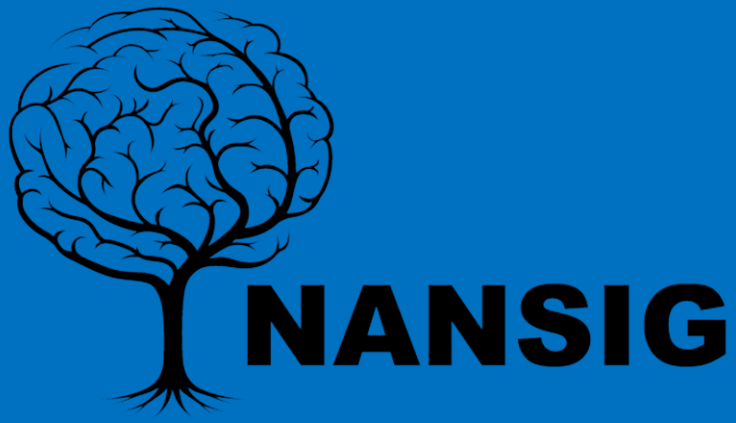
CRANIAL: **C**SF **R**hinorrhoea **A**fter E**n**donasal **I**ntervention to the **A**nterior Sku**l**l Base – A National Prospective Service Evaluation on Incidence and Management

A 'How to' guide with practical tips



Project Background:

- CSF leak remains the most common complication of endoscopic endonasal surgery of the skull base.
- Reported incidence is very variable, with no national standard yet established.

- One of the critical determining factors of leak rates is the method of the skull base reconstruction.
- There is significant heterogeneity in current practice with no established national standards for CSF leak prevention and repair.

- Therefore we hope this multicentre, prospective, clinical service evaluation will help to inform national benchmarks in future.

Project Aim:

We aim to prospectively evaluate contemporary practice and outcomes of:

- Patients undergoing endonasal (endoscopic or microscopic) **transsphenoidal** surgery for sellar tumours (e.g. pituitary adenomas)
- Patients undergoing an **expanded** endoscopic endonasal surgery for skull base tumours (e.g. giant pituitary adenomas, craniopharyngiomas, meningiomas, chordomas, etc.)

Looking at which methods of skull base repair are used and the corresponding rates of CSF rhinorrhoea.

This will happen over a prospective 6-12 month period
(6 months recruitment, 6 months follow-up ideally)

Why be involved?

- Contribution to a **collaborative, international** service evaluation, which will be evidenced by **certificates.**
- Facilitates **learning and mentorship** amongst junior trainees/students who will receive a lot of close senior support during the project.
- Collaborator status on the project **publication(s)**, with an opportunity to apply for contribution to the manuscript and full authorship.
- Opportunity to **present** the local service evaluation findings **at local audit meetings/equivalent.**

Local Process i)

- First apply to be a local CRANIAL lead via: https://forms.gle/XPyFy2a9hDoFynaR6
- Medical students and junior doctors (in training or clinical fellow) are eligible to apply form participating centres. Please see the list of eligible centres with consultant pre-approvals on this google form.
- Local teams will be selected by local consultants and the CRANIAL management committee. They will be sent a welcome pack to aid local set up.
- Next, register the service evaluation and gain Caldicott guardian approval (usually integrated).
  - Local processes will vary but there is an example proforma in the material you have been sent.
- Meet your team if possible (student lead(s), trainee lead(s) and consultant(s)

Local Process ii)

- Email cranialnansig@gmail.com with service evaluation/Caldicott guardian approvals.
- We will send you your team CASTOR log in details so you can start uploading details onto CASTOR, our chosen data collection system.
- Remember to keep a separate identifiable log of patients incase this needs to be accessed later.
  - See slide 14.
- Full details of the process can be found in our Local Lead Document (on our website) and Protocol – please review these before starting.

Teamwork: Roles:

- Student leads [**must have access to the clinical portal at their local trust**]:
  - Registers service evaluation.
  - Assists local data collection (e.g. gathers operative lists and identifies relevant cases each week)
  - Seeks support and mentorship from senior team members regularly.
  - Keeps a strict and accurate patient code identifier sheet.

- Trainee leads (neurosurgical ST trainees or clinical fellows):
  - Provides day-to-day support to local student lead(s).
  - Leads in data collection and maintains data accuracy (they must review all data points collected by medical students on Castor).
  - Confirms critical data points (slide 18) with the operating surgeon(s)

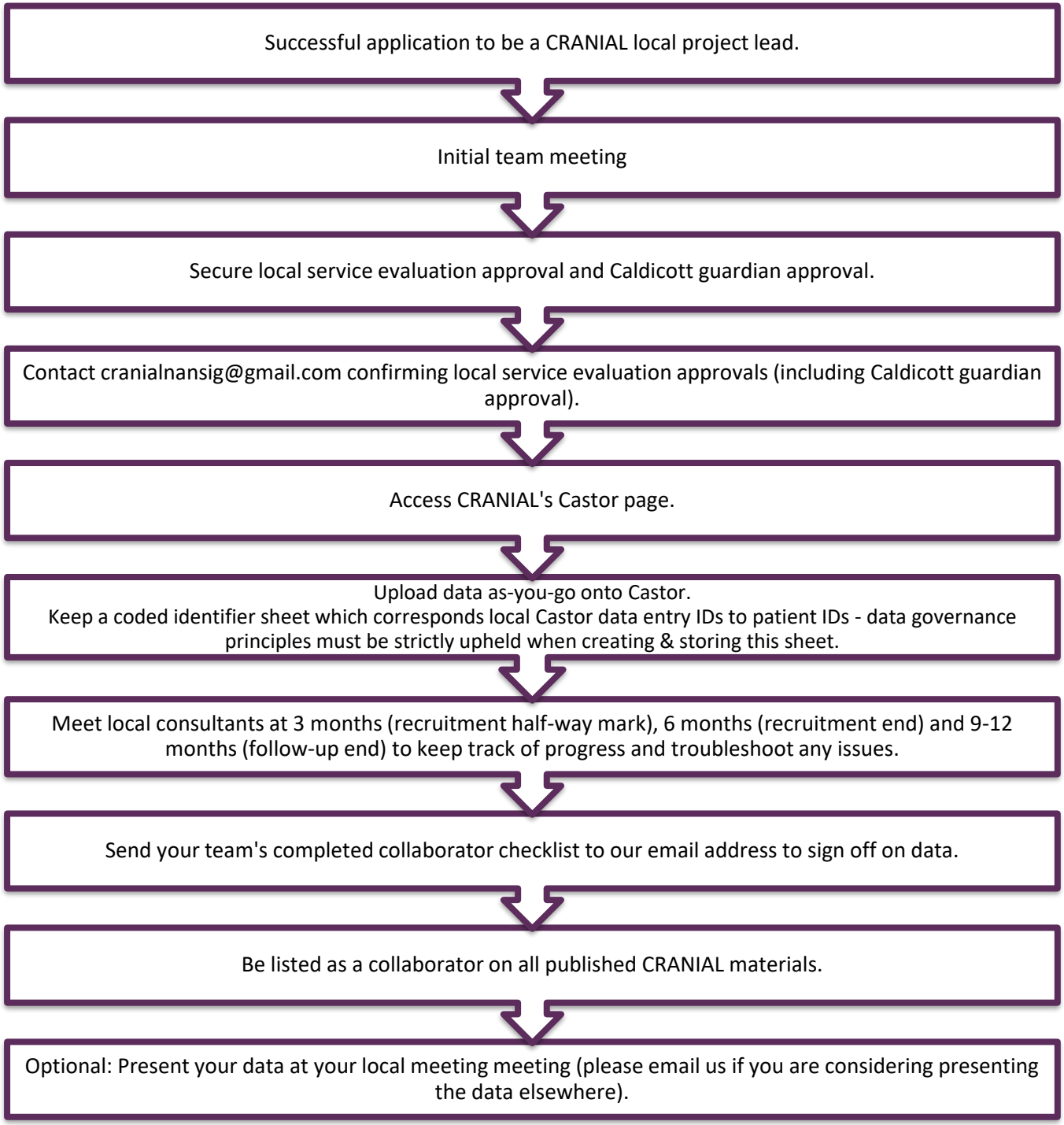
- Local supervising consultant(s):
  - Approves and oversees service evaluation
  - Meets with local CRANIAL lead for: mid-point review (3 month) and end-of-recruitment review (6 month) and end of project review (9-12 months).
  - Provides support and guidance as necessary.

