Are you a Super CRC?

SCRI-NUHS CRC Workshop

10 Oct 2019

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OF COURSE!! YOU ARE ☺


The
BIG Picture
first

Government's Strong Commitment to R&D

- Singapore started its research, innovation and enterprise (RIE) journey started 30 years ago
- Successive 5-year plans have seen increased public and private sector investments in R&D

Plan	National Technology Plan 1995	National Science & Technology Plan 2000	Science & Technology 2005 Plan	Science & Technology 2010 Plan	Research, Innovation and Enterprise 2015 Plan	Research, Innovation and Enterprise 2020 Plan
Budget	$2 billion	$4 billion	$6 billion	$13.5 billion	$16 billion	$19 billion

RIE2020 for HBMS (Health & Biomedical Sciences) $4 billion

Source: http://www.research.gov.sg/RIE2020

Health and Biomedical Sciences (HBMS)

- Initiatives include:
  - ❖ Developing talent base
  - ❖ Strengthening clinical research infrastructure & facilities
  - ❖ Developing investigational medicine capabilities and strengthening supporting enabling resources and regulatory frameworks
- Phase 1 (2000-2005)

  … *Strengthening basic research infrastructure*
- Phase 2 (2006-2010)

  … *Strengthening translational and clinical research capabilities*
- Phase 3 (2011-2015)

  … *Encouraging private-public partnerships*

HBMS Phase IV (2016-2020)

BMS Goal: To be a leading centre that advances human health and wellness, and creates economic value for Singapore and Singaporeans, through the pursuit of excellence in research and its applications.

Human Capital & Talent Development Programmes

- Singapore Translational Research (STaR) Investigator Award
- Clinician Scientist Award (CSA)
- Transition Award (TA)
- Clinician Scientist & Clinician Investigator Salary Support Programme (CS/CISSP)
- NMRC Research Training Fellowship
- MOH Healthcare Research Scholarship - Master of Clinical Investigation (MCI)
- Clinician Innovator Development Award (CIDA)

Research Grants

Competitive Grants

- Centre Grant (CG)
- Clinician Scientist Individual Research Grant (CS-IRG)
- Health Services Research Grant (HSRG)
- National Innovation Challenge on Active and Confident Ageing (NIC Ageing)
- Clinician Scientist Individual Research Grant New Investigator Grant (CS-IRG-NIG)
- Health Services Research New Investigator Grant (HSR-NIG)

Open Fund

- Large Collaborative Grant (LCG)
- Individual Research Grant (IRG)
- Young Individual Research Grant (YIRG)

Enablers & Infrastructure Grants

- Institutional Review Boards (IRBs)
- Research Space Funding
- HSA National Cell Therapy Facility
- National Large Animal Research Facility (NLARF)
- Investigational Medicine Units (IMUs)
- Singapore Clinical Research Institute (SCRI)
- **Clinical Research Coordinators (CRC) Funding Initiative**
- National Health Innovation Centre (NHIC)
- Bioethics Advisory Council (BAC) & Centre for Biomedical Ethics (CBmE)

RIE2020 Healthcare Research Strategy – 5 Therapeutic Areas of Focus

Cancers

Cardiovascular Diseases

Infectious Diseases

Neurological and Sense Disorders

Diabetes Mellitus and Related Metabolic/Endocrine Disorders

Source: NMRC e-Newsletter – 'The Scope', Jun 2019

CRC

How does it matter to me?

What can I do to be ready?

What are the skills I need?

CRCs

A CLINICAL TRIAL / CLINICAL RESEARCH STUDY

The success of clinical studies relies heavily upon CRCs' abilities to effectively manage day-to-day study activities.

