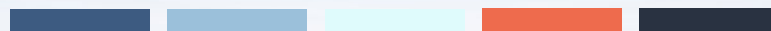




Your Global Solutions in One Nation

Clinical Research in Malaysia: Challenges and Opportunities

Dr Akhmal Yusof
CEO Clinical Research Malaysia
CRGo & ICN Symposium
Hong Kong



Challenges

LIST



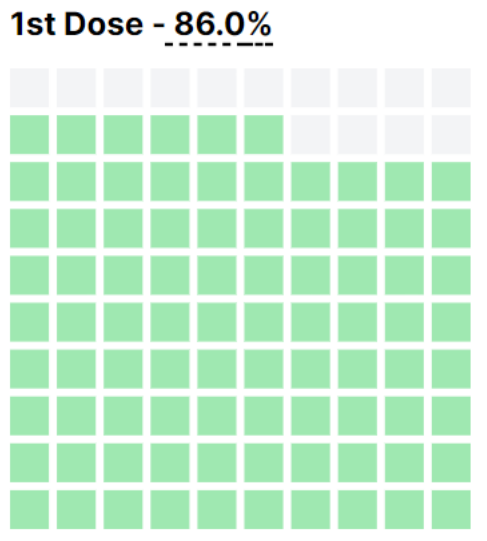
COVID-19 Impact:

How vaccinated against COVID-19 are we?

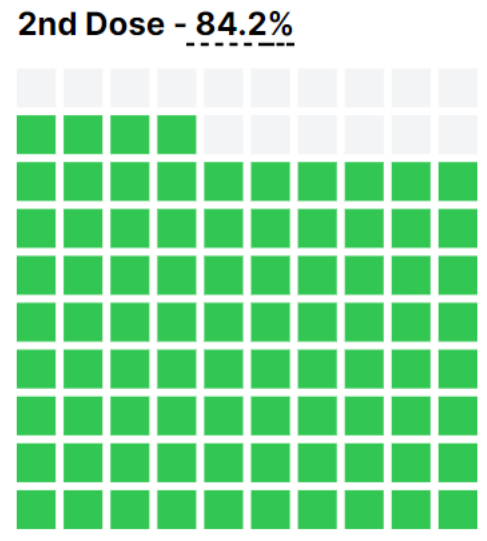
Data as of 05 Sept 2023, 23:59

Data for Malaysia | Total

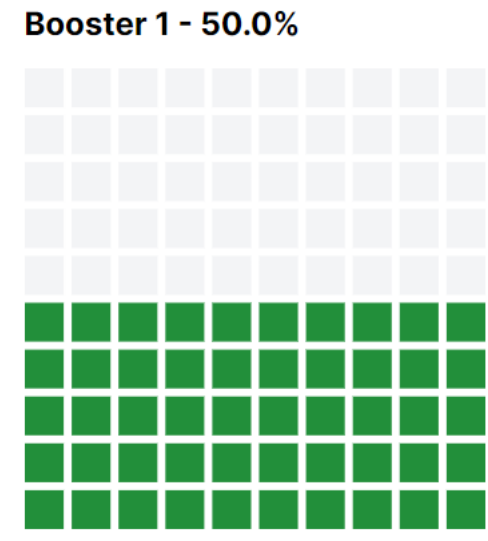
Total Filter by Age group Filter by Dose



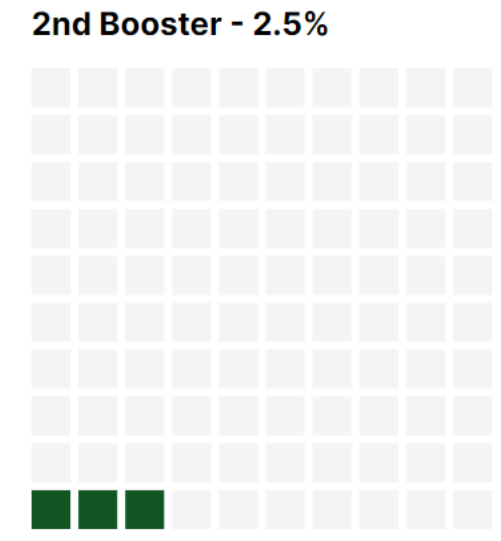
Total - 28,092,147
Daily - 10



Total - 27,506,629
Daily - 0



Total - 16,312,579
Daily - 107



Total - 823,802
Daily - 37

Global Impact Clinical Research

		YoY Difference (%) Mar 2020 vs. Mar 2019	YoY Difference Apr 2020 vs. Apr 2019
Asia	China	-68%	-33%
	India	-84%	-97%
	Japan	-44%	-69%
	South Korea	-61%	-42%
Europe	France	-68%	-81%
	Germany	-33%	-77%
	Italy	-53%	-49%
	Spain	-68%	-82%
	United Kingdom	-80%	-95%
North America	United States	-66%	-83%

- 4600 current clinical trials and more than 182,000 study sites worldwide shown significant declines
- 65% worldwide average decrease in new patient enrollment
- Among key world markets, there was a:
 - 84% decline in India
 - 66% decline in United States
 - 68% decline in China

Medidata (Melhem 2020)

