

viedoc clinic™
viedoc admin™
viedoc designer™



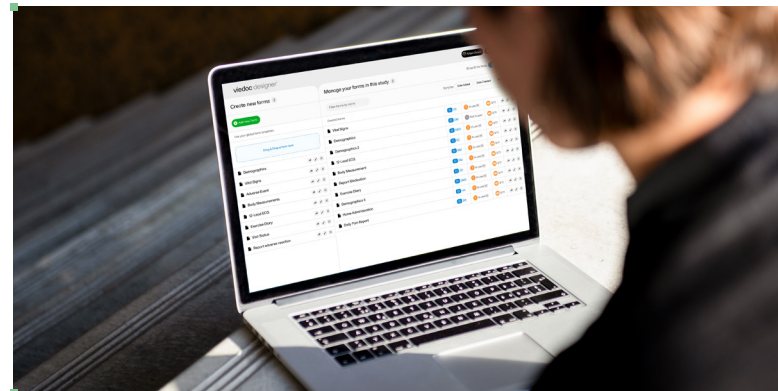
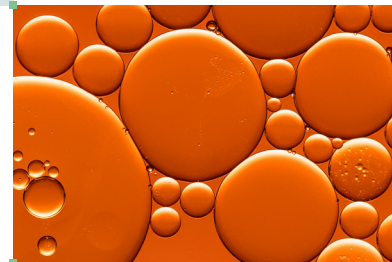
The essential
EDC system

Let's uncomplicate things



Viedoc simplifies your clinical trial from start to finish, by innovating, accelerating and improving its every aspect.

Viedoc Clinic, Viedoc Admin and Viedoc Designer form the backbone of our fully integrated EDC solution. Together, they allow you to set up, design and manage your clinical trials with minimal time and effort, as one scalable, beautifully integrated ecosystem.



viedoc clinic™

All of your trial data in one effortless solution

Viedoc Clinic is our fully integrated eCRF solution, designed for the clinical investigator's needs. It allows you to efficiently access, manage, review and share clinical trial data – from any device, at any time.

Essentially an end-user data hub, Viedoc Clinic is the heart of the Viedoc solution. That's why we've put a lot of effort into creating a smooth end-user experience – with a wide range of essential and next-level features behind one clean, streamlined interface.

US-31-038 <small>St. Luke's Hospital</small> STATUS: Ongoing AGE: 41.9 (1, 2)	US-31-037 <small>St. Luke's Hospital</small> STATUS: Ongoing AGE: 41.9 (2)	US-31-036 <small>St. Luke's Hospital</small> STATUS: Ongoing AGE: 42.3 (1, 2)
JP-40-017 <small>The University of Tokyo Hospital</small> STATUS: Ongoing AGE: 21.2 (2)	US-30-079 <small>New York Downtown Hospital</small> STATUS: Ongoing AGE: 36.6 (1, 2)	US-31-035 <small>St. Luke's Hospital</small> STATUS: Ongoing AGE: 41.9 (1, 2)
DE-95-090 <small>Berlin Hospital</small> STATUS: Ongoing AGE: 39.5 (1, 2)	DE-96-217 <small>University Medical Center Freiburg</small> STATUS: Ongoing AGE: 27.2 (2)	DE-96-216 <small>University Medical Center Freiburg</small> STATUS: Ongoing AGE: 31.1 (2)

Guided workflow

According to your user role, you'll be provided with prompts helping you take your next step: sign data, resolve a query, complete missing data, etc.

Keep track of subjects

A subject display with clearly labeled cards allows you to instantly locate and select specific subjects.

