

Driving Clinical Research Innovation and Translation for Singapore

CRIS's Vision

To nurture and build for Singapore,
cutting edge capabilities and innovation in
clinical research and translation

CRIS's Mission

To ensure unity of mission across research platforms and programmes under the CRIS stable.

To ensure synergies of capabilities, scientific resources, industry development, and finances across research platforms and programmes.

To ensure that the platforms and programmes stay relevant and are aligned to the needs of Singapore patients, researchers and industry, through constant and regular stakeholder engagement.

To build, review and sustain long term strategies for research platforms and programmes.

CRIS and its Business Units



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



- Drive impactful health and economic outcomes for Singapore by catalysing innovation and enterprise endeavours in the healthcare research community through public and industry partnerships



- To spearhead quality manufacturing of cellular-based therapeutics and develop cell therapy services
- Support and foster collaboration in research and development within the cell therapy ecosystem
- Train and educate the next generation of scientists and clinicians in cellular-based therapy



- To synergise the strongest basic, clinical and translational talent and expertise from across Singapore to create a cohesive and focused national-level cancer research and translational programme

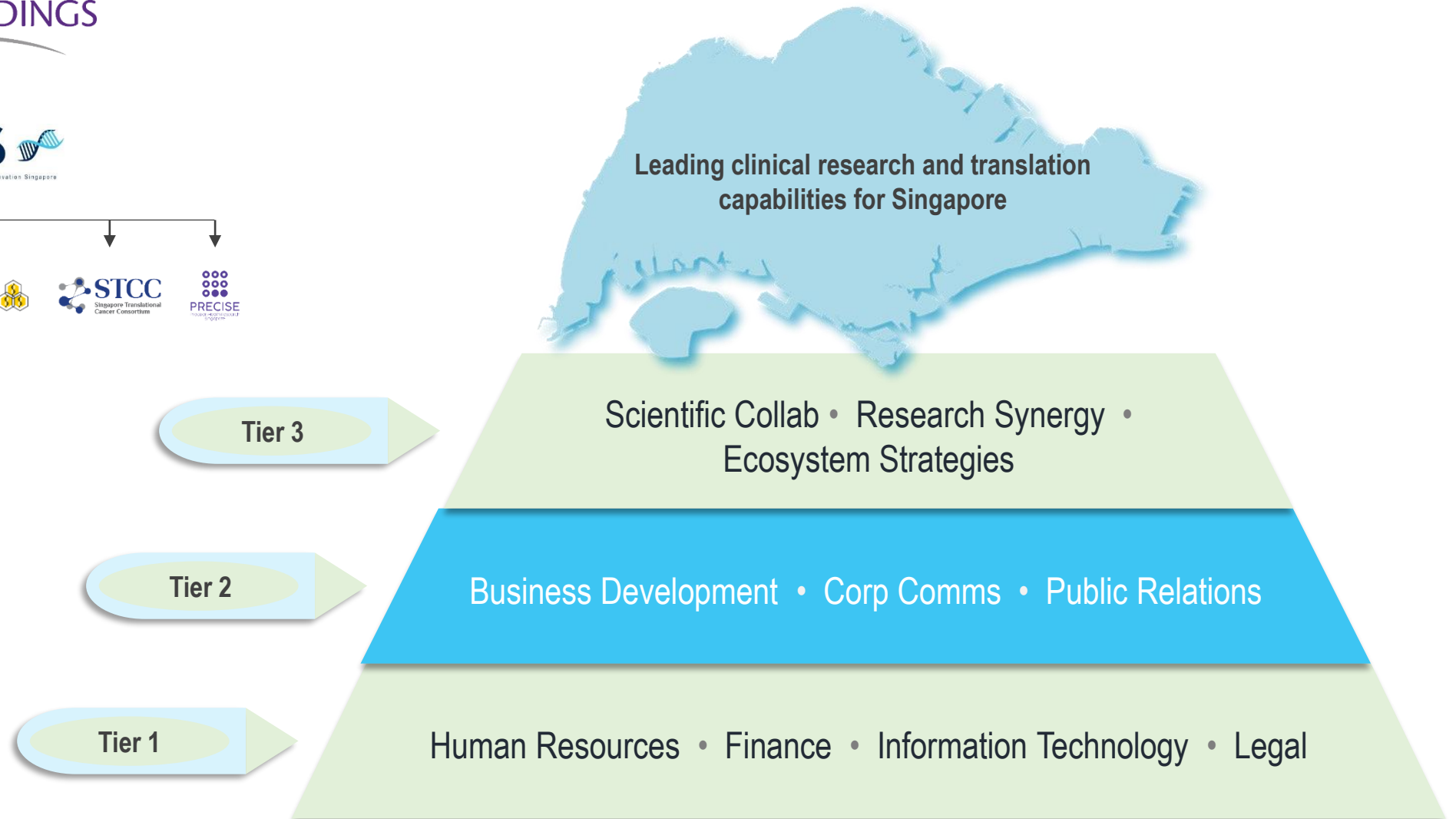
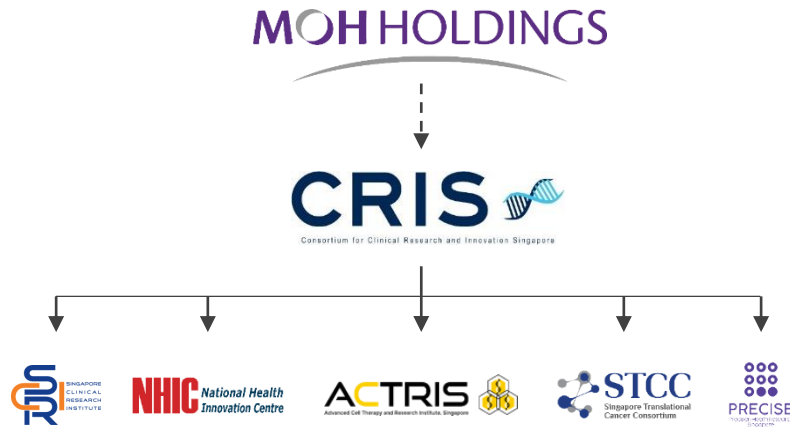


- Coordinate a whole-of-government effort to implement Singapore's National Precision Medicine programme, to drive at national level: data-driven healthcare, improved patients outcomes and economic value capture



- | | |
|-------------------------------|-------------------|
| • HR | • Finance |
| • Corporate Comms | • Procurement |
| • Planning | • IT/ IT Security |
| • Business Development | • Legal |
| • Quality, Compliance & Audit | • Science |

Three Tiers of Alignment and Support



About SCRI

Singapore Clinical Research Institute

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



SCRI AT A GLANCE (2018 – 2020)

93 Active Studies

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

1. Pre-Grant/ Concept Generation

Services provided:

- Biostatistics
- Epidemiology
- Data Management
- Project Management



139 pre-grant support provided from 2018 to 2020 (approximately 2/3 of PIs continued to work with SCRI upon successful award of grant)



>\$5m of successful grant awarded from 2018 to 2020 (some are pending results)

2. Study Execution

Services provided:

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



61 new research operations contracts signed from 2018 to 2020



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

3. Analysis/ Reporting

Services provided:

- Biostatistics
- Epidemiology



116 journal publications from 2018 to 2020



51 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**

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

CLINICAL RESEARCH NETWORKS

CRN DEPARTMENT: AT A GLANCE



8

**ACTIVE RESEARCH
NETWORKs**

From 2017 to 2020



4

**NEW INVESTIGATORS
INITIATED CRN**

From 2017 to 2020



321

OVERSEAS CRN MEMBERS

From 2017 to 2020



18

CRN MEMBER COUNTRIES

From 2017 to 2020

TALENT DEVELOPMENT

SCRI ACADEMY: WHAT WE DO

Event Planning and Management

- Planning, execution and implementation of event and training programmes
- Logistic and administrative management
- Stakeholders management (e.g. Committee Members, Trainers, Collaborators, PHIs, Participants, Vendors etc)

Digital Learning and Transformation

- Develop digital training materials (e.g. video, quizzes, games)
- Digital learning infrastructure: Software and IT hardware
- Free and publicly available online CRC training (on SCRI webpage)

