



DATA SHEET

CTMS

Cloudbyz's Clinical Trial Management System (CTMS) is a cloud-based clinical trial operations management solution natively built on Salesforce's platform. It enables end-to-end management across all phases of the clinical study with real-time visibility and analytics across study planning, start up, study management, and close out.



Key Features

Study Management

The Cloudbyz CTMS solution offers end-to-end management of clinical trials. Set up and visualize studies according to protocol requirements and easily access details such as phase, type, therapeutic area, indication, outcomes, eligibility, etc. Design and track protocols and amendments along with ethical and regulatory approvals and access IRB-approved content from one place. Organize the content by approval and expiry dates. Additional features include milestones and tasks management, study team management, and training management.

Projections

Update and keep track of projections for Site Activations, Subject Enrollment and Budget/ Payments using the Cloudbyz CTMS solution.

Feasibility Survey

Cloudbyz CTMS allows you to create, manage, and send mass survey's out to your contacts with the click of a button. Filter your survey recipients by therapeutic area, location, phase, and more. Review, analyze, and store site responses in real-time for future reference.

Study Start-Up

CTMS helps to accelerate the study start-up and activation process. The solution provides the ability to track site performance metrics and profiles, perform feasibility surveys via portal, and provides a centralized location for accessing and sharing all study-level information. Additionally, it also enables the registration process for CRAs and investigators to participate in a study as well as provides a Chatter based collaboration forum for investigators and study coordinators to discuss about the study. Study start-up also manages directories with contact information for all study personnel including external vendors and its study library serves as a repository for study-related training tools and documents.

Study Budget Management

The Cloudbyz Clinical Trial Budget Management (CTBM) solution provides a vantage view of budget estimation, planning, and payments management across clinical trials. The CTBM solution allows a template-based approach to budget planning at both site and study levels. Rate cards and a library of operational tasks and clinical procedures can be used to set up a study or site budget. Additionally, the CTBM can be easily integrated to any third party project management solution or other downstream systems through open APIs.

Site Payments

Cloudbyz CTBM solution ensures all site payments are recorded and tracked for approval and reference. Using the solution, sites can also submit invoices and payments online via the Site Portal, allowing for faster payment processing.

Monitoring (Central/Remote/Risk Based)

Set up a monitoring schedule based on the monitoring plan and pre-schedule monitoring visits. Create and manage study-specific trip report templates. Complete trip reports directly in the system with review and sign-off processes, as well as create reminders and notifications based on the workflows. Track site and CRA performances with metrics and reports.

eDOA

Cloudbyz CTMS solution comes with automatic generation of electronic delegation of authority (eDOA) log based on the study team members and roles assigned. Once completed, the eDOA can be signed via eSignature and filed within the electronic site binder.

Portals (Site, Sponsors and CRO)

The Cloudbyz Site Portal provides a single platform to deliver content and services to clinical research sites. With the Site Portal, sites can complete eCRFs, report protocol deviations and adverse events, maintain the electronic Investigator Site File, access study information, collect essential documents, perform investigational product accountability,

and communicate with monitors, CROs, Sponsors, and other vendors, all from a central location.

Additionally, Sponsor Portal can be implemented for sponsor stakeholders, providing them with a view of the trial operations and budgetary data, as well as enabling delivery of relevant information to the other stakeholders within the clinical study.

The CRO Portal ensures real-time collaboration between the CRO, and other partners and vendors within a clinical study with real-time status and progress updates, financials, key dates statuses, and reports and dashboards.

Training Management

The Cloudbyz CTMS enables management to create and assign trainings to study and site team members. Users will be notified of assigned or pending trainings until action is taken.

Resource Management

Cloudbyz CTMS solution comes with built in resource management capabilities and helps to track FTE allocation to tasks and procedures, ensuring optimal utilization and advanced tracking through reports and dashboards.

Integration, Reports & Dashboards

Cloudbyz CTMS can be seamlessly integrated with 3rd party applications via open APIs. Users can select from the available reports and dashboards to view and assess critical metrics. Create custom and ad-hoc reports through point and click configuration. Subscribe to critical reports and receive them directly to your inbox at a chosen frequency. Critical site and study metrics are presented using powerful graphs and analytics to enhance the effectiveness of current and future trials.

Unified with eTMF, EDC, and Safety & PV

Cloudbyz CTMS, eTMF, EDC and Safety & PV solutions are natively built on the Salesforce platform and leverage a common data model to ensure seamless integration between

the systems. Additionally, users can leverage the template-based approach to accelerate their trial operations and budget processes. Our solutions span across the entire life cycle of clinical trials and help customers to stay fully compliant with global industry regulations.

Benefits

Cloudbyz provides end-to-end management of the clinical trial lifecycle, including study setup, site management, study projections, monitoring, and financial management. With Cloudbyz, you can optimize your study planning, accelerate patient recruitment, and increase trial quality, while reducing costs and minimizing risk. The solution benefits are listed below-

- Secure, reliable & scalable
- Faster time to value
- Monitor study progress & risks from planning to close-out
- Seamless collaboration among sponsors, CROs & sites
- Improved clinical team efficiency

Cloudbyz CTMS solution is designed and built to be highly scalable, secure, and reliable, providing a robust and comprehensive solution for managing clinical trial operations. Our platform is built on cutting-edge Salesforce cloud technology and is fully compliant with global regulatory standards. The cloud platform benefits are listed below-

- Real-time analytics using reports & dashboards
- Robust Data Security through fine-grained access control
- Seamless processes through workflow orchestration
- Scalable Data processing & storage with audit trail
- Ease of integration through open APIs

System Requirements

- **Internet Connection:** The solution requires a stable internet connection to access the cloud-based platform.
- **Browser:** The solution supports the latest versions of Google Chrome, Mozilla Firefox, Microsoft Edge, and Apple Safari.
- **Device:** The solution is compatible with desktops, laptops, tablets, and smartphones running on Windows, MacOS, iOS, or Android.

Pricing

Cloudbyz CTMS solution offers a subscription-based pricing model, which is based on the module and per user per year.

Compliance

All Cloudbyz products and solutions are regulatory compliant. Security, privacy, compliance, and transparency are foundational pillars of our software development process and we ensure rigorous implementation of the same through several international standards, regulations and guidelines.

Our products and services meet below listed Standards, Frameworks and Guidelines. It includes national, regional, and industry-specific requirements governing the collection and use of data.

- ISO/ IEC 27001:2013
- ISO 9001
- Good Clinical Practice (GCP)
- Good Automated Manufacturing Practice (GAMP 5)
- Health Insurance Portability and Accountability Act (HIPAA)
- 21 CFR Part 11
- General Data Protection Regulation (GDPR)
- California Consumer Privacy Act (CCPA)

Support

Cloudbyz CTMS solution provides 24/7 customer support through phone, email, and online chat. The solution also offers training and implementation services to ensure seamless deployment and adoption.

