LSK Global PS

A Leading CRO In Asia Pacific

Total Solution to Successful
New Drug Development
from Consulting to Clinical Trials

LSK Global PS

At LSK Global PS, we are dedicated to delivering the most high-quality solutions to promote the health and well-being of individuals worldwide.

LSK Global PS stands out as the premier clinical trial service provider in Asia.
We are committed to advancing the health and happiness of humanity as our top priority.

Vision

A Leading CRO in Asia-Pacific

World Class Clinical Trial Service

Market Expansion for Domestic and Multinational Pharmaceutical Companies

LSK Global PS

A CRO with Global Ambition

- Compliance with Global Standard Quality
- Strategic and High Quality Planning
- Effective Project Management
- Rich Experiences with Global and Local Studies
- Technically Advanced Data Management
- Systematic and Professional Staff Training

LSK Global Pharma Service

Since the year 2000 March, for more than 20 years of the company establishment, we have conducted 1500+ clinical trials which are 800+ intervention studies and 155+ global trials.

20 years of experience in conducting clinical trials on a local and global scale, our extensive knowledge and understanding of the industry consistently deliver high satisfaction and credibility to our clients. With this trusted reputation, we are dedicated to being our client's business partner for successful market expansion.

History

Before 2016

2000.03 Westat- Korea established

2005.01 Initiated CDM System service

2006.01 Partnership with Target Health (US), Inc

