Mushroom Solutions

Make life better

Life Sciences Operations Automation

Mushroom Solutions delivers configurable automation solutions across clinical, regulatory, safety, and financial operations. Our CTOps platform provides a unified system for clinical trial workflows, while our solutions integrate with existing CTMS, EDC, and enterprise systems.

- ☑ **Reduce manual effort**
- ☑ **Improve compliance**
- ☑ **Accelerate submissions**
- ☑ **Deliver studies faster**

Our Capabilities

Clinical Trials & Data Management

Automate day-to-day study execution and oversight across CTMS, EDC, eSource, and site systems

- Patient recruitment and eligibility matching
- CTMS-based visit planning and tracking
- Protocol deviation tracking
- Source Data Verification (risk-based SDV)
- Query management and issue resolution

Supply Chain Optimization

Replace error-prone manual logistics with automated controls

- Serialization and shipment validation
- SAP exception reconciliation
- Partner system integrations
- Real-time tracking and audit trails
- Faster, compliant clinical supply operations

Finance Operations

Accelerate revenue and eliminate manual processes

- Lockbox and remittance automation
- Accounts receivable workflows
- Cash application acceleration
- SAP integration (RFC/BAPI)
- Reduced DSO and fewer exceptions

Regulatory & Compliance Oversight

Ensure continuous compliance with reduced manual oversight

- Protocol compliance and adherence monitoring
- Adverse event and safety signal tracking
- Automated regulatory reporting
- Global submission support (FDA, EMA)
- Inspection-ready audit trails and documentation

Solutions Across Life Sciences Workflows

We deliver configurable solutions tailored to each sponsor, CRO, and site — integrated with existing systems and governed by regulatory standards.

ICH M11 • ICH E2B(R3) • FDA • EMA • USDM • SPIRIT Compliant

Enables end-to-end digital data flow across clinical, safety, regulatory, and financial systems

CMC & eCTD Authoring

Accelerate regulatory document preparation

- Automated module ingestion
- Structured authoring with single source of truth
- Faster Module 3 and annual report generation
- Audit-ready eCTD submissions

Budget & Coverage Analysis

Automate site budgeting and clinical finance workflows

- Protocol-based site budget generation
- Coverage determination engine
- SOC classification
- Medicare billing rule alignment
- Site budget negotiation support
- Milestone-based payment tracking

Smart Study Design

Convert protocols into structured, digital assets

- Machine-readable protocol design
- Traceability across requirements and endpoints
- Amendment impact analysis
- Validation and publishing
- Reduced authoring and review time

CRA Operations Engine

Automate and standardize CRA workflows while maintaining full oversight

- Monitoring visit planning and tracking
- Site initiation, interim, and close-out visits
- Source Data Verification (risk-based SDV)
- Monitoring reports and follow-up tracking
- Risk-based monitoring and compliance alerts

Pharmacovigilance

Automate safety case processing from intake to submission

- Case intake and triage
- CIOMS narrative generation
- Signal detection support
- ICH E2B(R3)-compliant global submissions
- Faster, consistent, compliant safety reporting

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A unified platform for clinical trial workflows—integrating CTMS processes, CRA monitoring, site operations, safety reporting, budgeting, and regulatory submissions with built-in compliance and audit readiness.

Clinical Trials Operations Automation

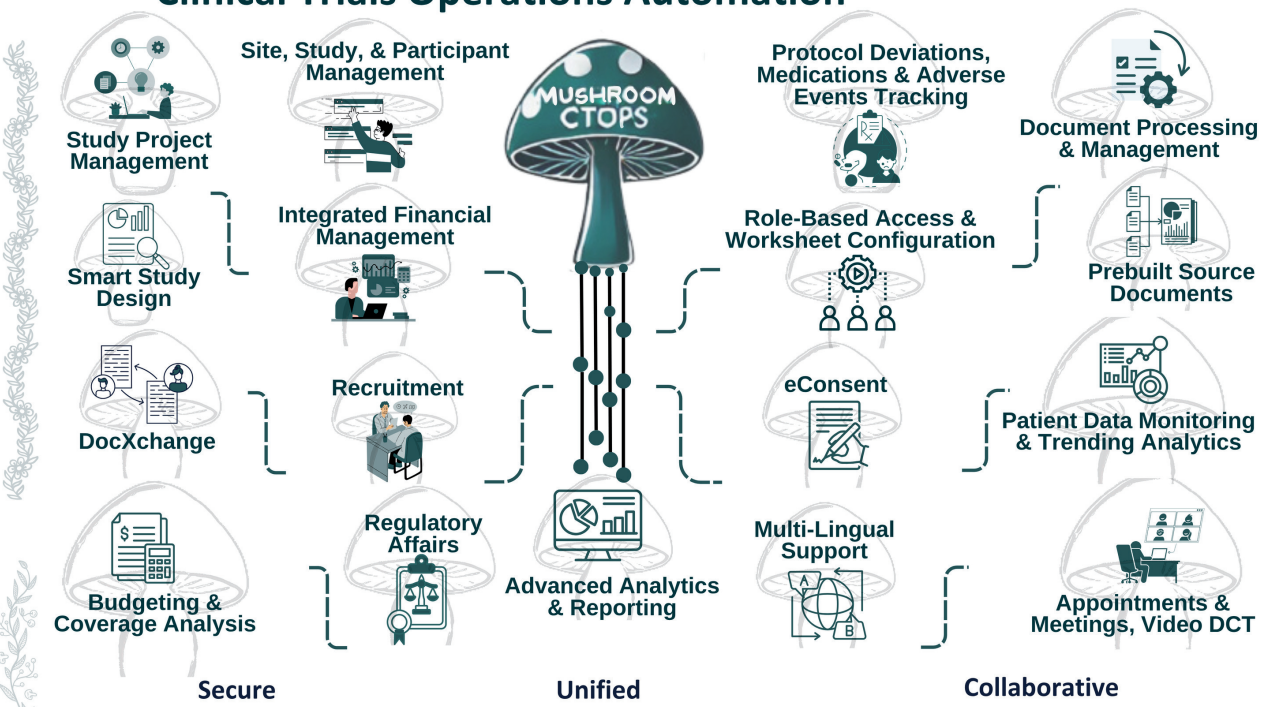
Site - Sponsor & CRO

Management Console

Site - Participant

Business Value

Operational Efficiency



Gain Competitive edge through comprehensive feature set, advanced data analytics, decentralized trials, and integrated financial management

DocuGenX

Document Processing

- PII redaction
- Narrative generation
- Structured data extraction
- FDA search automation

DocuGenX

MBotF

Conversational Agent

- Knowledge-based responses
- ERP, CTMS & website integration
- Self-learning support automation
- Faster internal & customer queries

MBotF

FlowGenX

Data Lineage

- End-to-end lineage visualization
- Audit readiness & transparency
- Impact analysis
- Nested node navigation

FlowGenX

AProX

Agentic Process Orchestration

- Task routing & approvals
- Evidence packaging for inspections
- Early data validation
- Consistent, compliant execution

AProX

Why Us?

- Business-driven, outcome-focused automation
- Agentic AI with built-in human oversight
- End-to-end automation delivery, proven at scale
- Regulatory-first design with audit readiness

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