VALOS Statistical solutions for your clinical trial

BIOSTATISTICS

DATA MANAGEMENT

STATISTICAL PROGRAMMING

REAL-WORLD EVIDENCE SOLUTIONS

OVERSIGHT SUPPORT

AUDITING

CONTACT VALOS:
+39.010.4077.182 Italy
+1.617.463.9446 USA

HEAD OFFICE:
Via Ceccardi 4/31, 16121
Genoa, Italy

info@valos.it
valos.it
valosboston.com

VALOS Statistical solutions for your clinical trial

OVERVIEW

VALOS is a leading specialized Contract Research Organization (CRO) headquartered in Genoa, Italy, known for its expertise and specialized services. Our core competencies lie in Biostatistics, Statistical Programming, Data Management, Real-World Evidence Solutions, Auditing, and Oversight services for Phase 1 to 4 Clinical Trials.

VALOS has an extensive team of over 80 clinical research professionals located across offices in Italy, Eastern Europe, and the USA, showing an exceptional 20+ years track record of consistently achieving milestones while delivering high-quality results.

VALOS has established itself as a trusted partner, earning a long-standing reputation for quality and reliability through a strong commitment to consistency and clarity.

Our Gold Standard approach ensures that our team is always prepared to tackle trial-related issues. We strive to provide our clients with the best possible service on time, every time, taking pride in our flexibility and high level of qualification.

OUR SERVICES: 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
- Post-hoc analyses of clinical trial data and evidence adaptation for HTA submissions

> "Another challenging year draws to a close and we want to thank you immensely for your support, your trust, and good cooperation!
>
> «Client since 2006»

