ACTA SUMMIT 2018

BUILDING A SELF IMPROVING HEALTHCARE SYSTEM

"A NSW bird's eye view: current and ongoing strategies to enhance research translation"

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Office for Health and Medical Research

Darlington NSW, 29th November 2018

NSW GOVERNMENT

Presentation overview

1. Role of Office for Health and Medical Research
2. ‘Bird’s eye view’ of initiatives/funding
3. Clinical Trial initiatives
4. Research Governance Framework
5. TRGS – Translation Research Grant Scheme
6. How to support Translational Research

NSW GOVERNMENT

1. Role of Office for Health and Medical Research

Role of NSW Office for Health and Medical Research

- The Office is focused on providing researchers, clinicians, managers and policy makers with the tools/infrastructure they need to translate research/innovation into policy and practice to create healthier communities and deliver better patient care

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Role of NSW Office for Health and Medical Research

- OHMR was established to implement the NSW Government's strategic plan to build research capacity NSW following its NSW Health and Medical Research Review in 2012. Key priorities included;
  - **Facilitating** engagement of stakeholders
  - **Assisting** with the development of statewide strategic research priorities
  - **Providing** a supportive policy framework
  - **Administering** funding programs that support research infrastructure and innovation
  - **Supporting** clinical trials
  - **Collaborating** and Working with
    - NSW Health LHDs, Pillars Agencies
    - Industry, Universities, MRIs, Consumer groups, Peak bodies, NGOs
    - Government agencies – state, jurisdictions, Commonwealth

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Some key principles

- Where ever and when ever possible a **statewide** approach/remit
- Attention to the needs of **vulnerable** groups/populations
- Reward **excellence** in a merit based approach/processes
- Support **innovation** – across continuum – idea/concept to translation into care/commercialisation
- Facilitate **value-add** collaboration
- Priority driven funding programs that address the **needs** of patients, populations, the health system and researchers (infrastructure)
- **Equity** of access to
  - Opportunity
  - Health Care

NSW GOVERNMENT

THE NSW PUBLIC HEALTH SYSTEM IS WORLD CLASS.
IT IS THE LARGEST PUBLIC HEALTH SYSTEM IN AUSTRALIA.

7.8 MILLION
NSW RESIDENTS ON **809,444** SQ. KM

$21.7 BILLION
2017-18 BUDGET

228 HOSPITALS*

17 LOCAL HEALTH DISTRICTS & SPECIALTY HEALTH NETWORKS*

114,000
FULL-TIME EQUIVALENT STAFF

* St Vincent's Hospitals Network
NSW Ambulance

NSW GOVERNMENT

NSW has natural strengths

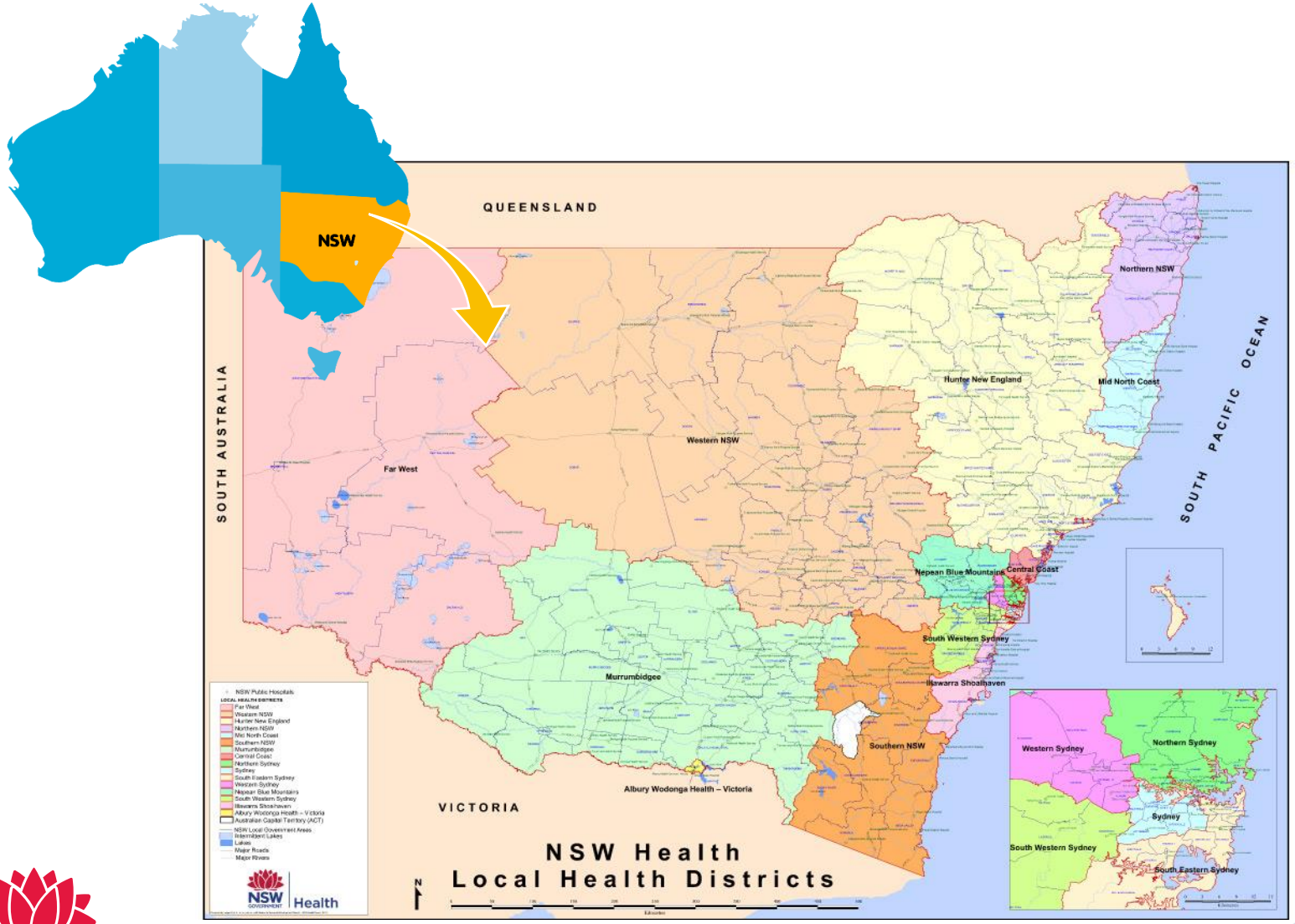
- Large and diverse population
- High quality health and education system
- Excellent clinical and research workforce
- Strong disciplines such as engineering and computing
- Data and analytics capacity
- Strengths in population health and health services research

- 55% of Australia's medtech companies are headquartered in NSW
- 60% of medtech IP registration (PCT) in NSW

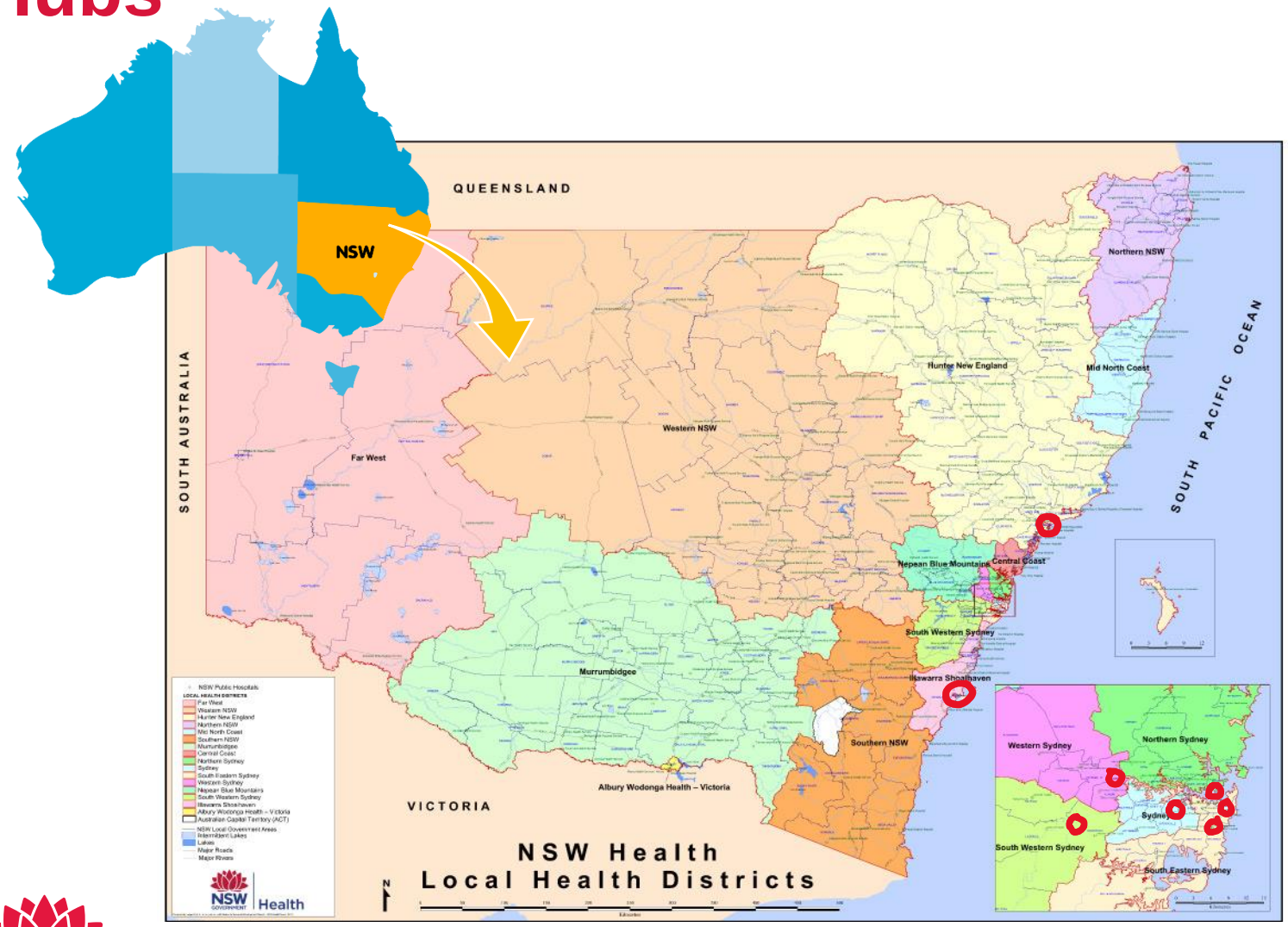
Strong clinical networks and clinical trials infrastructure

