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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 - 03 July 2023

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Sponsor: University of Oxford

Chief Investigator: Prof Peter Watkinson

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UNIVERSITY OF OXFORD

Agenda

- **Trial update**
- Investigator's Meeting
- Questions/site discussion

Trial Update

- Open sites: **33**
  - Welcome to **St Thomas' Hospital!**

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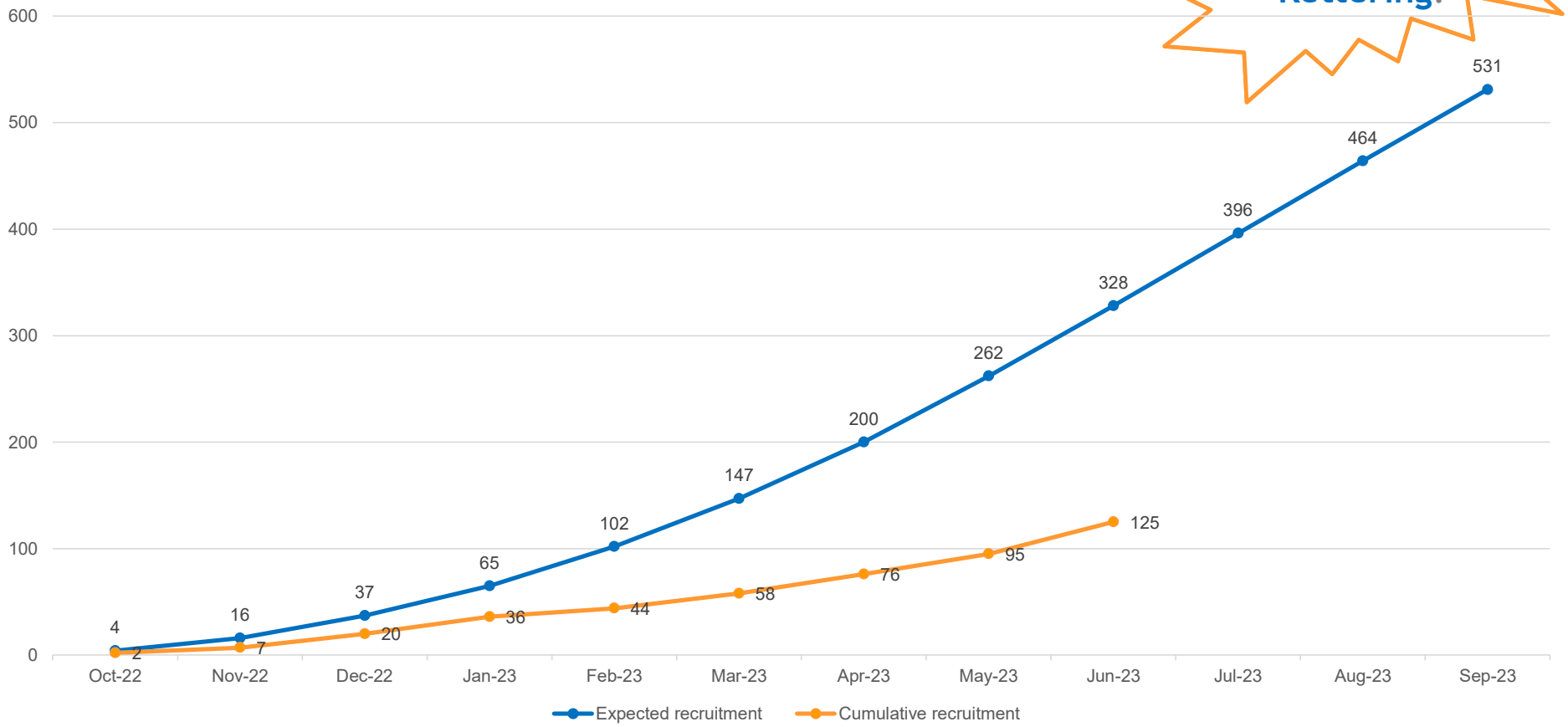
Trial Update