VALOS Statistical solutions for your clinical trial

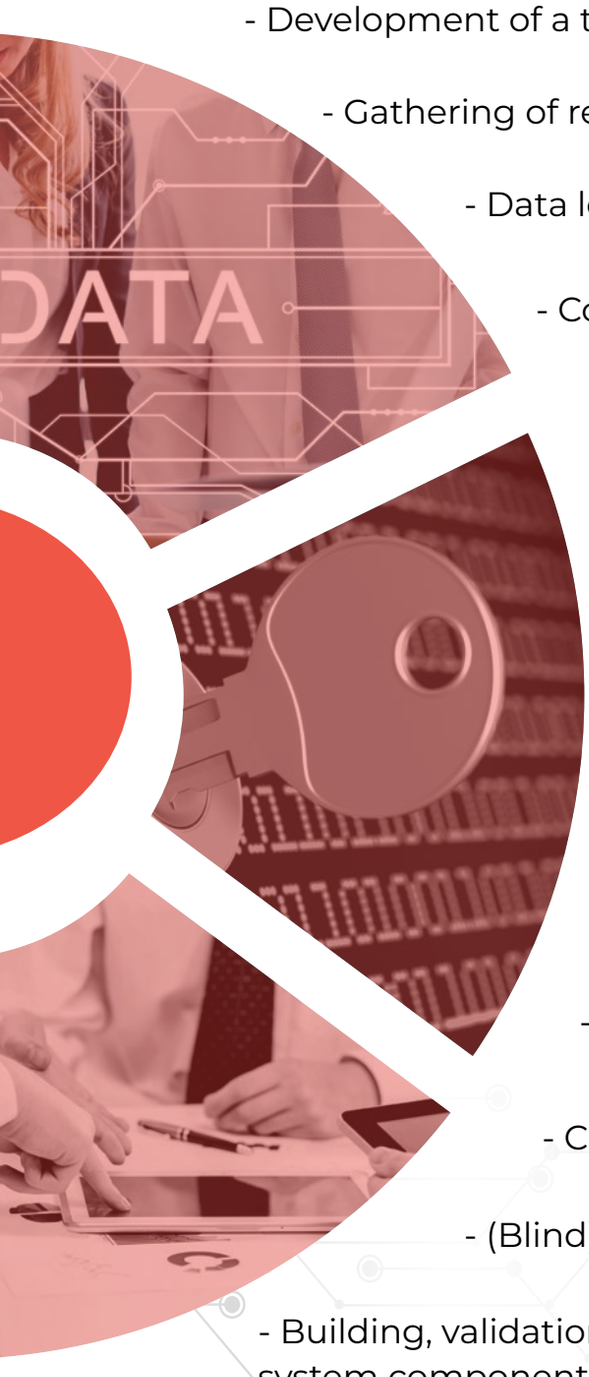
OUR SERVICES: STATISTICAL PROGRAMMING

- Statistical Programming in SAS® and R languages
- Data analysis, including designing analysis data sets, statistics, interim analysis, and customized DSMBs (also posted via a secure Web site)
- Reporting of results, production of analysis summaries: production of Tables Listings Figures (TLF) according to Client's needs
- Exploratory analyses for publications, abstracts, and marketing
- Double-independent validation
- CDISC data conversion (SDTM, ADaM)
- Graphical patient profiles
- Collaboration on ad hoc analyses, regulatory interactions, applications (IND) and annual safety reports, reconciliation of safety data
- Pharmacokinetics
- Programming support for Data Cleaning and Discrepancy Management
- Creation, validation, and auditing of clinical database and data warehouse

> "Thanks so much for your support this year and happy to continue next year on this very important submission."
>
> «FSP Client since 2006»

OUR SERVICES:

DATA MANAGEMENT



- Development of a trial-specific Data Management Plan
- Gathering of requirements for EDC system set-up
- Data lock and archival data transfer to the sites/sponsor
- Coordination of User Acceptance Testing (UAT)
- Devices (e.g. wearables) configuration, data collection, and analysis
- Data cleaning (automated, semi-auto, manual review)
- SAE reconciliation
- Thesaurus dictionaries coding
- External vendors' data integration and reconciliation
- Protocol deviation identification and reporting
- Clinical trial progress reporting
- (Blind) Data Review Meeting conduct
- Building, validation, maintenance, and decommissioning of EDC system components (eCRF, eConsent, ePRO, Randomization and Trial Supply Management, Medical coding, Data integration/ export, eTMF, and Reports)

OUR SERVICES: REAL-WORLD EVIDENCE SOLUTIONS

At Valos, we apply the same level of scientific rigor to Real-World Evidence (RWE) studies as we do to R&D trials. Our approach ensures that RWE is not only robust and reliable but also aligned with the highest standards of methodological excellence, delivering insights that truly support evidence-based decision-making. Our RWE projects are designed to support critical objectives such as market access, Health Technology Assessment (HTA), Joint Clinical Assessment (JCA) and beyond.

DATABASE ANALYSES FOR:

- Incidence/prevalence of the disease
- Disease epidemiology
- Patient journey
- Economic evaluation of the disease
- Effectiveness of therapies already in commerce

CHART REVIEW OR DATABASE STUDIES:

- Comparative Effectiveness Research
- Compliance, adherence, and persistence
- Outcomes Research
- Product Safety
- Pharmacoepidemiology
- Causal inference
- Target trial emulation

INDIRECT TREATMENT COMPARISONS:

- Comparing Individual Patient Data and Results from literature
- Comparing Individual Patient Data of different studies

REGULATORY SUBMISSIONS INCLUDING RWE DATA

VALOS Statistical solutions for your clinical trial

OUR SERVICES: AUDITING

INVESTIGATOR/STUDY SITE AUDITS

- Assessing the compliance with the applicable standards of Good Clinical Practice (GCP), National Regulation, and GDPR regulation
- Tour of site, documentation' check (availability, the validity of SOPs, protocol, ICF, CRF, source documents, etc.), archiving of documents
- Evaluation of Personnel, i.e. training and experience of the personnel, study team workload
- Source data access and verification
- Investigational Product (IP) handling, storage, and accountability

