C&R RESEARCH

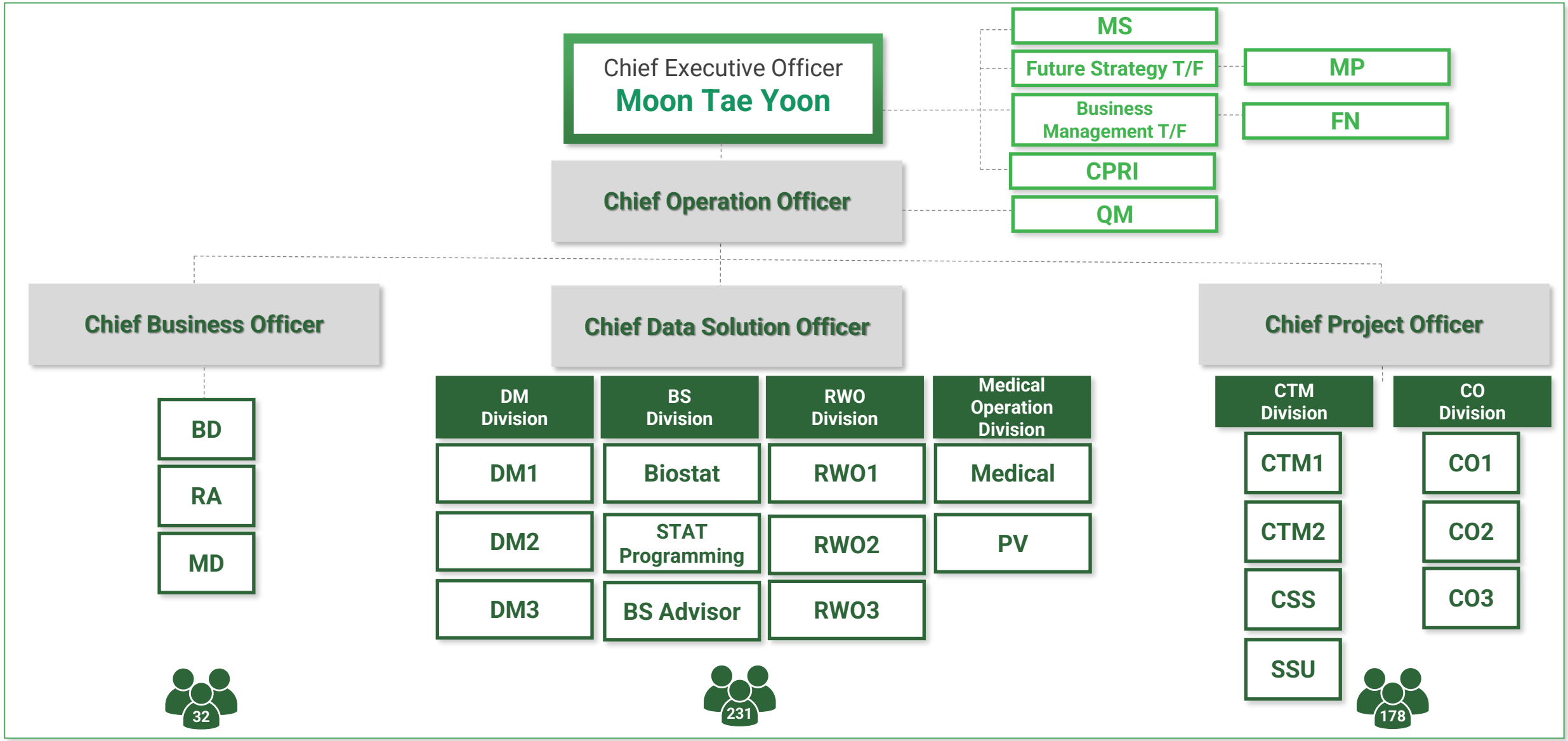
C&R RESEARCH

About C&R Research

C&R Research is South Korea’s the 1st CRO founded in 1997.
As a Full service CRO, we provide a comprehensive scope of services, from clinical trial to regulatory consulting. C&R Research has established a global network, with an exceptional strength in the Asian regions, serving as a gateway into Asia for global partners. As a total value chain CRO, we offer services that extend beyond those of conventional CROs. From drug discovery to commercialization, C&R Research increases capability through constant collaboration with renowned Korean bio-health institutes.

Company	C&R Research
Founded	1997.07.01
Headquarter	Seoul, South Korea
CEO	Moon Tae Yoon
Offices	Global: Singapore, Beijing, US, Thailand Korea: Gangnam (Seoul), Busan
Workforce	500+

Organization



*as of January 2025

Korea's No.1 CRO to Globally Competitive CRO

No.1 in Service Revenue
- No.1 CRO in clinical research for registration (IND/NDA) studies in Korea

Worldwide Network
- Branches in China, Singapore, Thailand, US
- Partnership in U.S., Australia, Europe, Thailand, Philippines, India

Korea's First CRO
- 28 years of experience
- Over 1,800 projects and highly customized solutions
- Strong hospital network for efficient site selection and patient enrollment.

