



About Dacima Software Inc.

Since 2006, Dacima Software has been a leading innovator of Software as a Service (SaaS) and hybrid SaaS (on-site) data management solutions for clinical research, epidemiological data collection, basic research, web surveys, registries and administrative database. Dacima offers a suite of data management solutions for the healthcare sector, academia, industry and governmental organizations.



Electronic Data Capture Made Easy!

Electronic Data Capture Solutions



Why Dacima?

DACIMA has...

- ▶ State-of-the-art robust technology infrastructure based on Microsoft .Net, ASPX, HTML and JavaScript.
- ▶ Advanced scalable web-based architecture.
- ▶ A multi-lingual software interface.
- ▶ Subscription pricing.
- ▶ Hosting options to suit your needs: Secure data hosting and storage (SaaS) or install the software in your premises with our hybrid SaaS services.
- ▶ Flexible software to meet your needs and requirements.
- ▶ An international clientele.

DACIMA offers...

- ▶ Cost-effective solutions.
- ▶ Professional technical support.
- ▶ Rapid development and implementation time.
- ▶ Technical training programs to keep your staff up to date on the software.
- ▶ Detailed user guides and training material.
- ▶ Customer orientated service.
- ▶ Variety of software products to meet all your needs.

Data Management Solutions

Solutions for all your data collection needs:

- ▶ Clinical Trials
- ▶ Epidemiological Research
- ▶ Patient Web Randomization
- ▶ Post-Marketing Studies
- ▶ Patient Registries
- ▶ Meta-analysis
- ▶ Public Health Research
- ▶ Pharmacoepidemiology
- ▶ Electronic Patient Reported Outcomes (ePRO)
- ▶ Patient eDiaries
- ▶ Physician Surveys
- ▶ Patient Health Surveys
- ▶ Social Science Surveys
- ▶ Business Surveys
- ▶ Marketing Surveys
- ▶ Scientific Research Databases
- ▶ Administrative Databases



Dacima Clinical Suite Electronic Data Capture Made Easy!



+1 (514) 656-9199
info@dacimasoftware.com
www.dacimasoftware.com

Technology Overview and Fonctionnalités

Autonomy

Build your study databases completely online
Collect and manage study data more efficiently

The modular design of Dacima's web EDC software gives you the autonomy to manage your study databases, allows you to configure your study databases and design electronic forms, collect and manage your data, and manage users and access permissions all through a user-friendly web interface.

Designer module: Configure the study design and build custom data entry forms, edit checks, skip patterns, formulas, piping, and more, all through an easy to use web interface. With many advanced design features and options, not found in any other EDC software, you can design professional, elegant and sophisticated web interfaces with no programming required.

Data Entry module: Dacima's intuitive and user-friendly data entry module allows users to add subjects, collect data, and track subject and data entry status. Powerful management features including dynamic dashboards for real-time study metrics, built in reports, ad oc report generator, visit scheduler, data query tracking, electronic signatures, audit trails, Source Document Verification (SDC), monitoring and many other features help you manage and coordinate your data collection.

Manager module: Administrator access allows you create and manage users, create user groups, assign access roles and permissions, configure secure fields, create centers/sites and define password requirements, and manage FTP/secure FTP sites for automatic data extraction. Dacima's manager module and role bases access gives you the ability to manage your users and control access to all your study databases.

Offline module: Dacima's Offline applications, for laptops, tablets and smart phones, allows for data collection in regions with poor or limited Internet connectivity. With Dacima's smart upload feature your data synchronizes with the web server once the offline computer or device connects to the Internet giving you the peace of mind in knowing that your offline data is secure and accessible.

Dacima's mobile app is available for iOS, Android and Windows.

Need more details?
Request a demo!

+1 (514) 656-9199
info@dacimasoftware.com
www.dacimasoftware.com

Rapid Deployment

No programming required.
Build and deploy studies in days not weeks.

Dacima's powerful and flexible web Electronic Data Capture (EDC) software simplifies study database setup and deployment. Built in workflow and version management allows for easy changes even after the study has gone-live. Dacima's web based Designer module allows you to easily configure study design parameters and create electronic Case Report forms (eCRFs) with no computer programming expertise required. Dacima's EDC software includes advanced features and options not available in other EDC software for designing sophisticated, elegant and user-friendly electronic data entry forms.

Lower Costs

Less expensive than other EDC vendors, with more advanced features, configuration and design options.
Eliminates the need for IT resources.
Improves efficiency.

