The Value Proposition of Clinical Trials In Singapore

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CEO Consortium for Clinical Research and Innovation Singapore ED Singapore Clinical Research Institute



The Consortium for Clinical Research and Innovation Singapore (CRIS)















The Promise of Clinical Trials: Transforming Tomorrow's Health

SCRI Clinical Trials Symposium 2024



What is the value of Clinical Trials?

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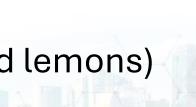
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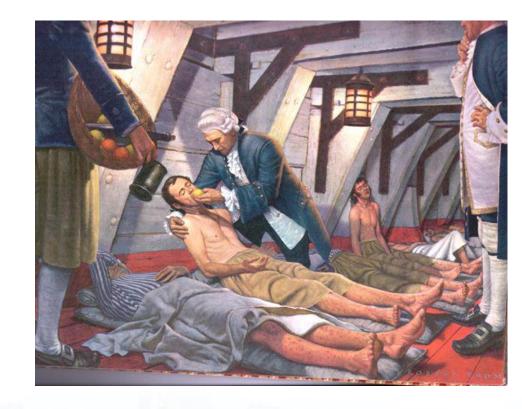


Clinical Trials

"Treatise of the Scurvy" - James Lind (1747)

- Used control groups (cider, vinegar, barley water, elixir of vitriol, sea water...)
- 12 seamen with scurvy
- Evaluated 6 treatments (2 subjects/treatment)
- One treatment (oranges and lemons)
 had two men recover









Independent report

Updated 26 May 2023

Commercial clinical trials in the UK: the Lord O'Shaughnessy review - final report

"Falling Levels of Commercial Research create a significant opportunity cost.....Therapies and Healthcare services that would otherwise have been funded by a pharmaceutical or technology company instead have to be funded by the taxpayer"

"...the total direct cost of the near halving of patients recruited to commercial research....over the last 5 years is in the region of £360 million."

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"Commercial research associated with the NIHR Clinical Research Network generated £1.8 Billion is gross value add to the UK economy in 2018 to 2019."

NGAPORE LINICAL ESEARCH ISTITUTE

Independent report

Updated 26 May 2023

Commercial clinical trials in the UK: the Lord O'Shaughnessy review - final report

Consequences of reduced commercial clinical trials –

"....it reduces the opportunities of British patients to have early access to innovative treatments that could improve, extend or even save their lives."

"NHS bodies that carry out research tend, on average, to provide better health outcomes for their patients"

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Source: ANZCTR; Clinicaltrials.gov; L.E.K. research and analysis



2024 Report on Australia's Clinical Trials Sector

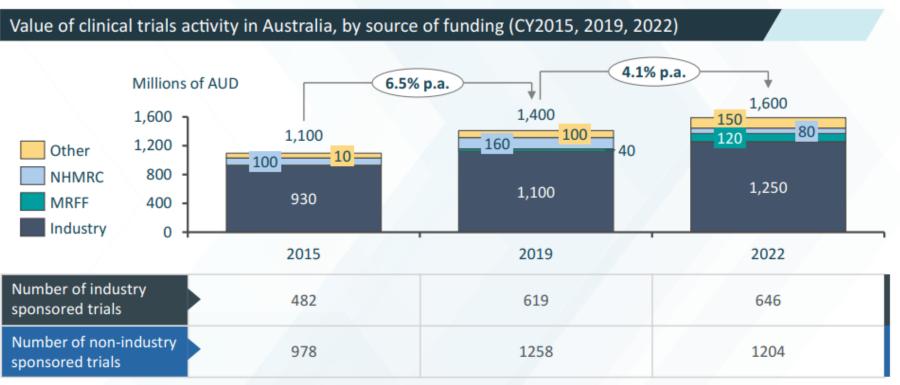
| Metric | 2015 | 2019 | 2022 | CAGR % (2019-22) |
|--|-----------------|-----------------|-----------------|------------------|
| S Expenditure | \$1.1 billion | \$1.4 billion | \$1.6 billion | 4.1 |
| Employment | 6,900 employees | 8,000 employees | 7,700 employees | (1.5) |
| Patient participation | Not reported | 95,000 | 90,000 | (1.8) |
| Number of trials started | 1,460 | 1,877 | 1,850 | (0.5) |
| Share of global industry- sponsored trials | c.5% | c.5% | c.5% | N/A |