NSW GOVERNMENT

A snapshot of NSW Health



Geographical Health and Medical Research Hubs



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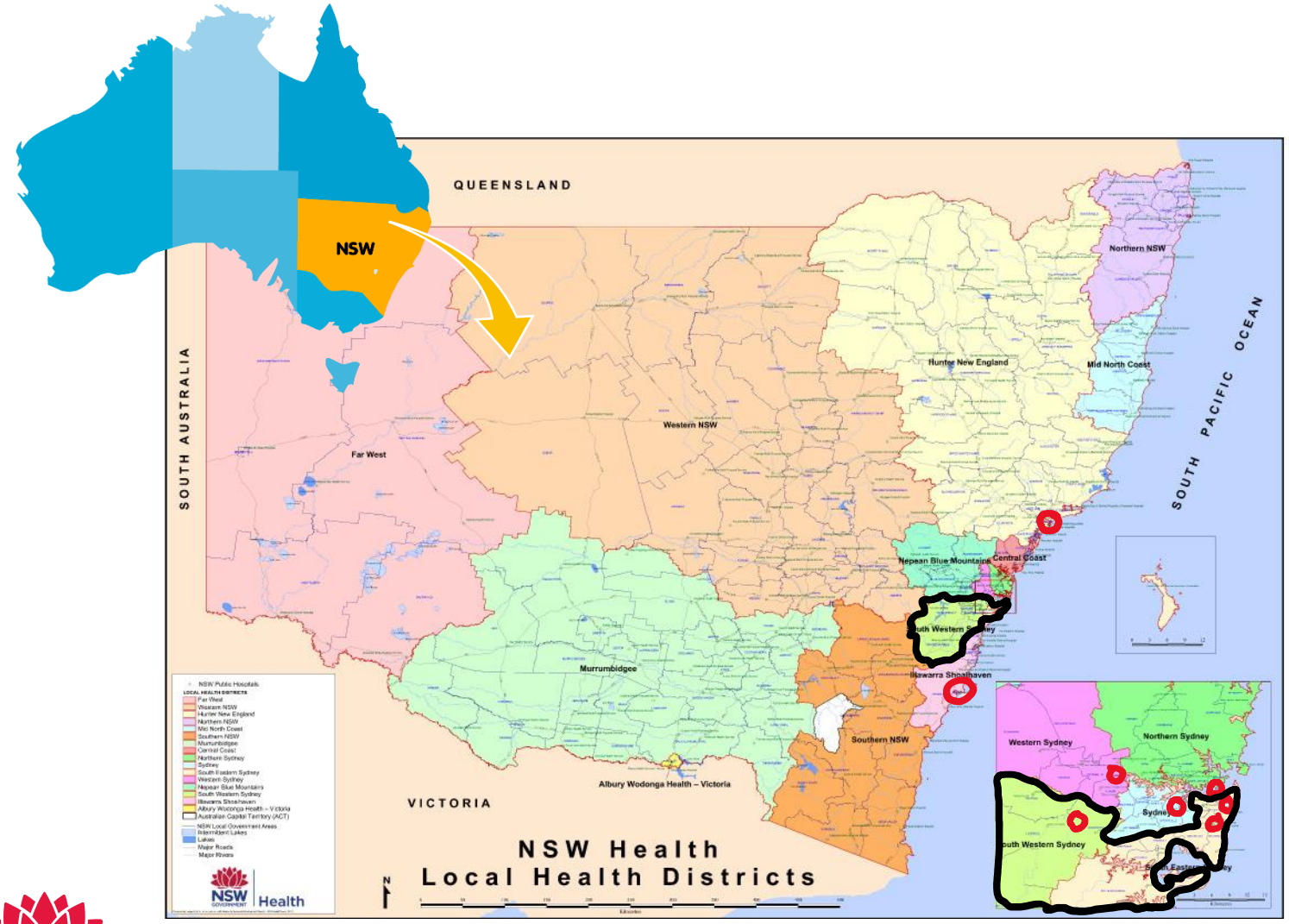
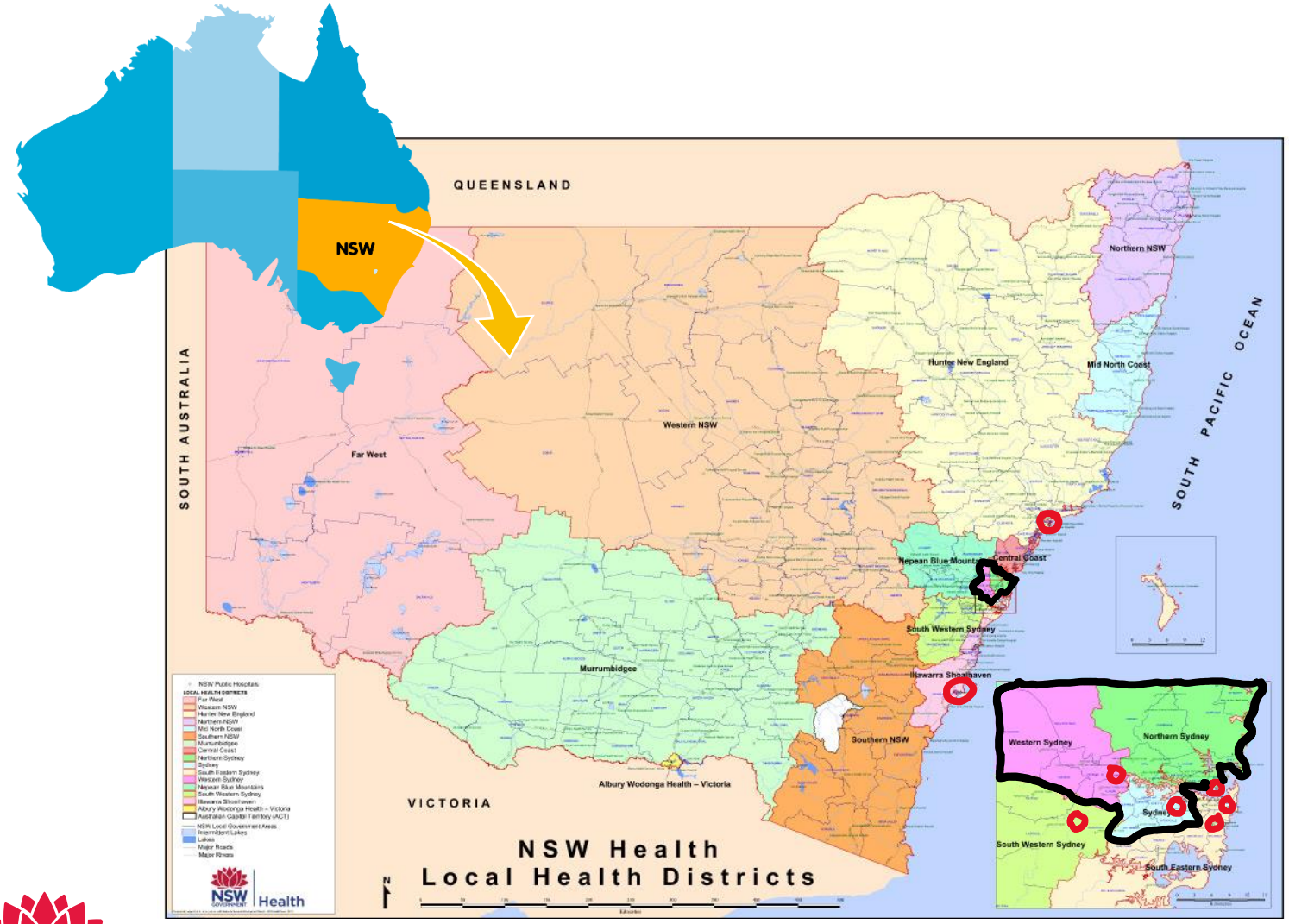
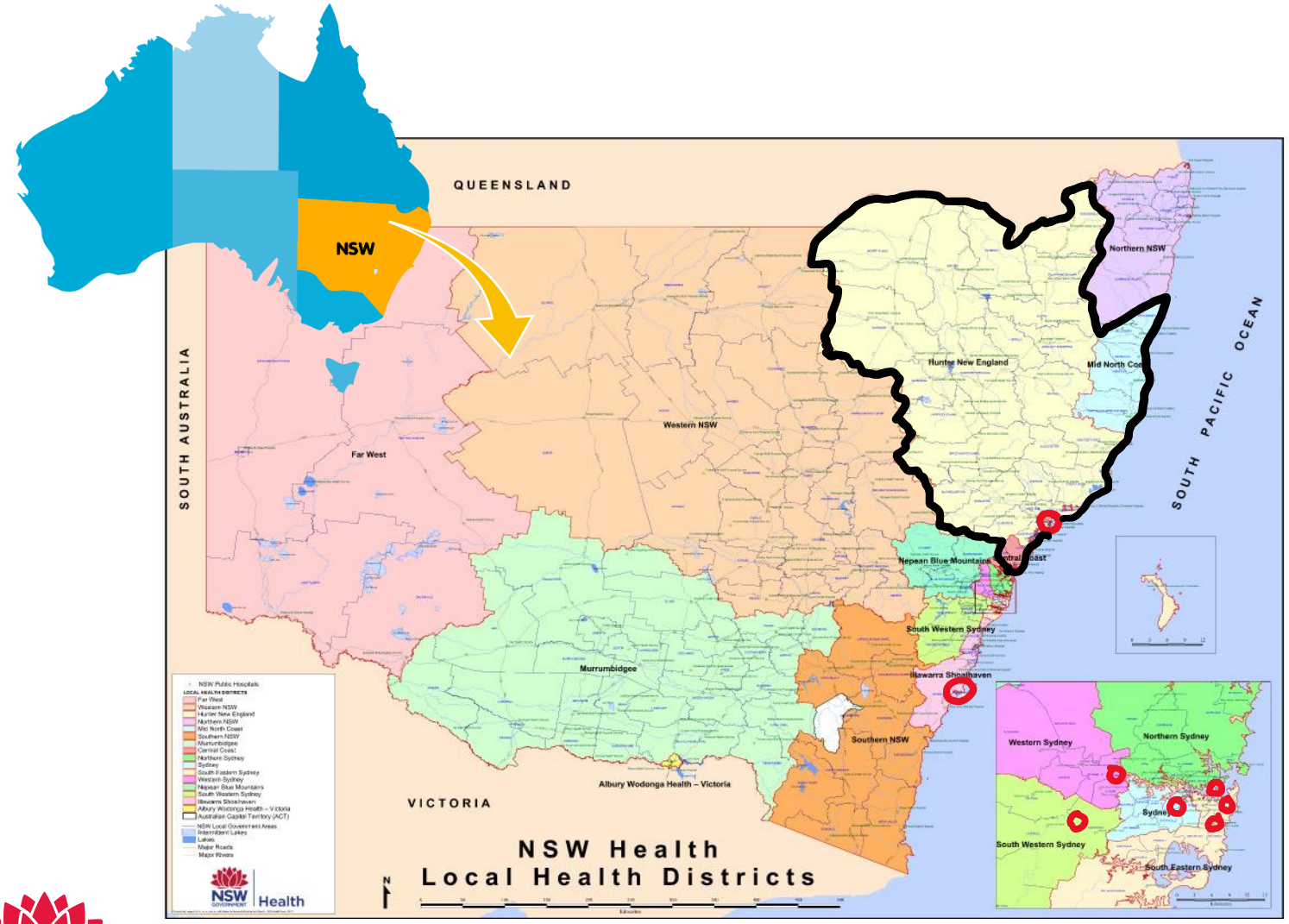

NSW
QUEENSLAND
SOUTH AUSTRALIA
VICTORIA
SOUTH PACIFIC OCEAN
Northern NSW
Hunter New England
Mid North Coast
Western NSW
Far West
Murrumbidgee
Southern NSW
Albury Wodonga Health – Victoria
Western Sydney
Northern Sydney
Sydney
South Western Sydney
NSW Health
Local Health Districts

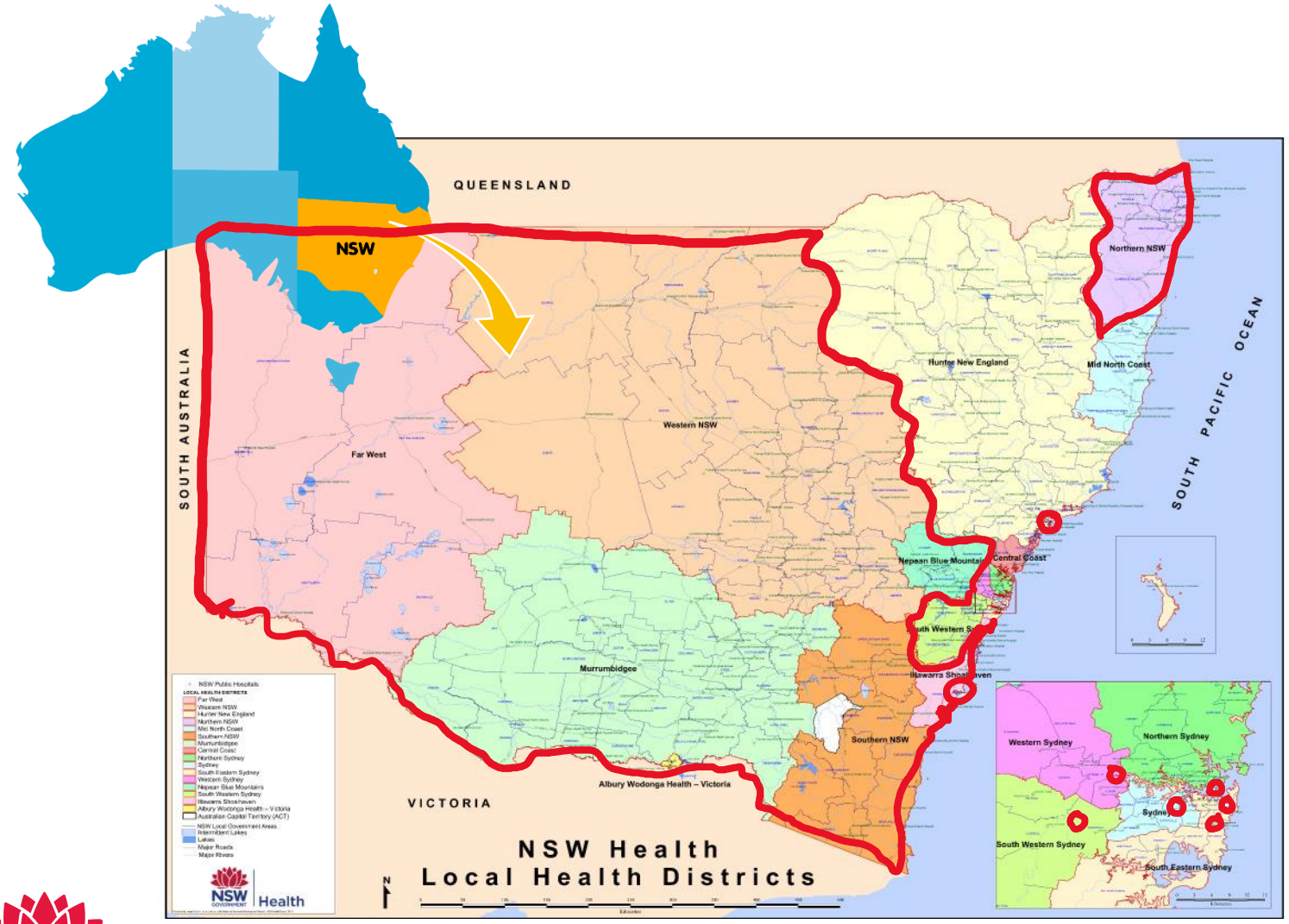
Sydney Health Partners



Regional Health Partners



LHDs not part of AHRTCs



2. ‘Bird’s eye view’ of initiatives/funding

2012-2022
NSW Health and Medical Research Strategy

Strategy 1. Foster translation and innovation from research

Strategy 2. Build globally relevant research capacity

Incentivise Collaboration

- NSW Health and Medical Research Hub Strategy
- Embedding research into the health system
- Genomics Collaboratives
- Partnerships in Proteomics
- Translational Research Grant Scheme

