

# COMPLETE SUITE OF BIOMETRICS SERVICES

ACL Digital is empowered with an in-house team of 1000+ consultants, 250+ SAS Programmers (80% SAS Certified), Biostatisticians and Clinical Data Management Specialists who are adequately positioned to deliver comprehensive state-of-the-art Biometrics solutions across the entire clinical continuum. Together with our parent company ALTEN Group, we leverage a strong workforce of 33,700 consultants spread across 20+ countries to ensure a scalable local presence, a flexible mode of engagement, coupled with timely delivery of any project on quality and on budget.

Get the statistical programming and data management services you need to take full control of your clinical trials NOW!

1000+

**Functional & Technology Consultants**

250+

**SAS Certified Clinical Programmers**

100+

**Clinical Data Managers**

9

of Top20

**Life Sciences Companies**

4

of Top10

**Medical Devices & Equipments**

10+

Years

**Industry Experience**

## THERAPEUTIC AREAS

› Oncology  
› Neurology

› Autoimmune  
› Endocrinology

› Haematology  
› Pulmonology

› Osteo disease  
› Urology

› Dermatology  
› Gastroenterology

› Cardiovascular  
› Pain Management

## NEED FASTER COMPLETION OF YOUR TRIAL?

We have three step Approach for you

### 1 Connect with us

- › We will setup a meeting with our Functional SME team
- › Understand your needs and requests
- › Consult with your strategies & existing processes
- › Guide you to a customized solution

### 2 Your Preferred Partner

- › Kick-off meeting and selection of the preferred approach
- › Resource allocation according to your preferred resourcing model
- › Focused on customer satisfaction and quality

### 3 Staffing Solution / Project Execution

- › Ensure data quality and integrity
- › Enhance trial efficiency
- › Committed to streamlining your Clinical Data Management
- › Support Regulatory Submission

## OUR BIOMETRICS SERVICES

### 1 Clinical Data Management

- › Development of CRF and Database Validation Processes
- › Data Quality Standards Management
- › Query Generation and Resolution
- › Management of Data Review and Clean-up Process
- › Data Management Plan Creation and Maintenance
- › Serious Adverse Event (SAE) Reconciliation & coding
- › Dictionary Services (MedDRA, Who-DD)
- › Remote Data Entry (RDE) CRF Log and Tracking
- › Data Locking, Archival and Storage
- › Audit Trail Generation (Per 21CFR Part 11)
- › Report Generation

### 2 Biostatistics

- › Clinical Trial Design and Protocol Development
- › Randomization Schemes
- › Independent Statistician Services
- › Statistical Analysis plans for different phases of clinical trials
- › Interim Analysis/Data Safety Monitoring Boards (DSMBs)
- › Development of CDISC compliant outputs (SDTM & ADaM, Define.xml)
- › TLF creation, In-text table, CSR and appendix
- › ISS/ISE Planning, Analyses and e- submission

### 3 Statistical Programming

- › Programming of Raw, SDTM and Analysis Datasets
- › Tables, Listings, and Figures creation and validation
- › CDISC conversion of Legacy data

- › Implementation of data management plans and approved SAP (Statistical Analysis Plan)
- › Post-marketing data analysis and reporting
- › Regulatory consultation and representation



ACL Digital is a design led Digital Experience, Product Innovation, Engineering and Enterprise IT offerings leader. From strategy, to design, implementation and management we help accelerate innovation and transform businesses.

ACL Digital is a part of ALTEN group, a leader in technology consulting and engineering services.

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