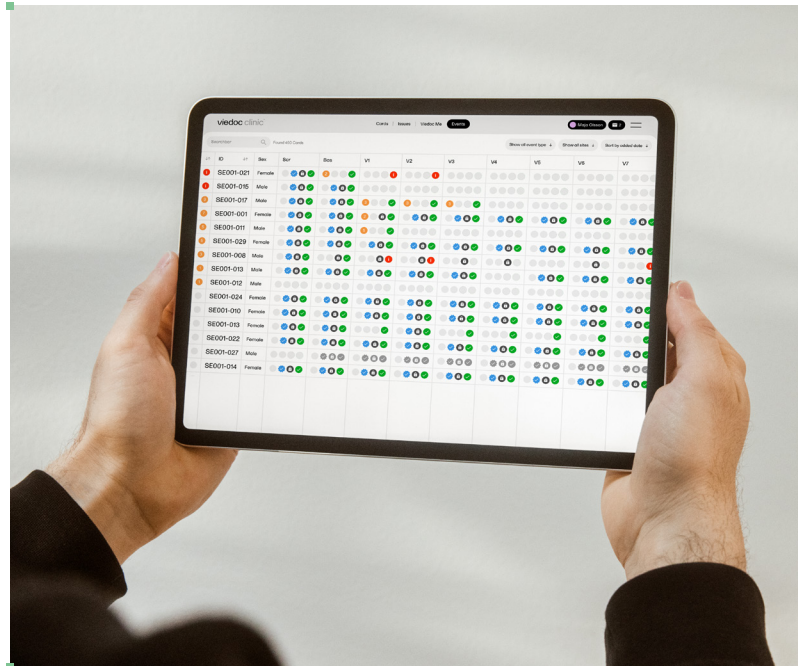


Do more in less time

Switching on batch mode lets you handle activities such as data review, data lock or data signing for multiple patients and events, all in one go.

Tablet support

Working on a tablet device? You'll enjoy Viedoc Clinic's interface, designed for maximum ease of use whichever platform you're on.



Full control and overview

From missing data to signing, review and lock status, the events overview makes it easy to identify and address any patients and events that require attention.

Batch Data Console

You've selected 77 forms in 12 events, on 4 subjects.

Apply

<input checked="" type="checkbox"/>		Lock all selected unlocked forms (36)	5
<input type="checkbox"/>		Unlock all selected locked forms (11)	0
<input checked="" type="checkbox"/>		CRA all selected unreviewed forms (41)	7
<input type="checkbox"/>		Un-CRA all selected reviewed forms (8)	0

Real-time metrics

Knowing that reliable data quality is essential to any study, we've designed the metrics page to provide you with fresh, real-time data – on study, country or site level.

Queries



TOTAL
639

TYPE

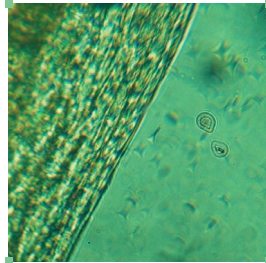
Validation	402
Manual	237 / 37%
Item	
Event Date	73 / 11.4%

Query State



TOTAL
110

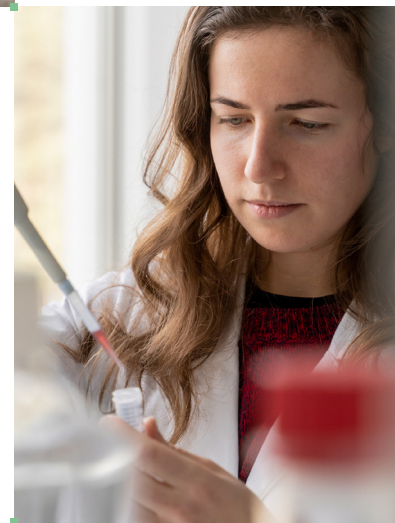
Raised	
Resolved	31 / 28.1%
Approved	22 / 20%
Rejected	14 / 12.7%
Closed	3 / 2.7%



Get the most out of your eCRF

While Viedoc's primary purpose is to collect data from research sites in a clinical trial, it also supports you with an extensive range of additional features: data verification, site monitoring, randomization, supply management, medical coding, adverse event reporting, user training, and certification.

ID	Sex	Scr	Bos	V1	V2
SE001-021	Female	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
SE001-015	Male	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
SE001-017	Male	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
SE001-001	Female	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
SE001-011	Male	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
SE001-029	Female	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
SE001-008	Male	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
SE001-013	Male	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>



Features

Electronic Data Capture

- Features for collection, viewing and reviewing of CRF data in an ICH GCP compliant manner, including capture of binary data (images / documents)
- Sign data on form, visit or patient level
- Link data between forms (e.g. AE and CM)
- Laboratory reference values with time, location and factor scope

Medical coding

- Feature supporting MedDRA, WHODrug B3- and C3-formats (certified by UMC)
- ATC classification system and IDF
- 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

Randomization and allocation

- Pre-computed static list or a dynamically generated / randomized list
- Individual and Global allocation lists
- RTSM (trial supply management in Viedoc Logistics)

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

Training and certification

- Online documentation and eLearning (documents, links, videos)
- Certification with automatic creation of user diploma
- User logs (PDF and Excel)

Messages

- Email alerts for data events, data status and milestones
- Local-language SMS / text messages / reminders sent to subjects