Strengthen Workforce Capabilities

- Commercialisation Programs (e.g. MDF, MDCTP)
- Bioinformatics Training Program (Genomics)
- Support for Early-Mid Career Researchers (EMC & PhD)
- Building clinical trial capabilities & leadership
- Cardiovascular Capacity and Capability Initiative
- Improving translational research methodology

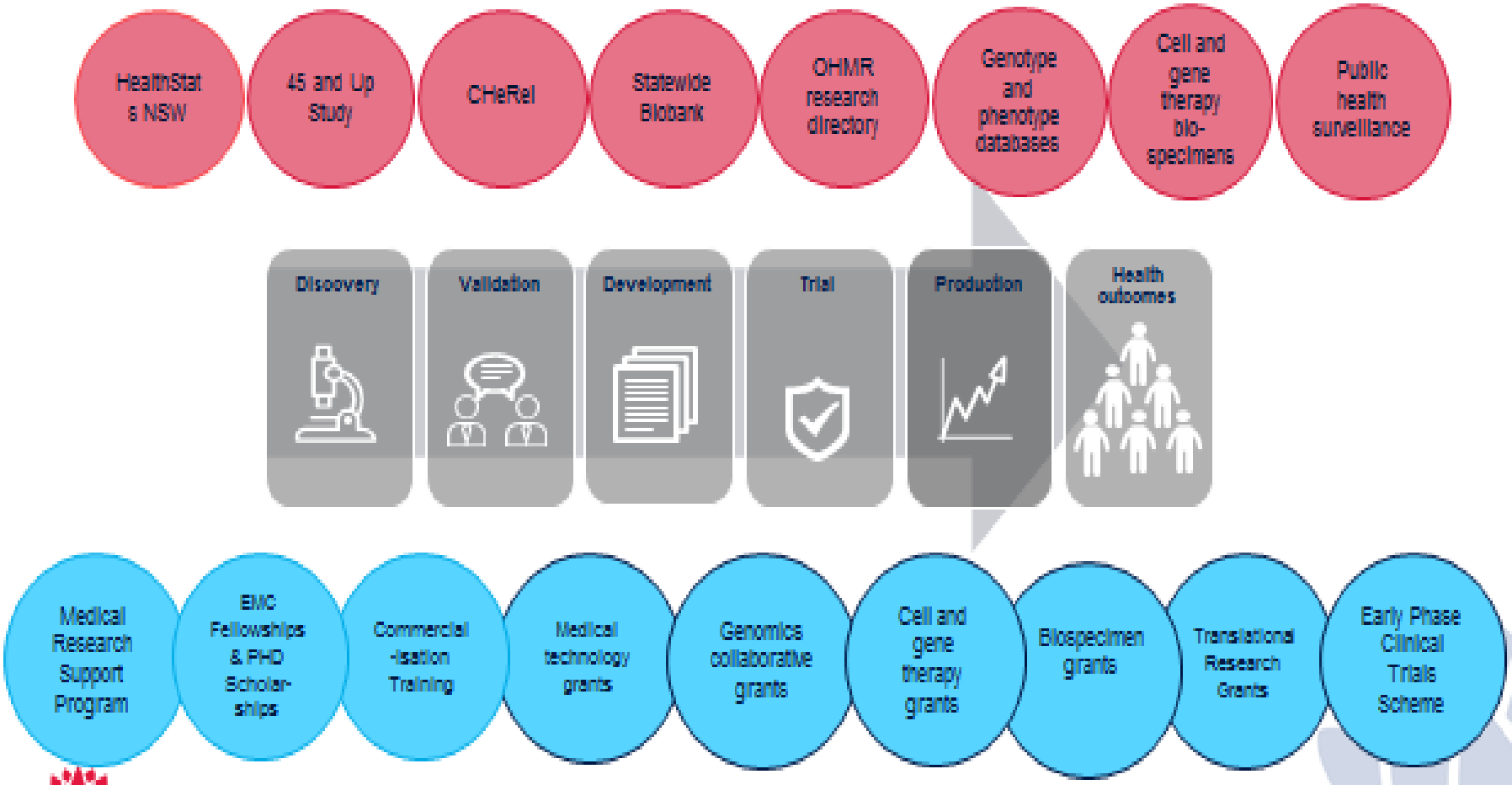
Invest in the Research System

- Medical Research Support Program
- Support research governance offices
- Enhancing biobanking
- Strengthen data linkage & access
- Capital Investments
- Prevention Research Support Scheme

Enablers

- Sector-wide Communications Strategy
- Office for Health and Medical Research (OHMR)

NSW Health and Medical Research Ecosystem



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Snapshot of some of the OHMR activities

- Translational Research
  - Translation Research Grant Scheme TRGS
  - Early Mid Career Fellowships
  - PhD Scholarships
  - **Cardiovascular Research Capacity and Capability initiative**
    - **Grants - Senior Scientist, Clinician Scientist, Early Mid-Career**

- Infrastructure
  - Medical Research Support Program (review)
  - 'Omics initiatives – genomics, proteomics, pathegenomics, metabolomics, microbiomics
  - Biobanking
    - Statewide Biobank, statewide consent, certification program, national NCRIS initiative, collection grants, second campus
  - Restricted Assets initiative
  - Grant Management System - procurement
  - **Cell and Gene Therapy**
  - Precision medicine initiative (Paediatric and Adult)
- S

Snapshot of some of the OHMR activities

- Commercialisation and Enterprise
  - Medical Devices Fund
  - Medical Devices Commercialisation Training Programs (including Clinical Trials, IP)
  - Medical Devices scholarships and awards
  - Intellectual Property Policy revision
  - Commercialisation support unit (OHMR)
  - Drug Discovery Initiative
  - Ideas Incubator and early discovery pipeline – drugs, medical devices
  - **International Desk**
    - **Collaboration and showcasing – local and overseas**
- Research Capital Initiative
- Stakeholder engagement
  - LHDs, Universities, Medical Research Institutes (AHRTCs, CIRH, Hubs)
  - Industry – MedTech and BioTech and peak bodies, Department of Industry
  - Research NGOs and networks
  - NSW Health Pillars
  - NHMRC, MRFF and Commonwealth (DHHS, DoH, DIIS)

Snapshot of some of the OHMR activities

- Research Ethics and Governance Unit
  - **Updated Research Governance Policy**
  - **Guidelines for Low and Negligible Risk**
  - Ethics approval processes for Statewide Quality Improvement
  - Review of Clinical Trials Indemnity
  - Clinical Trials Performance metrics
  - **REGIS – Research Ethics Governance Information System 'build and implementation'**
  - Clinical Trials Non-disclosure Agreements
  - Single Site Specific Assessment form
  - REG Roles and Responsibilities guidelines
- Clinical Trials
  - **Early Phase Clinical Trials Initiative (HRECs, Quality recognition scheme)**
  - OHMR Clinical Trials Unit
  - **Clinical Trials Budgeting tool**
  - Clinical Trials Support Infrastructure – guidelines
  - Tele-trials Initiative
  - Isolated Patient Travel Accommodation Assistance Scheme (IPTAAS) review

3. Clinical Trial initiatives

OHMR Metrics Program

- Australian health and medical research ecosystem creates significant value for the wider economy and society and is fundamentally critical to provide better value health care.
- There is a growing need to provide quality and validity measures to ensure a consistent performance in research at all sites.

- As of 1st of July 2016, OHMR has been collecting consistent data from NSW PHOs in research ethics and governance timelines.
- Two of these measures have been included to the Chief Executive Service Agreements as research KPIs.

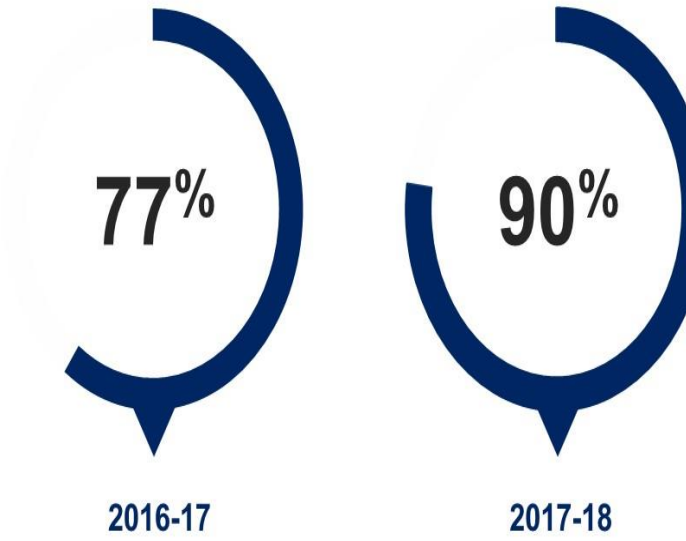
Clinical Trials

Early Phase Clinical Trials Scheme

Clinical Trials Support Unit

Performance targets

Percentage of NSW clinical trial ethics applications reviewed in under 60 days



Percentage of NSW clinical trial ethics applications reviewed in under 60 days

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REGIS

- National attempt to have one IT system failed
- NSW will have its IT system REGIS fully implemented by the end of this financial year.
- REGIS will steam-line all ethics and SSA approval processes – all on line
- By April 2019, use of REGIS to submit SSA at each site will become standard. Once the SSA application is completed by the PI in REGIS, the nominated Head/s of department/s will receive an email notification requesting they document their support decision within REGIS.
- LHDs will have an escalation protocol to manage delays in sign off
- Performance dashboards for all actors
- Regular metrics

Early Phase Clinical Trials Framework

Vision:

NSW is a centre of excellence that provides a high quality and efficient environment to conduct early phase clinical trials, with the ultimate aim of improving health outcomes for NSW residents.

The Framework comprises two key elements:

- NSW Health Early Phase Clinical Trials Human Research Ethics Committees
- Quality recognition scheme for early phase clinical trial sites and investigators in NSW

NSW Health Early Phase Clinical Trials Human Research Ethics Committees

- These committees will be appointed to review early phase clinical trials
- Mandated for use where NSW Public Health Organisation sites are involved
- Value to the health sector:
  - Support decision making for public health organisations as sites can have confidence in specialist ethics review
  - Increase the speed and reduce the administrative burden for early phase trial approval
  - Streamline ethics application timelines – 30 working day benchmark (aim for 20 working days benchmark)
  - Build early phase trial capability
  - Increase attractiveness of NSW to sponsors

Clinical Trials

Early Phase Clinical Trials Framework

- Consistent, high quality ethics approach to commence early phase clinical trials.
- NSW Health has appointed the following HRECS to the Scheme:
  - Bellberry Limited
  - Sydney Children's Hospital's Network HREC.
- Review of all applications within 30 working days, with a target to work towards 20 working days.