2006.05 ACTN (Asia Clinical Trials Network) established

2007.08 Company name changed to LSK Global Pharma Service Co, Ltd

2011.09 Asia CRO Alliance established

2016.06 Medidata CTMS service initiated

2016.08 MFDS designation of LSK Education Centre as a Training Centre for clinical trials service

2017 ~ 2021

2017.03 First Korean CRO to Acquire ISO 9001:2015

2017.11 MOU settlement with a Pre-clinical CRO Chemon

2019.05 Europe Branch(Poland) established

2019.06 CCDM®(Certified Clinical Data Manager) Industry Partners by SCDM

2020.02 LSK Global PS Taiwan Branch established

2020.07 Published "Understanding of clinical trial practice of a leading CRO in Korea"

2021.01 MOU with Korea University Medicine for drug and medical device clinical trial cooperation

2021.03 ISO 14155 certificate for medical device clinical trial management assurance

2021.06 Held the 1st Anticancer Drug Phase 1 Statistical Symposium in 2021

2022 ~ Today

2022.01 MOU with A Leading Yonsei Network for Biopharmaceutical R&D for healthcare Big Data research

2022.04 MOU with CLUPEA for the introduction of CDISC Data Management Platform (MediLake)

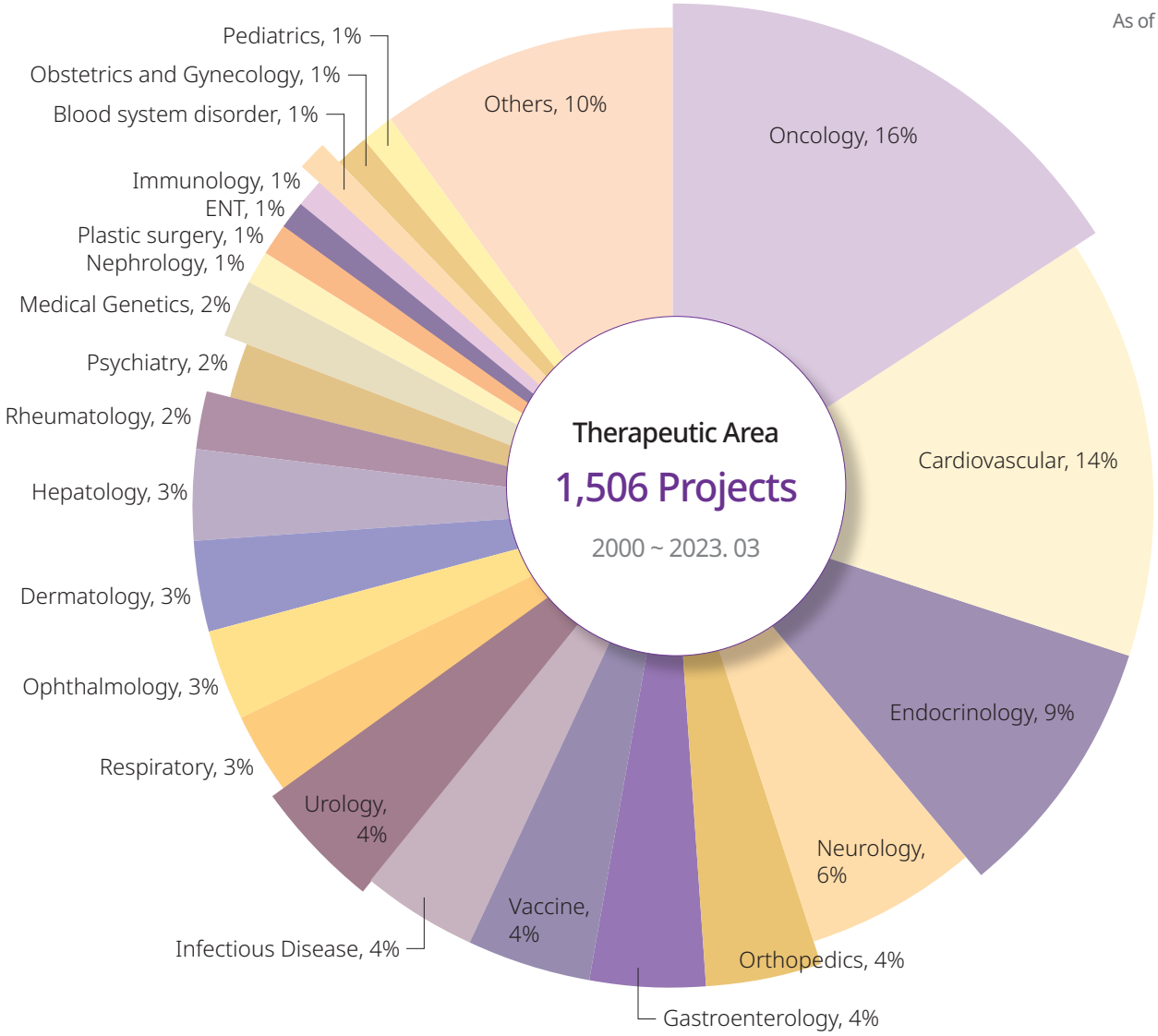
2022.05 Acquired 'ISO 37001:2021'Certification for Anti-Bribery Management System

2023.01 Acquired ISO 27001:2013 certificate for Information Security Management

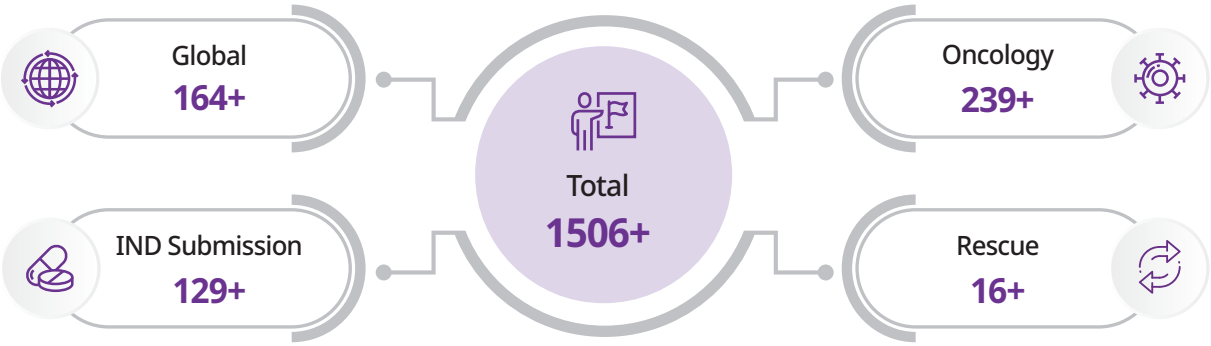
Extensive Therapeutic Experience

Since its establishment in March 2000, and as of March 2023, LSK Global PS has conducted more than 1,500 clinical trials of which 840 IND studies and 160 global clinical trials.

