We do all of cares for Clinical & Regulatory Research

in a global health care industry

C&R RESEARCH
INTEGRATED SOLUTION PROVIDER

- C&R Research Inc
- C&R-LEWEI JV
  (北京乐维创信医药科技有限公司)
- C&R Research China, Ltd
  (铨维亚医药科技发展(北京)有限公司)
- C&R ACADEMY
- C&R Healthcare Global Pte. Ltd
- C&R QA
- Q-fitter
- LeadTrial

In parallel to the constant growth of clinical research in Korea, C&R Research has grown continuously at a high compound annual growth rate of over 30% from 2004 until present. Now, with the government initiatives and structural changes within the Korean pharma industry, it is the right time for us to advance to the overseas market together with the pharmaceutical and biotech, medical devices companies. For our strategic movements, C&R Research has developed the integrated solutions as follows;

C&R Research China Ltd. (铨维亚医药科技发展(北京)有限公司), CRO & Partnering service provider targeting Korean clients' advancement to China.

A-PACT(Alliance for Pac-Asia Clinical Trials), Asia CRO alliance-consortium (China, Japan, South Korea, Taiwan)

C&R Academy, Clinical Trial Educational Institution authorized by Ministry of Food and Drug Safety

C&R QA Inc., Quality Assurance service provider

Q-fitter Inc., Pharmacometric Consulting service provider with Industry-Academia Collaboration

C&R-LEWEI JV(北京乐维创信医药科技有限公司), CRO service provider targeted to China market with glocalization strategy

C&R Healthcare Global Pte. Ltd., Singapore-based Total Healthcare solution provider with Incubation-Investment fund-Manufacture-Distribution service

LeadTrial, web-based integrated Clinical Trial Platform with EDC, CTMS, IWRS, e-TMF


Do the Best
Be the First

INTRO

With a rich legacy of experience and expertise, C&R Research has partnered with Korea's health and medical industries in clinical development for the past 20 years, since its foundation in 1997.

C&R Research's expertise is backed with over 20 years' experience and global networks. We will spare no effort to provide services customized to the needs of Korean companies in all phases of clinical trials (i.e., from discovery of new chemical entities to commercialization) by improving our global clinical capabilities and reinforcing the platform functions to suggest guidance on the way to rapid and successful advancement of our clients into global arena. It is our ultimate mission to contribute to new drug development and human healthcare as a leading CRO in the long run. Without dwelling on its past brilliant growth, C&R Research is poised for taking off another 20 years of growth and to this end, the company will further strengthen its proactive services and faithfully undertake its assigned role as the best reliable partner to be recognized in the global healthcare industry. We look forward to your continuous patronage and supporting the years to come.

Mission

Be the Competitive and Reliable Partner in Clinical Trials for the Development of New Drugs.
Provide the Total Solutions in Clinical Research with Excellent, Nimble and Proficient World-Class Professionals.

Vision

- Be the Top Market Leader in Asia Pacific & Emerging Markets.
- Be the Market Leader as Global Outsourcing Service Providers.