Teamwork: Process:

- The strength of the local team is integral to the success of CRANIAL.
- We encourage frequent communications (e.g. via WhatsApp, email or in person), particularly to support junior members of the data team.
- 3 month (halfway), 6 month (end of recruitment) and 12 month (end of project) meetings must happen and must include the CRANIAL local data leads and local supervising consultant at least (ideally all team members would be present).

- During our pilots, we found that collecting queries (data points that need confirmation) for each case on a secure document which can be sent to or discussed with operating surgeons periodic lumpsums was an efficient method of ensuring data accuracy.
- Try using our illustrations & definitions document to better understand skull base repair techniques and the terminology we are using for the project

Process Summary



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The CRANIAL Project

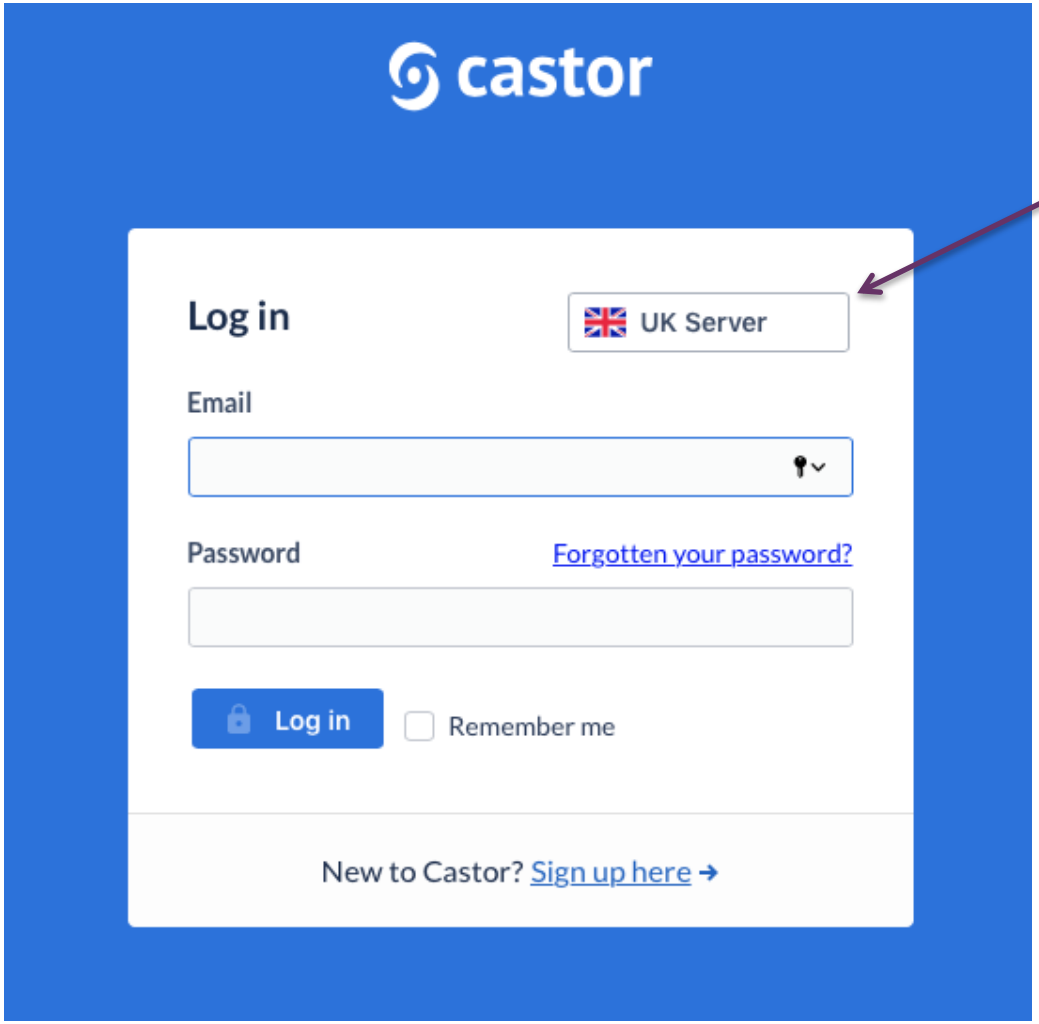
A Practical Guide to:

Set up your CASTOR accounts

- Each collaborator will be given a unique account with login details. These details will be assigned to you after you register your local team

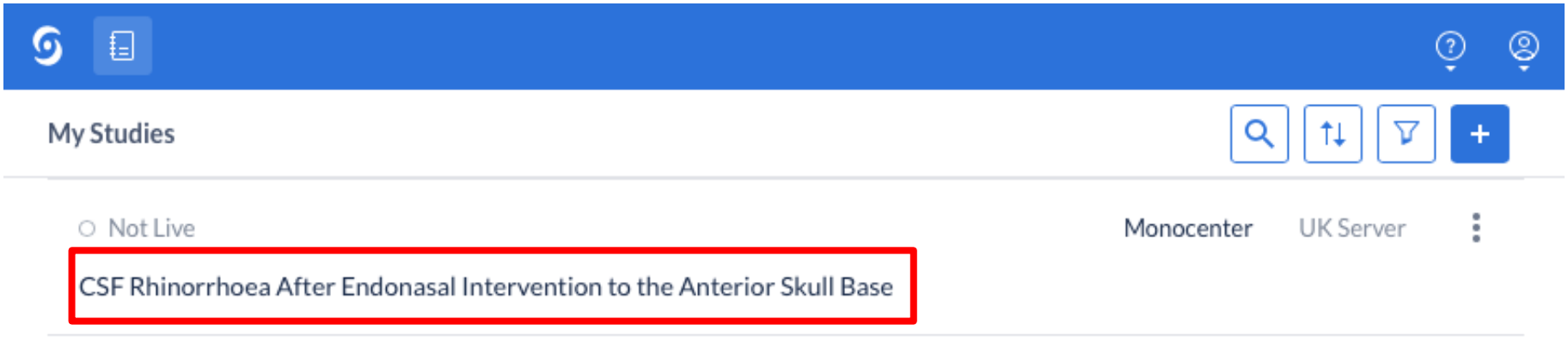
- If there are any problems then contact the CASTOR administrator or email cranialnansig@gmail.com

