




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.

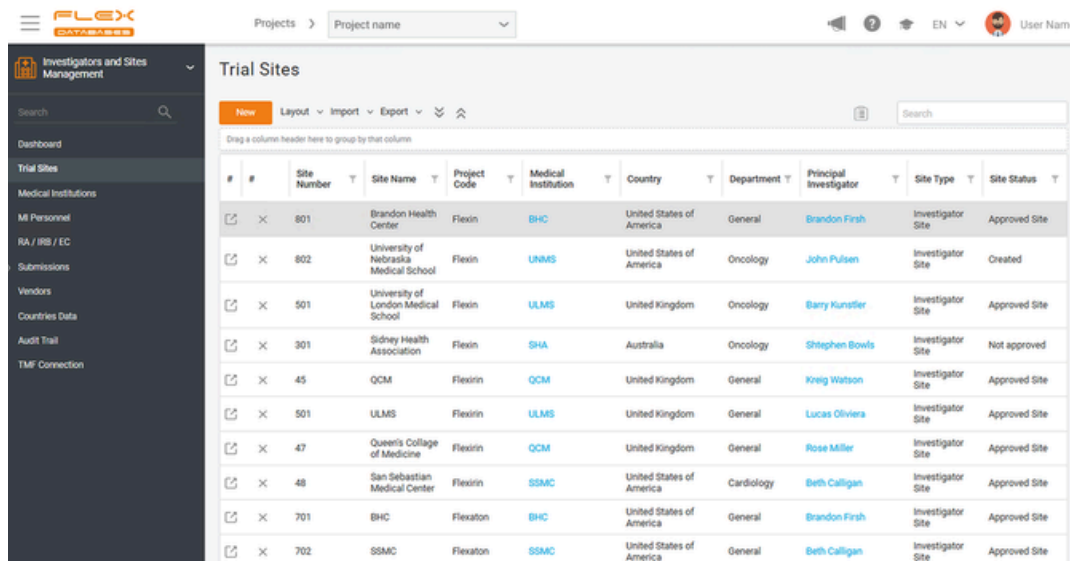
Some of our clients

Leading CROs, biotech, pharma, and academic research



Investigators & Sites Management

Module Overview



The screenshot displays the Flex Databases Investigators & Sites Management (ISM) interface. The top navigation bar includes the Flex Databases logo, a 'Projects' dropdown menu, and a 'Project name' search field. The main content area is titled 'Trial Sites' and features a table with columns for Site Number, Site Name, Project Code, Medical Institution, Country, Department, Principal Investigator, Site Type, and Site Status. The table lists 10 trial sites with their respective details.

#	Site Number	Site Name	Project Code	Medical Institution	Country	Department	Principal Investigator	Site Type	Site Status
801	Brandon Health Center	Flexin	BHC	United States of America	General	Brandon Firsh	Investigator Site	Approved Site	
802	University of Nebraska Medical School	Flexin	UNMS	United States of America	Oncology	John Pulsen	Investigator Site	Created	
501	University of London Medical School	Flexin	ULMS	United Kingdom	Oncology	Barry Kunstler	Investigator Site	Approved Site	
301	Sidney Health Association	Flexin	SHA	Australia	Oncology	Shlephen Bowls	Investigator Site	Not approved	
45	OCM	Flexin	OCM	United Kingdom	General	Krieg Watson	Investigator Site	Approved Site	
501	ULMS	Flexin	ULMS	United Kingdom	General	Lucas Oliviera	Investigator Site	Approved Site	
47	Queen's Collage of Medicine	Flexin	OCM	United Kingdom	General	Rose Miller	Investigator Site	Approved Site	
48	San Sebastian Medical Center	Flexin	SSMC	United States of America	Cardiology	Beth Calligan	Investigator Site	Approved Site	
701	BHC	Flexin	BHC	United States of America	General	Brandon Firsh	Investigator Site	Approved Site	
702	SSMC	Flexin	SSMC	United States of America	General	Beth Calligan	Investigator Site	Approved Site	

Flex Investigators & Sites Management (ISM) is your interactive data hub with investigators, sites, institutions, regulators, and vendors.

It supports feasibility and site selection, streamlines study start-up and submissions, and keeps all site- and start-up related documents aligned with your eTMF

