Nyttige funksjoner i Viedoc-Elektronisk studiearkiv (eTMF) og legemiddelhåndtering (Drug Logistics)

04.03.2025

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Om Viedoc i dag

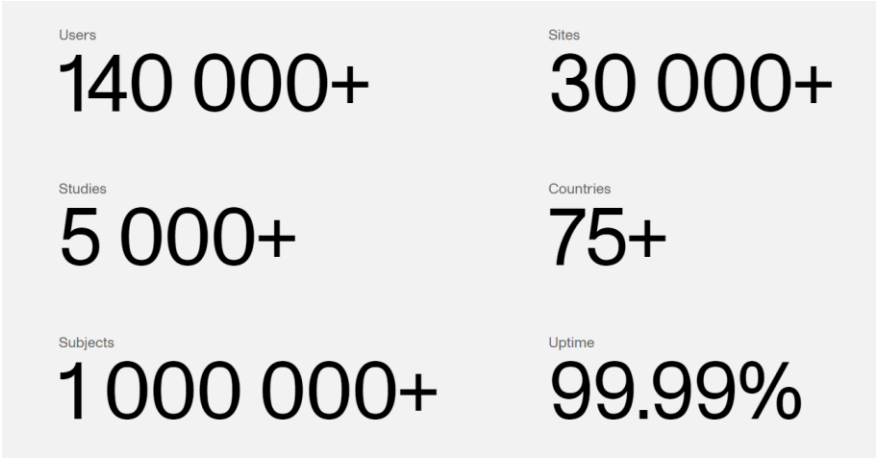
- Hva/Hvem er Viedoc
- Hvilken avtale har vi og hva inneholder den
- Funksjonalitet i Viedoc med fokus på:
  - Drug Logistics
  - eTMF/ISF
  - Reports

Viedoc, hvem og hva

DataCapture og Clinical Data Management System som utvikles og leveres av Viedoc Technologies AB, Uppsala Sweden

- OUS har brukt Viedoc ver. 4 siden 2014
- OUS har en rammeavtale med leverandørene
- OUS/CTU levere oppsett og tjenester i Viedoc i HSØ, sponsor er OUS og andre HF
- Andre universitetssykehus med sine forskningsstøtteenheter bruker avtale og kan være sponsor i studiene, inkludert andre HF i deres region