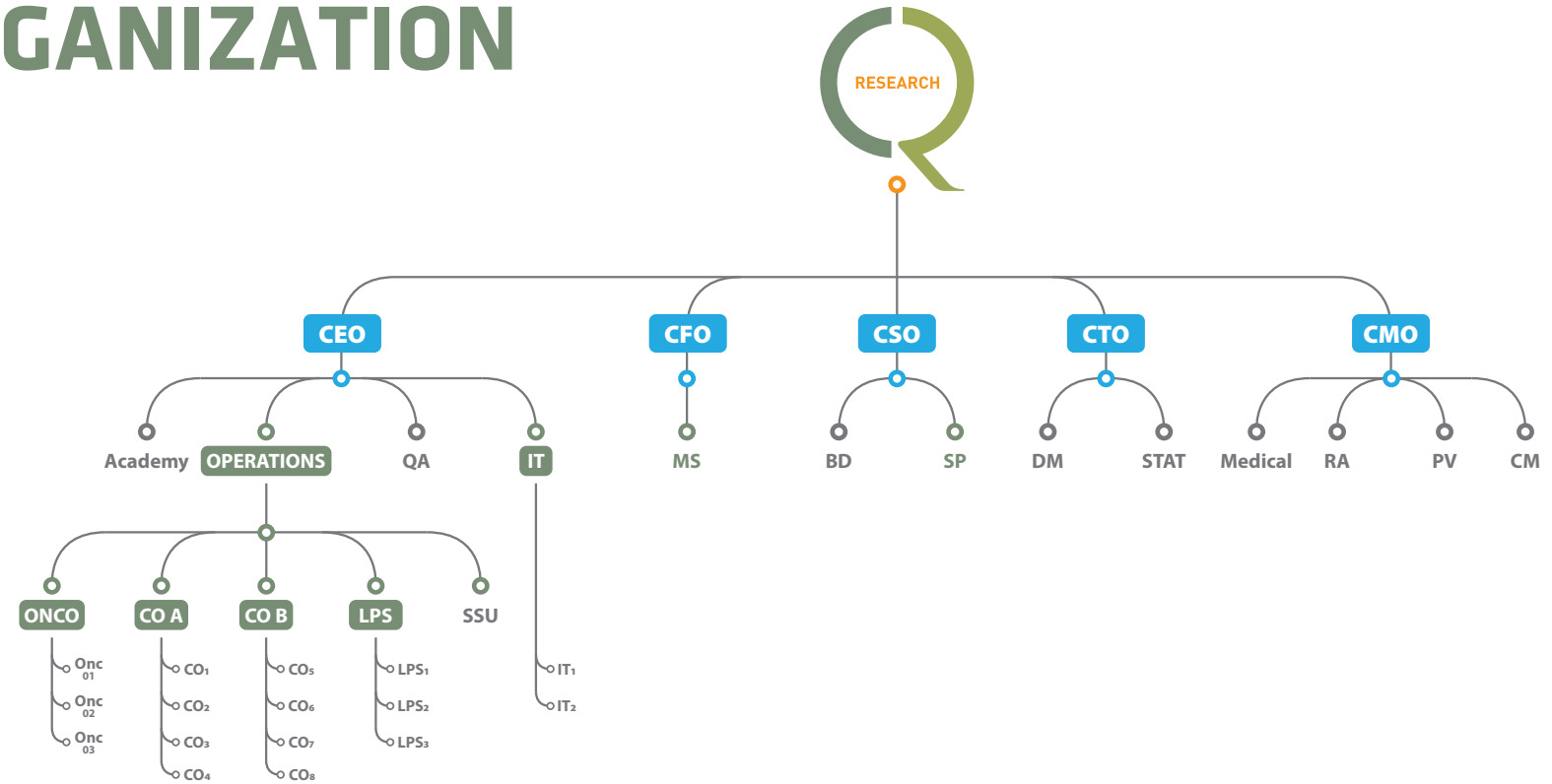
Core value

COMPANY HISTORY

2017	Nov	C&R Healthcare Global signed MOU with Dongguk Univ. Medical R&D center for fusion technology and commercialization
		Hosted 1st Korean - Chinese clinical symposium - Trend Updates in Clinical Trials
	Oct	C&R Healthcare Global signed MOU with US W Medical Strategy Group
		Launched LeadTrial CTMS
	Sep	Established C&R-LEWEI JV in China
		C&R Healthcare Global signed MOU with Singapore Golden Equator
	Aug	C&R QA signed MSA with ADAMAS
	Jul	Hosted 2017 C&R QA Conference
	Jun	Hosted the 4th C&R Symposium – Trend Updates in Clinical Trials
		Participated in DIA 2017 KoNECT delegation
	Apr	Established C&R Healthcare Global Pte. Ltd. in Singapore
	Feb	Hosted a celebration for a foundation of Q-fitter Inc.
	Jan	Signed MOU with Clinical Research Malaysia (CRM) in Malaysia
		Opened Singapore Incubating Center
		Appointed Park Kwan-soo as a new Representative Director and converted into a professional management system
2016	Nov	Participated in the recruitment fair of Seoul Biomedical Conference
		Exhibited a booth in an international conference organized by KoNECT
		Co-hosted a symposium with SCI-C
	Oct	Established Q-fitter Inc. for pharmacometric consulting, a subsidiary of C&R Research
	Aug	Signed MOU with KoNECT forattracting overseas clinical trials into Korea
		C&R ACADEMY achieved ISO9001 certified Quality Management System(ex post facto screening)
	Jun	Hosted the 3rd C&R Symposium – Trend Updates in Clinical Trials
	May	Launched LeadTrial, a web-based integrated platform for conduct and management of clinical trials
		Signed MOU with Severances-Catholic-Inha University Hospitals Consortium (SCI-C)
		Signed MOU with Apollo Bio in China
	Apr	C&R Academy was designated by Ministry of Food and Drug Safety (MFDS) as an official education center for clinical trials, with expansion of its training center
		Signed MOU with Biomedical Research Institute, Inha University Hospital for joint research in clinical trials