Login Page: https://uk.castoredc.com

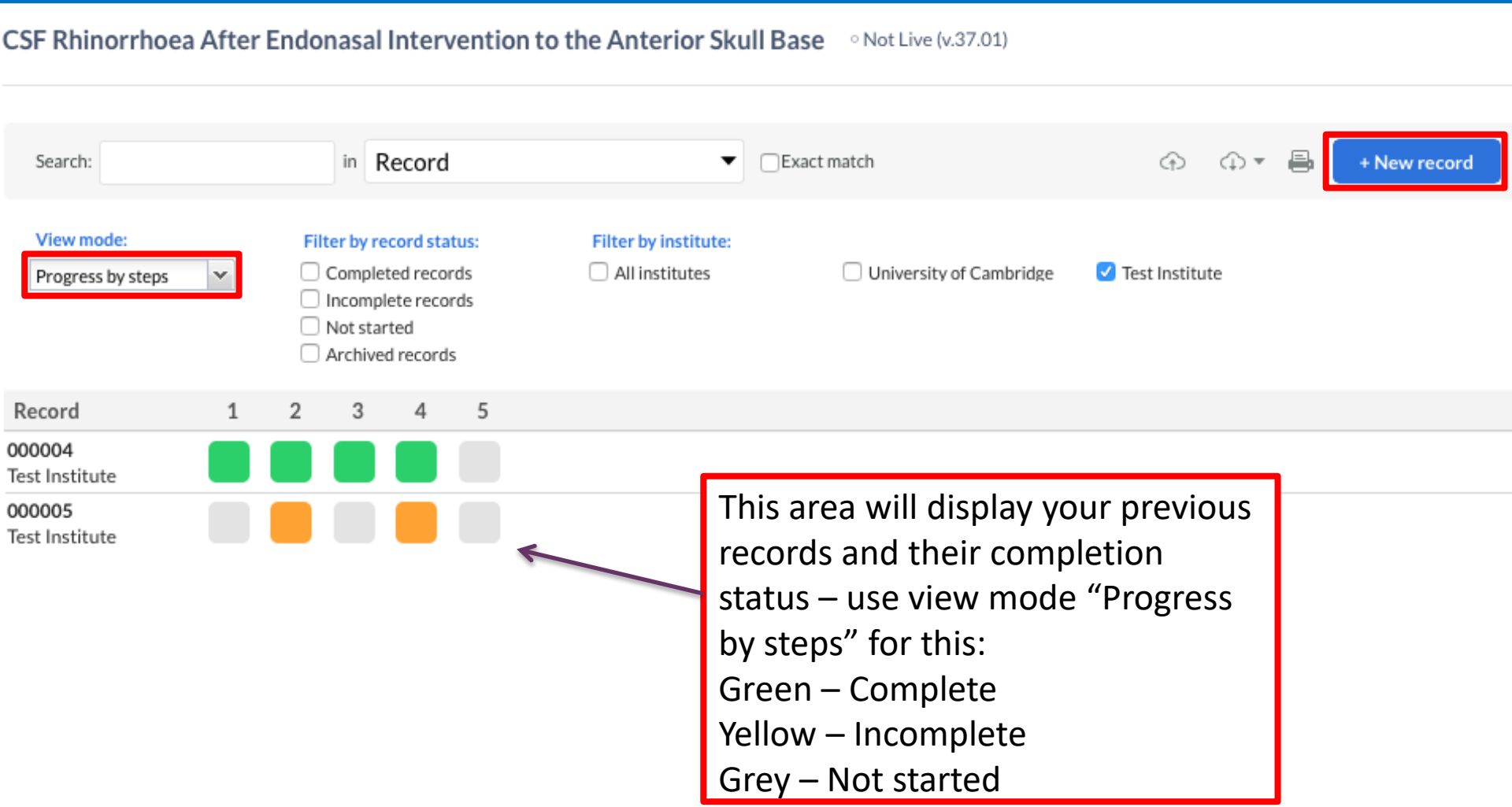


Be sure to select the UK server

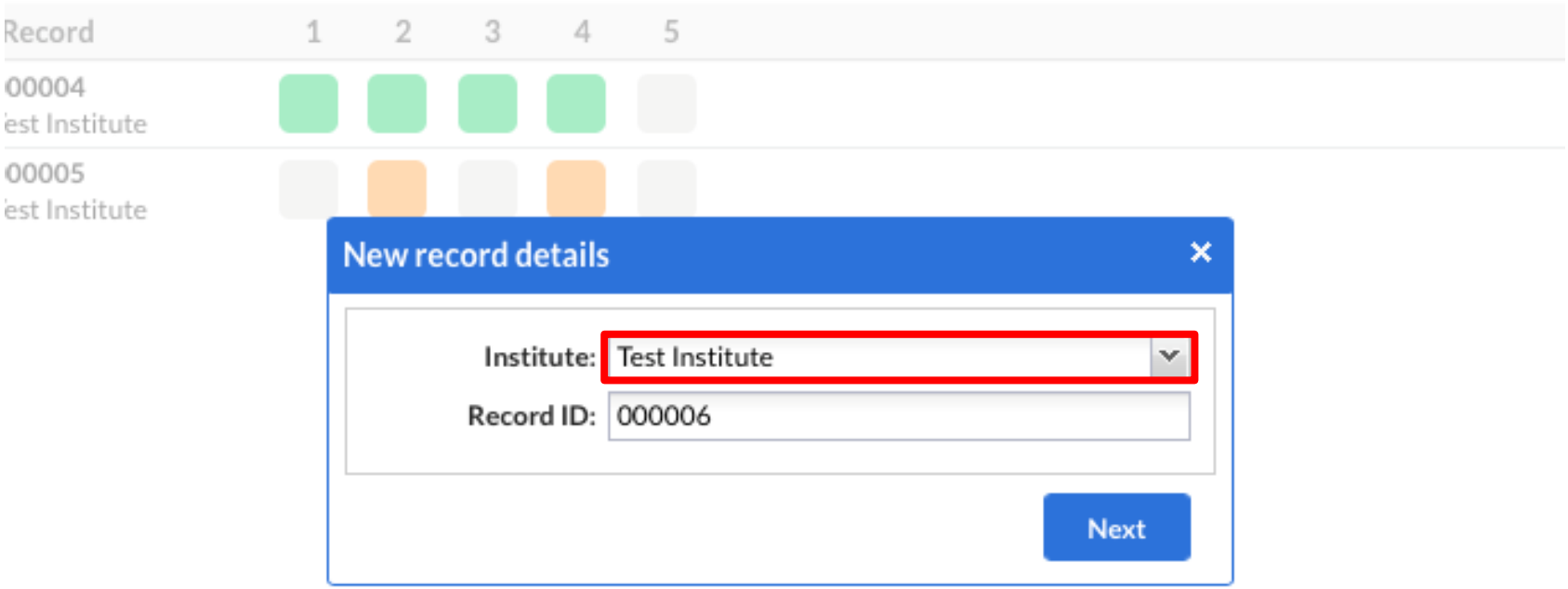
On ‘My Studies’, please select CRANIAL

