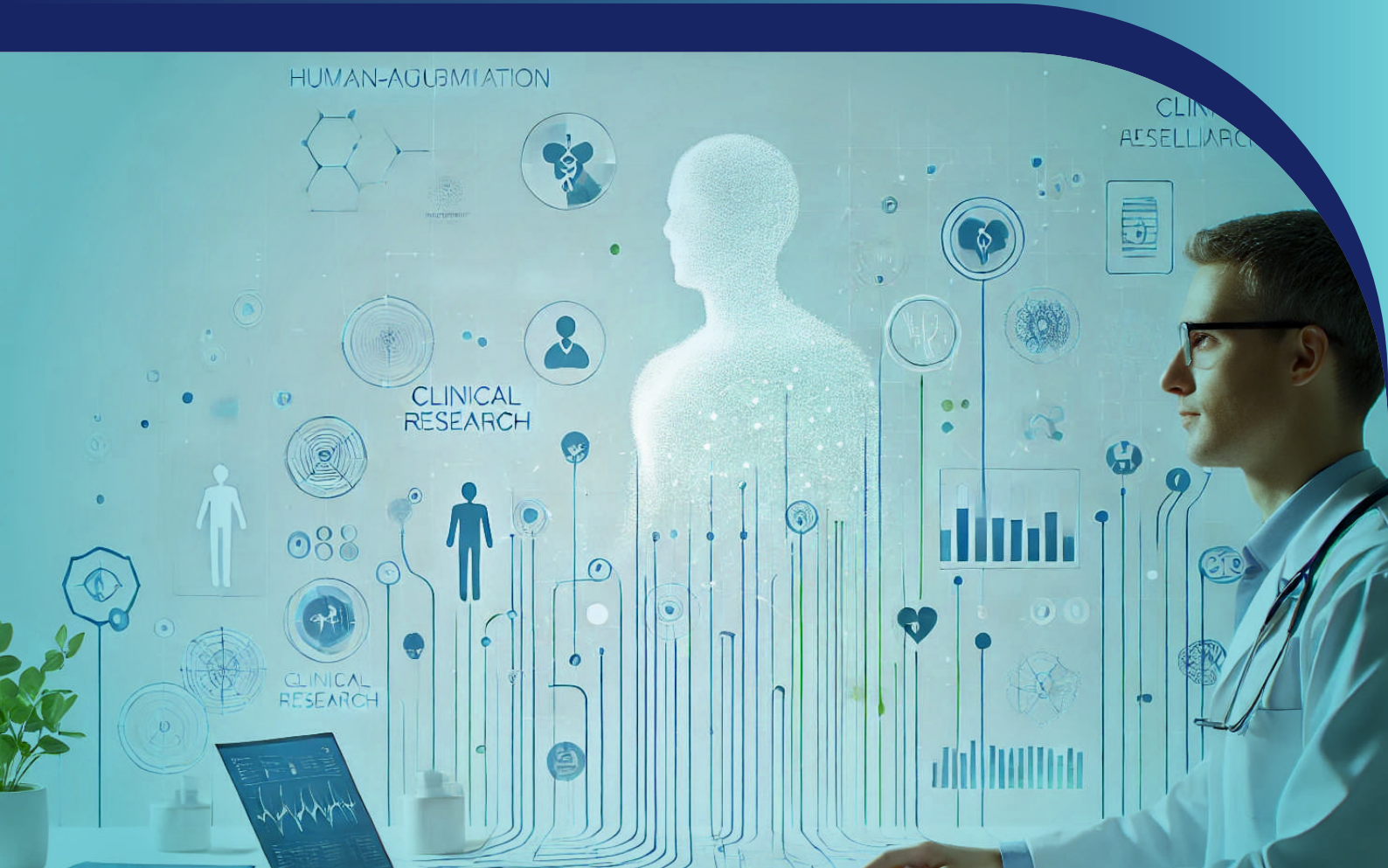
AQnix™
RESEARCH SOLUTIONS

“Leading the way in Next-Gen Research ecosystem”



Introduction

We provide integrated solutions in Site Management, GxP Documentation, Quality Audits, Trial Monitoring and Regulatory Compliance - enabling innovation, compliance and excellence in clinical research.

> Partnering with you to build the next-gen research ecosystem.
>
> — AQniX

Our Vision

To revolutionize clinical research through a quality-driven, compliant and transparent ecosystem built on innovation and trust.

Our Mission

To simplify and strengthen clinical research with efficient, compliant and audit-ready solutions that ensure accuracy, integrity and global regulatory confidence.

Core Values

Integrity

Honesty, transparency and ethical responsibility in every action.

Innovation

Forward-thinking solutions that redefine research excellence.