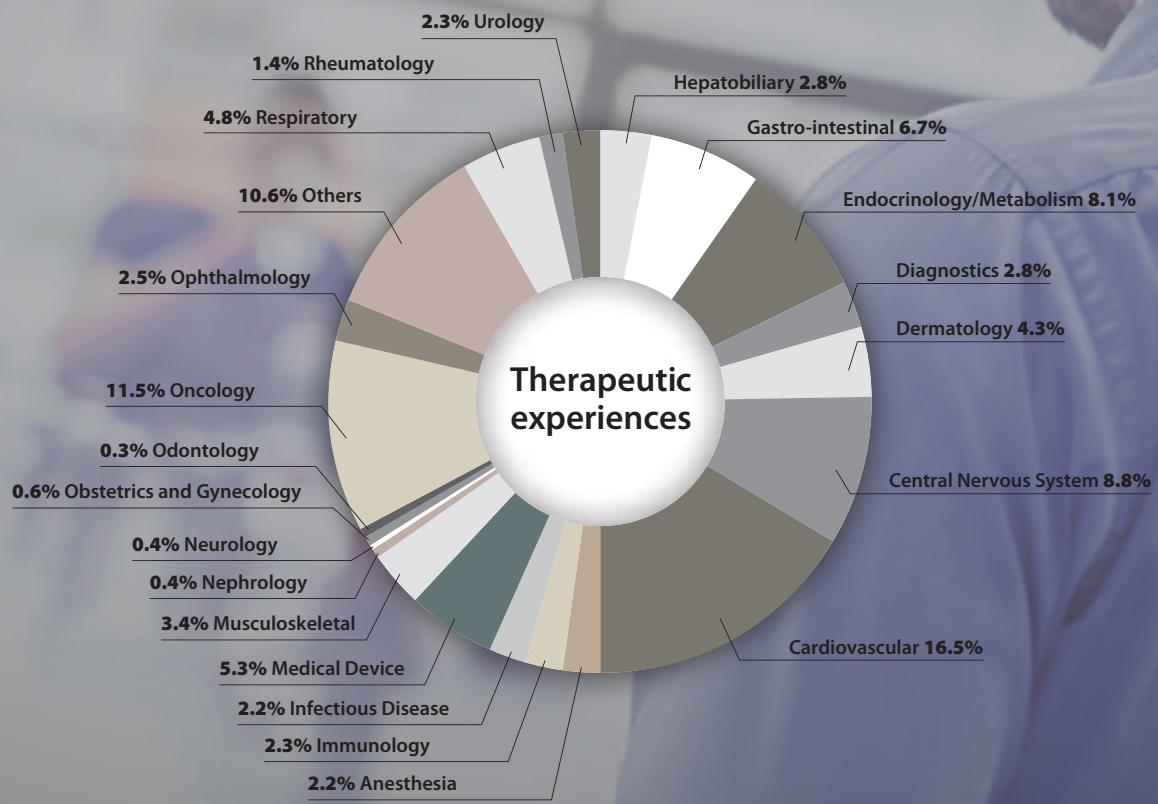
2016	Mar	Signed MOU with Pharmacometrics Institute for Practical Education and Training (PIPET) at Catholic University forpharmacometric consulting service
2015	Dec	Adopted MedidataClinical Cloud
	Nov	Participated in an international conference organized by Korea National Enterprise for Clinical Trials (KoNECT)
	Oct	Participated in Korea-ChinaMedical Device Seminar
		Signed MOU with Tego Sciencefor strategic partnership
		Signed MOU with CTC of Chonnam National University Hospital
	Aug	Signed MOU with CTC of Seoul National University Bundang Hospital for mutual collaboration
	Jul	Hosted the 2nd C&R Symposium – Trend Updates in Clinical Trials
	Jun	Completed the head office building of C&R Research in Gangnam
	May	Lectured by Medical Device Information & Technology Assistance Center (MDITAC); “Medical Device Clinical Trials” (intensified training)
	Apr	Lectured by Korea Medical Devices Industry Association (KMDIA); “National Human Resource Development Consortium Project (CHAMP)”
	Feb	Head of C&R Academy awarded by a Minister of Food and Drug Safety in recognition for “Development of Biopharmaceutical Industry”
	Jan	Completed stage II server duplication: Launch of Net backup solution
2014	Dec	Adopted document centralization and security reinforcement policy (ClouDoc)
	Nov	Lectured on Chinese Course on Drug Development and Regulatory Sciences (CCDRS) in Beijing University
	Oct	Lectured on “New Drug Development and Clinical Research Associates” in College of Pharmacy, Gachon University
	Jul	Separated Quality Assurance (QA) Department as a subsidiary of C&R QA
	Jun	Hosted the 1st C&R Symposium – Trend Updates in Clinical Trials
		Attended 2014 KASBP Spring Symposium
	May	Exhibited a booth in the 8th DIA Annual Conference in Japan for Asian New Drug Development (A-PACT)
		Participated in 2014 BioKorea Business Partnering
		Moved to Seongdong Office
	Mar	Exhibited a booth in 2014 BioPharma ASIA Convention, Singapore (A-PACT)
	Feb	Signed MOU with CTC of Chungnam National University and Meditip for mutual collaboration