Intellectual Property Management

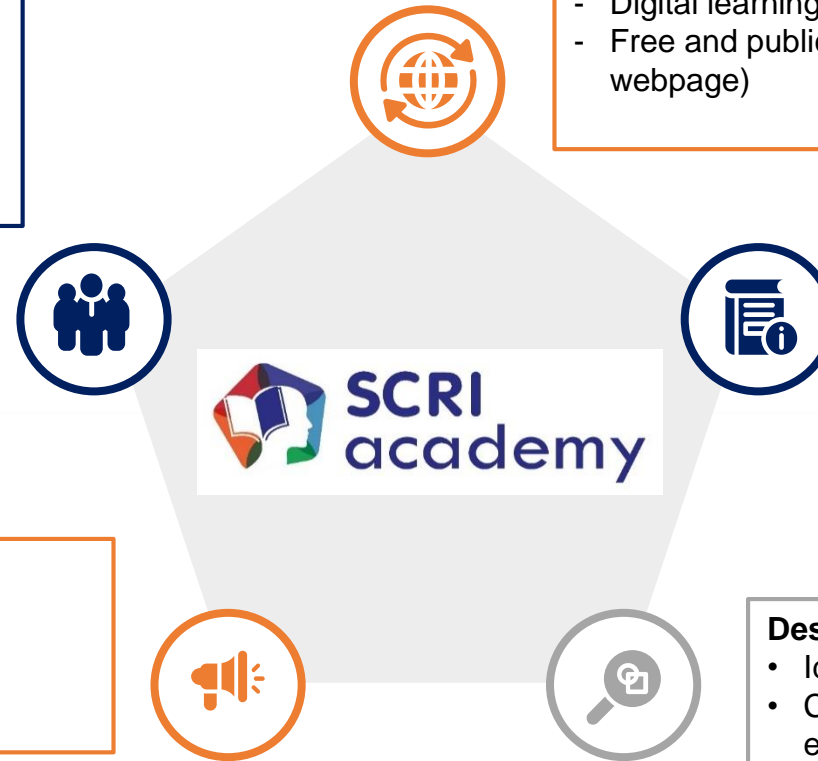
- Measures to safeguard the electronic training materials
- Develop Intellectual Property Copyright Clauses
- Implement Course and Educational Material Agreement for online training course

Publicity Awareness

- SCRI Academy webpage
- Mailing list
- Programme Flyer & Promotional Video
- A5 ICH-GCP Booklet & Collateral

Design of Training Curriculum & Delivery Method

- Identify the industrial technical experts
- Co-design training materials with internal & external experts
- Provide consultation on the classroom delivery method

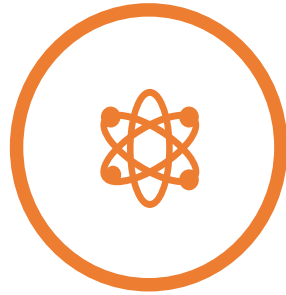


ENHANCING THE CLINICAL TRIAL LANDSCAPE

CLINICAL TRIAL IMPLEMENTATION COMMITTEE: AT A GLANCE



**CENTRALISE CLINICAL TRIAL
INFORMATION IN SINGAPORE**



**EFFICIENCIES IN CLINICAL
TRIALS**



**DEVELOPMENT FOR CLINICAL
RESEARCH PROFESSIONALS**



**BRIDGE NATIONAL &
ORGANISATIONAL ROLES**

OUR PARTNERS



About NHIC

NATIONAL HEALTH INNOVATION CENTRE SINGAPORE

An Innovation & Enterprise Office (IEO)
for Public Healthcare Institutions





NATIONAL HEALTH INNOVATION CENTRE

Founded in 2014, we provide the publicly-funded clinical research sector of Singapore with **translational funding** and **strategic guidance** to accelerate healthcare innovation and commercialization.

OUR VISION

Singapore as a leading hub for **health innovation & enterprise** in Asia

OUR MISSION

Drive impactful health and economic outcomes for Singapore by **catalysing** innovation and enterprise endeavours in the healthcare research community through public and industry **partnerships**

OUR VALUE PROPOSITION



FUNDING

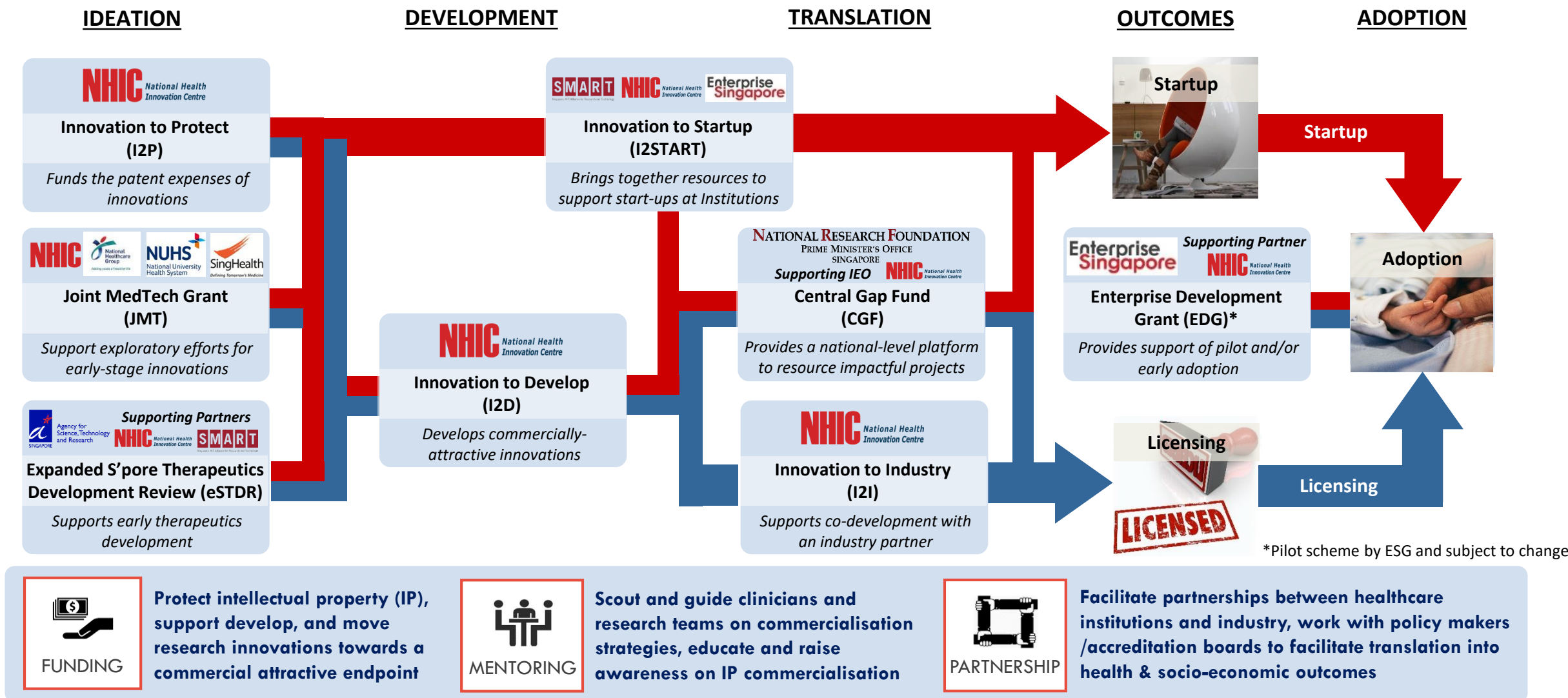


MENTORING



PARTNERSHIP

Strategic Pathway to Accelerate Healthcare Innovations



TECHNOLOGY AREAS FUNDED



DIAGNOSTICS

Diagnosis performed with the aid of AI based on imaging or sensor reading.

Biomarker based IVDs or CDx for clinical diagnostic and precision medicine applications.

MedTech



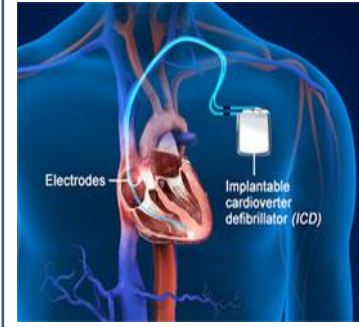
SURGERY TOOL

Use during a procedure, device that are largely mechanical.



HEALTH IT

Apps, VR/AR, Cloud, without a diagnosis.



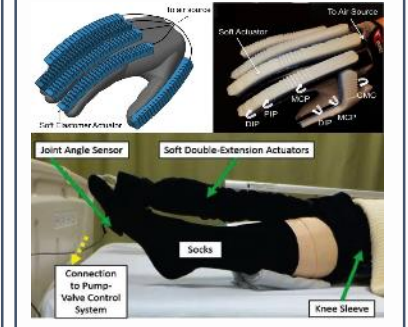
IMPLANT

Implantable devices



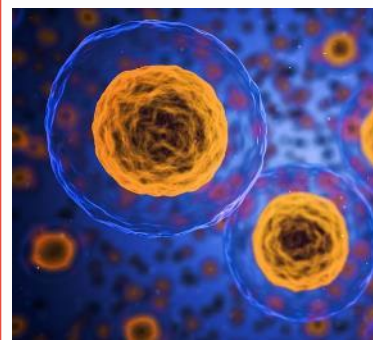
SENSORISED FEEDBACK SYSTEM

Sensor providing close loop feedback to users, semi or fully automated.



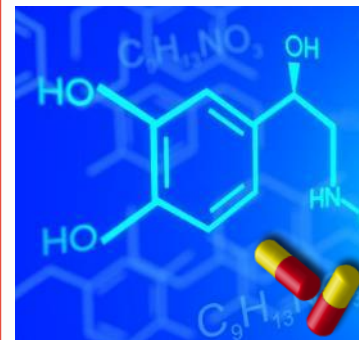
THERAPY

Therapeutic Tools



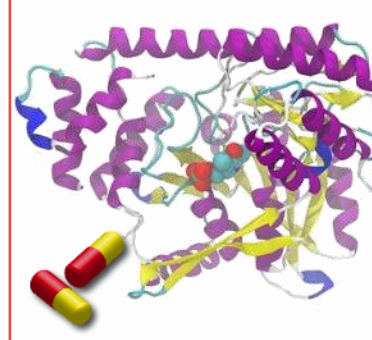
DRUG DELIVERY

Formulations, excipients and adjuvants that improve drug release, distribution and absorption profile.



