

Statistical Analysis Plan

Protocol No.: DW_DWP14012301

**미란성 위식도역류질환 환자에서 DWP14012의 유효성 및 안전성을
평가하기 위한 다기관, 무작위배정, 이중눈가림, 활성대조, 평행군, 3상,
치료적 확증 임상시험**

**A Multi-Center, Randomized, Double-Blind, Active-controlled, Parallel-
Group, Phase 3, Therapeutic Confirmatory Study to Evaluate the
Efficacy and Safety of DWP14012 in Patients with Erosive
Gastroesophageal Reflux Disease**

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Signature Page

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Why **LSK Global PS** ?

CRO

Leading
CRO
in Korea

20
Years

20 Years
Experience in
Biostatistics

COST

Cost
Effectiveness

Statistical Service Scope

Statistical Consulting and Study Design

- Sample Size Estimation

- (Adaptive) Randomization with IWRS

- CDISC ADaM / Define-XML / Reviewer's Guide

- Statistical Programming and Analysis

- Statistical Report Writing

- IDMC Support for Interim Analysis



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Biostatistics at **LSK Global PS**

Trying Best
for
Error-free Statistics



A Full Service Korean CRO Since Year 2000



Reliable CRO



Technically
Advanced CRO



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Transparent CRO



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Full Service CRO



CRO going Global
with Competitive
Service Delivery

About **LSK** Statistics Dept.

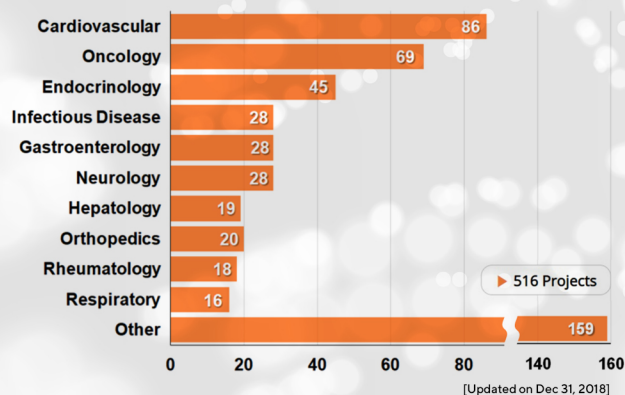
Our Biostatistics Team assists our clients in study design, sample size justification, determination of sample size, randomization, CDISC ADaM, statistical analysis (double programming) and preparation of statistical report and also offer statistical consultation services.

Statisticians with Ph.D. in statistics and managers with over 10 years of experience

work together to propose the study design optimal for each project and to provide statistical services necessary for IND and NDA submissions, thus addressing the needs of our clients accurately and swiftly.

Work Experience in Various Therapeutic Area

Therapeutic Area



Study Design & Sample Size

· Optimal Solution for Clinical Trials

- Group sequential design
- Futility analysis
- Seamless phase II/III trials
- Sample size re-estimation
- Statistical simulations

Statistical Programming

· Specialized in Statistical Programming

- Functional experts in the field of SAS-programming and CDISC data standards

· In-house Developed SAS Macro

- Automated TLFs generation
- Standardized QC process

· Improve Accuracy and Shorten Timeline

Global Data Standard Format

· CDISC ADaM

- Compliance with the requirements of FDA(U.S) and PMDA(Japan)
- Define-XML file and Reviewer's guide

Randomization Services

· Adaptive RDZ with IWRS

· Stratified Block RDZ

· Validated Randomization System

- Target IWRS (Target Health INC, US)
- Rave RTSM (Medidata, US)

Others

· IDMC Support

· Dry Run & Double Programming

· Secure STAT Server System

· Backup System for Disaster Recovery