

# NHS Blood and Transplant Clinical Trials Unit Efforts to Support UK Convalescent Plasma Clinical Trials Set-Up: Key Metrics and Challenges Encountered

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## Introduction

Convalescent plasma (CP) is plasma collected from patients who have recovered from SARS-CoV-2 infection and contains neutralising antibodies against it. A recent systematic review (Chai et. al, 2020) found inconclusive evidence regarding the efficacy and safety of CP as a possible treatment for coronavirus disease (COVID-19).

Hence, robust clinical trials are essential to confirm the efficacy and safety of CP. In the UK, there are currently two ongoing clinical trials assessing CP effectiveness and safety: RECOVERY (www.recoverytrial.net) and REMAP-CAP (www.remapcap.org). NHS Blood and Transplant (NHSBT) and other UK Blood Services are collaborating with both trial teams to set-up hospitals, provide training, supply CP, and support data collection for further CP efficacy and safety analyses.

NHSBT Clinical Trials Unit (CTU) collaborates with researchers in the design, conduct, analysis and publication of clinical trials and other prospective studies, primarily in the fields of transfusion medicine, organ donation and transplantation, tissue and stem cell transplantation.

## Aims and Objectives

This presentation aims to provide insights into NHSBT Clinical Trials Unit (CTU) efforts to support UK CP trials set-up, including key metrics and challenges encountered.

## Key Efforts By NHSBT CTU Team

1. Supported grant applications to obtain funding in response to COVID-19 urgent research initiatives

2. Rapidly redeployed its staff to ensure smooth delivery of CP trials and provided strategic planning for swift opening of hospitals to CP trials.

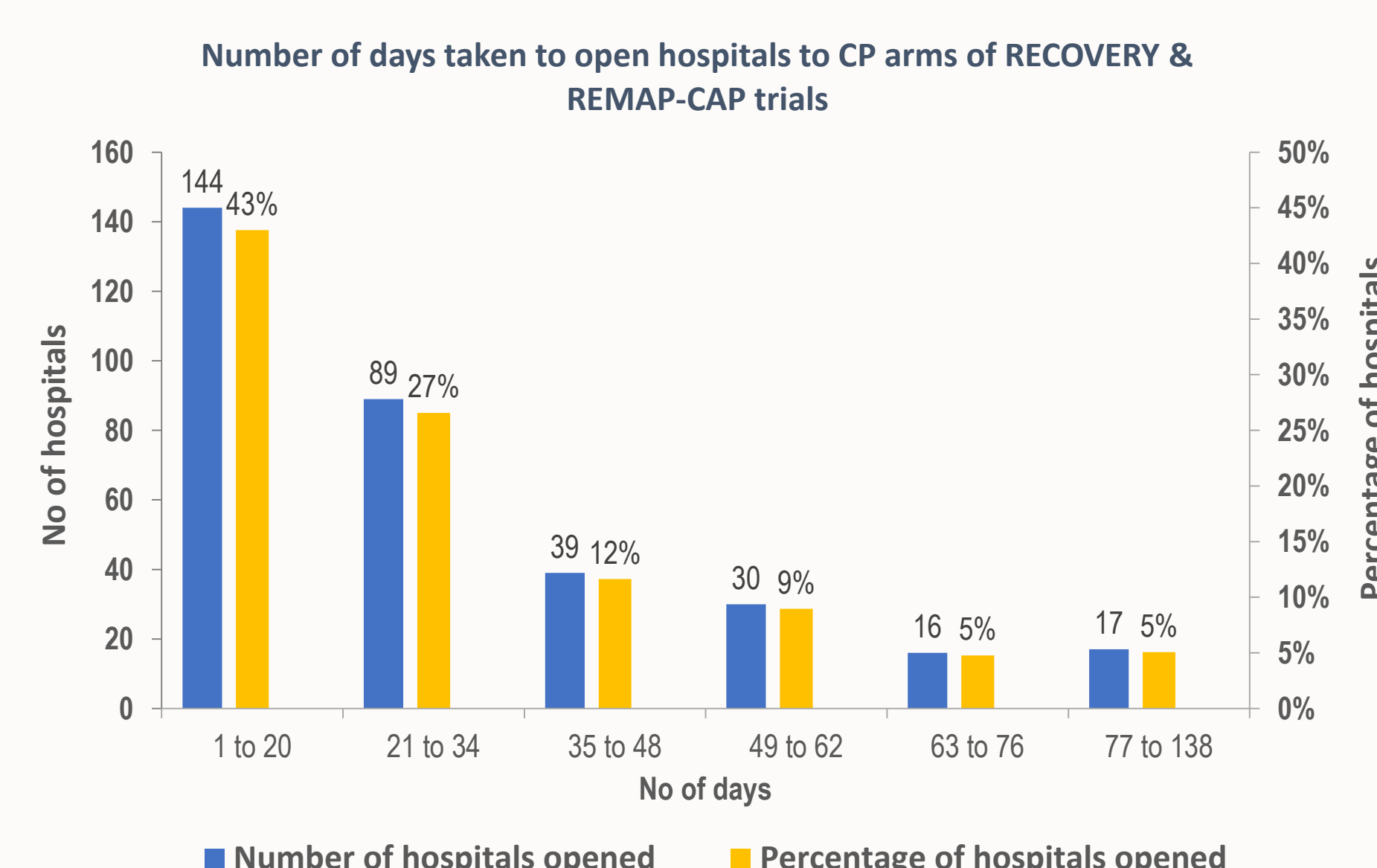
➤ Four Trial Managers have been assigned to manage the CP aspects of RECOVERY and REMAP-CAP trials supported by two Clinical Operations Managers. Other members of the CTU are also involved, including Senior Statisticians, Data Managers and Trial Administrators to support data collection linkage and analysis.