Best Certified CRO In Korea
- Highest Score in 2023 KoNECT CRO Certification Evaluation (PM, DM/STAT)
- ISO 9001:2015 (by International Certification Registrar Ltd.) (2021)

Total Value Chain CRO
- End-to-end solution from drug discovery to commercialization

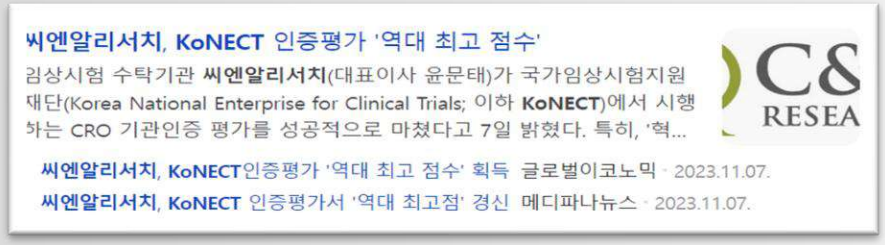
2023 Best Certified CRO In Korea

Project Management

Data Management/Statistics

C&R RESEARCH

- Analysis of External Inspections and Survey Results
- Implementation of ISO 9001 Quality Management System

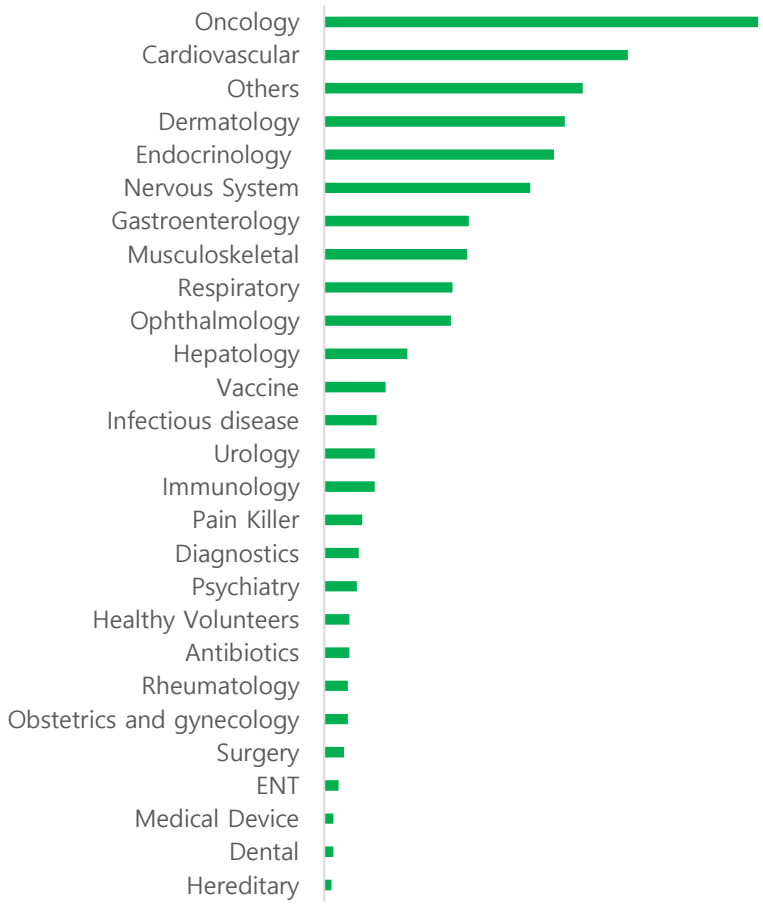


- Received a 'Compliant' Rating in Key Areas of On-site Inspections
- Achieved the Highest Score in 2014 in the KoNECT Institutional Accreditation Assessment

Total Study Experience (2010~2024.4Q)

