



# Introduksjon til Viedoc

Skorpa Nilsen

Pilskog

Mars 2023

# Welcome back Kristian Pilskog!

Access

Studies	Sites
1	0

Account


Last login	3 days ago
Number of logins	6
User level	Rookie
Active since	2023-02-24

Recent activities


Study PMF site TRAINING added to my studies	17 days ago
Password changed	17 days ago

Search

PMF



0% complete



Start new study

Trykk på PMF-ikonet  
Bekreft deretter at du har sett dokumentasjonen

DEMO

The study is currently set to operate in demonstration & training mode. Do not input any real data.

DEMO

## PMF

Randomized controlled trial of fixation versus no fixation of posterior malleolus fractures (PMF) associated with Weber B ankle fractures (PMFIX)

Launch






## 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!

Section	Read & Understood at
 <b>Protokol</b>	<input checked="" type="checkbox"/> Read & Understood
 <b>Viedoc User Guide for Site Users</b> <small>Text based eLearning for site staff.</small>	<input checked="" type="checkbox"/> Read & Understood

Optional sections

No optional documents available.

Access

Studies: 1

Sites: 0

Account

Last login: 17 days ago

Number of logins: 17 days ago

User level:

Active since:

Search

PMF

0% complete

Start new study

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

Bekreft med passord

DEMO The study is currently set to operate in demonstration & training mode. Do not input any real data. DEMO

PMF

Randomized controlled trial of fixation versus no fixation of posterior malleolus fractures (PMF) associated with Weber B ankle fractures (PMFIX)

Launch



## 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!

### Mandatory sections

Section	Read & Understood at
Protokol	✓ 2023-03-13 09:52 UTC
Viedoc User Guide for Site Users Text based eLearning for site staff.	✓ 2023-03-13 09:54 UTC

Confirm 'Read & Understood'

### Optional sections

No optional documents available.

# Welcome back Kristian Pilskog!

### Access

Studies	Sites
1	0

### Account

Last login	3 days ago
Number of logins	6
User level	Rookie
Active since	2023-02-24

### Recent activities

Study PMF site TRAINING added to my studies	17 days ago
Password changed	17 days ago

Search

PMF

0% complete

Start new study

Trykk «Launch» for å komme inn til pasientene i studien og for å legge til ny pasient

DEMO

The study is currently set to operate in demonstration & training mode. Do not input any real data.

DEMO

## PMF

Randomized controlled trial of fixation versus no fixation of posterior malleolus fractures (PMF) associated with Weber B ankle fractures (PMFIX)

Launch



## Documentation & Training

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### Mandatory sections

Section	Read & Understood at
<b>Protokol</b>	<input checked="" type="checkbox"/> Read & Understood
<b>Viedoc User Guide for Site Users</b> Text based eLearning for site staff.	<input checked="" type="checkbox"/> Read & Understood

### Optional sections

No optional documents available.

DEMO

The study is currently set to operate in demonstration & training mode. Do not input any real data.

DEMO

Selection ▾ Cards ▾

Search

FOUND 9 CARDS.



TRAINING ▾

Sort by added date ▾

99-009

TRAINING  
INIT AGE  
DEMO HJK 42

99-008

TRAINING  
INIT AGE  
DEMO DRF 33

99-007

TRAINING  
INIT AGE  
DEMO KOY 43

99-006

TRAINING  
INIT AGE  
DEMO HHH 32

99-005

TRAINING  
INIT AGE  
DEMO AAA 52

99-004

TRAINING  
INIT AGE  
DEMO QQQ 43

99-003


TRAINING  
INIT AGE  
DEMO WWW 62

99-002

TRAINING  
INIT AGE  
DEMO

99-001

TRAINING  
INIT AGE  
DEMO WWW 33

  
Add new card



Her ser dere alle inkluderte pasienter.  
99 = site/sykehus

Klikk på siluetten oppe til høyre eller  
«Add new card» for å legge til ny pasient

DEMO  
Details

99-010  
TRAINING  
INIT DJU AGE 28

0% of study 0/1 events 0/2 forms

Patient information  
Common events  
Protocol deviation / Note to file (0)

