



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

Agenda

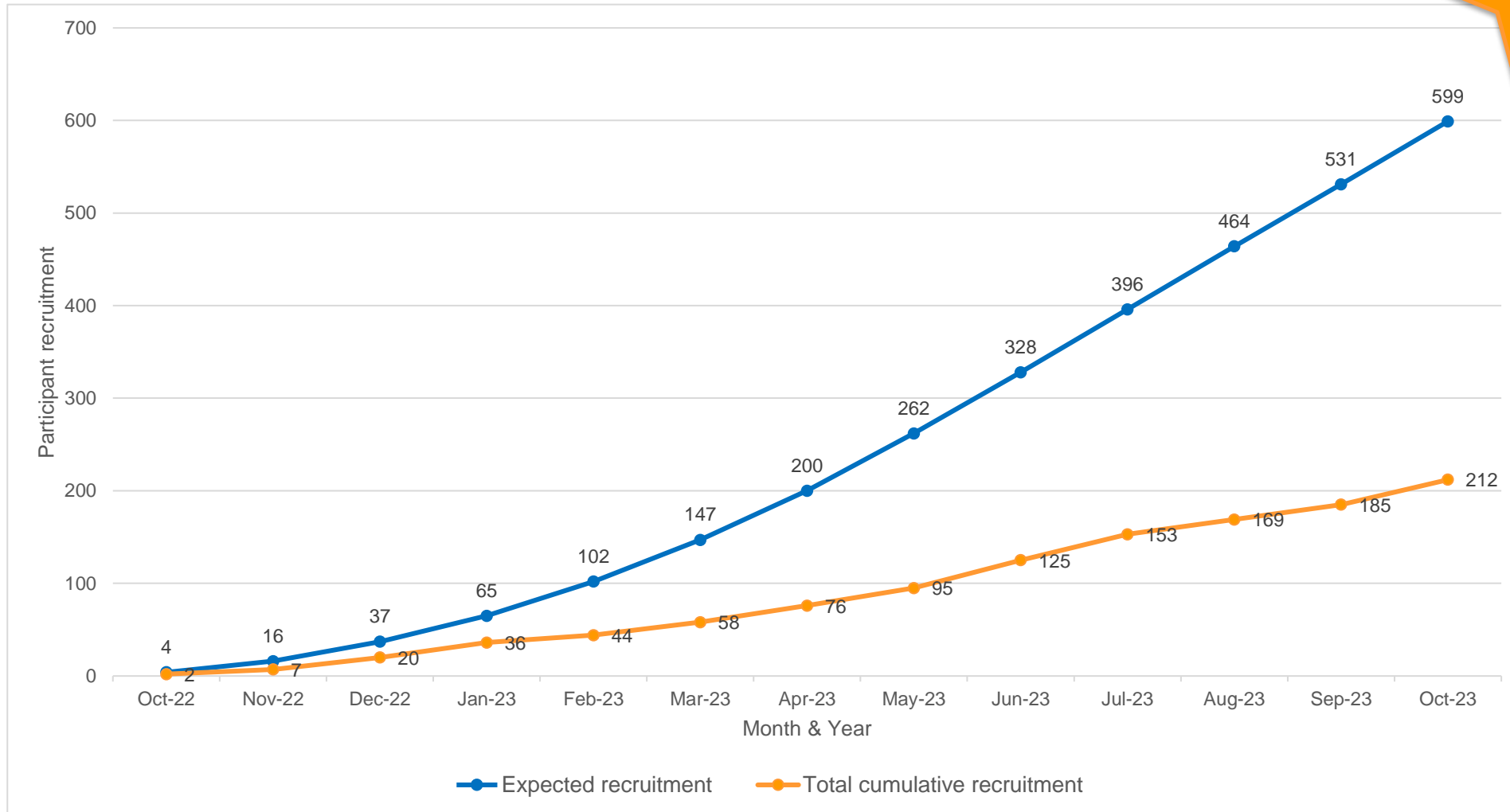
- Trial update
 - Sites
 - Recruitment
 - Non-substantial amendment #6
- Common Data Queries
- Questions/site discussion