SMALL MOLECULES

Small molecule drug candidates with specific druggable targets.



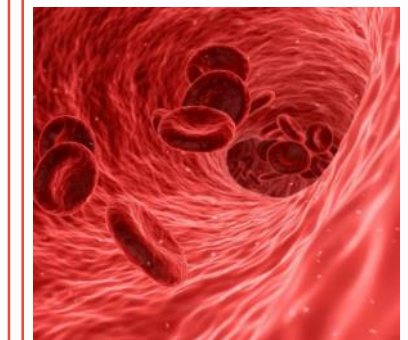
PEPTIDES/PROTEINS

Peptide and protein-based therapeutics targeting specific receptors or biomolecular interactions.



ANTIBODY

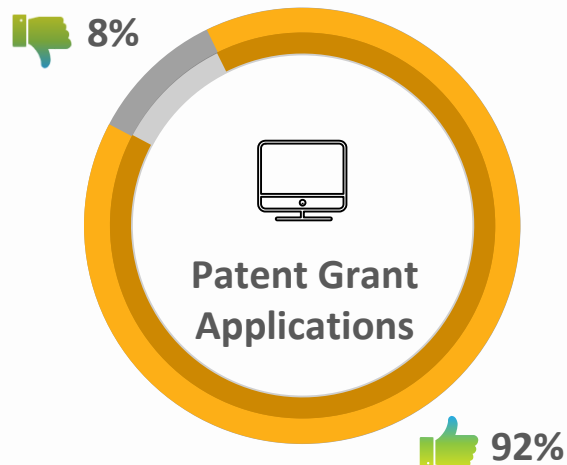
Antibody-based (mABs) therapeutics targeting immune/inflammatory systems or tumour surface antigens.



CELL THERAPY

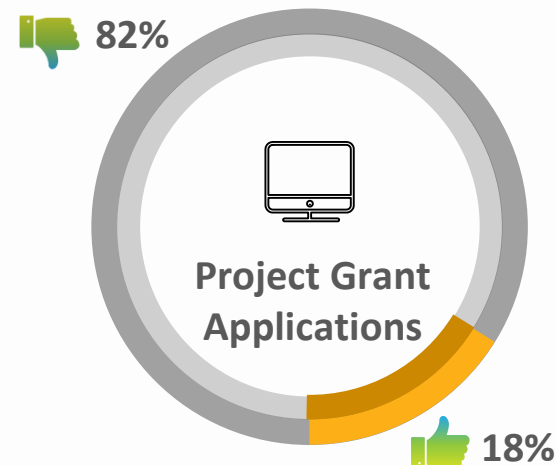
Approaches in autologous and allogeneic stem cell transplants or adoptive cell transplants (CAR-T).

BioPharma and
Stem Cell
Therapy



Innovation to Protect Grant

92% of the I2P applications have successfully obtained approval for funding for patenting expenses.



Innovation to Develop Grant

The success rate for I2D project grant is about 18%. About 65% are in MedTech, and 35% are in BioPharma areas.

Key Performance Indicators

Since the start of operation in June 2014, NHIC has achieved these KPIs through our funding and facilitation of the healthcare clusters in Singapore.

As of 31st March 2021



Licences
facilitated

46



Licensing
revenues

S\$2.4M



Start-up
companies

15



Innovators
participated

620



Private
investment

S\$22M



Start-up
valuation

S\$74M



Products
launched

6



Market
entries

15

NHIC DASHBOARD

NHIC

Industry Engagement

INDUSTRY ENGAGEMENT MODEL

NHIC has established multiple channels to engage industry partners in the health tech field.

- 

CREATE AWARENESS

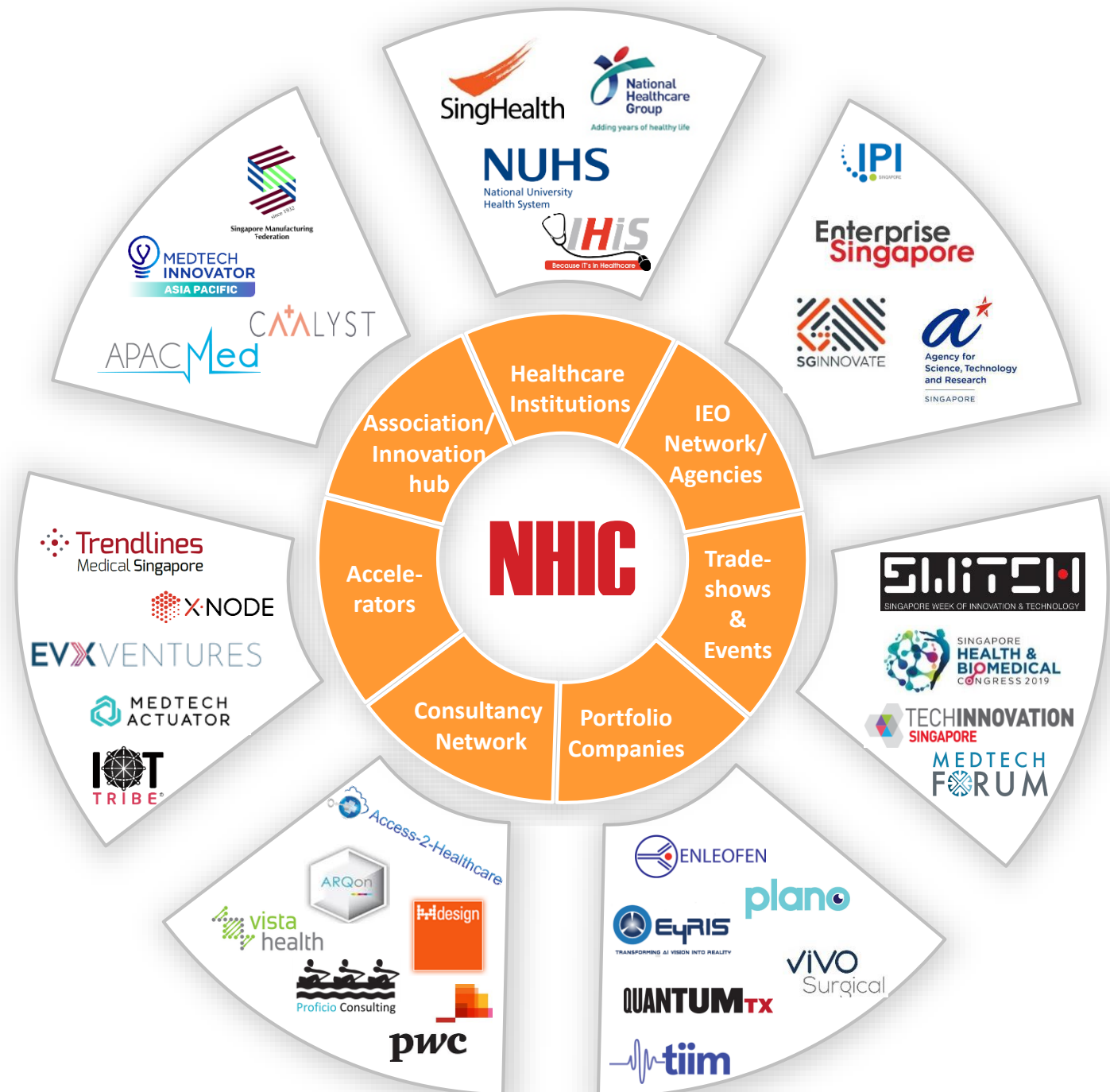
Through partners, exhibitions, and sharing at events to create awareness of co-innovation opportunities.
- 

FACILITATE COLLABORATION

Pre-engagement session with the industry partners. Connect clinician innovators with industry partners.
- 

SHARE INDUSTRY NEEDS

Work with industry associations and update with the latest industry interests and directions.



Thank you



About ACTRIS



Advanced Cell Therapy and Research Institute, Singapore



Dr Tan Lip Kun

Pro-tem Lead, ACTRIS

Senior Consultant (Haematologist), National University Health System

Supported by



MINISTRY OF HEALTH
SINGAPORE

Cellular Therapies in Immuno-oncology and Regenerative Medicine

Applying stem or differentiated cells with or without genetic engineering to cure diseases or replace diseased cells/tissues/organs.

>1,000 Clinical Trials in 2019

Products: >60 Approved; >100 in Review

Global Market Growth*

Compound Annual Growth Rate of 7% from 2020–24 (\$1.5B to \$2.2B)

Development



Therapeutics and Tools

- Pharmaceuticals
- Start-up/Biotech Companies
- Research/Academic Institutes

Productization



Regulatory and Manufacturing

- Regulatory Authorities
- Equipment Suppliers
- **Accelerators/Enablers** and CDMOs

Clinical Adoption



Clinical Trials and Commercial

- Hospitals
- Clinical Research Organizations
- Industry Players

ACTRIS's Vision: To be the national and regional Centre of Excellence for facilitating discovery, process development and clinical-scale manufacturing of cellular-based therapeutics.



