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The Threshold for Platelets study: A prospective randomised trial to define the platelet count below which critically ill patients should receive a platelet transfusion prior to an invasive procedure

All Site Meeting - 09 November 2023

IRAS ID: 312405
REC Ref: 22/SC/0186
Funding: NIHR HTA (131822)

NIHR CPMS ID: 53274
ISRCTN Registry: ISRCTN79371664
Sponsor: University of Oxford

Chief Investigator: Prof Peter Watkinson

FUNDED BY NIHR | National Institute for Health Research

UNIVERSITY OF OXFORD

Agenda

- Trial update
  - Sites
  - Recruitment
  - Non-substantial amendment #6
- Common Data Queries
- Questions/site discussion

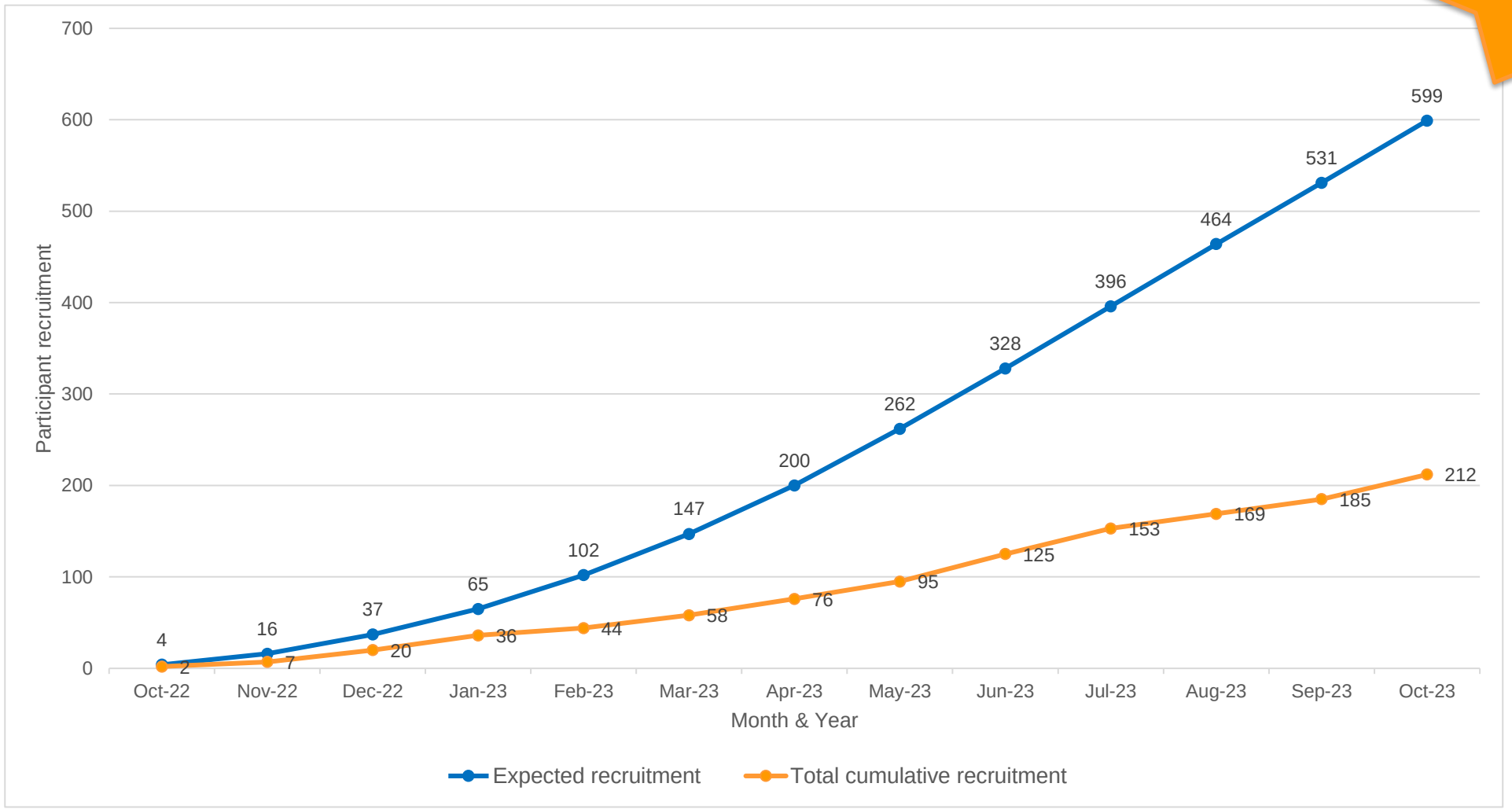
Trial Update - Sites

- Aim: **66**
- Open: **43**
  - Since our last meeting, welcome to:
    - **Newham University Hospital**
    - **University Hospital of North Durham**
    - **Darlington Memorial Hospital**
    - **Royal Glamorgan Hospital**
    - **Fairfield General Hospital**
- In set up: **10**

