QUANTUM QUIP

# eTrialTrack –

## A Unified, Integrated e-Clinical Research Solutions

Speeding up the start and completion of clinical trials, reducing costs, and increasing accuracy & efficiency...built with decades of industry experience and one seamless solution.


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# Executive Summary

## The Growing Need for a Robust Clinical Trial Application

In today's dynamic and highly competitive clinical research landscape, the rising costs and increasing complexities of clinical development have made it more difficult than ever for research sponsors—especially emerging biopharmaceutical companies—to navigate trials successfully. These challenges are further intensified when working with Contract Research Organizations (CROs), which must align seamlessly with sponsors to ensure trial efficiency and regulatory compliance.

To thrive in such an environment, speed, precision, and coordination are critical. Sponsors and CROs require not just capable personnel and scientific expertise, but also powerful, purpose-built digital tools that streamline every phase of the trial—from protocol design to final data submission. A great clinical trial application becomes indispensable in this context, as it:

- Centralizes information, minimizing communication gaps between stakeholders
- Automates repetitive and error-prone tasks, improving data accuracy and reducing human error
- Enables real-time monitoring, ensuring faster decision-making and proactive risk management
- Facilitates regulatory compliance, with built-in audit trails and documentation features
- Improves collaboration, especially in decentralized or global trials
- Speeds up timelines, ultimately accelerating the path to market for life-saving treatments

**A great clinical trial application is indispensable in today's competitive and rapidly evolving drug development landscape.**

For emerging biopharma companies, which often operate with leaner teams and tighter budgets, the right clinical trial application can be the difference between trial success and failure. It offers a scalable, efficient foundation upon which innovation can thrive—empowering sponsors and CROs to deliver results faster, more affordably, and with greater confidence.

# Introduction

## About Problem

A great clinical trial application is indispensable in today's competitive and rapidly evolving drug development landscape. The paragraph provided underlines several key challenges that necessitate such an application. Below is an in-depth exploration of why an advanced clinical trial solution is essential:

**1. Containing Rising Costs**

*Efficient Resource Allocation:*

Clinical trials often involve significant financial investments. With escalating costs in research and development, sponsors—particularly emerging biopharma companies—must carefully manage expenditures.

**2. Navigating Increasing Complexity**

*Integrated Data Management:*

As clinical trials grow more complex—incorporating diverse data types from multiple sources (laboratory results, imaging, electronic health records, etc.)—the need for an integrated platform is critical.

**3. Accelerating Speed to Market**

*Streamlined Communication and Coordination:*

Clinical trials involve multiple parties—sponsors, contract research organizations (CROs), investigators, and regulatory bodies.

## Discussion

As clinical development grows increasingly complex and expensive, emerging biopharma companies and their CRO partners face immense pressure to deliver faster, more efficient results in a constantly shifting regulatory and competitive landscape. In this environment, a robust clinical trial application is no longer optional—it is essential. By centralizing data, streamlining workflows, enhancing collaboration, and ensuring compliance, a great trial platform can significantly reduce delays, minimize errors, and accelerate decision-making. Ultimately, it serves as a strategic enabler that empowers sponsors and CROs to manage trials more effectively, shorten time to market, and increase the likelihood of clinical and commercial success.

**4. Enhancing Expertise and Decision-Making**

*Leveraging Advanced Analytics and AI:*

Modern clinical trial applications often integrate sophisticated analytics and, increasingly, artificial intelligence.

**5. Competitive Advantage in an Evolving Market**

*Adaptability to Change:*

The evolving regulatory environment and competitive market dynamics require a flexible platform that can adapt to new protocols, technologies, and regulatory guidelines.

## Conclusion

In summary, the high costs, complexity, and competitive nature of clinical development compel research sponsors and their CRO partners to adopt a great clinical trial application. Such a solution not only streamlines operations and enhances data integrity but also accelerates the development process through improved communication, real-time decision-making, and advanced analytics. By addressing these multifaceted challenges, a clinical trial application becomes a pivotal tool in driving success in clinical research while managing risks and keeping costs in check.