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Quality Recognition Scheme

- Quality recognition scheme will recognise sites and investigators that have the capability to conduct early phase trials at a high standard
- Clinical trial sites and units, and associated investigators will be awarded recognition and provided support to work towards recognition
- Value to the health sector:
  - Support decision making for Public Health Organisations who can have confidence that a trial site meets a high standard of conduct, built in requirements for good clinical governance
  - Ensure the operational conduct of early phase trials is aligned with best practice nationally and internationally
  - Increase attractiveness of site to potential sponsors

NSW Budget Costing Tool

Purpose of this Project

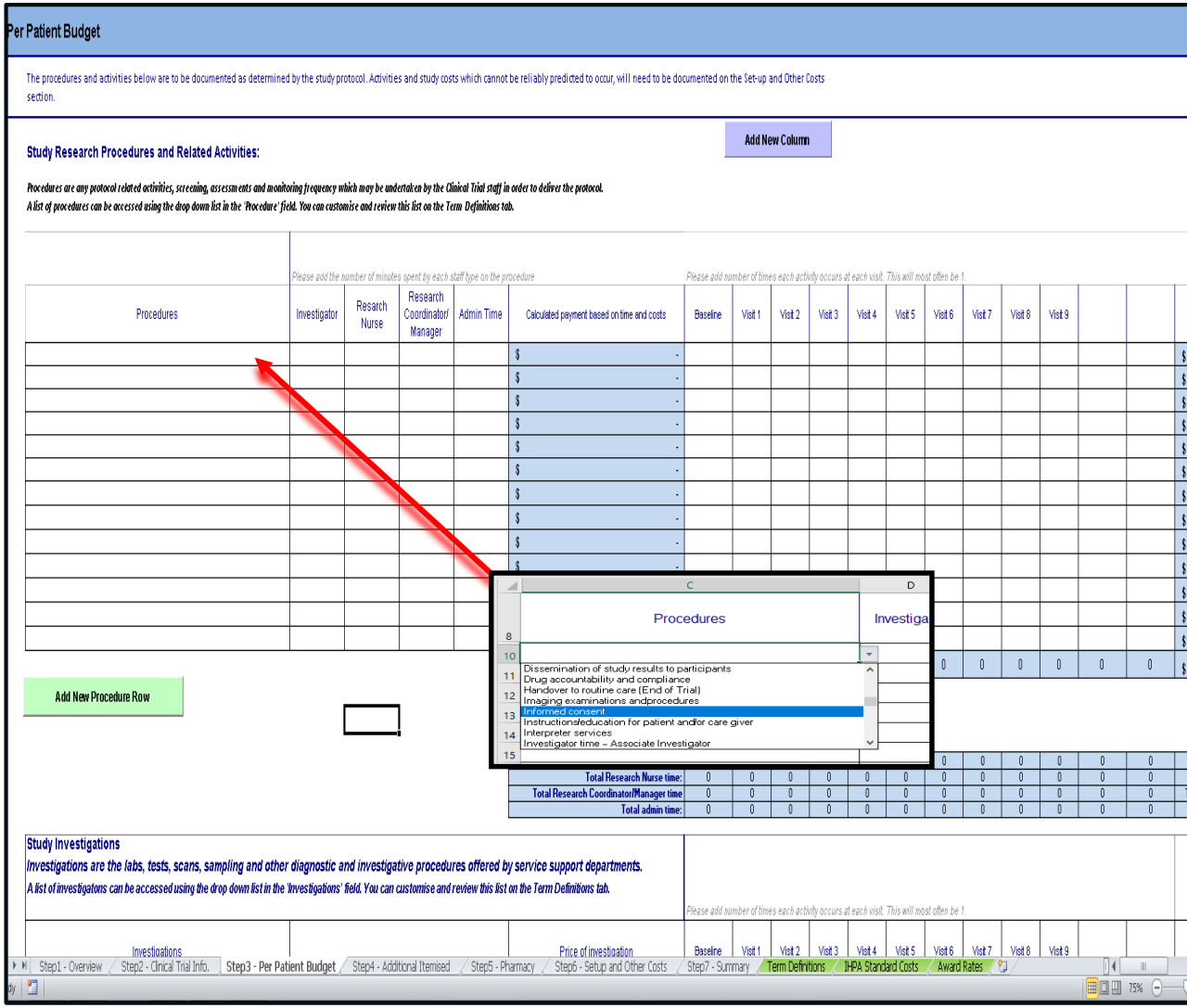
- Lack of accuracy and transparency in budgeting and finance processes for clinical trials identified in a recent consultation (CTSU project)
- A standard costing tool was requested by the Sector to support improved finance processes
- It is an Excel spreadsheet with clear and consistent methodology to calculate trial costs
- Enables all sites to be aware of the potential financial implications of research they conduct

Version 1 of the Budget Tool

Pre-populated procedures/investigations

Built by SLHD and based on the successful NIHR Costing Tool

Launched after Sector consultation and incorporation of feedback



Clinical Trial Support Unit (CTSU)

Providing an overarching framework for clinical trial governance

Function: Start-Up Facilitation/Recruitment Planning

Clinical Trials Liaison Officer

Facilitation of the start-up activities as the central point of contact for sponsors

Site feasibility assessment and development of site recruitment plan

Active management of recruitment issues

Function: Study Costing and Financial Management

Finance Manager

Study costing, contract review, invoice management, income tracking & distribution

Consistent point of contact between departments and finance

Single costing template, single tariff (through a partner agreement)

Function: Clinical Trial Services

Clinical Trials Manager

Provision of:

a) Data management support (e.g. REDCap for simple studies) b) Grant application support/grant finding service c) Study design and statistical support

Central pool of trial coordination staff

Function: Clinical Trial Quality Framework

Quality Manager

All Trials:

Maintaining clinical trials quality framework e.g. SOPs

Manage training and induction for clinical trials

Locally sponsored Inv-led Trials:

Develop audit plan and arrange audits

Oversee reciprocal monitoring service amongst partners

4. Research Governance Framework

Definition – Research Governance

Research governance is the system of administration and supervision through which research is managed, participants and staff are protected, and accountability is assured. Governance is not the remit of any single institution

Shaw et al, J R Soc Med 2005;98:496-502

Yes – Research Governance needs to improve ++++

- Many publications over the past 2 decades highlighting the **negative impact on research** of poor research governance practices and processes, causing;
  - **Increasing** costs
  - **Delays** in commencing research
  - Tainted Reputation
  - Impact on conduct of research study – particularly multi-site studies – **jeopardising integrity** of study

  - Issues
    - Inconsistencies – in interpretation
    - Duplication
    - Un-necessary time consuming tasks
    - Different IT systems
    - Lack of standardisation
    - Inadequate information on differences in jurisdictional regulations etc

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Research Governance

- Acknowledge that the Health System is **complex** –and there is increasing complexity if you include all the other players in the health and medical research arena – universities, medical research institutes, NGOs
- Over the past decade there has been a significant **increase in funding** for medical research and a big focus on health systems research, clinical research (translational research) and implementation science.
- Research is truly becoming **embedded** in the Health System
- Research Governance has appeared on the scene in a **less than organised** way – and it is a very necessary bureaucracy and management requirement – but it need not be burdensome
- There are initiatives both at National and Jurisdictional levels trying to address this ‘burden”

Research Governance initiatives – National

- National Aggregate Statistics
- Roles and Responsibilities document – RGOs, EOs
- Clinical Trials Governance Framework – Australian Commission on Quality and Safety in the Health System
- Single Site Specific Assessment/Authorisation form
- Non disclosure agreements between sponsors and sites
- National Clinical Trials Front Door Concept
- National Mutual Acceptance

Research Governance – NSW Initiatives

- Local Health District Chief Executive Performance Agreement – Research (Clinical Trials)KPIs
- REGIS – Research Ethics Governance Information System
- Research Governance Framework (including clinical trials) in NSW Public Health Organisations (Oct 2018)
- NSW OHMR Guidelines for Low and Negligible Risk (LNR) Research Review Processes or Exemption from Ethics Review (Sept 2018)
- Early Phase Clinical Trials Framework
- Guidelines for good clinical trials management
- OHMR Clinical Trials Support Unit
- Clinical Trials Budgeting Tool
- Alignment of Indemnity insurance with rest of Australia/World!!
- Restricted Assets initiative to allow for budget roll over across financial years
- Ethical review of Quality Improvement projects
- Tele-Trials steering committee
- Permission to Contact Initiative

Research Governance Framework (Inc Clinical Trials)

► PURPOSE

► The purpose of this document is to bring together general principles of good practice management and conduct of health and medical research to guide the development of systems and processes within NSW Public Health Organisations (PHOs).

► KEY PRINCIPLES & Attributes

► PHOs are expected to develop an effective research governance framework that:

- Quality driven research culture
- Facilitates research
- Proportionate governance
- Expeditious, efficient and effective administration
- Value for money
- Involvement of consumers
- Clarifies roles and responsibilities
- Transparency

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Research Governance Framework - Content

- Background – including definitions
- Components of an Effective Research Governance Framework
- PHOs as Research Sites and Research Sponsors
- Assessment of Institutional Risk
- Development of Overarching Quality Systems for Clinical Trials
- NSW PHOs as Clinical Trial Sites
- PHOs as Clinical Trial Sponsors
  - Determining whether a PHO is the sponsor
  - The sponsor assessment process
  - Allocation or delegation of sponsor functions
  - Sponsor oversight of delegated functions

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Research Governance Framework – Content (cont)

- List of Attachments
  - Key Attributes of a Research Governance Framework
  - Overview of Public Health Organisations Clinical Trial Responsibilities
  - Competencies of the Research Support Office
  - Questions to Ask as a PHO – Sponsor
  - Clinical Trial Sponsor Governance Checks
  - Sponsor Considerations: Examples of Clinical Trial Management Activites

Attachment 3: Competencies of the Research Support Office

A1. Supporting the Growth and Delivery of Clinical Research within Own Institution			
	A	B	C
A1.1 National objectives and priorities.	Is aware of national objectives and priorities for research.	Advises and promotes to stakeholders the national objectives and priorities for research.	Develops local strategy for research in line with national objectives and priorities.
A1.2 Local strategic direction.	Is aware of the local strategy for research in their institution.	Advises and promotes to stakeholders the local strategy for research through presentations and training and champions research within the institution.	Sets the local strategy for research in line with national objectives and priorities and ensures its implementation. Champions research at an executive level.
A1.3 Promotion of research.	Actively promotes research. Helps develop materials for promotional or educational forums for research.	Promotes the use of research in evidence-based practice to all relevant stakeholders and the importance of research to the community, patients and the institution. Develops and updates the RO's website to ensure appropriate web-based information is available to all stakeholders.	Develops a research management culture that understands and promotes the benefits of research to the community, patients and the institution.
A1.4 Chief executive/Board engagement to support research activity.	Understands the need and benefits of CE/Board level engagement in research.	Acts as the conduit for any communication requiring Board consideration/sign off. Understands the importance of keeping the Board aware of the institution's research performance metrics through the appropriate communication lines.	Maintains board engagement to continually strengthen the culture of research-led clinical practice. Identifies and presents opportunities and risks at executive level.