As of 2023.03

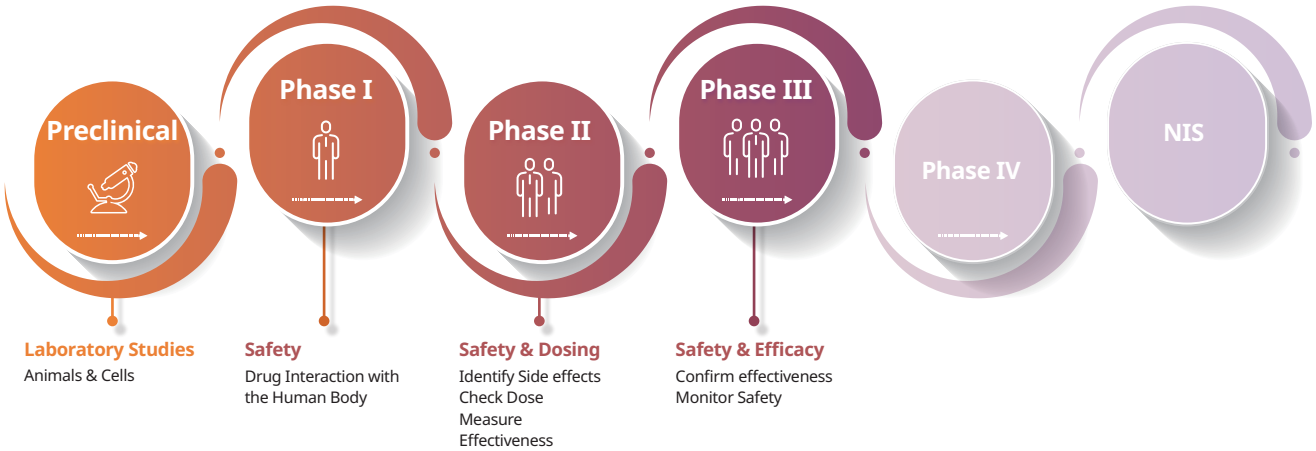


* Others : Anesthesiology, Dental, Hematology, General Surgery, Angina pectoris, Consulting, etc.



Scope of Service

LSK Global PS Consulting and Regulatory Affairs provides the perfect solution for the start of your clinical trial



Regulatory & Medical Consulting

LSK Consulting team medical doctors, statisticians, and new drug development professionals suggest the best solution for a customized drug development from various angles.

Drug Development Consulting

- Product Development Plan
- Non-Clinical Development Plan
- CMC Development Plan
- Regulatory Strategy Consulting
- Bridging Study Strategy

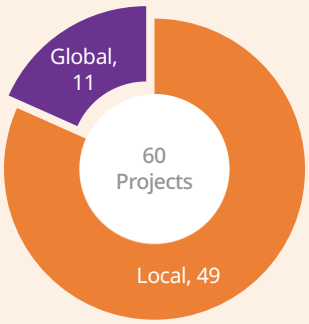
Medical Consulting

- Strategy of Integrated Development Planning
- Target Product Profile
- Clinical Development Plan
- Clinical Trial Design and Strategy
- Medical Training

- 60 domestic and global project consulting experience.
- Awarded to participate in national projects with Korea Biomedicine Industry Association (KoBIA), Korea Health Industry Development Institute (KhiDI), Ministry of SMEs and Startups, and Korea Intellectual Property Strategy Agency (KISTA).

