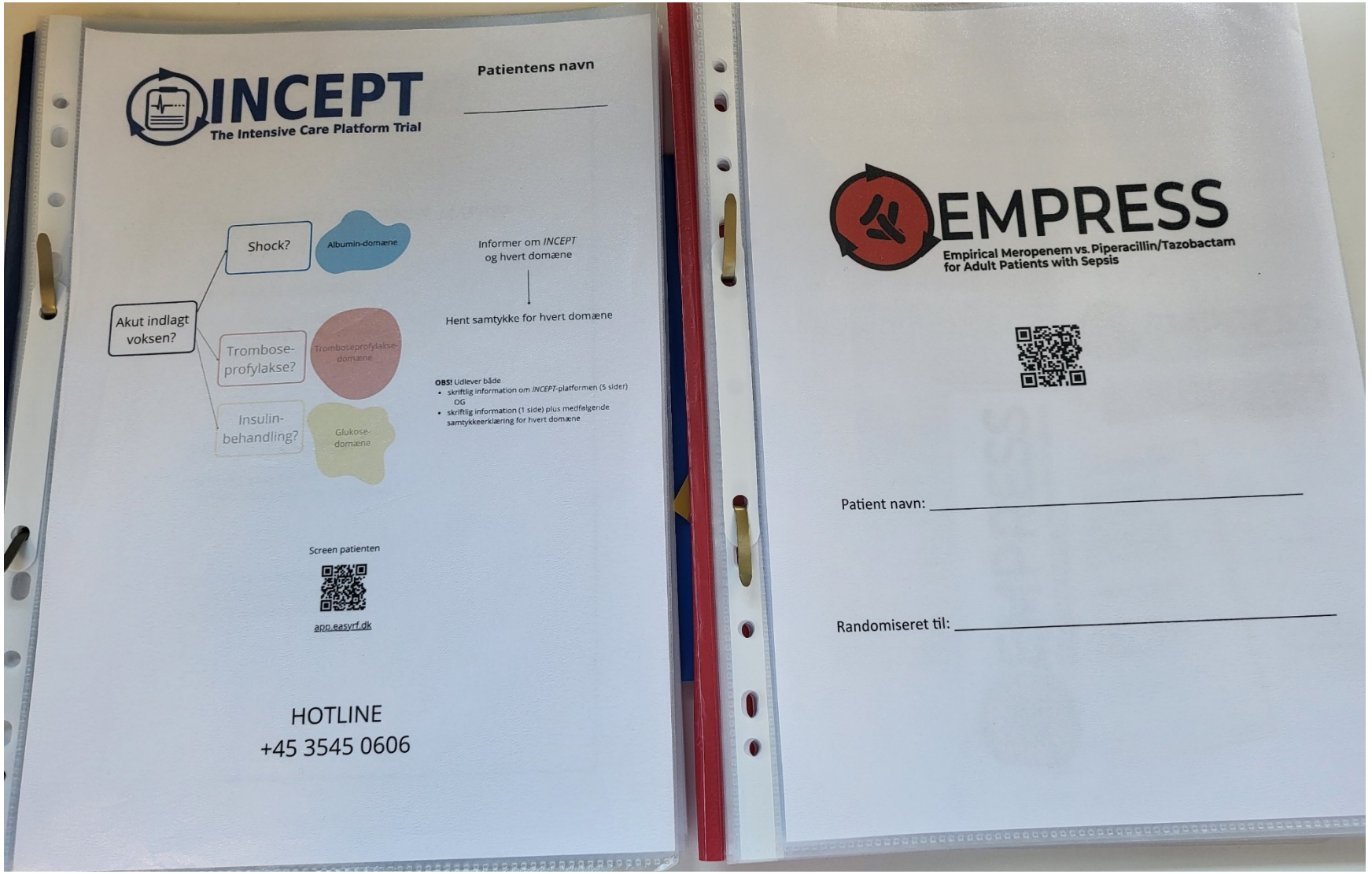
Arbejdsgange EasyRF Dataindsamling

Version 1.3, 09-07-2026

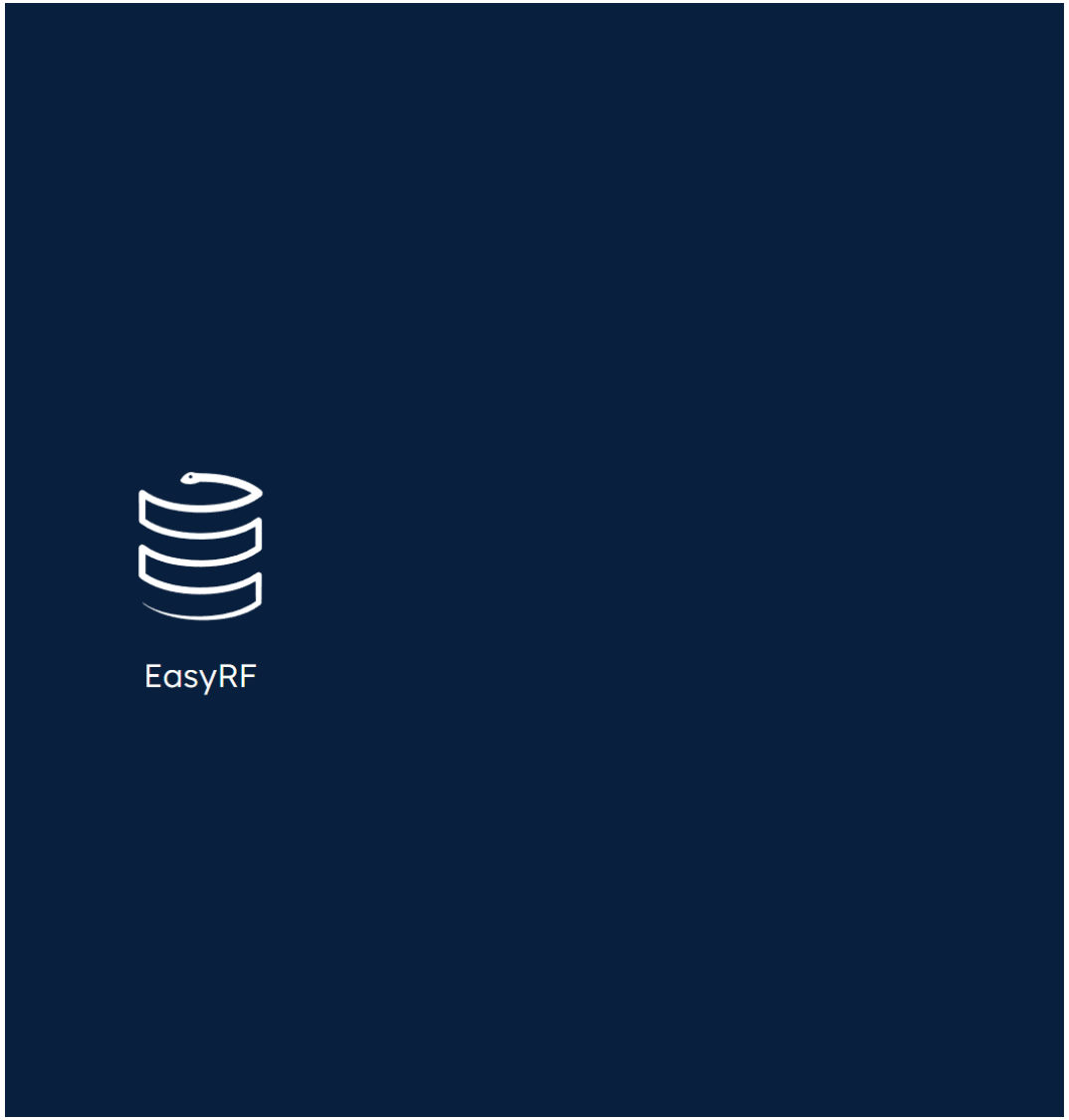
Arbejdsgange

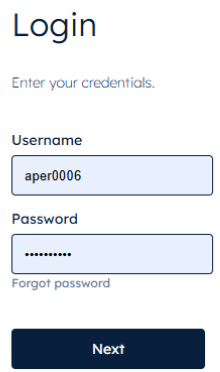


Forsøgsmateriale

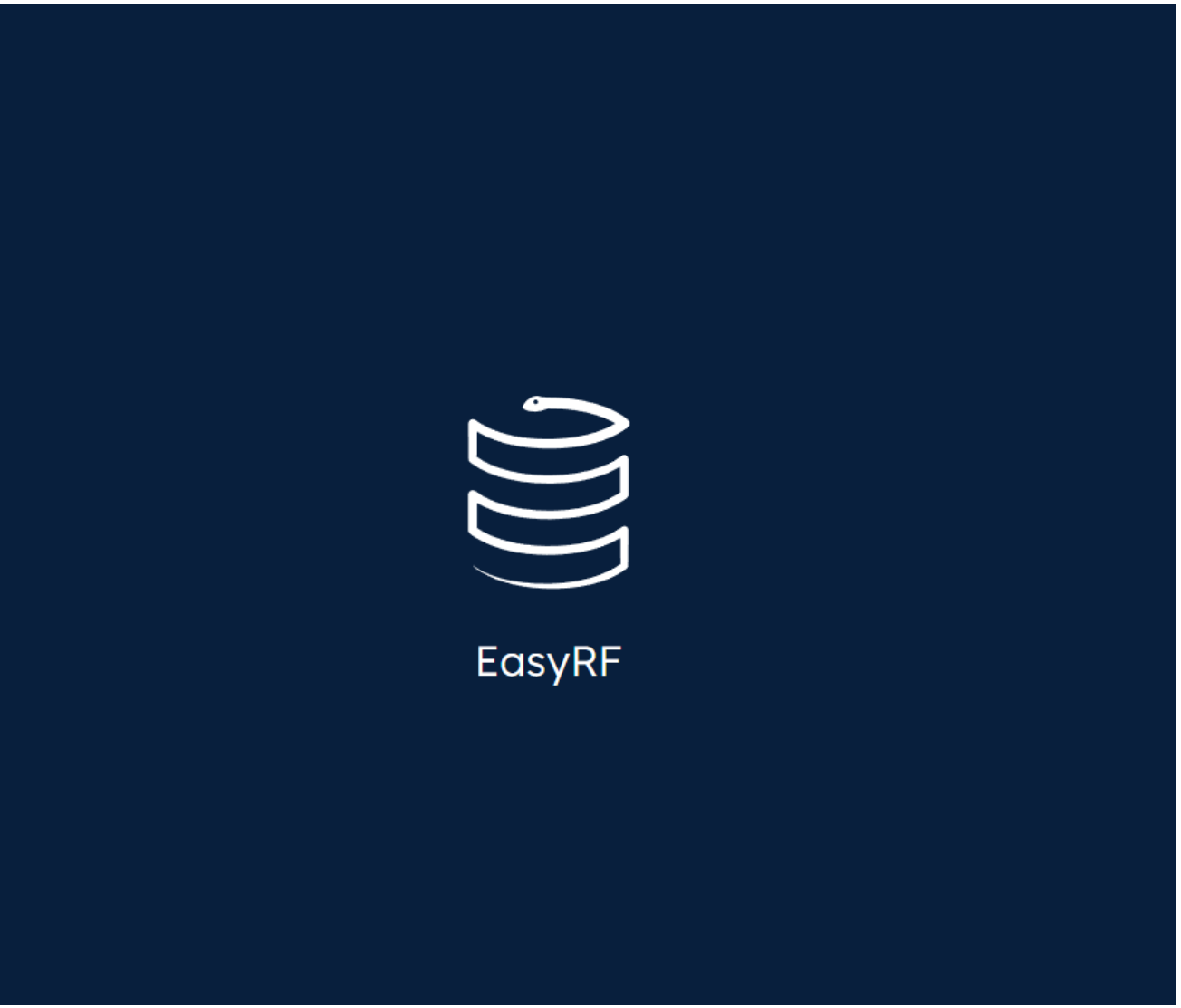
- Retningslinje for forsøgsdrift
- Lommekort
