

Upholding Research Integrity: Embracing the Responsible Conduct of Research (RCR) Principles in Malaysia's Ministry of Health Research Governance Framework

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Malaysia**

**2. Institute for Health Behavioural Research (IHBR), National Institutes of Health (NIH),
Ministry of Health (MOH), Malaysia**

3. Medical Research & Ethics Committee (MREC), Ministry of Health (MOH), Malaysia

DR. SWEE-PING TANG

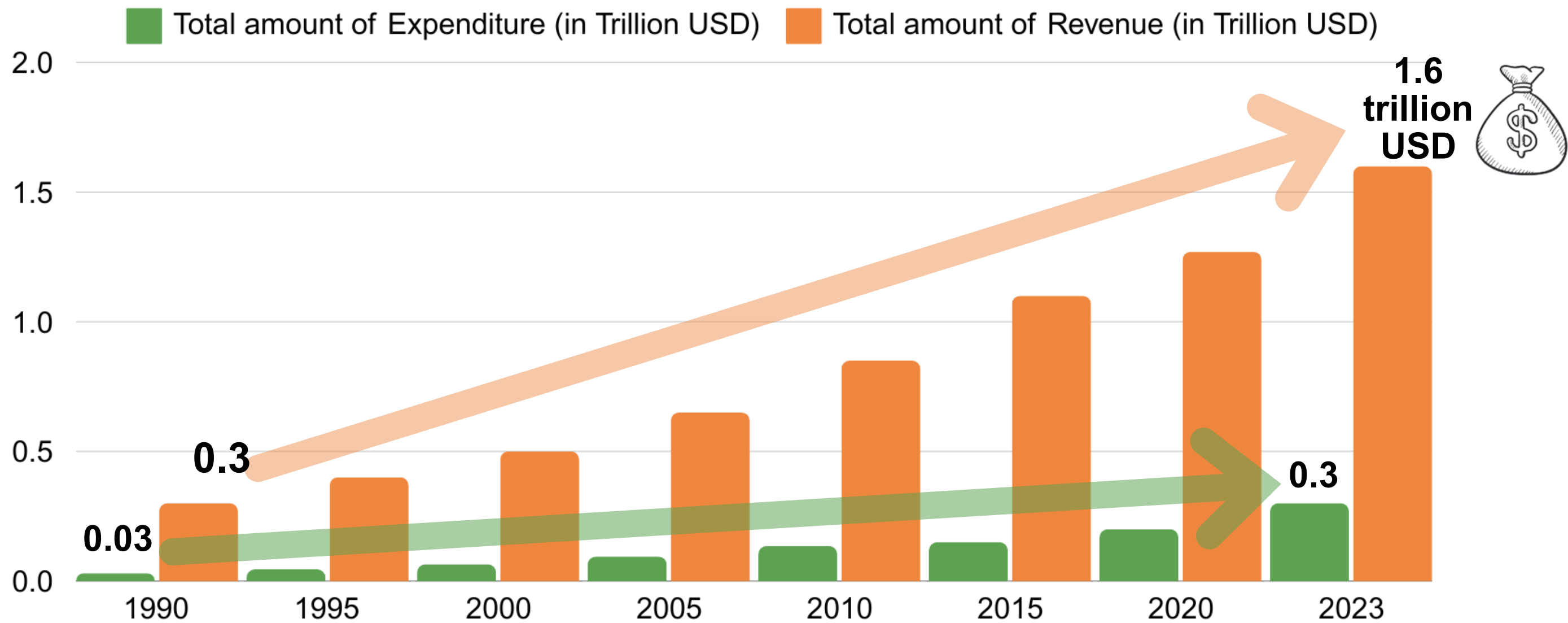
MBBS(Mal), MRCP(UK), FRCPCH(UK), CSER (UK)

- Senior Consultant Paediatrician and Paediatric Rheumatologist, Head of Paediatrics Department, Selayang Hospital, Ministry of Health Malaysia
- Deputy Chairperson of Medical Research & Ethics Committee (MREC), Ministry of Health Malaysia.

Dr. Tang is a distinguished clinician and researcher in paediatric autoimmune diseases, recognised for her extensive contributions, including numerous publications and book chapters. In 2003, she pioneered the Malaysia's paediatric rheumatology services, which have since grown to five additional states, revolutionising care for young patients nationwide. With a decade of dedicated service on the Medical Research & Ethics Committee (MREC) and as the current Deputy Chairperson, Dr. Tang is deeply committed to advancing ethical research practices, particularly for paediatric studies. As a passionate educator, she is dedicated to mentoring doctors on the importance of ethical standards in medical research.

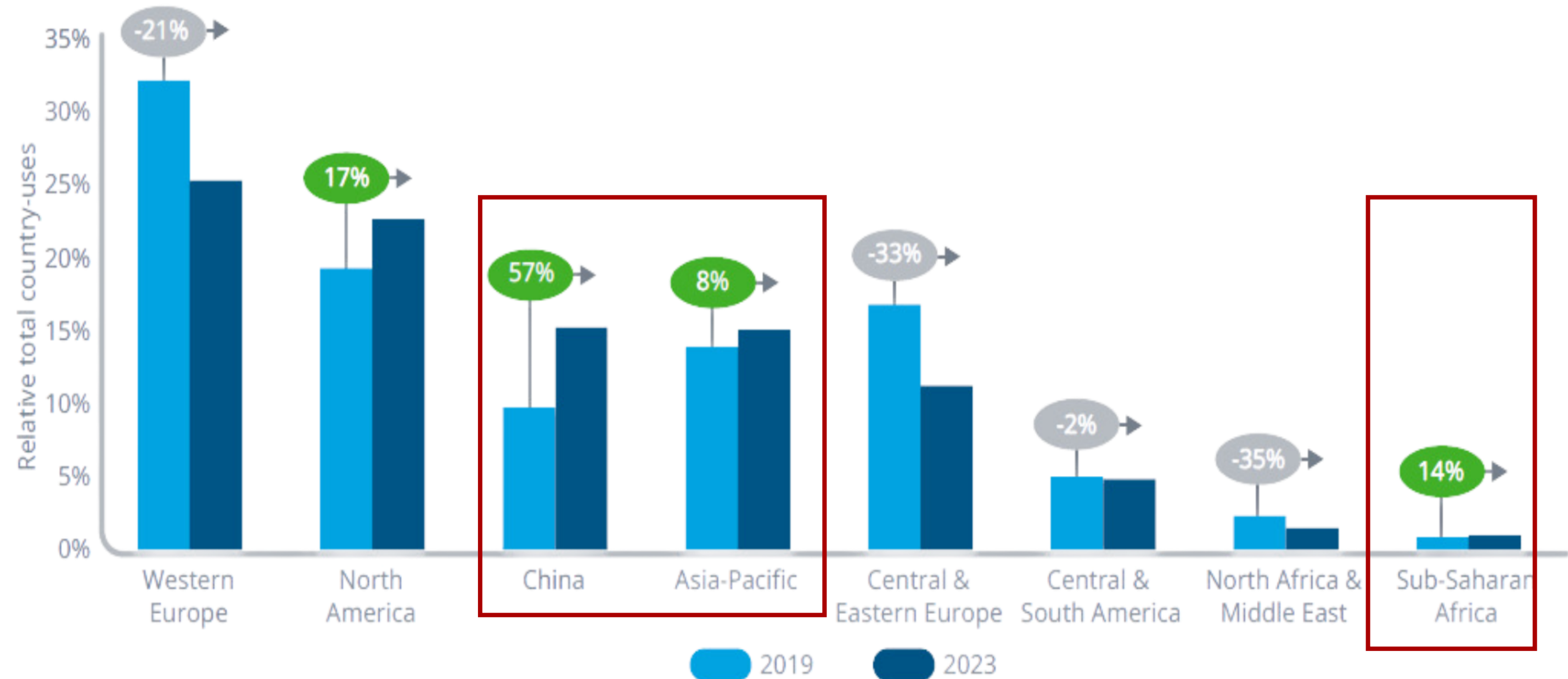


Estimated Global Pharmaceutical Industry's Expenditure Investment & Revenue in R&D



Statista. (2024). Global pharmaceutical industry - statistics & facts.

