CLUPEA

All your data.
One platform.
Accelerating Clinical Trials

MediLake

For ourselves
For next generation

We believe in people who can change lives, science, and the world itself for the happiness of ourselves and future generations.

We are innovating, accelerating, and improving every aspect of modern clinical research alongside all those who have brought about big and small changes in the filed of biotechnology.

Since 2017, we have been working alongside scientists and clinical trial experts with a shared mission to advance research that transforms and saves lives.

We provide integrated and efficient clinical trial software solutions through the digitalization of clinical research, ensuring that new treatments reach those in need faster.

Our solution aims to enhance and improve many clinical studies by making it easy to collect diverse data from patients and ensuring seamless data flow across various sites.

Innovate and Accelerate your clinical trial

All your need in MediLake

MediLake provides an integrated solution for clinical trial data collection and management, offering an innovative and expedited clinical trial experience.

This enables the design and management of clinical trials as an expandable and integrable ecosystem, from data collection to integration, with minimum time and effort.

The MediLake solution offers top-tier efficiency and reliability in data acquisition, management, and visualization.

It supports all types of clinical trials, from traditional multi-site studies to decentralized trials in the post-COVID era.

Essential

MediLake SEND

CDISC SEND-based data solution for non-clinical trial data collection and management

MediLake EDC/CDMS

Solution enables the collection, integration, and management of desired clinical trial data without the need for programming skills or complex tasks

MediLake eTMF

The solution allows all users to create and manage integrated documents at every stage of clinical trials

MediLake eCOA/ePRO

Offering reliable data collection directly from trial subjects, with full integration support for Televisits and eConsent

MediLake SEND

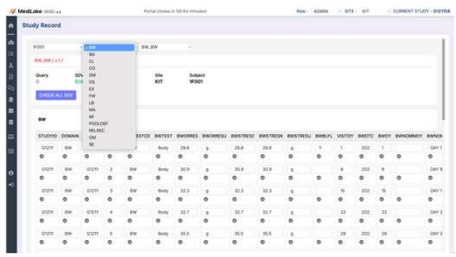
Fully integrated solution for preclinical research

All-in-One Solution

MediLake SEND handles all stages of non-clinical research within a single integrated platform, streamlining the research process and maximizing efficiency.

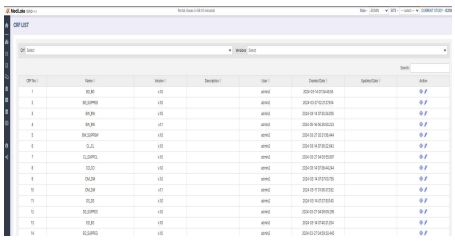
Easy to Use, Streamlined Processes

With its intuitive interface, MediLake SEND allows for quick adaptation and smooth operation. Researchers can focus on their studies without wasting time learning complex software.



Flexible and Scalable

Customized to fit the needs of small teams to large organizations. Easily scalable as your organization grows making it a suitable long-term solution



Features

Flexible, protocol-driven study support

Audit trail and electronic signatures compliant with FDA 21 CFR part 11

Integrated necropsy and histopathology data management

Facilitates the creation, management, and quality control of SEND datasets, ensuring compliance with regulatory standards

Manages clinical pathology data, including instrument calibration and sample results, fully integrated within the study workflow

Allows secure integration of external data into the MediLake, supporting comprehensive study analysis

Advanced statistical analysis and data tabulation

Digital management of GLP/non-GLP documentation

Managing and evaluating historical histopathology data, facilitating easier access to past study information