Add new event

Form is in view mode. Click 'Edit' to make it editable

### Patient information

DM CRA SDV

SHOW HISTORY 1

Format initials: ABC. If no middle name, format: A-C

Date of Informed Consent

13 Mar 2023

Patient Initials

DJU

Sex

Male  Female

Year of birth

27 Jun 1994

Age

28 years

Date of admission

13 Mar 2023

Date of injury

13 Mar 2023

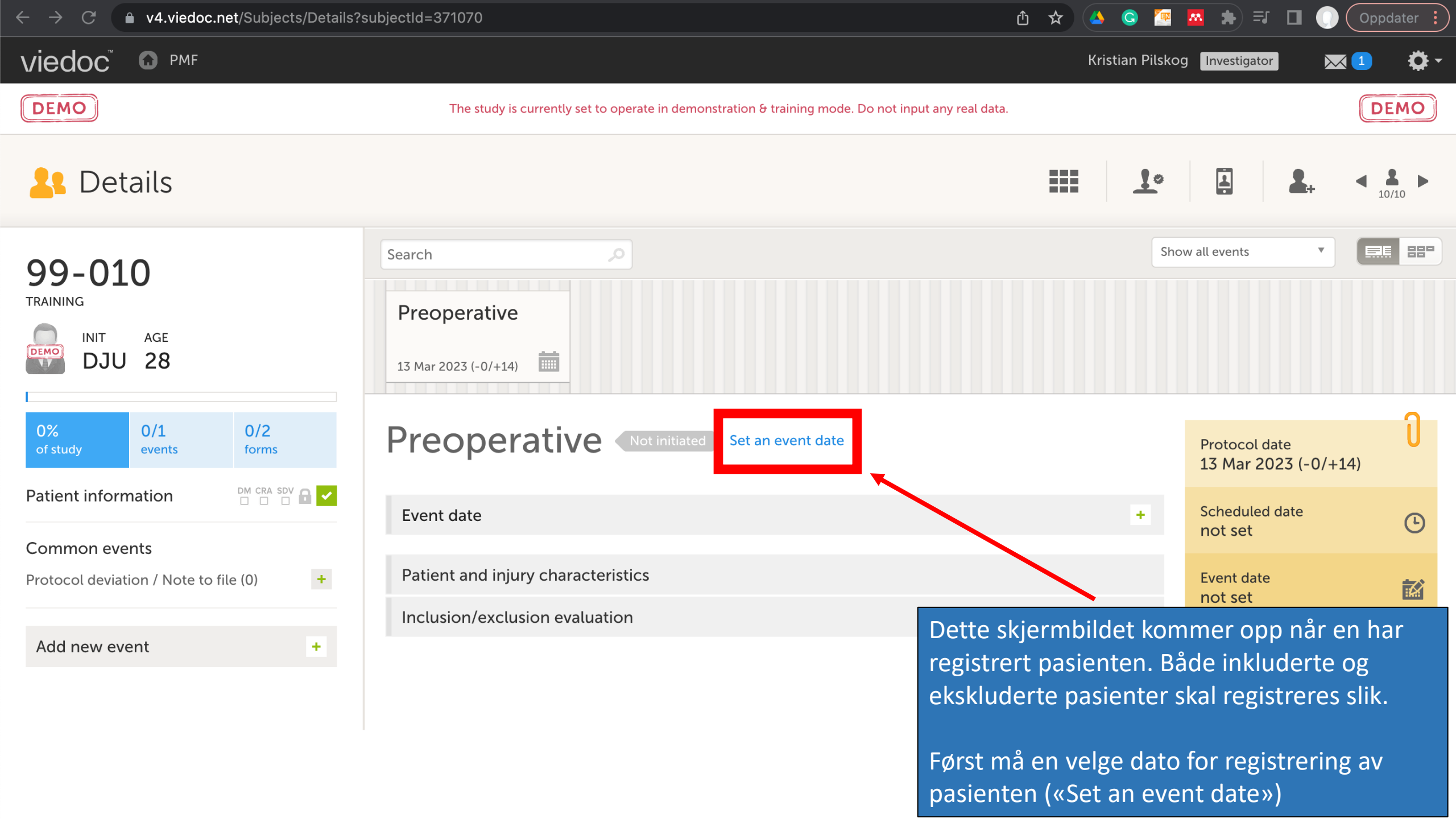
Injured side

Righth  Left

Dato kan velges enten ved å trykke på pilen eller kalender-ikonet  
Det må brukes tre initialer, husk blokkbokstaver.

Form History





DEMO

The study is currently set to operate in demonstration & training mode. Do not input any real data.

DEMO

## Details

# 99-010

TRAINING

INIT AGE  
DJU 28

0% of study | 0/1 events | 0/2 forms

Patient information DM CRA SDV

Common events  
Protocol deviation / Note to file (0) +

Add new event +

Search

Show all events

Preoperative  
13 Mar 2023 (-0/+14)

Preoperative Not initiated Set an event date

Event date +

Patient and injury characteristics

Inclusion/exclusion evaluation

Protocol date  
13 Mar 2023 (-0/+14)

Scheduled date  
not set

Event date  
not set

Dette skjermbildet kommer opp når en har registrert pasienten. Både inkluderte og ekskluderte pasienter skal registreres slik.

Først må en velge dato for registrering av pasienten («Set an event date»)

DEMO

Details

99-010  
TRAINING  
INIT AGE  
DJU 28

0% of study  
0/1 events  
0/2 forms

Patient information DM CRA SDV

Common events  
Protocol deviation / Note to file (0)

Add new event

### Preoperative

DM CRA SDV NO CHANGES

Protocol date  
13 Mar 2023- 27 Mar 2023 13 Mar 2023(-0/+14)

Plan event **Initiate event**

Kristian Pilskog | Viedoc™ 4.74.8454.15866 | 2023-03-13T13:36 CET  
200123 | 5.1 | PMF | TRAINING

DEMO

Show all events

Protocol date  
13 Mar 2023 (-0/+14)

Scheduled date  
not set

Dato for Preoperative vurdering skal registreres.  
Bruk «Initiate event»





99-010

Preoperative

Save changes

Close

## Preoperative

DM  CRA  SDV  

NO CHANGES

Protocol date

13 Mar 2023- 27 Mar 2023

13 Mar 2023(-0/+14)

Event date

13 Mar 2023



Dato er nå registrert,  
Trykk «Save changes» og gå videre

DEMO

The study is currently set to operate in demonstration & training mode. Do not input any real data.

DEMO

# Details

10/10

## 99-010

TRAINING

INIT AGE  
DEMO **DJU** **28**

0% of study
1/1 events
0/2 forms

Patient information
 DM CRA SDV 🔒 ✅

### Common events

Protocol deviation / Note to file (0) +

Add new event +

Search

Show all events

**Preoperative**  
 13 Mar 2023

## Preoperative Ongoing

Event date
 DM CRA SDV 🔒 ✅

Patient and injury characteristics +

Inclusion/exclusion evaluation +

📎  
 Protocol date  
 13 Mar 2023 (-0/+14)

🕒  
 Scheduled date  
 not set

📅  
 Event date  
 13 Mar 2023

Vi er nå klar til å registrere Pasient og skade karakteristika samt vurdere inklusjon/eksklusjonskriteriene.

DEMO

Details

99-010

TRAINING  
INIT AGE  
DJU 28

0% of study 1/1 events 0/2 forms

Patient information

Common events

Protocol deviation / Note to file (0)

Add new event

### Patient and injury characteristics

Mechanism of injury

- Tripped on flat ground
- Slipped on icy/wet surface
- Fell <50 cm
- Fell >50 cm
- Fell over >1m
- Motor vehicle accident
- Other

Former injury in same ankle

- Yes  No

#### X-RAY

Number of malleoli

- Medial  Lateral  Posterior

Dislocation fracture

- Yes  No  Not sure

PMF size on lateral radiographs, as percent of A-P

#### CT

Area of PMF on CT *i*

- Yes  No, will be measured later

Mason & Molloy classificaton

- 2A  2B

Flere kryss er tillat mtp. Antall malleoler.  
 Areal av PMF ift tibiaplafonden utføres av leger på Haukeland, med mindre opplæring er gitt til lokal koordinator.

DEMO

## Details

# 99-010

TRAINING

INIT AGE  
DJU 28

0% of study 1/1 events 0/2 forms

Patient information

Common events

Protocol deviation / Note to file (0)

Add new event

### CT

Area of PMF on CT  Yes  No, will be measured later

Mason & Molloy classificaton  2A  2B

Step off (posterior malleolus)  
Negative = PM distal, Positive= PM cranial  mm

Osteochondral impaction anterior to PM  Yes  No

Percent notch involvement of posterior malleolus, axial view  %

Soft tissue problem  Yes  No

### Medical history

Diabetes mellitus  No  Yes

Peripheral arterial disease  No  Yes, known angiopathy  Yes, poor pulses on clinical examination  Yes, plantar bleaching by elevation test

Ved å «Yes» på «Soft tissue problems» kommer ny bokser frem mtp typen bløtdelsproble og når de oppstod.

Protocol date  
13 Mar 2023 (-0/+14)

13 Mar 2023

DEMO

Details

99-010  
TRAINING  
INIT AGE  
DJU 28

50% of study 1/1 events 1/2 forms

Patient information

Common events  
Protocol deviation / Note to file (0)

Add new event

# Inclusion/exclusion evaluation

## Inclusion Criteria

- 1. Posterior malleolar (PM) fracture, of Mason & Molly type 2A/2B, associated with Weber B lateral malleolar fracture, and/or medial malleolar fracture  Yes  No
- 2. Patients informed, written consent  Yes  No
- 3. Age 18-65 years  Yes  No
- 4. Measurements are performed 5 millimeter (mm) cranial to the tibia plafond  Yes  No
- 5. Posterior malleolus fractures involving less than 40% of the fibular notch are included. See Figure 2 in study protocol for illustration of measurements.  Yes  No

Alle bokser må krysses av for å kunne gjøre ferdig dette skjemaet.

