

Improving Clinical Trial Capacity in Asia : Malaysia

Dr Akhmal Yusof
CEO, Clinical Research Malaysia

Content

- Introduction
- The Landscape
- Opportunity
- Charting the Future

Malaysia at a Glance



Consists of **13 states** and three federal territories

32.69 million population
in third quarter 2020¹

- 0 – 14 years : **23%**
- 15 – 64 years : **70%**
- 65+ years : **7%**

Comprises of Multiethnicities - **Malay (69.6%), Chinese (22.6%), Indian (6.8%), others (1%)¹**

1/3 of World Population Genomics in Malaysia

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

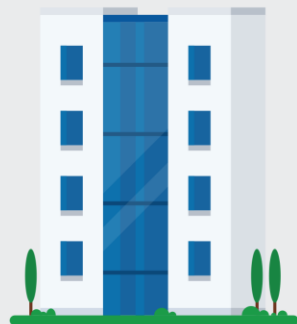
2022



10-Year Milestone

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

Sponsors & CROs

Notification/
Submission to
Regulatory
Authorities

Monitoring

Project
ManagementSUCCESSFUL CLINICAL
TRIALS IN MALAYSIA

SPEED

Start-up
Timeline

QUALITY

Data

RELIABILITY

Delivery
of StudyEnsure Sites & Investigators
focus on the delivery of trials bySupplying qualified
and high quality
study coordinatorReviewing of all
Clinical Trials
AgreementHandling
investigators trial
budget in a
transparent
mannerTackling issues at
the site level
including
recruitment

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

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

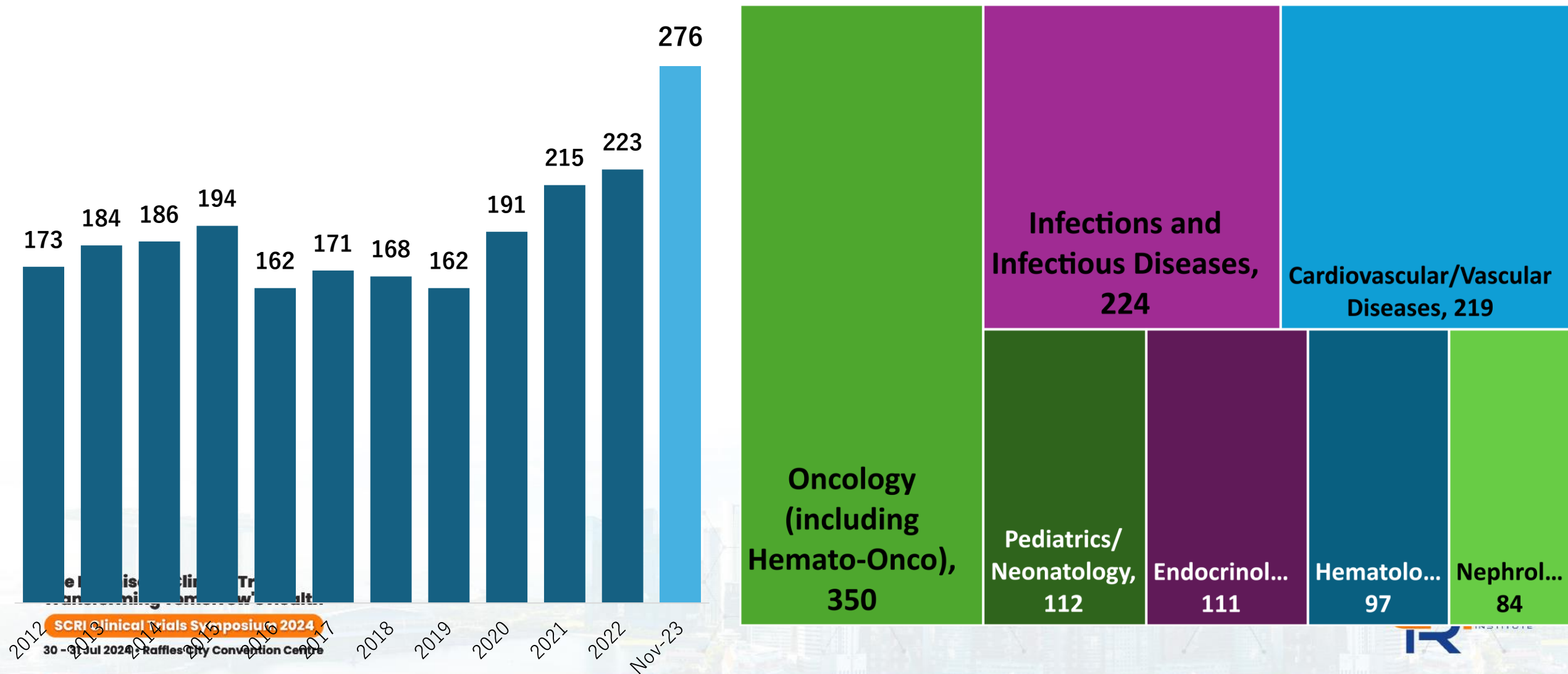
SCRI Clinical Trials Symposium 2024

30 - 31 Jul 2024 • Raffles City Convention Centre



Landscape

Sponsored Clinical Research in Malaysia (n=2305)