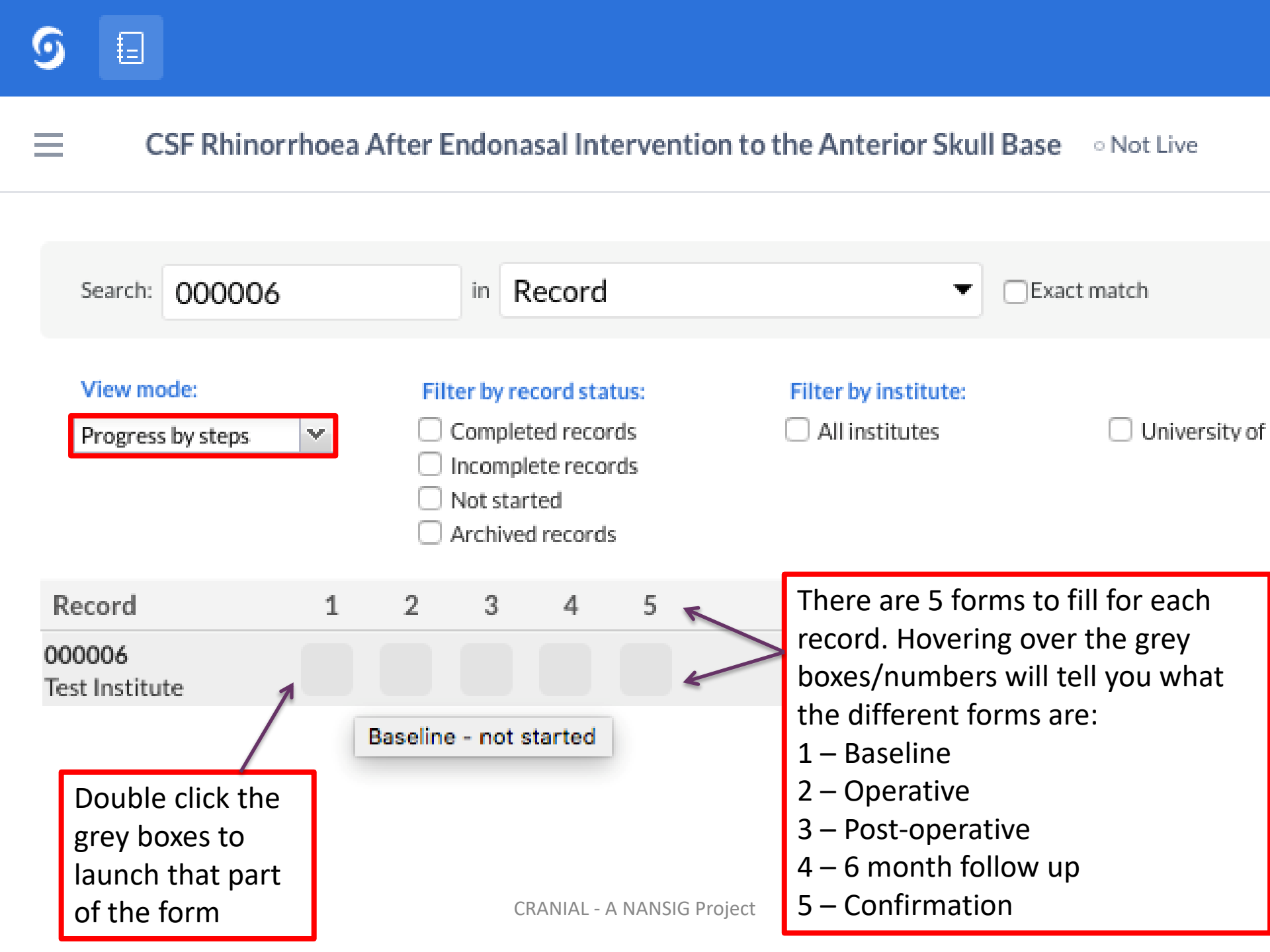


In the ‘Records’ tab, select ‘+New record’



Selecting your Institute will automatically generate a unique Record ID (000006 in this case)




