LSK Global PS

Reliable CRO · Technically Advanced CRO · Ethical & Transparent CRO · Quality Oriented Full Service CRO · CRO going Global with Competitive Service Delivery

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LSK CDISC & Analysis Services in Clinical Trial

Automated Approach
Streamlined Processes & Systems

SDTM
CDISC Study Data Tabulation Model

ADaM
CDISC Analysis Dataset Model

Analysis Outputs
Tables, Figures & Listings

Our Vision

LSK Global PS contributes to the entry of domestic **and global** pharmaceutical industry into the **world** market with competitiveness and expertise.

A Leading CRO in Asia-Pacific

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

One-Stop Full Service

Provision of One-Stop Full-Service for entire cycle of clinical trials.
Expertise spanning phases I-IV clinical trials in all major therapeutic areas across drug, biologic, diagnostic, and device.

SDTM

Standardization of study data is needed for submission to regulatory authorities or to integrate with other systems such as data warehouses.

SDTM Specification
SDTM Conversion
SDTM Annotated CRFs
SDTM Define.XML
Study Data Reviewer's Guide

ADaM

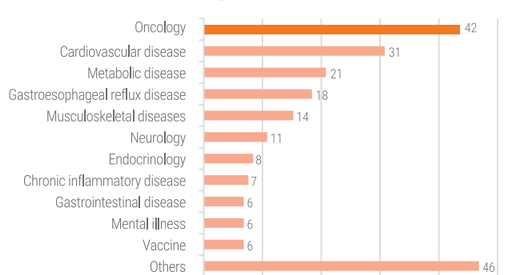
Analysis data are needed for submission to regulatory authorities and the generation of analysis outputs (Tables, Figures and Listings) for a clinical trial.

ADaM Specification
ADaM Conversion
ADaM Define.XML
Analysis Result Metadata
Analysis Data Reviewer's Guide

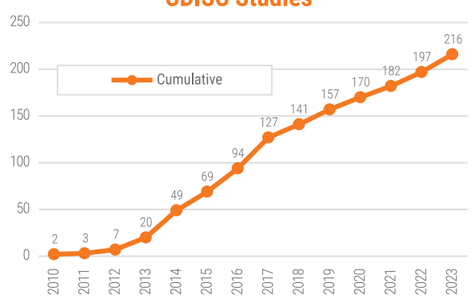
We Started CDISC since 2010!

SDTM Studies 200 + · **Experience 13 years +** · **ADaM Studies 80 +** · **CDISC Specialist 30 +**

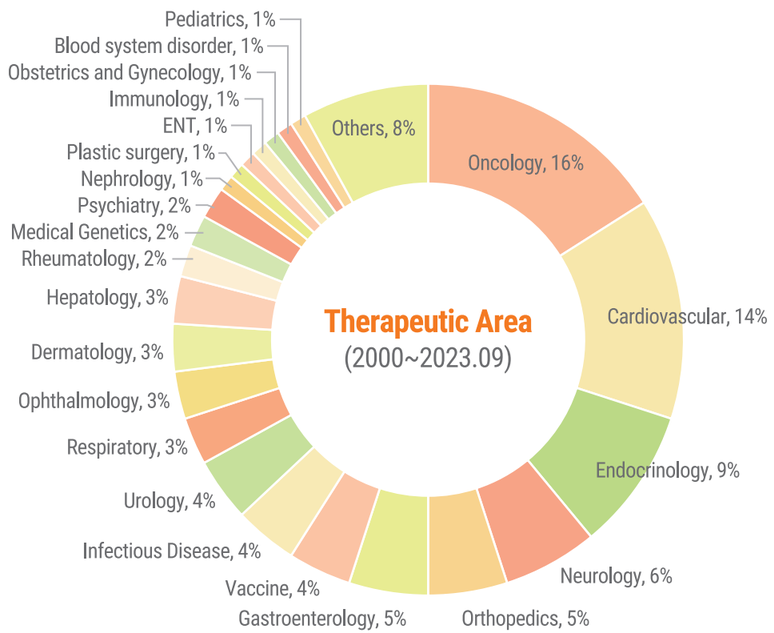
Therapeutic Areas



CDISC Studies



Experience by Therapeutic Area



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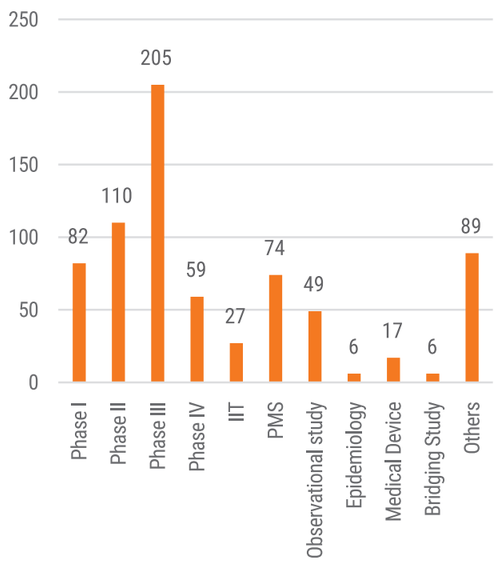
About LSK Statistics Dept.

