Initiation for clinicians and research staff

Version 1.0, 17-03-2026

novo nordisk foundation

danmark SYGEFORSIKRING

DANMARKS FRIE FORSKNINGSFOND

CRIC
Collaboration for Research in Intensive Care

Rigshospitalet
Copenhagen University Hospital

KØBENHAVNS UNIVERSITET

Steno Diabetes Center Copenhagen

Aalborg Universitetshospital

REGION SJÆLLAND
SJÆLLANDS UNIVERSITETSHOSPITAL
– vi er til for dig

AARHUS UNIVERSITY HOSPITAL

OUH &
Kolding Sygehus

Oslo universitetssykehus

University Medical Center Groningen

KAROLINSKA UNIVERSITY HOSPITAL

INSELSPITAL

Universitätsspital Basel

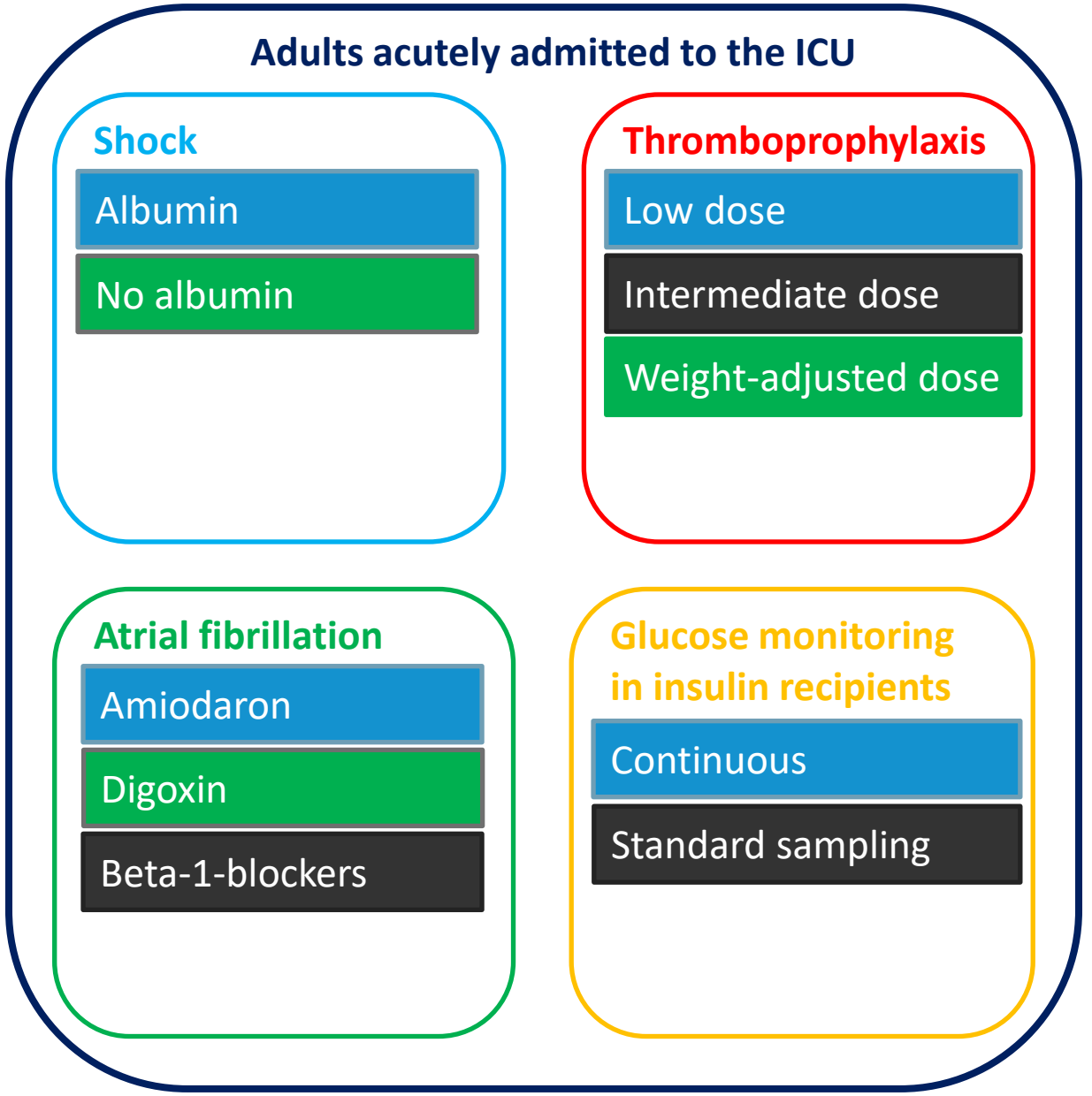
LANDSPÍTALI

Tays
Tampere University Hospital

HUS

INCEPT
The Intensive Care Platform Trial

Platform trial



INCEPT
The Intensive Care Platform Trial

Population

Inclusion criteria

- Adults acutely admitted to the ICU
- Eligible for at least one active domain

Exclusion criteria

- Informed consent after inclusion expected to be unobtainable
- Admitted under coercive measures

INCEPT-Albumin

Albumin versus no albumin in shock

Albumin

Received: 28 March 2024 | Revised: 24 May 2024 | Accepted: 7 June 2024
DOI: 10.1111/aas.14479

RESEARCH ARTICLE

acta Anaesthesiologica Scandinavica

Preferences for albumin use in adult intensive care unit patients with shock: An international survey

Praleene Sivapalan[1,2] | Karen Louise Ellekjaer[1,2] | Anders Perner[1,2,3] | Morten Hylander Møller[1,2,3] | Anders Granholm[1,2] | Lasse Grønningsæter[4] | Marlies Ostermann[5] | Rob Mac Sweeney[6] | Maria Cronhjort[7] | Johanna Hästbacka[8] | Carmen Pfortmueller[9] | Jan De Waele[10] | Marek Nalos[11] | Tomas Jovaisa[12] | Annika Reintam Blaser[13,14] | Maurizio Cecconi[15,16] | Begum Ergan[17] | Abdulrahman Al-Fares[18] | Paul J. Young[19,20,21,22] | Wojciech Szczeklik[23,24] | Eric Keus[25] | Fayez Alshamsi[26] | Ashish K. Khanna[27,28] | Martin Ingi Sigurdsson[29,30] | Tomoko Fujii[31] | Yaseen M. Arabi[32] | Tine Sylvest Meyhoff[1,2,33] | National investigators (NI) and site investigators

Correspondence
Praleene Sivapalan, Department of Intensive Care, Copenhagen University Hospital – Rigshospitalet, Blegdamsvej 9, DK-2100 Copenhagen, Denmark.
Email: praleene.sivapalan.01@regionh.dk

[Correction added on 19 November 2024, after first online publication: The Collaborator Group was added in the author byline.]

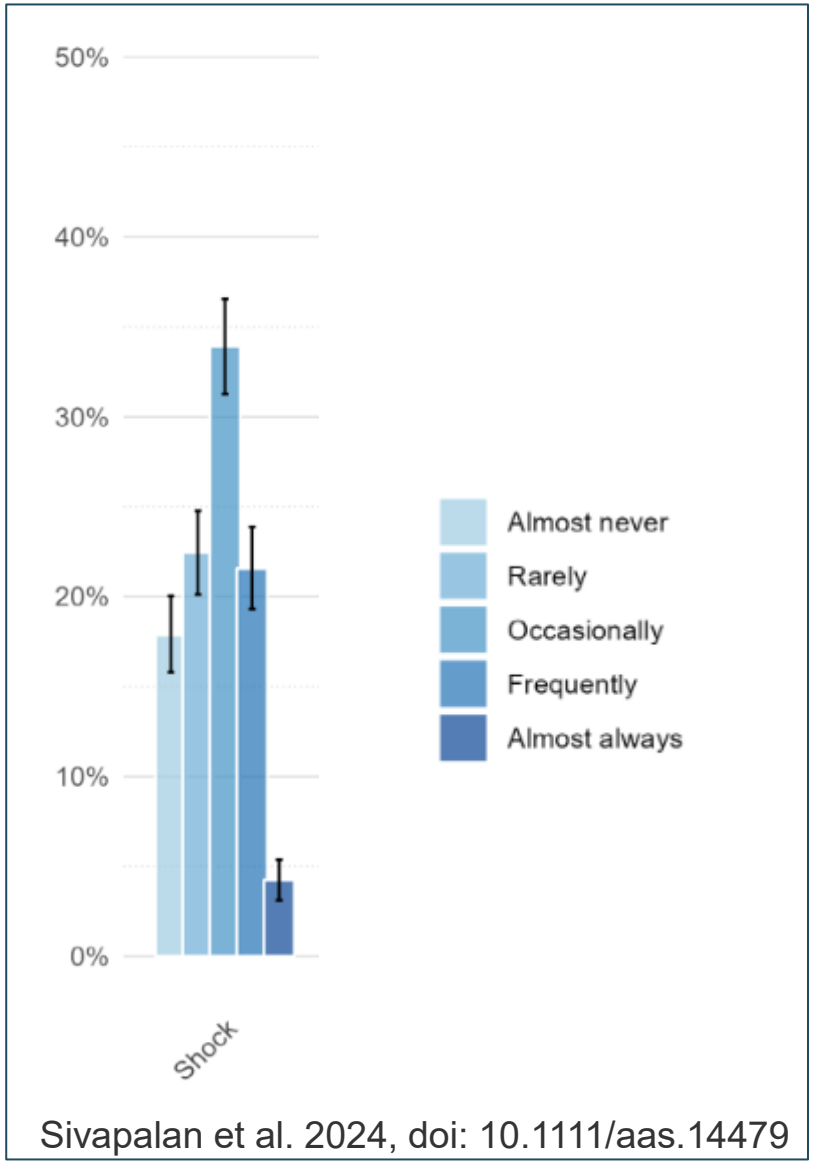
Abstract

Introduction: Use of albumin is suggested for some patients with shock, but preferences for its use may vary among intensive care unit (ICU) physicians.

Methods: We conducted an international online survey of ICU physicians with 20 questions about their use of albumin and their opinion towards a randomised trial among adults with shock comparing the use versus no use of albumin.