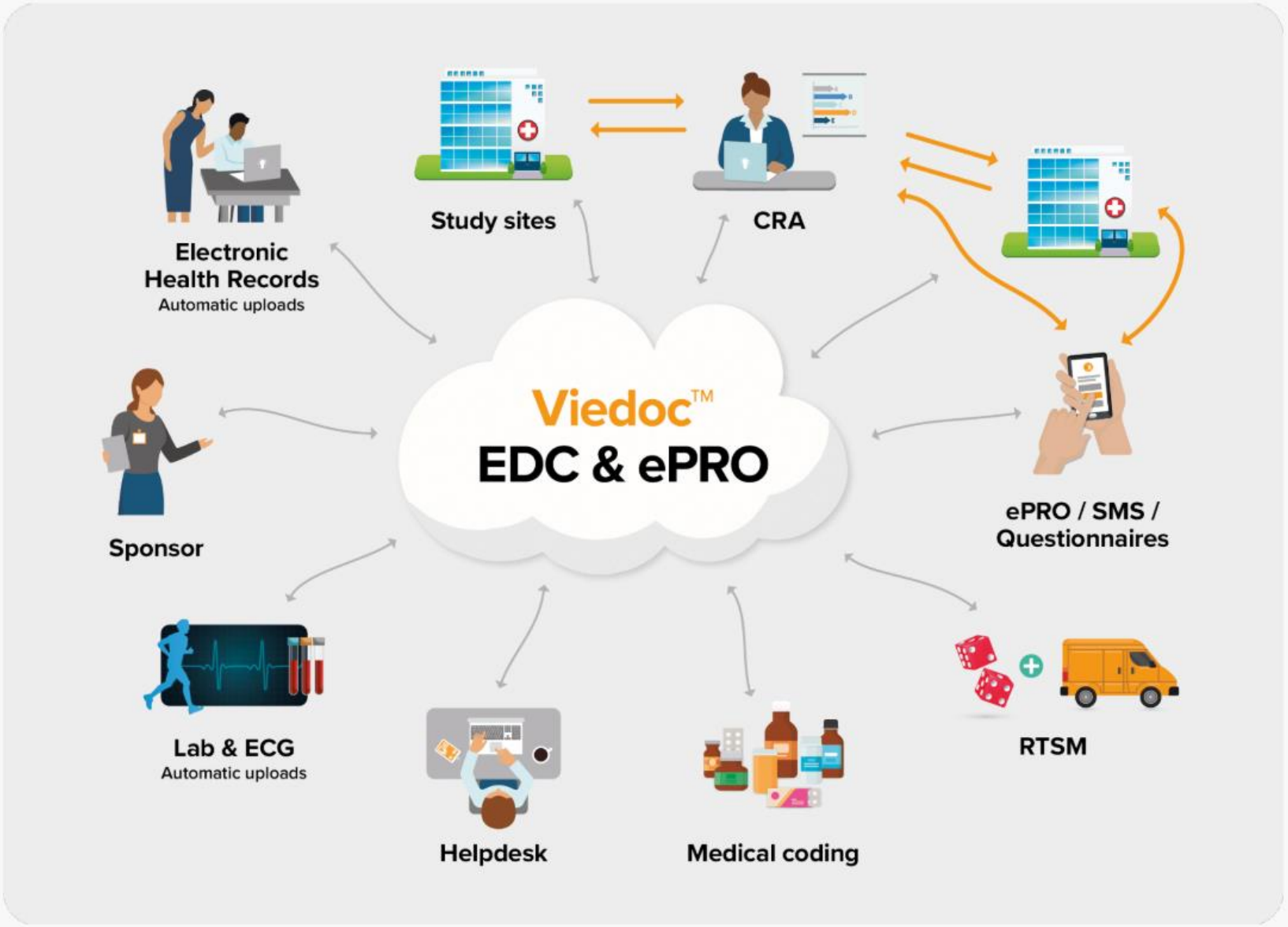
Bruk av Viedoc internasjonalt



Bruk av Viedoc gjennom rammeavtalen:

OUS : over 120 studier pågående og nærmere 6000 brukere i systemet

Andre USS: 32 studier


Electronic
Health Records
Automatic uploads
Study sites
CRA
Viedoc™
EDC & ePRO
Sponsor
ePRO / SMS /
Questionnaires
Lab & ECG
Automatic uploads
Helpdesk
Medical coding
RTSM

Viedoc

Inspection-ready

Full documentation that meets inspection requirements, updated with every release.

Future-proof

New updates are released regularly, all backward-compatible. No additional system validation is required for new releases.

