Flex Databases Platform

Unified eClinical platform for CRO, biotech, and pharma

GENERAL	DOCUMENTS	CLINICAL	PROJECT & FINANCE MANAGEMENT	QUALITY & COMPLINCE	SAFETY
HR Database	Trial Master File	CRA Activity Management	Project Management & Budgeting	Learning Management System	Pharmacovigilance
Project Catalogue	Document Management System	Investigators & Sites Management	Time Sheets & Utilization	Quality Management System	
Report Tool		Subject Tracking & Invoicing			

About Flex Databases

We develop a comprehensive clinical trial management solution since 2011.

- **10+ years** on the market
- **4 offices** in the US, Europe, and Asia
- **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

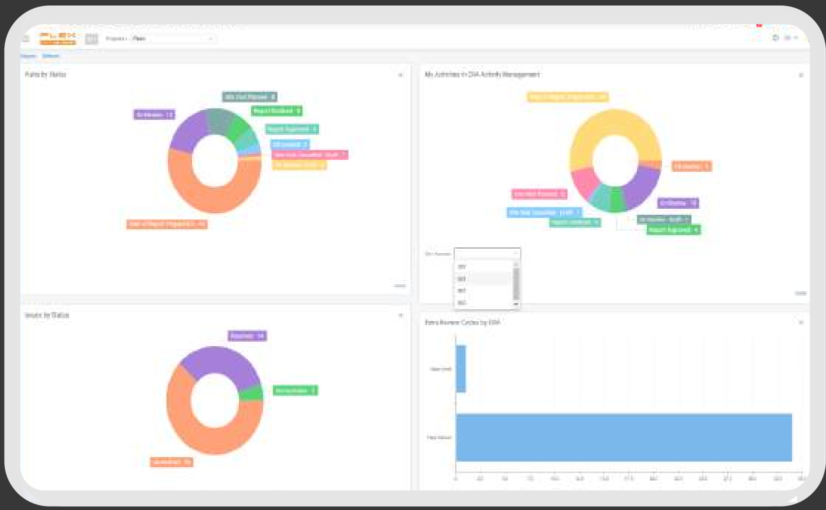
Some of our clients

Leading CROs, pharma, and biotech

novo nordisk · CMIC · FGK Clinical Research · Dr.Reddy's · ERGOMED · OPTIMAPHARM · WORLDWIDE CLINICAL TRIALS

CRA Activity Management

Module Overview



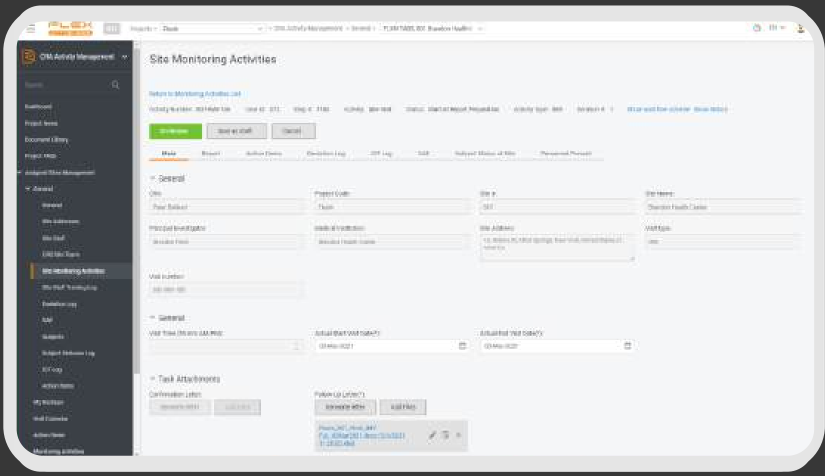
User-centric CTMS where you play by your rules, and we support your everyday work

