

# C&R RESEARCH



# Contents

**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

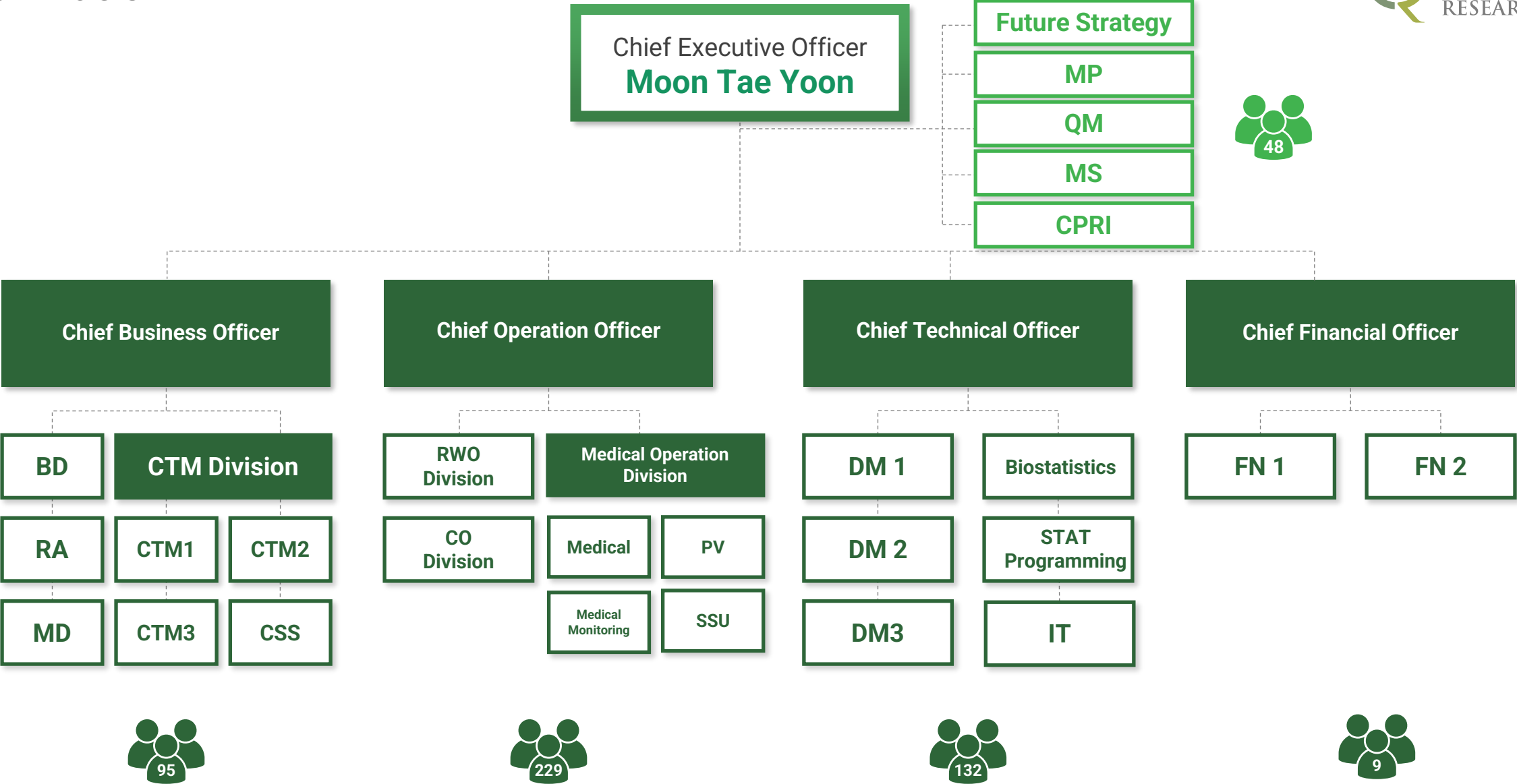
**Headquarter** ----- Seoul, South Korea

