Guidance on
Clinical Trial Submission Process

(Version 1-2020)

Ministry of Public Health
Health Research Governance Department

2020

Purpose

This Guidance document clarifies the mechanism of clinical trial submission in the State of Qatar. It helps sponsors, investigators and health care professionals to comply with national regulations and laws.

The objective of the Guideline is to provide sponsors and investigators seeking authorization to conduct a clinical trial in the state of Qatar with guidance to support the protection of clinical trial subjects and contribute to the high standards of excellence in research. This document specifies procedures for obtaining authorization to initiate a clinical trial in Qatar.

It is important to note that MOPH reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the research and governance department of MOPH to adequately assess the safety, efficacy or quality of an investigational product. MOPH is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

2. ABBREVIATIONS /DEFINITIONS

2.1 Abbreviations

CTA	Clinical Trial Application
GCP	Good Clinical Practice
ICF	Informed Consent Forms
ICH	International Council for Harmonization
IRB	Institutional Review Board

MOPH	Ministry of Public Health
ADR	Adverse Drug Reaction

2.2 Definitions

Adverse Drug Reaction: Any noxious and unintended response to a drug that is caused by the administration of any dose of the drug.

Adverse Event: Any unfavorable medical occurrence including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

Clinical Trial: - Per WHO definition "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioral treatments, process-of-care changes, preventive care, etc.

Pre-Clinical studies: Before a drug candidate can begin the clinical trial process, it is tested by its manufacturer through pre-clinical studies for toxicity, otherwise known as its ability to cause serious harm, as well as pharmacokinetic information. Dosing is also tested during pre-clinical research period. This is done using both in vitro (on cell cultures) and in vivo (on animals) methods, as well as occasionally with the help of computer models.

Phase I: Clinical trials designed to determine the pharmacokinetics/pharmacological actions of the drug and the side effects associated with increasing doses. Drug interaction studies are usually considered as Phase I trials regardless of when they are conducted during drug development. Phase I trials are generally conducted in healthy

volunteers but may be conducted in patients when administration of the drug to healthy volunteers is not ethical.

Phase II: Clinical trials to evaluate the efficacy of the drug in patients with medical conditions to be treated, diagnosed or prevented, and to determine the side effects and risks associated with the drug. If a new indication for a marketed drug is to be investigated, then those clinical trials may generally be considered Phase II trials.

Phase III: Controlled or uncontrolled trials conducted after preliminary evidence suggesting efficacy of the drug has been demonstrated. These are intended to gather the additional information about the clinical efficacy and safety under the proposed conditions of use. Phase III b Clinical Trial: is a clinical trial of a Licensed Product in human patients, which provides for product support (i.e., a clinical trial which is not required for receipt of initial Marketing Authorization, but which may be useful in providing additional drug profile data or in seeking a label expansion) commenced before receipt of Marketing Authorization for the indication for which such trial is being conducted.

Phase IV: All studies performed within the approved indication after the drug has been approved by the regulator for the market. These studies are often important for optimizing the drug's use. They may be of any type but must have valid scientific objectives. Commonly conducted studies include safety studies and studies designed to support use under the approved indication, e.g., mortality and morbidity studies, or epidemiological studies.

Clinical Trial Application: an application to a Regulatory Authority for purposes of requesting the ability to start or continue a clinical trial and any amendments or supplements to such application.

Clinical Trial Site: The location where trial-related activities are actually conducted.

Drug: A drug [that is (i.e.) pharmaceuticals, biologics, gene therapies, blood products, vaccines and radiopharmaceuticals] for human use that is to be tested in a clinical trial.

Good Clinical Practices: A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected

Informed Consent Form: A document that expresses certain elements, as detailed in the ministry basic policy, that describes: a) The risks and anticipated benefits to his or her health arising from participation in the clinical trial; and b) All other aspects of the clinical trial that are necessary for that person to make the decision to participate in the clinical trial.

Institution/Investigator-initiated Clinical Trial: A clinical trial that is initiated and conducted by an institution or an individual investigator. For such trials, the institution or investigator is the sponsor of the trial and must fulfill all the regulatory obligations of the sponsor as outlined in the Regulations.

Investigator's Brochure: A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects".

Sponsor: An individual, corporate body, institution or organization that conducts the clinical trial. The sponsor must comply with its obligations as set out in the MOPH regulations and the good clinical practices for the proper use of the drugs, drug labelling requirements, record keeping, submission of information, reporting of ADRs, and trial discontinuation reporting requirements.