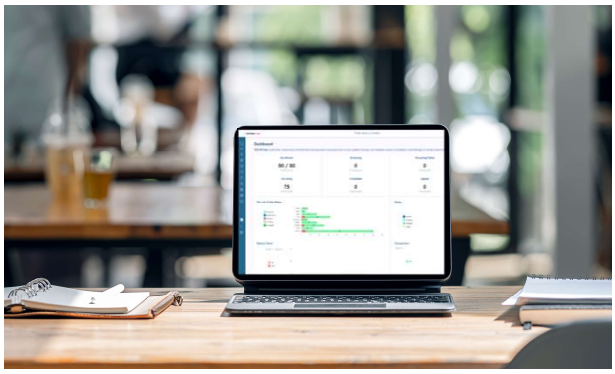
GAMP5 Certified

MediLake EDC/CDMS

All your trial data in one effortless solution

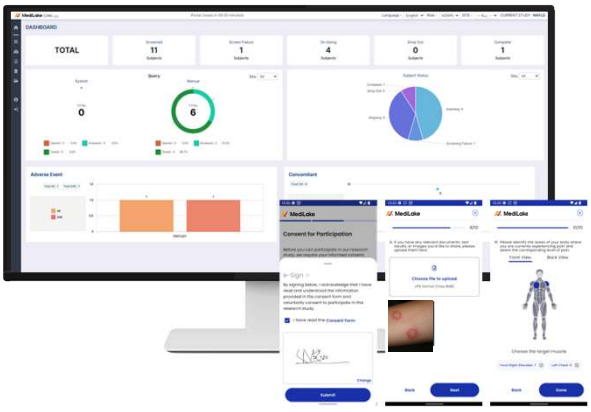
Let's keep it simple No prior skills needed

MediLake EDC features a design configuration interface seamlessly integrated into clinical data collection design, allowing you to create and adjust studies without the need for pre-design or coding skills.



Unified Solution

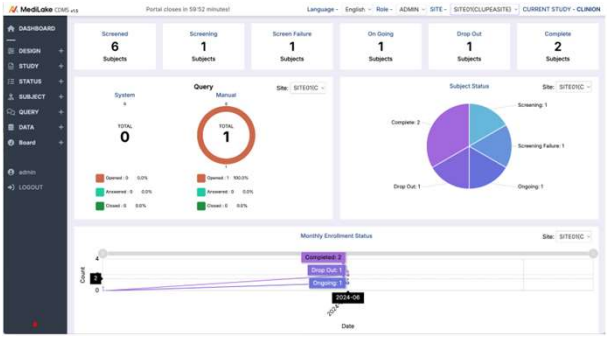
Provides all elements you need for your data from data collection, integration, and sharing with a perfect application.



All your data. One platform. Fulfil your potential.

The essential CDMS for every investigator

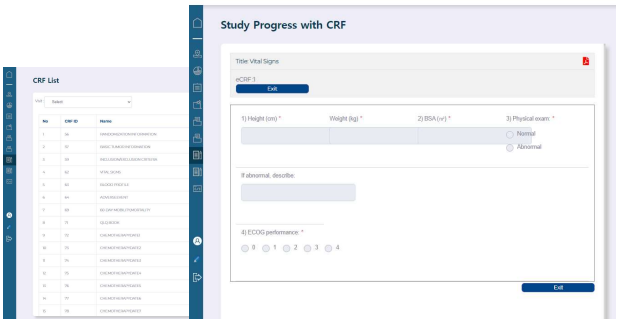
MediLake CDMS is a fully integrated eCRF solution designed for clinical research. You can efficiently access, manage, review, and share clinical trial data from any device at any time.



Professional study building in no time

Usable, reusable, and customized service available to the needs/ requirements of Study including CDISC CDASH template library.

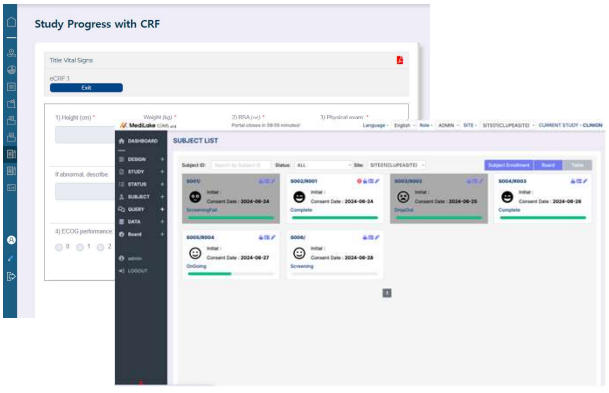
Saves your time as it also provides a full study design.