# About eTrialTrack

## We Didn't Just Build Another EDC. We Fixed What Others Missed

eTrialTrack is a unified, fully integrated EDC platform designed to simplify and accelerate clinical trials across geographies. Created by global clinical technology experts with over 15 years of domain experience, eTrialTrack supports trials of any size, phase, or complexity—from early-phase studies to large, multi-country programs.

Its intuitive no-code study builder with drag-and-drop functionality enables local teams and global sponsors alike to independently design and deploy studies—no programming or vendor dependence required. eTrialTrack consolidates eSource, RTSM, eConsent, ePRO, Medical Coding, CTMS & eTMF in a single interface, removing operational silos and improving data consistency across borders.

With built-in capabilities for risk-based monitoring, adaptive trial designs, and custom real-time reporting, the platform offers unparalleled visibility and control. Teams can generate data correction reports, access AllPrint functionality, and ensure compliance with international regulatory standards, including 21 CFR Part 11, GDPR, and ICH GCP.

Trusted by multinational sponsors and CROs alike, eTrialTrack empowers clinical operations with true oversight, centralized control, and audit readiness—anytime, anywhere.

# Single Configurable Builder FOR ALL

Our unified platform is supported by our configurable designer. Utilize one tool to configure any combination of eTrialTrack platform solutions through a highly configurable build, with no software coding.

The simple-to-use editor, its underlying CDISC ODM database, along with our library of preset forms, reusable study layouts and standards, makes it easy to deliver studies rapidly – typically in 4-6 weeks.

This unified platform is easy for sites and sponsors, with a single access point, role based access control per user, and a converged guided workflow allowing users to move seamlessly between solutions.

## WHY US

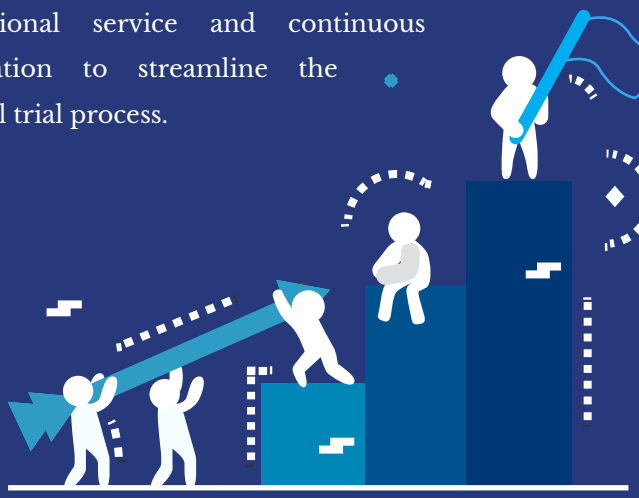
- **Built by Experts with 15+ Years of EDC Experience**
- **Scalable to any size of study**
- **Rapid Implementation**
- **24*7 global support**
- **Risk-Based Monitoring & Adaptive Trial Ready**
- **Flexible Engagement Models**

# Our MISSION

To revolutionize clinical trial management by providing a cutting-edge electronic data capture solution that ensures efficiency, accuracy, and compliance, ultimately accelerating the path to groundbreaking medical discoveries and improved patient outcomes.

# Our VISION

Empowering clinical trial professionals to efficiently manage trial data, ensure regulatory compliance, and enhance data integrity. We are committed to supporting our users with exceptional service and continuous innovation to streamline the clinical trial process.