Other

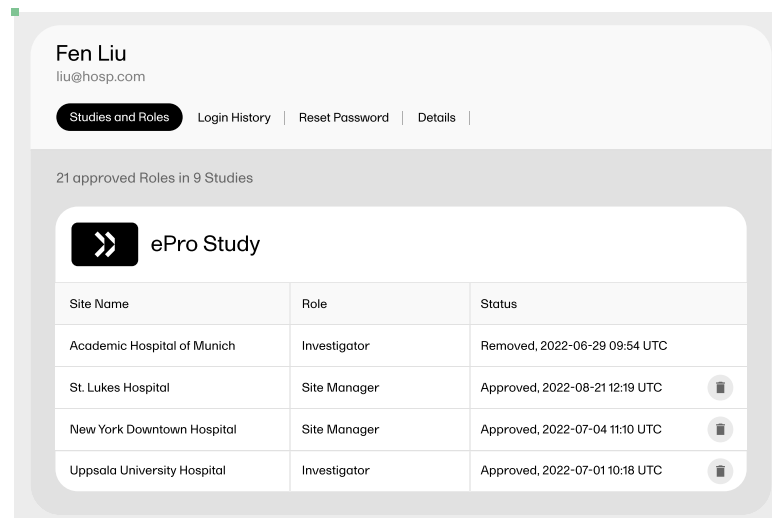
- ISO 27001 compliance
- Two-factor authentication
- SSO (single-sign-on)
- Support for eSource DDC
- Multilingual
- Regulatory compliance – EMA, FDA, JPMA, CFDA
- Compliance with personal data protection laws – GDPR (EU), APPI (Japan), HIPAA (US), PISS (China)
- Audit trail and electronic signatures compliant with FDA 21 CFR part 11
- Contemporaneous and independent investigator copy created at each CRF save
- Support for simultaneously running unlimited versions of a study configuration

viedoc admin™

Get your trial up and running

Viedoc Admin is our fully integrated solution for setup and everyday maintenance of clinical studies, designed to provide the study manager with full control.

Set up your study, manage sites and user roles, and close everything once you're done – no need to go through a helpdesk or tech manager.



Fen Liu
liu@hosp.com

Studies and Roles | Login History | Reset Password | Details

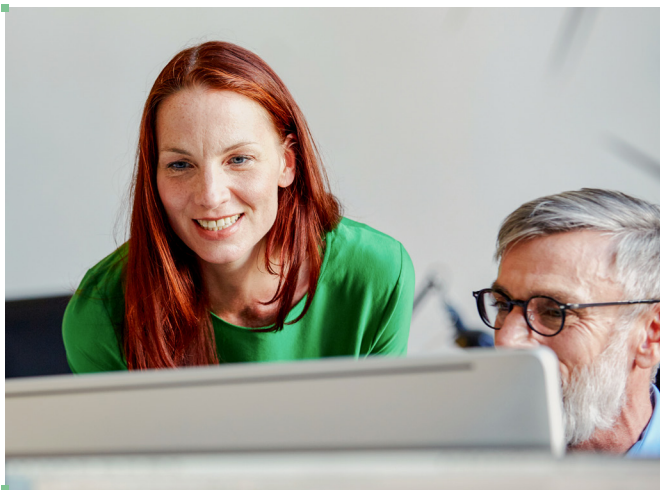
21 approved Roles in 9 Studies

ePro Study

Site Name	Role	Status
Academic Hospital of Munich	Investigator	Removed, 2022-06-29 09:54 UTC
St. Lukes Hospital	Site Manager	Approved, 2022-08-21 12:19 UTC
New York Downtown Hospital	Site Manager	Approved, 2022-07-04 11:10 UTC
Uppsala University Hospital	Investigator	Approved, 2022-07-01 10:18 UTC

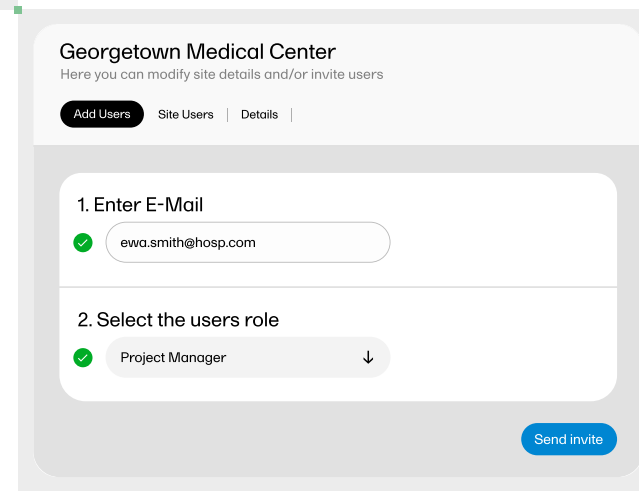
Everything under control

Assign and modify user roles, manage sites and delegate activities to different site managers – through one smooth interface.