Shifting trends in reallocating trial sites to LMIC

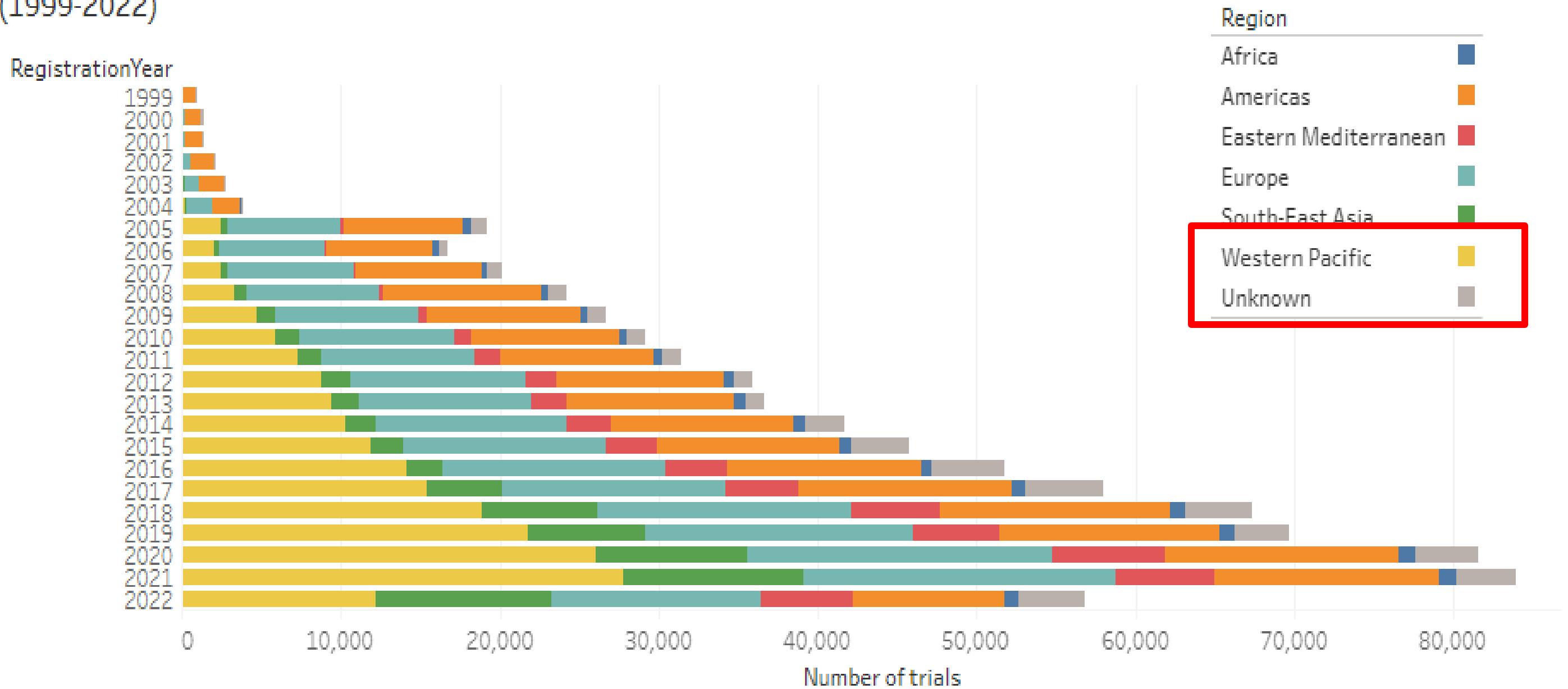


Shifting Trends In Reallocating Trial Sites Across Regions And Countries 2019 -2023
(Citeline Trialtrove, Jan 2024; IQVIA Institute, June 2024)

Rapid increase of trials registered in Western Pacific & South-East Asia, 1999-2022

Total Number of Trial Registry By WHO Region and Year

(1999-2022)



WHO International Clinical Trials Registry Platform (ICTRP) , Feb 2023

Ensuring Research Integrity (RI) & upholding principles of accountability, transparency and efficiency

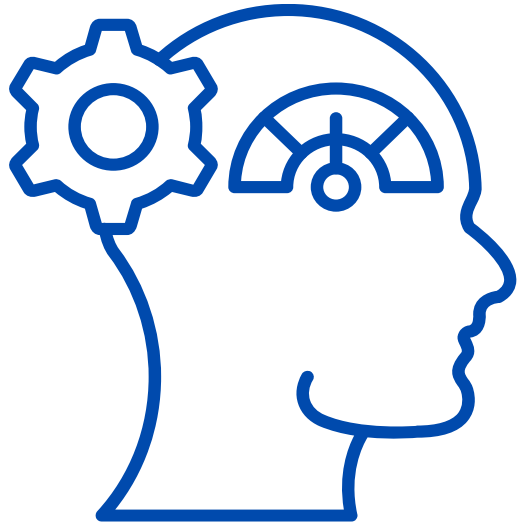


Self-regulation among
researcher
Responsible Conduct of
Research



Research Misconduct

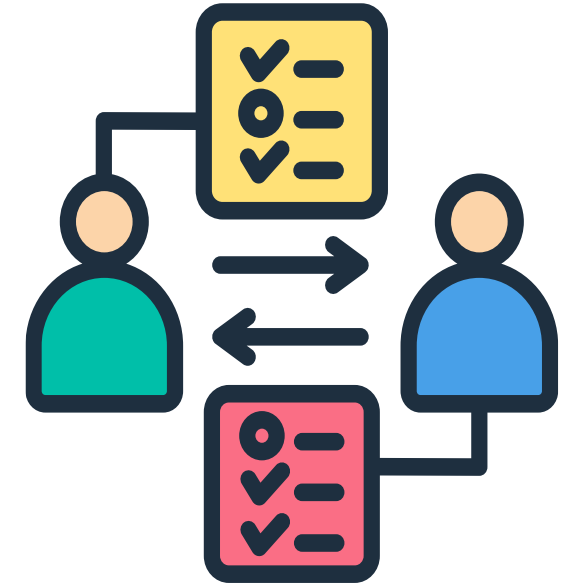
Ensuring Research Integrity (RI) & upholding principles of accountability, transparency and efficiency



Self-regulation among researcher
Responsible Conduct of Research

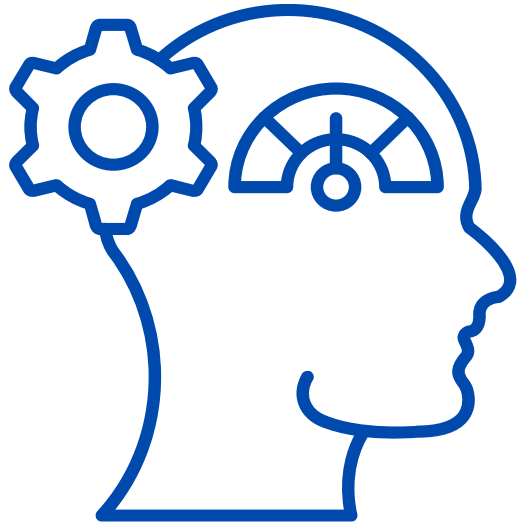


Research Misconduct



Stringent peer-review system for scientific publishing

Ensuring Research Integrity (RI) & upholding principles of accountability, transparency and efficiency



Self-regulation among researcher
Responsible Conduct of Research



Strict product licensing



Research Misconduct

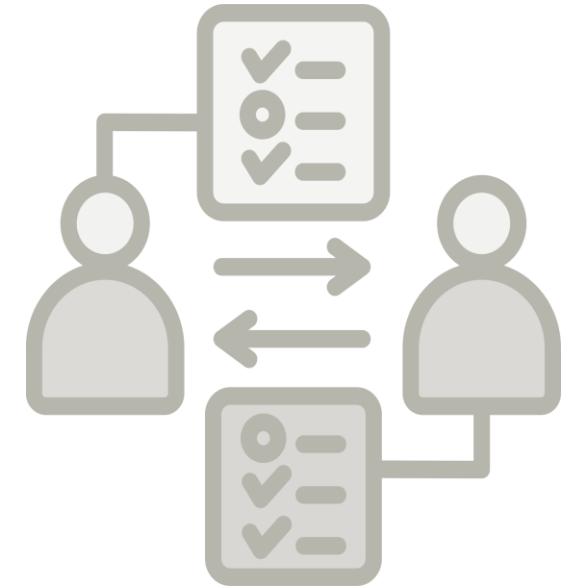


Stringent peer-review system for scientific publishing

Ensuring Research Integrity (RI) & upholding principles of accountability, transparency and efficiency



Self-regulation among researcher
Responsible Conduct of Research



Stringent peer-review system for scientific publishing



Research Misconduct

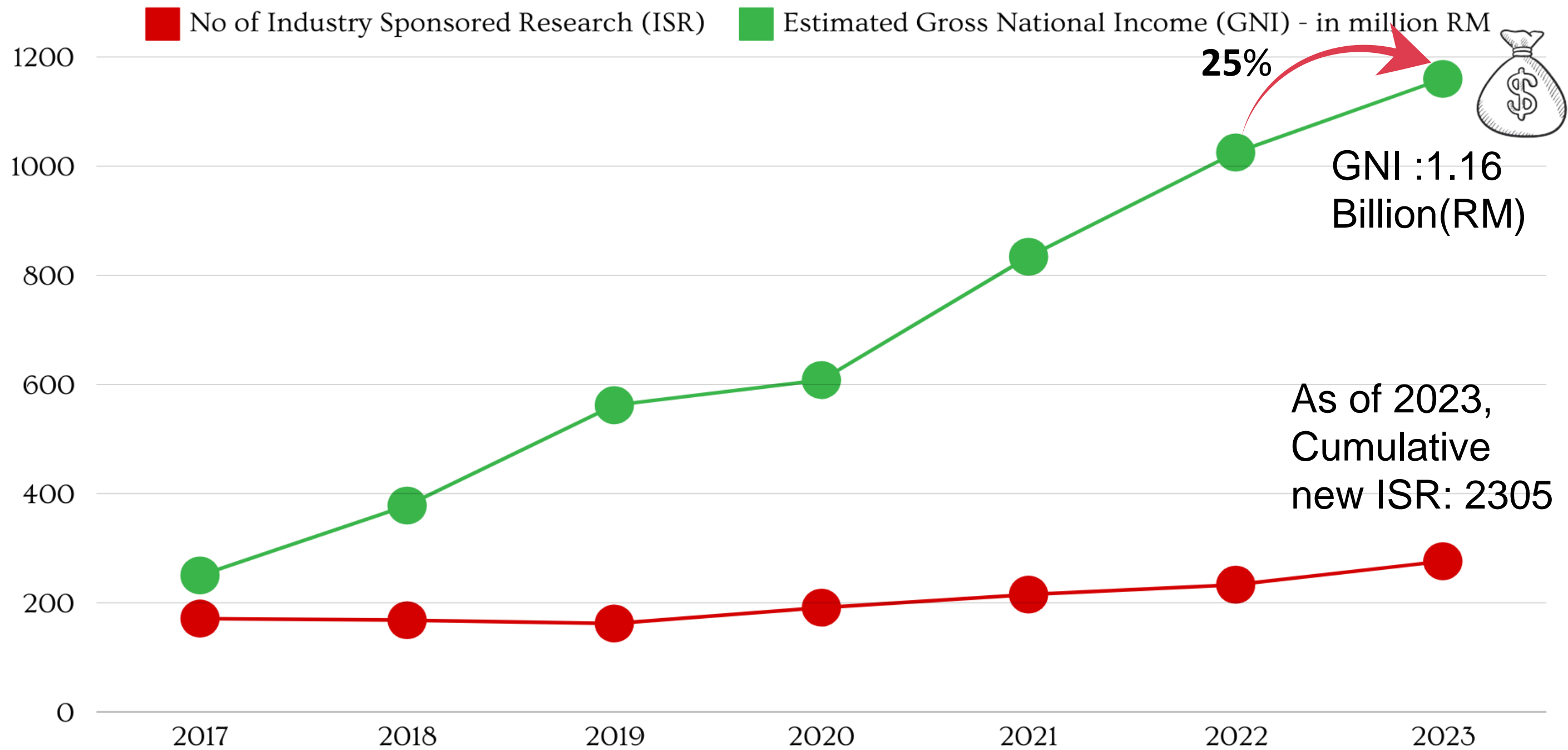


Strict product licensing



Robust governance within research ecosystem

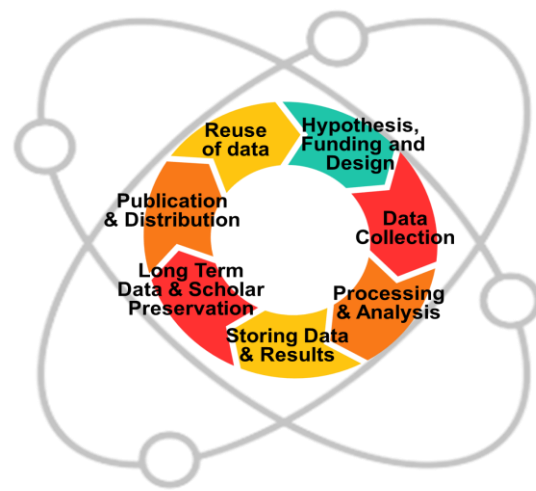
Health Research Industry in Malaysia



KPI Research Scorecard from 2017 (Clinical Research Malaysia (CRM) Annual Report ,2023)