Just some of the activities…

Study Initiation

- *Budget*
- *Study team*
- *IRB & RA Submissions*
- *Investigator Site File set-up*
- *Training (IM, SIV etc.)*
- *Recruitment strategies*
- *Study Work Flow*

Study Monitoring

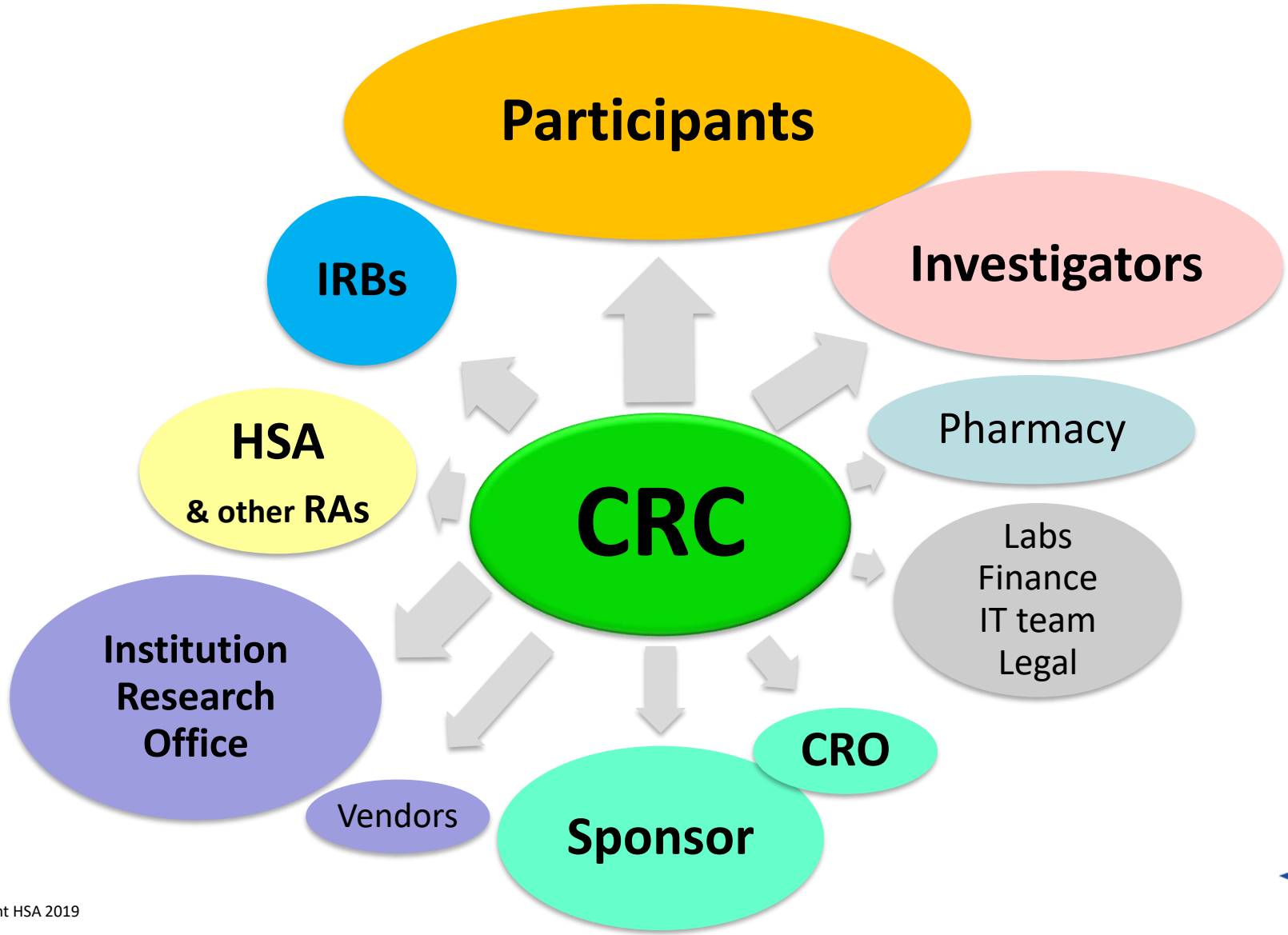
- *Subject Recruitment and Follow-up*
- *Investigational Product (IP) management*
- *Biological Samples handling*
- *Safety Reporting*
- *Data collection*
- *Investigator Site File maintenance*