Investigator: A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Principal Investigator: A person responsible for the management and integrity of the design, conduct, and reporting of the research project and for managing, monitoring, and ensuring the integrity of any collaborative relationships.

Institutional Review Board (IRB) : As detailed in the ministry basic policy, an independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

The Data and Safety Monitoring Board (DSMB): is an independent group of experts that advises NIDCR. The members of the DSMB serve in an individual capacity and provide their expertise and recommendations.

3. GUIDELINE STATEMENTS

The Ministry of Public Health acknowledges the guidelines on good clinical practice (GCP). The GCP is an internationally accepted standard for designing, conducting, recording, and reporting clinical trials, ensuring the protection of the rights, safety and well-being of clinical trial subjects

The sponsor of a clinical trial and the investigator shall ensure that the clinical trial is conducted in accordance the principles of GCP that ensure the protection of the rights, safety and well-being of clinical trial subjects and other persons. Sponsors are required by the national regulations to obtain IRB approval for each clinical trial site prior to commencing the trial at that site.

In a clinical trial the rights, safety, dignity and well-being of subjects should be protected, and the data generated should be reliable and robust. The interests of the subjects should always take priority.

The role of registered Institutional Review Boards (IRBs) is detrimental to provide the ethical review of a clinical trial. IRBs have an important role in the oversight of the conduct of clinical trials.

4. SCOPE AND APPLICATION

The information provided in this Guidance involves clinical trials that evaluate newly developed drugs (pharmaceuticals products and/or biologics and radiopharmaceuticals) and medical devices and other academical studies to compare treatments and medical procedures to be tested in in human subjects.

Per this guidance, A drug clinical trial is an investigation intended to discover or verify the clinical, pharmacological or pharmacodynamics effects of the drug, identify any adverse events in respect of the drug, study the absorption, distribution, metabolism and excretion of the drug, or ascertain the safety or efficacy of the drug.

A medical device clinical trial is a systematic investigation or study in human subjects, undertaken to verify the safety, effectiveness and performance of a device, under normal conditions of use.

This Guidance document applies to all sponsors (e.g., industry, academic, contract research organization, etc.) conducting the following clinical trials:

- **Clinical trials of a product or medical device that are not authorized for sale in Qatar including clinical trials for Phases I through IV of drug development and comparative bioequivalence studies and specific studies for biosimilars.**

- Clinical trials for marketed drugs/ medical devices where the proposed use of the drug or the medical device is outside the approved parameters of the market authorization in Qatar.

5. GENERAL PRINCIPLES

Prior to getting a support letter by MOPH, the clinical trial protocol must be reviewed and approved by IRB as described in the Basic Policy "*Policies, Regulations and Guidelines for Research Involving Human "*

-Every Clinical Trial shall be conducted under the responsibility and supervision of principal investigator.

-The clinical trial should be conducted only at site specified in the MOPH support letter for conducting an identified Clinical Trial.

-Where a Clinical Trial is discontinued, the holder, of the MOPH written determination for conducting an identified Clinical Trial, shall forthwith inform the MOPH of the discontinuance and the reasons therefor.

-In case there is a change of principal investigator during a Clinical Trial, the holder of the MOPH written determination for conducting an identified Clinical Trial shall timely notify MOPH of the change and shall furnish to MOPH qualification document for the new investigator.

-No person, other than the principal investigator, or investigators identified in the CTA approved by MOPH, shall treat a subject or administer any test materiel to him/her.

-In an emergency situation, exceptions to the above statement is accepted: physician or dentist may, in the absence of principal investigator, or investigators identified in the CTA approved by MOPH, can treat a subject if it is in the interest of the subject.

6. HOW TO SUBMIT A CLINICAL TRIAL FILE TO THE MOPH

6.1- Clinical trial registration

Irrespectively of the type, sponsor are required to register all their clinical trials on the publicly accessible registry accepting international clinical trial information and recognized by the World Health Organization (WHO): https://clinicaltrials.gov/ as well as on the MOPH registration portal

Sponsors are required to provide MOPH with the reference number assigned to the trial upon registration on clinicaltrial.gov

6.2 – Review by MOPH

The sponsor or sponsor-representative conducting a clinical trial in Qatar shall submit a complete CTA package to MOPH, with the required essential documents as per GCP.

. The sponsor needs to get the IRB approval, the DSMB approval (if needed) prior to get the MOPH Research and Governance Department support determination.

