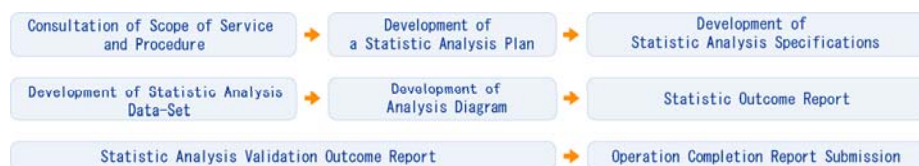


Statistical Analysis

From Development of a Statistical Analysis Plan to Creation of a Statistical Analysis Report

We analyze data and evaluate efficacy and safety relying on a wide range of knowledge and experience of our numerous experts. We are able to provide a series of services related to analytical processing, from development of a statistical analysis plan to creation of a statistical analysis report.



Major Services

- Support for Protocol Development (Including Analysis-Related Portions and Sample Size Design)
- Development of a Statistical Analysis Plan
- Development of an Analysis Program, Output of the Results and Performance of Validation
- Performance of an Interim Analysis
- Preparation of an Analysis at a Key-Opening Meeting
- Development of a Statistical Analysis Report
- Support for Development of a Clinical Study Report (Analysis-Related Portions)
- Performance of Analysis for Development of an Application Dossier (in response to CTD)
- Consulting for Analysis Activities of Clinical Trials

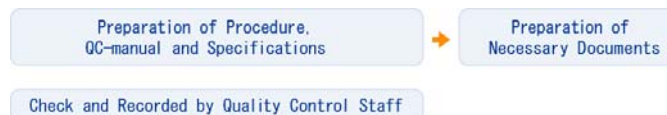
ADVANTAGE of EPS

- By utilizing double programming and double data entry, we assure the quality of analysis programs and outcomes.
- We are able to conduct an interim analysis in various therapeutic areas.
- Based on an abundance of experience, we deliver highly-precise short-term analysis.

Medical Writing

Advice on Effective Regulatory Strategies in Various Therapeutic Areas

From the development planning of a drug or medical device to NDA regulatory approval, we prepare various application documents and reports under strict quality control within the shortest timeline possible. Our experienced staff, having a wide range of expert knowledge in various therapeutic areas, proposes effective regulatory strategies.



Major Services

- Support for Development of Documents for Clinical Trials and Post-Marketing Clinical Studies, etc (Clinical Trial Plan Notifications, Protocol, Informed Consent Written Information, Case Report Forms, Investigator's Brochures, etc)
- Support for the Development of the Various Reports for Clinical Trials (Adverse Drug Reaction Reports, Clinical Study Reports)
- Support for the Development of Documents for Approval Applications and Reexamination Applications (Application Dossiers in Response to CTD, Reexamination Application Dossiers)
- Support for the Development of Thesis Papers, Articles, etc
- Support for the Development of Orphan Drug Designation Application Forms
- Preparation or Revision of Interview Forms
- Regulatory Consulting
- Translation of English Reports into Japanese and Quality Control in Translation
- Translation of Various Reports and Application Documents into English and Quality Control in Translation

ADVANTAGE of EPS

- We actively employ professionals with an emphasis on a high level of appropriate expertise and education.
- By holding extensive detailed discussions with clients and by preparing written specifications and outlines of the reports at services commencement, we strive to fully understand clients' requests and incorporate requests into outcomes.
- Through a standardized process of comprehensive documentation in accordance with established procedures, specifications, and etc, we guarantee the quality of data.