

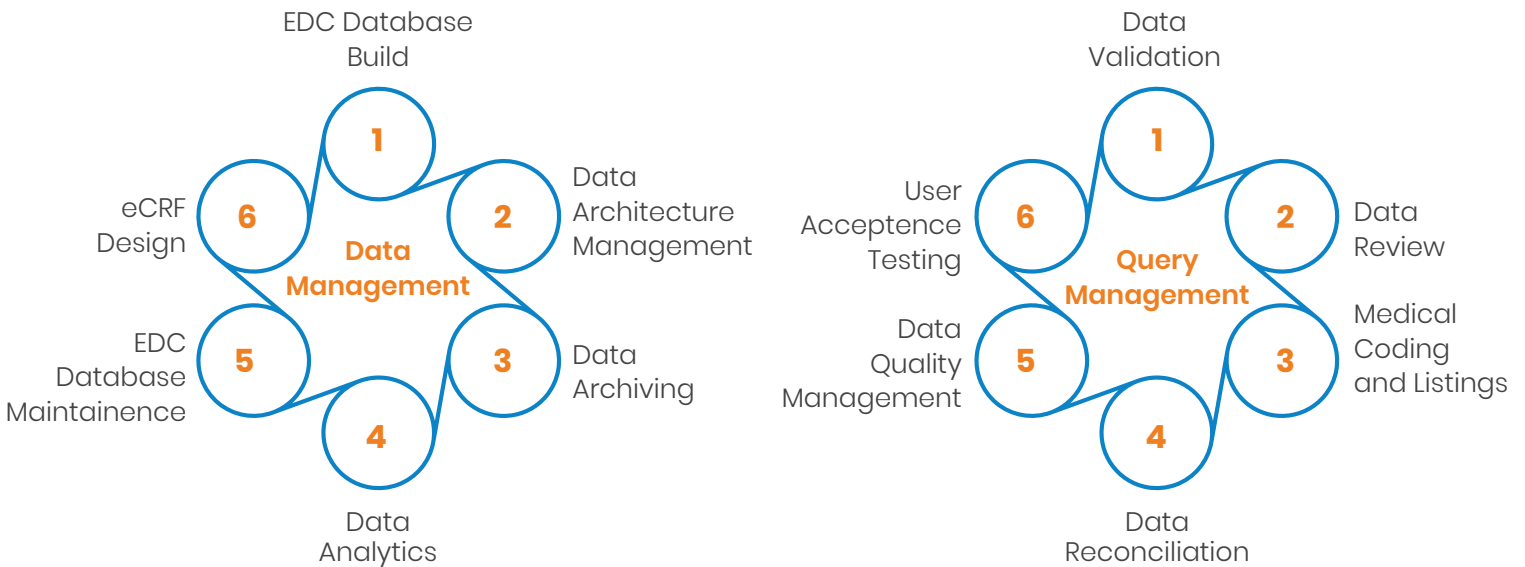


Trusted Global Life Sciences Partner

Staffing | FSP | Offshore | Digital

Clinical Data Management

Our expert clinical data managers deliver accurate and compliant data handling across all phases of clinical trials. We specialize in CDISC compliance, ensuring rapid and precise results across a broad range of therapeutic areas.



ACL Digital Life Sciences offers a wide range of clinical services for multiple areas of expertise, such as Statistical Programming, Clinical Data Management, Biostatistics, Medical Writing, Regulatory, Validation, and Pharmacovigilance. Our comprehensive suite of services is available via various flexible engagement strategies, including Contingent Staffing, Project-Based Solutions, Functional Service Provision (FSP), and Offshore Delivery Models designed to meet your unique needs.

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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Trusted Global Life Sciences Partner

FSP | MSP | Staffing | Digital | Medical Devices

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 actors 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 57,400 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 projects throughout the value chain of the most prestigious companies in all sectors of industry, services and telecommunications.



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

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 42,000+ employee ALTEN Group headquartered in the Silicon Valley in 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.