Ministry of Health Malaysia

Health Research Governance Framework & Responsible Conduct Of Research



Highest standards for research practices
Integrity and validity of research
Accountability, Transparency and Efficiency

Responsible Conduct of Research

Honesty

Reliability

Objectivity

Impartiality and Independence

Openness and accessibility

Duty of care

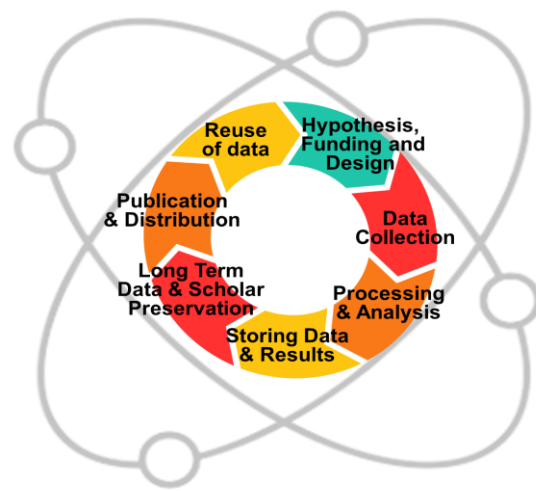
Fairness in giving credit

Responsibility for the future

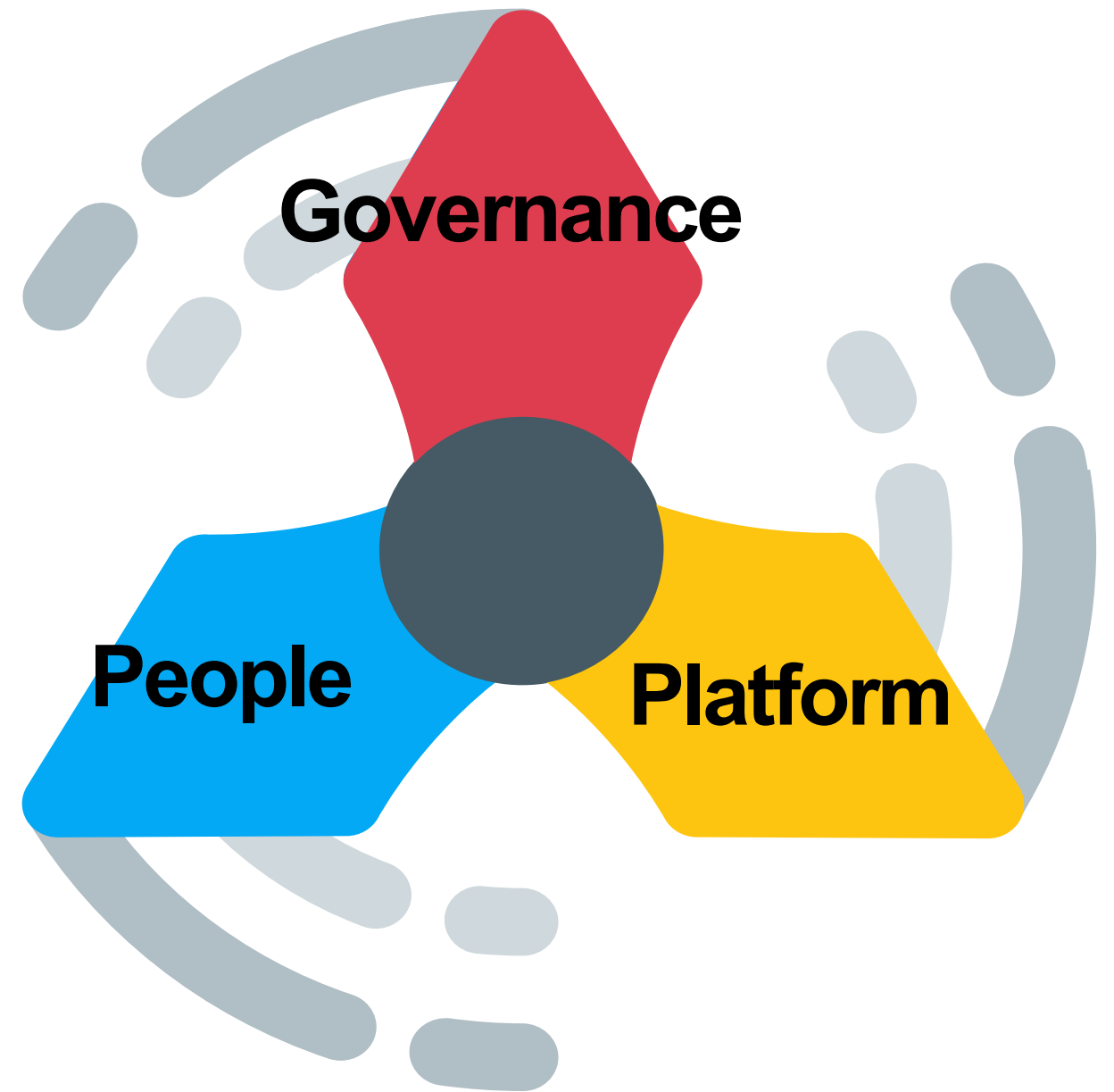
Malaysian Code of Responsible Conduct of Research,
2nd edition 2017

Ministry of Health Malaysia

Health Research Governance Framework & Responsible Conduct Of Research

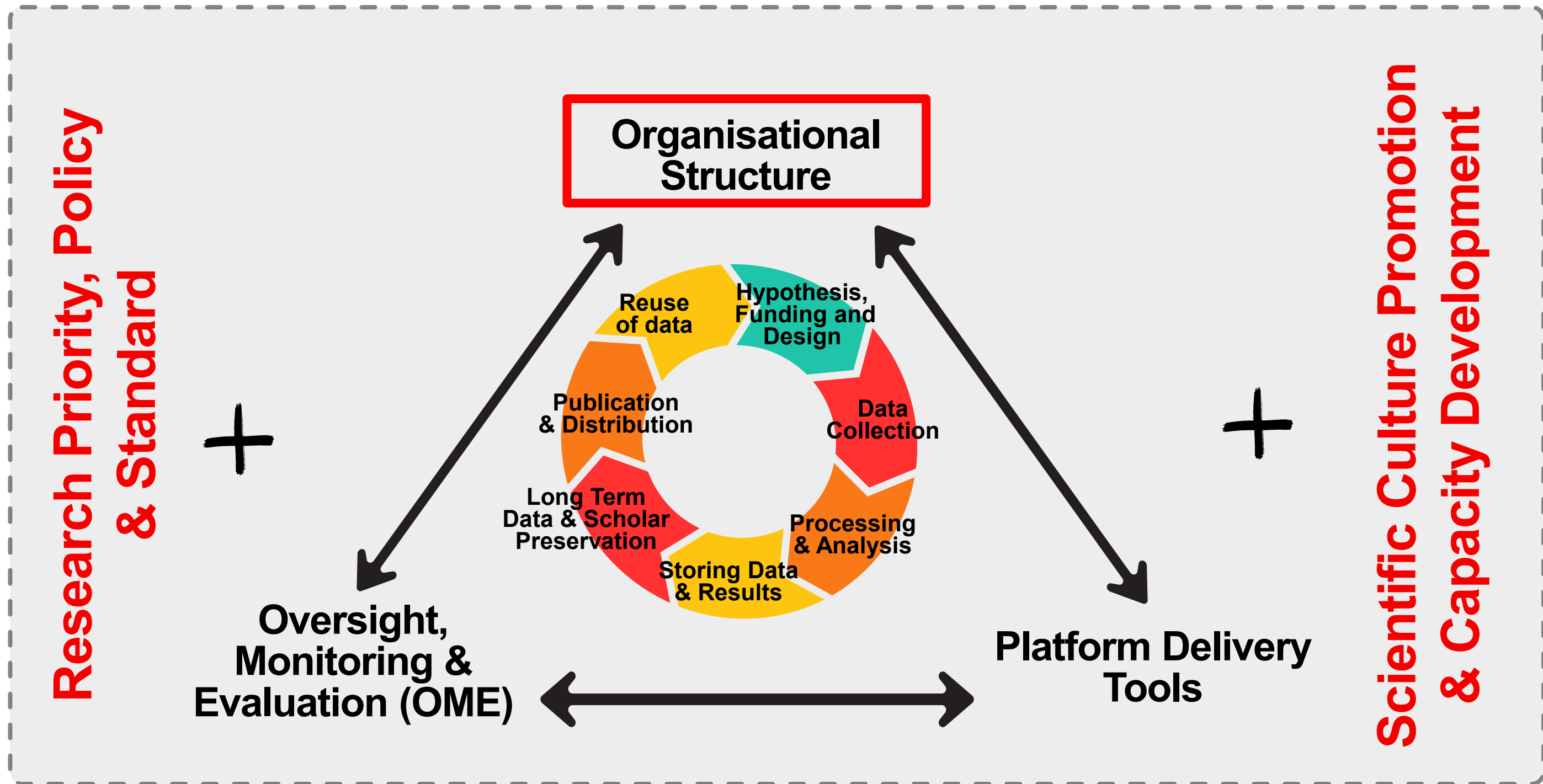


Highest standards for research practices
Integrity and validity of research
Accountability, Transparency and Efficiency