CRO AUDITS

- Assessing the compliance with the applicable standards of Good Clinical Practice (GCP), National Regulation, and GDPR regulation
- Tour of site, documentation' check (availability, the validity of SOPs Quality Management System (QMS)), archiving of documents
- Evaluation of Personnel, i.e. skills, training, and qualification
- CAPA Management System

LABORATORY AUDITS ACCORDING TO GCLP

- Assessing the compliance with the applicable standards of Good Clinical Practice (GCP), OECD principles, National Regulation
- Tour of site, documentation' check (availability, validity of SOPs, protocol), archiving of documents
- Evaluation of Personnel, i.e. skills, training, and qualification
- Samples handling, trace, and archive
- Instruments maintenance, calibration, qualification

> We are very grateful for the collaborative efforts and the excellent work from Valos.
>
> «Client since 2007»

valosboston.com | valos.it | info@valos.it

VALOS Statistical solutions for your clinical trial

OUR SERVICES: OVERSIGHT

IN-DEPTH OVERSIGHT, OPTIMIZATION OF CRO PROCESSES, IMPROVED TEAM COLLABORATION.

Valos is proud to introduce its new strategic oversight service – designed not just to keep your projects on track, but to bring struggling ones back to life. With deep expertise in biostatistics and data management, our team knows the pitfalls that often derail full-service CROs and has the precision and insight to turn rescue projects into success stories.

OVERSIGHT IS NOT JUST ABOUT MONITORING - IT'S ABOUT DRIVING

LOOKING FOR FAST, HIGH-QUALITY RESULTS?

- In-depth oversight to ensure accuracy in biostatistics and data management
- Rapid identification of areas for improvement in outsourced projects
- Seamless integration with your workflow, ensuring your project's success

The strategic changes stabilizes the project, reduces delays and saves the sponsor hundreds of thousands of dollars in just six months - without taking full control and by simply optimizing oversight.

CONTACT US NOW AND MAKE YOUR PROJECT A SUCCESS ONCE AGAIN!

valosboston.com | valos.it | info@valos.it

EXPERIENCE AND THERAPEUTICAL AREAS

EXPERIENCE

Our clinical research professionals are continuously developing their skills and gaining expertise in industry-standard protocols, including 21 CFR Part 11 and GCP and market trends. At VALOS we possess a deep understanding of CDISC standards and work compliantly with them to ensure the accuracy and integrity of your data.

Our team is firmly committed to excellence and is always looking for opportunities to learn and grow. Consequently, we actively participate in various conferences such as PHUSE, BIAS, DIA, and many others.

VALOS is dedicated to fostering the next generation of clinical research professionals. As part of this commitment, we collaborate with the universities to prepare SAS courses and provide students with the skills and knowledge they need to succeed in this field.

The team is led by Ph.D. Dmitri Petratchenko, VALOS CEO, a pragmatic mathematician with over 20 years of experience in clinical trials.

THERAPEUTICAL AREAS

- Oncology
- Neurology
- Cardiovascular
- Gastrointestinal
- Pulmonology
- Allergology
- Immunology
- Antibiotics
- Ophthalmology
- CAR-T Therapy
- Epidemiology
- Medical Devices

WHY US?

• ADHERING TO CLIENTS' DEADLINES:

With us as a partner, clients are guided through operational nuances, ensuring that deadlines are agreed upon and met.

• FLEXIBILITY:

Through a combination of proven expertise in regulatory requirements, global reach, and access to resources, we offer cost-effective and flexible solutions that help clients in managing clinical trials efficiently and effectively.