# e-Clinical Research Solution

**Speeding up the start and completion of clinical trials, reducing costs, and increasing accuracy & efficiency with decades of industry experience and one seamless solution.**

With rising costs & complexities in clinical development, research sponsor's – especially emerging biopharma – and their contract research organization (CRO) partners require the right resources, expertise, and speed to succeed in an ever-changing, competitive environment. **eTrialTrack** is a single unified platform containing all the key technology components for any clinical trial. Take advantage of some or all of the eClinical technologies in this singular, unified platform including fully integrated EDC, eCOA, eConsent, RTSM, Tele-Health, and Participant Tracker applications. Being part of the same unified platform means a streamlined experience for sites and sponsors: a single place to log-in, and a single set of access credentials; simpler, converged workflow across individual platform components; and a single database enabling consolidated oversight and reporting.

### One Build, One Database

Eliminate the need for back-end integration with fully integrated, out-of-the-box solutions and reporting

### Single Sign-On

Reduce site burden with a single access point, and a single set of user credentials.

### Rapid Design & Launch

Setup in 4-6 weeks, even for studies including multiple platform components.

### Comprehensive Solution Suite

Get all the solutions you need within a single, unified platform: EDC, ePRO, RTSM, eConsent, Tele-Visits, and Participant Tracker.

# eTrialTrack's comprehensive platform solutions

## EDC

Full-featured EDC solution suitable for simple and complex study designs alike

- Traditional EDC and eSource direct data capture (DDC) within a single solution
- Modern, responsive design supports mobile use for site and home-visit data collection
- Remote SDV capabilities reduce CRA travel burden
- Risk-based monitoring enables targeted SDV
- Intuitive, guided workflow for sites and CRAs

## PARTICIPANT TRACKER

- Transparent management and oversight of pre-screening activity
- Centralised tracking and management of patient enrolment
- Integration with recruitment vendors to drive site contact and follow up through a single management interface
- Real time sponsor visibility into site recruitment activity performance

## eCONSENT

- Secure, remote, or site-based informed consent management with multimedia content support
- Configurable workflow for consent and reconsent, including signatures of legally authorized representatives and witnesses
- Rapid mid-study changes and consent version updates deployed real-time at site, country, and study level
- Multilingual support for site-specific forms and amendments

## RTSM

- Robust, reliable randomization including stratification and cohort management.
- Demand-driven medication supply chain management including a resupply algorithm informed by real time EDC data
- Easy, configurable integrations with depots and CMO's, and other e-clinical systems
- Full chain of custody visibility and drug accountability