ACTRIS' Vision, Mission and Core Values

Vision: To be the national and regional Centre of Excellence for facilitating discovery, process development and clinical-scale manufacturing of cellular-based therapeutics.

Mission

- To spearhead quality manufacturing of cellular-based therapeutics & develop cell therapy services.
- Support and foster collaboration in research & development within cell therapy ecosystem.
- Train and educate next generation of scientists and clinicians in cellular-based therapy.






Core Values

- Accessibility: To cellular therapeutics.
- Commitment: To training, quality and standards.
- Teamwork: In fostering a vibrant ecosystem.
- Reliability: In our people and of our leaders.
- Innovative: In promoting research and development.
- Service Excellence: To our partners and our patients.



Core Capabilities and Service Provisions

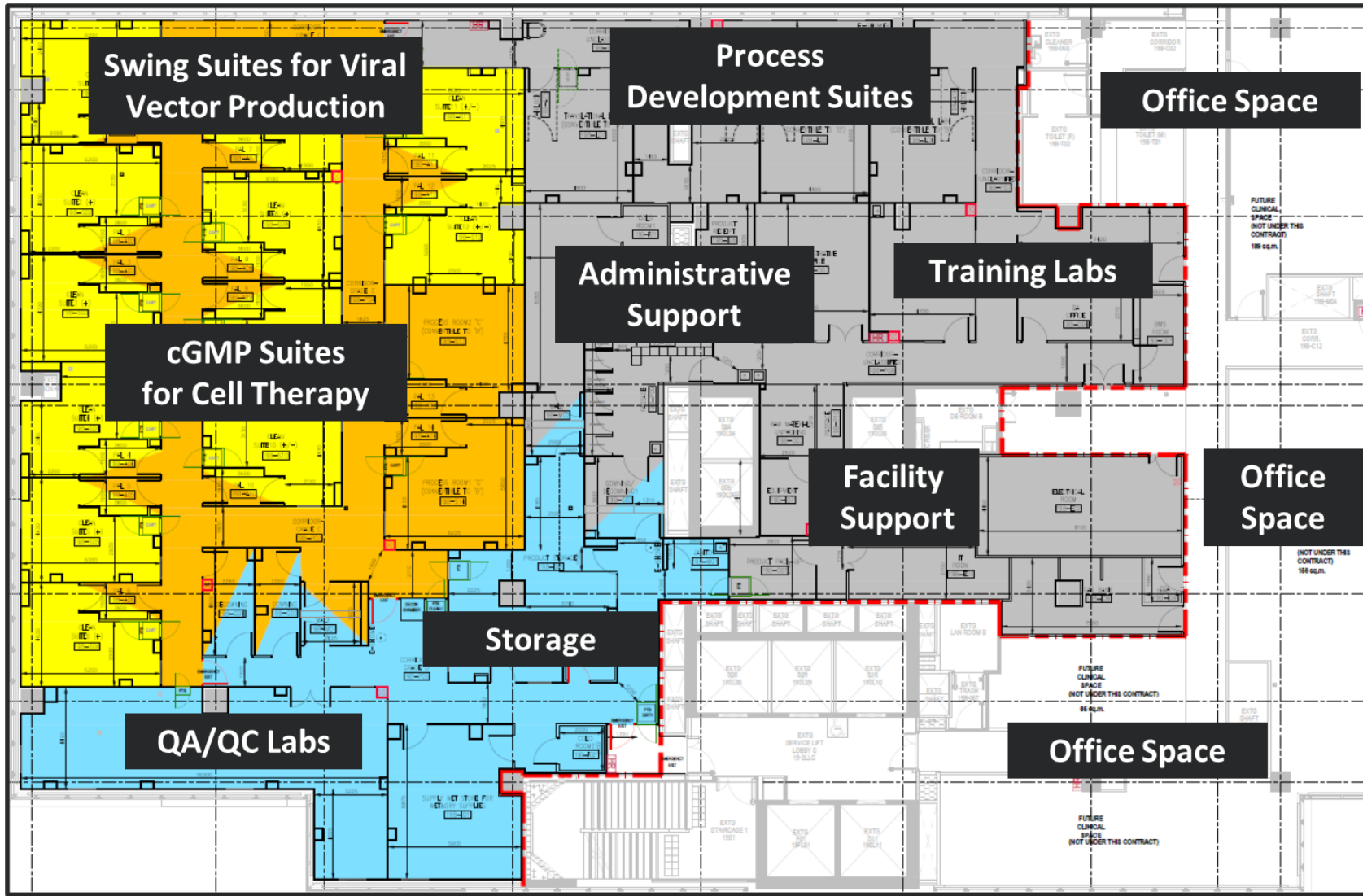
End-to-end Clinical Process Development and Manufacturing Capabilities

Process Development & Validation	Clinical Manufacturing	Product Characterization	Regulatory Facilitation	Clinical Trial Facilitation
				
Transition of processes from basic R&D processes to clinical-scale protocols.	Regulatory compliant manufacturing for clinical use in trials and routine services.	Product characterization to comply with product acceptance criteria.	Development and submission of regulatory documents for clinical trials and manufacturing.	Support in clinical trial design, patient access, trial data analysis and clinical adoption.

	Manpower and Training Certified training to perform CTGT manufacturing in cGMP suites.	
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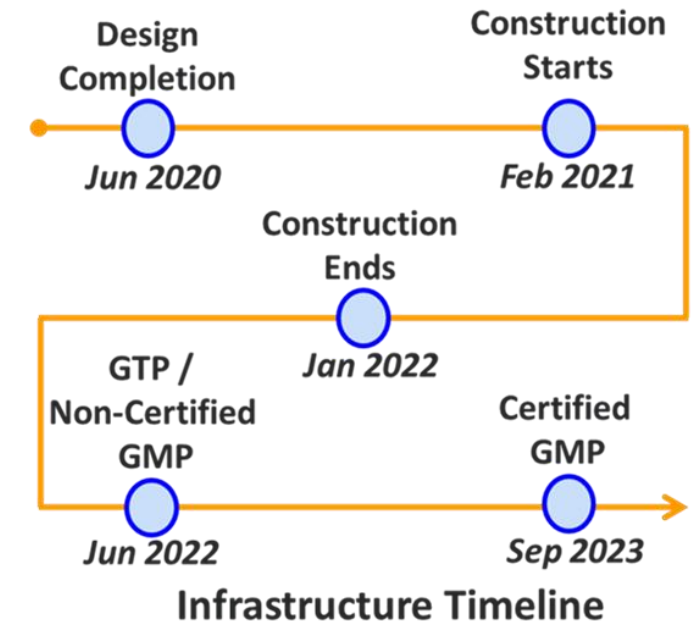
	Infrastructure; and Basic Equipment & Ancillary Materials (ACM) FDA and HSA reviewed design; manufacturing platform technologies; and quality system.	
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Infrastructure for Manufacturing Facility and Office Space



**Facility design reviewed by
FDA, USA and HSA, SG**

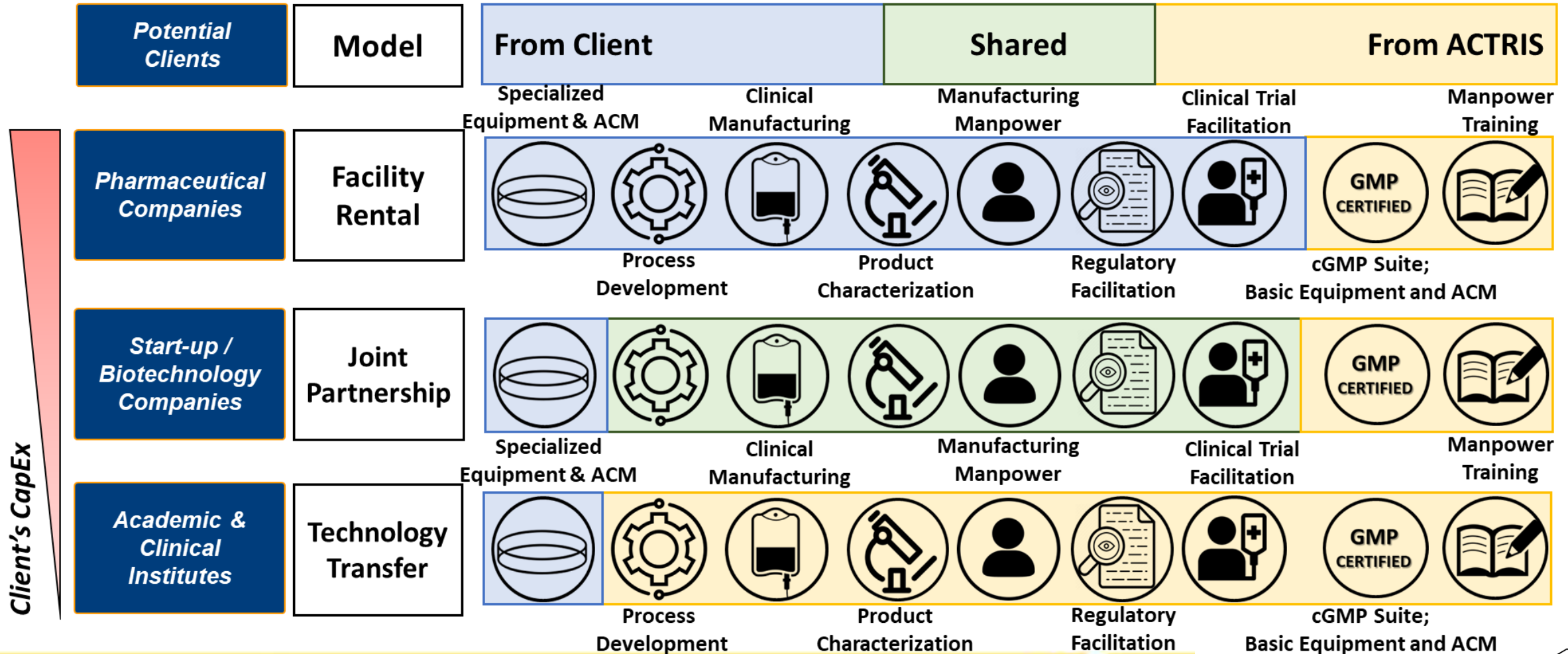
*The existing cGMP manufacturing facilities
at HSA, NUH and NCCS will eventually
transit under ACTRIS.*



