We do all of cares for Clinical & Regulatory Research

in a global health care industry

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GROW TOGETHER

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 Korean pharmaceutical and biotech companies.

For our strategic movements, C&R China was established in Beijing in 2010, targeting Korean clients' advancement to China. And in 2012, an Asia CRO alliance called, A-PACT (Alliance for Pac-Asia Clinical Trials) was established with the founding members including, C&R Research of South Korea, AC Medical of Japan, Rundo International of Mainland China, and VCRO of Taiwan. We have pursued a strong business and clinical operation with efficient cost as each founding members acquire proven track records and strong local market positions.

We have a promising future to be positioned as a global CRO, growing together with the Korean pharma industry.

INTRO

C&R Research, the first CRO in Korea was incorporated in 1997 leading the development of Korea CRO industry. C&R has since made a phenomenal growth by providing our excellent regulatory and clinical research services for Korea pharmaceutical and healthcare industries encompassing clinical development phase Ⅰ - Ⅲ and post approval clinical studies (phase Ⅳ to observational studies).

Considering market opportunity and threat by various market environmental changes in domestic and overseas pharmaceutical and biotech industry as well as CRO market, we have given our priority to emerging Asia Pacific market and have put our great effort to enter Asia and global clinical research market actively through strategic partnership and our branch office established in Asia Pacific market.

We have strived to provide differentiated clinical research service in aspect of quality and price for our global clients by enhancing three core values of quality, future and people.