**CEO** ----- Moon Tae Yoon

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

**Workforce** ----- 500+

# Organization

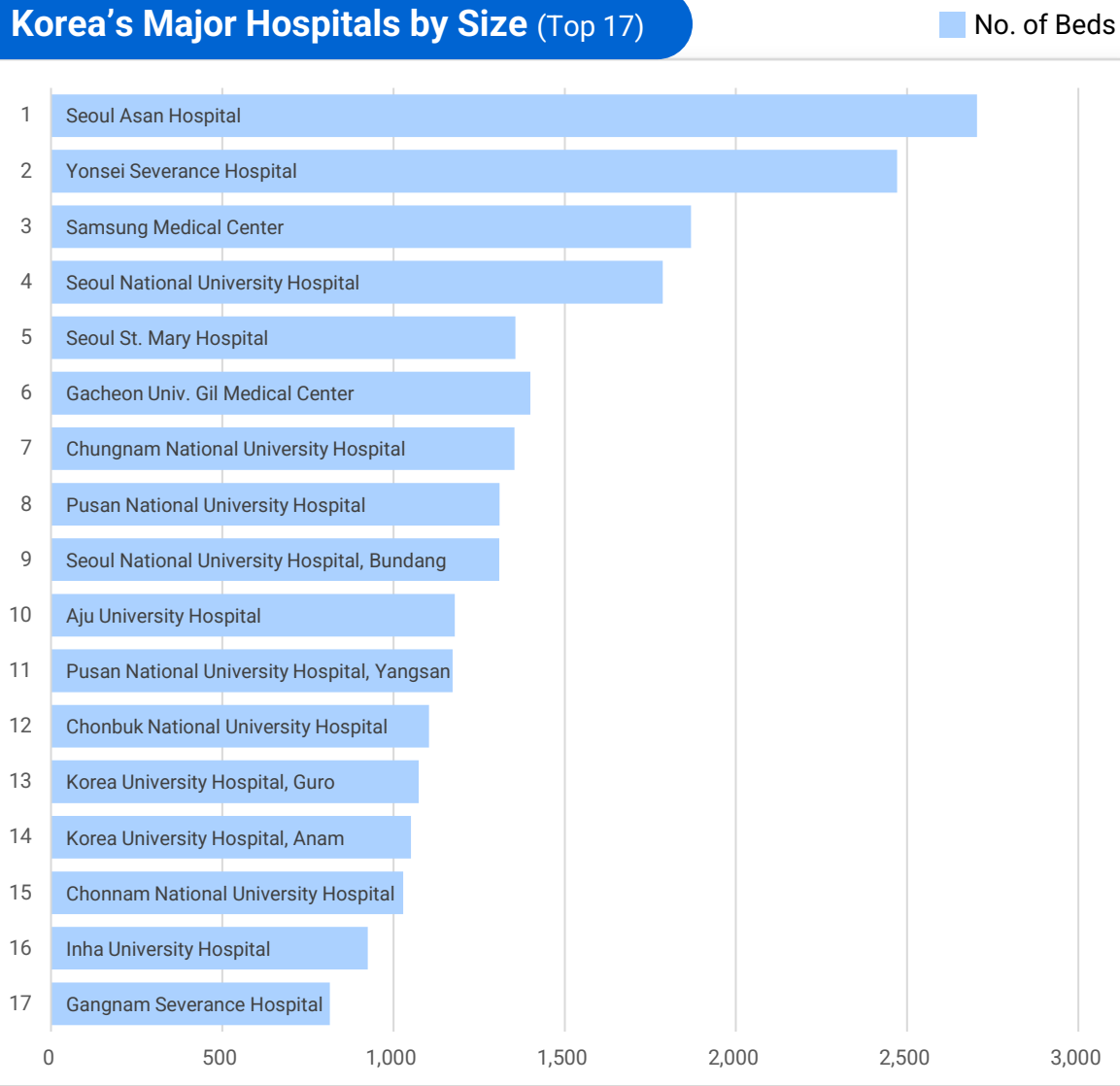




# Strong Presence in Korea, Embedded Global Competitiveness



Korea’s Major Hospitals by Size (Top 17)