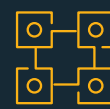
30+ years

of Sustained Growth



10+ years

Partnership with ALTEN



10+ Locations

Offshore Development Centers



6500+

Strong Digital Engineering Team



400+

Customers Worldwide



25+

Strategic Partnerships

Our Strategic Partnerships to Fuel Delivery



ACL Digital Life Sciences

ACL Digital Life Sciences has one of the largest pools of qualified resources in multiple functional areas, who are well-equipped to deliver comprehensive state-of-the-art Services and Solutions across the entire Life Sciences domain.

Our Offerings include



FSP, MSP, and Staffing

Your all-weather staffing partner. We offer flexible models to support your requirements. ACL Digital Life Sciences has access to one of the largest pools of qualified resources in multiple functional areas.



Digital Services and Solutions

Integrating digital transformation in Healthcare and Life Sciences. Solutions include biometrics dashboard, AI/ML solutions, and custom software and applications within the clinical space.



Medical Devices Hardware and Software

including Remote Patient Monitoring (e-diaries, IoT, wearables)

Life Sciences Staffing and Services

MSP and contingent staffing, project-based FSP, full-service FSP, and offshoring models

ACL Digital Life Sciences has a track record of partnering successfully with some of the leading Pharmaceuticals, Biotech companies, CROs, Medical Devices, and MSP companies.

We offer multiple sourcing models to suit your business needs. We work with an MSP of your choice, insourcing staff augmentation, insourcing and outsourcing FSP models, and Project-based deliverables.

We do this to provide you with the flexibility you need - whether it's for onsite or remote resources, long-term or project-specific resources, SME consultation, resources available across

multiple geographic areas, resources mapping US time zones, or working off-hours in local time zones, among other requirements.

Our areas of staffing include:

- BioStats
- Statistical Programming
- Clinical Data Management
- Pharmacovigilance
- Medical Writing
- Regulatory Affairs
- QA and Validation
- Other areas in Clinical Development

Client Engagement Models



Staff Augmentation (Insource / MSP)

Client retains:

- Full ownership and direction of projects
- Management and assignment of all tasks

Resources:

- Utilize sponsor's SOPs, systems and tools
- Remote-based, or onsite (client or ACL Digital Life Sciences)
- North America and Europe

ACL Digital Life

Sciences:

- Handles all employment matters
- HR
- Payroll
- Work visas

Contract:

- Resource-based / One-year renewable



FSP (Insource)

Client retains:

- Full ownership and direction of project

ACL Digital Life

Sciences:

- Liaises with client manager, or let client manage resources

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)

ACL Digital Life

Sciences:

- Handles all employment matters
- HR
- Payroll
- Work visas

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

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))

ACL Digital Life

Sciences:

- Handles all employment matters
- HR
- Payroll
- Work visas

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)

ACL Digital Life

Sciences:

- Handles all employment matters
- HR
- Payroll
- Work visas

Contract:

- Milestone / Deliverables-based

Digital Services & Solutions, Innovation Labs

The solution innovation team at ACL Digital Life Sciences works with biotechnology, pharmaceuticals, medical device companies, and CROs to understand the day-to-day challenges, cost optimization goals, the need for aggressive digital transformation, and a staggering pace of healthcare evolution.

Our seasoned transformation consultants apply their first-hand knowledge and expertise in strategy and execution gained outside and inside the industry to solve complex problems. We harness the power of data, capitalize on new technologies, transform into intelligent operations, master customer experience design, and build customer-centric digital talent and culture, while adhering to industry regulations in a highly regulated environment.