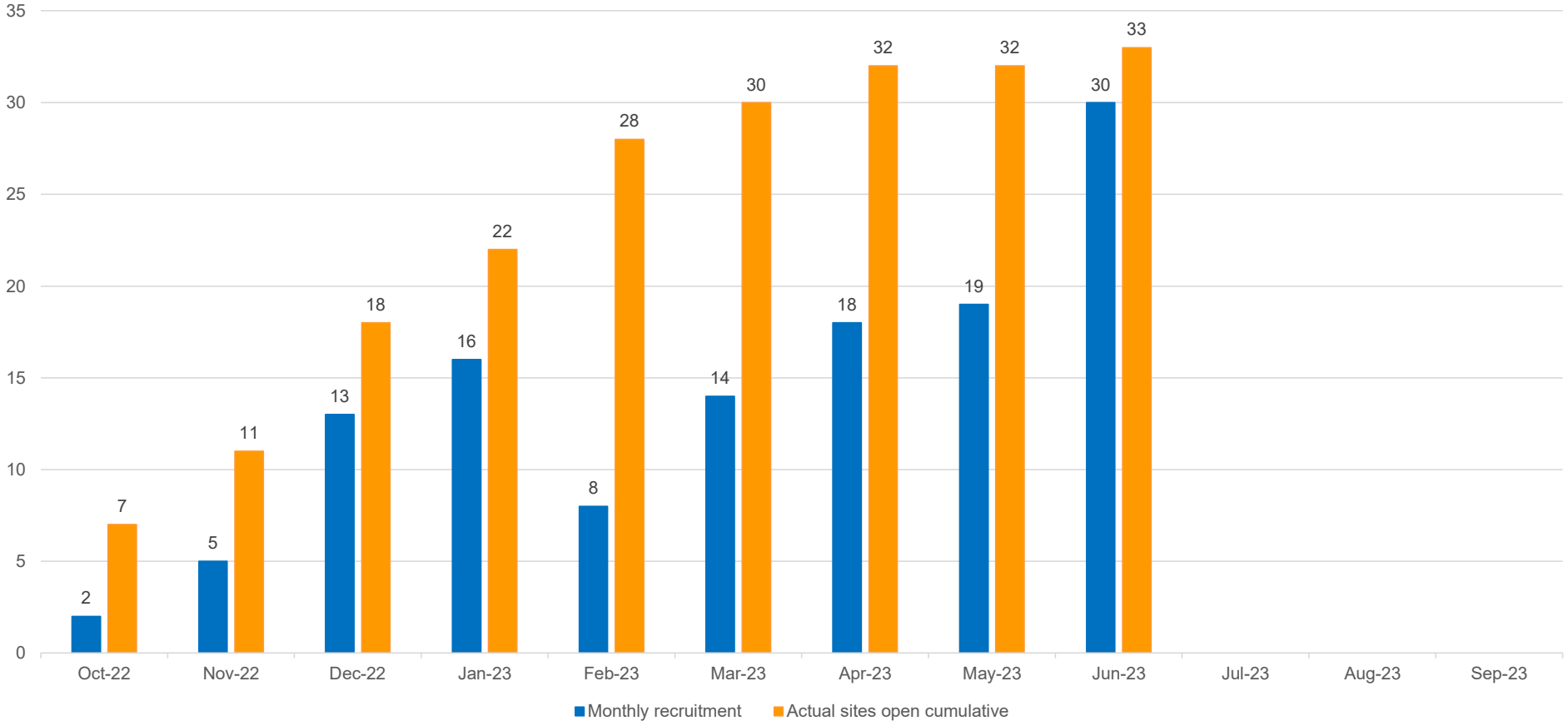
- As of 30 June 2023, **125** patients randomised

100th patient – **Kettering**!



Trial Update

- Recruitment in June – **30** patients randomised!



