

- Project Management
- Study Operations
- Clinical Monitoring
- OSMO – Oncology Site Management Organisation
- Pharmacovigilance
- Health Outcomes Research
- Medical Writing
- Document Management
- Electronic Publishing
- Statistical Programming
- Data Management
- Information Technology
- Quality Assurance

STATISTICAL SERVICES

Data Analysis and Data Integration

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

Do you need...

- ... top line statistical results within days of study completion?
- ... support for your data integration program or CTD/eCTD preparation?
- ... statistical consultancy for the design and management of a complete study or a drug development program?



We are statisticians with PhD or MSc qualifications and highly skilled statistical programmers with many years of experience in the pharmaceutical and bio-medical industries.

✓ We provide statistical services focused on your key medical questions:

- ✓ Statistical consultancy for study protocols and clinical development plans
- ✓ Statistical evaluation of individual datasets and complete studies
- ✓ Statistical reports and integrated clinical study reports
- ✓ Tables, figures, and listings in our standard format or according to your specifications
- ✓ Analysis datasets and integrated databases in CDISC format, thereby fulfilling electronic submission requirements
- ✓ Statistical sections of the common technical document (CTD), and integrated summaries of safety and efficacy
- ✓ Rapid response to inquiries from regulatory authorities
- ✓ Statistical support for presentations and publications

Our verification and validation procedures ensure that all analyses and reports are of the highest quality.

www.accovion.com



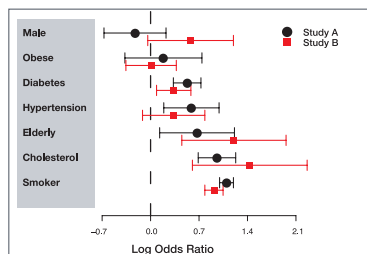
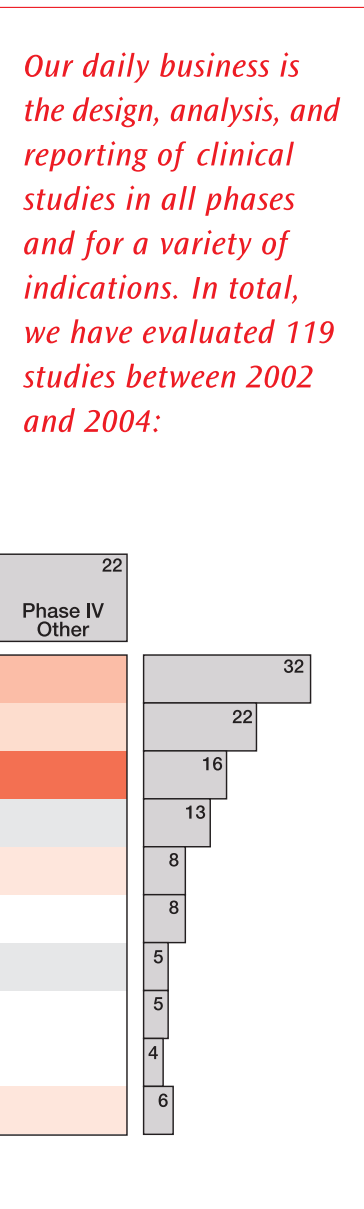
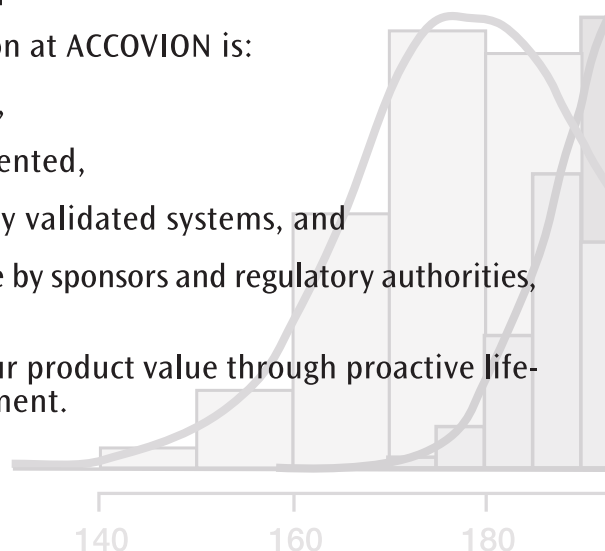
Data integration

Consistent integration of data generated during the drug development process plays a crucial role in the drug approval process.