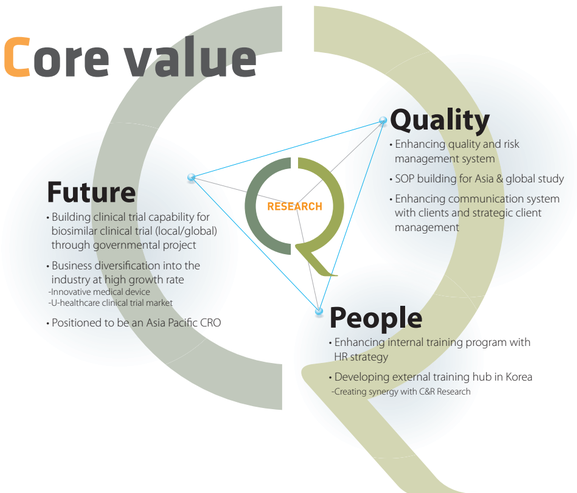
Mission

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

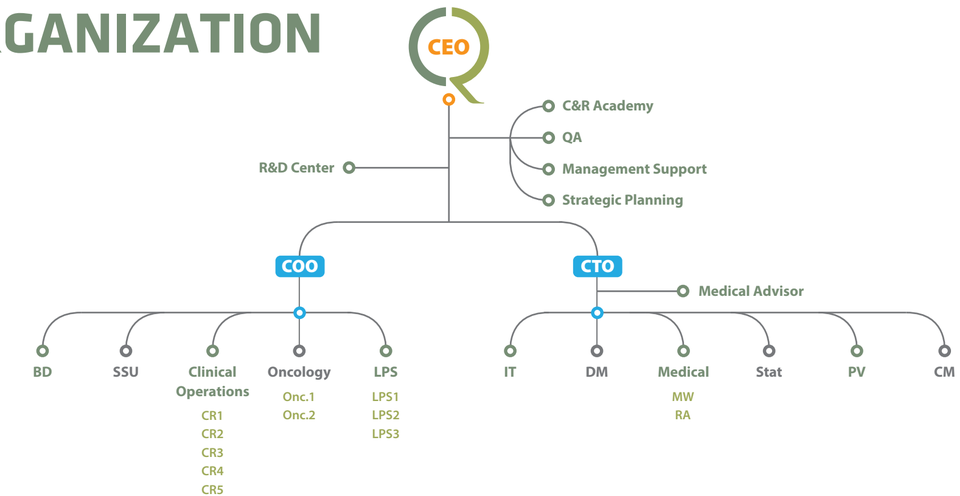


COMPANY HISTORY

2016	Aug	C&R ACADEMY has achieved ISO9001 for post-inspection
	Jun	Signed MOU with KoNECT
		Hosted "C&R Symposium – Trend Updates in Clinical Trials"
		Signed strategic alliance with ApolloBio, China
	May	Launched E-Clinical Trial Platform, "LeadTrial"
		Signed MOU with SCI-C
	Apr	C&R ACADEMY was appointed as an official clinical research training center by MFDS
	Jan	Beijing branch moved to new office
2015	Aug	Signed MOU with CTC of Seoul National University Bundang Hospital for mutual collaboration
	July	Hosted "The 2nd C&R Symposium - Trend Updates in Clinical Trials"
	Jun	Signed $1 billion Enterprise Subscription Agreement with Medidata to provide professional cost effective data mangement services to our clients
	Jun	Completed the head office building of C&R Research in Gangnam
	May	Lectured at Medical Device Information & Technology Assistance Center (MDITAC) on the topic, "Intensified Medical Device Clinical Trials"
	Apr	Lectured at Korea Medical Devices Industry Association (KMDIA) on the topic, "GCP & Clinical Trials of Medical Devices" as one of the "National Human Resource Development Consortium Project"
	Feb	Won the Ministry of Food and Drug Safety Prize for the dedication to development of biopharmaceuticals industry
2014	Dec	Adopted Document Centralization and Security Reinforcement Policy (ClouDoc)
	Nov	Guest lecture at Chinese Course on Drug Development and Regulatory Sciences (CCDRS), Beijing University, China
	Oct	Guest lecture at College of Pharmacy, Gachon University, Korea on the topic, "New Drug Production and Clinical Research Professionals"
	July	Launched C&R QA (a subsidiary of C&R Research)
	June	Attended KASBP Spring Symposium
	May	Exhibited at The 8th DIA Annual Conference in Japan for Asian New Drug Development (A-PACT)
	May	Participated at BioKorea 2014 Business Partnering
	Mar	Exhibited at BioPharma ASIA Convention 2014, Singapore (A-PACT)
	Feb	Signed MOU with CTC of Chungnam National University Hospital and Meditip for mutual collaboration

2013	Dec	Signed Service Partner Agreement with Medidata
	Nov	Presented at The 2nd A*STAR - KHIDI Workshop on Bio/Meditech Innovation 2013
	Nov	Exhibited at The 10th Annual Meeting DIA Japan 2013 (A-PACT)
	Sept	Exhibited at BIO Korea 2013
	Sept	Exhibited at DIA Korea 2013
	May	Signed MOU with Chungbuk National University for PSM (Professional Science Master) Program as Industry-Academy Cooperation
	May	Exhibited at The 2nd Global Clinical Trials Outsourcing Summit (Seoul)
	Apr	Exhibited at The 7th Annual Conference in Japan for Asian New Drug Development (A-PACT)
2012	Nov	Appointed as QA Services Vendor for the Global Lead Clinical Trials Center (Seoul National University Hospital Consortium)
	Oct	Exhibited in the KCROA booth at Bio Korea 2012
	Aug	Launched T-doc (EDC System)
	July	Launched Clinical Quality Management System Service
	May	Established Alliance for Pac-Asia Clinical Trials (A-PACT) with the leading CROs in Japan, Korea, Mainland China, and Taiwan
		Exhibited at DIA 4th Annual China Meeting 2012
	Mar	Launched website for C&R Research China
	Feb	Created Late Phase Study (LPS) Department
2011	Nov	Selected as Preferred CRO by National Onco Venture
		Hosted Strategic Partnership Seminar with Oracle Health Sciences InForm GTM
	Sept	Established C&R Research R&D Center, certified by Korea Industrial Technology Association
	Sept	ISO 9001:2008 certified for "Design, Development, Conduct and Service of Education & training for Clinical Research Professionals"
	July	Exhibited at Inter Biz Bio Partnering & Investment Forum
		Exhibited at New Drugs China 2011
	June	Exhibited at DIA USA 47th Annual Meeting 2011
	May	Launched COSMOS (C&R Optimal SAE Management Operating System)
	Apr	Exhibited at AHC-DIA-IFPMA Asia Regulatory Conference 2011