Proposed Business/Operational Model and Clients

Modular approach in allowing flexibility for wide range of clientele

Partnering with BMS IPO and EDB on client engagement strategies and business development



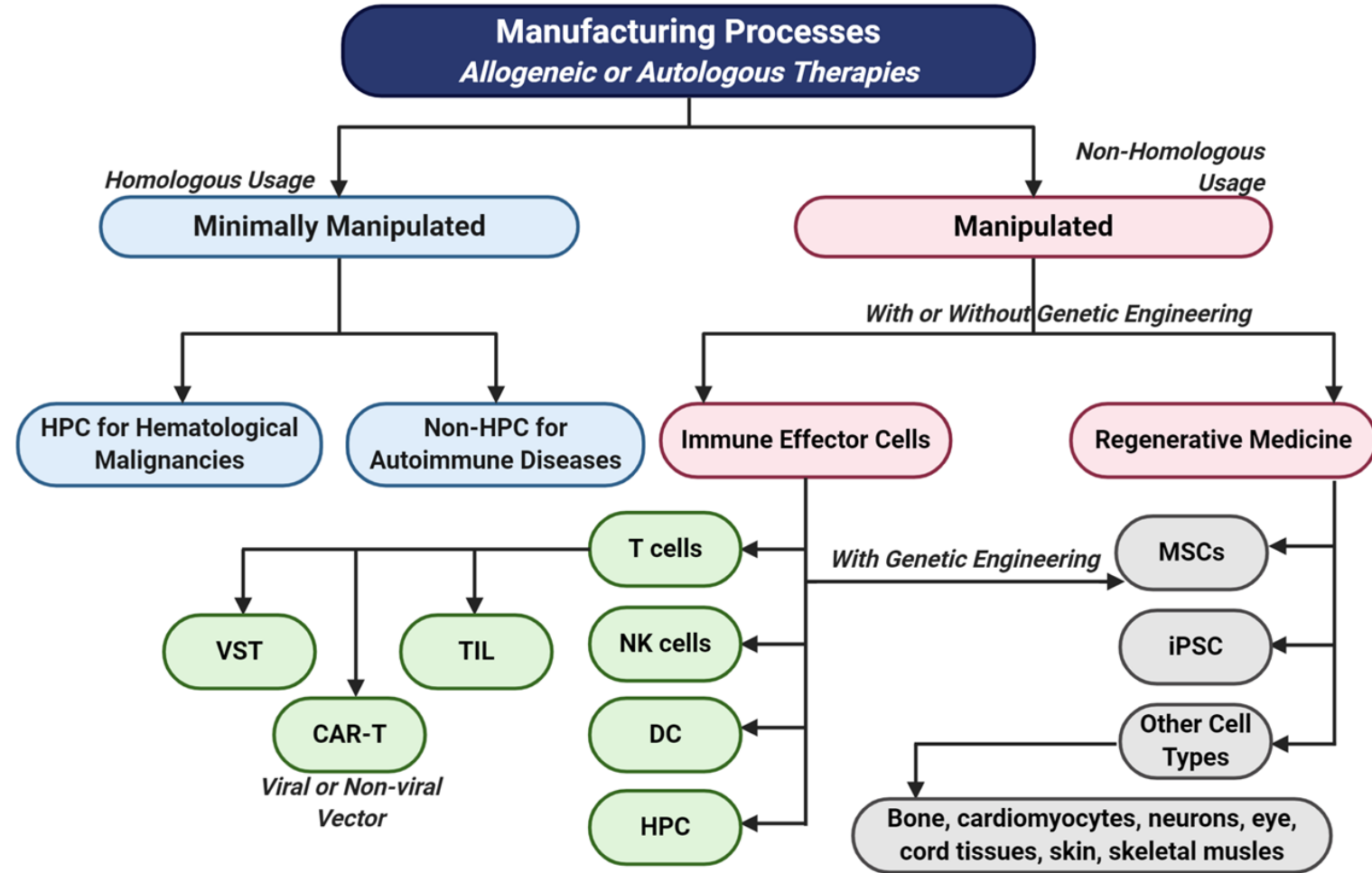
The above exemplified models can be further modified to meet clients' needs.

CTGTPs to be Manufactured

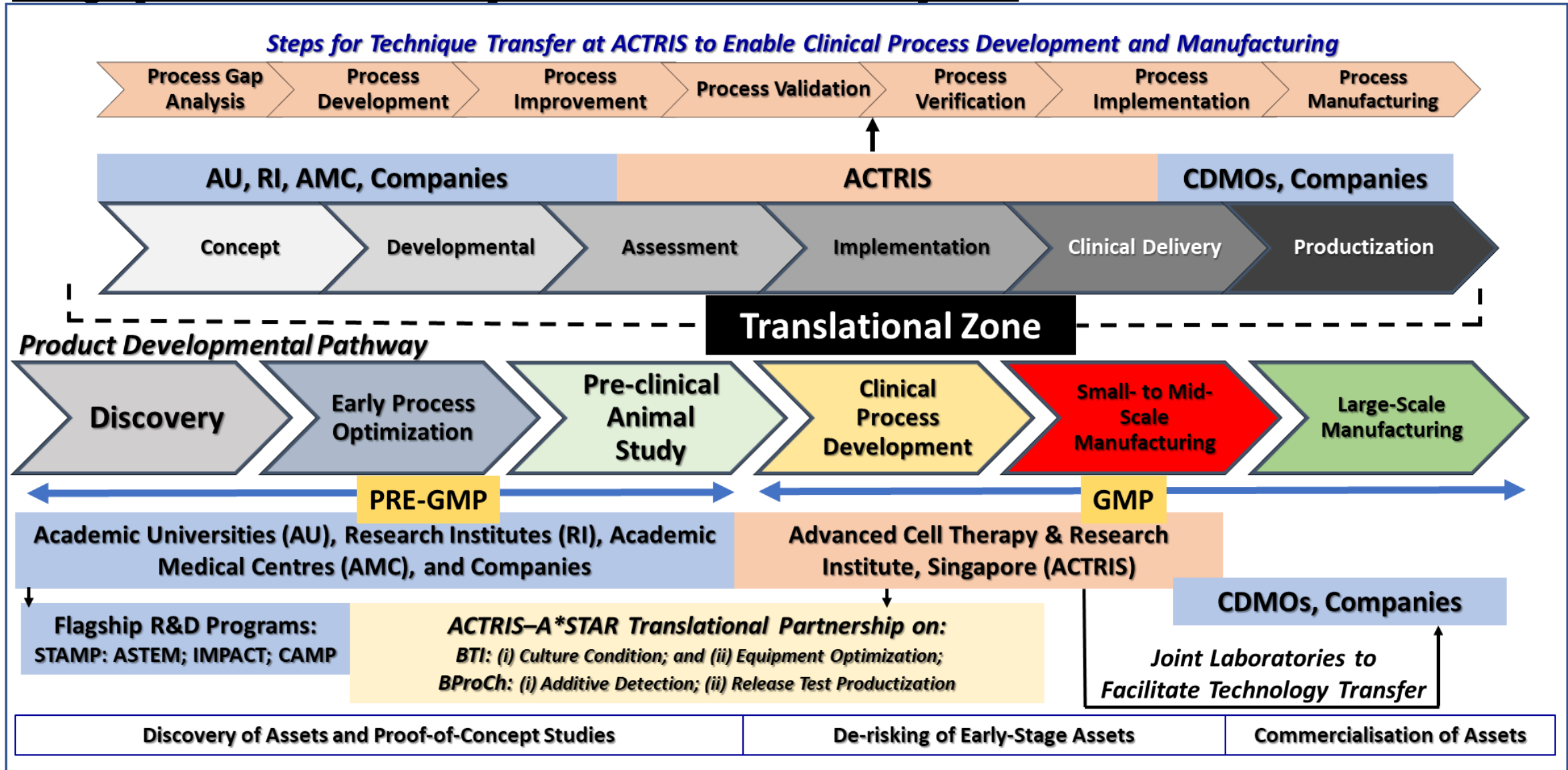
Cost-effective, small- to mid-scale, multi-product manufacturing.