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



## KoNECT CRO 기관인증 평가 임상시험 프로젝트 매니지먼트 (Project Management) 및 데이터 관리 / 통계분석 (Data Management/Statistics) 부문 역대기록 갱신

C&R  
RESEARCH

외부 점검, 실태조사 결과 분석

ISO 9001 품질경영시스템 도입 등 다년간 시스템 개선



현장 점검의 기본영역인 조직 및 인력관리, 시설, 품질, 전산시스템 관리 부문에서 '적합' 판정



특화 영역을 포함해 지난 2014년 KoNECT 기관 인증 평가 참여 이래 가장 높은 점수 획득

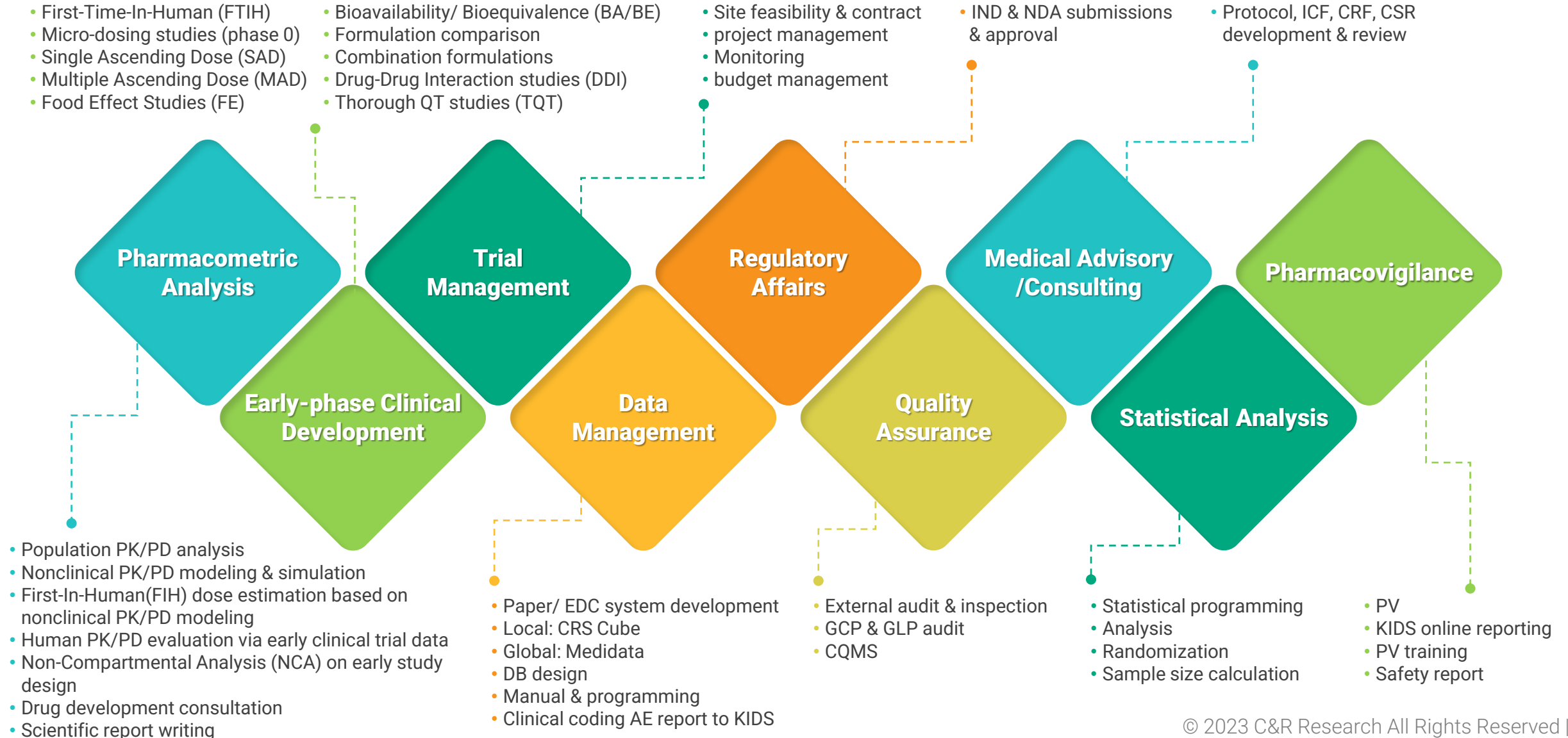




# Full Service CRO



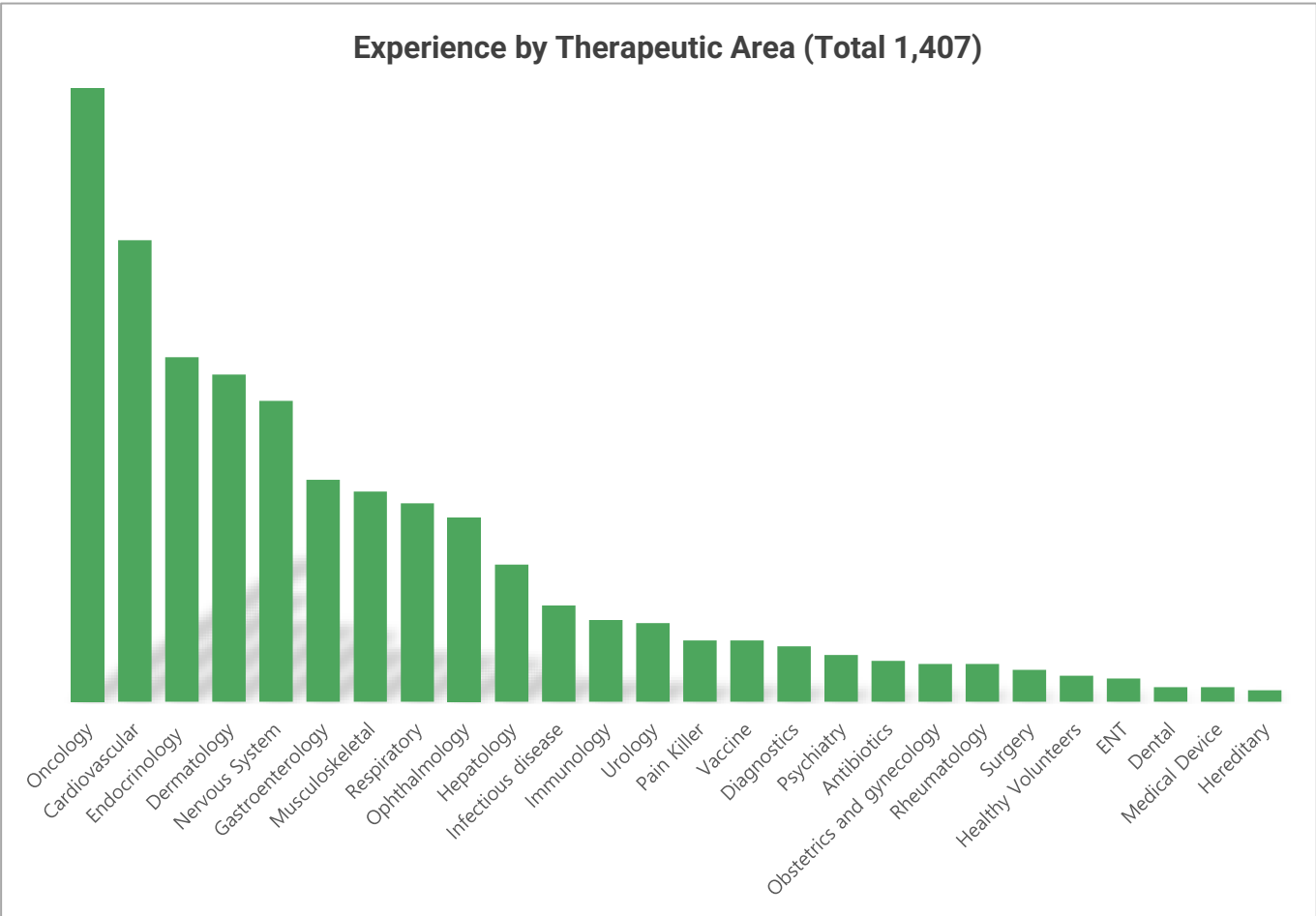
# Service Offerings for Global Trials



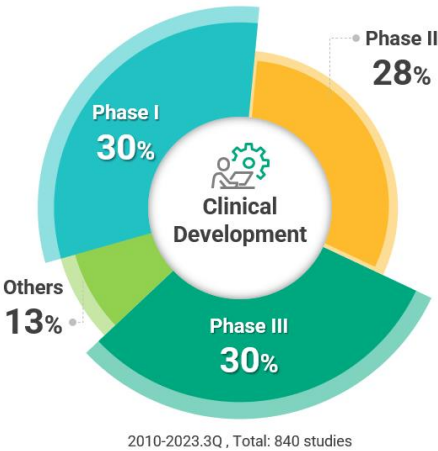
# Study Experience



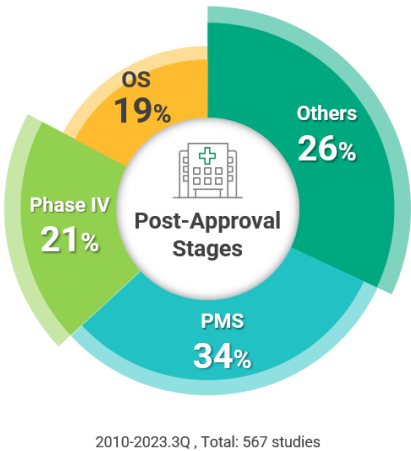
## 2010~Q3 2023 Experience by Therapeutic Area and Oncology