Dacima's customers realize significant saving over other EDC solutions and our powerful design and management features improve study efficiency, saving you time and money.

Powerful Data Entry and Management Features

Data collection and management tools improve efficiency.
User-friendly intuitive web interface.

Dacima's EDC software allows you to access live data anytime from anywhere through the web. Powerful design features allow you to create workflows and forms that are easy to use and enhance data collection efficiency. Study management features including dynamic dashboards that provide real-time study metrics, standard and ad hoc reports, and subject and data entry status tracking. Dacima's unique data extraction module lets you easily output your data for analysis and with many configuration options you can output your data on-demand or schedule automatic data extractions that can send your data to FTP sites or to email recipients. The extraction module outputs to different formats including CSV, tab-delimited, Excel, SAS export format, XML and ODM. The SAS and SPSS code generators, and the dynamic data dictionary generator simplifies data analysis.

Medical Coding

MedDRA and WHO Drug Dictionary auto-coding.

Dacima Clinical Suite includes auto-coding features for MedDRA and the WHO Drug Dictionary. Dacima is the first EDC vendor to be certified for the WHODRUG C/C3 format.

Regulatory Compliance

21 CFR Part 11, HIPAA, Safe Harbor.

Dacima supports compliance with regulatory requirements including FDA 21 CFR Part 11, HIPAA and Safe Harbor. Dacima's EDC software includes:

- Comprehensive and complete audit trails that track all changes to study data, and all user access, actions, and sessions
- Electronic signatures
- Access restrictions to protected health information (secure fields allow access by authorized users)
- Standard Operating procedures (SOPs) that protect data integrity and confidentiality

Secure

Encrypted.

All data transmitted to and from our servers is encrypted using 256-bit TLS/SSL. Dacima's servers are housed in secure, redundant data centers, that provide physical and network security including continuous video surveillance, on-premise guards, firewalls, electronic access control, virus protection and network intrusion detection-prevention.

Flexible and User-Friendly

Easy to use and intuitive web interface.
One software for all your database and study needs.
Tailor the database workflow to your study requirements.
Works on computers and mobile devices.
Configurable for different study designs.

Dacima's EDC is the most flexible EDC system on the market with modules and configuration options that let you create databases for Randomized Clinical Trials (RCTs), observational study design (cohort and cross-sectional), patient registries, electronic Patient Reported Outcomes (ePRO), patient eDiaries, post-marketing studies and web surveys. With an integrated web randomization module and Dacima's unique subject inclusion configuration capabilities you to create study databases that use single stage inclusion or multistage inclusion processes with status tracking at each stage of the inclusion process. Tailor the database workflow and requirements to match your study by simply activating or deactivating features and options through simple configuration screens. Dacima lets you build and manage all your study databases in one system.

Web Randomization (IWRS)

Integrated Interactive Web Randomizations (IWRS) module.
Emergency unblinding module.
Choice of randomization methods.
Simple randomization setup and configure.

Dacima's integrated web randomization (IWRS) offers built-in algorithms and configuration options for different randomization methods including: simple, block, permuted block and minimization (dynamic/adaptive). Easily configure study arms, stratified randomization, blinded/unblinded designs, parallel and cross-over study designs. Dacima Clinical Suite simplifies setup and configuration of web randomization by allowing you to generate randomization lists with a few clicks of the mouse or import your own externally generated randomization lists.

Dacima's Emergency unblinding module allows authorized users to unblind patients in the event of an emergency.

Drug Supply Management

Allocate drugs and manage supply levels.
Integrates with the Web Randomization module.

Dacima Drug Management module integrates with Dacima's web randomization (IWRS) module and allows you to allocate and resupply drugs (bottle or kit codes) to patient based on study arm. Inventory management features allows you to manage supply levels at sites with automatic email consignment requisition base low threshold levels to insure sites have adequate supplies on hand.

Data Monitoring

Source Document Verification (SDV).
Define and manage monitoring plans.

Dacima Clinical Suite includes an SDV feature that allows authorized users to mark and lock data entry fields as SDV.

Dacima's EDC software also includes a monitoring and verification module with the ability to specify forms that require verification and select all patient data for verification or generate monitoring plans that randomly create subsets of patients for monitoring.

CDISC

Create CDISC compliant forms.
Export and import ODM.

Dacima's CDISC module allows you to build CDISC compliant databases using a powerful wizard that helps you to create forms by selecting CDISC domains, topics and fields.