No helpdesk required

Manage user invitations and permissions without going through a helpdesk – a much-appreciated feature among our users.



Georgetown Medical Center
Here you can modify site details and/or invite users

Add Users | Site Users | Details

1. Enter E-Mail
 ewa.smith@hosp.com

2. Select the users role
 Project Manager ↓

Send invite

Tweak as you go

Any protocol amendments are easy to implement – just select the design version to be used by each specific site.

Design settings
View all your designs or assign designs to sites

Effective Design **Assign Design** Apply Revision Audit Trial

1. Select a design version

The Decentralized Trial (2022-09-30 20:08 UTC) ↓

2. Which sites do you want to include?

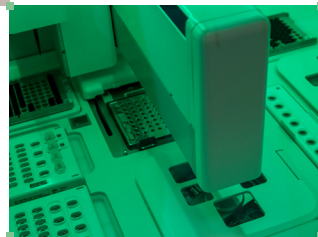
University Medical Center Freiburg ↓

3. When should the design be assigned?

YYYY-MM-DD ↓

HH:MM ↓

Assign Design



Features

General study maintenance

- Role delegation service
- Study level database lock feature
- Study-recreation from a previous snapshot (CDISC ODM)
- Unique and fully self-service study decommissioning feature including status reports and archiving recommendations
- Documentation and certification management
- Assignment of study designs
- Study settings
- Study license management
- API management
- TMF management
- RTSM management
- Reference data management
- Medical coding dictionary management

Site and user management

- Site creation, with code, time zone, type (production / training), recruitment metrics
- User management, with invites, resets, and removals

System / organization management

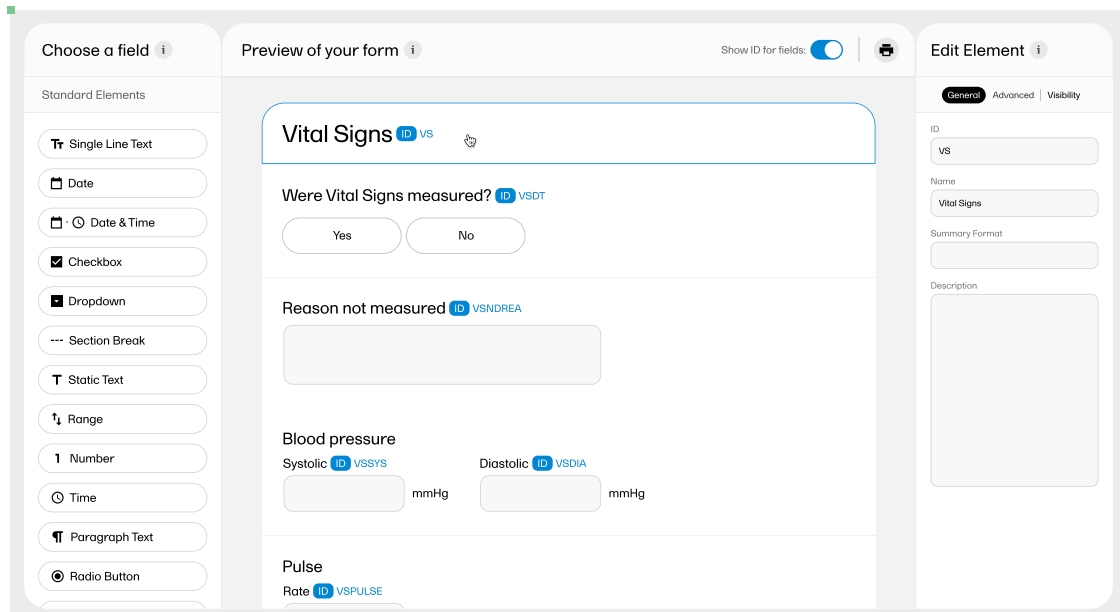
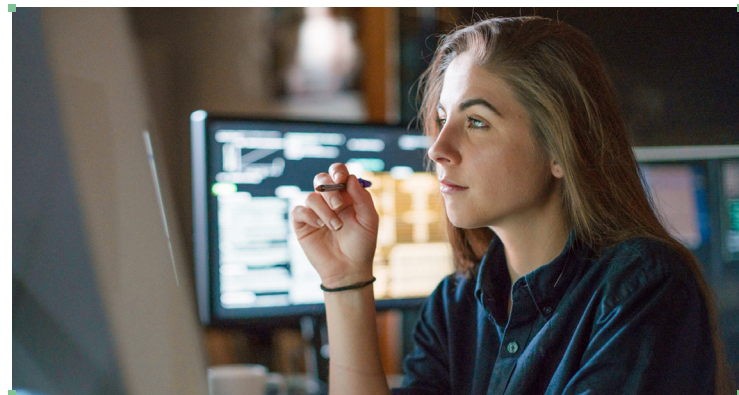
- System user management
- SSO configuration
- VIRP (Viedoc Inspection Readiness Packet)