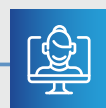
QInsight Dashboard

ClinOps and Clinical Trials data reporting dashboards designed to get better insight of data



Biopharma Ledger

Realtime Consolidated and Single Source of encrypted, Transparent, Immutable Patient Data Platform



Remote Patient Monitoring

IoT enabled wearables



Network Efficiency

- SAP for high-speed Packet Traffic Aggregation / Dis-aggregation
- Ultra-low Latency and High Bandwidth Interconnect
- Clutter-free Physical connectivity



Clinical Trials Automation

Digital automation into the drug and device development to transform trials by:

- Capturing routine clinical data (patient vital signs)
- Collecting operational data, such as drug administration dose and time
- Assessing potential data entry errors, such as duplicated or missing data points



SAS SCE

- Cloud based secure computing environment with validated SAS, R, scripting and other utilities
- Customizable file share, centralized and secure, ready for data warehouse, data lake setup
- Plug-in SAS macros for clinical trial data reporting/analysis

Medical Devices Hardware and Software

Multidisciplinary Capabilities across Hardware, Firmware, Software, V&V, and Product Engineering

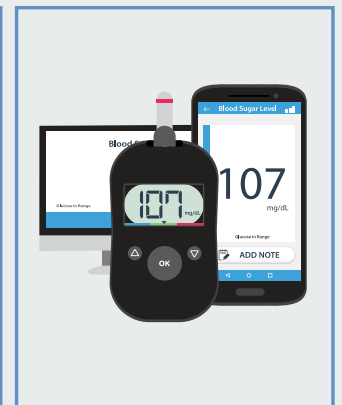
Digital Healthcare & Product Engineering Expertise

ACL Digital Product Engineering practice has helped multiple Healthcare, Pharma & Life Sciences, Medical device companies to design, develop, and verify medical device software for providing diagnostic and therapy solutions.

- Application Software
- Mobile, Hardware & Embedded V&V
- Connectivity Enablement
- Remote Patient Monitoring
- Regulatory Standards

Application Software

- Product Engineering, Cloud, DevOps, DevSecOps and MLOps
- Medical Imaging – Product Engineering, AI/ML & Imaging Analytics, Workflow Optimization
- Clinical Data Engineering – Data modernization, Data Warehouse, Data Lakes, Cloud-based and Data Quality
- Patient & Physician Engagement – Digital and Mobile health, Tele-health, Patient Portals and Clinical Decision Support
- Health IT Interoperability – IoT, Device Integration and Data Interoperability



Mobile, Hardware & Embedded V&V



- Native, Web, and Hybrid Patient and Clinician Application Development on Android, iOS
- Test Framework Development and Automation
- Data Communication over Bluetooth, BLE, USB, Zigbee, MQTT, RS 232, or Wi-fi
- Test Strategy, Definition & Protocols
- Compliance & Certification Firmware, Embedded, Hardware Design & Engineering

Connectivity Enablement

- Wireless enablement of devices using technologies like Bluetooth, BLE, ZigBee, Wi-Fi, GSM/GPRS
- Device communication using RS232 or USB interfaces
- Data transfer to back-end systems using various protocols such as SSL, HTTP, SOAP, TCP/IP



Remote Patient Monitoring



- Device Data Collection using Standard Protocols
- Alerts, Alarms Generation and Notification
- Data Management and Reporting
- Data Security and Privacy Handling
- Integration with EMRs/EHRs, PHMs and Business Systems
- Patient - and clinician - centric Portals and Apps

Regulatory Standards

- HL7, DICOM, CCHIT, HIPAA, and Meaningful Use
- Smart on FHIR Interoperability
- FHIR Framework supporting REST, Documents, Messages & Services
- Device Connectivity and Workflow Automation using IHE, IEEE 11073, HL7, and DICOM standards
- Federal & State Reporting
- ISO 13485, ISO 14971 and ISO 62304



ACL Digital Life Sciences

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

Strong Technical Community Involvement

Check out our recent R Programming for Biometrics Professionals webinar

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QInsight Dashboard

A secure comprehensive clinical trial data visualization solution with an interactive dashboard coupled with built-in analytics.

Why QInsight?

Enables study reporting visualization that substantially reduces reporting, resources, and processes burden.