Covid-19 Impact To Clinical Research in Malaysia

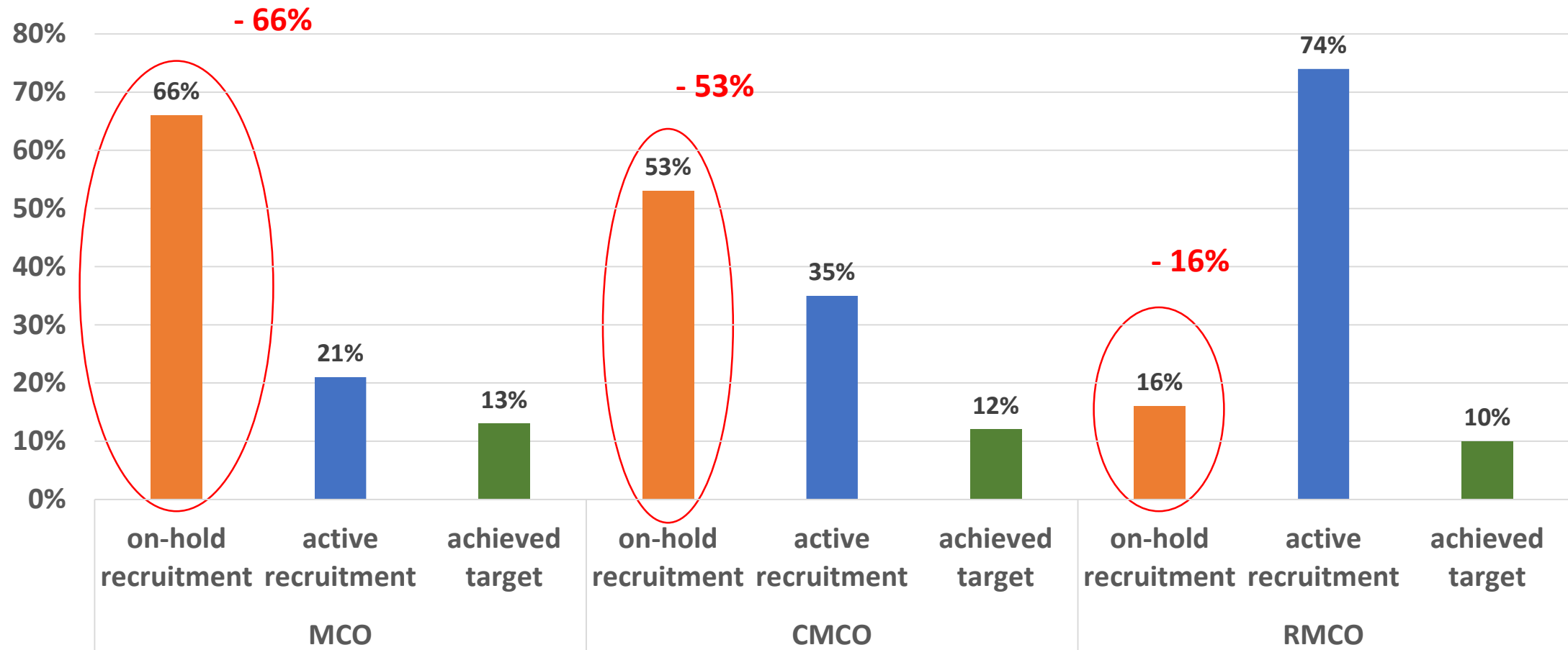
Facts

- 1) CRM personnel Work From Home (WFH) during the period of the Movement Control Order (MCO) by the government.
- 2) All non-essential patient visit related to CR need to withhold.
- 3) On site monitoring by Sponsors / CROs Clinical Research Assistant (CRA) withhold.

Actions

- 1) Adhere to the SOP from Department of Occupational Safety and Health to start the business operation.
- 2) CRM Assist Sponsors and CROs in remote monitoring.
- 3) Study recruitment and patient visit restarted.

Impact to Clinical Research



MCO: March – September 2020

CMCO: October 2020 – May 2021

RMCO: May 2021 – December 2021

Summary

- Even with the impact of COVID-19, many of the **essential clinical studies carried on**
- Impact on patient recruitment is **similar as compared to other countries but the recovery is fast.**
- CRM is operating in **strict SOP guidelines** and with collaboration between the hospital admin, Investigator and Sponsors/CROs

Opportunities

CRM Journey as Research Management Organisation

2012



Establishment

Corporatized company and 100% 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



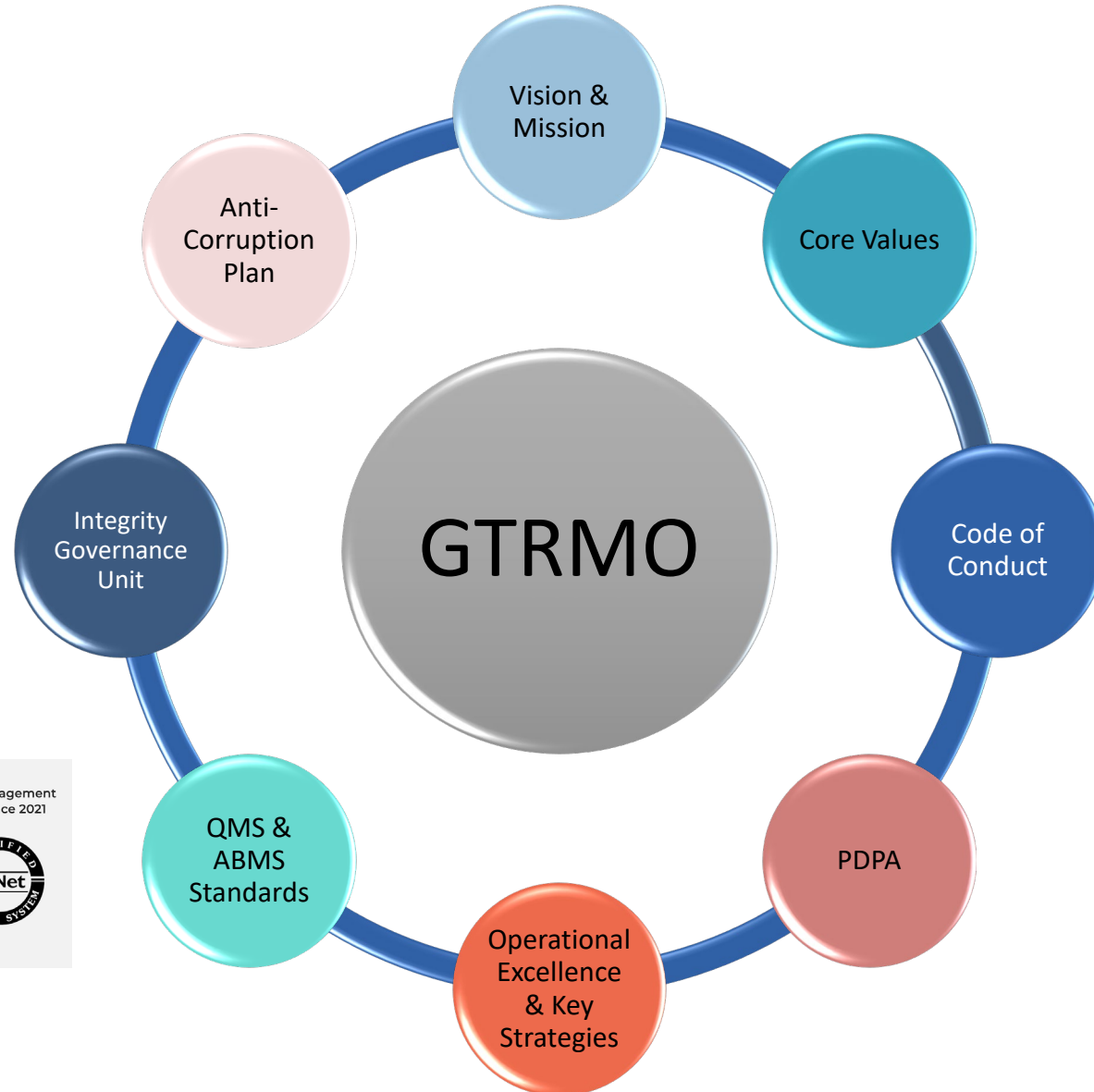
ISO37001:2016 (ABMS) accreditation
Anti-Bribery Management System