## Pivotal, Pilot



## Post Approval

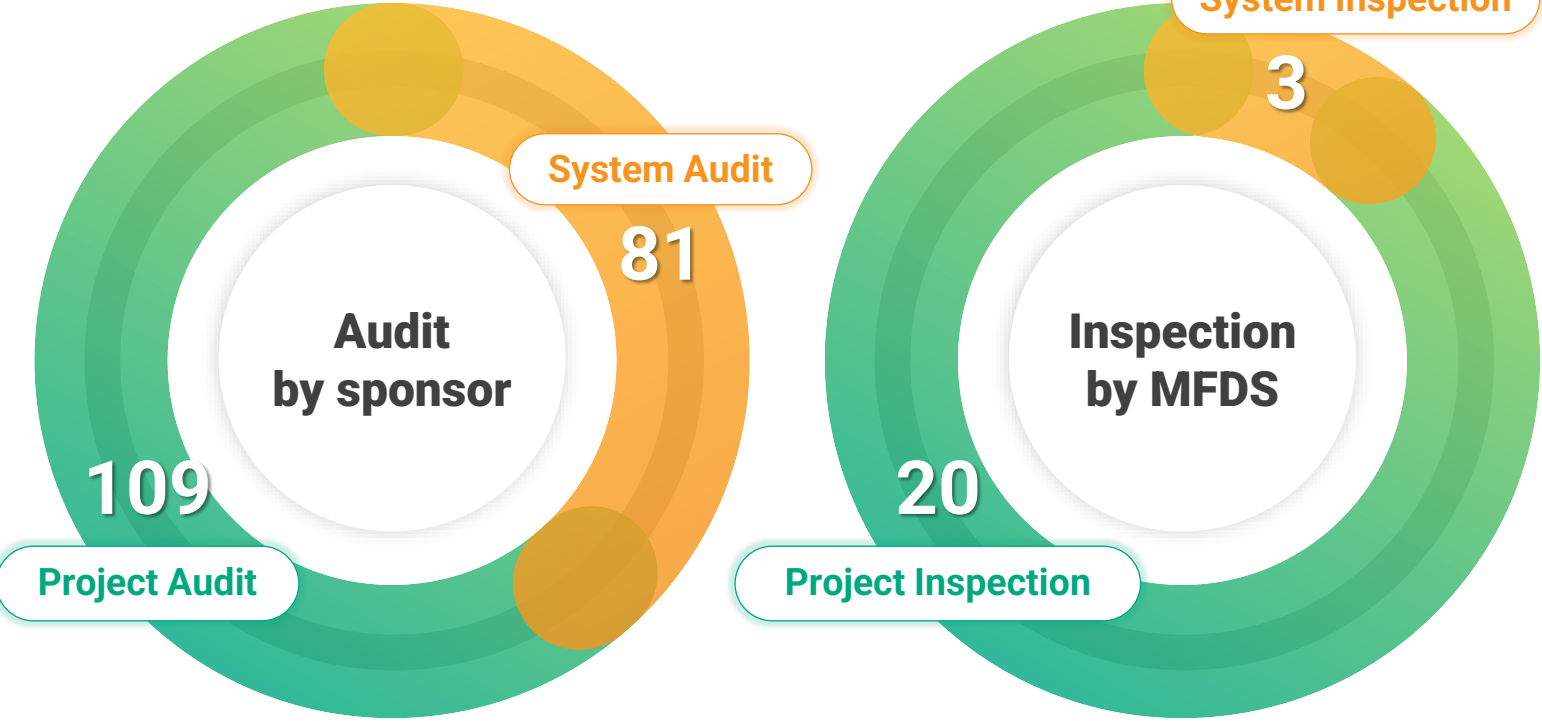


# Optimization Solutions: Quality Management Systems

## 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)



Therapeutic Area In Project Audit

(2015~2023)

Antibiotics	2
Anesthesiology	2
Cardiovascular	15
Dermatology	11
Diagnostics	1
Endocrinology/Metabolism	4
ENT (Ear,Nose,Throat)	4
Gastro-intestinal	7
Hepatobilliary(Pancreas)	0
Immunology	2
Infectious disease	2
Medical Device	2
Musculoskeletal	0
Nephrology	0
Neurology	8
Obstetrics and gynecology	0
Oncology	18
Ophthalmology	1
Orthopedics	2
Osteoporosis	0
Pain Killer	0
Respiratory	8
Rheumatology	1
Urology	2
Vaccines	1
Others	16
TOTAL	109

