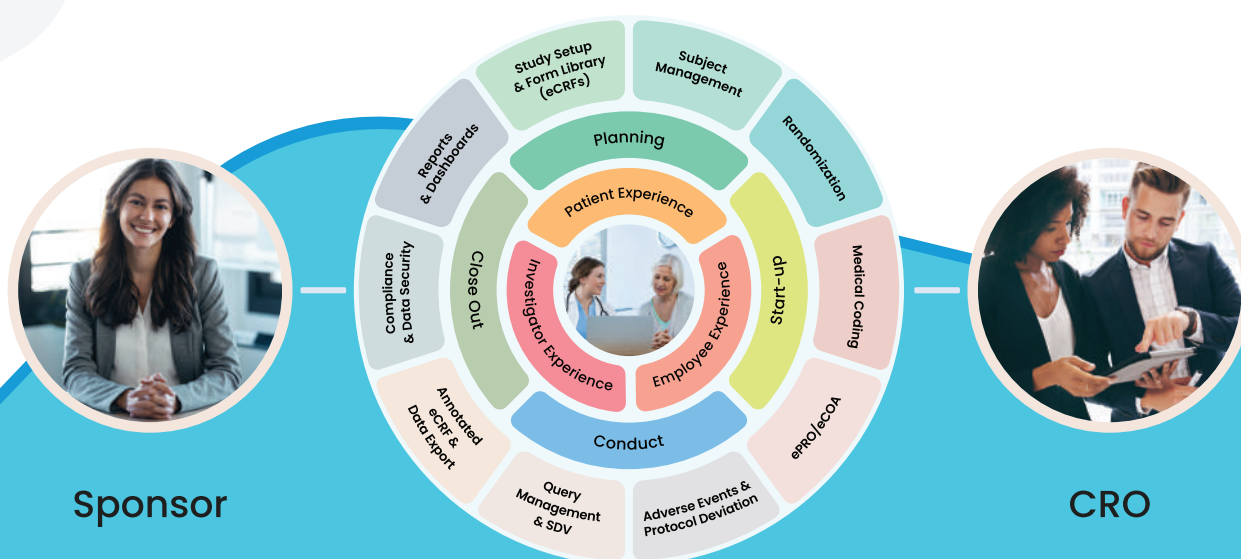




DATA SHEET

EDC

Cloudbyz EDC is a cloud-native solution with an intuitive interface that is designed to store and manage clinical data effectively throughout a clinical trial's life cycle. Our innovative solution enables clinical research teams to efficiently collect, analyze, and manage clinical data of different complexity and size. Build your study without code, with an interface that helps users build forms and easily navigate to the appropriate screens for data collection and analysis.



Key Features

Study Setup & Form Library (eCRFs)

With Cloudbyz EDC solution, set up and visualize studies according to protocol requirements and easily access details such as phase, type, therapeutic area, indication, outcomes, eligibility etc.

Cloudbyz eCRF (electronic case report form) is a cloud-based, easy-to-use solution that enables rapid data collection, more efficient data cleaning as well as an overall decrease in the efforts and costs involved in the data management process. Our solution, built on the Salesforce platform, is 21 CFR part 11 compliant and has features like data back-up, multi-language abilities, multimedia content support, customizability as well as security features such as access control and data encryption.

Rules Engine

Define data validation checks and validation messages, using the Cloudbyz Rules Engine. The No-code platform along with Cloudbyz rule builder will enable users to define the expressions that would be executed for data validation checks. Assign actions to prevent users from entering the wrong data, raise system queries and send notifications to the appropriate roles.

Subject Management

It offers capabilities for tracking the subject enrollment aspects of selected sites, regions, protocols & studies. Along with that, it consists of subject visit scheduling and related document tracking.