Trial Update - Recruitment

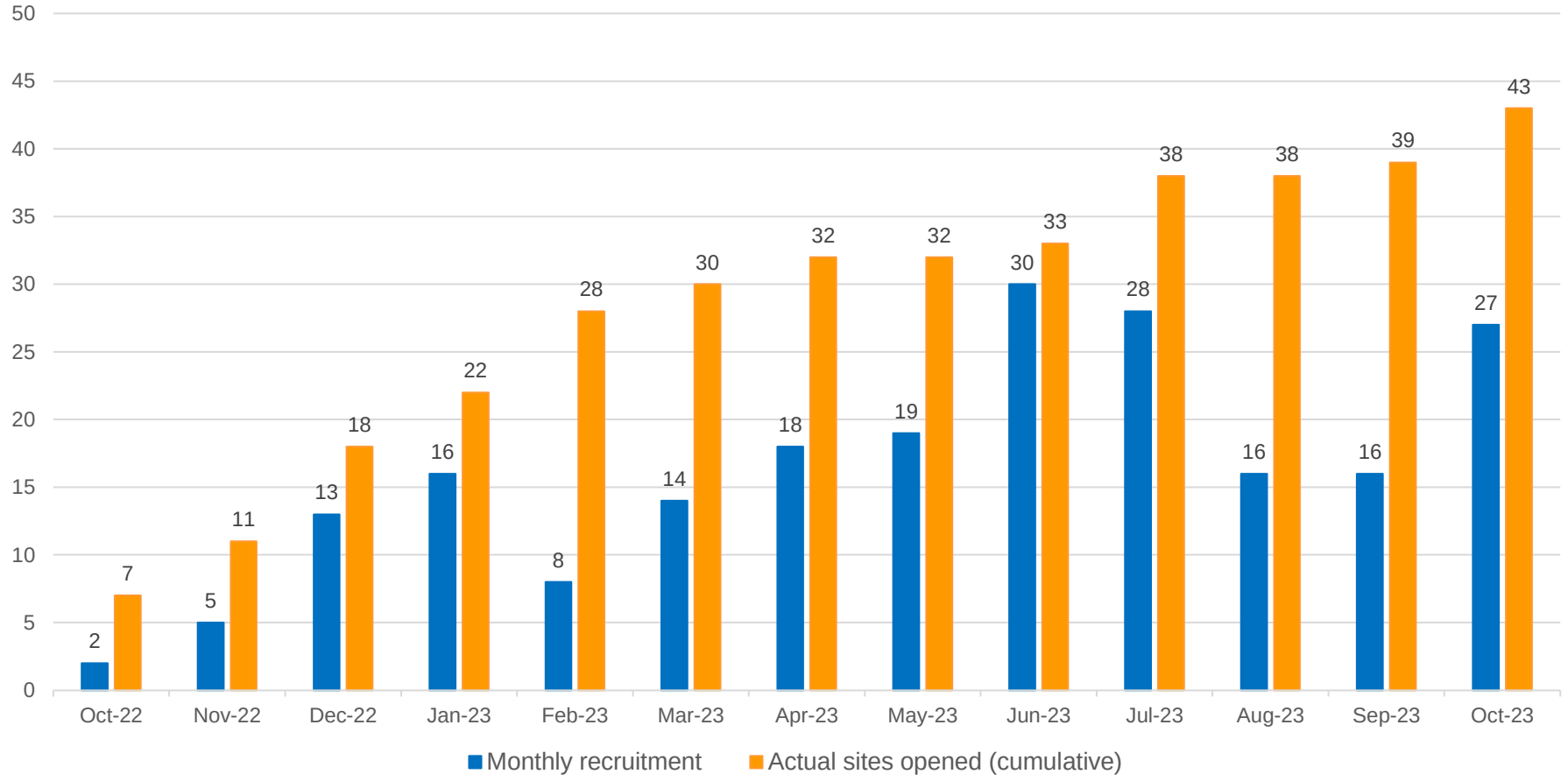
- As of 08 November 2023, 221 patients randomised

Patient 200! Royal Cornwall Hospital!