6.3. Submission process of a Clinical Trial File to MOPH

The sponsor must submit a clinical trial application **prior** to the initiation of the trial. CTAs are required for human clinical trials using drugs or medical devices, including clinical trials in Phases I through IV of drug development and comparative bioequivalence studies, and medical devices investigation; as well as trials involving marketed drugs/ medical devices , where the proposed use of the drug / medical device or medical procedures is outside the approved parameter of the market authorization (ex: change in the indication of use, change in the target population, change in dosage, change in route of administration) or outside the accepted international standard of care protocols for the medical procedures.

Sponsors must conduct all clinical trials in accordance with the principles of ICH-GCPs and obtaining IRB approval.

Sponsors will submit, when applicable, a complete file to the MOPH. The IRB approval letter and DSMB review (when needed) should always be submitted prior to MOPH final approval.

After satisfactory reviewing the documents, the Ministry of Public Health will issue a "support letter" within forty-five (45) days from the date of receiving the complete file. This letter is to document that the MOPH support and allow the initiation of the trial.

In case a longer period is needed for the review, the MOPH will notify the sponsor or representative.

In case of incomplete file, or additional requested document a stop clock will be applied until completion of the documentation/files.

In case there is no response from the sponsor to the MOPH request after 6 months the file will be closed, and a closure notification will be sent to the sponsor.

For Phase I and II Clinical Trials, the sponsor is invited to request a Pre-Clinical Application Meeting.

6.3.1. Pre-Clinical Trial Application (CTA) Consultation Meeting

MOPH invites sponsors/ investigators to request a pre-submission consultation meeting. Such consultations are recommended for new investigational product or applications that will include complex issues.

The pre-submission consultation meeting provides an opportunity for the sponsor to present relevant data, discuss concerns and issues regarding drug development. It also gives MOPH an opportunity to provide guidance on the acceptability of the proposed trial(s). Sponsors and the principal investigator(s) who will be involved in the proposed trial(s) in Qatar should attend the meeting, other investigators are invited to intend

6.3.1.1. Request for a Pre-Clinical Trial Application Meeting

Requests for a pre-CTA consultation meeting should be submitted by the sponsor to the Research and governance Department at the MOPH in the form of cover letter, in electronic format to clinicaltrial@moph.gov.qa

The cover letter should be accompanied by the following information:

- A brief synopsis of the proposed study.
- Enough information for MOPH to assess the utility of the meeting and Identify the appropriate staff necessary to discuss the eventual information.

The MOPH Research and Governance Department shall acknowledge the request for consultation in a timely manner. If the MOPH R&G Department accepts the request, a confirmation will be sent, with a request for a Pre-Clinical Trial Application documents (see section 4.2.1.2)

Upon reception of the Pre-Clinical Trial Application documents, the MOPH will propose a date for the meeting within a maximum of 30 days from the reception of the complete file.

6.3.1.2. Pre-Clinical Trial Application (CTA) document to be submitted

The Information Package, which should be submitted consist of:

1) Proposed agenda, any prepared slides and list of attendees
2) a brief summary of all available data including (Not applicable for marketed product and devices)
    - listing of completed nonclinical and clinical studies,
    - results of completed nonclinical and clinical studies
    - an outline of the observed toxicological manifestations and a discussion of their impact on the use of the drug in humans,
    - Listing of toxicological studies
    - an outline of the observed adverse events and a discussion of potential safety problems
3) Regulatory status of the drug/ medical device(I.E : US FDA approval or other approvals) .
4) Details of the proposed clinical trials to be conducted in Qatar, within the scope of the intended CTA, including when applicable:

    i) a statement of trial design,

    ii) parameters, values, ranges or limits for indication(s) and clinical use(s), patient study population(s) and routes of administration,

iii) parameters, values, ranges or limits for dosage form(s), dosage regimen(s) and formulation(s),

iv) proposed procedures and/or criteria for patient monitoring, clinical efficacy and safety assessments, alternative treatments, premature patient discontinuation and other considerations, as appropriate.

5) A summary of significant Quality (Chemistry and Manufacturing) aspects of the drug when applicable.

Should, the pre-CTA submitted documents be found not sufficient, the MOPH may request to reschedule or postpone the meeting to allow the sponsor to submit additional documentation. Please note that the MOPH Research and Governance Department reserves the right to modify or the proposed agenda as it sees fit to better achieve the stated goals of the meeting.

