nhra BAHRAIN
الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

Steps of the Clinical Trials (CT) Application Approval Process

1 Submit the CT Application Form

CT Application Form Submission via the following link: https://forms.office.com/r/Pzz4VM2kD8

2 Submit CT Application Package

After receiving the application form, the applicant will receive an email from CT@nhra.bh including a OneDrive link to upload the required documents, created specifically for his application request.

3 Administrative Review

After the CT application package submission, the administrative review will check whether the application package is complete or not.

3.1 If the CT package is incomplete, the CT unit will send the Principal Investigator (PI)/sponsor/Contract Research Organizations (CRO) applicant, an email from CT@nhra.bh requesting the missing documents, and the PI/sponsor/CRO applicant must respond to the same email within 10 working days. CT will be on hold (pending).

3.2 If the CT package is complete, the application request will be forwarded to the Clinical Trials Committee (CTC) and the Central Ethics Committees (CEC).

4 Clinical Trials (CTC) & (CEC)

The completed CT application package will be forwarded to both CTC and CEC for their experts' scientific and ethical review and opinion:

4.1 If the CTC & CEC board approves the CT, the PI/sponsor/CRO applicant will receive an email notification from CT@nhra.bh stating that the trial is approved.

4.2 If the CTC & CEC board requests modification or more documentation, the PI/sponsor/CRO applicant will receive an email notification from CT@nhra.bh requesting the modification and more documentation. The application request will be on hold until the PI/sponsor/CRO applicant submits the required/modified documentation.

4.3 If the CTC & CEC board does not approve the CT, the PI/sponsor/CRO applicant will receive an email notification from CT@nhra.bh to inform the PI/sponsor/CRO applicant about the reason for the rejection.

5 Final Approval Package (FAP)

Following the CTC & CEC approval, the PI/sponsor/CRO applicant will receive the final application package, which includes the following documents:

5.1 Official approval notification

5.2 Agreement on approval of CT Between PI/sponsor applicant & NHRA

6 Proceed with CT Activity

Following receipt of the FAP, the PI/sponsor/CRO applicant can announce and conduct the CT in accordance with the NHRA regulations, standards and conditions that have been approved.

7 Reporting

The PI, Sponsor, or CRO Applicant must submit to NHRA:

- Progress reports (including annual updates) throughout the course of the trial.
- Interim updates, when requested by NHRA.
- Safety reports, including prompt reporting of Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARs).
- A final clinical trial report with the complete study results upon completion of the approved clinical trial.