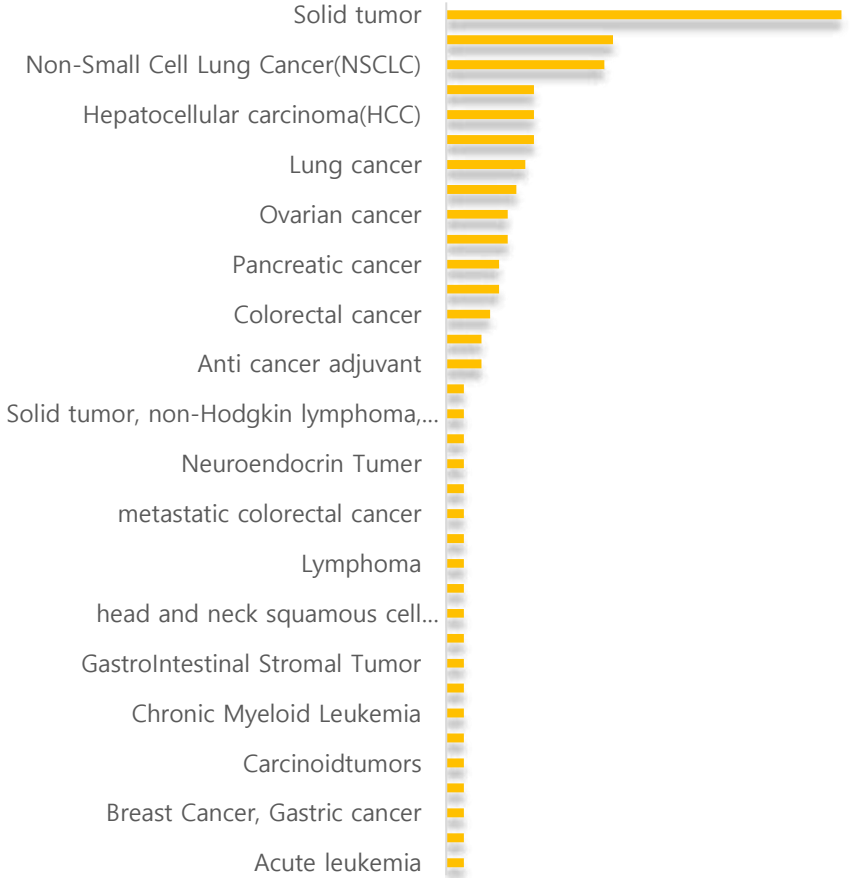
Therapeutic Area / Oncology

Therapeutic Area (1,535)



*Pivotal, Pilot, Post Approval

Oncology (240)



*Pivotal, Pilot, Post Approval

Pivotal, Pilot / Post Approval

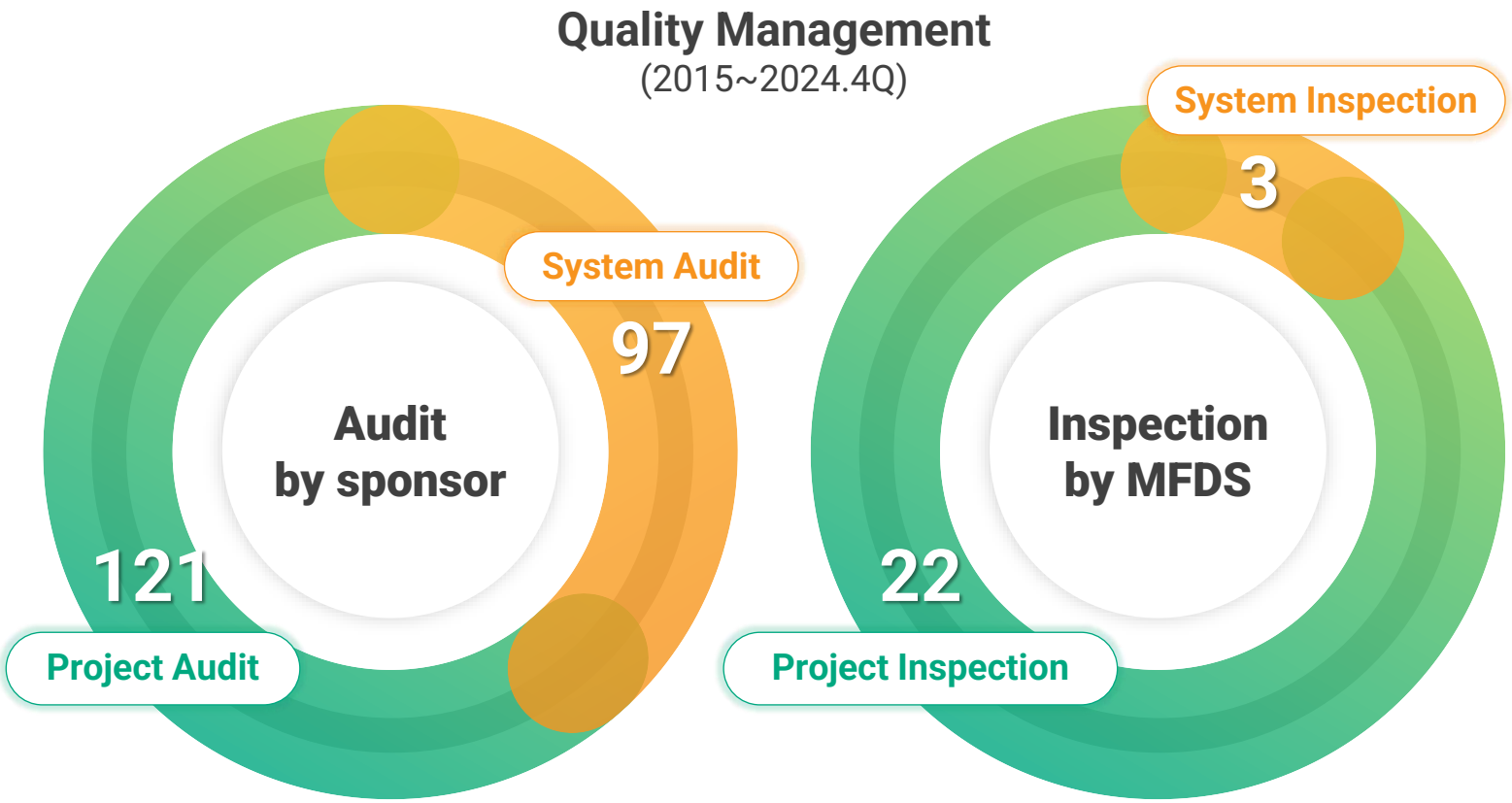
Pivotal, Pilot (918)