- Folder
- "FAQ's" på www.incept.dk
- Hotline – til akutte spørgsmål
- EasyRF workshops

Login


EasyRF


Login
Enter your credentials.
Username
aper0006
Password
Forgot password
Next

Login



Login

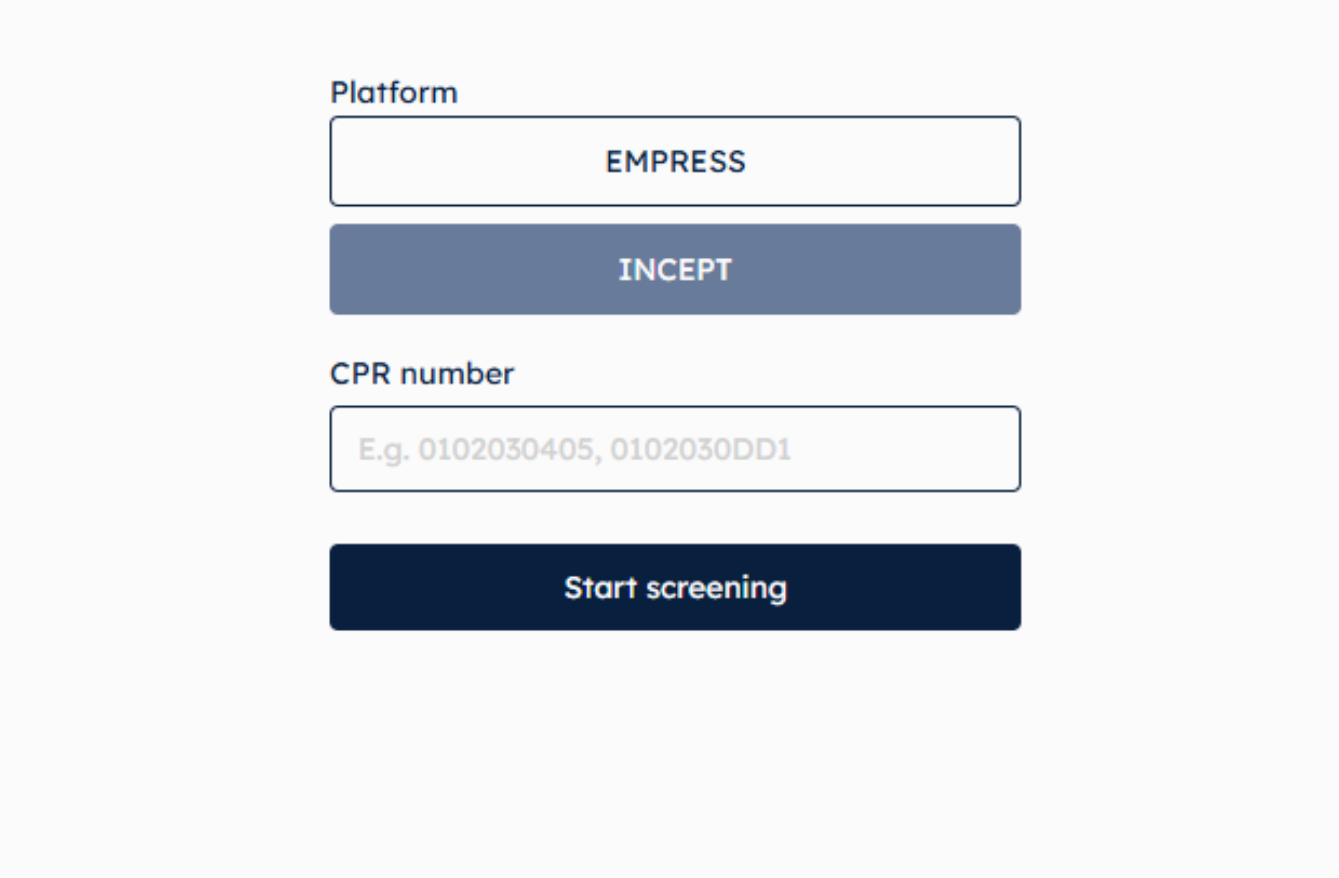
Please enter the token generated by your token generator.

