

# NHSBT Board Update

23<sup>rd</sup> July 2020

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*This document is a draft and the information contained herein is subject to change*

- **CP Programme Update**
- **CP Programme Governance**
- **Three options for the CP Programme beyond October**
- **Description of Option 2: ‘Optimise and Sustain’ for 6 months at a similar scale (incl. capacity, costs, and requirements)**
- **Description of Option 3: ‘Scale’ for 6 months at approx. double capacity**

# Convalescent Plasma: Phase 1 Objectives

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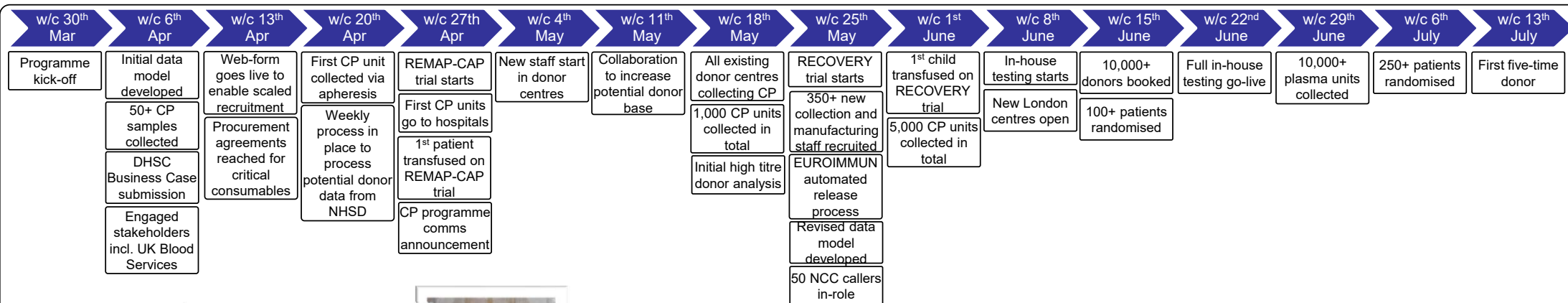
**To rapidly scale the access to and use of Convalescent Plasma to treat people who are critically ill with COVID-19 across the UK**

The initial aims were to supply ~4,000 units of plasma for two clinical trials (REMAP-CAP and RECOVERY), while simultaneously scaling up collection, production and distribution of CP in bulk to hospitals

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# CP Programme progress to date