Post Approval (617)

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)



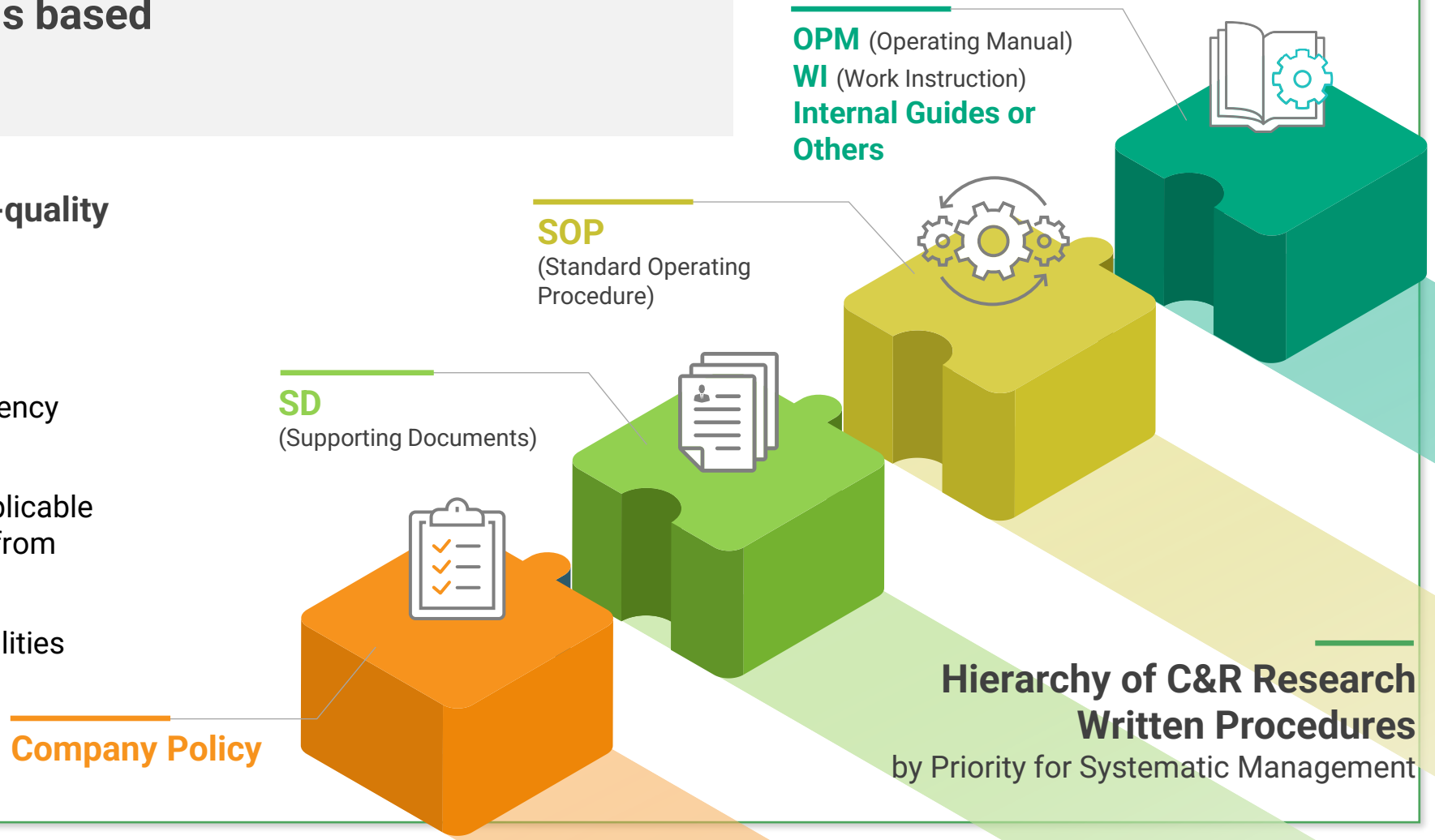
Therapeutic Area In Project Audit	
Antibiotics	2
Anesthesiology	2
Cardiovascular	17
Dermatology	13
Diagnostics	1
Endocrinology/Metabolism	4
ENT (Ear,Nose,Throat)	4
Gastro-intestinal	8
Hepatobilliary(Pancreas)	0
Immunology	2
Infectious disease	2
Medical Device	2
Musculoskeletal	0
Nephrology	0
Neurology	8
Obstetrics and gynecology	0
Oncology	22
Ophthalmology	3
Orthopedics	2
Osteoporosis	0
Pain Killer	0
Respiratory	9
Rheumatology	1
Urology	2
Vaccines	1
Others	16
TOTAL	**121**