The sponsor should prepare and send to the Research and Governance department of MOPH the minutes of the meeting and conclusions of the consultation meeting within 7 days of the consultation date. The final minutes approved by MOPH will be included in the final CTA file.

6.3.2 CLINICAL TRIAL APPLICATION

For conducting a clinical trial in Qatar, the sponsor or representative must register and submit a clinical trial file to the MOPH.

Clinical Trial documents must be submitted in Via MOPH web portal for clinical trial submission link to the portal by email to clinicaltrial@moph.gov.qa

A hard copy shall be submitted upon request to: Ministry of Public Health, Research and Governance Department P.O.Box: 42, District: Al Rumaila, Zone No.: 21, Street Name: Onaiza , Street No.: 222

The MOPH shall review the submitted application within **45 days**. In case longer time is needed the MOPH will notify the sponsor or representattive.

As deem necessary, the MOPH Research and Governance departement may request

a meeting with the Sponsor and/or the Principal Investigator.

The clinical trial may commence, only after the MOPH issues a support letter to attest that the clinical investigations may begin; or on earlier notification as applicable.

The clinical Trial support letter is valid for the period of the study conditioned by submission of an annual interim study report. Unless specificly requested by the MOPH.

A sponsor of a multi-center clinical trial may ship investigational products to participating institutions/ investigators in Qatar once the institution/investigator in Qatar has the Pharmacy departemnet shipment authorization. The investigational product must be safely stored and adequately labeled.

An investigator may not administer an investigational new drug to human subjects until the MOPH support letter to conduct a clinical trial is obtained.

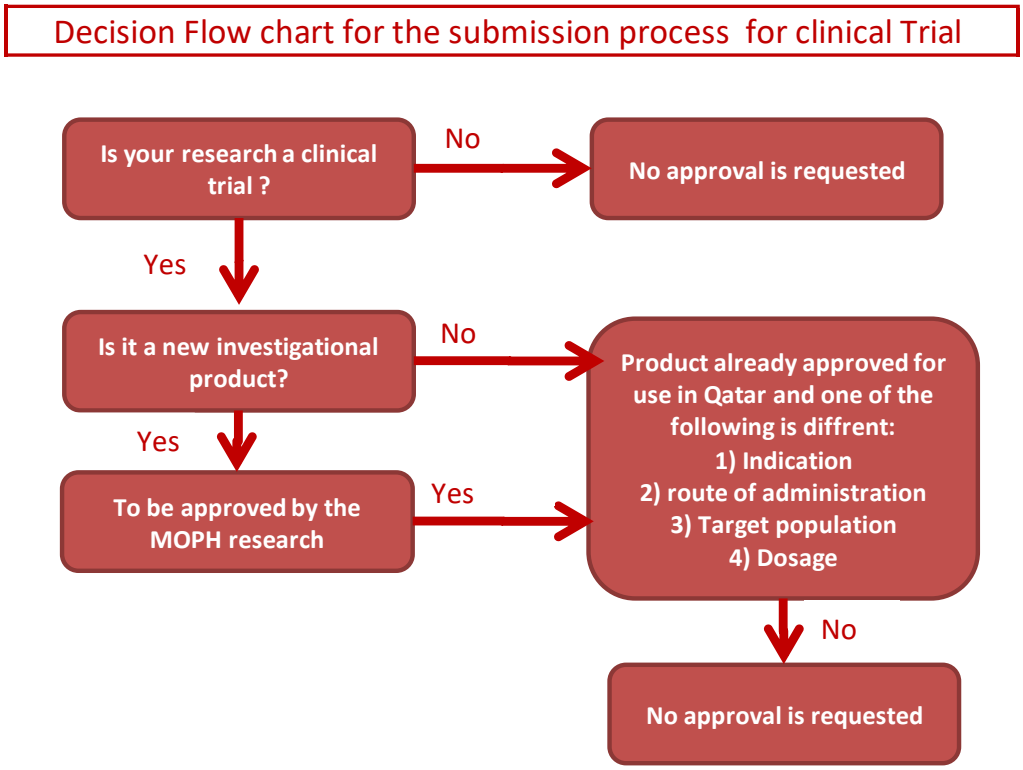
In case of major changes to the CT protocol after approval , the sponsor should notify the departement of research of MOPH. The Research and Governance departement will review the protocol and initiate an updated support letter. When several submissions with minor amendments are expected within a short period, sponsors are encouraged, to include all amendments in a single submission.

A stop clok will be applied to the review time in case additional documents or clarification is requested by the MOPH research departement.

