# viedoc learning

# Viedoc User Guide for Project Managers

20 Lessons 20 from Viedoc System

General		4 le:	ssons
Overview of Viedoc Clinic	1.1	\$ System requirements	1.2
Updated Managing your Viedoc account	1.3	\$ Overview of the landing page	1.4
Data entry		4 le:	ssons
Study start page	2.1	\$ Documentation & Training	2.2
Selection page	2.3	\$ Metrics	2.4
Data export		6 le:	ssons
Updated Exporting data	3.1	\$ Excel export	3.2
PDF export output	3.3	\$ Queries in Excel export	3.4
Updated Medical coding in Excel export	3.5	\$ Review status in Excel export	3.6

### Manage users (for Site Managers only)

	Managing users	4.1		
Video tuto	rials			5 lessons
	Create a user account	5.1	Log in/Log out and reset password	5.2
	Landing page	5.3	Activate demo mode	5.4
	User Management	5.5		



**Overview of Viedoc Clinic** 

# **Overview of Viedoc Clinic**

Published by Viedoc System 2021-11-24

#### 1. Introduction 2. Languages

This lesson provides an overview of Viedoc Clinic. It describes the user interface and summarizes the main settings that can be configured in Viedoc Clinic.

# 1 Introduction

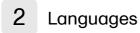
Viedoc Clinic is the interface for the end user, and is primarily used by site and study staff (Investigators, Study Coordinators, Monitors, Data Managers and so on) and keeps track of all the activities performed by the site.

Viedoc 📌 🕼 Demo Study				Soff Ann 📲	nvestigator 🔀	70 🔅 -
Letails				III <u>1</u> °	<b>L</b>	<ul> <li>▲ ▲ ▶</li> <li>1/254</li> </ul>
DE-95-077 BERLIN HOSPITAL	Search			Show a	ll events 🔻	
STATUS AGE Ongoing 41.1	Screening Screening	Baseline	Follow-Up test	Final Visit End of Study		
	14 07 2021	16 07 2021	23 07 2021	26 07 2021		
29% 4/4 8/27 of study events forms Demographics ™ CBA SOV D ✓	Screening	Ongoing			Protocol date not set	ე
	Screening				Scheduled date	
Common events DM CRA SDV D Common events Address Address Common events Address Common events Address Common ev	Event date			CRA SDV	not set	C
Prior and Concomitant Medications (0) +	Check Questions		DM	CRA SDV	Event date 14 07 2021	赵
Adverse Events (0) + Subject's non-study medications (0)	Physical Examination			٠		

The access to Viedoc Clinic is by invitation only and provided by either the Study Manager or Site Manager. If invited, you will find the invitation in your email inbox (from *no-reply@viedoc.net*). In some cases the email can be caught by your email spam filter and in that case you will find it in the email spam folder. For detailed instructions on account activation, see <u>Managing your Viedoc account</u>.

The following main actions can be performed in Viedoc Clinic:

- Data entry covered by the following lessons:
  - Selection page
  - Entering/Editing data
  - <u>Resetting and deleting data</u>
  - Signing data
  - Working with reference data
- Raise and resolve queries described in <u>Resolving queries</u>
- Data export described in Exporting data
- Medical coding described in <u>Medical coding</u>
- View study metrics described in <u>Metrics</u> and <u>Viedoc Reports</u>



Viedoc Clinic is available in the following languages:

- English
- Chinese (Simplified)
- Chinese (Traditional)
- German
- French
- Japanese
- PolishSpanish
- Swedish
  - onoulon



#### System requirements

### System requirements

Published by Viedoc System 2022-06-16

# 1. Customer computer requirements 1.1 Browser requirements 1.2 Screen resolution 1.3 Internet connection 1.4 Firewall policy

2. Security

### 1

### Customer computer requirements

Customer computer requirements are defined as capabilities required by the customer computer to use all features of Viedoc with the intended graphical presentation and within guaranteed response times of Viedoc.

#### 1.1 Browser requirements

Viedoc supports the following browsers:

- Chrome, the latest 10 major releases (6-week browser release interval)
- Firefox, the latest 15 major releases (4-week browser release interval)
- Edge (Chromium edition), the latest 10 major releases (6-week browser release interval)
- Safari (MacOS/iOS only), the latest 2 major releases (1-year browser release interval)

For non-compliant browsers you will receive a message on the login page that your browser is not supported.

For Viedoc Designer:

- Chrome is recommended
- Allow pop-ups must be enabled

Viedoc does not support the use of private mode browsing in Safari.

The following are required for Viedoc to run in the compatible web browsers:

- JavaScript
- Session cookies
- Local web storage (only required by the main portal of Viedoc 4)

No data is permanently stored on the customer computer. All data stored in session cookies or local web storage is deleted when the browser session is terminated. The only exception to this is the optional persistent cookie used in the main portal of Viedoc 4 to remember if a user chooses to issue a 2FA trust for the browser for 30 days, and thus avoid further second-factor authentication during this period.

Viedoc 3 has no automatic checks enforcing the above requirements. Viedoc 4 checks for, and enforces, browser type and version, and support for JavaScript, local web storage, and session cookies.

### 1.2 Screen resolution

The following screen resolutions are required:

- Viedoc 3: at least 800×600
- Viedoc 4: at least 1024×768

### 1.3 Internet connection

Viedoc requires an internet connection of at least 384 kbit/s.

### 1.4 Firewall policy

Viedoc requires an outbound firewall policy allowing encrypted HTTP to be established and communicated to a remote server on port 443 (HTTPS) using Transport Layer Security (TLS) version 1.2 or higher.

# 2 Security

There are several layers of security built into the platform. Below are some examples:

- Login attempts after three failed attempts to enter a correct password, your account is locked. Use the "Forgot your password?" link on the login page to unlock and reset your password. The reset password link must be used within 3 hours from a request. There are restrictions on how many times you can submit a request in 24 hours.
- Inactivity if you are inactive for more than 20 minutes, the system automatically logs you out. Inactivity means no activity whatsoever in the application.
- **Two-factor authentication** two-factor authentication is an extra security measure that requires an extra confirmation step at login, in addition to user name and password.
- Password expiration the password expiration time depends on the settings for your study. However, the
  default setting is 90 days. In addition to this, a history of the latest 10 passwords are kept to prevent
  reusing old passwords.



Managing your Viedoc account

### Managing your Viedoc account

Published by Viedoc System 2024-03-18

<u>1. Introduction</u>
2. Study access management
3. Access settings
<u>3.1 Study membership</u>
3.2 Deleting study access
<u>3.3 Deleting your Viedoc account</u>
<u>4. Pending invitations</u>
4.1 Approving a study invitation
4.2 Rejecting a study invitation
4.3 Postponing the approval/rejection of a study invitation
5. Logging out

### 1 Introduction

All information related to managing your Viedoc account can be found in the following user guide: <u>Viedoc User</u> <u>Account Management</u>

From the settings button (wheel) you can perform all actions related to managing your Viedoc account by selecting any of the following: Edit your profile, Change Password, Security Settings.

Selecting any of these options opens a new page, in the example below, the User Settings page. Select the Viedoc learning link to open the Viedoc User Account Management Guide:

viedoc			
User Settings Change Password	User Settings		
Security Settings	A Ownership of +4612345678 has not appendix to a second	ot been verified!	
Authentication Log	User name This is used to log in to Viedoc		
viedoc learning >	doctordemo@viedoc.com		
	First name	Last name	
	Doctor	Demo	
	Display name This is your Viedoc user name		
	Doctor Demo		

### 2 Study access management

From the settings button (wheel) you can perform all actions related to study access management in **Access Settings**.

viedoc			Doctor Demo
			Edit your profile
Welcome back Doctor Dem	10!		Change Password
Access	Account	Recent activities	Security Settings
Studies Sites	Last login S.diya.ago	Study Rechel's study site Site1 added to my studies	Access Settings
1 0	Number of logins 5	Password changed	Log out
1 0	User level 🛎 Rookie		
	Active since 2023-10-05		

# 3 Access settings

Select the settings button (wheel) in the top right corner of the window, and select Access settings.

### 3.1 Study membership

🏟 Access Settings			Close
			Rookie 9 logins
1 roles in 1 studies			
A Demo Study			
Site name	Role	Since (UTC)	
Stockholm	Site Manager	2018-05-04 11:45	Ê
Show login history			

The following information is provided, grouped by study:

- Site name
- Role
- Since (UTC) the date and time when the membership was approved, in Coordinated Universal Time (UTC)

For users with organization roles, these are listed in the top of the page, in a separate section, providing the following information:

- Organization name
- Role

1

• Since (UTC) - the date and time when the membership was approved, in UTC

#### 3.2 Deleting study access

To remove yourself from a certain role within a study:

#### Select the trash can icon on the right, corresponding to the role, site and study to be removed from:

2 roles in 2 studies

A Demo Study			
Site name	Role	Since (UTC)	
Stockholm	Site Manager	2018-05-04 11:45	Ē

A confirmation dialog is displayed.

Select Delete to confirm the deletion:

Confirm r	emove	Close
Â	Remove role: Site Manager Study site: Stockh Study: A Demo Stu Delete	

A notification email will be sent to all the Study managers, or to the Site managers if any roles are delegated.

#### 3.3 Deleting your Viedoc account

You can remove your Viedoc account when you have no study memberships left, that is, 0 roles in 0 studies.

To delete your Viedoc account:

1 Go to Access Settings. To be able to remove your account, you should have no roles left in any study and no pending invitations:

C Access Settings	Close
	Rookie 11 logins
0 roles in 0 studies	
前 Remove account from Viedoc	
Click 'Remove account from Viedoc' if you wish to remove your account from Viedoc. Thi data related to your account, but for identification purposes, Viedoc will keep the User ID, d address and login history until all studies you have participated in are deleted. All other int account will be removed from the system.	lisplay name, primary email
Show login history	

2 Select **Remove account from Viedoc**. You will be prompted to confirm the account removal by entering your password:

Confirm a	account removal		Close
â	Confirm with your	password	
	Delete	Cancel	

3 Enter your password and select **Delete**. A confirmation message is displayed and a notification email will be sent to your primary email address:



For identification purposes, Viedoc will keep: the user ID, display name, primary email address, and login history. They are kept until all the studies you have participated in are deleted. All other information related to your account will be removed from Viedoc.

2

### 4 Pending invitations

In case you have study invitations that you have not accepted or rejected yet, the **Pending invitations** window displays a list of all your pending study invitations:

Pending invitations	Close
Demo user	
Granted membership - 2 waiting for your approval	
By confirming access to the study I also approve that the organization handling my account can see my accoun information.	t
A Demo Study	iect
Reference Data Source Manager	
A Demo Study All sites / Site Manager	ject
-	

### 4.1 Approving a study invitation

To accept a study invitation, select **Approve** next to the respective study role. If this is the first role you have in the respective study, and if the study requires an activation password, you will be prompted to enter it:

Activation	n password required Close
Â	Activation password
	Please contact your study manager if you don't have the activation password.
	Confirm Cancel

Note! All the pending role invitations for a user are automatically approved when the Application Programming Interface (<u>API</u>) method GetToken / Token is used.

#### 4.2 Rejecting a study invitation

To reject a study invitation, select **Reject** next to the respective study role. The invitation will be removed from the Pending invitations list.

#### 4.3 Postponing the approval/rejection of a study invitation

To postpone the approval or rejection of study invitations, select **Close** in the top right corner of the **Pending invitations** dialog box and postpone providing an answer to the study invitation. To access the pending invitations again, the **Pending invitations** dialog box is shown:

- Automatically, after logging in.
- By selecting Pending invitations on top of the landing page.

# 5 Logging out

From Viedoc you can log out from different locations:

/iedoc					Doctor Demo
					Edit your profile
Welcome back	Octor Der	nol			Change Password
					Security Settings
Access		Account		Recent activities	Access Settings
Sudies	Sites	Last login	5.days.ago	Study Rachel's study site Site1 added to my studies	Log out
4	0	Number of logins	5	Password changed	Log our
1	0	User level	🦉 Rookie		
		Active since	2023-10-05		

• To log out from settings, select the settings button (wheel) in the top right corner of the window, and select **Log out**. Use this link every time you leave the application from this location.

Note! If you exit the system without logging out, any subject you are currently working with will be locked for other users. After 5 minutes, the subject will be automatically unlocked.

To log out from User Settings, Security Settings, Change password or Authentication Log: select your avatar on the top right and side and select Log out.

viedoc		Doctor Demo
User Settings	User Settings	
Change Password Security Settings	Ownership of +4812345678 has not been verified!	Doctor Demo
Authentication Log	User name This is used to log in to Viedoc	
viedoc learning #	doctordemogy/edoc.com	
	First name Last name Doctor Demo	
	Display name The synut Vedeo care name Doctor Demo	
	System language The transport will be used inform conditate English 4	
	Primary email address actordramogesedoc.com	
	Hone number           +46234578           This phone can receive text messages	
	Contact Information       Penes laws your contact Information up to date       Street address     City       Country     Stole       Stelet country     Up	
	0 Viedos Technologies M2 2023 - Termin drame - Ferenz policy Viedos <sup>en</sup> vension 4/7/2017/3423 - 2023-10-10 24:223 U/C	



#### Overview of the landing page

# Overview of the landing page

Published by Viedoc System 2022-10-18

#### This lesson describes the landing page, which is displayed directly after a successful log in:

Studies Sites 1 1	Account Last login Number of logins		ent activities	
		6 minutes ago Stu		
1 1	Number of logins		dy Medical coding site Site 2 demo added to my studies	6 da
1 I			dy Medical coding site Site 2 demo added to my studies	6 da
	User level		dy Medical coding site Site 2 demo added to my studies	6 da
	Active since	2022-08-31 Stud	dy Medical coding site Site 2 demo added to my studies	6 da
arch Marine and Anna Marine and Anna Anna				
Medical coding 1 site	Ð			
	new study			
0% complete				2012

The landing page provides the following summary information:

- Access
- Studies the total number of studies you have access to
- Sites the total number of sites you have access to
- Account
  - Last login the time passed since the last time you have logged in to Viedoc
    - Number of logins the total numbers of logins to Viedoc since you activated your account
  - User level the number of logins by a user, giving an indication of how experienced the user is in using Viedoc

Skill level	lcon	Description
Rookie	<u>I</u>	≤ 20 logins
Semi-pro		21-100 logins
Pro		101-1000 logins

Skill level	lcon	Description
Legend		> 1000 logins

- Active since the date when you activated your Viedoc account
- Recent activities a short summary of the most recent four activities, such as last password change and being assigned a role within a new site

The study slider shows the studies you have access to - each study is represented by a study logo. If you have access to many studies, you can easily find a specific study by entering the study name in the search field. All studies containing characters of the search string appear in the search results.



A progress bar is shown below each study logo. The percentage displayed is calculated by the mean completion of each subject (rounded down). Thus, it measures the total completion of the study.

#### Note!

- Only production sites are included in the calculation.
- Deleted subjects are not included in the calculation.
- If the expected number of subjects is not set in Viedoc Admin > Study Settings, then 0% will be displayed.

Click on a study logo to select a study to work with. The study start page is loaded on the bottom-half of the screen, see <u>Study start page</u>.

If you are an Administrator and/or Designer you will also have access to Viedoc Admin and Viedoc Designer. Click the respective icon at the top right corner of the landing page:

viedoc				¢.
Welcome back Access Studies 1	Sites 1	Account Las login Emissions as Nontre of logins 2000 Deter low Rook Active since 2002.08	Soudy Medical coding site Site 2 demo added to my studies     Study Medical coding site Site 2 demo added to my studies	Designer Edaysago Edaysago Edaysago Edaysago
Search	٩			
Medical coding 2 size	Start new study			



Study start page

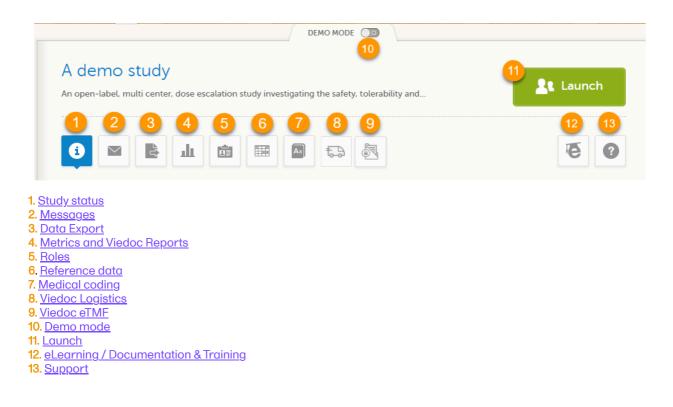
### Study start page

Published by Viedoc System 2023-10-09

1. Introduction 2. Study status 3. Messages 3.1 Alert messages 4. Data export 5. Metrics and Viedoc Reports 6. Roles 6.1 My roles 6.2 All roles and users for my site(s) 6.2.1 User logs 6.2.1.1 Log of users and roles in PDF format 6.2.1.2 User administration log in Excel format 7. Reference data 8. Medical coding 9. Viedoc Logistics 10. Viedoc eTMF 11. Demo mode 12. Launch 13. eLearning / Documentation & Training 14. Support

# 1 Introduction

When you select the study logo in the landing page, the study start page loads, which contains the following icons that give access to different features, or enable you to view information about the study:



- The export, metrics and medical coding icons, the demo mode switch, and the launch button are only visible if you have access to the respective features. Whether you have access to these features, depends on the role assigned to you, and on the permissions that are included in your role.
- Roles and permissions are set up in the study design. The latest effective design for each site will be used to define the permissions that will apply to each role.

The first page displayed when you select a study is, depending on the status of the mandatory documentation and training materials, as below:

 If you have mandatory documentation pending to be read and signed, then the first page that opens is the <u>Documentation & Training</u>.

Important! All the mandatory materials must be "Read & Understood" and signed before you can launch the study. You might be able to launch the study in demo mode, depending on the study settings performed by the Study Manager.

 If you do not have any mandatory documentation pending signing, then the first page that opens is the Study status page.

# 2 Study status

The Study status page is the first page that is shown when accessing a study, <u>if you do not have any mandatory</u> <u>documentation and training material that needs to be signed</u>. This page gives you an overview of the progress of the study - on study, country and/or site level (depending on which sites you have access to):

#### Study status

All sites Germa	ny Sweden	United States		
lssues			My statistics	
Resolved queries	Open queries	Forms	Patients added:	146
160	26	21	FPA: 30 S	EP 2014
TOO	20	<b>4</b>	LPA: 09 0	CT 2015
Review				
CRA %	DM %	SDV %		
20	5	19		
Approval				
Inv. sign %	Queries %	Locked forms %		
46	22	17		

You can filter the displayed data for country or site by selecting the name of the country or site:

Study status All sites Academic Hospit				
Issues			My statistics	
Resolved queries	Open queries	Forms	Patients added:	71
12	16	54	FPA:	04 OCT 2016
12	10	JT	LPA:	27 AUG 2018
Review				
CRA %	DM %	SDV %		
1	0	1		
Approval				
Inv. sign %	Queries %	Locked forms %		
0	0	7		
U	0	5		

The following statistical information is provided, for the selected site(s):

- Issues
- Resolved queries total number of resolved queries
- Open queries total number of open queries
- Forms total number of forms with issues

- Review
- CRA % percentage of forms that were marked as Clinical Research Associate (<u>CRA</u>) reviewed out of total number of forms that can be CRA reviewed within the study
- DM % percentage of forms that were marked as DM reviewed out of total number of forms that can be DM reviewed within the study
- SDV % percentage of forms that were marked as Source Data Verification (SDV) reviewed out of total number of forms that can be SDV reviewed within the study
- Approval
  - Inv. sign % percentage of the forms signed by investigator out of total number of forms
  - Queries % percentage of approved queries out of total number of queries that await
  - approval. For details about query states and process, see Queries Overview.
  - Locked forms % percentage of the locked forms out of total number of filled in forms
- My statistics
  - Patients added the total number of patients added to the study
  - FPA date when the First Patient was Added
  - LPA date when the Last Patient was Added

Notel All the numbers reflect the data entered in the selected operation mode (demo or production), that is, <u>if demo</u> <u>mode is selected</u>, then the numbers reflect <u>only the data entered in demo mode</u>.

3 Messages

A message can either be a <u>system message</u> (such as notifications on password expiration), a <u>study message</u> (such as eCRF changes - for more information, see <u>Approving eCRF changes</u>, or other notifications according to the study configuration).

An indicator in the top bar of the application indicates whether you have unread messages.

Messages All sites Sweden United States G	ermany
<ul> <li>Consider changing your password. Your password will expire in 5 days. To change password, selec</li> <li>2 months ago by System</li> </ul>	System 2 months ago Consider changing your password.
Consider changing your password. Your password will expire in 10 days. To change password, sele 2 months ago by System	Consider changing your password. Your password will expire in 5 days. To change password, select the account settings in upper right corner and click Change password.
1-2/2	Mark as unread

### 3.1 Alert messages

According to the study configuration, you can receive alert notifications about important occurrences in the data. (For example, in case of a Serious Adverse Event). Alert notifications can be received in the Messages page and as an email.

Depending on the configuration/study setup, the email might have the PDF of the form that triggered that alert as an attachment.

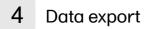
If the option to enable password protection for the alert email attachments has been selected for your study, you should receive a password to enter to open the attachments. The password is provided by your Study Manager.

When you receive an email copy of the alert message with a password-protected attachment, when you open the file you will see the dialog box below where you can enter your password:

Password required

This document is password protected. Please enter a password.

Submit



The Data export page enables you to review and download study data in the following formats:

- Excel
- PDF
- Comma-Separated Values (CSV)
- Statistical Analysis System (<u>SAS</u>)
- Operational Data Model (<u>ODM</u>)

Note! Data export might not be available to all users.

For more information about data export and preview, see Exporting data.



The Metrics page gives an overview of the quality of data in terms of open queries and missing data.

Notel Metrics might not be available to all users.

For a detailed description, see Metrics.

If Viedoc Reports is included in the study license and enabled, it is accessed from the Metrics feature. For more information, see <u>Launching Viedoc Reports</u>.

6

Roles

Note! The Roles page is only available for users with special permission to view roles, as per the study design.

The Roles page provides information on:

- The roles that are assigned to you, see <u>My roles</u>
- All the roles for the sites you have access to, see <u>All roles and users for my site(s)</u>

#### 6.1 My roles

Under My roles you can see the roles that you have in the respective study:



The following information is displayed (with *examples*):

- The role name (Investigator)
- The list of the permissions (Save, sign, reset, delete and export data, resolve queries)
- The site(s) you have access to (Stockholm, Uppsala)

By selecting the green arrow button to the right, you will be directed to the <u>Selection page</u>. This is equivalent to selecting the **Launch** button.

### 6.2 All roles and users for my site(s)

Here you can see a list of all the roles and the respective user(s) for the site(s) you have access to:

ll roles and users f	for tł	ne sites I have access to			
<b>A</b>	2	Investigator(s)			Hide log 👻
User/Site			Access granted	Access revoked	Data edits/Sessions
Mihaela Pavel (362), Group: All sites	-	alladoration as	2018-04-05 12:22 UTC Doctor Demo	-	0 0
Doctor Demo (317), Multiple sites	nih s	da paninjenska com	2017-08-11 12:37 UTC Doctor Demo	•	143 77
	1	Monitor(s)			Show log 👻
	1	Data Manager(s)			Show log 👻
			Download log of users and role	s as a PDF file	

To see user details of each role, select Show log. The log displays:

- User/Site the name of the user, email address and site
- Access granted when\* and by whom (user name) access was granted
- Access revoked when\* and by whom (user name) access was revoked (if applicable)
- Data edits/Sessions the number of times the user edited any data, and the total number of login sessions by the user (defined as the number of times the user has accessed the study)

\*date and time in Coordinated Universal Time (UTC) time zone

#### 6.2.1 User logs

For each study, you can download user logs with information about all users and roles for the sites you have access to. The generated file reflects the country/site selection in the language you have currently set in Viedoc. The following logs can be downloaded:

- Log of users and roles in PDF format
- User administration log in Excel format

If it's the first time the log is generated for the country/site selection in the language you have currently set in Viedoc, you can generate it by selecting the **Generate a PDF file / Generate an Excel file** link at the bottom of the page:



After the user log was generated you can choose to:

- Download the latest generated log for the country/site selection the most recent version generated has
  a date and time stamp and is stored on the server, making it possible to directly download the file instead
  of generating a new one, or
- Select Regenerate if you need a more recent version than the one available for download.



#### 6.2.1.1 Log of users and roles in PDF format

The Log of users and roles PDF contains the following chapters:

- Summary the summary of active/inactive roles, active/inactive users as well as data contributors, grouped in one section per site.
- Roles a list of the permissions associated with each role and corresponding history, grouped in one section per site.

- User log per site a list of all users who ever had access to data, including user activity, grouped in one section per site.
- User account logs a list of the change history of all user accounts for the users listed in the above sections of the log, grouped per user (identified by the user ID).

#### 6.2.1.2 User administration log in Excel format

The User administration log contains the following sheets:

- Report Info general information about when and by whom the log was generated, and some information about the study status.
- User Access Log a list with detailed information about user access, showing one row per site and role, including clinic roles and system roles. Some columns in this sheet are further explained here:
  - Site Group indicates when a user is granted access to the site through a site group
     indicates and Training sites. Countries and All sites
    - invitation. Possible values are Training sites, Countries, and All sites.
    - 2FA indicates what level of two-factor authentication the user has. Possible values are Study level, Account level, or No two-factor authentication enabled.
- Certification Log a list of certifications per user. Certifications performed before release 4.65 lack information about what roles the certification applies to. That is, the cells in column "Certified With Roles" are empty.
- Summary a summary of users per site with information about country, side code, site name, number of active/inactive users, and date/time of last access change.
- Account Settings Log a list with all user accounts setting changes with user id, change log, user name, and date/time.

### 7 Reference data

When you select the reference data icon, the list of available reference data source-scope combinations is displayed. From here you can open the reference data editor. For details see <u>Working with reference data</u>.

Notel Reference data might not be available to all users.

### 8 Medical coding

The medical coding feature allows you to code reported events like Adverse Events, Medical History and Concomitant Medications. When you select the medical coding icon, the page displays metrics regarding medical coding. There is one set of metrics for each medical coding scope available.

Note! Medical coding might not be available to all users.

For more information about medical coding, see Medical coding.

### Viedoc Logistics

9

Viedoc Logistics is the interface for managing the supply of your study. A valid license is required to use Viedoc Logistics.

For more information about Viedoc Logistics, see Viedoc Logistics User Guide.

# 10 Viedoc eTMF

Viedoc eTMF is a digital repository for capturing, managing, sharing, and storing essential documents.

For more information about Viedoc eTMF, see Viedoc eTMF User Guide.

# 11 Demo mode

If enabled, a study can operate in demo mode. You can easily switch between demo mode and production mode using the **DEMO MODE** switch:



The DEMO MODE switch is only visible when you have access to both production and demo mode.

The demo mode is clearly indicated with demo icons. Make sure you do not enter any real data in demo mode!

See also the video tutorial Activate demo mode.

# 12 Launch

Select the Launch button to access the patient data and electronic Case Report Forms (<u>eCRF</u>s). The button is only visible when you have access to the study in Viedoc Clinic.

If multiple roles are assigned to you in this study, you are first prompted to select the role you would like to use to access the study.

# 13 eLearning / Documentation & Training

If you have mandatory documentation pending to be read and signed, this is the first page that is displayed when you access the study.

Under this section, you have access to several eLearning programs and various documentation, depending on the roles that have been assigned to you. For details about the user documentation and certificates, see <u>Documentation</u> <u>& Training</u>.

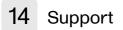
The Viedoc Clinic User Guides are available in the following languages:

- English
- Chinese
- Japanese

To change the language of the Viedoc User Guide, once opened, select the language from the upper right corner, as illustrated below:

			English 🔺 Español (España) 🔺
Viedoc User Guide for Site Us 30 lessons • Viedoc System 30 🖾 Download all lessons in a P			Français (France) 日本語 (日本) Polski (Polska) Svenska (Sverige) 中文(中华人民共和国)(h)、*
General			5 lessons
Overview of Viedoc Clinic	1.1	System requirements	12
Managing your Viedoc account	1.3	Overview of the landing page	14
Approving study design changes	1.5		

Tip! The various lessons in the Viedoc eLearning can easily be compiled into a PDF and printed if you need to store them in the investigator binder.



Select the support icon to open a pop-up with contact details to the users that can help you in case you need support. Normally you will find the contact details of the Monitor here, as the Monitor typically is the first point of contact to the site.

-

Documentation and Training

# **Documentation & Training**

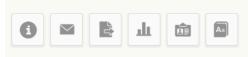
Published by Viedoc System 2020-06-04

1. Introduction

- 2. Becoming a certified user
- 3. Downloading your user certificate

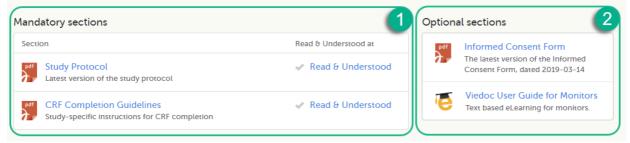
# 1 Introduction

Depending on the study settings and on the role(s) you have within a study, you might have access to various user documentation. This lesson describes the scenario when, under the eLearning section, you get access to the Documentation & Training page, with mandatory and/or optional documentation section(s), as illustrated in the following image:



### Documentation & Training

Before getting access to the study, please read all mandatory sections below and mark them as "Read & Understood". Once confirmed, Viedoc will generate a certificate of your completed training. Enjoy your trial!