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Attachment 3: Competencies of the Research Support Office

A1. Supporting the Growth and Delivery of Clinical Research within Own Institution

A2. Working with External Partners

A3 Working as a Team to Deliver Successful Research Projects

B1. Supporting Development of New Studies – Early Stages

B2. Supporting Good Financial and Contractual Management

B3. Supporting Feasibility and Risk Assessments of Proposed Research

B4. Supporting Research Study Management and Delivery

C1. Understanding and Assessing the Regulatory and Legislative Compliance of a Study

C2. Understanding the Principles of Good Clinical Practice and Good Research Practice within Research

C3 Understanding Research Roles and Responsibilities

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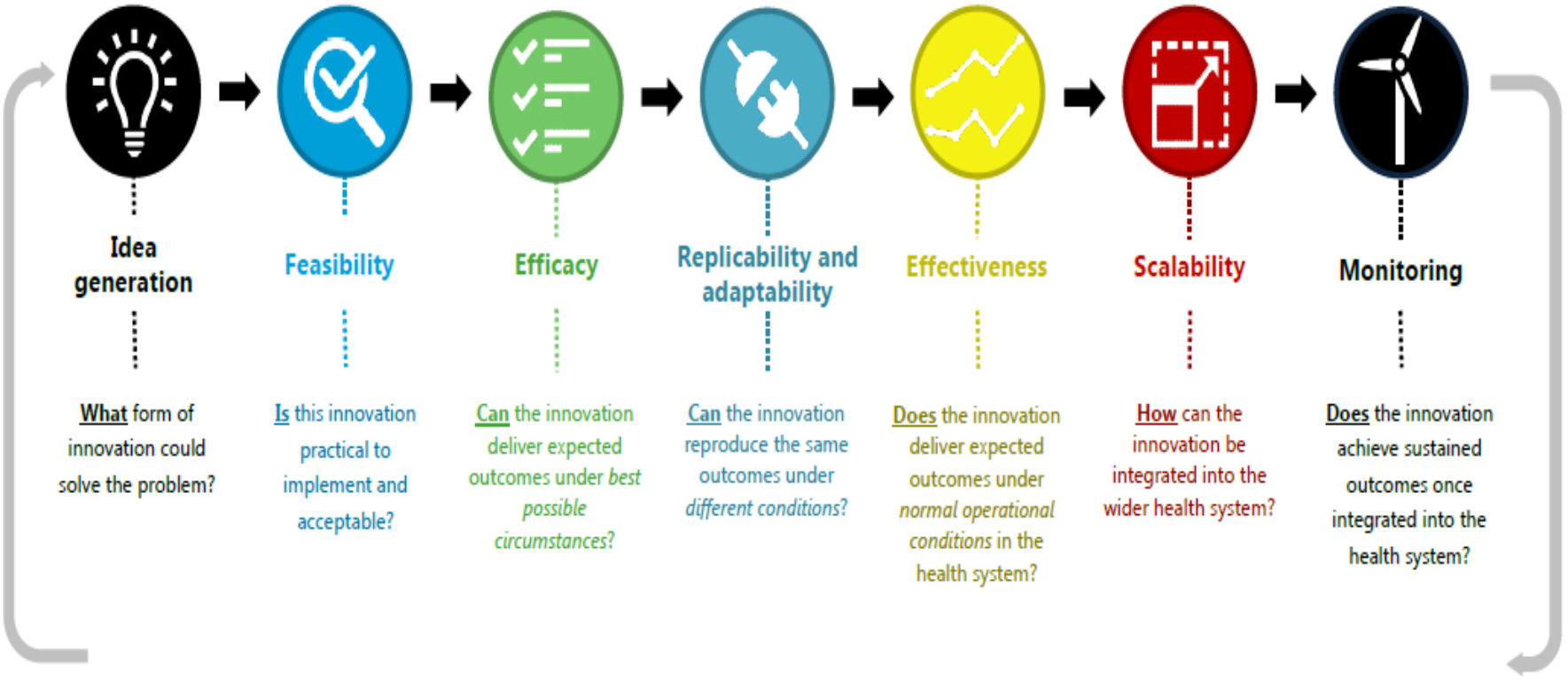
5. TRGS – Translation Research Grant Scheme

Driving translational research

- Designed to:
  - fund priority-driven implementation science ‘in place’
  - reduce the time from generation to practice implementation at scale
  - connecting groups; front line, decision makers, policy and academics
  - accelerate research and knowledge translation capability
- ~AU$10m per round
- Chief Executive signs agreement to implement practice change based on results

Translational research framework



TRGS application process

Stage 1

Chief Investigator submits EOI

Reviewed by the host organisations Research Directors

Approved by the Chief Executive of Host Organisation.

Stage 2

Participatory feedback

to:
enhance the quality of research proposals

capitalise on potential synergies b/w projects

build research and translation capability

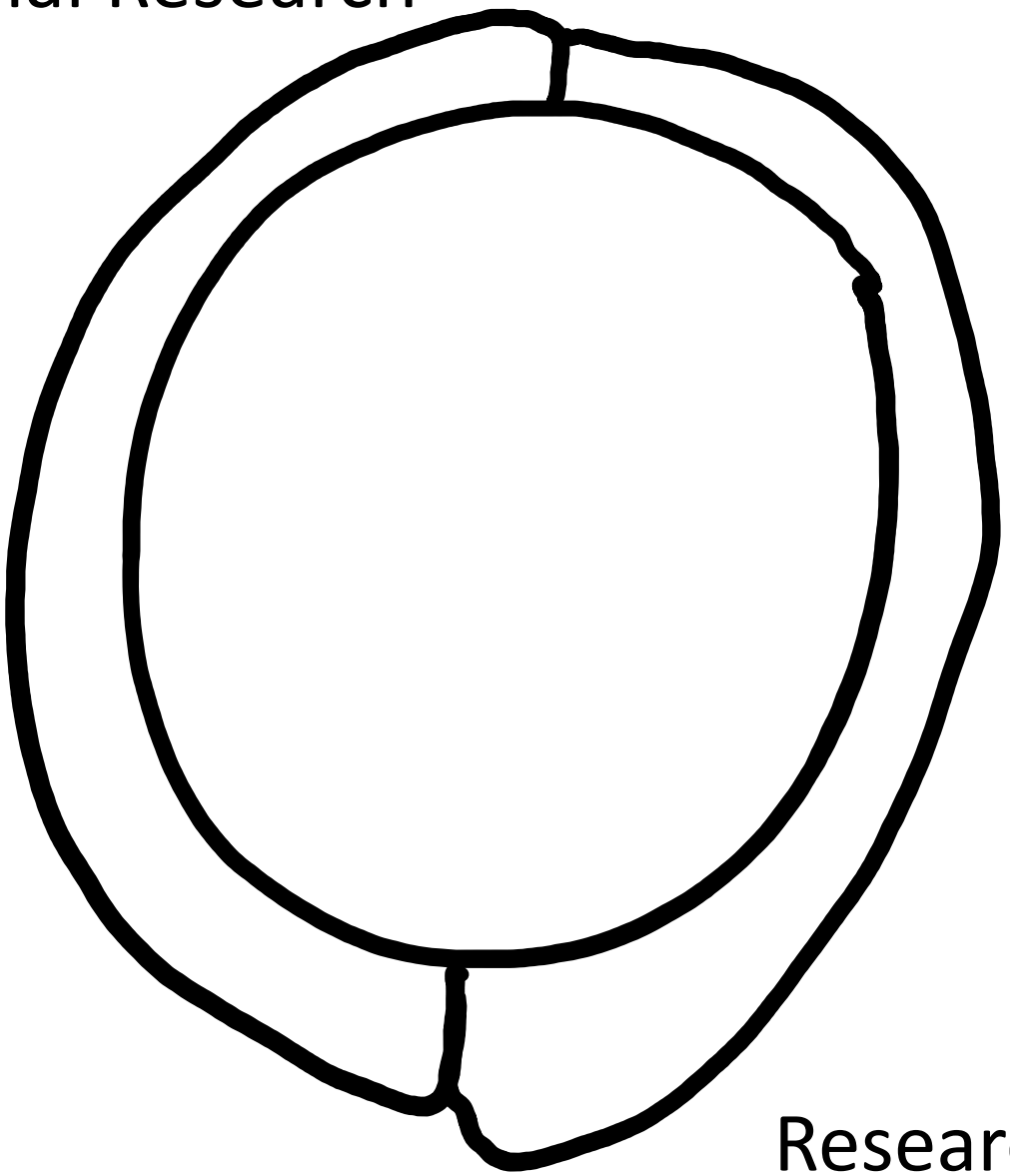
Stage 3

By invitation

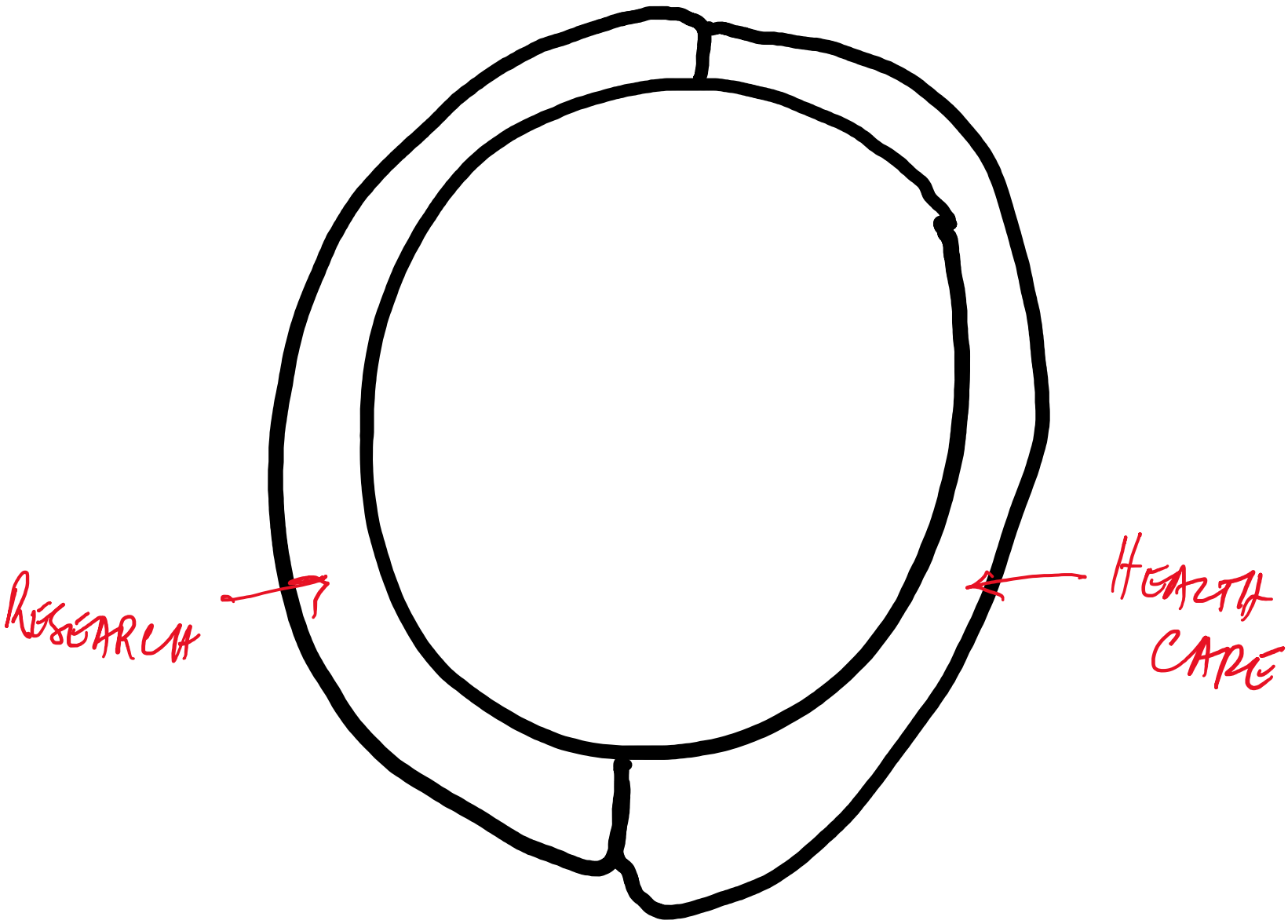
Chief Executive of Host Organisation approves and commits to implement findings at the end of project