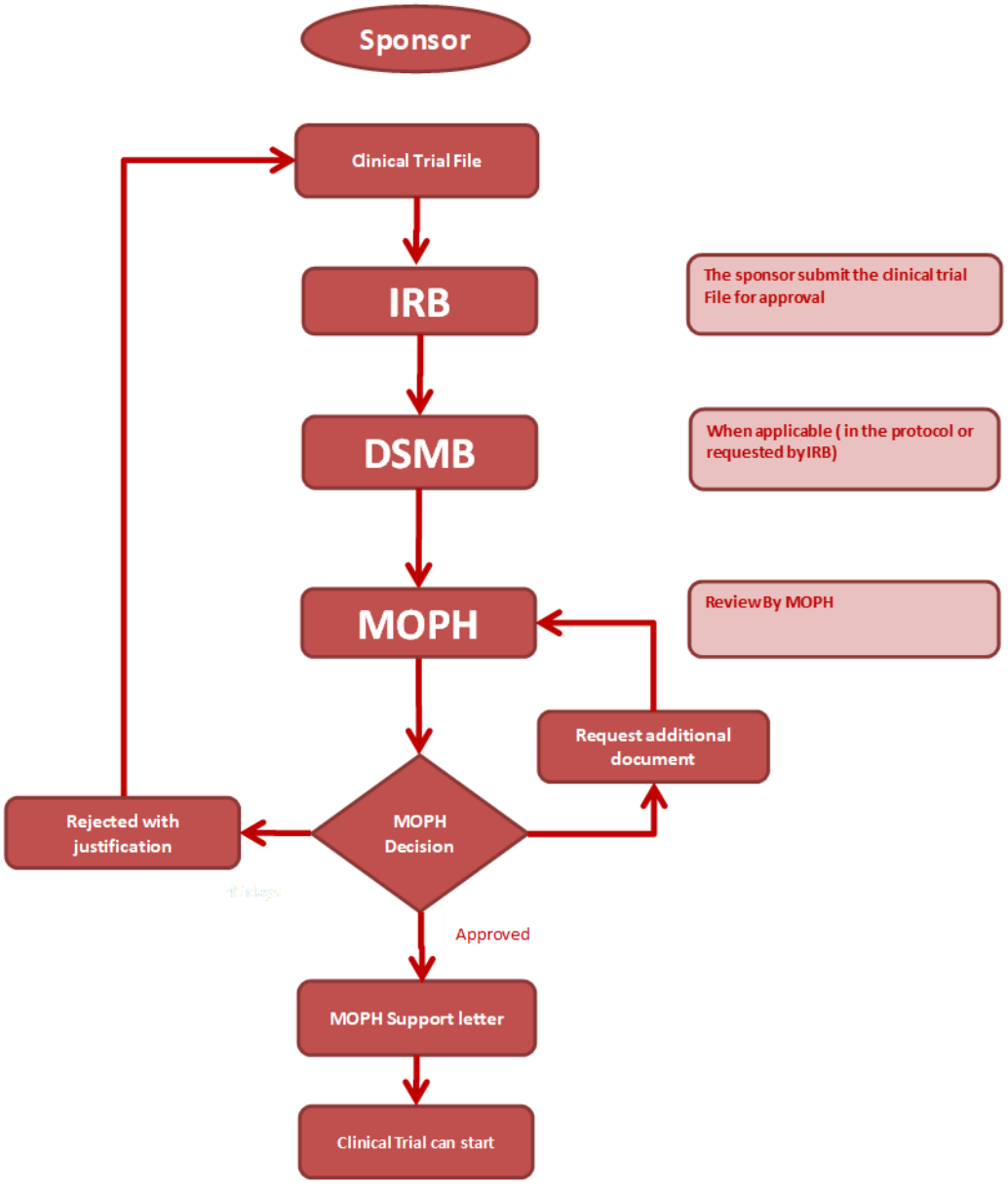
In case of non response of the sponsor in the applicaple time line and /or without justification of the delay, the process will go back to the start point.

In case there is no reponse from the sponsor to the MOPH request after 6 months the file will be closed and a closure notification will be sent to the sponsor.