Abbreviations:

HPC: Hematopoietic Progenitor Cells;
VST: Viral-Specific T Cells;
CAR-T: Chimeric Antigen Receptor T Cells;
TIL: Tumor Infiltrating Lymphocytes;
DC: Dendritic Cells
MSC: Mesenchymal Stromal Cells; and
iPSC: Induced Pluripotent Stem Cells.



Singapore's CTGT Ecosystem, 2021 and Beyond



Current Team of ACTRIS

- **Dr Tan Lip Kun (Pro-Tem Lead)**
Senior Consultant, NUHS
Medical Director, Stem Cell Laboratory (SCL) and
Tissue Engineering and Cell Therapy (TECT) Lab
- **Mr Soh Teck Guan**
Supervisor, SCL and TECT Lab, NUH
- **Mr Christofer Thow**
Senior Medical Technologist, TECT Lab, NUH
- **Dr Sudipto Bari**
Senior Research Fellow and
Principal Medical Laboratory Scientist, NCCS

Desk Head at MOH: Hospital Services Division, Ministry of Health

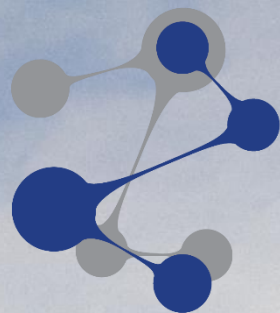
Funding Support: MOH, NMRC and NRF (pending review and finalisation)

- **Dr Marieta Chan**
Laboratory Director, Cell Therapy Facility
(CTF), HSA
- **Ms Madelaine Niam**
Senior Scientist, CTF, HSA
- **Ms Tan Siew Fong**
Senior Medical Technologist, TECT Lab, NUH
- **Dr Yap Eng Soo**
Senior Consultant, Haematology, NUHS
- **Dr Chandramouli Nagarajan**
Senior Consultant, Haematology, SGH

ACTRIS Staff

- Mr Terence Chua
Project Management
- Mr Sebastian Koh
Business
- Ms Shew Theng Chang
Quality
- Ms Florence Tan and Ms
Sreeranjani Mahalingam
Administration
- Mr Vernon Tan and Ms
Shelly Nyien
Information Technology
- Ms Esther Wong
Regulatory
- Ms Julie Goh
Project Coordination
- Mr Chris Liow and Lim
Shi Jie
Logistics

About STCC



STCC

Singapore Translational
Cancer Consortium

*A Nationally Coordinated
Consortium to Synergise Cancer
Research Capabilities Across
Singapore*

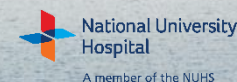
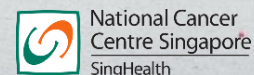
Supported by



NATIONAL RESEARCH FOUNDATION
PRIME MINISTER'S OFFICE
SINGAPORE



STCC Partners



STCC: Mission & Vision

MISSION

Chng Wee Joo
Executive Director



STCC brings together the best **basic, clinical and translational** talent in Singapore to create globally significant peaks of excellence in selected cancers, and provides these teams with an enabling research and innovation environment.

Peaks of excellence & thought-leadership

- Build leading Research & Translational **programmes** in selected Asian cancers
- Become a **reference** centre for clinical trials in Asia
- Grow critical mass of local key opinion leaders

LONG TERM OUTCOMES



- Conduct **world-class cancer research** with high-impact applications that improve health & healthcare
- Develop **new ways of delivering** cancer prevention, screening, treatment and care for Singapore

Healthcare impact

Economic Impact

- Anchor **critical mass** of industry research, innovation and **enterprise partnerships**

VISION

Lim Soon Thye
Co-Director



The STCC envisions for Singapore to become a **global leader** for selected Asian cancers in **research translation** and its application to **health** and/or **economic value creation**.

STCC: Driving Innovation & Synergy in Cancer R&D



Prof Goh Boon Cher
NCIS



A/Prof Daniel Tan
NCCS



Dr Eng Chon Boon
NUHS



A/Prof Kenneth Chang
SingHealth



Prof Teh Bin Tean
Duke-NUS



Dr Anand Jeyasekharan
CSI, NUS



Dr Alexander Lezhava
GIS, A*STAR



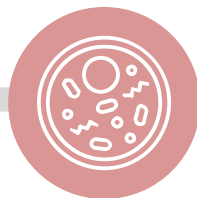
Seck Yee Kwang
A*STAR/ BMS IPO

Cancer Clinical Trials & Investigational Medicine Units



Streamlined clinical trial start-up framework that facilitates PI/KOL engagement and a single agreement contract process

Cancer Databases & Tissue Banks



Robust, secure and harmonised central catalogue portal for Asian-centric cancer samples & associated clinical research data

Research-Based Molecular Diagnostics



A cooperative translational cancer research framework for the development of a catalogue of novel molecular diagnostics and assays

Business Intelligence & Development



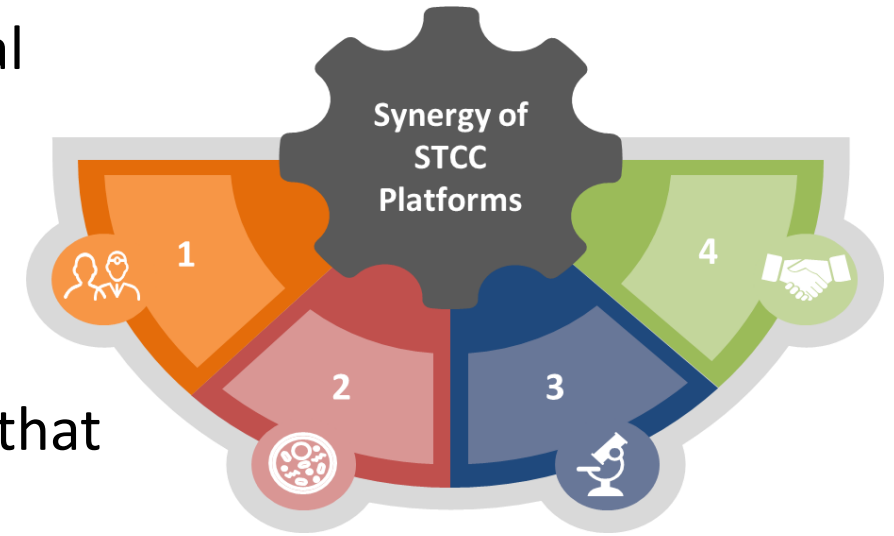
A dedicated team that facilitates partnerships and leads engagements between industries & STCC

STCC – A “ONE-STOP SHOP” FOR INDUSTRY PARTNERS

STCC: Our Approach to a Use Case Collaboration

A STCC USE CASE would also strive towards the following:

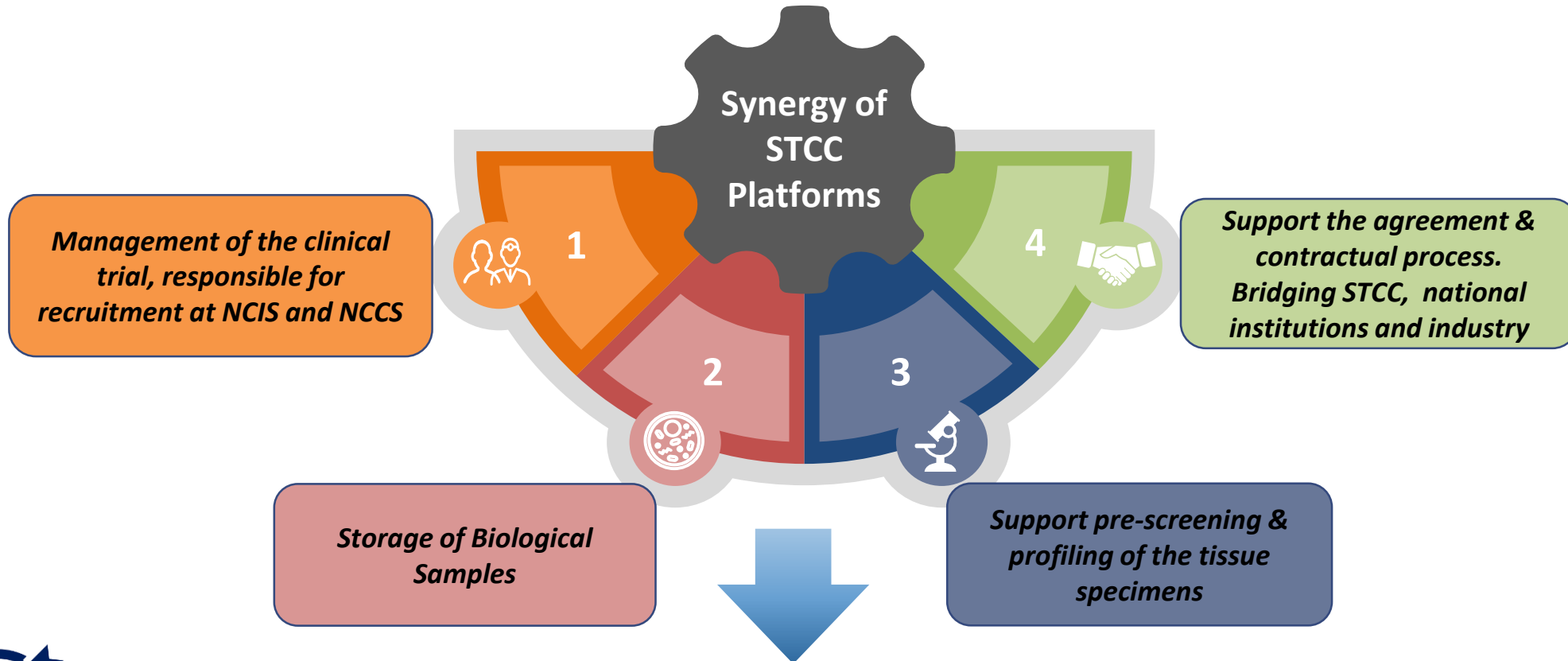
- Enhance **healthcare policies** and practices, local clinical practice guidelines and improve care and outcomes
- **Address healthcare challenges** of Singapore
- **Create and capture economic value**
- **Seed national-level translational cancer** programmes that will **generate healthcare** impact with **value-based healthcare** outcomes and evaluations
- **Innovative Oncology** early phase clinical trials that will generate better understanding of cancer biology and advance novel therapies for cancer treatment