➤ The following table highlights key milestones that have been achieved since the start of the work in April 2020:

	RECOVERY	REMAP-CAP
Number of hospitals opened to recruitment	217	118
Number of participants recruited to the CP arm	>5000	>800
Number of staff attended CP training	>1000	>950
Number of virtual training sessions delivered	130	102
Number of hospitals in set up stage	9	2
Number of CP units issued to recruiting hospitals	6656	

➤ The CTU team set-up and opened 335 hospitals to both trials (RECOVERY: n=217, REMAP-CAP: n=118, hospitals open to both: n=115) across the UK including staff training and CP delivery (updated 16<sup>th</sup> November 2020).

➤ On average it took 30 days to open each of these hospitals ranging from 1 to 138 days (median=22). The majority of hospitals (n=233, 70%) were opened within less than 5 weeks of the initial invitation (Chart 1).



The maps below show the distribution of hospitals recruiting to CP arms of RECOVERY (Figure 1) and REMAP-CAP (Figure 2) trials across the UK. The size of the bubbles correlate with the number of participants recruited to the trial.

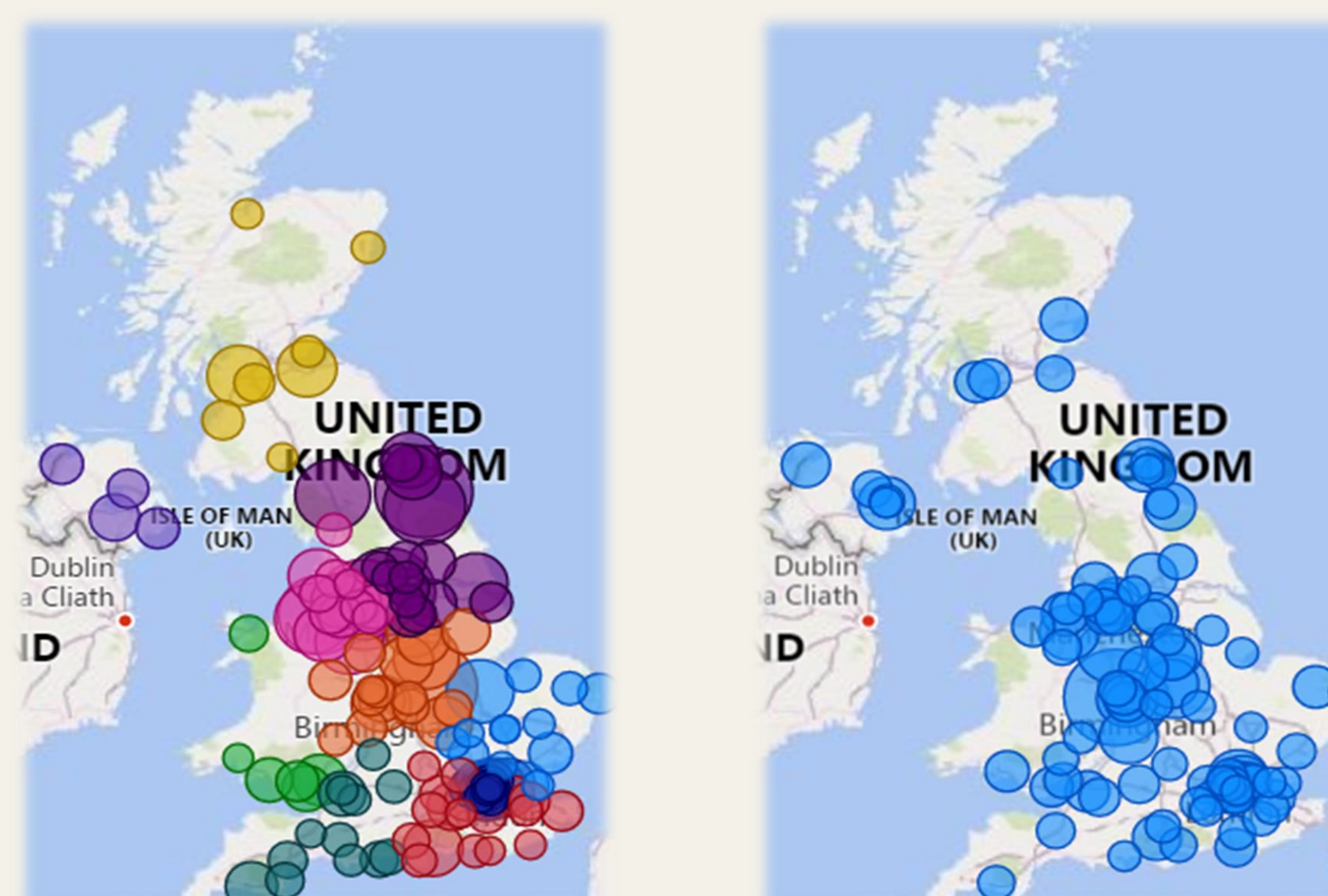


Figure 1: RECOVERY recruiting hospitals



Figure 2: REMAP-CAP recruiting hospitals

3. Established communication channels with relevant internal and external stakeholders/collaborators.

➤ The team prepared CP training materials and related data collection tools, which were shared with and reviewed by UK devolved nations' blood services.

➤ Working closely and meeting regularly (daily/weekly/bi-weekly) with internal and external stakeholders/collaborators (Figure 3) to support discussions, decision making and subsequent prompt actions.

