iMedidata®—Leverage the Power of Unified Access to the Medidata Clinical Cloud®

For clinical study teams and investigative sites, iMedidata provides a powerful user experience. With a modern approach to user interaction and centralized, single sign-on access to web-based training (eLearning) and core Medidata Clinical Cloud capabilities across all studies, iMedidata helps sites and teams get up and running quickly to streamline the conduct of clinical trials.

Today's study teams and investigative sites are required to quickly access, gain proficiency in and use a growing number of online clinical capabilities to execute their roles in clinical development. Along with the promise of greater automation, efficiency and quality comes the burden of memorizing or safely documenting a multitude of web addresses, usernames and passwords. Moreover, administrators must coordinate user training and access permissions across a complex array of systems. For users, workflow can be disjointed as they toggle back and forth across a number of applications.

iMedidata's innovative Clinical Cloud portal technology streamlines daily work by offering:

- Unified access to all studies with a single URL, login and password,
- Decentralized user account administration without bottlenecks,
- Ability to use the self-service 'Help Center' to log tickets, find status, as well as investigate previously documented issues and solutions,
- Centralized,"train once, use again" eLearning with compliance-gating and
- Single sign-on access to all clinical capabilities in the Medidata Clinical Cloud providing a single source of truth for all users.

One URL, One Login, One Password

Logging in to any Medidata study can be as simple as pointing your browser to imedidata.com and entering a single username and password you've chosen, then selecting a Medidata capability. No more memorizing URLs, multiple usernames or multiple passwords—no matter how many studies you participate in or manage. Once you log in to iMedidata, all your studies and eLearning courses are a single click away, and joining a new study is as easy as clicking the link in an email invitation.

Unified Access to All eClinical Applications

iMedidata offers out-of-the-box, CFR 21 Part 11 and ER/ES compliant single sign-on access to all Medidata:

- Studies,
- Applications,
- eLearning.

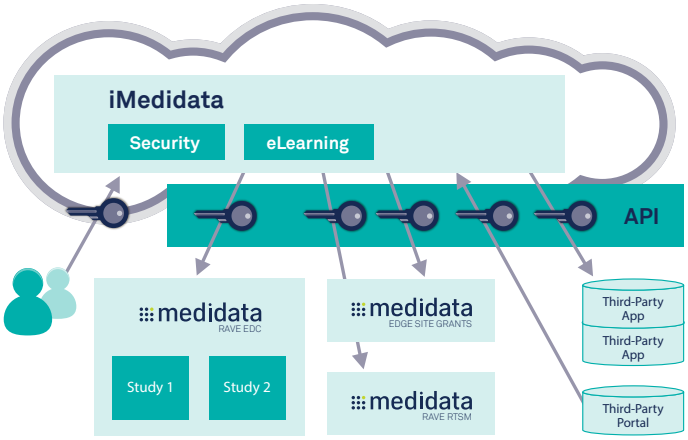
Leveraging iMedidata's open source, CAS and SAML 2.0-compliant API, the Medidata Clinical Cloud can be securely extended to provide unified SSO access and user administration to all your best-in-class eClinical applications:

- Electronic data capture and management (EDC/CDMS),
- Randomization and trial supply management (IVRS/IWRS/RTSM),
- Safety reporting,
- Electronic patient reported outcomes (Rave eCOA/ePRO) (formerly ePRO),
- Trial management (Edge Central Monitoring)(formerly CTMS),
- Document exchange (EDM).

User Administration Simplified

iMedidata employs an efficient, decentralized user account administration system that avoids user administration bottlenecks. Study owners are empowered to create teams and invite users and sites through a simple electronic process, intuitive interfaces and automated emails.

Participants at all levels of the organization can easily join the teams and studies they are invited to and immediately access the appropriate clinical capabilities and data per their designated role, or complete the required eLearning to maintain compliance and gain access. Investigators and other site staff have full access to their accounts and the ability to maintain their most up-to-date contact information.



Centralized eLearning

iMedidata's integrated eLearning delivery engine provides centralized, flexible and web-based learning management to efficiently offer study teams and sites easy and dynamic training in the Medidata Clinical Cloud where they access their clinical capabilities.

- Effective on-demand, interactive and self-paced lessons for all Medidata clinical capabilities
- Seamless account activation with gated study access until successful course completion
- No separate learning management system required
- Compatible with client-supplied, standard (SCORM) eLearning courseware
- Capability and Role specific localized content

Validation Portal Access

The Medidata Validation Portal (MVP) represents yet another addition to Medidata's Clinical Cloud and our commitment to transparency. It's free and exclusively available through iMedidata. The MVP makes viewing SDLC/CSV (software development lifecycle/computer system validation) documentation quick, easy and secure, from wherever you are. This new level of access will also save you valuable time and money by reducing or eliminating travel. View Medidata validation plans, tests and many other validation documents from your own computer, wherever you are. See what was tested and how the testing was done, including all the test steps. Why repeat what we've already tested? View all of the testing Medidata has done and target your tests elsewhere. Take advantage of this free offering and streamline your validation and auditing processes.

Rave Data Capture and Management

It Starts with Data Capture

Rave Data Capture and Management is a product suite that powers clinical trials of the future including virtual, mobile, adaptive, and master protocols. It seamlessly captures and integrates all data streams and biomarker measurements that today's targeted therapies demand, going beyond clinic and lab data to also include data from sensors, apps, images, genomics and RWE (Real World Evidence)

By capturing and integrating such a wide array of study data, **Rave Data Capture and Management** also automates many of the most challenging data management workflows across randomization, supply, coding, and safety. It is now possible for a patient to be electronically consented, randomized, provided their first supply, and automatically be coded – all in their first visit.

About Medidata

Medidata is reinventing global drug and medical device development by creating the industry's leading cloud-based solutions for clinical research. Through our advanced applications and intelligent data analytics, Medidata helps advance the scientific goals of life sciences customers worldwide, including over 950 global pharmaceutical companies, biotech, diagnostic and device firms, leading academic medical centers, and contract research organizations.

The Medidata Clinical Cloud® brings a new level of quality and efficiency to clinical trials that empower our customers to make more informed decisions earlier and faster. Our unparalleled clinical trial data assets provide deep insights that pave the way for future growth. The Medidata Clinical Cloud is the primary technology solution powering clinical trials for 18 of the world's top 25 global pharmaceutical companies and is used by 18 of the top 25 medical device developers—from study design and planning through execution, management and reporting.

info@mdsol.com | mdsol.com
+1 866 515 6044