**MOH Health
Research Ecosystem**

MOH Malaysia – Health Research Governance Framework

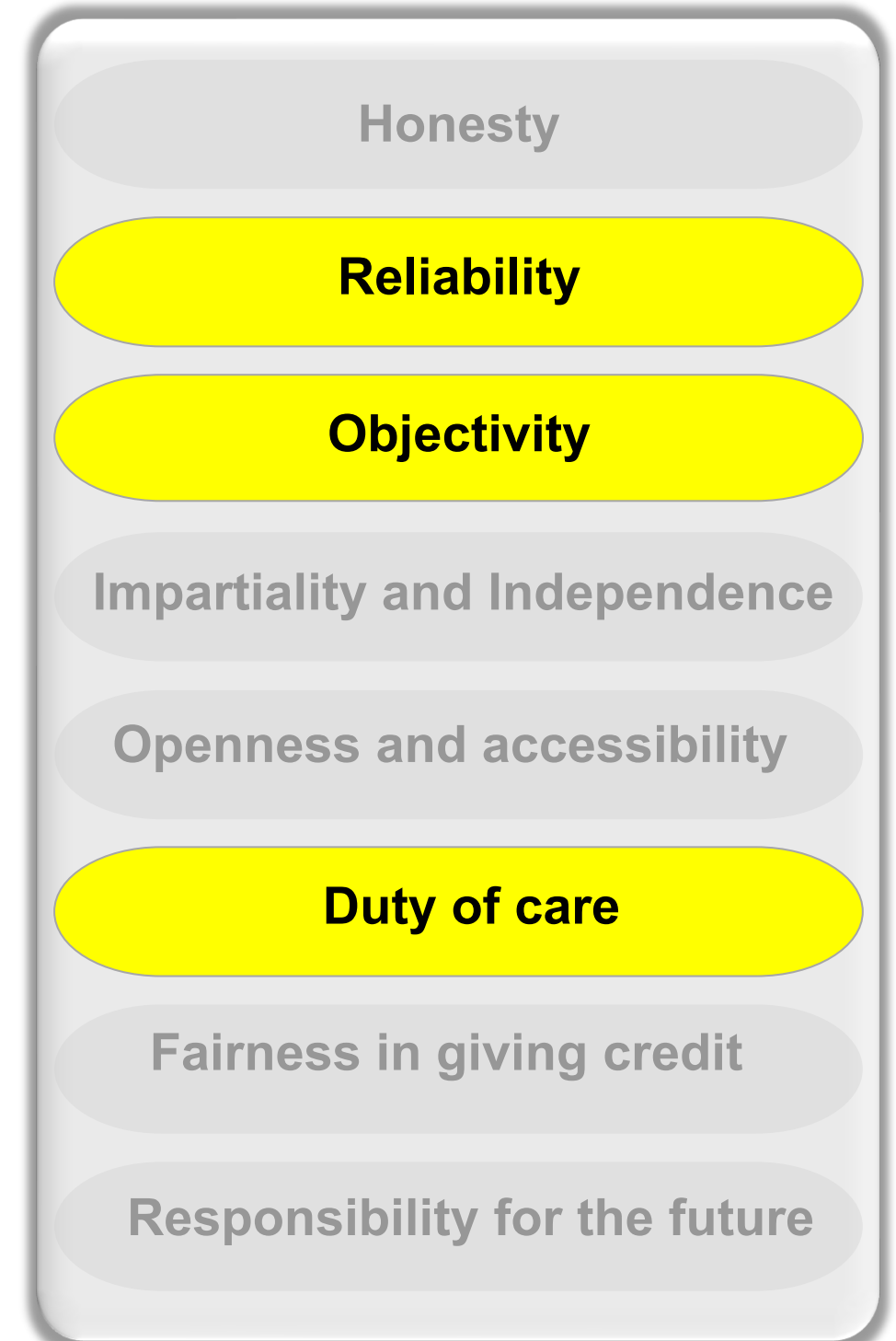
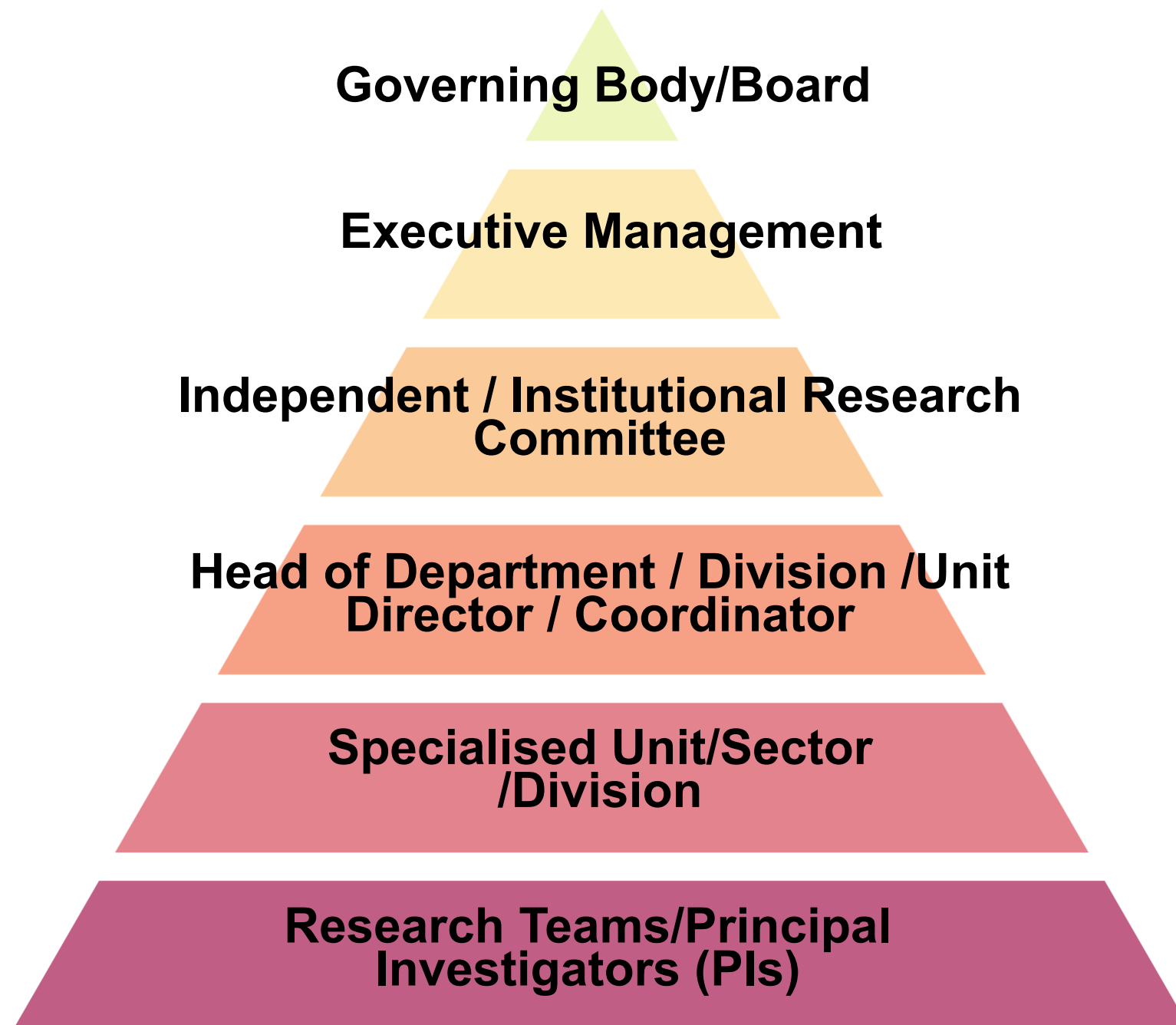


1. Rani M et. al. J Evid Based Med. 2011 Nov;4(4):204-13. doi: 10.1111/j.1756-5391.2011.01161 2. Smits P, Champagne F. Health Res Policy Syst. 2020 Feb 18;18(1):22. doi: 10.1186/s12961-020-0525-

2. Department of Health, UK. Research governance framework for health and social care. 2nd edition London: Department of Health, 2005