A STCC Use Case Summary



A Phase II Multi-Centre Study Evaluating The Efficacy of Dacomitinib for Patients With Epidermal Growth Factor Receptor (EGFR)-Driven Advanced Solid Tumours With Low EGFR-AS1 IncRNA Expression Or Other Novel Emerging Biomarkers



Identification of novel prognostic or predictive biomarkers through RNA sequencing, epigenetic and molecular profiling on plasma and tumour tissue



A STCC Use Case Summary



A signed Memorandum of Understanding that aims to establish a critical infrastructure to advance the adoption of personalized healthcare in Singapore



- Clinical adoption of a precision oncology care model in Singapore
- Building a real-world data analysis infrastructure, and generation of real-world evidence
- Development of a national clinico-genomic cancer database
- Enhance patient access to comprehensive genomic profiling and molecularly-guided therapeutic options, effectively improving treatment outcomes

Discover More at STCC

SECK Yee Kwang

Head of Business Intelligence & Development

Singapore Translational Cancer Consortium

Director

Biomedical Sciences

Industry Partnership Office

seck_yee_kwang@hq.a-star.edu.sg

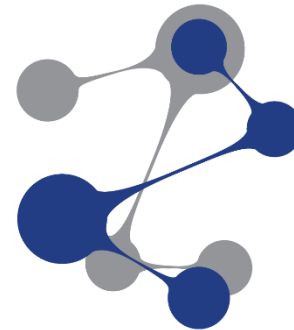
YAP Han

Manager

Business Intelligence & Development

Singapore Translational Cancer Consortium

han.yap@stcc.cris.sg



STCC

Singapore Translational
Cancer Consortium

About PRECISE



Singapore's National Precision Medicine Strategy

A 10 Year Roadmap

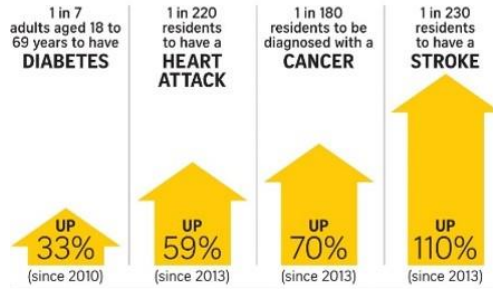


The Need For Precision Medicine In Singapore

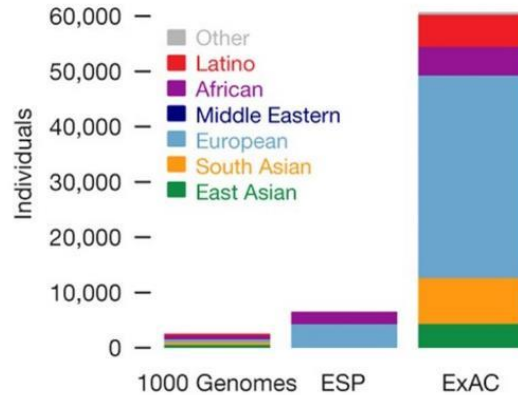
1. Rising Healthcare Costs

Diseases on the rise due to ageing population

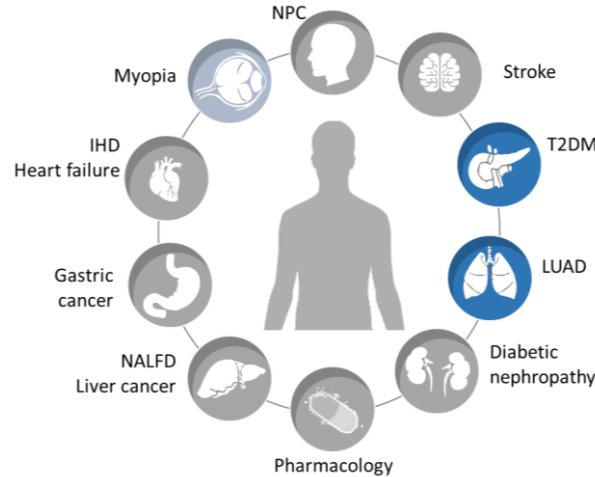
Estimated numbers by 2030



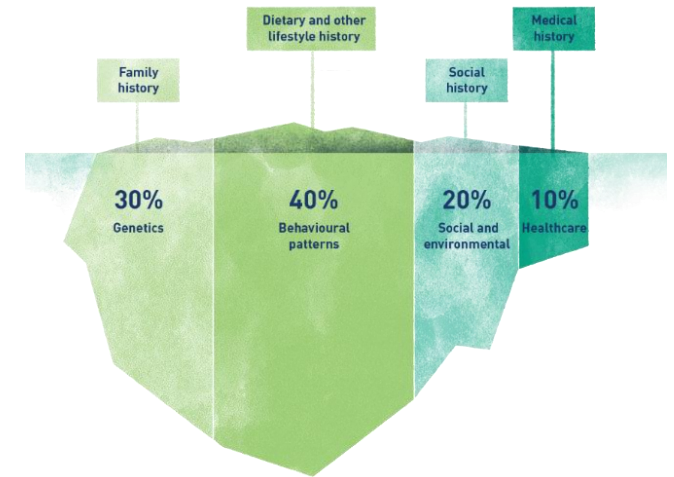
2. Missing Asian Genome



3. The Asia Phenotype



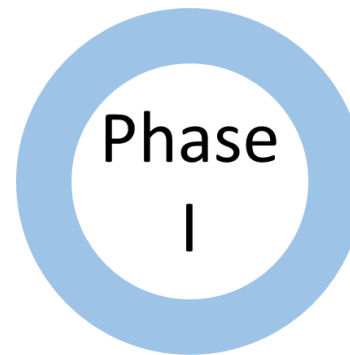
4. Gene-Environment



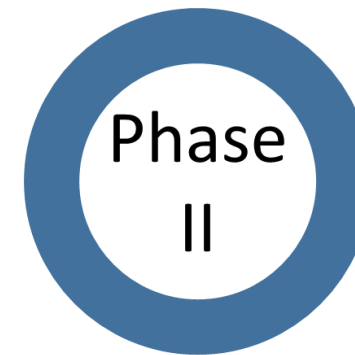
Strategy 10-year research roadmap to accelerate biomedical research, improve health outcomes and enhance opportunities for economic value across sectors



A central entity incorporated to **coordinate a whole of government effort to implement Phase II** of Singapore's 10-year National Precision Medicine (NPM) strategy.



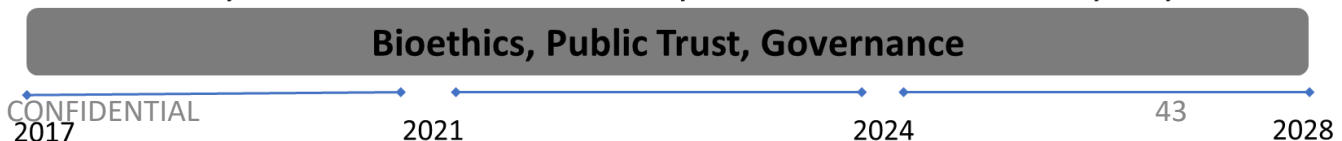
"Proof of Concept"
N = 10,000



"Proof of Value"
N = 100,000



"Proof of Scale"
N = 1,000,000



Singapore's Competitive Advantages

ASIAN DIVERSITY



DEEP PHENOTYPES



LONGITUDINAL



CONSENTED
FOR RECALL



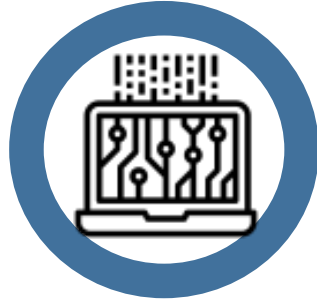
UNIQUE IDENTIFIER



STRONG IP
PROTECTION



DATA SCIENCE



GOOD
HEALTHCARE OUTCOMES



WHOLE OF GOV.