## What we've achieved in 16 weeks!

20,000+ donors booked in

15,000+ units collected

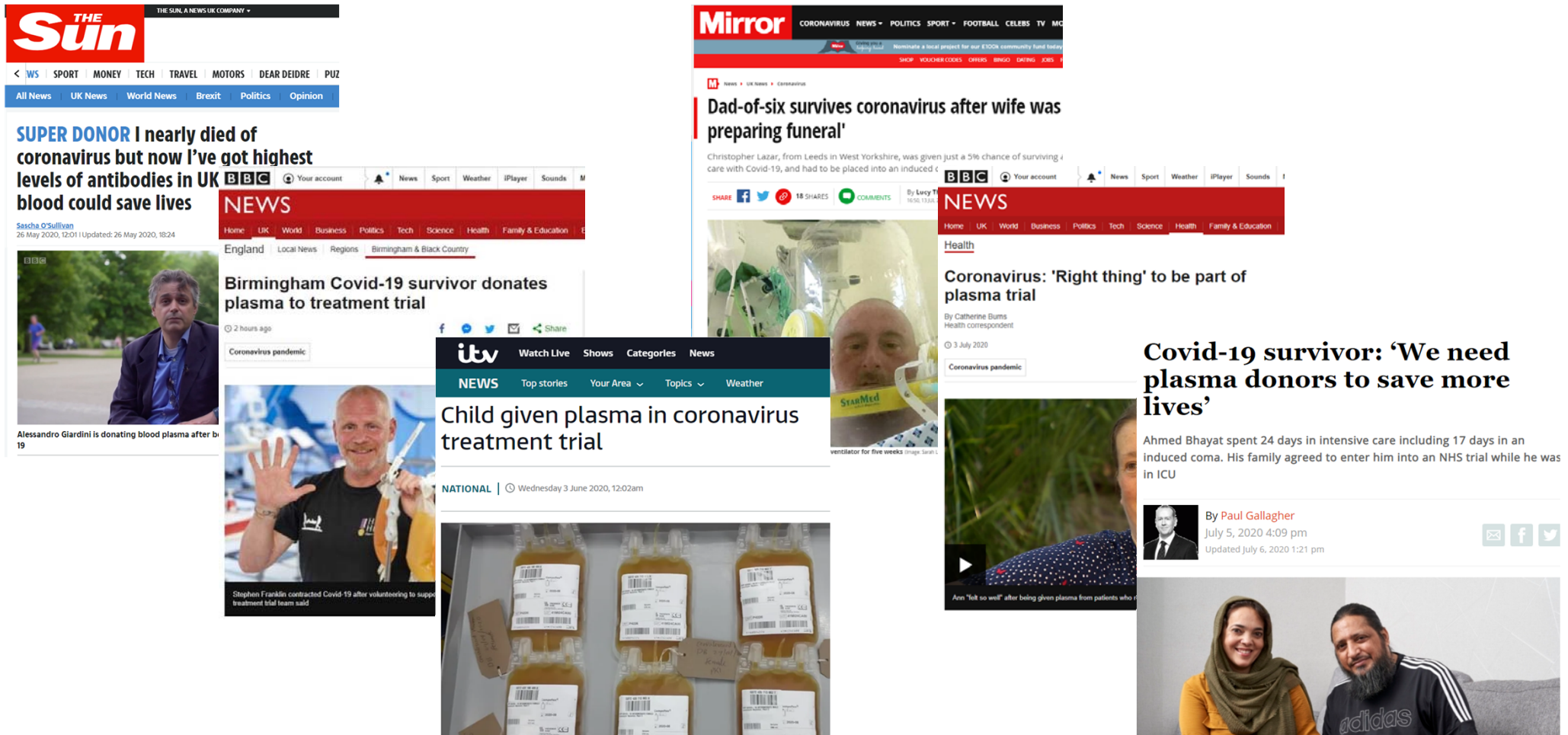
~1.3k units issued to hospitals

300+ patients randomised across 2 clinical trials

**"The progress we've made has been incredible. Thank you for all your hard work – I hope you're as proud as I am of all we've achieved together."**

*Gail Mifflin, Chief Medical Officer, NHSBT*

# We have received a great deal of positive media coverage



# Key learnings from the last 12 weeks: Scaling up and managing the Programme alongside normal operations

## Time to recruit and train operational staff

- **A fully-operational new donor centre team (incl. recruitment and training) can have lead times of up to 6-10 weeks** – requirement to build training infrastructure local to donor centres and implement new ways of training (incl. e-learning)

## Management bandwidth

- **Management** of both **core NHSBT operations** and **CP Programme** with existing capacity is **not sustainable beyond current phase** – requirement for additional management capacity (reflected in the Programme resourcing)

## Agility to respond to outbreaks

- **Outbreaks can often be localised in nature** – requirement to identify suitable locations for new centres as soon as possible, and to be more agile with national reach by using existing local capacity flexibly (e.g. moving whole blood and platelets to another part of the country)

