AQnix GLOBAL

“Leading the way in Next-Gen Research ecosystem”

Introduction

AQniX is a next-generation clinical research consultancy, transforming trial operations through innovation, digital excellence, and scientific integrity.

With specialized expertise in site management, monitoring, third-party audits, and regulatory compliance, AQniX empowers sponsors, CROs, and biotech companies to achieve operational excellence, regulatory readiness, and consistently high-quality outcomes.

Driven by innovation, precision and integrity, AQniX integrates technology- enabled workflows, expert teams, and robust quality systems to deliver efficient, compliant, and patient-focused solutions. Every clinical program is executed with transparency, rigor, and a commitment to accelerating drug development responsibly.

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

Our Vision

To redefine clinical research standards through quality, compliance, and data-driven excellence, enabling impactful healthcare innovations globally.

Our Mission

To ensure excellence in clinical research through accurate data, regulatory compliance, and quality- driven oversight. Reliable site management, independent audit, and clinical monitoring services strengthen trial integrity and safeguard participant safety supporting the advancement of innovative healthcare solutions worldwide.

Core Values

Accuracy & Data Integrity

Precise, reliable, real-time clinical data ensuring transparency, scientific validity, and confidence in every outcome.

Quality & Excellence

Robust processes, continuous improvement, and uncompromising quality standards across all aspects of research.

Integrity & Ethical Responsibility

The highest ethical principles — transparency, accountability, and respect for participant safety and credibility.

Regulatory Compliance

Strict adherence to global regulatory frameworks, ensuring inspection -ready research and trusted compliance.

13+

Years Of Team Experience

Who We Are

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INNOVATION **PRECISION** **INTEGRITY**

Why Choose Us ?

AQniX Intelligence

Where Science, Strategy, and Data Converge

Clinical development today is more connected and more complex than ever before. Breakthrough science, evolving regulations, fragmented data, and diverse patient populations demand more than execution. They require integration.

At AQniX Global, we bring together scientific expertise, strategic thinking, and advanced data intelligence into a unified approach—AQniX Intelligence. This connected framework enables smarter decisions, streamlined development, and faster pathways from discovery to delivery.

Our Services

AQSite SITE MANAGEMENT

Delivering Excellence Across Every Trial Site

AQSite is a trusted leader in clinical research and site operations, delivering high-quality, efficiently managed trials across diverse therapeutic areas. We specialize in seamless coordination among investigators, ethics committees, and sponsors, supported by proactive planning, transparent communication, and technology-driven oversight.

Our expertise in subject recruitment, site activation, regulatory documentation, and quality monitoring ensures streamlined operations, accelerated study start-ups, and consistent performance across multi-site programs. With a collaborative approach and unwavering commitment to excellence, AQSite empowers sponsors to achieve successful outcomes while advancing clinical research with integrity and precision.

Outcome

Efficient site operations, reduced protocol deviations, and improved trial timelines delivering reliable results for sponsors and research partners.

Core Activities

- Site Feasibility & Selection Support
- Site Initiation & Documentation Coordination
- Regulatory Document Management
- Site Performance Monitoring
- Patient Recruitment Tracking
- Study Close-Out Support
- Trial Master File (TMF) & Investigator Site File (ISF) Oversight

Our Services

AQSure THIRD-PARTY AUDITS

Safeguarding Quality, Strengthening Compliance, Inspiring Confidence.

AQSure provides independent, high-quality audits that safeguard compliance, strengthen quality assurance, and maintain inspection readiness across the clinical research landscape.

AQSure delivers independent audits that ensure compliance, reinforce quality assurance, and maintain inspection readiness across the full spectrum of clinical research. With a risk-based, technology-enabled approach, AQSure empowers sponsors, CROs, and vendors to strengthen operational processes, safeguard data integrity, and achieve global regulatory confidence.

Outcome

Enhanced regulatory confidence, minimized inspection risks, and reinforced research integrity ensuring trials are conducted to the highest global standards.