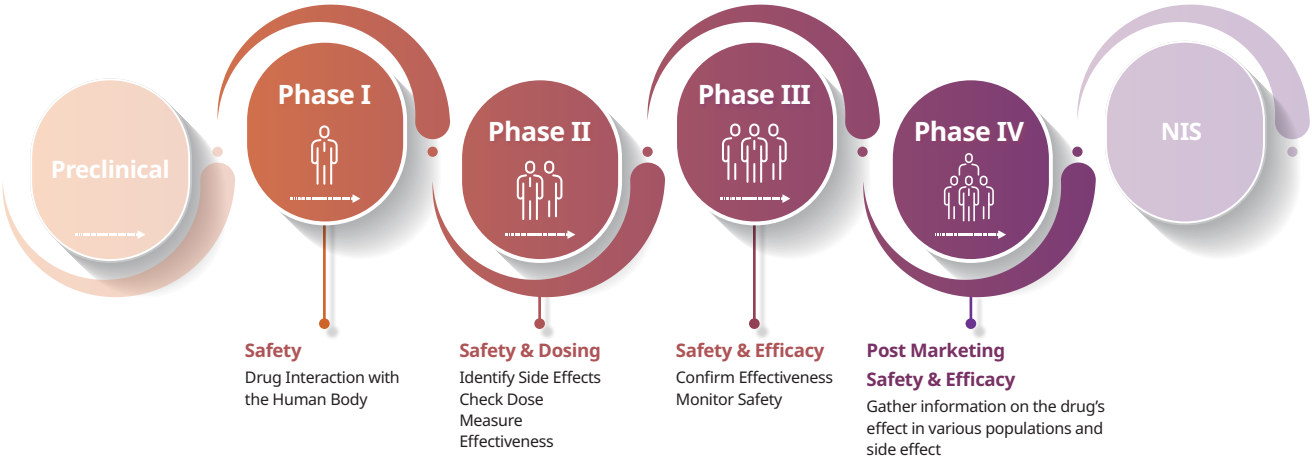
Therapeutic Area

Cardiovascular	Nephrology
Dermatology	Neurology
Diet Supplement	Oncology
Endocrinology	Ophthalmology
Gastroenterology	Orthopedics
Hematology	Rare Disease
Immunology	Respiratory
Infectious Disease	Urology
Medical Genetics	Other Various Indications



As of 2023.03

LSK Global PS IND Clinical Trials, Qualified by Numerous Inspections and Audits



Medical Writing & Regulatory Affairs

Our team of in-house medical doctors employs a rigorous approach in reviewing study designs and reports, meticulously ensuring that our clients receive the utmost high-quality medical writing service.

- 700+ medical writing experience (379 Protocols and 415 CSRs)
- 130+ IND submissions and strategic global clinical trial medical writing.

Medical Writing & Research

- Protocol Development
- ICF Development
- CSR Writing
- CTD Writing

Regulatory Affairs

- IND NDA Package Preparation / Submission
- IP Non-IP Import Permit
- Pre-Submission Meeting
- Gap Analysis for Regulatory Approval
- CMC Writing
- CTD Writing
- Bridging Exemption Report Writing
- Reimbursement Package / Submission

Clinical Research

With the integrated effort of Project Management and Clinical Operation in CR (Clinical Research) Division, our operating system remarkably enhances the management capabilities and operational efficiency.
The synergy between the departments maximizes the opimized communication throughout the entire clinical trial process.

Study Start-Up

- Feasibility (Site / Investigator)
- IRB Submission
- CTA (Clinical Trial Agreement)
- Contract & Budget Negotiation
- PSSV (Remote / On-site)

Clinical Operation

- Monitoring (SIV, MV, COV, Query Resolution etc.)
- Documentation (Collection and Maintenance)
- Safety Management
- Site Management
- Quality Control

Project Management

- Milestone Management
- Risk Mitigation Plan
- Budget Management
- Vendor Management
- Communication Management
- Monitor & Control the Project

Data & Safety

LSK Global PS, as the only CRO in Korea, has a unique seamless data management and pharmacovigilance system within our D&S Division.
We ensure the effective data and safety management, prioritizing integrity and data security in data collection, processing, and safety monitoring.

Data Management

- CRF Development / Design
- Database Design & Study Setup
- Medical Coding
- Data Handling / Validation
- Management of Data Quality & Technical Services
- External Data Management
- Data Science

Pharmacovigilance

- PV System Set-up & Management
- ICSR Processing
- DSUR / PBRER Development
- RMP Development
- Literature Surveillance
- Safety Data Management
- Signal Detection
- Customized Development of PV SOP

Biostatics

Our team of highly experienced biostatisticians provides data analysis that enhances the evaluation of efficacy and safety, delivering insightful and reliable results.
Our comprehensive service includes statistical consulting, statistical analysis planning, generating analysis results tailored to CDISC standards.

Statistical Analysis Service

- Sample Size Calculation
- Randomization
- SAP Development
- Statistical Analysis
- IDMC Support for Interim Analysis
- SAS Programming
- Statistical Report Writing

CDISC

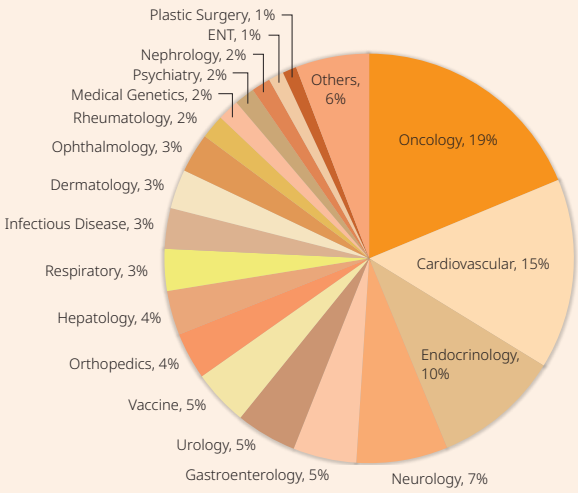
- CDISC SDTM
- CDISC ADaM
- SDTM / ADaM Implementation Consulting