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2024 Report on Australia's Clinical Trials Sector



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Source: MRFF; AAMRI; NHMRC; PBS; ANZCTR; Clinicaltrials.gov; L.E.K. research and analysis

SINGAPORE LINICAL RESEARCH NSTITUTE



Your Global Solutions in One N

Clinical Research Malaysia (CRM) is a Global Trusted Research Management Organisation established by the Ministry of Health Malaysia in 2012.

CRM delivers sponsored clinical trials with Speed, Reliability and Quality through operational excellence and working with stakeholders by providing end-toend clinical research support services.

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New Industrial Master Plan (NIMP)
2030

Vision – To make Malaysia the preferred hub for clinical research in Asia

MALAYSIA'S CLINICAL RESEARCH VALUE PROPOSITION









>2,000 SPONSORED RESEARCH SINCE 2012



>RM 1.1 BILLION

IN GROSS NATIONAL INCOME FROM CLINICAL RESEARCH CONTRACT VALUE

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Quantified Effects

- Skill Development of Health Professionals
- Increased work time
- **Employment**
- **Substituted Treatments**

E OF CLINICAL

Clinical trials initiated

- 902,000 Dkk GDP impact per trial
- 1,169,000 Dkk Public finance impact per trial
 - > 175 industry trials in 2015 improved the Danish GDP by 158 million Dkk

Ross Kirk

6 July 2017



Note: The gains per trial imply that the 175 clinical trials initiated by the industry in 2015 improve Danish GDP by 158 million kroner and public finances by 205 million kroner. Source: Copenhagen Economics



MISSION

Trial Nation contributes substantially to Denmark's position as the leading public-private ecosystem for clinical trials in Europe – to the benefit of patients, research and the economy.

- . We create the foundation for expansion, and we maintain a position for Denmark among the top three countries in Europe, measured as number of clinical trials per million inhabitants.
- . We strengthen frameworks and conditions to attract significantly more clinical trials at the highest international level.
- We lead in state-of-the-art methods and technologies in set-up and execution of clinical trials.

VISION

We pave the way to a future where:

Patients enjoy stronger sustainable health driven by fast access to cutting-edge medicine and medical technology.

Healthcare professionals save more lives and promote stronger health by always having state-ofthe-art medical research and the latest discoveries right at their hand.

Clinical research create a better health and wealth for Denmark.



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Denmark must be in the lead in early phase research

We have an eye for the entire pharmaceutical development process, but believe that Denmark has the potential to excel in

the development of new trial designs, trials with more complex medicines related to rare diseases or personaliced medicines, and early **phase** research, including 'First in Human' (FIH) trials.

This is partly due to Denmark's skilled and specialised researchers and Denmark's many technological opportunities.

Early phase trials give Danish patients access to the latest therapies and builds a crucial knowledge capacity among both authorities and researchers. This is expected to have a knock-on effect in the later phases of pharmaceutical development. We are continuously working on initiatives to support early

research. We have strong capabilities to support the transition

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APORE NICAL EARCH

Healthcare Benefits JAMA Internal Medicine

Better Outcomes for Patients Treated at Hospitals That Participate in Clinical Trials (2008)

Sumit R. Majumdar, MD, MPH; Matthew T. Roe, MD, MHS; Eric D. Peterson, MD, MPH; Anita Y. Chen, MS; W. Brian Gibler, MD; Paul W. Armstrong, MD