Trial Update - Recruitment

- Monthly recruitment up to 31 Oct 2023



- Average recruitment rate = **0.6** patients/site/month

Non-substantial amendment #6

- Changes:
  - Protocol V3.0
    - Scotland specific consent procedures have been added
  - Patient follow-up documentation, mNCA and OID
    - Scotland IRAS number added to footer
    - These do not require implementation at sites

- Scotland A REC have approved the protocol changes, but we now have to submit to the English REC for notification

- Implementation date for new protocol: **12 December 2023**
  - CTU team will confirm implementation on this date
    - Save/print new protocol in ISF, circulate to rest of team and use this version from this date onwards

Common Data Queries – Responding to DCRs

1

Drag a column header and drop it here to group by that column

	Priorit	Date	Status	Subject	Visit	eForm	Question
>	5	2023/10/03 14:17:57	Raised	T4P/ncaa2cr/245005	Outcomes	Outcomes	Date of discharge
>	5	2023/09/12 13:39:27	Raised	T4P/ncaa2cr/245005	Observations Day	Daily Data Page 2	Received low bleeding risk invasive procedure tod
>	5	2023/09/06 17:20:15	Raised	T4P/ncaa2cr/245005	Observations Day	Daily Data Page 3	Bleeding Episodes Completed
>	5	2023/10/03 11:59:16	Raised	T4P/ncaa3bw/149002	Outcomes	Outcomes	Date/time of discharge

- Click on the red flag at the top of the screen
- This will bring up a list of all queries for your site across each patient
- You can double click on each query to see more information