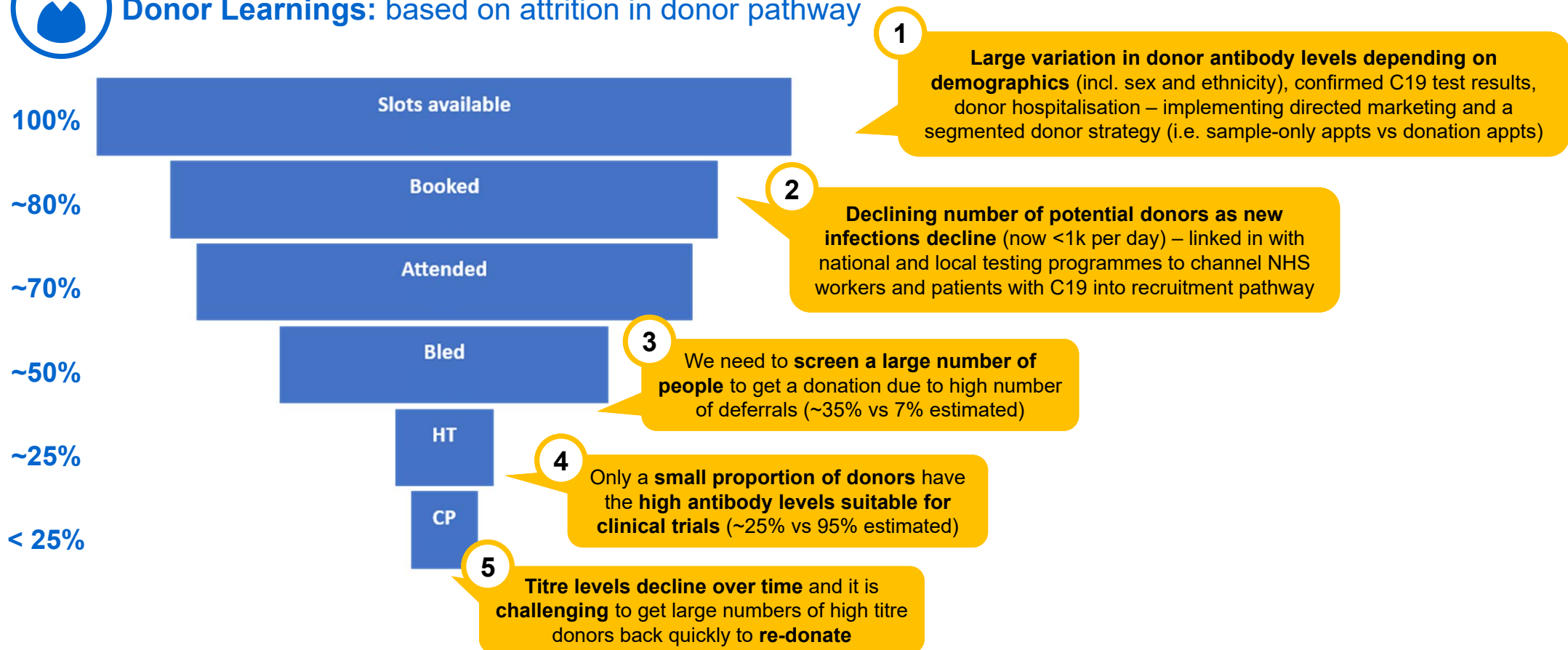
## Securing equipment for CP

- **In Phase 1 existing equipment and capacity was utilised**, which **cannot be relied upon during Phase 2** due to machine expiry
- There are clear signals there will be **very high global demand for plasma collection equipment**. To increase capacity, **more machines will be required** – requirement to make an **early order** to secure apheresis equipment