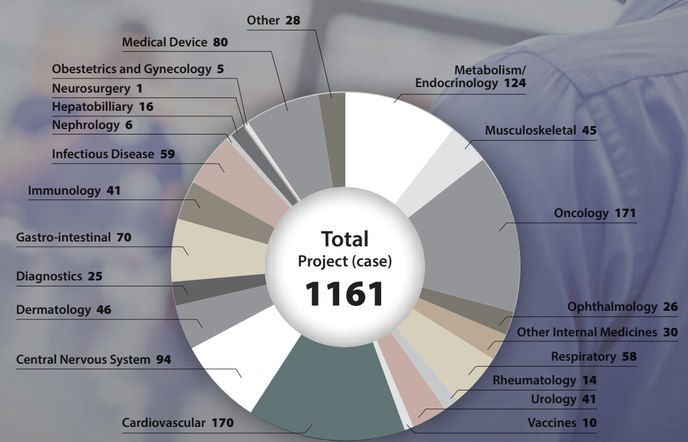
ORGANIZATION






EXPERIENCE

In the past 18 years, C&R Research has implemented over 1161 projects in various global therapeutic areas with over 318 customers/clients around the world. 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 study experiences.

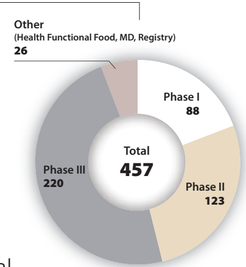


During 2011~2015

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.

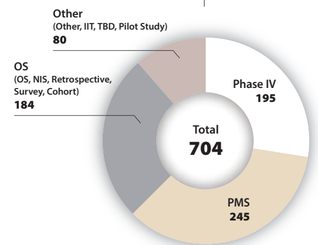
Clinical Development

2011~2015

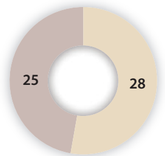


Post-Approval Study

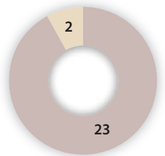
2011~2015



QUALITY MANAGEMENT



Audit by Sponsor
(~2015)
- System Audit
- Project Audit



Inspection by MFDS
(~2015)
- System inspection
- Project inspection

We've successfully passed all of Quality Assurance checks including inspections and audits by regulatory authority(MFDS) and various sponsors without any major findings/concerns.

Quality management for customer satisfaction

We have put our strategic focus on customer satisfaction by enhancing quality management system to build systemic operation procedure for claim handling and internal issue handling as well as periodic customer satisfaction. It is expected to contribute to realization of customer satisfaction management and quantitative quality measurement.

SCOPE OF SERVICE

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)
- 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 & pharmacovigilance service

- Protocol & CRF development
- Investigational staff training
- Project management
- Data collection and monitoring
- Data entry /query management
- Safety report & management
- Periodic and final report writing

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
- Safety management
  -Intensive safety/pharmacovigilance training
  -Timely SAE reporting system set up & maintenance
  -Safety review for initial/follow up report

PM

- CR unit 1/2/3/4/5
- Oncology unit 1/2
- LPS unit 1/2/3
- SSU

CRM

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, and SSU 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.

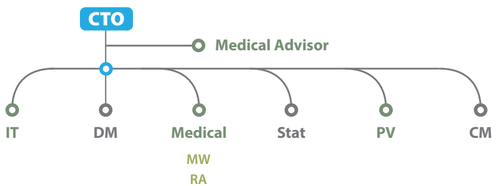
It is expected for our CRM and PM to contribute to providing value added for our clients by managing comprehensive project progress and CRA training in each local country through strategic communication with our overseas CRO partners and our branch offices based on our know-how and to deal with cultural 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.

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.



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.

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 Research China

C&R Research China was established in Beijing in 2010 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 local 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.

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.

Name Card