Full control and overview

MediLake CDMS is the Key of the MediLake platform for integrated management of clinical trial data.

Streamlined interface holds optimized user environment with various essential functions and data infrastructure.



MediLake

Features

Electronic Data Capture	Features for collection, viewing and reviewing of CRF data in an ICH GCP compliant manner, including capture of binary data Sign data on form, visit or patient level Laboratory reference values with time, location and factor scope Ready-to-use study templates in CDISC ODM XML format
Medical coding	Feature supporting MedDRA, WHODrug B3- and C3-formats Batch coding Coding approval
Data review and cleaning	Data management review Clinical review Data lock on form, visit patient and study level Selective SDV on item level Role based query management
Data export, API and metrics	24 / 7 output to Excel, CSV, SAS, PDF / A (compliant to FDA submission, eCTD) and CDISC ODM formats Scheduled exports Online data preview and chart visualization API for import and export of data in CDISC ODM Real-time metrics on data quality and performance

Features

Others	ISO 27001 compliance
	Audit trail and electronic signatures compliant with FDA 21 CFR part 11
	Contemporaneous and independent investigator copy created at each CRF save
	Regulatory compliance – EMA, FDA
	Support for simultaneously running unlimited versions of a study configuration
	GAMP5, CDISC ODM Certified

MediLake eTMF

Powerful documentation management

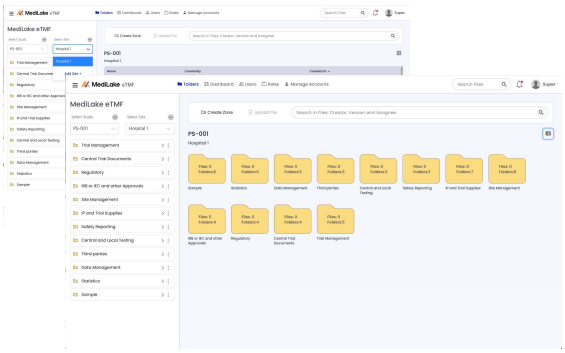
MediLake eTMF is a fully integrated document management system designed to provide quick, secure, role-based access to all documents.

With permissions, document review, and customizable structures based on industry standards(e.g. CDISC), MediLake eTMF makes documents easier, smoother, and faster.

Fast access

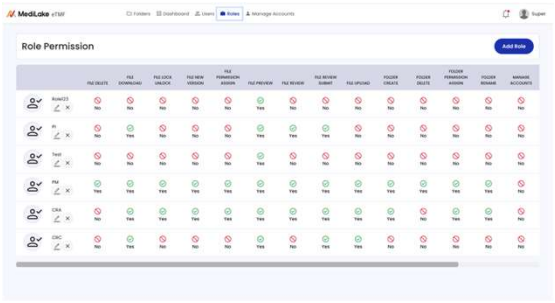
You can create and generate your own TMF structure for quick access through one interface.

It helps you to get the documents you need immediately and accurately. Also effectively reduces time through placement and other smart features.



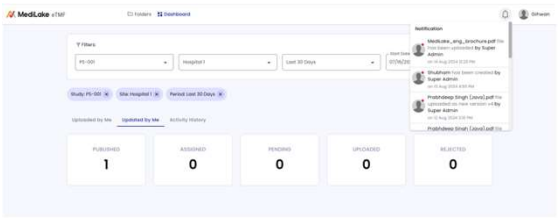
User permissions

Role-based end-user access ensures that documents are not transferred to errors. Setting end-user permissions is fast and simple based on existing user roles.



One interface

End users can upload, access, review, approve and sign documents from a single interface with full audit tracking function ensuring complete transparency.