- Negate data silos, and improve understanding of data.
- Reduce the burden on Biometrics resources for non - submission reports.
- Reduce turn-around time.
- Useful for patient profiles, narratives, safety signal reporting, data cleaning, time-to-event reporting, adhoc, and more.
- Built-in library includes pivot tables, patient profile graphs, KM curves, Waterfall, Labs spaghetti, change from baseline, and AE graphs among others.

Traditional Biometrics Processes

- Built for pre-defined scope and timelines
- Follow time and resources consuming audit compliance process to report data
- Output format limited to .pdf or .rtf
- A stand-alone system, no UX interface for the user

QInsight

- On-demand instantaneous data reporting
- Provide team access to data effortlessly, negate data silos
- Can support PowerPoint, In-Text, and publishing user-friendly and high-quality image formats
- Provide the dynamic ability for users to apply filters and use multi-panel graphs as needed

QInsight Features & Benefits

- Multiple Plug-in Input Data Streams
- Data Friendly Platform
- Multi-Panel Display
- Create Custom Widgets
- Compliance and Audit Transparency
- Enhanced Secured System
- Useful Visualizations
- In-built Advanced Analytics
- Negate Data Silos
- On-premises Deployment Availability

Redefining Life Sciences with Cutting-edge Generative AI Solutions

- **AI-Powered Document Search for Life Sciences**

Revolutionize document management with AI-enhanced search capabilities that enable seamless navigation through complex information landscapes.

- **Accelerate Omics Research**

Harness advanced AI technology to expedite target identification and biomarker discovery, optimizing your omics experiments with the innovative Gene Inspector tool.

- **Intelligent Research Assistant for Life Sciences**

Effortlessly explore research literature with AI-driven search, delivering rapid insights into genes and diseases from various scientific publications.

- **Streamlined Data Analysis Across the Pharma Value Chain**

Leverage a groundbreaking AI-powered query tool, Data Lens, to efficiently summarize and analyze extensive datasets from diverse data hubs.

- **Make Informed Decisions with Enhanced Analytical Power**

Unlock the potential of Generative AI to integrate Descriptive, Diagnostic, and Predictive analytics, providing transformative insights for more strategic decision-making in the life sciences sector.

- **Unleash the Full Potential of Your Data**

Achieve comprehensive data visibility and resolve real-time issues to minimize downtime using our Data Observability solution.

- **Accelerate Insights with a Plug-and-Play Data Analytics Solution**

Our innovative tool is designed specifically for the life sciences industry. It accelerates the transition from data ingestion to actionable insights, facilitating faster and more efficient decision-making.

- **Decoding Global HCP Sentiments**

Utilize a GenAI-powered multilingual analysis tool to translate and generate insights from any global language into English, capturing healthcare professional sentiments worldwide.

- **AI-Enhanced Clinical Document Creation**

Streamline the creation of essential clinical documents, such as study reports, journal publications, and IPD documents, with AI-assisted content generation, leveraging templates and multiple data sources.

- **Optimize Medical Legal Regulatory Reviews**

Improve efficiency and compliance with automated content analysis and pre-review, utilize AI to proactively assess documents before formal reviews, ensuring adherence to regulatory standards and speed up approval processes.

- **Advanced Knowledge Graph Analytics for Life Sciences**

Employ an enterprise-level knowledge graph toolset to seamlessly integrate, transform, and analyze data, simplifying complex information from multiple sources and turning it into actionable insights.

- **Comprehensive Data Management Solution**

Automating data ingestion, integration, and quality control processes enhances data integrity and availability. This solution ensures accurate, consistent, readily available data across various life sciences functions, supporting faster decision-making and regulatory compliance.

- **Boost Sales Effectiveness with Field Sales Analytics**

Enhance sales performance with deep insights into regional trends, proactive sales intelligence, and targeted HCP engagement strategies.