## Exclusion Criteria

- 1. Non-compliant patient, i.e.: dementia, alcohol- or substance abuse  Yes  No
- 2. Known congenital bone disease  Yes  No
- 3. Pathological fractures  Yes  No
- 4. Immunocompromised patients  Yes  No
- 5. Tourists or patients on a short-term work/study permit  Yes  No

DEMO

10/10

How all events

Protocol date  
13 Mar 2023 (-0/+14)

Scheduled date  
not set

Event date  
13 Mar 2023

DEMO

# Details

## 99-010

TRAINING

INIT DJU AGE 28

50% of study 1/1 events 1/2 forms

### Patient information

### Common events

Protocol deviation / Note to file (0)

Add new event

- 5. Tourists or patients on a short-term work/study permit  Yes  No
- 6. Previous fracture of the ipsilateral ankle or ipsilateral lower extremity with a resulting dysfunction  Yes  No
- 7. Poor controlled diabetes  Yes  No
- 8. Patients with known arterial insufficiency  Yes  No
- 9. Open fractures  Yes  No
- 10. Severely traumatized patients (ISS>16)  Yes  No
- 11. Patient declined inclusion to participate in study  Yes  No

Are all inclusion criteria and none of the exclusion criteria fulfilled?  Yes  No

Inclusion date

- Event date
- Current date
- Yesterday
- Day not known

Kommer til syne når alle kriterier er kryssset ut.



# Details

## 99-010

TRAINING  
INIT AGE  
DJU 28

3% of study | 1/13 events | 2/66 forms

Patient information  DM  CRA  SDV  Lock

Common events  
Protocol deviation / Note to file (0) +

Add new event +

Search  Show all events

Preoperative	VieDocMe Pre	Postoperative	Week6	VieDocMe W6	Week12
13 Mar 2023	13 Mar 2023 (-7/+2)	14 Mar 2023 (-0/+14)	25 Apr 2023 (+7)	25 Apr 2023 (+7)	12 Jun 2023 (+7)

### Preoperative Ongoing

- Event date  DM  CRA  SDV  Lock
- Patient and injury characteristics  DM  CRA  SDV  Lock
- Inclusion/exclusion evaluation  DM  CRA  SDV  Lock

- Demographics\_SVAR +
- Health Questionnaire EQ-5D-5L\_SVAR +
- Self-Reported Foot and Ankle Score (SEFAS)\_SVAR
- Anchor questions\_SVAR +
- Randomization +**

Protocol date 13 Mar 2023 (-0/+14)

Scheduled date not set

Event date 13 Mar 2023

Da er en klar til randomisering

# Details

## 99-010

TRAINING  
INIT AGE  
DJU 28

4% of study  
1/13 events  
3/66 forms

Patient information

Common events

Protocol deviation / Note to file (0)

Add new event

DEMO 99-010 Preoperative [13 Mar 2023] Close

Form is in read-only mode.

### Randomization

Please press the randomization button

Site	Randomization date	Randomization time
99	13 Mar 2023	13:49

The patient is randomized to:

No fixation of PMF

Fixation of PMF

Dato og tidspunkt settes automatisk. En trykker på «Randomize» og deretter kommer bildet vi nå ser frem. Pasienten er her randomiser til ingen fiksasjon av PMF (se rammen)

Kristian Pilskog | Viedoc™ 4.74.8454.15866 | 2023-03-13T13:49 CET  
200123 | 5.1 | PMF | TRAINING

- Health Questionnaire EQ-5D-5L\_SVAR
- Self-Reported Foot and Ankle Score (SEFAS)\_SVAR
- Anchor questions\_SVAR
- Randomization

# Details

## 99-010

TRAINING  
INIT AGE  
DJU 28

4% of study | 1/13 events | 3/66 forms

Patient information  DM  CRA  SDV

Common events  
Protocol deviation / Note to file (0) +

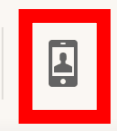
Add new event +

Preoperative 13 Mar 2023	VieDocMe Pre 13 Mar 2023 (-7/+2)	Postoperative 14 Mar 2023 (-0/+14)	Week6 25 Apr 2023 (±7)	VieDocMe W6 25 Apr 2023 (±7)	Week12 12 Jun 2023 (±7)
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### VieDocMe Pre Not initiated

- Event date
  - Demographics
  - Self-Reported Foot and Ankle Score (SEFAS)
  - Health Questionnaire EQ-5D-5L
  - Anchor questions
- Protocol date  
13 Mar 2023 (-7/+2)

Scheduled date  
not set



Etter Inklusjon og randomisering skal pas. fylle ut preoperativ informasjon om seg selv samt svare på PROM. Dette gjøres enten på pasientens mobil eller via PC.

Denne applikasjonen kalles ViedocMe og aktiveres ved å trykke på mobiltelefonen opp til høyre (se ramme)

# Details

## 99-010

TRAINING  
INIT AGE  
DJU 28

4% of study | 1/13 events | 3/66 forms

Patient information

Common events

Protocol deviation / Note to file (0)

Add new event

DEMO 99-010

Activate account

Close

### Activate ViedocMe account

Language displayed to the subject

Norwegian (Bokmål)

Subject email address

Send reminders to this e-mail address

Subject phone number

+4798217343

Send reminders to this phone number

Kristian Pilskog | Viedoc™ 4.74.8454.15866 | 2023-03-13T13:51 CET  
200123 | PMF | TRAINING

Fyll inn riktig mobilnummer, hak av for å sende påminnelser til dette nummeret. Trykk deretter på «Activate account»

Health Questionnaire EQ-5D-5L

Anchor questions

Oppdater

10/10

DocMe W6 | Week12

12 Jun 2023 (±7)

Protocol date 13 Mar 2023 (-7/+2)

Scheduled date not set

# Details

## 99-010

TRAINING  
INIT AGE  
DJU 28

4% of study 1/13 events 3/66 forms

Patient information

Common events

Protocol deviation / Note to file (0)

Add new event

DEMO 99-010

Close

### ViedocMe account

Details Status

User name

EHD866

PIN code

9306

Language displayed to the subject

Norwegian (Bokmål)

Subject email address

Send reminders to this e-mail address

Subject phone number

\*\*\*\*

Send reminders to this phone number

[Send test text message](#)

[Print login info](#)

[Reset PIN](#)




[Lock account](#)

Trykk ev. «Send test text message» om pas. ikke har fått sms med link til ViedocMe.

Hjelp pasienten med å huske brukernavn og pinkode. Trykk «Print login info» for å åpne et eget vindu med link til ViedocMe og brukernavn/pin (se neste slide).



---

	<a href="https://me.viedoc.eu/">https://me.viedoc.eu/</a>
	EHD866
	9306
	PMF 99-010

Dette PDF-skjemaet lastes ned når en trykker «Print login info». Det kan skrives ut til pasienten eller det kan tas et skjermbilde.

Legg merke til pasientnummeret nederst (99 = studiested, 010 = nummer til pas. på det studiestedet).



13:52

This message is sent from Viedoc to confirm your contact information. Click the following link to login to ViedocMe: <https://me.viedoc.eu/>



Trykk for å laste inn forhåndsvisningen



13:52

Slik ser SMSen fra ViedocMe ut.

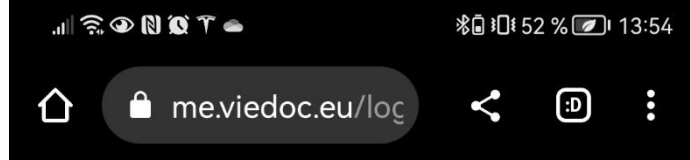
Trykk på linken for å komme til siden hvor pas. skal fylle ut PROM og informasjon om seg selv.