The essentials

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

The addons

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

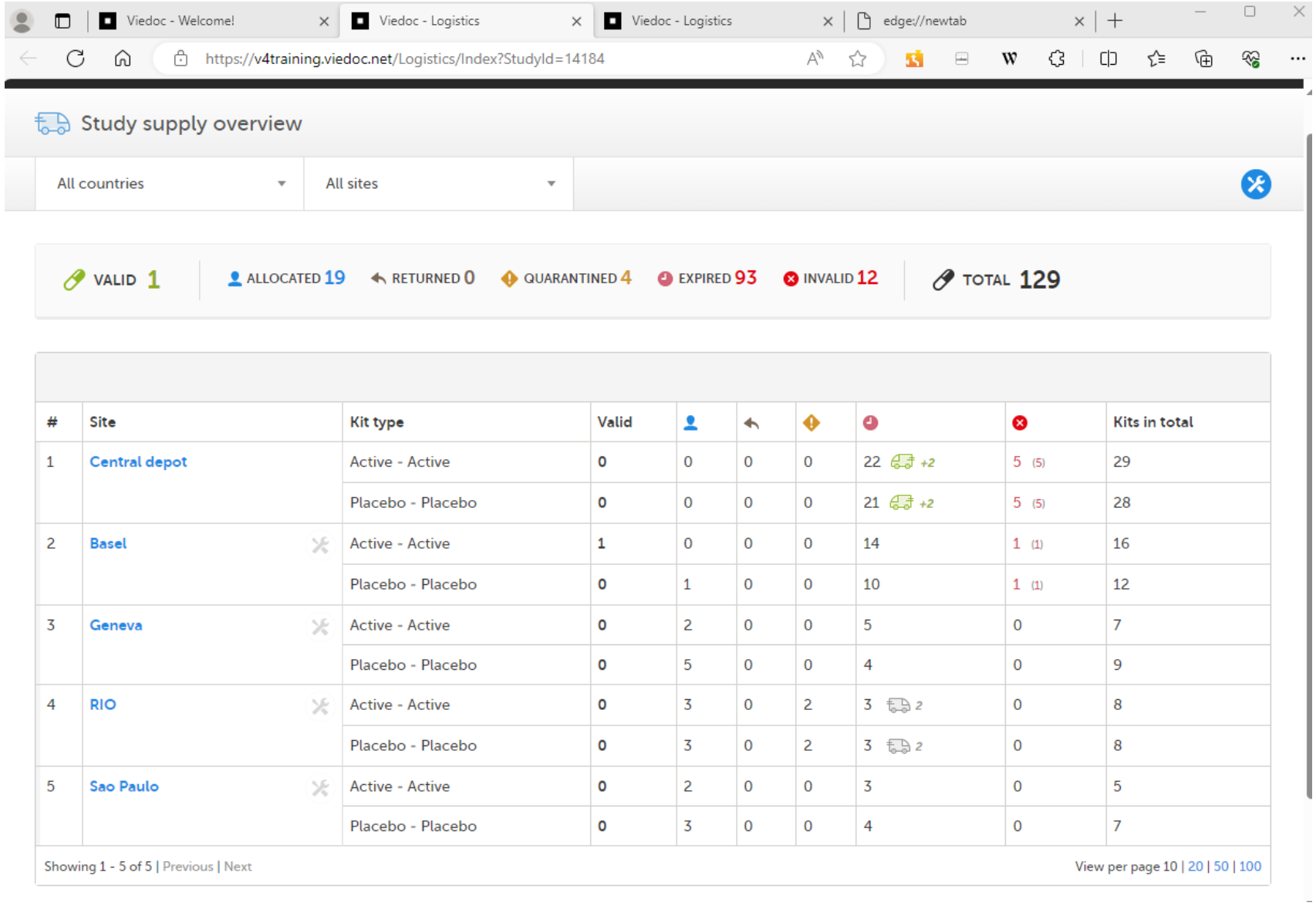
Secure

All data is safeguarded using high-level security measures, including robust backup systems, advanced data encryption, and audit trails of all activity.

Viktig funksjonalitet man bør se om det er behov for i hver enkelt studie

https://v4.viedoc.net/
https://v4idptraining.viedoc.net/
https://www.viedoc.com/

Drug logistics



#	Site	Kit type	Valid						Kits in total
1	Central depot	Active - Active	0	0	0	0	22 +2	5 (5)	29
		Placebo - Placebo	0	0	0	0	21 +2	5 (5)	28
2	Basel	Active - Active	1	0	0	0	14	1 (1)	16
		Placebo - Placebo	0	1	0	0	10	1 (1)	12
3	Geneva	Active - Active	0	2	0	0	5	0	7
		Placebo - Placebo	0	5	0	0	4	0	9
4	RIO	Active - Active	0	3	0	2	3 2	0	8
		Placebo - Placebo	0	3	0	2	3 2	0	8
5	Sao Paulo	Active - Active	0	2	0	0	3	0	5
		Placebo - Placebo	0	3	0	0	4	0	7

Showing 1 - 5 of 5 | Previous | Next

View per page 10 | 20 | 50 | 100

Essensielle dokumenter

“Essential documents are those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced”.

EMA:Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic)