The available documentation and training materials are split in two main categories:

**1. Mandatory sections** - contains all the materials that are mandatory for you to read, understand and sign before starting to work.

If you have mandatory documentation pending to be read and signed, then the first page that opens when you access the study is the Documentation and Training.

Important! All the materials under Mandatory sections must be "Read & Understood" and signed before you can launch the study. You might be able to launch the study in demo mode, depending on the study settings performed by the Study Manager.

2. Optional sections - contains additional educational and reference materials that you have access to. Simply click on the link to open each of the available documents/links.

To work within a study for which mandatory training sections were assigned, you need to read, understand and sign all the sections listed as mandatory.

To obtain the user certificate:

1 Click the link to open the section. Read through and, when you're done, go back to the Documentation and Training page and click **Read & Understood**. A date and time stamp in Coordinated Universal Time (UTC) will be shown in the **Read & Understood at** column:

		ē
Documentation & Training		
Before getting access to the study, please read all mandatory s certificate of your completed training. Enjoy your trial!	ections below and mark them as "Read $ heta$ Un	Iderstood". Once confirmed, Viedoc will generate a
Mandatory sections		Optional sections
Mandatory sections Section	Read & Understood at	Pet Informed Consent Form
	Read & Understood at	

2

Repeat step 1 for each of the mandatory sections. When all the mandatory sections are marked as "Read & Understood", a Confirm 'Read & Understood' link becomes available:

Mand	atory sections	
Secti	on	Read & Understood at
pdf	Study Protocol Latest version of the study protocol	🖌 2019-04-11 14:44 UTC 🛛 🕲
pdf	CRF Completion Guidelines Study-specific instructions for CRF completion	✓ 2019-04-11 14:55 UTC ⊗
	Confirm 'Read & Unde	rstood'

3

Click Confirm 'Read & Understood'. A confirmation pop-up opens:

S Documentation & Training	Cancel
Confirm 'Read & Understood' Please confirm that you have read and understood all mandatory sections. Once confirmed. Viedoc will generate a certificate of your completed training and you get access to the study.	
Confirm with your password	
Confirm	

4 Enter your Viedoc account password and click **Confirm**. A confirmation message together with the date and time stamp (<u>UTC</u>) is displayed at the bottom of **Mandatory sections**. Also, a link to Download your User Certificate becomes available:

ections	
	Read & Understood at
	🖌 2019-04-11 14:44 UTC 🛛 🕲
	✓ 2019-04-11 14:55 UTC
✓ 'Read & Understood' confirmed 20	19-04-11 15:02 UTC
🤶 Download your User Ce	rtificate
	Protocol version of the study protocol ompletion Guidelines specific instructions for CRF completion V Read & Understood' confirmed 20

5 Now you got your certification and are able to access the study. The Launch button is now available.

You can also Download your User Certificate. For details, see Downloading your user certificate.

The mandatory sections are still available for your further reference, you can at any time go back and open any of those by clicking the section link.

# 3 Downloading your user certificate

After you have completed all your mandatory readings and have signed and confirmed, as described in the previous section, you can download your user certificate in PDF format by clicking **Download your User Certificate** in the bottom of **Mandatory sections**.

The following information is provided on the certificate:

- User name (user ID is available on the page footer)
- User role(s) for which the certificate was obtained
- Date and time (UTC) when the certification was obtained (confirmed with password)
- Mandatory sections that were confirmed as "Read & Understood"



Selection page

# Selection page

Published by Viedoc System 2023-10-09

 1. Introduction

 1.1 Sorting and filtering

 1.2 Searching

 1.3 Icons

 2. Views of the Selection page

 2.1 The Cards view

 2.1 The subject card overview

 2.2 The issues view

 2.3 The Viedoc Me view

 2.4 The Events view

 3. Adding a new subject

# 1 Introduction

The Selection page displays all the subjects from all the sites you have access to:

Lection · Cards ·			<b>2</b> .
Search 🔎 *	FOUND 11 GARDS.		Show all sites
SE-KI-004 PARCURASA INSTITUTE STOCKNOM Statu: Age Screened 51.2	SEE-KI-003 HAROLINGKA MISTITUTE STOCKHOLM Status Age Screened 27.9	FI-HU-005 HELSIND LINUESITY HOSPITAL Status Age Screened 26.9	SE-UU-002 UPFALA UNIVERITY HOSEITAL Status Age Screened 58.2
FI-HU-004 HELINEY UNIVERSITY HOSPITAL Screened 37.1	FI-HU-003 HELSING UNRESTITY HOSPITAL Status Age Screened 29.1	FI-HU-002 HELSARD UNIVERSITY HOSPITAL Status Age Screened 30.6	SE-UU-001 UPSALA UNIVERSITY HOSENTAL Status Age Screened 38.8
FI-HU-001 HELMINGUMVERSTY HOSPITAL Status Age 35.0	SE-KI-002 KARCINGKA MISTITUTE STOCKHOLM Status Age Screened 50.9	SE-KI-001 KAROLINGKA HISTITUTE STOCKHOLM Status Age Screened 36.7	Add new card
Showing 1-11 of 11 PREVIOUS NEXT			View per page 20 50 100 500

In the default view, each subject is represented by a card. Depending on your study setup, the Selection page can be displayed in several ways. See <u>Views of the Selection page</u>.

### 1.1 Sorting and filtering

In the top right corner of the Selection page, you have dropdown menus to sort and filter the view. The options depend on the selected view. The selected sorting will be kept throughout your session.

		<b>2</b> .
Show all sites	v	Sort by added date 🔹

In the table view of the Selection page, you can also sort by column in descending or ascending order by selecting a column header with the arrow symbol. Lit-up arrows indicate the selected sorting in orange:

<mark>北</mark> Select	ion · Cards ★		
Search	• ۵٫	FOUND 11 CARDS.	
Gender 🗤	ID 4†	Status 41	Age ↓†
2	SE-KI-004	Screened	51.2
2	SE-KI-003	Screened	27.9
2	FI-HU-005	Screened	26.9
2	SE-UU-002	Screened	58.2
2	FI-HU-004	Screened	37.1
2	FI-HU-003	Screened	29.1
2	FI-HU-002	Screened	30.6
2	SE-UU-001	Screened	38.8
2	FI-HU-001		35.0
2	SE-KI-002	Screened	50.9
2	SE-KI-001	Screened	36.7

#### 1.2 Searching

To search for a specific subject or any other information collected for a subject, you can type the text you are looking for in the search field:

Lection ·	Cards *
Search	,0 <b>*</b>
	Subject key
SE-KI-004	All data

The system will return the subjects with the information sought that has been entered in the Case Report Form (CRF).

Subject key and All data are two filters that can be applied to the search.

- Subject key will return results where the search term is part of the subject ID.
- All data will return results where the search term is mentioned.
- All data also requires specificity when you commit a search for visit name and form name. It does not return partial results in these instances.

Note! For faster searches, we recommend that you select the Subject key filter.

Important! If your search returns nothing, it could indicate a problem with your study design. Please contact your Professional Services representative to assist you.

### 1.3 Icons

The Selection page displays a number of icons explained in the following table:

lcon	Description
i	Issue - at least one open query and/or missing data
7	Task - there are tasks to be completed, the number indicates the number of tasks
<ul> <li>Image: A start of the start of</li></ul>	Complete - all initiated events have been completely filled in

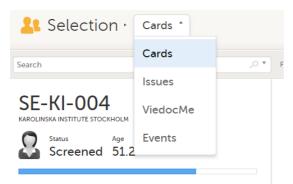
lcon	Description
٢	Signed - all data that is possible to sign has been signed
8	<b>Read-only</b> - the card is being open for edit by another user. Note that the subject card can still be accessed for review or SDV by a user without edit permissions, for example a monitor or a data manager.
X	<b>In progress</b> - the event is initiated but not completed This icon is only shown when none of the other status icons apply
6	Locked - the data in all forms of the event is locked

Notel The icons showing depend on your user role permissions.

### 2 Views of the Selection page

Depending on the study setup, the Selection page looks a bit different.

If the study is configured with extended selection pages, you can select a view at the top of the page.
 Select Cards, Issues, Viedoc Me or Events from the dropdown menu to open the view. The Viedoc Me view is only available to select if the Viedoc Me feature is included in your study.



 If the study is <u>not</u> configured with extended selection pages, you can select between the views Cards and Issues by clicking the buttons next to the search field.



#### The Cards view

In the **Cards** view, you can see all the subjects from all the sites you have access to. Select to display the subject cards side-by-side (default) or in a table:

• م	FOUND 29 CARDS.				
i	SE-01-018 UPPALA STATUS AGE	3	AE-423-00		
i	SE-01-017		Lina-001		
	42.0	FOUND 29 CARDS.	S 41	AGE 41	Rand. Numbe
i	SE-01-015	On	going		
_		On	going		
				60.5 42.0	
				42.0	

The subjects are sorted by added date, where the most recently added subject is displayed first. You can sort the subject cards by selecting an option in the upper right corner:

Show all sites	Ŧ	Sort by added date	
PROGRESS #		Sort by importance	
		Sort by modified date	
		Sort by added date	

- Sort by importance sort on forms with issues in descending order
- Sort by modified date sort on modified forms in descending order
- Sort by added date sort on added forms in descending order

To display only the subjects for a particular site, select the site from the dropdown list. Click **Include deleted subjects** at the bottom of the dropdown menu to display deleted subjects:

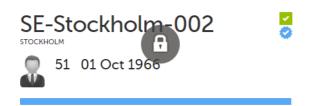
			<u>.</u> .
		Show all sites	Sort by added date 🔹
002 ospital ed 58.2	FI-HU HELSINKI UNIVE	Show all sites Karolinska Institute Stockholm Uppsala University Hospital Helsinki University Hospital Martin Luther Hospital United Richmond	
ospital Age ed 38.8		Include deleted subjects	

#### 2.1.1 The subject card overview

Each card provides subject information as per the respective study design:

- Subject ID
- Site name
- Gender indicated by an avatar
- Some <u>CRF</u> data
- Subject status indicated by the icon in the top right corner

If all the forms were locked (typically by the Monitor), this is shown with a padlock icon on the respective subject card:



Progress bar indicating the completion status (in blue)

Notel The Selection page does not consider the role visibility except for task count; therefore, the subject status reflects the general status of the subject in the study, regardless of the user who has work to be performed. The subject details view reflects the subject status considering the role visibility. This could result in a subject status where a subject could have a green check mark or be locked, while in the Selection page it is not (due to some other user role having unfinished work or forms to complete on the respective subject). See <u>Entering and Editing data</u> for more information on the subject details view.

#### 2.2 The issues view

In the Issues view, you can see the existing issues listed in a table:

Selection · Issues *					
Search	FOUND 9 ISSUES.			Show all sites	All open issues
ID 41	REFERENCE 41	ISSUE DETAIL 41	CONFIRMATION 41	STATE #	
EI-HU-002	Medical History Medical History Description of condition / event / surgery	T Missing data		Missing data	
FI-HU-002	Prior and Concomitant Medications Prior and Concomitant Medications Dose	! Missing data		Missing data	
EI-HU-002	Prior and Concomitant Medications Prior and Concomitant Medications Dose form	! Missing data		Missing data	
FI-HU-002 Hetsinki University Hospital	Prior and Concomitant Medications Prior and Concomitant Medications Frequency	! Missing data		Missing data	

Click any row to open the form where the issue was raised:

Selection · Issues *	L L	🔝 FI-HU-002 🐣 #1 - Term: - Start Date: 🐣	Edit Close	
		Form is in view mode. Click 'Edit' to make it editable     This form contains 8 required field(s)		
Search ID it o FI-HU-002	REFERENCE #1 Medical History	Prior and Concomitant Medications	SHOW HISTORY 1	Show all sites * All open issues STATE at
Hetsinki University Hospital     FI-HU-002     Hetsinki University Hospital	Medical History Description of condition Prior and Concomitant / Prior and Concomitant / Dose Prior and Concomitant /	Sequence number Name of drug / medication / therapy	Ð	Kicong data Misong data
FI-HU-002 Heteinki University Hospital	Prior and Concomitant / Dose form Prior and Concomitant / Prior and Concomitant / Prior and Concomitant / Frequency	Adverse event Other	( <del>)</del>	Kissing data Missing data
		Dose Unit Ut Dose form Choose one.	•	
		Frequency Choose one. * Choose one.	•	
		Start date Ongoing?   dd MMM yyyy   Yes  No	Đ	
			P Form History	
		Nicholas Hall   Viedoc <sup>14</sup> 472.8258.15573   2022-08-16715-45 NA   1.0   Viedoc Me study   Helsinki University Hospital	EEST	

Close the form to go back to the Issues list.

You can filter the **Issues** list using the dropdown lists in the upper right corner of the page:

			<b>.</b>
	Show all sites	v	All open issues
CONFIRMATION 11		STATE #1	All issues
			All open issues
			All queries Open queries Queries awaiting approval
			Missing data
			Form upgrade pending
			Form link broken
		Missing data	
		Missing data	l
		Missing data	

- By site view data from a specific site or from all sites
  - Include deleted subjects
- By issue type/status:
  - All issues:
    - a. Missing data
    - b. All queries, regardless of status
    - c. Form upgrade pending
    - d. Pending reference data upgrade
    - All open issues:
      - a. Missing data
      - b. Queries with the status "Awaits answer"
      - c. Form upgrade pending
      - d. Pending reference data upgrade
    - All queries
    - Open queries
    - Queries awaiting approval
    - Missing data

- Form upgrade pending
- Form link broken

#### 2.3 The Viedoc Me view

In the **Viedoc Me** account view, you can monitor and follow up on the subjects' expected Viedoc Me event submissions.

rch		,O * FOUND 11 CARDS.				Show all sites	* All accounts
		# LOGINS (LAST LOGIN) 41	COMPLIANCE #1	# MISSED EVENTS (LAST MISSED) 41	STUDY COMPLETION 41	NEXT SCHEDULED 41	ACCOUNT STATUS 41
2	SE-KI-004 Karolinska Institute Stockholm	2 2022-06-16 08:31 CEST	50%	1/2 (2022-06-11 00:00 CEST)	100%	-	Open
2	SE-KI-003 Karolinska Institute Stockholm	<b>1</b> 2022-06-02 11:59 CEST	0%	2/2 (2022-06-02 00:00 CEST)	100%		Open
2	FI-HU-005 Helsinki University Hospital	<b>1</b> 2022-06-01 11:39 EEST	-		0%		Open
2	SE-UU-002 Uppsala University Hospital	0	-		0%		Initiated
2	FI-HU-004 Helsinki University Hospital	14 2022-06-21 21:15 EEST	100%	0/2 -	100%		Open
2	FI-HU-003 Helsinki University Hospital	0	-		0%		Initiated
2	FI-HU-002 Helsinki University Hospital	<b>19</b> 2022-06-16 09:29 EEST	-	-	-		Open
2	SE-UU-001 Uppsala University Hospital	1 2022-05-13 17:18 CEST	-	-	-		Open
2	FI-HU-001 Helsinki University Hospital	14 2022-05-23 19:15 EEST	-	-	-		Open
-	SE KI 002	10		1/2			

For each subject, the following information is listed:

- ID the subject ID, avatar, and site
- # LOGINS (LAST LOGIN) the total number of logins with the last login shown in parentheses
- COMPLIANCE how well the subject is submitting events, counted on scheduled Viedoc Me events
- # MISSED EVENTS (LAST MISSED) the total number of missed Viedoc Me events, with the last missed event shown in parentheses
- STUDY COMPLETION how far into the study the subject is, counted on scheduled Viedoc Me events
   NEXT SCHEDULED the date and time of the next Viedoc Me event
- ACCOUNT STATUS the current status of the subject account, which can be filtered in the upper right corner:
  - All accounts all created Viedoc Me accounts: Initiated/Open/Locked
  - Initiated accounts that are created but the subjects have never logged in to their accounts
  - Open accounts that the subjects have logged in to (at least once)
  - Locked accounts that are locked
  - Not created accounts that are not yet created

#### 2.4 The Events view

In the Events view, you can see the status of each event for each subject listed in a table.

Search		,o *	FOUND 11 CARDS.						Show event types	Show all sites	* Sort	by added date
ID 41	Study Start	Screening	Baseline	Home adm.	Follow-Up	End of St	Unschedu	Extra Lab	Extra Lab	Extra Kit A	Medical H	Adverse E
SE-KI-004	<b>•</b>	<b>•</b>	Ξ	×			×				<b>•</b>	1
SE-KI-003	<b>•</b>	<b>•</b>	≍									
🚨 FI-HU-005		Ξ									×	1
SE-UU-002	<b>~</b>	⊠										
FI-HU-004	🗢 🔽	<b>•</b>	Ξ	🔒 🗹			0					
🚨 FI-HU-003		⊠										
🚨 FI-HU-002	<b>~</b>	Ξ						×	×		ž	
🚨 SE-UU-001		<b>•</b>										
🚨 FI-HU-001	<b>~</b>											
SE-KI-002	<b>•</b>	<b>•</b>	≍	⊼								
SE-KI-001	<b>~</b>	×	Ξ		X							

The first column indicates if there are issues/tasks in any of the subjects' events. If there are both issues and tasks for a subject, then issues [i] are shown in the column.

Select any cell to go to the event in the Details page:

Search	,O * FOI	JND 11 CARDS.					Show event types	▼ Show all sites	<ul> <li>Sort by add</li> </ul>	ded date
ID 41	Study Start Screening	Baseline	(Home adm.) Follow-Up	End of St	Unschedu	Extra Lab	Extra Lab	Extra Kit A	Medical H	Adverse E
🚨 SE-KI-004	Letails							<u>1</u> • 1 1	(i) <b>2</b> , <b>4 2</b>	
SE-KI-003	SE-KI-003		Search					Show all eve	vents * Ett 88°	
FI-HU-005 SE-UU-002	KAROLINSKA INSTITUTE STOCHHOLM		Screening Baseline	Home adm. Home Administration 01 Jun 2022 (-0/+7)						
8 FI-HU-004	92% 2/3	9/17		01 Jun 2022 (-0/+7)					0	
🚨 FI-HU-003	of study events	forms	Screening 🕬					Protocol date not set	U	
& FI-HU-002	Demographics	DM CRA SDY 📾 🔽	Event date				04 (8A 107 🖻 🗹	Scheduled date not set	٩	
SE-UU-001 FI-HU-001	Common events Medical History (0) Adverse Events (0)		Check Questions Physical Examination					01 Jun 2022	包	
SE-KI-002	Prior and Concomitant Medications (0)		Vital Signs				8 8 8 A 🗸			
SE-KI-001	Subject's adverse reactions (0) Cognitive Test Sample (0)		Body measurements				0M 0M 00V 🖻 🗹			
	Add new event		12-Lead Electrocardiogram Laboratory results							
			Wound Examination				0M 00A 00V 🔒 🔽			

Click back in the browser to return to the Events view.

Select an empty cell to view the subject's latest event.

The list of subjects can be filtered using the dropdown lists in the upper right corner of the page:

- By event type
  - Scheduled events
  - Unscheduled events
  - Common events
  - Subject-initiated events
- By site select to view data from a specific site or from all sites
  - Select to Include deleted subjects

Note! On the selection page, in the **Events** view, the <u>event name</u> (as set in the Study event settings in the study design) is displayed. If there is a recurring event, a counter is shown under the event name, for example: Follow up 1, Follow up 2.

### Adding a new subject

To add a new subject:

3

1

Make sure that you have selected a site (center) from the sites dropdown list. Click **Add new card** on the last card or select the icon in the top right corner of the page:

Selection · Cards *			<u>.</u>
Search 🖉 🔹	FOUND 11 CARDS.		Show all sites   Sort by added date
SE-KI-004 WARKING STOCHECK Some Age Screened 51.2	SE-KI-OO3 NACUNAN INSTITUTE STOCKINGA Simis Age Screened 27.9	FI-HU-005 INCLINATI UNIVERSITY INCOMINA. Status Agr. Screened 26.9	SE-UU-002 UMALU MARKINI HADARA Strate Age Screened 58.2
FI-HU-004 HELISHELUKARKISKY HOUMTA Screened 37.1	FI-HU-003 ILLIAND UNIVERSITY HODATAL Stems Age Screened 29.1	EI-HU-002 NELINARI UNRESETY INCOMTA Strutor Age Screened 30.6	SE-UU-001 UMALA LANGREIN HOURTAL Screened 38.8
FI-HU-001	SE-KI-OO2 MICLAROUX NOTIFUT FOCUMENT Serie Age Screened 50.9	SE-KI-001 NANCANINA WITHING TOCOMICAN Service And Art Screened 36.7	Add new card
Showing 1-11 of 11 PREVIOUS NEXT			View per page 20 50 100 500

The first form in the study is displayed.

2 Complete the form and select **Save changes** on the top right side of the page. A new subject is now added.

Note! Only user roles with editing permissions for the <u>study start event</u> form can add a new subject. If you do not have editing permissions, you cannot select **Add new card** and no icon is visible in the top right side of the page.

See also the video tutorial Add and select subjects.

If you receive the following message, the maximum number of subjects that is configured for your site has been reached, and you cannot add new subjects. If you need to add a new subject anyway, contact your Study Manager.

Add new sub	ject	e
i	The maximum number of subjects reached. New subjects can no longer be added. Ok, I understand	



#### Metrics

### Metrics

Published by Viedoc System 2022-02-10

**1. Metrics overview** 1.1 Viedoc Reports 2. Queries 2.1 Queries - filter 2.2 Queries 2.3 Query state 2.4 Top 5 events 2.5 Top 5 forms 2.6 Top 5 items 2.7 Top 5 check OIDs 2.8 Top 5 subjects (raised queries) 2.9 Save and export 3. Performance 3.1 Review status 3.2 Subjects 3.3 Queries 3.4 Missing data 3.5 Other 3.6 Save and export 4. Missing data 4.1 Top 5 events 4.2 Top 5 forms 4.3 Top 5 items 4.4 Subjects with confirmed missing data 4.5 Subjects with unconfirmed missing data 4.6 Save and export

### 1 Metrics overview

Note! As a Viedoc Clinic user, you need a special permission to view the metrics.

The metrics feature gives an overview of the quality of data in terms of open queries, missing data and overall site performance. You can filter the displayed data by country and site.



The metrics graphs depict:

- Open queries the number of currently open (not resolved) queries.
   A column graph shows five bars indicating the progress of posted queries during the last five weeks, where each bar indicates a seven day period.
   The latest seven days including today are shown in orange and the previous weeks are gray.
   A percentage indicator is also displayed to indicate the trend between the current week and the previous week. For example, +10% means that in the recent seven days, 10% more queries were in the state 'raised' as compared to the previous 7-day-period.
   Query rate the current query rate, counted as the total number of queries / number of subjects
- (according to the selection). A column graph shows five bars indicating changes to the query rate during the last five weeks, where each bar indicates a seven day period. The latest seven days including today are shown in orange and the previous weeks are gray. A percentage indicator is also displayed to indicate the trend between the current week and the previou

A percentage indicator is also displayed to indicate the trend between the current week and the previous week.

Unconfirmed missing data items - the amount of unconfirmed missing data items.

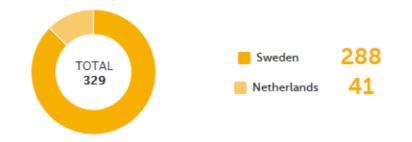
A column graph shows five bars indicating the changes to the missing data rate during the last five weeks, where each bar indicates a seven day period.

The latest seven days including today are shown in orange, other weeks are gray.

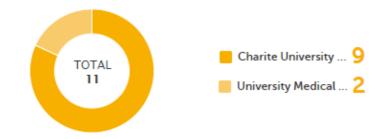
A percentage indicator is displayed to indicate the trend between the current week and the previous week.

A ring graph shows the distribution of missing data over those countries / sites / subjects with the most unconfirmed missing data, according to the selection made at the top of the page, as follows:

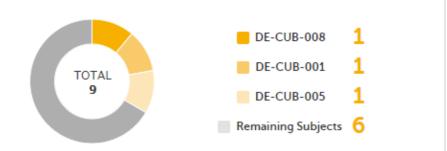
• All sites (default) - distribution over those countries with most unconfirmed missing data:



- **Country** - distribution over those sites within the selected country, with most unconfirmed missing data:



Site - distribution over those subjects with most unconfirmed missing data (in orange) out of
the total number of subjects with unconfirmed missing data within the selected site (in gray):



#### **Viedoc Reports** 1.1

#### If you have access to Viedoc Reports, you can open it from the Metrics feature.

			ē
Metrics			
All sites Sweden United States			
	🔥 Vied	oc Reports	
Open Wedoc Records			
	OPEN QUERIES		DUERY RATE
	1		0.50
More about queries		More about performance	

#### 2 Queries

The Queries page includes filtering possibilities and a bar to show the review status for the entire study.

For detailed information about the query process in Viedoc, see Queries overview.

#### **Queries - filter** 2.1

You can filter the data by selecting from the drop-down lists in the top of the page:

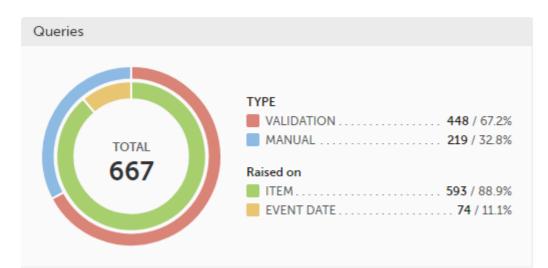
A Demo Study / Met	rics						
? Queries 🕜	Performance 🖉 Missing data						
Show All countries	▼ All sites ▼	All subjects 🔹	All time 🔹	Draw			
<ul> <li>Country</li> <li>Site</li> <li>Subject</li> <li>Time period - choose between: <ul> <li>All time</li> <li>Last 24 hours</li> <li>Last 3 days</li> <li>Last week</li> <li>Last 3 weeks</li> </ul> </li> </ul>							
Based on the se	lected filter, the following	information is provi	ided:				
- Quer	ries						

- <u>Query state</u>
- Top 5 events
- Top 5 forms
- Top 5 items
- Top 5 OIDs
- Top 5 subjects (raised queries)
- . Save and export

#### 2.2 Queries

Queries - a diagram that shows the graphical distribution, the total number as well as the percentage of:

- The distribution of the type of queries that have been raised (VALIDATION, MANUAL)
- The number of queries that were raised on item or event date, respectively (ITEM, EVENT DATE)



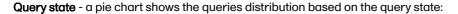
The number in the center of the circle shows the total number of queries.

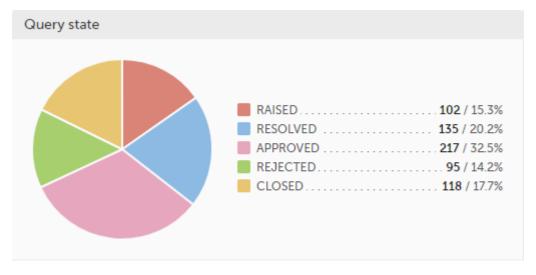
#### Notel

- All queries are included, regardless of the query state.
- Missing data is not regarded as queries, and therefore not included in the count.

For detailed information about query states and pro, see Queries overview.

## 2.3 Query state



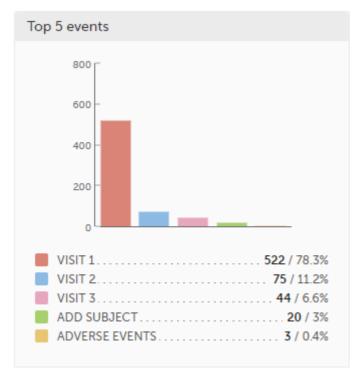


- RAISED number of raised queries / percentage of raised queries out of total number of queries
- RESOLVED number of resolved queries / percentage of resolved queries out of total number of queries
- APPROVED number of approved queries / percentage of approved queries out of total number of queries
- REJECTED number of rejected queries / percentage of rejected queries out of total number of queries
- CLOSED number of closed queries / percentage of closed queries out of total number of queries

For detailed information about query states and process, see Queries overview.

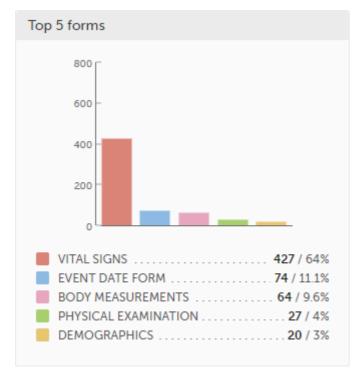
## 2.4 Top 5 events

**Top 5 events** - a column bar shows the top five events with the highest number of raised queries (numeric and percentage). The legend of the graph displays the event name.



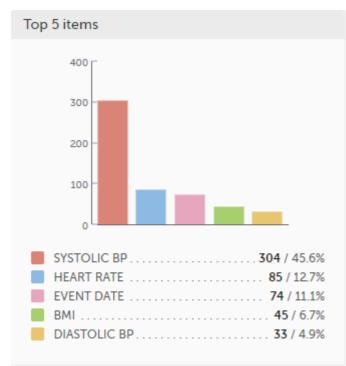
### 2.5 Top 5 forms

**Top 5 forms** - a column bar shows the top five forms with the highest number of raised queries (numeric and percentage). The legend of the graph displays the form name.