- **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

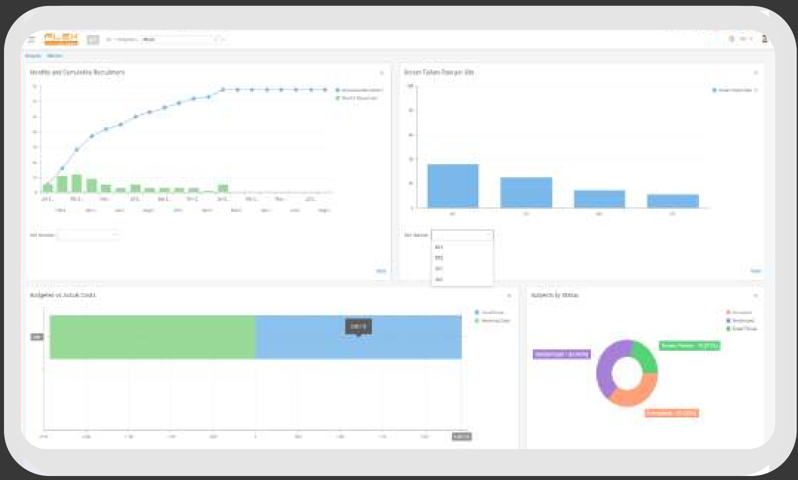
- All trackers are completely flexible and configurable – action items, issues, deviations, subjects enrollment and any other logs
- Templates designer for all documents – full flexibility with confirmation letters, follow-up letters, site visits reports and questionnaires
- Customizable fields & trackers – 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

Subject Tracking & Invoicing

Module Overview



Track what is going on at sites and gain full transparency of sites payments

Enrollment, inclusion curve, in and out of time window visits, screen failures and so much more in one place.

Widgets, reports, and graphs, all exportable and at your disposal.

Plan budgets for site payments, get automated information on visits and procedures completed, invoices are generated automatically – check, confirm, see the big picture or dive into details.

Planned vs actual reports are everywhere on every data point you can think of.

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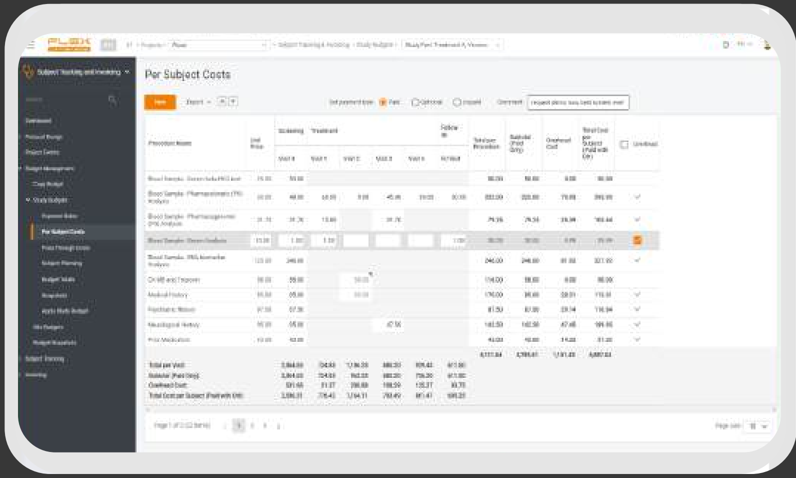
Subject Tracking & Invoicing

List of Features



Study and Site Budget Management

- Create study and site budgets
- Invoice based on various triggers: visit, procedures, milestones, etc.
- Set up any payment rules with overhead percentage, cost and extra cost reductions
- Keep different site budget versions and invoice according to specific version
- Copy budget template to speed up trial set-up
- Export and report any data on invoicing into sites
- Multi-currency budgets

On-site activities

- Track non-visit related activities (PTC management)
- Track unscheduled visits and procedures
- Manage open queries resolution

Enrollment and Patient Tracking

- Plan enrollment and compare it with a real picture
- Plan and schedule patients visits
- Track all patient visits related data
- Import data from your EDC system or add subjects manually

Invoicing

- Get overall reports on ready to be invoiced, approved and paid activities
- Generate invoices on configurable client-specific or ready-to-use templates
- Track invoices status
- Void or approve invoices
- Multiple beneficiaries at sites
- Automated invoincing based on EDC data
- Payments per visit or per procedure