Results: A total of 1248 respondents participated, with a mean response rate of 37%, ranging from 18% to 75% across 21 countries. Respondents mainly worked in mixed ICUs and 92% were specialists in intensive care medicine. The reported use of albumin in general shock varied as 18% reported 'almost never', 22% 'rarely', 34% 'occasionally', 22% 'frequently' and 4% 'almost always' using albumin. In septic shock, 19% reported 'almost never', 22% 'rarely', 29% 'occasionally', 22% 'frequently' and 7% 'almost always' using albumin. Physicians' preferences were more consistent for haemorrhagic- and cardiogenic shock, with more than 45% reporting 'almost never' using albumin. While the reported use of albumin for other purposes than resuscitation was infrequent (40%–85% reported 'almost never' for five other indications), the most frequent other indications were low serum albumin levels and improvement

For affiliations refer to page 1241

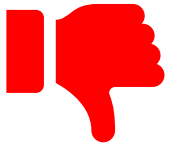


Sivapalan et al. 2024, doi: 10.1111/aas.14479

Albumin

Alive and without life-support?

Improved hemodynamics?
Less fluid use?



Kidney failure?
Coagulopathy?

Albumin

Inclusion criteria

- Shock
  - Ongoing infusion of vasopressor/inotrope AND
  - Plasma lactate ≥2 mmol/L within the last 3 hours
- Both interventions considered clinically appropriate

  (to use albumin or not)

Albumin

Exclusion criteria

- Traumatic brain injury
- Use of albumin during current ICU stay
- Known pregnancy
- Religious objection towards albumin
- Known albumin allergy
- Inclusion in another trial or INCEPT domain where co-enrolment with INCEPT-Albumin is not permitted

Intervention

Albumin use in the ICU (max 90 days)

- During circulatory failure in addition to crystalloid (resuscitation)
- Substitution in case of:
  - Suspected/overt albumin loss
  - P-albumin ≤25 g/L

Timing, volume and concentration at clinician's discretion
P-albumin measured according to usual practice

Comparator

No albumin use in the ICU (max 90 days)

Albumin may be considered if the following special circumstances occur:

- Large volume ascites drainage
- Spontaneous bacterial peritonitis
- Hepatorenal syndrome

Outcomes

Primary: Days alive without life-support at 30 days

Secondary:
INCEPT core outcomes

- All-cause mortality at 30, 90, and 180 days
- Days alive without life support at 90 days
- Days alive and out of hospital at 30 and 90 days
- Days free of delirium at 30 days
- Health-related quality of life (EQ-5D-5L and EQ-VAS) at 180 days
- Cognitive function (MiniMoCA) at 180 days
- Domain specific safety outcomes (anaphylaxis and major bleeding) at 30 and 90 days

INCEPT-Thromboprophylaxis

Low versus intermediate versus weight-adjusted LMWH dose

novo nordisk foundation

University Medical Center Groningen

RHS Rigshospitalet Copenhagen University Hospital

CRIC Collaboration for Research in Intensive Care

Thromboprophylaxis

OPEN ACCESS

Check for updates

Anticoagulants for thrombosis prophylaxis in acutely ill patients admitted to hospital: systematic review and network meta-analysis

Ruben J Eck,[1] Tessa Elling,[2] Alex J Sutton,[3] Jørn Wetterslev,[4] Christian Gluud,[4,5] Iwan C C van der Horst,[6,7] Reinold O B Gans,[1] Karina Meijer,[2] Frederik Keus[8]

For numbered affiliations see end of the article

Correspondence to: R J Eck r.j.eck@umcg.nl (ORCID 0000-0001-7440-2465)

Additional material is published online only. To view please visit the journal online.

Cite this as: *BMJ* 2022;378:e070022 http://dx.doi.org/10.1136/bmj-2022-070022

Accepted: 21 May 2022

ABSTRACT

OBJECTIVE
To assess the benefits and harms of different types and doses of anticoagulant drugs for the prevention of venous thromboembolism in patients who are acutely ill and admitted to hospital.

DESIGN
Systematic review and network meta-analysis.

DATA SOURCES
Cochrane CENTRAL, PubMed/Medline, Embase, Web of Science, clinical trial registries, and national health authority databases. The search was last updated on 16 November 2021.

ELIGIBILITY CRITERIA FOR SELECTING STUDIES
Published and unpublished randomised controlled trials that evaluated low or intermediate dose low-molecular-weight heparin, low or intermediate dose unfractionated heparin, direct oral anticoagulants, pentasaccharides, placebo, or no intervention for the prevention of venous thromboembolism in acutely ill adult patients in hospital.

MAIN OUTCOME MEASURES
Random effects, bayesian network meta-analyses used four co-primary outcomes: all cause mortality, symptomatic venous thromboembolism, major bleeding, and serious adverse events at or closest timing to 90 days. Risk of bias was also assessed using the Cochrane risk-of-bias 2.0 tool. The quality of evidence was graded using the Confidence in Network Meta-Analysis framework.

RESULTS
44 randomised controlled trials that randomly assigned 90 095 participants were included in the main analysis. Evidence of low to moderate quality suggested none of the interventions reduced all cause mortality compared with placebo. Pentasaccharides (odds ratio 0.32, 95% credible interval 0.08 to 1.07), intermediate dose low-molecular-weight heparin (0.66, 0.46 to 0.93), direct oral anticoagulants (0.68, 0.33 to 1.34), and intermediate dose unfractionated heparin (0.71, 0.43 to 1.19) were most likely to reduce symptomatic venous thromboembolism (very low to low quality evidence). Intermediate dose unfractionated heparin (2.63, 1.00 to 6.21) and direct oral anticoagulants (2.31, 0.82 to 6.47) were most likely to increase major bleeding (low to moderate quality evidence). No conclusive differences were noted between interventions regarding serious adverse events (very low to low quality evidence). When compared with no intervention instead of placebo, all active interventions did more favourably with regard to risk of venous thromboembolism and mortality, and less favourably with regard to risk of major bleeding. The results were robust in prespecified sensitivity and subgroup analyses.

CONCLUSIONS
Low-molecular-weight heparin in an intermediate dose appears to confer the best balance of benefits and harms for prevention of venous thromboembolism. Unfractionated heparin, in particular the intermediate dose, and direct oral anticoagulants had the least favourable profile. A systematic discrepancy was noted in intervention effects that depended on whether placebo or no intervention was the reference treatment. Main limitations of this study include the quality of the evidence, which was generally low to moderate due to imprecision and within-study bias, and statistical inconsistency, which was addressed post hoc.

SYSTEMATIC REVIEW REGISTRATION
PROSPERO CRD42020173088.

WHAT IS ALREADY KNOWN ON THIS TOPIC

The optimal anticoagulant type and dose for the prevention of venous thromboembolism in acutely ill adults in hospital is unknown

Previous pairwise meta-analyses have had a limited number of direct comparisons between different anticoagulant drugs and doses

WHAT THIS STUDY ADDS

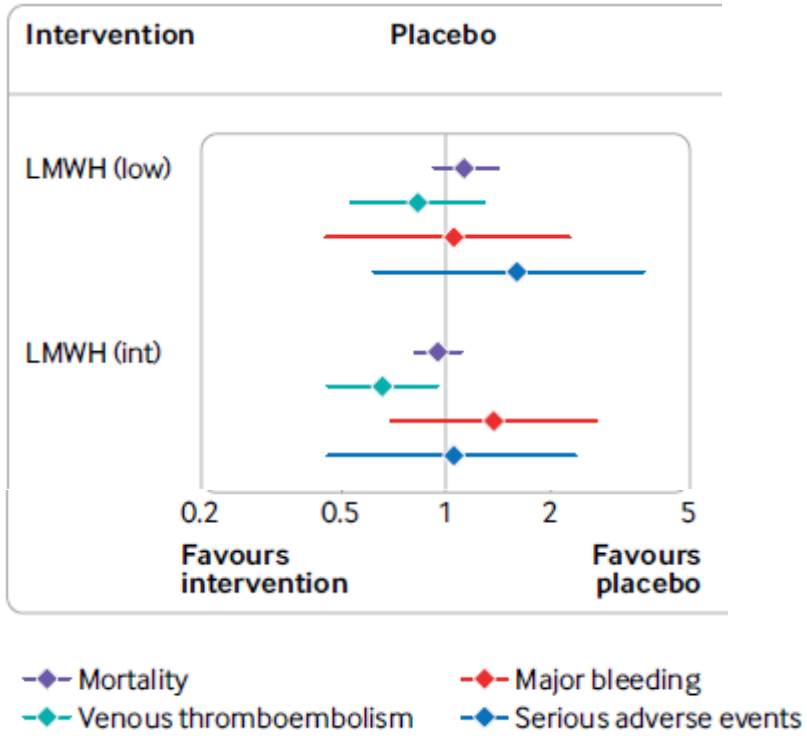
Low-molecular-weight heparin in an intermediate dose might confer the best balance between benefits and harms for prevention of venous thromboembolism; other anticoagulant types and doses had smaller thromboembolism reductions or an increased bleeding risk

A systematic discrepancy was noted in intervention effects that depended on whether placebo or no intervention was the reference treatment; future network meta-analyses should consider separating placebo and no intervention arms

The main limitations of this study were the quality of the evidence, which was generally low to moderate, and statistical inconsistency, which was dealt with post hoc

Introduction

Venous thromboembolism is a multifactorial disease frequently complicating the course of acute illness.[1] Up to half of all thrombotic events have been estimated to be attributable to a current or recent hospitalisation, making prevention of in-hospital venous thromboembolism a worthwhile aim.[2] Any anticoagulant intervention such as coumarin, unfractionated heparin, low-molecular-weight heparin, pentasaccharides, or direct oral anticoagulants can be

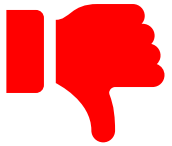


BMJ 2022;378:e070022

Alive and out of hospital?

Low versus intermediate versus weight-adjusted dose

Improved thromboprophylaxis?



More bleeding?