## 2.6 Top 5 items

**Top 5 items** - a column bar shows the top five items with the highest number of raised queries (numeric and percentage). The legend of the graph displays the item name.



## 2.7 Top 5 check OIDs

**Top 5 check OIDs** - top five most triggered edit checks are displayed in a table including the actual number, percentage, Object Identifier (OID), form name as well as the query message. The last row of the table shows the total number of queries.

Top 5 check OIDs						
	• n	%	FORM NAME	ITEM NAME	QUERY MESSAGE	OID
	0 244	54.5	Vital Signs	Systolic BP	Value is outside of normal range. Please verify.	RC_VSSYS_0_0_1
	65	14.5	Event Date form	Event Date	Visit date is not within the protocol visit window	
	• 44	9.8	Body measurem	BMI	BMI is outside of normal range. Please verify.	RC_BMBMI_5_0_1
	• 24	5.4	Vital Signs	Diastolic BP	Value is outside of normal range. Please verify.	RC_VSDIA_0_0_1
	0 20	4.5	Vital Signs	Heart rate	Value is outside of normal range. Please verify.	RC_VSPULSE_0_0_1
	0 448	100	In total			

## 2.8 Top 5 subjects (raised queries)

**Top 5 subjects (raised queries)** - top five subjects that have the highest number of queries with current status *raised* are displayed in a table including the actual number, percentage, subject ID, study progress, site name as well as date of when the latest query was raised, name of who raised the query as well as the actual query message. The last row of the table shows the total number of subjects.

Top 5 subjects (raise	d queries)					
	l n	%	SUBJECT ID	PROGRESS	SITE NAME	LATEST QUERY (date, by, message)
	• 5	4.9	SE-01-045		Karolinska U	28 Feb 2018 09:46, Richard Schlomann, Test Query.
	• 5	4.9	SE-01-119		Karolinska U	20 May 2016 08:24, Mr Demo, Correct?.
	• 4	3.9	SE-01-118		Karolinska U	07 Sep 2016 11:51, System, Value is outside of normal range. Plea
	• 3	2.9	SE-01-219		Karolinska U	07 Jun 2017 17:06, Lyle Wiemerslage, r?.
	0 2	2	SE-01-348		Karolinska U	28 Mar 2018 12:44, System, Visit date is not within the protocol vi
	O 102	100	In total			

For detailed information about query states and process, see Queries overview.

### 2.9 Save and export

In the bottom of the Queries details page you have the options to:

- Save as a PDF file all the metrics data as displayed on the screen.
- Send by email to your primary email address, a PDF file with all the metrics data as displayed on the screen.

# 3 Performance

The Performance page allows you to compare data from:

- Selected country (individual country or All countries)
- Selected site(s) in the previously selected country (individual site or All sites)

With data in one of the following:

- Entire study (default)
- All sites in selected country
- A particular site in the selected country

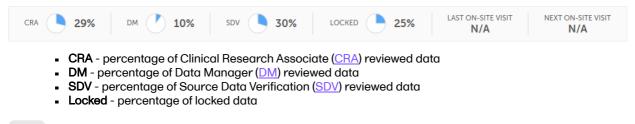
8	Queries	Performance	Missing data					
Show	All countries	•	All sites	•	Compare with	Entire study	•	Draw

Based on the comparison selection the graphs will show statistics about:



- Missing data
- Other
- Save and export

3.1 Review status



### 3.2 Subjects

Subjects - detailed data on the subjects on the selected site(s) (in orange) and compared site(s) (in gray):



The conditions for the following subject statuses are defined in the study design (in Viedoc Designer under *Study Settings > Subject status*):

- Screened the number of subjects screened:
  - at selected site(s) in orange
  - at site(s) to compare to in gray

- percentage of screened subjects at selected site(s) out of total number of expected subjects in the center (number of expected subjects for a study/site, is defined in Study/Site Settings in Viedoc Admin)
- Enrolled the number of subjects enrolled:
  - at selected site(s) in orange
  - at site(s) to compare to in gray
  - percentage of enrolled subjects at selected site(s) out of total number of screened subjects in the center
- Completed the number of subjects completed:
  - at selected site(s) in orange
  - at site(s) to compare to in gray
  - percentage of completed subjects at selected site(s) out of total number of screened subjects
     in the center
- Withdrawn the number of subjects withdrawn:
  - at selected site(s) in orange
  - at site(s) to compare to in gray
  - percentage of withdrawn subjects at selected site(s) out of total number of screened subjects
     in the center

Tipl If there is an *i* symbol inside of a ring graph, you can hover over it to see a description of the status.

### 3.3 Queries

Queries - detailed data on queries on the selected site(s) (in orange) and compared site(s) (in gray):

Queries				
Sweden Entire study				
QUERIES TOTAL				
		28 /	70%	40 / 100%
QUERY		#	QUERIES OPEN MORE THAT	١
[# queries / #	# subjects] 40 / 116	$\frown$	$\frown$	$\frown$
28773	407110	7 DAYS	14 DAYS	21 DAYS
LAST 7 DAYS	LAST 7 DAYS	16	16	16
0%	0%			

- Queries total the total number of queries on selected site(s) (in orange) and compared site(s) (in gray) are shown both in % and in actual numbers.
- Query rate total number of raised queries out of total number of subjects. The column graph consists of 5 bars indicating the progress of the query rate the last 5 weeks period, where each bar indicates a 7 days period.

Columns for selected sites are displayed in orange and columns for compared site(s) in gray. A percentage indicator shows the trend of the number of queries compared to the previous 7 days period for selected (to the left) and compared site(s) (to the right):

- down green
- up red
- equal black
- Queries open more than three circles display the number of queries currently in a Raised state, that have been open for more than, 7, 14 and 21 days on the selected site(s), which give a good indication of the pace queries are processed within different sites.

For detailed information about query states and process, see Queries overview.

## 3.4 Missing data

**Missing data** - detailed information on missing data (both confirmed and unconfirmed data) on the selected site(s) (in orange) and compared site(s) (in gray):

Missing data					
Sweden 📃 Entire stud	dy				
MISSING DATA TOTAL				288 / 82.765	6 348 / 100%
	MISSING DATA RATE [# missing data / # subjects]		# UNCONFI	RMED MISSING DATA OPEN	MORE THAN
288 / 73 0 LAST 7 DAYS 0%		348 / 116 0 LAST 7 DAYS -100%	7 DAYS 288	14 DAYS 288	21 DAYS 288

- Missing data total - Total number of missing data on selected site(s) (in orange) and compared site(s) (in gray) both numeric and percentage out of all missing data in the entire study. Hidden forms/items are not included in the count.

• Missing data rate - current missing data rate calculated as total number of missing data per total number of subjects.

The column graph consists of 5 bars indicating the progress of the missing data rate the last 5 weeks period where each bar indicates a 7 days period.

Columns for selected sites are displayed in orange and columns for compared site(s) in gray. A percentage indicator shows the trend of the missing data compared to the previous 7 day period for selected (to the left) and compared site(s) (to the right):

- down green
- up red
- equal black
- Unconfirmed missing data open more than three circles display the number of currently unconfirmed missing data items that has been missing for more than, 7, 14 and 21 days (counted from the date the form was edited with unconfirmed missing data until current date) on the selected site(s).

### 3.5 Other

Other - miscellaneous detailed data on the selected site(s) (in orange) and compared site(s) (in gray):



 Time to enter data - the average time (in days) it takes to enter data for selected site(s) (in orange) and compared site(s) (in gray). This is calculated as a difference between the event date and the date the item data was entered, <u>per form</u>.

The column graph consists of 5 bars indicating the average time to enter data over the last 5 weeks period where each bar indicates a 7 days period.

Columns for selected sites are displayed in orange and columns for compared site(s) in gray. A percentage indicator shows the trend compared to the previous 7 days period for selected (to the left) and compared site(s) (to the right):

- down green
- up red
- equal black
- Time to resolve queries the average time to resolve a query (in days) for selected site(s) (in orange) and compared site(s) (in gray). This is calculated as the difference in days from the date the query was <u>Raised</u> until the date the query was <u>Resolved</u>. The queries that are automatically closed by the system (see <u>Queries overview</u> for details on when a query is automatically closed) are also included in the count.
   Note! The queries that were removed or automatically resolved are not included in the count.
   For detailed information about query states and process, see <u>Queries overview</u>.

The column graph consists of 5 bars indicating the average time to resolve queries over the last 5 weeks period where each bar indicates a 7 days period.

Columns for selected site(s) are displayed in orange and columns for compared site(s) in gray. A percentage indicator shows the trend compared to the previous 7 days period for selected (to the left) and compared site(s) (to the right):

- down green
- up red
- equal black
- Deleted forms rate the rate of deleted forms, calculated as the number of deleted forms per number of subjects, for selected site(s) (in orange) and compared site(s) (in gray).

The column graph consists of 5 bars indicating the deleted forms rate over the last 5 weeks period where each bar indicates a 7 days period.

Columns for selected site(s) are displayed in orange and columns for compared site(s) in gray. A percentage indicator shows the trend compared to the previous 7 days period for selected (to the left) and compared site(s) (to the right):

- down green
- up red
- equal black

### 3.6 Save and export

In the bottom of the **Performance** details page you have the options to:

- Save as a PDF file all the metrics data as displayed on the screen.

- Send by email to your primary email address, a PDF file with all the metrics data as displayed on the screen.

# 4 Missing data

The Missing data page includes filtering possibilities and a bar to show the review status for the entire study.

You can filter the data by selecting from the drop-down lists in the top of the page:

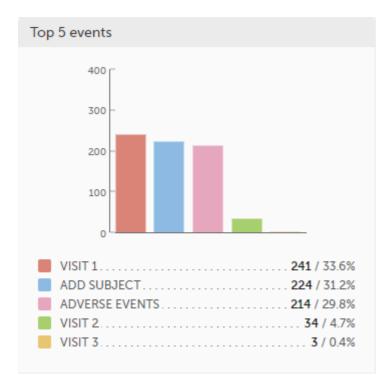
A Demo 2018 / Metri	cs			
Queries	Performance 🖉 Missing data	a		
Show All countries	▼ All sites	<ul> <li>All subjects</li> </ul>	▼ All time	▼ Draw
<ul> <li>Coun</li> <li>Site</li> <li>Subje</li> <li>Time</li> </ul>		reen:		
Based on the sel	ected filter the araph	e will show statisti	cs about	

Based on the selected filter the graphs will show statistics about:

- Top 5 events
- Top 5 forms
- <u>Top 5 items</u>
- <u>Subjects with confirmed missing data</u>
- <u>Subjects with unconfirmed missing data</u>
- Save and export

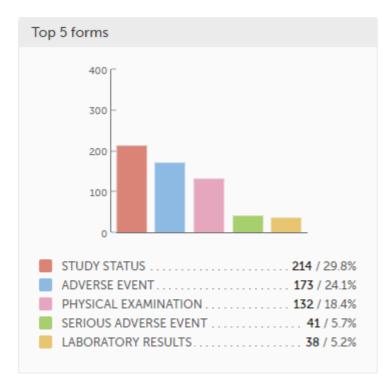
#### 4.1 Top 5 events

**Top 5 events** - a column bar shows the top five events with the highest number of items with missing data (confirmed and unconfirmed), both numeric and percentage. The legend of the graph displays the event name.



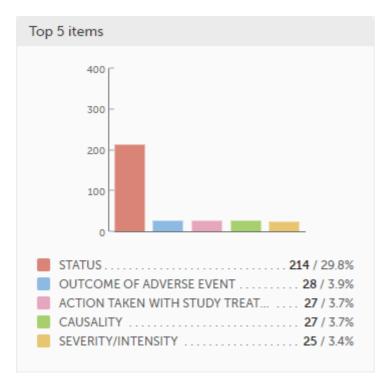
## 4.2 Top 5 forms

**Top 5 forms** - a column bar shows the top five forms with the highest number of items with missing data (confirmed and unconfirmed), both numeric and percentage. The legend of the graph displays the form name.



## 4.3 Top 5 items

**Top 5 items** - a column bar shows the top five items with missing data (confirmed and unconfirmed), both numeric and percentage. The legend of the graph displays the item name.



### 4.4 Subjects with confirmed missing data

The top 5 subjects that have the highest level of confirmed missing data are displayed in a table including:

- The actual number
- Percentage
- Subject ID
- Study progress

- Site name
- Date, visit, form and item (item output label if defined, otherwise the field label of the item) taken from the visit where the missing data occurs

The last row of the table shows the total number of subjects with confirmed missing data.

n	%	SUBJECT ID	PROGRESS	SITE NAME	LATEST MISSING ITEM (date, visit, form, item)
0 2	4.1	SE-01-332		Karolinska Uni	12 Mar 2018 15:33, Visit 1, Body measurements, Wei.
2	4.1	SE-01-284		Karolinska Uni	25 Jan 2018 08:43, Lyle W, Visit 1, Safety Laboratory Parameters, Pleas.
2	4.1	SE-01-316		Karolinska Uni	24 Jan 2018 10:53, Visit 1, 12-Lead ECG, Performed.
0 2	4.1	SE-01-166		Karolinska Uni	07 Feb 2017 14:05, Visit 1, Physical Examination, Lymph
0 2	4.1	SE-01-110		Karolinska Uni	30 Mar 2016 11:58, Visit 1, Body measurements, Hei
48	100	In total			

### 4.5 Subjects with unconfirmed missing data

The top 5 subjects that have the highest level of unconfirmed missing data are displayed in a table including:

- The actual number
- Percentage
- Subject ID
- Study progress
- Site name
- Date, visit, form and item (item output label if defined, otherwise the field label of the item) taken from the visit where the missing data occurs

The last row of the table shows the total number of subjects with unconfirmed missing data.

-			00000000		
<b>n</b>	%	SUBJECT ID	PROGRESS	SITE NAME	LATEST MISSING ITEM (date, visit, form, item)
6 42	6.2	SE-01-320		Karolinska Uni	12 Feb 2018 10:59, Adverse Events, Serious Ad
24	3.5	SE-01-344		Karolinska Uni	19 Mar 2018 11:05, Adverse Events, Serious Adverse E.
0 22	3.2	SE-01-331		Karolinska Uni	08 Mar 2018 16:35, Adverse Events, Adverse Event,
• 19	2.8	SE-01-249		Karolinska Uni	18 Aug 2017 09:52, Adverse Events, Adverse Event,
<b>1</b> 6	2.3	SE-01-281		Karolinska Uni	28 Sep 2017 09:07, Visit 1, Laboratory results, Crea
669	100	In total			

### 4.6 Save and export

In the bottom of the Missing data details page you have the options to:

- Save as a PDF file all the metrics data as displayed on the screen.
- Send by email to your primary email address, a PDF file with all the metrics data as displayed on the screen.



#### Exporting data

## **Exporting data**

Published by Viedoc System 2024-03-19

1. Introduction 2. Filtering the data to be previewed/exported 2.1 Filtering data by country and site 2.2 Including subjects 2.3 Events and time period 2.3.1 Selecting events 2.3.2 Selecting a time period 2.4 Forms and items 2.5 Type of data 2.5.1 Filter data by review status 2.5.2 Additional information 2.5.2.1 Booklet status 2.5.2.2 Queries and Query history 2.5.2.3 Review status 2.5.2.4 Event dates 2.5.2.5 Uploaded files 2.5.2.6 Pending forms 2.5.2.7 Medical coding 2.5.2.8 Edit status 2.5.2.9 Subject status 3. Export output formats 3.1 Microsoft Excel / CSV 3.2 CSV 3.3 PDF 3.4 CDISC ODM 4. Export compatibility with previous Viedoc versions 4.1 Output versions 5. Previewing data 5.1 Data table 5.1.1 Column menu 5.1.1.1 Column display options 5.1.1.2 Column filter 5.1.1.3 Column selection options 5.1.2 Data table context menu 5.2 Pie chart 5.3 Column chart 5.4 Line chart 6. Data export templates 6.1 Saving export settings as a template 6.2 Applying a data export template 6.3 Editing a data export template 6.4 Deleting a data export template 7. Exporting data

```
7.1 Latest exports
```

## 1 Introduction

The Data Export page can be accessed by clicking the Data Export icon in the study start page:

## A Demo Study



The Data Export page enables you to preview and download study data:

- Preview Using the preview feature, you can review the data directly on the screen, and generate different types of graphs from the data. It is also possible to directly access the underlying electronic Case Report Form (<u>eCRF</u>) pages.
- Export You can export the data to an external file for further analysis or archiving. Viedoc supports export of data to the following formats:
  - Excel
  - PDF
  - Comma-Separated Values (CSV)
  - Statistical Analysis System (<u>SAS</u>)
  - Operational Data Model (ODM)

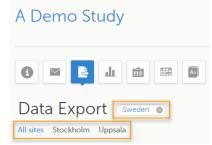
## 2 Filtering the data to be previewed/exported

You can filter the data that you want to preview/export, as described in the following sections.

### 2.1 Filtering data by country and site

If you have access to multiple sites, you can filter the data for a specific country or site.

To filter data for a specific country, click on the name of the country. The selected country appears in blue letters besides the **Data Export** header, while the site(s) for the selected country are listed below:



For a specific country, you can choose to export the data for:

- All sites (default)
- A specific site that you select. The current selection is highlighted in blue text. Note! Only one site can be selected at a time.

To undo the selection of the site, click **All sites**.

To undo the selection of a country, click the cross  $\mathbf{x}$  icon beside the name of that country.

While filtering for country or site, the number of subjects depicted in between brackets in the **Subjects to include** field is updated accordingly.

### 2.2 Including subjects

You can choose to include all subjects in the data preview or export, or include a selection of subjects.

To select which subjects to include:

1 Select Include single subject(s).

Click the + icon and select from the drop-down list the subject you want to add. The selected subject appears in the **Subjects to include** field:

ľ	Subjects to include ( 20 )				
	O Include all subjects				
	• Include single subject(s):	SE-Stockholm-001	*	• •	
			Q,		
	Events and time period	SE-Stockholm-001			

Repeat this step for each subject you want to include in the data preview/export.

To undo the selection of certain subjects, click the - icon, or click the cross x icon next to the subject ID:

ľ	Subjects to include ( 20 )	holm-002 SE-Stockholm-003 S	
	Include all subjects		
	• Include single subject(s):	SE-Stockholm-001 SE-Stockholm-002 SE-Stockholm-002	Stockholm-003 🔹 🖨 🛨

#### 2.3 Events and time period

You can choose to include all the data or only for certain events. You can also filter the data added or edited during a certain time period.

Note! The available events are the ones existing in the latest design version applied on <u>the first</u> of the selected sites to be included in the export. If there are multiple design versions running for different of the selected sites, you have to select one site at a time in order to get the available events for the respective site.

#### 2.3.1 Selecting events

You can choose to:

- Include all events (default)
- Include Single events. See below the instructions for selecting single events.

To select which events to include:

#### 1 Select Single event(s).

2 Click the + icon and select from the drop-down list the event you want to add. The selected event appears in the **Events and time period** field:

Events and time period         Visit 1 (S)       Lab Visit (S)         between 01 Jan 2018 00:00       (S)	
O Include all events	
● Single event(s): Visit 1   ▼ ⊖ Lab Visit ▼ ⊖ ↔	

Repeat this step for each event you want to include in the data preview/export.

Events and Visit 1	d time peri Lab Visit (		n 01 Jan 2018 00:	:00 🛞		
🔵 Inclu	de all events	5				
<ul> <li>Singl</li> </ul>	e event(s):	Visit 1	•	Lab Visit	•	• •

#### 2.3.2 Selecting a time period

To include data from a specific time period:

~	Time period:	Edited (l	JTC)	,	b	etwe	en 🔻		
•	01 Jan 2018 0	0:00	i	C	and		dd MMM yyyy HH:mm	i	C
						Cu	rrent date & time _ நிரு		
						Yes	sterday		

- 2 Select one of the following options from the first drop-down list:
  - Edited (UTC) to include data based on the date they were added or last edited. Notel This feature includes data based on Coordinated Universal Time (UTC), not on the local time a user has added or edited data. Note that also the time period should be specified in UTC.
  - Event date to include data based on the event date.
- 3 Select whether to define the time period until a certain date, from a certain date, or between two dates.
- 4 Select the date(s).

Tip! Filtering for data that were added or edited since a specific date is especially useful if you want to see all new and changed data since for example your last monitoring visit.

To undo the selection of a certain time period, click the cross x icon next to it:

Events and time period         All events (2018)         Until 16 May 2018         00:00
Include all events
Single event(s): 🔸
Time period: Edited (UTC)
▼ 16 May 2018 00:00 🗰 🕒

### 2.4 Forms and items

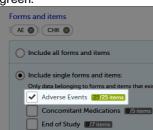
You can choose which forms and items to be included in the export output:

- Include all forms and items (default)
- Include single forms and items see the instructions below on how to select forms and items.

Notel Only data belonging to forms and items that exist in the latest effective design applied to <u>the first</u> of the selected sites will be included in the export. Also note that the forms and fields available to choose from are determined by the visibility settings for your user role.

To include data from specific form(s):

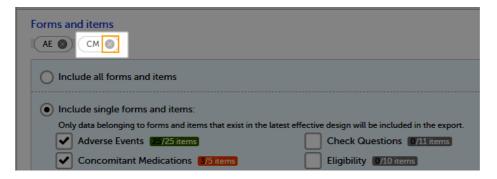
- 1 Select Include single forms and items.
- 2 Select the forms and items to be included, in one of the following ways:
  - Select the checkbox corresponding to a form in the list displayed, to include the respective form with all the items contained. The selected/total number of items will be highlighted in green:



Click the field [..]/[..] items next to the form name, and select/deselect specific items. You can also use Select all / Deselect all for selecting/deselecting all the items in the form at once. If selecting only some of the items in the form, the selected/total number of items will be highlighted in orange:

Forms and items		
Include all forms and items		
Include single forms and items		
Only data belonging to forms and it		ffective desig
Adverse Events 25/25 iten	ns	Che
Concomitant Medications	s 3/5 items	0
Select all Deselect all		
CM Id:	Drug/Medictaion/T	
✓ Indication	🕢 Dose	
Unit		

To undo the selection of a certain form, click the cross x icon next to it:



### 2.5 Type of data

#### 2.5.1 Filter data by review status

You can filter the data to be included in the export by the review status, as follows:

- Signed data (selected by default) data that has been signed in Viedoc Clinic (typically by the Investigator). For information on how data is signed see <u>Signing data</u>.
- Not signed data (selected by default) unsigned data.
- SDV performed or N/A (selected by default) data on which the Source Data Verification (SDV) was
  performed (marked by the SDV flag in Viedoc Clinic) and data that does not require SDV.
- SDV pending (selected by default) data that requires SDV that was not performed (not yet marked by the SDV flag in Viedoc Clinic).

#### 2.5.2 Additional information

You can select to include additional information, depending on the <u>export output format</u>, as described in the following sections.

#### 2.5.2.1 Booklet status

For PMS studies, there is an option to include booklet status and booklet status history in the export.

When selecting to include Booklet status, the Booklet status history option becomes available.

Depending on if the booklet status is included in the export or not, the export contains the following information:

- Without **Booklet history** there is one row for each booklet, providing information about the current status of the booklet.
- With **Booklet history** there is one row for each change in the booklet status, that is, there can be many rows for one and the same booklet.

Booklets in submitted status are not included in exports triggered by users on the sponsor side. The booklets are included to those users when they are received.

Note! Clinic actions to submit/recall back and forth are not available on the sponsor side. Only the latest submit of the booklet that was received by the sponsor is included.

If the **Booklet Status** is selected and the following options: **Require Responsible Investigator** for booklet submission, and **Require Contract** for booklet submission, are enabled for the study, two columns are added to the export.

- Contract number of the selected contract for the specific booklet.
- Responsible Investigator user name (internal ID) of the user selected as Responsible Investigator for the specific booklet.

If **Booklet histor**y is selected at export, the historically selected Contract and Responsible Investigator are included in the respective booklet status. The most recent contract information shall be shown, regardless of the booklet status.

Note! If the contract linked to a booklet is edited, the contract information is updated in the existing row for that booklet in the export performed *after the information was updated*.

The booklet status can be exported to the following export output formats:

- Microsoft Excel Office Open XML
- <u>CSV</u>
- <u>ODM</u> in this case, the Booklet history is not available.

When selecting to include **Booklet status** in the Excel export, a separate **Booklet status** sheet is created that lists all the forms with the following information:

Column name	Description
Site sequence number	A counter that identifies the site globally within the study
Site name	The site name, as set in Viedoc Admin
Site code	The site code, as set in Viedoc Admin
Subject sequence number	A counter that identifies the subject within the site
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.
Booklet sequence number	A counter that identifies the booklet within the sequence of booklets for the same subject
Booklet Id	The booklet ID, as set in the study design (in Viedoc Designer)
Booklet name	The booklet name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic
Booklet status	One of Not initiated, Initiated, Submitted, Received, Returned, or Frozen
Booklet activity	Initiated, Submitted, Recalled, Received, Frozen, Unfrozen, or Returned
Date & time (UTC)	The date and time of the status change
User name (ID)	The name (ID) of the user who changed the booklet status
Contract number	The number of the selected contract for the specific booklet. Notel This column is present in the export only if the option to link the booklet to a contract is enabled for the study.
Responsible Investigator	User name (internal userID ) of the user selected as Responsible Investigator for the specific booklet. Note! This column is present in the export only if the option to link the booklet to a contract is enabled for the study.

#### 2.5.2.2 Queries and Query history

When selecting to include Queries, the Query history option becomes available.

The Queries can be exported to the following export output formats:

- Microsoft Excel Office Open Extensible Markup Language (XML)
- <u>CSV</u>
- Operational Data Model <u>ODM</u> in this case, the **Query history** is not optional, but will be included regardless. For this reason it is not displayed as an option.

#### See also:

- <u>Queries in ODM export</u>
- Queries in Excel export

#### 2.5.2.3 Review status

The review status can be exported to the following export output formats:

- Microsoft Excel Office Open <u>XML</u> when selecting one row per item as Layout, the review status is not included in the export.
- <u>CSV</u> when selecting **one row per item** as **Layout**, the review status is not included in the export.
- PDF PDF Archive (PDF/A) only the signature information is included (not SDV, lock status, or CRA review status).
   ODM

- <u>Review status in ODM export</u>
- Review status in Excel export

#### 2.5.2.4 Event dates

The event dates can be exported to the following export output formats:

- Microsoft Excel Office Open <u>XML</u>
- <u>CSV</u>
- ODM

When selecting to include **Event dates** in the Excel export, a separate **Event dates** sheet is created that lists all the events with the following information:

Column name	Description
Site sequence number	A counter that identifies the site globally within the study
Site name	The site name, as set in Viedoc Admin
Site code	The site code, as set in Viedoc Admin
Subject sequence number	A counter that identifies the subject within the site
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.
Event Id	The event ID, as set in the study design (in Viedoc Designer)
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic
Event repeat key	For recurring events, the counter that identifies different occurrences of the same event (identified by the Event ID). Available for output versions Viedoc 4.39 and onward.
Event status	The current status of the event. It can be one of the following: <ul> <li>Initiated</li> <li>Proposed</li> <li>Not Initiated</li> <li>Planned</li> </ul>
Event date	The event date, as set in Viedoc Clinic when the event is initiated
Planned date	The event planned date, as set in Viedoc Clinic when the event is planned
Proposed date	The proposed date for the event, if set in the study design
Window start date	The event time window start date, if set in the study design.
Window end date	The event time window end date, if set in the study design
Initiated by	The name and ID of the user who initiated the event
Initiated date (UTC)	The date and time (UTC) when the event was initiated
Last edited by	The name and ID of the user who last edited the event
Last edited date (UTC)	The date and time (UTC) when the event was last edited
Design version	The design version/revision that is active for the event

#### 2.5.2.5 Uploaded files

When selecting the **Uploaded files** option, the uploaded file together with the thumbnail (if it exists) are part of the Excel, CSV and PDF export output:

- Excel the export file (.xls) together with all the referenced file uploads are included in a zip file.
- CSV, PDF A folder with all the referenced file uploads is included in the export zip file.
- When you select **Include history** (available only for **one row per item**), the current version of the uploaded file will be included as usual, and the previous versions of the files will be stored in subfolders named as the *Edit sequence number*.

The export output (Excel, PDF, <u>CSV</u>, <u>ODM</u>) as well as the **Data preview** provides the following information about uploaded files:

- File Name
- File Size (in bytes)
- File Hash
- Path to where the actual file is located in the exported zip file

The following information on the uploaded file is available in the full history:

- Who has uploaded the file
- Upload date
- Initial/Updated (first file uploaded/update of an existing file)
- File Name
- File Size (in bytes)
- File Hash (MD5)
- Link to file

#### 2.5.2.6 Pending forms

The pending forms can be exported to the following export output formats:

- Microsoft Excel Office Open XML
- <u>CSV</u>

Forms are considered pending when they are uninitiated in initiated events. This applies to all types of events, including subject-initiated events. For repeating forms, if the first instance of the form is uninitiated, the form is considered pending. Resetting a form results in that form being pending.

