



## Track 6: Trends in Clinical Trials

# Sponsored Clinical Research : Challenges and Opportunities in Malaysia

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**The Promise of Clinical Trials:  
Transforming Tomorrow's Health**

**SCRI Clinical Trials Symposium 2024**

**30 - 31 Jul 2024 • Raffles City Convention Centre**



# Outline

- Our Journey
- The Landscape
- Opportunity
- Charting the Future

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# Our Journey

2012



## Establishment

Corporatized company and owned by  
Ministry of Health  
One-stop centre & Site Management  
Organisation (SMO)

2019



## Self-Sustainable

2019



**ISO 9001:2015 (QMS) accreditation**  
Quality Management System

2021



**ISO37001:2016 (ABMS) accreditation**  
Anti-Bribery Management System

2022



## 10-Year Milestone



# CRM's Guiding Principles



## HUMANITY

Address unmet medical needs, access to innovative treatments and transform health outcomes for patients through clinical trials



## STABILITY

Excellent & consistent performance to deliver speed, reliability & quality



## SUSTAINABILITY

Create business sustainability through core values, code of conduct & operational excellence

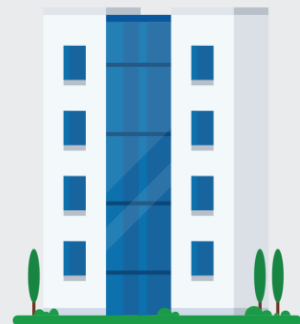
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## PLANNING STAGE

Site/Country Selection Process



### Sponsors

(Pharmaceutical, Biotechnology,  
and Medical Device Companies)

### CROs

(Contract Research Organization)



**One Stop Centre**  
for both Sponsors and CROs



**Fast and Accurate Feasibility  
Database of Malaysia**

since 2012, updated every 6 months-information on  
site capabilities, investigators across all therapeutic  
areas