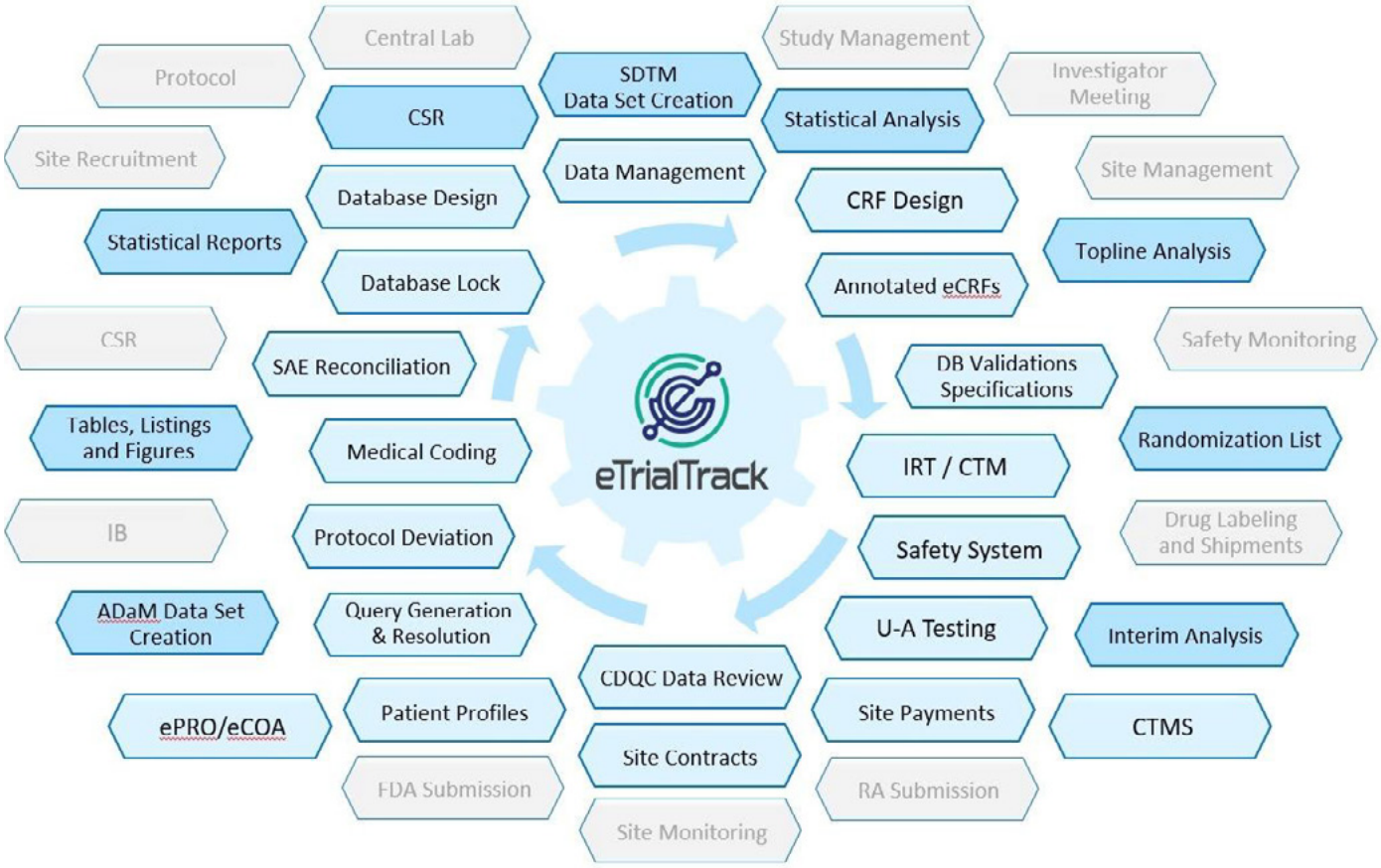
## e-PRO

- Simple, intuitive solution to capture accurate, timely data from patients, caregivers and clinicians at-site or at-home
- Device-agnostic, patient centric experience with authentication and engagement tools to optimize compliance
- Standard design and library supports rapid study set-up

## TELE-HEALTH

- Secure and compliant video visits available alongside EDC, eConsent & e-PRO
- Simple user experience enables participants to use any device and join with one click, even in low-bandwidth environments
- Ad-hoc or scheduled tele visits
- Optional video recording to facilitate compliance & adherence