When selecting to include **Pending forms** in the Excel export, a separate **Pending forms** sheet is created that lists all the forms with the following information:

Column name	Description
Site sequence number	A counter that identifies the site globally within the study
Site name	The site name, as set in Viedoc Admin
Site code	The site code, as set in Viedoc Admin
Subject sequence number	A counter that identifies the subject within the site
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.
Event sequence number	A counter that identifies the event within the sequence of events for the same subject
Event Id	The event ID, as set in the study design (in Viedoc Designer)
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic
Event repeat key	For recurring events, the counter that identifies different occurrences of the same event (identified by the Event ID). Available for output versions Viedoc 4.39 and onward.

Column name	Description
Activity Id	The activity ID, as set in the study design (in Viedoc Designer)
Activity name	The activity name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic
Form Id	The form ID, as set in the study design (in Viedoc Designer)
Form name	The form name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic
Event date	The event date, as set in Viedoc Clinic when the event is initiated
Pending since	The date and time since when the form has been pending
	This is not always the date when the event was initiated. For a form that has been hidden due to a visibility condition, the pending since date is the date when the form is made available.

#### 2.5.2.7 Medical coding

The medical coding can be exported to the following export output formats:

- Microsoft Excel Office Open XML. For details, see Medical coding in Excel export.
- <u>CSV</u> similar output information as in Excel.
- <u>ODM</u> for details, see <u>Medical coding in ODM export</u>.

#### 2.5.2.8 Edit status

The edit status can be exported to the following export output formats:

- Microsoft Excel Office Open XML
- CSV
- PDF <u>PDF/A</u>
- ODM

#### 2.5.2.9 Subject status

The subject status can be exported to the following export output formats:

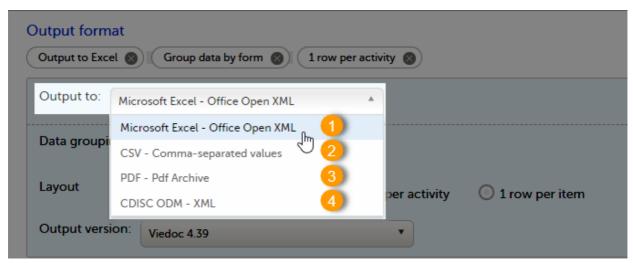
- Microsoft Excel Office Open XML
- <u>CSV</u>
- ODM

The sheet Calculated subject status contains the following columns:

- Site sequence number
- Site name
- Site code
- Subject sequence number
- Subject Id
- Screened state
- Screened on date/datetime (site local)
- Enrolled state
- Enrolled on date/datetime (site local)
- Completed state
- Completed on date/datetime (site local)
- Withdrawn state
- Withdrawn on date/datetime (site local)

3 Export output formats

Select the export output format of the data under Output format > Output to:



You can export the data to one of the following formats:

1. Microsoft Excel - Office Open XML

2. <u>CSV</u>

3. PDF - PDF/A

4. <u>ODM</u>

### 3.1 Microsoft Excel / CSV

Viedoc uses Microsoft Excel Open XML format which is compatible with Excel version 2007 and later.

For details about the Excel export options and the format/structure of the output file, see Excel export.

## 3.2 CSV

The output of the <u>CSV</u> export is similar to the Excel export output. The CSV export output consists of a zip archive containing one CSV file that corresponds to each sheet from the Excel export. For details about the Excel export options and the format/structure of the output file, see <u>Excel export</u>.

For the CSV export and **one row per activity** selected layout, there is also the option to **Include corresponding SAS** script. For details, see <u>Exporting for SAS</u>.

### 3.3 PDF

For details about the PDF export and the format/structure of the output file, see PDF export output.

## 3.4 CDISC ODM

The Clinical Data Interchange Standards Consortium (CDISC) Operational Data Model (ODM) is a vendor neutral, platform independent format for interchange and archive of clinical trials data. The format includes the clinical data along with its associated metadata, administrative data, reference data and audit information. All of the information that needs to be shared among different software systems during the setup, operation, analysis, submission or for long term retention as part of an archive is included in the model.

This is used to export the data to an <u>ODM</u> file, with or without Viedoc extensions. To include the Viedoc extensions in the exported file, select the **Include extensions** checkbox. Viedoc extensions are Viedoc specific settings that cannot be described as part of the CDISC standards. If the exported file is to be imported to Viedoc at a future time, the checkbox should be checked.

The ODM export file is built up as follows:

- The Study tag contains the information on the study settings, study design, workflow.
- The AdminData contains data about the user and site settings.
- The ClinicalData tag contains the data that was filled in in Viedoc Clinic.

 The Association tag contains information about the performed actions such as <u>SDV</u>, raising and approving queries, medical coding, lock, <u>CRA</u> and <u>DM</u> reviews.

#### See also:

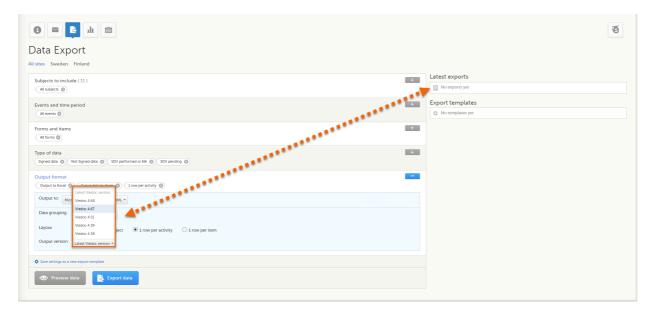
- <u>Queries in ODM export</u>
- Medical coding in ODM export
- Review status in ODM export
- Excel export (See for more information on how to export Audit trail history.)

# 4 Export compatibility with previous Viedoc versions

It is possible to select the Viedoc version that the exported file should be compatible with. This option enables you to export files that have the same format as files exported from previous Viedoc versions.

Notel This functionality is optional and set in the study settings in Viedoc Admin. It might not be activated for your study.

If activated for your study, you can select the Viedoc version that you wish the exported file to be compatible with under **Output format and export**, from the **Output version** drop-down menu. If you wish to create an export file according to the latest Viedoc version, select **Latest Viedoc version**:



The Viedoc version used for data export is listed in the Latest exports area on the right side of the export page.

The exported file contains information about which Viedoc version was used to create it. You can find information about the Viedoc version in the following places:

- For Excel, the Viedoc version used is displayed in the README sheet.
- For <u>CSV</u>, the Viedoc version used is displayed in the *README* text file.
- For PDF, the Viedoc version used is displayed on every page in the footer or side bar.
- For <u>ODM</u>, the Viedoc version used is displayed in the *Export version* extension.

#### 4.1 Output versions

The Viedoc versions available in the **Output version** dropdown menu are <u>only</u> those versions in which changes to the data structure were introduced.

As of Viedoc release 4.77, the following output versions are available:

Output version	Changes in data structure
Latest Viedoc version	When choosing <b>Latest Viedoc version</b> , the exported data will automatically follow the structure of the latest Viedoc release in which changes to the data structure were introduced.

Output version	Changes in data structure
Viedoc 4.77	For studies where item-level SDV is enabled, when exporting review status, the SDV sheet in the CSV and Excel data exports will include only the items that require SDV and are visible to the user. On the Review status sheet, items that do not require SDV are indicated with N/A.
Viedoc 4.68	Introduction of pdf archive export system check which splits the archive into one pdf file per subject and stores resultant PDF in a zip file.
Viedoc 4.67	Introduction of two new columns for approving medical coding: "approved by" and "approved on date".
Viedoc 4.51	Introduction of three new form repeat keys and the table of contents in the PDF export, see the table below for details
Viedoc 4.39	Introduction of repeating forms and recurring events, see the table below for details.
Viedoc 4.38	Original output format (Viedoc versions 4.38 or older).

In Viedoc 4.51, the following changes to the export output were introduced:

File type	Changes in the export output format
Excel	<ul> <li>Addition of three columns for the new form sequence numbers introduced:</li> <li>SubjectFormSeqNo - Counter that uniquely identifies the instance of a specific form on a subject level, that is, it starts with 1 and is incremented each time a new instance of the form is created for that subject.</li> <li>OriginSubjectFormSeqNo - For a copied form instance, it identifies the form instance from which data was copied for the first time. For the first instance of the form (that is, not copied) it gets the value of the SubjectFormSeqNo .</li> <li>SourceSubjectFormSeqNo - For a copied form instance, a counter that identifies the source of a copied form instance (the form instance the data was copied from). It gets the value of the SubjectFormSeqNo from which the form instance was copied. For the first instance of the form (that is, not copied) it gets the value of the subjectFormSeqNo from which the form instance was copied. For the first instance of the form (that is, not copied) it is empty.</li> </ul>
ODM	Three new form sequence numbers were introduced, as Viedoc extensions: v4:SubjectFormSeqNo , v4:OriginSubjectFormSeqNo and v4:SourceSubjectFormSeqNo , within the FormData , right after the FormRepeatKey .
PDF	A table of contents was added to the PDF archive, starting on page 2 of the file.

In Viedoc 4.39, the following changes to the export output were introduced:

File type	Changes in the export output format
Excel	Addition of a column for Form sequence number ( ${\tt FormSeq}$ ) that contains the ${\tt FormRepeatKey}$ .
ODM	The FormRepeatKey now contains the activity ID as well, in the following format: FormRepeatKey\$ActivityId . The ExportVersion attribute has been added to the ODM.
PDF	The summary formats are used to display the event and form names.

# 5 Previewing data

The Preview data button is only available when you have selected Excel or CSV as output format for the export.

The preview is not available when you have selected 1 row per item.

## 5.1 Data table

On the data tab, you can preview the data in table format:

	6	lili li		×					6				
ncluded forms	1		Filter	, (2)									3
Screening Diary /	SCRD		Sea	rch				4			5		=
Site name	=	Site code	=	Subject Id ≡	Ev	ent name	=	Event date	≡	Activity name	1	Completion period	≡
	7		X	<b>v</b>			7		V		<b>v</b>		<b>v</b>
AutoRecur1		AR1	6	AR1-50001	Sc	reening - Visit	La	2018-01-15				Prior to or during the B	PS
AutoRecur1		AR1		AR1-50002	Sc	reening - Visit	La	2018-01-17				After the BPS	
AutoRecur1		AR1		AR1-50003	Se	reening - Visit	La	2018-01-17				After the BPS	
AutoRecur1		AR1		AR1-50004	Se	reening - Visit	La	2018-01-17				Prior to or during the B	PS
AutoRecur1		AR1		AR1-50005	Sc	reening - Visit	La	2018-01-17				Prior to or during the B	PS
AutoRecur1		AR1		AR1-50006	So	reening - Visit	La	2018-01-17				After the BPS	
AutoRecur1		AR1		AR1-50008	So	reening - Visit	La	2018-01-17				After the BPS	
AutoRecur1		AR1		AR1-50009	Se	reening - Visit	La	2018-01-17				Prior to or during the B	PS
AutoRecur1		AR1		AR1-50010	Sc	reening - Visit	La	2018-01-17				Prior to or during the B	PS
AutoRecur1		AR1		AR1-50013	Sc	reening - Visit	La	2018-01-17				Prior to or during the B	PS
AutoRecur1		AR1		AR1-50014	So	reening - Visit	La	2018-01-17				After the BPS	
AutoRecur1		AR1		AR1-50015	Se	reening - Visit	La	2018-01-17				Prior to or during the B	PS •

Cross-check

1. If you have selected Group data by form, you can select the form for which you want to display data.

2. Use the **Filter** text box to filter the preview data by any text in any field. The preview is filtered on all words in this field.

3. Toggle between spacious view and compact view.

4. Click a column header to sort the data in ascending order. Click again to sort in descending order. A third click removes the column sort order. To rearrange the order of the columns in the table, simply click on a column header and drag the column sideways.

5. Click to open the column menu. For more information, see Column menu.

6. Click to access the column filter. For more information, see Column filter.

7. Click any hyperlink data point in the table to view the underlying form in read-only mode.

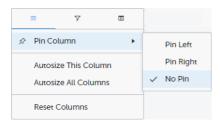
8. Select **Cross-check** to display a second data table. This lets you cross-check data between the two tables. Form selection and the filtering and sorting of data in the second table are independent of the settings in the first table.

#### 5.1.1 Column menu

The column menu contains:

- column display options
- column filter
- column selection options

For more information, see the following sub-sections.



Pin Left/Right makes a column remain visible in the leftmost or rightmost position when you scroll sideways. Select No Pin to unpin the column.

Autosize adjusts the column width to the width of the text in the column.

Reset Columns resets the pinning, sizing, and order of columns to the initial state.

#### 5.1.1.2 Column filter

Use the column filters to narrow down the selection of preview data.

1
•
0 OR 2
•
Clear
3
-
Reset

1. Depending on the type of item in the column, you can specify one of these types of filters:

- Text filter with the following filter operators:
  - Contains
  - Not contains
  - Equals
  - Not equal
  - Starts with
  - Ends with

Form items that are radio buttons, drop-down menus, checkboxes, dates, or date/time items are treated as text.

Note! The text filters are case-insensitive.

• Number filter with the following filter operators:

- Equals
- Not equal
- Less than
- Less than or equals
- Greater than
- Greater than or equals
- In range

2. Once you have specified a filter, you can specify another one for the same column, either as an AND filter or an OR filter.

3. Predefined filter options based on the data available in the column.

#### 5.1.1.3 Column selection options

Select the columns to be displayed in the preview table.

	=	7	m
> E	Search		
> [	] System data		A
	Site name		
~	Site code		
~	Subject Id		
~	Event name		
~	Event date		
~	Activity name		
~	Completion period	l	_
_			*

Use the Search field to search for columns.

By default, system data is excluded from the table. To include system data, select the column(s) to include from the **System data** category. Note that some system data columns are only available when you have selected 1 row per activity. For more information, see <u>Excel export</u>.

5.1.2 Data table context menu

When you right-click in a cell in the data table, this context menu is displayed:

Ō	Сору	Ctrl+C
D	Copy with Headers	
<u>↓</u>	Excel Export (.xlsx)	

Copy: Copies the cell value to your clipboard.

Copy with Headers: Copies the cell value and its column header to your clipboard.

**Excel Export**: Exports the preview data on the data tab. The resulting Excel file will have the same sorting and filtering of data and order of columns as the preview.

## 5.2 Pie chart

Select the data set you wish to plot in a chart, and click Draw:

Export Data Preview / A demo study	Close X
Series/Categories	
Site name * Draw	
Site name	
Academic Hospital Uppsala: 11 %	
King's College Hospital London: 7 % VU Medical Center Amsterc iversity College Hospital London: 7 %	
University of Brescie: 4 %	
Helsinki University Hospital: 7 %	

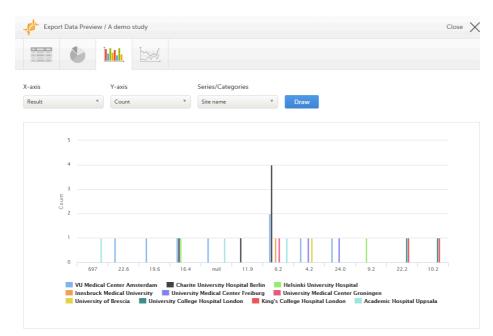
If you have selected **Group data by form**, you can only choose data sets from the form you have selected on the data table tab.

Click any data point to view its details.

Note! The pie chart has access to the same data as the data tab. That means that if you applied filters on the data tab, only the filtered data will be available in the pie chart.

## 5.3 Column chart

Select which data you would like to plot on the X-axis and Y-axis, which series should be created, and click Draw:



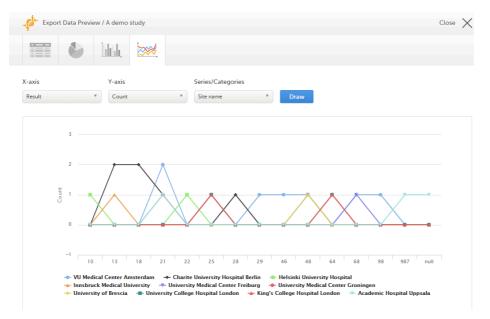
If you have selected **Group data by form**, you can only choose data sets from the form you have selected on the data table tab.

Click any column to view details of the data.

Note! The column chart has access to the same data as the data tab. That means that if you applied filters on the data tab, only the filtered data will be available in the column chart.

### 5.4 Line chart

Select which data you would like to plot on the X-axis and Y-axis, which series should be created, and click Draw:



If you have selected **Group data by form**, you can only choose data sets from the form you have selected on the data table tab.

Notel The line chart has access to the same data as the data tab. That means that if you applied filters on the data tab, only the filtered data will be available in the line chart.

# 6 Data export templates

When you have made settings for an export, you can save them as a template. Then you, and optionally others, can use the template to easily make new exports with the same settings.

6.1 Saving export settings as a template

To save your settings as a template:

1 Click Save settings as a new export template.



In the pop-up that is displayed, enter a name for the template and select whether it should be private or shared.

If you select **Shared**, you are prompted to also select the roles that will be able to use the template. The roles available in the drop-down list are the ones with export permissions for the latest effective design of the study in question.

/	New export template
Ν	Name
	CDISC ODM template
(	Private 💽 Shared
	Select role(s)
	Investigator
	Study Coordinator
	Monitor
ıll Mar	Project Manager
	Data Manager
	Sponsor
	Medical Coder
	Medical Coding Reviewer

Click **Save**. Now the **Export templates** list is displayed, with your newly created template at the top of the list:

					Close
Expo	ort templates	Show	All templ	lates	Ŧ
	CDISC ODM template Last edited 03 Apr 2020 07:29 UTC by		¢	/	Ê
	Study coordinator export Last edited 01 Apr 2020 11:47 UTC by		¢	/	Ê
	SAS export Last edited 31 Mar 2020 14:04 UTC by		£		Ê
	My export template Last edited 31 Mar 2020 08:52 UTC by		¢		Ê
	Shared to all Last edited 31 Mar 2020 08:51 UTC by		¢		Ê

6.2 Applying a data export template

To apply a data export template:

1

2

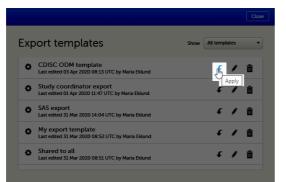
3

Click View all templates in the Export templates area of the Data export page.



2

Click the apply icon for the template that you want to apply.



Click **Export data** to perform an export with the settings in the template.

Tip! Alternatively, you can use the quick access apply, available in the **Export templates** area:

Export templates
CDISC ODM template
Apply oordinator export
SAS export

## 6.3 Editing a data export template

To edit a data export template:

1 Click View all templates in the Export templates area of the Data export page.



2 The **Export templates** list is displayed. Click the edit icon for the template that you want to edit.

Show	All temp	lates	, 1
	¢	6	â
	r		
	•		
	¢	1	Ô
	¢	1	â
	¢	1	â
		t t	\$ } \$ } \$ }

3 In the pop-up that is displayed, you can edit the name of the export template and the settings for **Private/Shared**.

Note! You can only edit a template that you created yourself.

### 6.4 Deleting a data export template

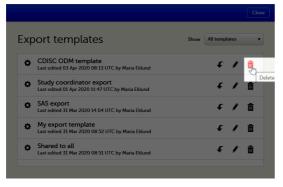
To delete a data export template:

1 Click View all templates in the Export templates area of the Data export page.



3

The **Export templates** list is displayed. Click the trash can icon for the template that you want to delete.



3

2

In the pop-up that is displayed, click **Delete**.

Confirm r	remove		Close
Ê	Remove template: CDISC ODM templ	ate	
	Delete	Cancel	

Note: You can only delete a data export template that you created yourself.

# 7 Exporting data

To perform a data export:

- 1 Filter the data to be exported. See <u>Filtering the data to be exported</u>.
- 2 Select the Output format.
- **3** Optionally, select the <u>Output version</u>.
- 4 Optionally, <u>preview the data</u> to be exported.
- 5 Click **Export data**. The status of the export is displayed in the **Latest exports** area, on the top of the list. When the export is completed, you can download the exported file:

Lat	est exports
1 1	31. Mar 2020 15.02 UTC [Ready] <u>Valeda - 45.1</u> 3 aubjects, CDISC DDN - XML [25.13.188] Download <b>31. Mar 2020 0 4:05 UTC [Ready]</b> Video 4 51.3 subjects, CSV - Comma-separated values, 1 row per activity, IS5KB
	Si Mar 2020 08:24 UTC [Ready]     Viedoc 4.51, 2 subjects, CDISC ODM - XML [2496K8]
E	31 Mar 2020 08:23 UTC [Ready] Viedoc 4.51, 2 subjects, Microsoft Excel - Office Open XML, 1 row per activity, [78KB]

The exported file is downloaded locally. The filename is generated as follows: SponsorCode\_CountryCode\_SiteCode\_Date\_Time, where:

- SponsorCode the sponsor code, as set in Viedoc Admin, under Study Settings.
- CountryCode the code of the country selected in Viedoc Admin, under Site Settings.
- *SiteCode* the site code, as set in Viedoc Admin, under Study Settings.
- Date the date when the export was requested, in format yyyymmdd.
- *Time* the time (UTC) when the export was requested, in format *hhmmss*.

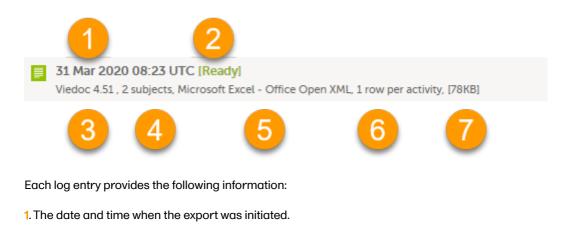
Note! If any of the characters that are invalid for a filename in Windows are used within any of the *SponsorCode* or *SiteCode*, these characters will be automatically replaced with - within the exported filename.

## 7.1 Latest exports

You can see a log of the requested exports in the **Latest exports** area, where you can download the exported files or delete the logs.

Notel The list of the latest exports is user-specific, that is, you can only see the exports made by yourself.

The latest five exports are shown in the list. To get the complete list of the initiated exports, click the **View all exports** link at the bottom of the list.



- 2. The export status:
  - In Queue the export request is in queue, waiting to be processed.
  - In Progress the exported started and is in progress.
  - Ready the file was successfully exported and is ready for download.
  - Error an error was encountered and the export was not performed.
- Viedoc output version see <u>Output versions</u>.
- 4. The number of exported subjects.
- 5. The format of the output file.
- 6. The selected layout, if applicable.
- 7. File size

Notel If data has been masked after an export was made, it is not possible to download that export because it could include the data that was later masked.

Lat	est exports	
	<b>2012-09-12 22:50 [in queue]</b> Viedoc 4.51, 31 subjects, 1 row per activity, [45KB]	
	<b>2012-09-11 15:27 [Ready]</b> Viedoc 4.51, 31 subjects [45KB]	
	<b>2012-09-11 15:27 [Ready]</b> Viedoc 4.51, 31 subjects [45KB]	
ŀ	<b>2012-09-11 15:27</b> [No data] Viedoc 4.51, 31 subjects [OKB]	
	2012-09-11 15:27 Removed due to data anonymization	
View all exports		



Excel export

# Excel export

Published by Viedoc System 2022-05-05

1. Introduction 2. File structure 2.1 Header rows 3. Data filtering - Type of data 4. Data grouping 4.1 Group data by form 4.2 Do not group data 5. Layout 5.1 One row per subject 5.2 One row per activity 5.3 One row per item 5.3.1 Include history 5.3.2 Checkboxes 6. Form link items in the export output 6.1 One row per activity 6.2 One row per item 6.3 One row per subject 7. Recurring events in the export output 8. Repeating forms in the export output 9. Forms initiated by copying data from previous event

# 1 Introduction

Viedoc uses Microsoft Excel Open Extensible Markup Language (XML) format which is compatible with Excel version 2007 and later.

When selecting Microsoft Excel as **Output format** in the Data export page, you have different options for grouping data and for the layout, as described in the following sections.

For general information about data export in Viedoc, see Exporting data.

Note! Since the maximum number of rows supported for Excel is 1048576, in case data in a sheet exceeds this number, data will be split into multiple sheets.

# File structure

2

The Excel export contains the following sheets:

- README always the first sheet in the Excel export output, with general information about:
  - the Viedoc output version (for details see Exporting data)
    - the time zones used for date/time fields
    - the meaning of the signature, <u>only if the **Review status** was selected to be included in the export</u>
- Depending on the selected Data grouping:
  - If Group data by form is selected, there is one separate sheet for each form, as described below in Group data by form.
  - If Do not group data is selected, there is one sheet called Data that contains all exported data.
     See Do not group data.

- Items after the data sheet(s), there is the Items sheet, that lists all the existing items in the exported data with the following information (columns):
  - Note! This sheet is not included when selecting the **one row per item** layout.
    - ID the item ID, as set in the study design
    - Label the field label, as set in the study design
    - Data type the type of data, as set for the respective item in the study design. Can be one of the following:
      - integer
      - double
      - text
      - string
      - date
      - datetime
      - base64Binary (for File upload items)
    - Mandatory:
      - True if the item was set as mandatory in the study design
      - False if the item was not set as mandatory in the study design
    - Decimals the number of allowed decimals in the data content.
    - **Min Length** the minimum required length for the respective field, if set in Viedoc Designer. For checkbox items, this is the minimum number of checkboxes required to be set, a set in Viedoc Designer.
    - Max Length the maximum number of characters that can be entered, if set on item level in Viedoc Designer.
    - Format Name the format name, if set in Viedoc Designer (under *Outputs and Validation > Formats*). For the codes of the checkbox or radio button items, a default value is generated even if no format name is set in Viedoc Designer.
    - Content Length the maximum number of characters of the data content. That is, this is set by the length of the content
- CodeLists the last sheet in the export, containing all the code list items in the exported data with the following information:

Notel This sheet is not included when selecting the one row per item layout.

- Format Name
- Data Type
- Code Value
- Code Text

The table below lists which sheets are included in the Excel file, depending on the selected Grouping and Layout:

	Group data by form	Do not group data
one row per subject	<ul> <li>README</li> <li>one separate sheet for each form</li> <li><i>Items</i></li> <li>CodeLists</li> </ul>	<ul> <li>README</li> <li>Data</li> <li>Items</li> <li>CodeLists</li> </ul>
one row per activity	<ul> <li><i>README</i></li> <li>one separate sheet for each form</li> <li><i>Items</i></li> <li><i>CodeLists</i></li> </ul>	<ul> <li>README</li> <li>Data</li> <li>Items</li> <li>CodeLists</li> </ul>
one row per item	<ul> <li><i>README</i></li> <li>one separate sheet for each form</li> </ul>	<ul><li>README</li><li>Data</li></ul>

### 2.1 Header rows

The headers are always represented by the first two rows in a sheet, as illustrated in the following image:

- 1. Human-readable format
- 2. Machine-readable format

Site sequence number	Site name	Site code	Subject sequence number	Subject Id	Event sequence number	Event Id	Event name	Event date
SiteSeq	SiteName	SiteCode	SubjectSeq	SubjectId	EventSeq	EventId	EventName	EventDate
1	Karolinska	01	1	SE-01-001	1	SCR	Add subject	2014-10-02
1	Karolinska	01	3	SE-01-003	1	SCR	Add subject	2014-11-14
1	Karolinska	01	4	SE-01-004	1	SCR	Add subject	2014-11-25
1	Karolinska	01	5	SE-01-005	1	SCR	Add subject	2014-12-05

An item that was changed within a new/revised study design version will have a "\_\_n" suffix added, where *n* is incremented for each study design version where the respective item was changed:

Race2		Race2	- Code						
DMRACE	_2	DMRACE	_2CD						
Native Ha	waiian	4							
Native Ha	waiian	4							
Black		1							

# 3 Data filtering - Type of data

Under Type of data, you can filter the data to be exported. If you filter data for Signed data, Not signed data, SDV performed or NA, or SDV pending, certain cells in the data sheets in the exported Excel file may appear empty. The data rows that contain empty cells due to the filtering are marked by an "X" in the last column of the data sheets that is named Empty cells on row may be due to export filter.

For example, let's say that we have an *Add Patient* event, and the *Date of Birth* is one of the data entered during this event. For a particular subject, this data was entered, signed by the Investigator, and afterwards modified, but not signed after the change. We perform an export that includes <u>only</u> the signed data, as illustrated in the image below:

Type of data	
Signed data SDV performed or NA SDV pending	g 🛞
✓ Signed data	🕑 Not Signed data
SDV performed or NA	SDV pending

The value of the *Date of birth* field that was recently changed and not signed is not included in the export (the cell appears empty). The data row containing the empty cell is marked by a "X" the **Empty cells on row may be due to export filter**, as shown below:

	Site name SiteName	Site code		Subject Id		Event Id EventId	Event name EventName	Event date EventDate	Activity Id ActivityId	Form sequence number FormSea	version	Gender GENDER	Gender - Code GENDERCD	Date of Birth	Age	Number Pl2	Empty cells on row may be due to export filter HAS_FILTER	ED VALUES
	Stockholm			EH-D8-002		AP		2017-08-11	APA	 1	-	Male	M	1966-10-01	51			
2	Uppsala	Uppsala:2	2	SE-Uppsala	1	AP	Add Patien	2017-08-11	APA	1	2.0	Female	F	1959-09-21	58			
2	Uppsala	Uppsala:2	5	SE-Uppsala	1	AP	Add Patien	2017-08-11	APA	1	2.0	Male	м	1977-03-15	40			
2	Uppsala	Uppsala:2	15	SE-Uppsala	1	AP	Add Patien	2018-10-12	APA	1	14.2	Female	F	1965-02-22	54			
2	Uppsala	Uppsala:2	17	SE:Uppsala	1	AP	Add Patien	2018-11-12	APA	1	19.0	Male	м	1989-11-24	29			
2	Uppsala	Uppsala:2	19	SE:Uppsala	1	AP	Add Patien	2018-11-30	APA	1	20.2	Male	м	1954-02-10	65			
2	Uppsala	Uppsala:2	20	SE:Uppsala	1	AP	Add Patien	2018-11-30	APA	1	20.2	Female	F	1968-04-29	51			
2	Uppsala	Uppsala:2	24	SE:Uppsala	1	AP	Add Patien	2019-01-16	APA	1	20.2	Male	M		63		х	

# 4 Data grouping

You can select whether the data should be grouped by form or not, from the Data grouping dropdown list.