Token

Back

Next

Screening


Platform
EMPRESS
INCEPT
CPR number
E.g. 0102030405, 0102030DD1
Start screening

Screening

INCEPT
ID: 123456789

Back

Inclusion criteria

Age ≥ 18 years

Yes | No

Acutely admitted to the ICU

Yes | No

Exclusion criteria

Informed consent following inclusion expected to be unobtainable

Yes | No

Patient is under coercive measures

Yes | No

Screening

INCEPT
The Intensive Care Platform Trial

EMPRESS
Empirical Meropenem vs Piperacillin/Tazobactam for Adult Patients with Sepsis

INCEPT-Albumin
ID: 123456789

Back

Before you continue

If the patient is currently in shock, are both interventions in this domain considered clinically appropriate?

Albumin use in ICU (intervention)

No albumin use in ICU (control)

Yes | No

Inclusion criteria

Plasma lactate ≥ 2 mmol/L in any blood sample performed within the last 3 hours

Yes | No

Ongoing infusion of a vasopressor or inotropic agent

Yes | No

Screening

INCEPT-Thromboprophylaxis

ID: 0505051234

Back

Are all interventions in this domain considered clinically appropriate?

Thromboprophylaxis - fixed intermediate dose

Thromboprophylaxis - fixed low dose

Thromboprophylaxis - weight-adjusted dose

Yes

No

Screening

INCEPT
The Intensive Care Platform Trial

EMPRESS
Empirical Meropenem vs Piperacillin/Tazobactam for Adult Patients with Sepsis

INCEPT-Thromboprophylaxis

ID: 0505051234

Back

Stratification variables

History of venous thromboembolism

Yes | No

Additional variables

Suspected sepsis

Yes | No

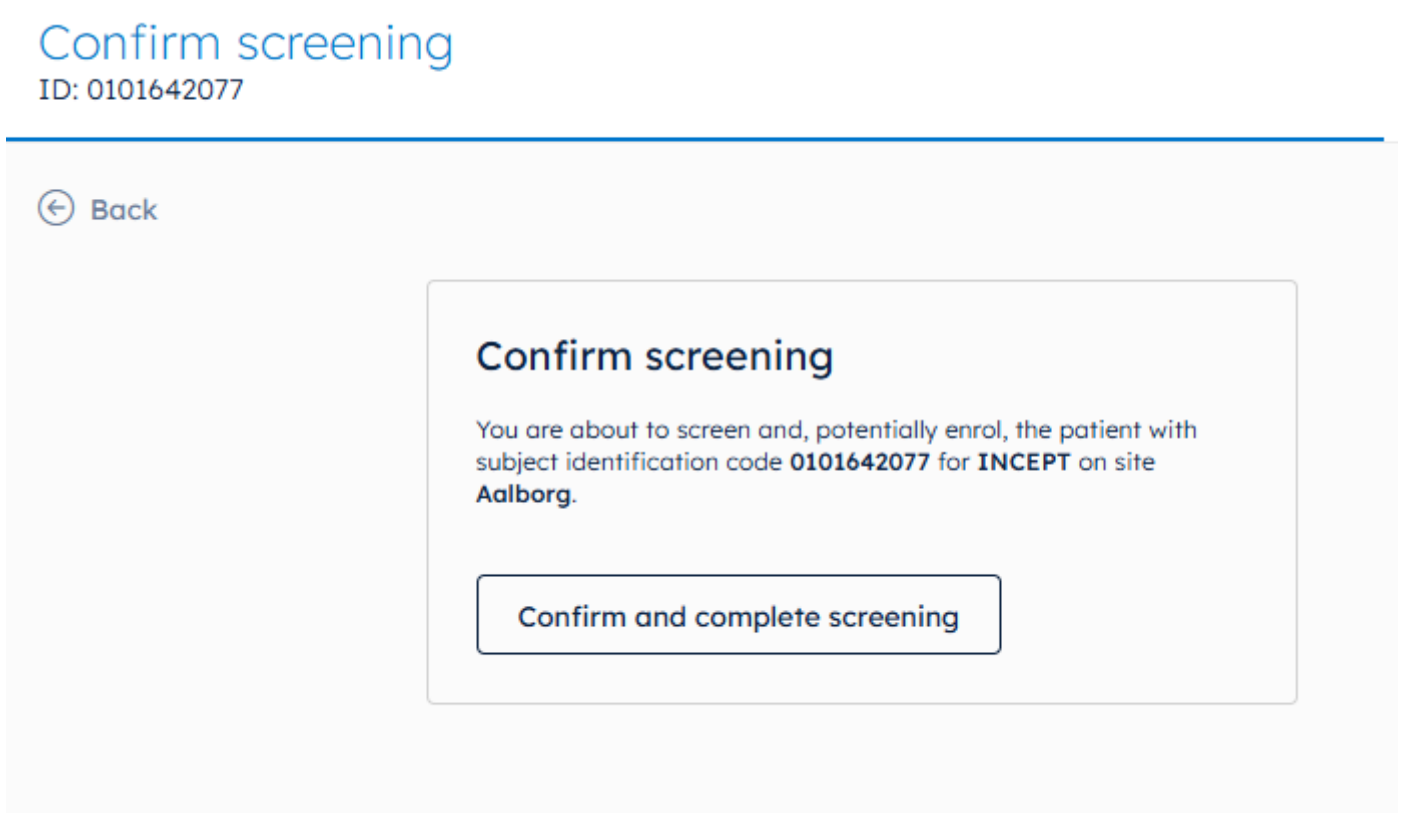
Sex

Female | Male

Presence of a central venous catheter

Yes | No

Screening


Confirm screening
ID: 0101642077
Back
Confirm screening
You are about to screen and, potentially enrol, the patient with subject identification code 0101642077 for INCEPT on site Aalborg.
Confirm and complete screening

Randomiseret

Enrolment status

ID: DK-494 / Name unavailable / 0505051234

Active

Thromboprophylaxis - weight-adjusted dose

in

INCEPT-Thromboprophylaxis

09-09-2025 / 12:34

Pending

Click to screen

in

INCEPT-Albumin

Not screened yet

Randomiseret

Enrolment status

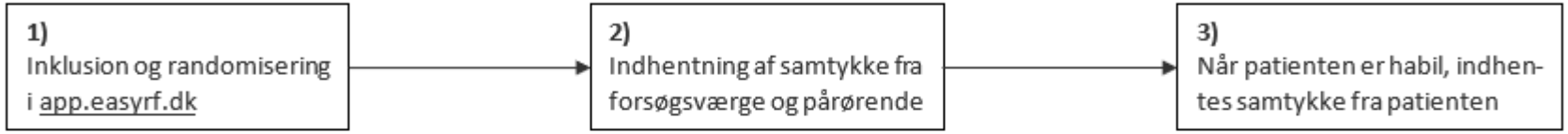
ID: DK-487 / Name unavailable / 0812670573