# 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

Company Policy



# Optimization Solutions: Data Driven Clinical Trial

**BOIM** **imtrial***CsafeR*

## System Build



## RTSM



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



## Safety Management

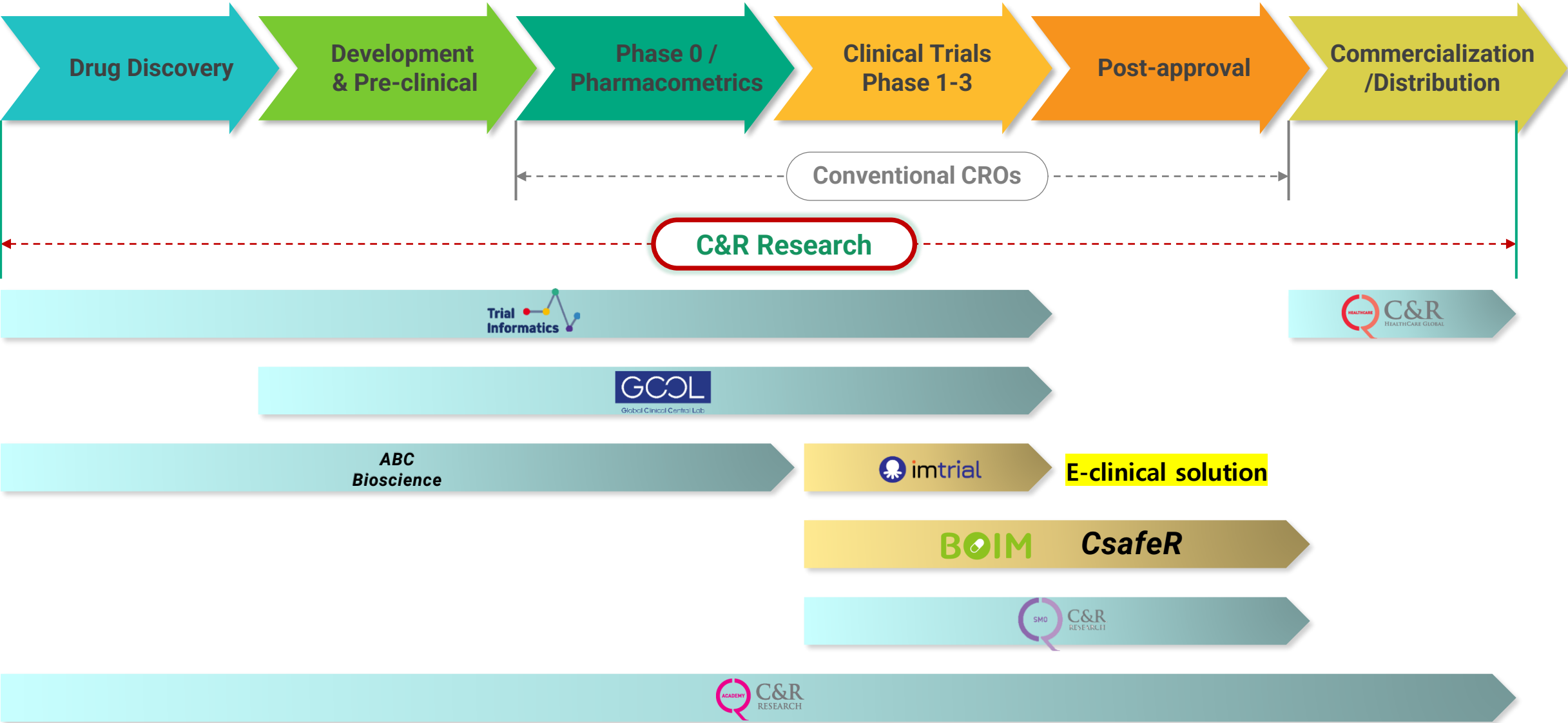




# Beyond a CRO



# 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

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	
신규 심화 보수	Clinical Research of Medical Device (1Day)										20		
	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