Optimization Solutions: Quality Management Systems

Well-Organized SOP Systems based on Local / Global Guidelines

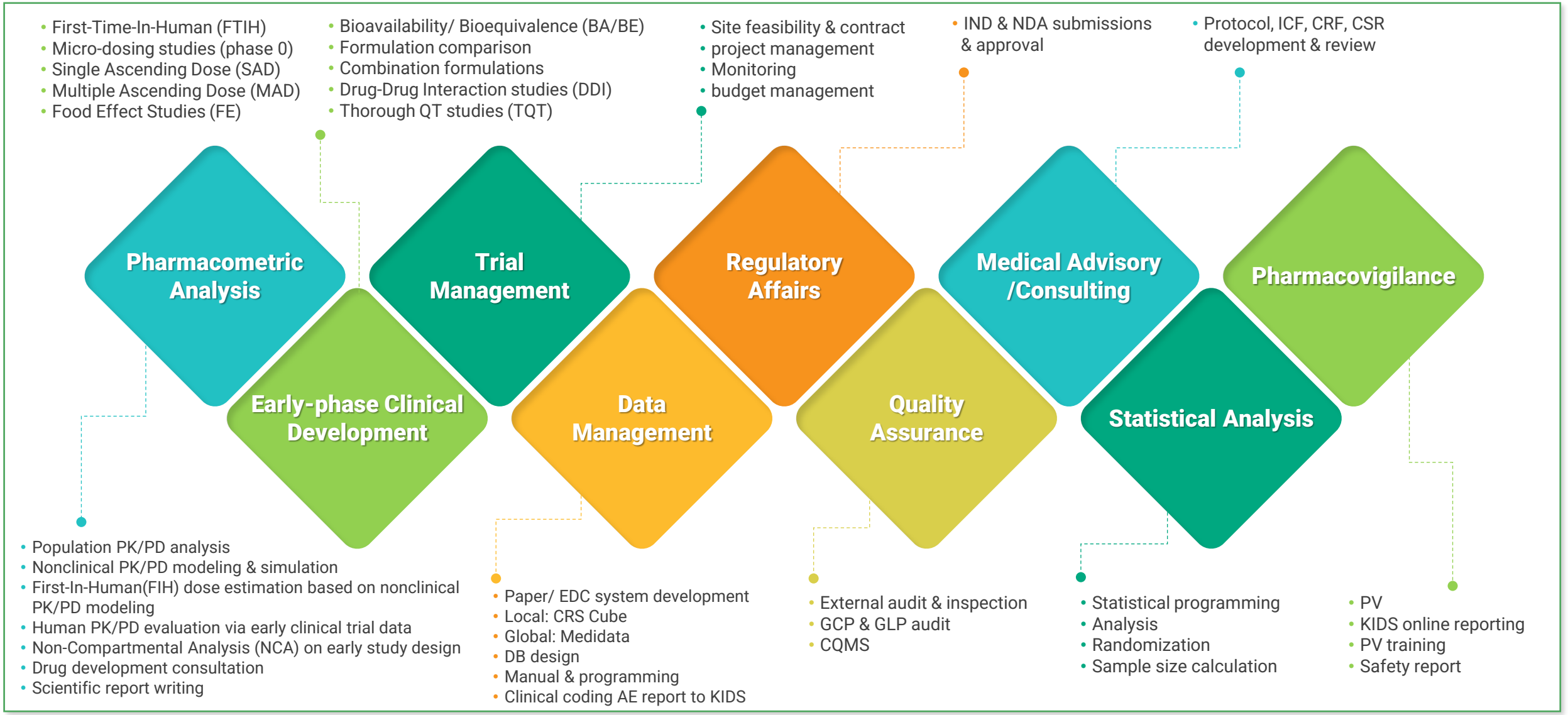
The steps make the following high-quality services available

- Efficient clinical trial
- Maintenance of integrity and consistency in clinical service
- Helping personnel understand all applicable regulations & minimizing deviations from the requirements
- Clearly defining personnel responsibilities



Hierarchy of C&R Research Written Procedures
by Priority for Systematic Management