- **Secure GenAI Environment for Development and Delivery**

Experience a scalable, optimized, and compliant cloud platform for software development and delivery, ensuring a secure and reliable environment for GenAI applications.

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ACL Digital Life Sciences

Your Trusted Partner in Technology Innovation

ACL Digital, an ALTEN Group Company, is at the forefront of driving transformation in the Life Sciences sector. We are committed to placing customer journeys and cutting-edge design at the core of everything we do. As a leader in design-led digital experiences, enterprise IT modernization, and product engineering, we empower businesses to thrive in an ever-evolving digital landscape.

Our Expertise

We offer a comprehensive suite of services tailored to meet the diverse needs of the Life Sciences industry, ensuring operational excellence and innovation at every stage of the business lifecycle.

Core Services

Clinical Data Management

1

Our expert clinical data managers deliver accurate and compliant data handling across all phases of clinical trials. We specialize in CDISC compliance, ensuring results that are both rapid and precise across a broad range of therapeutic areas.

Statistical Programming

2

Leverage ACL Digital's pool of skilled statistical programmers for high-quality, timely clinical data solutions. From CDISC implementation to safety monitoring, we deliver expert-driven programming services, ensuring compliance, accuracy, and insightful analysis for your regulatory needs.

Biostatistics

3

Our biostatistics team offers in-depth expertise in clinical trial design, data analysis, and regulatory interactions ensuring high-quality outcomes delivered swiftly.

Regulatory Affairs

4

We provide strategic regulatory consulting to help you navigate the complexities of global regulatory approvals, ensuring your products reach the market with efficiency and compliance.

Advanced Life Sciences Solutions



AI-Driven Analytics

Revolutionize your processes with our AI-powered analytics platform, QInsight, which provides real-time insights and interactive analytics to optimize clinical trial management and decision-making.



Digital Transformation Services

Partner with us to implement robust digital transformation strategies that optimize operations, enhance customer-centric design, and maintain compliance in highly regulated environments.



Regulatory Compliance Tools

Our digital solutions streamline regulatory management, ensuring seamless interactions with health authorities and adherence to industry regulations.



Consulting and Support

SME Consultancy

1

Our subject matter experts provide precise guidance to tackle complex challenges, bringing deep industry knowledge to every project.

Project-Based Staffing

2

Our flexible staffing models provide on-demand expertise for both short-term and long-term projects, ensuring your teams are equipped for success.

Managed Services

3

Our managed services optimize your IT infrastructure, ensuring secure, agile operations that can deliver seamless digital experiences.

Client Engagement Models

We offer a variety of client engagement models, tailored to meet the unique needs of our clients in the Life Sciences sector.

Key Benefits



Domain Expertise

1500+ Life Sciences professionals with expertise across Biometrics, Pharmacovigilance, Medical Writing, Regulatory Affairs, Quality Assurance, and more.



Therapeutic Areas Expertise

Extensive experience in the top 12 therapeutic areas, including Oncology, Rare Diseases, and Ophthalmology.



Proven Experience

With over 30 years in the industry, we have a deep understanding of ICH and FDA guidelines, CDISC standards, and technical expertise in SDTM and ADaM.



Geographical Presence

With a presence in more than 30 countries, we offer various engagement models with guaranteed deliverables.



Cost-Effective Solutions

We provide exceptional value at unbeatable prices by combining our domain expertise, efficient processes, and global operational capabilities.

Clientele

9

of the top **20** Life Sciences Companies

4

of the top **10** Medical Devices and Equipment Companies

Case Studies/Success Stories

1

Streamlined Vendor Management

Successfully resolved critical challenges for a mid-sized CRO, ensuring compliance with regulatory requirements and mitigating audit risks.

2

Seamless QMS Integration

Integrated Quality Assurance processes for a global CRO, facilitating the smooth implementation of a Quality Management System at a new site.

ACL Digital is your trusted partner for all Life Sciences staffing and services, integrating digital transformation in healthcare to realize the full value of your medical innovations.

Visit our Site



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