

■ viedoc™ ■ Introduction

# Accelerating clinical trials since 2003





#### The addons

viedoc reports	For the data manager Tailorable reporting for quicker, deeper insights Always included with Viedoc Clinic	
viedoc me <sup>™</sup>	For the subject Reliable data collection, directly from the source	
viedoc connect <sup>™</sup>	For the decentralized trial Fully integrated support for Televisits and eConsent	
viedoc logistics	For the supply manager Smooth, secure and seamless inventory tracking and randomization	
viedoc tmf <sup>™</sup>	For the trial manager Powerful documentation management on investigator and sponsor level	

#### The essentials

viedoc clinic	For the investigator Manage all your trial data in one engaging solution	
viedoc admin"	For the study manager Get your study started – and keep it running smoothly	
viedoc designer	For the study builder Create your own professional study – no advanced design or coding skills needed	





■ viedoc™

### viedoc clinic<sup>™</sup>

### 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.

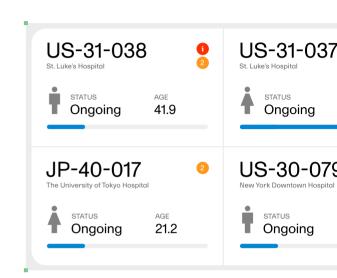


### Manage your subjects

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

#### **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.



Clinic

Features

EDC: Features for collection, viewing and reviewing of CRF data, including capture of images and documents

Medical Coding supporting MedDRA, WHODrug B3, C3 formats, and ATC-classification

Data review and cleaning: Data management, clinical review, and data lock on form, visit, patient, and study level

Randomization and treatment allocation

Data export, API and metrics

Messages: E-mail alerts and text message reminders / notifications

ISO27001, GDPR, APPI, HIPAA, PISS, EMA, FDA, JPMA, CFDA data protection, and regulatory compliance

SSO, two-factor authentication, and role-based queries



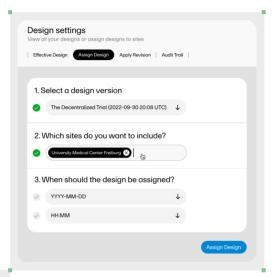
■ viedoc™ ■ Admin ■

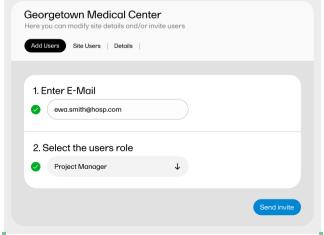
### viedoc admin<sup>™</sup>

### 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.





### No helpdesk required

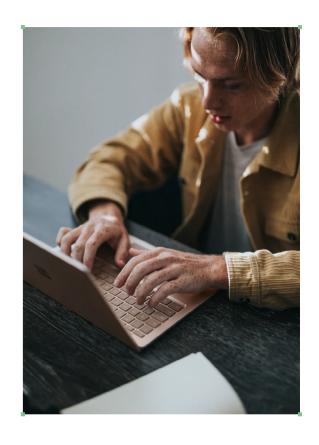
Manage user invitations and permissions without going through a helpdesk – a much appreciated feature among our users.

### Everything under control

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

#### Tweak as you go

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



**Features** 

Role delegation service

Study level database lock feature and study settings

Study-recreation from previous snapshot (CDISC ODM)

Unique and self-service study decommissioning feature with status reports and archiving recommendations

Assignment of study designs

Management: Docs and certification, Study license, API, TMF, RTSM, medical coding dictionary, and reference data

Site creation with recruitment metrics, time zone, and more

User management with invites, resets and removals

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

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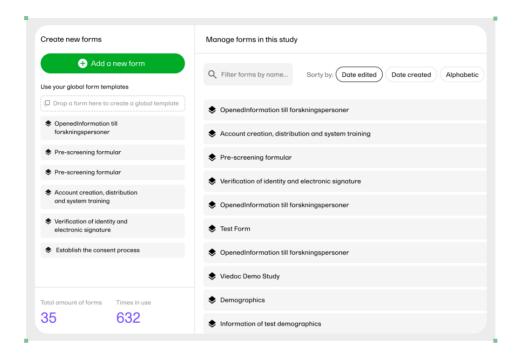
■ viedoc™ ■ Designer ■

### 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 – no advanced design or coding skills needed.

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.



#### Global template library

Use, re-use and finetune templates from our comprehensive library, including CDISC CDASH templates, as well as entire study designs.