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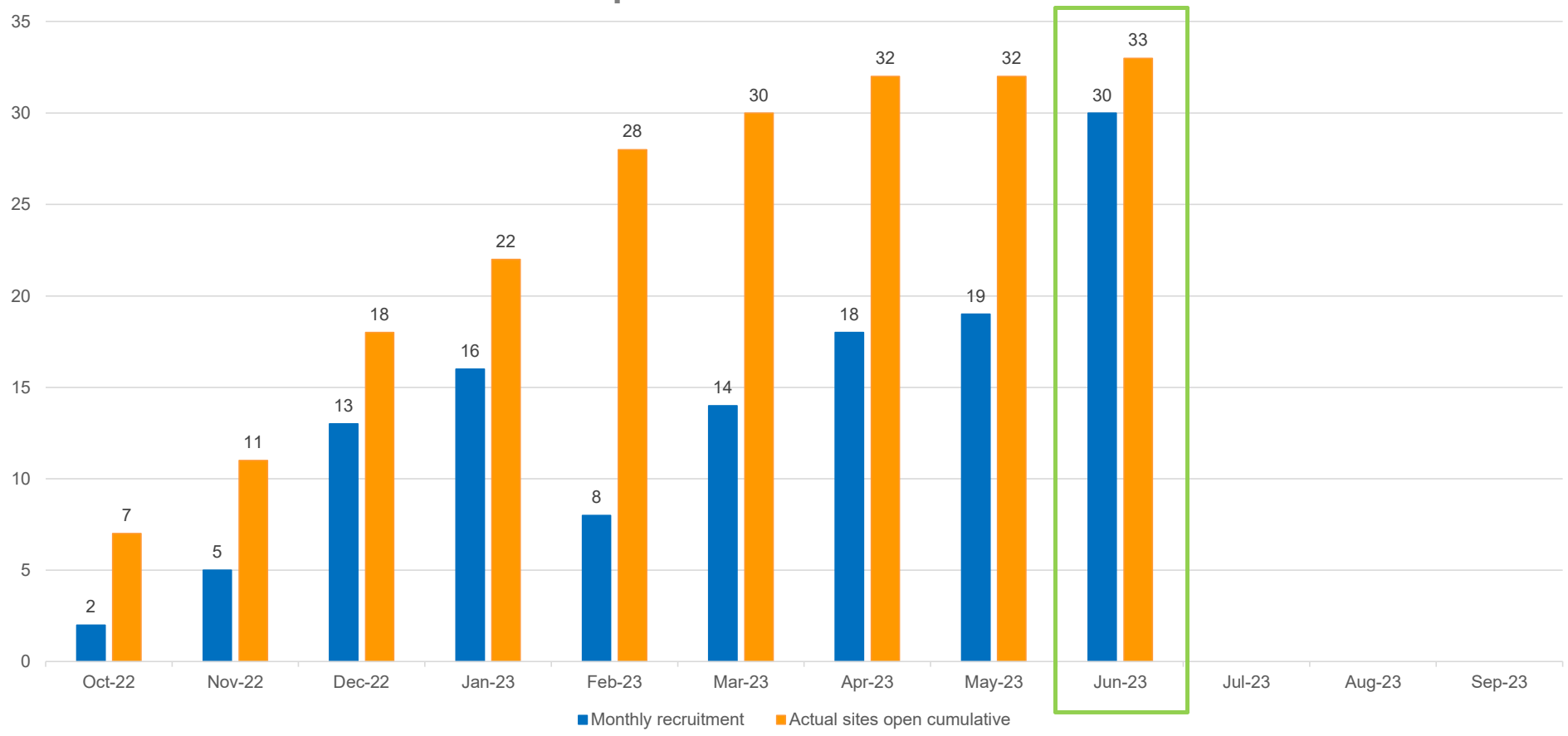


Agenda

- Trial update
- **Investigator's Meeting**
- Questions/site discussion

Investigator's Meeting

- Weds 07 June 2023 – London
- 62 delegates from participating sites
- Programme:
  - Progress update
  - Evidence review
  - Group working
    - Wider engagement (critical care, haematology, emergency department)
    - Patient screening and randomisation
    - Equipoise and transfusion
    - Deferred consent