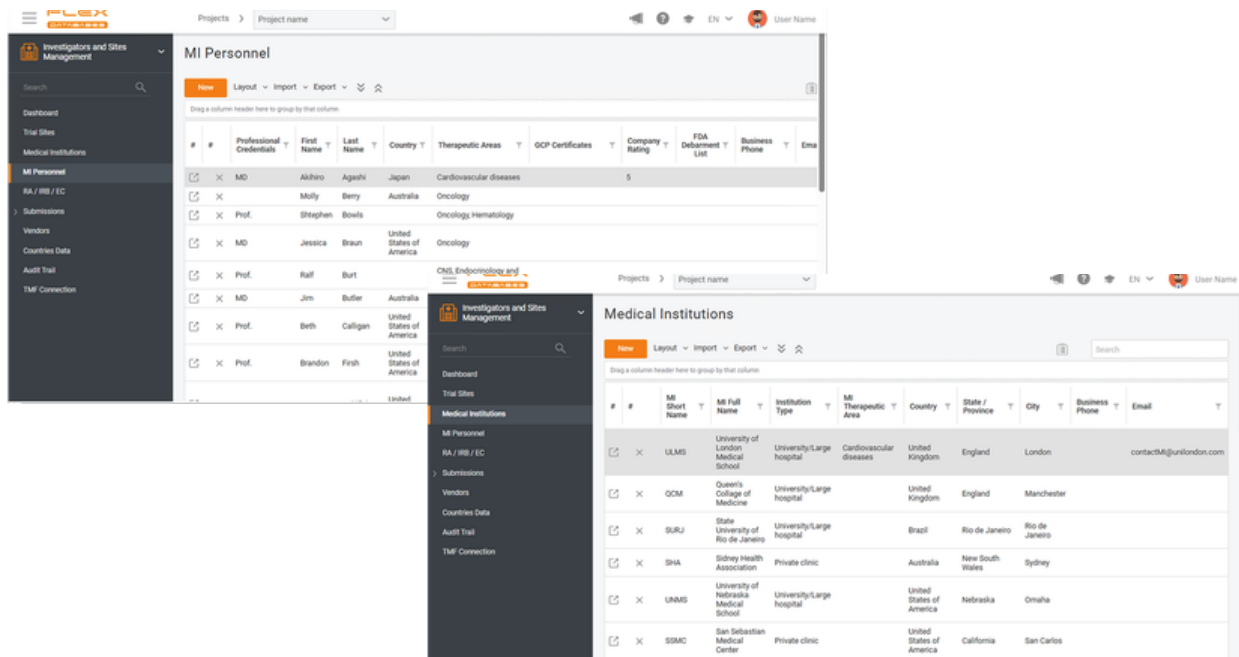
Key Benefits

- **Build and maintain a global site & investigator universe** – all investigators, medical institutions, sites, regulators, and vendors in one structured repository
- **Support feasibility and smarter site selection** – reuse structured data on experience, therapeutic areas, capacity and performance instead of chasing Excel lists every time
- **Streamline study start-up across countries** – manage submissions, approvals and contracts in a single interface and keep start-up packages synchronized with eTMF
- **Keep vendors, hospitals and clinics under control** – capture capabilities, services and pricing to support start-up, recruitment and country selection decisions
- **Provide real-time oversight** – dashboards and ad-hoc reporting across studies, countries and modules give clinical operations and other teams a clear picture of where things stand



Investigators & Sites Management

Module Overview



Feasibility & Site / Investigator Tool

- Central repository of investigators with contacts, CVs, licenses, certificates, experience, prior studies and therapeutic areas
- Profiles for medical institutions (hospitals, clinics) including addresses, descriptions and equipment
- Ability to capture feasibility-relevant attributes to support site pre-selection and feasibility analysis
- Search and filters across the entire investigator / site space to quickly identify suitable sites for upcoming studies

Site & Staff Management

- Structured information for sites: address, accreditation certificates, study team, participating studies, performance indicators
- Site team assignment and tracking of roles and responsibilities across studies and countries

- Site status management (pre-selected, in feasibility, in start-up, active, on hold, closed, etc.) to support portfolio-level oversight

Study Start-Up, Regulators & Submissions

- Records for regulatory authorities, IRBs and Ethics Committees: addresses, contacts, session periodicity, submission terms and local specifics
- Management of submission packages across countries, studies and sites in a single interface
- Tracking of regulatory and site start-up documents (contracts, licenses, certificates, site regulatory docs) with status, expiry and responsible owner
- Centralized IRB/IEC submission and approval tracking to avoid local spreadsheets and email threads

Investigators & Sites Management

Module Overview

#	RA / IRB / EC Name	RA / IRB / EC Type	Country / Region	Chargeable	Phone/Fax	Email
×	San Francisco Medical Center Ethics Review Board	Review Board/Ethics Committee	United States of America (Country)	✓		
×	Tokyo University Ethics Review Board	Review Board/Ethics Committee	Japan (Country)			
×	University Review Board	Review Board/Ethics Committee	United Kingdom (Country)	✓		
×	SHA Ethics Committee	Local EC	Australia (Country)			
×	Brazilian Central Ethics Committee	Central EC	Brazil (Country)			

Hospitals, Clinics & Vendors

- Profiles for hospitals and out-patient clinics with addresses, descriptions, equipment and capacity to support feasibility and country/site strategy
- Vendor management for local labs, imaging, home nursing and other service providers with contact details, pricing and service catalogues
- Ability to link vendors to sites, studies and countries so study start-up and operations teams can see who supports which trial

Connection to eTMF & Documentation

- Tracking of site and start-up related documents (contracts, regulatory documents, licenses, certificates) with status, expiration dates and document owners
- Seamless integration with Flex eTMF so executed contracts, approvals and key start-up documents are filed automatically into the correct TMF sections
- Detailed reporting to align operational milestones with document completeness and inspection readiness

Tracking, Reporting & Oversight

- Ad-hoc reporting tool for cross-project reporting (graphs, widgets, pivot tables) to support governance and portfolio reviews
- KPIs and dashboards for key start-up and site metrics (e.g. time from site selection to activation, submission and approval timelines, contract cycle times)

Compliance, Security & Configuration

- Web-based access with configurable roles and permissions per project, country, site, institution, regulator and vendor
- Designed to support GCP-aligned processes and inspection expectations, with full audit trail of changes and submissions