#### No prior skills needed

Create a new, professional study from scratch in no time, even if you've never designed or programmed one before.



#### **Features**

Study building: Drag and drop form design, CDISC CDASH form library, ready-to-use templates, and form translator  $\,$ 

Form preview: Verify layout, conditions and checks directly

Real-time field-level edit and cross-form checks

Support for mid-study changes and adaptive trial design

Import / export and off-line examination / revision of the configuration in CDISC ODM XML format

Configurable responsive / interactive visibility conditions on a role-, study schedule- or data dependency level

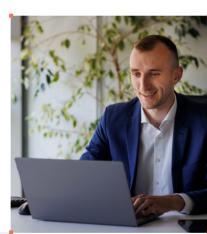
Automatic design validation upon publishing a study design Javascript expression editor for faster, higher-quality code

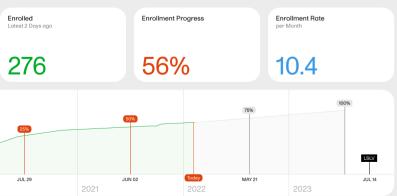
■ viedoc™ ■ ■ Reports ■ Reports

### viedoc reports<sup>™</sup>

### Tailorable reporting, for quicker, deeper insights

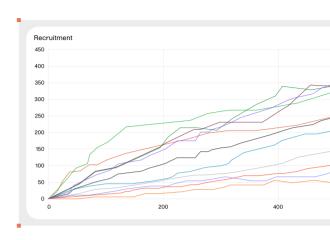
Access high-level metrics for an instant overview, dig deep into details, and make sure important data reaches the right people at the right time. Viedoc Reports is our fully integrated reporting tool for the busy project manager, designed to provide you with clear, understandable access to your data – for more efficient, higher-quality trial execution.





#### **Custom reports**

In addition to standard report templates, you can also customize your own reports, allowing endless options for viewing and analyzing data. Once a report is added, it's immediately available, and each user only sees what he or she has permission to see. Data can be exported in Excel, CSV, and SAS XPT formats. Graphs can be exported in PNG.



#### Powerful tools

Viedoc Reports allows you to zoom, sort, search, compare, cross-check, and export data – making it easy to view and predict study progress, and enabling you to draw valuable conclusions about trends and patterns in your trial. Real-time overviews with metrics based on actual recruitment help you keep track of progress on study, country, and site levels.

**Features** 

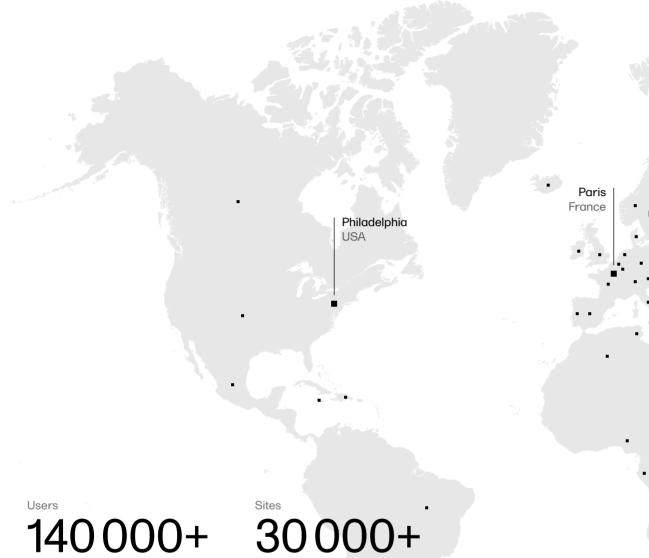
Create unlimited custom, user generated reports
ATR (Audit Trail Review)
Key Performance Metrics
Operational metric reporting
Self-service role-based report administration
Data browser including cross-check mode
Data downloads in XLSX, CSV and SAS XPT format
Study plan for recruitment and milestone forecasts
Customizable dashboard

Over 50 standard out-of-the-box reports

Multilingual

viedoc Benefits and facts

> Uppsala Sweden



30000+

5000+

75+

1million+

99.99%

#### Worldwide coverage

Tokyo

Japan

Shanghai China

Hanoi Vietnam

Viedoc's head office is in Uppsala, Sweden, with additional offices in North America, Europe, and Asia, servicing customers and studies in over 75 countries.