Organisational Structure in Health Research Governance

Responsible Conduct of Research

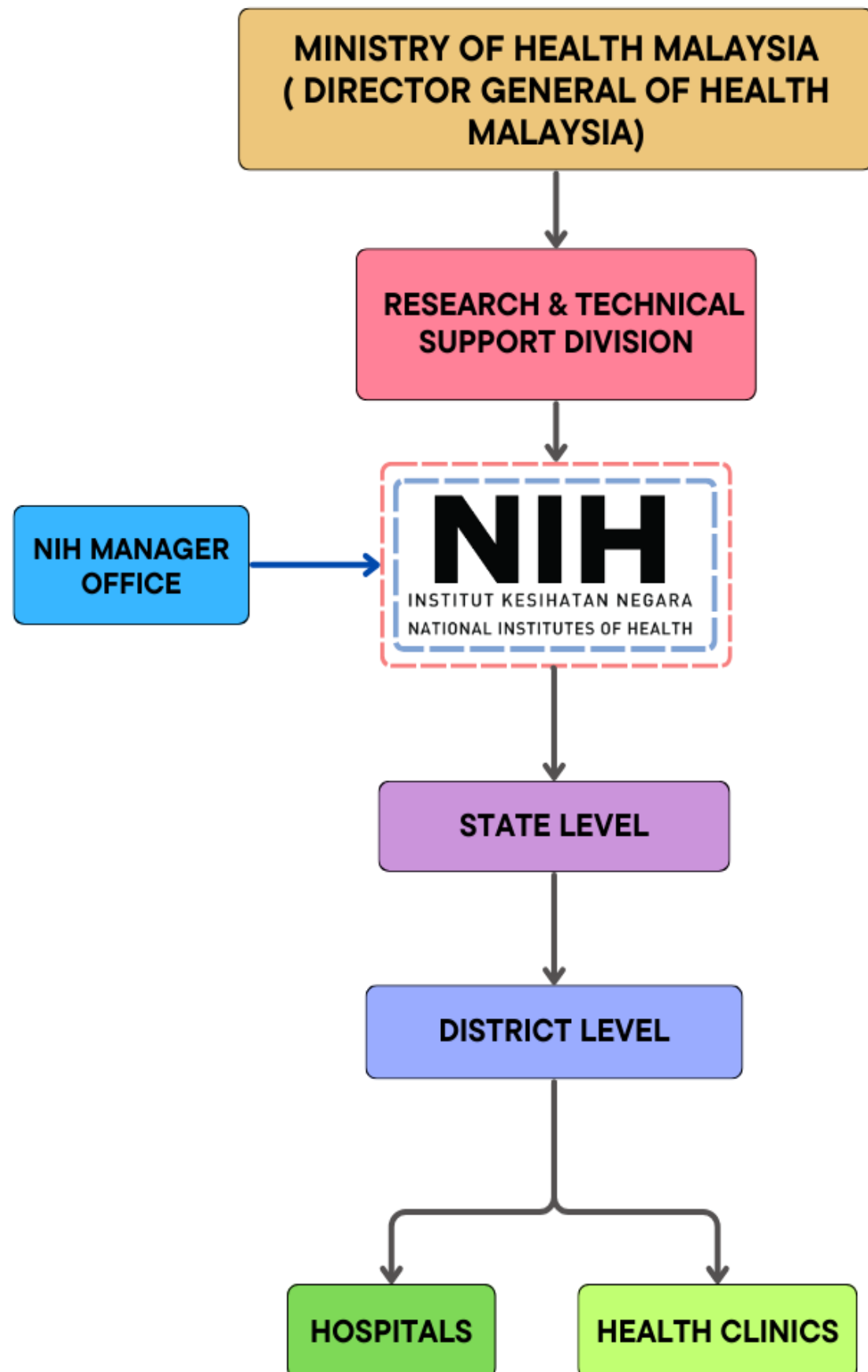


1. World Health Organization. (2014). Standards and operational guidance for ethics review of health-related research with human participants. World Health Organization.

2. National Health and Medical Research Council, Australian Research Council, & Universities Australia. (2018). Australian code for the responsible conduct of research. Commonwealth of Australia

3. Department of Health, UK. Research governance framework for health and social care. 2nd edition London: Department of Health, 20054. Smits P, Champagne F, Health Res Policy Syst. 2020 Feb 18;18(1):22. doi: 10.1186/s12961-020-0525-z.

MOH Malaysia's Organisational Structure

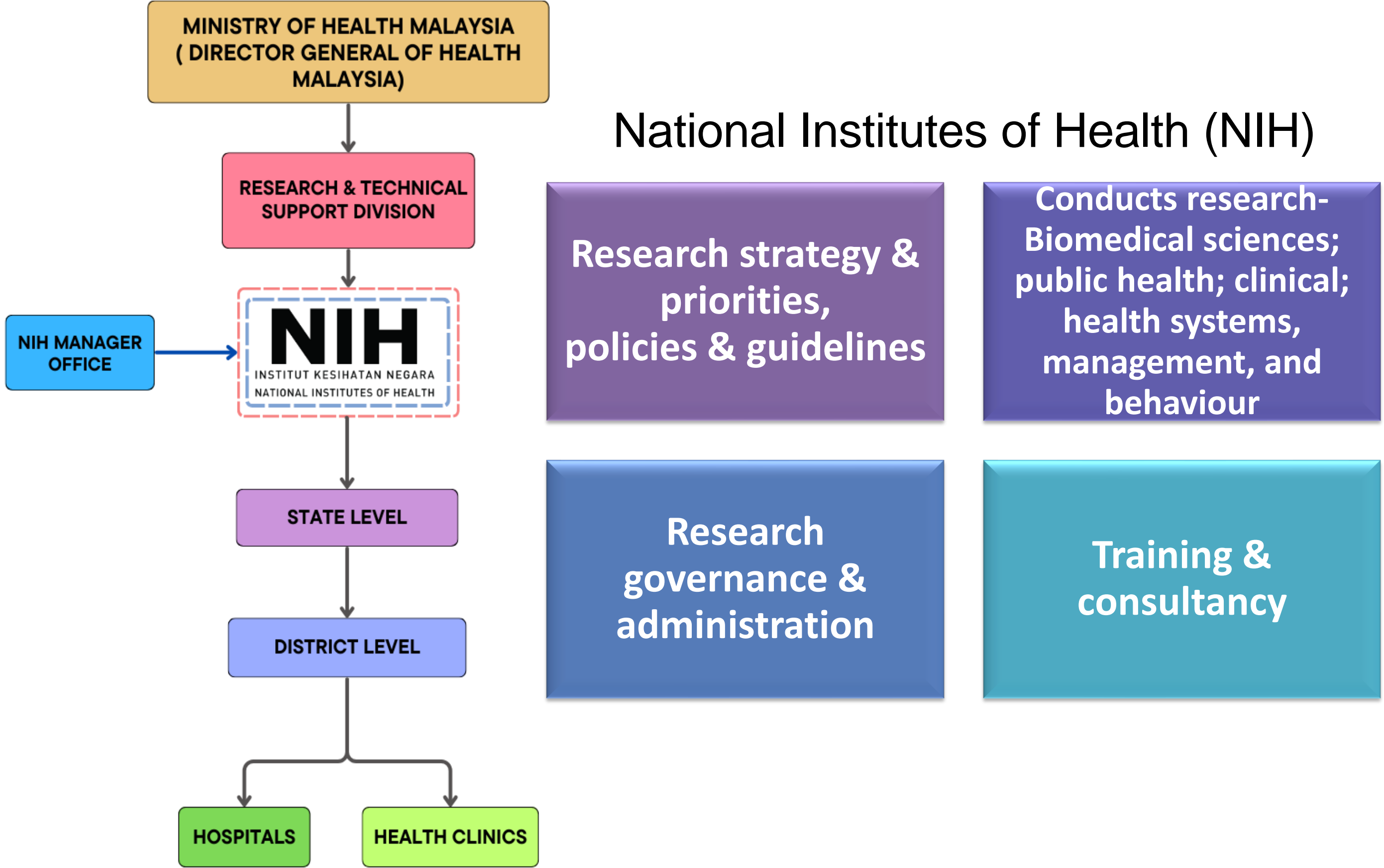


National Institutes of Health (NIH)

