

Digital Disruption: A way of life for Life Sciences

With rapid adoption of digitalization by Life sciences ecosystem (**Pharma, Bio-Tech and Medical devices**), organizations are embracing digital products, platforms and models that redefine the way they work, carry research & development, innovate digital supply chains, distribute products, and meet rising consumer expectations.

ALLEN Calsoft Labs leverages inhouse team of 200+ SAS Programmers (80% SAS certified), Biostatisticians, Industry experts to deliver comprehensive biostatistics, clinical data management services. Together with our parent company ALLEN Group, we leverage a strong workforce of 28,000 consultants spread across 20 countries, to deliver next generation, futuristic solutions across the continuum.

Functional,
Technology
Consultants

1000+

SAS Certified
Consultants

180+

200+

SAS Programmers
& Biostatisticians

Life Sciences
Companies

9

of Top 20

Industry
Experience

25
Years

4

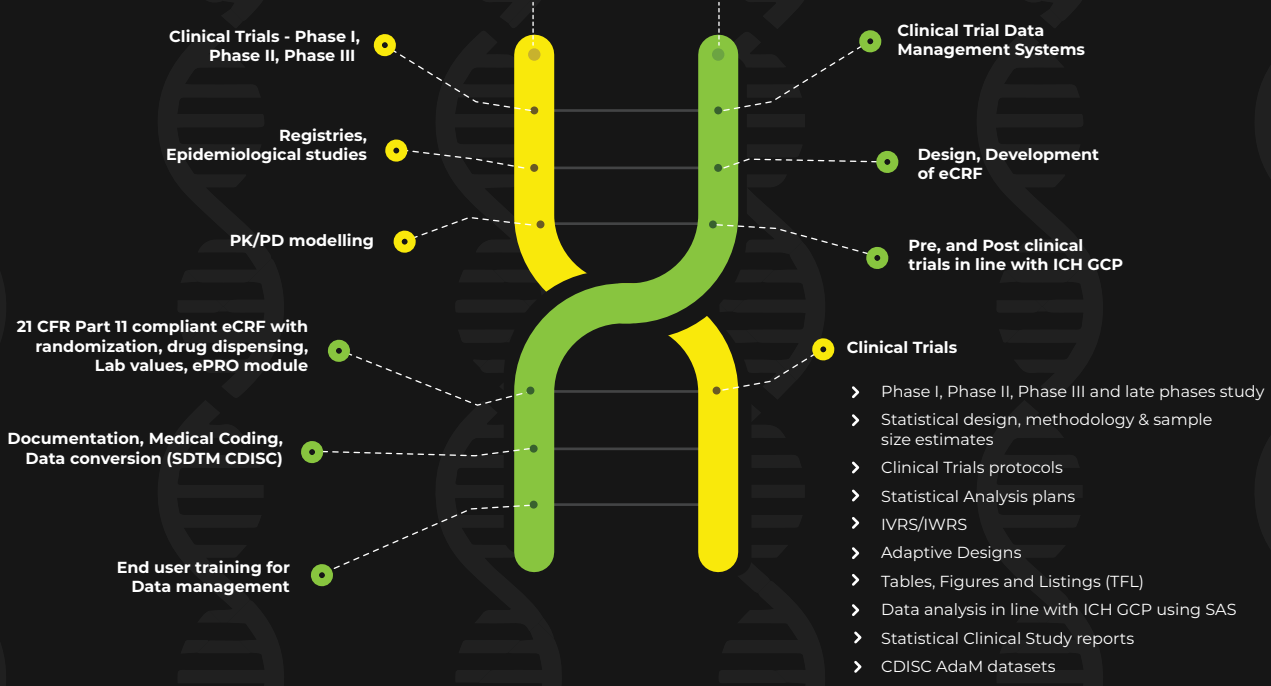
of Top 10

Medical Devices
& Equipments



1 BIOMETRY

Biostatistics Data Management



2 Clinical Operations

Clinical Ops & Research

- > Phase I, II and III clinical studies,
- > FDA Review, Phase IV research
- > Project Management
- > Compliance, Audit and Validation
- > Safety & PV

Therapeutic areas

- > Oncology
- > Cardiovascular
- > Dermatology
- > Infectious Diseases
- > Neurology
- > Pharmacology
- > Alzheimer
- > Immunology
- > Gastroenterology
- > Ophthalmology
- > Haematology
- > Vaccines

3 Pharmacovigilance

- > AE Collection and Follow up
- > Case Processing
- > Report writing
- > Report development
- > Proactive Pharmacovigilance
- > Knowledge Services
 - Statistical Analysis & Reporting
 - Population Studies
 - Pharmacoepidemiologic assessment
 - Pre-marketing, Post-marketing clinical trials
 - Medical device vigilance

4 Regulatory submissions

- > Medical Writing
- > Clinical Trial Audit & Monitoring
- > GxP auditing and best practices
- > Submissions management, Labelling
- > NDA/BLA/PMA submission
- > Digital assets/documents management, Master data management
- > CTD / eCTD formats, variations, renewal
- > Active Substance Master File (ASMF) variation files, certificate of suitability (CEP)
- > Quality Over all Summary (QOS)

5 Quality Assurance

- > Clinical Audit (investigator sites, CROs, PV System audit)
- > QC on Regulatory submission docs
- > Drafting and revision of processes and procedures
- > Quality support for operations team



ALTEEN Calsoft Labs is a next-gen **digital transformation, enterprise IT** and **product engineering** services provider. The company enables clients to Innovate, Integrate, and Transform their business by leveraging disruptive technologies like **mobility, big data analytics, cloud, IoT, DevOps, RPA, software-defined networking (SDN/NFV)**. We are a pioneer technology consulting and engineering services company that helps Life Sciences companies with CRO, Clinical Data Management, Clinical Trails, PV, Regulatory submissions and Quality Management services. Our innovative and cost-effective talent and workforce solutions are focused around SAS Programming, Biostatistics, Data base programming, CDSIC conversion.

ALTEEN Calsoft Labs is a part of ALTEEN group, a leader in technology consulting and engineering services.