Assessment of Medical Products for Pharmacological Research and Clinical Studies of Drugs

This service enables clients to apply for the receipt, assessment and approval of medical products for medical research and clinical studies of drugs, in accordance with the 'Guidelines for Conducting Clinical Trials of Medicines and Medical Devices According to Good Clinical Practices' of 2017.

Department name
Drug

Sector
Health Regulation

Main Service
Medical, Pharmaceutical and Drug Licencing and Registration

Service Code
110-04-010-000

Service Classification
Transactional

Variation / Auxiliary
Variation

Service Type
Government to Business

Service Process

01 The client must submit the application online.

02 The application must be submitted with the required documents as per Article 47 of 'Guidelines for Conducting Clinical Trials with Investigational Products and Medical Devices 2017'.

03 The documents and the application will be reviewed by the officer in charge for initial approval.

04 The Regulatory Committee at the Ministry of Health and Prevention will assess the application.

05 An approval letter will be issued to conduct the clinical trial.

Required Documents

New Submission:

- **Administrative documentation:**
  - Payment receipts
  - Cover Letter: The applicant shall submit a signed cover letter as an attachment. The cover letter should contain, the protocol number and title and a full list of all essential documents accompanied the proposed clinical trial
  - List of Regulatory Authorities and Ethics Committees apart from UAE ones, to which the application has been submitted and information about their decisions
  - List of all study centers and investigators planned to participate in the UAE
  - Power of Attorney or Agreement authorizing the applicant of the submission on behalf of the sponsor, in cases where the applicant is not the sponsor of the trial
  - Evidence of registration of the clinical trial on the ClinicalTrials.gov website
  - Certified copy of the CRO license granted by the MOHAP
- **Information about subjects:**
  - Information for the patient/ subject and Informed Consent Form (in English; in Arabic and any other language that will be used)
  - Description of the procedures for obtaining informed consent from a legal representative, where applicable
  - Any other information that will be used for subject enrollment and/ or presented to patients before or during the course of a study (in English and in Arabic). Project-specific documents for the trial subjects could be any of the following:
    - Patient diary
    - Patient card
    - Adverse events diary
    - Scales and questionnaires (including quality of life questionnaires)
    - Calendar(s)
    - Patient advertisement
    - Additional trial information given in writing and / or multimedia technology to the subject
    - Pictures of any materials intended to be given to the patient
- **Documentation concerning the trial protocol:**
  - Study protocol and all current amendments, developed in accordance with ICH-GCP requirements
  - Peer review of the scientific value of the trial, where available
  - Protocol pages signed by the sponsor and by the Investigator from each study site participating in the trial
  - Case report form
- **Documentation about the medicinal product tested:**
  - Investigator's brochure (issued not later than one year before application submission)
  - Summary of product characteristics, when applicable
  - Outline/ summary of all currently active clinical trials with the investigated product
- **Documentation about the technical requirements and the staff:**
  - Description of the equipment and/ or the technical requirements necessary to perform the protocol procedures
  - Certificates for external quality assessments (for the local laboratories) or certificate for successful accreditation procedure (for the Central laboratories). Those documents are submitted for each laboratory that will be participating in the study procedures
  - CV and/ or other documents confirming the qualification, experience and training of study staff members (investigator and sub-investigators)
  - GCP training certificates of all study staff members
  - Financial disclosure of principal investigator
  - Confidentiality agreement of principal investigator
  - Documents, confirming the accreditation of the institution
- **Data about funding and the administrative organization of trials:**
  - Insurance covering the liability of the sponsor and the principal investigator(s) in case of property or non-property damages caused to the subjects related to their participation in the trial
  - Provision for compensation or a sample agreement between sponsor and study subjects, when such compensation is considered
  - Sample agreement between sponsor, institution and investigator, defining terms and conditions of conducting the clinical trial
  - Written approval statement by the director of the institution regarding permission for conducting the study (if applicable)
  - Information about a clinical trial finance resource in case the sponsor is a not-profit organization
  - Pre site assessment report signed by the sponsor or its representative
- **Additional documents:**
  - Investigational Product Dossier (IPD)
  - Statement from the manufacturer, in all cases when the investigational product has a market authorization
  - Copy of the manufacturing authorization for medicinal products that are in the process of research and development, if the investigational product does not have a marketing authorization
  - Document to certify the conformity of the manufacturing conditions of the active substances of biological origin, control and storage standards to be equivalent to the requirements of the GMP for medicinal products in a process of research and development
  - Results/ reports from viral safety studies, where applicable
  - Examples of drug labels in English & Arabic, according to the requirements to the information on the packaging of medicinal products used in clinical trials
- **Re-submission (substantial amendment):**
  - Cover letter
  - Application form
  - Summary of the proposed amendment
  - List of modified documents with their effective dates and version numbers
  - Pages from the amended documents according to Appendix 02 (initial submission) with previous and new wording
  - Comments of any novel aspect of the amendment (if any)

Requirements & Conditions

- The approval of the regulatory committee at the Ministry of Health and Prevention (RCMOHP) is required before clinical trials can commence.

Service Channels

MOHAP Website: www.mohap.gov.ae

Resources

- Guidelines for Conducting Clinical Trials with Investigational Products and Medical Devices 2017

FAQs

None.

Average Service Time
90 calendar days

Payment channels
E-Payment

Target Audience
Doctors, medical store, marketing offices, local manufactures, government hospitals, private hospitals, pharmaceutical companies, government universities, private universities, CRO (contract research organizations)

Service Locations
- MOHAP Website
  www.mohap.gov.ae

Related Services
This service is not linked to any other services

Service Bundle
This service is not linked to any bundles

Contact Details
Email:
drugreg.inquiries@mohap.gov.ae

Service Fees

AED 5000

Sustainable Development Goals

Notes

None