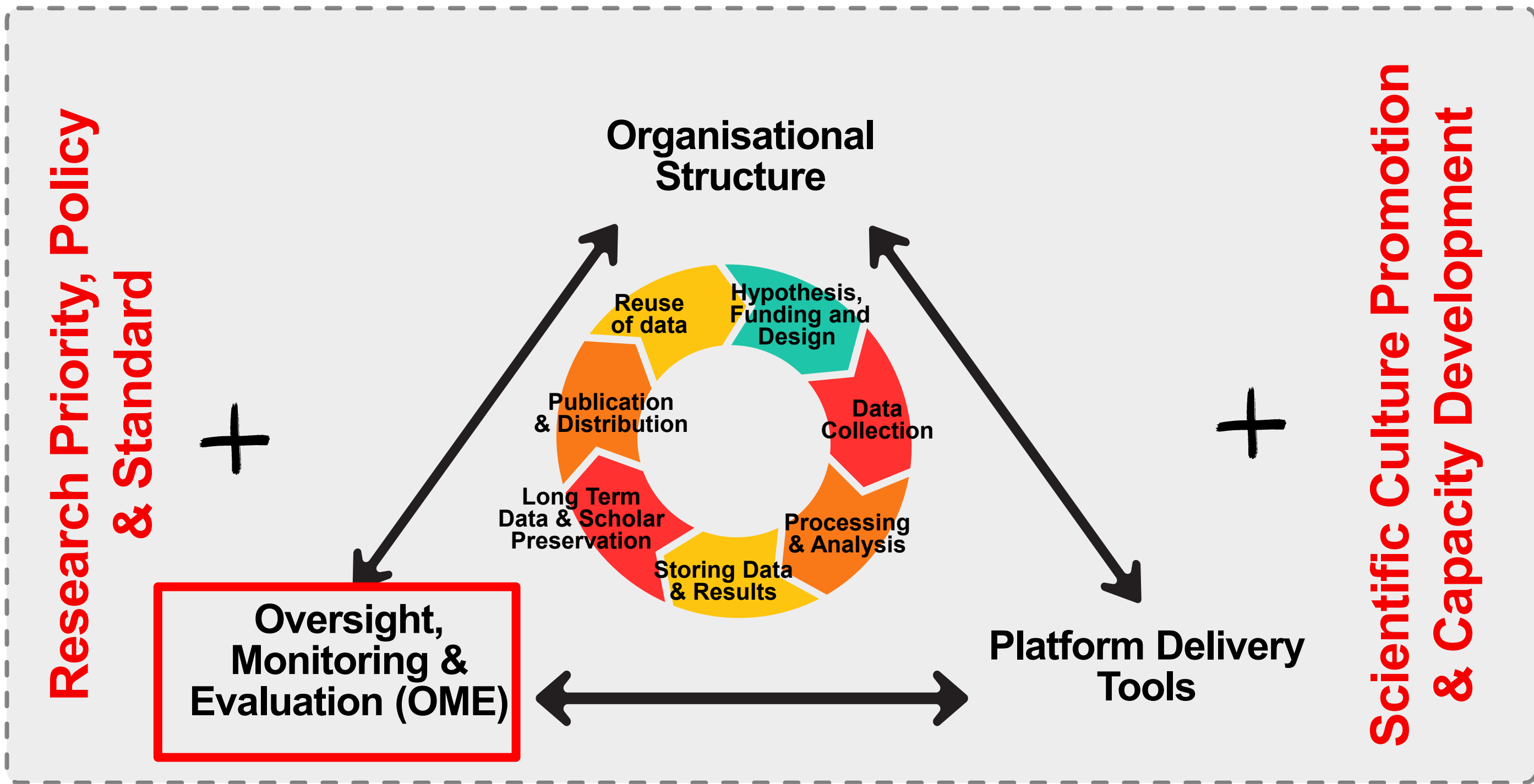


Established under the 7th Malaysia Plan and launched in August 2003

MOH Malaysia's Organisational Structure

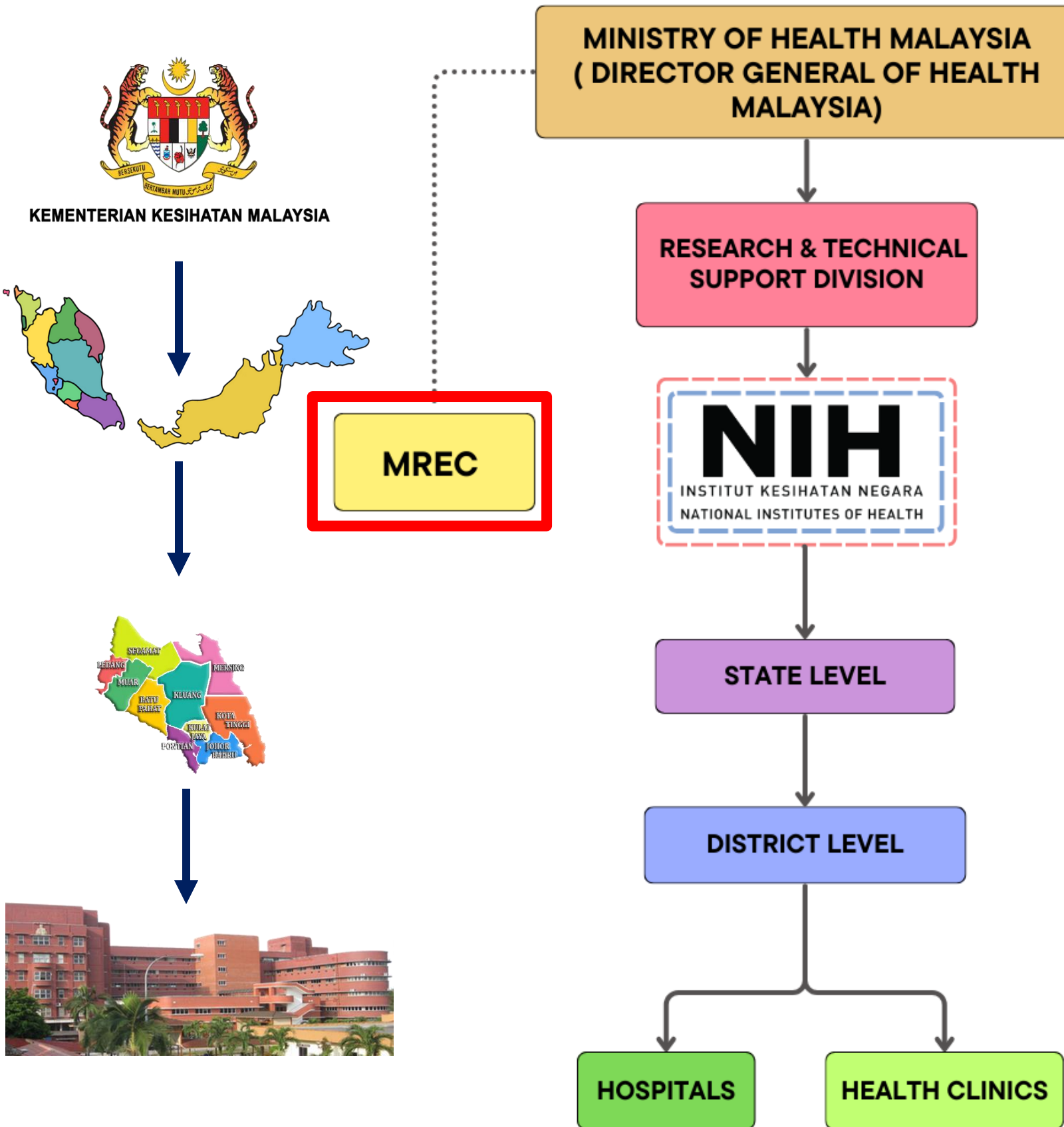


MOH Malaysia – Health Research Governance Framework



Oversight , Monitoring & Evaluation

Responsible Conduct of Research



- Honesty
- Reliability**
- Objectivity**
- Impartiality and Independence**
- Openness and accessibility
- Duty of care**
- Fairness in giving credit
- Responsibility for the future

Oversight , Monitoring & Evaluation By Independent Research Ethics Committee

MREC

Est. 2002

MEDICAL RESEARCH & ETHICS COMMITTEE

**Ethical
Review &
Approval**

**Research
Conduct
Oversight**

**Monitoring
of Adverse
Events**

**Monitoring
of Protocol
Deviation**

**Compliance
Audit**

Provides independent guidance, advice and decision on ethical issues of health research

involving human subjects conducted by MOH staff or in MOH facilities.

Ensures that research is not only ethically accepted but, Scientifically sound and rights of subjects are protected

Oversight , Monitoring & Evaluation By Independent Research Ethics Committee

NATIONAL COMMITTEE FOR CLINICAL RESEARCH (NCCR)

MREC

MEDICAL RESEARCH &
ETHICS COMMITTEE

NRDHM

NATIONAL RESEARCH &
DEVELOPMENT FOR HERBAL
MEDICINE COMMITTEE

NSCERT

NATIONAL STEM CELL RESEARCH
& THERAPY COMMITTEE

FIH

FIRST IN HUMAN SCIENTIFIC
REVIEW COMMITTEE

ESTABLISHMENT OF INSTITUTIONAL -LEVEL COMMITTEE

ACUC

ANIMAL CARE & USE
COMMITTEE

GRP

GRANT REVIEW PANEL

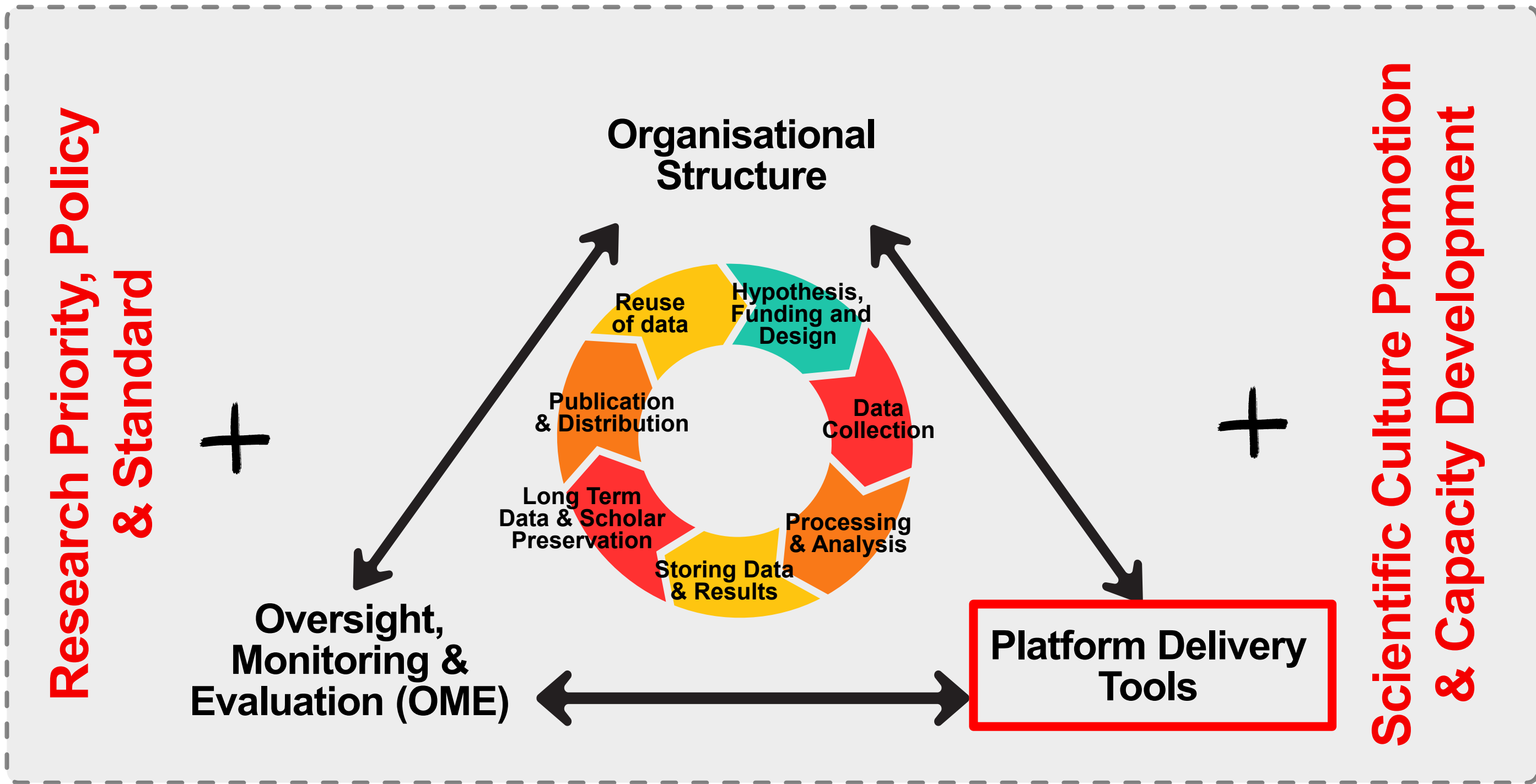
RRB

RESEARCH
REVIEW BOARD (JPP-
NIH)