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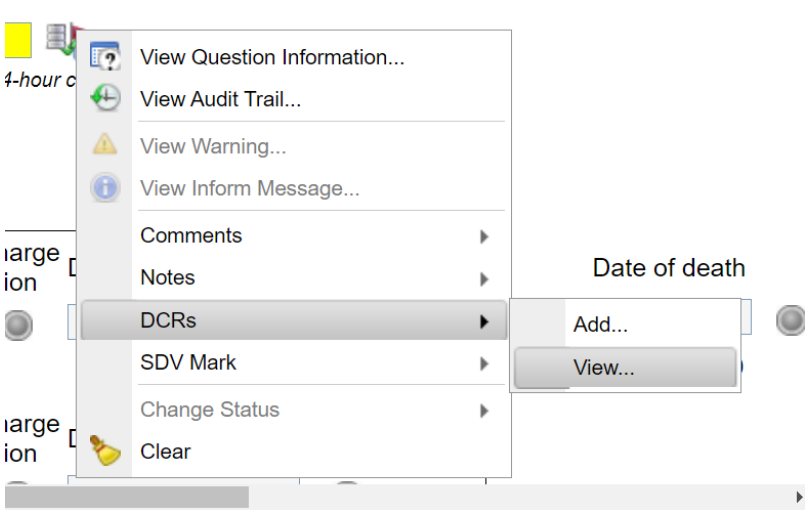
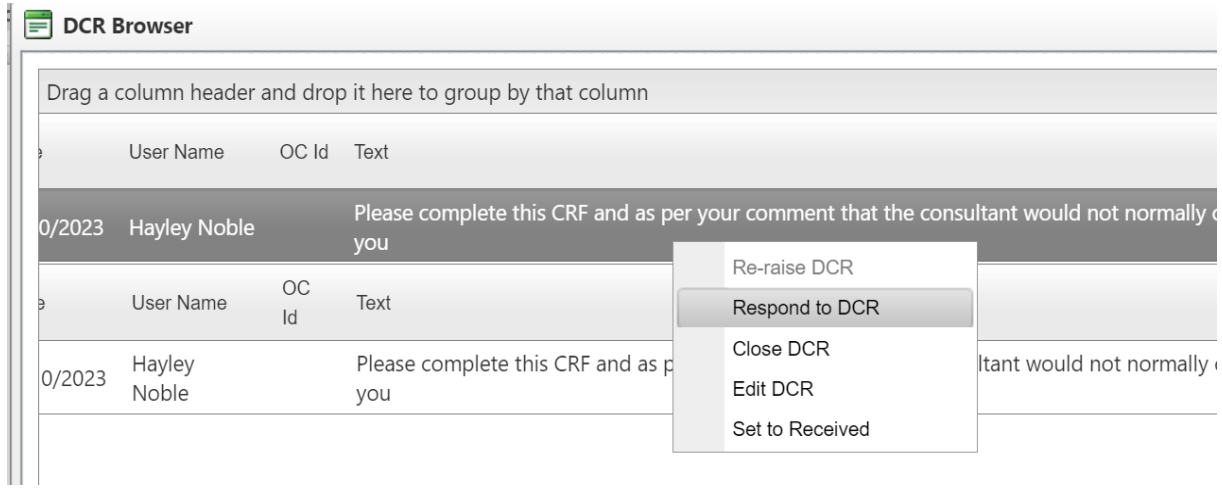
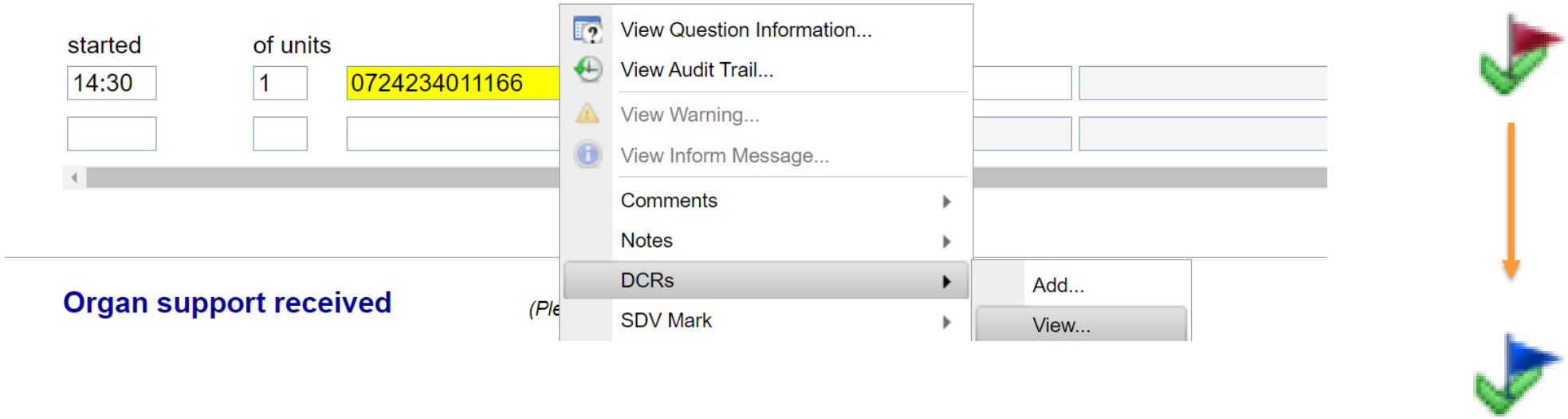
2





- Next to the field with a DCR there will be a red flag
- Right click, go to DCRs and ‘view’ the DCR
- Read the CTU comment and right click to ‘respond to DCR’
- Data on the eCRF may need changing depending on the response