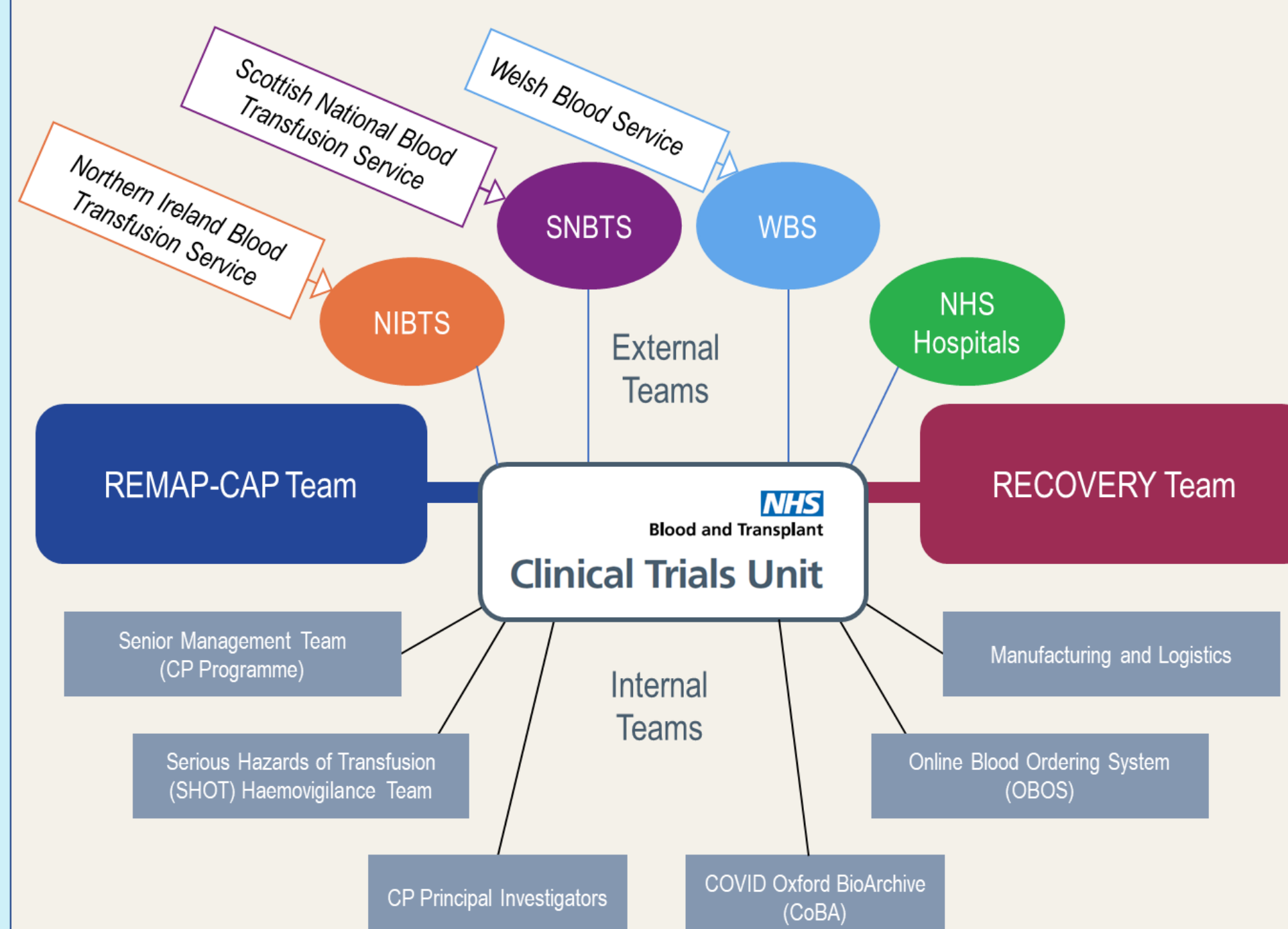


Figure 3: NHSBT CTU internal and external collaborators

4. Processes for CP stock monitoring, ordering and distribution have been set-up and implemented.

➤ Close working with Manufacturing and Logistics colleagues to match the supply and demand of CP (Figure 4).

➤ The main virtual training platforms used to deliver CP training to participating hospitals are Zoom and Microsoft Teams.

➤ Other online tools that streamlined the training and set-up processes include Eventbrite, which reduced the admin work required and helped to keep track of the training attendees; and SharePoint where the team stored, and worked collaboratively on, key documents.