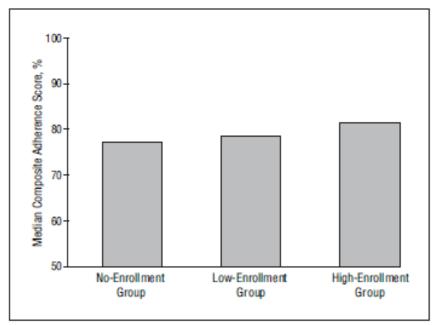
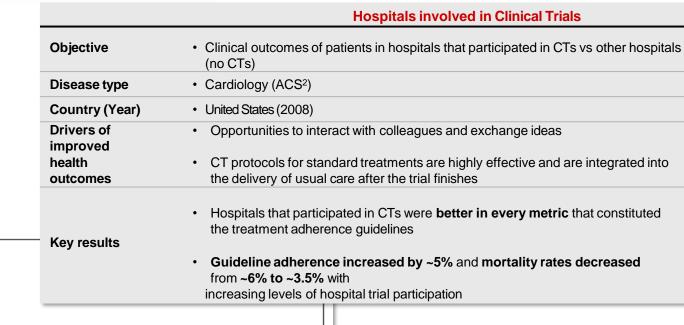


Figure 1. Adherence to evidence-based guideline recommendations at 494 CRUSADE (Can Rapid Risk Stratification of Unstable Angina Patients Suppress Adverse Outcomes With Early Implementation of the American College of Cardiology/American Heart Association Guidelines) hospitals, according to tertiles of hospital-level clinical trial participation. Tertiles of



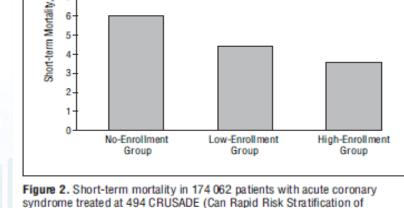


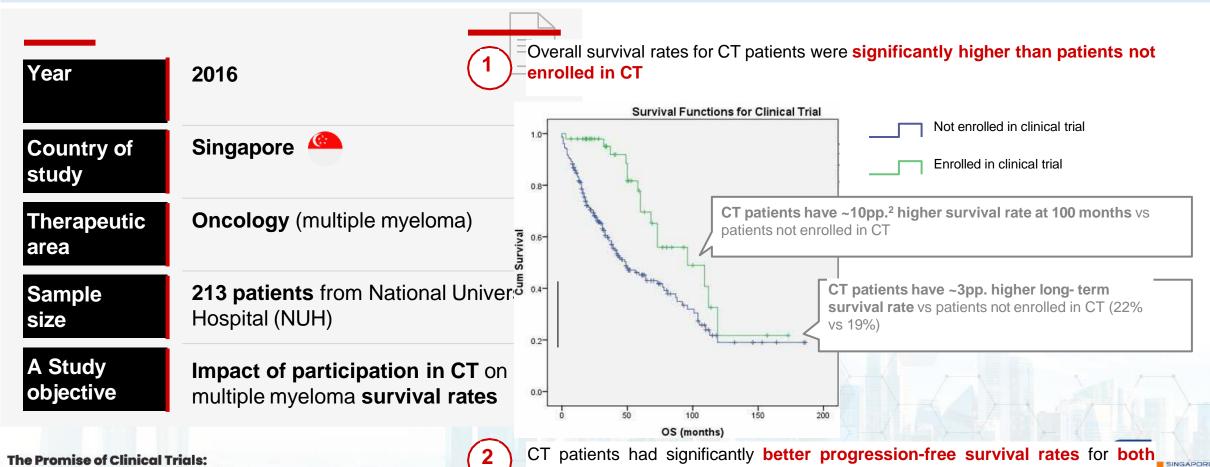
Figure 2. Short-term mortality in 174 062 patients with acute coronary syndrome treated at 494 CRUSADE (Can Rapid Risk Stratification of Unstable Angina Patients Suppress Adverse Outcomes With Early Implementation of the American College of Cardiology/American Heart Association Guidelines) hospitals, according to tertiles of hospital-level clinical trial participation. Tertiles of hospital-level trial participation include no participation tertile (0% of patients enrolled in trials) vs low trial participation (1.0% enrolled [interquartile range, 0.5%-1.4%]) vs high trial participation tertile (4.9% enrolled [interquartile range, 3.5%-9.7%]). P=.04



Healthcare Benefits

Cytogenetic Abnormalities and Treatment with New Drugs on Clinical Trials Are Important Prognostic Markers for Myeloma in the Era of ISS and FISH Analysis (2016)