2022



10-Year Milestone

Building a Globally Trusted Research Management Organisation (GTRMO)



ABOUT **CRM**
CLINICAL RESEARCH MALAYSIA
Your Global Solutions in One Nation

Our Vision To establish Malaysia as a preferred destination for industry sponsored research (ISR)

Our Core Values These values convey the philosophy behind every decision and move we make. Transparency, honesty, accountability and trustworthiness – are our core value.

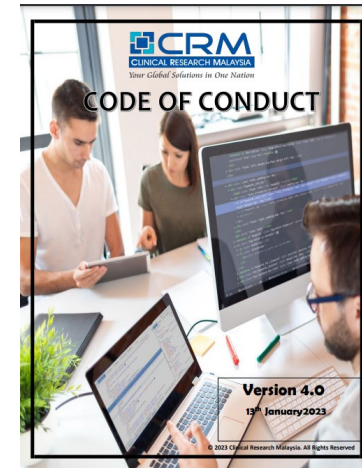
- Transparency**
We practice transparency and openness in all our operations, including financial processes and budget management.
- Honesty**
We aspire to be honest with one another, our clients and our business partners.
- Accountability**
We set a high performance expectations and hold ourselves responsible for the quality of our work and the results we achieve as individual, as a team and as a company.
- Trustworthiness**
We adhere to the highest standards of professionalism and integrity and uphold the faith and confidence our clients have placed in us.

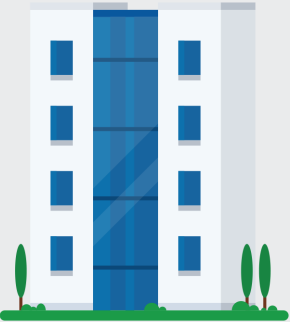
Accredited with Quality Management System (ISO 9001:2015) since 2019

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

CERTIFIED TO ISO 9001:2015
CERTNO.: QMS 03360-

CERTIFIED TO ISO 37001:2016
CERTNO.: ABMS 0218






Sponsors
(Pharmaceutical, Biotechnology, and Medical Device Companies)

CROs
(Contract Research Organization)

PLANNING STAGE

Site/Country Selection Process



Malaysian Sites & Investigators

- 152**
Public Hospitals / Health Clinics
- 12**
MOHE Hospitals
- 68**
Private Hospitals
- 1105**
Investigators Multi Therapeutic

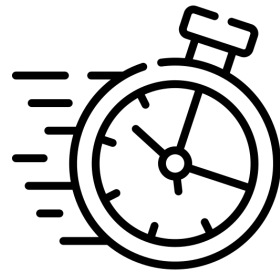
SPEED – Improved Start-up

MREC Review



MREC Review Timeline (2022): **32 calendar 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

