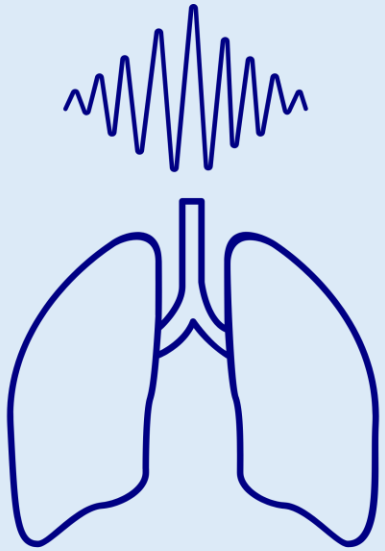
Confederation of Respiratory Critical Care Trials
CoReCCT



WARWICK
THE UNIVERSITY OF WARWICK

NHS
King's College Hospital
NHS Foundation Trust

UK NAVA

Clinical Staff Recruiters

V1.0

23June2025

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UK NAVA Summary

UK NAVA

CoReCCT

WARWICK
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UK NAVA is a randomised controlled trial investigating whether the use of NAVA technology can reduce the length of time patients spend on a ventilator, in comparison with standard care.

UK NAVA sits within a family of trials called The Confederation of Respiratory Critical Care Trials; CoReCCT.

- **Coordinating Centre** – Warwick Clinical Trials Unit (WCTU)
- **Chief Investigators** – Dr Dan Hadfield and Dr Phil Hopkins (King's College Hospital)
- **Nurse Educator** – Louise Payne (King's College Hospital)
- **Trial Team (Trial Manager and Trial Coordinator)** – Maddy Hill and Kirsty Lea
  NAVA@warwick.ac.uk

This training is for any clinical member of staff who may be assessing eligibility for, and randomising, into the UK NAVA trial. If you are listed on the delegation log and have completed any other UK NAVA training, you do not need to complete this training module.

Introduction to GCP

You do not need to have completed GCP to recruit into the UK NAVA trial. The following slides provide a summary of key GCP principles and how this relates to your role in the UK NAVA trial.

Internationally agreed and harmonised ethical & scientific quality standard

Ensures that the rights, safety, dignity & wellbeing of participants are protected

Covers trial design, conduct, recording & reporting

Ensures credibility of data

Working to GCP Principles ensures:

That **Participants** rights, safety, well-being and confidentiality are protected

That **Data** is seen as credible and verifiable and will ensure accurate results

Key GCP principles for your role in UK NAVA

3. Participant safety

- Ensure participant rights & safety prevail
- Number 1 priority

6. Follow the protocol

- Trial must be conducted to approved protocol (see trial guidance documents)

8. Training, education, experience

- Everyone involved in a trial must be suitably educated, trained and experienced to perform specific tasks with oversight from the Principal Investigator (clinician responsible for the trial at your site)

9. Informed consent

- Freely given informed consent must be obtained from each participant, OR
- Provisions in the Mental Capacity Act 2005 allow for enrolment of participants in emergency situations

10. Trial documentation

- Record, handle & store information in a way that allows for accurate reporting, interpretation & verification

