



# Flex Databases Platform

Unified eClinical platform for CRO, biotech, and pharma

## GENERAL



eTMF



EDC



Workflow Management

## CTMS



CRA Activity Management



Investigators & Sites Management



Subject Tracking & Invoicing

## PM & BUDGETING



Project Management & Budgeting



Expense Reporting



Time Sheets & Utilization

## COMPLIANCE & SAFETY



Learning Management System



Quality Management System



Pharmacovigilance

## 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**, 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

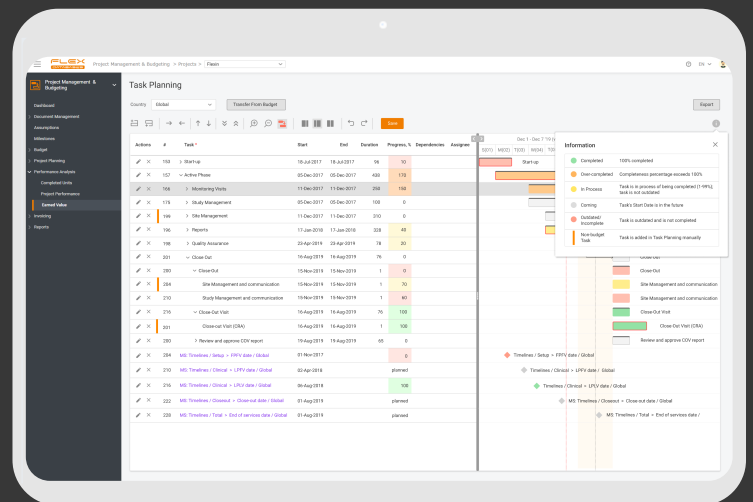
## Some of our clients

Leading CROs, pharma, and biotech



# Project Management & Budgeting

## Module Overview



- **Helicopter view** of project performance both operational and financial – a nice visual for sponsors, clients, stakeholders.
- **Zero manual work** creating trackers, tables, measuring performance, milestones, percentages, what is done and what is not – all is done for you.
- **Hard things simplified into one logical flow** – budget a project, transfer it into planning with one button, plan a project, get automated reporting on project progress, visuals and automated invoicing, see earned value analyses, and so much more.
- **Data available to make informed strategic decisions:** what projects are most profitable, do I need more people, for what, etc.
- **A transparent picture** of your team tasks and timelines.
- **Draft, update, and amend** complex budgets, compare versions, import/export budget to/from the system, transfer project to Operations as a breeze.
- **See a full picture** and invoice sponsors based on any payment rule, project performance.

# Project Management & Budgeting

## List of Features

The screenshot displays the 'Earned Value' report within the Flex Databases Project Management & Budgeting software. The interface includes a sidebar with navigation options like 'Project Management & Budgeting', 'Project Management', 'Budgeting', 'Reporting', 'Tools', and 'Help'. The main area shows a table with columns for 'Task', 'Responsible Role', 'Cost Planned Period', 'Cost Performed Period', 'Period Progress', and monthly columns from January 2020 to June 2020. The table lists various tasks such as 'Startup', 'Investigator Selection', 'Pre-Study visit', 'Documents Preparation', 'Country Startup', 'Site Start-Up', 'Country Startup', 'Site initiation visit', 'Investigator meeting(s)', 'Trainings', 'Active Phase', and 'Close Out'. The 'Totals' row at the bottom summarizes the planned and performed costs and progress. The page number 'Page 1 of 3 (20 items)' is visible at the bottom left, and 'Page size: 10' is at the bottom right.