Investigator's Meeting

- Working Groups – key feedback

Investigator's Meeting – key feedback

- Buddy Scheme
  - Aim:
    - To link up two sites who can help each other
    - This may be on screening, out of hours, engaging clinical teams, etc.
  - Plan:
    - CTU team will set up initial meeting between two sites
    - After that, site teams can then meet at their own frequency, email, etc.
  - Outcome: sharing and implementing new ideas

Investigator's Meeting – key feedback

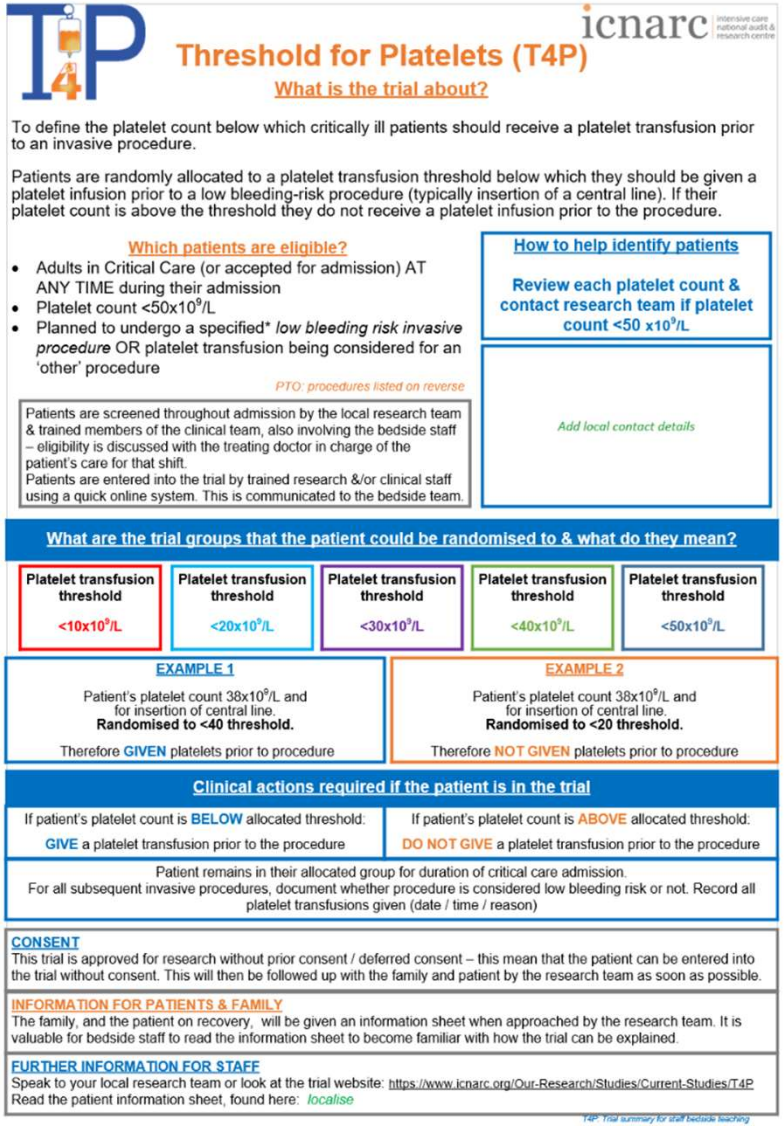
- Buddy Scheme
  - Please let us know if you would like to be part of the buddy scheme!
    - Highlight to us a particular area you'd like help with or to share experiences on
  - Conversely, we may approach you to be part of the scheme (no pressure to oblige)

Investigator's Meeting – key feedback

- Bedside training
  - Importance highlighted of engaging bedside staff
  - Suggestion of a 5-minute training resource for bedside staff
  - Aim to make them 'study aware' so they can flag potential patients to the research team
  - Particularly important if patients are screened in the mornings, but then become eligible later on the day

Investigator's Meeting – key feedback

- Bedside training
  - Template created for bedside teaching
  - Can be localised with research team contact details
  - CTU team will circulate following this meeting



T4P

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Threshold for Platelets (T4P)

What is the trial about?

To define the platelet count below which critically ill patients should receive a platelet transfusion prior to an invasive procedure.