En slik SMS vil pas. få ved Preoperative, 6 uker, 12 uker, 1 år, 2 år, og 5 år postop.

Kan ikke svare til dette  
spesialnummeret

Finn ut mer





viedoc me™

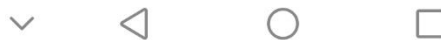
Velkommen.  
Flott å se deg  
her.

Brukernavn

PIN-kode

Logg inn

viedoc™



Dette er førstesiden i ViedocMe for login.

Bruk det brukernavn og pin som er angitt tidligere.



Trykk på det grønne feltet for å komme i gang med registrering.

me.viedoc.eu/ev

viedoc me™

Demographics 1/3

Høyde (cm)

Vekt (kg)

→

viedoc™

Trykk på den grønne pilen for å komme videre. All info må fylles ut for å kunne trykke på grønn pil.



### Røyker du nå?

Ja    Nei

### Yrke/stilling

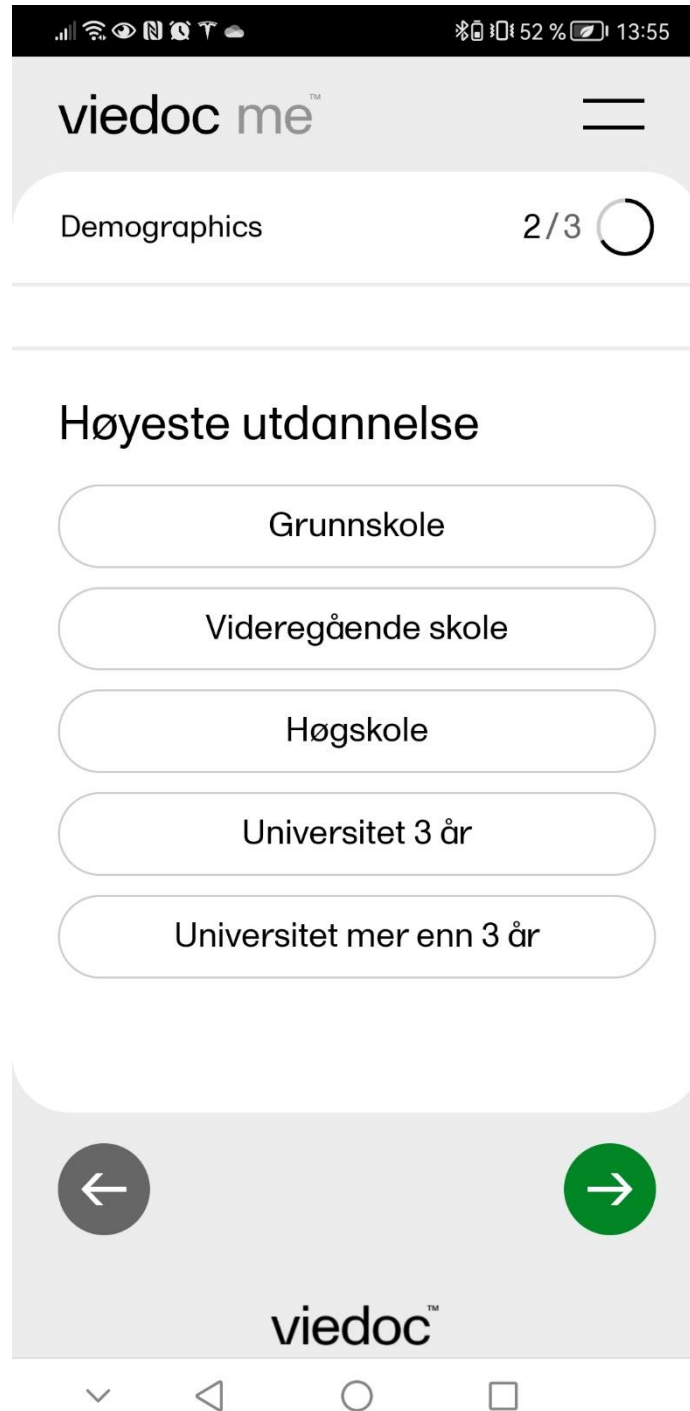
Student

Fulltidsansatt

AAP

Uføretrygd

Pensjon

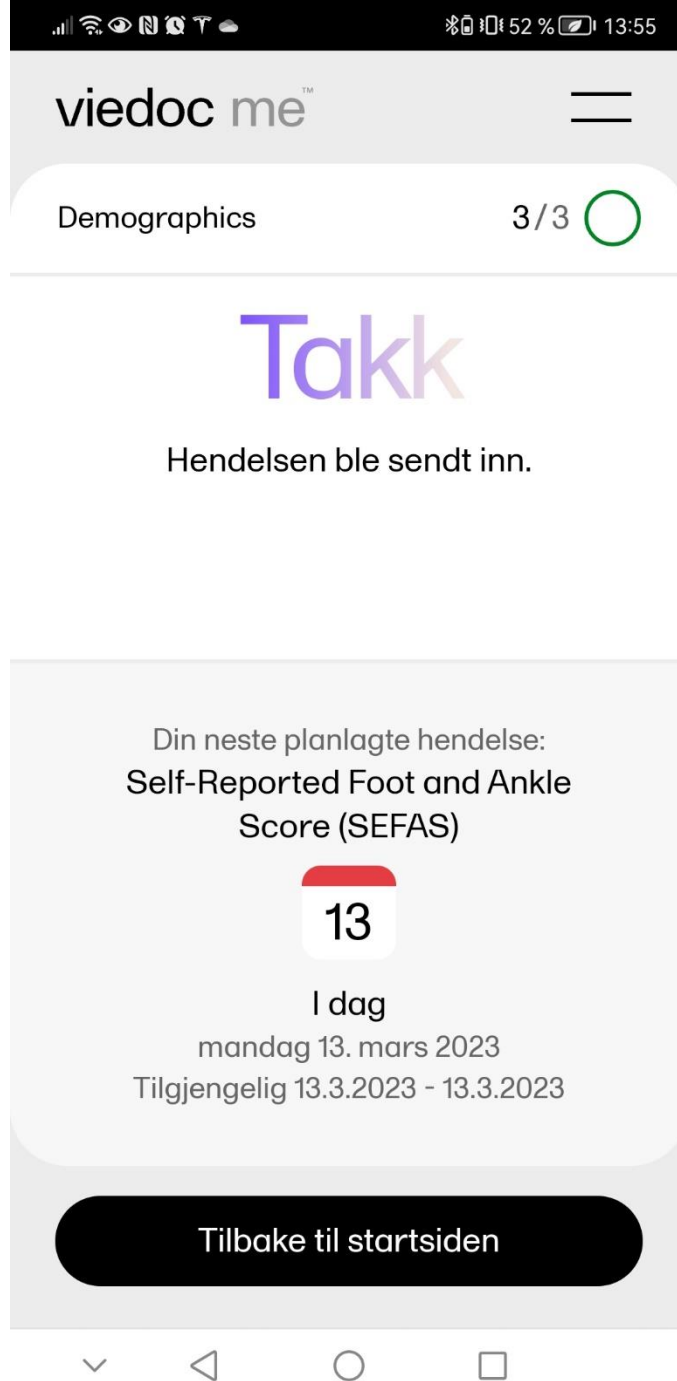


Trykk på den grønne pilen for å komme videre. All info må fylles ut for å kunne trykke på grønn pil.