| Task                    | Responsible Role | Cost Planned Period | Cost Performed Period | Period Progress | January 2020 | February 2020 | March 2020 | April 2020 | May 2020  | June 2020 |
|-------------------------|------------------|---------------------|-----------------------|-----------------|--------------|---------------|------------|------------|-----------|-----------|
| Startup                 | CBA              | 78,543.00           | 0                     | 1,258.00        | 0.00         | 2,545.00      | 0.00       | 1,258.00   | 0.00      | 1,258.00  |
| Investigator Selection  | CBA              | 78,543.00           | 0                     | 1,258.00        | 0.00         | 2,545.00      | 0.00       | 1,258.00   | 0.00      | 1,258.00  |
| Pre-Study visit         | CBA              | 78,543.00           | 0                     | 1,258.00        | 0.00         | 2,545.00      | 0.00       | 1,258.00   | 0.00      | 1,258.00  |
| Documents Preparation   | CBA              | 78,543.00           | 0                     | 1,258.00        | 0.00         | 2,545.00      | 0.00       | 1,258.00   | 0.00      | 1,258.00  |
| Country Startup         | CBA              | 78,543.00           | 0                     | 1,258.00        | 0.00         | 2,545.00      | 0.00       | 1,258.00   | 0.00      | 1,258.00  |
| Site Start-Up           | CBA              | 78,543.00           | 0                     | 1,258.00        | 0.00         | 2,545.00      | 0.00       | 1,258.00   | 0.00      | 1,258.00  |
| Country Startup         | CBA              | 78,543.00           | 0                     | 1,258.00        | 0.00         | 2,545.00      | 0.00       | 1,258.00   | 0.00      | 1,258.00  |
| Site initiation visit   | CBA              | 78,543.00           | 0                     | 1,258.00        | 0.00         | 2,545.00      | 0.00       | 1,258.00   | 0.00      | 1,258.00  |
| Investigator meeting(s) | CBA              | 78,543.00           | 0                     | 1,258.00        | 0.00         | 2,545.00      | 0.00       | 1,258.00   | 0.00      | 1,258.00  |
| Trainings               | CBA              | 78,543.00           | 0                     | 1,258.00        | 0.00         | 2,545.00      | 0.00       | 1,258.00   | 0.00      | 1,258.00  |
| Active Phase            | CBA              | 78,543.00           | 0                     | 1,258.00        | 0.00         | 2,545.00      | 0.00       | 1,258.00   | 0.00      | 1,258.00  |
| Close Out               | CBA              | 78,543.00           | 0                     | 1,258.00        | 0.00         | 2,545.00      | 0.00       | 1,258.00   | 0.00      | 1,258.00  |
| Totals                  |                  | Planned             | Performed             | Planned         | Performed    | Planned       | Performed  | Planned    | Performed | Planned   |
|                         |                  | 16,224,397.00       | 0.00                  | 16,656.00       | 0.00         | 16,656.00     | 0.00       | 16,656.00  | 0.00      | 16,656.00 |
|                         |                  | Variance            |                       | Variance        |              | Variance      |            | Variance   |           | Variance  |
|                         |                  | 16,224,397.00       | (0.000%)              | 16,656.00       | (0.000%)     | 16,656.00     | (0.000%)   | 16,656.00  | (0.000%)  | 16,656.00 |

### Project Management

- Project assumptions and milestones
- Project planning including Gantt chart
- Business analytics and custom outcome reports
- Project performance analysis
- Project news
- Ad-hoc reporting tool for cross-project and cross-module reporting (graphs, widgets)

### Budget Management

- Budget template management by country and per contract
- Budget amendments
- Unit-based, milestone-based and combined planning and budgeting
- Invoicing based on milestones, Project Performance Report, Units, ad-hoc invoicing
- Earned value analysis

# Project Management & Budgeting

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| Task                    | Responsible Role | Cost Planned Period | Cost Performed Period | Period Progress | January 2020 | February 2020 | March 2020 | April 2020 | May 2020  | June 2020 |
|-------------------------|------------------|---------------------|-----------------------|-----------------|--------------|---------------|------------|------------|-----------|-----------|
| Start-up                | CBA              | 78,543.00           | 0                     | 1,258.00        | 0.00         | 2,545.00      | 0.00       | 1,258.00   | 0.00      | 1,258.00  |
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| Documents Preparation   | CBA              | 78,543.00           | 0                     | 1,258.00        | 0.00         | 2,545.00      | 0.00       | 1,258.00   | 0.00      | 1,258.00  |
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| Active Phase            | CBA              | 78,543.00           | 0                     | 1,258.00        | 0.00         | 2,545.00      | 0.00       | 1,258.00   | 0.00      | 1,258.00  |
| Close Out               | CBA              | 78,543.00           | 0                     | 1,258.00        | 0.00         | 2,545.00      | 0.00       | 1,258.00   | 0.00      | 1,258.00  |
| <b>Totals</b>           |                  |                     |                       |                 | Planned      | Performed     | Variance   | Planned    | Performed | Variance  |
|                         |                  | 16,224,397.00       | 0.00                  | 16,656.00       | 0.00         | 16,656.00     | 0.00       | 16,656.00  | 0.00      | 16,656.00 |
|                         |                  | 16,224,397.00       | (0.000%)              | 16,656.00       | (0.000%)     | 16,656.00     | (0.000%)   | 16,656.00  | (0.000%)  | 16,656.00 |

## Resource utilization

- Possibility to store all information needed for planning in one single platform;
- Advanced management of the budgeted activities: connection to a specific employee, country, and timeline, changes in the distribution of budgeted hours and FTE, saving of the project, etc.
- Budgets and units (workload) planning tool to define how many team members are needed at certain time point;
- Possibility to see during the resource planning stage if the employee is already allocated to some other projects;
- Staff workload review within the project or in a cross-project mode to check who is overloaded and who is available;
- Deep analytics of data coming from multiple sources;
- Flexible notifications on reaching full FTE allocation and budget limits;
- Project data export.