ORGANIZATION



EXPERIENCE

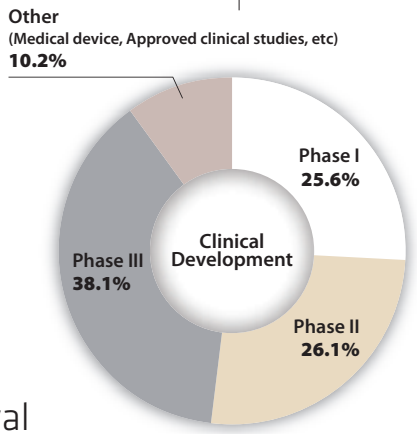
In the past 20 years, C&R Research, Inc. has conducted over 1,200 projects in various therapeutic areas with over 200 customers/clients around the world successfully. From accumulated proven capability, we are the No.1 CRO in the clinical research for registration(IND/NDA) studies in Korea with solid and successful global/multi-national studies experiences.



We've built our strong expertise in oncology, cardiovascular and metabolism/endocrinology as well as infectious disease therapeutic areas in the last decades. Moreover, we've had numerous years of experience in various therapeutic areas.

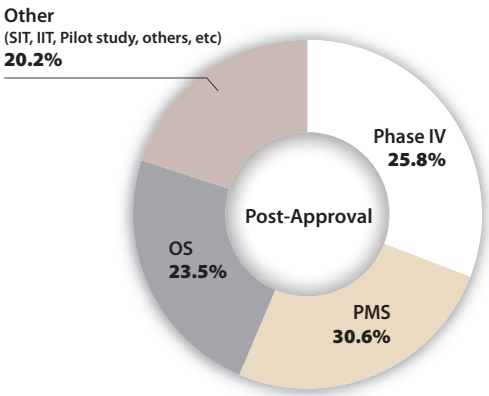
Clinical Development

2011~2015



Post-Approval Study

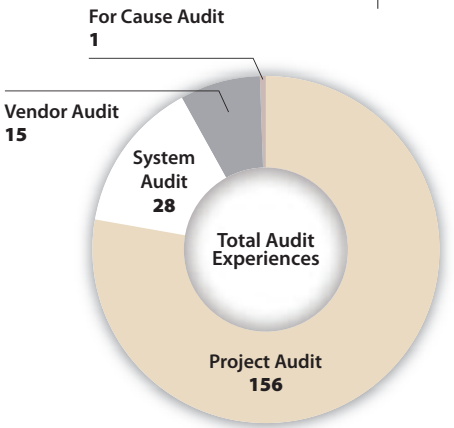
2011~2015



QUALITY MANAGEMENT

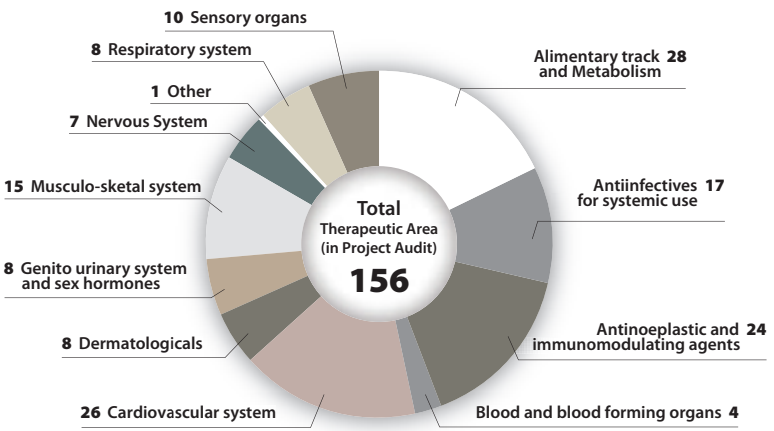
Total Audit Experiences

(~2016 3Q)



Therapeutic Area in Project Audit

(~2016 3Q)



SCOPE OF CLINICAL SERVICES

Regulatory affairs service

- Regulatory strategy consultation
- CMC/ Preclinical Strategy development & preparation
- Preparation, validation, submission and maintenance of regulatory applications
- Regulatory filing assistance
- Local IND/NDA
- International IND/NDA (USA, EU, East Asia including China, ASEAN)
- Product licensing consultation
- Importation of IP and IP supply management
- Communication with health authorities
- Regulatory change reporting
- cGMP/DMF consulting and preparation

Clinical operation service

- Clinical development phase I-IV
- Marketing & observational study
- Feasibility
- Investigator & site selection
- Clinical development planning (CDP)
- Project management
- Investigational staff training
- Pre-study activities/initiation
- Clinical trial management
- Monitoring
- Close out activities

PMS service

- Protocol & CRF development
- Investigational staff training
- Project management
- Data collection and monitoring
- Data entry /query management

Pharmacovigilance service

- Pharmacovigilance system establishment
- Pharmacovigilance writing
- Clinical & post-approved safety data management

Consulting service

- Early clinical development
- Clinical trial development