Thromboprophylaxis

Inclusion criteria

- Decision by treating clinician to start/continue thromboprophylaxis with LMWH
- All interventions considered clinically appropriate
  (low versus intermediate versus weight-adjusted dose)

- ICUs with systematic screening for deep vein thrombosis (DVT) cannot participate in domain

Exclusion criteria

- More than one prophylactic dose of anticoagulation during current ICU stay (including days in another ICU)
- Known/suspected previous adverse reactions to heparin (including allergy and heparin-induced thrombocytopenia)
- Known pregnancy
- Mechanical circulatory support
- Solid organ transplant during current hospital admission
- Weight < 40 kg
- Inclusion in another trial or INCEPT domain where co-enrolment with INCEPT-Thromboprophylaxis is not permitted

Intervention

Each ICU chooses one LMWH for everyone

(Dalteparin, enoxaparin, tinzaparin or nadroparin)

Shelf medication

Low versus intermediate versus weight-adjusted LMWH prophylaxis in ICU for max 90 days

INCEPT
The Intensive Care Platform Trial

Thromboprophylaxis

Intervention

Site preferred LMWH Intervention	Weight (kg)*	Enoxaparin dose (mg)	Tinzaparin dose (IE)	Dalteparin dose (IE)	Nadroparin dose (IE)
Fixed low dose	All	40	2500	2500	2850
Fixed intermediate dose	All	60	4500	5000	5700
Weight-adjusted dose	≥40 - 50	40	2500	2500	2850
	≥50 - 60	40	2500	2500	3800
	≥60 - 70	40	4500	5000	3800
	≥70 - 80	60	4500	5000	3800
	≥80 - 90	60	4500	5000	5700
	≥90 - 100	80	7000	7500	5700
	≥100 - 110	80	7000	7500	7600
	≥110 - 120	80	8000	7500	7600
	≥120	100	8000	10000	7600

*Actual body weight as estimated or measured at time of screening

Thromboprophylaxis

Intervention

Dose adjustment or pausing of the intervention at clinician's discretion when …

- Acute and/or chronic kidney injury
- Renal replacement therapy
- Thrombocytopenia
- Invasive procedures
- Use of thrombolysis
- Active (major) bleeding

Suggested triggers and dose adjustment strategies available in domain-specific appendix and patient folder

Intervention

Intervention should stop permanently when…

- Therapeutic anticoagulation (e.g., treatment of VTE or atrial fibrillation)
- Serious adverse reaction (anaphylaxis or heparin-induced thrombocytopenia)

Other deviations from the allocated intervention will be considered a protocol violation

Outcomes

Primary: Days alive and out of hospital at 30 days

Secondary:

INCEPT core outcomes

- All-cause mortality at 30, 90, and 180 days
- Days alive without life support at 30 and 90 days
- Days alive and out of hospital at 90 days
- Days free of delirium at 30 days
- Health-related quality of life (EQ-5D-5L and EQ-VAS) at 180 days
- Cognitive function (Mini-MoCA) at 180 days

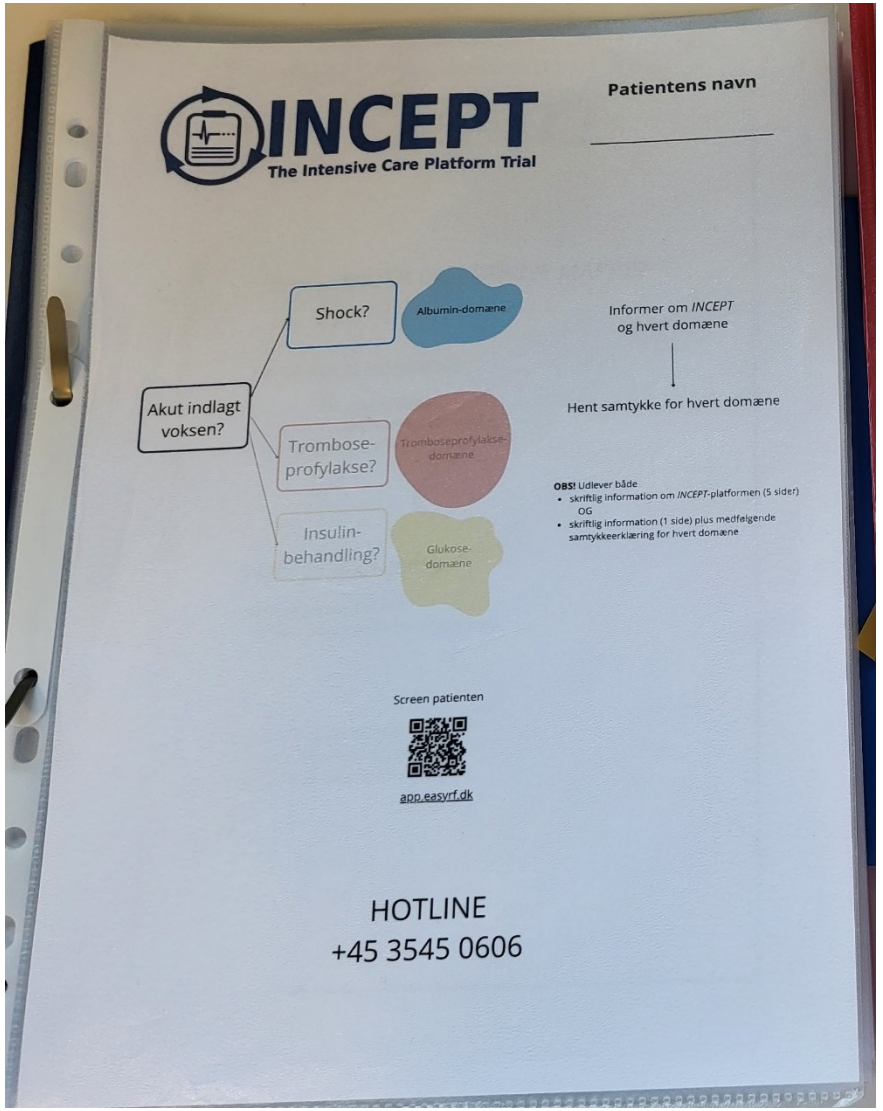
Domain specific secondary outcomes

- Venous thromboembolism (DVT or pulmonary embolism) at 30 and 90 days
- Major bleeding at 30 and 90 days
- Domain specific safety outcomes (anaphylaxis and heparin-induced thrombocytopenia) at 30 and 90 days

Thromboprophylaxis

?

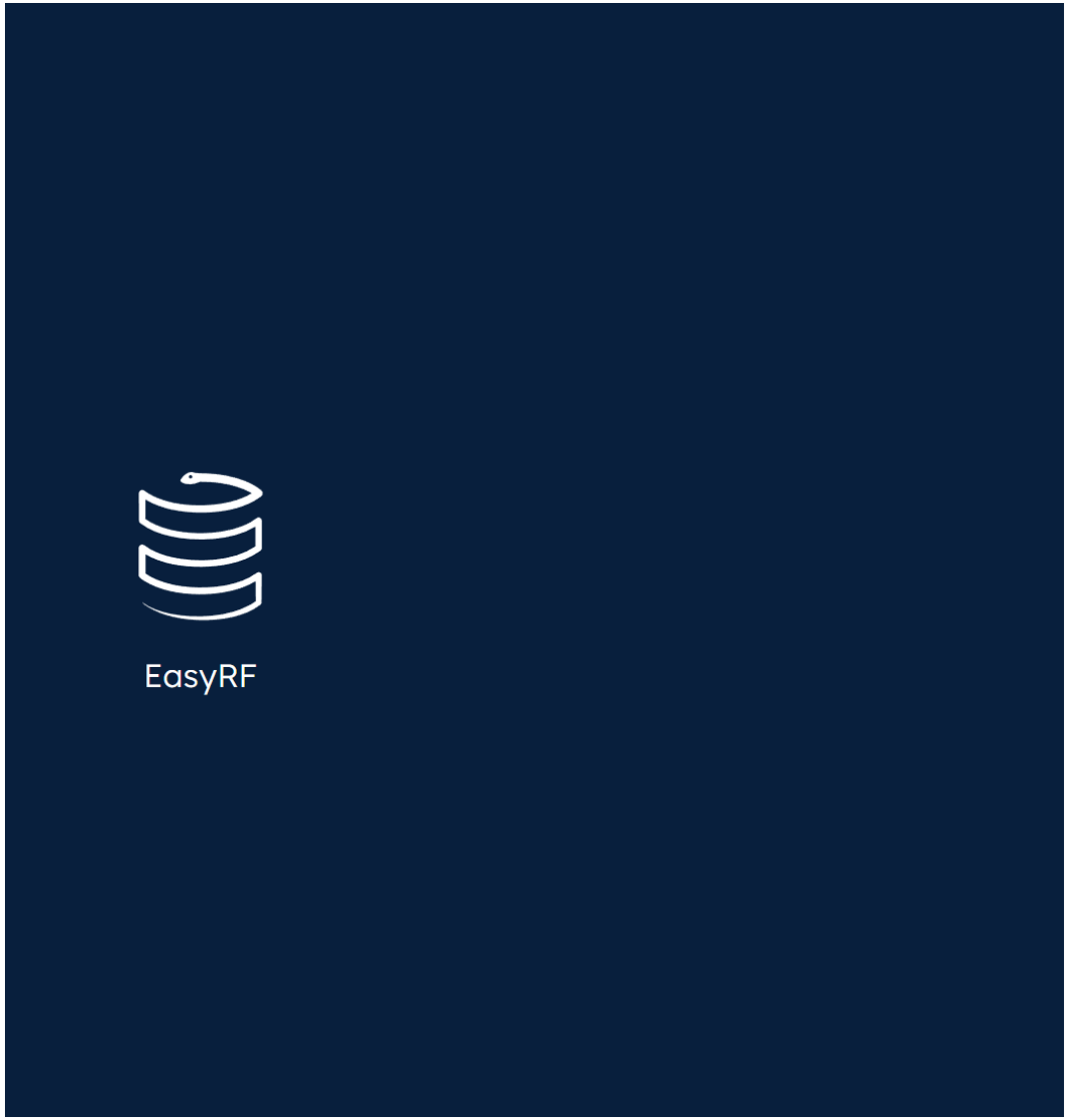
Workflow

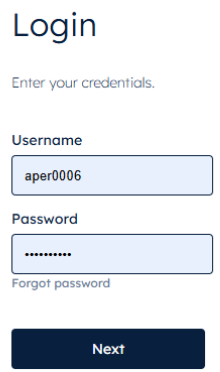

INCEPT
The Intensive Care Platform Trial
Patientens navn
Shock?
Albumin-domæne
Akut indlagt voksen?
Trombose-profylakse?
Trombose-profylakse-domæne
Insulin-behandling?
Glukose-domæne
Informer om INCEPT og hvert domæne
Hent samtykke for hvert domæne
OBS! Udlever både
skriftlig information om INCEPT-platformen (5 sider) OG
skriftlig information (1 side) plus medfølgende samtykkeerklæring for hvert domæne
Screen patienten
app.easyrf.dk
HOTLINE
+45 3545 0606

