www.kmri.co.kr



The Best Companion!

KOREA MEDICINE RESEARCH INSTITUTE - CRO

Based on Reliability and Promise, KMRI will accompany you



Introduction



The field of life science now is estimated to be important more than any other time to open the era of life prolongation and abundance wished by all mankind.

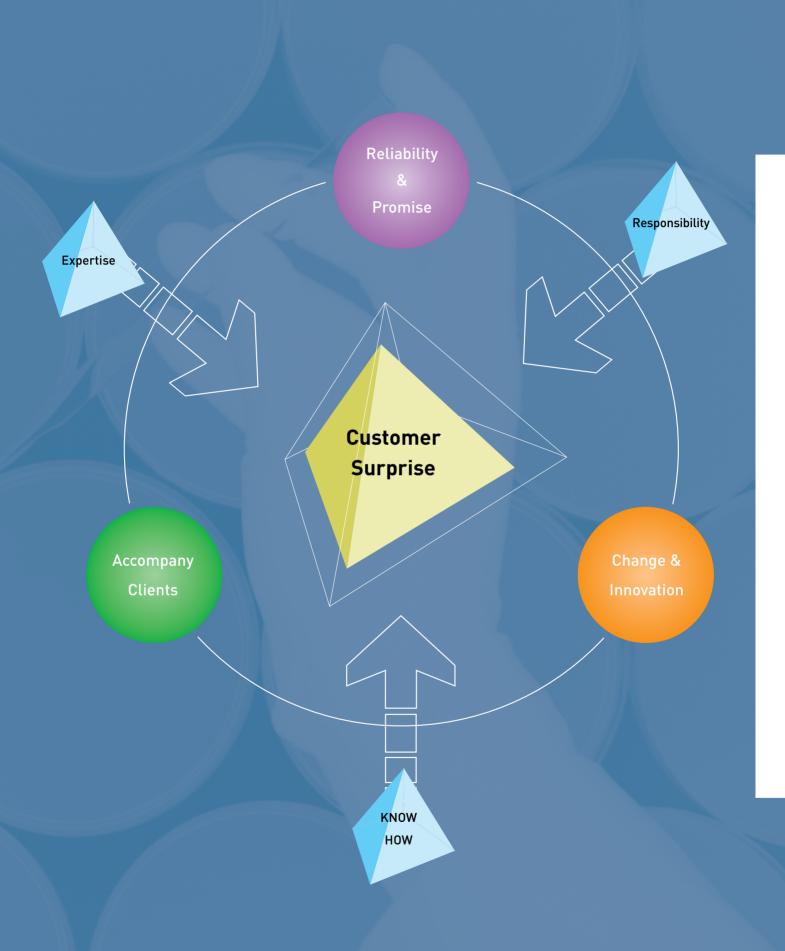
KOREA MEDICINE RESEARCH INSTITUTE (KMRI) is a CRO (Contract Research Organization) established for the purpose of providing clinical trial service and analytical lab service required for development of drugs and quasi-drugs.

KMRI has Clinical Research div. and GLP lab (Bio Analytical div.) together, and provides One-stop Service for early stage clinical trial as a benefit, which proceeds integrated clinical trial and analytical trial at the same time.

Especially, as an officially approved analytical organization with GLP certification by KFDA, it promises to provide you with the best service based on the highest technology and quality.

Every trial taken KMRI is managed under the scientific and organized system in accordance with GCP and GLP regulations based on the quality assurance system and strong ethics, and serves differentiated know-hows.

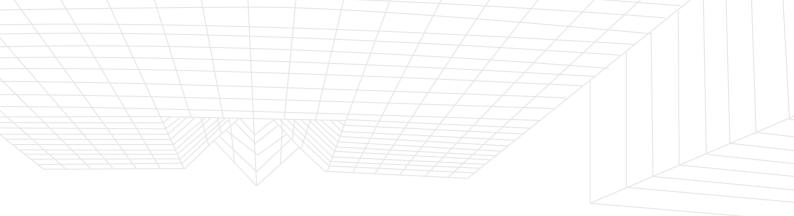
Based on reliability and promise, KMRI will become a CRO developing with you.



Company Profile

CEO	Hohyun Kim, Ph.D
Establishment	2010. 6. 7.
Business Area	Clinical Trials (Medicine, Medical Device) - Clinical Research Service (Phase I~IV) - Bioequivalence Study - DATA Management / Statistical Analysis - Medical Translation Service - Quality Assurance Service Bio-analysis (PK & TK analysis - GLP) - Bio analytical Lab Service - PK & PD Analysis in Clinical & Non-clinical Study
Certification	GLP, MSA (ISO 9001 : 2008 - IAF)
Head Office	B-8F, (WoolimLionsValley 5 Cha), Galmachi-ro 302, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea
Clinical Trial Div.	4F, CC Building, Bongeunsa-ro 439, Gangnam-gu, Seoul, Korea