Accelerating Healthcare

TECHNOLOGY TRANSFER

- DESIGN STUDY PROTOCOL
- STUDY METHODOLOGY
- DATA MANAGEMENT

EXPANDING RESOURCES

- **TREATMENT OPTIONS FOR THE PATIENTS**
- PROVIDE RESOURCES TO STUDY SITES
- PROVIDE NEW KNOWLEDGE

GLOBAL RECOGNITION

- CONSISTENT TIMELINE
- RELIABILITY
- QUALITY

CRM's Guiding Principles



HUMANITY

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

STABILITY

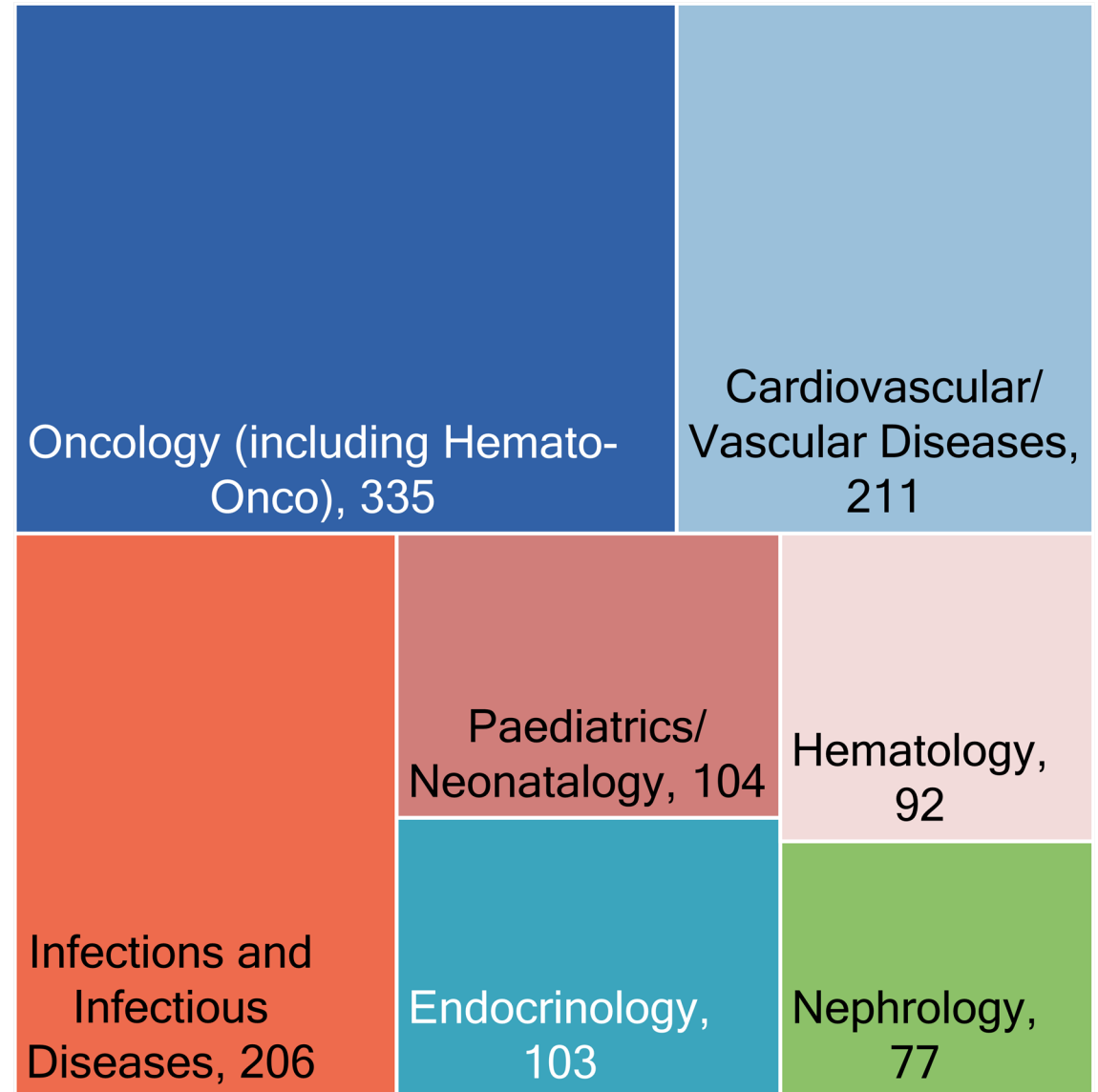
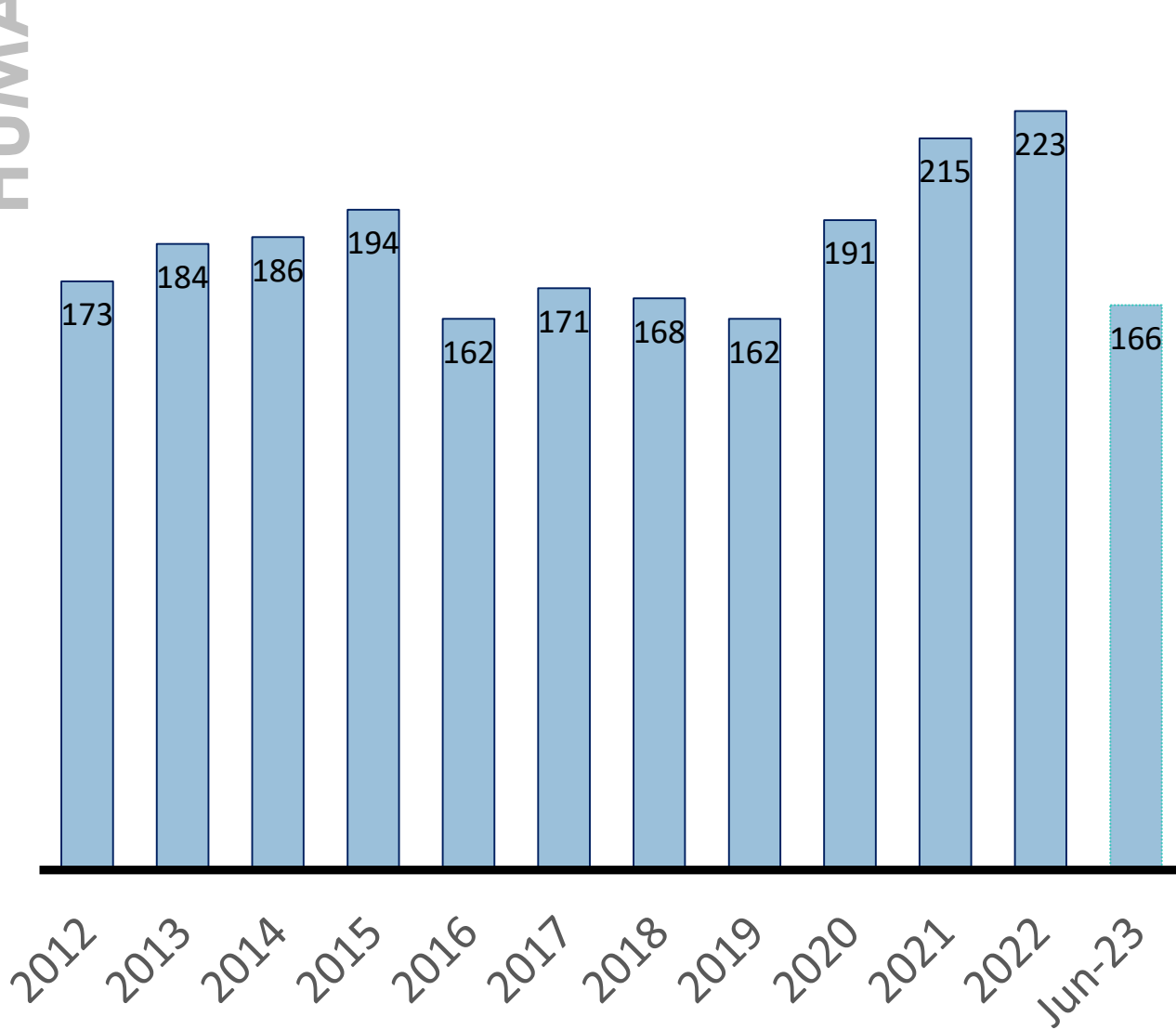
Excellent & consistent performance to deliver speed, reliability & quality