Cinnie Yentia Soekojo, Adeline Lin, Michelle Poon, Liang Piu Koh, Lip Kun Tan, Melissa G. Ooi, Wee Joo Chng, MB ChB, MRCP, PhD



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CT patients had significantly better progression-free survival rates for both control group and patients exposed to novel treatments



Clinical Trials

- Increases access to novel, potentially transformative medications for patients
- Increases the capabilities, skills and competencies of clinicians and institutions
- Patients on trials fare better, even if they are not on an active treatment

In particular, Industry Sponsored Clinical Trials

- Provide paid medications both investigational and control to patients, defraying costs that otherwise have to be borne by the tax-payers
- Support trial performers directly, coordinators, clinicians, nurses, departments
- Support the biomedical ecosystem at large





How About Singapore?

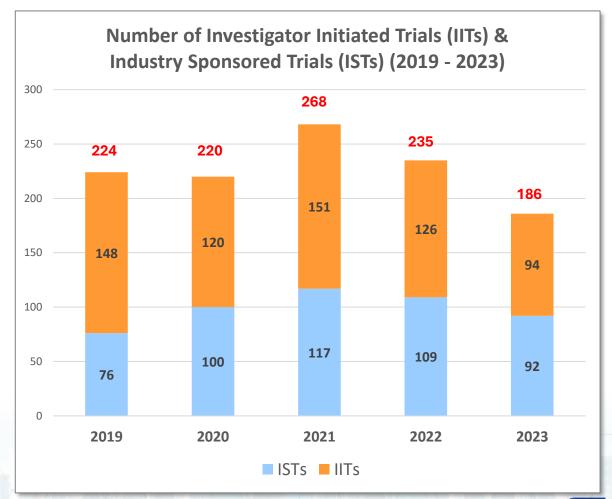
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Singapore Clinical Trials by the Numbers

- US\$205M direct contribution to the economy/year
- US\$120-180M in cost savings from drugs provided to patients from trials
- 1600 jobs directly supporting clinical trials
- 600 jobs by supporting existing and new biotechs





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What does success look like?

Cancer patients may have greater access to latest drugs under trial



Singapore cancer consortium admitted to global network that lets it take part in trials





"The immunonotherapy Centres of Research Excellence (imCore) network is a global alliance of scientific and clinical experts in cancer immunotherapy,"

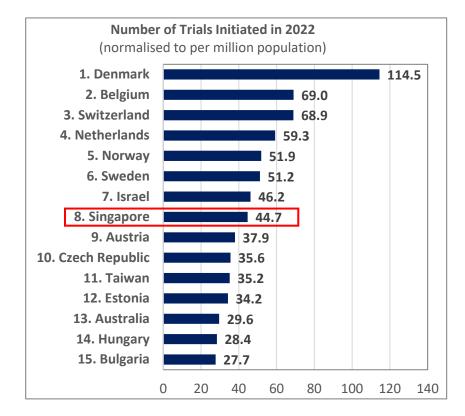
"Singaporean patients will have access to the very latest types of pharmaceuticals that we're developing." - Dr Ira Mellman, VP cancer immunology at Genentech

"a number of STCC members had in the past sought unsuccessfully to gain entry into imCore......However as a consortium, STCC presented a completely different proposition....having greater resources to contribute to the network" - Prof Chng Wee Joo, ED STCC

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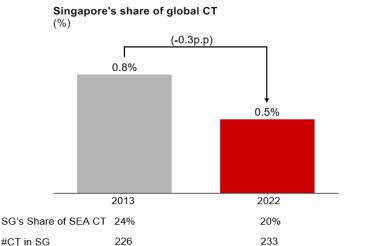
As a benchmark, in 2022, **Denmark initiated 2.5 times** more clinical trials while **Belgium and Switzerland initiated 1.5 times** more clinical trials compared to Singapore.

Data Source –

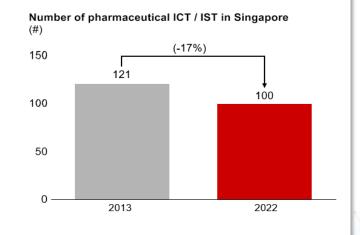
Data Source – Clinicaltrials.gov (obtained in July 2024)

Falling share of Clinical Trials

Singapore share of CT declined by nearly half over the past 10 years...