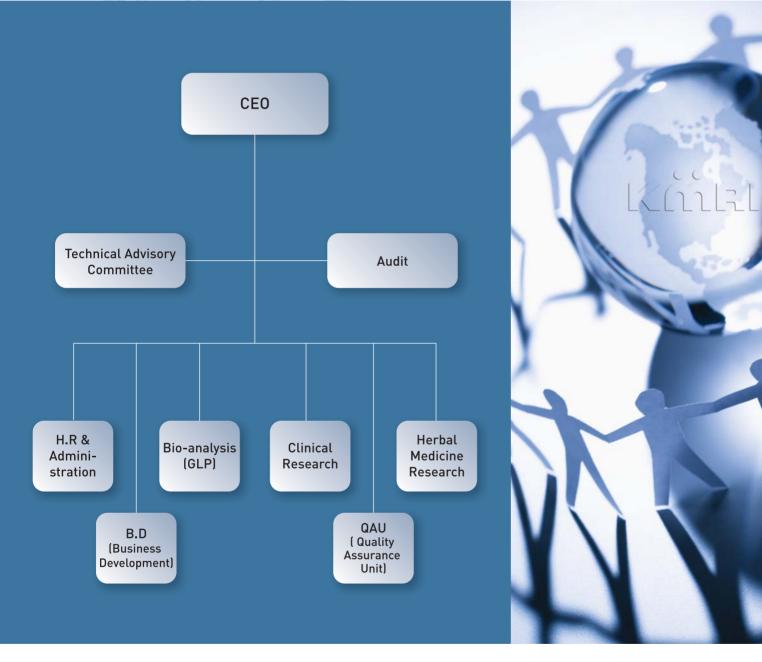


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MSA Certification Co., Ltd.

Medicine Research Institude Inc

Organization Chart



Service area





Client Satisfaction & Value Creation

Clinical Research Service

KMRI provides the clinical Research service which complies with the international standards to KGCP and ICH-GCP Guideline.

KMRI Clinical Research div. has know-hows of numerous clinical tests of various drugs that have a wide range of treatment and skilled experts who carry out tasks fast and precisely, and provides reliability-proven clinical trial documents data through the well-organized QA system.

KMRI maintains a close relationship with the CTC (Clinical Trial Center) of many university hospitals and general hospitals, and increases the quality of clinical trial based on smooth communication with the clinical trial related person such as Principle Investigator and Clinical Research Coordinator.

KMRI has such a benefit as providing One-stop Service for early stage clinical trial to proceed integrated clinical research service and analytical lab service at the same time. Cardiovascular-Hematopoietic system Central nervous system Genito-urinary system Antidiuretics Gastrointestinal-Hepatobiliary system Respiratory system Oncology Allergy & Immune system etc. New Drug Endocrine & Metabolic system Musculoskeletal system Dermatologicals Gout preparations Anti-infectives Endogenous compoun 50 10 20 30 40 Λ

KMAI

Clinical Research Service • Phase I - IV Clinical trial • PV & PMS · Protocol & CRF Development Investigator Recruitment & Site Selection • IRB Submission · Clinical trial management . Monitoring

· Clinica trial Report Writing

Quality Assurance Service

- Project Audit
- In-House Audit • On-Site Audit
- Sponsor Audit
- For-Cause Audit CRO Audit
- System Audit

Statistical Analysis Service • Randomization Code Generation • Sample Size & Power

- Sample Size of Fower
 Calculation
 Statistical Analysis Plan
 Development
 Statistical Programming and
- Validation Statistical Analysis and Reporting Statistical Consulting

Data Management Service • Data Management Plan Development • Detailed CRF Design and Review

- Double-Data Entry
- · Database Quality Check
- Data Validation Specification • Data Transfer

Clinical Research Service

Medical Translation

- Service Investigator Brochures
- Translation
- Protocol Translation
- Informed Consent Form Translation
- Clinical trial Report
- Translation
- · IRB Submission Document Translation

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Project Strategic Planning • Information Searches

- Clinical Plan Development
- Feasibility Study
- Submission Strategy
- Budget Development

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Bioanalytical Lab Service

As an officially approved analytical organization with GLP certification by KFDA, KMRI promises to provide you with the best service on the basis of the highest technology and quality. KMRI Bioanalytical div. consists of bioanalytical experts, and performs analytical tests of biopsy specimen with cutting-edge analytical devices including HPLC, and LC-MS/MS under GLP system which complies with the international standard. A number of analytical methods of drugs are already set up and provides reliability-proven analytical testing data through the well-organized QA system.



Analytical Lab Service

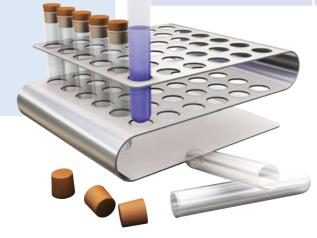
GLP related TK & PK analysis

Method Development Method Validation Analysis of Drug & Metabolites Chiral separation analysis Biosimilar analysis

Facility & Equipments



LC-MS/MS	Thermo, TSQ series mass (Audit trail setting) etc.
LC-MS/MS	Waters, XEVO TQ MS (Audit trail setting) etc.
LC-MS/MS	Waters, XEVO TQ-S (Audit trail setting) etc.
Deep Freezer	SANYO, MDF-U74V less than -70 °C etc.
Deep Freezer	Daihan-sci, WUF-21 less than -70 ℃ etc.
UPS	MAPS-sci, MAPS 3000 etc.
Data Sever	HP server ML110G7 Mirroring : RAID Supported
Backup Server	SUN 4150
Cloud Server (outside)	KT-cloud Server (outside)
Security Server	HP DL360G7 E5606
Automatic call system	SYStronics, SVC2010-VOICE connect the UPS
Automatic call system	Daeil-tech, Automatic call system connect the Refrigerator, Deep freezer [FR01, 02, 04, 05]







Head Office

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Clinical Trial Div.

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