Mushroom Solutions
Make life better

CTOps

CTOps is an advanced, all-in-one Clinical Trials Operation Automation System designed to streamline study execution, enhance compliance, and accelerate decision-making. With AI-driven automation, real-time analytics, and seamless integrations, it optimizes trial efficiency from startup to closeout. Empower your research with smarter workflows, improved collaboration, and faster regulatory approvals.

Project Management

Optimize clinical trial execution with an end-to-end project management framework, ensuring seamless planning, coordination, and monitoring. From pre-study planning to post-study analysis, this system enhances resource allocation, real-time tracking, and stakeholder collaboration. Automated alerts, compliance tracking, and proactive issue resolution improve efficiency, regulatory adherence, and patient safety.

Smart Study Design

Harness AI and machine learning to automate study design, optimize site and patient selection, and proactively identify trial risks. By leveraging real-world data and predictive analytics, this feature enhances protocol accuracy, streamlines recruitment, and ensures compliance, accelerating trial execution

Site Management & Payments

Optimize site selection, activation, and performance tracking with AI-driven insights and automated workflows. Real-time dashboards enhance oversight, ensuring efficient study execution. Integrated financial management streamlines invoicing and milestone-based payments, ensuring accuracy and compliance. Seamless integration with Budget Management and Coverage Analysis enhances financial transparency.

Investigator Portal

A centralized platform for investigators to manage study documents, protocol updates, and training materials. It enhances communication between sites and sponsors, ensuring compliance with regulatory requirements and improving operational efficiency. Role-based access controls, real-time notifications, and document versioning simplify trial oversight and collaboration

Patient Portal

The Patient Portal enhances participant engagement with self-scheduling, milestone tracking, and secure access to health records. Automated reminders, medication adherence tracking, multilingual support, and virtual collaboration tools enable real-time communication, document sharing, and role-based access for seamless interaction with study teams.

Document Processing & Management

Streamline document handling with automated data extraction, role-based retrieval, version control, and indexing. These tools improve workflow efficiency, enhance security, and reduce manual effort in managing clinical trial documentation.

Integrated Financial Management

Combining Coverage Analysis and Budget Management, this module automates financial planning, cost allocation, and compliance. It determines sponsor vs. insurance responsibility for procedures, generates unit counts, and provides dynamic budget creation with real-time negotiation workflows. Automated financial tracking minimizes risks, accelerates approvals, and ensures billing compliance.

Recruitment Management

Accelerate participant recruitment with AI-driven site and patient matching, automated eConsent, and real-time tracking. Integrated communication tools facilitate seamless follow-ups, while recruitment analytics optimize enrollment strategies, reducing operational costs and enhancing trial success.

Prebuilt Source Documents

Access standardized templates for essential trial documents, including eConsent, Case Report Forms (CRFs), eCOAs, ePROs, eClinROs, and eObsROs. These prebuilt resources streamline study setup, enhance consistency, and reduce administrative burden while ensuring compliance.

Decentralized Trials

Enable hybrid and fully decentralized trials with remote patient monitoring, virtual site visits, and seamless data capture. Integrated eConsent, ePROs, and wearables facilitate real-time participant engagement while ensuring compliance and reducing site visits

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eConsent

Ensure participants fully understand the trial process with AI-powered eConsent, featuring video-based explanations, multilingual subtitles, and interactive quizzes. Secure, 21 CFR Part 11-compliant eSignatures enable seamless digital approvals while maintaining regulatory compliance.

eSource

Enable real-time, electronic data capture with automated validation checks, ensuring accuracy and compliance. Seamless integration with clinical systems supports customizable forms and secure remote monitoring, streamlining decentralized and hybrid trial workflows.

eTMF & eReg

eTMF centralizes trial documentation with automated version control, audit trails, and real-time collaboration, ensuring ICH-GCP and 21 CFR Part 11 compliance. **eReg** digitizes regulatory workflows, enabling seamless document tracking, digital signatures, and submission management for faster approvals.

Advanced Analytics & Reporting

Transform trial data into actionable insights with real-time dashboards and predictive analytics. Monitor site performance, patient trends, study progress, and adverse events while leveraging AI-powered reports to optimize decision-making and mitigate risks.

Participant Payments

Integrated with platforms like Finix, Marqeta, and Intercash, this system ensures seamless merchant onboarding, compliance management, and global transactions. Secure, real-time payment solutions enhance financial transparency and operational efficiency.

DocXchange

A centralized platform for secure and encrypted document sharing with role-based access control, real-time collaboration, version control, and audit trails. It ensures compliance and enhances efficiency in clinical document management.

SDTM Analytics

Drive clinical trial success with automated SDTM data validation and insightful analytics. Our AI-powered platform ensures data quality, compliance, and submission readiness by detecting anomalies and generating real-time reports. Visual dashboards enable quick interpretation of safety and efficacy metrics, supporting informed decision-making and regulatory adherence.

Data Lineage

Gain complete visibility into your data journey with our intuitive data lineage solution. Track data flow across systems with interactive visualizations, real-time change tracking, and rich metadata context. Collaborative features enable shared stewardship, helping ensure data integrity, reduce compliance risks, and accelerate data-driven initiatives across your organization.

Coordination of Chatbot

An integrated AI-powered chatbot within patient and investigator portals streamlines communication and real-time coordination. Features like automated reminders, multilingual support, and secure messaging enhance engagement and reduce response times. Milestone tracking, virtual interactions, and role-based document access ensure synchronized study operations.

Treatment Response Prediction

Leverages advanced analytics and real-time patient data to predict treatment response and support adaptive trial designs. Integration with diverse data sources enables continuous monitoring and timely, data-driven decisions. Predictive modeling reveals efficacy and safety trends, enhancing the precision of therapeutic evaluations.

Protocol Development

Smart Study Design in CTOps uses AI and real-world data to automate protocol development, optimize site and patient selection, and anticipate trial risks. Predictive analytics enable early identification of clinical and operational challenges. This supports adaptive design and accelerates trial startup while ensuring regulatory compliance.

IRB Submissions

CTOps streamlines IRB submissions through eReg and eTMF modules with digitized workflows for document management and version control. Audit trails, e-signatures, and compliance checks ensure adherence to ICH-GCP and FDA 21 CFR Part 11 standards. Real-time collaboration accelerates approvals and enhances regulatory oversight.

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Compliance

CTOps is designed to meet the highest regulatory standards, ensuring data security, integrity, and compliance throughout the clinical trial lifecycle. With built-in audit trails, electronic signatures, and role-based access controls, CTOps helps organizations adhere to global regulatory frameworks while maintaining operational efficiency.

CTOps complies with major regulatory and industry standards, including:

ICH-GCP

Ensures ethical, scientific, and quality standards for clinical research

FDA 21 CFR Part 11

Supports compliance with electronic records and digital signatures

EU Annex 11

Governs computerized systems used in clinical trials within the European Union

HIPAA

Protects patient health information

Support

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