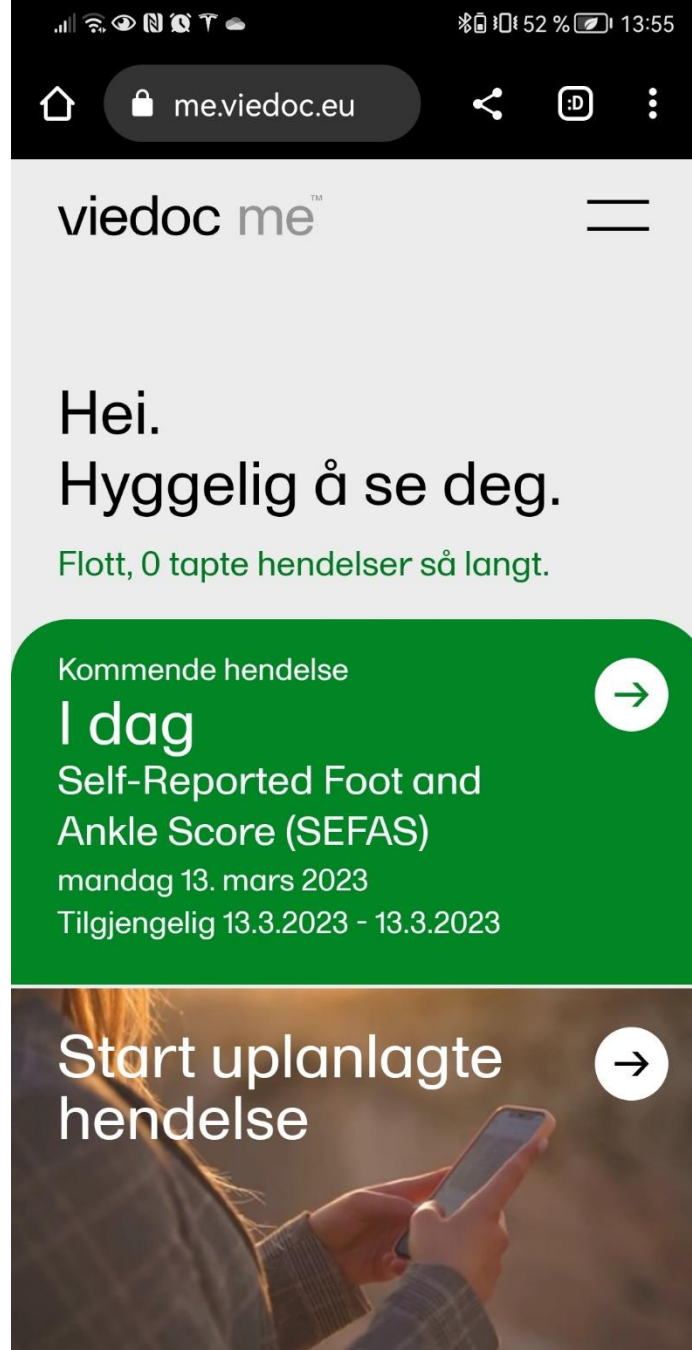




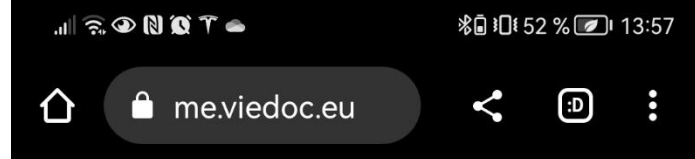
Trykk på den grønne boksen for å komme videre.



Trykk på den svarte boksen for å komme tilbake til startside og for å kunne trykke deg inn på SEFAS-skjemaet. Dette kan være vanskelig å forstå i begynnelsen, lurt å hjelpe pas. med denne rekkefølgen.



Trykk på det grønne feltet for å komme videre.  
Fyll ut skjema og returner til startside  
igjen for å ta resterende skjema:  
- EQ-5D  
- Anchor questions



viedoc me™



Hei.  
Hyggelig å se deg.

Flott, 0 tapte hendelser så langt. 100 % samsvar.

Kommende hendelse

tirsdag 25. april

Self-Reported Foot and Ankle  
Score (SEFAS)

Tilgjengelig 18.4.2023 - 2.5.2023

Start uplanlagte  
hendelse



Etter at en har fylt ut alle skjema for den aktuelle datoen/kontakten kommer en tilbake til denne startside.

Legg merke til at SEFAS-feltet nå er hvitt og dato for tilgjengelighet er angitt. Feltet blir grønt når det er tilgjengelig.



# Details

## 99-010

TRAINING  
INIT AGE  
DJU 28

10% of study | 2/13 events | 7/66 forms

Patient information DM CRA SDV

Common events  
Protocol deviation / Note to file (0) +

Add new event +

Preoperative	VieDocMe Pre	Postoperative	Week6	VieDocMe W6	Week12
13 Mar 2023	13 Mar 2023 <input type="checkbox"/> <input checked="" type="checkbox"/>	14 Mar 2023 (-0/+14) <input type="checkbox"/>	25 Apr 2023 (±7) <input type="checkbox"/>	25 Apr 2023 (±7) <input type="checkbox"/>	12 Jun 2023 (±7) <input type="checkbox"/>

### VieDocMe Pre Ready

Event date	DM <input type="checkbox"/>	CRA <input type="checkbox"/>	SDV <input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Demographics	DM <input type="checkbox"/>	CRA <input type="checkbox"/>	SDV <input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Self-Reported Foot and Ankle Score (SEFAS)	DM <input type="checkbox"/>	CRA <input type="checkbox"/>	SDV <input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Health Questionnaire EQ-5D-5L	DM <input type="checkbox"/>	CRA <input type="checkbox"/>	SDV <input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Anchor questions	DM <input type="checkbox"/>	CRA <input type="checkbox"/>	SDV <input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Protocol date  
13 Mar 2023 (-7/+2)

Scheduled date  
not set

Event date  
13 Mar 2023

Slik ser det ut når alt er klart mtp ViedocMe.

DEMO

The study is currently set to operate in demonstration & training mode. Do not input any real data.

DEMO

# Details

1/10

# 99-010

TRAINING

INIT AGE  
DEMO **DJU** **28**

16% of study
3/13 events
11/66 forms

Patient information
 DM CRA SDV 🔒 ✅

## Common events

Protocol deviation / Note to file (0) +

Add new event +

Search	Show all events				
Preoperative	VieDocMe Pre	Postoperative	Week6	VieDocMe W6	Week12
13 Mar 2023	13 Mar 2023 <span>🔒</span> <span>✅</span>	13 Mar 2023 <span>✅</span>	24 Apr 2023 (±7) <span>📅</span>	24 Apr 2023 (±7) <span>📅</span>	11 Jun 2023 (±7)

# Postoperative Ready

Event date	DM	CRA	SDV	🔒	✅
Clinical Examination and complications	DM	CRA	SDV	🔒	✅
Patient and injury characteristics	DM	CRA	SDV	🔒	✅
Treatment summary	DM	CRA	SDV	🔒	✅
Summary at discharge					

📎  
 Protocol date  
 14 Mar 2023 (-0/+14)

🕒  
 Scheduled date  
 not set

📅  
 Event date  
 13 Mar 2023

Etter operasjonen brukes «Postoperative». Det kan gjøres delvis rett etter operasjon, men noe informasjon har en ikke før selve utskrivelsen.