Active	Active
Albumin use in ICU (intervention) in INCEPT-Albumin	Thromboprophylaxis - weight-adjusted dose in INCEPT-Thromboprophylaxis
09-09-2025 / 10:43	09-09-2025 / 10:41

Efter randomisering

- Informér det kliniske personale
- Opret ordinationer af forsøgsmedicin (hvis 'ikke-albumin', sep. evt. albumin)
- Opret inklusionsnotat
- Opdatér intensivresumé
- Informér forsøgsværge og pårørende mhp. samtykke

Samtykker



Samtykke er en proces, der omfatter

- Læge informerer og underskriver
- Skriftlig information udleveres
- Evt. betænkningstid og uddybning
- Samtykkende part underskriver

Hvis et samtykke trækkes, spørges om tilladelse til fortsat dataindsamling og opfølgning

Sikkerhedsrapportering

Serious Adverse Reactions (SARs)

- Registreres dagligt via eCRF

Suspected, Unexpected, Serious Adverse Reaction (SUSARs)

- Investigator rapporterer SUSAR'er til sponsor indenfor 24 timer (hotline: 3545 0606). eCRF / papirformular

Alvorlige hændelser (SAEs)

- Investigator har mulighed for at rapportere alvorlige hændelser via eCRF'en

GCP-krav

CV'er og GCP kursus

For alle der udfører forsøgsspecifikke procedure

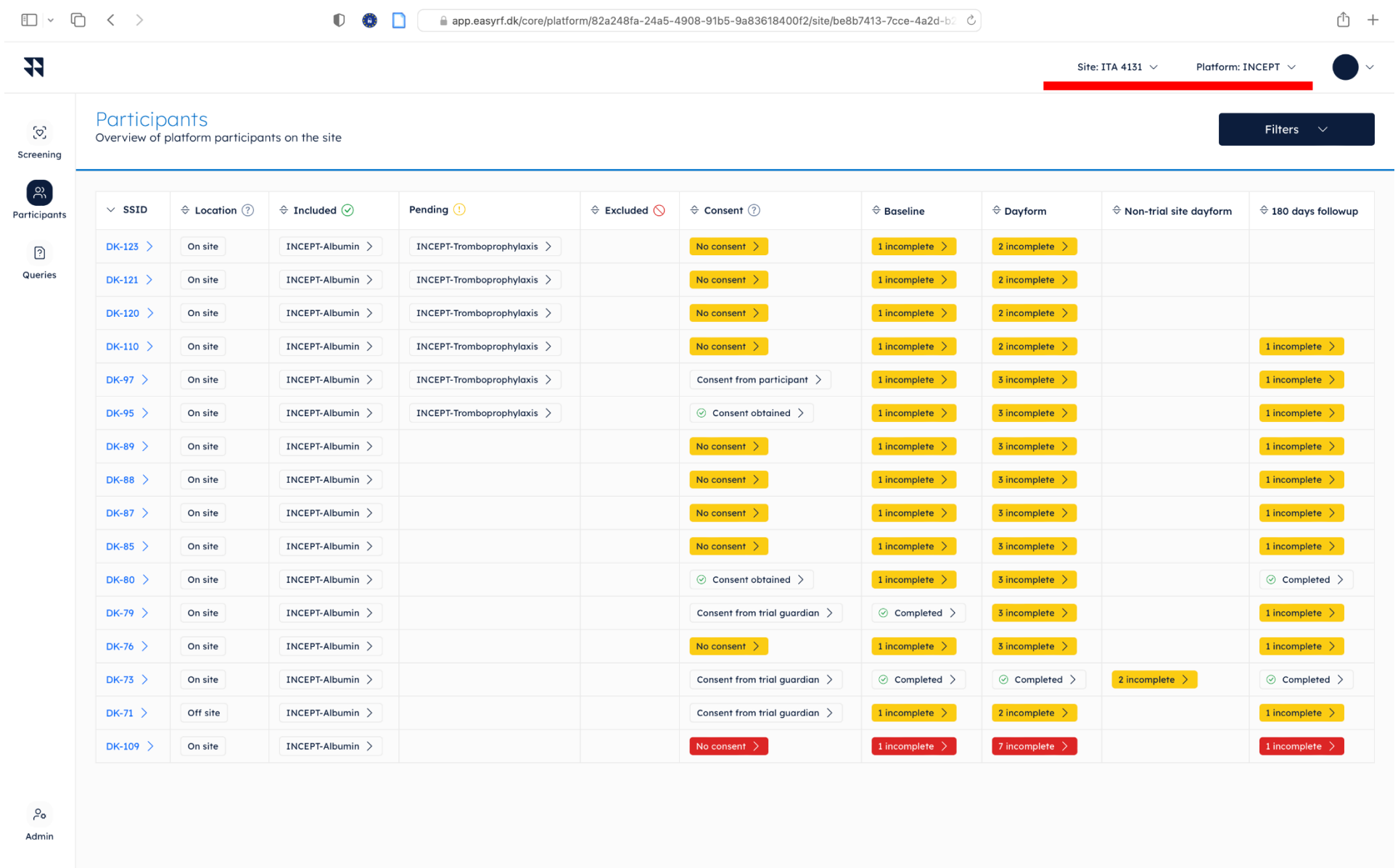
(screening, indrapportering af alvorlige hændelser, information før samtykke, indhentning af samtykke, data indtastning)



Dataindsamling



Overblik


app.easyrf.dk/core/platform/82a248fa-24a5-4908-91b5-9a83618400f2/site/be8b7413-7cce-4a2d-b
Site: ITA 4131
Platform: INCEPT
Screening
Participants
Queries
Admin
Participants
Overview of platform participants on the site
Filters
SSID
Location
Included
Pending
Excluded
Consent
Baseline
Dayform
Non-trial site dayform
180 days followup
DK-123 | On site | INCEPT-Albumin | INCEPT-Thromboprophylaxis | No consent | 1 incomplete | 2 incomplete | | 1 incomplete
DK-121 | On site | INCEPT-Albumin | INCEPT-Thromboprophylaxis | No consent | 1 incomplete | 2 incomplete | | 1 incomplete
DK-120 | On site | INCEPT-Albumin | INCEPT-Thromboprophylaxis | No consent | 1 incomplete | 2 incomplete | | 1 incomplete
DK-110 | On site | INCEPT-Albumin | INCEPT-Thromboprophylaxis | No consent | 1 incomplete | 2 incomplete | | 1 incomplete
DK-97 | On site | INCEPT-Albumin | INCEPT-Thromboprophylaxis | Consent from participant | 1 incomplete | 3 incomplete | | 1 incomplete
DK-95 | On site | INCEPT-Albumin | INCEPT-Thromboprophylaxis | Consent obtained | 1 incomplete | 3 incomplete | | 1 incomplete
DK-89 | On site | INCEPT-Albumin | | No consent | 1 incomplete | 3 incomplete | | 1 incomplete
DK-88 | On site | INCEPT-Albumin | | No consent | 1 incomplete | 3 incomplete | | 1 incomplete
DK-87 | On site | INCEPT-Albumin | | No consent | 1 incomplete | 3 incomplete | | 1 incomplete
DK-85 | On site | INCEPT-Albumin | | No consent | 1 incomplete | 3 incomplete | | 1 incomplete
DK-80 | On site | INCEPT-Albumin | | Consent obtained | 1 incomplete | 3 incomplete | | Completed
DK-79 | On site | INCEPT-Albumin | | Consent from trial guardian | Completed | 3 incomplete | | 1 incomplete
DK-76 | On site | INCEPT-Albumin | | No consent | 1 incomplete | 3 incomplete | | 1 incomplete
DK-73 | On site | INCEPT-Albumin | | Consent from trial guardian | Completed | Completed | 2 incomplete | Completed
DK-71 | Off site | INCEPT-Albumin | | Consent from trial guardian | 1 incomplete | 2 incomplete | | 1 incomplete
DK-109 | On site | INCEPT-Albumin | | No consent | 1 incomplete | 7 incomplete | | 1 incomplete

