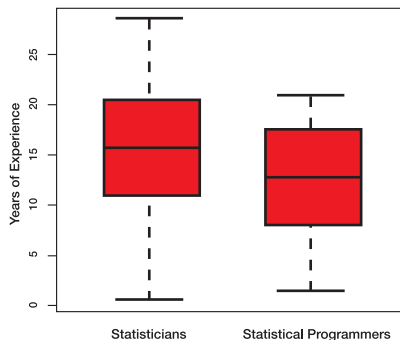


## Statistical Services

### Statistical Services, Data Analysis, and Data Integration



When working with ACCOVION, you will benefit from the proficiency and efficiency of a well-integrated and effectively-sized group of statisticians and statistical programmers with many years of experience in the pharmaceutical and biomedical industries.

**✓ We support your product development in the following areas of nonclinical and clinical development**

- ✓ Statistics for nonclinical studies, including animal toxicology and pharmacology, statistical process and quality control, and stability testing
- ✓ Phase I, including pharmacokinetic and pharmacokinetic/pharmacodynamic studies
- ✓ Pharmacogenomic studies
- ✓ Proof-of-concept studies
- ✓ Dose-ranging studies
- ✓ Pivotal trials in phase III
- ✓ Phase IV studies and investigator-initiated trials
- ✓ Observational studies
- ✓ Post-marketing surveillance
- ✓ Epidemiological and pharmaco-economic analysis

**✓ Our services include**

- ✓ Statistical consulting
- ✓ Trial design and statistical input into study protocols
- ✓ Sample size estimation and power calculations
- ✓ Randomization
- ✓ Statistical analysis plans
- ✓ Programming of tables, listings, and graphs
- ✓ Study reports
- ✓ Design and analysis of group-sequential and adaptive trials
- ✓ Interim analyses, including support of data monitoring committees
- ✓ Integrated databases
- ✓ Integrated safety and efficacy summaries (e.g. for CTD preparation)
- ✓ Meta-analyses and data mining
- ✓ Statistical presentations for regulatory authorities and communication with authorities
- ✓ Publications, conference presentations, and marketing material

- ✓ **The right information at the right time**
- ✓ **Rapid turnaround**
- ✓ **Accurate and reliable results**

for more information visit us at

[www.accovion.com](http://www.accovion.com)

## Statistical Services

✓ At ACCOVION, we use the major IT systems common in drug development. Our statisticians and programmers have extensive expertise with the following statistical software programs

- ✓ SAS® with an extensive library of SAS® programs and macros
- ✓ StatXact®
- ✓ LogXact®
- ✓ WinNonlin®
- ✓ nQuery Advisor®
- ✓ SigmaPlot®
- ✓ S-PLUS®, R
- ✓ Rando® (ACCOVION's proprietary randomization software)
- ✓ SASenv (ACCOVION's proprietary Clintrial®/Oracle Clinical®-SAS®-interface)

Our IT team provides a validated and 21 CFR part 11-compliant environment with the highest standards of data security and systems validation according to FDA guidelines. Systems, data, and programs are hosted in an ISO-9001-certified data center.

**Our experienced statisticians apply the right balance of urgency, quality, and cost.**

**Finding the right solution is our business and reputation.**

Our Good Programming Practice Guidelines and Standard Operating Procedures for quality assurance and validation of statistical programs are part of our quality management system to ensure the highest level of quality in statistical programming and statistical analysis.

We recognize that training is a cornerstone of quality management and our staff members participate regularly in internal and external training events to ensure that they are familiar with the most recent international developments. ACCOVION's statisticians and statistical programmers regularly attend and present at training courses and seminars and at national and international conferences such as the annual meetings of the DIA, the International Biometric Society, the CDISC group, and the SAS Pharma User Group meetings.

*for more information visit us at*

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