Essensielle studiedokumenter håndterer elektronisk i **eTMF/ISF**

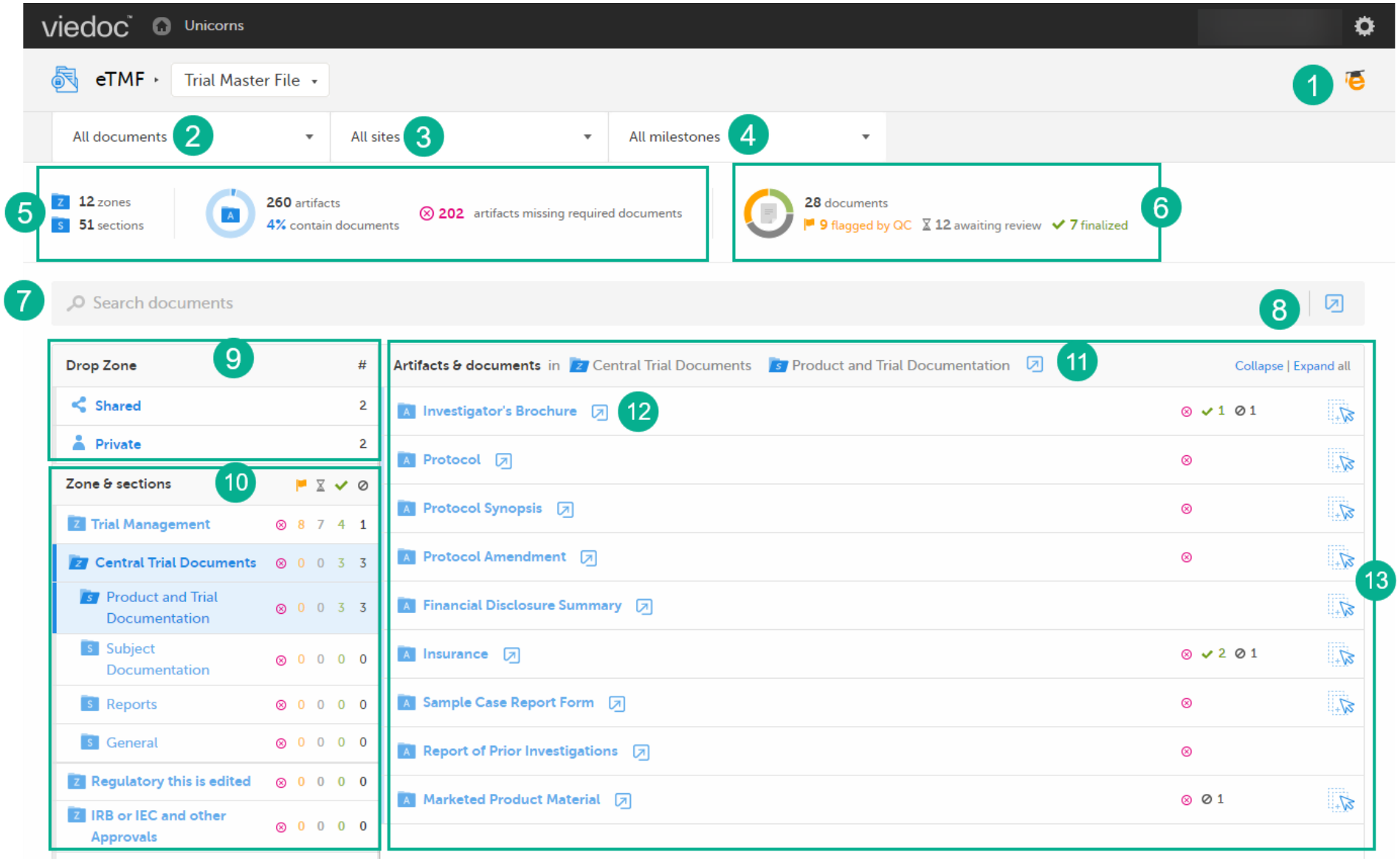
To mulige strukturer

- Trial Master File Reference Model – (a Community Group now part of CDISC) (tmfrefmodel.com)
- NorCRIN TMF og ISF

Viedoc eTMF/ISF tilbakemeldinger

- Det blir mindre dobbeltarkivering
- Datamanagement og statistikk kan legge inn deres dokumentasjon fortløpende under hele studieforløpet.
- Når alle legger inn dokumentene ett sted, så vil TMF/ISF være mye mer oppdatert til enhver tid enn det man har sjanse til med permer spredt på flere steder
- Lettere for monitorene
- Viktig med «Guidelines»
  - Navngiving av filer
  - Hvilke dokumenter skal i hvilke mapper

