Management of Clinical Trials During COVID-19 Pandemic

Ministry of Public Health
Department of Health Research Regulation

Version 1\ 3 June, 2020

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This Guidance is to provide the research community in Qatar with information regarding the review and conduct of clinical research during COVID-19 Pandemic.

The Qatar MOPH is aware of the impact of the pandemic on the conduct of clinical trials, including the need for participants to self-isolate the need for research staff to work remotely, and the deployment of healthcare personnel involved in clinical trials to other duties during this public health emergency, resulting in delays in completing certain tasks.

The sponsor and investigator must maintain complete and accurate records in respect of the use of a drug in a clinical trial, including records respecting the shipment, receipt, disposition, return and destruction of the drug. Products must be transported, handled, and stored in a manner that mitigates the risk of exposure to temperatures outside labelled storage conditions

The clinical trial site(s) should have a system in place to identify, document, assess and report all protocol deviations to the sponsor and IRB in accordance with sponsor and IRB requirements. Protocols' deviations need to be documented, to facilitate future analysis of the study findings. The sponsor should define and identify the protocol deviations to be reported. The deviation that could put patient at serious risk must be reported to MOPH.

The trial must always be conducted in accordance with Good Clinical Practices (GCP) and the MOPH regulations. It is the sponsor's responsibility to ensure that the drug is administered in accordance with those Regulations.

Monitoring activities may need to be re-assessed and should prioritize critical activities to ensure participant safety. Sponsors and investigators should document any changes and their impact. Certain processes may need to be changed: for example, an electronic alternative may have to be considered for signatures.

The MOPH supports the shipment of clinical trial investigational products (IP) from investigation site in Qatar directly to patients. This approach would be acceptable for all product formulations (e.g., tablets, injectables); however ,This approach can only be considered for drugs that a subject could take on their own (e.g., subject already in a trial and on medication, and if the trial uses a medication that doesn't have to be administered in a hospital/clinic setting or have any special conditions for handling).

Clinical trial applications during COVID-19

To accelerate the approval process for COVID-19 related research's applications. Those applications are exempt from the MOPH approval and should only receive Institutional IRB approval.

Sponsors may continue to file other CTA according to the MOPH requirements.

Institutional IRBs and COVID-19

Institutional registered IRBs should be fully operational. While IRB staff may not be able to meet with study teams in person or answer direct phone calls, the use of web conferencing and voice mails have been successfully used during the pandemic.

It is important for institutional IRBs to acknowledge that the COVID-19 outbreak and isolation/quarantine requirements may result in deviations that are intended to eliminate apparent immediate hazard to a research participant. Some deviations pose little to no threat to participant safety or scientific integrity. For example, when the subject misses a clinic visit and the only available re-schedule date is outside the study visit window, though no study procedures or medication doses are missed. In this case, the subject may not incur possible harm from a missed dose or missed procedures meant to maintain or evaluate the subject's safety and welfare. As such, reporting is left to the discretion of the investigator within the context of the IRB's reporting policy. While an increase in protocol deviations is expected, the sponsor and investigator must ensure that the clinical trial is conducted in accordance with the requirements of the IRB approved protocol approved and the MOPH regulatory policies.

Participants affected with COVID19

Sponsors and Investigator must decide quickly whether the participation should be placed on hold (i.e. not administering the investigational product until the participant has recovered) or whether the participant's involvement in the study should be discontinued.

All participants affected by a COVID19 related study disruption should be documented by unique participant identifier, and description of how the individual's participation was altered.

Trial Participants

The ongoing safety of trial participants must be maintained.

Risks and risk mitigation strategies related to use of any immunosuppressive agents should be discussed with medical professionals with expertise in immunology.

Study participants must be informed of any risks/changes to the study and monitoring plan that could impact on their wellbeing.

Documentation of medical oversight is required to determine participants' eligibility to take part in study.

Sponsors should discuss with IRBs whether it is in the best interest of the safety, welfare and rights of the participant to continue the participant as per the study protocol or to halt the study.

Sponsors should discuss with IRBs alternative methods of informed consent for the study or amendments to the study protocol if in-person visits are not possible (e.g., electronic consent, recorded telephone consent).

Clinical trial visit

Investigators may need to evaluate whether alternative methods for safety assessment are feasible should participants not be able to come to the investigational sites as specified in the study protocol. Alternative methods may include phone contact, virtual visits via telemedicine or alternative care sites. Alternative locations for imaging studies and laboratory tests may need to be considered.

If alternative monitoring is done, careful documentation will be required to capture the reason why it was done; the method used to collect the information; what data was collected; who provided the information; how the source of the information was verified and the reason why. Study protocol amendments will not be needed.

Trial participants will need to consent to any identifiers leaving the original site and be assured that their confidentially will be protected.

Participant recruitment

Sponsors should consider suspending additional site activation and recruitment.

Any delayed site visits must be documented.

Central monitoring of clinical trials should be considered.

Increased number of protocol deviations

Though a deviation may not pose a conceivable threat or possible harm, it may represent possible continuing non-compliance if an amendment is not pursued with the IRB. All deviations must be documented in the research record, regardless of whether they meet the IRB's reporting criteria.

Placing study on hold

Researchers are encouraged to consider whether their study or parts of the study should be placed on hold during the pandemic. This hold may be for all research procedures. Perhaps placing a hold on enrollment, study visits, data collection, or data analysis separately is reasonable. It is recognized that discontinuing a participant's care during this time may not be safe or may dramatically jeopardize the results of the project. The decision to place a hold on a particular study needs to be made on a study by study basis, likely in consultation with institutional procedures to ensure department and participant needs are met.

Should the study needs to be put on hold, notification should be made to MOPH by email on irb@moph.gov.qa

Reference

This guidance has been informed by the Health Canada: Management of clinical trials during the COVID-19 pandemic, and others.