

C&R Research Inc.

KOSDAQ listed



Korea's First & The Largest CRO



Drug Development Consulting

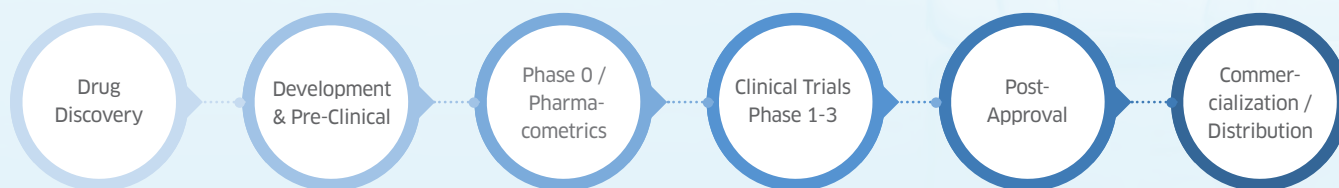


Best Certified CRO In Korea



Global Standard Phase I Study Including Caucasian & Asian Patients

The Top Total Value Chain CRO with One-stop Network Solution



E-Clinical Solution

Csafer

Csafer
PV DB & Safety Reporting Management System

imtrial

imtrial
Automatic Clinical Trial Solution Using MDR & CDISC

BOIM

BOIM
Best Operating solutions for Innovative clinical Management

Family Site



C&R Academy
Academy for Comprehensive Clinical Education



GCCL
Global Clinical Central Lab



C&R Healthcare Global
Healthcare Acceleration Platform for ASEAN Business Expansion



Trial Informatics & TI Image
Imaging IT Solution & Imaging CR

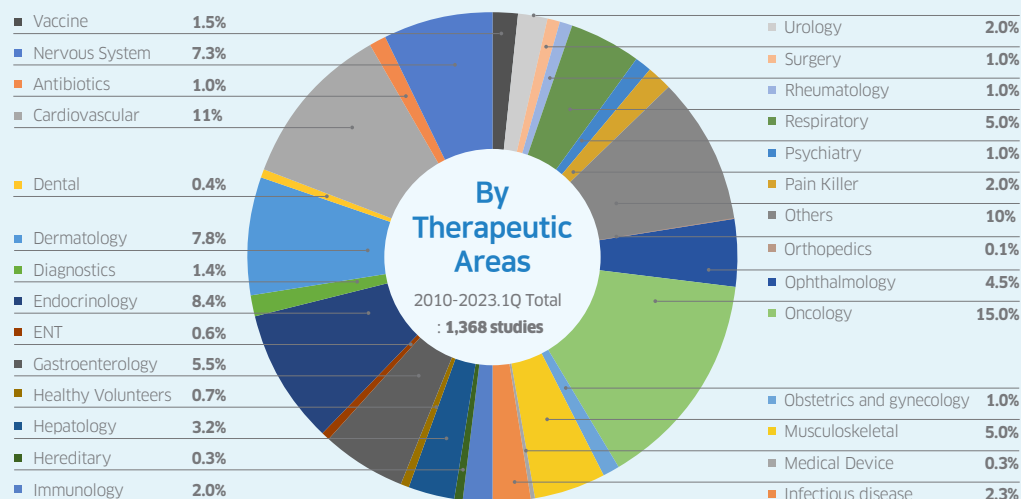


C&R SMO
Site Management Organization for CRC Out-sourcing



ABC BioScience
Early Drug Development Platform

C&R Project Experience



- 205 +**
Oncology
- 120 +**
Hypertension & Hyperlipidemia
- 80 +**
Cell Therapy
- 74 +**
Diabetes Mellitus
- 59 +**
Rare Disease
- 38 +**
Botulinum Toxin
- 25 +**
Eye Drop
- 9 +**
CAR-T & CAR-NK



Contact Us

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C&R RESEARCH



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- 01 C&R Research Overview
- 02 Full Service CRO
- 03 Global CRO
- 04 Beyond a CRO
- 05 C&R Team Introduction

C&R Overview



- 01 **About C&R Research**
- 02 **Organization**
- 03 **Strong Presence In Global Market**
- 04 **Optimization Solutions**
- 05 **Early phase clinical trials for global**

About C&R Research

Company Name ----- C&R Research

Foundation Year ----- 1997.07.01

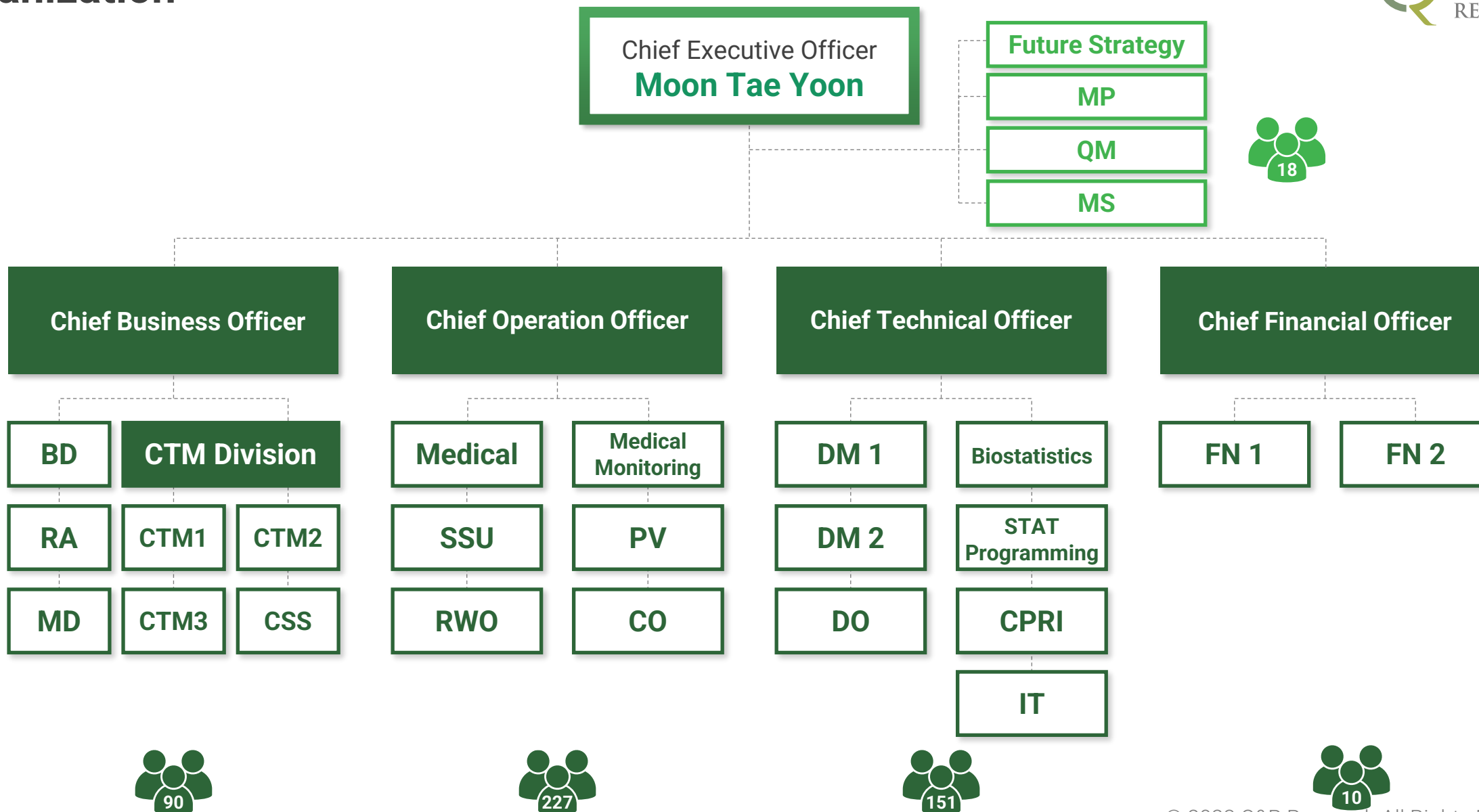
Headquarter ----- Seoul, South Korea

CEO ----- Moon Tae Yoon

Offices ----- Global: Singapore, Beijing
Korea: Gangnam (Seoul), Busan

Workforce ----- 500+

Organization



Team of Experienced Industry Leaders

COO

Byung Jin Ahn

Executive Vice President

- Medical Advisory Board member, C&R Research
- Assistant Professor, Dongguk University
- M.D., Ph.D., Catholic University of Korea

CTO

Sook Jung Jo

Executive Director

- Director in Biostatistics, ICON Clinical Research
- Biometrics Manager, ChongKunDang Pharm. Corp
- Ph.D in Statistics, Korea University

MEDICAL

Yong Joo Jung

Medical Advisor

- Clinical Examiner, MFDS (9 years)
- M.D., M.S. in Pharmacy, Master of Medicine (Mmed) in Clinical Pharmacology, Seoul National University

MEDICAL

Hyun Chul Baek

Medical Advisor

- Medical Advisor, C&R research
- M.D. College of Medicine, Korea University
- Master of Medicine, College of Medicine, Ulsan University (Neurosurgeon)

QM

Yunjeong Choi

Quality Management, Director

- Clinical Trial Manager, PAREXEL Korea
- Clinical Trial Manager, Hanmi Pharmaceutical
- Ph.D in Pharmacy M.S. in Pharmacy, Seoul National University

Advisory Board

C&R Research also has a global-level advisory board composed of eminent industry leaders across the world including medical professors, statisticians, and pharmaceutical experts. The board allows C&R Research to execute tasks in a closely-connected relationship with university hospitals' Principle Investigators (PIs) and medical staffs.