6. How to support Translational Research

Translational Research



Research Translation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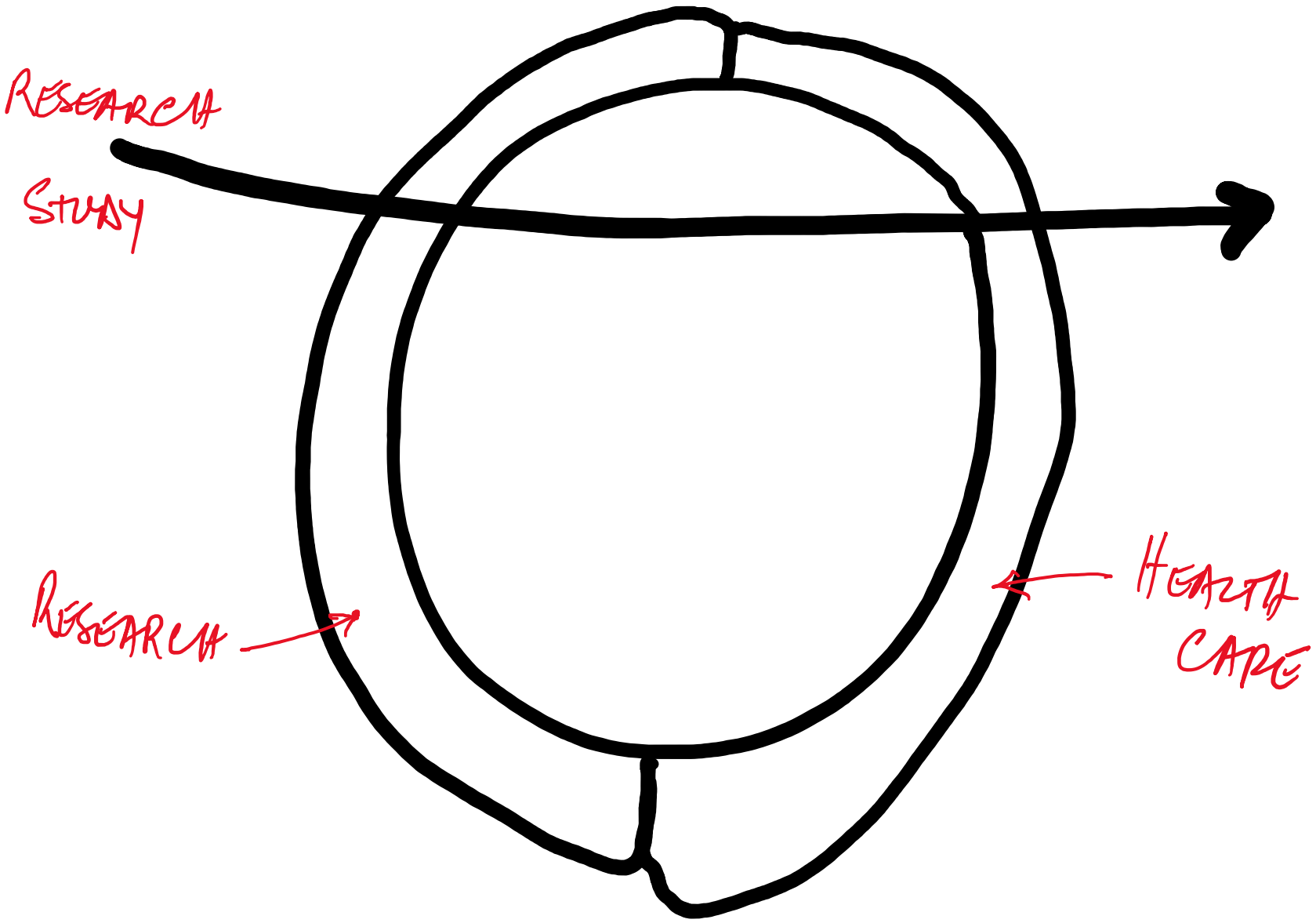
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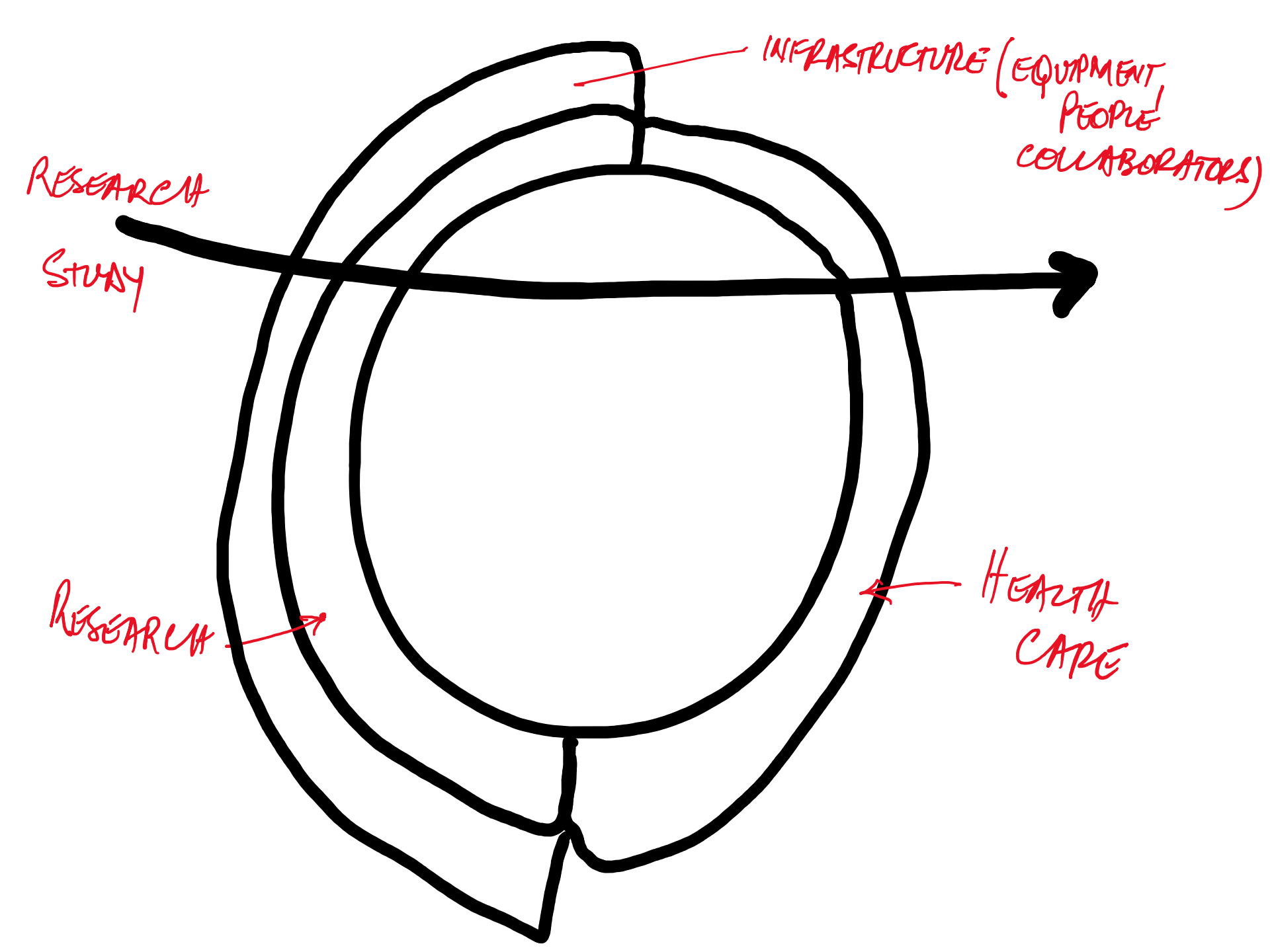
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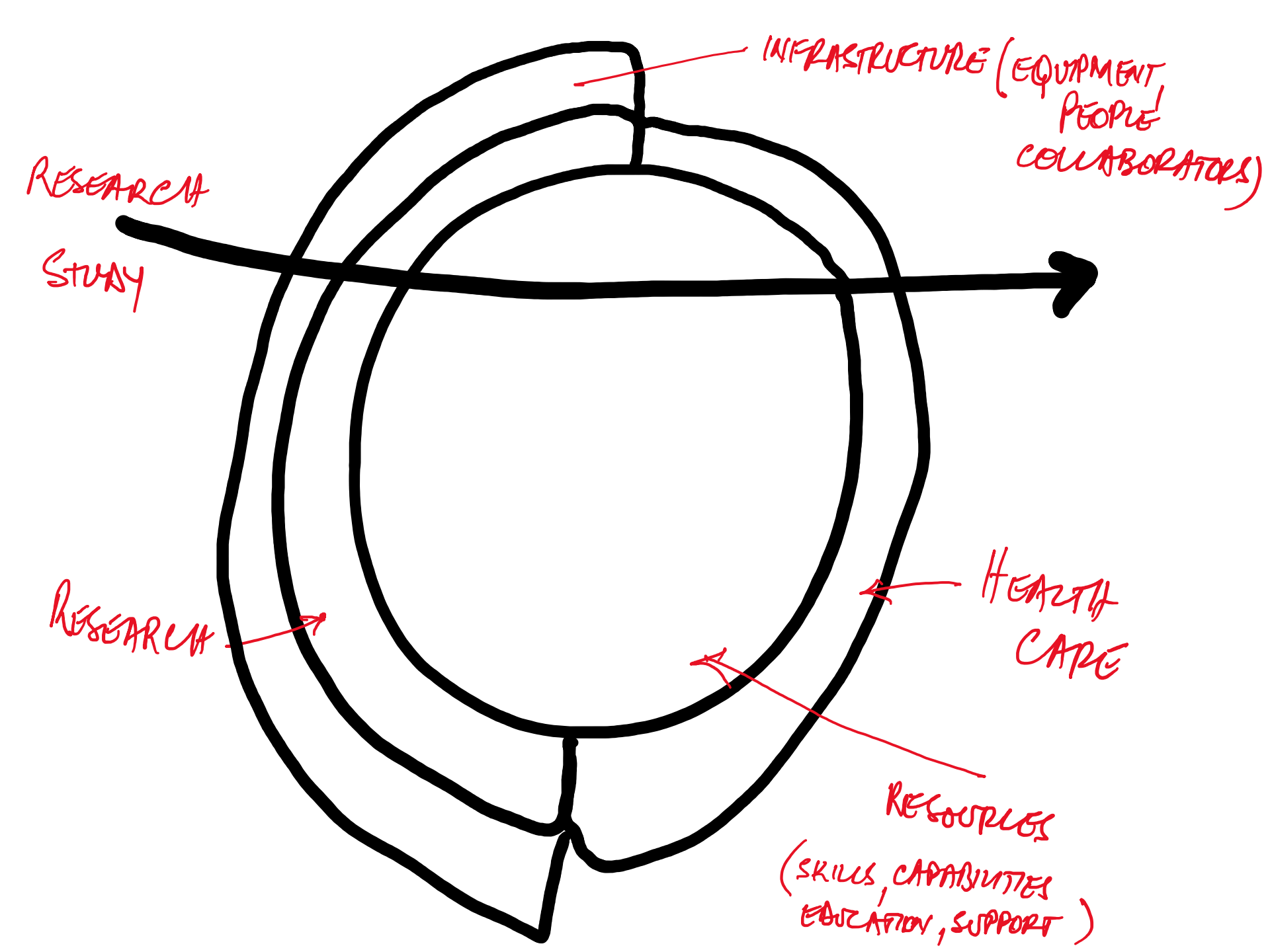
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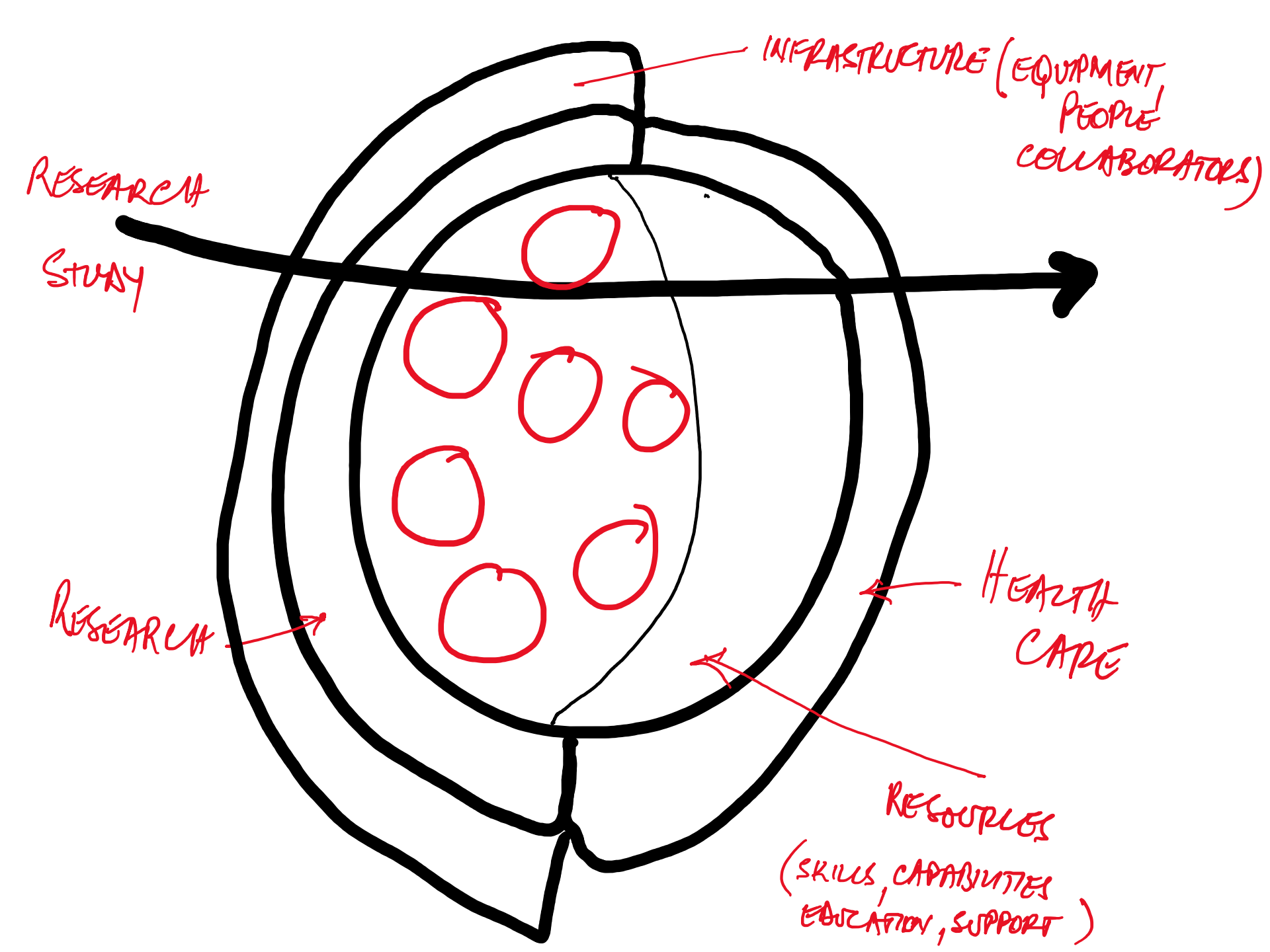
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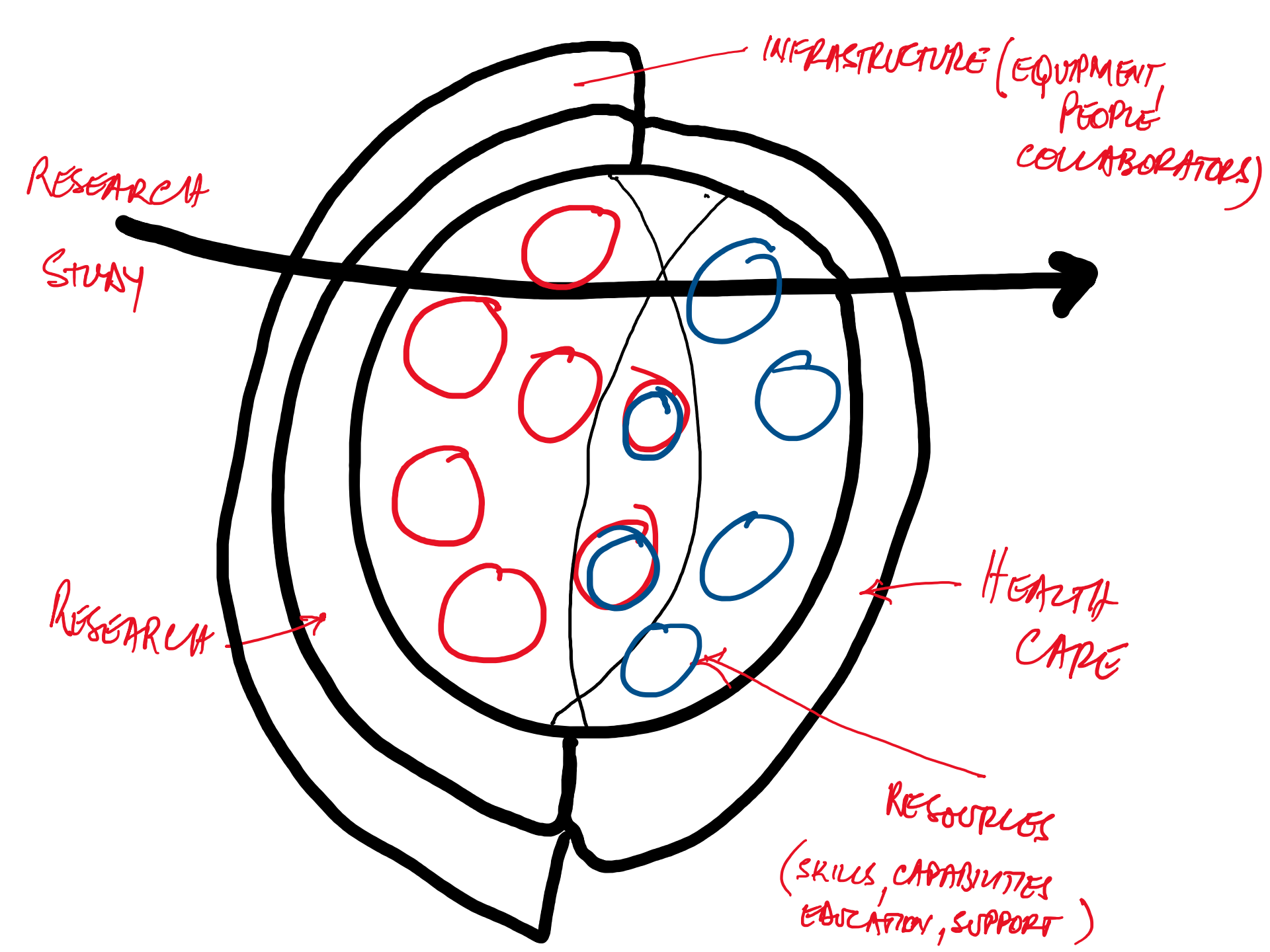
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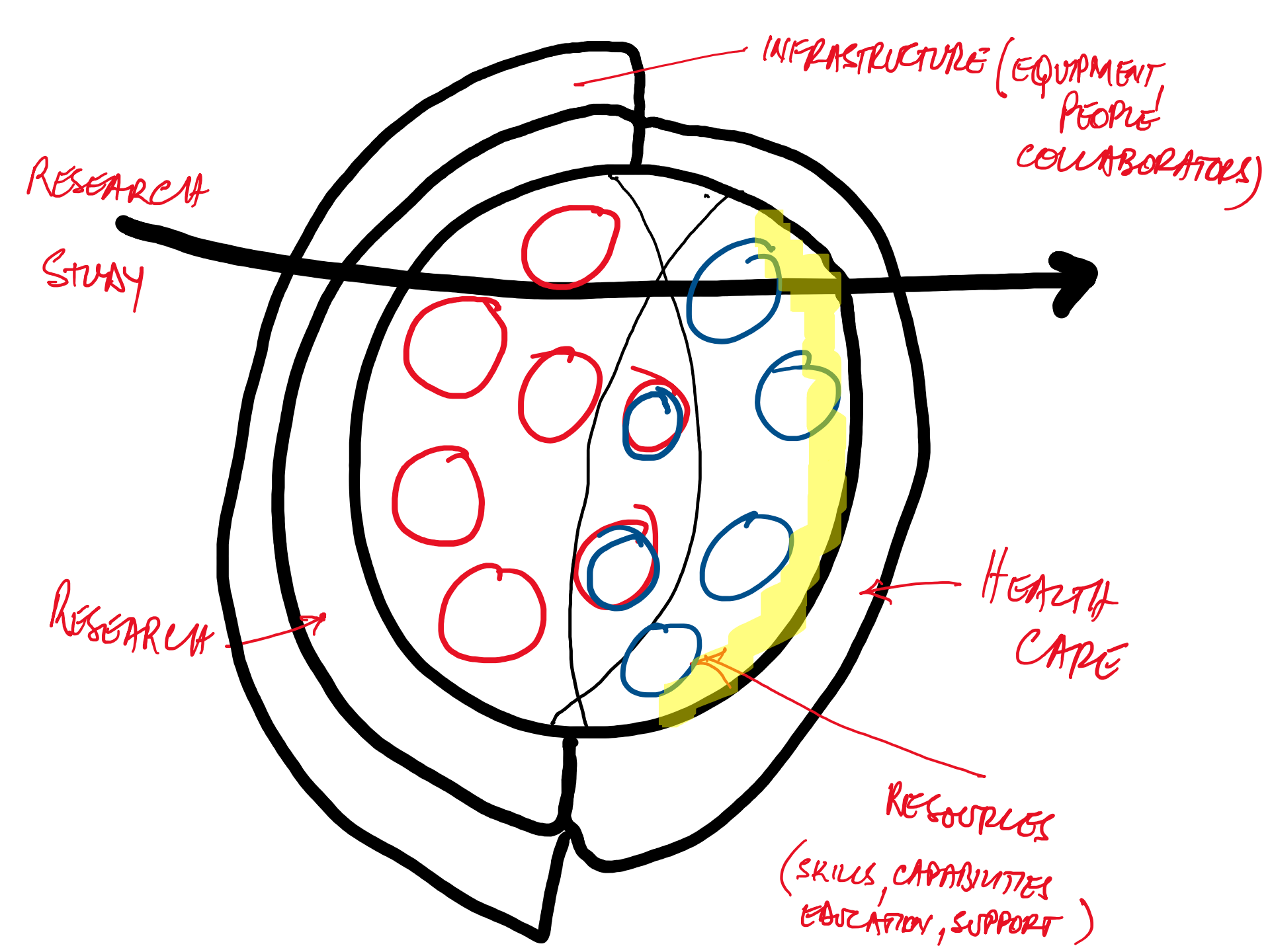
