter VIII: FAQs

Q: Why is registration in the Pharmaceutical Establishments Registration and Licensing System important?

Registration in the pharmaceutical establishments' registration and licensing system is an important matter for several reasons:

1. Issuing a license to practice activity for a pharmaceutical establishment.

2. Building a database for all pharmaceutical establishments and their products in the Kingdom of Saudi Arabia.

3. Improving communication between SFDA and local pharmaceutical establishments.

4. Enabling pharmaceutical establishments to update their data continuously, besides facilitating the process of communicating with SFDA as a supervisory body over these establishments.

Q: Who does register in the electronic establishment licensing system?

The registration process for a pharmaceutical establishment shall be carried out by a responsible and authorized person by the establishment who has sufficient technical information to complete the technical and administrative registration steps.

Q: When could the application for a license to practice activity with SFDA submitted?

A license to practice the activity shall be submitted via the electronic system.

Q: When shall the investor apply to renew the license for practicing the activity?

The establishment shall apply for the license renewal 6 months before the expiration date of the valid license.

Q: If the investor has more than one pharmaceutical establishment, are they registered as one in SFDA registration and licensing system?

The investor shall register each pharmaceutical establishment separately (two independent applications).

Q: Is it necessary to update the file of the registered establishment?

Yes, the data, such as the commercial registration, industrial license, or contact information, shall be updated when needed.

Q: What contact addresses can I call if I need help?

If they need assistance, applicants can call the unified number 19999 and send to an e-mail to Est-license.drug@sfda.gov.sa

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www.sfda.gov.sa