

NMRC GRANT CALL

MAY-2021

ABOUT SCRI



Vision

· To be the ASEAN hub of academically oriented clinical research efforts

Mission

• To spearhead and develop core capabilities, infrastructure and scientific leadership for clinical research in Singapore





SCRI AT A GLANCE (Y2018 – 2020)



93 Active Studies

- 77 distinct PIs out of 93 active studies
- <u>42</u> interventional studies and <u>27</u> observational/ registry studies

1. Pre-Grant/ Concept Generation

Services provided:

- Biostatistics
- Epidemiology
- Data Management
- Project Management

2. Study Execution

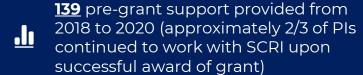
Services provided:

- Data Management
- Project Management
- Research Informatics
- Research Monitoring

3. Analysis/Reporting

Services provided:

- Biostatistics
- Epidemiology







<u>61</u> new research operations contracts signed from 2018 to 2020



<u>\$1.5m</u> of new contracts in the provision of research ops services from 2018 to 2020



116 journal publications from 2018 to 2020



<u>51</u> out of 116 publications have Impact Factors of greater than 3

4. Key Enablers: Clinical Research Networks/ SCRI Academy/ National Clinical Trial Coordination

SCRI EXPERTISE





- Strong experience with IIT & IST, especially multi cluster/ site trials
- Ability to work with vendors/ CROs/ networks
- Ability to support multicentre trial studies & support multiple therapeutic areas
- Ability to provide support to Young Investigators
- Ability to provide flexible services & quick start up time
- Ability to provide cost effective clinical research services



- Provision of in-house Randomisation system
- Ability to provide customised and high quality services
- Ability to train investigation site personnel to fulfil study requirements

SCRI EXPERTISE



Niche Areas where SCRI HEOR Supports



Unique HEOR support from SCRI

- Multi-centre HSR studies
- HEE alongside RCTs
- HEE alongside diagnostic test accuracy (DTA) studies



All needed skills & expertise under one roof

- Design for clinical research and health economic evaluation, database development, data management, project management, research monitoring, data analysis and reporting
- Efficient team work and one-stop collaboration



FOR MORE INFORMATION, PLEASE CONTACT US AT:

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ANNEXES



PRE-GRANT/ CONCEPT GENERATION

Supported by our Epidemiology, Biostatistics, Data Management & Project Management teams

1. Pre-Grant/ Concept Generation

2. Execution

3. Analysis/Reporting

1. PRE-GRANT/ CONCEPT GENERATION FUNCTIONS



Study design **Pre-grant Protocol development Support** Sample size estimation **Budget estimation** Randomization **Database standardization** Statistical analyses **Post-grant** Collaboration **Manuscript writing Systematic Review CRF design & Data Analysis**



STUDY EXECUTION

Supported by our Data Management, Project Management, Research Informatics & Research Monitoring teams

Pre-Grant/ Concept Generation

2. Execution

3. Analysis/ Reporting

02. STUDY EXECUTION FUNCTIONS



Project Management

Overall Project Management

- Planning and organisation,monitoring and control of projects from study feasibility to close out
- Managing budget, scope, timeline, risk, quality, resources
- Protocol Preparation and implementation

Communication and Stakeholder Management

- Ensure that studies operations are planned properly.
- Manage key stakeholder expectations.
- Maintain communication with all stakeholders.

Research Monitoring

Clinical Trial GCP

• Ensure that all projects adheres to GCP

Data Quality Monitoring

 Ensure that trials are in compliance with protocol, regulatory, IRBs requirement, sponsors quidelines etc.

Nurturing Clinical Research Manpower

 Provision of training for investigator sand site personnel

Conduct and perform site feasibility evaluation

• Coordinate and conduct sire initiation visit

02. STUDY EXECUTION FUNCTIONS



Data Management

Access to Electronic Data Capture Platforms & Subscriptions

- Medidata Rave
- MedDRA & WHO-Drug Dictionary
- SCDM Membership

Provide advice and consultation on data management such as:

- Data cleaning strategy
- Database Selection
- CRF/ Data Design

Generate Customised Reports to increase data cleaning speed, improve data quality and enhance productivity

- Progress Report
- Data Trend Report
- Backlog Notification

Research Informatics

Information Technology

 Supply of information technology to SCRI clinical research operations to increase productivity