**Budget Negotiations  
and Enquiries**



**Legal Enquiries**  
CTAs, NDA/CDAs



**Regulatory and IRB  
Submissions Enquiries**



**Malaysian Sites  
& Investigators**

**175**

Public Hospitals / Health Clinics

**15**

MOHE Hospitals

**69**

Private Hospitals

**1700**

Investigators Multi Therapeutic

## STUDIES AWARDED TO MALAYSIA / APPROVED STUDIES IN MALAYSIA



Ensure Sites & Investigators  
focus on the delivery of trials by

Supplying qualified  
and high quality  
study coordinator



Reviewing of all  
Clinical Trials  
Agreement



Handling  
investigators trial  
budget in a  
transparent  
manner

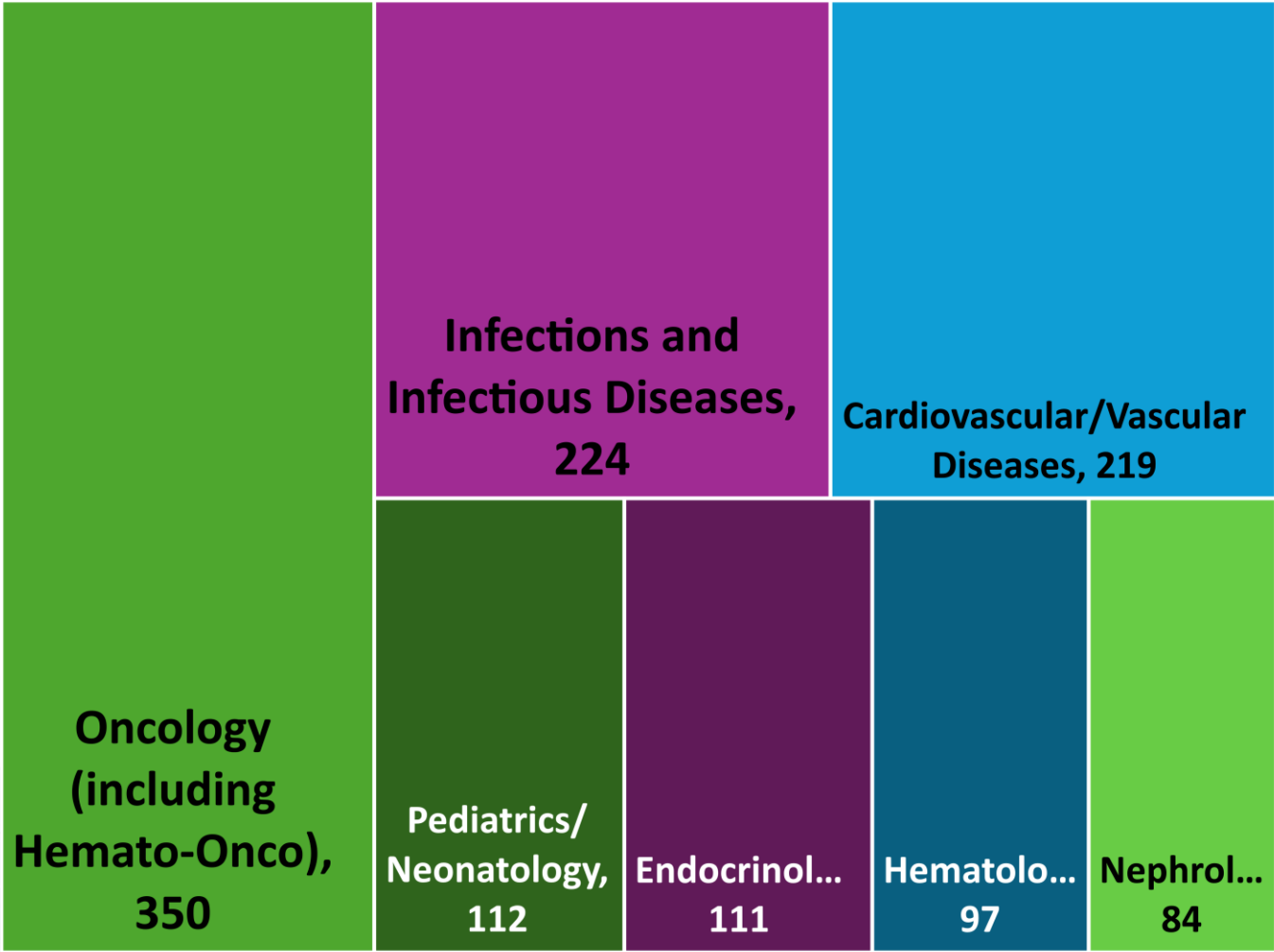
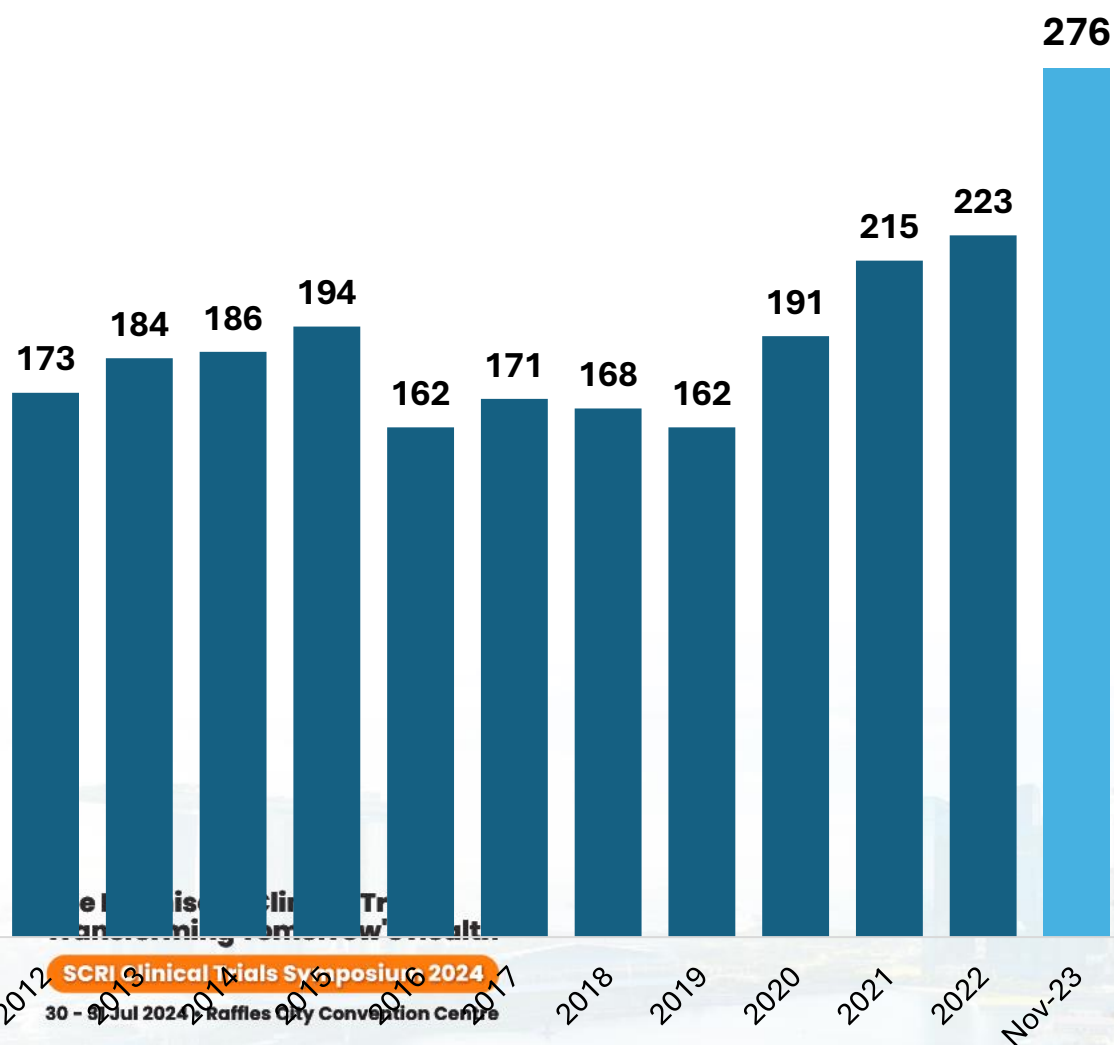