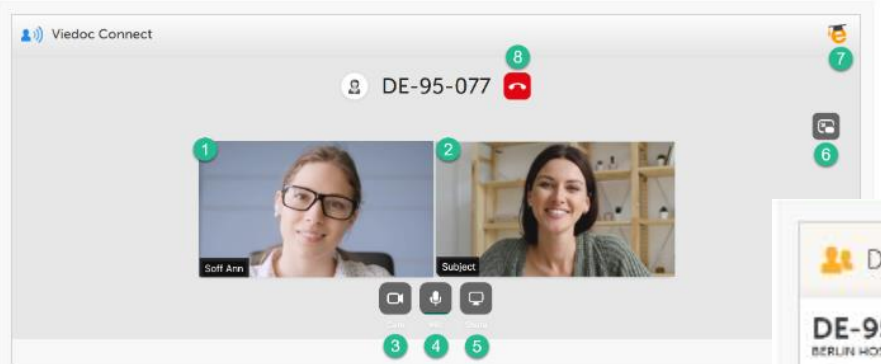
eTMF/ISF

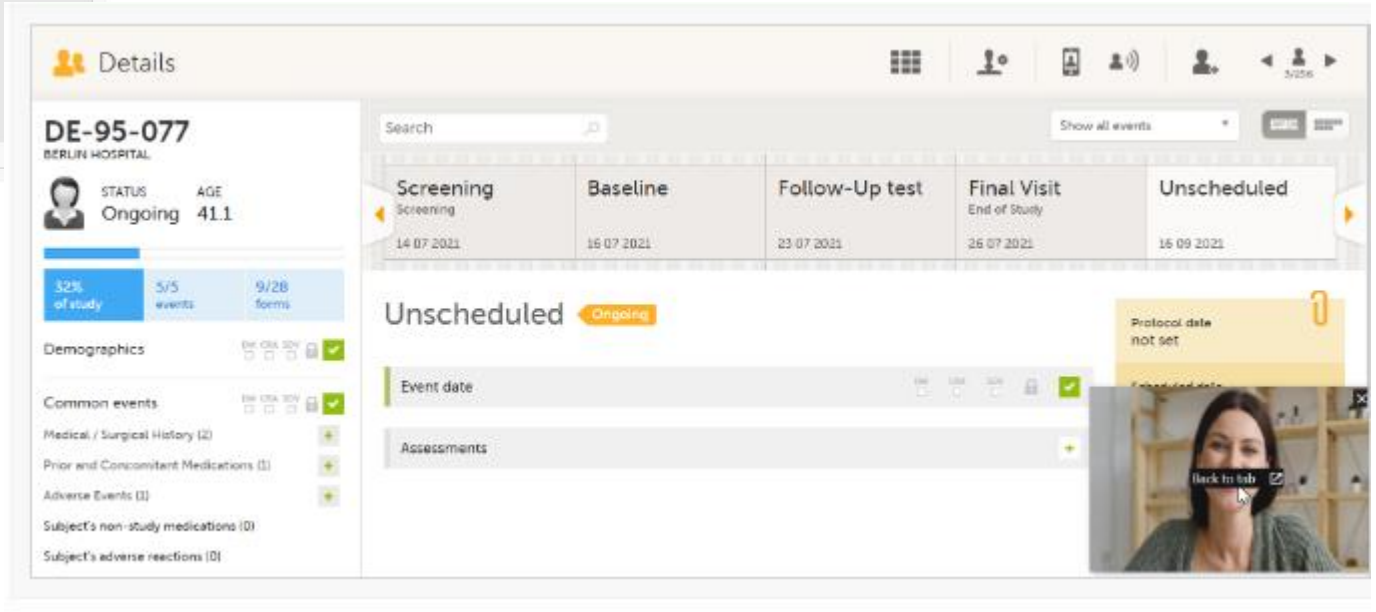

viedoc
Unicorns
eTMF
Trial Master File
1
All documents
2
All sites
3
All milestones
4
5
12 zones
51 sections
260 artifacts
4% contain documents
202 artifacts missing required documents
28 documents
9 flagged by QC
12 awaiting review
7 finalized
6
7
Search documents
8
Drop Zone
9
#
Shared
2
Private
2
Zone & sections
10
Trial Management
Central Trial Documents
Product and Trial Documentation
Subject Documentation
Reports
General
Regulatory this is edited
IRB or IEC and other Approvals
Artifacts & documents in Central Trial Documents
Product and Trial Documentation
11
Collapse | Expand all
Investigator's Brochure
12
Protocol
Protocol Synopsis
Protocol Amendment
Financial Disclosure Summary
Insurance
Sample Case Report Form
Report of Prior Investigations
Marketed Product Material
13

Viedoc Connect

To initiate a call, click the **green** phone icon.