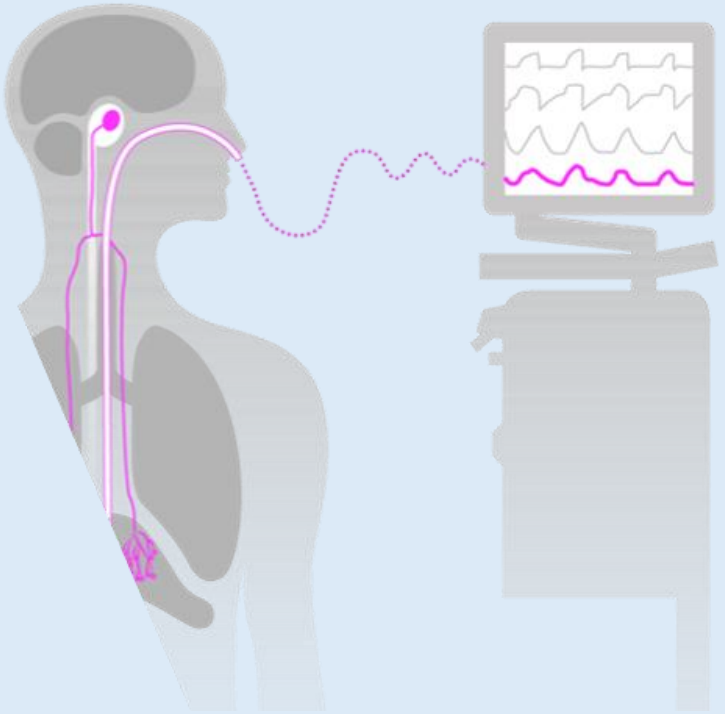
UK NAVA Background

- Approximately half of all ICU patients need invasive mechanical ventilation

- Invasive mechanical ventilation is a ‘necessary evil’, but it can cause significant harm (e.g. airway injury, lung injury, muscle injury, sepsis and adverse effects from sedation or muscle relaxants)

- Invasive mechanical ventilation is also uncomfortable and dehumanising (eg impairs sleep, prevents communication, leads to symptoms of thirst, loss of autonomy)

- **Primary objective: to investigate whether the use of NAVA Technology in addition to standard care reduces the duration of mechanical ventilation when compared to standard care alone**



Inclusion Criteria



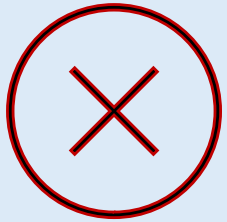
- Adult (Age >/= 18)
- Receiving Invasive Mechanical Ventilation
- Expected invasive ventilation ≥ 48 hrs
- Expected weaning difficulty
  (Any clinical risk factor for difficult or prolonged weaning from invasive ventilation)

- Examples of acute clinical risk factors include major trauma, pneumonia, ARDS, multiple organ failure, pancreatitis, stroke, shock

- Examples of chronic clinical risk factors include COPD, heart failure, obesity, frailty

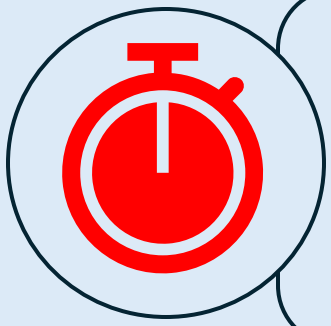
Co-enrolment with Awake Prone and PROTECT Airways *but not* RELEASE

Exclusion Criteria



- Death or treatment withdrawal expected within 48 hours
- Contraindication to NAVA catheter insertion (oesophageal injury
- A temporary/permanent pacemaker
- Phrenic nerve injury, Myaesthenia gravis, Gullain-Barre
- Severe central neurologic disorder (TBI, refractory status epilepticus) causing elevated intracranial pressure, impaired control of breathing, requiring specific ventilator adjustments or requiring neurosurgical intervention
- Known or suspected severe or progressive neuromuscular disorder likely to result in prolonged or chronic ventilator dependence (MND, Duchenne Muscular Dystrophy, Amyotropic Lateral Sclerosis, Spinal Cord Injury above C6)
- Severe, end-stage, irreversible respiratory or cardiac disease with a referral to/accepted by chronic weaning unit/palliative care for likely chronic ventilator dependence
- Home ventilation prior to ICU admission, excluding nocturnal CPAP
- Previous participation in the UK NAVA trial

Consent



If **approaching a consultee will delay urgent treatment** e.g. clinicians want to place the NAVA catheter after a Rapid Sequence Induction (emergency procedure) or whilst the patient is deeply sedated for a tracheostomy or other procedure)



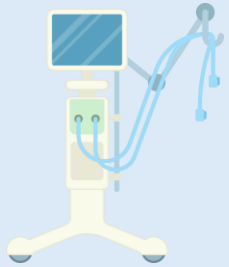
There is no consultee available and waiting to identify or contact a consultee would delay urgent treatment



According to the above criteria, if in your opinion it seems reasonable to proceed using deferred consent, proceed to randomisation