Note! The data grouping is available only for the Excel/Comma-Separated Values (CSV) output.

## 4.1 Group data by form

When grouping the data by form, a separate sheet is created for each form. The sheet name is the Form ID, as set in the study design (in Viedoc Designer).

In each form sheet, the first columns (to the left) are the same for all the forms and provide information about the site, subject, event, activity and design version:

Column	Description
Site Sequence number	Counter that identifies the site globally within the study.
Site name	The site name, as set in Viedoc Admin.
Site code	The site code, as set in Viedoc Admin.
Subject sequence number	Counter that identifies the subject within the site.
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.
Event sequence number	Counter that identifies the event within the sequence of events for the same subject.
Event Id	The event ID, as set in the study design (in Viedoc Designer).
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Event date	The event date, as set in Viedoc Clinic when the event is initiated.
Activity Id	The activity ID, as set in the study design (in Viedoc Designer).
Activity name	The activity name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Form sequence number	Counter that identifies the instance of the respective form within the respective activity. This is mostly used for repeating forms.
	For non-repeating forms, this is "1". If a form is reset and then saved again the new form has sequence number "2", and so on.
	Form sequence number increases one step every time reset/initiate occurs.
Subject form sequence number	Counter that uniquely identifies the instance of a specific form on a subject level, that is, it starts with 1 and it is incremented each time a new instance of the form is created for that subject.
Origin Subject form sequence number	For a copied form instance, it identifies the form instance from which data was copied for the first time. For the first instance of the form (that is, not copied) it gets the value of the SubjectFormSeqNo .
Source Subject form sequence number	For a copied form instance, a counter that identifies the source of a copied form instance (the form instance the data was copied from). It gets the value of the SubjectFormSeqNo from which the form instance was copied. For the first instance of the form (not copied) it i empty (null).
Design version	The design version used at the time of data edit for the respective form.

The example in the image below shows an export with the default settings for the Layout, that is, 1 row per activity.

The following columns are specific to each form, one column for each item in the respective form. Each column has the *<ltem name*>, as set in the study design (in Viedoc Designer) as column header.

		Export weden Finland Germany	Netherl	ands Au	ustria Be	elgium	Italy Ur	nited Kingdom	Switzerland	I							
	Subjects All subje	s to include ( 112 )							+								
	Events a	nd time period s 🕲															
	Forms a	nd items							+								
	Type of Signed d		V performed o	or NA 🛞	SDV pendin	g 🕲											
	Output f	format o Excel 🔕 Group data by form ဈ	1 row p	oer activity (	8				+								
	-	ings as a new export template review data	ata				£										
			ļ,														
	Α	в	с	D	E	F	G	н	1	1	к	L	м	N	0	Р	Q A
	Site sequence			Subject sequence		Event sequence						Form	Design	Date/Time of Informed		Gender -	Date/Time of
		Site name			Subject Id		Event Id	Event name	Event date	Activity Id		number	version	Consent	Gender	Code	Birth
2	SiteSeq	SiteName	SiteCode	SubjectSec	SubjectId	EventSeq	EventId	EventName	EventDate	ActivityId	ActivityNar I	FormSeq	DesignVer	DMIC	DMSEX	DMSEXCD	DMDOB
3	i	Academic Hospital Uppsala		1	SE-AHU-00	1	SCR	Add subject	2016-10-04	SCR	Add subjec	i	3.0	2016-07-04	Male	1	1964-06-11
4	i	Academic Hospital Uppsala			SE-AHU-00	1	SCR	Add subject	2016-10-04	SCR	Add subjec	i	3.0	2016-10-02	Female	2	1979-05-28
5	í	Academic Hospital Uppsala			SE-AHU-00	1	SCR	Add subject	2016-10-04	SCR	Add subjec	i	3.0	2016-09-04	Male	1	1968-08-04
6	i	Academic Hospital Uppsala		4	SE-AHU-00	1	SCR	Add subject	2016-10-04	SCR	Add subjec	i	3.0	2016-06-05		1	1952-10-01
7		Academic Hospital Uppsala			SE-AHU-00	í1 -	SCR	Add subject	2016-10-04	SCR	Add subjec	i	3.0	2016-08-07	Female	2	1959-04-06
8	4	Charite University Hospital Berlin			DE-CUB-00	1	SCR	Add subject	2016-10-04	SCR	Add subjec	i	3.0	2016-08-07	in the second	1	1980-02-22
9		Charite University Hospital Berlin	000		DE-CUB-00		SCR	Add subject	2016-10-04	SCR	Add subjec		3.0	2016-03-02		1	1960-11-02
10		VU Medical Center Amsterdam		1	NL-VUA-00		SCR	Add subject	2016-10-04	SCR	Add subjec		3.0	2016-10-02		1	1961-07-31
11		VU Medical Center Amsterdam		2	NL-VUA-00		SCR	Add subject	2016-10-04	SCR	Add subjec		3.0	2016-08-07		1	1973-12-21
12		Academic Hospital Uppsala			SE-AHU-00		SCR	Add subject	2016-10-05	SCR	Add subjec		12.0	2016-10-02		2	1976-02-01
13		Academic Hospital Uppsala			SE-AHU-00		SCR	Add subject	2016-10-05	SCR	Add subjec		12.0	2016-10-02		1	1965-06-29
14		Karolinska Institute Stockholm		1	SE-KIS-001		SCR	Add subject	2016-10-05	SCR	Add subjec		12.0	2016-10-03		1	1964-03-31
15		Academic Hospital Uppsala			SE-AHU-00		SCR	Add subject	2016-10-05	SCR	Add subjec		13.0	2016-10-02		2	1973-05-21
16	5	VU Medical Center Amsterdam	VUA	6	NL-VUA-00	1	SCR	Add subject	2016-10-20	SCR	Add subjec	1	13.0	2016-10-20	Female	2	1977-10-25
	•	README DM SS VS	RAND C	Q PE	EC BM	LB IE	STAT	CC LAB	мн на	⊕ : ◄							Þ
Read	tu .		1											<b></b>	ΞШ		+ 100 %
near	.,		-	_		+											1 100.0
		one sheet for eac	ch form	Sta	andard in	fo for all t	forms								Form s	pecific in	fo (items)

### 4.2 Do not group data

If you choose not to group the data, then all data from all forms will be exported in the same sheet (**Data**) of the output file.

The example in the image below shows an export with the default settings for the Layout, that is, 1 row per activity.

In the **Data** sheet, the first columns (to the left, marked in green) are the common for all the forms and provide information about the site, subject, event and activity.

The following columns (to the right, marked in orange) contain form-specific information for all the forms within the event. For each of the forms, the following columns are added:

- <FormName>\_Design Version the form name, as set in the study design (in Viedoc Designer) and displayed in Clinic. In the example in the image, the form name is *Demographics*.
- <FormName>(<Form Repeat Key>)\_<ItemName> for each item in the respective form. The form name and item name, as set in the study design (in Viedoc Designer) and displayed in Clinic. The Form Repeat Key identifies the instance of the form (for repeating forms). For non-repeating forms, the Form Repeat Key is always 1.

A	В	С	D	E	F	G	н	1	J	К	L	M	N	0	р	Q	R	S	т	U	V	w
Site	Site nam	e Site code	Subject	Subject Id	Event	Event Id	Event	Event date	Activity Id	Activity	Demograp	Demographics(1	Demograp	Demograp	Demographics(1	Demograp	Demograp	Demograp	Demograp	Demograp	Demograp	Demo
seque	nce		sequence		sequence		name			name	hics-	)-Date/Time of	hics(1)-	hics(1)-	)-Date/Time of	hics(1)-	hics(1)-	hics(1)-	hics(1)-	hics(1)-	hics(1)-	hics(1)
numbe	er		number		number						Design	Informed	Gender	Gender -	Birth	Age	CHB	CHB	Reason	Reason	Race	Race -
											version	Consent		Code			Result	Result -	for No	for No		Code
																		Code		CHB -		
SiteSe	q SiteNam	e SiteCode	SubjectSee			EventId	EventNam	EventDate	ActivityId	ActivityNa	DesignVer	1.DMIC		1.DMSEXCE	1.DMDOB	1.DMAGE	1.DMCBP	1.DMCBPC	1.DMCBPR	1.DMCBPR	E1.DMRACE	1.DMR
1	Academi	C FAHU	1	SE-AHU-00	ū 🕇 👘	SCR	Add subje	2016-10-04	SCR	Add subje	3.0	2016-07-04	Male	1	1964-06-11	52.1 🔶					White	5
1	Academi	CFAHU	1	SE-AHU-00	1	V1	Visit 1	2016-10-04	V1													
1	Academi	CFAHU	2	SE-AHU-00	ú i	SCR	Add subje	2016-10-04	SCR	Add subje	3.0	2016-10-02	Female	2	1979-05-28	37.3	Yes	1			Asian	3
1	Academi	CEAHU	2	SE-AHU-00	ú1 -	V1	Visit 1	2016-10-04	V1													
1	Academi	CEAHU	3	SE-AHU-00	1	SCR	Add subje	2016-10-04	SCR	Add subje	3.0	2016-09-04	Male	1	1968-08-04	48.1					White	5
1	Academi	CEAHU	3	SE-AHU-00	1	V1	Visit 1	2016-10-02	V1													
1	Academi	CEAHU	4	SE-AHU-00	1	SCR	Add subje	2016-10-04	SCR	Add subje	3.0	2016-06-05	Male	1	1952-10-01	63.7					Black	1
1	Academi	CEAHU	5	SE-AHU-00	4	SCR	Add subje	2016-10-04	SCR	Add subje	3.0	2016-08-07	Female	2	1959-04-06	57.3	No	0	Postmenor	ú.	White	5
1 1	Academi	CEAHU	5	SE-AHU-00	61	V1	Visit 1	2016-10-02	V1													
2 4	Charite L	IN CUB	1	DE-CUB-00	1	SCR	Add subje	2016-10-04	SCR	Add subje	3.0	2016-08-07	Male	1	1980-02-22	36.5					White	5
3 4	Charite U	INI CUB	1	DE-CUB-00	4	V1	Visit 1	2016-10-02	V1													
1 4	Charite U	IN CUB	5	DE-CUB-00	4	SCR	Add subje	2016-10-04	SCR	Add subje	3.0	2016-03-02	Male	1	1960-11-02	55.3					White	5
5 4	Charite L		2	DE-CUB-00		V1		2016-10-04	V1													
	And Advanta		<u>x</u>	ALL 1011A OF		000		0010 10 04	000			2010 10 02		5	1001-07-01						A Reading	<b>5</b>
	READN	IE Data	Items	CodeLists	$\oplus$								E 4									Þ
					÷											÷						

standard info for all forms

form specific info (items)



In the Layout section, you can select whether the data should be organized in the output file as:

- one row per subject
- one row per activity (default)
- one row per item

Output to: Mic	rosoft Excel - Office Open XML	T	
Data grouping:	Group data by form <b>*</b>		
Layout	1 row per subject	• 1 row per activity	1 row per item
Output version:	Viedoc 4.39	•	

#### 5.1 One row per subject

The output in this case will look as shown in the below image. The example shows an export performed with all the default settings except for the **Layout** which is set to **1 row per subject**.

	В	С	D	E		F	G	н	1.1	J	K	L	М	N	0	Р	Q
															Add		
													Add	Add	subject(1)	-	
						Add			Add			Add	subject(1)-	- subject(1)-	Add		Add
						subject(1)-	Add subject(1)-	Add	subject(1)-		Add	subject(1)	Add	Add	subject-	Add	subject(1)-
						Add	Add subject-	subject(1)	Add	Add subject(1)-	subject(1)-	Add	subject-	subject-	(1)Reason	subject(1)-	Add
			Subject			subject-	(1)Date/Time of	Add	subject-	Add subject-	Add	subject-	(1)CHB	(1)Reason	for No	Add	subject-
			sequence			Design	Informed	subject-	(1)Gender	(1)Date/Time of	subject-	(1)CHB	Result -	for No	CHB -	subject-	(1)Race -
1	Site name	Site code	number	Subject Id		version	Consent	(1)Gender	- Code	Birth	(1)Age	Result	Code	CHB	Code	(1)Race	Code
2	SiteName	SiteCode	SubjectSec	SubjectId		SCR[1].SCR	SCR[1].SCR[1].DN	SCR[1].SCF	SCR[1].SCR	SCR[1].SCR[1].DI	SCR[1].SCR	SCR[1].SCF	SCR[1].SCR	SCR[1].SCR	SCR[1].SCF	SCR[1].SCR	SCR[1].SCR
3	Academic I	AHU	1	SE-AHU-001		3.0	2016-07-04	Male	1 🛉	1964-06-11	52.1					White	5
4	Academic I	FAHU	2	SE-AHU-002		3.0	2016-10-02	Female	2	1979-05-28	37.3	Yes	1			Asian	3
5	Academic I	FAHU	3	SE-AHU-003		3.0	2016-09-04	Male	1	1968-08-04	48.1					White	5
6	Academic I	AHU	4	SE-AHU-004		3.0	2016-06-05	Male	1	1952-10-01	63.7					Black	1
7	Academic I	FAHU	5	SE-AHU-005		3.0	2016-08-07	Female	2	1959-04-06	57.3	No	0	Postmeno	1	White	5
8	Charite Un	CUB	1	DE-CUB-001		3.0	2016-08-07	Male	1	1980-02-22	36.5					White	5
9	Charite Un	CUB	2	DE-CUB-002		3.0	2016-03-02	Male	1	1960-11-02	55.3					White	5
10	VU Medica	VUA	1	NL-VUA-001		3.0	2016-10-02	Male	1	1961-07-31	55.2					White	5
11	VU Medica	VUA	2	NL-VUA-002		3.0	2016-08-07	Male	1	1973-12-21	42.6					White	5
12	Academic I	AHU	6	SE-AHU-006		12.0	2016-10-02	Female	2	1976-02-01	40.7	Yes	1			White	5
	< •	README	DM	SS VS RAND	CQ PE	EC BM	LB IE S	ТАТ СС	LAB	ИН НА С.	. + :	4					
			+						1								

Form Standard info for all forms

♥ Form specific info (items)

There is one sheet for each form, as the default setting is to Group data by form.

There is one row per subject, that is, one row for each SubjectID (that uniquely identifies the subject).

The first columns provide information on the site and subject:

Column	Description
Site name	The site name, as set in Viedoc Admin.
Site code	The site code, as set in Viedoc Admin.
Subject sequence number	Counter that identifies the subject within the site.
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.

The following columns are the item-specific values, one set as described below for each item in the exported data. The order of the items is by event, as set in the study workflow.

- In case Do not group data is selected under Data grouping (see <u>Do not group data</u>):
   <Event name>(<Event Repeat Key>) <Activity name> <Form name> <Item name> <Code list value>, where:
  - <Event name> the event name, as set in the study design and displayed in Clinic.
  - <Event Repeat Key> the event repeat key, applicable <u>only for the unscheduled/common</u> events.
  - <Activity name> the activity name, as set in the study design
  - <Form name> the form name, as set in the study design and displayed in Clinic.
  - Item name> the item label, as set in the study design and displayed in Clinic.
  - <Code list value> applicable only for the checkbox items. This is the code list value set in Viedoc Designer for each choice of the respective checkbox item
- In case Group data by form was selected under *Data grouping* (see <u>Group data by form</u>), the columns are
  named similar as for the not grouped data above, without the <*Form name*>, as the form is identified by
  the sheet name.

Notel The columns Event sequence number, Event Id, Activity Id, Form sequence number, Subject form sequence number, Origin Subject form sequence number, and Source Subject form sequence number are <u>not</u> included when you have selected **1 row per subject**.

## 5.2 One row per activity

The output in this case will look as shown in the below image. The example shows an export performed with all the default settings except for the **Layout** which is set to **1 row per activity**.

There is one sheet for each form, as the default setting is to Group data by form.

The data is grouped so that, for each subject (1), there is one row for each activity (2).

	Α	В	С	D	E	F	G	Н	1	J	K	L	M	N	0
														Physical	Physical
														Examinati	Examinati
5	Site			Subject		Event						Form		on	on
9	sequence			sequence		sequence		Event			Activity	sequence	Design	performe	performe
L r	number	Site name	Site code	number	Subject Id	number	Event Id	name	Event date	Activity Id	name	number	version	d	d - Code
2 9	SiteSeq	SiteName	SiteCode	SubjectSec	SubjectId	EventSeq	EventId	EventNam	EventDate	ActivityId	ActivityNa	FormSeq	DesignVer	PEYN	PEYNCD
1	i	Academic H	AHU	11	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		1	32.0	Yes	1
1	i	Academic H	AHU	14	SE-AHU-014	1	V1	Visit 1	2017-11-10	V1		1	33.0	No	0
; 1	i	Academic H	AHU	14	SE-AHU-014	1	UNS_1	Unschedul	2017-11-13	UNS_1		1	34.0	Yes	1
1	i	Academic H	AHU	18	SE-AHU-018	1	V1	Visit 1	2017-11-14	V1		1	36.0	Yes	1
1	i	Academic H	AHU	22	SE-AHU-022	1	V1	Visit 1	2017-11-14	V1		1	39.0	Yes	1
1	i	Academic H	AHU	23	SE-AHU-023	1	V1	Visit 1	2017-10-16	V1		1	27.0	Yes	1
) 1	i	Academic H	AHU	23	SE-AHU-023	1	V3	Visit 3	2017-10-27	V4		1	33.0	Yes	1
0 1	L	Academic H	AHU	24	SE-AHU-024	1	V1	Visit 1	2017-11-01	V1 👩		1	33.0	Yes	1
1 1	L	Academic H	AHU	24	SE-AHU-024	1	V3	Visit 3	2017-11-14	V4 🧹	P	1	39.0	Yes	1
2 1	L	Academic H	AHU	32	SE-AHU-032	1	V1	Visit 1	2017-11-21	V1		1	44.0	Yes	1
3 1	i	Academic H	AHU	34	SE-AHU-034	1	V1	Visit 1	2017-11-21	V1		1	46.0	Yes	1
4 1	i	Academic H	AHU	36	SE-AHU-036	1	V1	Visit 1	2017-11-20	V1		1	44.0	Yes	1
5 1	i	Academic H	AHU	43	SE-AHU-043	1	V1	Visit 1	2018-01-01	V1		1	51.0	Yes	1
6 1	i	Academic H	AHU	44	SE-AHU-044	1	V1	Visit 1	2018-01-02	V1		1	51.0	Yes	1
7 1	i	Academic H	AHU	50	SE-AHU-050	1	V1	Visit 1	2018-01-06	V1		1	55.0	Yes	1
8 1	i	Academic H	AHU	73	SE-AHU-073	1	V1	Visit 1	2018-03-20	V1		1	57.0	Yes	1
9 1	i.	Academic H	AHU	75	SE-AHU-075	1	V1	Visit 1	2018-08-13	V1		1	59.0	Yes	1
0		README	DM	ss vs	RAND CO PE	EC BN	1   LB	IE STAT	(+) :	4					

## 5.3 One row per item

The output in this case will look as shown in the below image. The example shows an export performed with all the default settings except for the **Layout** which is set to **1 row per item**.

There is one sheet for each form, as the default setting is to Group data by form.

The data is grouped so that there is one row for each item (3) within an activity (2) for a subject (1).

	E	F	G	Н	1	J	К	L	M	N	0	P	Q	R
1	Subject Id	Event sequen	Event Id	Event name	Event date	Activity Id	Activity name	Form Id	Form name	Form sequence number	Item group Id	Item group sequ	Item Id	Item export label
2	SubjectId	EventSeq	EventId	EventName	EventDate	ActivityId	ActivityName	FormId	FormName	FormSeq	ItemGroupId	ItemGroupSeq	ItemId	ItemExportLabel
3	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	IG_10217_1	1	PEYN	Physical Examination performed
4	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	IG_10217_1	1	PEDT	Date/Time of Examination
5	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG2	1	PEHERES	HEENT - result
6	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG3	1	PESKRES	Skin - result
7	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1	-	PE	Physical Examination	1	PEG4	1	PETHRES	Thyroid - result
8	SE-AHU-011	11)	V1	Visit 1	2017-10-20	V1	2	PE	Physical Examination	1	PEG5	1 (3)	PENERES	Neurological - result
9	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG6	1	PERERES	Respiratory - result
10	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG7	1	PECARES	Cardiovascular - result
11	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG8	1	PEABRES	Abdomen - result
12	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG9	1	PELYRES	Lymph nodes - result
13	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG10	1	PEEXRES	Extremities - result
14	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG11	1	PEOTHRES	Other - result
15	SE-AHU-014	1	V1	Visit 1	2017-11-10	V1		PE	Physical Examination	1	IG_10217_1	1	PEYN	Physical Examination performed
16	SE-AHU-014	1	V1	Visit 1	2017-11-10	V1		PE	Physical Examination	1	IG_10217_1	1	PENDREA	Examination not performed reas
17	SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	IG_10217_1	1	PEYN	Physical Examination performed
18	SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	IG_10217_1	1	PEDT	Date/Time of Examination
19	SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	PEG2	1	PEHERES	HEENT - result
20	SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	PEG3	1	PESKRES	Skin - result
21	SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	PEG4	1	PETHRES	Thyroid - result
22	SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	PEG5	1	PENERES	Neurological - result
23	SE-AHU-014	6	LINS 1	Unscheduled	2017-11-13	UNS 1		PF	Physical Examination	1	PEG6	6	PERFRES	Respiratory - result
	• • …	RAND SS	DM	VS   LB   EC	CQ PI	BM	IE STAT	LAB CC	MH ExampleFor	m 🕂 🗄 🖪				•

The data is sorted by: site, subject, event date, event repeat key, form repeat key, form ID, item group ID, item ID. If the **Include history** option is selected (see following section), the data is ordered from the oldest to the current item data (that is, by the **Edit sequence number**).

#### 5.3.1 Include history

When selecting **1** row per item, the option to **Include history** becomes available. If selected, the edit history information (audit trail) will be included in the exported output (that is, the information shown in Viedoc Clinic on form level when selecting **Show history**).

The following information (columns) is added for each entry in the output file:

- Edit sequence number a counter for each change per item.
- Edit reason reason for change (initial or given reason at data edit).
- Edit by the user who performed the changes (user name and user id in parentheses).
- Edit date/time (UTC) edit date/time (Coordinated Universal Time (UTC)).

The items belonging to a reset or deleted form/event/subject are included as well in the export, together with a full history that gives the reason for resetting or deleting the form/event/subject.

#### 5.3.2 Checkboxes

Checkbox items are output as one row per code list item. All code list items are listed, regardless if they contain data or not. Each row is labeled, in the **Item Id** column, with the item Object Identifier (<u>OID</u>) and an 1-based index, as illustrated in the following image:

the OLD index

					li I	tem OID	nde	X	
Activity name	Form Id	Form name	Form sequence number	Item group Id	Item group sequen	Item Id		Item export label	Edit sequence
ActivityName	FormId	FormName	FormSeq	ItemGroupId	ItemGroupSeq	ItemId 🍦 🕴	,	ItemExportLabel	EditSeqNo
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes1		Check boxes - 1	1
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes <mark>2</mark>		Check boxes - 2	1
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes <mark>3</mark>		Check boxes - 3	1
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes <mark>4</mark>		Check boxes - 4	1
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes <mark>5</mark>		Check boxes - 5	1
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes <mark>6</mark>		Check boxes - 6	1
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes1		Check boxes - 1	2
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes2		Check boxes - 2	2
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes3		Check boxes - 3	2
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes4		Check boxes - 4	2

If the option to **Include history** is selected, then the code list items are ordered by the time of data entry (that is, by the **Edit sequence number**).



Form link items in the export output

Form link items can be organized in the Output format as:

- One row per activity (default)
- One row per item
- One row per subject

## 6.1 One row per activity

Selecting **1 row per activity** generates the output as shown in the image below. The exported file contains two columns <u>per linked form instance</u>, the Data column and the Identifier column, (the header is labelled Identifier).

In the example below:

- Each linked form instance shows its display value (as displayed in Clinic) and the Identifier.
- The medication Paracetamol in this example is linked to two different entries in the Adverse Event log.
- The format for the identifier: EventId-EventSeq-ActivtyId-FormId-FormSeq.

	Reason for		Adverse event link 1 -		Adverse event link 2 -
Name of drug / medication / therapy	administration	Adverse event link 1	Identifier	Adverse event link 2	Identifier
CMTRT	CMINDC	CM31	CM31CD	CM32	CM32CD
Paracetamol	Adverse event	1 - Headache - 14 Mar 2022	COMMON_AE-1-LOG_AE-AE-1	2 - Migraine - 13 Mar 2022	COMMON_AE-2-LOG_AE-AE-1

There are also two header rows in the output:

Header rows, one row per activity	
Row 1: Data column	Item Label, Counter of the selected link starting at one
Row 1: Identifier column	Item Label, Counter of the selected link starting at one, Identifier
Row 2: Data column	Item ID, Counter of the selected link starting at one
Row 2: Identifier column	Item ID, Counter of the selected link starting at one, ID

## 6.2 One row per item

Selecting **1 row per item** generates the output as shown in the image below. The exported file contains two additional columns with the headers Item value and Item code, and <u>one row per linked form instance.</u>

Item value	Item code
ItemValue	ItemCode
3	
Alvedon	
Adverse event	2
16 Dec 2021 - Headache	COMMON_AE-1-LOG_AE-AE-1
250	
Milligram	2
Capsule	2
Twice daily	2
Oral	1
2021-12-16	
01:20	
No	Ō
2021-12-16	
01:25	
4	
Alvedon	
Adverse event	2
16 Dec 2021 - Headache	COMMON_AE-1-LOG_AE-AE-1
500	
Milligram	2
Tablet	1
Once daily	1
Oral	1
2021-12-16	
09:00	
No	o
2021-12-16	
End time not available	99

Note! In the export preview the form identifier column is excluded by default. The order the form link item was added (time of data entry) is followed in the export.

## 6.3 One row per subject

Selecting **1 row per subject** generates the output as shown in the image below. The exported file adds two columns <u>per linked form instance</u> to the exported file, the Data column and the Identifier column:

Prior and Concomitant Medications(1)-	Prior and Concomitant Medications(1)-
(1)Medical history link(s) 1	(1)Medical history link(s) 1 - Identifier
COMMON_CM[1].LOG_CM[1].CM41	COMMON_CM[1].LOG_CM[1].CM41ID
Headache - 07 Jan 2022	COMMON_MH-1-LOG_MH-MH-1

There are also two header rows in the output:

Header rows, one row per subject	
Row 1: Data column	Event Label (event counter), Activity label (activity counter), Item label (counter of the selected link.)
Row 1: Identifier column	Event Label (event counter), Activity label (activity counter), Item label (counter of the selected link), Identifier
Row 2: Data column	Event ID (event counter), Activity ID (activity counter), Item ID (counter of the selected link.)
Row 2: Identifier column	Event ID (event counter), Activity ID (activity counter), Item ID, (counter of the selected link), ID

# 7 Recurring events in the export output

Recurring events are identified in the export output by the StudyEventRepeatKey .

The image illustrates the form *Vital Signs* in the Excel export output. The form is used in three events (Visit 1, Visit 2 and Visit 3), of which Visit 3 is a recurring event. The four instances of Visit 3 are identified by the StudyEventRepeatKey that is listed in the **Event sequence number (EventSeq)** column:

A h	В	С	D	E	F	G	н	1	J	K	L	M	N	0	P	Q	R	S	Т	U
								1												
Site			Subject		Event						Form			Vital Signs		Not		Body		
sequenc	2		sequence		sequence						sequence		Vital Signs	done? -		measured		temperat	Systolic	Diastolic
number	Site name	Site code	number	Subject Id	number	Event Id	Event name	Event date	Activity Id	Activity name	number	Design version	done?	Code	Date/Time	reason	Heart rate	ure	BP	BP
SiteSeq	SiteName	SiteCode	SubjectSeq	SubjectId	EventSeq	EventId	EventName	EventDate	ActivityId	ActivityName	FormSeq	DesignVersion	VS_YN	VS_YNCD	VS_DATE	VS_NDrea	VS_HR	VS_TEMP	VS_SYS	VS_DIA
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	1	V1	Visit 1	2018-01-01	V1		1	55.0	Yes	1	2018-01-01 00:00		61	37.0	120	65
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	1	V2	Visit 2	2018-01-05	V2		1	55.0	Yes	1	2018-01-05 00:00		62	37.1	125	70
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	1	V3	Visit 3	2018-01-06	ACT_2		1	55.0	Yes	1	2018-01-06 00:00		62	37.2	130	65
i 1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	2	V3	Visit 3	2018-01-07	ACT_2		1	55.0	Yes	1	2018-01-07 00:00		64	37.4	125	70
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	3	V3	Visit 3	2018-01-08	ACT_2		1	55.0	Yes	1	2018-01-08 00:00		65	37.5	125	75
: 1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	4	V3	Visit 3	2018-01-09	ACT_2		1	55.0	Yes	1	2018-01-09 00:00		66	37.6	125	70
0		much Mite.				de de						مم معين								سينس خ
	and a second										and the second second	Charles and Charles	100	- Jane 1	and the second second			and the second sec	and the same	-
· · · ·																				
1																				
2																				
	README DM SS	/s co	PE FC F		STAT	RAND	CC LAB	мн на с	MAE	Items CodeLis	sts (+)									

Notel Support for recurring events has been added in Viedoc release 4.39. That means that if you would like to export recurring events, you should select Viedoc version 4.39 or later in the **Output version** dropdown menu under **Output format**.