Supportive material

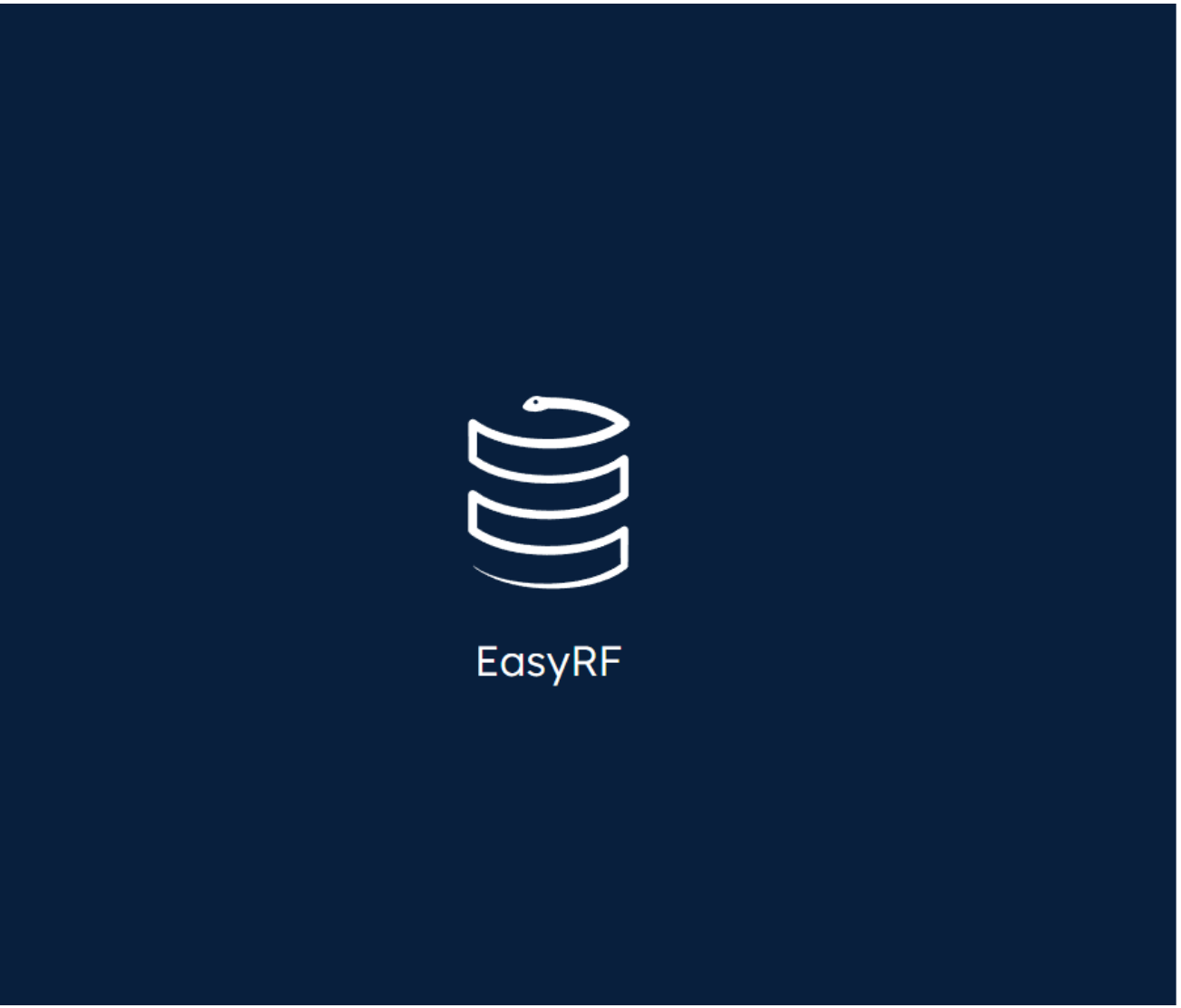
- Operational guideline (to be adapted nationally)
- Pocket cards
- Leaflets
- “FAQ’s” at www.incept.dk
- Hotline – for urgent matters
- EasyRF workshops

Login


EasyRF


Login
Enter your credentials.
Username
aper0006
Password
Forgot password
Next

Login



Login

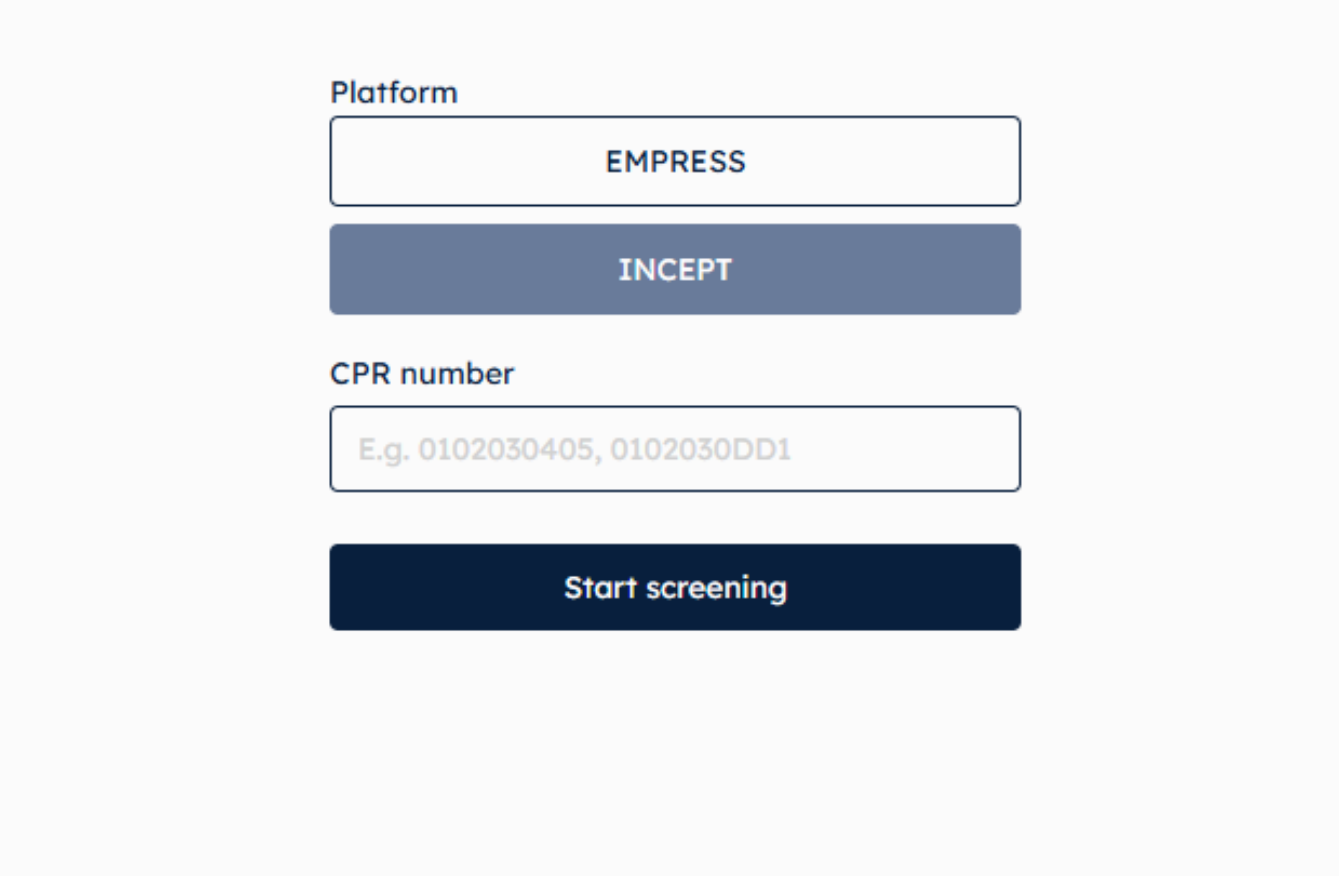
Please enter the token generated by your token generator.

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

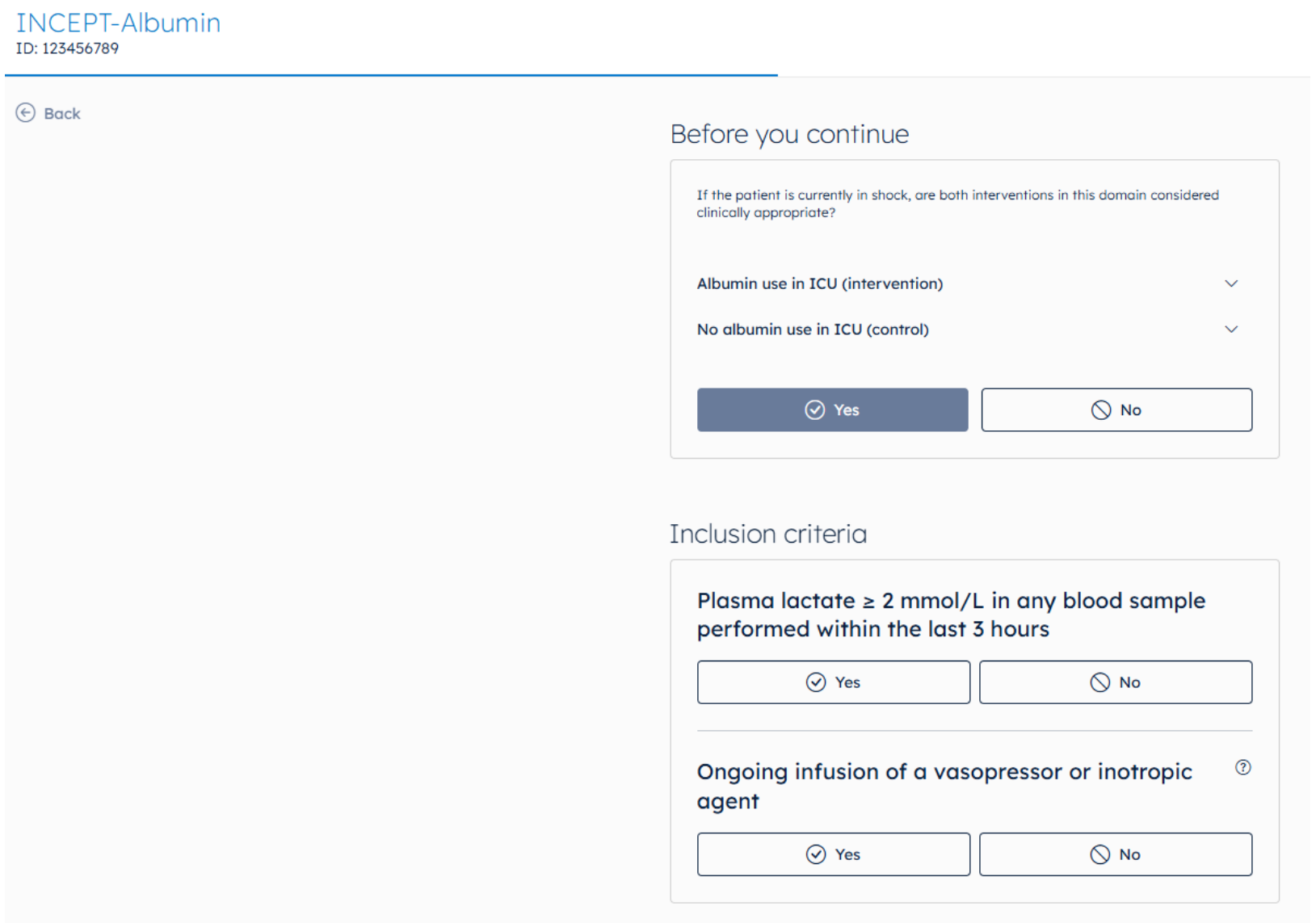
Informed consent following inclusion expected to be unobtainable

