EXCELION™
RESEARCH
Precision.Innovation.Excellence

EXCELION RESEARCH

PROFILE

- **Next-Gen Research Ecosystem**

www.excelionresearch.com

TRANSFORMING CLINICAL RESEARCH WITH PRECISION, INNOVATION, AND EXCELLENCE

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Vision & Mission

OUR VISION:

To become the global benchmark for regulatory confidence in clinical research. We envision a world where every trial outcome is unquestionable, accelerating the delivery of life-saving therapies through transparency and precision.

OUR MISSION:

To deliver flawless execution in clinical trials through rigorous compliance and innovative quality assurance. We empower pharmaceutical leaders by mitigating risk and ensuring absolute data integrity from day one.

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Core Values

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Integrity

Unwavering ethical standards in every data point we collect and every partnership we build.

Innovation

Pioneering new methodologies to streamline the complex path from laboratory to patient.

Excellence

A zero-tolerance approach to error, ensuring the highest caliber of clinical outcomes.

Collaboration

Fostering unified global partnerships that amplify the strengths of every stakeholder.

Accountability

Total ownership of every process, standing behind our results with absolute confidence.

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About us

Founded with a vision to strengthen clinical research standards, Excelion Research is committed to delivering precision-driven and compliant clinical research services. We specialize in Site Management, Independent GCP Audit, Clinical Trial Monitoring, and Regulatory affairs services with a strong focus on quality, innovation, and operational excellence, we help optimize trial performance and ensure regulatory readiness. Our experienced team collaborates closely with sponsors, CROs, and research institutions across diverse therapeutic areas

20+
Years of Team Experience

250+
Clinical Trial Supported

50+
Regulatory Inspection Faced

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Leadership Team

Mr. Niraj Thakkar
Co-Founder & Director

Strategy . Regulatory .
Operations

Mr. Viral Savaliya
Co-Founder & Director

Quality . Compliance .
Digital Systems

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Our Services

01. Site Management: A comprehensive site-level support solution focused on regulatory compliance, protocol adherence, and operational excellence. From site activation to close-out, we streamline coordination, strengthen documentation practices, and ensure high-quality clinical trial execution.

02. Independent GCP Audit: A structured and objective audit solution focused on evaluating compliance with ICH-GCP guidelines, regulatory standards, and study protocols. We conduct site, vendor, and CRO audits, identify gaps, and provide actionable recommendations to strengthen quality systems, ensure data integrity, and maintain inspection readiness.

03. Clinical Trial Monitoring: A comprehensive monitoring solution designed to ensure protocol adherence, participant safety, and accurate data verification across study sites. Through risk-based oversight, structured reporting, and proactive issue management, we enhance site performance and maintain regulatory compliance throughout the trial lifecycle.

04. Regulatory Affairs: A focused regulatory support solution aimed at ensuring timely submissions, compliance alignment, and inspection preparedness. We assist with documentation management, regulatory coordination, query resolution, and gap analysis to help sponsors and research organizations navigate regulatory requirements efficiently and confidently.

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01. Clinical Trial Site Management

50% Faster Start-up

Patient Recruitment:

Patient recruitment is supported through identification via EMR systems, along with community outreach initiatives and structured referral management to enhance enrollment efficiency.

Investigator Training:

Investigator training includes GCP certification, protocol workshops, and ongoing mentorship to strengthen site competency, ensure protocol adherence, and maintain regulatory compliance.

Site Infrastructure:

Site infrastructure is strengthened through standardized SOP deployment across all sites, along with structured contract and budget coordination to ensure operational consistency and timely study activation.

Documentation & Compliance:

Documentation and compliance activities include real-time eISF/ISF maintenance and audit-ready source document verification to ensure data integrity, regulatory compliance, and inspection preparedness.

10+	20+	50+	100%
Therapeutic Areas	Operational Sites	Research Professionals	Regulatory Focus

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02. Independent GCP Audit

100% Compliance

GCP Auditing:

- We conduct investigator site audits, mock inspections, and vendor qualification assessments to evaluate compliance with ICH-GCP and applicable regulatory standards.
- Our structured audit approach identifies gaps, strengthens quality systems, and enhances inspection readiness.

CAPA Management:

- We conduct investigator site audits, mock inspections, and vendor qualification assessments to evaluate compliance with ICH-GCP and applicable regulatory standards.
- Our structured audit approach identifies gaps, strengthens quality systems, and enhances inspection readiness.

Risk Management:

- We implement Risk-Based Quality Management (RBQM) practices to proactively identify, assess, and mitigate operational risks.
- Through structured data integrity assessments and ongoing oversight, we support consistent and compliant trial execution.

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03. Clinical Trial Monitroing

60% Deviation Drop

Clinical Monitoring:

- We conduct Site Initiation, Interim, and Close-Out Visits to ensure protocol adherence, participant safety, and regulatory compliance across study sites.
- Through Source Data Verification (SDV/SDR) and structured documentation follow-up, we support data accuracy and operational consistency.

Centralized Monitoring:

- We perform remote data review and analytics to monitor site performance, query trends, and Key Risk Indicators (KRIs).
- Our risk-based oversight approach enables early identification of potential issues and supports timely corrective actions.

Oversight & Compliance:

- We track protocol deviations, coordinate escalations, and support corrective action implementation to maintain compliance standards.
- Through inspection readiness preparation and structured sponsor reporting, we ensure transparent and audit-ready trial execution.

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04. Regulatory Affairs

30% Faster Approval

Global Submissions:

- We conduct Site Initiation, Interim, and Close-Out Visits to ensure protocol adherence, participant safety, and regulatory compliance across study sites.
- Through Source Data Verification (SDV/SDR) and structured documentation follow-up, we support data accuracy and operational consistency.

Agency Liaison:

- We support regulatory meeting preparation, briefing package development, and structured coordination with regulatory agencies.
- Our team assists in managing agency queries and deficiency letters through organized response preparation.
- We also provide regulatory communication support to maintain clarity, compliance, and timely engagement with authorities.

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Systems We Leverage

Quality Management Systems (QMS)

Implementing structured quality governance frameworks to ensure standardized processes, regulatory compliance, and continuous operational oversight across all study activities.

Clinical Trial Management Systems (CTMS)

Utilizing centralized tracking systems to monitor study progress, site performance, milestones, and reporting for enhanced visibility and controlled execution.

Electronic Trial Master File (eTMF)

Maintaining organized, compliant, and audit-ready documentation through structured electronic trial master file governance and real-time documentation control.

Data Protection & Compliance Standards

Applying robust data security practices and regulatory-aligned protection standards to safeguard clinical data integrity and confidentiality.

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Let's Connect

At Excelion Research, we are committed to strengthening clinical research operations through structured quality systems and regulatory-focused support. Whether you are preparing for regulatory inspections, enhancing site performance, or strengthening compliance frameworks, our experienced team is here to support you. Connect with us to explore how our site management, audit, monitoring, and regulatory services can enhance the quality, efficiency, and reliability of your clinical programs.

GET IN TOUCH

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