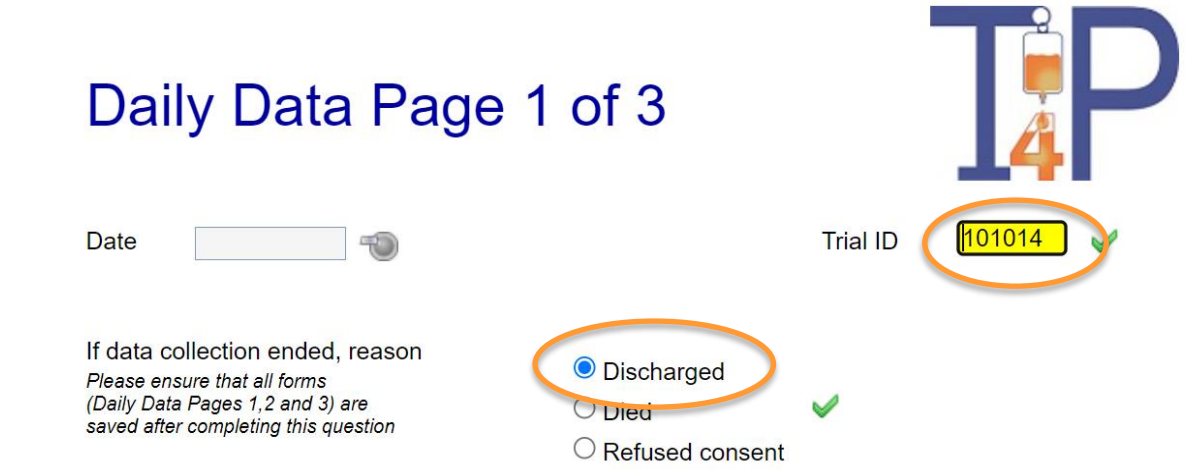
3



- For G-number DCRs right click on the G-number field
- ‘View’ the DCR and respond in the usual way
- Once a DCR has been responded to the flag will change from red to blue
- This will come up on our system for the CTU to close the DCR and the flag will turn green!

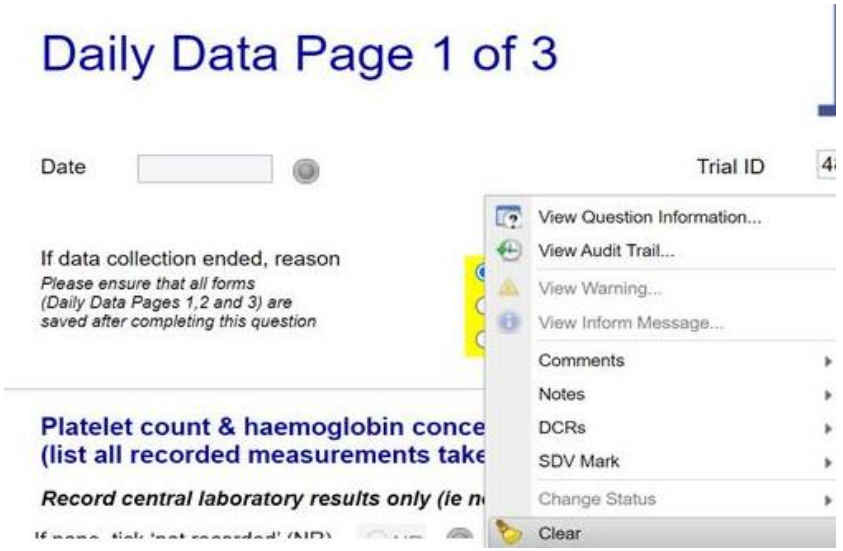
Common Data Queries – Stopping Data Collection

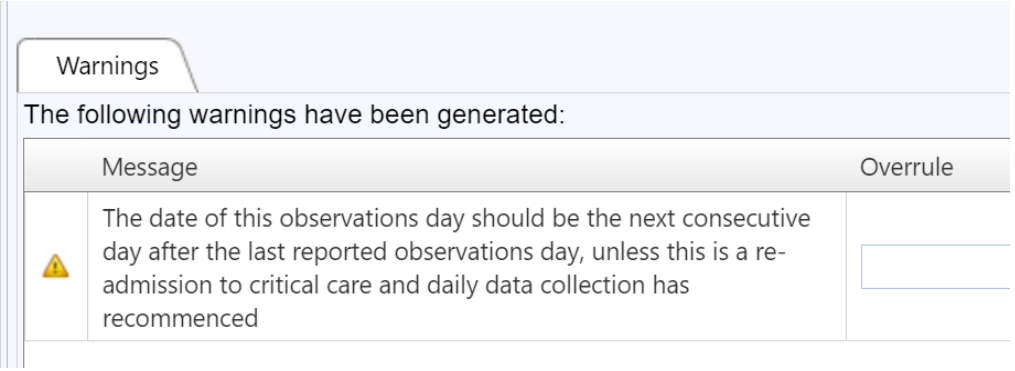
- When a patient has died, been discharged, or refuses consent daily data collection will stop
- On the day after the last obs day, daily data page 1 – enter trial ID and select the reason
- Then remember to save daily data pages 2 and 3 BLANK
- This will green tick all pages and stop further observation days opening