... driven by a sharp drop in industry led trials (ICT/IST)



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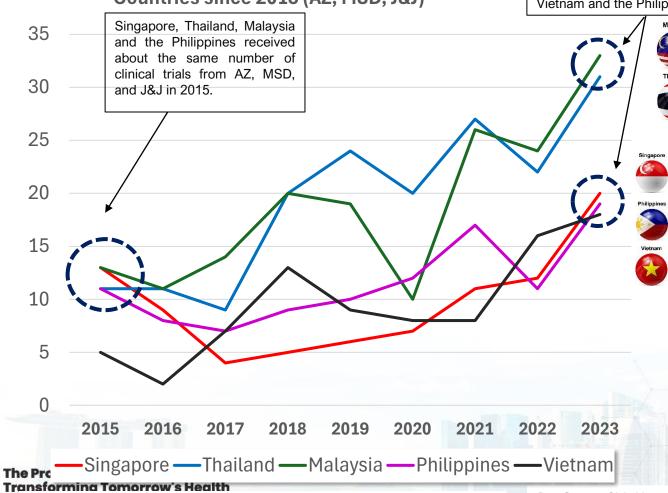
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Drug Trials by selected Pharma Companies in ASEAN AZ, MSD and J&J

Number of Clinical Trials Initiated in Selected ASEAN Countries since 2015 (AZ, MSD, J&J)

In 2023, **Malaysia and Thailand** are favoured by AZ,
MSD and J&J who collectively
initiate 50% more clinical **trials** than in Singapore,
Vietnam and the Philippines.



Truqab (Capivasertib) (AZ)

Capivasertib was approved by the US FDA in November 2023 for hormone receptor-positive, HER2-negative breast cancer in combination with Fulvestrant. The oral medication is considered as a **first-in-class** medication.

Phase III clinical trials were conducted in 2021 in many APAC countries including Thailand, Malaysia and Vietnam, but NOT Singapore.



Winrevair (Sotatercept) (MSD)

Sotatercept was approved by the US FDA and EMA in March 2024 and June 2024 respectively for the treatment of pulmonary arterial hypertension (PAH).

Phase III clinical trials were conducted in 2022 in APAC countries like Australia, South Korea and Taiwan. However, the cardiovascular drug was never tested in Singapore.



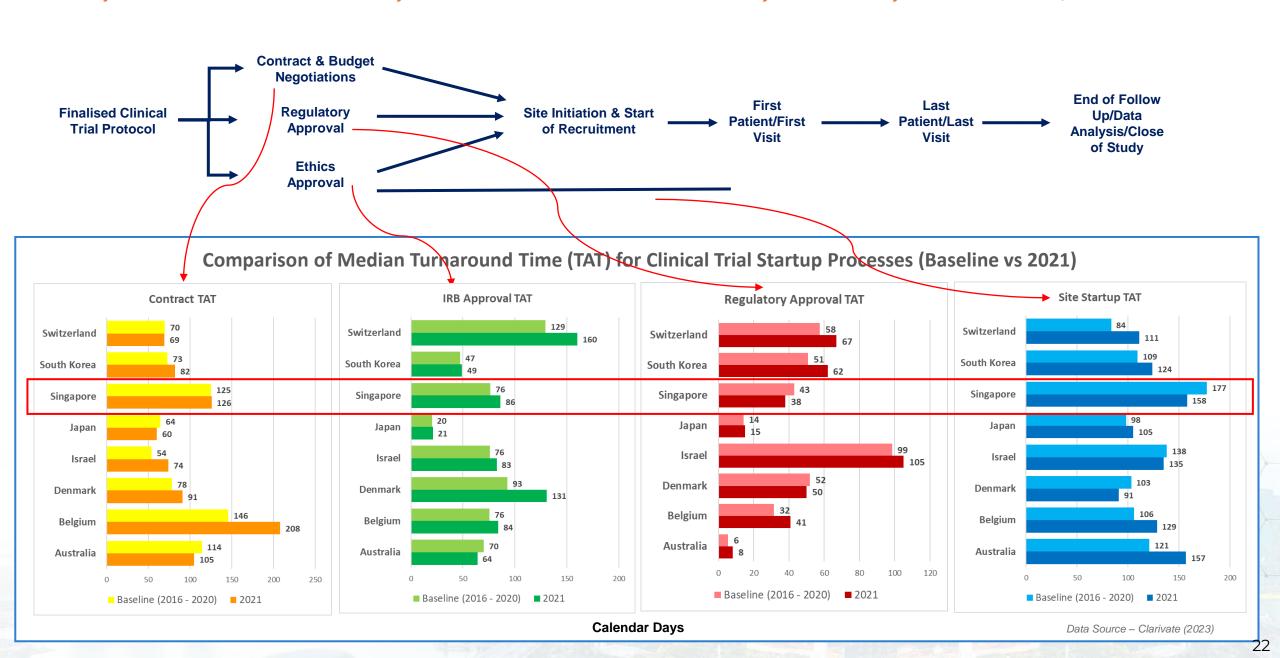
Data Source - Globaldata (obtained in July 2024)