Randomization

This feature comes integrated with the Cloudbyz EDC. Our randomization module helps studies maintain balance between their respective treatment groups and among the recruited subjects. It enables the statisticians to generate the randomization schedule with just defining the parameters from a schedule generator form. Cloudbyz Randomization module supports and uses its own algorithms for the randomization types mentioned below

- Simple Randomization
- Block Randomization
- Permuted Block Randomization (Stratified Block Randomization)

Medical Coding

With Cloudbyz medical coding feature, maintain MedDRA and WHO Drug dictionaries and use them to code the terms by auto coding functionality which would code the values automatically as soon as they are entered or manually code the terms when needed. Medical coders will be provided with views to search dictionaries and raise queries, and approve the auto/manual coded terms.

ePRO/ eCOA

Cloudbyz eCOA (Electronic Clinical Outcome Assessment) solution engages innovative technologies to capture the clinical-outcome data. This includes ePROs (electronic patient reported outcomes), performance outcomes, clinician reported outcomes and eDiary functionalities. Our solution is handheld device friendly, supports time-sensitive data collection, enables upload of multimedia content for better patient education, and uses various edit checks to minimize data errors.

Adverse Events & Protocol Deviation

Cloudbyz EDC allows effective management of safety data for better risk management and response planning. It enables the clinical research team to monitor, track and report safety events.

Protocol deviations can be easily tracked and reported using Cloudbyz solution. Timely tracking of protocol deviations enables the research team to deploy response planning including preventive action and corrective action.

Query Management & SDV

Cloudbyz Query Management solutions provide efficient communication between monitors, data managers and coordinators. Features include automated query generation, posting the queries into the EDC system, real-time notifications, review of site responses, reissuing/closing of the queries and generation of custom dashboards and reports for query tracking and metrics.

Cloudbyz EDC allows efficient source data verification to ensure that clinical and patient data collected are accurate, complete and verifiable.

Annotated eCRF & Data Export

Cloudbyz EDC provides end-to-end eCRF configuration and workflows based on CDISC standards. Our system supports CDISC data import and export, full CDISC ODM and PDF archiving allowing adherence to global regulatory standards.

Compliance & Data Security

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.

Integration

The following integrations are available with the Cloudbyz EDC solution-

- It can be easily integrated with our patient recruitment solution which delivers end-to-end remote patient recruitment. The solution offers features such as study listing, patient portal, pre-screening, templates, eligibility testing and appointment scheduling.

- Cloudbyz DCT solution offers end-to-end project management of the clinical trials. It supports in-depth site feasibility study, monitoring, study management, IRB approval tracking, training, real-time performance tracking, among others. The Cloudbyz EDC can be integrated to the CTMS for easy extraction of data directly on to the specified fields of the eCRFs.
- Our EDC solutions easily integrate with our centralized cloud-based pharmacovigilance software solution for advanced analytics set-up along with data integrity. It empowers the end-user with proactive pharmacovigilance, smart features with data-backed predictability, scalability and cost-effective support.
- Cloudbyz EDC and decentralized clinical trial solutions enable patient data extraction via integration with third-party applications and wearable medical devices through APIs.
- The Cloudbyz EDC platform allows easy integration with various Electronic Medical Record (EMR) and Electronic Health Records (EHR) systems to populate the eCRFs directly and save huge amounts of time and effort for the sites. Our system is comprehensive, safe, secure and is HIPAA and 21 CFR Part 11 compliant to ensure data security.

Reports & Dashboards

The Cloudbyz EDC offers ready to use and customized reports and dashboards to track various metrics. Reports can be created with a point and click configuration to track metrics such as enrollment numbers, protocol deviations, adverse events, queries

Unified with CTMS, eTMF 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 industry regulations globally.

Benefits

The all-new Cloudbyz EDC application comes packed with user-friendly features. All other Cloudbyz applications such as CTMS, eTMF, CTBM, RTSM and Safety/ PV are native to the same platform as our EDC, allowing customers to have one single source of truth for a clinical trial. Furthermore, you can set up each study independently.

- Secure, Reliable & Scalable
- Faster time to value
- Monitor Subject Enrolment & Clinical Data in real-time
- Seamless collaboration amongst Sponsors, CROs & Sites
- Improved Clinical Team Efficiency
- Real-time analytics using reports & dashboard
- 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 EDC 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 EDC 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.