Yes | No

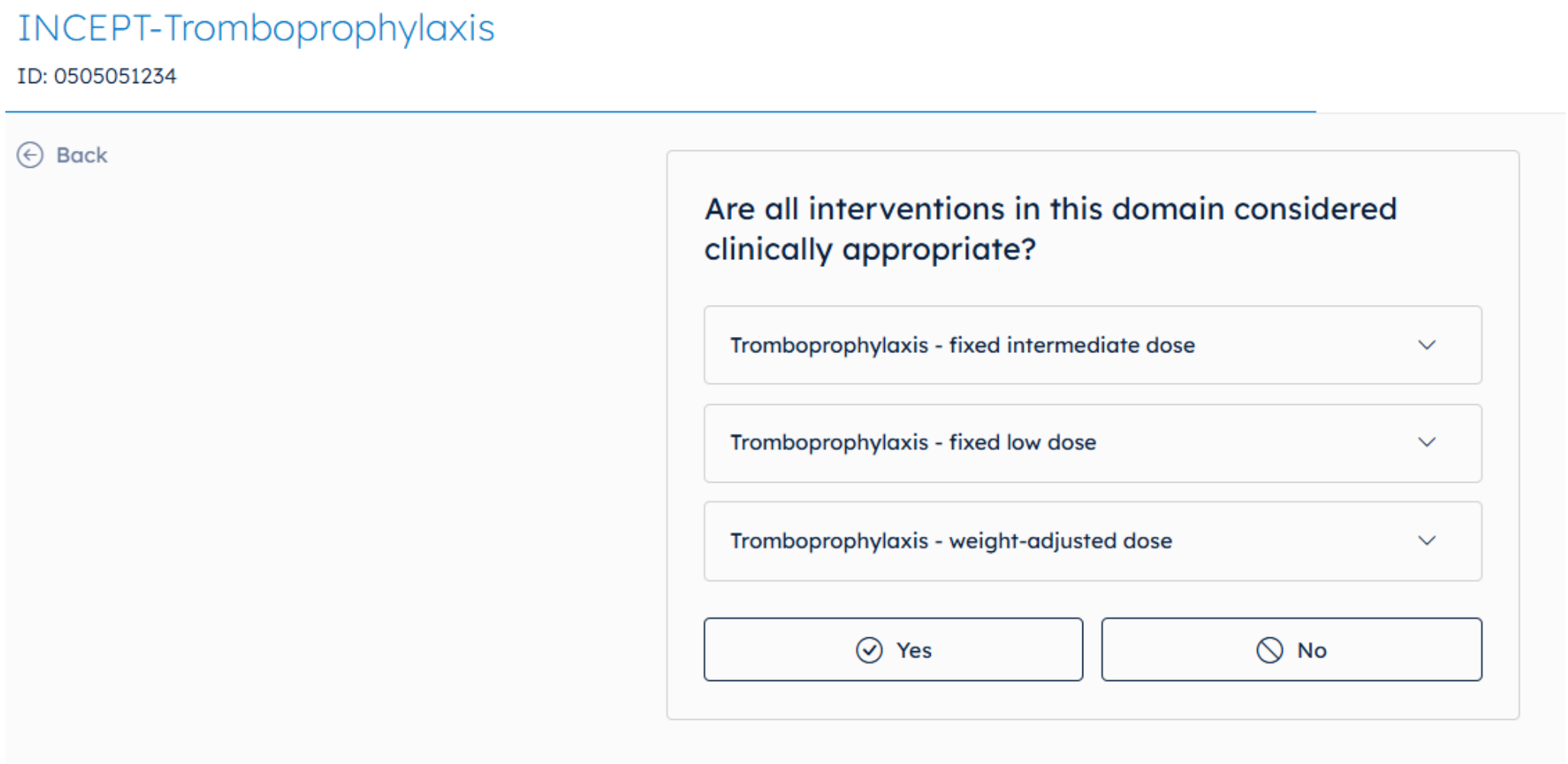
Patient is under coercive measures

Yes | No

Screening


INCEPT-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-Tromboprophylaxis

ID: 0505051234

Back

Stratification variables

History of venous thromboembolism

Yes | No

Additional variables

Suspected sepsis

Yes | No

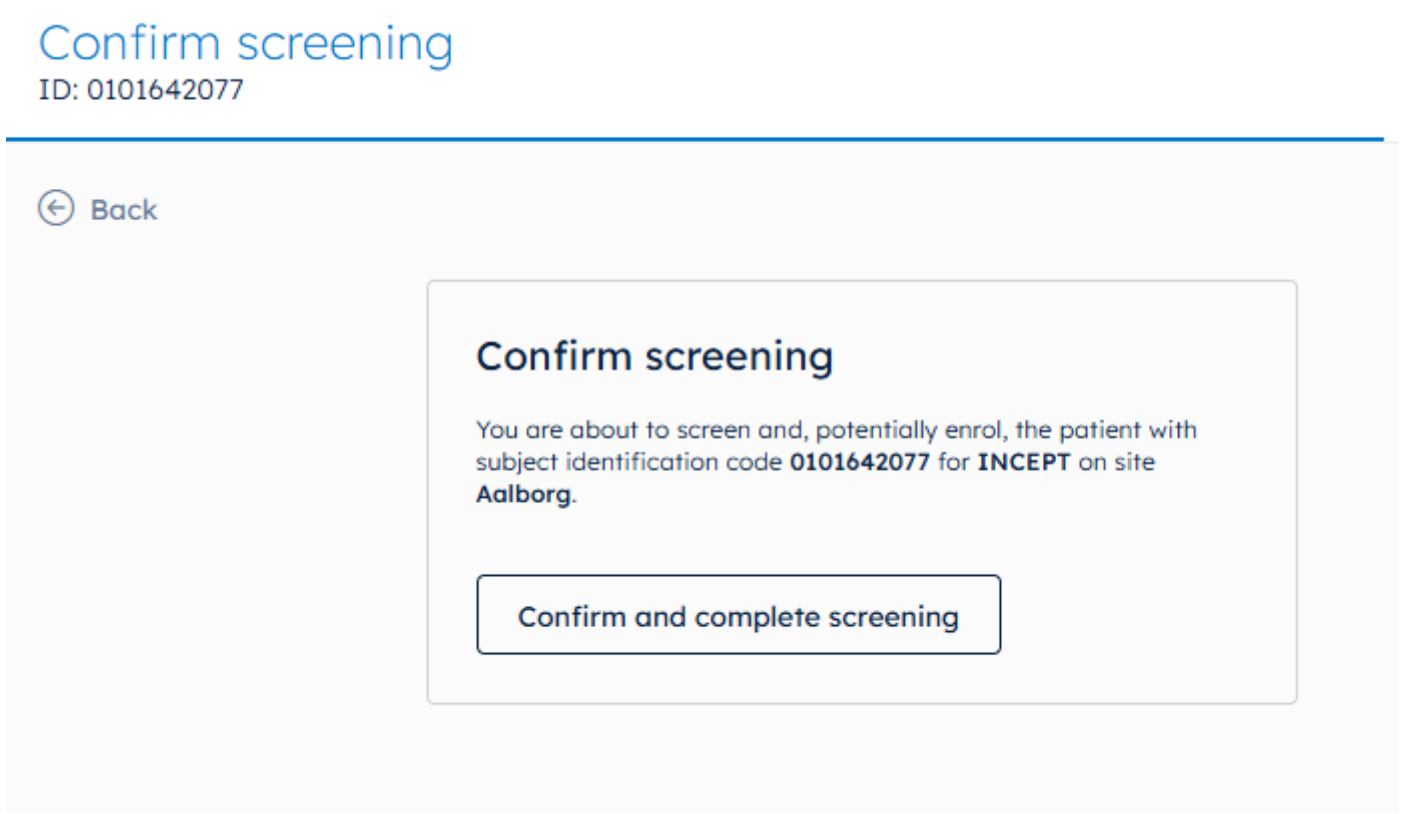
Sex

Female | Male

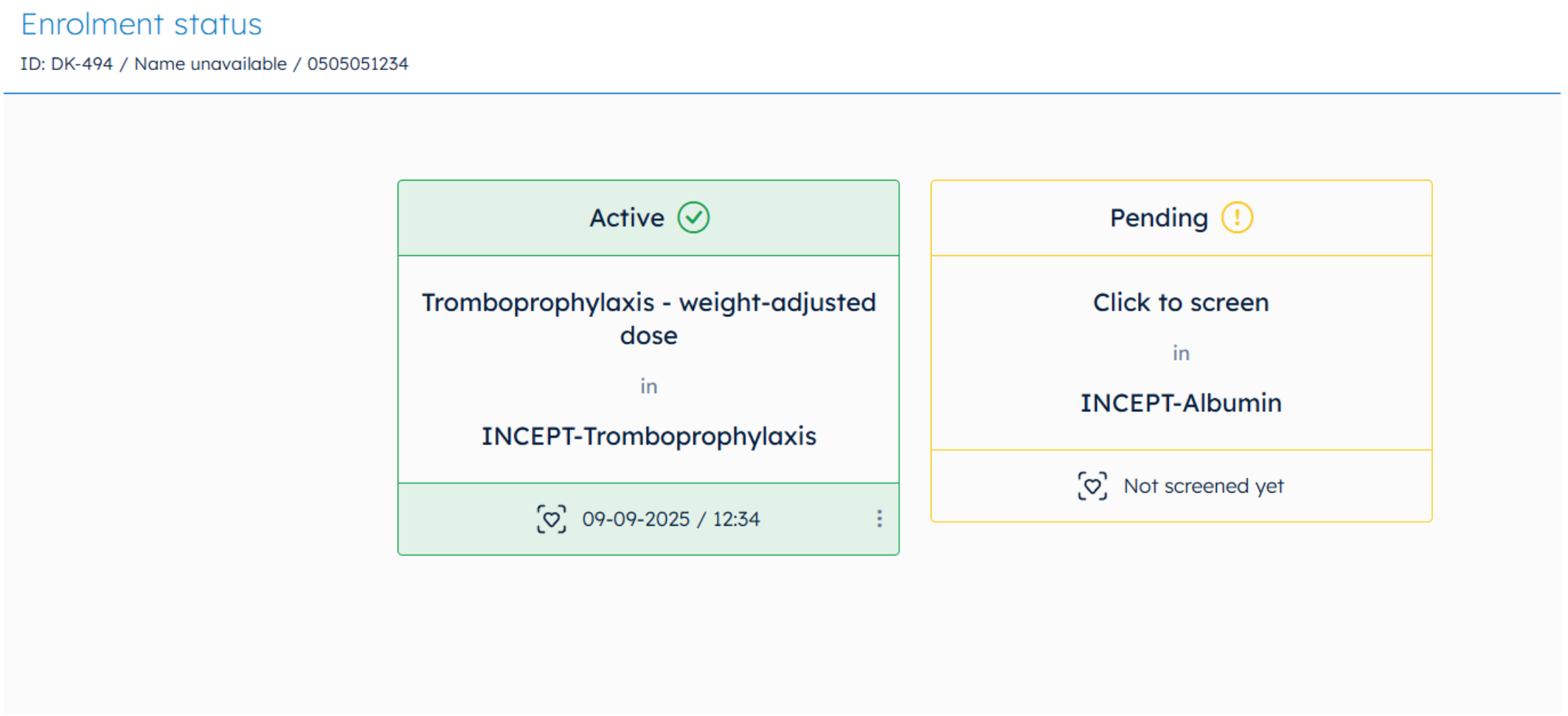
Presence of a central venous catheter

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

Enrolment status



Enrolment status

Enrolment status

ID: DK-487 / Name unavailable / 0812670573

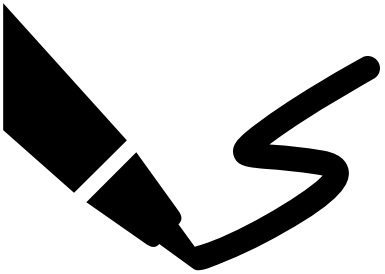
Active	Active
Albumin use in ICU (intervention) in INCEPT-Albumin	Thromboprophylaxis - weight-adjusted dose in INCEPT-Thromboprophylaxis
09-09-2025 / 10:43	09-09-2025 / 10:41

Following randomisation

- Inform clinical staff
- Prescribe trial medication (if patient is in ‘no albumin’ stop any prescribed albumin)
- Register enrolment in patient medical record
- Note enrolment in medical record, bedside sign etc.
- Start/continue consent procedure according to national law

Consent

INCEPT is a clinical trial conducted in emergency situations



Clarification of national consent legislation

If consent has been withdrawn → always ask for permission to continue data collection

Safety reporting

Serious Adverse Reactions (SARs)

- Registered daily in the eCRF

Suspected, Unexpected, Serious Adverse Reaction (SUSARs)

- Investigator reports SUSARs to sponsor within 24 hours (hotline: +45 3545 0606) eCRF/document

Serious adverse events (SAEs)

- Investigators have the possibility to report serious adverse events in the eCRF

External monitoring

Certification according to Good Clinical Practice

Clarification of national requirements for trial staff

(Staff involved in screening, reporting of serious adverse events, information to participants, consent collection, data entry)

INCEPT
The Intensive Care Platform Trial

?