Korea's No.1 CRO to Globally Competitive CRO

No.1 in Service Revenue

- The fastest growing CRO, CAGR 12.7%
- ONE out of FOUR approved new drugs in Korea is developed by C&R Research
- No.1 CRO in clinical research for registration(IND/NDA) studies in Korea



Worldwide Network

- Branches in China, Singapore
- Partnerships with ACROSS GLOBAL
- Partnership in U.S., Australia, Europe, Thailand, Philippines, India



Korea's First CRO

- 26 years of experience
- Over 1,700 projects and highly customized solutions
- Well-Established network with hospitals in Korea, allowing convenient and efficient site selection and patient enrollment



Best Certified CRO In Korea

- Highest Score in 2020 KoNECT CRO Certification Evaluation



Total Value Chain CRO

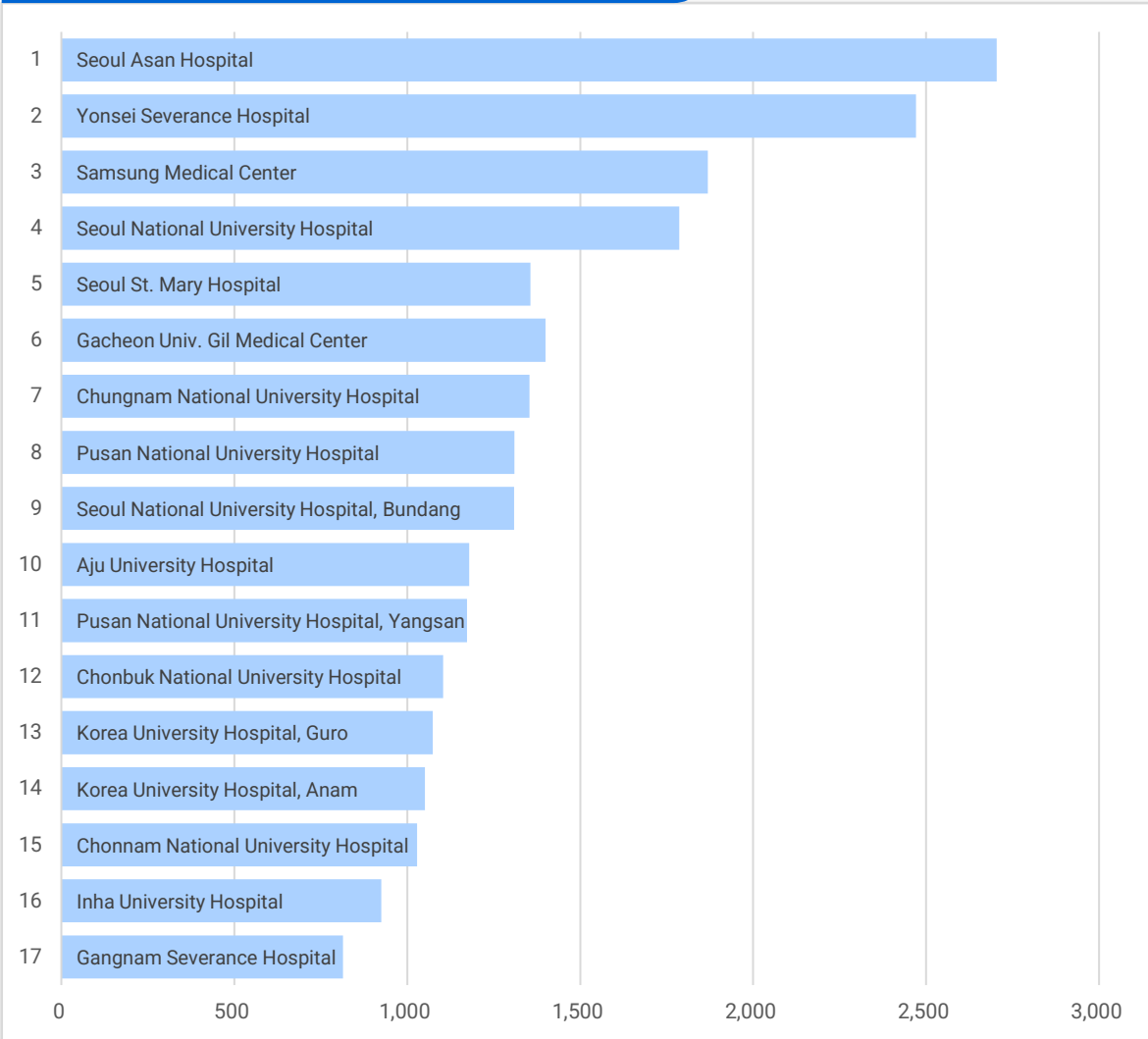
- End-to-end solution from drug discovery to commercialization
- Comprehensive service scope in line with global standard and best practice – supported by integrated services and global partnerships



Strong Presence in Korea, Embedded Global Competitiveness

Korea's Major Hospitals by Size (Top 17)

No. of Beds



C&R Research's Partnerships with Korea's Major Hospitals



*Approximately 35% of Korea's clinical trials take place at the top 5 hospitals in Korea, also known as the "Big 5"

C&R Research's Partnerships with Renowned BioHealth



C&R Research in Action



Full Service CRO

C&R Research provides comprehensive therapeutic & development cycle coverage



Global CRO

C&R Research has an integrated range of worldwide network, which enhances its clinical trial expertise and extends the scope of services beyond expectation



Beyond a CRO

C&R Research is a total value chain CRO that provides end-to-end services that exceed the scope of a conventional CRO



Full Service CRO



Service Offerings for Global Trials

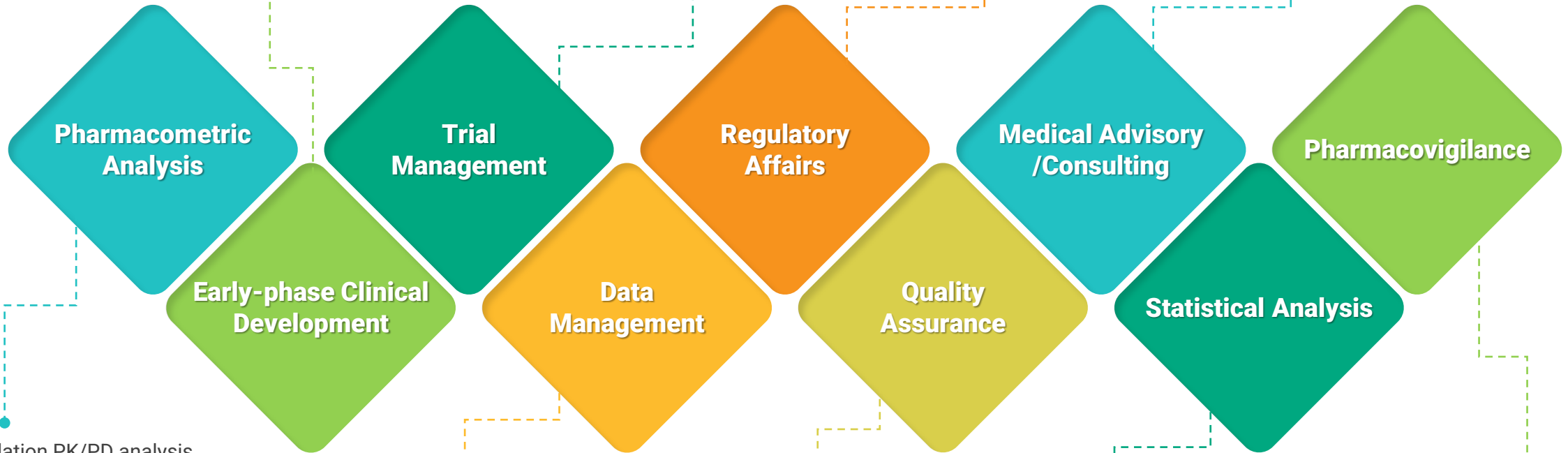
- First-Time-In-Human (FTIH)
- Micro-dosing studies (phase 0)
- Single Ascending Dose (SAD)
- Multiple Ascending Dose (MAD)
- Food Effect Studies (FE)