# 8 Repeating forms in the export output

Repeating forms are identified in the export output by the FormRepeatKey .

The image illustrates the repeating form *Lab* in the export to Excel. The instances of the form are identified by the FormRepeatKey that is listed in the Form sequence number (FormSeq) column:

A	В	С	D	E	F	G	H	1 I	J	к	L	м	N	0	Р	Q	R	
Site			Subject		Event						Form							
sequence			sequence		sequence						sequence		Collection Date and		Low	High		
number	Site name	Site code	number	Subject Id	number	Event Id	Event name	Event date	Activity Id	Activity name	number	Design version	Time	Result	Normal	Normal		
	SiteName	SiteCode	SubjectSeq	SubjectId	EventSeq	EventId	EventName	EventDate	ActivityId	ActivityName	FormSeq	DesignVersion	LAB_DATE	LAB_WBC	LAB_WBC	LAB_WBC	LAB_NEUT	LAE
1	Academic Hospital Uppsala	AHU	44	SE-AHU-044	1	V2	Visit 2	2018-01-08	V2		1	51.0	2018-01-08 00:00	4589	4000	8000	1235	110
1	Academic Hospital Uppsala	AHU	44	SE-AHU-044	1	V2	Visit 2	2018-01-08	V2		2	51.0	2018-01-09 13:26	6987	5500	11000	3569	120
1	Academic Hospital Uppsala	AHU	44	SE-AHU-044	1	V2	Visit 2	2018-01-08	V2		3	51.0	2018-01-08 00:00	5877	5500	11000	1658	120
	and an and a second	in territ	the second		-		un fra	e Ca		-		~~				a man		h.,
p/																		
1																		
$\leftarrow \rightarrow$	README   IE   CQ   V	S EC	STAT MH	LAB Iter	ns Code	Lists	+						4					

Notel Support for repeating forms has been added in Viedoc release 4.39. That means that if you would like to export repeating forms, you should select Viedoc version 4.39 or later in the **Output version** dropdown menu under **Output format**.

9

The following form sequence numbers are used to make it easier to track different form instances at subject level, which are useful especially for the form instances initiated by copying the data from previous event.

- FormRepeatKey Counter that identifies the specific instance of a repeating form within a specific activity. This is available in the export output for Viedoc output version 4.39 and onwards.
- SubjectFormSeqNo Counter that uniquely identifies the instance of a specific form on a subject level, that is, it starts with 1 and it is incremented each time a new instance of the form is created for that subject. This is available in the export output for Viedoc output version 4.51 and onwards.
- OriginSubjectFormSeqNo For a copied form instance, it identifies the form instance from which data
  was copied for the first time. For the first instance of the form (that is, not copied) it gets the value of the
  SubjectFormSeqNo. This is available in the export output for Viedoc output version 4.51 and onwards.
- SourceSubjectFormSeqNo For a copied form instance, a counter that identifies the source of a copied form instance (the form instance the data was copied from). It gets the value of the SubjectFormSeqNo from which the form instance was copied. For the first instance of the form (that is, not copied) it is empty, that is, null. This is available in the export output for Viedoc output version 4.51 and onwards.

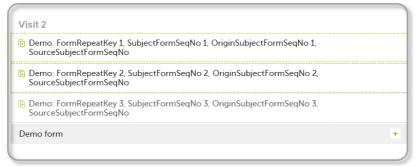
The example below illustrates how the values for these sequence numbers are assigned. The demo form used is set as repeatable and copyable and is included in Visit 1, Visit 2 and Visit 3.

We perform the following actions in Viedoc Clinic:

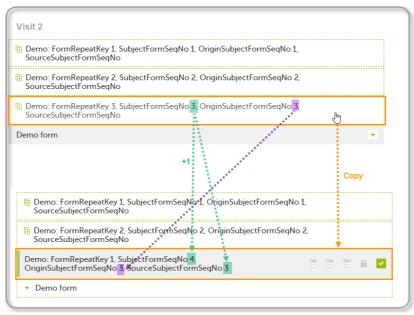
1 Initiate Visit 1 and fill-in three instances of the Demo form, these instances will get the sequence numbers as illustrated below:

Visit 1					
Demo: FormRepeatKey 1, SubjectFormSeqNo 1, OriginSubjectFormSeqNo 1, SourceSubjectFormSeqNo	DM	CRA	SDV		
Demo: FormRepeatKey 2, SubjectFormSeqNo 2, OriginSubjectFormSeqNo 2, SourceSubjectFormSeqNo	DM	CRA	SDV	6	
Demo: FormRepeatKey 3, SubjectFormSeqNo 3, OriginSubjectFormSeqNo 3, SourceSubjectFormSeqNo	DM	CRA	SDV	6	
+ Demo form					

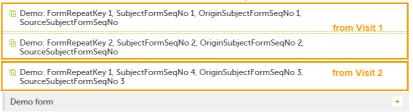
2 Initiate Visit 2. Demo form will be available to be initiated by copying data from one of the previously filled-in form instances within Visit 1, so all the three instances will be shown as ghost forms:



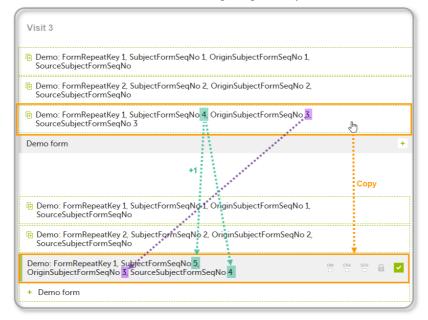
Create an instance of Demo form within Visit 2 by copying the data from the third instance of the form filled in within Visit 1. This will result in the new form instance getting the sequence numbers as illustrated below:



Initiate Visit 3. Demo form will be available to be initiated by copying data from one of the previously filled-in form instances within Visit 1 and Visit 2, as below:



5 Create an instance of Demo form within Visit 3 by copying the data from the form filled in within Visit 2. This will result in the new form instance getting the sequence numbers as illustrated below:



These sequence numbers are available to be used within expressions only to get the value of the sequence number for a specific form instance, that is, by using {SubjectFormSeqNo}, {OriginFormSeqNo}, {SourceFormSeqNo}.

In the above example, the form Summary format was configured by using these sequence numbers as below:

Form Repeat Key {FormRepeatKey}, SubjectFormSeqNo {SubjectFormSeqNo}, OriginFormSeqNo {OriginFormSeqNo}, SourceFormSeqNo {SourceFormSeqNo}

4

- Only the FormRepeatKey is used to identify a specific instance of the form in data mapping for data import, as well as in the item identifier used in JavaScript (for example *EventID.FormID*\$ActivityID[FormRepeatKey].ItemID).
- When resetting a form, the sequence numbers are still allocated to it, and the next available ones are used for the new instances.

In the excel export output, these form sequence numbers allows to track, for the form instances that were initiated by copying data from previous events, where the data originates from, as below:

		Origin	Source	
	Subject	Subject	Subject	
Form	form	form	form	
sequence	sequence	sequence	sequence	Design
number	number	number	number	version
FormSeq	SubjectFor	OriginSubj	SourceSubj	DesignVers
1	1	1		2.1
2	2	2		2.1
3	3	3		2.1
1	4	3	> 3	2.1
1	5	3	►4	2.1

Analyzing the values of the form sequence numbers, only the form instances that were initiated by copying the data from previous visits have values populated in the *Source Subject form sequence number* column, that is, the last two rows in the example. The data was copied from the form instance having the same *Subject form sequence number* value, highlighted in green in the above image. The form instance that the data was copied for the first time is identified by the value of the *Origin Subject form sequence number*, that is, "3" in our example.



PDF export output

# PDF export output

Published by Viedoc System 2022-02-10

 1. Introduction

 2. Output file(s)

 3. PDF file structure/content

 3.1 First page

 3.2 Site summary page

 3.3 Subject summary page

 3.4 Event summary page

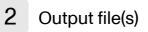
3.4.1 The sort order of the forms

## Introduction

When choosing PDF as output format, you have the following options:

- Exclude deleted subjects / events / forms if checked, the deleted subjects, events and forms will be excluded from the PDF export.
- Create PDF/A compliant archive if checked, the PDF export output will be in a Portable Document Format Archive (PDF/A) compliant format. The PDF/A is a standardized format specialized for long-term preservation of electronic documents.
- Embed complete fonts (no subsets) if checked, this will force embedding the complete fonts (not only subsets) into an archive and all the font subsets embedded in the PDF file will be replaced with fully embedded fonts.
- Note! Please note that this will lead to significantly larger file sizes.
- FDA submission format (eCTD) if checked, the PDF export output will be structured according to the
  electronic Common Technical Document (eCTD) format specified by the Food and Drug Administration
  (FDA). The eCTD format provides a structure where the Case Report Forms (CREs) are listed twice,
  ordered by event/workflow and ordered by domain.
- Notel For non-production data, the number of subjects in the PDF archive are limited to improve
  performance. The most recently added subjects are included according to the date the subject card was
  created.

An information message is displayed: For this mode the PDF Archive is limited to a sample of [X] subjects.



One .zip file is downloaded for each PDF export performed.

 One separate PDF file is generated for each site and all the PDFs are archived in a .zip file. The PDF file names reflect the site code and site name, as set in Viedoc Admin, under site settings.

This PC > Downloads > _20180903_094044	
Name	~ Туре
违 AHU Academic Hospital Uppsala	Adobe Acrobat Document
🔁 CUB Charite University Hospital Berlin	Adobe Acrobat Document
🗾 HUH Helsinki University Hospital	Adobe Acrobat Document
🔁 IMU Innsbruck Medical University	Adobe Acrobat Document
🗾 KCH King's College Hospital London	Adobe Acrobat Document
🗾 KIS Karolinska Institute Stockholm	Adobe Acrobat Document
🗾 UBR University of Brescia	Adobe Acrobat Document
🗾 UCH University College Hospital London	Adobe Acrobat Document
🔁 UMF University Medical Center Freiburg	Adobe Acrobat Document
违 UMG University Medical Center Groningen	Adobe Acrobat Document
🗾 VUA VU Medical Center Amsterdam	Adobe Acrobat Document

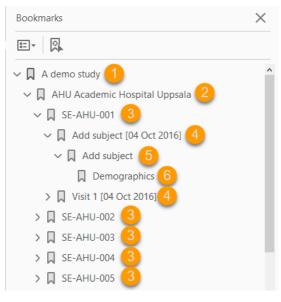
• For the FDA submission format (eCTD), there is one folder for each site, and each folder contains one separate PDF file for each subject (file name is the same as the subject ID):

Name	Туре	Compressed size
Name	Type	Compressed size
🟃 SE-AHU-001	Adobe Acrobat Document	98 KE
🟃 SE-AHU-002	Adobe Acrobat Document	100 KE
🟃 SE-AHU-003	Adobe Acrobat Document	98 KB
🟃 SE-AHU-004	Adobe Acrobat Document	86 KE
🟃 SE-AHU-005	Adobe Acrobat Document	100 KE
🟃 SE-AHU-006	Adobe Acrobat Document	115 KB
🟃 SE-AHU-007	Adobe Acrobat Document	97 KE
🟃 SE-AHU-008	Adobe Acrobat Document	100 KE
🟃 SE-AHU-009	Adobe Acrobat Document	85 KE
🟃 SE-AHU-010	Adobe Acrobat Document	108 KE
🟃 SE-AHU-011	Adobe Acrobat Document	198 KE
🟃 SE-AHU-012	Adobe Acrobat Document	84 KB
🟃 SE-AHU-013	Adobe Acrobat Document	112 KB

# PDF file structure/content

3

This section describes the structure of the exported PDF file.



The file is structured as follows:

1. A study summary on the <u>first page</u>.

2. A site summary page.

3. One separate sub-section for each <u>subject</u> in the respective site.

- 4. For each subject, one sub-section for each event.
- 5. For each event, one sub-section for each activity.

6. For each activity, one sub-section for each form. The latest version of the form PDFs are included here. See also **Audit trail and Form History** section in <u>Entering/editing data</u>.

The meaning of the signature in Viedoc is included on the last page.

Note! If the number of forms for a site exceeds 1000, the system splits the archive into one PDF file per subject and stores them in a zip file.

#### 3.1 First page

The first page provides a short summary, as illustrated in the image and explained below:



- 1. The study logo image, if any, as set in Viedoc Admin, under Study Settings.
- 2. Study name, as set in Viedoc Admin, under Study Settings.
- 3. Study description, as set in Viedoc Designer.
- 4. The dates for:
  - First Patient Added (FPA) in the study
  - Last Patient Added (LPA) in the study
- 5. The number of sites:
  - In this archive the number of sites selected to be included in the export.
  - Study total the total number of sites in the study.
- 6. The number of subjects:
  - In this archive the number of subjects selected to be included in the export.
  - Study total the total number of subjects in the study.

## 3.2 Site summary page

The site summary page provides a summary of the site, as illustrated in the image and explained below:



	Site code	Country	_
3	AHU	Sweden	4
_	Time zone		_
5	(UTC+01:00) Amsterdam, Berlin, Bern, Rome	, Stockholm, Vienna	
-	FPA	LPA	
6	04 Oct 2016	27 Aug 2018	7
~		5	-
8	Subjects (in this archive/total)		
•	71/71		

1. The study name, as set in Viedoc Admin.

- 2. The site name, as set in Viedoc Admin.
- 3. The site code, as set in Viedoc Admin.
- 4. The country for the respective site, as set in Viedoc Admin.
- 5. The site time zone, as set in Viedoc Admin.
- 6. Date of First Patient Added (FPA) to the site, in the site timezone.
- 7. Date of Last Patient Added (LPA) to the site, in the site timezone.

8. Number of subjects from the site included in the export / total number of subjects in the site (this number will exclude deleted subjects if *Exclude deleted subjects/events/forms* is checked).

Following the site summary page, comes a Contents list of the subjects included in the export for the respective site, with the Subject ID and corresponding pages. After that, comes one sub-section for each subject, described in the next topic.

## 3.3 Subject summary page

The subject summary page provides the following information:

A demo study / Academic Hospital Uppsala		
Subject added 17 Nov 2017 11:11 CET	Forms (in this archive/total) 23/24	
5 Contents		
Add subject [17 Nov 2017]		5 - 6
Visit 1 [16 Oct 2017]	Initiated	7 - 19
Visit 2 [23 Oct 2017]	Initiated	20 - 28
Visit 3	Initiated	29 - 39

1. The study name and site name, as set in Viedoc Admin.

2. Subject ID in the format set in Viedoc Designer.

3. The date and time the subject was added.

4. The number of Forms filled in / the total number of forms for that subject.

5. A table of **Contents** with a list of all the events that contain data for the respective subject, the event status and the page numbers where the data related to the respective event can be found.

#### 3.4 Event summary page

The event summary page provides the following information:

A demo study / Academic Hospital Uppsala 1 SE-AHU-023 / Visit 1 [16 Oct 2017] 2				
Contents 3 4 Visit 1 [16 Oct 2017]	5 Awaits signing	6		
Check Questions	Awaits signing	9		
Physical Examination	Awaits signing	10 - 11		
Vital Signs	Awaits signing	12		
12-Lead ECG	Awaits signing	13		
Body measurements	Awaits signing	14		
Safety Laboratory Parameters	Awaits signing	15		
Eligibility	Awaits signing	16		
Visit status	Awaits signing	17		
Clinical chemistry	Awaits signing	18 - 19		

1. The study name and site name, as set in Viedoc Admin.

2. Subject ID in the format set in Viedoc Designer and the event name together with the date when it was initiated.

3. A table of **Contents** with a list of all the forms within the respective event for Scheduled and Unscheduled events, providing the following information:

- Form name (4)
- Status (5) one of the following, depending on if the form was signed by the site:
  - Awaits signing
  - Signed, followed by the name of the user who has signed and the timestamp (in site timezone).

Page numbers (6) where the respective form can be found.

For Common Events, each entry will have its own Event summary page.

For each form, the form PDF is included, in the same format as for the form history pdf file. For details, see Form history PDF in Entering/editing data.

3.4.1 The sort order of the forms

The forms in the PDF are sorted by these characteristics:

- 1. Subject key, in ascending order
- 2. Event type (scheduled, unscheduled, common)
- 3. Date the date of the first form save of the activity
- 4. The order of the forms according to the study design

The following example illustrates the sort order.

Suppose the study design looks like this:

Ď	New Study Design [7.0]	Close
_	dy workflow y Start Scheduled Events Common Events	Show time OFF 📮 Print
1	E01:E01         # E01_A01:         Form A         Ø X         Form B         Ø X	T N
2	E02_A01:       Image: E02_A02       Image: E02_A03:       Image: E	

For the event E01, all forms belong to the same activity. This means that the order of the forms in the PDF will always be like this:

- Form A
- Form B
- Form C

For the event E02, there are three activities. This means that if any form from A02 gets saved first, then any form from A01 gets saved second, and then any form from A03 gets saved third, the order of the forms will be:

1. All forms from A02 according to the design

- 2. All forms from A01 according to the design
- 3. All forms from A03 according to the design

In other words, the order of forms for event E02 for this specific example will be like this:

- Form C
- Form D
- Form A
- Form B
- Form E



Queries in Excel export

# Queries in Excel export

Published by Viedoc System 2020-06-04

The Queries can be exported to the following export output formats:

- Microsoft Excel Office Open Extensible Markup Language (XML)
- Comma-separated values (CSV)
- Operational Data Model (ODM)

To include the query information in the exported file, you need to select **Queries** under **Type of data** in the Data export page. When selecting to include **Queries**, the **Query history** option becomes available.

Data Export All sites Sweden		
Subjects to include ( 21 ) All subjects		+
Events and time period All events		
Forms and items		+
Type of data Signed data () Not Signed data () SDV perfor	med or NA 🕘 SDV pending 🕘 Queries 🕘 Query history 🕲	
✓ Signed data	✓ Not Signed data	
SDV performed or NA	SDV pending	
In addition to data, also include the following in Queries Review status Event dates Uploaded files	the export (will not be included in Preview data)          Image: Output data         Imag	

Depending on if the **Query history** is included in the export or not, the information in the export output file is grouped as follows:

- Without **Query history** there is one row for each query, providing information on the current state of the query.
- With Query history there is one row for each change in a query state, that is, there can be many rows for one and the same query.

In the Excel export output, considering as an example the default settings under Output format:

- Output to Excel
- Group data by form
- 1 row per activity

...the query information is grouped in a separate sheet of the excel file, called Queries.

The columns provide information on the item that the query was raised on, followed by the query specific information, as illustrated in the image (the image shows the query-specific information only) and listed in the following table:

4	R	S	Т	U	V	W	Х
	Query item sequence number	Raised on	Query type	Range check OID	Query text	Query state	Query resolution
	QueryItemSeqNo	RaisedOn	QueryType	RangeCheckOID	QueryText	QueryState	QueryResolution
)2	1	Item	Validation	RC_DMAGE_1_0_1	Age is not within the expected range (19-65), defined per	Query Raised	
03	1	Item	Validation	RC_DMAGE_1_0_1	Age is not within the expected range (19-65), defined per	Query Closed	Closed due to data edit
4	2	Event date	Manual		Visit date is not within the protocol visit window	Query Raised	
05	1	Item	Validation	RC_VSSYS_0_0_1	Value is outside of normal range. Please verify.	Query Raised	
06	1	Item	Validation	RC_VSSYS_0_0_1	Value is outside of normal range. Please verify.	Query Resolved	Correct
07	1	Item	Validation	RC_VSPULSE_0_0_1	Value is outside of normal range. Please verify.	Query Raised	
08	1	Item	Validation	RC_VSPULSE_0_0_1	Value is outside of normal range. Please verify.	Query Resolved	Correct
09	1	Item	Validation	RC_VSSYS_0_0_1	Value is outside of normal range. Please verify.	Query Raised	
0	1	Item	Validation	RC_VSSYS_0_0_1	Value is outside of normal range. Please verify.	Query Resolved	Correct
11	1	Item	Validation	RC_VSPULSE_0_0_1	Value is outside of normal range. Please verify.	Query Raised	
12	1	Item	Validation	RC_VSPULSE_0_0_1	Value is outside of normal range. Please verify.	Query Resolved	Correct
3	1	Item	Validation	RC_VSSYS_0_0_1	Value is outside of normal range. Please verify.	Query Raised	
14	1	Item	Validation	RC_VSPULSE_0_0_1	Value is outside of normal range. Please verify.	Query Raised	
15	1	Item	Validation	RC_VSPULSE_0_0_1	Value is outside of normal range. Please verify.	Query Raised	
16	1	Event date	Validation		Visit date is not within the protocol visit window	Query Raised	
17	1	Event date	Validation		Visit date is not within the protocol visit window	Query Raised	
18	1	Item	Manual		Is data correct?	Query Raised	
9	1	Item	Manual		Is data correct?	Query Resolved	Data correct
20	1	Item	Validation	RC_VSPULSE_0_0_1	Value is outside of normal range. Please verify.	Query Raised	
-		 I HA (	CM AE ExampleForm	Items CodeLists	Queries + i (	<u> </u>	

Column name	Description				
Query study sequence number	Counter that identifies the query globally within the whole study. This field is empty for the <i>Unconfirmed missing data</i> .				
	Columns that identify the item				
Site sequence number	Counter that identifies the site globally within the study.				
Site name	The site name, as set in Viedoc Admin.				
Site code	The site code, as set in Viedoc Admin.				
Subject sequence number	Counter that identifies the subject within the site.				
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.				
Event sequence number	Counter that identifies the event within the sequence of events for the same subject.				
Event Id	The event ID, as set in the study design (in Viedoc Designer).				
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.				
Event date	The event date, as set in Viedoc Clinic when the event is initiated.				
Activity Id	The activity ID, as set in the study design (in Viedoc Designer).				
Activity name	The activity name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.				
Form Id	The form ID, as set in the study design (in Viedoc Designer).				
Form name	The form name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.				
Form sequence number	Counter that identifies the instance of the respective form within the respective activity. This is used for the repeating forms. For non-repeating forms, this is always "1".				
ltem Id	The item ID, as set in the study design (in Viedoc Designer).				

Column name	Description						
Item Name	The item name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.						
	Query specific information						
Query item sequence number	Counter that identifies the query within a sequence of queries for the same item.						
Raised on	Specifies if the query was raised on an item or on the event date: <ul> <li>Item</li> <li>Event date</li> </ul>						
Query type	<ul> <li>Specifies the query type, depending on how it was raised:</li> <li>Validation - for automatically raised queries, as a result of validation.</li> <li>Manual - for manually raised queries.</li> <li>Unconfirmed missing data</li> </ul>						
Range check OID	Only for automatically raised item queries (i.e. <b>Query type</b> = <i>Validation</i> and <b>Raised on</b> = <i>Item</i> ). The unique Object Identifier (OID) of the edit check that generated the query, as set in Viedoc Designer.						
Query text	The text of the query.						
Query state	Can be one of the following (see also <u>Query overview</u> ): <ul> <li>Query Raised</li> <li>Query Resolved</li> <li>Query Approved</li> <li>Query Rejected</li> <li>Query Closed</li> <li>Query Removed</li> </ul> Notel The queries that were automatically closed due to form reset/delete (with status Query Closed) are not included in the export.						
Query resolution	The resolution text entered when resolving (answering) the query. Not applicable for those changes performed by the system (i.e. <b>User name</b> = <i>System (0)</i> )						
User name	The name of the user who performed the changes, followed by the user ID in parentheses. Note! For those changes performed by the system (such as validation queries, that are automatically raised by the system) the <b>User name</b> = <i>System (0).</i>						
Date & time (UTC)	The date and time when the change was performed.						



Medical coding in Excel export

# Medical coding in Excel export

Published by Viedoc System 2024-03-19

 1. Introduction

 2. Medical coding information in Excel

 3. An example - WHODrug in Excel exported file

 3.1 When selecting Drug

 3.2 When selecting Preferred name

# 1 Introduction

This lesson describes how the medical coding information is structured within an Excel file exported from Viedoc.

To include the medical coding information in the exported file, you need to select **Medical coding** under **Type of data** in the Data Export page:

<ul> <li>Signed data</li> <li>SDV performed or NA</li> <li>SDV pending</li> <li>In addition to data, also include the following in the export (will not be included in Preview data)</li> <li>Queries</li> </ul>	Type of data       Signed data       Not Signed data       SDV performance	ormed or NA 🛞 SDV pending 🛞 Medical coding 🛞
In addition to data, also include the following in the export (will not be included in Preview data)	Signed data	✓ Not Signed data
	SDV performed or NA	SDV pending
Review status     Medical coding       Event dates     Edit status       Uploaded files	Queries	

For general details about data export, see Exporting data.

# 2 Medical coding information in Excel

For medical coding, in the Excel export output file, there is one sheet for each dictionary. Only values that have been coded will be present in the export:

Form Id	Form name	Form sequence number	Item Id	Item name	Term	Dictionary instance	Coding scope description	Coding scope leve
FormId	FormName	FormSeq	ItemId	ItemName	Term	DictInstance	CodingScopeDesc	CodingScopeLevel
CM	Prior and Concomitant Medications	1	CMDRUG	Drug	Paracetamol	WHODrug, Version 180829	Concomitant medication	Item
CM	Prior and Concomitant Medications	1	CMDRUG	Drug	Paracetamol	WHODrug, Version 180829	Concomitant medication	Item
СМ	Prior and Concomitant Medications	1	CMDRUG	Drug	Paracetamol	WHODrug, Version 180829	Concomitant medication	Item
CM	Prior and Concomitant Medications	1	CMDRUG	Drug	Cinnarizine	WHODrug, Version 180829	Concomitant medication	Item
СМ	Prior and Concomitant Medications	1	CMDRUG	Drug	Cinnarizine	WHODrug, Version 180829	Concomitant medication	Item
CM	Prior and Concomitant Medications	1	CMDRUG	Drug	Montelukast	WHODrug, Version 180829	Concomitant medication	Item
СМ	Prior and Concomitant Medications	1	CMDRUG	Drug	Humalog insulin	WHODrug, Version 180829	Concomitant medication	Item
CM	Prior and Concomitant Medications	1	CMDRUG	Drug	Paracetamol	WHODrug, Version 180829	Concomitant medication	Item
СМ	Prior and Concomitant Medications	1	CMDRUG	Drug	Aspirin	WHODrug, Version 180829	Concomitant medication	Item
<b>↓</b> ) .	HA   CM   AE   ExampleForr	n Items CodeLists	MedDRA	WHOD	ug (+)	•		•

The columns provide information on the item that was coded, followed by the medical coding specific information, as listed in the following table:

Column name	Description							
Columns that identify the item								
Site sequence number	A counter that identifies the site globally within the study							
Site name	The site name, as set in Viedoc Admin							
Site code	The site code, as set in Viedoc Admin							
Subject sequence number	A counter that identifies the subject within the site							
Subject IdThe Subject ID, in the format configured in Viedoc Designer. The Subj subject identifier displayed in Viedoc Clinic on the subject card, subje page, and so on.								
Event sequence number	A counter that identifies the event within the sequence of events for the same subject							
Event Id	The event ID, as set in the study design (in Viedoc Designer)							
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic							
Event date	The event date, as set in Viedoc Clinic when the event is initiated							
Activity Id	The activity ID, as set in the study design (in Viedoc Designer)							
Activity name	The activity name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic							
Form Id	The form ID, as set in the study design (in Viedoc Designer)							
Form name	The form name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic							
Form sequence number	Counter that identifies the instance of the respective form within the respective activity. This is mostly used for repeating forms.							
	For non-repeating forms, this is <b>1</b> . If a form is reset and then saved again the new form has sequence number <b>2</b> , and so on.							
	Form sequence number increases one step every time reset/initiate occurs.							
Item Id	The item ID, as set in the study design (in Viedoc Designer)							
Item Name	The item name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic							

Column name	Description							
Subject form sequence number	Counter that uniquely identifies the instance of a specific form on a subject level, that is, it starts with 1 and it is incremented each time a new instance of the form is created for that subject.							
Origin Subject form sequence number	For a copied form instance, it identifies the form instance from which data was copied for the first time. For the first instance of the form (that is, not copied) it gets the value of the SubjectFormSeqNo .							
Source Subject form sequence number	For a copied form instance, a c instance (the form instance the SubjectFormSeqNo from wh instance of the form (not copie	e data was copied from). It ich the form instance was	gets the value of the					
	Medical coding-specific	information						
Term The coded term								
Dictionary instance	The description of the dictionary instance, as set in Viedoc Admin when uploading the dictionary							
Coding scope description	g scope description The coding scope description, as defined in Viedoc Designer							
Coding scope level	The coding scope level, as defined in Viedoc Designer, can be one of the following: Event Activity Form Item group Item							
Code sequence number	A counter that identifies the code for those values with more than one code							
Approved by user	The name and ID of the user who approved the items							
Approved on date (UTC)	The date and time (UTC) when	the item was approved						
	Dictionary-specific inf	ormation						
WHODrug: DrugCode DrugName NameSpecifier OldForm Ingredients ATCCodes CountryCode CountryName MAH (MAH) PharmForm Strength MedProdId Generic	MedDRA: • soc_code • soc_name • soc_abbrev • hlgt_code • hlgt_name • hlt_code • hlt_name • pt_code • pt_name • pt_soc_code	ATC without DDD: L1code L1name L2code L2name L3code L3name L4code L4name	IDF: ・ L1薬剤 コード ・ L1薬剤 名 ・ L1薬剤 名カナ ・ L2薬剤 コード ・ L2薬剤 名 ・ L2薬剤 名 ・ L2薬剤 名 ・ L2薬剤 コード ・ L3薬剤 コード					
Interpretation	The medical coder's interpreto	ition of the applied coding	value					
Coded by user	The name of the user who perf parentheses	ormed the coding, followe	d by the user ID in					

Column name	Description					
Version	The dictionary version					
Dictionary-specific information						

WHODrug:	MedDRA:	ATC without DDD:	IDF:
• PreferredCode	• Ilt_code	- L5Code	・ L3名は3名はコレスの
• PreferredName	• Ilt_currency	- L5Name	薬 薬 か 薬 一薬 薬 か 薬 一 一 か 使 1 使 2 超 コ メ コ イ ・ 1 とう こう

Column name	Description	
		<ul> <li>L6メー カーコー ド</li> <li>L6メー カーの略 称</li> <li>L6剤形 コード</li> <li>L6薬剤 コード区 分1</li> <li>L6メン テ年月</li> </ul>

# 3 An example - WHODrug in Excel exported file

This section illustrates an example of how the data coded using the World Health Organization Drug Dictionary (<u>WHO DD</u>) dictionary looks in the Excel export output.