# Key learnings from the last 12 weeks: Donor Learnings



## Donor Learnings: based on attrition in donor pathway

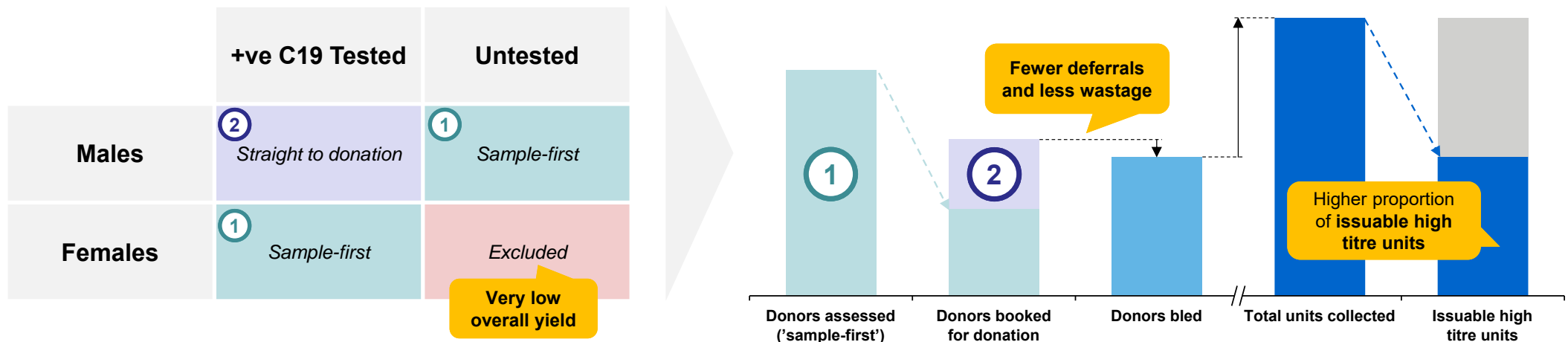




# As a result, we are refining our collection strategy

New segmented strategy (pilot underway, national roll out expected early-August 2020)

- 1 Sample-first segment** (donors less likely to provide issuable high titre units): Samples taken for testing alongside pre-screening (donor health check and vein assessment) to determine **suitability to provide a donation**, and donor called back to donate if suitable
- 2 Straight to donation segment** (donors more likely to provide issuable high titre units – *all positively tested male donors for pilot*): Donors booked for donation, samples for testing are taken alongside donation





# CP Programme Phase 1 update



## Original Phase 1 aims

We would **meet demand for**:

- 2k units for **REMAP CAP**
- 2k units for **RECOVERY**

We would **collect**:

- **85k units** collected in total, of which assumed **95% units were issuable**



## Progress to date

**All CP requests met** for both trials:

- 74 units issued for **REMAP CAP**
- 227 units issued for **RECOVERY**

We have **collected**:

- **15k units** collected in total
- **3.5k high titre units** collected, of which:
  - ~1.3k HT units issued to hospitals
  - ~2.2k HT units in stock
- **~6k medium / low titre units**



## Current forecasted Phase 1 targets with new collection strategy

*Assuming sufficient supply of donors*

We will be **meet demand for up to**:

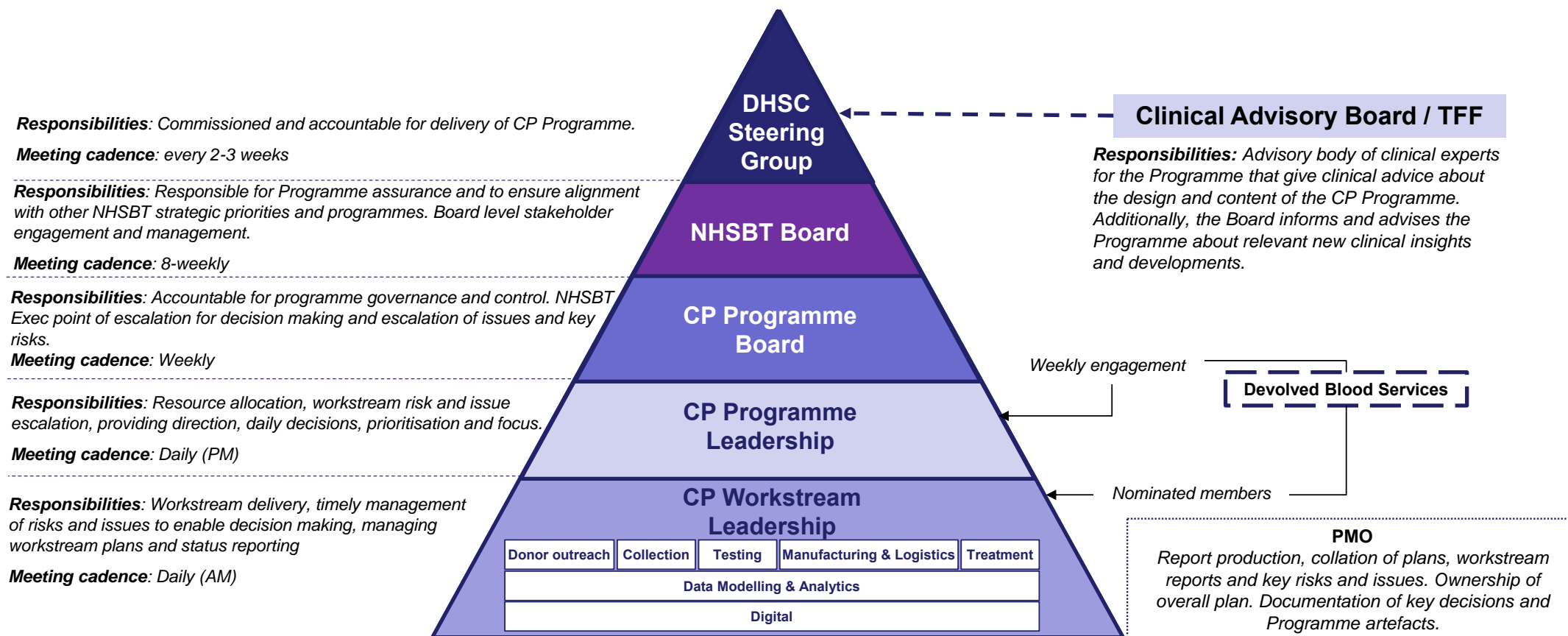
- 2k units for **REMAP CAP**
- 5k units for **RECOVERY**