Tackling issues at  
the site level  
including  
recruitment



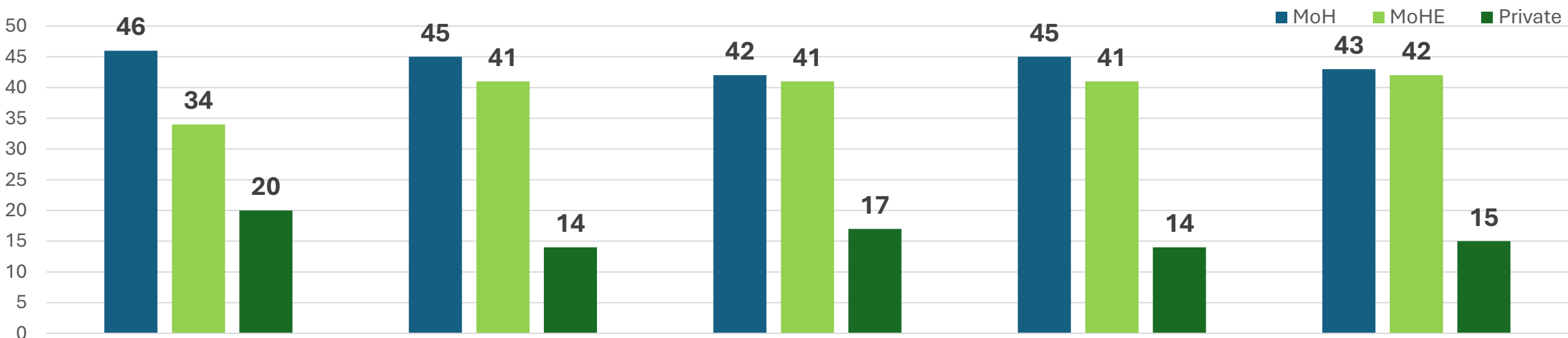
**Landscape**

# Sponsored Clinical Research in Malaysia (n=2305)





# Market share



Year	MoH (%)	MoHE (%)	Private (%)
YTD 2024	43 (63/146)	42 (61/146)	15 (22/146)
2023	45 (188/422)	41 (172/422)	14 (62/422)
2022	42 (135/322)	41 (133/322)	17 (54/322)
2021	45 (143/315)	41 (129/315)	14 (43/315)
2020	46 (115/250)	34 (84/250)	20 (51/250)