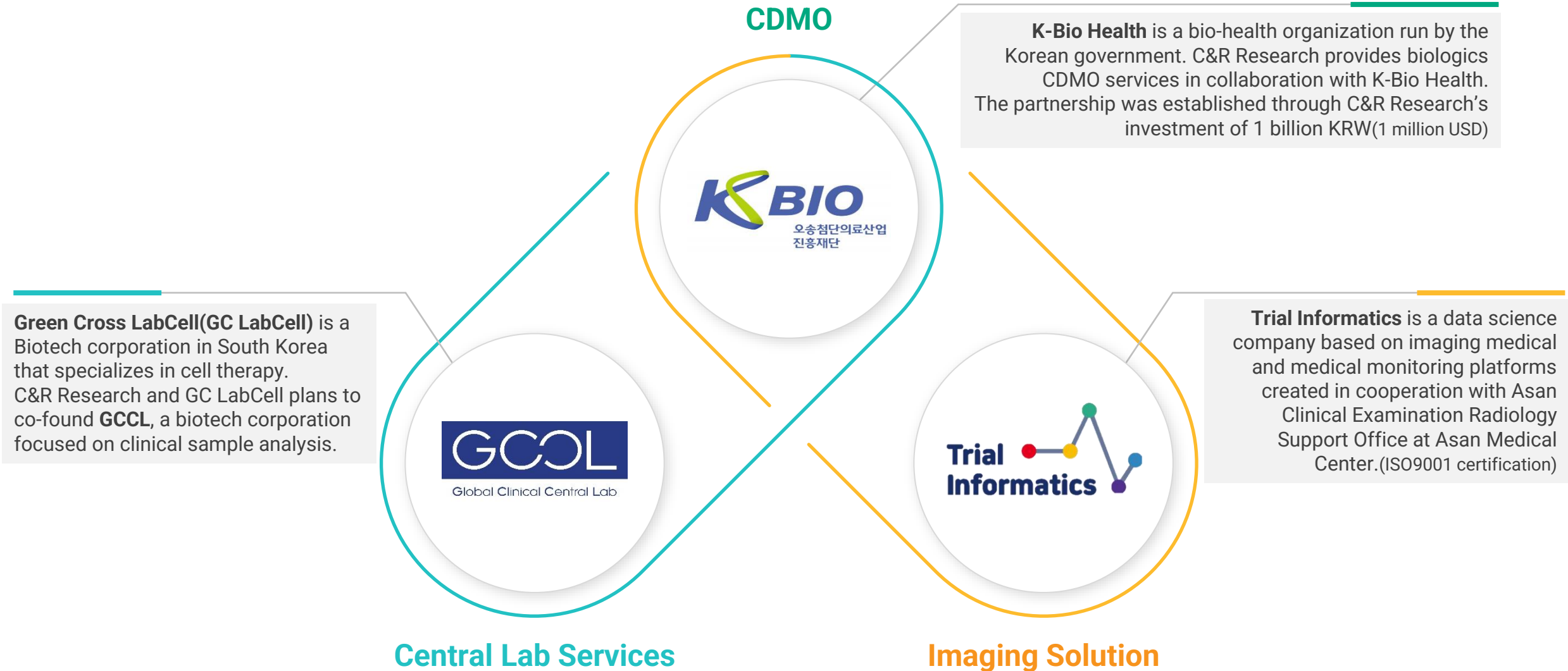
GCP Training Management System

Curriculum & Schedule

<https://lms.cnracademy.org>



# C&R Research Partners & Collaborative Services





## Global CRO

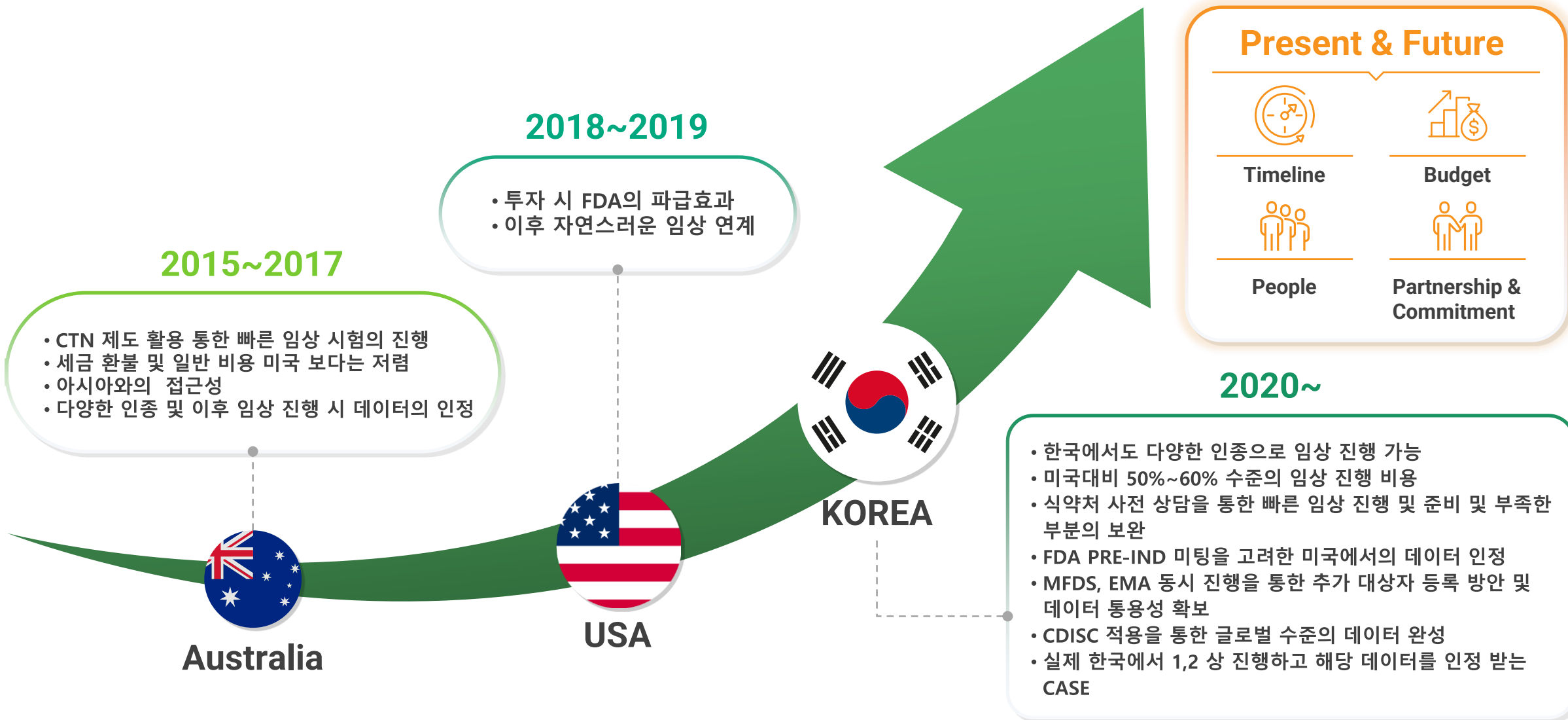
C&R Research has an integrated range of worldwide network, which enhances its clinical trial expertise and extends the scope of services beyond expectation

**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) 2023년10월 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

- Outbound** : C&R as a central CRO (PRT, CO, PV, DM, STAT, CSR) / local PM reporting to C&R GPM -25 Projects
- Inbound** : C&R as a local CRO (CO, PV, RA) / C&R local PM reporting to central CRO or Global sponsor -16 Projects