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**

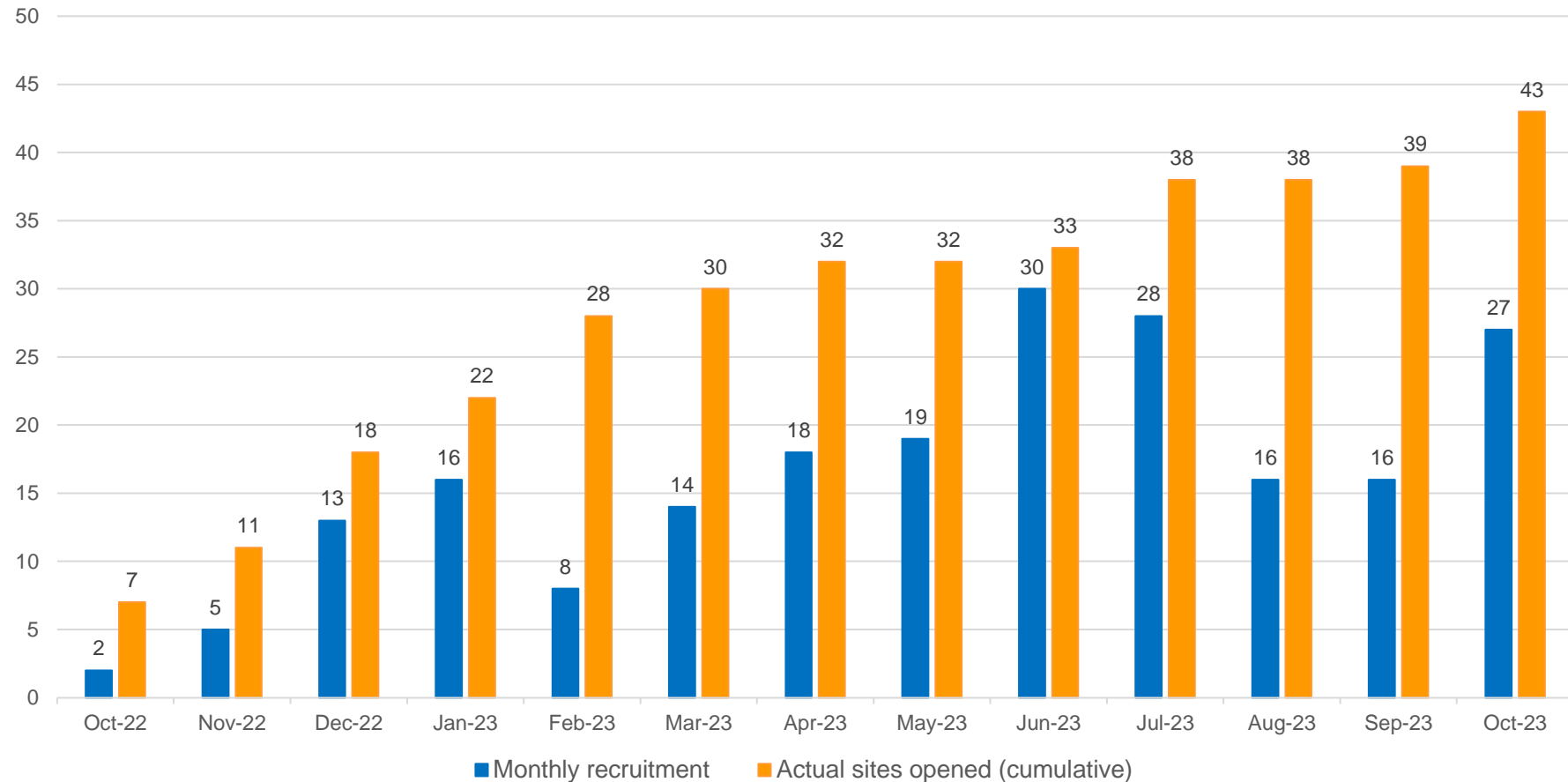
Trial Update - Recruitment

- As of 08 November 2023, **221** patients randomised



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

2



4-hour c

- View Question Information...
- View Audit Trail...
- View Warning...
- View Inform Message...
- Comments
- Notes
- DCRs
- SDV Mark
- Change Status
- Clear

Date of death

Add...

View...

