Trusted Global
Life Sciences Partner
CRO | MSP | FSP | Digital | GCCaaS

ALTEN Group
Leader in Engineering and IT Services

ALTEN supports its customers' development strategies in the areas of innovation, R&D, and technological information systems.

Created more than 30 years ago and based in 30 countries, the Group has established itself as a world leader in Engineering and IT Services. We work with key players in the

Aeronautics & Space, Defense & Naval, Security, Automotive, Rail, Energy, Life Sciences, Finance, Retail, Telecommunications and Services sectors.

With a financial turnover of more than €4 billion, we currently have more than 57,700 employees all over the world.

Within 30 years, ALTEN has become leader in both outsourced Engineering and IT Enterprise Services.

ALTEN, composed of 88% engineers, carries out complex and highly technical digital transformation and engineering projects throughout the value chain of the most prestigious companies (Tier 1s) in diverse industries.

Employees	Clients	2024 Turnover	Countries
57,700	**6,500**	**€4,143 B**	**30+**

Awards & Accolades

ACL Digital

ACL Digital is a leading technology service company recognized worldwide for delivering cutting-edge engineering and IT solutions. Our expertise and excellence in digital experience, product innovation, and consulting services equip businesses with the fuel to drive into the digital future.

ACL Digital, an ALTEN Group Company, is committed to enabling transformation while keeping customer journeys and high-end design.

ACL Digital is a pioneer in design-led digital experience, innovation, enterprise IT

modernization, and product engineering services. We help organizations accelerate product development by leveraging digital technologies, monetizing services, modernizing technology platforms, and providing immersive total experience solutions at core. Thousands of businesses worldwide trust ACL Digital to bring in competitive advantage, extraordinary innovation, and revolutionary solutions for complex industry challenges.

We are a talented workforce, and part of the 57,700+ employee ALTEN Group headquartered in Silicon Valley, California, spread across more than 30 countries, offering a multicultural workplace and a collaborative knowledge environment.

Digital Engineering & Transformation Company

ACL Digital is a pioneer in design-led digital experience, innovation, enterprise IT modernization, and product engineering services.

We help organizations accelerate product development by leveraging digital technologies, monetizing services, modernizing technology platforms, and providing immersive total experience solutions.

30+ years of Sustained Growth

10+ Locations Offshore Development Centers

25+ Strategic Partnerships

6500+ Strong Digital Engineering Team

400+ Customers Worldwide

Our Strategic Partnerships to Fuel Delivery

SAS · DS MEDIDATA · salesforce · mongoDB · ORACLE

ZOHO · vmware · Google Cloud · snowflake · lectroNeek

UiPath · SAP · aws · Microsoft · intel · NXP GOLD PARTNER

Pharma & Life Sciences Services

Your Trusted Partner for all Life Sciences Staffing and Services
Contingent & MSP staffing, project-based FSP, full-service FSP, and offshoring models.

Integrating Digital Transformation in Healthcare and Life Sciences
Realize the full value of your medical innovations by leveraging our talent and industry expertise.

Access to One of the Largest Pools of Qualified Resources in Multiple Functional Areas
1000+ functional and technology consultants, 250+ SAS certified programmers, 100+ clinical data managers.

Domain Expertise

1500+ Life Sciences professional

250+ Statistical Programmers

100+ Clinical Data Managers

20+ Regulatory & Quality Professionals

Service Offering

- Biometrics Staffing and Data CRO Services
- Medical Writing Services
- Pharmacovigilance Staffing and Services
- Gen AI implementation in Biometrics

Global Presence & Experience

50+ Offices in **30+** Countries

30+ Years of Experience

Therapeutic Area Expertise

Data Focused CRO with Deep Expertise in Top **12** Therapeutic Areas

Diverse Industry Experience

4 of Top **10** Medical Device and Equipment Customers

Top Pharma Clients

9 of Top **20** Pharma (Life Sciences) Customers

Our Core Capabilities:
Source Data to Submission

We deliver AI-powered life sciences services and solutions that enhance interoperability and improve patient outcomes.

Biostatistics & SAS Programming

At ACL Digital, we provide expert biostatistical services and SAS®/R programming to support clinical trials across all phases.

- Creation of Safety and Efficacy Tables, Listings, and Graphs (TLGs)
- Development of CDISC-compliant datasets (SDTM & ADaM)
- Support for submissions to health authorities

Submission Experience:

Extensive experience preparing data and statistical deliverables for a wide range of regulatory and scientific documents:

- Interim Analysis (IA)
- Clinical Study Report (CSR)
- Data Monitoring Committee (DMC)
- Investigator's Brochure (IB)
- Periodic Safety Update Report (PSUR)
- Development Safety Update Report (DSUR)
- Integrated Summary of Safety/Efficacy (ISS/ISE)
- Pooling Analyses

SDTM Package – Activities & Deliverables

SDTM Annotations on Blank CRF, SDTM Mapping and Dataset Creation, SDTM Compliance Validation, Define.XML, SDRG (Reviewer's guide for SDTM Data), CDISC SDTM Compliance Report

