RESEARCH
@ SINGHEALTH DUKE-NUS ACADEMIC MEDICAL CENTRE

amri Academic Medicine Research Institute SingHealth Duke-NUS

INITIATING CLINICAL TRIALS AT SINGHEALTH

SingHealth Clinical Trials Coordinating Centre (CTCC)

- Initiate discussions and signing of Non-Disclosure Agreement (NDA) with Sponsor
- Be the liaison between Sponsor and appropriate therapeutic group Principal Investigator (PI) of SingHealth institutions
- Provide protocols to PI, Institution Research Department or Clinical Trial Unit (CTU)

Feasibility Study

- Protocol will be assessed by the relevant interested PI
- Sponsor will review PI's comments and revise protocol accordingly to suit local context

These tasks can be done concurrently

Ethics Committee Submission

to SingHealth Centralised Institutional Review Board (CIRB)

Two types of review:

- Full Board Review - Complete set of dossier is required
- Exemption/Expedited Review

Applications should be submitted to CIRB by the 1st working day of the month (except December when there is no full board meeting).

Estimated first response by CIRB is on the 4th week.

Regulatory Authority Submission

to Health Sciences Authority (HSA)

Application dossiers can be submitted anytime. Target processing timelines are:

Application Type	New Application
Clinical Trial Certificate (CTC)	30 working days
Clinical Trial Authorisation (CTA)	30 working days
Clinical Trial Notification (CTN)	5 working days
Clinical Research Materials Notification (CRM)	Immediate

Clinical Trial Agreement (CTA) Negotiations

between Sponsor and Institution

Budget negotiation is part of the CTA process.

Negotiations may take longer if there isn't an existing CTA or budget template in place between Sponsor and Institution.

Timeline for CTA and budget negotiations vary for each protocol and institution.

Clinical Trial Processes at Site

- Obtain approvals from CIRB and HSA
- Execute CTA
- Detailed site preparation for trial
- Conduct Site Initiation Visit (SIV)
- First Subject First Visit (FSFV) Screening

Reach us at ctcc@singhealth.com.sg