**Opportunity**

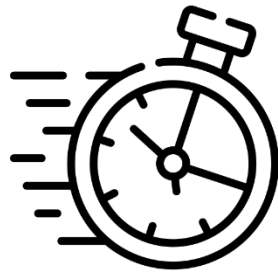
# SPEED – Improved Start-up

## MREC Review



MREC Review Timeline (2022): **32 days**

## CTA Review



Reduced from  
**60 days to 14 days**



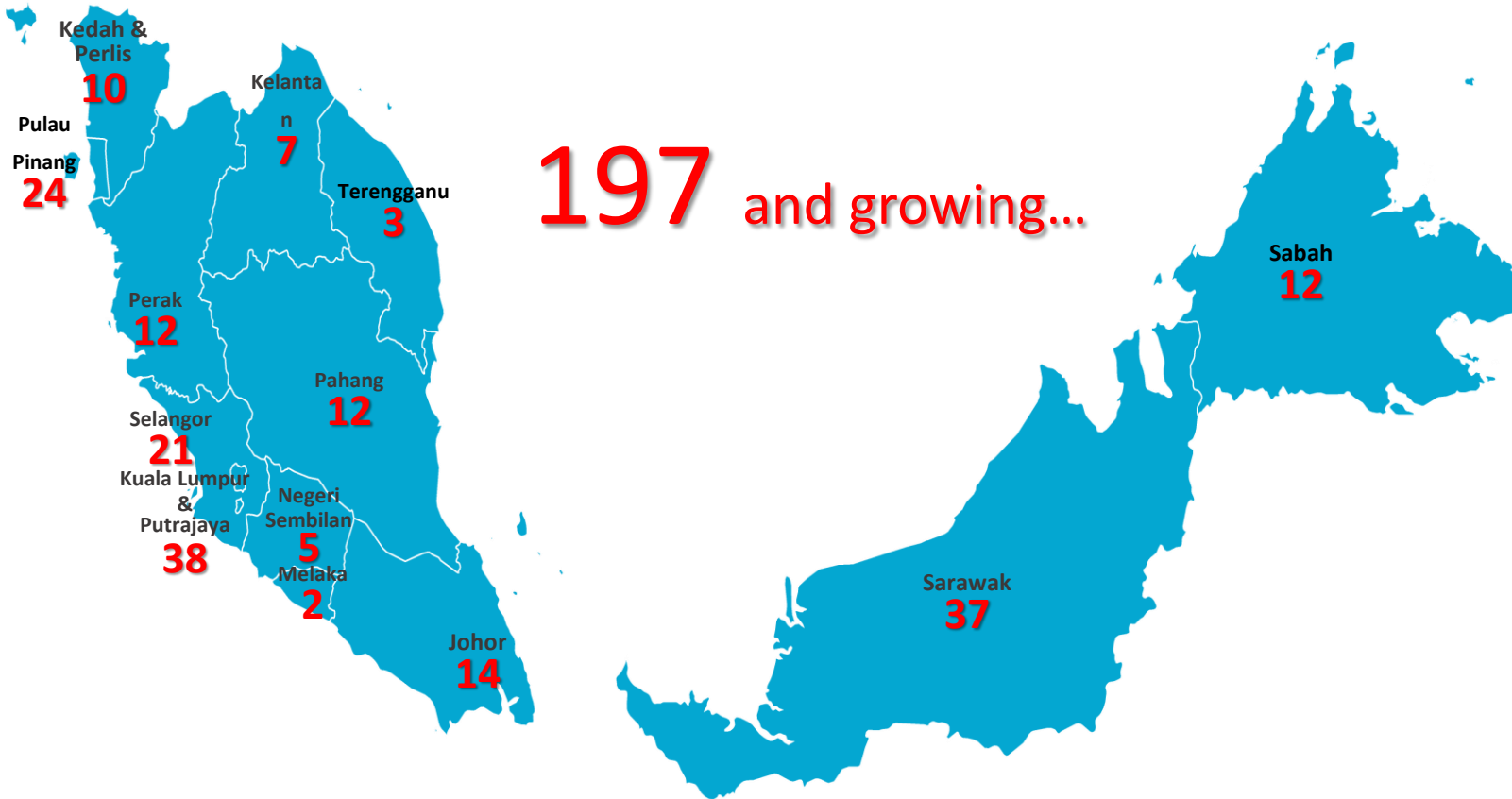
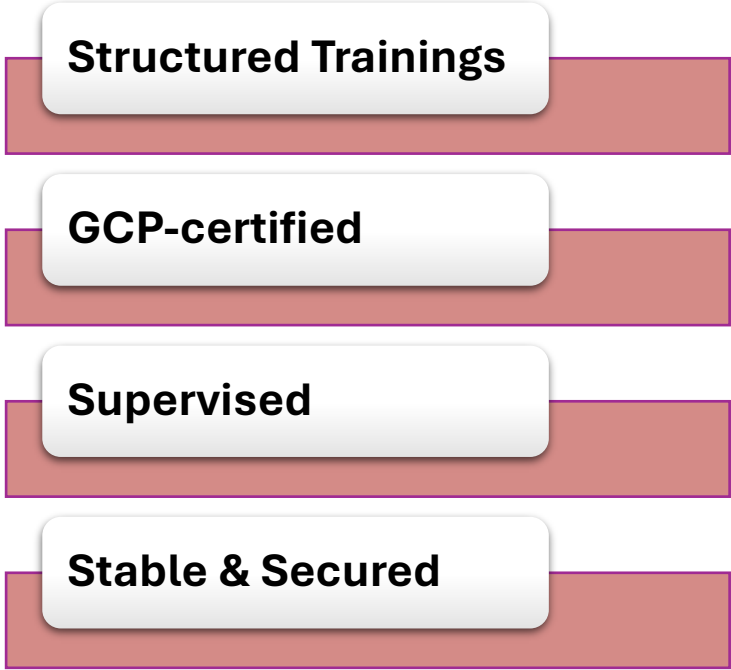
The timeline to review  
the CDA :  
**24 working hours**