Statistical Research

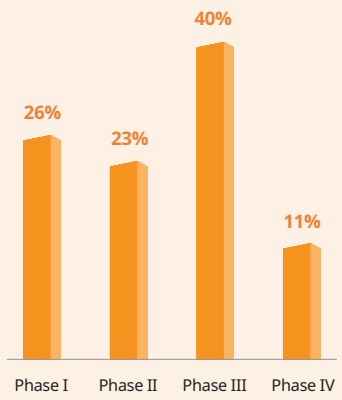
- Statistical Consulting and Study Design
- Sample Size Calculation & Justification
- Modeling & Simulation
- Introduce a new trial design
- Expert in BOIN(Bayesian optimal interval) design approach, Basket trial, etc.

- Various Therapeutic Areas / Study Types Experience

Therapeutic Area



Study Type



* Others : Immunology, OBGY, Dental, Anesthesiology, Pediatrics, etc.

Quality Management

An independent LSK Global PS QA department oversees the clinical trial inspection, SOP development/revision management, CAPA management, client inspection, regulatory due diligence, and SOP training.
Our QA team, consisted of U.S. Registered Quality Assurance Professionals (RQAP-GCP) deliver top-notch inspection services to meet our clients' requirements.

Clinical QMS Service

- SOP and SOP Mapping Management
- SOP Development
- CAPA Management
- Responding to Inspection / Audit
- Trend Analysis and Reporting
- Document Review
- Providing Advice / Training

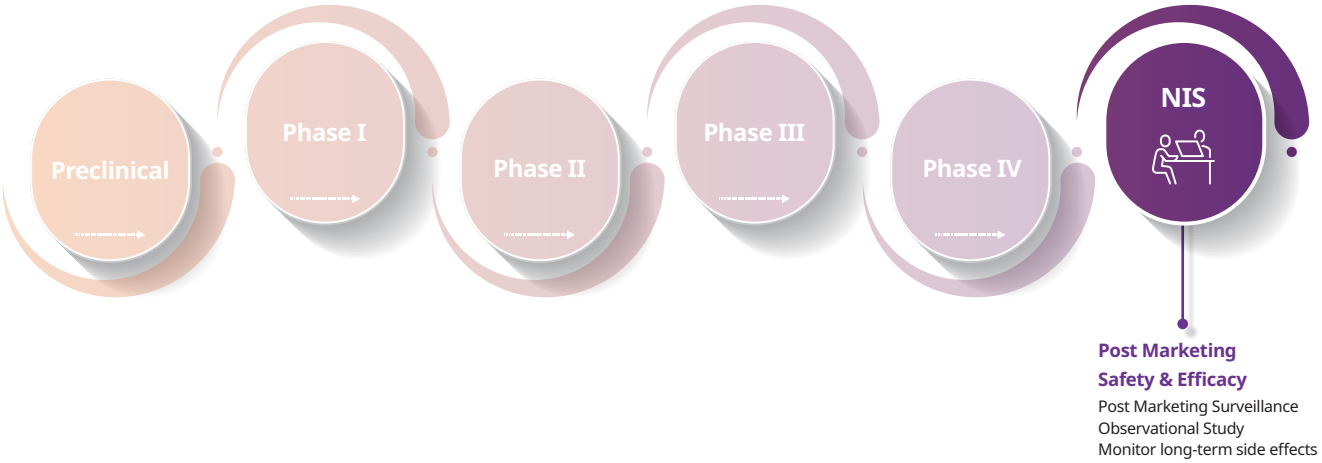
LSK QA Service for Sponsors

- System / Process Audit / Study Specific Audit
- GCP / GVP / GCDMP / GCLP
- Vendor Assessment
- Training / QA Consulting
- Dedicated QM Service

The significance of clinical trial quality assurance is receiving growing recognition, as it enhances organizational and system quality while ensuring the reliability of trial data and results by complying with relevant laws and requirements.

