

REMAP-CAP NEWSLETTER

UK EDITION

SUMMER 2022
... and beyond

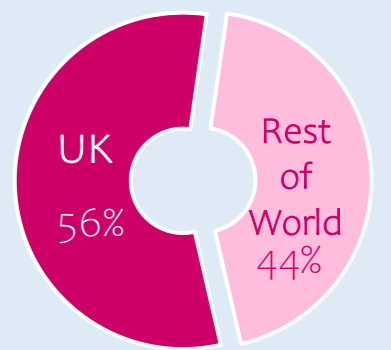
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Updates

RECRUITMENT

We would like to extend a **MASSIVE** thank you to **EVERYONE** for their commitment to the REMAP-CAP study. **UK sites** have now recruited **5539 COVID-19 patients!**



DOMAIN CLOSURES/PAUSES



- ACE2 RAS: Closed (link to [letter](#); please respond **ASAP** to any Urgent Data Queries)
- Continuous therapeutic anticoagulation: Closed (link to [letter](#))
- Vitamin C non-pandemic and pandemic : Paused (link to [letter](#) and [LOVIT trial publication](#))

LATEST DOMAIN

- Immunoglobulin domain



Featured in this Newsletter and in [The Guardian!](#) Read on to find out more...



IMPORTANT REMINDER

- The REMAP-CAP PIS Summary **cannot** be used for full consent. Please follow up with full consent using the REMAP-CAP Informed Consent Form. The FAQ document details the full consent process and can be found [here](#).

FAREWELL TO FARAH

As you may already know, Farah left the REMAP-CAP team at the end of May. We appreciate all the hard work she put into REMAP-CAP and wish her all the best!

The rest of the trial team (Liz, Lucy, Janis, Walton) will now be managing REMAP-CAP as a team.



It's back... The updated Immunoglobulin Domain!

There was evidence that this was potentially beneficial amongst **immunosuppressed** patients in the Severe state randomised to Version 1.0 of the Immunoglobulin Domain of REMAP-CAP. Although this was not conclusive, it provided strong support to further **investigate the efficacy of HIGH TITRE convalescent plasma in this sub-group.**

RECRUITMENT STATUS : Already recruiting!

To **activate** the domain, the following are required:

- ❖ Approval of **Substantial Amendment 32** by your local R&D department
- ❖ Completed **Domain choice page** ([link](#))
- ❖ Completed **self-training log**, which is located within the training pack ([link](#)), for research team members
- ❖ Confirmation from NHSBT that the **transfusion team** have attended **training** (training slots can be arranged with Hannah Tolley – [email](#))

Domain inclusion criteria:

- ✓ SARS-CoV-2 infection is confirmed by microbiological testing
- ✓ Underlying immunodeficiency or has received recent immunosuppressant therapy

Domain exclusion criteria (any of):

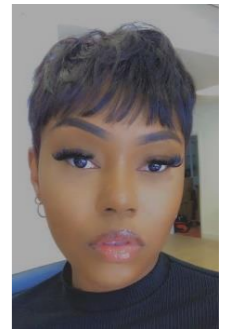
- ✗ If in the Severe State, more than 48 hours have elapsed since ICU admission, unless the patient has already been assigned to an intervention in another domain in the Moderate State, in which case exclusion will occur if more than 48 hours has elapsed since commencement of sustained organ failure support in an ICU
- ✗ Patient has already received treatment with any non-trial prescribed polyclonal antibody therapy (hyperimmune immunoglobulin, or convalescent plasma) intended to be active against SARS-CoV-2 during this hospital admission
- ✗ More than 14 days have elapsed since hospital admission
- ✗ The treating clinician believes that participation in the domain would not be in the best interests of the patient

Current REMAP-CAP

Trial Team ([email](#))



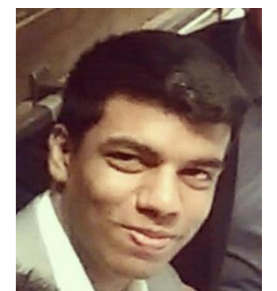
Janis (Imperial)



Liz (Imperial)



Lucy (Imperial)



Walton (ICNARC)

Open Domains

Active Pandemic Domains

- ❖ Simvastatin
- ❖ Anticoagulation
- ❖ Updated Immunoglobulin
- ❖ Cysteamine (Cysteamine bitartrate IMP supplied on request)

Active Non-pandemic Domains

- ❖ Antibiotics
- ❖ Macrolide Duration (only in association with the antibiotic domain)
- ❖ Antiviral
- ❖ Corticosteroid
- ❖ Cysteamine (Cysteamine bitartrate IMP supplied on request)

Substantial Amendment 36

- ❖ Submission of the **Region-Specific Appendices** (V3.3, V3.4, V3.5). This involves updates to the Region-Specific Appendix for Europe (that do not involve current active UK interventions)
- ❖ **Extension of the study end date** to 11th December 2023
- ❖ **Pause of the ‘continuation of therapeutic dose anticoagulation’** intervention in the severe state patients in the ‘Prior Therapeutic Anticoagulation Stratum’ of the Anticoagulation domain, due to crossing of a futility boundary (now closed)

Cysteamine

- ❖ Significant changes to the IMPD for Cysteamine – The shelf-life for cysteamine has been extended to December 2023.
- ❖ For those sites who already have stock, these kits will be relabelled accordingly and we will inform site teams of the process and timelines for this process in due course.