- Bioavailability/ Bioequivalence (BA/BE)
- Formulation comparison
- Combination formulations
- Drug-Drug Interaction studies (DDI)
- Thorough QT studies (TQT)

- Site feasibility & contract project management
- Monitoring
- budget management

- IND & NDA submissions & approval

- Protocol, ICF, CRF, CSR development & review



- Population PK/PD analysis
- Nonclinical PK/PD modeling & simulation
- First-In-Human(FIH) dose estimation based on nonclinical PK/PD modeling
- Human PK/PD evaluation via early clinical trial data
- Non-Compartmental Analysis (NCA) on early study design
- Drug development consultation
- Scientific report writing

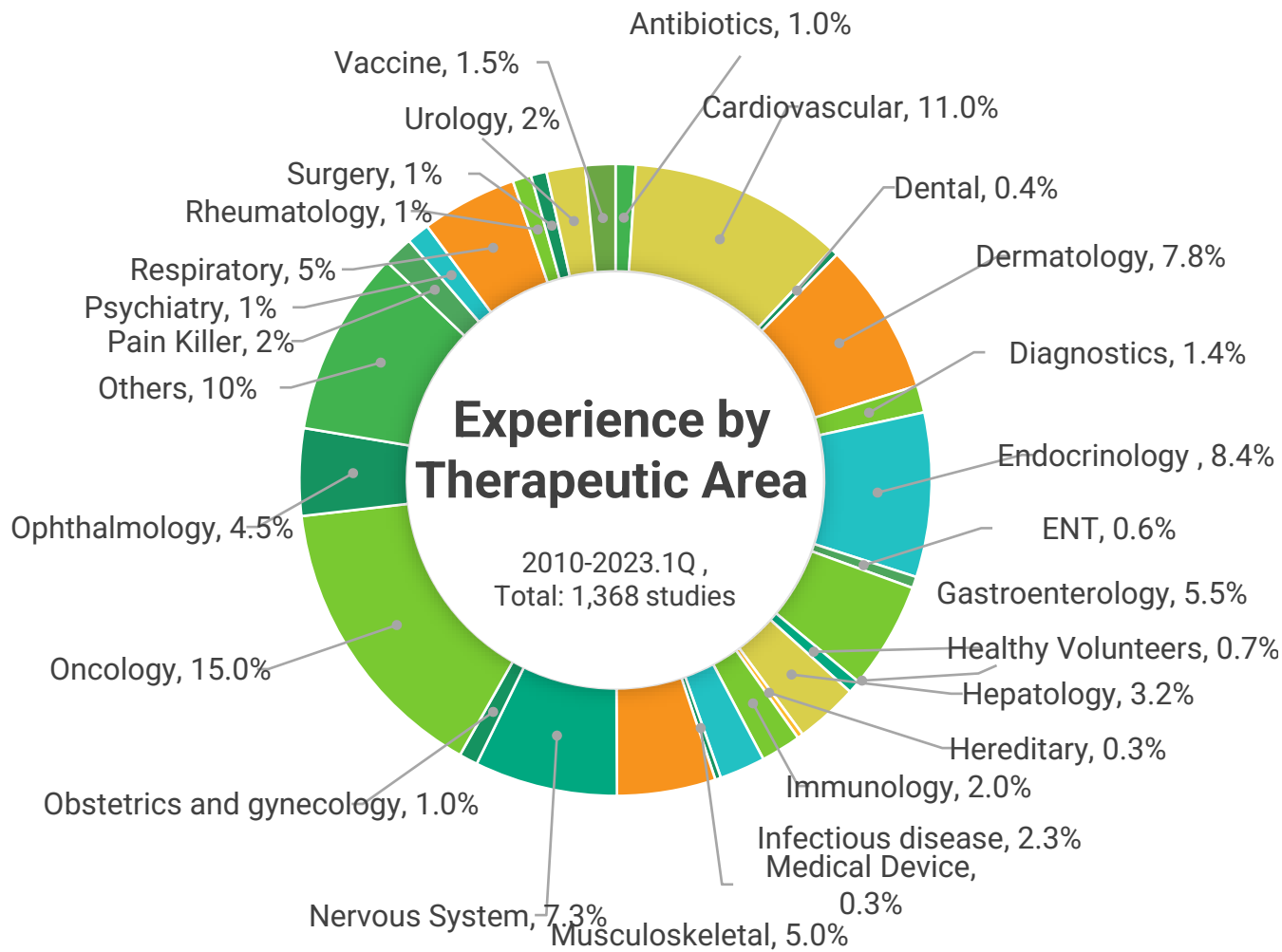
- Paper/ EDC system development
- Local: CRS Cube
- Global: Medidata
- DB design
- Manual & programming
- Clinical coding AE report to KIDS

- External audit & inspection
- GCP & GLP audit
- CQMS

- Statistical programming
- Analysis
- Randomization
- Sample size calculation

- PV
- KIDS online reporting
- PV training
- Safety report

Study Experience

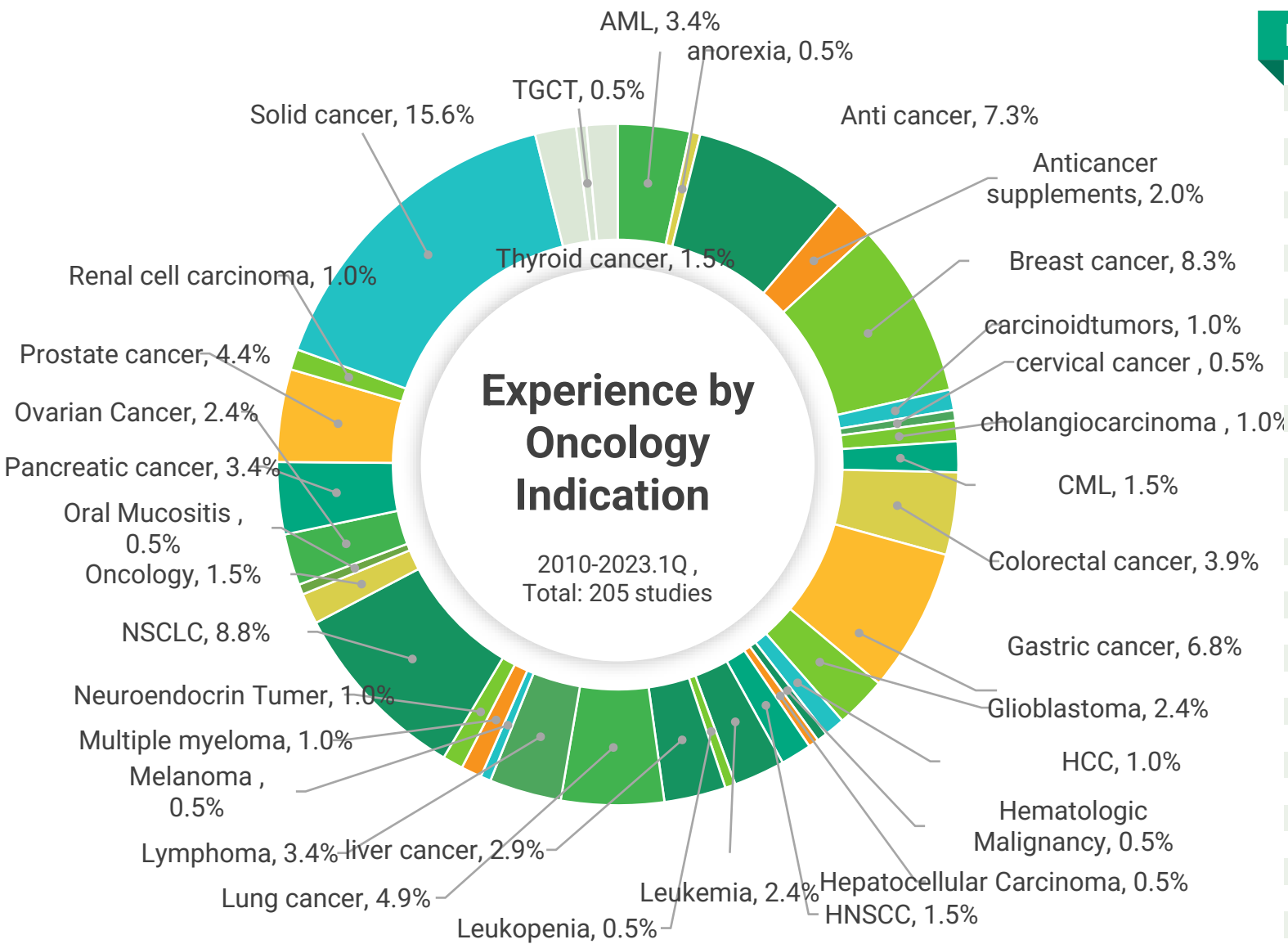


Experience by Therapeutic Area

(2010~2023.1Q)