Contact

INCEPT hotline

+45 3545 0606

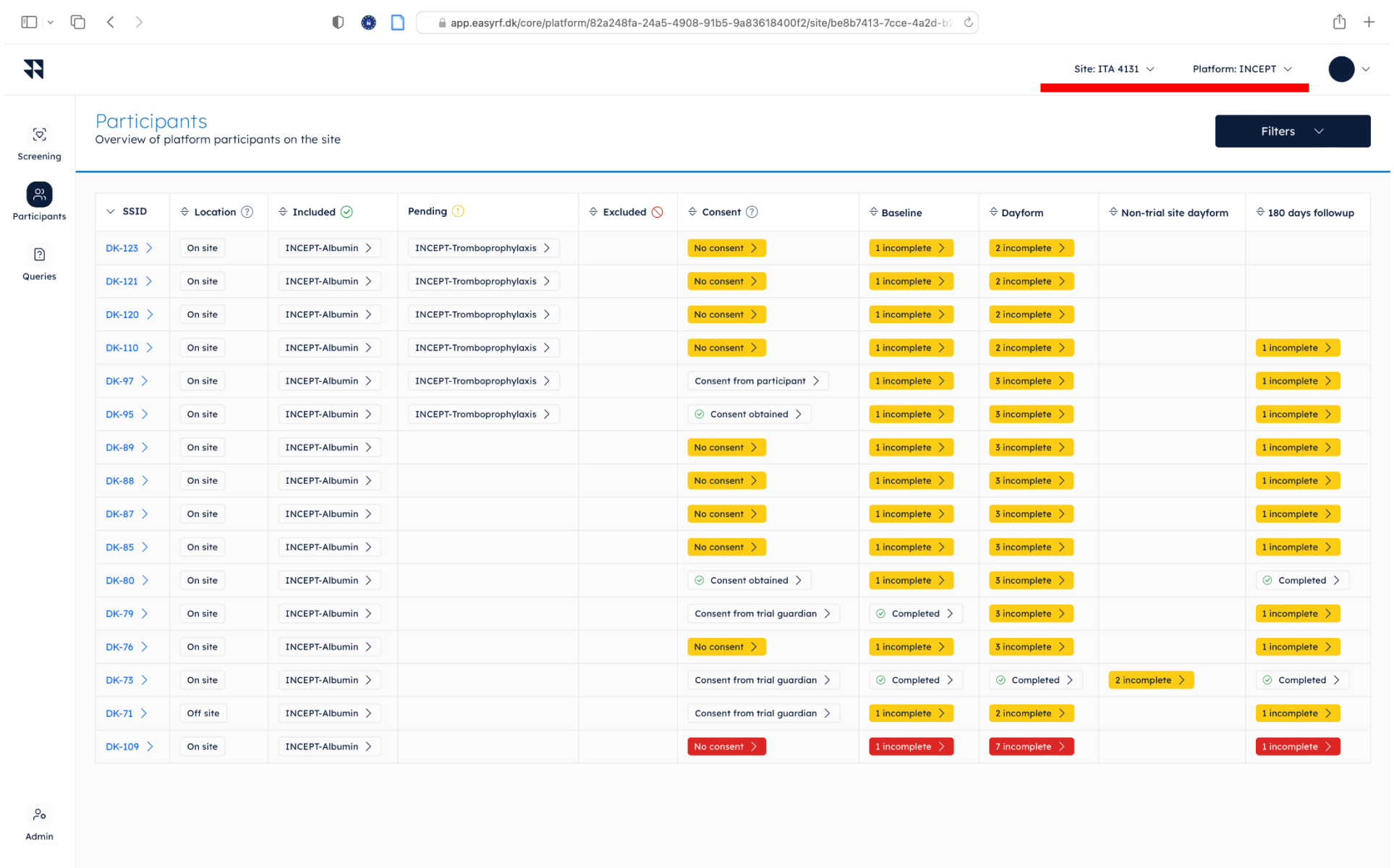
open 24/7

contact@incept.dk

INCEPT
The Intensive Care Platform Trial

Data collection

Overview



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

Dayforms

Dayform

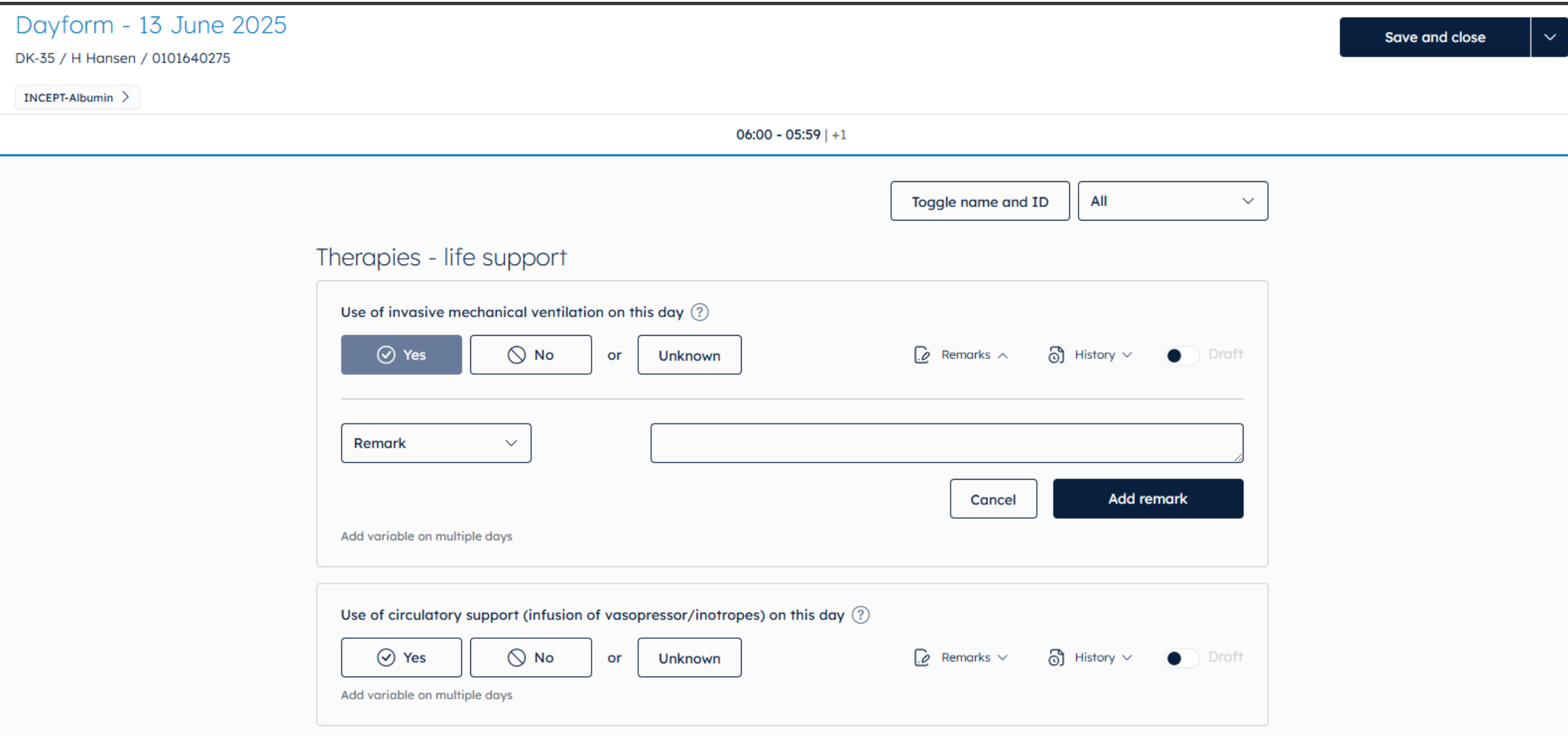
DK-35 / H Hansen / 0101640275

Back

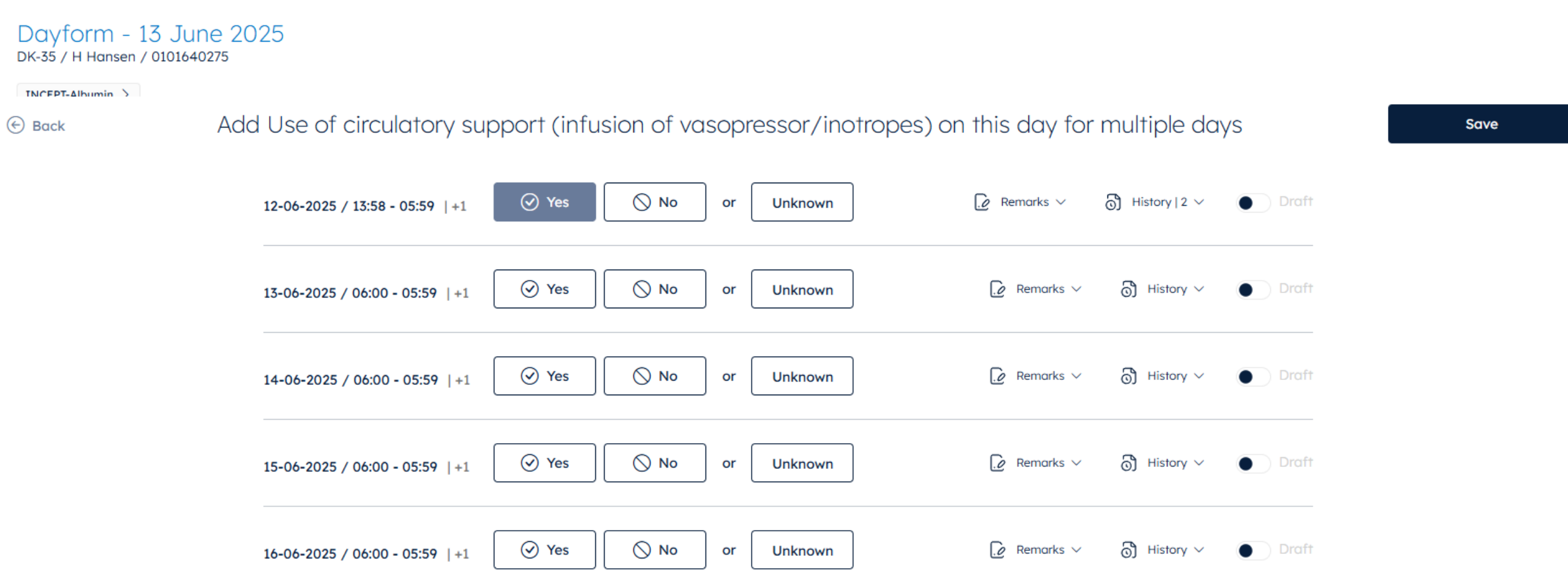
June 2025

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						

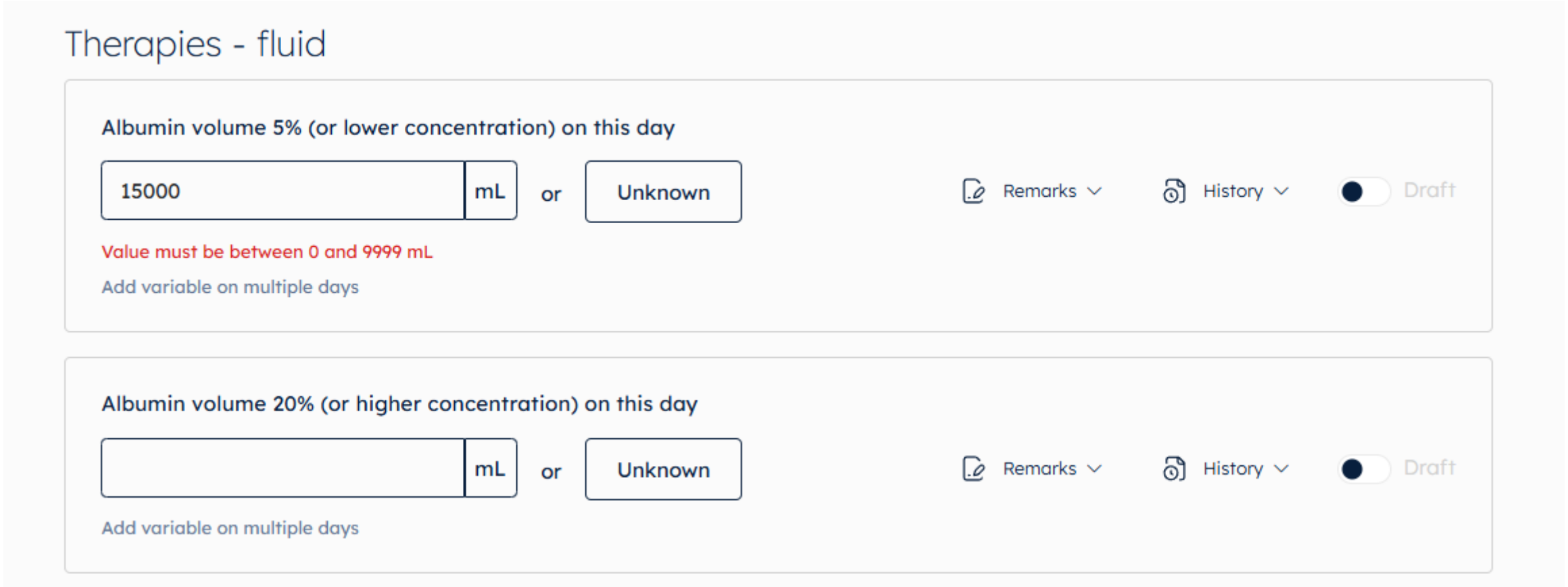
Dayforms


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