Features

Simple TMF structure creation and configuration, including TMF DIA Reference Model

Maintenance mode, for smooth updates, after the TMF is taken into production

Dashboard including real-lime metrics of timelines, quality, and completeness

Powerful search feature

Milestones

ISF for site

Drop zone for easier document management by site

Easy archiving (eTMF-EMS)

Access control, based on role, sites, countries, and folders

Full Audit Trail

Document preview, comment, approve, lock, and electronic signature

Batch document upload drag and drop function

GAMP5 Certified

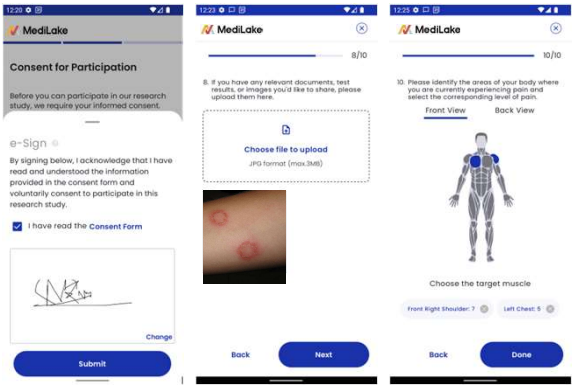
MediLake eCOA/ePRO

eCOA / ePRO solution for engaging data collection

Collect data On your hand

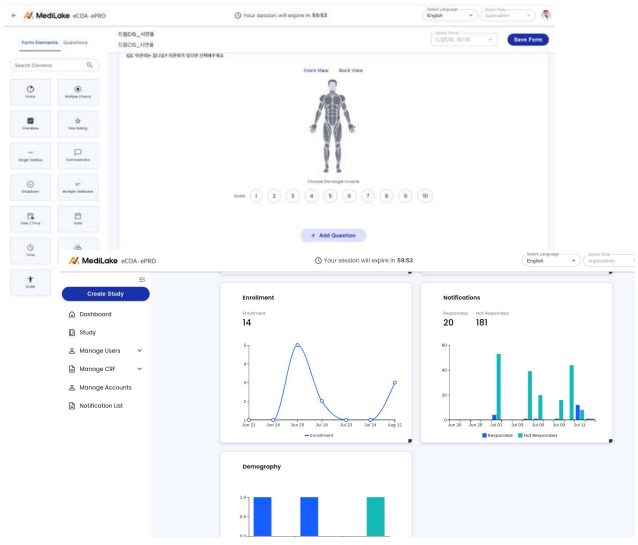
MediLake eCOA/ePRO is an integrated solution for smart, rapid data collection.

Subjects can report their data on their smartphone, tablet or computer via MediLake eCOA/ePRO



Faster, more accurate data

The file upload function on all smartphones makes it faster and easier to capture image data for all subjects.



AI-based medication management

MediLake eCOA/ePRO solutions support reliable clinical trials by increasing medication compliance through medication verification using smartphone cameras and AI.

Features

Secure peer to peer video calls

Flexible questionnaire configuration

Real time data capturing via a smartphone APP

e-Signature authentication

Easy access

Audit log tracking date, time, duration and participants

MediLake for Enterprise

Custom for your business, designed for your success

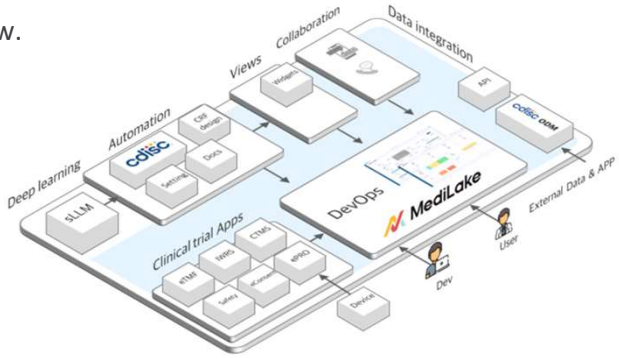
MediLake offers customized solutions.

Enables to meet all your needs of all data for new drug development from clinical/non-clinical data management to automation.

Optimize Your need, Empowering Your Clinical Trials to Succeed

MediLake deploys flexibly to meet your needs or workflow.

Depends on the scale of projects and enterprise data management, it offers customized service for your needs and consult if necessary to enhance your data management/analyzing capabilities..



Features

Custom services

Support Certification for custom service
(GAMP5, FDA/EMA)

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