CLINICAL TRIALIST DEVELOPMENT AWARD (CTDA)

Objective:

To recognise and promote interest in pursuing clinical research that will enhance institutional, national prestige and reputation, and to provide protected time for Clinical Trialists to focus on clinical trials and ensure successful recruitment, good quality of care and patient safety.

General Information

1. Clinical Trials refer to the assignment of participants to receive specific interventions according to a research plan or protocol created by the Investigators. The interventions may include medical products (drugs or devices); procedures; or changes to participants' behavior, such as diet, ranging from Phase 1 to Phase 4 clinical trials. Clinical Trials are used to determine the safety and efficacy of the intervention by measuring certain outcomes in the participants.

2. Clinical Trials do not include observational studies (Registries / database), translational studies, surveys and qualitative studies.

3. A Clinical Trialist is a site Principal Investigator (PI) of multiple Clinical Trials or Chief PI who develops the clinical trials protocol and secures funding. He / she is usually experienced in conducting multiple clinical trials with a good track record and is also recognised as a Key Opinion Leader in the particular field. It is not compulsory for a Clinical Trialist to have an academic degree and certification in clinical research (Masters / PhD).

4. Clinical Trialists can be self-identified, or identified via the SingHealth Clinical Trials Coordinating Centre (CTCC) database, the SGH Clinical Trials and Research Centre databases (REDATA and JESSED). Clinician Scientists who hold national award(s) with protected time will not be eligible to apply for this Clinical Trialist Development Award.

5. The Clinical Trialist Development Award aims to:
   i) Support the development of clinicians with expertise and interest in the conduct of clinical trials
   ii) Retain talent
   iii) Motivate, mentor and train junior investigators to perform clinical trials
   iv) Ensure trial quality and patient safety
   v) Achieve KPIs for research

6. The CTDA provides **protected time for 2 years** for 2 categories of Clinical Trialists to ensure that there is successful recruitment, good quality of care and patient safety.
   i) **0.2 FTE** for **Clinical Trialist**
   ii) **0.4 FTE** for **Master Clinical Trialist**

7. The protected time aims to allow the awardee to:
   i) Run 1 -2 sessions of Clinical Trial Clinic for patient recruitment and follow-up visits
   ii) Perform Clinical Trial Administration such as report preparation, perform feasibility requests and update sponsors / stakeholders, conduct data / lab review, attend meetings and trial-related activities, writing protocol and writing / review of manuscript etc.

Application Requirements & Evaluation Criteria

8. Each submission must be made using the prescribed forms:
   i) CTDA Application Form (to be completed by applicant)
   ii) Applicant CV & Career Development Plan (to be completed by applicant)
   iii) Nomination Form (to be completed and endorsed by Clinical HOD, ACP Chair and SDDC Head (where applicable)).

   Applications that fail to comply with requirements in any of the templates and / or incomplete applications will be disqualified and will not be reviewed.

9. Proposals should define **clear and measurable deliverables / outcomes**.

10. The criteria of the applicant and the expected outcomes are as follow:

	Clinical Trialist	**Master Clinical Trialist**
Criteria	A Clinician who: ✓ Is a PI of **2 or more Clinical Trials** in the past 2 years; ✓ Secured trial contract value of >S$500,000 over a 2-year period and ✓ Achieved **average** recruitment target of ≥50% for all the trials in the past 2 years **OR** Is **overall Chief PI of Investigator Initiated Clinical Trial** who has designed the trial and secured funding for the trial with contract value of **>S$500,000**	A Clinician who: ✓ Is a PI of **5 or more Clinical Trials** in the past 2 years; ✓ Secured trial contract value of **>S$1 million SGD** over a 2-year period and ✓ Achieved **recruitment target of ≥50%** for all the trials in the past 2 years **OR** Is **overall Chief PI of Investigator Initiated Clinical Trial** who has designed the trial and secured funding for the trial with contract value of **>S$1 million SGD**
Protected Time	**0.2 FTE** per individual, to be reviewed every 2 years	**0.4 FTE** per individual, to be reviewed every 2 years
KPIs	New trials, recruitment target, actualised budget, compliance, training of junior investigators	New trials and grants, recruitment target, actualised budget, compliance, mentorship and training of junior investigators, publications, guideline / policy impact

11. All submitted documents and data therein will be made available to any persons who are reasonably required to review, evaluate, recommend, and approve the award. They shall also subsequently be used to facilitate administration, talent management and development within the SingHealth Duke-NUS Academic Medical Centre.

12. For shortlisted candidates, a short interview with the review panel may be required. Details concerning the interview will be disseminated once it is finalised.

13. Successful applicants are expected to submit a Mid-term Progress Report and a Final Report periodically during and after the tenure of the award.