Late Phase Trials with LSK Global PS

Late Phase Specialist Team



Late Phase Study

LSK Global PS established a dedicated department for Epidemiological Research in 2010 to provide specialized services for the entire process. The team specialized in rPMS (regulatory post-marketing survey), Prospective and Retrospective Observation Study and RWD/RWE study with Big Data Analysis.

PMS / Observational Studies

- Safety Study
- Efficacy Study
- Survey
- Drug Utility Research
- Database Research
- Chart Review Study

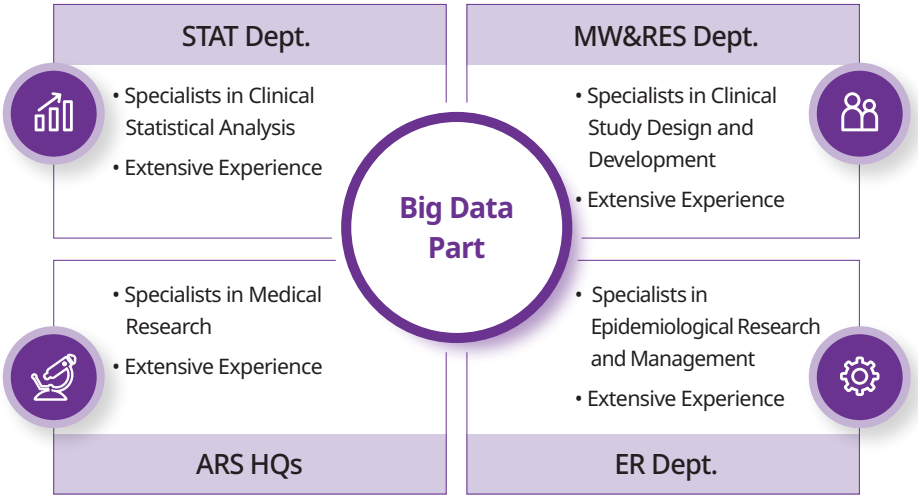
In the Fast-Evolving Industry, LSK Global PS Constantly Provides Highly Professional and Specialized Service

Phase 1 Specialist team

LSK Global PS Phase 1 Specialist Team is dedicated to providing a high-quality, fast, and optimized clinical operation service for Healthy Volunteers (HV) studies. Extensively experienced Clinical Research Managers (CRM) supervise the Phase 1 studies to increase the clinical operation efficiency.