Service Offerings for Clinical Trials

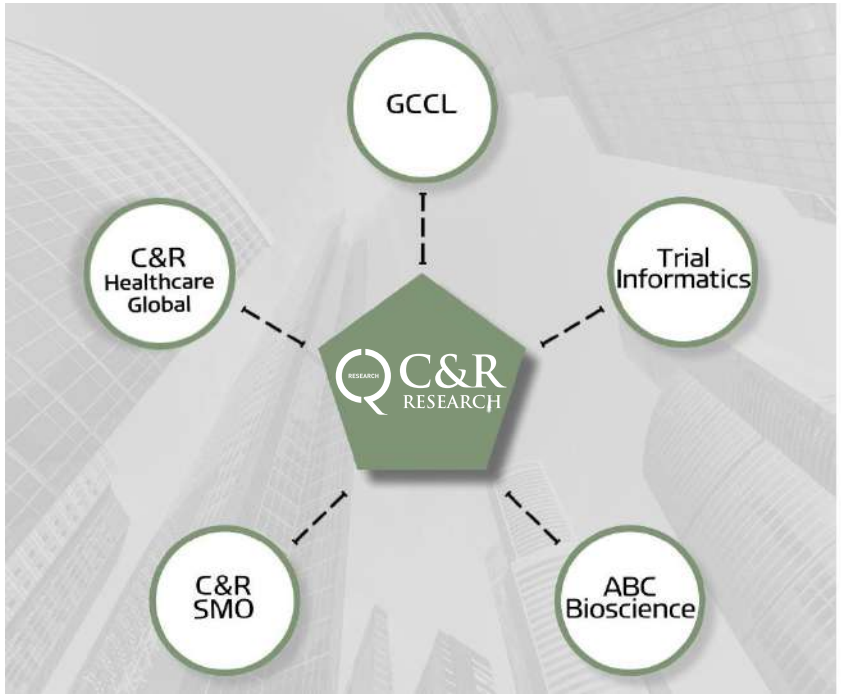


Value Chain CRO

Drug Discovery | Development & Pre-clinical | Phase 0 / Pharmacometrics | Clinical Trials Phase 1-3 | Post-approval | Commercialization /Distribution

GCCL — Global Clinical Central Lab
Trial Informatics
ABC BIOSCIENCE
C&R RESEARCH SMO
C&R HEALTHCARE GLOBAL

Affiliated Company



01 **GCCL**
Global Clinical Central Lab

02 **Trial Informatics**
Imaging IT Solution & Imaging CR

03 **ABC Bioscience**
Early Drug Development Platform

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

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

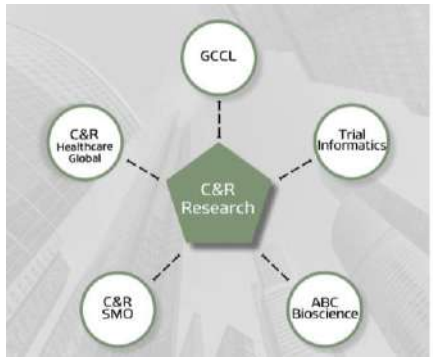
IT Solution

01 **BOIM**
Best Operation Solutions for Innovative Clinical Management

02 **CsafeR**
PV DB & Safety Reporting Management System

03 **Imtrial**
Automatic Clinical Trial Solution

C&R Research Partners & Collaborative Services



01 GCCL
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05 C&R Healthcare Global
Healthcare Acceleration Platform for ASEAN Business Expansion

Drug Development

ABC Bioscience offers comprehensive consulting services for successful drug development, providing full-cycle support from the research stage to early phase clinical trials.

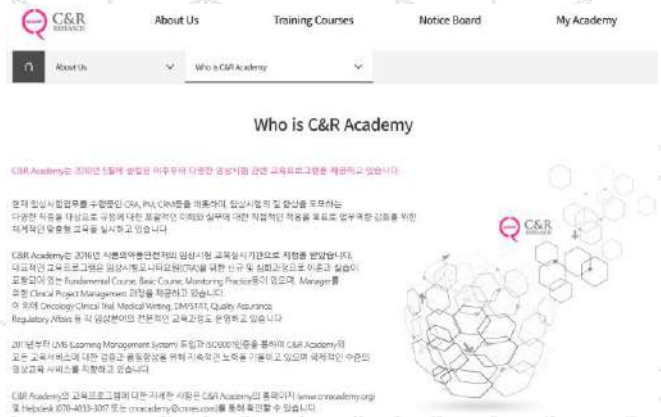
GCCL ,leading Lab CRO specializing in the analysis of clinical trial samples, offering comprehensive services from Phase 1 to Phase 4 for new drug development. GCCL has earned a reputation as a trusted partner, facilitating successful clinical trials not only in Korea but also through Asia and across international borders.

Trial Informatics is a global endpoint player, offering end-to-end clinical trial services integrated with advanced IT solutions.

Central Lab Services

Imaging Solution

Integrated Services



C&R Academy is a clinical training institute 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 expanded its expertise in clinical training beyond the scope of C&R Research, offering education for CRAs of all affiliation.

C&R Healthcare Global is a leading provider of Multi-Regional Clinical Trials(MRCT) services, headquartered in Singapore with subsidiary in Thailand, enabling efficient clinical research throughout the ASEAN region.