Data integration at ACCOVION is:

- ✓ transparent,
- ✓ well documented,
- ✓ generated by validated systems, and
- ✓ reproducible by sponsors and regulatory authorities,

to enhance your product value through proactive life-cycle management.

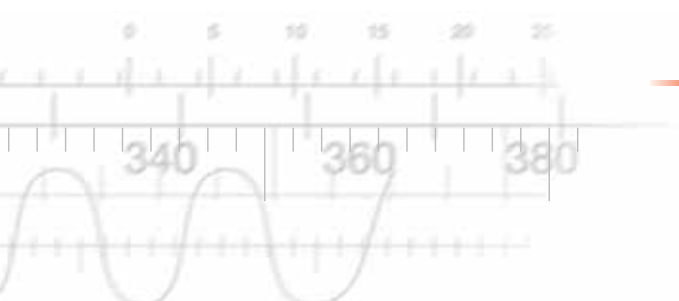


Data integration

- ✓ Data integration by ACCOVION simplifies the aggregation of heterogeneous data from multiple studies and various vendors.
- ✓ We were among the first to use CDISC standards for data integration.
- ✓ We developed validated software tools for the mapping of data based on SAS macros.
- ✓ ACCOVION statisticians and programmers have created numerous integrated safety and efficacy databases.

To accelerate your clinical development program, we recommend starting cumulative data integration as early as proof-of-concept has been established. This ensures that the safety and efficacy summaries will be provided shortly after database closure for the last study and that the submission will be performed without delay and based on reliable results.

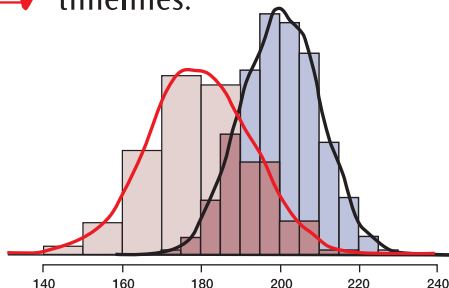
Accelerated summary and analysis of data lead to earlier marketing approval.



Statistical Consulting

We know how to design studies to find the right balance between:

- ✓ scientific advice,
- ✓ ethical and regulatory guidance,
- ✓ marketing strategy,
- ✓ budget constraints, and
- ✓ timelines.



Whether your study is

- ✓ an early phase study,
- ✓ a pivotal study, or
- ✓ a marketing study,

ACCOVION can provide the right solution. We help you avoid needless complexity, errors, and excessive cost.

—✓ Early proof-of-concept will be enabled by the use of innovative study designs (e.g. internal pilot studies or adaptive designs).

—✓ Your study will be optimized with the selection of an appropriate statistical strategy for testing and parameter estimation.

Whatever your objectives are:

- ✓— superiority,
- ✓— non-inferiority, or
- ✓— equivalence,

we will identify a strategy that

- ✓— complies with regulatory guidelines,
- ✓— maximizes the chance of success, and
- ✓— supports your marketing strategies.

—✓ ACCOVION statisticians understand the balance between clinical science, sound methodology, and financial constraints, and can determine a sample size to suit the questions you wish to answer.



If desired, we will perform interim analyses to enable sample size adjustments and early decision making on critical development milestones as required by your executive management.

Finding the right solution is our business and reputation.

Contact us to access the right information at the right time from ACCOVION!

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ACCOVION. Global reach. Personal touch.

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