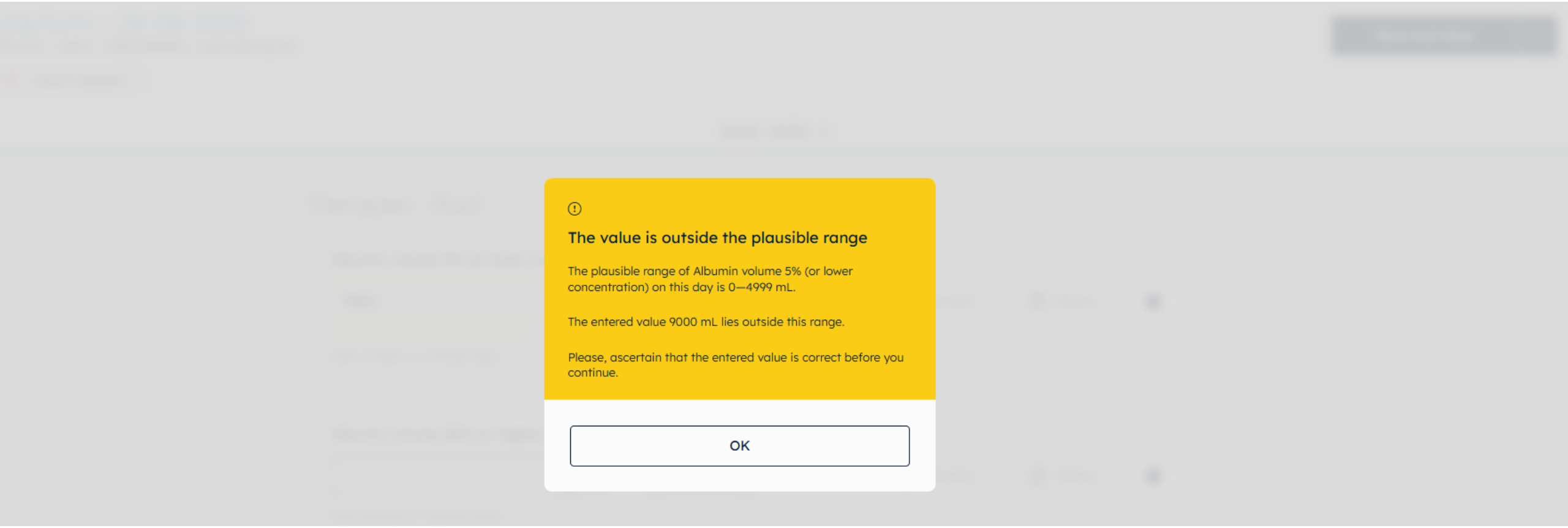
Dayforms


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

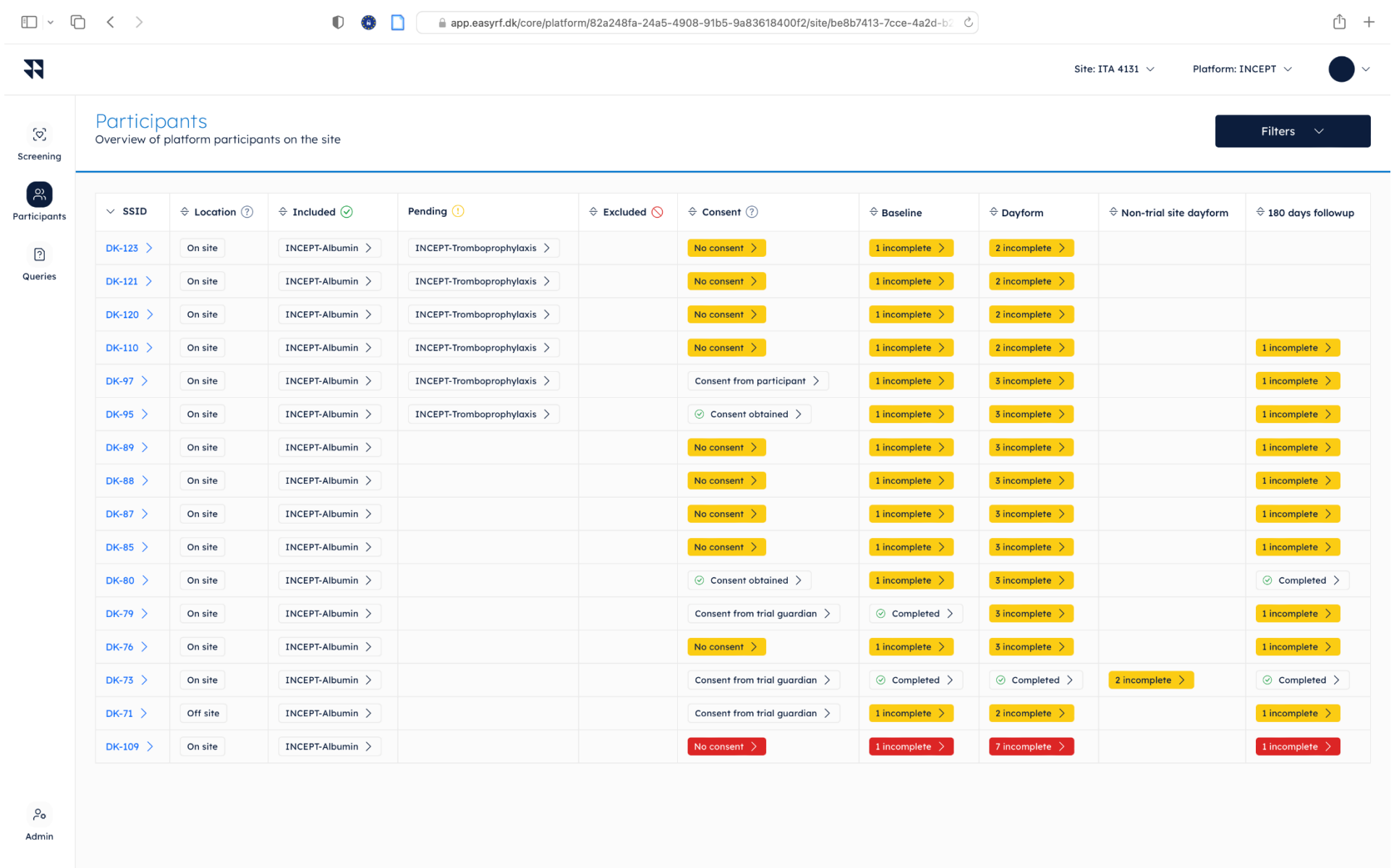
Dayforms


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

Overview



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
Surgical consultant

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

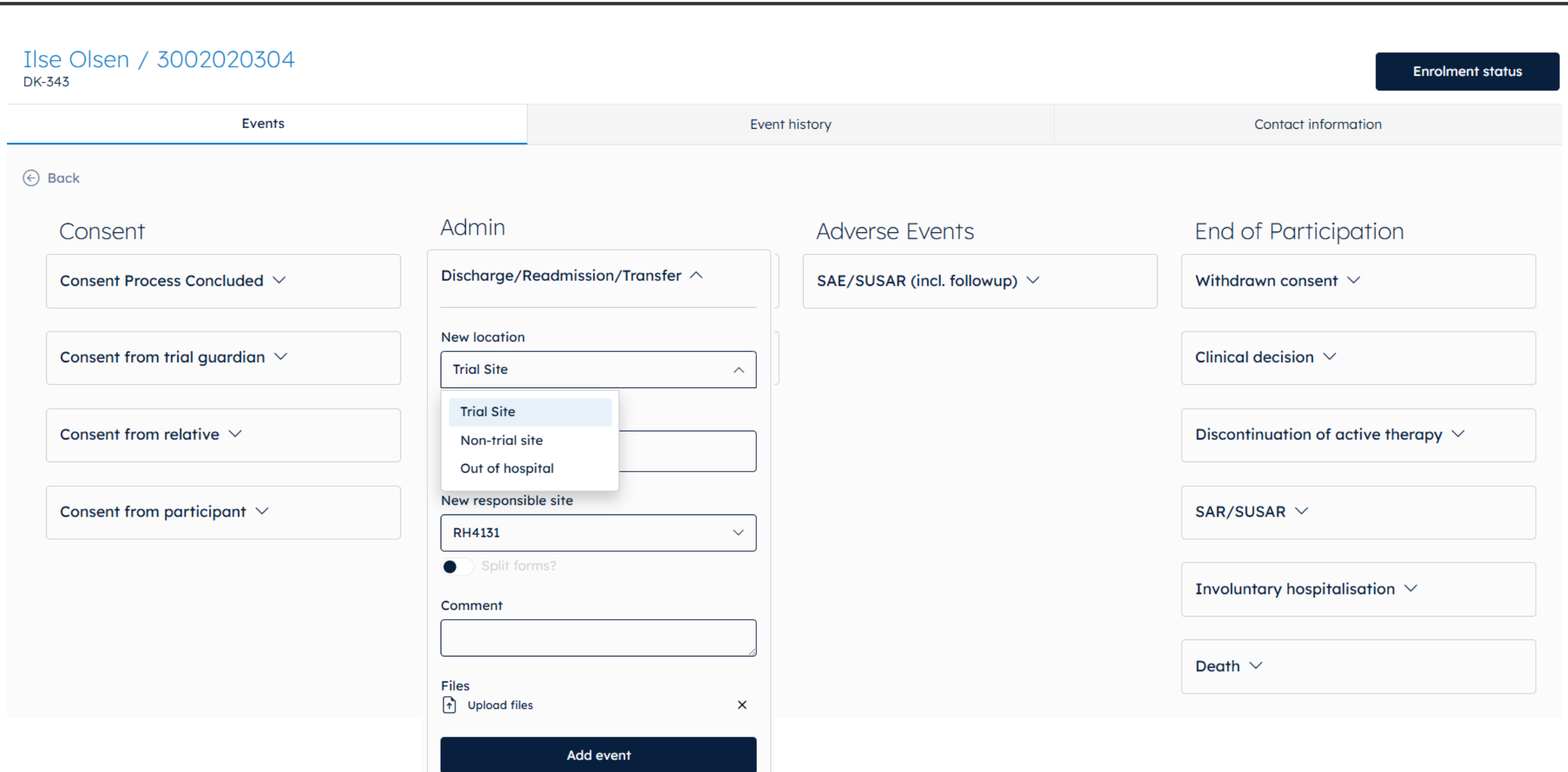
Adverse Events

- 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

End of participation

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