C&R Academy

MFDS Designated CRA Training Institute

분류	Course	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
신규	Introduction to Clinical Trial [4H]			6									
	Fundamental of Clinical Trial Process [20H]				10-16				4-8				
	EDC System Basic Training in Clinical Research [4H]		27										
신규 심화	연구비 관리에 대한 이해 [3H]			27					28				
	연구비 정산에 대한 이해 [3H]							28					
	Practical exercise of Source Document Verification [3H]		6										
	항암제 임상시험의 기초 [3H]						16						
신규 심화 보수	GCP R3 Training				28							27	
	CAPA Training [3H]							14		26			
	Regulatory Update for Clinical Research (1) [3H]	23						24					
	Central Monitoring Training [2H]					19							
	의약품 임상시험 목적별 디자인 [2H]					15							
심화 보수	Global Regulatory Affairs [3H]	16										17	
	임상시험 질환 교육_면역항암요법 [3H]											13	
	Oncology in clinical trial_Advanced [4H]							10					
	Basic Course of Clinical Research_Site Visit Reporting Process [8H]					26,27					3,4		
	Clinical Project Management [6H]										16		
	Data Management in Clinical Research [2H]						20						15
	Monitoring Practice for Clinical Research [8H]		17,18								27,28		
	Data Management in Clinical Research (1) [2H]				3								4
	Medical Writing in Clinical Research [4H]					20			5				
	Biostatistics in Clinical Research_ICH E9 (1) [2H]					12					13		
	Quality Assurance in Clinical Research [4H]					22							

- *상기 과정 및 일정은 변동 될 수 있습니다.*

C&R Academy 신규/심화/보수

실시간 비대면 교육

GCP Training Management System

Curriculum & Schedule

https://lms.cnracademy.org

cnracademy@cnrres.com

C&R Academy

MFDS Designated CRA Training Institute

Course
신규 대상
임상시험 입문과정 [1.5H]
신약개발과 임상시험의 이해 [1H]
임상시험 역사 및 윤리에 대한 이해 [1H]
임상시험 설계 및 수행과정에 대한 이해 [1H]
임상시험 시험자 모임 및 개시모임에 대한 이해 [1H]
점검 절차 및 후속조치에 대한 이해 [1H]
임상시험 대상자 동의서의 개발 및 동의 절차에 대한 이해 [1H]
임상시험 모니터링 방문/보고서 [1H]
임상시험 시험기관 및 시험자 선정 방문에 대한 이해 [1H]
Overview of drug development [1H]
Overview of IND, NDA Process [1H]
Overview of Non-Interventional Study_Observational Study [50m]
Overview of Non-Interventional Study_Post-Marketing surveillance [1H]
Overview of Long Term Follow up Study [50m]
Communication Skill [1H]
신규/심화 대상
Overview of Study Start-up & IRB Package preparation for IRB Initial submission [1H]
Biostatistics in Clinical Research_Fundamental [1H]
Data Management in Clinical Research_Fundamental [1H]
신규/심화/보수 대상
GCP Training [4H]
Pharmacovigilance in Clinical trial & Post marketing pharmacovigilance [2H]

Course
심화/보수 대상
Regulation and guideline training for DSUR [2.5H]
Clinical Trial Guidance_Depression [1H]
Clinical Trial Guidance_Ulcerative Colitis [1H]
Clinical Trial Guidance_Peptic Ulcer [1H]
Clinical Trial Guidance_Gastritis [1H]
Clinical Trial Guidance_Rheumatoid Arthritis [1H]
Clinical Trial Guidance_Osteoarthritis [1H]
Clinical Trial Guidance_Osteoporosis [1H]
Clinical Trial Guidance_Gastroesophageal Reflux Disease [1H]
Clinical Trial Guidance_Dyslipidemia [1H]
Clinical Trial Guidance_Hypertension [1H]
Clinical Trial Guidance_Alzheimer's Disease [50m]
Clinical Trial Guidance_Vaccine [1H]
Clinical Trial Guidance_Antibiotics [1H]
Study Start-up_Budget & Contract Negotiation [1H]
MedDRA Terminology Selection [1H]
Safety evaluation in oncology study [1H]
Overview of Response Evaluation Criteria in Solid Tumor(RECIST) [1H]
SAE handling & Reconciliation [1H]
Study Start-up_Budget & Contract Negotiation [1H]

- *신규 CRA 우선 교육 20시간 이상*
- *심화/보수 24시간 이상*
- *온라인 과정 상시 운영 중*

C&R Academy 신규/심화/보수

온라인 녹화 교육

GCP Training Management System

Curriculum & Schedule

https://lms.cnracademy.org

cnracademy@cnrres.com

Early Phase Clinical Trial For Global

01 Oncology Study

02 Global Presence

EARLY PHASE CLINICAL TRIALS FOR GLOBAL

2015~2017

- Fast clinical trial progression using CTN system
- Tax refunds are lower than in the U.S.
- Accessibility to Asia
- Recognition of data from diverse populations

Australia

2018~2019

- Impact of FDA on investment
- Subsequent natural connection to clinical trials

USA

KOREA

2020~

- Trials can be conducted with diverse populations
- Costs are ~50%-60% lower than in the U.S.
- Rapid clinical progression through prior consultation with the MFDS
- Consideration of FDA Pre-IND meetings for data recognition
- Subject enrollment and data compatibility through simultaneous submission to MFDS and EMA.
- Global-level data completion through CDISC application.