**Current forecast with new collection strategy:**

- **55-65k units<sup>1</sup>** collected in total, of which:
- **15-18k HT units<sup>1</sup>** collected in total
- End date: **31<sup>st</sup> Oct 2020**

Notes: 1) Detailed assumptions in appendix

# This is the governance approach we have used to date, which we would like to review with you today for Phase 2



# The DHSC has suggested expanding the CP programme beyond Phase 1 for a number of reasons



**Emerging international evidence** from clinical trials **indicates positive outcomes from use of CP**



**Planning for a potential second wave**



**Potential treatment that can be sourced domestically**, as opposed to requirement to compete globally for other treatments



Had convalescent plasma been available for the **first wave in the UK**, the **number of CP units<sup>1</sup>** required to have treated **all COVID-19 patients**:

- **~25k CP units** to treat **all ICU patients<sup>2</sup>**
- **~200k CP units** to treat **all hospitalised patients<sup>3</sup>**

In order to **proactively collect additional stock** for use in future waves, there is an option to **collect CP units beyond current phase**

Notes: 1) Assuming 2 units per patient, 2) ICNARC COVID-19 report: <https://www.icnarc.org/Our-Audit/Audits/Cmp/Reports>, 3) Government daily briefing (15 Jun): <https://www.gov.uk/government/publications/slides-and-datasets-to-accompany-coronavirus-press-conference-15-june-2020>

# Three options for CP collection for 6 months after Phase 1 (November 2020 – April 2021)

<b>Option 1</b> <b>Shut down CP Programmes</b>	<b>Option 2</b> <b>Optimise &amp; Put in place a sustainable operating model</b>	<b>Option 3</b> <b>Scale up above Option 2 collection capacity</b>
<ul style="list-style-type: none"> <li>▪ Decommission all new donor centres and freezer capacity and release staff</li> <li>▪ Develop communication to protect against reputational risk</li> </ul>	<ul style="list-style-type: none"> <li>▪ Maintain collection capacity for another 6 months to respond to 2<sup>nd</sup> wave</li> <li>▪ Reduce reliance on current BAU management capacity</li> <li>▪ Provide ability to flex collection footprint to respond to localised outbreaks</li> </ul>	<ul style="list-style-type: none"> <li>▪ Build additional capacity in collections testing and manufacturing in an attempt to fully maximize collection of CP during a potential 2<sup>nd</sup> wave</li> <li>▪ Build in excess capacity in to operating model - approximately double the supply chain capacity)</li> </ul>
<b>Collection Capacity</b> <ul style="list-style-type: none"> <li>• At least 3-4 months to scale back up for a second wave</li> <li>• Would miss peak collection opportunity</li> </ul>	<b>Collection capacity</b> <ul style="list-style-type: none"> <li>• Up to ~4,000 CP units per week</li> <li>• Up to ~2,500 sample slots per week</li> </ul>	<b>Collection capacity</b> <ul style="list-style-type: none"> <li>• Up to ~7,500 CP units per week in total</li> <li>• Up to ~4,500 sample slots per week in total</li> </ul>

# Main elements of Option 2: Optimise and Sustain for 6 more months at a similar scale



## **Keep current national footprint**

Maintain current capacity to collect CP in all existing 24 donor centres plus extra space created at WEDC , Birmingham, Newcastle, and Southampton, and the new donor centres in London (3) and Liverpool Speke