Preparing to randomise

Equipment availability





Eligibility assessment



CoReCCT database link

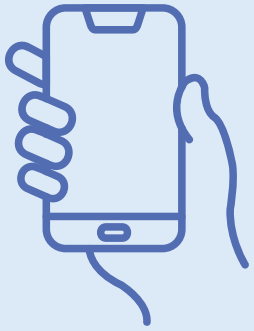
Randomisation system



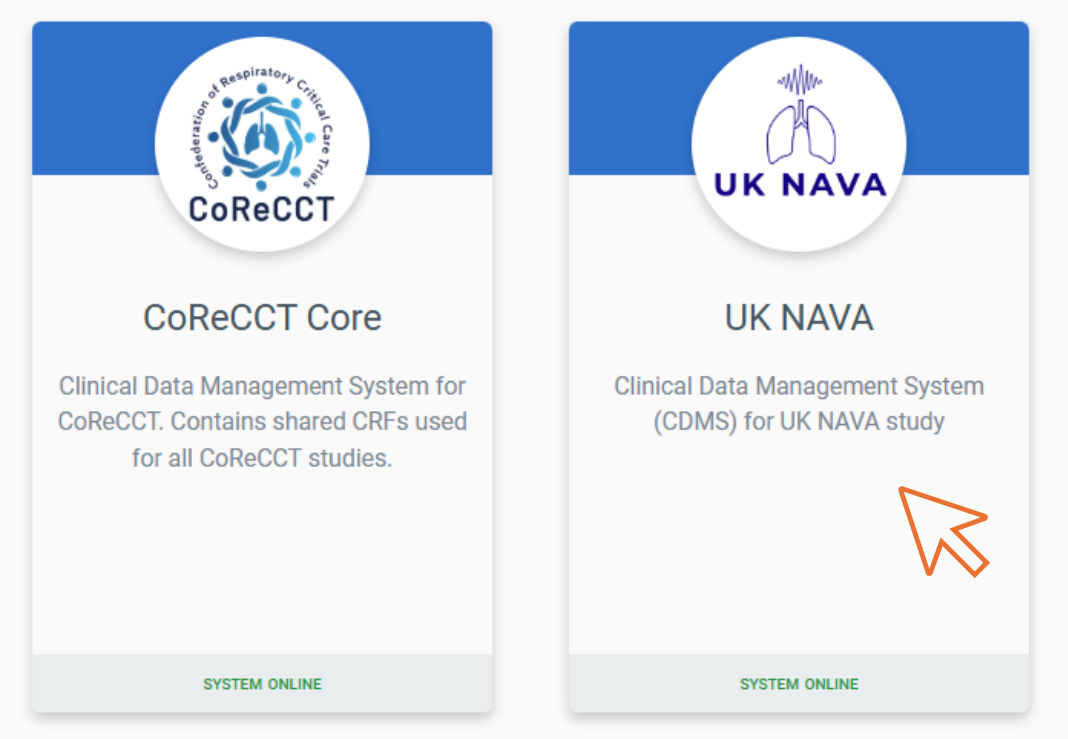
Your access will be set up once you have completed this relevant training, and have confirmed this on the CoReCCT training log.