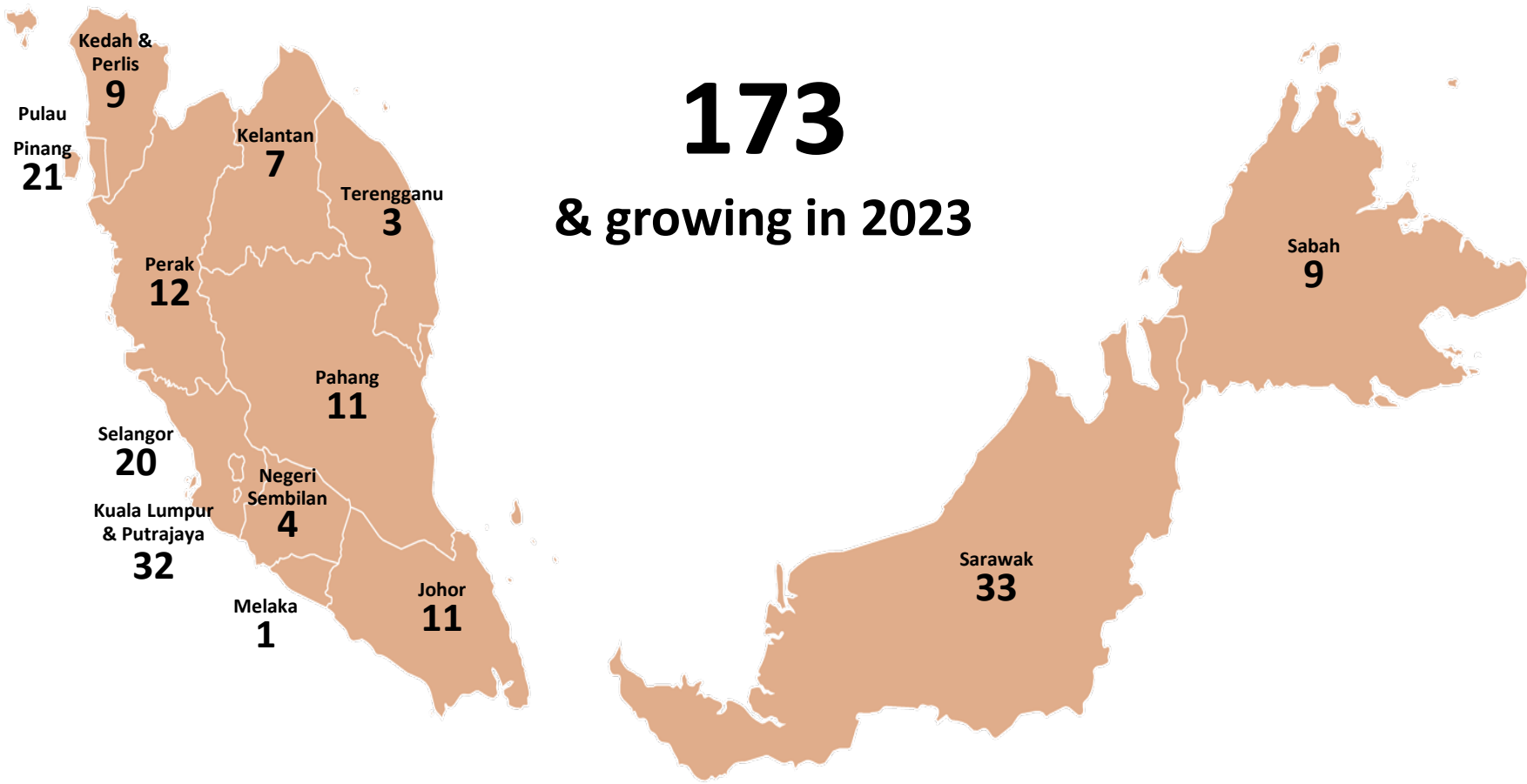
SUSTAINABILITY

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

Sponsored Clinical Research in Malaysia 2012-June 2023 (n=2195)



QUALITY: Creating a Line of Clinical Research Professionals - CRM Study Coordinators