Oncology	14.8%
Cardiovascular	10.9%
Others	9.6%
Endocrinology	8.5%
Dermatology	7.8%
Nervous System	7.3%
Gastroenterology	5.5%
Musculoskeletal	4.9%
Respiratory	4.8%
Ophthalmology	4.6%
Hepatology	3.2%
Infectious disease	2.3%
Immunology	2.1%
Urology	1.9%
Pain Killer	1.6%
Diagnosics	1.4%
Vaccine	1.4%
Psychiatry	1.2%
Antibiotics	1.0%
Obstetrics and gynecology	1.0%
Rheumatology	1.0%
Surgery	0.8%
Healthy Volunteers	0.7%
ENT	0.6%
Dental	0.4%
Hereditary	0.3%
Medical Device	0.3%

Oncology Study Experience

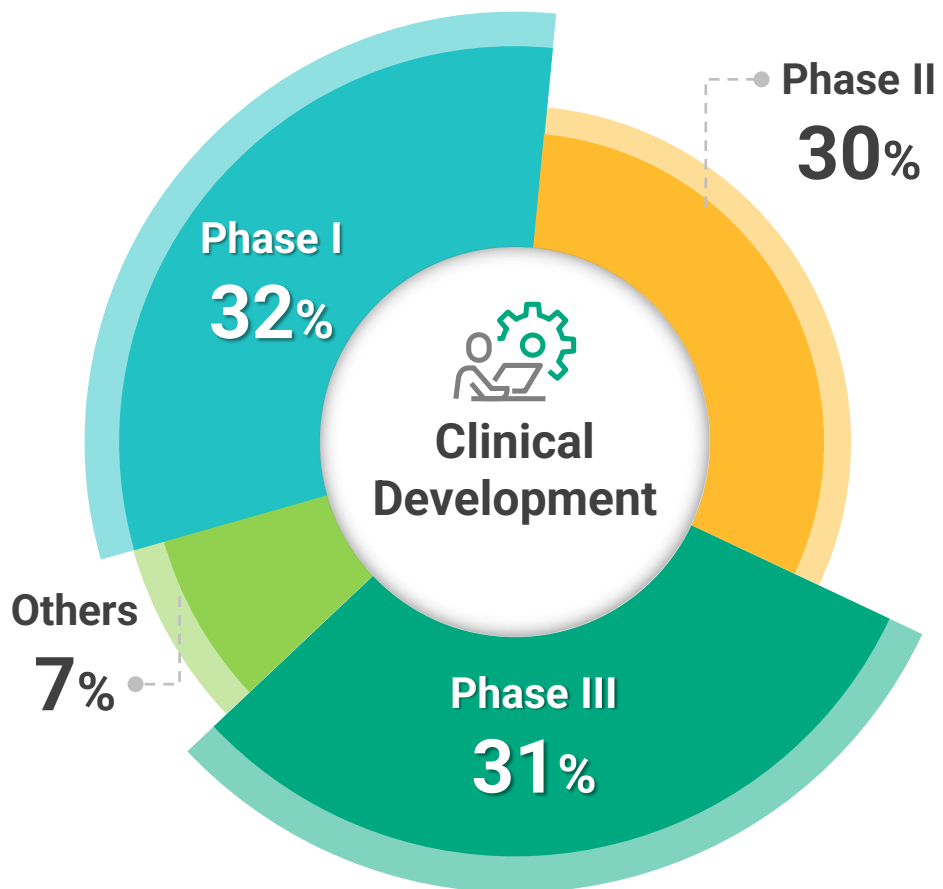


Experience by Indication

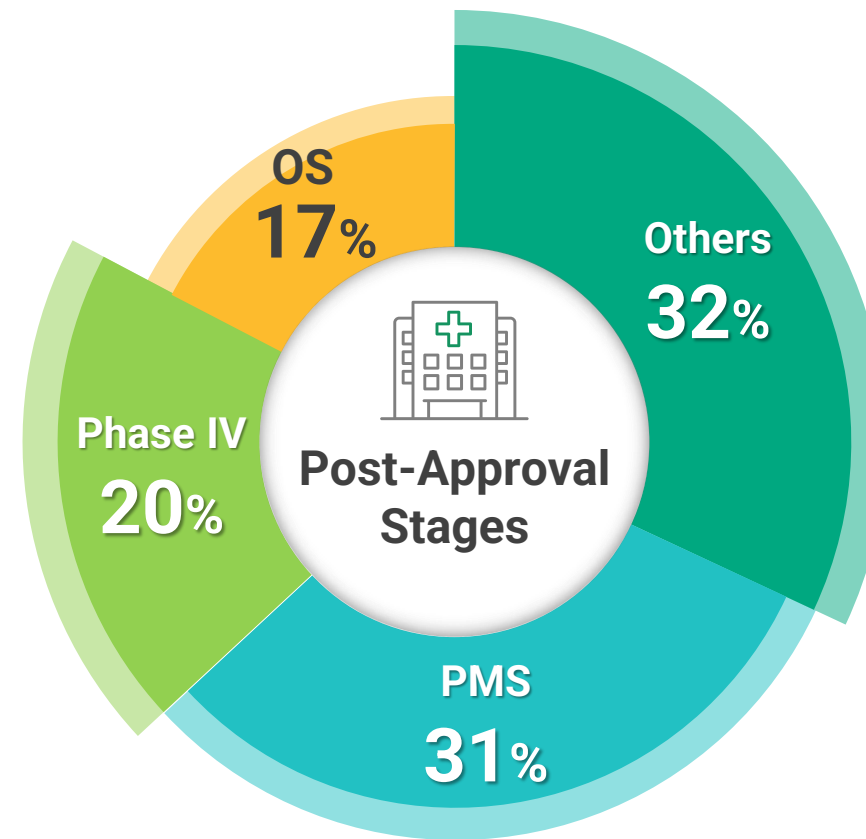
(2010~2023.1Q)

Solid cancer	15.6%
NSCLC	8.8%
Breast cancer	8.3%
Anti cancer	7.3%
Gastric cancer	6.8%
Lung cancer	4.9%
Prostate cancer	4.4%
Colorectal cancer	3.9%
AML	3.4%
Lymphoma	3.4%
Pancreatic cancer	3.4%
liver cancer	2.9%
Glioblastoma	2.4%
Leukemia	2.4%
Ovarian Cancer	2.4%
Anticancer supplements	2.0%
Solid Tumor	2.0%
CML	1.5%
HNSCC	1.5%
Oncology	1.5%
Thyroid cancer	1.5%
carcinoidtumors	1.0%
cholangiocarcinoma	1.0%
HCC	1.0%
Multiple myeloma	1.0%
Neuroendocrin Tumer	1.0%
Renal cell carcinoma	1.0%
anorexia	0.5%
cervical cancer	0.5%
Hematologic Malignancy	0.5%
Hepatocellular Carcinoma	0.5%
Leukopenia	0.5%
Melanoma	0.5%