ADaM Package – Activities & Deliverables

Review of SAP, ADaM Mapping, ADaM Dataset Creation, ADaM Compliance Validation, Define.XML, ADRG (Reviewer's guide for ADaM Data), CDISC ADaM Compliance Report

Clinical Data Management

ACL Digital provides comprehensive clinical data management solutions, supporting studies of all sizes across all phases. Our services include:

- EDC Services Using Various EDC Platforms
- Database Build
- eCRF Development
- Edit Check Programming
- Master User List Setup
- Portal Setup
- User Training
- IRT Integration

Pharmacovigilance

AE Processing & Management

- Case Intake, Book-In and Triage Assessment
- Case Processing
- MedDRA Coding and Medical Review
- Narrative Writing and Submission to Agencies

Aggregate Reporting

- Write PADER/PBRER/PSUR
- Quality and Medical Review
- Publishing and Submission Readiness

Signal Detection

- Screening, identifying, prioritizing
- Tracking and Trending
- External Data Search
- Analysis and Report

Medical Writing Services

Our experienced medical writers craft high-quality regulatory and scientific documents that meet global standards, including:

- Regulatory Documents
- Protocol and Protocol Amendments
- Clinical Study Reports (CSRs)
- Investigator's Brochure (IB)
- Informed Consent Forms (ICF)
- INDs, NDA Submissions
- Safety update reports

Scientific Documents

Abstracts, Posters, Manuscripts, Literature Reviews, Summaries

Digital Solutions

- QInsight – Data Visualization Tool
- SAS to Any Open Source – Code Translator
- Statistical Programming Datasets and TLFs Generator
- Gen AI-based Clinical Study Report Generator

Data Standardization

With over 25 years of expertise in data conversion, ACL Digital provides industry-leading data standardization services to ensure accuracy, consistency, and compliance.

Expertise Areas

- Standardization of clinical and non-clinical data to meet regulatory requirements.
- Mapping and validation of data against global standards.
- Development and implementation of controlled terminology.
- Compliance checks and submission-ready deliverables.
- Data harmonization to support AI, analytics, and real-world evidence.

Key Standards Supported

- CDISC (SDTM, ADaM, SEND, Define-XML)
- MedDRA (adverse event coding)
- WHODrug (concomitant medication coding)
- HL7/FHIR (health records, RWE integration)
- ISO IDMP (medicinal product identification)

Therapeutic Expertise and Depth

Specialized In

- Cardiovascular
- Ophthalmology
- Cell and Gene Therapy
- Neuroscience
- Dermatology
- Endocrine & Metabolic
- Gastroenterology
- Haematology
- Immunology and Inflammation
- Infectious Diseases
- Medical Devices & Diagnostics
- Oncology
- Paediatrics
- Respiratory

Specialized in Oncology TA

- Advance Solid Tumor
- Advanced and/or metastatic GI stromal tumors
- Advanced carcinoid tumor
- Advanced pancreatic neuroendocrine tumor (NET)
- Bone Cancer
- Breast Cancer
- Chronic Myeloid Leukemia (CML)
- Gastric Cancer
- Generic Abnormalities in ALK
- Hodgkin's Lymphoma
- Liver Cancer
- Lung Cancer
- Metastatic renal cell carcinoma of the kidney
- Skin Cancer
- Tuberous Sclerosis Complex (TSC)
- Mantel Cell Lymphoma

Client Engagement Models

FSP (Insource)

Client retains:
- Full ownership and direction of project

ACL Digital Life Sciences:
- Liaises with client manager, or let client manage resources
- Handles all employment matters
- HR
- Payroll
- Work visas

Resources:
- Utilize client's SOPs, systems, and tools
- Remote-based, onsite (client or ACL Digital Life Sciences site)
- Onshore or Off-shore / India (cost advantage)

Contract:
- Resource-based / One-year renewable

FSP (Outsource)

Client retains:
- Full ownership and direction of project

ACL Digital Life Sciences:
- Liaises with client manager
- Assigns tasks to resources - Typically complete functional team
- Handles all employment matters
- HR
- Payroll
- Work visas

Resources:
- Utilize ACL Digital Life Sciences SOPs, systems and tools
- Remote-based, or at ACL Digital Life Sciences site (On shore or Off-shore / India (cost advantage)

Contract:
- Resource-based or Milestone-based/ One-year renewable

Project-work (Outsource)

ACL Digital Life Sciences:
- Has full project ownership
- Complete line management responsibility
- Assigns workload and determines resource allocation
- Utilized ACL SOPs, systems, and tools
- Can be remote-based or work onsite at ACL Digital Life Sciences site
- Onshore or Off-shore / India (cost advantage)
- Handles all employment matters
- HR
- Payroll
- Work visas

Contract:
- Milestone / Deliverables-based

Let's Create Impact Together

We're eager to help you unlock new possibilities and achieve your goals. Get in touch with us today to explore how we can collaborate for success.

ACL Digital | **Life Sciences**
an ALTEN group company