DEMO

Details

99-010  
TRAINING  
INIT AGE  
DEMO DJU 28

10% of study 2/13 events 7/66 forms

Patient information DM CRA SDV

Common events  
Protocol deviation / Note to file (0)

Add new event

### Postoperative

DM CRA SDV

SHOW HISTORY 0

Protocol date  
14 Mar 2023- 28 Mar 2023 14 Mar 2023(-0/+14)

Event date  
13 Mar 2023

? Event date same day as admission and operation **Awaits approval**

Kristian Pilskog | Viedoc™ 4.74.8454.15866 | 2023-03-13T14:15 CET  
200123 | 5.1 | PMF | TRAINING

DEMO

Show all events

VieDocMe W6 Week12  
25 Apr 2023 (+7) 12 Jun 2023 (+7)

Protocol date  
14 Mar 2023 (-0/+14)  
Scheduled date  
not set  
Event date  
not set

Patient and injury characteristics  
Treatment summary  
Summary at discharge

Her er Postoperative aktivert samme dag som Admission og operasjonsdato, dermed må en godkjenne med tekst at det er «riktig» dato –utenfor «Protocol date» (boksen over).

DEMO

Details

99-010

TRAINING  
INIT AGE  
DJU 28

16% of study 3/13 events 11/66 forms

Patient information

Common events

Protocol deviation / Note to file (0)

Add new event +

Form is in view mode. Click 'Edit' to make it editable

# Clinical Examination and complications

DM CRA SDV [lock] [check]

SHOW HISTORY 1

Nerve injury?  Yes  No

Complications  
Any complications?  Yes  No

Form History

Kristian Pilskog | Viedoc™ 4.74.8454.15866 | 2023-03-13T14:29 CET  
200123 | 5.1 | PMF | TRAINING

- Patient and injury characteristics [DM] [CRA] [SDV] [lock] [check]
- Treatment summary [DM] [CRA] [SDV] [lock] [check]
- Summary at discharge [DM] [CRA] [SDV] [lock] [check]

DEMO

1/10

Show all events

DocMe W6 Week12

2023 (±7) 11 Jun 2023 (±7)

Protocol date  
14 Mar 2023 (-0/+14)

Scheduled date  
not set

Event date  
13 Mar 2023



DEMO

## Details

# 99-010

TRAINING  
INIT AGE  
DJU 28

12% of study 3/13 events 8/66 forms

Patient information

Common events

Protocol deviation / Note to file (0)

Add new event

## Patient and injury characteristics

### CT

Area of PMF on CT  Yes  No, will be measured later

Step off (posterior malleolus)  
Negative = PM distal, Positive = PM cranial  mm

Syndesmosis width measurement  
Positive value = increased distance  
Negative value = tighter  Yes  No

Soft tissue problem  Yes  No

- Soft tissue status
- Clear blisters
  - Bloody blisters
  - Skin necrosis
  - Subcutaneous degloving
  - Severe swelling
  - Wound dehiscence
  - Wound edge necrosis

Soft tissue problems  At admission

Preoperative

Postoperative

DEMO

10/10

How all events

DocMe W6 Week12

2023 (+7) 11 Jun 2023 (+7)

Protocol date  
14 Mar 2023 (-0/+14)

Scheduled date  
not set

Event date  
13 Mar 2023

### Patient and injury characteristics

#### CT

Area of PMF on CT  Yes  No, will be measured later

Step off (posterior malleolus)  
Negative = PM distal, Positive= PM cranial  mm

**Syndesmosis width measurement**  
Positive value = increased distance  
Negative value= tighter  Yes  No

Trykker en «Yes» på «Syndesmosis width measurement» kommer disse boksene frem.

- Anterior, Injured ankle  mm

- Anterior, Non-injured ankle  mm

- Anterior, Difference  mm

- Middle, Injured ankle  mm

- Middle, Non-injured ankle  mm

- Middle, Difference  mm

- Posterior, Injured ankle  mm

- Posterior, Non-injured ankle  mm

- Posterior, Difference  mm

DEMO Details

99-010 TRAINING  
INIT AGE  
DEMO DJU 28

13% of study 3/13 events 9/66 forms

Patient information

Common events

Protocol deviation / Note to file (0)

Add new event

### Treatment summary

Talar drawer test performed  Posterior luxation of talus  No luxation  Not performed

ASA  1  2  3  4

Posterior malleolus fixed  Yes, Plate  Yes, Screws only  No

Approaches used  
 lateral  medial  posterolateral  posteromedial  medial-posteromedial

Fixation of syndesmosis  
 No fixation  1 screw (3.5 mm)  2 screws (3.5 mm)  Suture button

Flere kryss tillates mtp «Approaches used»

Treatment summary

Summary at discharge

Protocol date  
14 Mar 2023 (-0/+14)

Scheduled date  
not set

Event date  
13 Mar 2023

+ Add new event

+

+

DEMO

### Details

# 99-010

TRAINING  
INIT AGE  
DJU 28

16% of study 3/13 events 11/66 forms

### Patient information

### Common events

Protocol deviation / Note to file (0)

Add new event

Form is in view mode. Click 'Edit' to make it editable

## Summary at discharge

DM CRA SDV [locks]

SHOW HISTORY 1

Dette skjemaet fylles ut ved utskrivelse

Date of injury

External fixation  Yes  No

Date of definitive surgery

Reoperation  Yes  No

Time from injury to definitive surgery  days

Date of admission

Date of discharge

Length of stay (calculated from admission vs discharge)  days

Postoperative length of stay (calculated from definitive surgery vs discharge)  days

Form History

DEMO

1/10

Show all events

DocMe W6 Week12

2023 (±7) 11 Jun 2023 (±7)

Protocol date 14 Mar 2023 (-0/+14)

Scheduled date not set

Event date 13 Mar 2023

DEMO

The study is currently set to operate in demonstration & training mode. Do not input any real data.

DEMO

# Details

1/10

# 99-010

TRAINING

INIT AGE  
 DJU 28

16% of study | 3/13 events | 11/66 forms

Patient information  DM  CRA  SDV

Common events

Protocol deviation / Note to file (0)

Add new event

Search	Show all events				
Preoperative	VieDocMe Pre	Postoperative	Week6	VieDocMe W6	Week12
13 Mar 2023	13 Mar 2023 <input checked="" type="checkbox"/>	13 Mar 2023 <input checked="" type="checkbox"/>	24 Apr 2023 (±7)	24 Apr 2023 (±7)	11 Jun 2023 (±7)

## Postoperative Ready

Event date	DM <input type="checkbox"/>	CRA <input type="checkbox"/>	SDV <input type="checkbox"/>	<input checked="" type="checkbox"/>
Clinical Examination and complications	DM <input type="checkbox"/>	CRA <input type="checkbox"/>	SDV <input type="checkbox"/>	<input checked="" type="checkbox"/>
Patient and injury characteristics	DM <input type="checkbox"/>	CRA <input type="checkbox"/>	SDV <input type="checkbox"/>	<input checked="" type="checkbox"/>
Treatment summary	DM <input type="checkbox"/>	CRA <input type="checkbox"/>	SDV <input type="checkbox"/>	<input checked="" type="checkbox"/>
Summary at discharge	DM <input type="checkbox"/>	CRA <input type="checkbox"/>	SDV <input type="checkbox"/>	<input checked="" type="checkbox"/>

Protocol date 14 Mar 2023 (-0/+14)   
 Scheduled date not set   
 Event date 13 Mar 2023

Da er alt klart mtp første utskrivelse og neste konsultasjon er 6 uker postop. Da skal pas. også fylle ut ViedocMe.

