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 facilitate the signing of Non-Disclosure Agreement (NDA) with Sponsor
- Be the liaison between Sponsor and appropriate therapeutic group Principal Investigator (PI) of SingHealth institutions
- Send the protocols provided by Sponsor 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 for full board review should be submitted to CIRB by the **1st working day of the month**

(except December when there is no full board meeting).

No. of working days to review from date of receipt:

- Full board review - 60
- Exempted/ Expedited Review - 30

Regulatory Authority Submission

to Health Sciences Authority (HSA)

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

Application Type	Processing Time
Clinical Trial Certificate (CTC)	30 working days
Clinical Trial Authorisation (CTA) - Class 2 Cell, Tissue, and Gene Therapy Product (CTGTP)	30 working days (CTA) 60 working days (CTGTP)
Clinical Trial Notification (CTN) *After IRB approval is obtained*	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 contactctcc@singhealth.com.sg

*Master CTA is available for download at SCRI website.