Experiences by Phase



2010-2023.1Q , Total: 769 studies



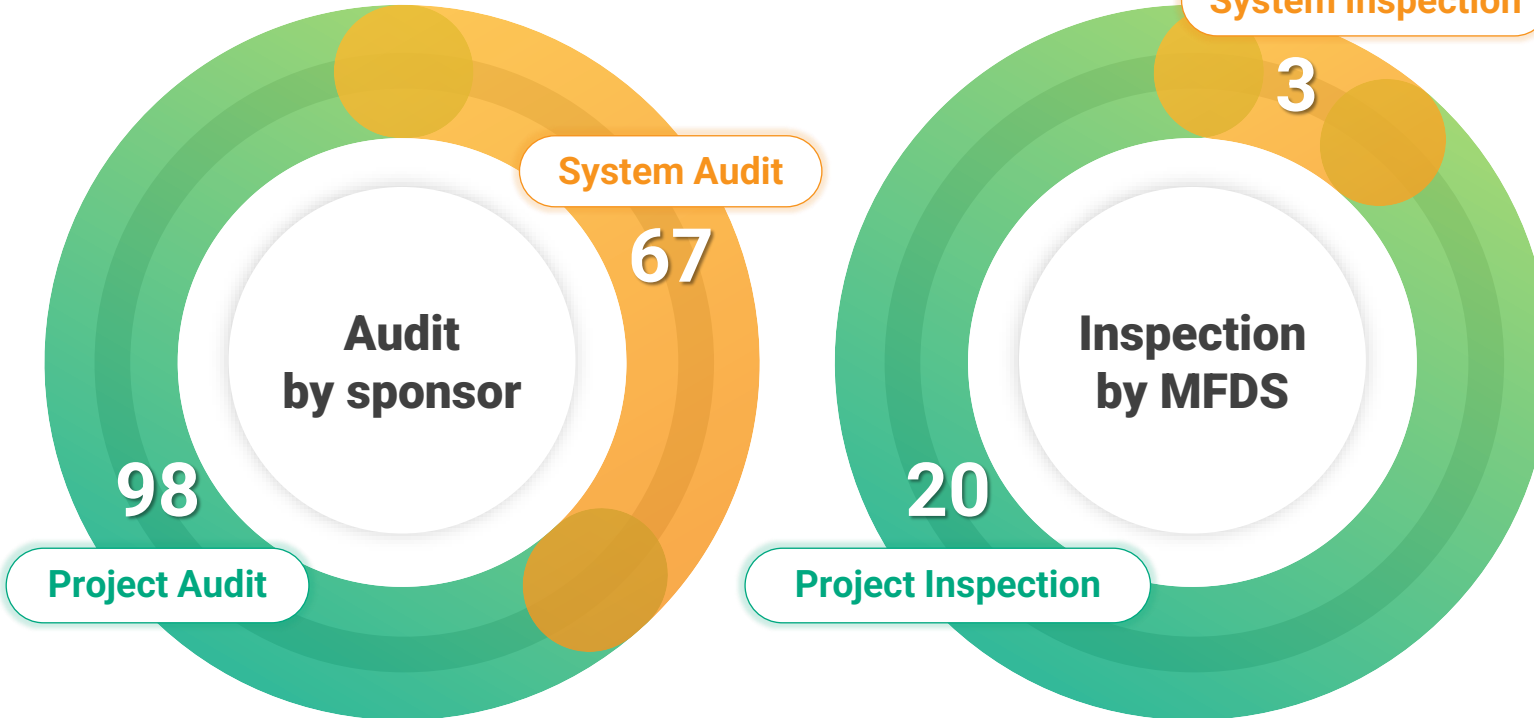
2010-2023.1Q , Total: 599 studies

Optimization Solutions: Quality Management Systems

Highly-Advanced Internal Audit Process

- C&R Research has an independent QA team to ensure high quality clinical service.
- Internal audit is conducted under an annual quality assurance plan(QAP)

Quality Management (2015~2023.1Q)

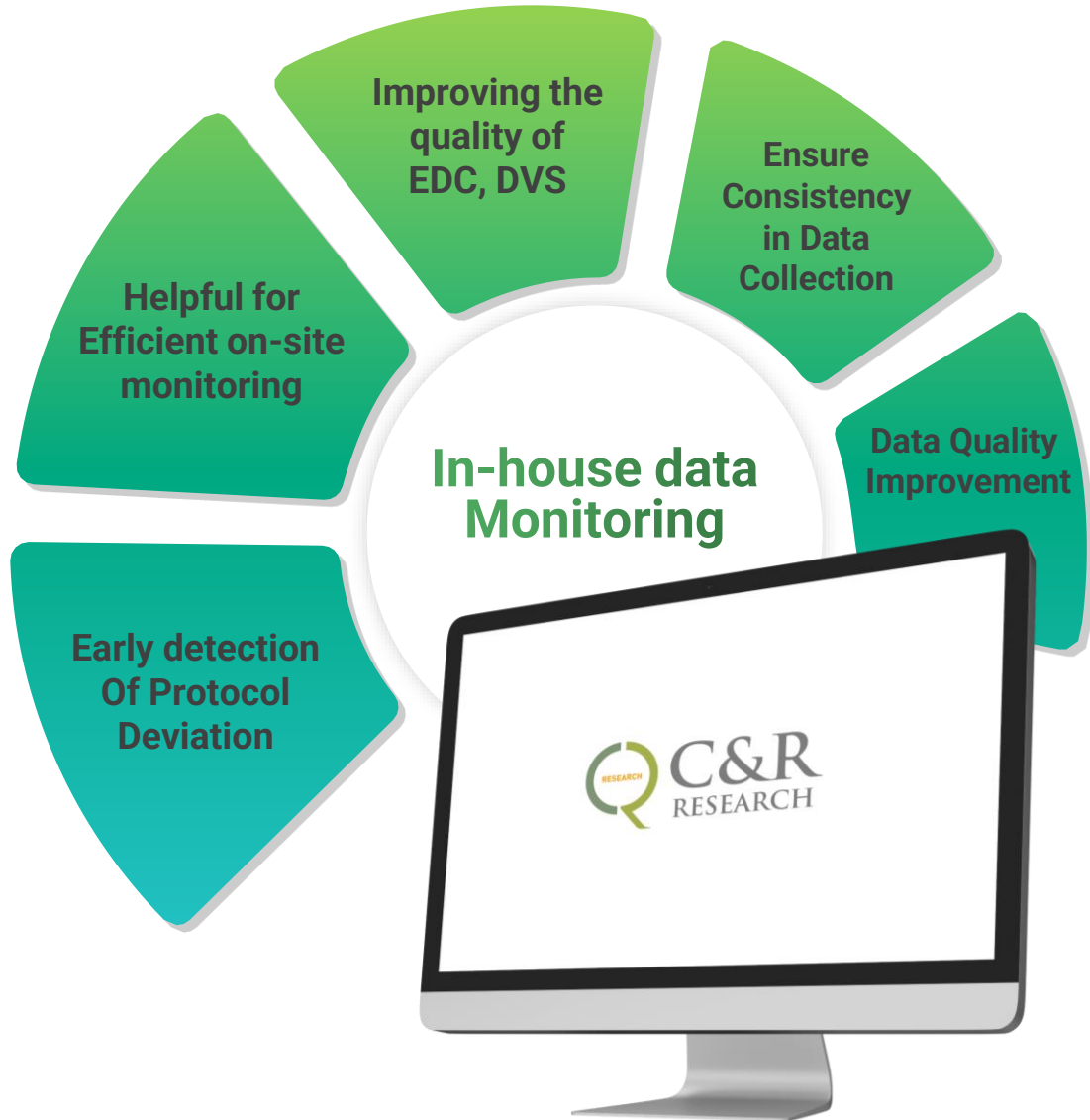


Therapeutic Area In Project Audit

(2015~2022)

Antibiotics	1
Anesthesiology	1
Cardiovascular	15
Dermatology	9
Diagnostics	1
Endocrinology/Metabolism	3
ENT (Ear,Nose,Throat)	4
Gastro-intestinal	6
Hepatobilliary(Pancreas)	0
Immunology	1
Infectious disease	2
Medical Device	2
Musculoskeletal	0
Nephrology	0
Neurology	7
Obstetrics and gynecology	1
Oncology	13
Ophthalmology	2
Orthopedics	2
Osteoporosis	0
Pain Killer	2
Respiratory	8
Rheumatology	1
Urology	1
Vaccines	1
Others	18
TOTAL	98

Optimization Solutions: In-house data Monitoring



Cost-Efficiency

- Helps in efficient SDV performance during on-site monitoring
- Early stage data review
- Investigator/site staff to reduce the noncompliance
- Fix errors of protocol (CRF, DVS, CCG)
- Reduce the number of queries during data cleaning

Low Risk

- Data routine review to identify on inconsistent data, missing data and potential protocol deviations
- Investigator/site staff to reduce the noncompliance
- Finding confirmation of essential documents that can be checked after real data collection