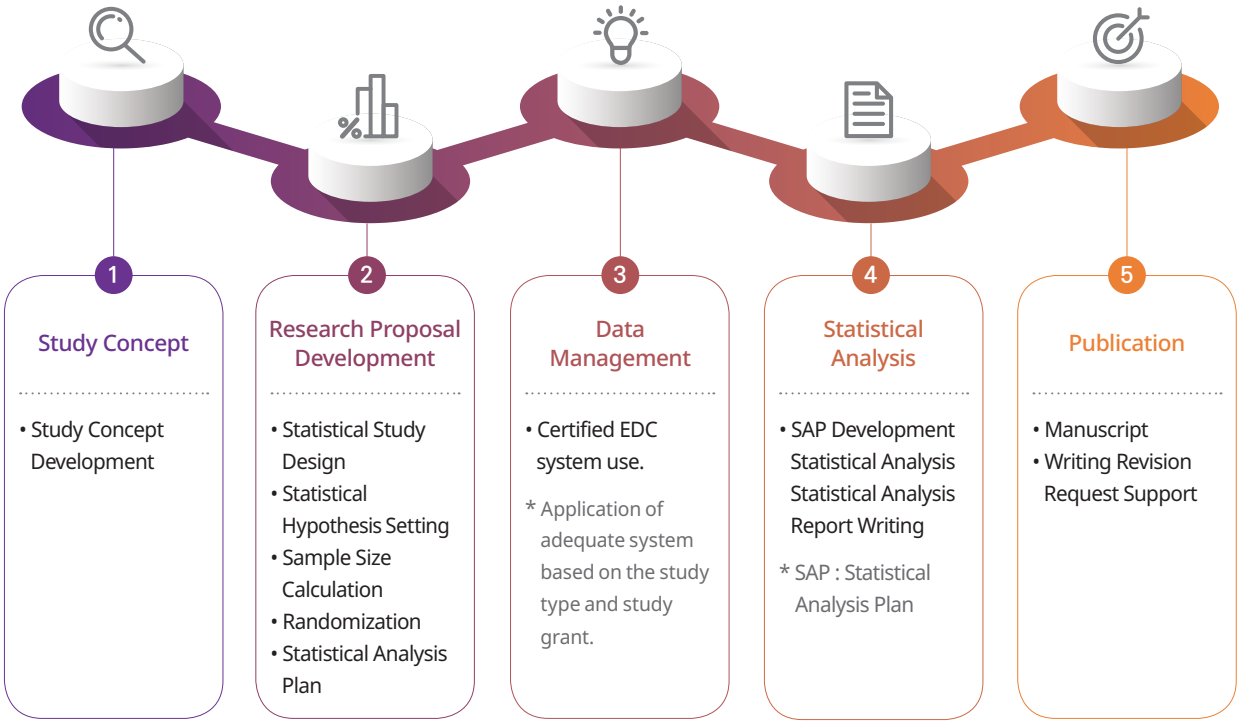
Big Data Part

LSK Global PS Big Data team provides the RWD/RWE service to ensure transparency and objectivity in research design, analysis, and results using real-world databases, health insurance claims, electronic medical records (EMR), patient registration, and surveys.



Academic Research Service (ARS)

LSK Global PS Academic Research Service (ARS) department provides excellent service for academic research based on decades of scientific expertise.
Transparency and objectivity will be the top consideration in research planning and development, research design, data management, statistical analysis, and publication.



Global Clinical Trials

LSK Global PS, fast decision-making with the drug development process.

The accumulated know-how, global standardized operating process, and ICH-GCP guideline complying SOPs allows us to provide expedited solutions to your project.

Our Project Manager minimizes unnecessary burdens in communication and enhances the efficiency of clinical trial management.

Global Project Organization Structure

- MA : Medical Affairs
- MW : Medical Writing
- DM : Data Management
- STAT : Statistical Analysis
- PV : Pharmacovigilance
- PM : Project Management
- RA : Regulatory Affairs
- CO : Clinical Operation

Global Clinical Trial Competency

1 Global Clinical Trials Infrastructure

- Identification of the updated global regulations
- Adoption of international standards in the trial management system
- Provides solutions best suited for local and global clinical trials

2 Global Project Management

- Systematic clinical trial management by LSK Project Manager with extensive global clinical trial experience

3 Global Clinical Trial Conduct Expertise

- Over 160 Global Clinical Trials experience
- Korea's first CRO to successfully complete a large-scale anticancer drugs in the U.S., Europe, and Asia *(95 sites in 12 countries)*

Why LSK?

A Leading CRO in Korea

As the premier CRO in Korea, our dedication extends to facilitating the global expansion of the industry with our exceptional services and expert teams.

Provision of One-Stop Full Service for Entire Cycle of Clinical Trials

LSK Global PS offers top-tier project management and clinical development services throughout the entire clinical trial cycle, leveraging our rich experience, support systems, and world-class infrastructure.

Wide and Diverse Experience in Clinical Trials

Our proven track record of success is evidenced by the 1,500+ projects we have completed across diverse treatment areas and clinical trial phases, each of which attests to our commitment to achieving the highest standards of clinical trial performance.

Study Rescue Experience

LSK Rescue Study process successfully completes the clinical trial projects for multiple sponsors by effectively identifying and addressing challenges encountered during clinical trial operation.

Asia Centric Global CRO Global Standard Quality Services

LSK Global PS clinical trial development and operation have been verified through audits by domestic and non-Korean pharmaceutical companies, CROs, and inspections by the Ministry of Food and Drug Safety (MFDS). In March 2017, we became the first Korean CRO to obtain ISO 9001:2015 certification in all of our service scopes, once again validating our commitment to quality.

Specialized Human Resource

Our team of clinical trial professionals with over 10 years of experience in each service area results in world-class quality data. With three medical specialists (M.D.), we provide medical considerations and advice during new drug and technology development, also conduct medical reviews and safety evaluations throughout each study.
At LSK Global PS, we bring a unique blend of expertise, efficiency, and innovation to every project we undertake, ensuring quality consistency that meets the global standards of clinical trial management.

LSK Global PS

Start with LSK Global PS

97 Toegye-Ro, Coryo Daeyungak Tower 16th Fl. Jung-Gu, Seoul, Korea 04535

Tel 02. 546. 1008
Fax 02. 584. 9008
Inquiry For budget bd_dept@lskglobal.com
General information@lskglobal.com
Website www.lskglobal.com