- Global clinical trial development
- Partnering licensing

Data management service

- Data management plan development
- Customized database design & development
- Verification & edits
- Medical coding by MedDRA, WHO-ART, KIMs etc.
- Double data entry
- Full electronic audit trail
- Data comparison
- Query generation & resolution
- Data transfer & management

Statistical analysis service

- Statistical analysis plan development
- Statistical reports
- Statistical programming & validation
- Statistical consulting

Quality assurance auditing service

- Investigator site audits
- Essential document audits
- System audits
- Pharmacovigilance audits
- GLP audits
- GCP mock inspection/Gap analysis
- Competency check for internal staff

Medical writing service

- Protocol development
- Essential documents development (CRF, ICF, study related materials)
- CSR writing

Translation

- Protocol, informed consent form, clinical study report, IB, IRB submission dossier

Training & operation service

- CRA training
- Project management training
- Site staff training
- In-company customized training
- Online training

Centralized Monitoring service

- Central data review
- Centralized statistical data review

CLINICAL MONITORING

Unique clinical operation teams

Our Clinical Operation team is the largest internal organization consisting of clinical research managers, project managers and CRAs at C&R Research. We have operated 4 segmented teams of CR, Oncology, LPS, SSU, and Centralized Monitoring together with project management group in order to provide customized and specialized clinical research services for our clients.

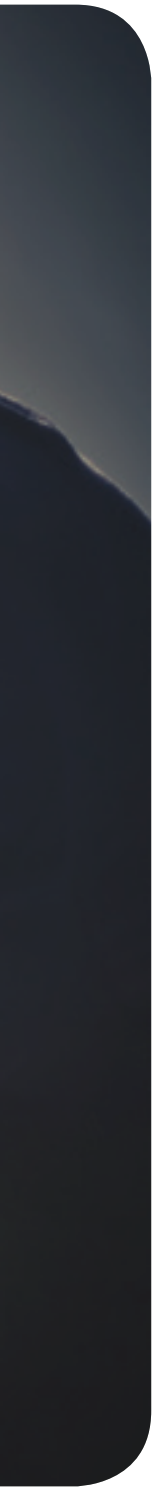
Strong clinical monitoring capabilities

Our rich experiences in various therapeutics areas as well as inspections and audits have allowed our clinical operation team to enhance our monitoring capabilities. Especially, by taking part in many global study opportunities since 2007 provided by global CRO partners, our monitoring capability was strengthened significantly and at the same time, it has contributed to the training of our project managers and CRAs for global EDC systems and global communication.

