Flex Databases Platform

Unified eClinical platform for CRO, biotech, and pharma

About Flex Databases

We develop a comprehensive clinical trial management solution since 2011.

- **10+ years** on the market
- **4 offices** in Europe & the US
- **All-in-one platform** from study planning to safety database

What sets us apart

Easy implementation

Full compliance

Complete data safety

Flexible solution

- System implementation in **3 to 10 weeks**
- A robust **backup & disaster recovery and data protection strategy**, including distributed data storages around the world
- All major **international and local regulations** covered, including FDA 21 CFR Part 11, GDPR, etc.
- Reports, workflows, trackers are **under user configuration**. Web-based solution, no installation required

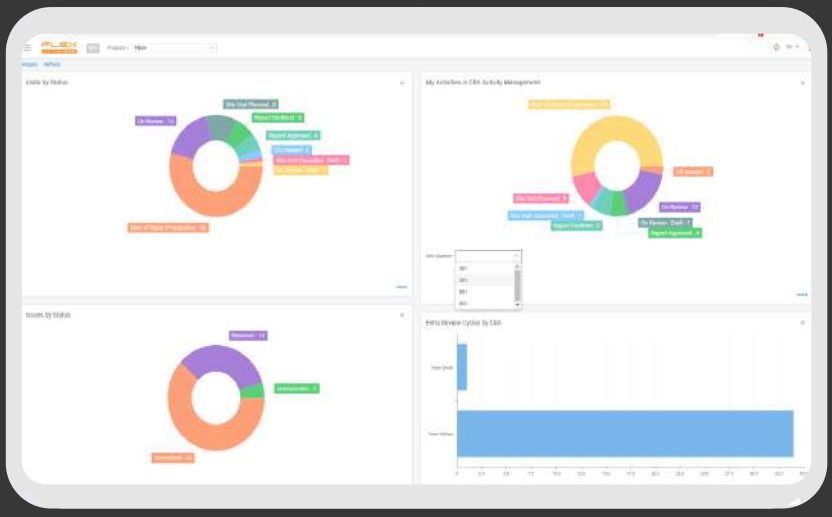
Some of our clients

Leading CROs, pharma, and biotech

novo nordisk® · CMIC · FGK CLINICAL RESEARCH · Dr.Reddy's · ERGOMED · OPTIMAPHARM · WORLDWIDE CLINICAL TRIALS

CRA Activity Management

Module Overview



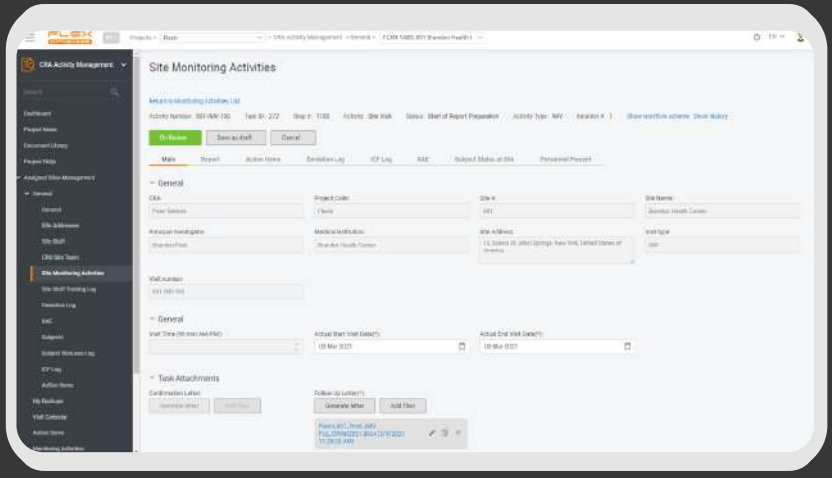
User-centric CTMS where you play by your rules, and we support your everyday work

- **There is no limit to what you can track and measure** with flexible smart trackers including action items, issues, deviations, etc.
- **Change of plans in the middle of the road?** Implement changes and use new versions of templates and trackers
- **Create Confirmation or Follow-up Letters in one click**, with all related trackers added automatically
- **Flexible and configurable Site Visit Report workflow** replicating your exact processes
- **Hard to keep track of all visits?** Use visits calendar and your tasks tab
- **Poor internet connection at site?** Use offline reporting capabilities of the system
- **Things are out of control?** KPIs are tracked, alerts are set for you to never miss a bit of a quick running study
- All templates and documents are **version controlled and automated**

Contact us to learn more about Flex Databases Platform: contact@flexdatabases.com

CRA Activity Management

List of Features



Monitoring

- Site visit planning and scheduling: Qualification, Site Initiation, Interim Monitoring, Monitoring Visits, Close-Out and any other type
- Centralized calendar and personalized calendars of planned visits
- Monitoring Visits reports, Confirmation & Follow-up letters generated automatically on customers templates
- Offline Site Visit Reports – you no longer depend on internet connection at sites
- Separate CRA cabinet
- Sponsor step: enable optional sponsor step in the workflow to allow sponsor review and sign reports

KPIs and Reporting

- Ad-hoc reporting tool for cross-project and cross-module reporting – graphs, widgets, pies, grids – all exportable
- Business Intelligence reporting – ANY report is possible
- Assessment metrics creation and CRA performance assessment

Flexibility

- All trackers are completely flexible and configurable – action items, issues, deviations, subjects enrollment and any other logs
- Templates designer for all documents – full flexibility with confirmation letters, follow-up letters, site visits reports and questionnaires
- Customizable fields & trackers – all fields in monitoring section can be changed by user at no extra fee
- Configurable workflows
- Automated notifications and alerts based on various parameters
- Site visits workflows are flexible and can be configured to reflect customer's exact process

Must-haves

- Electronic signature
- Study role-based permissions
- API for integrations – full integration with TMF, EDC systems