RECRUITMENT ACHIEVEMENTS IN GLOBAL SPONSORED RESEARCH 2024

Global Top Recruiter

Sultanah Aminah Hospital

Dr Muhammad Firdaus
Ulcerative Colitis

Global 1st Recruiter

Sarawak General Hospital

Dr Voon Pei Jye
Carcinoma,
Non-Small-Cell
Lung Cancer

Queen Elizabeth II Hospital

Dr Liew Houg Bang
Acute Myocardial
Infarction (AMI)

APAC 1st Recruiter

Sultan Idris Shah Hospital

Dr Fairol Huda Ibrahim
Active Lupus Nephritis

Pulau Pinang Hospital

Dr Choong Swee Hsia
Melanoma

Sultanah Aminah Hospital

Dr Boo Yang Liang
Chronic
Lymphocytic Leukemia

MALAYSIA 1st Recruiter

Pantai Hospital Kuala Lumpur

Dr Mastura Md Yusof
• Triple Negative Breast Cancer
• Breast Cancer
• Endometrial Cancer
• Metastatic Breast Cancer

University Malaya Medical Center

Assoc. Prof. Dr Wan Zamaniah
Solid Tumors

Dr Wong Chee Kuan
Chronic Obstructive
Pulmonary Disease

Dr Aishah Binti Ibrahim
Chronic Obstructive
Pulmonary Disease

Sultanah Bahiyah Hospital

Dr Zalwani Zainuddin
Functional Dyspepsia

Dr Abd Syukur Abdullah
Heart Failure

Sultanah Fatimah Specialist Hospital

Dr Evelyn Yap Wen Yee
Chronic Inducible Urticaria

Dr Zaid Bin Azhari
Uncontrolled Hypertension

Queen Elizabeth II Hospital

Dr Liew Houg Bang
Atrial Fibrillation

Miri Hospital

Dato' Dr Fam Tem Lom
• Cardiovascular Disease
• Dengue

Sarawak General Hospital

Dr Chua Hock Hin
HIV-1 Infection

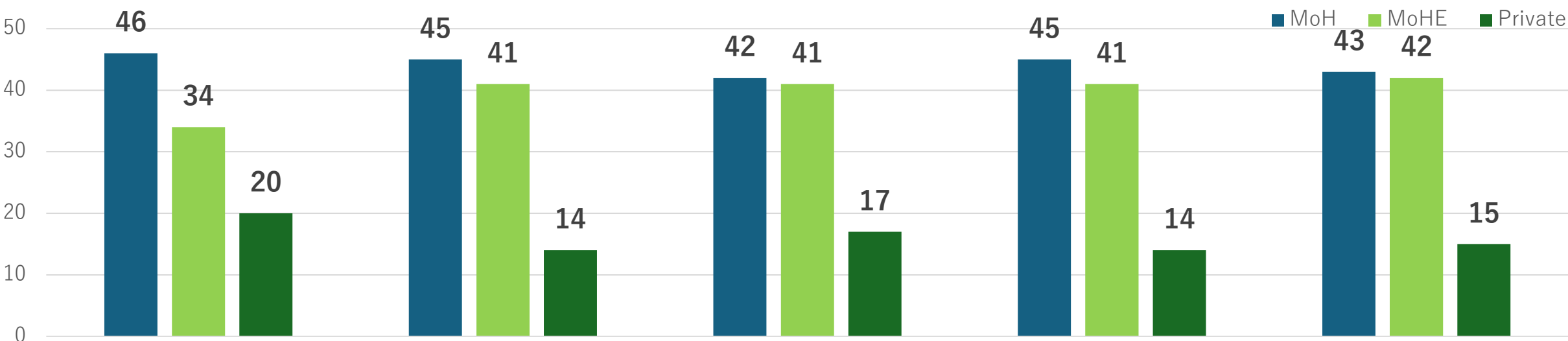
Seri Manjung Hospital

Dr Lee Li Yuan
Gout Patients
with Hyperuricemia

Pulau Pinang Hospital

Dr Soo Hoo Hwoei Fen
Breast Cancer

Clinical Trial Distribution



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)