Quality Assurance

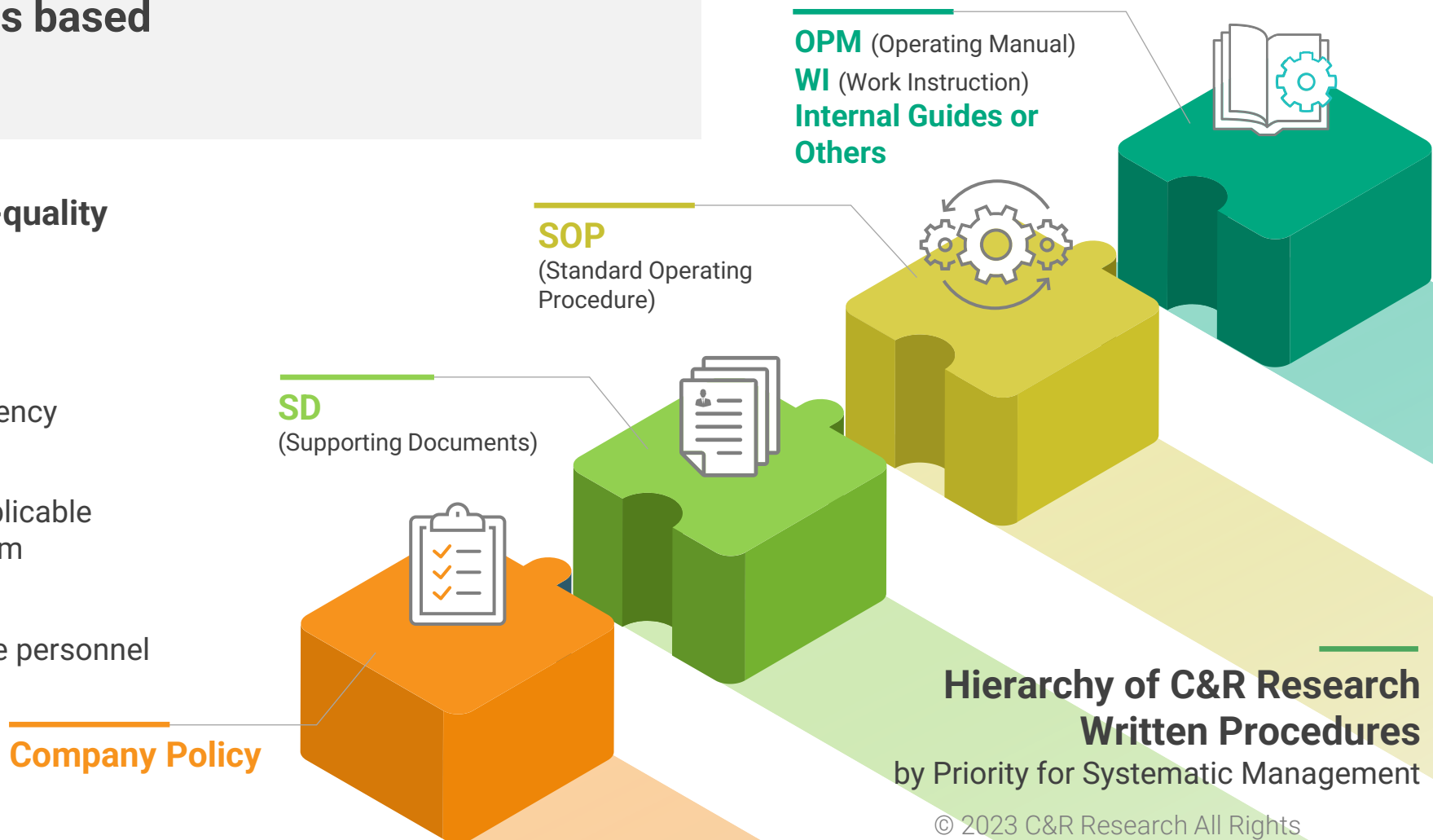
- Enables data to be collected consistently
- Checks for unusual distribution of data
- Intensive targeted monitoring in risk sites Improved
- Cross-functional collaboration of DM (Data Management) part and CDM (Clinical Data Management) part.

Optimization Solutions: Quality Management Systems

Well-Organized SOP Systems based on Local / Global Guidelines

The steps make the following high-quality services available

- ✓ Efficient clinical trial
- ✓ Maintenance of integrity and consistency of clinical service
- ✓ Helping personnel understand all applicable regulation & minimizing deviation from the requirements
- ✓ Clearly defining responsibilities of the personnel



Optimization Solutions: Data Driven Clinical Trial

BOIM

 **imtrial**

CsafeR

System Build



RTSM



**CDMS (EDC) /
CTMS (incl. e-TMF)**



**Safety
Management**

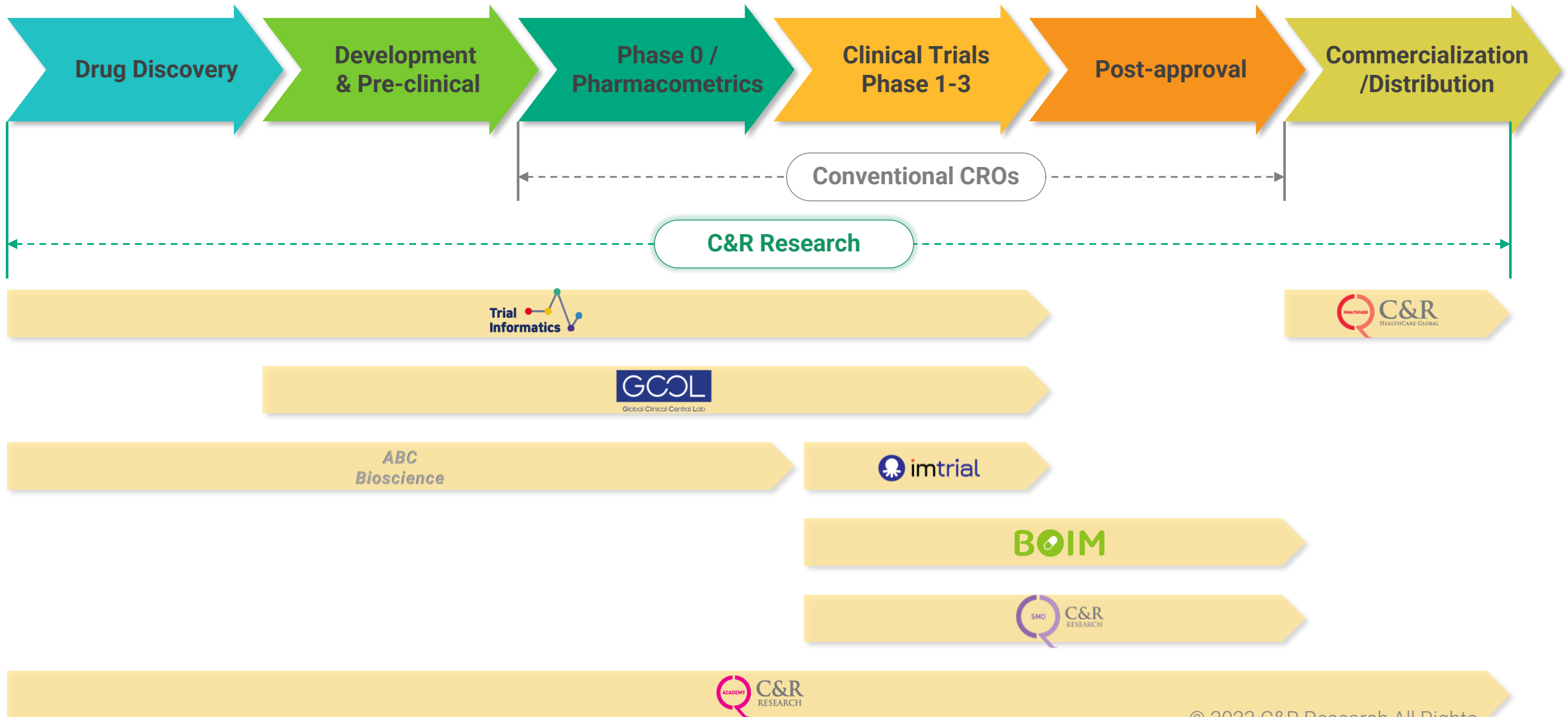




Beyond a CRO



Total Value Chain CRO



Integrated Services



C&R Academy is a clinical training institute that has been officially designated by the Ministry of Food and Drug Safety (MFDS). By providing global-level, systematic education programs for CRAs, C&R Academy enhances their contributions to the clinical sector. C&R Academy has grown its expertise in clinical training beyond the perimeter of C&R Research, providing education for CRAs of all affiliation.



C&R Healthcare Global is a leading healthcare business platform that guides clients to effectively execute their business strategy throughout the entire drug development process from incubation to commercialization. Located in Singapore, C&R Healthcare Global sets a solid foundation for bio/health companies to make a successful transition from local/regional to global entities.