Study Closure

- *Data cleaning*
- *IP return / destruction*
- *Study Closure support*
- *Archiving*
- *Finance matters*

CRC

"Central to Research Quality Control"



nature medicine

News Feature | Published: 07 January 2019

Twenty-five ways clinical trials have changed in the last 25 years

Mike May

Nature Medicine **25**, 2–5 (2019) | Download Citation

Exploring the evolution, from analysis and endpoints to registration and regulations

Some of these changes…

- General changes

  …. ‘Ever more molecular’, ‘Ramped-up training’ (… *to make clinical trials safer and to improve the value of the results by ensuring that everyone on a team understands the standards for running a trial, from design through reporting, including revealing any problems encountered during the trial.*)

- Types of trials

  …. ‘Adaptive trials’, ‘Basket trials’, ‘Umbrella trials’, ‘Platform trials’, ‘Real-world evidence studies’…

- Trials procedures

  … ‘Complicated criteria’, ‘Complicated protocols’, …

- Data collection/analysis

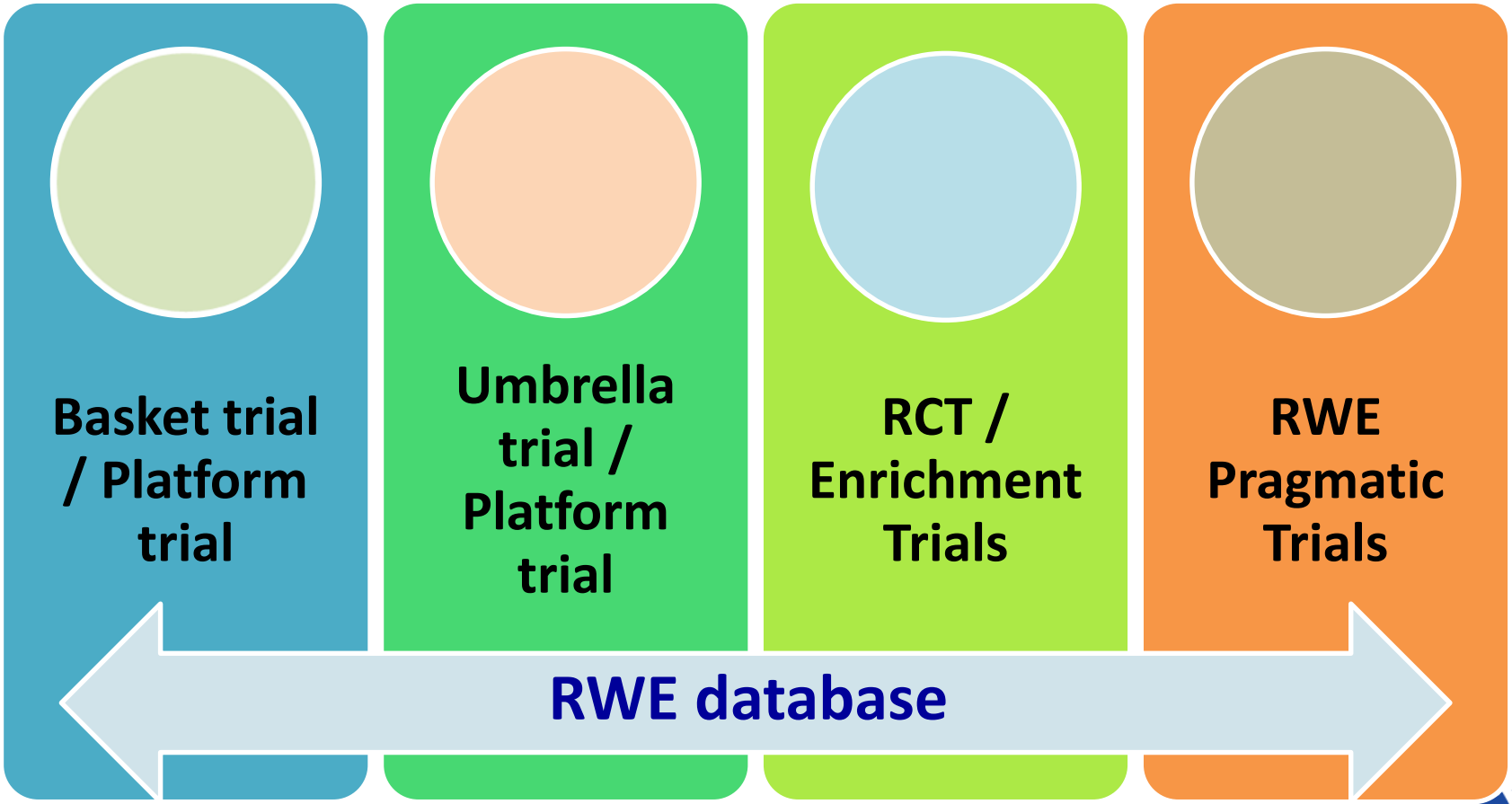
  … ‘Information control’ (… need to keep everything organized and avialable), ‘Data sharing ’, ‘Caring in sharing’