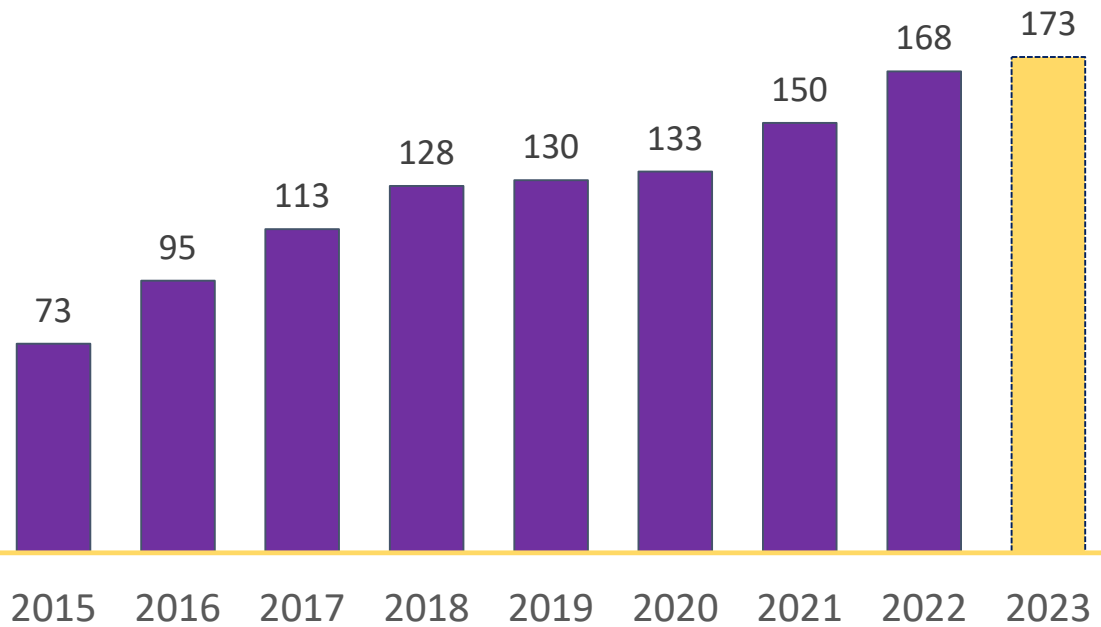


173
& growing in 2023

- Structured Trainings
- GCP-certified
- Supervised
- Stable & Secured

Updated as of 8 May 2023

Develop Clinical Research Professionals - CRM Study Coordinators



RELIABILITY: Recruitment Achievements in Global Sponsored Research 2023

Global 1st Recruiter

Hospital Tengku Ampuan Afzan

Non-Small Cell
Lung Cancer
Prof How Soon Hin

ASIA 1st Recruiter

Hospital Umum Sarawak

Non-Small Cell
Lung Cancer
Dr Voon Pei Jye

Hospital Sultanah Aminah

Warm Autoimmune
Hemolytic Anemia
Dr Azizan Bin Sharif

SEA 1st Recruiter

Institute of Respiratory Medicine

Idiopathic
Pulmonary Fibrosis
Dr Syazatul Syakirin

Hospital Umum Sarawak

Atherosclerotic
Cardiovascular Disease
Dr Diana Foo

APAC 1st Recruiter

Institute of Respiratory Medicine

Idiopathic
Pulmonary Fibrosis
Dr Syazatul Syakirin

Hospital Tengku Ampuan Afzan

Non-Small Cell
Lung Cancer
Prof How Soon Hin

Hospital Umum Sarawak

Advanced Solid Tumor
(First in Human)
Dr Voon Pei Jye

Hospital Pulau Pinang

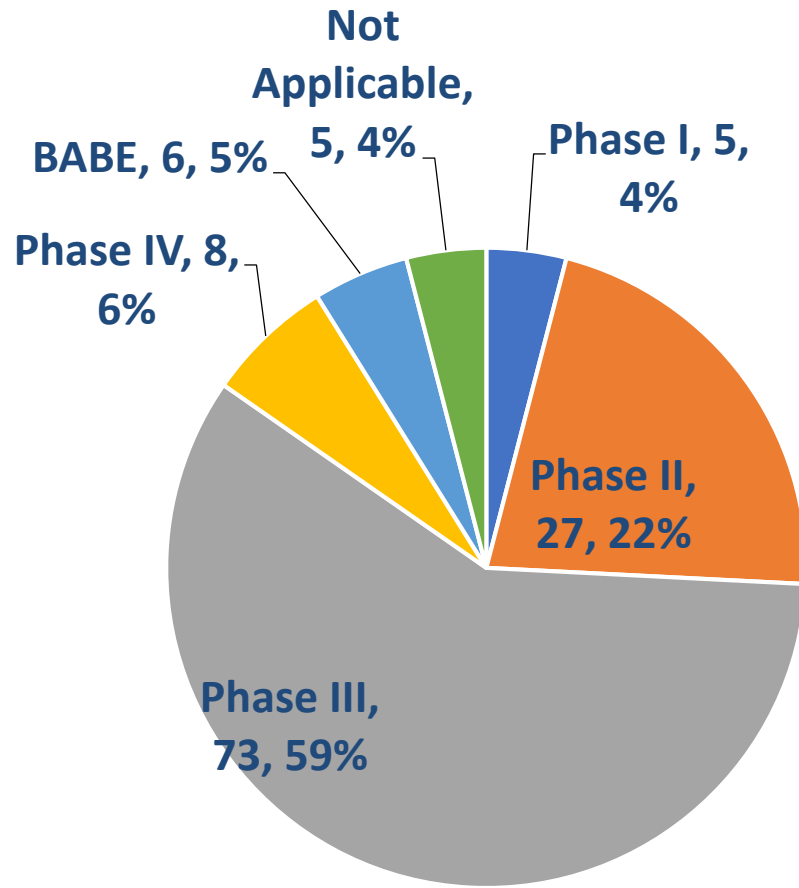
Hidradenitis Suppurativa
Dr. Tan Wooi Chiang

Focus on Early Phase Research

Breakdown of Study Phases from 2015 to 2022


	2015	2016	2017	2018	2019	2020	2021	2022
INTERVENTIONAL								
Phase I	3	5	5	7	2	2	4	5
Phase II	16	7	13	12	17	18	31	27
Phase III	47	48	53	59	44	48	58	73
Phase IV	11	16	11	16	5	2	7	8
Bioequivalence	56	52	51	37	26	20	10	6
Others	12	-	11	-	10	7	11	5
OBSERVATIONAL	50	34	27	37	58	94	94	99
TOTAL	194	162	171	168	162	191	215	223

**Interventional Sponsored Research
2022, by Phase Breakdown
(N=124)**





International Phase 1 Clinical Research 2018

Structured
FIH
Ecosystem 

FIH/ Early
Phase
Expertise 

FIH
Accredited
Site 

P1RP

P1RP 2.0

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

Phase 1 Guidelines

2 Regulatory officers - UK

Scientific Review Panel

2 SCs - NUH Singapore

NPRA Accreditation Program

2 SCs & 2 PIs - NCC Japan

Capability
Development

3 Regulatory Officers

NPRA's acceptance of FIH biologics

1 Investigator

International events & global partnerships

Improve
Access

2 Sites

IKN - Support for lab accreditation

Site
Development

First-in-Patient study progress 2021

- Study Title: **A randomised, single-blind, placebo-controlled, phase 1, single-ascending and multiple-dose study in adult subjects with alpha/beta-thalassaemia and very low- and low-risk myelodysplastic syndrome to investigate the safety, tolerability, pharmacokinetic, and pharmacodynamic response of SLN124**
- Principal Investigator: Dr Chew Lee Ping, Hospital Umum Sarawak (Sarawak General Hospital).
- Sponsor: Silence Therapeutics Plc
- Recruitment target: 4
- No. of patient randomized: 3
- Recruitment achievement : **Global First Recruiter**
 - Other participating countries include UK, Germany, Italy, Thailand, Lebanon, Jordan, Israel and Egypt

CONGRATULATIONS!