Spon.	Indication	Phase	Scope	Country	Partner CRO by Country	Spon.	Indication	Phase	Scope
B	Pancreatic Cancer	2	PRT RA CO PV	Korea, US, Israel	• NA	B	COPD	3	RA CO PV
D	Breast Cancer	2/3	PRT CO PV DM STAT CSR	Korea, China, Bulgari, Hungary, Serbia	• Hungary & Serbia – Hungaro Trial • China – TigerMed	B	NSCLC	3	CO PV
D	Breast Cancer	1	DM STAT	Korea, China, Czech, Hungary	• Czech & Hungary – Hungaro Trial • China – TigerMed	N	Gastrointestinal Stromal Tumor	3	RA CO PV
B	Anti-Cancer	2	RA	China	• China – C&R China	G	Lung cancer	2	RA CO
G	Alzheimer's Disease	2	DM STAT CSR	Australia	• Australia – Premiere Research	B	Asthma	3	RA CO
S	Solid Cancer	1	PRT	Korea, US	• NA	N	Chronic Myeloid Leukemia	2	RA CO
P	AML	1	Dedicated PM	Korea, Spain, Australia	• Spain, Australia – Covance	B	Stroke	3	RA CO
R	Solid Tumor	1	Dedicated PM	Bulgaria	• NA	G	COPD	2	CO
Y	Antibiotics	1	RA	China	• C&R China	G	COPD	2	CO
G	Covid-19	2	PRT	Korea, US	• NA	G	Pancreatic cancer	2	CO
J	NASH	1/2	RA	Korea, US	• US – WMSG	B	Type 2 DM	2	RA CO PV
N	Solid Tumor	2	PRT	Korea, US	• NA	B	Lung cancer	2	CO
D	Breast Cancer	1	DM STAT	US	• US – KCRN	G	asthma	3	CO
Y	Antibiotics	2	RA (API filing agent)	China	• NA	G	SLE	3	CO
G	Covid-19	2	CO PV DM	Korea, US, Bulgaria, North Macedonia, Puerto Rico	• Korea (DM) – C&R • Other countries – Catalyst	G	SLE	3	CO
I	BMD	2	PRT	Korea, US	• NA				
I	DMD	2	CO PV DM STAT CSR	Korea, US	• US – Target Health				
N	Solid Tumor	1,2a	CO PV DM STAT CSR	Korea, US	• US – Target Health				
R	Wet AMD	3	CO PV DM STAT CSR	Korea, US, Russia, Europe (5 countries)	• US – Target Health • Europe – Hungaro Trial				
F	NASH	2	RA CO PV	Korea, Hungary, Poland, Spain	• Europe – Syneos Health				
C	Ulcerative Colitis	2	RA	Korea, Bosnia, Serbia, North Macedonia	• Europe – Hungaro Trial				
Q	Solid Cancer	1/2	CO	Korea, US	• US – TD2				
S	Atopic Dermatitis	1/2	CO PV DM STAT CSR	Korea, US	• US – Biorasi				
N	Alzheimer's Disease	2	PRT RA	Korea, US	• US – Independent contract				
N	Obesity	2	PRT RA	Korea, US	• US – Independent contract				

# Global Services and Coverage

## '글로벌 임상 인프라 확충' 씨엔알리서치...태국·미국 법인 설립

씨엔알리서치 · 2023. 11. 22, 13:30

URL 복사

+이웃추가

“

'글로벌 임상 인프라 확충' 씨엔알리서치...태국·미국 법인 설립

'씨엔알 헬스케어 글로벌 타일랜드(C&R Healthcare Global Thailand)'

임상시험수탁기관(CRO) 씨엔알리서치는 **글로벌 임상시험**을 주도적으로 수행하기 위한 해외법인을 태국에 설립했다.

태국의 안정적인 의료 인프라와 고품질의 임상시험 인력 등을 바탕으로 **동남아시아 시장에서의 임상시험 시장 확장**을 계획하고 있다.

태국 치앙마이 병원을 기반으로 **비용 효율적이고 수준 높은 임상시험**을 제공한다는 구상으로 백신 관련 연구를 포함하여 다수의 글로벌 임상시험을 진행하기 위해 국내의 여러 의회사와 관련 조율을 이어오고 있다고 전했다.

씨엔알리서치는 “이번 태국 법인 설립은 **국내 의회사의 동남아시아 수요 대응**과 **글로벌 임상시험의 자체적인 수행 및 현지 네트워크**를 활용한 임상시험 수행이 목표”라고 설명했다.

씨엔알리서치는 북미 시장도 겨냥해 미국에 해외 법인 '**C&R Research US**'를 설립했다. 씨엔알리서치 관계자는 “**미국 식품의약국(FDA)**에 **사전 임상시험계획(Pre-IND)**과 **임상시험계획(IND)** 승인 관련 업무를 시작으로 점진적으로 수행영역을 확대해 나가겠다”고 전했다.



### C&R Research US

Address : 1 Broadway – Cambridge MA 02142 United States

CEO : Jinhak Kim

Service Scope : RA Consulting

### C&R Healthcare Global Thailand

Address : 1000/40, Sukhumvit Road (Sukhumvit 55, Thonglor), Khlong Tan Nuea, Watthana, Bangkok (Liberty Plaza)

CEO : Yunho Kim, Dr. Prapan Jutavijittum

Service Scope : RA Consulting, Site Feasibility, Clinical Operation



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# Thank You