DCR Browser

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

	User Name	OC Id	Text
0/2023	Hayley Noble		Please complete this CRF and as per your comment that the consultant would not normally c
			you
	User Name	OC Id	Text
0/2023	Hayley Noble		Please complete this CRF and as p
			you

- Re-raise DCR
- Respond to DCR
- Close DCR
- Edit DCR
- Set to Received

Set DCR to Responded

Name Date/time of discharge

Text

OK

Cancel

- 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

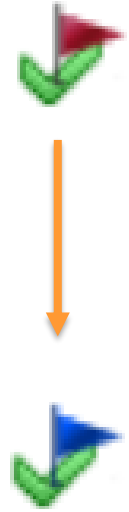
The screenshot shows a table with the following data:

started	of units	G-number
14:30	1	0724234011166

A context menu is open over the G-number field, with the following options:

- View Question Information...
- View Audit Trail...
- View Warning...
- View Inform Message...
- Comments
- Notes
- DCRs** (selected)
- SDV Mark

Below the table, the text "Organ support received" is displayed in blue. The context menu also shows sub-options for "DCRs": "Add..." and "View...".



- 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

Daily Data Page 1 of 3

Date

Trial ID ✓

If data collection ended, reason
Please ensure that all forms
(Daily Data Pages 1, 2 and 3) are
saved after completing this question

- Discharged ✓
- Died
- Refused consent



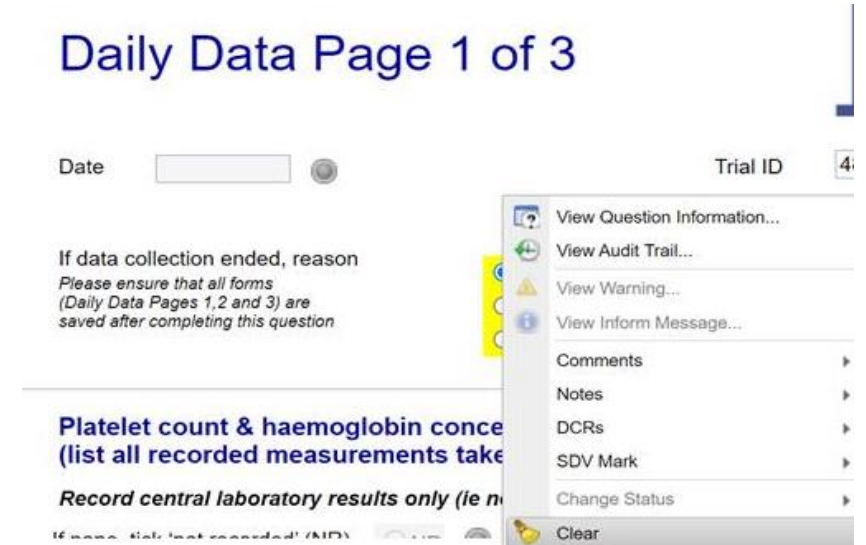
- ✓ Daily Data Page 1
- ✓ Daily Data Page 2
- ✓ Daily Data Page 3
- Deviation
- ✓ Consent


Daily Data Page 2 of 3

Date ✓

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



Warnings	
The following warnings have been generated:	
Message	Overrule
 The date of this observations day should be the next consecutive day after the last reported observations day, unless this is a re-admission to critical care and daily data collection has recommenced	<input type="checkbox"/>

Common Data Queries

- One-pager summarises these common data queries:

T4P Common Data Queries T4P Top Tips

If a planned procedure did not go ahead, please email the CTU team to explain why and they will advise further on how to reflect this on the eCRF

Received low bleeding risk invasive procedure today? Yes No

Properties Warnings Comments Audit Trail

The following warnings have been generated:

Message

⚠ The patient has been randomised. Thus, according to protocol the patient must have undergone at least one low bleeding risk invasive procedure. Please complete accordingly

Right click on warning symbols to see why something needs to be checked or changed

Deviation forms cannot be deleted once created. If they were triggered by a data entry error and are not needed, then please mark all fields on the deviation form as 'not available' and save the page.

Date/ Time of deviation 24/12/2022 ✓ (dd/mm/yyyy) (hh:mm 24)

Reason for deviation

Platelet count greater than allocated threshold, but platelet tr before/during low bleeding risk invasive procedure

Select main reason

Missing Not Available

View Question Information... View Audit Trail... View Warning... View Inform Message... Comments Notes DCRs SDV Mark Change Status Clear

If data collection ended, reason

Discharged

Please complete data collection up to the time of discharge (this now means completion of eCRF)

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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