

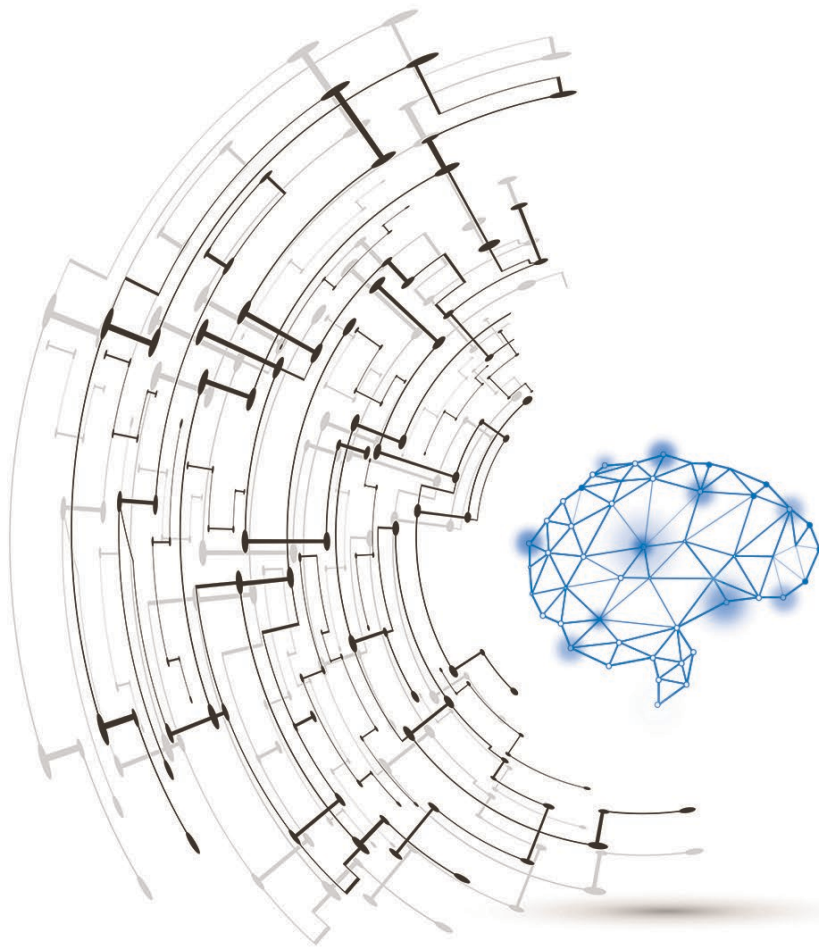


# VALOS

Statistical solutions  
for your clinical trial

Data Management   Statistical Analysis   Statistical Programming

Regulatory Submission   CDISC Specialists   Strong Education



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# VALOS

Statistical solutions  
for your clinical trial

**VALOS** provides comprehensive **data management, biostatistics, and statistical programming services** for Phase I-IV studies and retrospective analyses.

If you need to outsource a part of your clinical trial or drug development project, **VALOS** is the partner you can count on.

**VALOS's** professionals will communicate effectively and will meet project milestones using processes that match the Sponsor's systems.

**VALOS** ensures best quality and increases the success of your clinical trial.

## Biostatistics

- Statistical consulting: program development plans, statistical evaluation of clinical trial design (analysis strategies, supporting methodologies, etc.) according to ICH guidelines and GCP
- Protocol design and review: Clinical Trials (phase I-IV), Simulation and modeling studies, Dose-Response Studies, Group Sequential Designs, Adaptive Designs, Diagnostic Studies
- Sample Size calculation
- Data Management Plan and (electronic) Case Report Forms review
- Randomization Schedule generation
- Interim Analysis Planning
- Statistical Analysis Plan (SAP)
- Integrated summary for safety and effectiveness (ISS/ISE) according to Sponsor's requirements
- Collaboration on ad hoc analyses, regulatory interactions, applications (IND), and annual safety
- Analysis of imaging systems (ROC, FROC, JAFROC)
- Statistical reports (including tables, figures, and listings)
- Statistical Review of Clinical Study Report

### Our people

At VALOS all 80+ of our professionals hold a University degree in Mathematics, Statistics, Genomic Statistics or Informatics and have 10+ years' experience in clinical trials. 4 statisticians hold a PhD in Statistics.

### Focus Areas

- Oncology
- Neurology
- Cardiovascular
- Gastrointestinal
- Respiratory
- Allergology
- Immunology
- Antibiotics
- Ophthalmology
- Epidemiology
- Medical Devices



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