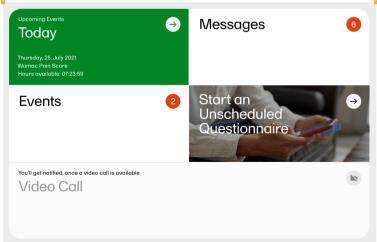
viedoc™ Me

### viedoc me<sup>™</sup>

### Reliable data collection, directly from the source

Viedoc Me is our fully integrated ePRO / eCOA solution for smarter, faster, and more engaging data collection. Choose whichever collection method suits you best – in-person, remote, or both. Subjects can use Viedoc Me to report their own data via their smartphone, tablet, or computer, for maximum flexibility. Meanwhile, sponsors and sites have access to a complete, real-time overview of how patients are progressing throughout their trial.

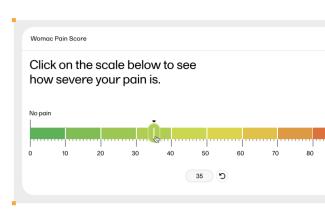




### Maximize flexibility and engagement

Auto-reminders via text message or email ensure timely reporting, and subjects can upload image documentation from their smartphones.

Viedoc Me also features customizable visual analog scales compliant with EQ-5D for flexible data display. Simultaneously setting up the CRF and subject questionnaires saves valuable time.



**Features** 

An integrated and configurable ePRO / eCOA feature according to the Bring-Your-Own-Device (BYOD) model

Supports custom workflows and complex decision trees

**Televisits** 

Reminders in local language via text message and email

Customizable VAS

File upload

Drawing pad with body map, signature line, or blank background

Support for unscheduled data entries

40+ languages including right-to-left typing

Vast library of validated ePRO / eCOA forms

Integration with smartwatches, thermometers, scales, and more

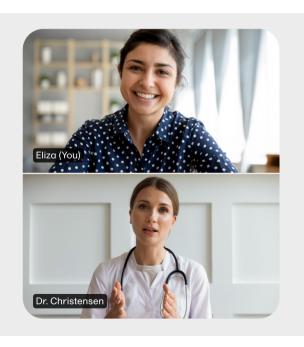
■ viedoc™

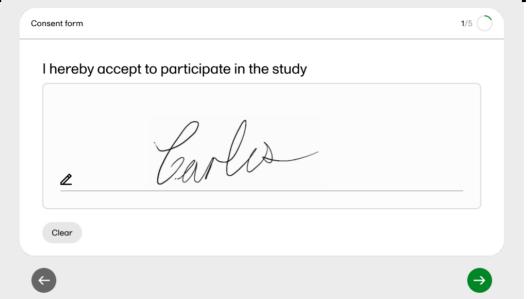
#### Connect

### viedoc connect™

### Go remote and optimize the site-patient interaction

Viedoc Connect is our fully integrated telemedicine solution, enabling flexible investigator and patient interaction with the help of secure video calls. Facilitate the eConsent process, run pre-screening and recruitment activities, and conduct follow up visits where on-site visits are not possible.





#### Remove barriers

With Viedoc Connect you can facilitate the eConsent process, verifying the identity of the patient and confirming the handwritten signature, while being executed.

Comfortably train patients on the protocol remotely with the screen sharing functionality in Viedoc Connect. Demonstrate how to use the ePRO application, facilitate troubleshooting, and more.

### Accessible from any device

Patients can easily and securely join the call from their phone, tablet, or desktop through Viedoc Me to interact with the investigator and / or study coordinator.



Features

Secure peer-to-peer video calls

Screen sharing

No installs or downloads

Easy access

Join in one click

Audit log tracking date, time, duration and participants

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■ viedoc™ ■ Logistics ■

### viedoc logistics<sup>™</sup>

### Smooth, secure and seamless inventory tracking

Viedoc Logistics is our fully integrated supply management system, designed to optimize and secure the inventory of your trial. With a wide range of useful features and configuration options, Viedoc Logistics offers a modern, effective and cost-efficient RTSM solution for trials of all sizes.



#### **Simplicity**

Designed with the end user in mind, Viedoc Logistics' interface features intuitive tools and comprehensive overviews. Real-time visibility to the eCRFs in Viedoc Clinic allows for maximum transparency.

#### Flexibility

Configure your own user roles, set up your scope of allocation, and make general settings to the handling of your IP. Setup is quick, and getting started requires minimal training.