viedoc designer™

Professional study building in no time

Viedoc Designer is our fully integrated design configuration interface, allowing the study designer to create and tailor their own studies without any prior design or coding skills.

With features that include reusable study building blocks, a WYSIWYG editor, and comprehensive version management, Viedoc Designer allows for complete independence – as well as complete confidence that the end results will be professional.



No prior skills needed

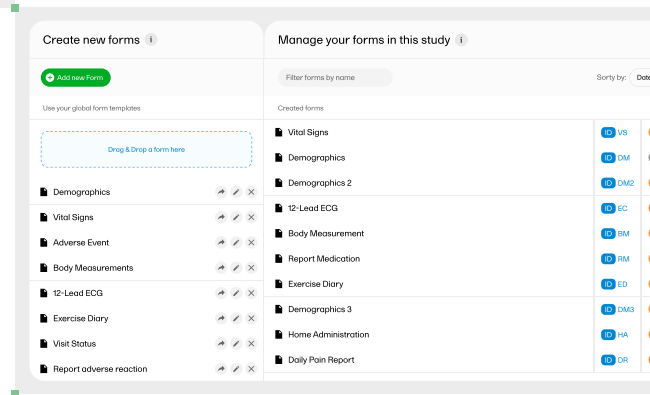
Create a new, professional study from scratch in less than 60 minutes, even if you've never designed or programmed one before.

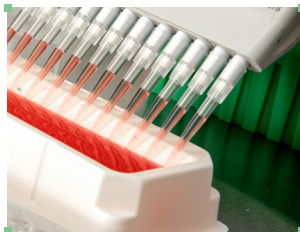
Future proof

Created the perfect study template? Keep using it for as long as you like – every update we release is backward compatible.

Global template library

To save you time, a library of ready-to-use, easily adaptable CDISC CDASH templates – even entire study designs – is included. Just use, re-use and fine-tune according to each particular study's requirements.





Features

Study building

- Drag-and-drop form design with more than 18 different item types to choose from
- Form preview allowing the designer to verify layout, conditions and checks directly onscreen
- Automatic creation of blank and annotated CRFs
- CDISC CDASH form library with over 20 ready-to-use forms
- Ready-to-use study templates in CDISC ODM XML format
- Form translator for managing multiple study languages
- Best-in-class support for complex study designs/requirements

Version management

- Seamless support for mid-study changes due to protocol amendments, updated requirements or adaptive trial design
- No migration of data like in other systems
- Support for simultaneously running unlimited versions of a study configuration
- Transportability / import / export and off-line examination / revision of the configuration in CDISC ODM XML format
- Automatic creation of abbreviated and complete study configuration report

Conditions / Validation / Logic

- Support for configurable responsive / interactive visibility conditions on a role-, study schedule- or data dependency-level
- Automatic design validation upon publishing a study design
- Java script expression editor for faster, more high-quality code
- Support for configurable calculated values (close to unlimited in algorithm complexity level)
- Realtime field-level edit checks, cross-form checks and data derivations

Value added services

- Custom study build services
- Study build certification



Viedoc designs engaging software for the life science industry. By accelerating clinical trials on all levels, our solutions support major pharmaceutical, biotech, and medical device companies, as well as renowned research institutions worldwide. Headquartered in Uppsala, Sweden, Viedoc also has offices in America, France, Japan, Vietnam, and China. Since our inception in 2003, over 1 million patients in more than 75 countries have participated in studies powered by Viedoc. Discover more at www.viedoc.com