Present & Future

- Timeline
- Budget
- People
- Partnership & Commitment

EARLY PHASE CLINICAL TRIALS FOR GLOBAL(Patients- Onco , GCT)

Dose level 5

Dose level 4

Dose level 3

Dose level 2

Dose level 1

Dose level 4+Combination

Dose level 3+Combination

· Optimal dosage for specific cancer types

Cancer 1

Cancer 2

Cancer 3

Monotherapy, Solid tumor

- Rule-based designs
  - Traditional 3+3
  - Accelerated titration designs
  - Pharmacologically guided dose escalation(PGED)
- Rule-based designs

Combination

Expasion

- Phase 1 will be conducted quickly in Korea while concurrently proceeding with FDA Pre-IND.
- Starting from Expansion, it will be conducted in the U.S.
- U.S. cGMP and European EU GMP.

Ideal strategy on clinical trial considering country specific requirements

		FDA (US)	PMDA (Japan)	NMPA(China)	EMA (EU)	MFDS (Korea)
IND	CTD	05/2018 Mandated		09/2021 Mandated	IMPD Mandate * CTD: Module 3,4,5 * IMPD: CTD Module 2	
	CDISC	12/2017 Mandated				
NDA	CTD	05/2017 Mandated	04/2020 Mandated	09/2021 Mandated	01/2020 Mandated Some countries allow non-eCTD submissions.	03/2009 Mandated (new drugs only) 10/2023 Mandated for all drugs
	CDISC	12/2016 Mandated	04/2020 Mandated	09/2019 Mandated		

IND Most countries, excluding the U.S. and China, don't require CTD submission / CDISC submission is only required in the U.S.

NDA CTD submission is required in most countries / CDISC submission is needed only in the U.S. and Japan

Global Study Experience (2016~2024.4Q)

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

Spon.	Indication	Phase	Country
B	Pancreatic Cancer	2	Korea, US, Israel
D	Breast Cancer	2/3	Korea, China, Bulgari, Hungary, Serbia
D	Breast Cancer	2	US, Czech
B	Anti-Cancer	2	China
G	Alzheimer's Disease	2	Australia
S	Solid Cancer	1	Korea, US
P	AML	1	Korea, Spain, Australia
R	Solid Tumor	1	Bulgaria
Y	Antibiotics	2	China
G	Covid-19	1/2	Korea, US
N	Alzheimer's Disease	2	Korea, US
N	Obesity	2	Korea, US
N	Solid Tumor	1	Korea, US
Y	Antibiotics	1	China
J	NASH	1/2	Korea, US
G	Covid-19	2	Korea, US, Bulgaria, North Macedonia,
I	BMD	2	Korea, US
I	DMD	2	Korea, US
R	Wet AMD	3	Korea, US, Russia, Europe (5 countries)
C	Ulcerative Colitis	2	Korea, Bosnia, Serbia, North Macedonia
S	Atopic Dermatitis	1/2	Korea, US
N	Alzheimer's Disease	2	Korea, US
M	Obesity	2	Korea,US
I	Atopic Dermatitis	1/2	Korea,US
T	Diabetes, Hypertension	3	Korea, Thailand
I	Advanced Tumor	1	Korea, US
I	Atopic dermatitis	1/2	US

Spon.	Indication	Phase	Country
S	Solid tumor	2	Korea, US
T	NASH	2	US
N	Obesity	2	US
N	Alzheimer's disease	2	US
A	Solid tumor	1	Korea, US
I	Solid tumor	1	Korea, US

Spon.	Indication	Phase
F	NASH	2
Q	Solid Cancer	1/2
B	COPD	3
B	NSCLC	3
N	GastroIntestinal Stromal Tumor	3
G	Lung cancer	2
B	asthma	3
N	Chronic Myeloid Leukemia	2
B	Stroke	3
G	COPD	2
G	COPD	2
G	Pancreatic cancer	2
B	Type 2 DM	2
B	Lung cancer	2
G	asthma	3
G	SLE	3
G	SLE	3
G	SLE	3
T	Solid tumor	1
M	chronic pulmonary aspergillosis	2
M	Infectious disease	Others

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 임상시험을 주도적으로 수행하기 위한 해외법인을 태국에 설립했다.
태국의 안정적인 의료 인프라와 고품질의 임상시험 인력 등을 바탕으로 동남아시아 시장에서의 임상시험 시장 확장을 계획하고 있다.

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

씨엔알리서치는 "이번 태국 법인 설립은 국내 의뢰사의 동남아시아 수요 대응과 글로벌 임상시험의 자체적인 수행 및 현지 네트워크를 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