CSF Rhinorrhoea After Endonasal Intervention to the Anterior Skull Base
Not Live
Search: 000006
in Record
Exact match
View mode:
Progress by steps
Filter by record status:
Completed records
Incomplete records
Not started
Archived records
Filter by institute:
All institutes
University of
Record 1 2 3 4 5
000006
Test Institute
Baseline - not started
There are 5 forms to fill for each record. Hovering over the grey boxes/numbers will tell you what the different forms are:
1 – Baseline
2 – Operative
3 – Post-operative
4 – 6 month follow up
5 – Confirmation
Double click the grey boxes to launch that part of the form
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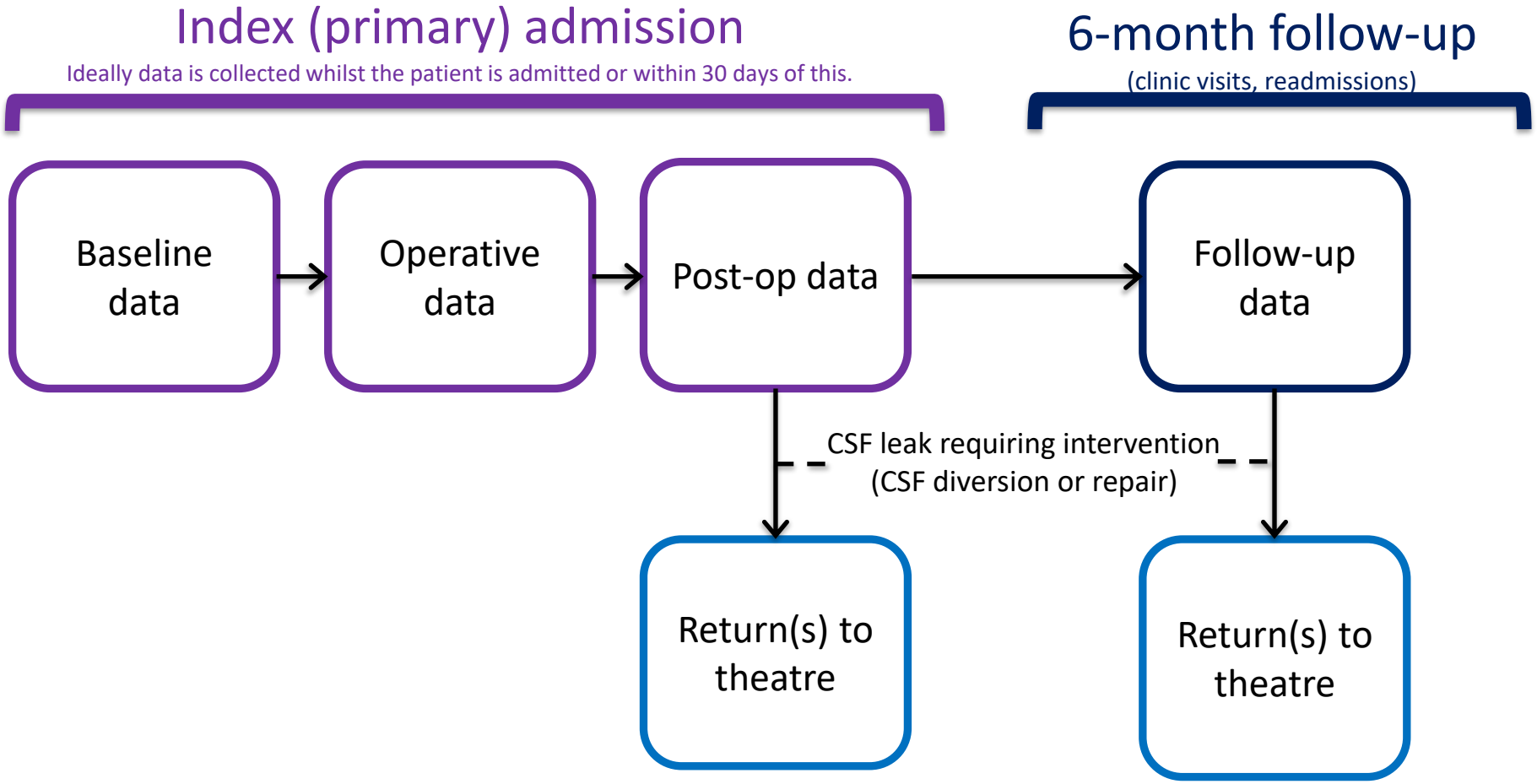
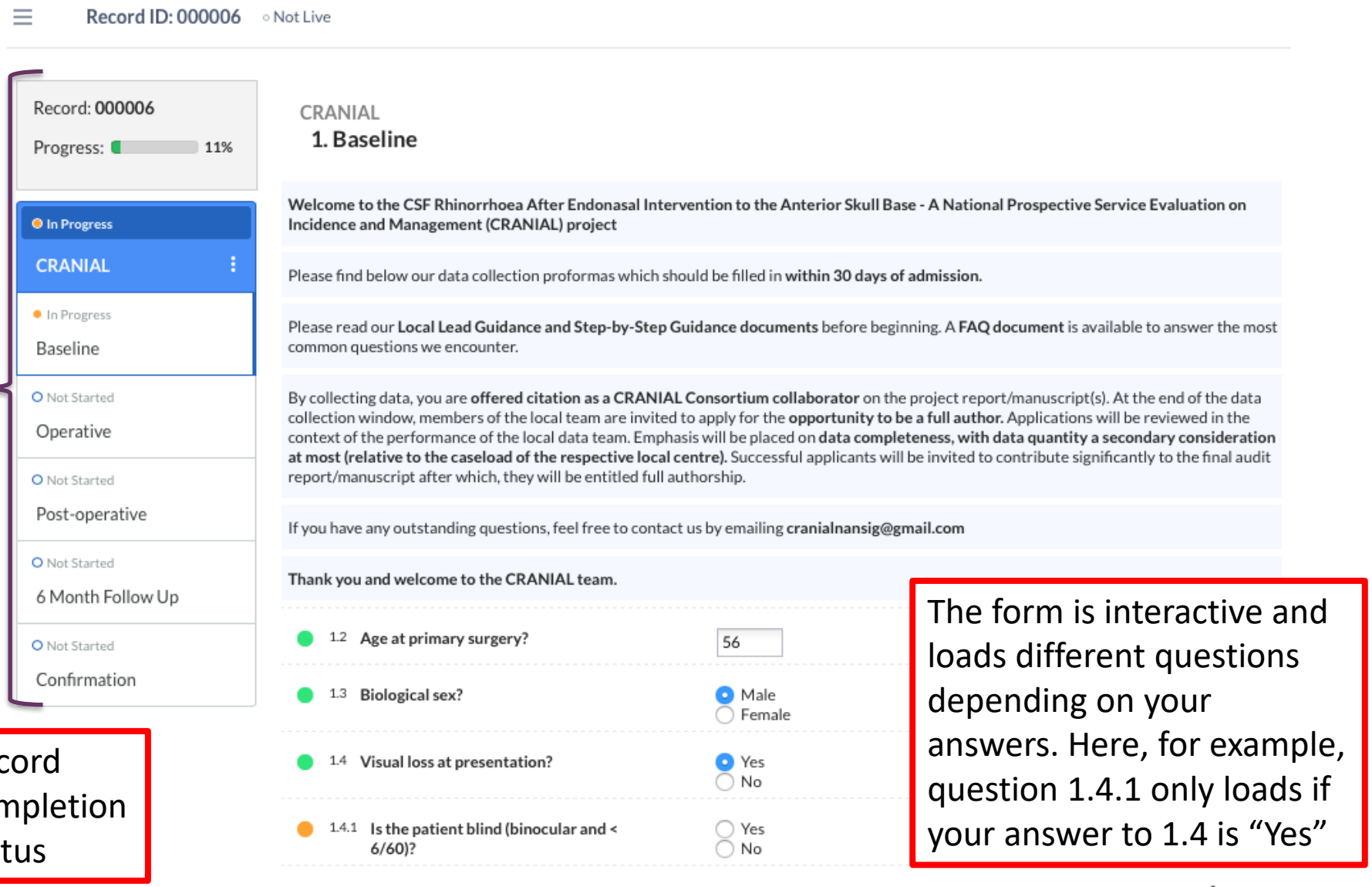
Case journeys



Fill in the survey – The FAQ document contains useful tips if you need them



Record completion status

The form is interactive and loads different questions depending on your answers. Here, for example, question 1.4.1 only loads if your answer to 1.4 is “Yes”

