




Flex Databases




eClinical platform for CROs, biotech,
pharma, and academic research



CTMS

-  CRA Activity Management
-  Investigators & Sites Management
-  Subject Tracking & Invoicing



DOCUMENTS

-  Trial Master File
-  Document Management System
-  Investigator Site File



EDC

-  Electronic Data Capture
-  Risk-Based Monitoring
-  Randomization and Trial Supply Management
-  Electronic Patient-Reported Outcome


PROJECT & FINANCE MANAGEMENT

-  Project Management & Budgeting
-  Time Sheets & Utilization

QUALITY & COMPLIANCE

-  Learning Management System
-  Quality Management System

SAFETY

-  Pharmacovigilance

About Flex Databases

We develop a comprehensive clinical trial management solution since 2011.

- 15+ 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, biotech, pharma, and academic research



Project Management & Budgeting

Module Overview

Task	Code	Unit Type	Task Card	Performed Units for This Period	Hours Spent for This Period	Cost of Units Performed for This Period	Responsible R
15,000							
Start-up				0	98	4,800	
Investigator Selection and recruitment				0	24	1,800	
Initial telephone calls		Site		0	24	1,800	
Initial telephone calls		Site	☑	12	24	1,800	Project Manag
Initial telephone calls		Site	☑	0	0	0.00	CTA
Letters/Surveys to potential investigators		Site	☑	0	0	0.00	CTA
Obtain confidentiality agreement		Site	☑	0	0	0.00	CTA
Communication with sponsor		Site	☑	0	0	0.00	Project Manag
Pre-Study visit				0	72	2,880	
Pre-Study Visit Preparation		Visit		3	24	0.00	
Pre-Study Visit Preparation		Visit	☑	0	0	0.00	Project Manag
Pre-Study Visit Preparation		Visit	☑	0	0	0.00	CTA
Pre-Study Visit Preparation		Visit	☑	0	0	0.00	CRA
Pre-Study Visit Preparation		Visit	☑	0	0	0.00	CRA
Pre-Study Visit Conduction		Visit	☑	3	24	1,440	CRA

Plan, run, and understand your clinical projects – operationally and financially
Flex Project Management & Budgeting brings together everything you know about a clinical project – scope, timelines, budgets, workload and financials – into one practical workspace. Instead of juggling spreadsheets, emails, and separate trackers, project teams see what was promised, what has been delivered, how much it costs, and where attention is needed next.

Why Flex?

- From proposal to live project without copy-paste – draft complex study budgets and turn them into operational plans and invoicing rules in a few clicks
- Instant understanding of project health – combine milestones, scope, workload, planned vs actual effort and cost, earned value, risks and margin in one view, so you immediately see whether the project is on time, in scope and financially healthy
- Decisions based on numbers, not guesses – identify which projects and clients are truly profitable, and where you actually need more people
- No more “home-made” trackers – activities, percentages done, earned value, budget consumption and FTE are calculated from real project data, not manually maintained Excel files



Project Management & Budgeting

Module Overview

The screenshot displays the 'Budget Settings - Flexin' interface. At the top, there are dropdown menus for 'Document' (Initial Budget) and 'Country' (Global), along with 'Clear All Mapping', 'Save', and 'Cancel' buttons. Below this is a 'Layout' and 'Export' section with a search bar. The main area is a table with columns: Category, Task, Responsible Role, and Unit Type. The table lists various tasks under the 'Main' category, such as 'Start-up', 'Investigator Selection and recruitment', 'Initial telephone calls', 'Letters/Surveys to potential investigators', 'Obtain confidentiality agreement', 'Communication with sponsor', 'Pre-Study visit', 'Pre-Study Visit Preparation', 'Pre-Study Visit Conduction', and 'Pre-Study Visit Report'. Roles listed include 'Project Manager', 'CTA', and 'CRA'.

Category	Task	Responsible Role	Unit Type
Main	Start-up		
Main	Investigator Selection and recruitment		
Main	Initial telephone calls	MULTI ROLE FOR: CTA, Project Manager	Site
Main	Letters/Surveys to potential investigators	CTA	Site
Main	Obtain confidentiality agreement	CTA	Site
Main	Communication with sponsor	Project Manager	Site
Main	Pre-Study visit		
Main	Pre-Study Visit Preparation	MULTI ROLE FOR: CRA, CTA, Project Manager	Visit
Main	Pre-Study Visit Conduction	MULTI ROLE FOR:	Visit
Main	Pre-Study Visit Report	MULTI ROLE FOR:	Visit

Project & Portfolio Planning

- Capture and keep visible project assumptions and milestones
- Plan tasks and milestones on an interactive Gantt chart with dependencies and clear milestone tracking
- Track project performance using built-in business analytics and custom outcome reports
- Use a portfolio view to see status, timelines and key indicators across all projects & clients
- Build complicated reports with graphs, widgets and tables in the ad-hoc reporting tool, without involving IT

Budgeting & Financial Control

- Manage budget templates by country and contract type, reuse them to speed up new proposals and change orders
- Support unit-based, milestone-based or combined planning and budgeting
- Draft, update and amend complex budgets, compare versions and keep a record of updates over the project lifetime
- Trigger invoicing based on different rules, without re-entering data for finance
- Run earned value analysis and clearly see if you are ahead or behind schedule and budget



Project Management & Budgeting

Module Overview

Task	Responsible Role	Unit Type	Num... of Units	Allocat... Number of Units	Allocati... Progress	Start	End	Jan	Feb	Mar	Apr
Documents review			0		0%	17-Jun-2021	17-Jun-2021	0	0	0	
Familiarization with study documents			0		0%			0	0	0	
Start-up											
Investigator Selection and recruitment											
Initial telephone calls											
		Site	265		0%	23-Jan-2020	04-Mar-2020	0	0	0	
Initial telephone calls	Project Manager	Site	0	343	0%	23-Jan-2020	04-Mar-2020	0	0	0	
Initial telephone calls	CTA	Site	0	321	0%	23-Jan-2020	04-Mar-2020	0	0	0	
Letters/Surveys to potential investigators	CTA	Site	265	321	121.13%	05-Mar-2020	16-Apr-2020	0	0	0	
Obtain confidentiality agreement	CTA	Site	265	361	136.23%	27-Jan-2020	07-Feb-2020	0	0	0	

Resource Planning & Utilization

- Store all information needed for planning – roles, rates, locations, scopes – in one place, ready for budgeting and allocation
- Use budgets and units (workload) planning tools to see how many people and FTE you actually need at each time point
- Assign budgeted activities to specific employees, countries and timelines, and adjust distribution of hours and FTE as the project evolves
- During planning, immediately see if a person is already allocated to other projects – avoid overbooking and last-minute surprises
- Review staff workload within a project or across projects to spot who is overloaded and who has capacity
- Export project and resource data for further analysis or integration with HR, finance or BI tools

Compliance & Security

- Web-based solution, no local installation required
- Configurable roles and permissions to control who can view, edit or invoice by project, client, region or department



manage all in one