Benchmarking Singapore Against Competitor Countries in startup processes

Industry Feedback was substantiated by Procured Data from an unbiased survey conducted by data consultants, Clarivate



What ails us?

SCRI Engagement with trial performers and industry partners

- Slow and fragmented contracting and budget negotiations
- Slow feasibility assessments
- Lack of dedicated resources for trial start up and operations





What are other countries doing?

TRIAL NATION

TRIAL NATION OFFERS A SINGLE NATIONAL ENTRY POINT FOR LIFE SCIENCE COMPANIES, PATIENT ORGANISATIONS AND CLINICAL RESEARCHERS WISHING TO SPONSOR, PARTICIPATE IN AND CONDUCT CLINICAL TRIALS IN DENMARK.

At Trial Nation we offer:

- Identification of relevant specialists and clinical researchers.
- . An expedited feasibility process with a collated national response from hospital sites within five days.
- Access to our legal network, offering national contract temp.
- Access to established clinical specialty centres and national dermatology, haematology, infectious diseases, oncology, r. respiratory diseases.
- Access a national structure covering clinical trials in medical
- A national approach to increasing performance in clinical tri
- Access to established partnerships with hospitals, scientists

READY TO USE TEMPLATES

The healthcare regions in Denmark have formed a legal network within Trial Nation to ensure that the regions act as a united negotiation party for contract templates in relation to the industry.

The network provides efficient negotiation of contract templates (for CDAs, CTAs and Clinical Investigations) relating to clinical trials and investigations in Denmark. Contract templates can be used as they are or be tailored to your company. Consider using the standard templates below for the fastest possible processing time as they are pre-approved in all regions and no negotiation time is need. Please note that the Trial Nation network only negotiate contract templates, individual contracts are handled in each region. Please also note that the Trial Nation network does not provide general legal advice.

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RESEARCH

What are other countries doing?



Clinical Trial Research Agreements

- Clinical Trial Research Agreement Medicines Australia Standard Form
- Clinical Trial Research Agreement CTRA: Contract Research Organisation acting as the Local Sponsor
- Clinical Trial Research Agreement Collaborative or Cooperative Research Group (CRG) Studies
- Clinical Trial Research Agreement Phase 4 Clinical Trial (Medicines)
- Clinical Trial Research Agreement Phase 4 Clinical Trial (Medicines)
 Contract Research Organisation acting as the Local Sponsor

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Medicines Australia welcomes funding for clinical trials and One Stop Shop

2 May 2024: The announcement by the Albanese Government of \$80.8 million in funding for clinical trials and a centralised approach to clinical trials known as One Stop Shop is a significant step towards improving access to medicines for all Australians.

"Australia is recognised globally as a preferred location for companies to conduct clinical trials thanks to our excellent healthcare facilities, researchers, a diverse population, and strong legal frameworks with robust IP protections," Ms de Somer said.

"Currently there are different processes and systems for clinical trials in each state and territory and within area health services. This creates



What are other countries doing?