NB: Data points which must be confirmed with the operating surgeons

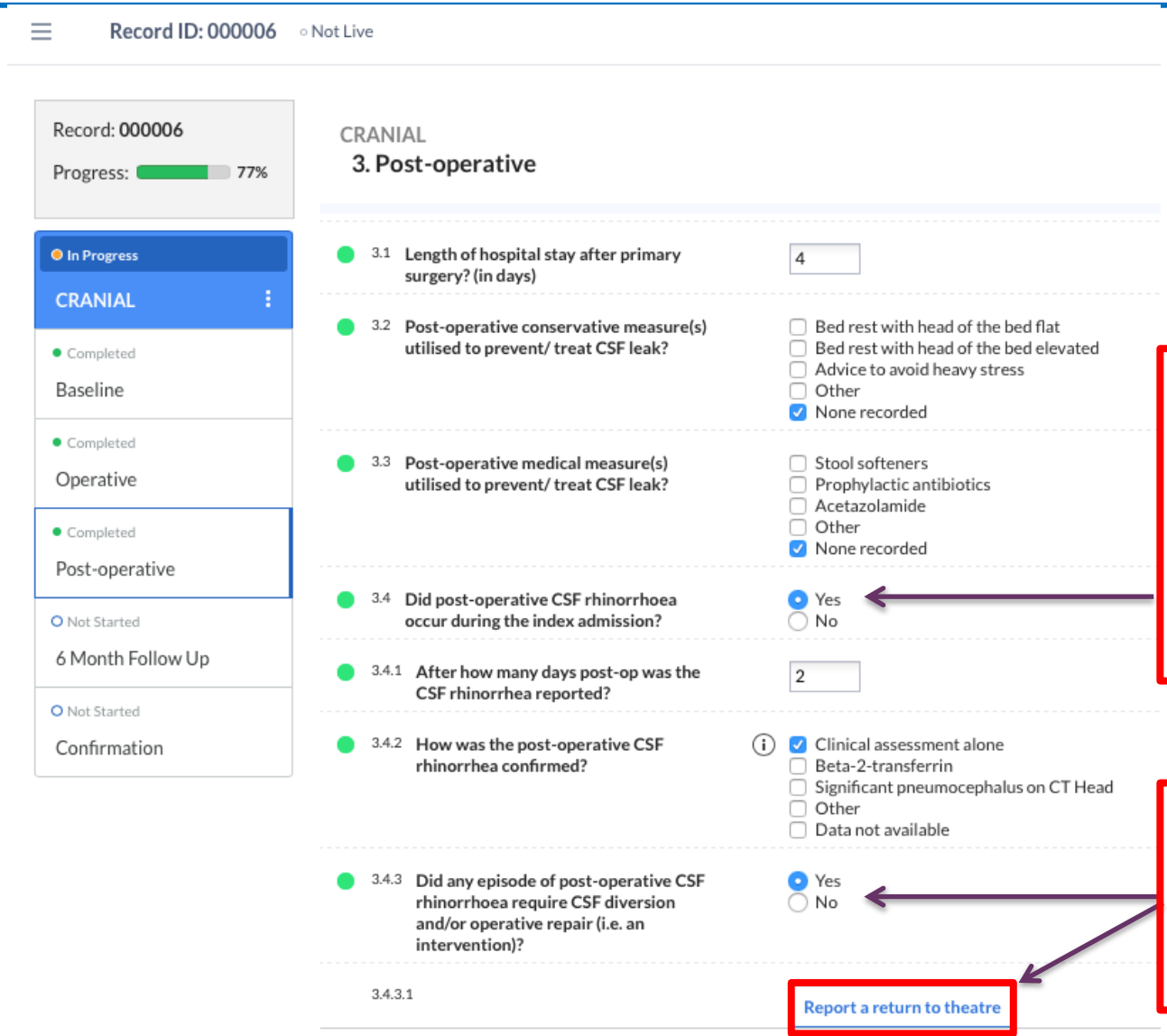
- Maximum diameter of dural defect?
- Intra-op CSF leak (and grade)?
- Post-op CSF leak and confirmation method?
- Details of intra or post -operative method of CSF leak repair/prevention used (CSF diversion or direct skull base repair)
  - Method of CSF diversion used and for how long?
  - Was dura closed directly?
  - Flap used in repair?
  - Please select which types of grafts were used in the skull base repair?
  - Buttress used in skull base repair?
  - Tissue glue used in skull base repair?
  - Use of nasal pack?

NB: Post-op CSF leak interventions

- If a case requires re-intervention (CSF diversion and/or direct operative repair) for management of post-op CSF leak, then you will need to add an additional Report for this record.
- This is done via the ‘Report a return to theatre’ link (question 3.4.3.1 in the next slide).
- This is in addition to the standard 5 forms for this patient (Baseline, Operative, Post-operative, 6 month follow up and Confirmation).

- If the patient has multiple readmissions/reinterventions for post-op CSF leak management, you can add multiple :return to theatre” reports.
- Please discuss with the rest of the local team and ask for senior support if you need it.

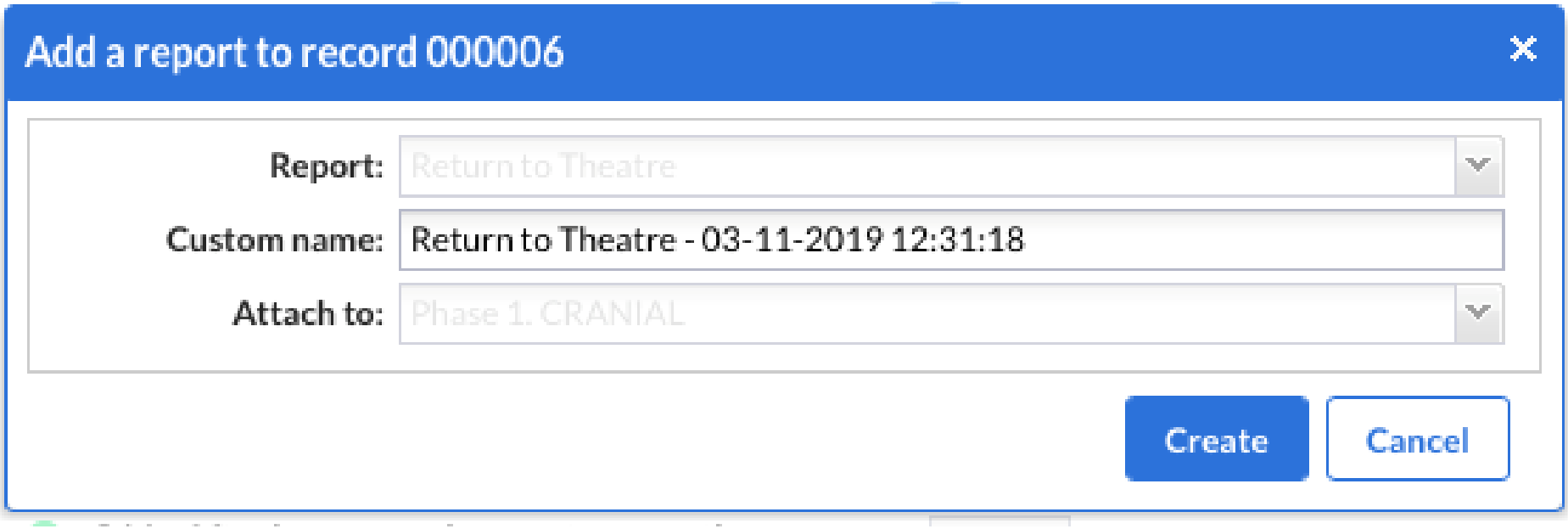
3.4.3.1: Report a Return to Theatre



If your answer to 3.4 is "No" then this concludes the "Post-operative" form and there is no need to Report a return to theatre