IBBC

INSTITUTIONAL BIOSAFETY
& BIOSECURITY COMMITTEE

MOH Malaysia – Health Research Governance Framework



1.Rani M et. el. J Evid Based Med. 2011 Nov;4(4):204-13. doi: 10.1111/j.1756-5391.2011.01161 2. Smits P, Champagne F. Health Res Policy Syst. 2020 Feb 18;18(1):22. doi: 10.1186/s12961-020-0525-

2.Department of Health, UK. Research governance framework for health and social care. 2nd edition London: Department of Health, 2005

Platform Delivery Tools



Responsible Conduct of Research

Honesty

Reliability

Objectivity

Impartiality and Independence

Openness and accessibility

Duty of care

Fairness in giving credit

Responsibility for the future

Network of systems in MOH



Data Repository System (NIH-DaRS)

**RESEARCH
DIGITAL
REPOSITORY
SYSTEM**

Scholars Archival System (NIH-DSpace)



Research Registration , Approval & Monitoring System (NMRR v2)

National Medical Research Register (NMRR)

- Prospective research registration
- Funding application
- Ethical approval
- Monitoring during the research conduct
- Submission of final reports

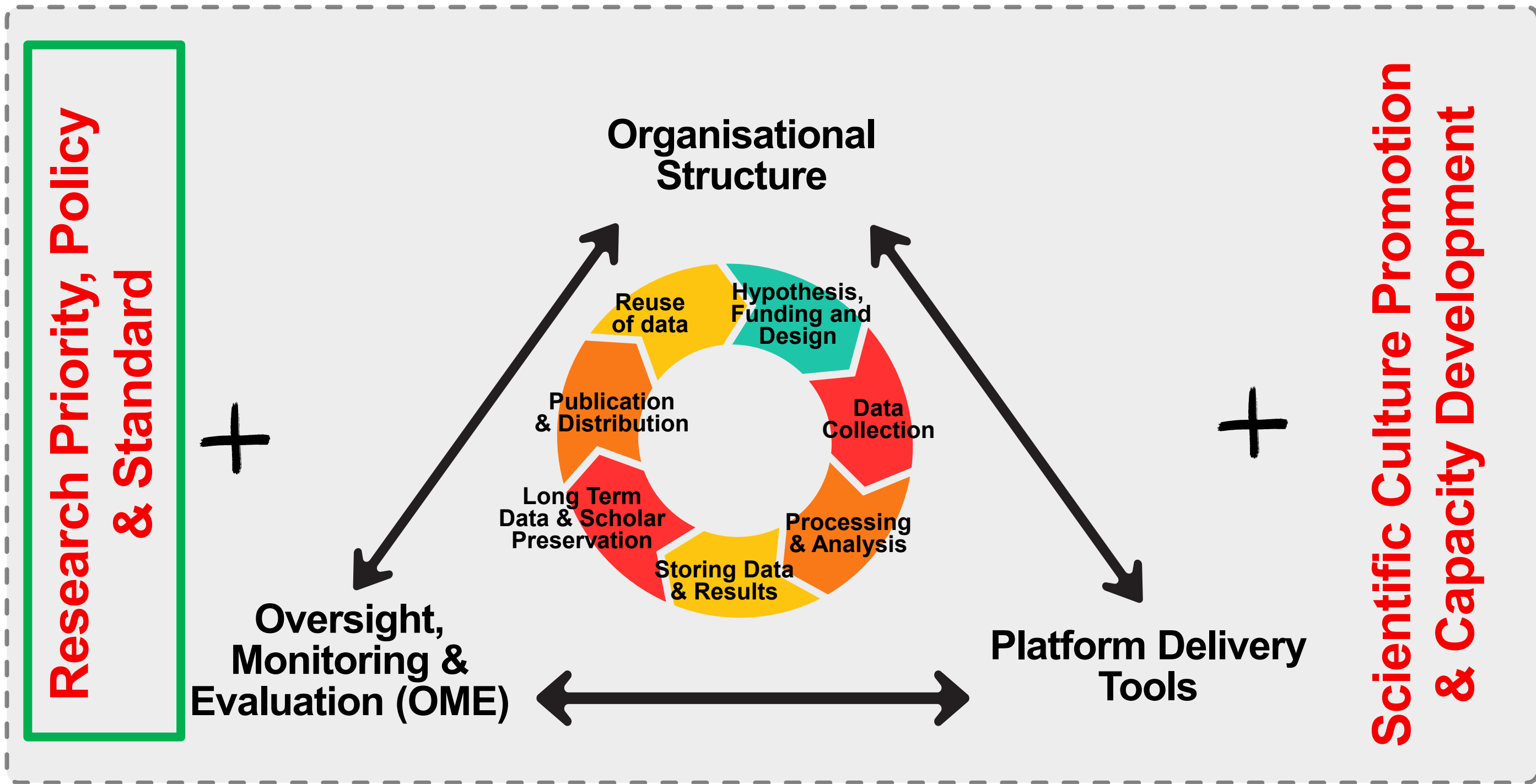
NIH Data Repository System (NIH- DaRS)

- Archives and preserves research data

NIH Research Digital Repository System (NIH - DSpace)

- Archives scholarly works and outputs
- Allows open access

MOH Malaysia – Health Research Governance Framework



Research Priorities ,Policies, Guidelines & Standards



Responsible Conduct of Research

Honesty

Reliability

Objectivity

Impartiality and Independence

Openness and accessibility

Duty of care

Fairness in giving credit

Responsibility for the future

Health Research Priorities for 12th Malaysia Plan (2021-2025)

- Priority given to certain Health Research Area in order to improve the universal health coverage and transforming the nation into a high income country by 2030

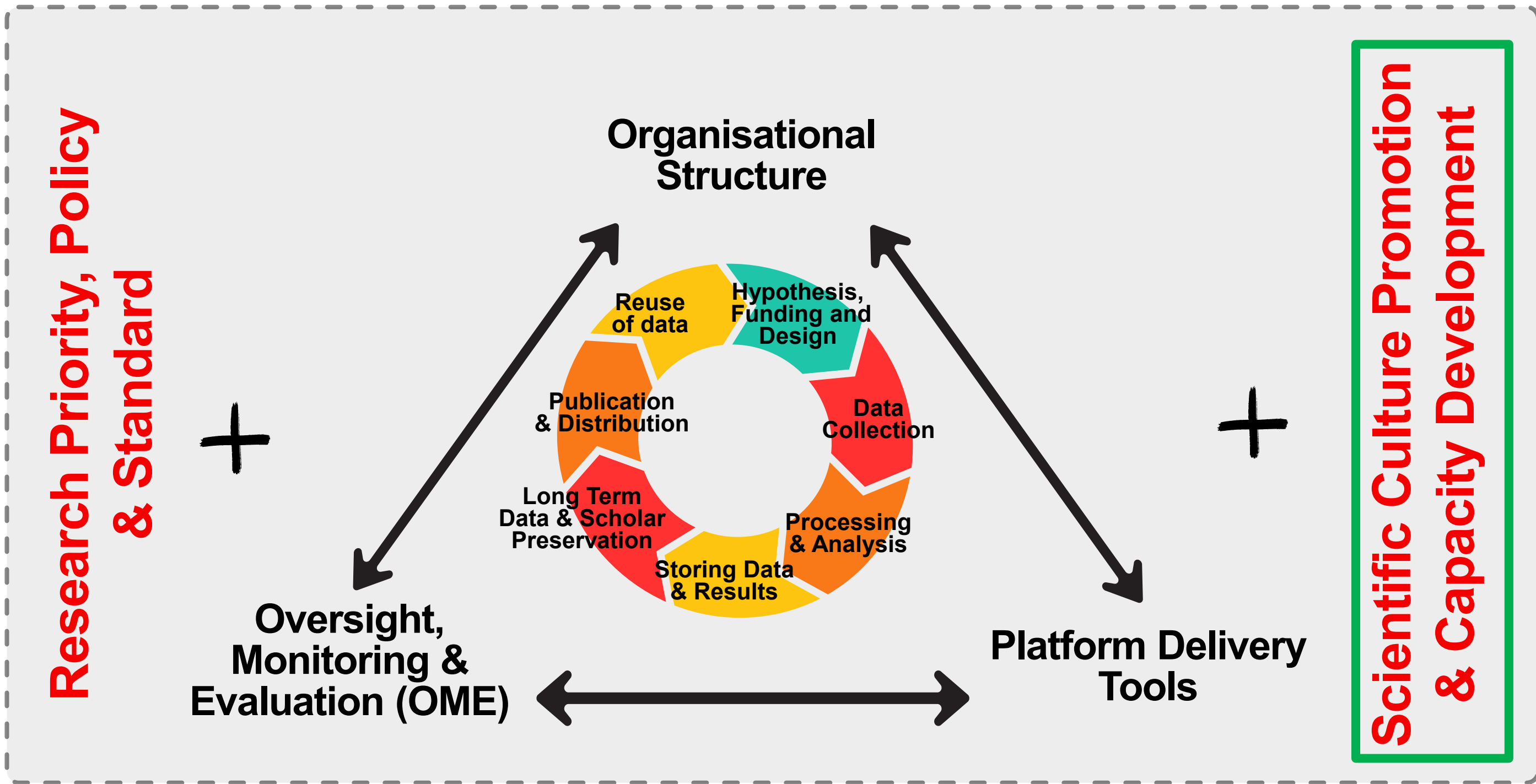
MOH's Research & Technical Support Programme Strategic Planning (2021-2025)