Final Reminders

- ❖ Updated immunoglobulin domain samples:

Please keep in the fridge over the weekend if they are taken on Thursday afternoon onwards (to avoid them sitting in the warm temperatures over the weekend)

- ❖ To get Spinnaker access, please send your:

- Signed CV
- GCP certificate
- Self-training log
- Site delegation log

- ❖ Please only contact ukremap-cap@icnarc.org for study specific queries and not the database team in New Zealand: REMAP-CAP (info@remapcap.org) / Spiral Support (support@spiral.co.nz)

- ❖ Study documents can be found on the ICNARC website [here](#)

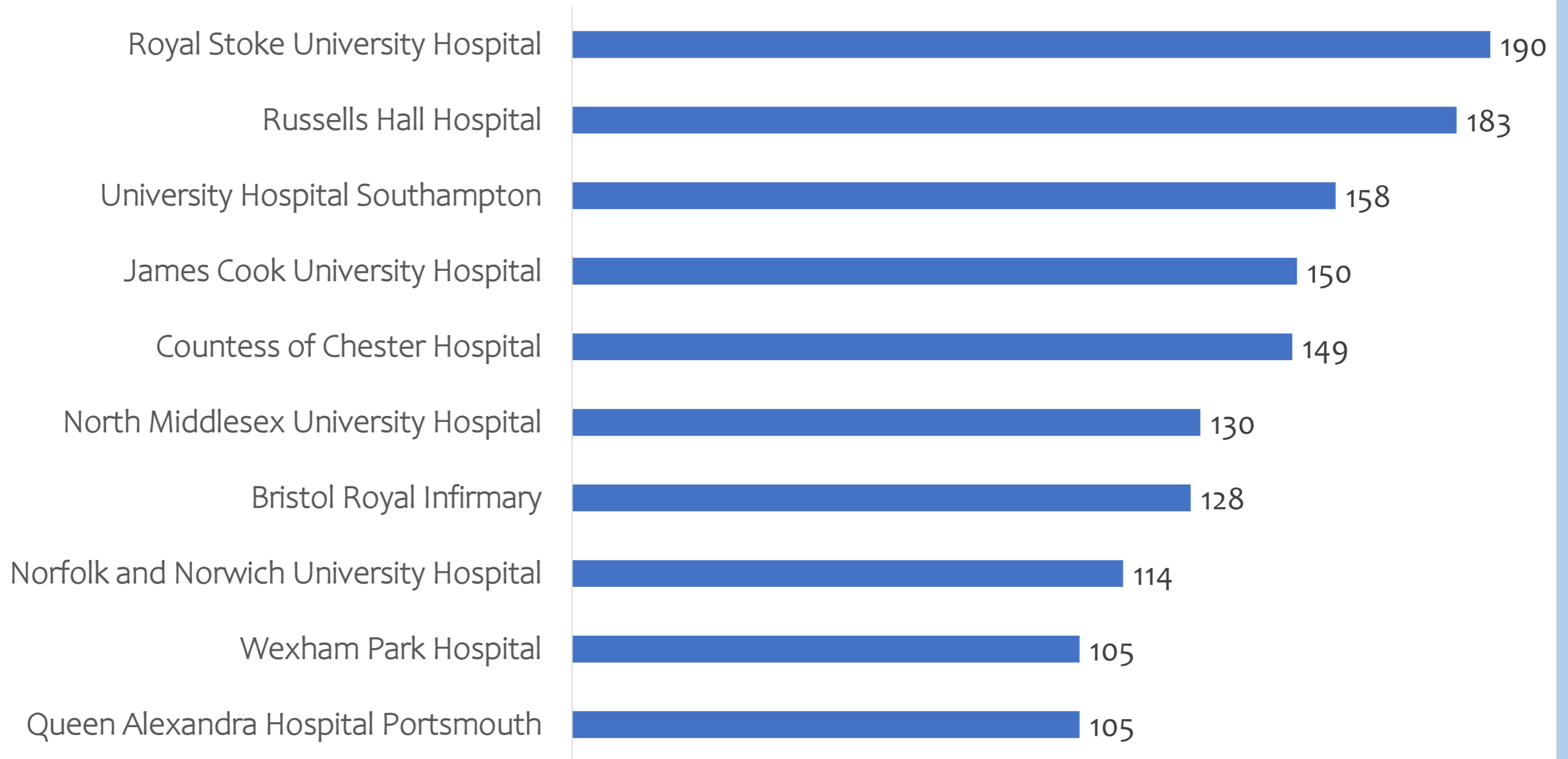
- ❖ All documents relating to amendments for the study can be found [here](#)

Recruitment

Overall top recruiting sites -Pandemic

❖ Top of leader board for overall pandemic patient recruitment is Royal Stoke Hospital with 190 patients. A special thanks goes to all the sites listed below.

