# **Open**Clinica Enterprise

## EDC|ePRO|Randomization

OpenClinica Enterprise simplifies the capture, cleaning, and management of your clinical trial data. Trusted and proven in thousands of studies in over 100 countries, OpenClinica:

- Increases productivity
- Accelerates study timelines
- Fits to your study needs

| Benefits | Features |
|---|---|
| Efficient study startup | ■ Quickly implement simple to complex studies using intuitive design tools<br>■ Reuse eCRFs, users, and other assets across studies<br>■ Library of CDISC-standardized eCRFs |
| Flexible data capture | ■ Streamline data capture with edit checks, dynamic logic, scheduling, and rules<br>■ Capture data directly from patients<br>■ Batch import data or auto-capture via API<br>■ Support for multiple languages |
| Full management & control | ■ Dashboards deliver actionable information to the right users at the right time<br>■ Conduct data management, monitoring, and randomization<br>■ Manage protocol amendments and versioning |
| Easy access to data | ■ Configure your data sets and export in many popular formats<br>■ Data Mart for enhanced ad hoc reporting |
| Strict Regulatory & GCP Compliance | ■ 21 CRF Part 11 and HIPAA compliant<br>■ Audit logs & electronic signatures<br>■ Fully auditable quality system |
| Rock solid security | ■ SSL encryption<br>■ Security certifications: SSAE16 SOC1, SOC2 Type II, ISO 27001 |
| Trusted reliability | ■ 99.99% uptime<br>■ 24/7/365 system monitoring identifies issues before they become problems<br>■ Support SLA ensures quick and effective resolutions to issues |
| Seamless integration with other systems and data sources | ■ Extensive web services API enables integration with other systems<br>■ Built from the ground up on non-proprietary CDISC standards<br>■ Numerous existing extensions and integrations |

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# **Open**Clinica
## *Enterprise Edition*

## ▶ OpenClinica Optimized Cloud

Deliveries the reliability, security, and performance behind OpenClinica Enterprise. Validated, fully managed infrastructure purpose-built for running OpenClinica in strict regulatory environments. 24/7/365 support ensures system is always running.

**More details**

## Upgrades Included

Choose when and how you want to upgrade in a way that's best for you. We ensure your system is maintained in a validated state.

## Test & Production Environments

Separate test and production environments allow you to make changes without affecting your live studies. Use your test environment to safely test and validate your studies, or any system upgrades, prior to moving these into production.

## ▶ Super User Support

Super User Support provides ongoing, consultative assistance for trained users. OpenClinica experts not only react to your inquiries, but work proactively to help guide you to success with OpenClinica Enterprise.

**More details**

## ▶ Super User Training

Comprehensive instruction how to use OpenClinica from the perspectives of all user roles, both site-level and study level. Emphasis is placed on building and managing studies according to best practices, and the course incorporates workshop, tailored to your own study protocol(s).

**More details**

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# OpenClinica
### Enterprise Edition