Dayforms

Dayform

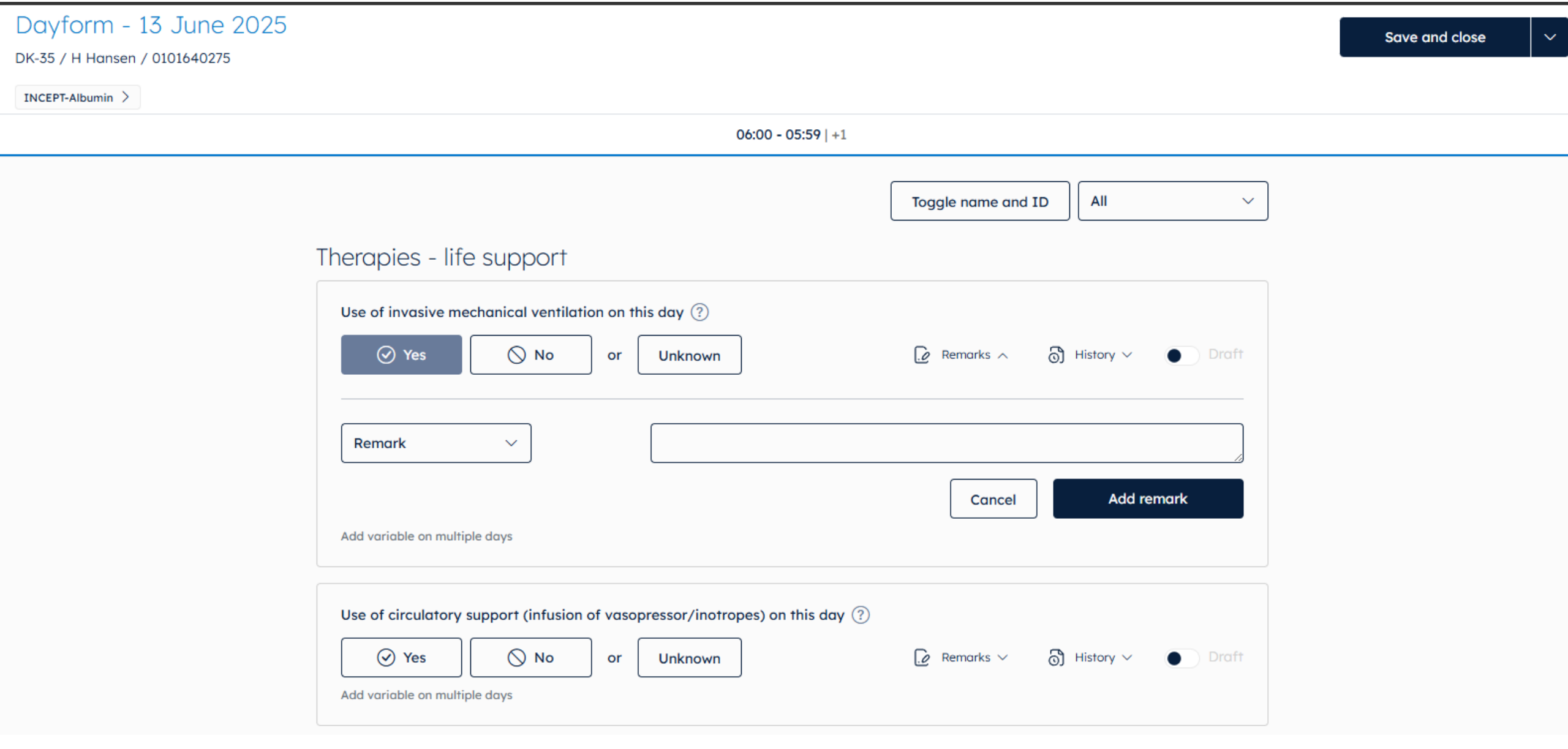
DK-35 / H Hansen / 0101640275

Back

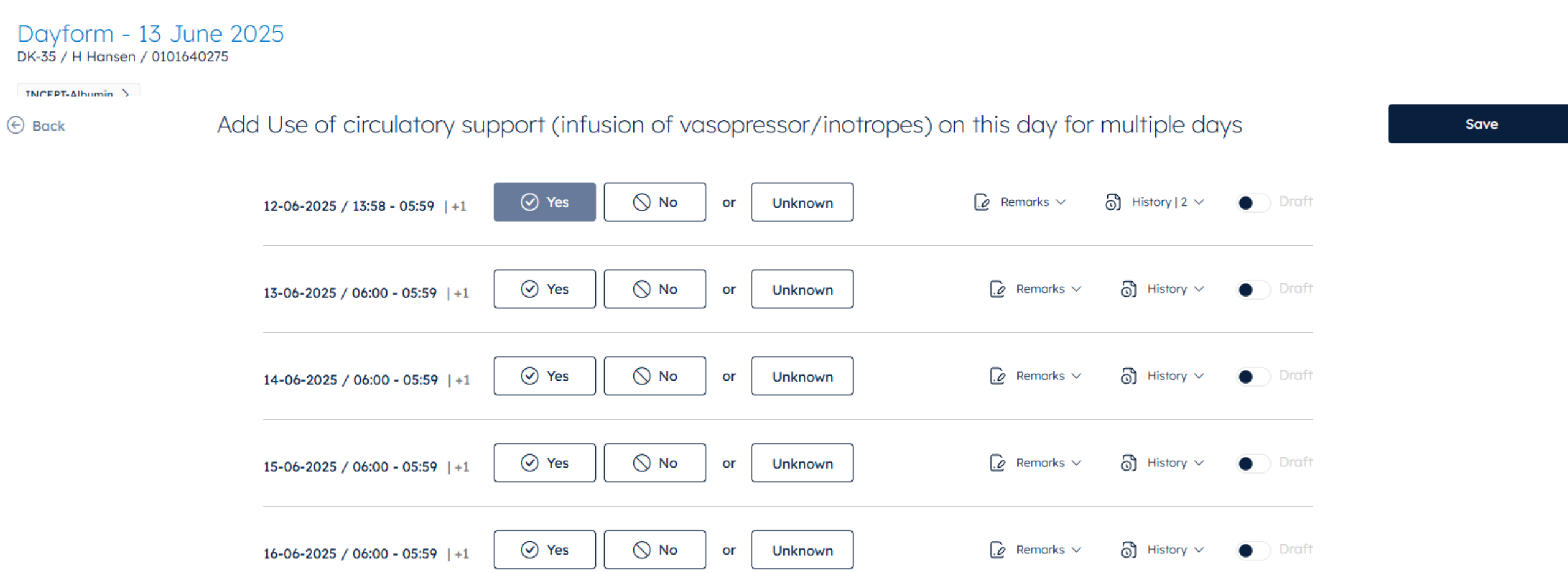
June 2025

Mo	Tu	We	Th	Fr	Sa	Su
						1
2	3	4	5	6	7	8
9	10	11	12 (1)	13 (1)	14 (1)	15 (1)
16 (1)	17	18	19	20	21	22
23	24	25	26	27	28	29
30						

