



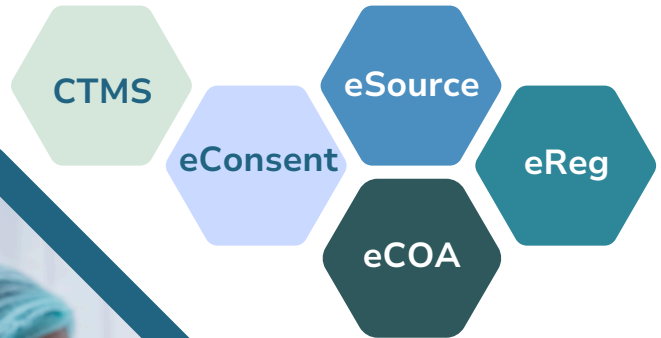
Mushroom Solutions
Make life better

CTOps

CTOps by Mushroom Solutions is a next-generation Clinical Trial Operations Automation Platform purpose-built to drive smarter, faster, and more compliant trials. Designed to unify every aspect of clinical trial execution—from AI-powered protocol design, decentralized trial support, real-time analytics, regulatory automation, to financial transparency—CTOps helps teams seamlessly manage complexity, improve participant engagement, and accelerate time-to-submission. With built-in compliance for ICH-GCP, 21 CFR Part 11, and HIPAA, CTOps is the digital backbone for transformative, patient-centric trials.



KEYWORD



Protocol Development



Streamlines protocol creation with an intuitive, AI-assisted workflow that auto-generates key sections like objectives, methodology, and eligibility. Real-time editing and one-click PDF export make protocols faster to build, easier to customize, and ready for regulatory submission.

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.

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.

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.

Integrated Financial Management



Combining Coverage Analysis and Budget Management, this module automates financial planning, cost allocation, and compliance. 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.

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.

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.

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.

Coordinator Chatbot



Acts as a centralized digital coordinator, providing real-time access to trial metrics like eConsent, meds, protocols, and participant data. Supports site tracking, user activity, and document access through a conversational interface, boosting efficiency and oversight.

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.



Treatment Response Prediction

Leverages AI to predict treatment efficacy using real-time and historical clinical data for each participant. Provides lab trends, personalized scores, and diagnostic insights to support adaptive, data-driven decisions and better outcomes.



Regulatory Compliance

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.

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.

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.

IRB Submissions



Simplifies IRB submissions with configurable workflows, digital signatures, and automated email delivery of documents. Users can manage study details, upload files, track status in real time, and access submission history with one-click downloads. This ensures regulatory accuracy, faster coordination, and accelerated review timelines.

Investigator Portal



A centralized platform for investigators to manage study documents, protocol updates, and training materials with ease. Real-time notifications, role-based access, and version control streamline collaboration and ensure regulatory compliance.

Data Lineage(FlowGenX)



Gain full visibility into your data journey with interactive lineage visualizations, real-time change tracking, and rich metadata context. Collaborate seamlessly to ensure data integrity, reduce compliance risks, and drive data-driven initiatives.

SDTM Analytics

Transform SDTM data into actionable clinical insights with AI-powered validation, real-time anomaly detection, and submission-ready reports. Interactive dashboards and automated quality checks enable smarter, risk-based decisions and regulatory compliance.



eSource

Streamlines clinical data capture with ready-to-use forms for AEs, deviations, and compliance checks. Designed for oncology, records ECOG scores, B symptoms, and physical exams while ensuring traceability and audit-readiness.

eConsent

Enables secure, compliant digital consent with support for minors, vulnerable populations, and re-consent workflows. Includes screening, comprehension checks, and clear data/specimen use disclosures, ensuring patient understanding and regulatory readiness.



eNcounter

streamlines site-patient interactions with structured visit documentation, clinical notes, and encounter-specific assessments. Supports both in-person and virtual visits—ensuring consistent data capture, protocol adherence, and smooth coordination across study teams

eClinRo

Enables structured clinician-reported outcomes with forms for AE observations, QoL assessments, and global evaluations. Supports condition-specific inputs like HBV liver imaging, ocular exams, and medication compliance to ensure accurate, site-driven insights.



ePerfo

Digitizes performance outcome assessments with validated tools like the 6-minute walk test, TUG test, and hand grip strength. Captures real-world functional and cognitive metrics through structured forms and activity tracking, ensuring standardized, regulator-ready data collection.



eObsRo

Captures caregiver-reported outcomes through structured forms for daily routines, symptom tracking, behavioral changes, and medication administration. Enables consistent, real-time reporting from caregivers—enhancing data depth for at-home and long-term care settings.



ePRO

Empowers participants to self-report health data with forms for symptoms, QoL, mood, and medication adherence. Supports real-time capture of daily activity, AEs, and mental health status—boosting engagement and data reliability in decentralized trials.



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

EU Annex 11

Governs computerized systems used in clinical trials within the European Union

FDA 21 CFR Part 11

Supports compliance with electronic records and digital signatures

HIPAA

Protects patient health information



Support



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