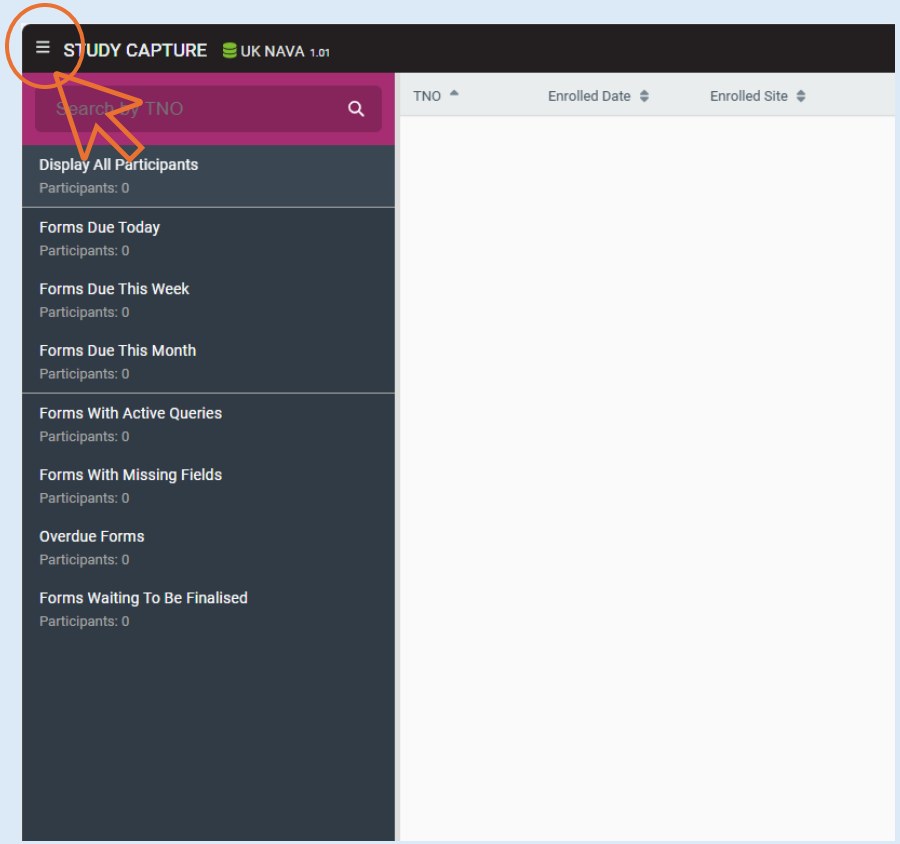
You can use your NHS email and password to access the CoReCCT database and the trial randomisation wizard.

The randomisation wizard can be accessed on a desktop computer, tablet or mobile device.