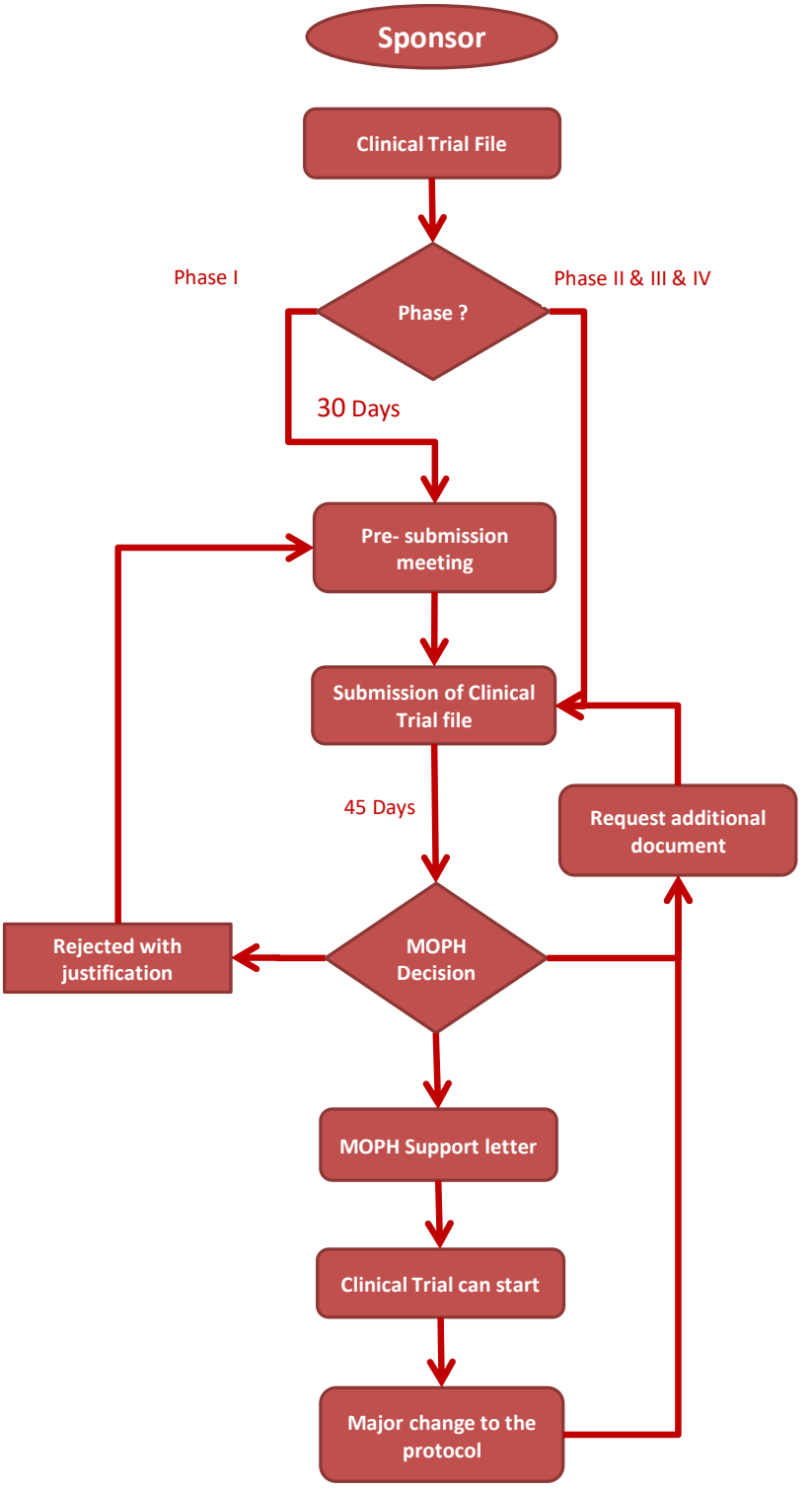
6.3.3 . FLOWCHARTS FOR CLINICAL TRIAL SUBMISSION PROCESS



General Review of Clinical Trial in the State of Qatar



MOPH Review of Clinical Trial in the state of Qatar



6.3.4. Clinical Trial Application Requested Documents

In order to request the MOPH support letter, the sponsor should submit the following documents in electronic format directly into the web portal after filling the requested information. The check list (Annex 1) should be completed and added to the submission file:

1) Investigator's brochure / additional safety data whenever available.
2) Available safety literature
3) Protocol Synopsis or Submission Rationale / Brief Summary of the Drug Product
4) Signed protocol and amendment if any
5) Sample of case report form (CRF)
6) Information regarding refusals by regulatory authorities outside Qatar
7) Information given to trial subject
   -Informed Consent Form (Arabic/ English/Other language when applicable)
   -Any additional supportive document to the consent and recruitment process
8) Insurance statement
9) Signed agreement between the parties involved in the trial (i. e CRO, central laboratories...etc.)
10) Dated, documented approval/ favorable opinion of IRB
11) Signed and dated Curriculum vitae and/ or other relevant documents evidencing qualifications of investigator(s)
12) Approval of the new investigational product by the Pharmacy Department of MoPH (investigational product not approved for use in Qatar)
13) Samples of the label(s) attached to new investigational product container (s)
14) Instructions for handling of investigational product(s) and trial related material (if not included in protocol or investigator's brochure)
15) Decoding procedures for blinded trials

16) Masters randomization plan (if not included in the protocol)
17) Pre-trial monitoring report or feasibility study to document that the investigation site is suitable for the trial.
18) Analytical/ Quality documents for drug development trials as applicable:

- Quality Overall Summary (QOS)
- Normal value(s) range(s) for medical / laboratory / technical procedure(s) and / tests included in the protocol.
- Medical/ laboratory/ technical procedures and test certification, accreditation or validation certificate (where required).

6.3.4.1. Additional document for Multicenter clinical trial cx

19) Letter signed by the sponsor containing the list of competent authorities to which the application has been submitted and details of decisions.
20) Refusal by regulatory authority or EC/ IRB in other countries (please communicate reasons for refusal).

6.3.4.2. Additional documents / information for the <u>Clinical trials involving medical devices if not included in the Investigator Brochure</u>

• Classification of device

• Brief description of device and its intended use / Design drawings, diagrams of operation and diagrams of components, subassemblies, circuits etc., including descriptions and explanations necessary to understand the aforementioned drawings/diagrams.

• Identification of any features of design that are different from a previously similar marketed product (if relevant).

• Summary of experience with any similar devices manufactured by the company including length of time on the market and a review of performance related complaints.

• Risk benefit analysis to include identification of hazards and estimated risks associated with the manufacture (including factors relating to device design, choice of materials, software) and the use of the device (ISO 14971), together with a description of what actions have been taken to minimize or eliminate the identified risk.

• Description of materials coming into contact with the body, why such materials have been chosen, and which standards apply (if relevant).

• Identification of any special manufacturing conditions required and if so, how such requirements have been met.

• A description of the methods of manufacturer, in particular as regards sterilization and identification of packaging used for sterilization of device.

• The reports of quality controls tests, etc.

• Instructions for use.

• Photograph (preferably in color)/diagram/sample if appropriate.

• Identification of any tissues of animal origin. including details of sourcing and collection of the animal tissue(s) prior to manufacturing operation; and details with regard to validation of manufacturing procedures employed for the reduction or inactivation of unconventional agent; and any other risk management measures that have been applied to reduce the risk of infection.

During the review process, MOPH keeps the right to request further information.

6.4. Protocol's Amendment and Changes:

Changes to existing protocol(s) should be identified as **"Protocol Amendment: Change in Protocol".**

The sponsor holder of a clinical trial support letter is expected to submit a protocol amendment in cases when there are changes in the existing protocol that significantly affect safety of subjects, scope of the investigation, or scientific quality of the study. Such amendment should contain a brief description of the change and reference to the submission that contained the original protocol.

For example, changes requiring an amendment to a previous application may include: Any increase in drug dosage or duration of exposure of individual subjects to the drug beyond that described in the current protocol, or any significant increase in the number of subjects under study.

Any significant change in the design of a protocol (such as the addition or elimination of a control group).

Addition of a new test or procedure intended to improve monitoring for, or reduce the risk of, a side effect or adverse event; or elimination of a test intended to monitor safety.

Note: a protocol change intended to eliminate an apparent immediate hazard to human subjects may be implemented immediately, provided that the MOPH is subsequently notified by a protocol amendment and the reviewing IRB is also notified.

Addition of a new investigator should be identified as **"Protocol Amendment: New Investigator"**: The sponsor holder of MOPH support letter is expected to submit a

protocol amendment when a new investigator is added to carry out a previously submitted protocol. The amendment should include the investigator's name, the qualifications to conduct the investigation, and any reference to the previously submitted protocol, if relevant.

Acknowledgment

A draft of the present document has been shared with national stakeholders and we acknowledge their valuable feedback and comments in the building of the present guideline.