- Sets the direction, standards and goals in health research

Policies / Guidelines

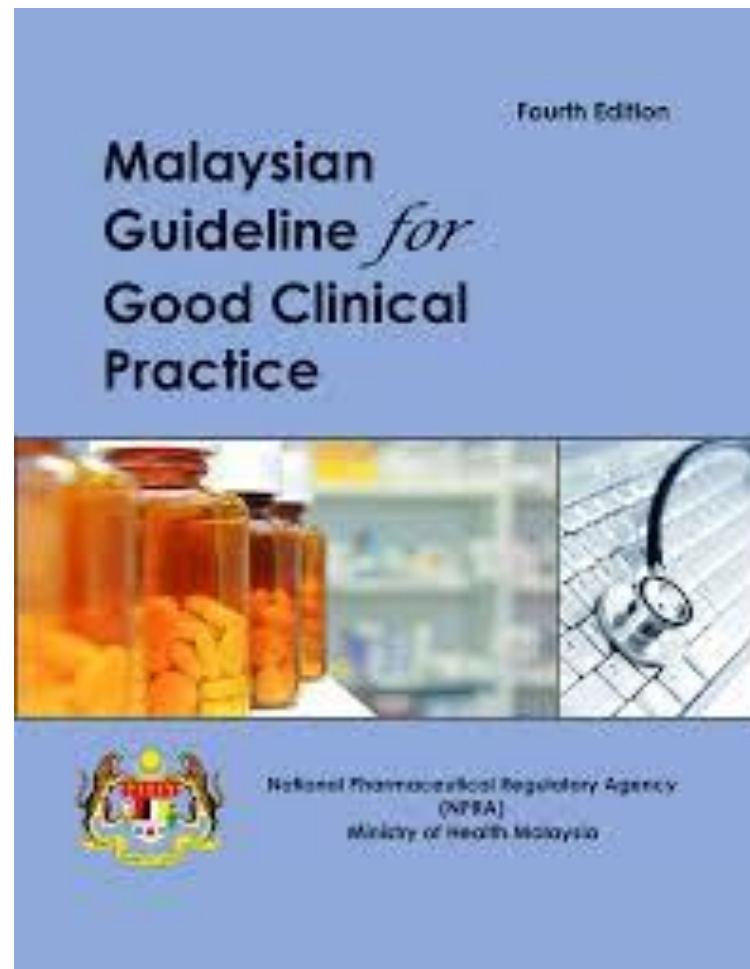
- NIH Guidelines for Conducting Research in MOH's Facilities & institution, 3rd Edition 2021
- Laid out the general rule and requirement for conducting research in the MOH facilities & institutions

MOH Malaysia – Health Research Governance Framework



Scientific Culture & Human Capacity Development

Responsible Conduct of Research



Mandatory Good Clinical Practice (GCP) Certification

- For all participating in interventional research and clinical trials



Honesty

Reliability

Objectivity

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Fairness in giving credit

Responsibility for the future

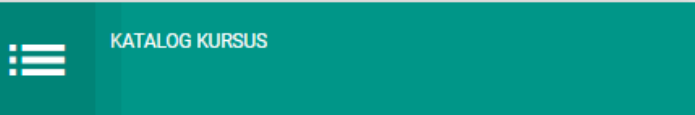
Scientific Culture & Human Capacity Development

NIH- MyKursus

INSTITUT KESIHATAN NEGARA
NATIONAL INSTITUTES OF HEALTH

Courses & Workshops on best research practices

- Organised by MOH all year round
- Offered to both novices as well as established researchers



Tajuk	Penganjur
BENGKEL PEMURNIAN MODUL TADBIR URUS KLINIKAL UNTUK BAKAL PEMIMPIN KEMENTERIAN KESIHATAN MALAYSIA	PUSAT PEMBANGUNAN KECEMERLANGAN TADBIR URUS KLINIKAL, INSTITUT PENGURUSAN KESIHATAN
IMPLEMENTING GLP PRINCIPLES IN RESEARCH FACILITY ACCORDING TO THE OECD PRINCIPLES	UNIT ENTOMOLOGI, PUSAT PENYELIDIKAN PENYAKIT BERJANGKIT (IDRC), INSTITUT PENYELIDIKAN PERUBATAN

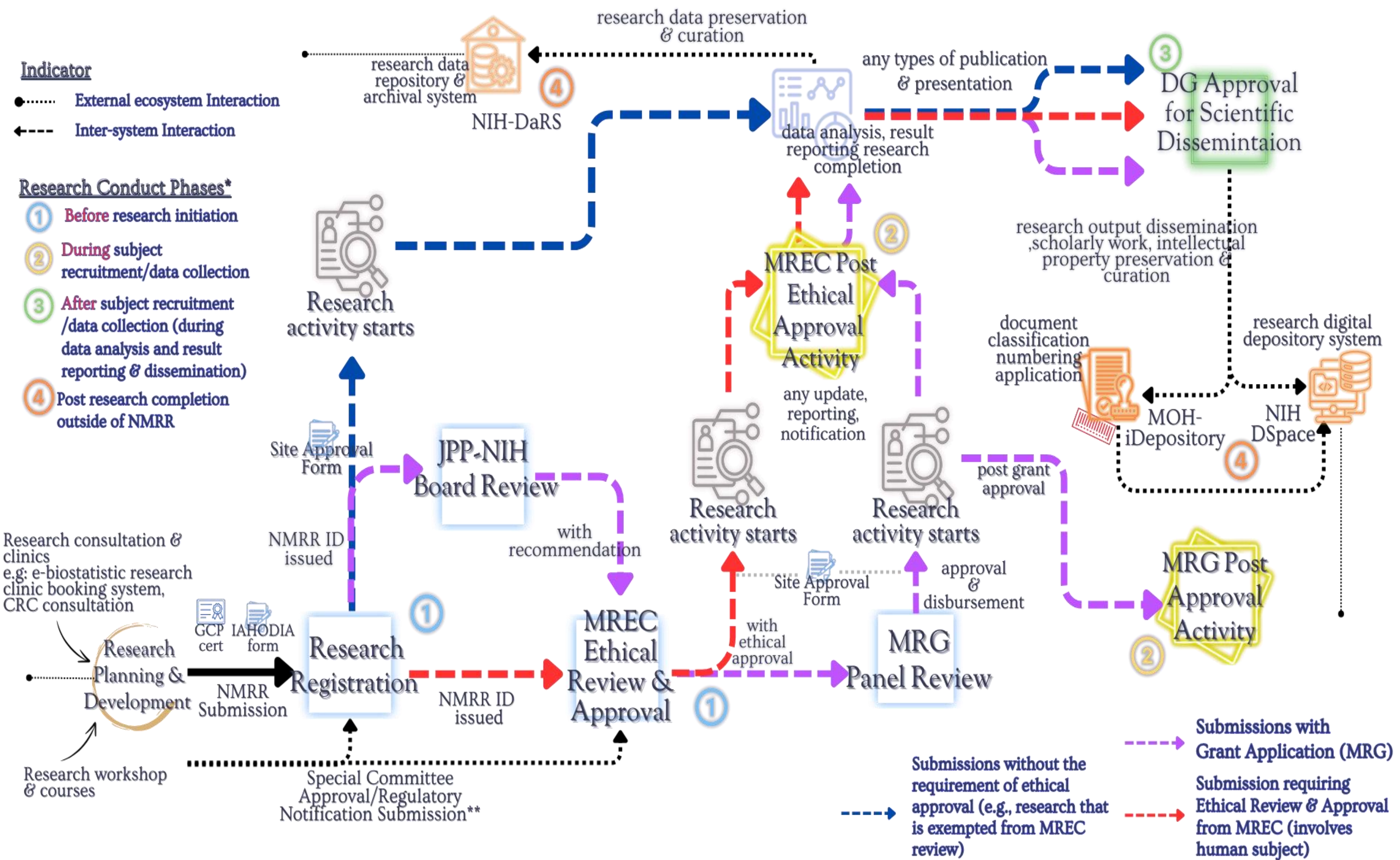
TAKWIM LATIHAN RANGKAIAN PUSAT PENYELIDIKAN KLINIKAL (CRC) BAGI TAHUN 2024

No.	BULAN	NAMA KURSUS	TARIKH	ANJURAN
1	JANUARI	Proposal Writing Workshop	16 Jan	CRC Hospital Seri Manjung
2		CRC in House CME	17 Jan	CRC Hospital Taiping
3		Introduction to Clinical Research	17-18 Jan	CRC Hospital Sibu
4		Pubmed Short Training	18 Jan	CRC Hospital Taiping
5		NMRRR Registration Workshop	24 Jan	CRC Hospital Umum Sarawak
6		Clinical Audit Workshop	30-31 Jan	CRC Hospital Putrajaya
7	FEBRUARI	Training of Trainers Workshop : ICR Module Ver 2	1 Feb	CRC Hospital Umum Sarawak
8		Introduction to Clinical Research Workshop	5-8 Feb	CRC Hospital Pakar Sultanah Fatimah
9		Introduction to Clinical Research for Cluster Hospital	5-8 Feb	CRC Hospital Sultan Ismail, Johor
10		Introduction to Clinical Research	6-7 Feb	CRC Hospital Seberang Jaya
11		Introduction to Clinical Research (Paramedic)	19-20 Feb	CRC Hospital Raja Perempuan Zainab II, Kelantan
12		Research Promotion Week	19-22 Feb	CRC Hospital Sungai Buloh
13		Introduction to Clinical Research (TOT)	20-21 Feb	CRC Hospital Queen Elizabeth, Sabah & CCRN, ICR

BENGKEL PEMANTAPAN HALATUJU STRATEGIK INSTITUT KESIHATAN UMUM
CME NIH 9/2024: DIALLING FOR DATA: OVERCOMING CHALLENGES IN A NAT
BENGKEL PENULISAN SAINTIFIK BAGI INSTITUT KESIHATAN UMUM
CME NIH 10/2024: HARNESSING GENE EDITING TECHNOLOGY FOR TREATING
ENSURING ACCURACY: A WORKSHOP ON QUALITY CONTROL IN THE MICROB

General Overview of Conduct of Research Involving MOH facilities & institution

@WORK & visualisation by :
Research Registry & Data Coordination , Sector for Ethics &
Research Surveillance , NIH, MOH



Conclusion

- The need for a robust health research governance framework to uphold research integrity.
- The MOH Malaysia's health research governance framework providing robust governance and administration within the MOH health research ecosystem.
- By embracing the RCR principles within its framework, MOH Malaysia is committed to ensure the continuity and sustainability of its health research ecosystem while always upholding the principles of accountability, transparency and efficiency.

Thank
You

Terima
Kasih

“Dhanyabaad”
धन्यवाद