Project management capability for Asia studies

We have built project management capability for Asia studies provided by Korean and global sponsors effectively.

It is expected for our CRM and PM to contribute to providing value added for our clients by managing comprehensive project progress and CRA training in each local country through strategic communication with our overseas CRO partners and our branch offices based on our know-how and to deal with cultural and regulatory differences and to manage all processes for clinical research as well as country specific issues.



Medical Advisor

C&R Research's Medical Advisory team is composed of MD and pharmacologists. They consult about the key issues that are necessary for the development of protocol synopsis and provide education about the protocol and the major disorders of the study.
Our doctors also provide consultation for the evaluation of validity in medical product and device developments, differentiated strategies to the existing products, and strategies for the overall product development.

Data Management

Data Management Team uses the standard model for electornic data capture (EDC), management and communications. And through the application of various EDC systems, the quality of our clinical data has been enhanced by a systematic approach to quality control.
The standard of domestic clinical data management has advanced to a global standard and so we brought in the global standard format further to contribute in minimizing any unnecessary conversions or integrations of clinical data. The team also offers services to conduct an effective review of the clinical data that is collected by conducting relevant validation processes for the EDC system.

Medical Writing

C&R Research provides comprehensive medical writing services for all points that are necessary for the product and clinical development.
More than 10 writers at C&R Research are pharmacists with vast experiences in medical writing.
We are proud to have our writers' skills and experience in a wide array of document that are complying with all regulatory guidelines and accurately presenting study results.

Biostatistics

Statisticians at C&R Research are composed of more than 10 members with the team leader of more than 10 years of experience.
Our experts provide a complete array of biostatistics analysis and reporting, including but not limited to sample size calculations, randomization schemes, study design & protocol development, statistical analysis plan, data conversion, statistical reports & consulting, and interpretation.

About C&R-LEWEI JV

(北京乐维创信医药科技有限公司)

C&R-LEWEI JV was established between C&R Research Inc. and Beijing Lewei Bio&Tech. Co. in Beijing in 2017 following increasing demand for collaboration and transaction between Korean and Chinese pharmaceutical industry.

Our aim is to create two-way business opportunities between China and Korea which enter pharmaceutical market based on our rich experience and proven knowhow.

- CRO Service
- Regulatory Affair Service
- Market Feasibility Study
- International Pharmaceutical Licensing
- Global Strategic Alliance
- HR Management

Covering a series of Value Chain for New Drug & Medical Device Development in China

A-PACT

THE ALLIANCE FOR PAC-ASIA CLINICAL TRIALS

Who We Are

The A-PACT are the members of the leading CROs in Japan, South Korea, Mainland China and Taiwan. With a unified focus on Pac-Asia region, we are a full service provider with strong local experience in each region, global standards and cost-effectiveness, and a harmonized infrastructure (global SOP) for Asia clinical development.

A-PACT
Alliance for Pac-Asia Clinical Trials

ACM, aiming to be a one-stop service provider as a CRO, has been merged with AGREX INC., specialized for DM, and CRONOVA INC., specialized for clinical studies.

ACメディカル
AGREX Group

With the longest history in Korean CRO industry, C&R has kept its position as market leader since its establishment in 1997. With vast experience, C&R has positioned as No. 1, especially in clinical trial for registration.

RESEARCH C&R RESEARCH

RUNDO is a full service CRO and is the first Chinese CRO to be inspected by FDA with no major observation foundings. It has been awarded “TOP Chinese CRO” in 2014.

RUNDO

VCRO has the longest experience, and the only CRO with 100% GCP inspection approval in Taiwan. Incorporating a full service range from IND to NDA, VCRO is in the leading position of ICH CTD writing and cell therapy trials.

VCRO

Global Business

We take pride in working with a group of experts in the specialized therapeutic areas. We believe that learning about your investigators and patients and the challenges you might face and how you might overcome them are all the things we take into account for a smooth and efficient study progress. This is why we have an extensive network with Pac-Asia site investigators and health authorities, and all of the A-PACT members were selected as a preferred CRO by global pharmas.

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