Klikk for å gå tilbake – hold for å se logg

Form is in view mode. Click 'Edit' to make it editable

### Inclusion/exclusion evaluation

**Inclusion Criteria**

- Posterior malleolar (PM) fracture, of Mason & Molly type 2A/2B, associated with Weber B lateral malleolar fracture, and/or medial malleolar fracture  Yes  No
- Patients informed, written consent  Yes  No
- Age 18-65 years  Yes  No
- Measurements are performed 5 millimeter (mm) cranial to the tibia plafond  Yes  No
- Posterior malleolus fractures involving less than 40% of the fibular notch are included. See Figure 2 in study protocol for illustration of measurements.  Yes  No

**Exclusion Criteria**

- Non-compliant patient, i.e.: dementia, alcohol- or substance abuse  Yes  No
- Known congenital bone disease  Yes  No
- Pathological fractures  Yes  No
- Immunocompromised patients  Yes  No
- Tourists or patients on a short-term work/study permit  Yes  No
- Previous fracture of the ipsilateral ankle or ipsilateral lower extremity with a resulting dysfunction  Yes  No
- Poor controlled diabetes  Yes  No
- Patients with known arterial insufficiency  Yes  No
- Open fractures  Yes  No
- Severely traumatized patients (ISS>16)  Yes  No
- Patient declined inclusion to participate in study  Yes  No

Her er pasienten Non-compliant og ekskluderes.



DEMO

The study is currently set to operate in demonstration & training mode. Do not input any real data.

DEMO

### Details

# 99-011

TRAINING  
INIT AGE  
DEMO KLO 29

100% of study | 1/1 events | 2/2 forms

Patient information DM CRA SDV

Common events

Protocol deviation / Note to file (0)

Add new event

Search

Show all events

## Preoperative

14 Mar 2023

## Preoperative Ready

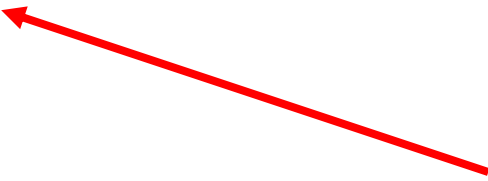
Event date	DM	CRA	SDV	✓
Patient and injury characteristics	DM	CRA	SDV	✓
Inclusion/exclusion evaluation	DM	CRA	SDV	✓

Protocol date  
14 Mar 2023 (-0/+14)

Scheduled date  
not set

Event date  
14 Mar 2023

Når en pasient ekskluderes må vi legge til en hendelse, velg «Add new event»



Klikk for å gå tilbake – hold for å selogg

DEMO

### Details

# 99-011

TRAINING

INIT AGE  
KLO 29

100% of study 1/1 events 2/2 forms

Patient information DM CRA SDV

Common events

Protocol deviation / Note to file (0)

Add new event

Search

### Preoperative

14 Mar 2023

## Preoperative

Event date

Patient and injury characteristics

Inclusion/exclusion evaluation

99-011 Add new event

Close

### Add new event

Event name

End of study

Plan event Initiate event

Kristian Pilskog | Viedoc™ 4.74.8454.15866 | 2023-03-14T13:09 CET  
200123 | 5.2 | PMF | TRAINING

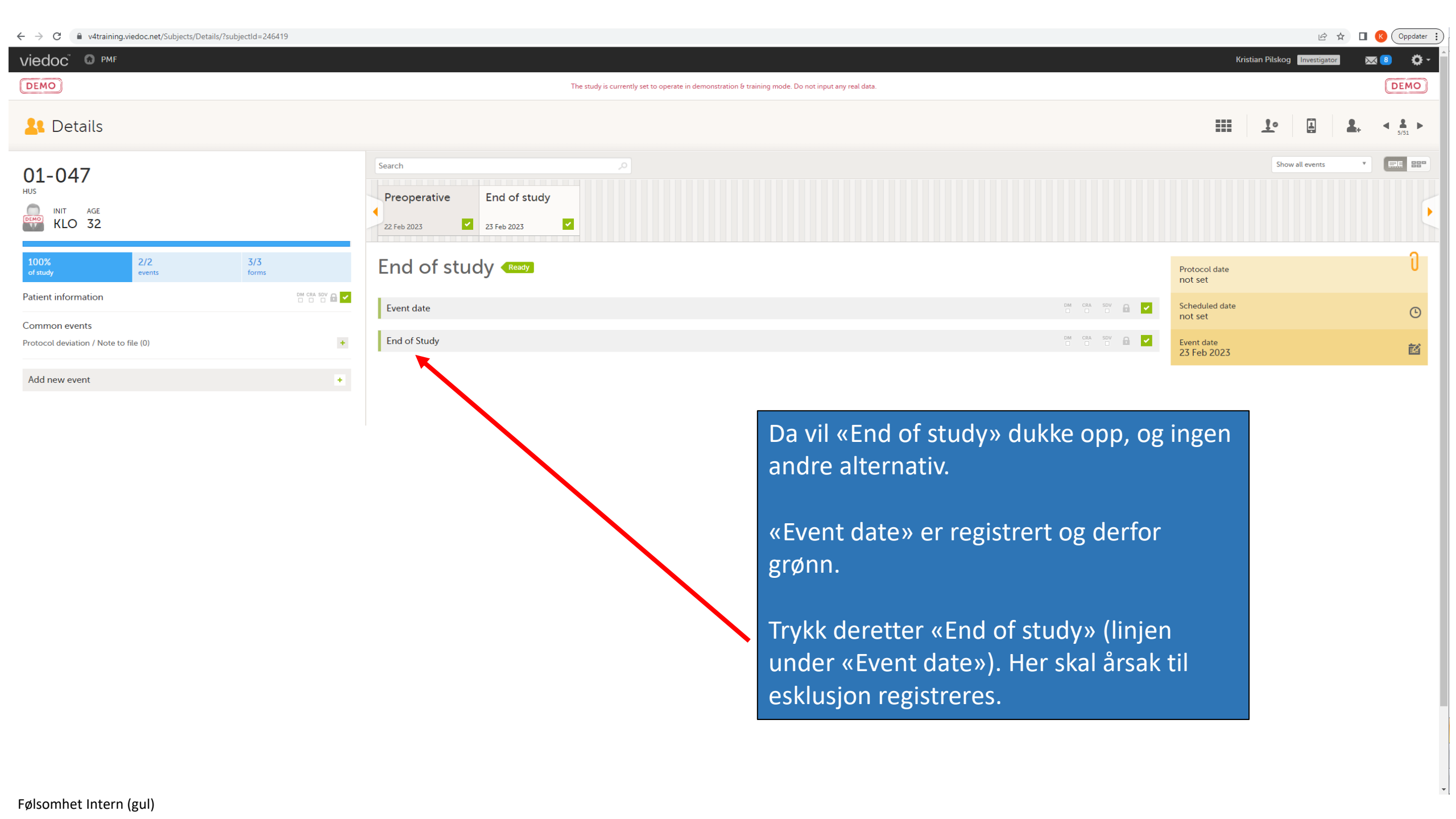
Velg «Initiate event» og registrer dato på samme måte som tidligere.