Quality Excellence

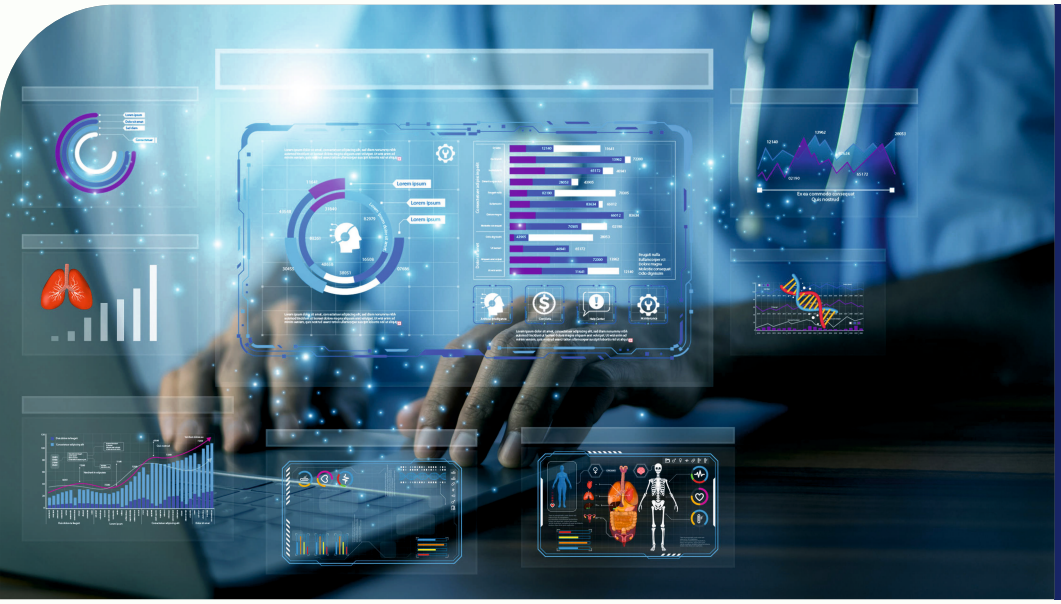
Precision, consistency and full regulatory compliance.

Collaboration

Working together with clients and partners for shared success.

Accountability

Ownership, reliability and trust in every outcome.



13+

Years Of Team Experience

Who We Are

A next-generation clinical research consultancy driving excellence in site management, Quality Audit, Trial Monitoring and regulatory compliance. We empower sponsors, CROs and biotech companies to achieve quality, compliance and operational efficiency with integrity and precision.

Why Choose Us ?

At AQniX Research Solutions, we deliver next-generation research support that combines regulatory precision, operational efficiency and compliance excellence. Our services are built on a foundation of independent expertise, technology-enabled workflows and global regulatory alignment, empowering sponsors, CROs and sites to achieve superior outcomes and inspection readiness.

Team
Experience Strength

300+
Clinical Trials Executed

200+
Trials Audited

10+
Countries Covered

20+
Trial Sites

50+
Regulatory Inspections Faced

05+
Years Of Experience in Regulatory Query Management

Expertise in
QMS, CTMS, eTMF & QA systems

Proven
global compliance leadership

Our Differentiators

Site Excellence through - AQSite

Our AQSITE model transforms site operations through proactive feasibility, regulatory readiness and GDP-driven documentation practices.

Delivers 50% faster start-up, improved patient recruitment and contemporaneous record creation at point-of-process.

Independent Compliance Assurance - AQSure

Through AQSURE, we conduct unbiased third-party audits, CAPA verification and compliance assessments that streng then trust and eliminate recurring findings.

100% independent and unbiased compliance assurance, Early gap detection, structured CAPA closure, and enhanced regulatory awareness lead to greater inspection confidence.

Continuous Oversight with - AQ360

Our AQ360 Trial monitoring model offers complete visibility into trial progress integrating on-site, centralized, remote and risk-based monitoring.

Ensures data integrity, subject safety and 60% reduction in major deviations through proactive issue identification, 100 % audit-ready documentation.

Regulatory Confidence via - AQRegX

AQREGX delivers regulatory strategy, submission support, post-approval compliance and remediation for 483s or warning/ deficiency letters.

Structured road maps, mock inspections and CAPA-driven responses enable 30% faster approvals, 70% faster deficiency resolution through effective remediation strategies and sustained compliance.

Our Expertise

We specialize in empowering clinical research organizations, sponsors and sites with structured, compliant and globally aligned operational excellence.

Site Management Services - AQSite

- End-to-end site life cycle management - feasibility to close-out
- Proactive regulatory and ethics submissions
- GDP-based staff training ensuring contemporaneous documentation
- Patient recruitment and retention strategies with complete traceability
- Integrated communication channels for real-time oversight.

Third-party Audit Services - AQSure

- Independent audits for sites, study, vendors and systems
- CAPA development, closure validation and follow-up tracking
- Regulatory compliance audits aligned with ICH-GCP, NABL, USFDA, EMA
- Comprehensive audit reporting and staff training programs
- Early detection of documentation and process deviations.

Trial Monitoring Services - AQ360

- 360° continuous monitoring across on-site centralized and remote models
- Risk-based monitoring in line with FDA and EMA guidance
- Integration of data integrity an pharma covigilance oversight
- Real-time deviation tracking, safety monitoring and protocol compliance
- Audit-ready documentation supporting faster submissions

Regulatory Compliance Services - AQRegX

- Strategic regulatory planning and submission management
- Audit-ready documentation an TMF structuring aligned with ALCOA++
- Post-approval compliance and safety reporting support
- Mock inspections, deficiency response and remediation planning
- Global authority alignment - USFDA, EMA, CDSCO, WHO, MHRA

AQniX™

RESEARCH SOLUTIONS

Committed to Quality | **Driven by Integrity** | **Focused on Compliance**

Stay Connected !

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