DR CHEW LEE
PING & SARAWAK
GENERAL
HOSPITAL TEAM

GLOBAL FIRST
RECRUITER IN
FIRST-IN-
PATIENT STUDY



AACR-NCI-EORTC International Conference on

MOLECULAR TARGETS AND CANCER THERAPEUTICS

October 11-15, 2023 | Hynes Convention Center | Boston, MA

Preliminary Safety and Anti-Tumor Activity of RMC-6291, a First-in-Class, Tri-Complex KRAS^{G12C}(ON) Inhibitor in Patients With or Without Prior KRAS^{G12C}(OFF) Inhibitor Treatment

Pasi A. Jänne¹, F. Bigot², K. Papadopoulos³, L. Eberst⁴, D. Sommerhalder⁵, L. Lebellec⁶, P.J. Voon⁷, B. Pellini⁸, E. Kalinka⁹, K. Arbour¹⁰, B. Herzberg¹¹, V. Boni¹², S. Bordenave¹³, HW. Lee¹⁴, SI. Ou¹⁵, JW. Riess¹⁶, JT. Beck¹⁷, M. Ponz-Sarvisé¹⁸, PA. Ascierto¹⁹, YJ. Choi²⁰, D. Tan²¹, M. Yang²², L. Bao²², R. Raman²², L. Yang²², Y. Mu²², S. Wong²², R. Dua²², M. Johnson²³

¹Dana-Farber Cancer Institute, Boston, MA, USA; ²Institut de Cancérologie de l'Ouest Angers, Angers, France; ³START, San Antonio, TX, USA; ⁴ICANS-Institut de Cancérologie de Strasbourg Europe, Strasbourg, France; ⁵NEXT Oncology™, San Antonio, TX, USA; ⁶Centre Oscar Lambret, Lille, France; ⁷Hospital Umum Sarawak, Kuching, Malaysia; ⁸Moffitt Cancer Center & Research Institute, Tampa, FL, USA; ⁹Instytut Centrum Zdrowia Matki Polki, Łódź, Poland; ¹⁰Memorial Sloan Kettering Cancer Center, New York, NY, USA; ¹¹Columbia University Irving Medical Center, New York, NY, USA; ¹²NEXT Madrid-University Hospital QuironSalud, Madrid, Spain; ¹³Centre Hospitalier Universitaire de Nantes, Nantes, France; ¹⁴The Ajou University Hospital, Suwon, South Korea; ¹⁵University of California Irvine, Irvine, CA, USA; ¹⁶University of California Davis Comprehensive Cancer Center, Davis, CA, USA; ¹⁷Highlands Oncology, Springdale, AR, USA; ¹⁸Cancer Center Clinica Universidad de Navarra, Pamplona, Spain; ¹⁹Istituto Nazionale Tumori IRCCS G. Pascale, Napoli, Italy; ²⁰Korea University Anam Hospital, Seoul, South Korea; ²¹National Cancer Centre Singapore, Singapore; ²²Revolution Medicines, Inc., Redwood City, CA, USA; ²³Sarah Cannon Research Institute, Tennessee Oncology, Nashville, TN, USA

14:53

58%

For you

Following

Congratulations

@Clin posted



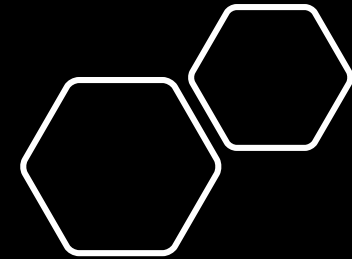
Institute for Clinical... · 21m

We are thrilled to announce a historic achievement at the Clinical Trial Unit in Hospital Ampang – the commencement of the First-in-Human (FIH) clinical trial on November 23, 2023. Spearheaded by Dr. Veena Selvaratnam, Principal Investigator and Consultant Haematologist.



Saiful Safuan and 4 others

2 1 3 34 +





Partnership with Global Clinical Research Players

PARTNERSHIPS



Relocation of regional clinical research team from Taiwan to Malaysia
 Double number of studies in Malaysia compared to 2022



CRM-ICR-IQVIA Prime Network recognized as global top performing network
 IQVIA – Top CRO for Sponsored Research

Malaysia Studies by Milestone (14-May-2023)

Malaysia Total: 20 Studies

BIOPHARMA
 ONCOLOGY

TA covered:
 - CVRM: NASH, hypertension and CKD
 - R&I: Asthma and acute respiratory failure
 - Oncology: BC, LC and HCC

COPD NGP Efficacy	ALXN2220-ATTTCM-301	Baxdrolat resistant hypertension	ARTEMIDE		
AZD4604 asthma			SUNRISE		
eVOLVE-Cervical01			LITHOS		
AZD5305 mCSPC			ARTEMIDE	Stabilize CKD	
ARTEMIDE-Biliary (TOPAZ 3)			VATHOS	EMERALD-3	
TL10 and e-VOLVE Lung 02			FORTUNA	TILIA	
LOGOS			DIALIZE-OUTCOME	PACIFIC-8	
TROPION-Breast 04	ALXN-2050-PNH-302	Zibo/Dapa High Proteinuric CKD	DESTINY-Lung 03	PROXYMO-ADVANCE	
	ALXN-2050-PNH-301	AZD9592	ADAURA-2	LAURA	
	TROPION-Breast 03	CAPitello-292	SERENA-4	CAPitello-290	
In Feasibility	Start-Up	Recruiting	Maintenance	Closing and F/U	
Unallocated	(Before FSI)	(FSI-LSI)	(LSI-LSLV)	DBL-CSR	
12	10	7	3	0	



Home-health services
 DCT Guidance Document working group
 --> Guidance Document to be launched on 27 July



BUSINESS ROOM
08C

BUSINESS ROOM
05B



A SNAPSHOT OF CRM TRIAL CONNECT 2023



530

ATTENDEES

14

EXHIBITORS

OR

12

COUNTRIES

SAVE THE DATE!