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Complimentary feasibility studies & investigator matching

- CRM evaluates feasibility studies/request that are forwarded by sponsors/CROs and disseminates them to a large pool of potential investigators.
- CRM assists investigators who are interested to take-on the trial to complete and submit the feasibility study/request to the sponsor



Consultation and management of clinical trial budget

- CRM advices investigators and sponsors/CROs on the clinical trial budget. This service ensures that resources are sufficient in order to complete all obligations of the clinical trial.
- CRM manages the trial budget with full transparency and schedule reports to



Review of Clinical Trial Agreement (CTA) & Non-Disclosure Agreement (NDA)

- CRM assists investigators & sponsors/CROs by reviewing and advising on Clinical Trial Agreements (CTAs) & Non-Disclosure Agreements (NDAs).
- CRM's experience TRIAL!

 assistance to review the CTA/NDA.
- A Watch this video to learn more of CDM's





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Development & placement of study coordinators

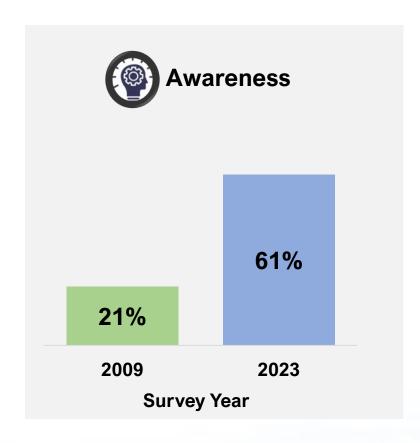
- CRM recruits suitably qualified candidates and trains them to become capable Study Coordinators (SCs) who will then be placed at trial sites in order to assist investigators.
- CRM currently has a pool of close to 130 trained SCs based in major clinical research centres nationwide.

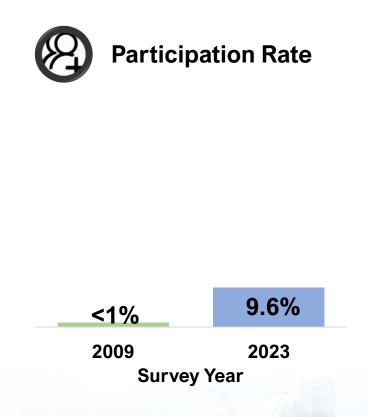
One-stop centre for the industry

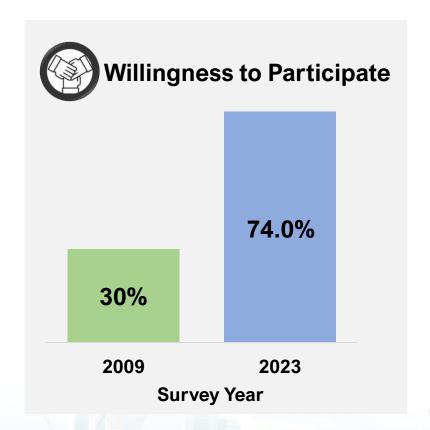
- CRM assists industry players in resolving issues or delays faced with government agencies and regulators (eg. MREC, MDA, NPRA, IRBs) that may delay the approval or initiation of trials.
- Access relevant guidelines and resources here



Singaporean's Awareness and Perceptions of Clinical Trials







Since 2009, there has been a significant increase in Singapore residents' awareness of clinical trials and willingness to participate in trials.

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Note:

- 2009 Survey by MOH / NMRC (n = 2000 healthy public; telephone interview)
- 2023 Survey by SCRI (n = 1000 general public; online & street survey) Both surveys were commissioned to Frost & Sullivan.



Our Public may be more receptive to clinical trials than we think



Health Check Podcast: All you need to know about Covid-19 clinical trials



Joyce Teo Senior Health Correspondent The Straits Times



PUBLISHED: Apr 07, 2021, 06:00pm









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SINGAPORE



X

Science Talk

Fast and Furious. Can we trust the speedy development of Covid-19 vaccines?