Our Biostatics Team assists our clients in study design, sample size justification, randomization, CDISC SDTM & ADaM, statistical analysis, IDMC and provide statistical consultation services.

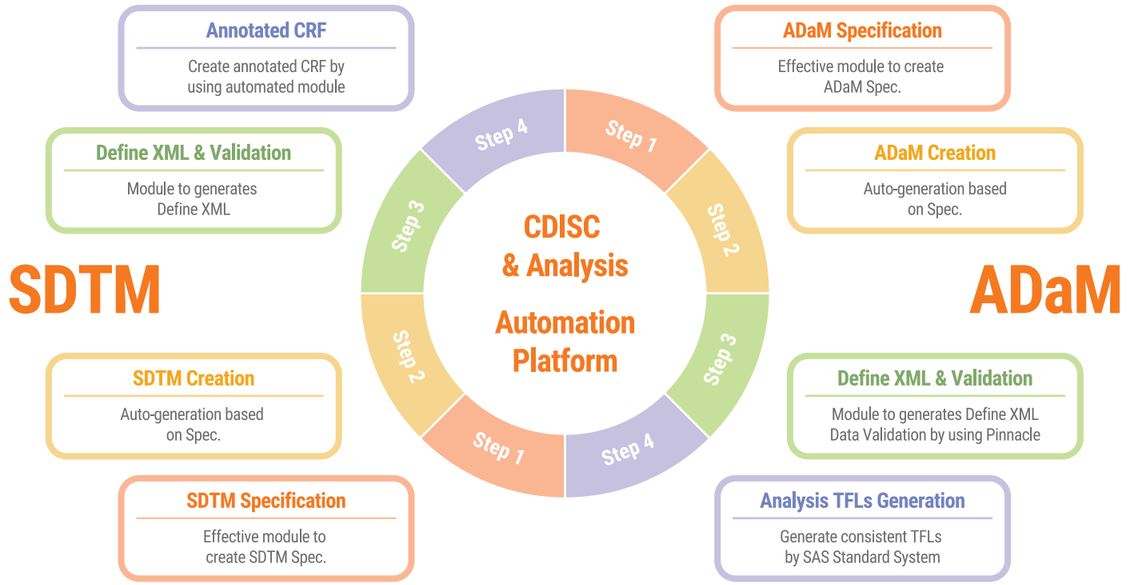
Ph.D statisticians, alongside team leaders with 15+ years of expertise, collaboratively craft tailored study designs for projects and deliver precise statistical services crucial for IND and NDA submissions, ensuring swift and accurate fulfillment of our clients' requirements.

STAT Experience

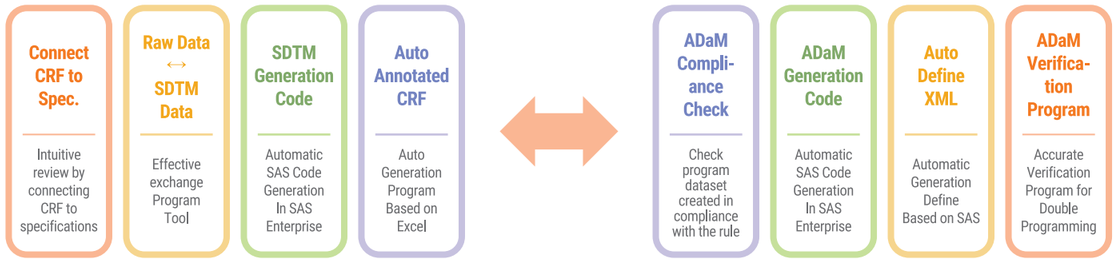


LSK CDISC and Analysis Process

Seamless SDTM & ADaM to Analysis: Elevate Your CDISC Experience with Us



Streamlined Services from SDTM & ADaM to Analysis



Reduce 30% of the Study Timeline and Significant Increase in the Quality

Effective CDISC modules from consistent generation of datasets to TFL generation
Accelerate progress and increase traceability by leveraging faster automated system modules

LSK Statistical Programming

Highly qualified experts specialize in statistical programming and CDISC data standards for clinical trials. CDISC programmers are committed to adhering to CDISC guidelines and maintaining full compliance with the requirements of the FDA in the United States and the PMDA in Japan.

- **Standard macro system for Analysis & QC**
- **Automated conversion to SDTM & ADaM**
- **LSK CDISC Part : Group of CDISC Experts**

Global Regulatory Submission

Successfully executed 17 global regulatory submission tasks, including 8 for the FDA, 2 for the EMA, 3 for the PMDA, and more (as of 2023.03)

CDISC Experience

CDISC Specialist **30 +**	Submission **17 +**
Automation Utility & Tool	Time Saving **30% ↓**