Singapore

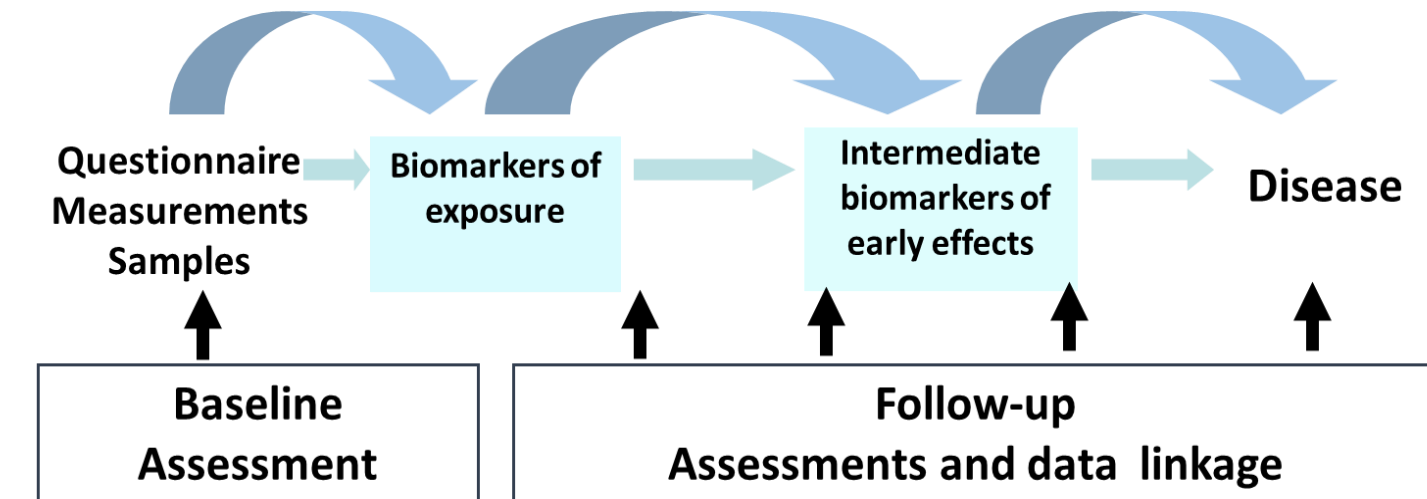
PRECISE
100,000
POPULATION 
Public Financing

Overview: Phase II Research Goals

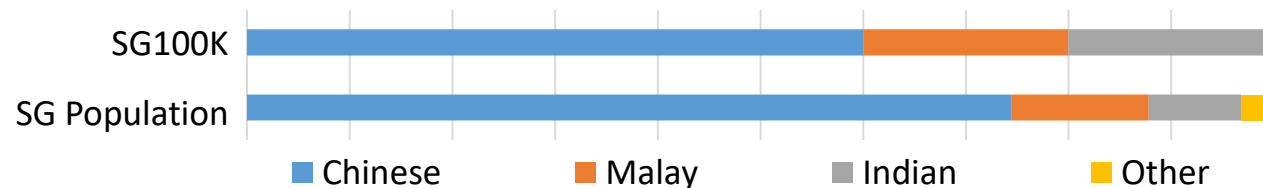


100,000 Singaporeans Research Study

Follow-up over time



Over sampling of Malay and Indian to ensure proper representation and sufficient statistical power.



Comprehensive Phenotypic Measurements & High Quality Biological Samples



Questionnaires

Demographic, lifestyle, environment, nutrition, cognition, etc.



Physical Measurements

Cardiovascular, respiratory, visual, adiposity



Biochemical Laboratory Assays

Serum creatinine, glucose & HbA1c, blood lipids



Imaging

Bone density, body fat, carotid imaging, retina



Lifestyle

Accelerometry



Molecular Characterisations

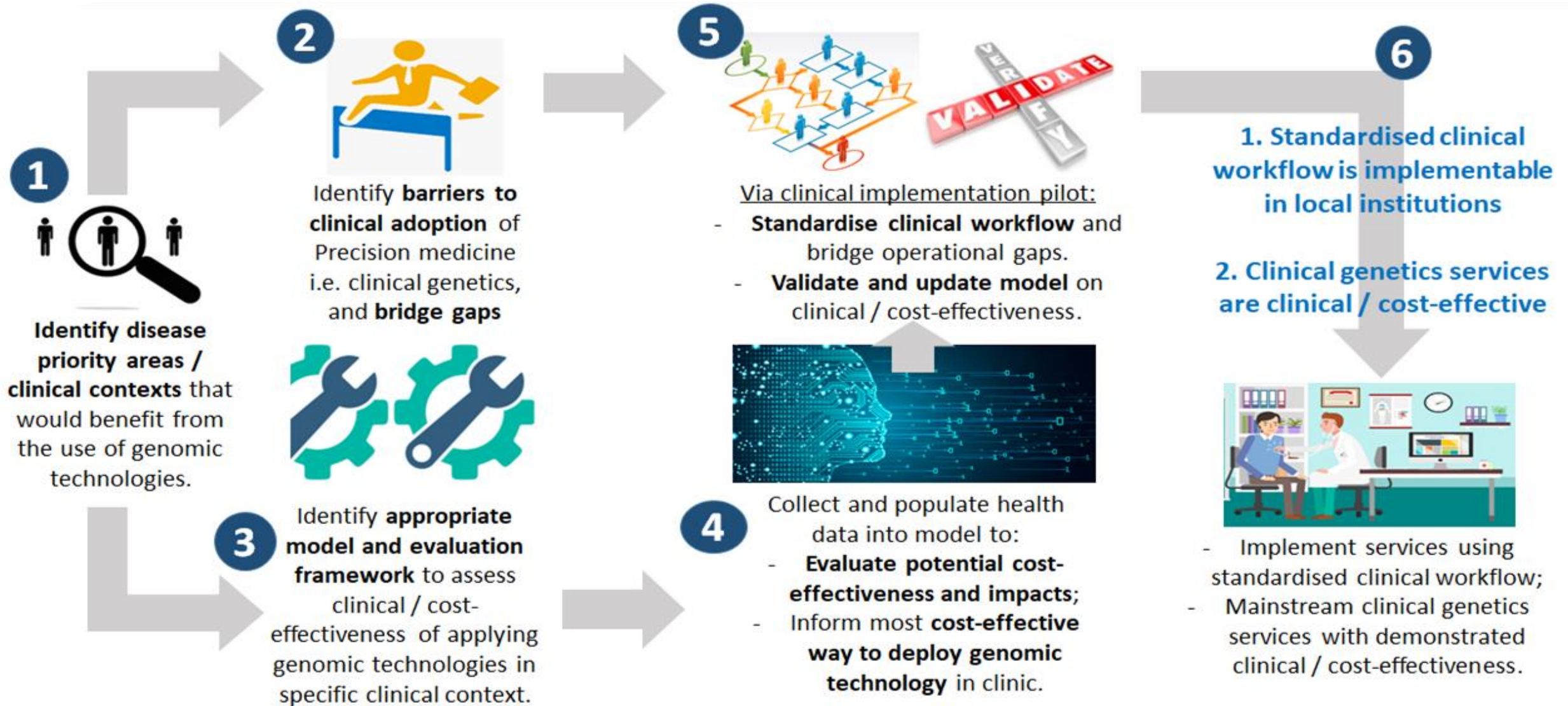
Genomic, metabolomics, methylomic



Biological Samples

Blood, urine, stool, skin tapes

Overview: Phase II Innovation Goals



Overview: Phase II Enterprise Goals

Desired Economic Outcomes

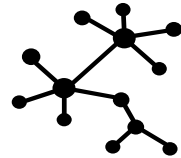
01 Create Industry Jobs in Singapore



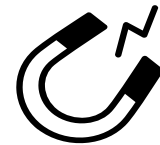
02 Increase Industry R&D Spending



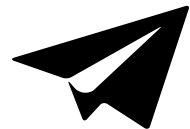
03 Embed New Capabilities



04 Attract Foreign Companies



05 Uplift Local Companies



Pathways to Achieve Economic Outcomes

Establish **Public-Private Partnerships (PPPs)** to achieve data generation and analysis goal

Establish a **Pre-competitive Industry Consortium (PCC)** to co-invest for access to data/cohort

Co-build **Clinical Implementation Pathways** to generate real-world evidence for proof-of-value

THANK YOU

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For enquiries, pls email contact@precise.cris.sg



Thank you