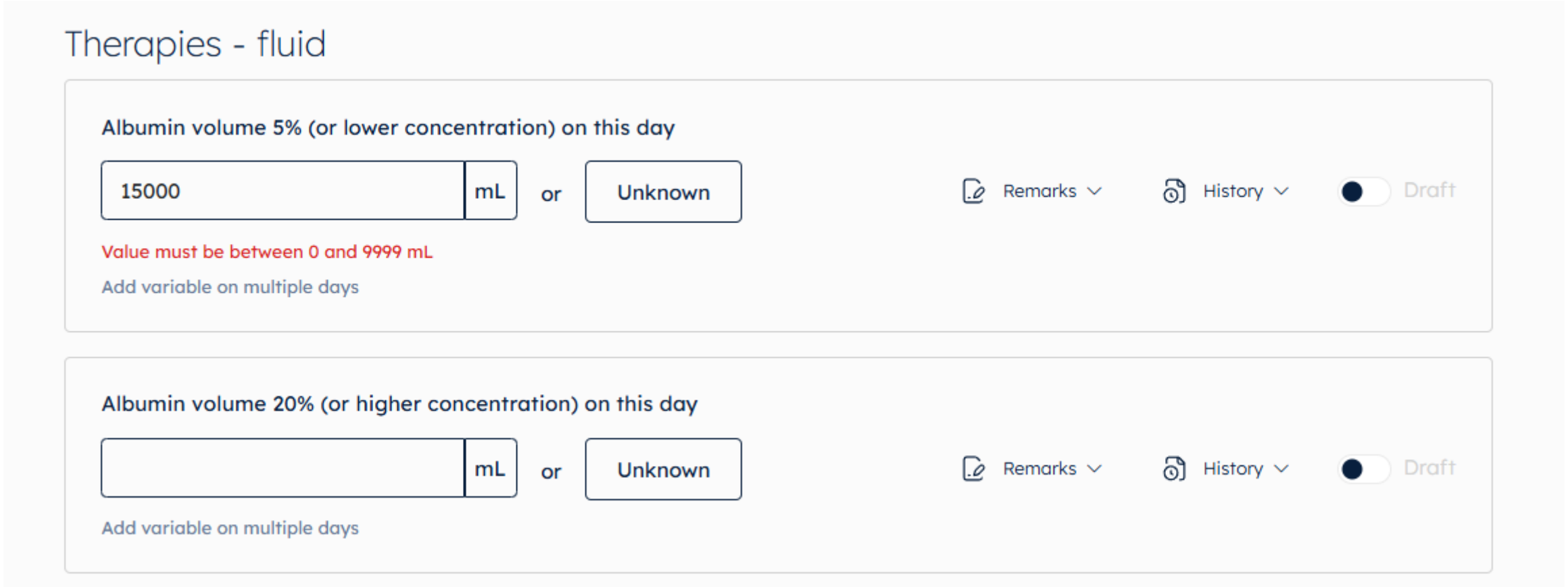
Dayforms


Dayform - 13 June 2025
DK-35 / H Hansen / 0101640275
Save and close
INCEPT-Albumin
06:00 - 05:59 | +1
Toggle name and ID
All
Therapies - life support
Use of invasive mechanical ventilation on this day
Yes
No
or
Unknown
Remarks
History
Draft
Remark
Cancel
Add remark
Add variable on multiple days
Use of circulatory support (infusion of vasopressor/inotropes) on this day
Yes
No
or
Unknown
Remarks
History
Draft
Add variable on multiple days

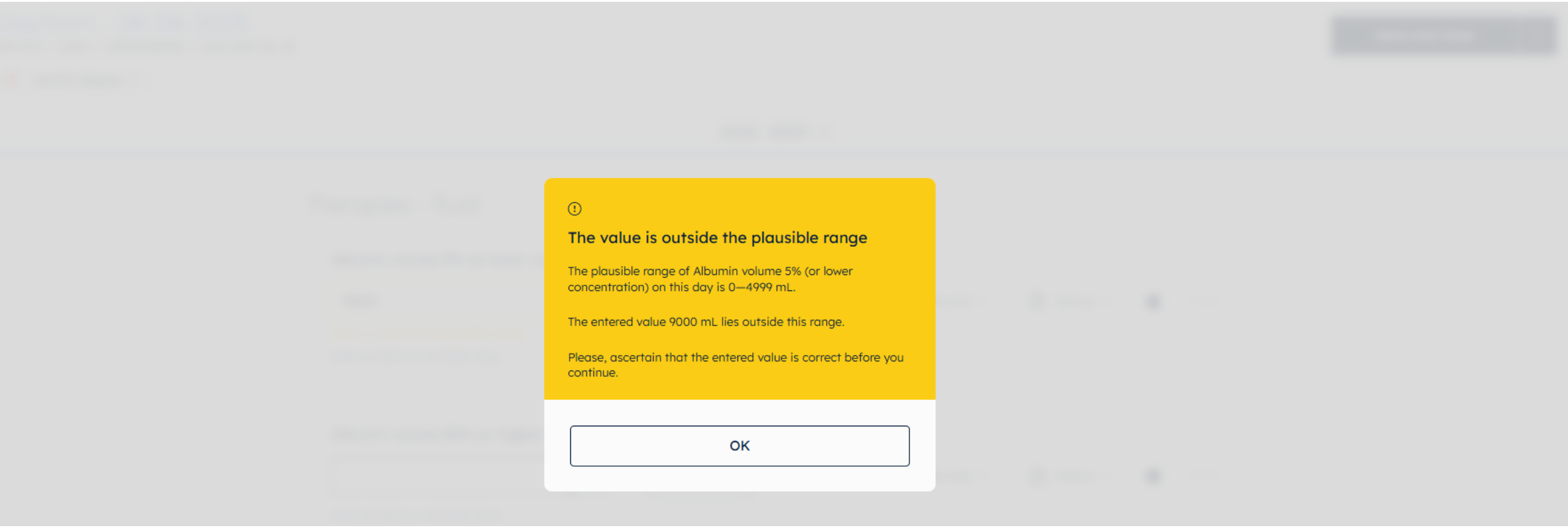
Dayforms


Dayform - 13 June 2025
DK-35 / H Hansen / 0101640275
INCERT-Albumin
Back
Add Use of circulatory support (infusion of vasopressor/inotropes) on this day for multiple days
Save
12-06-2025 / 13:58 - 05:59 | +1
Yes
No
or
Unknown
Remarks
History | 2
Draft
13-06-2025 / 06:00 - 05:59 | +1
Yes
No
or
Unknown
Remarks
History
Draft
14-06-2025 / 06:00 - 05:59 | +1
Yes
No
or
Unknown
Remarks
History
Draft
15-06-2025 / 06:00 - 05:59 | +1
Yes
No
or
Unknown
Remarks
History
Draft
16-06-2025 / 06:00 - 05:59 | +1
Yes
No
or
Unknown
Remarks
History
Draft