There are two different use cases, depending on the which level of granularity is selected when applying the code in Viedoc Clinic:

#### 1. Drug (default)

#### 2. Preferred name

Find	and apply code				
WHO	Drug				
Search options					
code	ine	9			
Pref	12818602001 Acetylsalicylic acid;Caffeine;Codeine phosphate	2			
Drug	12818602012 A. c. with codeine	<b>0</b> 1			

## 3.1 When selecting Drug

The image below illustrates how the coded data looks in the export output, if the **Drug** is selected when applying the code in Viedoc Clinic.

When **Drug** is selected, the **Preferred code** and **Preferred name** come out in the export as well, in the last columns, as illustrated in the image.

# Find and apply code WHODrug Search options codeine Pref 12818602001 Acetylsalicylic acid;Caffeine;Codeine phosphate Drug 12818602012 A. c. with codeine Spec INGR Acetylsalicylic acid;Caffeine;Codeine phosphate #

Applied code in Excel export output

_		W	X	Y		Z			AA
2	DrugCode	DrugName	NameSpecifier	OldForm	Ingredients			ATCCode	25
	DrugCode	DrugName	NameSpecifier	OldForm	Ingredients			ATCCode	25
3	12818602012	A. c. with codeine		N	Acetylsalicylic acid;0	affeine;Codeir	ne phosphate	N02AJ O	pioids in combination with non-opioid analgesics
4									
5									
5									
7									
3									
•									
0									
1									
	< >   F	README   PI   LA	B PainLevel	LABR	Items CodeLists	WHODrug	(+)		:
								AM	AN
								red Code	Preferred Name
								redCode	PreferredName
							128180	502001	Acetylsalicylic acid;Caffeine;Codeine phosphate

## 3.2 When selecting Preferred name

The image below illustrates how the coded data looks in the export output, if the **Preferred name** is selected when applying the code in Viedoc Clinic.

After the **Preferred name** is selected and the code is applied, for the respective coded item, the value of the **Preferred name** ends up in both **Drug** and **Pref** fields, in both Viedoc Clinic, as well as in the exported output.

Find a	and apply code						
WHOD	)rug						
Searcl	Search options 🔻						
codei	ne 🔎						
Pref	12818602001 Acetylsalicylic acid;Caffeine;Codeine phosphate						
Drug	12818602012 A. c. with codeine						
Spec							
INGR	Acetylsalicylic acid;Caffeine;Codeine phosphate						
ATC	N02AJ Opioids in combination with non-opioid analgesics 🗶						
	Select Pref and apply code						
Find a	and apply code						
WHOE	Drug						
Searc	h options						
Searc	h 🖉						
Pref	12818602001 Acetylsalicylic acid;Caffeine;Codeine phosphate						
Drug	12818602001 Acetylsalicylic acid;Caffeine;Codeine phosphate						
Spec							
INGR	Acetylsalicylic acid;Caffeine;Codeine phosphate						
ATC	N02AJ Opioids in combination with non-opioid analgesics 🗙						

#### Find and apply code

WHO	Drug	
Sear	ch options	•
Sear	ch	
Pref	12818602001 Acetylsalicylic acid;Caffeine;Codeine phosphate	۲
Drug	12818602001 Acetylsalicylic acid;Caffeine;Codeine phosphate	0
Spec		
INGR	Acetylsalicylic acid;Caffeine;Codeine phosphate	
ATC	N02AJ Opioids in combination with non-opioid analgesics 🗶	

Applied code in Excel export output

		· · · · · · · · · · · · · · · · · · ·				
1	V	W	X	Y	Z	AA
1	DrugCode	DrugName	NameSpecifier	OldForm	Ingredients	ATCCodes
2	DrugCode	DrugName	NameSpecifier	OldForm	Ingredients	ATCCodes
3	12818602001	Acetylsalicylic acid;Caffeine;Codeine phosphate		N	Acetylsalicylic acid;Caffeine;Codeine phosphate	N02AJ Opioids in combination with non-opioid analgesics
4						

AM AN
Preferred Code Preferred Name
PreferredCode PreferredName
12818602001 Acetylsalicylic acid;Caffeine;Codeine phosphate



Review status in Excel export

# Review status in Excel export

Published by Viedoc System 2023-10-09

#### <u>1. Review status</u> <u>2. SDV</u>

This lesson describes how the review status information is structured within an Excel file exported from Viedoc.

For general details about data export, see Exporting data.

## 1 Review status

Notel When selecting one row per item as Layout, the review status is not included in the export.

In the Excel export output file, there is one separate sheet for the Review status:

Reviewed item	Clinical review by	Clinical review date (UTC)	Data review by	Data review date (UTC)	SDV by	SDV date (UTC)	Signed by	Signed date (UTC)	Lock by	Lock date (UTC)
ReviewedItem	CrBy	CrDate	DmBy	DmDate	SdvBy	SdvDate	SignBy	SignDate	LockBy	LockDate
Event date	Demo User (317)	2018-09-10 08:01			Demo User (317)	2018-09-10 08:01				
Event date	Demo User (317)	2018-09-10 08:00			Demo User (317)	2018-09-10 08:00				
Event date	Demo User (317)	2018-09-10 08:00			Demo User (317)	2018-09-10 08:00			Demo User (317)	2018-09-10 08:00
Event date										
Event date										
Event date										
Event date										
Event date					Demo User (317)	2018-07-31 11:45				
Event date										
Event date										
Event date										
Event date	Demo User (317)	2018-09-07 11:44			Demo User (317)	2018-09-07 11:44			Demo User (317)	2018-09-07 11:45
Event date	Demo User (317)	2018-09-10 08:00			Demo User (317)	2018-09-10 08:00			Demo User (317)	2018-09-10 08:00
Form										

The first columns provide information for identifying the form that was reviewed, followed by the review information, as listed in the following table:

Column name	Description						
Columns that identify the form							
Site sequence number	Counter that identifies the site globally within the study.						
Site name	The site name, as set in Viedoc Admin.						
Site code	The site code, as set in Viedoc Admin.						
Subject sequence number	Counter that identifies the subject within the site.						
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.						
Event sequence number	Counter that identifies the event within the sequence of events for the same subject.						

Column name	Description
Event Id	The event ID, as set in the study design (in Viedoc Designer).
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Event date	The event date, as set in Viedoc Clinic when the event is initiated.
Activity Id	The activity ID, as set in the study design (in Viedoc Designer).
Activity name	The activity name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Form Id	The form ID, as set in the study design (in Viedoc Designer).
Form name	The form name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic
Form sequence number	Counter that identifies the instance of the respective form within the respective activity. This is mostly used for repeating forms.
	For non-repeating forms, this is <b>1</b> . If a form is reset and then saved again the new form has sequence number <b>2</b> , and so on.
	Form sequence number increases one step every time reset/initiate occurs.
	Review status information
Reviewed item	Can be one of the following:
	<ul> <li><i>Event date</i> - if the review action was performed on the event date.</li> <li><i>Form</i> - if the review action was performed at form level.</li> </ul>
Clinical review by	User name and user ID of the user that performed the clinical review.
Clinical review date (UTC)	The date and time in Coordinated Universal Time ( $\ensuremath{\text{UTC}}$ ) when the clinical review was performed
Data review by	User name and user ID of the user that performed the data review (marked by the DM review flag).
Data review date (UTC)	The date and time (UTC) when the data review was performed.
SDV by	User name and user ID of the user that performed the Source Data Verification (SDV) (marked by the SDV review flag). For studies where SDV is performed on item level, this column will contain N/A for items that do not require SDV.
SDV date (UTC)	The date and time (UTC) when the SDV was performed. For studies where SDV is performed on item level, this column will contain N/A for items that do not require SDV.
Signed by	User name and user ID of the user that signed the form.
Signed date (UTC)	The date and time (UTC) when the form was signed by investigator.
Lock by	User name and user ID of the user that locked the form.
Lock date (UTC)	The date and time (UTC) when the form was locked.



If, on the Data Export page, it was selected to include the <u>SDV</u> information, there is one separate sheet for the **SDV** information in the Excel export output file:

Activity name	Form Id	Form name	Form sequence number	Item Id	Item name	<b>Reviewed item</b>	SDV by	SDV date (UTC)
ActivityName	FormId	FormName	FormSeq	ItemId	ItemName	ReviewedItem	SdvBy	SdvDate
	PI	Patient Info	1	AGE	Age	Item	Demo User (317)	2017-11-17 12:26
	PI	Patient Info	1	DOB	Date of Birth	Item	Demo User (317)	2017-11-17 12:26
	PI	Patient Info	1	GENDER	Gender	Item	Demo User (317)	2017-11-17 12:26
	LABR	CBC LAB Results (Hematology)	1	LABR_RANGE	Normal Range	Item	Demo User (317)	2018-09-10 08:01
	LABR	CBC LAB Results (Hematology)	1	LABR_RESULT	Result	Item	Demo User (317)	2018-09-10 08:01
	LABR	CBC LAB Results (Hematology)	1	LABR_TYPE	Lab results type	Item	Demo User (317)	2018-09-10 08:01
	LABR	CBC LAB Results (Hematology)	1	LABR_UNIT	Unit	Item	Demo User (317)	2018-09-10 08:01
	LABR	CBC LAB Results (Hematology)	1	LABR_DATE	SampleDate	Item	Demo User (317)	2018-09-10 08:01
	PI	Patient Info	1	AGE	Age	Item	Demo User (317)	2018-09-10 08:00
	PI	Patient Info	1	DOB	Date of Birth	Item	Demo User (317)	2018-09-10 08:00
	PI	Patient Info	1	GENDER	Gender	Item	Demo User (317)	2018-09-10 08:00
• →   F	I LAB	PainLevel LABR Items	CodeLists Review st	atus SDV (+	) : 1			

Note! For studies where SDV is performed on item level, this sheet will include only the items that require SDV and are visible to the user.

The first columns provide information for identifying the item that was SDV-ed, followed by the review information, as listed in the following table:

Column name	Description
	Columns that identify the item
Site sequence number	Counter that identifies the site globally within the study.
Site name	The site name, as set in Viedoc Admin.
Site code	The site code, as set in Viedoc Admin.
Subject sequence number	Counter that identifies the subject within the site.
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.
Event sequence number	Counter that identifies the event within the sequence of events for the same subject.
Event Id	The event ID, as set in the study design (in Viedoc Designer).
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Event date	The event date, as set in Viedoc Clinic when the event is initiated.
Activity Id	The activity ID, as set in the study design (in Viedoc Designer).
Activity name	The activity name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Form Id	The form ID, as set in the study design (in Viedoc Designer).
Form name	The form name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.

Column name	Description
Form sequence number	Counter that identifies the instance of the respective form within the respective activity. This is mostly used for repeating forms.
	For non-repeating forms, this is <b>1</b> . If a form is reset and then saved again the new form has sequence number <b>2</b> , and so on.
	Form sequence number increases one step every time reset/initiate occurs.
Item ID	The item ID, as set in the study design (in Viedoc Designer)
ltem name	The item name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
	SDV information
Reviewed item	Can be one of the following:
	<ul> <li><i>Event date</i> - if the review action was performed on the event date.</li> <li><i>Form</i> - if the review action was performed at form level.</li> </ul>
SDV by	User name and user ID of the user that performed the SDV.
SDV date (UTC)	The date and time (UTC) when the SDV was performed.



Managing users

## Managing users

Published by Viedoc System 2023-10-09

1. Introduction
1.1 Important information about signatures
1.2 About roles in Viedoc
1.2.1 Two types of roles
1.2.2 System roles
1.2.3 Clinic roles
1.3 About the study users
1.3.1 Overview of users in the organization/study/site
1.3.2 Users
1.3.3 Study crew
1.3.4 Site users
1.3.5 Viedoc skill level
1.3.6 User status
1.4 User settings
1.5 User report
1.5.1 Log of users and roles in PDF
1.5.2 User administration log in Excel
1.5.3 Communication log in Excel
1.5.3.1 User-specific information
1.5.3.2 Study-specific information
1.6 System site groups
2. Step-by-step guides for the Study Manager
2.1 Assigning users to system roles and/or clinic roles
2.2 Resending the invitation to a user
2.3 Removing access to a role
<u>2.4 Unlocking a user account</u>
2.5 Delegating user management to the Site Managers
<u>2.6 Downloading the user logs</u>
3. Step-by-step guides for the Site Manager
3.1 Assigning users to clinic roles
<u>3.2 Removing a user</u>
<u>3.3 Unlocking a user account</u>

This lesson describes the types of roles that are supported by Viedoc, how to assign roles to users and where to view the users that have access to a study, and their user details. The instructions are intended for Study Managers (STM) and Site Managers (SIM).

# 1 Introduction

## 1.1 Important information about signatures

The Study Manager should, in cooperation with the Site Manager(s), ensure that all users of Viedoc are informed, and certify that all electronic signatures created in the system are intended to be the legally binding equivalent of a traditional handwritten signature.

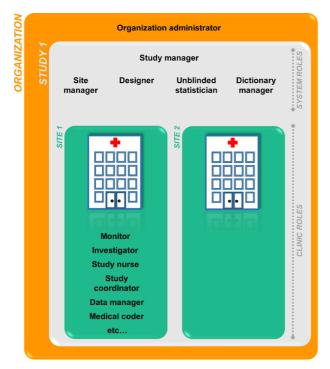
In Viedoc, the purpose/meaning of a signature is always "responsibility" as used in Sec. 11.50 of Food and Drug Administration (FDA) 21 Code of Federal Regulations (CFR) part 11. The signer is thereby acknowledging his/her responsibility for the entered data. Viedoc keeps account of what was signed, who signed it, and when the signature was performed.

## 1.2 About roles in Viedoc

#### 1.2.1 Two types of roles

Viedoc supports two different types of roles.

- 1. System roles are roles that are predefined in the system and give access to Viedoc Admin or Viedoc Designer, see <u>System roles</u>.
- 2. Clinic roles are roles that are study-specific and give access to Viedoc Clinic, see Clinic roles.



The Organization Administrator invites the Study Manager. The Study Manager can assign users to system roles and clinic roles. The Study Manager can also delegate the management of clinic roles to the Site Manager.

#### 1.2.2 System roles

The system roles are predefined in Viedoc, they cannot be adjusted for your study. The system roles give access to various features in Viedoc Admin or Viedoc Designer.

The following system roles are available.

Role	Description
Organization Administrator	The Organization Administrator is responsible for all projects within the organization. The Organization Administrator initiates projects, and assigns Study Managers to every project in Viedoc Admin.
Study Manager	The Study Manager assigns roles to users, adds sites to the study and applies study designs to the sites in Viedoc Admin. For a typical clinical trial, the role of Study Manager in Viedoc is assigned to the project manager.
Designer	The Designer builds the study in Viedoc Designer.
Site Manager	The Site Managers are appointed by the Study Manager and use Viedoc Admin to assign clinic roles to site users. For a typical clinical trial, the role of Site Manager in Viedoc is assigned to the Clinical Research Associate ( <u>CRA</u> ).
Unblinded Statistician	The Unblinded Statistician manages the randomization lists in Viedoc Admin. This role is only used for randomized studies, when it is necessary to have control over who has access to and can manage the randomization lists.
Dictionary Manager	The Dictionary Manager uploads medical coding dictionaries.

Role	Description
Reference Data Source Manager	The Reference Data Source Manager manages the reference data sources at study level. The Reference Data Source Manager can also delegate the management of data sources at site level to the Site manager.
API Manager	The Application Programming Interface (API) Manager has access to the API settings and performs the API configurations. Complete instructions on how to configure the API are provided in <u>Viedoc API</u> .
eTMF Manager	The eTMF Manager manages the <u>eTMF</u> application in Viedoc Admin. The eTMF Manager maps Viedoc Clinic roles to eTMF roles. The eTMF Manager also has permission to manage the eTMF structure in Viedoc eTMF.

One organization can have more than one Organization Administrator. One study can have more than one Study Manager, Designer, Unblinded Statistician, Dictionary Manager, Reference Data Source Manager and API Manager. One site can have more than one Site Manager.

#### 1.2.3 Clinic roles

The clinic roles, and the rights that belong to these roles, can be set up in the study design in Viedoc Designer. They are study-specific and give access to Viedoc Clinic. Clinic roles are assigned to site users by the Study Manager or the Site Manager. Each study can have an unlimited number of clinic roles.

Examples of clinic roles are:

- Investigator
- Study Nurse
- Study Coordinator
- Data Manager
- Medical Coder
- 1.3 About the study users

1.3.1 Overview of users in the organization/study/site

A list of users can be viewed at the following three places:

/ie	edoc's demostudy					🛠 Study	y settings
•	Randomization is on Check for ava	ailable slots, appe	end existing or add	new lists.			×
a	Medical coding. Create and edit in	istances, upload	files.				×
	Reference data source(s). Manage	contact informa	tion, design scope	s, and applicable sites.			×
PI	API configuration Add and edit API	l clients, view dat	a history.	0			×
		ly crew / Managers (2) Des ,	igners (1) Helpdesk	tearrr (0) Kearrr (0) Kultiple des	atest		8
		/ Managers (2) Des	igners (1)   Helpdesk	team (0)	atest	Show	w all sites
	Study	/ Managers (2) Des	a gentang	team (0)	atest	Show	
	Study Sites 3 Sites 5	/ Managers (2) Des	Site users	tearr (0) Multiple des	igns in use.	_	w all sites
	Study Sites  Site name	( Managers (2) Des Countries 6	Site users Country	Effective Design	igns in use. Production	Users	w all sites
	Study Sites (a) Sites (5) ( Site name Karolinska Institute Stockholm	(Managers (2) Des Countries 6 ( O Code Ki	Site users Country SE	Effective Design DemoStudyDesign 4.0	igns in use. Production	Users	w all sites
	Study Sites	Managers (2) Des Countries 6 0 Code KI UU HU	Site users Country SE SE SE	Effective Design DemoStudyDesign 7.0	igns in use. Production	Users 1 / 6 1 / 6	v all sites

**1.** On the **Users** page. This page displays a list of users assigned to any role in any study within the organization.

In the Study crew window. This window displays a list of all users assigned to a system role in the study.
 On the Site users tab of the site settings window. This tab displays a list of all users assigned to a <u>clinic role</u> within that specific site.

Notel All three user lists only display the users and roles you have permission to manage (invite or remove). If you are a Study Manager, you can also see the Organization Administrator. If you are a Site Manager, you can also see the Study Manager. However, in both cases you cannot invite users to these roles or remove these roles from users.

🛠 Studies Users 🧕			<b>4</b> Đ	Invite Organia	zation user
Search by name or e-mail 🔎	2 Sort by Name 47	Status # Date created	4t Gro	up by None	• ÷
9 users					
User	Study and site	Role	Skill level	Status	
the large hanglishes in				<b>≩×</b>	×
Dr. Demo (383)	Viedoc's demostudy Multiple sites	Dictionary Manager + 3 other roles	oo	$\checkmark$	8
Dr. Investigator (490)	Viedoc's demostudy Multiple sites	Investigator + 1 other roles	<u></u>	?	8
(294)	Multiple studies Multiple sites	Study Manager + 3 other roles	-	$\checkmark$	8
(296)	Viedoc's demostudy Multiple sites	Investigator	<u></u>		8
Technical Writer (304)	Multiple studies Multiple sites	Organization Admin + 10 other roles	2	<b>~</b>	8
Technical Writer (305)				•	8
TW CN (371)				•	8
Viedoc Admin (90)		Organization Admin	<u></u>	$\checkmark$	×

The Users page lists all users within the organization, and displays the following information:

- Name of the user
- User ID (in parentheses behind the user's name)
- E-mail address
- Study/studies and site(s) the user has access to
- Role(s) assigned to the user
- Viedoc skill level of the user (see <u>Viedoc skill level</u>)
- Status of the user (see <u>User status</u>)

If a user has no approved roles, because the invitation is still pending or rejected, or because the roles have been removed, only the user's e-mail address is displayed and all the other fields remain empty.

On this page, you can (see image):

1. Search for a specific user among all users within the organization by entering the user's name or e-mail address in the search field

- 2. Sort the list of users by name, status or date of creation
- 3. Group the list of users by study by selecting Studies in the Group by field
- 4. Invite organization users (only available for the Organization Administrator)

#### 1.3.3 Study crew

🛠 Viedoc's dem	ostudy					CI	lose
Study cre Here you can view ad		nd/or invite more people					
Study crew	Add study users						
User #1		Role #1	Since 👫	Skill level	Status 🕸		
Technical Write		Study Manager Designer	2018-04-10 08:49	20	$\checkmark$	*	1
Dr. Demo (383)		Dictionary Manager	2018-04-27 08:04	<u>100</u>	$\checkmark$	*	
Else Langeritat stragendise con	(294)	Study Manager Reference Data Source Manager	2018-05-02 14:36	<u> </u>	<b>~</b>	*	
allow income from the	printing g	Dictionary Manager	2018-05-15 08:32		?	*	
illin te ge for g					?×?	*	•

The Study crew window lists all users in the study that are assigned to a <u>system role</u>, and displays the following information:

- Name of the user
- User ID (in parentheses behind the user's name)
- E-mail address
- Role(s) assigned to the user
- Date and time the user has been invited to that role (if the invitation is still pending) or has access to that role (if the invitation has been accepted)\*
- Viedoc skill level of the user (see <u>Viedoc skill level</u>)
- Status of the user (see <u>User status</u>)

\*If the user has multiple roles, the date and time of invitation or acceptance of <u>the first role</u> that gives access to that site is displayed.

You can sort the users by name, role, date of (accepted) invitation and status. To sort the users, click on the column headers, or click on the arrows to the right of the column header. You can sort the users in ascending and descending order.

#### 1.3.4 Site users

🛠 Viedoc's demostudy								
Uppsala Unive Here you can modify site details	•							
Details Site users	Add users							
User #1	Role #1	Since (UTC) 🕴	Skill level	Status 🗤				
Technical Writer (304)	Site Manager + 1 other roles	2018-05-15 09:18 UTC	-	×	8			
Dr. Demo (383)	Data Manager	2018-05-15 09:23 UTC		?	8			
(294)	Medical Coder	2018-05-15 09:21 UTC	<u> </u>	~	8			
Dr. Investigator (490)	Investigator + 1 other roles	2018-05-15 09:21 UTC	<u>م</u>	✓	*			

The Site users tab in the Site settings window lists all users with <u>clinic roles</u> that have access to that site, and displays the following information:

- Name of the user
- User ID (in parentheses behind the user's name)
- E-mail address
- Role(s) assigned to the user
- Date and time the user has been invited to that role (if the invitation is still pending) or has access to that role (if the invitation has been accepted)\*
- Viedoc skill level of the user (see Viedoc skill level)
- Status of the user (see <u>User status</u>)

\*If the user has multiple roles, the date and time of invitation or acceptance of <u>the first role</u> that gives access to that site is displayed.

You can sort the users by name, role, date of (accepted) invitation and status. To sort the users, click on the column headers, or click on the arrows to the right of the column header. You can sort the users in ascending and descending order.

#### 1.3.5 Viedoc skill level

The Viedoc skill level gives an indication of how experienced the user is in using Viedoc. It is based on the number of logins by that user.

Skill level	lcon	Description
Rookie		≤ 20 logins
Semi-pro	<u> </u>	21-100 logins
Pro		101-1000 logins
Legend		> 1000 logins

### 1.3.6 User status

The status of the users is displayed in the status column:

Status	lcon	Description
Online	✓	The user is currently logged in to Viedoc, and has no pending invitations.
Offline	$\checkmark$	The user is currently not logged in to Viedoc, and had no pending invitations.
Pending	?	The user has at least one pending invitation to a role. The question mark is displayed even if the user has accepted invitations to other roles.
Pending certification	S×.	The user has mandatory documentation assigned that was not confirmed as read & understood.
Rejected	?×:	The user has rejected all invitations to roles. The user has never had access to the study.
Locked out	A	The user is locked out from Viedoc (the user has entered the wrong password three times in a row).
Removed	•	The user has had roles in the study before, but has currently no roles left.

For the **Users** page (see <u>Users</u>), the following applies:

If the users are not grouped by study, the user's status symbol will reflect the overall status in all studies you have access to. That means, if the user has one pending invitation in one of the studies, the status will be *pending* and a

red question mark will appear. If the users are grouped by study, the status symbol will reflect the status per study. That means that a user's status can be *pending* in one study, and *logged in* in another study.

## 1.4 User settings

To view the details of a specific user, click the toolbox icon behind the name of that user in any of the previously described user lists. The User Settings window opens:

)r Investigator (	1714)	4	5 Offline	Rookie 2 logins
Details Studies and Role		Reset Password	Communication Log	
User name				
testuser@r.com				
First name	Last name		Display name	
Dr	Investigator		Dr Investigator (1714)	
Phone				
46 7 12345678				
Street address			City	
Main Street 101			Uppsala	
Postal code	Country		State	
	SE			

The **User Settings** window displays the name and email address of the user, the user ID (in parentheses), the status and the skill level. You can perform the following actions:

1. On the **Details** tab, you can view the user's name and contact details.

2. On the **Studies and Roles** tab, you can view a list of all roles and sites the user has access to, including the date and time of invitation/acceptance of that role. The roles are grouped per study. You can delete roles by clicking the trash can icon next to the role.

3. On the **Login History** tab, you can view a list of logins by the user, including date and time, the IP address, and the browser that was used. The number of displayed entries is limited to the latest 100 logins.

4. On the **Reset Password** tab, you can reset the password for that user, if the user has forgotten his/her password <u>and</u> the answer to his/her challenge question. Viedoc will send a notification to the user with a link to create a new password.

5. On the **Communication Log** tab, you can view the latest 20 communication logs for a user and download an Excel file with the complete user-specific **Communication Log** containing information about email and SMS communication to study users. All users with access permissions (Study/Site Managers) to the User settings in Viedoc Admin can access the Communication Log.

Note! Email and SMS communication logs before the Viedoc 4.70 release are available, however these do not have the same level of detail.

## 1.5 User report

For each study, you can download user logs in PDF and Excel format with information about all users and roles for the sites you have access to. See <u>Downloading the user logs</u> for instructions.

Note! Only production sites and roles/users for production sites are included in the logs.

The content of the logs depends on the system role that you have, as follows:

lf you are a	then the logs contain:
Organization Administrator	The system roles Application Programming Interface (API) Manager, Dictionary Manager, Unblinded Statistician, Reference Data Source Manager, and eTMF Manager.
Study Manager	The system roles API Manager, Dictionary Manager, Unblinded Statistician and Reference Data Source Manager, eTMF Manager, and all sites and site users in the study.
Site Manager	The system roles API Manager, Dictionary Manager, Unblinded Statistician and Reference Data Source Manager, eTMF Manager, and all sites you have access to, together with their site users.