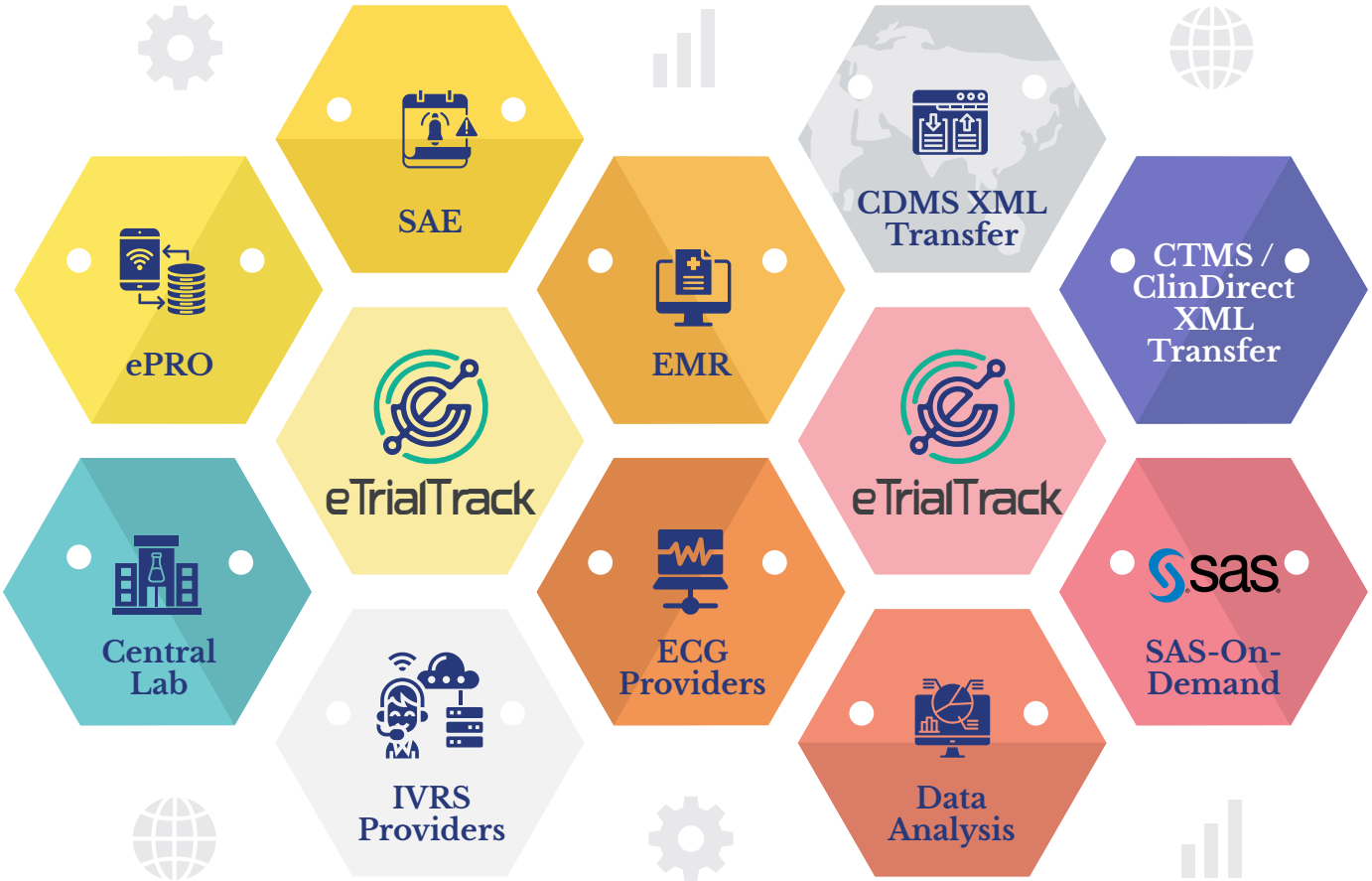
# Clinical Space Services




## Key Features and Benefits

- Customizable eCRFs with drag-and-drop design
- ODM export capabilities for seamless interoperability
- Auto encoding of medical terms using MedDRA & WHODD dictionaries
- Real-time analytics and reporting dashboards
- Automated data validation and compliance checks
- Integrations with other EHR and Lab systems
- Global Compliance & Data Security
- One build, One Database

# Plugin Ready Integrations




## Implementation Process

**1**

- Kick Off Meeting
- eCRF Layout
- Subject Portal

**2**

- Template Design
- Edit Specifications
- Report Specifications

**3**

- Coding
- QC Process
- UAT Release
- Go-Live

**4**

- Encoder
- SAS
- User Training

## eTrialTrack

Complete Unified Electronic Data Management Platform

Sponsor/CRO-driven build-and-deploy flexibility

Always audit-ready, by design

Built to scale—from pilot studies to global, multi-site trials

## Our Locations

- NOIDA
- MUMBAI
- MD, USA

## Streamlining Clinical Trials

eTrialTrack built with decades of industry experience and one seamless solution helps organizations speed up the start and completion of clinical trials, reduce costs and increase accuracy & efficiency.

## Contact Info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