Clinical
Trials Day

2024 SPONSORED
RESEARCH AWARDS

"Thank you for the opportunity" Tham Sue Fern (NCSM)

"Very good platform for networking amongst the researchers" Dr. Damenthi Nair (Hospital Ampang)

DR CHEW LEE PING
Consultant Haematologist
Sarawak General Hospital



DR KANANATHAN RATNAVELU
Consultant Medical Oncologist
Columbia Asia Bukit Rimau

PROF DATO' DR ADEEB
KAMARULZAMAN
Chief Executive Officer
Monash University Malaysia
And Pro Vice-Chancellor
& President (Malaysia),
Monash University Australia

NG KEK
entre



Charting the
future...



2033

VISION

To be the preferred hub for clinical research in Asia

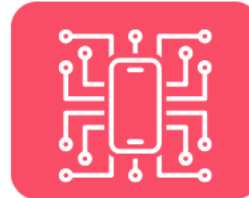
MISSION



**Global Trusted Research
Management Organisation**

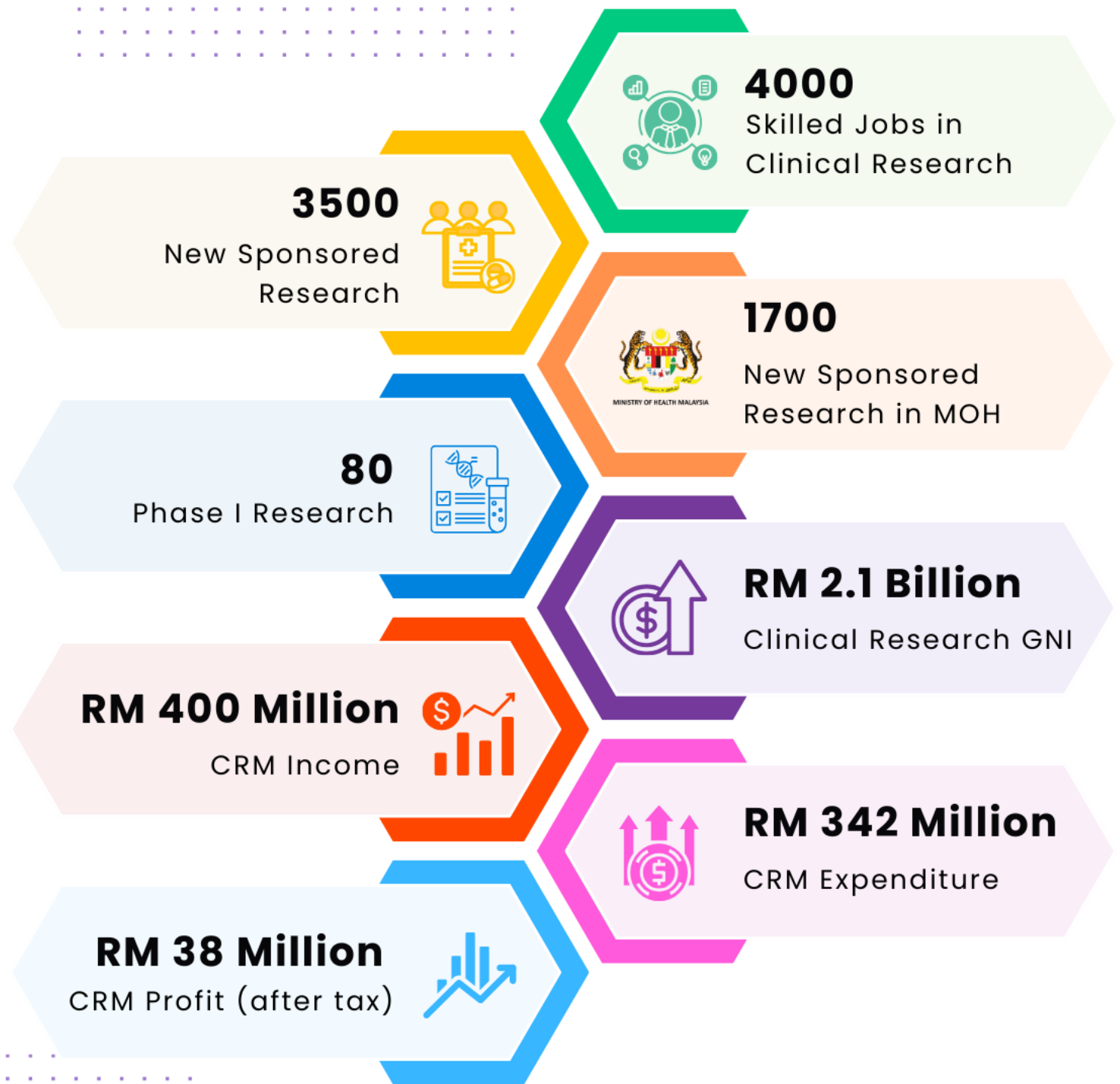


**Clinical Research
Professions Development**



**Digitalise
Processes**

KPI 2023 - 2033





Conclusion

**SPONSORED
RESEARCH
ACCELERATE
HEALTHCARE**

**CRM COMPLETES
THE ECOSYSTEM
FOR SPONSORED
RESEARCH**

**MALAYSIA IS THE
PREFERRED SITE
FOR SPONSORED
RESEARCH**



Verily, along with every hardship is relief

THANK YOU