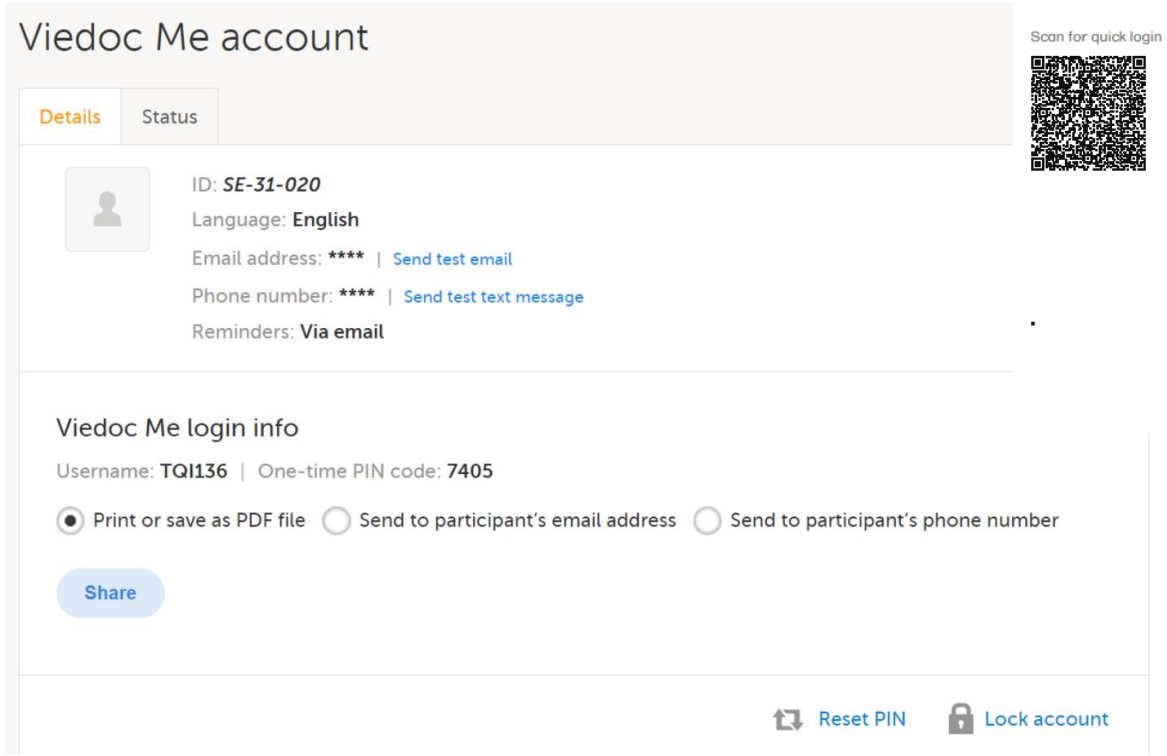
When the subject joins the call, you will see the following view:

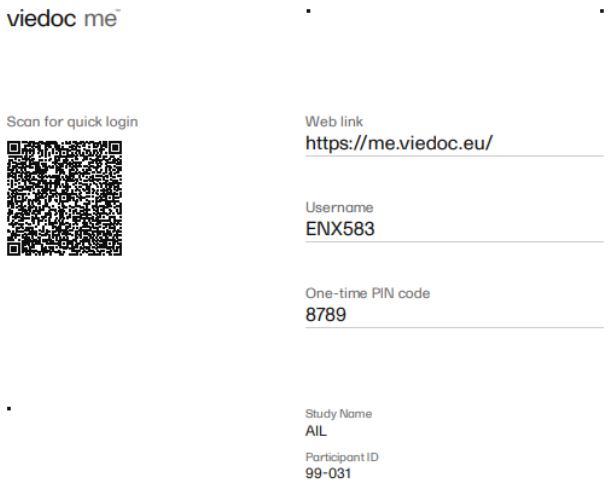


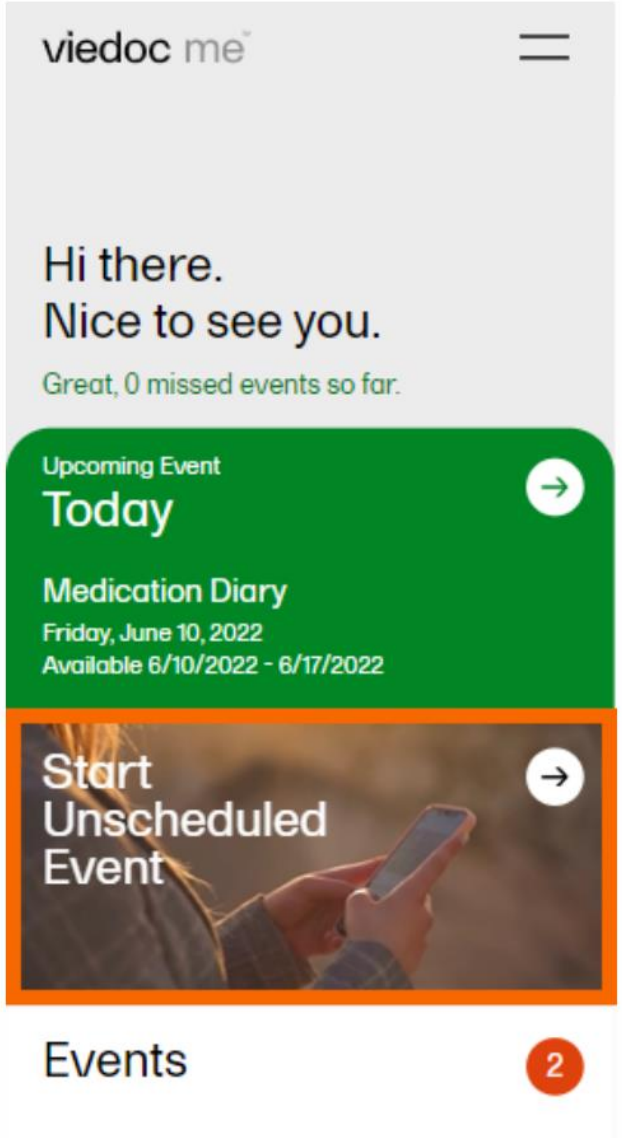


ViedocMe

- Deltaker bruker eget utsyr for å legge inn data
- Data rett inn i eCRF for gjennomsyn og evt beregning av score



