

# EDC-System »DTM«

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**Conduct decentralized clinical trials  
securely and flexibly, with ease**

## Overview

- Suitable for both mono- and multicenter studies, as well as decentralized and fully digital trials
- Digital data collection with centralized management of digital questionnaires, ECRF, and ePROMs
- Integration of wearables, sensors, and patient apps for capturing electronic patient-reported outcomes (ePRO)
- EDC and eCRF with GDPR-compliant data management
- Fully compliant with EMA guidelines (EMA/INS/GCP/112288/2023)
- Backend data management adhering to the HL7® FHIR® standard
- Deployment options as a Docker container in your own IT infrastructure or in ISO 27001-certified cloud data centers in Germany

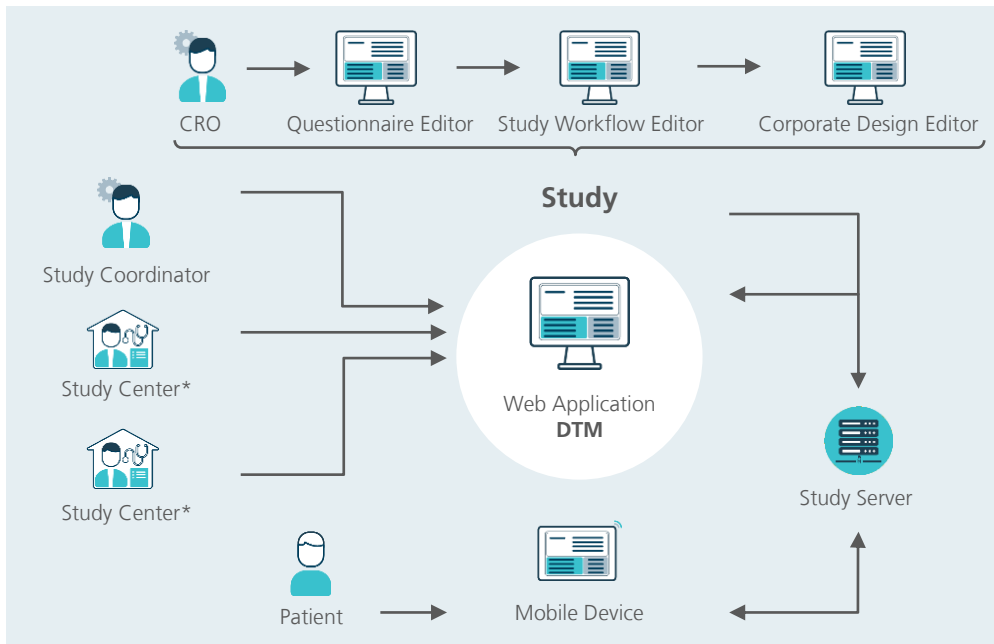
**Participating in clinical trials has never been easier or more secure than with our innovative web-based EDC system.**

Our all-in-one solution, »DTM,« is a GCP-compliant study management system tailored for CROs, digital health application (DiGa) providers, medical technology manufacturers, as well as clinics and research institutions. The »DTM« significantly enhances cost and time efficiency through:

- Accelerated study completion
- Reduced costs
- Fewer dropouts thanks to improved compliance

The Digital Trial Manager »DTM« is fully customizable and enables effective cross-site collaboration, making it ideal for multicenter and decentralized trials (DCTs) as well as entirely digital studies.

Data is collected directly from patients via an intuitive app. Additionally, it offers the option to integrate wearables or sensors as needed, along with a patient app for capturing Patient Reported Outcome Measures (PROMs).



Our EDC system »DTM« enables an effective workflow: from study planning through execution to evaluation and completion.  
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\*Relevant only for mono- and multicenter studies

## Transparency and control throughout all phases of a clinical study

Clients, medical professionals, and study personnel value the simplicity and efficiency of our EDC system, which facilitates a quick setup, seamless execution, and effective completion of clinical trials and studies.

### Features of »DTM«

- Dashboard with real-time reporting on study progress
- Scheduling feature for seamless planning and organization of visits
- Intuitive capture of queries and adverse events
- Secure audit trails for data entry, output, and modifications
- Effortless monitoring and analysis of all study data, with reporting and export functions available for individual patients
- Collection of patient data via eCRFs
- Capabilities for randomization and pseudonymization
- eConsent facilitated through video tools and digital signatures
- Compliance with modern authentication standards
- Data storage in HL7® FHIR® format
- Optional support for multiple languages

## Efficient study management for clinical research – Our offering

- **Streamlined Study Setup and Data Management:** Paperless data collection with centralized oversight of patient and study information.
- **Flexibility:** Easily adapt to any study protocol while integrating wearables, sensors, and ePROs.
- **Decentralized and Digital Collaboration:** Facilitate seamless teamwork and cross-site management of all study participants and their roles.
- **Comprehensive Data Visibility:** Benefit from an intuitive, user-friendly interface featuring clear dashboards and monitoring tools.
- **Secure Communication Channels:** Appointment scheduling, integrated video calls, and automated notifications.
- **Customizable Solutions:** Agile development and extensive support provide tailored configurations to meet your needs.
- **Collaborative Strength:** Gain access to a vast network of Fraunhofer expertise along with academic and clinical partners.

### Demo



Test our study management system »DTM« interactively and without obligation (German only).

[demo.mhlab01.iis.fraunhofer.de](https://demo.mhlab01.iis.fraunhofer.de)

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