Protocol date  
14 Mar 2023 (-0/+14)

Scheduled date  
not set

Event date  
14 Mar 2023





DEMO

The study is currently set to operate in demonstration & training mode. Do not input any real data.

DEMO

## Details

# 01-047

HUS  
INIT AGE  
DEMO KLO 32

100% of study | 2/2 events | 3/3 forms

Patient information DM CRA SDV

Common events

Protocol deviation / Note to file (0)

Add new event

Search

Show all events

Preoperative	End of study
22 Feb 2023 <input checked="" type="checkbox"/>	23 Feb 2023 <input checked="" type="checkbox"/>

## End of study Ready

Event date	DM <input type="checkbox"/> CRA <input type="checkbox"/> SDV <input type="checkbox"/> <input checked="" type="checkbox"/>
End of Study	DM <input type="checkbox"/> CRA <input type="checkbox"/> SDV <input type="checkbox"/> <input checked="" type="checkbox"/>

- Protocol date not set
- Scheduled date not set
- Event date 23 Feb 2023

Da vil «End of study» dukke opp, og ingen andre alternativ.

«Event date» er registrert og derfor grønn.

Trykk deretter «End of study» (linjen under «Event date»). Her skal årsak til eksklusjon registreres.

viedoc PMF

DEMO

Details

99-011  
TRAINING

INIT AGE  
KLO 29

66% of study 2/2 events 2/3 forms

Patient information

Common events

Protocol deviation / Note to file (0)

Add new event

Preoperative  
14 Mar 2023

End of stud

Event date

End of Study

99-011 End of study [14 Mar 2023] Save changes Close

### End of Study

Did the patient complete the study?

Yes  No

Date of completion/discontinuation

14 Mar 2023

Primary reason for discontinuation:

- Screening failure
- Withdrawal of informed consent
- Death
- Investigator decision
- Lost to follow-up
- Study termination
- Other

Kristian Pilskog | Viedoc™ 4.74.8454.15866 | 2023-03-14T13:11 CET  
200123 | 5.2 | PMF | TRAINING

Trykk «No» for å bekrefte at pas. ikke fullfører studien (ekskluderes)

Deretter vil alternativene under dukke opp.

Dersom pas. ikke ønsker å delta eller på annen måte ekskluderes fra studien velger vi det øverste alternativet: «Screening failure».

De resterende alternativene brukes dersom pas. har samtykket til å delta, men senere faller ut av studien.

DEMO The study is currently set to operate in demonstration & training mode. Do not input any real data. DEMO

### Details

# 01-047

HUS  
INIT AGE  
DEMO KLO 32

100% of study 2/2 events 3/3 forms

Patient information DM CRA SDV

Common events Protocol deviation / Note to file (0)

Add new event

Search	Show all events
Preoperative	End of study
22 Feb 2023 <input checked="" type="checkbox"/>	23 Feb 2023 <input checked="" type="checkbox"/>

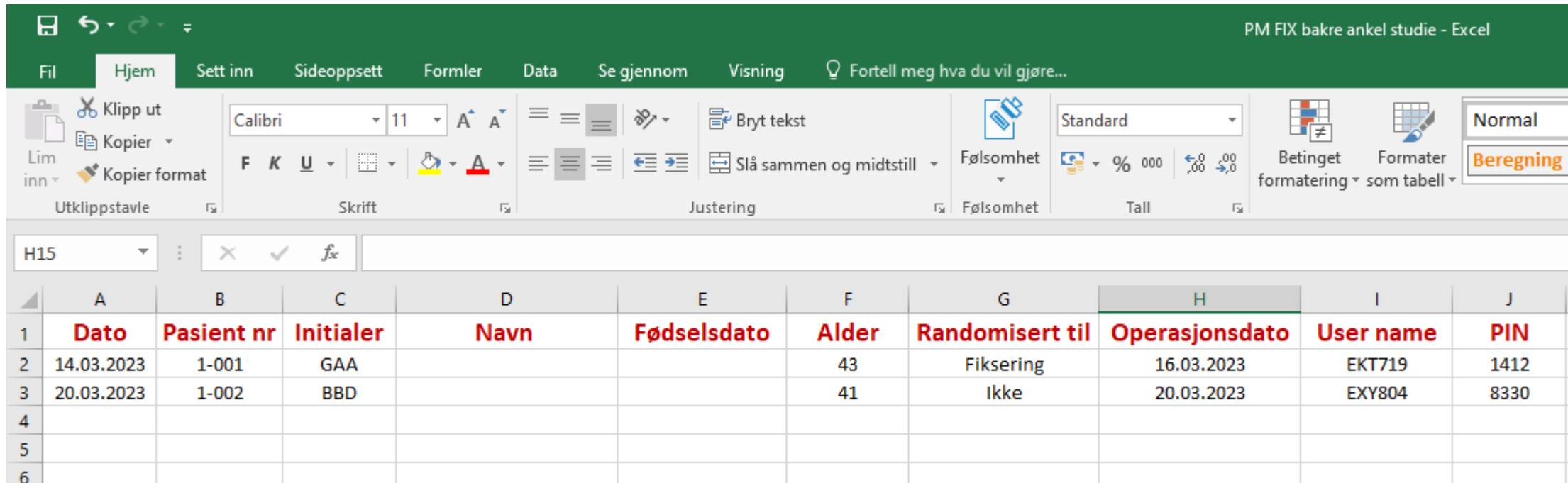
## End of study Ready

Event date	DM <input type="checkbox"/> CRA <input type="checkbox"/> SDV <input type="checkbox"/> <input checked="" type="checkbox"/>
End of Study	DM <input type="checkbox"/> CRA <input type="checkbox"/> SDV <input type="checkbox"/> <input checked="" type="checkbox"/>

- Protocol date not set
- Scheduled date not set
- Event date 23 Feb 2023

Pas. er nå er nå registrert og ekskludert.  
Da har vi info om antall «Eligible patients» og eksklusjonsårsaker.

HUSK Å LAGE OVERSIKT OVER INKLUDERTE PASIENTER,  
For eksempel Excel fil med følgende opplysninger:



The screenshot shows the Microsoft Excel interface with the following data table:

	A	B	C	D	E	F	G	H	I	J
1	<b>Dato</b>	<b>Pasient nr</b>	<b>Initialer</b>	<b>Navn</b>	<b>Fødselsdato</b>	<b>Alder</b>	<b>Randomisert til</b>	<b>Operasjonsdato</b>	<b>User name</b>	<b>PIN</b>
2	14.03.2023	1-001	GAA			43	Fiksering	16.03.2023	EKT719	1412
3	20.03.2023	1-002	BBD			41	Ikke	20.03.2023	EXY804	8330
4										
5										
6										