Nature Medicine | VOL 25 | JANUARY 2019 | 2–11 | www.nature.com/naturemedicine

Traditional Clinical Trials – Then and Now

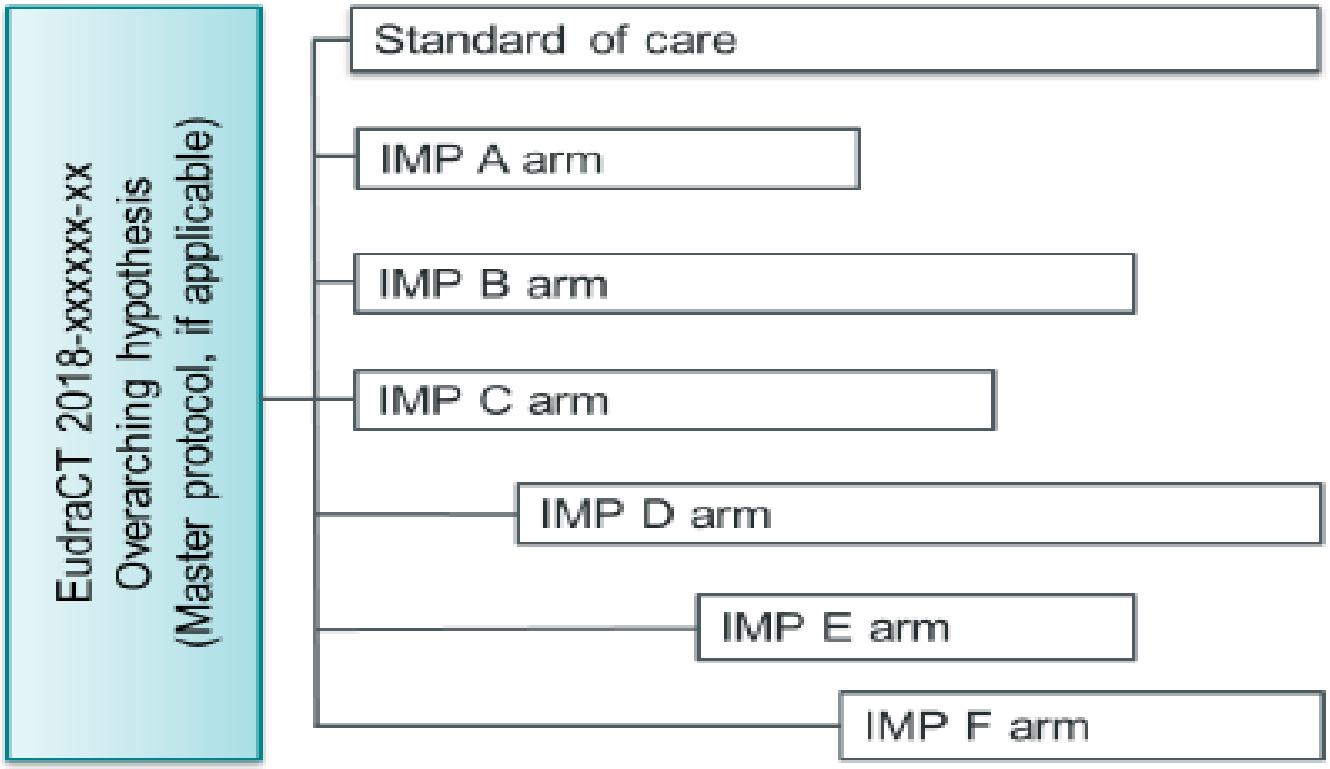
Phase 1 Safety Pharmacology → **Phase 2** Therapeutic Exploratory → **Phase 3** Therapeutic Confirmatory → **Phase 4** Therapeutic Use