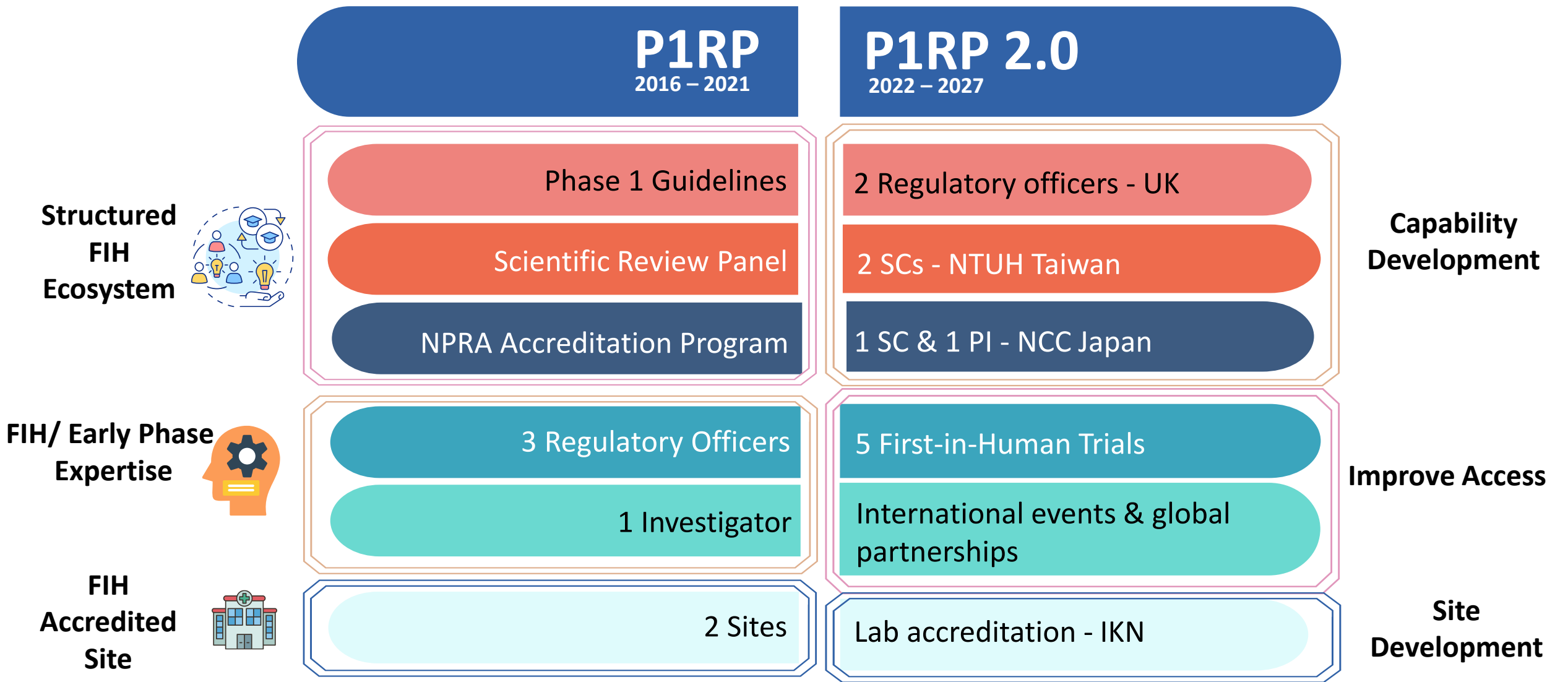
The timeline to review the CTA:  
**14 calendar days**

# Develop Clinical Research Professionals

## - CRM Study Coordinators

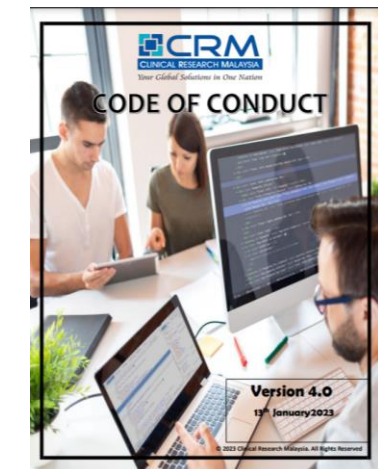


# Enabling Early Phase through CRM's Phase 1 Realisation Project (P1RP)





# Globally Trusted Research Management Organisation (GTRMO)



Accredited with Quality Management System (ISO 9001:2015) since 2019



CERTIFIED TO ISO 9001:2015  
CERTNO.: QMS 033604

Accredited Anti Bribery Management System (ISO 37001:2016) since 2021



CERTIFIED TO ISO 37001:2016  
CERTNO.: ABMS 00211



# Charting the Future





# 2033

## VISION

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To be the preferred hub for  
clinical research in Asia

## MISSION

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**Global Trusted Research  
Management Organisation**



**Clinical Research  
Professions Development**



**Digitalise  
Processes**

# KPI 2023 - 2033







# Thank You!

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