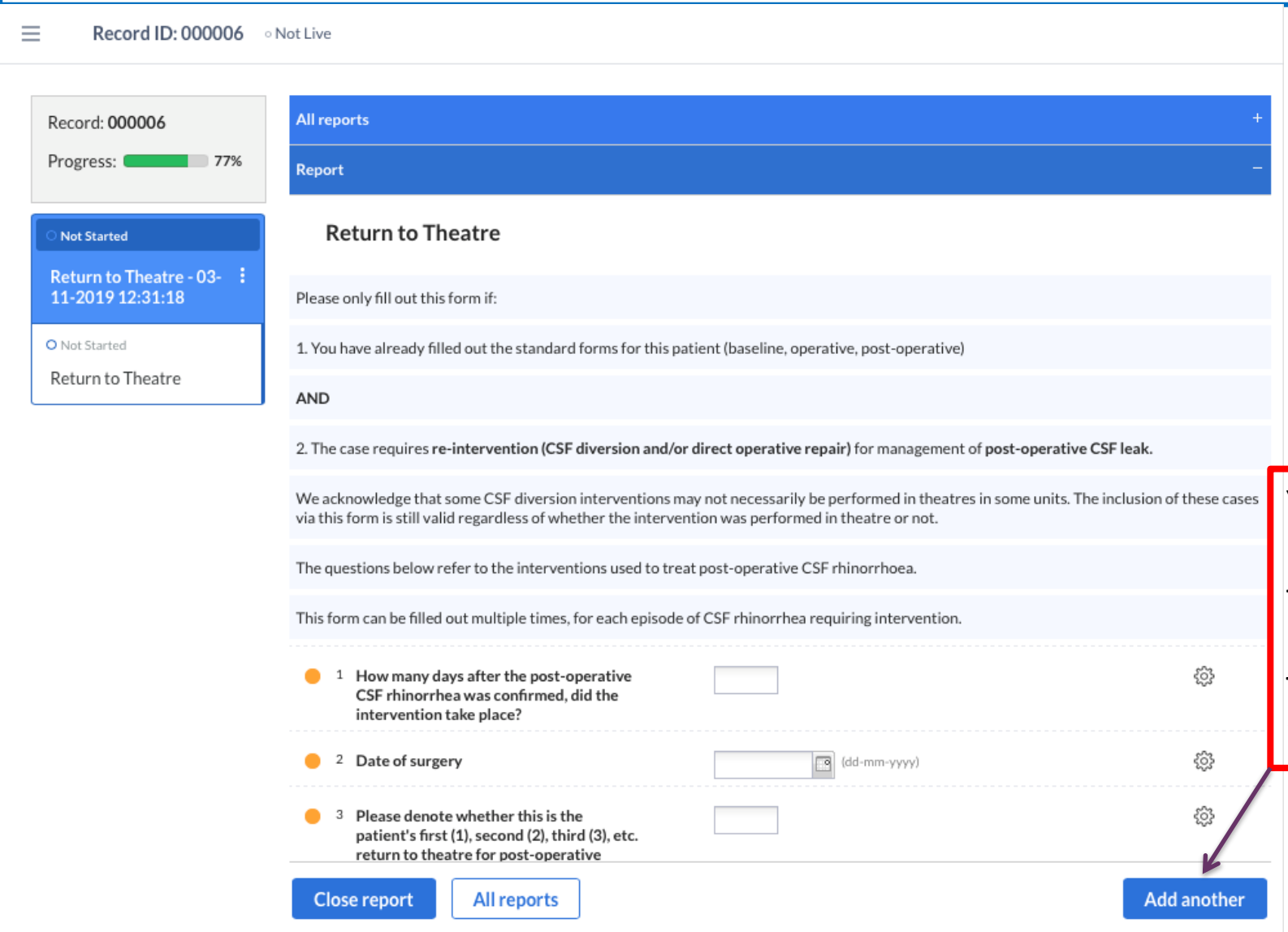
Similarly, you will only need to "Report a return to theatre" if your answer to 3.4.3 is "Yes"

Create a Return to Theatre Report



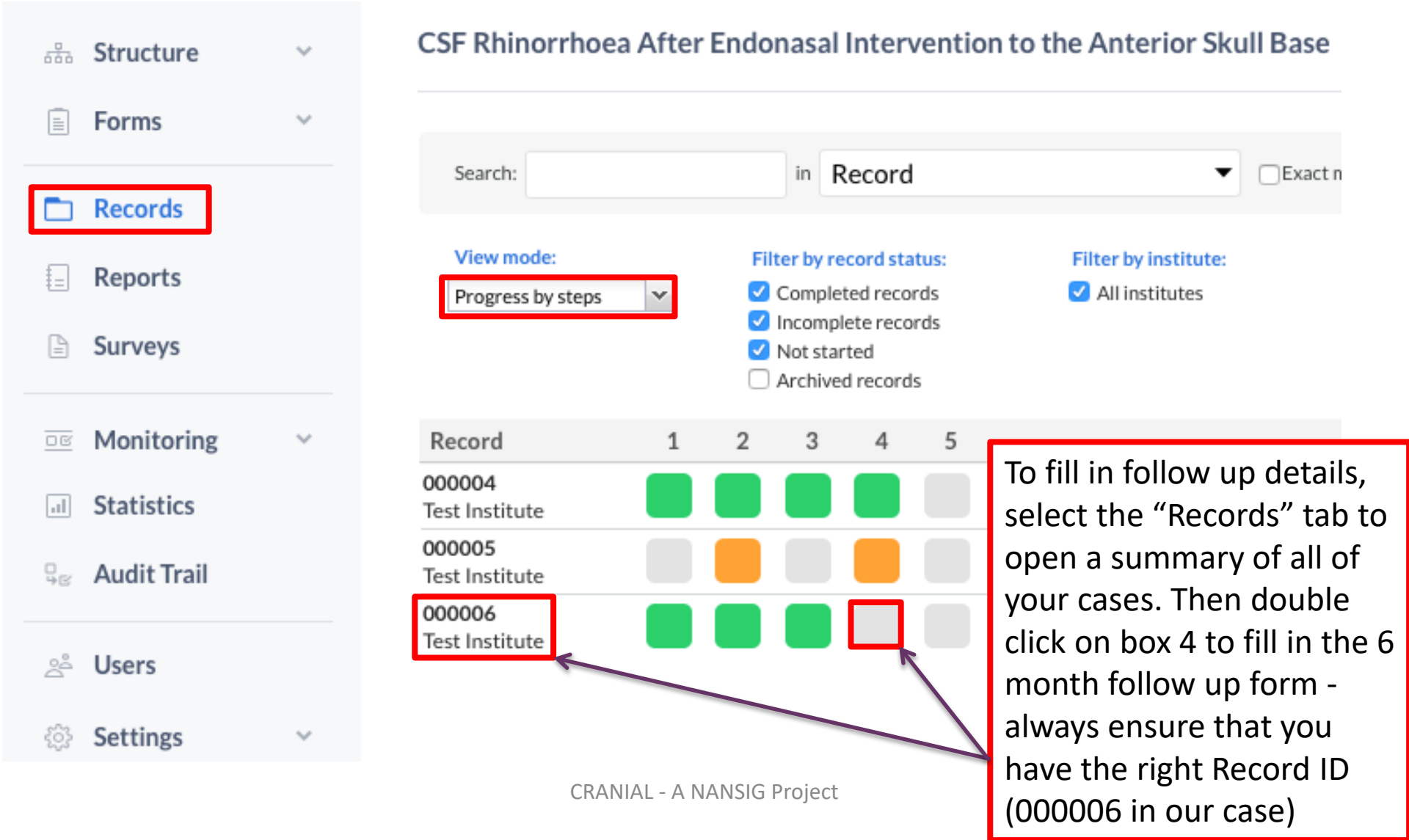
We recommend naming the Report the date and time of when the Return to theatre occurred