ATLAS Activity Milestone



ATLAS Study Milestone

Top 5 recruiting ATLAS sites (as of Dec. 12)

	MKA (Nov. 30)	CHOICE (Sep. 29)	HARMONY (Dec. 12)	ATRAIN (Dec. 12)	Total
National Cancer Center Hospital (JP)	-	-	24	99	123
Hospital Pulau Pinang (MY)	103	5	-	-	108
Sarawak General Hospital (MY)	63	2	-	27	92
Institut Kanser Negara (MY)	63	5	-	19	87
National Taiwan University Hospital(TW)	22	0	-	52	74
K Hospital (VN)	30	-	-	41	71
St. Luke's Medical Center (PH)	35	0	3	20	58
University Malaya Medical Center (MY)	36	5	-	16	57
Hospital Kuala Lumpur (MY)	41	0	-	12	53
Hospital Sultan Ismail (MY)	49	1	-	-	50
Siriraj Hospital (TH)	19	12	-	9	40
National Cancer Center Korea (KR)	37	-	-	-	37
Srinagarind Hospital (TH)	22	11	-	-	33
Ho Chi Minh City Oncology Hospital (VN)	-	-	-	31	31
Taipei Veterans General Hospotal (TW)	19	9	-	-	28
National Cancer Centre Singapore (SG)	-	-	-	17	17
National University Hospital (SG)	-	-	-	16	16
Ramathibodi Hospital (TH)	5	1	-	9	15
Pusan National University Hospital(KR)	10	-	-	-	10
Prince of Sonkla University Hospital (TH)	6	2	-	0	8
Vajira Hospital (TH)	-	-	-	7	7
King Chulalongkorn Memorial Hospital (TH)	-	-	-	5	5
Phramongkutklao Hospital (TH)	-	-	-	4	4
Maharaj Nakorn Chiang Mai Hospital(TH)	2	1	-	1	4
Severance Hospital Yonsei University Health System (KR)	-	-	-	1	1
	562	54	27	386	1029