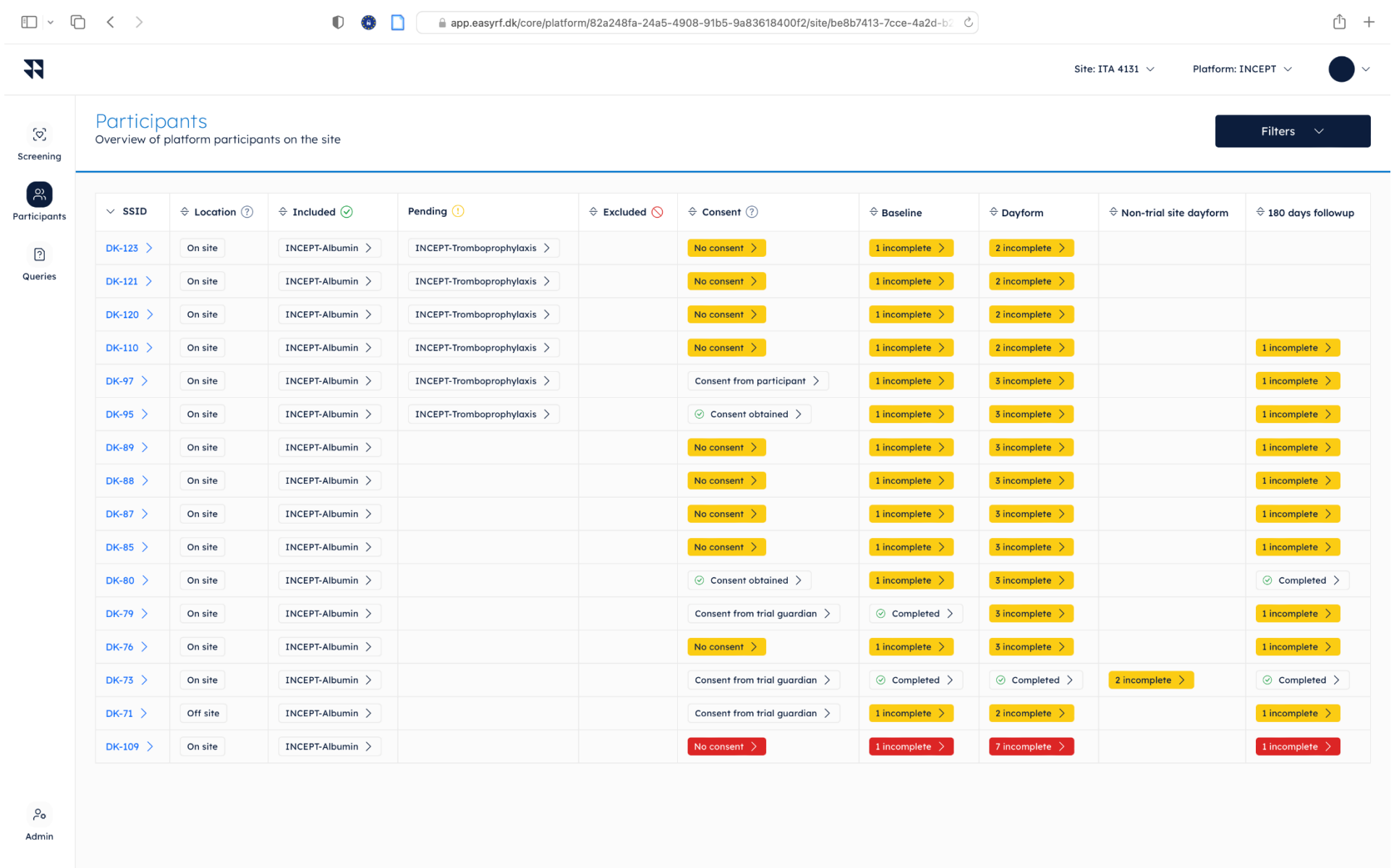
Dayforms


Therapies - fluid
Albumin volume 5% (or lower concentration) on this day
15000
mL
or
Unknown
Remarks
History
Draft
Value must be between 0 and 9999 mL
Add variable on multiple days
Albumin volume 20% (or higher concentration) on this day
mL
or
Unknown
Remarks
History
Draft
Add variable on multiple days

Dayforms


The value is outside the plausible range
The plausible range of Albumin volume 5% (or lower concentration) on this day is 0—4999 mL.
The entered value 9000 mL lies outside this range.
Please, ascertain that the entered value is correct before you continue.
OK

Overblik



SSID	Location	Included	Pending	Excluded	Consent	Baseline	Dayform	Non-trial site dayform	180 days followup
DK-123	On site	INCEPT-Albumin	INCEPT-Thromboprophylaxis		No consent	1 incomplete	2 incomplete		
DK-121	On site	INCEPT-Albumin	INCEPT-Thromboprophylaxis		No consent	1 incomplete	2 incomplete		
DK-120	On site	INCEPT-Albumin	INCEPT-Thromboprophylaxis		No consent	1 incomplete	2 incomplete		
DK-110	On site	INCEPT-Albumin	INCEPT-Thromboprophylaxis		No consent	1 incomplete	2 incomplete		1 incomplete
DK-97	On site	INCEPT-Albumin	INCEPT-Thromboprophylaxis		Consent from participant	1 incomplete	3 incomplete		1 incomplete
DK-95	On site	INCEPT-Albumin	INCEPT-Thromboprophylaxis		Consent obtained	1 incomplete	3 incomplete		1 incomplete
DK-89	On site	INCEPT-Albumin			No consent	1 incomplete	3 incomplete		1 incomplete
DK-88	On site	INCEPT-Albumin			No consent	1 incomplete	3 incomplete		1 incomplete
DK-87	On site	INCEPT-Albumin			No consent	1 incomplete	3 incomplete		1 incomplete
DK-85	On site	INCEPT-Albumin			No consent	1 incomplete	3 incomplete		1 incomplete
DK-80	On site	INCEPT-Albumin			Consent obtained	1 incomplete	3 incomplete		Completed
DK-79	On site	INCEPT-Albumin			Consent from trial guardian	Completed	3 incomplete		1 incomplete
DK-76	On site	INCEPT-Albumin			No consent	1 incomplete	3 incomplete		1 incomplete
DK-73	On site	INCEPT-Albumin			Consent from trial guardian	Completed	Completed	2 incomplete	Completed
DK-71	Off site	INCEPT-Albumin			Consent from trial guardian	1 incomplete	2 incomplete		1 incomplete
DK-109	On site	INCEPT-Albumin			No consent	1 incomplete	7 incomplete		1 incomplete

Events

Ilse Olsen / 3002020304
DK-343

Enrolment status

Events | Event history | Contact information

Back

Consent

- Consent Process Concluded
- Consent from trial guardian
- Consent from relative
- Consent from participant

Admin

- Discharge/Readmission/Transfer
- Note to file

Adverse Events

- SAE/SUSAR (incl. followup)

End of Participation

- Withdrawn consent
- Clinical decision
- Discontinuation of active therapy
- SAR/SUSAR
- Involuntary hospitalisation
- Death

Events

Ilse Olsen / 3002020304
DK-343

Enrolment status

Events | Event history | Contact information

Back

Consent

Consent Process Concluded

Consent from trial guardian

Time of event
12-08-2025

Comment
BV kirurgisk afd.