Fill in the Return to Theatre Report



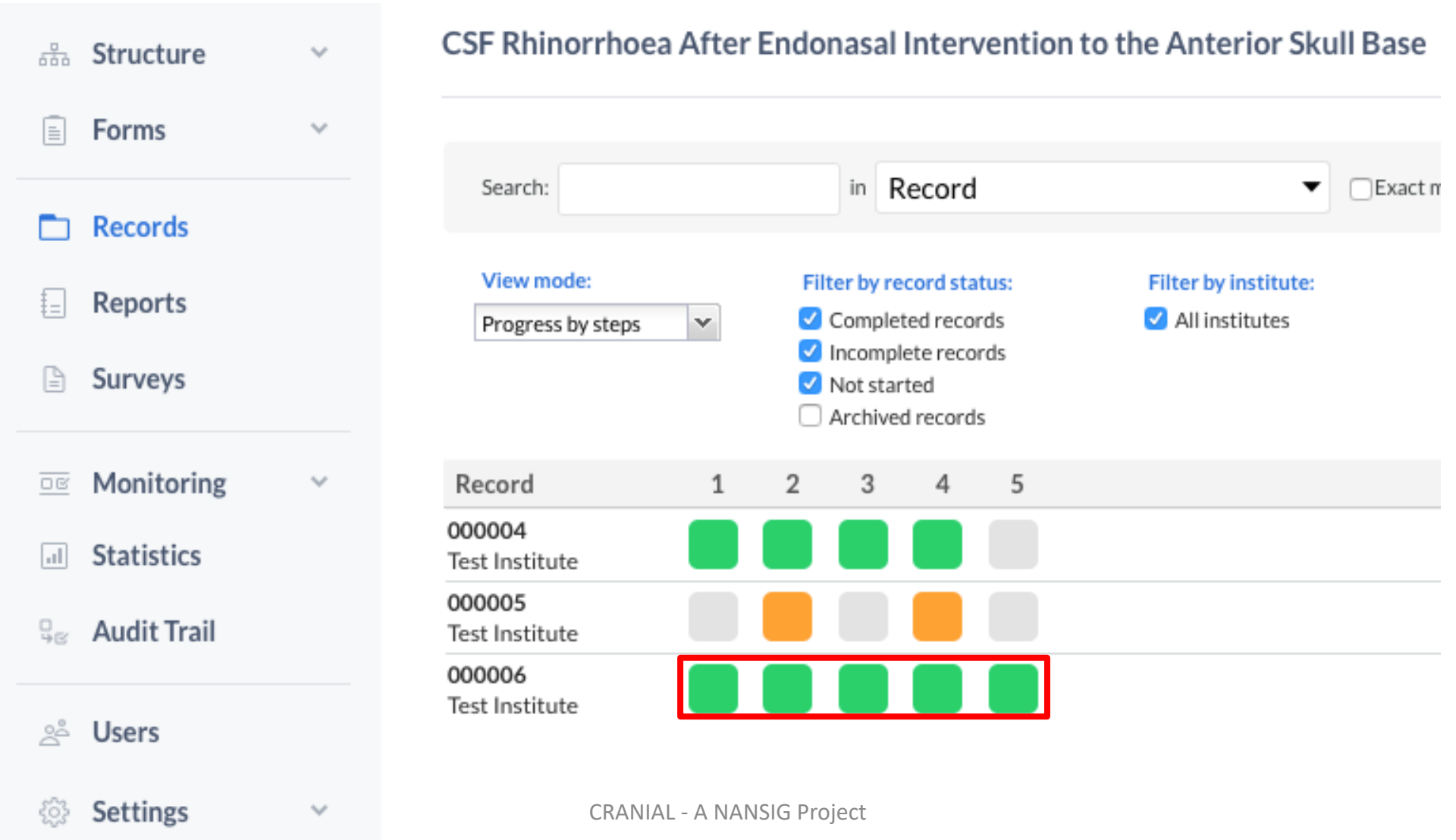
You can also use this screen to add further Return to Theatre Reports if needed

3-6 Month follow up



To fill in follow up details, select the “Records” tab to open a summary of all of your cases. Then double click on box 4 to fill in the 6 month follow up form - always ensure that you have the right Record ID (000006 in our case)

The Record is complete once all 5 boxes are green – there is no “submit” button



Data submission and confidentiality

- Submit your data via computer.
- Each patient will get a unique anonymised Castor Record ID as shown above (000006 in this example case).
- As the Record ID is the only way to identify patients within Castor, it is important that you make a physical/excel list of patient NHS numbers and their corresponding Castor IDs.
- This 'coded identifier sheet' should be kept **secure** and on-site and will only be consulted if there is a query regarding a particular patient ID, or to re-open a record at a later date to enter follow up data.
- When data analysis is complete, your local team will receive instructions to destroy this sheet, thereby ensuring patient confidentiality, as all remaining data will be anonymised.

Further advice

- Please feel free to email us at: cranialnansig@gmail.com

- Please visit our website at: https://nansig.org/cranial
  - Here lies all the necessary project documents: Protocol, FAQ doc, Local Lead Guidance, Data Collection Checklist, etc.