Core Activities

- Clinical Site Audits
- Sponsor & CRO Audits
- Vendor, CRO, & BA/BE Audits
- Trial Master File (TMF) Audits
- Compliance Audits Across Therapeutic Areas
- Risk-Based Audit Planning & Execution
- Continuous Compliance Monitoring
- Data Integrity & Documentation Review
- Training & Advisory Support
- Technology-Enabled Reporting
- Regulatory Inspection Preparation & Mock Audits
- Corrective & Preventive Action (CAPA) Recommendations

Our Services

AQ360 TRIAL MONITORING SERVICES

Independent Monitoring. Assured Performance.

AQ360 delivers independent monitoring services across all phases of clinical trials, ensuring protocol adherence, participant safety, and data integrity. Our proactive, risk-based approach emphasizes issue detection, comprehensive data verification, and transparent reporting providing sponsors and CROs with actionable insights that enhance site performance, operational efficiency, and regulatory readiness.

Outcome

Accurate data, compliant sites, and successful trial execution delivering confidence to sponsors and advancing reliable research outcomes.

Core Activities

- Independent Site Monitoring
- Site Initiation, Interim & Close-Out Visits
- Adverse Event & SAE Review
- Investigational Product (IP) Accountability
- Performance Tracking & Reporting
- Remote & On-Site Monitoring
- Source Data Verification (SDV)
- Informed Consent Process Review
- Protocol Compliance Monitoring
- Risk Identification & Mitigation
- Regulatory Readiness Support
- Continuous Oversight

Our Services

AQRegX TRIAL MONITORING SERVICES

Transforming regulatory complexity into confident clinical progress.

Built on a foundation of regulatory intelligence, disciplined workflows, and technology-enabled systems, AQRegX delivers end-to-end compliance support across diverse therapeutic areas and study phases.

From inspection readiness and audit support to documentation, query management, and advisory, AQRegX transforms regulatory processes into a streamlined, transparent, and value-driven function—strengthening both operational performance and regulatory outcomes.

Outcome

Smooth regulatory approvals, audit -ready trials, reduced delays due to compliance issues, and successful study progression with minimal regulatory risk.

Core Activities

- Pre-Inspection Readiness & Mock Audits
- Submission Tracking & Documentation Review
- Gap Analysis & Corrective Action Planning
- SOP Review & Regulatory Advisory
- Regulatory Query Management
- Compliance Audits Across Sites & Vendors
- Risk-Based Compliance Monitoring
- Training & Stakeholder Guidance

Continuous updates and insights on evolving regulatory requirements.

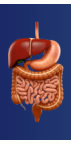
Therapeutic areas

Therapeutic areas refer to specific fields of medicine focused on diagnosing, treating, and managing particular groups of diseases or conditions. In clinical research, each therapeutic area requires specialized scientific knowledge, tailored trial design, and regulatory understanding.

AQniX Global supports a wide range of therapeutic areas, enabling efficient and compliant clinical development across diverse indications.

Oncology
Breakthrough cancer therapy development

Neurology / CNS
Complex neurological disorders



Gastroenterology
Digestive and liver disease therapies

Hematology
Blood disorder conditions

Nephrology / Urology
Renal and urological conditions

Ophthalmology
Vision care & ocular therapies

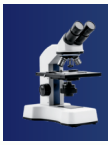
Cardiology
Cardiovasculor research

Infectious Diseases
Ropid adoptive clinical responses

Pulmonology
Chronic & ocute respiratory core

Dermatology
Targeted skin therapies

Endocrinology & Metabolic
Hormonal & metabolic disorders



Rheumatology / Autoimmune
Autoimmune & inflammatory conditions

Women's Health
Diverse conditions across life stages

Pediatrics
Safety-first younger populations

Orthopedics
Mobility & musculoskeletal health

Psychiatry / Mental Health
Adaptive mental health strategies

Pain Management
Acute & chronic pain conditions

Otolaryngology (ENT)
Ear, nose & throat disorders

Radiology & Imaging
Diagnostic imaging endpoints

Rare & Specialty
Cross-therapeutic adaptable methodology

AQniX GLOBAL

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

Stay Connected !

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