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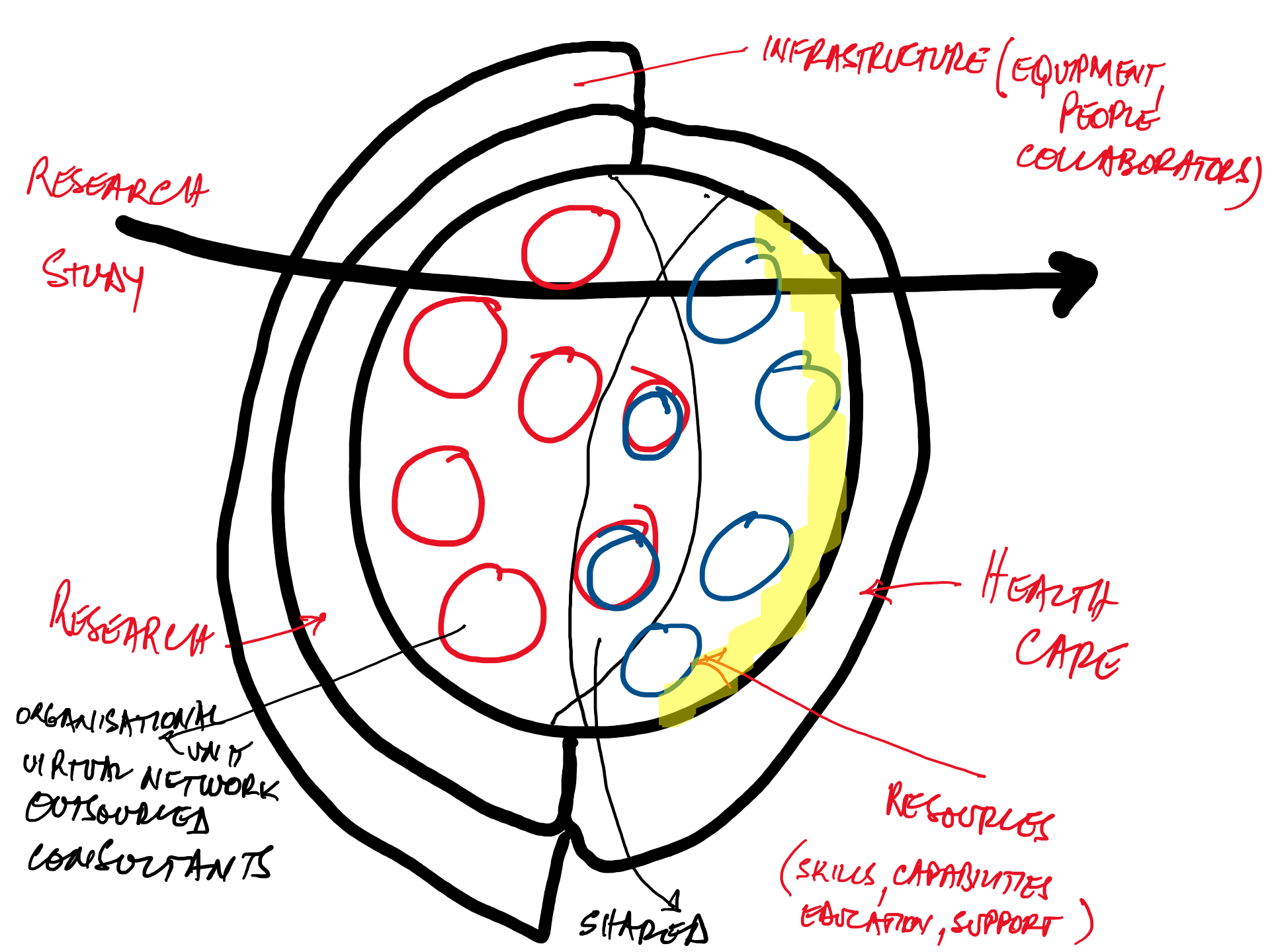
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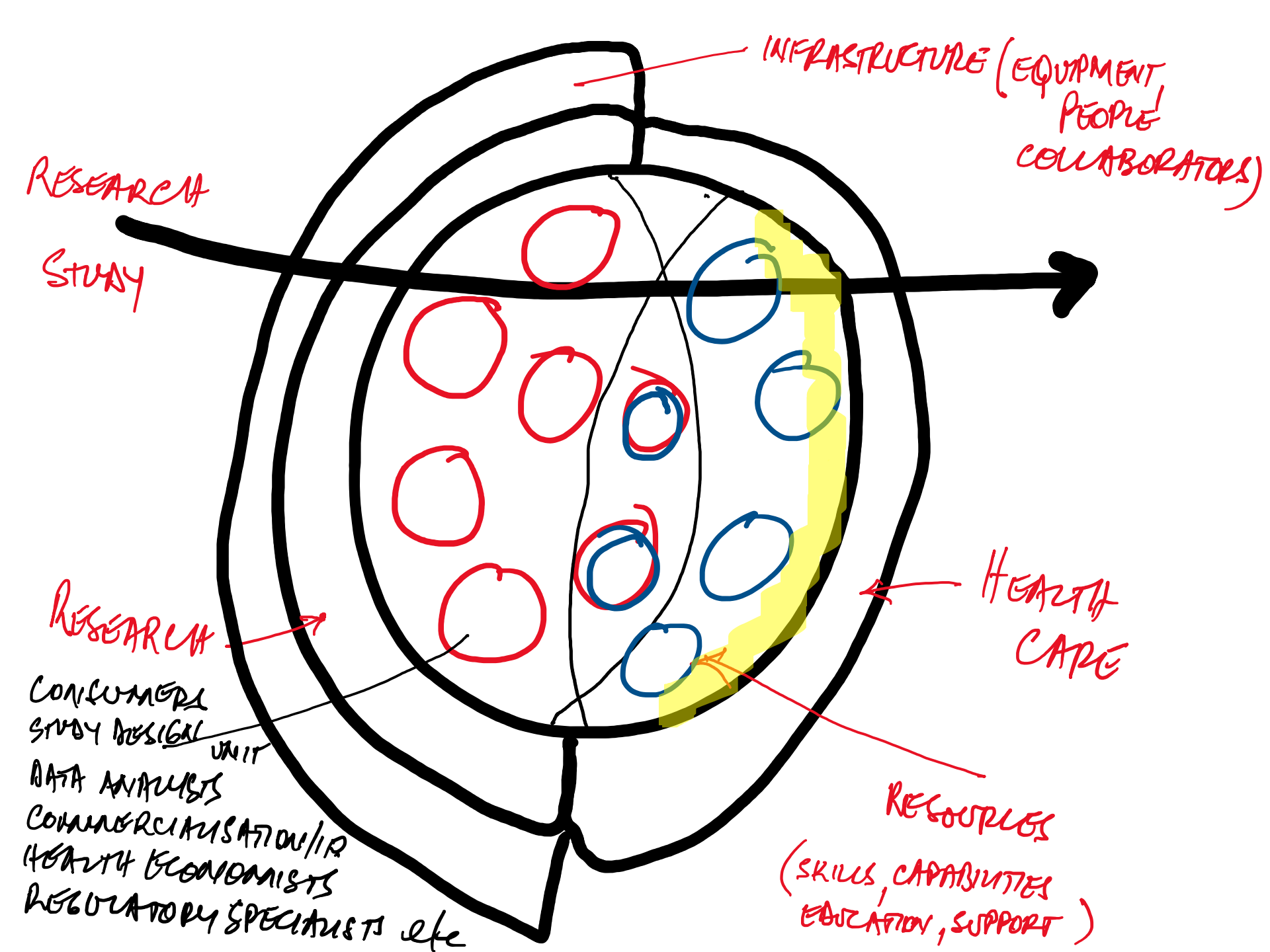
OUTSOURCED CONSULTANTS
HEALTH CARE
RESOURCES (SKILLS, CAPABILITIES EDUCATION, SUPPORT)
SHARED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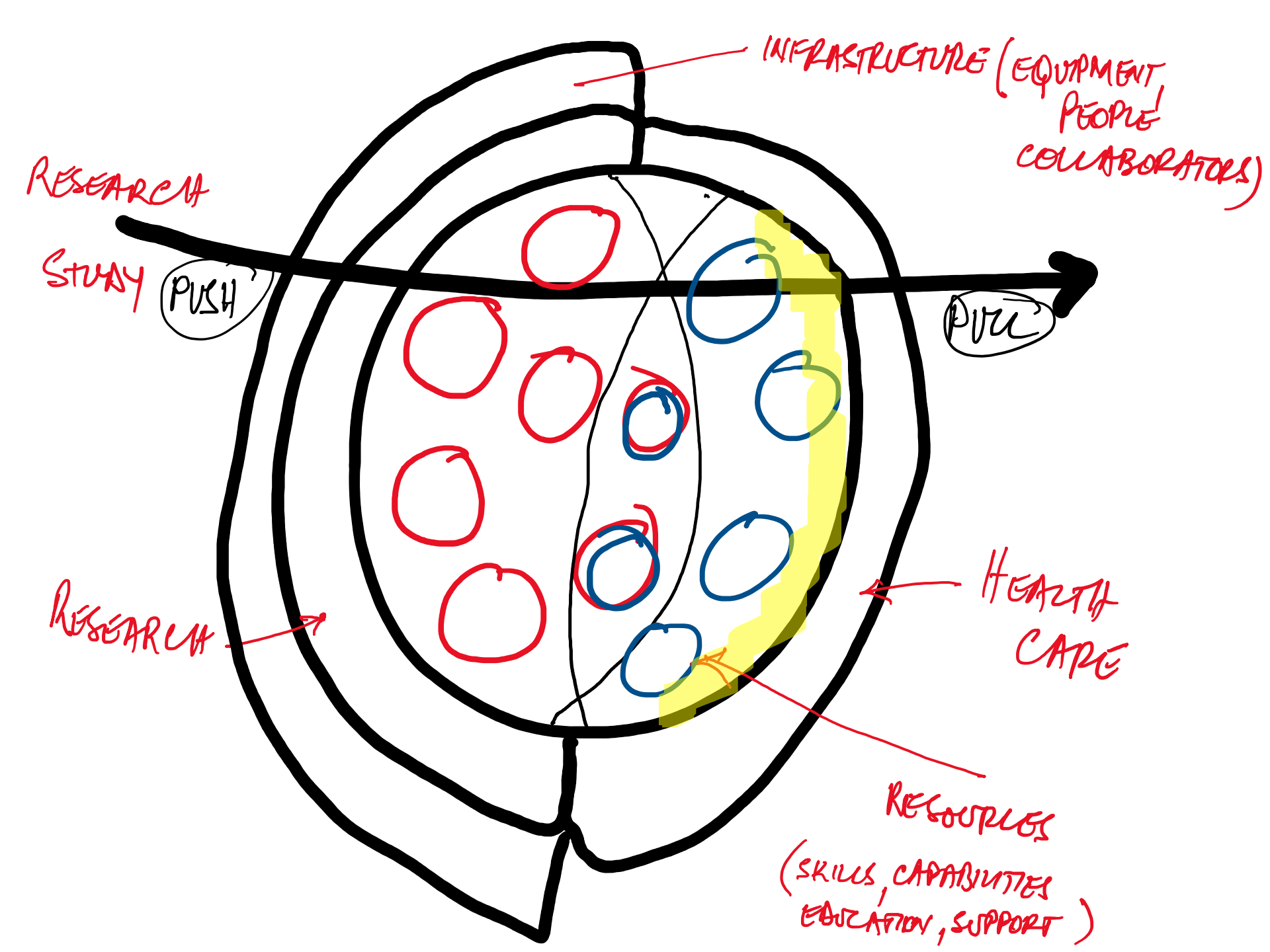
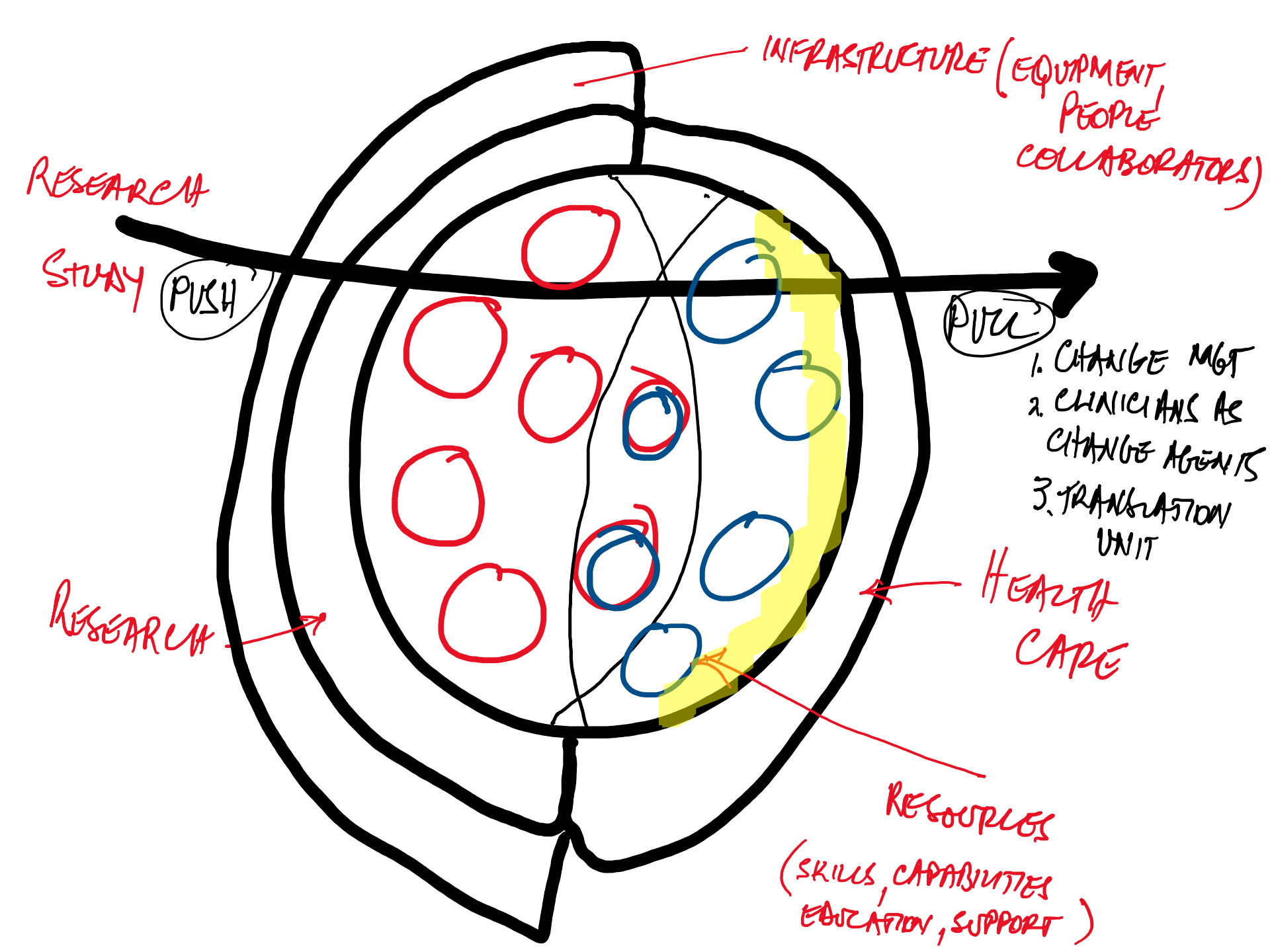
CONSUMERS
STUDY DESIGN
UNIT
DATA ANALYSTS
COMMERCIALISATION/IP
HEALTH ECONOMISTS
REGULATORY SPECIALISTS etc
HEALTH CARE
RESOURCES
(SKILLS, CAPABILITIES EDUCATION, SUPPORT)


INFRASTRUCTURE (EQUIPMENT PEOPLE COLLABORATORS)
RESEARCH
STUDY
PUSH
PULL
RESEARCH
HEALTH CARE
RESOURCES
(SKILLS, CAPABILITIES EDUCATION, SUPPORT)


INFRASTRUCTURE (EQUIPMENT PEOPLE COLLABORATORS)
RESEARCH
STUDY
PUSH
PULL
1. CHANGE MGT
2. CLINICIANS AS CHANGE AGENTS
3. TRANSLATION UNIT
RESEARCH
HEALTH CARE
RESOURCES
(SKILLS, CAPABILITIES EDUCATION, SUPPORT)

THANK YOU TO

My colleagues in The Office for Health and Medical Research

Tanya Symons – Research Governance, Clinical Trials (incl budget tool)

Professor Sarah Thackway – TRGS

Health and Medical Research Sector in NSW, other jurisdictions and Commonwealth

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