Updated during 5th ATLAS Semiannual Meeting 22 Dec 2023

ATLAS BOARD MEMBER & EORTC CONVENTION 2024



Opportunity

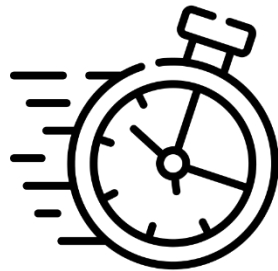
SPEED – Improved Start-up

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

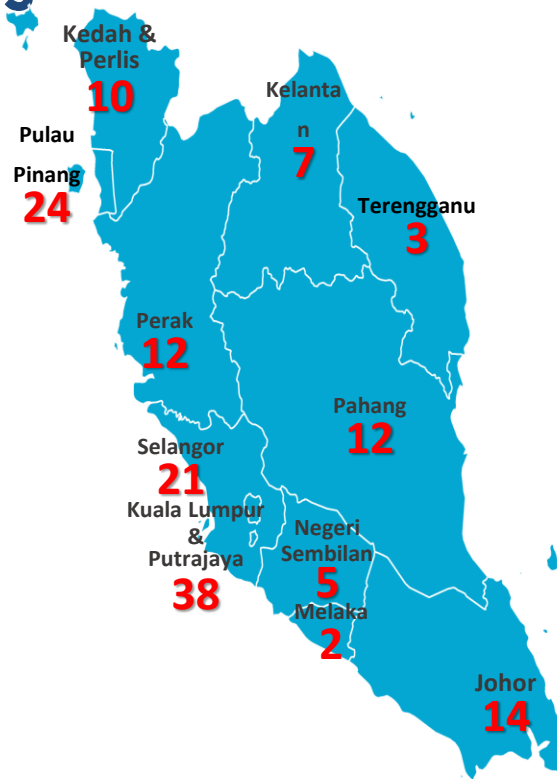
- CRM Study Coordinators

Structured Trainings

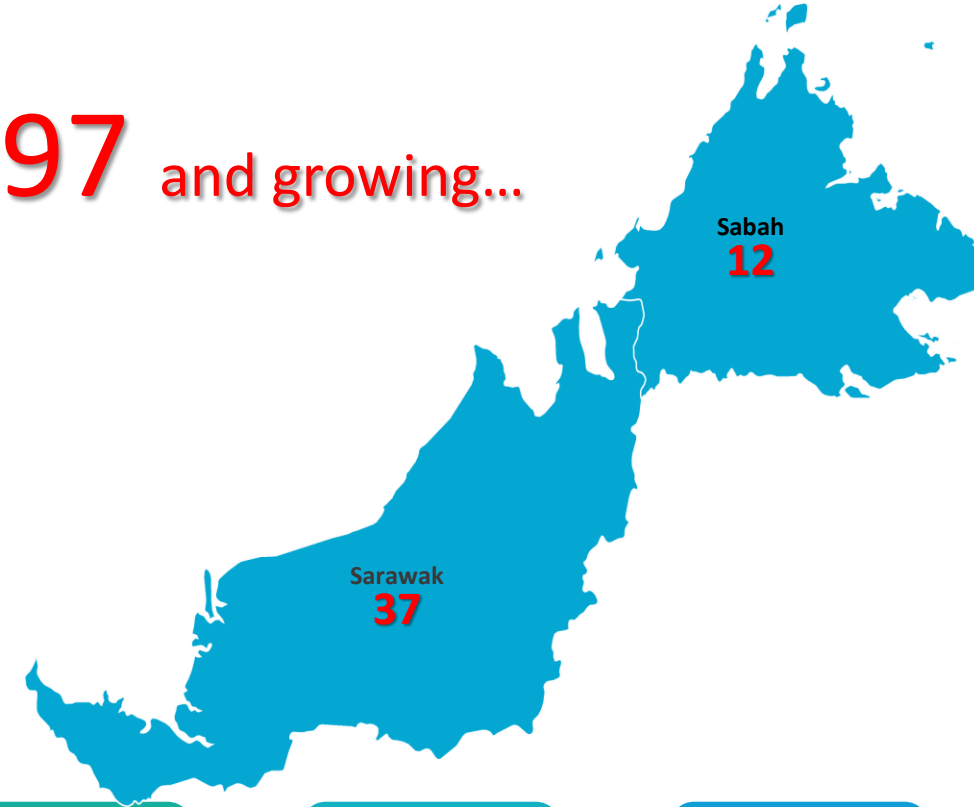
GCP-certified

Supervised

Stable & Secured



197 and growing...



SC Level 1

SC Level 2

Senior SC

Assoc
Regional
Manager

Clinical
Operations
(CO)
Manager

Senior CO
Manager

Head of
CO

Structured
FIH
Ecosystem



FIH/ Early
Phase
Expertise



FIH
Accredited
Site



P1RP

Phase 1 Guidelines

Scientific Review Panel

NPRA Accreditation
Program

3 Regulatory Officers

1 Investigator

2 Sites

P1RP 2.0

2 Regulatory officers - UK

2 SCs - NUH Singapore

2 SCs & 2 PIs - NCC Japan

NPRA's acceptance of FIH
biologics

International events & global
partnerships

IKN - Support for lab
accreditation

Updates: FIH
Study in SGH –
1st Patient
dosed in June
2023

Capability
Development

Improve
Access

Site
Development

1H 2024 Activities & Outcome

Activities	Outcome
National Taiwan University Hospital	<ul style="list-style-type: none">• CRM Study Coordinator Observer ship
DIA China	<ul style="list-style-type: none">• CRM & NPRA participate as Speaker• Engagement with sponsors from China
DIA USA Annual Meeting	<ul style="list-style-type: none">• CRM & NPRA participate as delegate
Novartis & Roche meeting with YBMK at Basel	<ul style="list-style-type: none">• Promote Malaysia capabilities in global sponsored clinical trials
MoU with CUHK	<ul style="list-style-type: none">• New opportunity for CRM SC training in Phase 1
18th ASEAN SOMHD & AHMM	<ul style="list-style-type: none">• ASEAN Prosperity through ISCT



Charting the future

2033

VISION

To be the preferred hub for
clinical research in Asia

MISSION



**Global Trusted Research
Management Organisation**



**Clinical Research
Professions Development**



**Digitalise
Processes**

Centre of Excellence (CoE)

Program : Study Coordinator Foundation
12-week program

ACCOMPLISHED

- 1st Batch Intake graduated on 14 June (8 trainees)
- 3 already employed as CRM SCs

ONGOING

- 2nd Batch: 11 Jul – 27 Sep 2024 (10 trainees)

KPI 2023 - 2033



CRM Trial Connect 2025

1000
attendees

14
Sponsor
Exhibitors

14
Countries

142
Organisations



Clinical
Trials Day

2024 SPONSORED
RESEARCH AWARDS



CRM Trial Connect 2025

7-9 May 2025

ATLAS, EORTC and NCC Japan

The largest clinical research
conference in SEA

Excellent ratings on program, quality
speakers and topics

Thank You For Your Attention