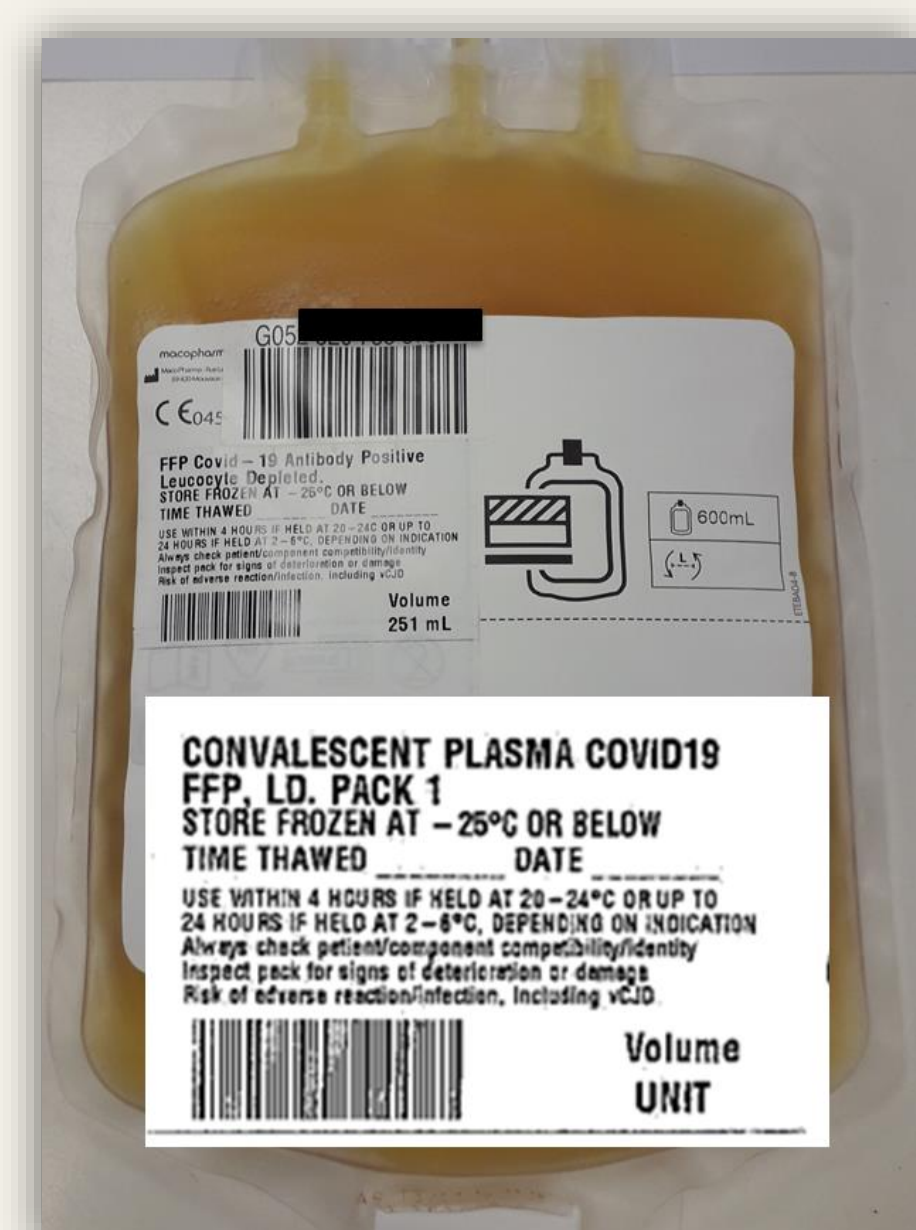


Figure 4: Convalescent Plasma Unit

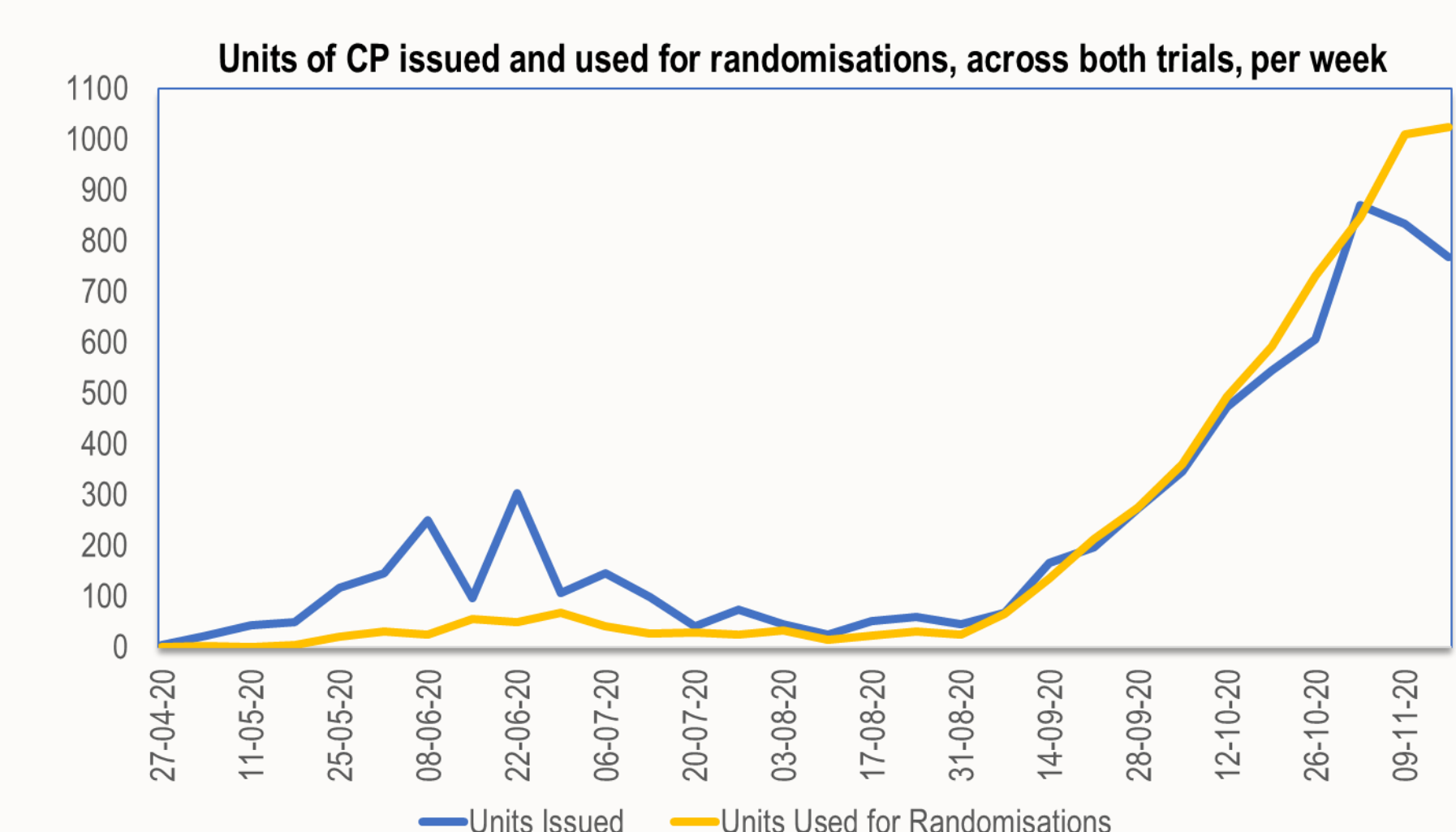
## Key Challenges Encountered

➤ CP collection started in April 2020. Since then, CP stock levels gradually increased (Graph 1). However, during the first few weeks, the team were only able to approach a limited number of hospitals in waves to avoid shortages of CP stock. Once stock had reached sufficient levels, the team adapted the approach, aiming to open as many sites as quickly as possible. This required a close working relationship with other teams within NHSBT (e.g. manufacturing)

➤ Progress slowed over the summer as potential hospitals became less motivated to participate due to the reduction in COVID-19 hospital admissions. In August 2020, hospital admissions decreased by 73% and trial randomisations by 38% compared to June 2020; consequently 34 (10.1%) hospitals were opened in August compared to 121 (36.1%) hospitals in June. An opposite trend has been observed since the start of the COVID-19 second wave in September 2020. Six hospitals that initially expressed no interest in taking part in the CP arm subsequently contacted the team wishing to participate.

➤ Other reasons that caused delays in opening hospitals include; lack of freezer space to stock CP at site (n=4), blood bank IT problems (n=4), staff being on annual leave particularly during the summer period (n=14).

➤ Working with commercial supplier and Royal Mail to create bespoke packaging kits for serum samples sent from hospital sites to central lab in a short time frame.



Graph 1: Number of CP issued and used for randomisation in both trials

## Conclusion

NHSBT and the CTU team have contributed to the world's largest CP trials aimed to assess CP safety and effectiveness. The remarkable efforts of the wider NHSBT, CTU team and our collaborators have been fruitful. Both trials are very close to completion (with more than 6000 participants recruited to date) and data collection to provide a definitive answer about whether CP is safe and effective for hospitalised COVID-19 infected patients. This success can be attributed to resilience, teamwork, innovative methods of working, and motivation from the urgent public health need for a rapid development of COVID-19 interventions.

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## References

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## Acknowledgements

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➤ Special thanks to the NHSBT OBOS and hospital services teams for their support in ensuring prompt provision of CP barcodes and delivery of CP to participating sites when requested.

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