Adaptive Clinical Trials – Now and the Future



Source: Trusheim et al, Clin Pharm & Therap Dec 2016, 100; 6; p713-729

Complex Clinical Trials



Example of a complex trial design with arms compared to a shared control arm. The design is characterised by extensive adaptations where arms with new IMPs are being opened and closed during the conduct of the trial via substantial amendments.

Source: EMA CTFG Recommendation Paper on the Initiation and Conduct of Complex Clinical Trials

Complex Clinical Trials

EMA CTFG
Recommendation Paper on the Initiation and Conduct of Complex Clinical Trials

12 February 2019

Key recommendations

1. Clearly describe and justify design
2. Maintain **scientific integrity**
3. Ensure **quality** of trial conduct and optimise clinical feasibility
4. Ensure **safety** of trial subjects
5. Maintain **data integrity**
6. Reassess benefit-risk balance at critical steps throughout clinical trial
7. Validate companion diagnostics
8. Consider data transparency

Clinical Trials Facilitation and Coordination Group (CTFG) is a working group of the Heads of Medicines Agencies on clinical trials. This document is published on the CTFG webpage: http://www.hma.eu/ctfg.html

Are **YOU** ready for the future of clinical research?

A Super CRC!

Systematic: You are tasked with many study responsibilities, prioritise them. You need to have Exceptional Organisational skills.

Understanding: You are usually the first point of contact with the subjects and families, demonstrate care and empathy to build trust.

Professional **D**evelopment: A super CRC will consistently enhance his/her education and knowledge through a dedicated support system.

Ethical & **E**ngaged: You must always be ethical and do the right thing (effective) and do things right (to achieve the objectives). You have to be engaged by reading the study material, understand the requirements of the protocol and staying on top of the updates.

Responsible: You are responsible to protect the goals of GCP i.e. subject protection & data quality (compliance with protocol, regulations, guidelines and SOPs).

Conscientious: You are conscientious to keep to your commitment and promise.

Resilient & be a clinical research **R**esource – You are resilient to handle stress and setbacks. When times get tough, the CRC may often bear the brunt of the problem.

Caring, **C**ommunicate, **C**oordinate & **C**reative – You are creative to develop tools to enable them to manage multiple studies efficiently and effectively.

HSA Health Sciences Authority

YOU are a **VITAL** member of the clinical research team to develop and deliver evidence-based care!

Scientific discoveries and new research evidence are fundamental in the development of medical innovations that can translate into better clinical practices and policies, leading ultimately to improved patient care and better health for our people.

Minister for Health,
Mr Gan Kim Yong

Source:
NMRC Awards Ceremony and Research Symposium 2019
NMRC e-Newsletter – 'The Scope', Jun 2019

Thank You