#### Reliability

Viedoc Logistics is cloud-based with 24/7 access and backup, alerts that notify when you're low in stock, and detailed history records – ensuring a safe, accountable handling of your trial supply.

All Kits   Type/Scan Kit No or Shipment ID  Q				105 Kits for
#	Kit No	Status ↓↑	Location ↓↑	Expiry Date ↓↑
1	379-10001	Available	Göteborg	2025-01-01
2	379-10002	<ul> <li>Allocated to SE001-008</li> </ul>	Göteborg	2025-01-01
3	379-10003	Available	←·· Göteborg, ETA 0 Days	2025-01-01
4	379-10004	• Invalid	Göteborg	2025-01-01
5	379-10005	Allocated to SE001-021	Göteborg	2025-01-01
6	379-10006	<ul> <li>Allocated to SE001-009</li> </ul>	Göteborg	2025-01-01
7	379-10007	Available	Göteborg	2025-01-01
8	379-10008	Available	Göteborg	2025-01-01
9	379-10009	Returned	Göteborg	2025-01-01

**Features** 

Fully integrated with Viedoc Clinic – eliminates duplicate data entry, reduces reconciliation, decreases administration

Completely configurable

Dashboard with real-lime metrics

Powerful search feature

Static and dynamic randomization

Simple and advanced allocation

Emergency unblinding

Email alerts on thresholds

Export kit, including history

Unique shipment ID

Editable expiry dates

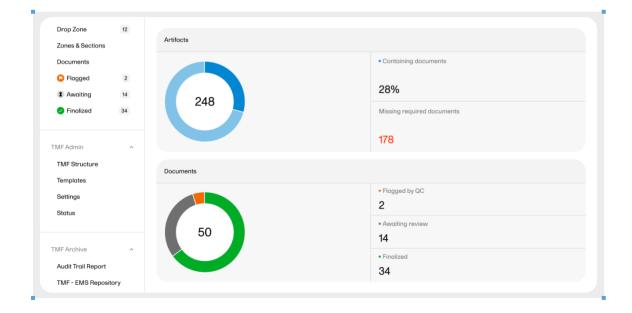
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■ viedoc™ ■ TMF ■

### viedoc tmf™

### Powerful documentation management

Viedoc TMF is our fully integrated document management system, designed to allow swift, secure, role-based access to all trial documentation, 24/7. Based on industry standards and equipped with permissions, document review, and a customizable structure, Viedoc TMF makes documentation easier, smoother and above all: faster.



#### Fast access

Create and configure your own TMF structure for swift access through one interface. A powerful search engine helps pinpoint the document you need in an instant, while batch features and other smart tools save valuable time.

#### User permissions

Role-based end-user access helps ensure that documents don't fall into the wrong hands. Setting up end-user permissions is swift and simple, based on existing user roles.



End users can upload, access, review, approve and sign documents from a single interface – with full audit trails for complete transparency.



**Features** 

Simple TMF structure creation based on DIA RM  $\,$ 

Maintenance mode for smooth structure updates

Searching, filtering, and sorting of documents based on all metadata values – export to Excel to create customized reports

Powerful search functionality to retrieve documents by name and content

Drop zone for easier document management

Document sharing with Viedoc users and subjects for information or electronic signature

ISF for site

Access control based on roles, permissions, sites, and countries

Archiving according to the market standard (EMS)

Full audit trail report

Document preview, comment, approve, and lock

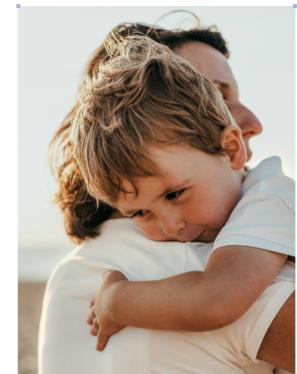
Batch document upload with support for drag and drop

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■ viedoc™ ■ Mission

## Working for a healthier world





At Viedoc, we believe in life and science, in people, and in our collective power to change the world and build a healthier future. That unmatched driving force is what pushes us to innovate, accelerate and improve every aspect of modern clinical studies.

Since 2003, Viedoc has united scientists and clinical trial professionals in a shared mission of pushing life-changing research forward.

Our solution has been used to power thousands of studies, by collecting data from over a million patients and allowing it to flow smoothly across sites and countries. We take great pride in helping bridge the gap between patient and researcher – and, in the best of cases, between research and breakthrough.



Discover more viedoc.com





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 North 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