C&R Academy

C&R Academy

MFDS Designated CRA Training Institute

분류	Course	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
신규	Fundamental of Clinical Research (5Days)			2~6	6~10	18~22	1~5	13~17	24~28		12~16	9~13	
	Clinical Research of Medical Device (1Day)										20		
신규 심화 보수	GCP Training (1Day)	21					16		20				2
	Non-Interventional Study (1Day)						11					4	
심화 보수	Basic Course of Clinical Research (3Days)							22~24		23~25		24~26	
	CPM_Fundamental (2Days)					27,28							
	CPM_Advanced (2Days)										6,7		
	DM/STAT (1Day)			24								19	
	Drug Development (1Day)			21				8					
	Early Phase Study (1Day)			1						2			
	Monitoring Practice (2Days)				13,14			12,13					8,9
	Medical Writing in Clinical Research (2Days)				25,26							17,18	
	Oncology Clinical Trial (2Days)					17,18					22,23		
	Pharmacovigilance (1Day)			14						9			
	Quality Assurance (1Day)				21						29		
	Regulatory Affairs in Clinical Research (1Day)		24								27		
	Risk-based Quality Management (2Days)			26,27									16,17
	Study Start up Training (1Day)		22						19				

C&R Academy 기초/심화

On/Off-line Training

GCP Training Management System

Curriculum & Schedule

<https://lms.cnracademy.org>



C&R Research Partners & Collaborative Services



CDMO



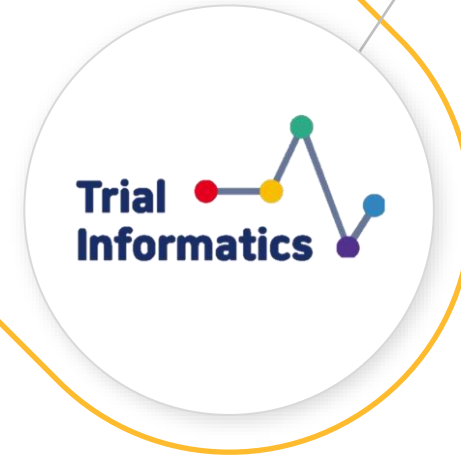
K-Bio Health is a bio-health organization run by the Korean government. C&R Research provides biologics CDMO services in collaboration with K-Bio Health. The partnership was established through C&R Research's investment of 1 billion KRW(1 million USD)

Green Cross LabCell(GC LabCell) is a Biotech corporation in South Korea that specializes in cell therapy. C&R Research and GC LabCell plans to co-found **GCCL**, a biotech corporation focused on clinical sample analysis.



Central Lab Services

Trial Informatics is a data science company based on imaging medical and medical monitoring platforms created in cooperation with Asan Clinical Examination Radiology Support Office at Asan Medical Center.(ISO9001 certification)



Imaging Solution

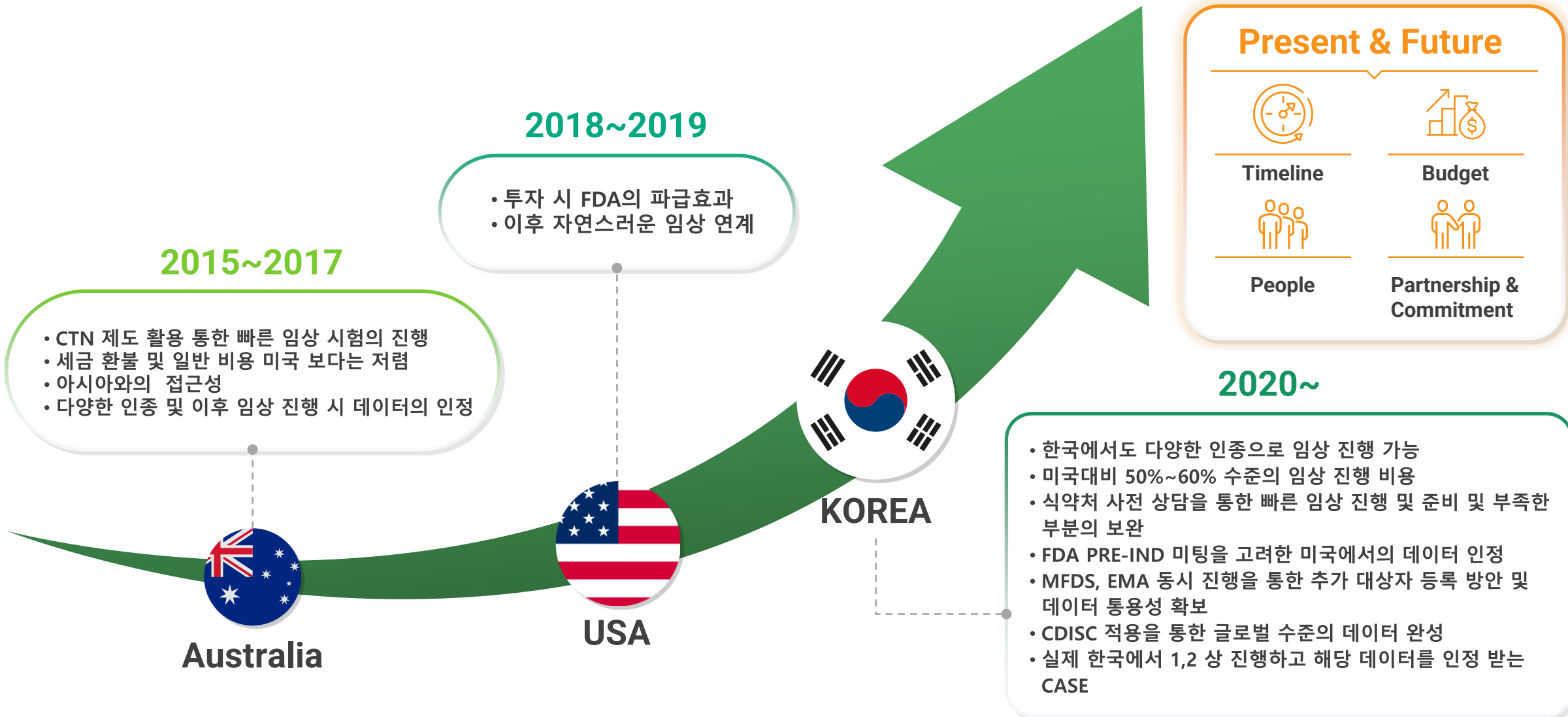


Global CRO

C&R Research has an integrated range of worldwide network, which enhances its clinical trial expertise and extends the scope of services beyond expectation

- 01 Global Services and Coverage
- 02 Global Presence

EARLY PHASE CLINICAL TRIALS FOR GLOBAL



Ideal strategy on clinical trial considering country specific requirements

		FDA (US)	PMDA (Japan)	NMPA(China)	EMA (EU)	MFDS (Korea)
IND	CTD	2018년 05월 의무화		2021년 9월 의무화	IMPD 의무화 * CTD: Module 3,4,5 * IMPD: CTD Module 2	
	CDISC	2017년 12월 의무화				
NDA	CTD	2017년 05월 의무화	2020년 4월 의무화	2021년 9월 의무화	2010년 1월 의무화 국가별로 비 eCTD를 허용하는 국가도 있음	2009년 3월 의무화 (신약 only) 2023년 10월 전문의약품 의무화 예정
	CDISC	2016년 12월 의무화	2020년 4월 의무화	2019년 9월 권고		

IND

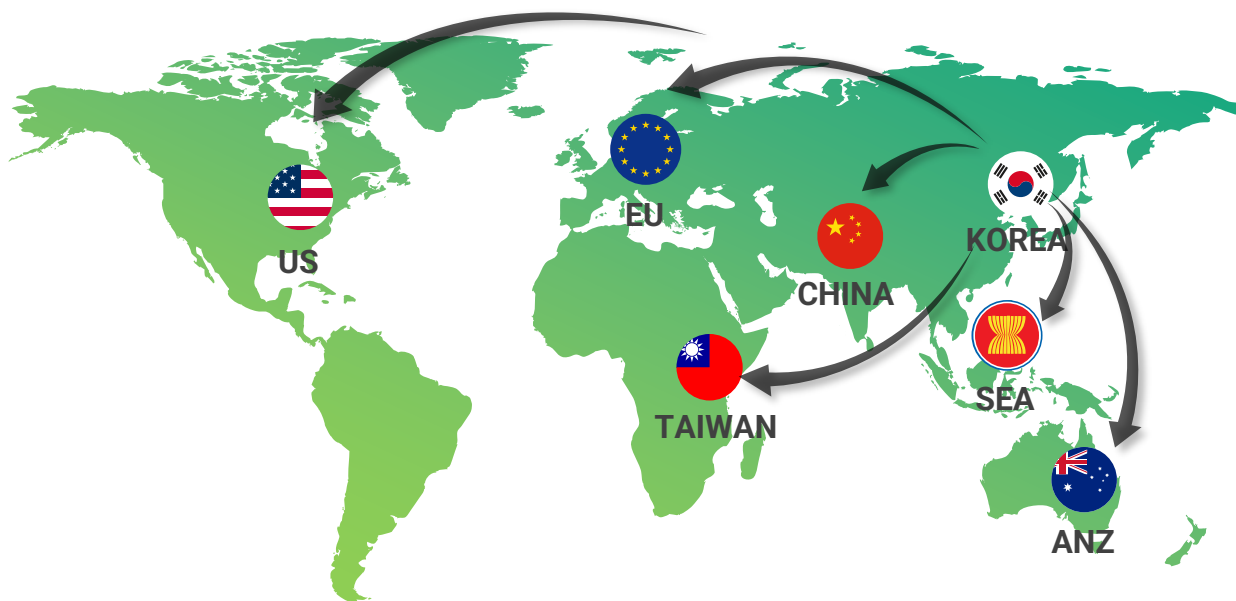
미국 및 중국을 제외한 대부분의 국가는 CTD 제출 필요 없음 / CDISC는 미국만 제출 필요