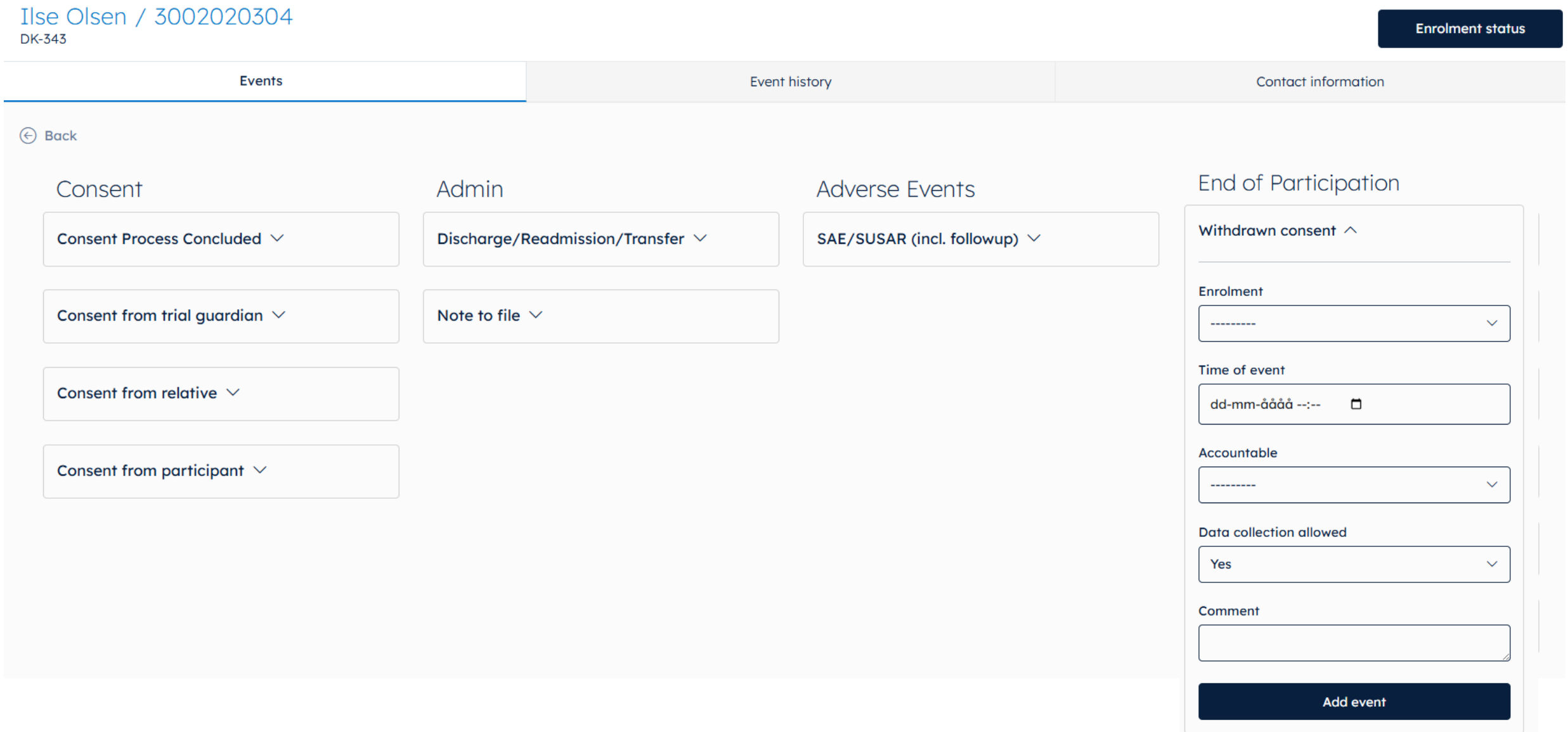
Adverse Events

- SAE/SUSAR (incl. followup)

End of Participation

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

End of participation



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

Contact 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

Follow-up at 180 days

Use ‘Guideline for obtaining 180-day follow-up’ (available in Site File)

1. Survival
2. Cognitive function
3. Health-related quality of life

By trial staff who cannot see or discuss the allocation with the participant (bias reducing procedure)