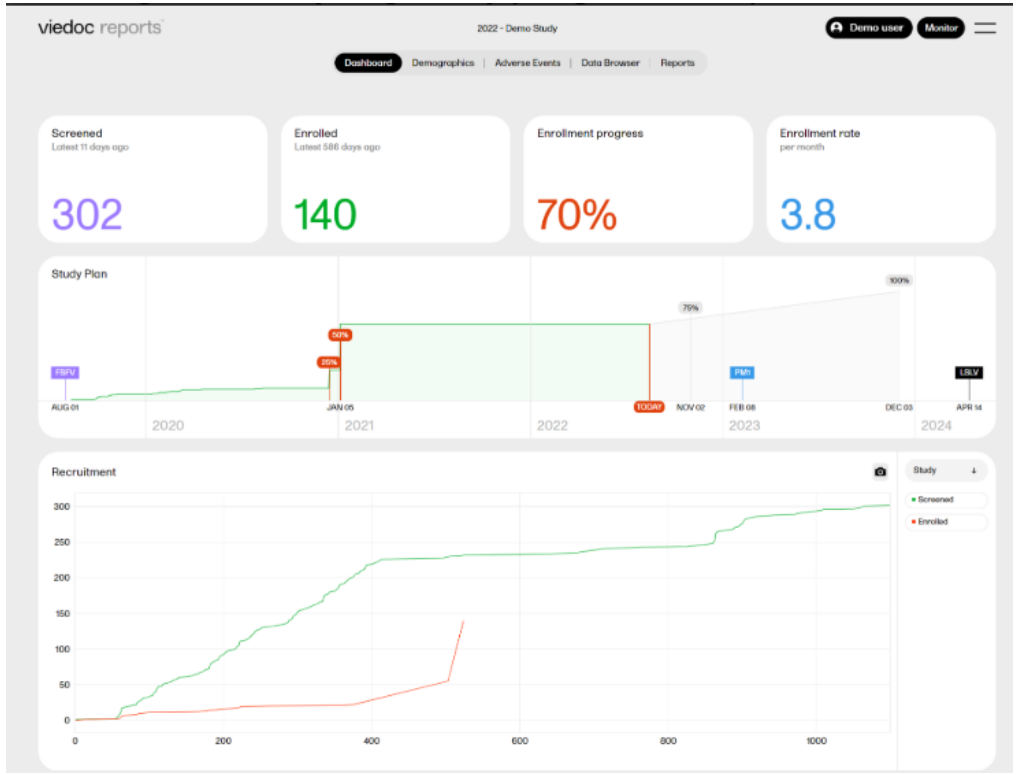


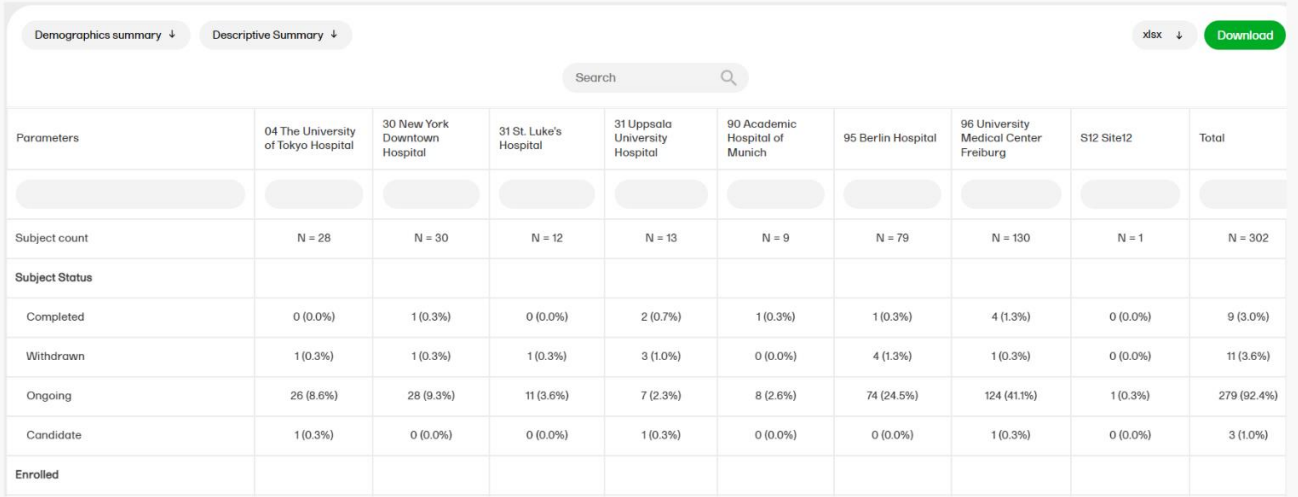


Viedoc Clinic User Guide | Managing Viedoc Me| Viedoc eLearning

Viedoc Clinic User Guide | Using Viedoc Me (information for study participants)| Viedoc eLearning

Viedoc Reports





Parameters	04 The University of Tokyo Hospital	30 New York Downtown Hospital	31 St. Luke's Hospital	31 Uppsala University Hospital	90 Academic Hospital of Munich	95 Berlin Hospital	96 University Medical Center Freiburg	S12 Site12	Total
Subject count	N = 28	N = 30	N = 12	N = 13	N = 9	N = 79	N = 130	N = 1	N = 302
Subject Status									
Completed	0 (0.0%)	1 (0.3%)	0 (0.0%)	2 (0.7%)	1 (0.3%)	1 (0.3%)	4 (1.3%)	0 (0.0%)	9 (3.0%)
Withdrawn	1 (0.3%)	1 (0.3%)	1 (0.3%)	3 (1.0%)	0 (0.0%)	4 (1.3%)	1 (0.3%)	0 (0.0%)	11 (3.6%)
Ongoing	26 (8.6%)	28 (9.3%)	11 (3.6%)	7 (2.3%)	8 (2.6%)	74 (24.5%)	124 (41.1%)	1 (0.3%)	279 (92.4%)
Candidate	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	3 (1.0%)
Enrolled