Study Databases

 Design and development & manage of study databases to enhance information collection efficiency

Support & Maintenance

- Provision of support & maintenance services in relation to clinical research operations
- Provision of technical and user support to clinical research operations including troubleshooting, analysis and recovery of systems and applications



ANALYSIS/ REPORTING

Supported by our Epidemiology & Biostatistics teams

Pre-Grant/ Concept Generation

2. Execution

3. Analysis/ Reporting

03. ANALYSIS/ REPORTING FUNCTIONS - EPIDEMIOLOGY



HEOR

- Evaluate the <u>effectiveness</u> of health-care interventions through <u>improvements in patient-important outcomes</u> (morbidity, QoL and mortality) in <u>real-life settings</u>
- Evaluate the <u>efficiency</u>, <u>cost-effectiveness</u> and overall value of healthcare at the micro-economic level



Real World Evidence

- Generate <u>clinical evidence</u> regarding the usage and potential <u>benefits or</u> <u>risks</u> of a medical product derived from analysis of RWD
- Develop <u>quidelines</u> and <u>decision support tools</u> for use in clinical practice





Systematic Review & Meta-analysis

- Cochrane Singapore
- Support local researchers contributing to filling-in knowledge gaps by taking on impactful systematic reviews

EPIDEMIOLOGY

HTA/DTA

 Evaluate the <u>properties and effects</u> of a health technology, addressing its <u>direct and intended</u> <u>effects</u>, as well as its <u>indirect and unintended</u> <u>consequences</u>





Teaching

- Focus on training of <u>young</u> academic clinical investigators through delivering training workshops & providing ad-hoc consultations
- Focus on teaching <u>cutting-edge methodologies</u> to keep research skills updated
- Contribute to research ecosystem (ethics, grant & manuscript review activities, talent development)

03. ANALYSIS/ REPORTING FUNCTION - BIOSTATISTIC





Clinical Trials

Phase I - IV Trials

(incl. adaptive design)

Interventional Trials

(incl. cluster RCT)

MedTech Trials



Diagnostic Accuracy Studies

Diagnostic and Screening Accuracy
Studies

Prognostic Index Development & Validation Studies



PRO Studies

HRQOL Measurement Studies
Health Valuation Studies
Instrument Development &
Validation Studies

Study Design, Analysis Planning, Publication



CLINICAL RESEARCH NETWORKS

Providing research infrastructure to support high quality clinical research

1. Pre-Grant/ Concept Generation

2. Execution

3. Analysis/ Reporting

4. CLINICAL RESEARCH NETWORKS: IMPACT & BENEFITS TO ECOSYSTEM



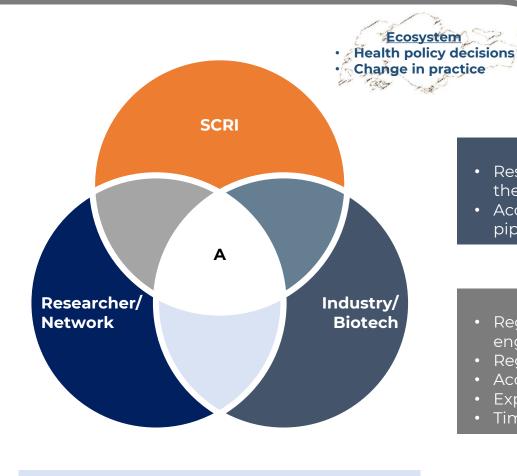
SCRI

• Regional research hub

- High impact <u>SCRI +</u> <u>Researcher/Network</u>
- Publications
- Increase funding opportunities

Researcher/ Network

- Shared vision
- Governance policies & ToR
- Build research capacity & culture
- Succession planning to address membership change over time
- Increase research involvement
- Accountability framework
- Mentorship by experienced researchers
- opportunities for professional development (KOLs)



Industry/ Biotech

- Resource for local biotech/pharma for their product/drug development
- Accelerate the drug development pipeline

All

- Regular, effective communication & engagement
- Regular review of goals and timelines
- Access to large, diverse patient pool
- Expedite patient recruitment
- Time & cost effectiveness

Researcher/ Network + Industry/ Biotech

• Access to research support staff and sites



THANK YOU.