REMAP-CAP LEAGUE TABLE - PANDEMIC



NUMBER OF RECRUITS

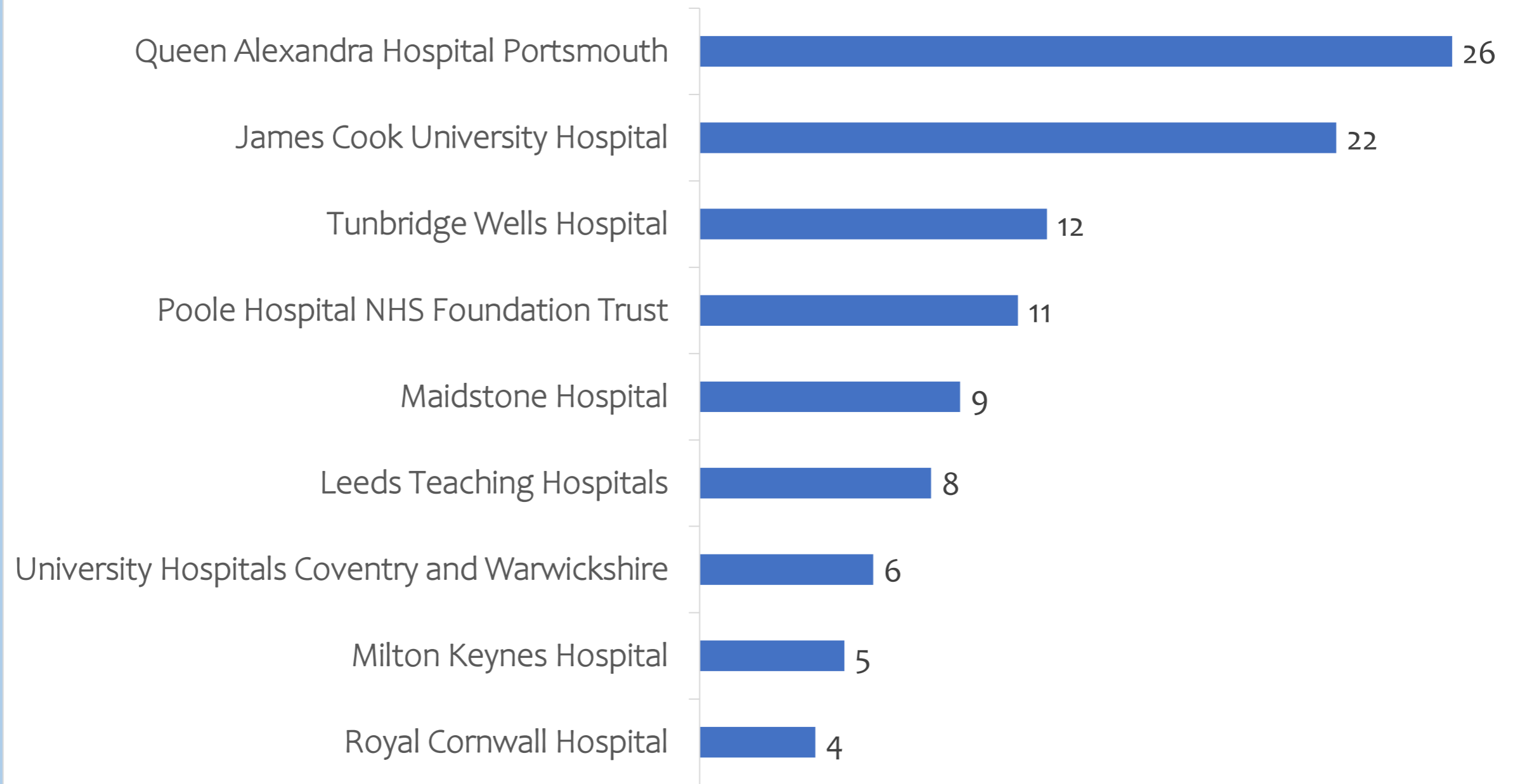
AS OF 18/07/2022

Recruitment

Overall top recruiting sites -Non-Pandemic

- ❖ Top of leader board for overall non-pandemic patient recruitment is Queen Alexandra Hospital Portsmouth with 26 patients. A special thanks goes to all the sites listed below.

REMAP-CAP LEAGUE TABLE - NON-PANDEMIC



NUMBER OF RECRUITS

AS OF 18/07/2022



REMAP-CAP

COVID-19

MILESTONES 2022

JANUARY 11 2022

Updated Immunoglobulin domain opens

FEBRUARY 24 2022

ACE2 RAS domain closed for critically ill (i.e., severe state) patients

MARCH 22 2022

[Antiplatelet](#) paper published

APRIL 22 2022

1st patient randomised to Updated Immunoglobulin domain

JUNE 16 2022

ACE2 RAS domain closed for moderate state patients

JUNE 17 2022

Vitamin C domain paused for non-pandemic patients due to results from the LOVIT trial

JULY 06 2022

'Continuation of the therapeutic dose anticoagulation' intervention of the Anticoagulation domain was closed.

JULY 16 2022

Vitamin C domain paused for pandemic patients due to hitting a statistical trigger