NDA

대부분의 국가에서 CTD 제출 필요 / CDISC는 미국 및 일본만 제출 필요

Global Services and Coverage

2016~2023.1Q Global Study Experience : 23 Studies



Year	Sponsor	Indication	Phase	Scope
2016	Company B	Oncology	2	PRT RA CO PV
2016	Company D	Oncology	2/3	PRT CO PV DM STAT CSR
2017	Company D	Oncology	2	DM STAT
2018	Company B	Oncology	Others	RA
2018	Company G	Nervous System	1/2	DM STAT CSR
2018	Company D	Oncology	PMS	PRT
2019	Company S	Oncology	1	PRT CO PV DM STAT CSR Others
2019	Company P	Oncology	1	CO
2019	Company R	Others	Others	PRT
2019	Company R	Others	Others	Others
2020	Company Y	Antibiotics	Others	RA
2020	Company G	Infectious disease	1/2	PRT
2021	Company D	Oncology	3	DM STAT
2021	Company Y	Others	Others	RA
2021	Company G	Infectious disease	2	CO PV DM
2022	Company E	Dermatology	1	RA CO PV DM STAT
2022	Company I	Musculoskeletal	2	PRT
2022	Company I	Musculoskeletal	1	DM STAT CSR
2022	Company F	Hepatology	2	RA CO PV
2022	Company T	Hepatology	2	RA
2022	Company R	nAMD	3	PRT RA CO PV DM STAT CSR
2023	Company C	Gastroenterology	2	RA
2023	Company Q	Oncology	1/2	CO

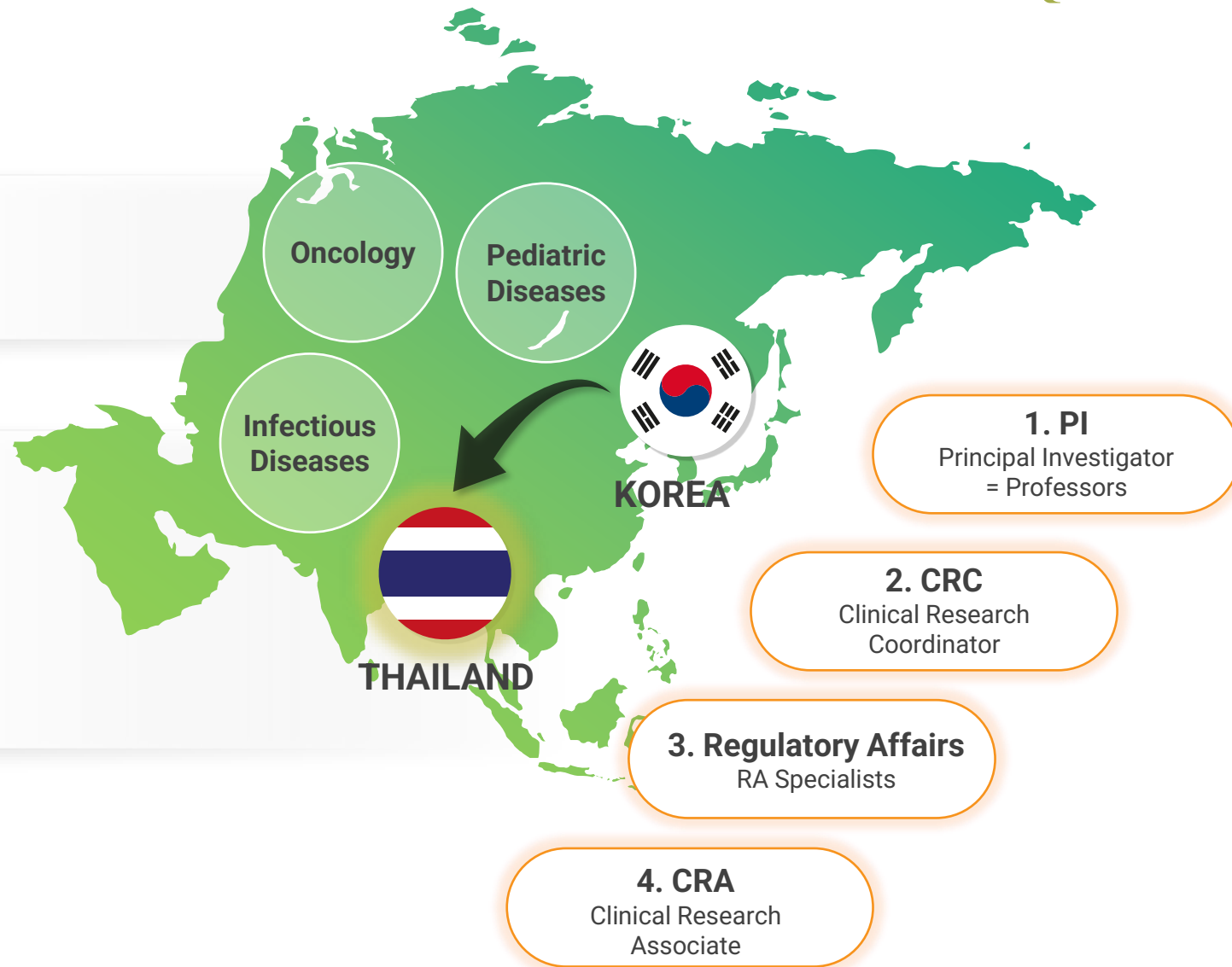
C&R Thailand.

MOU with CMU

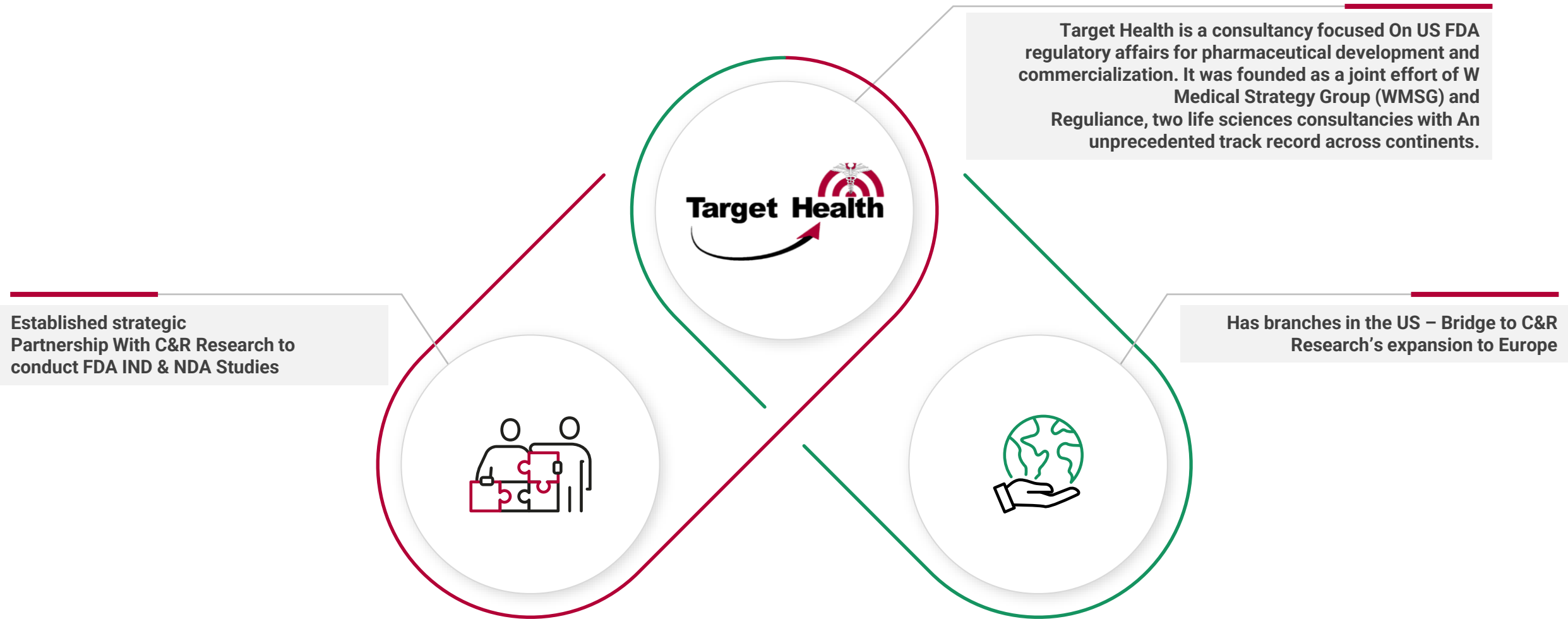
Chiang Mai University와 MOU를 체결

Local Office

- A** Dr. Prapan. Director of C&R Chiang Mai
- B** 1 CRA 계약 for Feasibility



Global Presence



One Team – Study Management Technologies & Tools

