Data Management at LSK Global PS

CLINICAL DATA **MANAGEMENT**

LSK Global PS Clinical Data Management Headquarters is committed to provide high-quality, fast and proactive data management services in compliance with global standards.

LSK Global PS

WHY LSK CDM?

- **Global EDC Systems Partner**

  Established partnerships with leading EDC technology vendors, provide full-service design, build, and support activities in the following platforms.

  - Medidata® Accredited Partner
  - Target e*studio®, Target Health Inc.

- **Qualified Services**

  Specialized collaboration among well-trained staff for the life of a study.

  - Certified Medical Coder (MedDRA)
  - Medidata Rave Certified Study Builder
  - Medidata Rave Certified Study Administrator
  - SAS® Certified Advanced Programmer
  - Certified Engineer for Information Processing
  - Oracle® Database Certified Professional
  - Certified Java Programmer
  - Certified Clincial Data Manager

- **Data Quality Management**

  Dedicated Quality Control Team for Data Management

- **Proactive**

  Data Awareness & Profiling
  Data management consulting

- **Fast Communication**

No change in orders unless the scope of the project increases significantly

CORE SERVICES

01 Clinical Data Management

- Paper CRF/eCRF design, Database development
- Development of DMP (Data Management Plan) DVS(Data Validation Specification) and other project-specific documnets
- Study setup for EDC ready for sites to use
- Data cleaning through manual reviews and query management
- Medical coding using industry standards (MedDRA/WHODrug)
- Reconciliation of SAE and external data (lab data, etc.)

02 Randomization and Supply Management

- Randomization / IWRS services
- IP supply and inventory management with real-time online report

03 Global Standard Data Format

- Data Consolidation, Migration, Mapping and Conversion of Legacy Data to CDISC/ SDTM Compliant Datasets include Define.XML file

CDISC

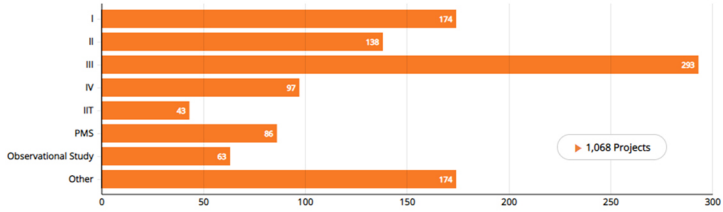
04 Expedited and Efficient Rescue Services

05 Strategic Data Science

ABOUT US

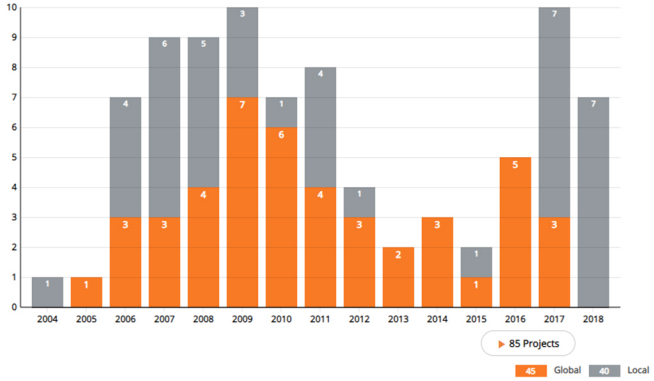
LSK Global Pharma Services Co., Ltd. (LSK Global PS) is a leading Contract Research Organization (CRO) in Korea and is making its endless effort to contribute to the expansion of Korean pharmaceutical industry into the global market.

Study Type Experience



[updated on Dec 31, 2018]

IND Type Experiences



[updated on Dec 31, 2018]

Since March 2000, when LSK Global PS kicked off its business, LSK Global PS has established its position as a one-stop, full-service CRO encompassing all of the major areas of clinical research, i.e. registration trials from phase I to III, investigator-sponsored clinical studies, post-registration studies such as phase IV studies, PMS studies, observational studies, etc., and consulting services for new drug development. As of June 2018, we have conducted about 1068 clinical studies so far, including about 585 registration trials and about 124 global clinical studies.

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