Patients are randomly allocated to a platelet transfusion threshold below which they should be given a platelet infusion prior to a low bleeding-risk procedure (typically insertion of a central line). If their platelet count is above the threshold they do not receive a platelet infusion prior to the procedure.

Which patients are eligible?

- Adults in Critical Care (or accepted for admission) AT ANY TIME during their admission
- Platelet count <50x10^9/L
- Planned to undergo a specified* *low bleeding risk invasive procedure* OR platelet transfusion being considered for an 'other' procedure

PTO: procedures listed on reverse

Patients are screened throughout admission by the local research team & trained members of the clinical team, also involving the bedside staff – eligibility is discussed with the treating doctor in charge of the patient's care for that shift.
Patients are entered into the trial by trained research &/or clinical staff using a quick online system. This is communicated to the bedside team.

How to help identify patients

Review each platelet count & contact research team if platelet count <50 x10^9/L

Add local contact details

What are the trial groups that the patient could be randomised to & what do they mean?

Platelet transfusion threshold	Platelet transfusion threshold	Platelet transfusion threshold	Platelet transfusion threshold	Platelet transfusion threshold
<10x10^9/L	<20x10^9/L	<30x10^9/L	<40x10^9/L	<50x10^9/L

EXAMPLE 1

Patient's platelet count 38x10^9/L and for insertion of central line.
Randomised to <40 threshold.

Therefore **GIVEN** platelets prior to procedure

EXAMPLE 2

Patient's platelet count 38x10^9/L and for insertion of central line.
Randomised to <20 threshold.

Therefore **NOT GIVEN** platelets prior to procedure

Clinical actions required if the patient is in the trial

If patient's platelet count is **BELOW** allocated threshold:	If patient's platelet count is **ABOVE** allocated threshold:
GIVE a platelet transfusion prior to the procedure	**DO NOT GIVE** a platelet transfusion prior to the procedure

Patient remains in their allocated group for duration of critical care admission.
For all subsequent invasive procedures, document whether procedure is considered low bleeding risk or not. Record all platelet transfusions given (date / time / reason)

CONSENT
This trial is approved for research without prior consent / deferred consent – this mean that the patient can be entered into the trial without consent. This will then be followed up with the family and patient by the research team as soon as possible.

INFORMATION FOR PATIENTS & FAMILY
The family, and the patient on recovery, will be given an information sheet when approached by the research team. It is valuable for bedside staff to read the information sheet to become familiar with how the trial can be explained.

FURTHER INFORMATION FOR STAFF
Speak to your local research team or look at the trial website: https://www.icnarc.org/Our-Research/Studies/Current-Studies/T4P
Read the patient information sheet, found here: *localise*

T4P: Trial summary for staff bedside teaching

Investigator's Meeting – key feedback

- Trainee education
  - Teams highlighted the importance of training new intakes of junior doctors, but noted it was a time consuming effort, especially as 6-monthly
  - To try to help, CTU team will host several virtual 'drop-in' training sessions during first couple weeks of August
  - Going forward, we will then host monthly drop-in training sessions
  - Drop-in training sessions will be suitable for those undertaking eligibility/randomisation tasks only

Investigator's Meeting – key feedback

- Top tips
  - T4P stickers/posters/bedside signs
  - Engaging outreach teams
  - Providing certificates for training/randomisation
  - Associate PI scheme
  - Trial trained person/s rota system
  - Research team at daily safety briefings, medical handovers
  - WhatsApp groups
  - Working folders on unit

Investigator's Meeting – key feedback

- Resource summary
  - Lists all available T4P resources, found either online or available on request from the CTU team
    - Training slides
    - Tools, stickers, etc.
    - Guides
    - SOPs

Investigator's Meeting – key feedback

- Equipoise
  - Any concerns within wider teams, please do let us know!
  - T4P clinical investigators happy to meet with teams

- Deferred consent
  - Next training session 14 August 12:30
  - Will hold 2-3 monthly sessions going forward

Questions/site discussion

- Any questions?

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Icnarc.org/Our-Research/Studies/T4P