Files
Upload files

Add event

Consent from relative

Admin

Discharge/Readmission/Transfer

Note to file

Adverse Events

SAE/SUSAR (incl. followup)

End of Participation

Withdrawn consent

Clinical decision

Discontinuation of active therapy

SAR/SUSAR

Involuntary hospitalisation

Death

Events

Ilse Olsen / 3002020304
DK-343

Enrolment status

Events | Event history | Contact information

Back

Consent

- Consent Process Concluded
- Consent from trial guardian
- Consent from relative
- Consent from participant

Admin

- Discharge/Readmission/Transfer
- Note to file

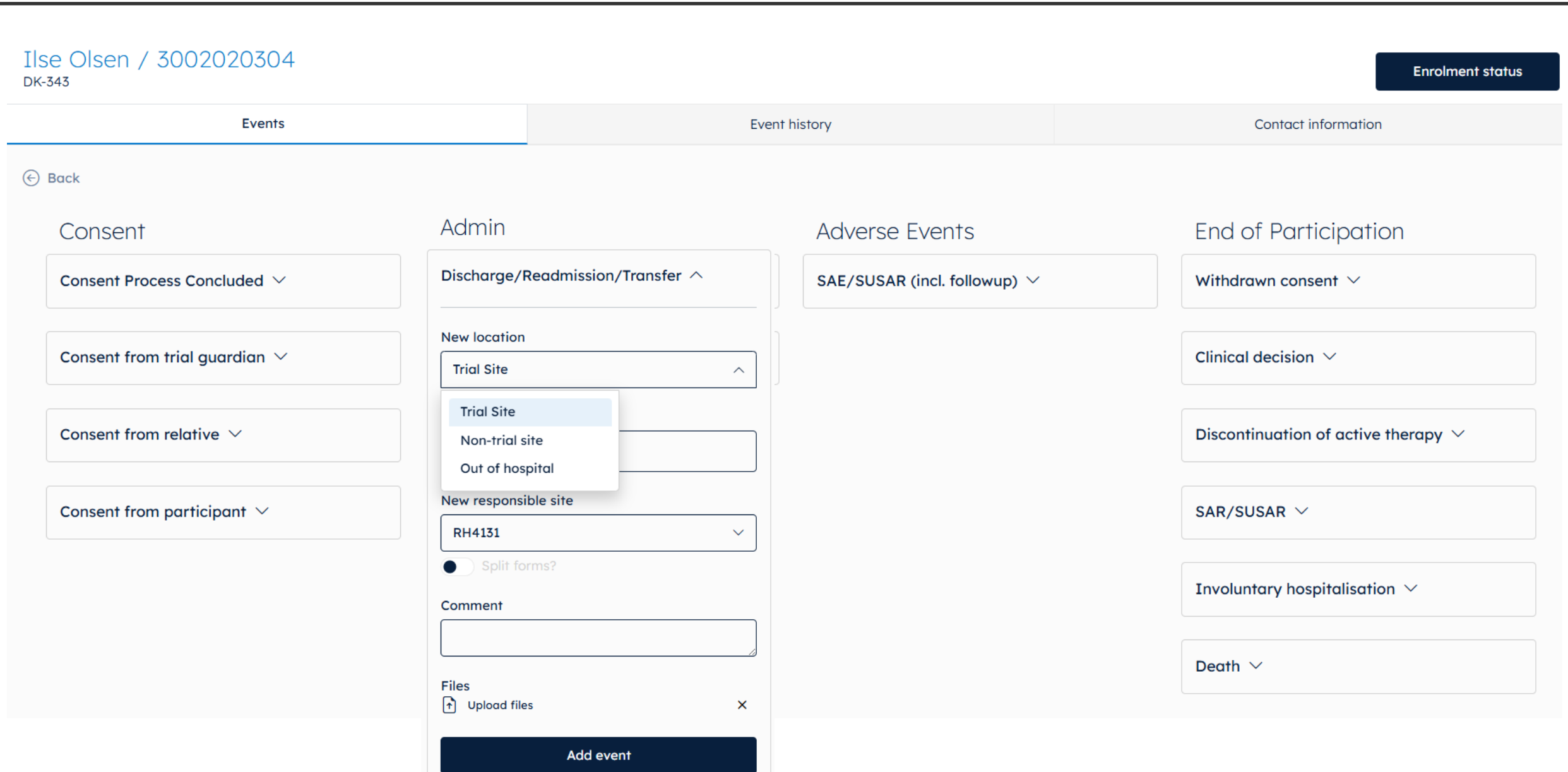
Adverse Events

- SAE/SUSAR (incl. followup)

End of Participation

- Withdrawn consent
- Clinical decision
- Discontinuation of active therapy
- SAR/SUSAR
- Involuntary hospitalisation
- Death

Events


Ilse Olsen / 3002020304
DK-343
Enrolment status
Events
Event history
Contact information
Back
Consent
Consent Process Concluded
Consent from trial guardian
Consent from relative
Consent from participant
Admin
Discharge/Readmission/Transfer
New location
Trial Site
Trial Site
Non-trial site
Out of hospital
New responsible site
RH4131
Split forms?
Comment
Files
Upload files
Add event
Adverse Events
SAE/SUSAR (incl. followup)
End of Participation
Withdrawn consent
Clinical decision
Discontinuation of active therapy
SAR/SUSAR
Involuntary hospitalisation
Death

Ophør af deltagelse

Ilse Olsen / 3002020304
DK-343

Enrolment status

Events | Event history | Contact information

Back

Consent

- Consent Process Concluded
- Consent from trial guardian
- Consent from relative
- Consent from participant

Admin

- Discharge/Readmission/Transfer
- Note to file

Adverse Events

- SAE/SUSAR (incl. followup)

End of Participation

- Withdrawn consent
- Clinical decision
- Discontinuation of active therapy
- SAR/SUSAR
- Involuntary hospitalisation
- Death

Ophør af deltagelse

Ilse Olsen / 3002020304
DK-343

Enrolment status

Events | Event history | Contact information

Back

Consent

- Consent Process Concluded
- Consent from trial guardian
- Consent from relative
- Consent from participant

Admin

- Discharge/Readmission/Transfer
- Note to file

Adverse Events

- SAE/SUSAR (incl. followup)

End of Participation

Withdrawn consent

Enrolment

Time of event
dd-mm-åååå --:--

Accountable

Data collection allowed
Yes

Comment

Add event

Event history

Ilse Olsen / 3002020304
DK-343

Enrolment status

Events | Event history | Contact information

Back

Event history

Filter event

Events	Date and time	Info	Files	Remarks
Enrolment	11-08-2025 / 09:27	INCEPT	Upload files	Remarks
Enrolment	11-08-2025 / 09:27	INCEPT-Albumin | Albumin use in ICU (intervention)	Upload files	Remarks
Consent from trial guardian	12-08-2025	INCEPT	Upload files	Remarks | 1

Event history

Ilse Olsen / 3002020304
DK-343

Enrolment status

Events | Event history | Contact information

Back

Event history

Filter event

Events	Date and time	Info	Files	Remarks
Enrolment	11-08-2025 / 09:27	INCEPT	Upload files	Remarks
Enrolment	11-08-2025 / 09:27	INCEPT-Albumin | Albumin use in ICU (intervention)	Upload files	Remarks
Consent from trial guardian	12-08-2025	INCEPT	Upload files	Remarks | 1

Type Remark BV kirurgisk afd.
Date and time 30-08-2025 / 13:10
User ap

(●) Remark
( ) Open query

Cancel | Add remark

Kontakt information

Ilse Olsen / 3002020304
DK-343

Enrolment status

Events | Event history | Contact information

Back

Personal information

First name: Ilse

Last name: Olsen

Email address: ilse@ilse.dk

Phone number (mobile):

CPR number: 3002020304

Contacts

Add contact

Update personal information and contacts

Opfølgning ved 180 dage

Følg 'Guideline for obtaining 180-day follow-up'

INCEPT
The Intensive Care Platform Trial

1. Overlevelse
2. Kognitiv function
3. Helbredsrelateret livskvalitet



EMPRESS
Empirical Meropenem vs Piperacillin/Tazobactam for Adult Patients with Sepsis

1. Overlevelse
2. Helbredsrelateret livskvalitet

Af blindet forsøgspersonel