Danny Soon











Clinical Trials Flywheel, Coupling ISTs and IITs

ECOSYSTEM ENABLEMENT

Bring existing capabilities to full potential through operating model tweaks

Streamlined regulations

Talent pipeline

Centralized governance - e.g., CT one-stop shop

FURTHER INNOVATION

Continued innovation on cutting edge trial designs and capabilities

Synthetic trials

Network trials

Decentralized trials

ACTIVE DEMAND GENERATION

Actively market Singapore to sponsors/CROs; support PIs in pursuing CTs

Pipeline assessment & targeted marketing

Tiered incentives for biotechs

Grants for Pls



Continued trial execution excellence

Centralized trial coordination

Centralized data stewardship

Adoption of Al tools



SINGAPORE CLINICAL

TRIALS

FLYWHEEL

Continued upskilling of research talent (incl. KOLs); development of Singapore's reputation as a CT hub

HEALTH BENEFITS

Improved public health and patient outcomes

ECONOMIC BENEFITS

GDP uplift & job creation (directly & through 2nd order effects)

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What could the solutions be?

- Centralised and dedicated resources for contracting and budget negotiations
- Better harmonised data platforms and single point of contact for feasibility assessments
- Dedicated talent and resources for trial operations
- "One-Stop Shop"

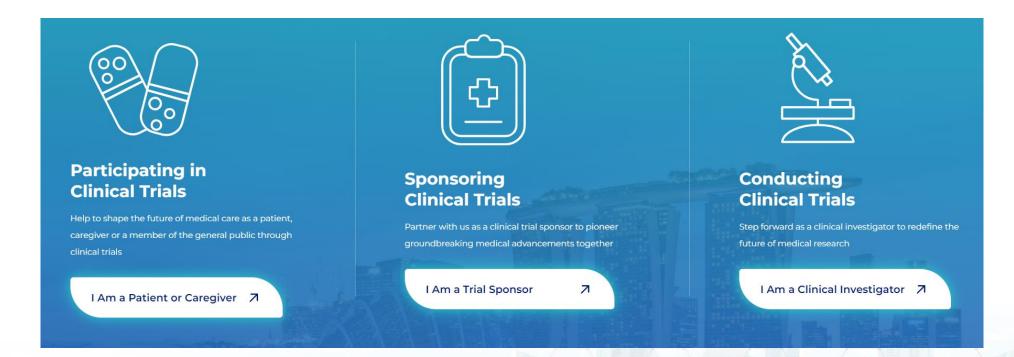
To be further elaborated in our Value Proposition of Clinical Trials Report







CTSG - Your centralised hub for clinical trial information and resources in Singapore. (clinicaltrials.sg)



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Ultimately.....

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Clinical Trials offer new hope to Patients





- Emily Whitehead, diagnosed with blood cancer in 2010, aged 5
- Received experimental CAR-T in 2012, at Penn State University Hershey Children's Hospital
- Enrolled in Penn State University in 2023
- Kymriah[™] was approved 2017

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'Breakthrough' therapy for the most common type of leukaemia among children approved in Singapore



White blood cells are removed, genetically modified to attack cancer cells and put back into patients, in a treatment that was recently approved in Singapore. (Photo: Novartis)









24 Apr 2021 06:01AM | (Updated: 29 Apr 2021 09:28PM)



Clinical Trials offer new hope to Patients

Use of living cells to treat cancer offers new hope

- May 2021, Mdm Fung was diagnosed with large diffuse B-cell lymphoma.
- She went through a series of conventional treatments that were unsuccessful.
- Not suitable for a stem cell transplant.
- Jul 2022, received her infusion via experimental CAR Tcell therapy.
- Jul 2024, Mdm Fung remains in remission from lymphoma

THE STRAITS TIMES

Cell therapy: Using living cells to cure disease

of patients for almost a month after the inflama, a type of cancer that affects had to be fully cooked to protect which brings together several re-

gene therapies offer hope as possi- there are potential side effects,

Cell therapy refers to the harness.

ing of living cells to treat diseases

SOMETHING TO BELIEVE IN With today's advanced have hope, provided we don't give up.

dromes, where the immune system circumstances - is reported to

science, we do have hope, p we don't give up," she said.



Madam Fung Mei Fong is now in remission after receiving experimental chimeric antigen receptor T-cell therapy. ST PHOTO: BRIAN TEO

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