• QUALITY OF RESULTS:

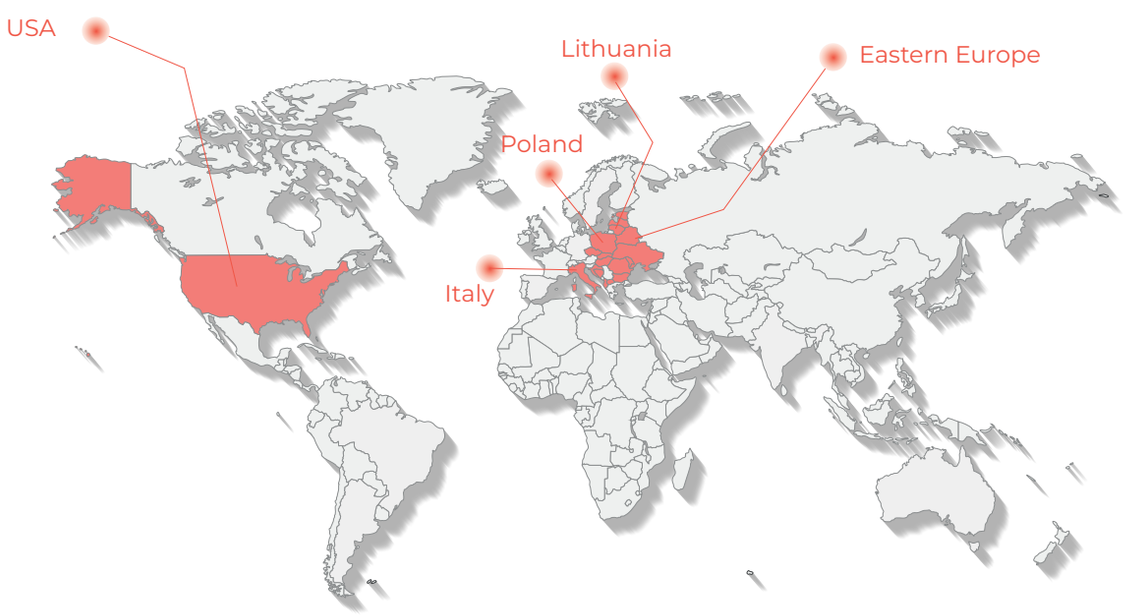
By developing statistical models, providing data management, RWE, and programming solutions, we assist clients identifying data patterns, creating models and algorithms, and predicting outcomes, ultimately enhancing the success of the clinical trial.

OUR RESOURCES

At VALOS, all 80+ of our professionals hold a University degree in Mathematics, Statistics, Genomic Statistics, or Informatics and have more than 15 years of experience in clinical trials, 5+ years' of experience in quality assurance and GxP auditing, collectively with over 20 years of experience. Additionally, 4 statisticians hold a Ph.D. in Statistics.

VALOS LOCATIONS:

At VALOS we have the advantage that we are able to leverage resources from our satellite locations.



OUR PARTNERS

IF YOU ARE:

Small Biotech and Pharma

Medium Biotech and Pharma

Large Biotech and Pharma

VALOS can be the reliable partner you can count on. We have established successful long-term collaborations with pharmaceuticals, medical devices, and biotech companies located all over Europe and the USA.

One of the world's leading Top 5 pharmaceutical companies utilizes VALOS services as part of their operations.

One of the world's most renowned biopharmaceutical companies in Europe, chooses VALOS as its preferred provider, recognizing our expertise and capabilities.

A leading device software company based in California, USA, relies on VALOS as its service provider, benefitting from our specialized solutions.

A global medical device organization with offices in Houston selects VALOS as its preferred provider for programming and statistics services, leveraging our extensive experience ad knowledge in the field.

> I would like to use this opportunity to express my sincere appreciation for all your and your team's amazing work for the study.
>
> «Client since 2006»

VALOS Statistical solutions for your clinical trial

WOULD YOU LIKE

- to have a collaboration with a successful international Team?
- to have access to 80+ Professionals in Statistics and Data Management?
- to solve the Data issue, Statistics problem before the Data Base Lock?
- to have the Key Results in 24 hours after SDTM unbinding?

If yes, **CONTACT US**

+39.010.4077.182 Italy
+1.617.463.9446 USA

HEAD OFFICE:
Via Ceccardi 4/31, 16121
Genoa, Italy

info@valos.it
valos.it
valosboston.com