#### 1.5.1 Log of users and roles in PDF

The Log of users and roles PDF contains information about all users and roles for the sites you have access to, grouped in the following chapters:

- 1. Summary the summary of active/inactive roles, active/inactive users as well as data contributors, grouped in one section per site.
  - An Active role is the current distinct role all active users have for a site.
  - An Inactive role is a role that was previously assigned but currently lacks any active user.
  - An Active user is a user with at least one active role.
  - An **Inactive user** is a user who had at least one role at a site, but all roles for the site have been revoked.
- 2. Roles a list of the permissions associated with each role and corresponding history, grouped in one section per site.
- 3. User log per site a list of all users who ever had access to data, including user activity, grouped in one section per site.
- 4. User account logs a list of the change history of all user accounts for the users listed in the above sections of the log, grouped per user (identified by the User ID).

### 1.5.2 User administration log in Excel

The User administration log contains information about all users and roles for the sites you have access to, with the following sheets:

- 1. Report Info general information about when and by whom the log was generated, and some information about the study status.
- 2. User Access Log a list with detailed information about user access, showing one row per site and role, including clinic roles and system roles. Some columns in this sheet are further explained here:
  - Site Group indicates when a user is granted access to the site through a site group invitation. Possible values are *Training sites*, *Countries*, and *All sites*.
  - 2FA indicates what level of two-factor authentication the user has. Possible values are *Study level, Account level, or No two-factor authentication enabled.*
  - **Certified** indicates if the user is certified for the role. Possible values are *Yes, No*, or an empty cell for roles that don't have mandatory training sections to read.
- 3. Certification Log a list of certifications per user. Certifications performed before the release of 4.65 lack information about what roles the certification applies to. That is, the cells in column Certified With Roles are empty.
- 4. Summary a summary of users per site with information about country, side code, site name, number of active/inactive users, and date/time of last access change.
- 5. Account Settings Log a list with all user accounts setting changes with user ID, change log, user name, and date/time.

#### 1.5.3 Communication log in Excel

There are two different Communication logs. One contains user-specific and one contains study-specific communication information.

#### Note!

- This Communication log does not include any subject-related communication (Viedoc Me).
- Email and SMS communication logs before the Viedoc 4.70 release are available, however these do not have the same level of detail.

#### 1.5.3.1 User-specific information

The user-specific Communication log contains information about email and SMS communication to the study users.

All users with access permissions (study/site managers) for the User Settings in Viedoc Admin can view the Communication Log for a specific user. The **Communication Log** tab has the following columns:

- Date & Time
- Message type
- Status Notel The status labels are Success or Failed, where Success means that the message was
  successfully sent from Viedoc, and Failed means that the message failed to send from Viedoc. Further, if
  the status was Success but the recipient did not receive a message, then the problem lies outside of
  Viedoc. Please contact your PS representative if this should occur, or if your status returns Failed.

r.one-@mail	ne (1234)			×	Online 25 Pro
Details	Studies and Roles	Login History	Reset Password	Communication Lo	×g
Date and Ti	ime	Message type		Status	
2022-03-2	1 09:41:50 (UTC)	Two factor aut	hentication	Success	
2022-03-2	1 09:25:18 (UTC)	Two factor aut	hentication	Success	
2022-03-2	1 04:41:07 (UTC)	Two factor aut	hentication	Success	
2022-03-2	1 04:39:28 (UTC)	Recover accou	unt request	Success	
2022-03-19	9 07:09:22 (UTC)	Two factor aut	hentication	Success	
2022-03-18	8 09:59:30 (UTC)	Two factor aut	hentication	Success	
2022-03-18	8 09:50:58 (UTC)	Two factor aut	hentication	Success	
2022-03-18	8 06:16:34 (UTC)	Two factor aut	hentication	Success	
2022-03-18	8 05:40:42 (UTC)	Verify phone r	umber	Success	
2022-03-18	8 05:40:39 (UTC)	Change phone	e number	Success	

The Excel file contains a sheet named User Communication Logs and includes all email and text message (SMS) communications to the study user on the same Excel sheet.

Note! Users must have activated the Viedoc account and accepted at least one invitation in order to have their communication included in the Communication Log tab in the **User Settings** window.

The User Communication Logs sheet in the Excel file contains information about user-specific communication – this is the user activity in Viedoc that is <u>unrelated to a specific study</u>:

- Reset password
- Verification & notifications (changing telephone number/email address)
- 2FA (email/SMS)

The file name format is: UserCommunicationLog-UserID-YYYYMMDDhhmmss. (Using UTC)

All the logs are included in the same Excel sheet. The excel sheet has the following columns:

Column	Description
Message ID	GUID: A unique identifier for the message
Type of Communication	SMS/email
Datetime (UTC)	Date and time for the communication
Message Type	<ul> <li>The action that the communication is related to:</li> <li><i>Reset password</i> - for messages related to password reset</li> <li><i>2FA login</i> - for messages related to the 2 factor authentication</li> </ul>
То	The email address the message is sent to. For SMS messages, this column is empty.
Status	Success/Failed
Provider	Provider name - the provider that was used to send the message to the recipient

		Communication lo	σς				
-	A	В	С	D	E	F	G
1	Message Id	Type of Communication	Datetime (UTC)	Communication logs Message Type	To	Status	Provider
	9970d495-aa67-4bed-b246-	Type of Communication	Datetime (OTC)	wiessage type	10	Status	Provider
3	cc3f8b1c8d47	Email	2022-03-01 07:46:25	Two Factor Authentication	user1@viedoc.com	Success	Primary-Primary
4	a96f1beb-c63c-4376-9ae0- e9dcdabcb8d4	Email	2022-03-01 07:44:29	Recover Account Request	user2@gmil.com	Success	Secondary-Secondary
	00520b3e-f26a-4077-9dac- edc9458cc30a	Sms	2022-03-01 06:16:22	Verify Phone Number		Success	Primary-Primary
	e01f2d59-8af4-48ba-81b7- fb4045d18767	Email	2022-03-01 06:16:20	Verify Email Address	123@mail.com	Success	Primary-Primary
	9ad92c51-7582-4bce-b243- d63737bb079d	Sms	2022-03-01 06:11:07	Verify Phone Number		Success	Primary-Primary
	448b70b8-faea-4dc3-b07a- a892457eb358	Email	2022-03-01 06:11:00	Verify Email Address	999@gml.com	Success	Primary-Primary
	1de6048b-a1a9-48bb-85e2- 94ab6ecf4f42	Sms	2022-03-01 04:44:05	Verify Phone Number		Failed	Secondary
	399a561a-4299-4ceb-a0ac- a87825cdfbaa	Sms	2022-03-01 04:42:42	Verify Phone Number		Failed	Secondary
	8aec881c-78ab-45c9-95e4- 5123e09ce129	Sms	2022-03-01 04:42:42	Verify Phone Number		Failed	Secondary
	f8ef8347-de0e-422b-be2a- d8bba0a7d650	Email	2022-03-01 04:42:41	Verify Email Address	789@gmil.com	Failed	Secondary
	16c884e2-3cf3-4063-8f47- a8cf0c02233a	Email	2022-03-01 04:39:43	Verify Email Address	abcd@gmil.com	Failed	Secondary
	9c813fce-6633-4dee-b0ba- 3666ee14cf5f	Sms	2022-03-01 04:39:38	Verify Phone Number		Success	Secondary-Primary
	fc98775c-01f2-4b4d-aad7-	Email	2022-03-01-04-39-29	Verify Email Address		Failed	Secondary
1	User Communicat	tion Logs (+)			E 🛛		

#### 1.5.3.2 Study-specific information

In Admin, under Users - Group by Studies, in the User Logs dropdown list, a separate file called User communication log is available containing the information listed below.

Studies Us	ers 7			+ Invite Organizati	onus
Search by name or e-mail	2	Sort by Name	an Status n Date cr	eated II Group by Studies	4
7 users					
Fire	st study			User logs	•
User		Study and site	Role	Generate	
Dr Investigator (1714) testuser@r.com		First study Multiple sites	Investigator	User administration log Generate	
Rachel McKie (1680) rachel@viedoc.com		First study Multiple sites	Study Manage + 12 other roles	User communication log Download (2022-03-02 09:25)	
Technical Writer (1736) Name.lastname@mail.com		First study Multiple sites	Investigator	Regenerate	(X

This log contains information about study-specific communication and emails only, related to:

- Alerts
- Invitations to a specific role within a study
- Notifications (study access deletion, etc.)

The Excel file contains a sheet named Study Communication Logs.

The file name format is: UserCommunicationLog-YYYYMMDDhhmmss. (Using UTC)

The Excel sheet has the following columns:

Column	Description
Message ID	GUID: A unique identifier for the message
Communication Type	Email
Date time (UTC)	Date and time for the communication
Message Type	The action that the communication is related to: <ul> <li>Invite user</li> <li>Event Reminder</li> <li>Remove User Access Notification</li> <li>Subject Account Lock Notification</li> <li>Study Unlock Notification</li> <li>Export Chart</li> <li>Export Metric</li> <li>Reject User Invitation</li> </ul>
Site Type	Training/Production (For the message types Invitation and Invitation rejected, this column is empty.)
То	Email address(es) (For SMS messages, this column is empty.)
CC	The email address(es) of the recipients of a copy
BCC	The email address(es) of the recipients of a blind copy
Status	Success/Failed
Provider	Provider name - The provider that was used to send the email to the recipient

Communication Logs									
Message Id	Communication Type	Datetime (UTC)	Message Type	Site Type	To	00	BCC	Status	Provider
176302cc-8c85-4f33-a932- 87bde89b8bd2	Email	2022-03-03 06:52:07	Form Alert True Action	Production	rb@doc.com		gf53@mail.com, user11.pghryam@amail.com	Success	Secondary-Secondary
573fef21-bceb-477d-9b94- ad0ffe080e64	Email	2022-03-03 06:52:05	Event Reminder	Production	rb@doc.com	user1@mail.com	dyuhftst7@dmail.com, user78.hjystfg@amail.com	Success	Secondary-Secondary
d2e09907-1b90-4945-9d17- fffb594a0b2a	Email	2022-03-03 06:52:03	Study Unlock Notification	Production	user1@mail.com	user3@amail.com	fdfdtr3@dmail.com, user56.klofd@amail.com	Success	Secondary-Secondary
9757c6d5-60c1-435a-8d97- 81f677cdb022	Email	2022-03-03 06:52:01	Invite User	Production	user2@se.com	user@vc.com	fnmkj378@amail.com, user8971.uhafm@amail.com	Success	Secondary-Secondary
85e5a421-d529-40b3-979e- Je4acb183902	Email	2022-03-03 06:43:53	Remove User Access Notification	Production	ghu.nustf@mail.com	mol.hbdb@mail.com	gfdgs65@amail.com, fsfsuifs.fklj@mail.com	Success	Secondary-Secondary
									100 C
Study Comm	Study Communication Logs								

Note!

- This log does not include user-specific information related to Reset Password, 2FA, etc.
- This log file is available in Viedoc Admin only.

## 1.6 System site groups

The Study Manager can give users access to individual sites, or to a groups of sites at once. These groups of sites are called system site groups and are automatically created by the system when sites are added to the study. The following systems site groups are created by the system:

- All sites, containing all sites in the study.
- All production sites, containing all production sites in the study, including the sites that are in both production and training mode.
- Country-specific, for example 'Sweden', containing all production sites (including the sites that are in both production and training mode) in that specific country in the study.

When you invite users to a system site group, the users will <u>automatically receive instant access</u> to all sites in that group, including all future sites that will be added to that group at a later time. For example, if you invite a user to the country 'Hungary', that user will receive access to all sites in Hungary. Similarly, users that were invited to a system site group will automatically lose access to a site if that site is removed from the group. For more information about system site groups, see <u>Managing study sites</u>.

# 2 Step-by-step guides for the Study Manager

### 2.1 Assigning users to system roles and/or clinic roles

Only the Study Manager can invite users to system roles. The Study Manager can also invite users to clinic roles, or he/she can delegate the management of (some of the) clinic roles to the Site Manager, see <u>Delegating user</u> management to the Site Manager for instructions. Once the management of clinic roles is delegated to the Site Manager, the Study Manager cannot invite users to these roles anymore.

If a user should receive access to multiple sites, the quickest way to invite the user is through the study crew window (described in this section). If a user should receive access to only one site, you can also invite the user through the site settings window of that site (see <u>Assigning users to clinic roles</u> for instructions).

To invite users:

- 1 In Viedoc Admin, open the study to which you would like to invite users.
- 2 Click the toolbox icon in the **Study crew** field. The Study crew pop-up opens.
- 3 On the Add study users tab, enter the e-mail address of the user you would like to invite. Click Continue.

X Viedoc's demostudy	Close
Study crew Here you can view admins for the study and/or invite more people	
Study crew Add study users	
Add users to this study	Step 1/2
E-mail address	
<u>Name_Lasmame</u> @email.com	
Multiple email addresses can be included by separating with semi-colon or comma.	
	Continue O

Tip! You can invite multiple users at once by adding multiple e-mail addresses in the field. Separate the e-mail addresses with a semi-colon or comma.

#### 4 Select the role to which you would like to invite the user.

🔀 Vied	loc's demostudy		Close
	dy crew	and/or invite more people	
Stud	y crew Add study user	s	
Add	users to this study		Step 2/2
	Name.Lastname@em First name	ail.com	
~	Investigator	Select site group(s) or site(s)	0
0	Study Manager Designer Unblinded Statistician Dictionary Manager	Q     Send	invite 💿
	Reference Data Source Manager	Solutions AB 2018 · Terms of Use · Privacy Policy version 4.42.6680.24523 [2018-04-17T08:47 UTC]	
100	API Manager Site Manager	Multiple designs in use.	
Study Site	Investigator Study Coordinator	D Site users	

You can add multiple roles by clicking the + icon. Newly added roles can be removed by clicking the - icon.

Notel If any of the clinic roles are delegated to the Site Manager (see <u>Delegating user management to</u> <u>the Site Managers</u>), the delegated roles do not appear in the dropdown list.

5 If you selected the role Site Manager or a clinic role, select the system site group or the individual sites to which the user should get access. To select a system site group, click on the name of the group (displayed in bold). To select an individual site, click on the name of the site.

🔀 Viedoc's demostudy		Close
Study crew Here you can view admins for the study and/or i	nvite more people	
Study crew Add study users		
Add users to this study		Step 2/2
<ul> <li>Name.Lastname@email.com</li> <li>First name</li> </ul>	m Last name	
V Investigator *	Select site group(s) or site(s)	0
Back	All sites     All production sites     Finland	invite 🔿
	Helsinki University Hospital	
© PCG Viedoc™		-
Technical Writer.	Karolinska Institute Stockholm	-

#### Note!

- Sites that do not belong to a system site group (for example training sites) are listed under a separate header (for example "Training sites") at the bottom of the list of site groups and sites. This header lacks the folder icon, and does not represent a system site group (see image).
- For Demo sites to work with Viedoc Reports, a user must be invited with direct site access (not through All sites site group). For Production sites, Viedoc Reports is available for all site groups (All sites and the country-specific groups).

#### 6 Click Send invite.

An invitation e-mail will be sent to the e-mail address(es) you specified.

## 2.2 Resending the invitation to a user

It is possible to re-invite a user to those roles that are in state <u>pending</u>, i.e. to resend the invitation email to the user for that role.

To resend an invitation:

1 On the **Users** page, scroll to the user whom you would like to re-invite. Click the toolbox icon behind the name of the user:

🔀 Studies Users 😰			Ð	Invite Organiz	ation users
Search by name or e-mail 🔎	Sort by Name	11 Status II Date creat	ted If Grou	up by None	¢
12 users					
User	Study and site	Role	Skill level	Status	
eritariad vedec tet	Demo All sites	Investigator		?	

The User Settings pop-up opens.

2

In the User Settings pop-up, click the Resend invitation icon for the pending role:

🔀 User Settings			Close
minada de la document			? Pending
Details Studies	and Roles		
0 approved role	es in 0 studie(s)		
Percenting events	>		
Site name	Role	Status	
🗎 All sites	Investigator	Pending, 2018-05-23 08:47 UTC	🧟 💼
			Resend Invitation

A new invitation email is sent and:

- a notification message is displayed on the top of the pop-up
- the date displayed in the Status column is updated to the date of the last invitation

🔀 User Settings			
<ul> <li>A new invitation was sent successful</li> </ul>	lly!		
education of			<b>?</b> Pending
Details Studies and Roles			
0 approved roles in 0 st	udie(s)		
recurring events			
Site name	Role	Status	
🗂 All sites	Investigator	Pending, 2018-12-14 09:56 UTC	<b>e</b> 1

## 2.3 Removing access to a role

It is possible to remove a user's access to a role. This can only be done by the Study Manager. If the Study Manager has delegated the management of clinic roles to the Site Managers, only the Site Managers can remove access to these roles and sites.

To remove the access from users:

On the **Users** page, scroll to the user whose access you would like to remove. Click the toolbox icon behind the name of the user.

Search by name or e-mail 🔎	Sort by Name #	Status 41 Date created	4t Gro	oup by None	
10 users					
User	Study and site	Role	Skill level	Status	
for large large large of the st				<b>≧×</b>	℅
Firstname.Lastname@email.com		Organization Admin + 1 other roles		?	8
Dr. Demo (383)	Viedoc's demostudy Multiple sites	Dictionary Manager + 2 other roles	<u>9</u>	$\checkmark$	
Dr. Investigator (490)	Viedoc's demostudy Multiple sites	Dictionary Manager + 3 other roles	<u>.</u>	$\checkmark$	Edi
(294)	Multiple studies Multiple sites	Study Manager + 5 other roles	<u> </u>	$\checkmark$	×
(296)	Viedoc's demostudy Multiple sites	Investigator	<u>.</u>		*
Technical Writer (304)	Multiple studies Multiple sites	Organization Admin + 10 other roles	2	×	8
TW CN (371)				•	8
Viedoc Admin (90)		Organization Admin	2	$\checkmark$	8

#### The User Settings pop-up opens.

Dr Investigator (1714) testuser@r.com	
Details Studies and Roles Login History Reset Password Communication Log	
User name	
testuser@r.com	
First name Last name Display name	
Dr Investigator (1714)	
Phone	
46 7 12345678	
Street address City	
Main Street 101 Uppsala	
Postal code Country State	
SE	

1

On the **Studies and Roles** tab, scroll to the study, site and role for which the access should be removed. Click the trash can icon.

🔀 User Set	ttings				Close
Dr Inv testuser(ar.c	estigator ( <sup>om</sup>	1714)		<b>v</b> off	line Rookie
Details	Studies and Role	s Login History	Reset Password	Communication Log	
1 appro	ved roles in 1 st	udie(s)			
C	First	study			
Site name		Role	St	atus	
💼 All site	es	Investigator		pproved, 2022-03-02 14:5 TC	° .
A pop up app	oears.				-

- 3 Click Delete to confirm that the access should be removed, or click Cancel to cancel. The role for which you removed the access, will be removed from the Studies and Roles list. If all roles for that user have been removed, the user's status will appear as *Removed* on the Users page.

Any records generated by the user are stored in the audit trail even when the user has been removed.

### 2.4 Unlocking a user account

If a user has typed in the wrong password more than three times, and forgotten the answer to the challenge question – and therefore cannot use the *Forgot your password* link – the account will be locked. The Study Manager or Site Manager can unlock a locked account.

To unlock a user account:

2

1 On the **Users** page, scroll to the user whose account you would like to unlock. Click the toolbox icon behind the name of the user.

🛠 Studies Users 🔟			÷	Invite Organi	zation users
Search by name or e-mail 🔎	Sort by Name #	Status # Date creat	ed 11 Gro	oup by Non	• •
10 users					
User	Study and site	Role	Skill level	Status	
the large large large other of				?×	×
Firstname.Lastname@email.com		Organization Admi + 1 other roles	n	?	8
Dr. Demo (383)	Viedoc's demostudy Multiple sites	Dictionary Manage + 1 other roles	r 👳		
Dr. Investigator (490)	Viedoc's demostudy Multiple sites	Dictionary Manage + 3 other roles	r 🚑	$\checkmark$	8
(294)	Multiple studies Multiple sites	Study Manager + 5 other roles	<u></u>	$\checkmark$	8
(296)	Viedoc's demostudy Multiple sites	Investigator	<u>ق</u>	P	8
Technical Writer (304)	Multiple studies Multiple sites	Organization Admit + 10 other roles	n 쟬	<b>~</b>	8
Technical Writer (305)				•	8
TW CN (371)				•	8
Viedoc Admin (90)		Organization Admi	n 쟬	$\checkmark$	8
↑ To the top					

The User Settings pop-up opens.

#### On the Reset Password tab, click Reset Password.

🔀 User Settings				Close
Dr Investigator (1) testuser@r.com	714)		V Offline	e Rookie
Details Studies and Roles	Login History	Reset Password	Communication Log	
Use 'Reset password' when the notification to the user when the	-		llenge question. Viedoc will s	send a
	Re	eset Password	assword	

The user will receive an e-mail with a link to reset the password.

The link directs the user to a window where the user is asked to set an answer to the challenge question, and to create a new password. The challenge question is the same as previously chosen by the user, but any answer is accepted for resetting the password.

Vied	doc
Reset your passwor	rd
Security question Set a new security answer. You can char Mother's birthplace	nge the security question and answer after login.
Set a new password Set a password that you will be using to logir letters, numeric and special characters. Mix c Create a password	to Viedoc from now on. Be creative, include both apital and lowercase letters.
Create a password Confirm your password Confirm your password	Password must contain at least       8 characters       1 lower case letter       1 upper case letter       1 special character (I, @, #, S, %, ^.6+, etc.)
Submit	

Once the password has been reset, the user can login and select a new challenge question in the security settings.

Note! The email with the link to reset the password is only valid for twelve hours. If the user has not reset the password within twelve hours, a new e-mail needs to be sent.

## 2.5 Delegating user management to the Site Managers

The Study Manager can delegate the management of clinic roles to the Site Manager.

To select the roles that should be managed by the Site Manager:

1 In Viedoc Admin, click **Study settings**. The study settings window opens. On the **Settings** tab, in the field **Clinic roles to be administered by Site Manager**, select which roles should be assigned by the site manager.

🛠 Viedoc's demostudy			Save changes	Close
Study settings Here you can set settings for study.				
Settings ! Date & time format	Medical Coding	Import ODM File		
Ongoing , FPA 2017-02-02 Full functionality.	(	O Invalid license		
Study name 🚯		Study Logo		
Viedoc's demostudy Sponsor Code CRO Code		E CO	Upload a file	
Reference ID		PNG, GIF or JPG file height.	s of maximum 180 px width and 90 p	x
Study Type	Sponsor Type		Study Phase	
Pharmaceutical - Clinical *	Pharmaceutical co	mpany *	Phase III	¥
Therapeutic Area	Expected number	r of subjects		
Gastroenterology *	800			
Study access				
Password expiration time for all users			90 days	
Clinic roles to be administered by Site	e Manager 🚯			
Investigator Study Coord DRC Coordinate	inator Monitor			
Helpdesk team				
PCG Helpdesk Britanica	Helpdesk			
Allow reminders in ViedocMe to be se	ent as			
Email Text message				
Show more options				

The roles that can be selected here are the clinic roles that are defined in the study design.

3 Click Save changes, and click Close.

Note! These settings apply to all sites and all Site Managers involved in the study. When the assignment of (some of the) clinic roles is delegated to the Site Manager, these clinic roles can no longer be managed by the Study Manager.

## 2.6 Downloading the user logs

To download the user logs:

#### On the Users page, select to group the users by Studies.

🛠 Studies Users 1			•	Invite Organi	zation user
Search by name or e-mail 🔎	Sort by Name IT	Status # Date creater	d It Gro	up by Stud None Studie	
L2 users					Ð
Viedoc's demostudy		<b>5</b> G	enerate a PDF f	ile 'Log of users	and roles'
lser	Study and site	Role	Skill level	Status	
for large for generation or				( <sup>2</sup> ×	×
0r. Demo (383)	Viedoc's demostudy Multiple sites	Dictionary Manager + 2 other roles	<u>90</u>	?	8
Dr. Investigator (490)	Viedoc's demostudy Multiple sites	Dictionary Manager + 3 other roles	<u>.</u>	$\checkmark$	8
echnical Writer (304)	Viedoc's demostudy Multiple sites	Study Manager + 8 other roles	<u> </u>	<b>~</b>	8
echnical Writer (305)				•	8
W CN (371)				•	8
Documentation of Life		🥦 G	enerate a PDF f	ile 'Log of users	and roles'
Jser	Study and site	Role	Skill level	Status	
(294)	Documentation of Life Multiple sites	Study Manager + 3 other roles	<u> </u>	$\checkmark$	8
echnical Writer (304)	Documentation of Life Multiple sites	Study Manager + 1 other roles	<u> </u>	<b>~</b>	8
echnical Writer (305)				_	

2 Scroll to the study from which you would like to download the user log and click **User logs** to open the dropdown menu.

1		IC.		rc
	u	13	C	13

First study		(	User logs
User	Study and site	Role	Generate
Dr Investigator (1714) testuser@r.com	First study Multiple sites	Investigator	User administration log Generate
Dr Investigator (1714) testuser@r.com	First study Multiple sites	Study Manage + 12 other roles	; International (2022-03-02.09:25)
Technical Writer (1736) Name.lastname@mail.com	First study Multiple sites	Investigator	Regenerate

If the log was not previously generated, click **Generate a PDF file** or **Generate an Excel file**. If the log was previously generated, the most recent version is stored on the server, shown with a date and time stamp. You can download it by clicking the link, or, generate an updated version by clicking **Regenerate**.

Note! The user logs are generated in the language set by the user who is generating the log. Therefore, the previously generated file is available for download only if it was generated in the language you have currently set in Viedoc.

## 3 Step-by-step guides for the Site Manager

### 3.1 Assigning users to clinic roles

The Site Manager can invite users to (some of the) clinic roles, if the study manager has delegated the management of these clinic roles to the site manager.

To invite users to a specific site:

1

In Viedoc Admin, click the toolbox icon behind the site to which you would like to invite users.

	edoc's demostudy						🗶 Stud	y settings
	Study cr Study Man Technical V	agers (1) Design	ers (1) Helpdesk t	<b>8</b> eam (0)	Study de Effective Multiple des	atest		8
•	Study Sites 8 Sites 5 Cour	ntries  Site	e users				Sho	w all sites
4.1	Site name	Code	Country	Effective De	esign	Production	Users	
	Karolinska Institute Stockholm	кі	SE	DemoStud	lyDesign 4.0	~	1/5	8
	Uppsala University Hospital	UU	SE	DemoStud	lyDesign 3.0	~	1/5	×
	Helsinki University Hospital	HU	FI	DemoStud	lyDesign 4.0	~	1/4	8
	University College Hospital London	CL	GB	DemoStud	lyDesign 6.0	~	1/4	8

#### The site settings pop-up opens.

On the Add study users tab, enter the e-mail address of the user you would like to invite. Click Continue.

		titute Stock	
Details	Site users	Add users	
Add use	ers to this st	ıdy	Step 1/2
E-mail a	address		
Name.La	<u>stname</u> @email.	com	
Multiple en	nail addresses can	be included by separating	with semi-colon or comma.
			Continue 🕤

Tip! You can invite multiple users at once by adding multiple e-mail addresses in the field. Separate the e-mail addresses with a semi-colon or comma.

2

Select the role to which y	ou would like to invite the user
----------------------------	----------------------------------

		s demostudy	,		Close
		nska Ins modify site details		tockholm sers to site.	
D	etails	Site users	Add users		
A	dd use	ers to this stu	ıdy		Step 2/2
	Nan	ne.Lastname	aemail.co	m	
	_	First name		Last name	
	Inve	estigator	*	0	
0	Inv	estigator	م راس 1		Send invite 🚭
		dy Coordinator nitor	Ð		
		iject Manager :a Manager	- 1	Solutions AB 2018 • Terms of Use • Privacy Policy version 4.42.6681.26619 [2018-04-17112:54 UTC]	
		onsor C Coordinator	- 1	Multiple designs in use.	
	Z.	il Manager			
tudy S		dical Coder		5 Site users	Channel
tudy S	Lab	Import	-	Site users	Show al

You can add multiple roles by clicking the + icon. Newly added roles can be removed by clicking the - icon.

#### 4 Click Send invite.

An invitation e-mail will be sent to the e-mail address or e-mail addresses you specified.

## 3.2 Removing a user

Click <u>here</u> for instructions on how to remove a user.

## 3.3 Unlocking a user account

Click here for instructions on how to unlock a user account.



Create a user account

## Create a user account

Published by Viedoc System 2018-11-12

This video walks you through the process of creating a Viedoc user account.

If you have difficulties in viewing this video click <u>here</u>.



Log in/Log out and reset password

# Log in/Log out and reset password

Published by Viedoc System 2019-11-14

This video shows how to log in/log out to/from Viedoc and how to reset your password.

If you have difficulties in viewing the video, click here.



Landing page



Published by Viedoc System 2018-11-07

This video provides a quick overview of the landing page as well as of the study start page.

If you have difficulties in viewing this video, click here.



Activate demo mode

# Activate demo mode

Published by Viedoc System 2018-11-07

This video demonstrates how to switch between demo and production mode within a study.

If you have difficulties in viewing this video, click here.



User Management

# User Management

Published by Viedoc System 2018-12-12

This video demonstrates how to manage users in Viedoc Admin.

If you encounter difficulties in viewing this video click here.

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Version 2.1