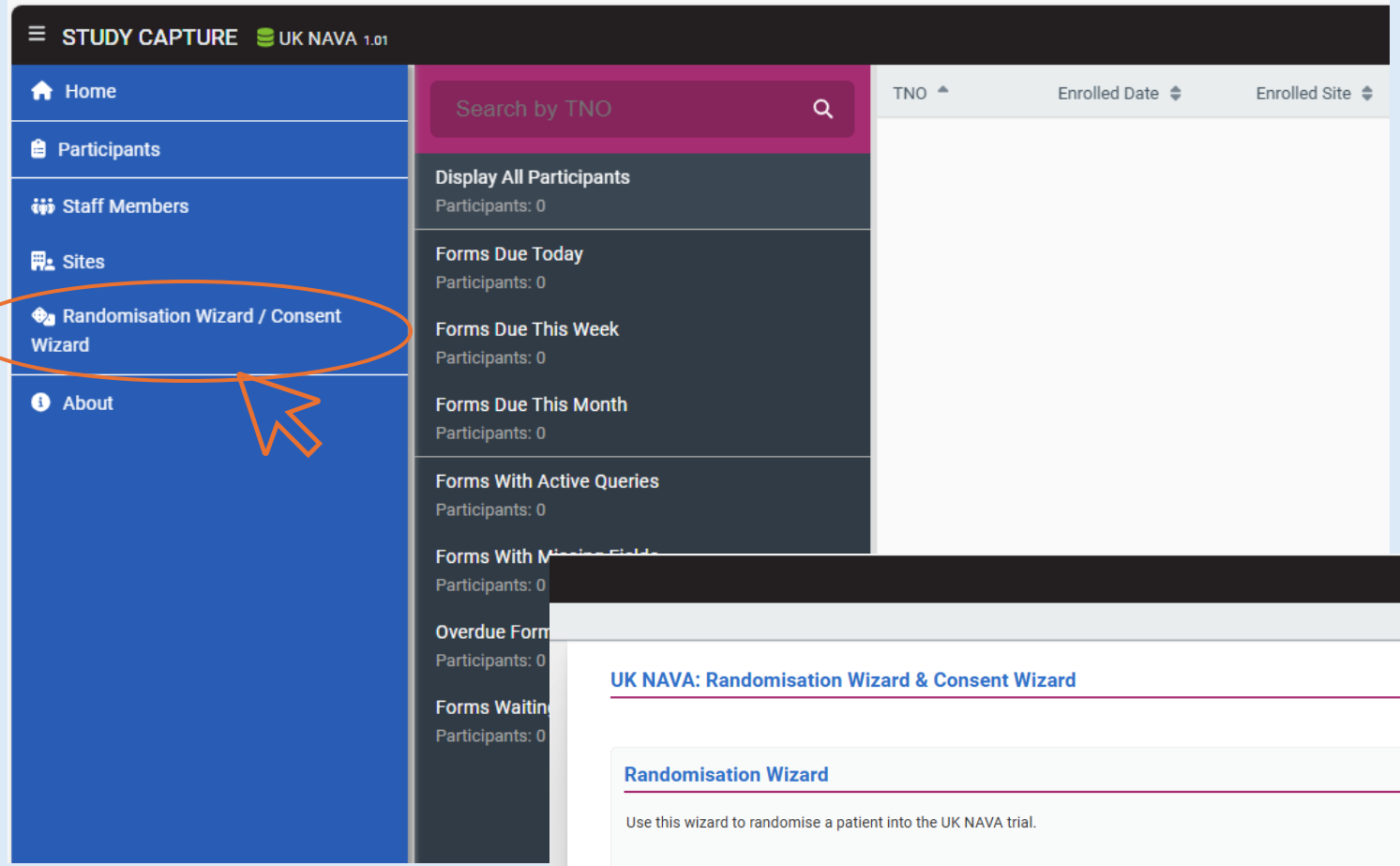
Randomisation system



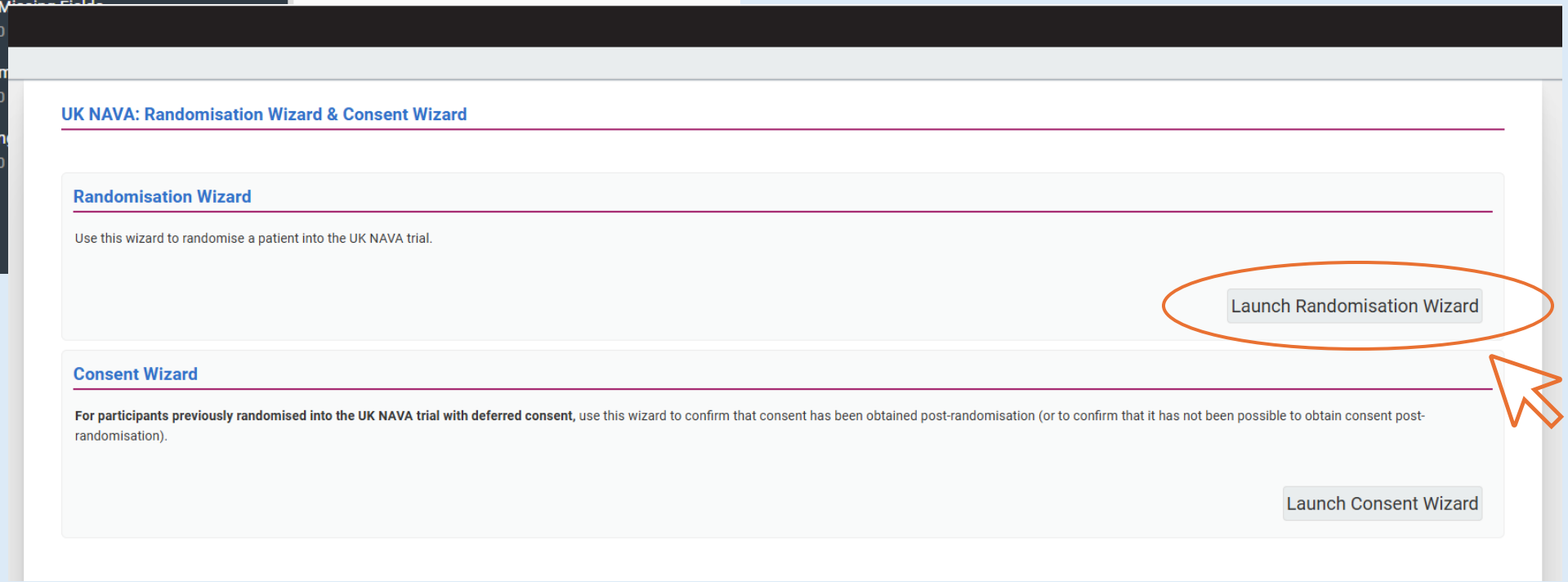


1. Select the UK NAVA database

2. Open the menu by clicking on the 3 lines in the top left-hand corner



3. Select the Randomisation Wizard



4. Click ‘Launch Randomisation Wizard’

After randomisation



Trial arm allocation

Participant allocated to intervention or control arm.