This document has also been informed by:

- FDA, Investigational New Drug (IND) Application
- FDA, IND Application Reporting: Protocol Amendments
- Health Canada guidance document For Clinical Trial Sponsors: Clinical Trial Applications.
- MHRA Guidance on legislation, Clinical investigations of medical devices – guidance for manufacturers September 2018

Annexe 1: Check list for the submitted documents for Clinical Trial Application file

1) Investigator's brochure / additional safety data whenever available.

Yes	
No	
Not Applicable	
Comments	

2) Available safety literature (if not included in the investigator brochure)

Yes	
No	
Not Applicable	
Comments	

3) Protocol Synopsis or Submission Rationale / Brief Summary of the Drug Product

Yes	
No	
Not Applicable	
Comments	

4) Signed protocol and amendment if any

Yes	
No	
Not Applicable	
Comments	

5) Sample of case report form (CRF)

Yes	
No	
Not Applicable	
Comments	

6) Information regarding refusals by regulatory authorities outside Qatar

Yes	
No	
Not Applicable	
Comments	

7) Informed Consent Form (Arabic/ English/Other language when applicable)

Yes	
No	
Not Applicable	
Comments	

8) Any additional supportive document to the consent and recruitment process

Yes	
No	
Not Applicable	
Comments	

9) Insurance statement

Yes	
No	
Not Applicable	
Comments	

10) Signed agreement between the parties involved in the trial (i. e CRO, central laboratories...etc)

Yes	
No	
Not Applicable	
Comments	

11) Dated, documented approval/ favorable opinion of IRB

Yes	
No	

Not Applicable	
Comments	

12) Data and safety monitoring plan

Yes	
No	
Not Applicable	
Comments	

13) Signed and dated Curriculum vitae and/ or other relevant documents evidencing qualifications of investigator(s)

Yes	
No	
Not Applicable	
Comments	

14) Approval of the new investigational product by the Pharmacy Department of MoPH

Yes	
No	
Not Applicable	
Comments	

15) Samples of the label(s) attached to new investigational product container (s)

Yes	
No	
Not Applicable	
Comments	

16) Instructions for handling of investigational product(s) and trial related material (if not included in protocol or investigator's brochure)

Yes	
No	
Not Applicable	
Comments	

17) Decoding procedures for blinded trials

Yes	
No	
Not Applicable	
Comments	

18) Masters randomization plan (if not included in the protocol)

Yes	
No	
Not Applicable	
Comments	

19) Pre-trial monitoring report or feasibility study to document that the investigation site is suitable for the trial.

Yes	
No	
Not Applicable	
Comments	

20) Analytical/ Quality documents for drug development trials as applicable:

Yes	
No	
Not Applicable	
Comments	

Additional document for Multicenter clinical trials

19) Letter signed by the sponsor containing the list of competent authorities to which the application has been submitted and details of decisions.

Yes	
No	
Not Applicable	
Comments	

20) Refusal by regulatory authority or EC/ IRB in other countries (please communicate reasons for refusal).

Yes	
No	
Not Applicable	
Comments	

Additional documents / information for the Clinical trials involving medical devices if not included in the Investigator Brochure

• Classification of device

Yes	
No	
Not Applicable	
Comments	

• Brief description of device and its intended use.

Yes	
No	
Not Applicable	
Comments	

• Identification of any features of design that are different from a previously similar marketed product (if relevant).

Yes	
No	
Not Applicable	
Comments	

• Summary of experience with any similar devices manufactured by the company including length of time on the market and a review of performance related complaints.

Yes	
No	

Not Applicable	
Comments	

• Risk benefit analysis to include identification of hazards and estimated risks associated with the manufacture

Yes	
No	
Not Applicable	
Comments	

• Description of materials coming into contact with the body, why such materials have been chosen, and which standards apply (if relevant).

Yes	
No	
Not Applicable	
Comments	

• Identification of any special manufacturing conditions required and if so, how such requirements have been met.

Yes	
No	
Not Applicable	
Comments	

• A description of the methods of manufacturer, in particular as regards sterilization and identification of packaging used for sterilization of device.

Yes	
No	
Not Applicable	
Comments	

• The reports of quality controls tests, etc.

Yes	
No	
Not Applicable	
Comments	

• Instructions for use.

Yes	
No	
Not Applicable	
Comments	

• Photograph (preferably in colour)/diagram/sample if appropriate.

Yes	
No	
Not Applicable	
Comments	

• Identification of any tissues of animal origin

Yes	
No	
Not Applicable	
Comments	