Common Data Queries – Restarting Data Collection

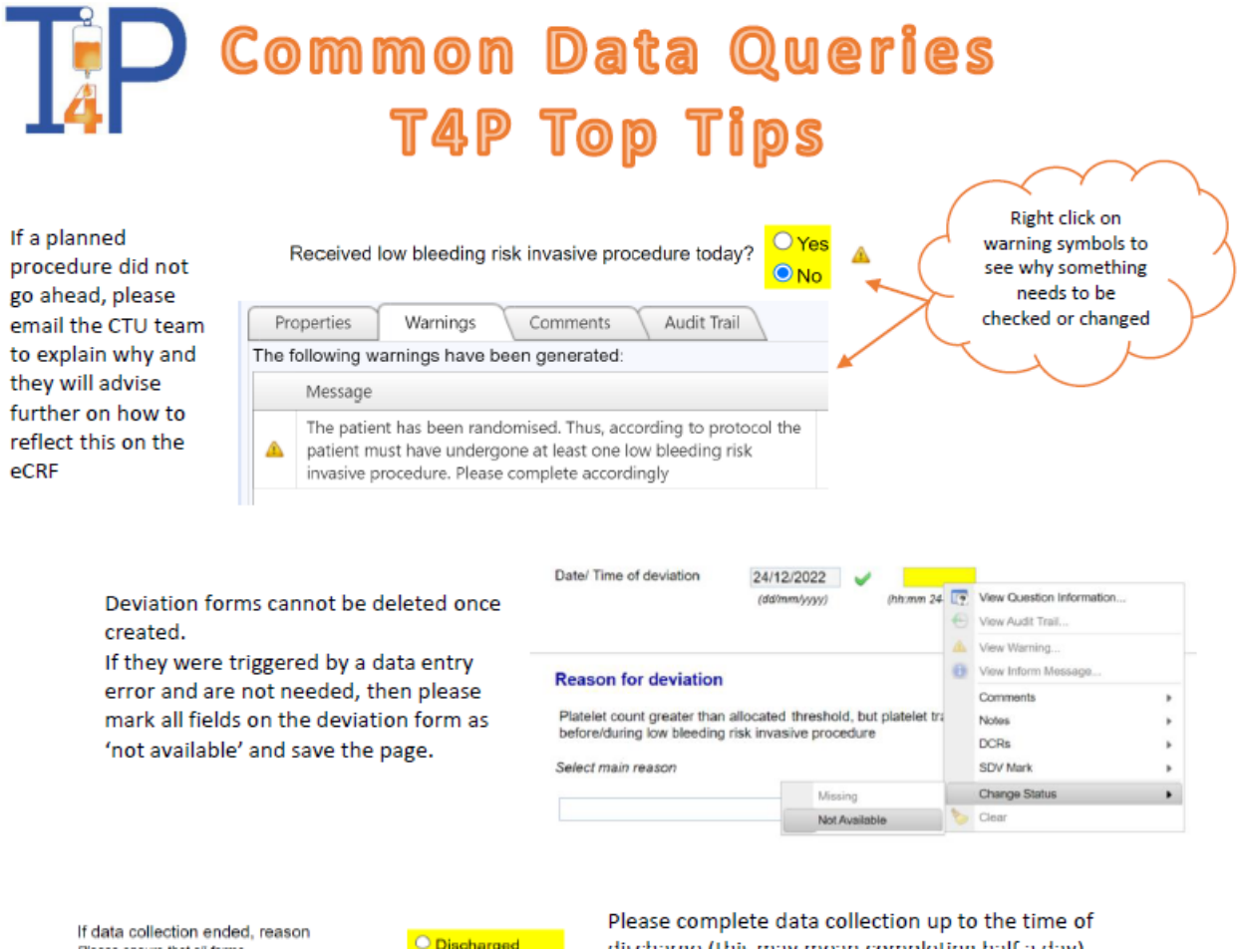
- If you have selected 'discharged' and stopped obs days, but then patient is readmitted – data collection restarts
- Do not create a new patient page
- Clear 'discharged' from daily data page 1 of last obs day so another day opens
- Continue data collection at normal from current date
- Warning will flash as dates not consecutive – ignore and provide comment, CTU will override
- Discharge and re-admission dates are also captured on the CRF, and should match obs day dates





Common Data Queries

- One-pager summarises these common data queries:



Coming up…

- Next **drop-in training** session:
  - Monday 27 November, 12:30 – 13:00
- Next **consent training** session:
  - Thursday 23 November, 14:00 - 15:00
- **Individual site reports**:
  - Coming soon!

Questions/site discussion

- Any questions?

- Discussion points:
  - How can we help to improve out of hours recruitment?
  - 24/7 helpline?

Thank you!

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