Medical note update

Participant will be allocated a trial number (TNO). Ensure TNO and treatment arm allocation are recorded in the medical notes.



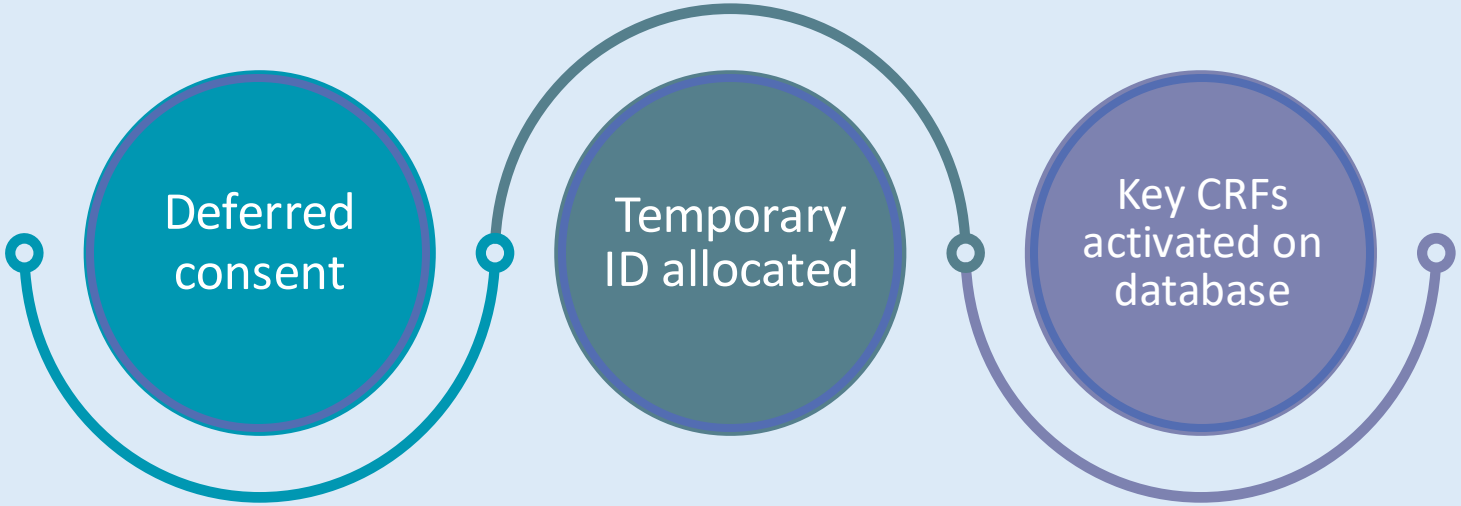
Next steps

If the participant has been allocated the NAVA Technology Arm, a NAVA Catheter should be placed within 6 hours, and NAVA Technology should commence as soon as possible.

A NAVA Catheter should not be placed in participants allocated the Conventional Treatment arm.

Randomising under deferred consent

Following randomisation under deferred consent, the participant will be provided a temporary trial reference number (e.g. UTEMP1234)



Only some data will be able to be entered onto the UK NAVA database. No personal details will be collected until consultee agreement is in place and the temporary reference number is converted into the permanent TNO (e.g. TNO 1234)

Co-enrolment

- Co-enrolment will be permitted with non-interventional observational studies without the need for a co-enrolment agreement.
- If you are aware of patient being in another interventional trial at time of screening, consult the list of approved trials on the study website.
- If the trial is on the list, proceed to randomisation. The co-enrolment CRF will capture the name of the co-enrolled trial.
- If the trial is not on the list, contact WCTU to discuss and do not randomise the patient.





UK NAVA

Thank you for completing this training.
If you have any questions, please contact
nava@warwick.ac.uk

To record training visit
https://warwick.ac.uk/fac/sci/med/research/ctu/trials/corecct/health/training/traininglog/