## **Replace any borrowed capacity from existing BAU and create some initial flexibility to move collection requirements geographically (i.e. depending on location of outbreaks)**



## **Create dedicated project team with sustainable workload, for whom this is their full time job**

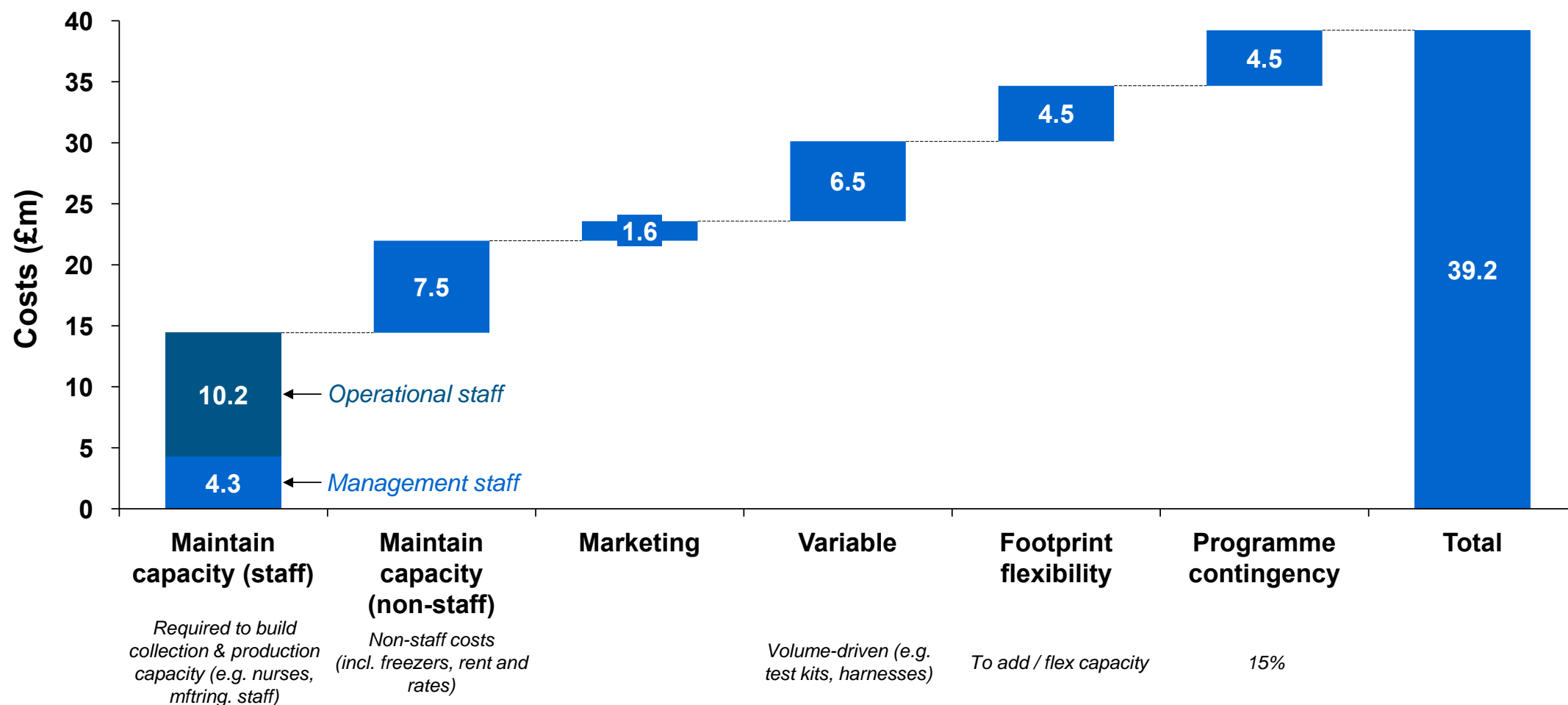
For costing, a reasonable worst case scenario has been assumed with all team roles needing to be backfilled. In practice, there will be a mix of dedicated backfill roles and additional SMEs



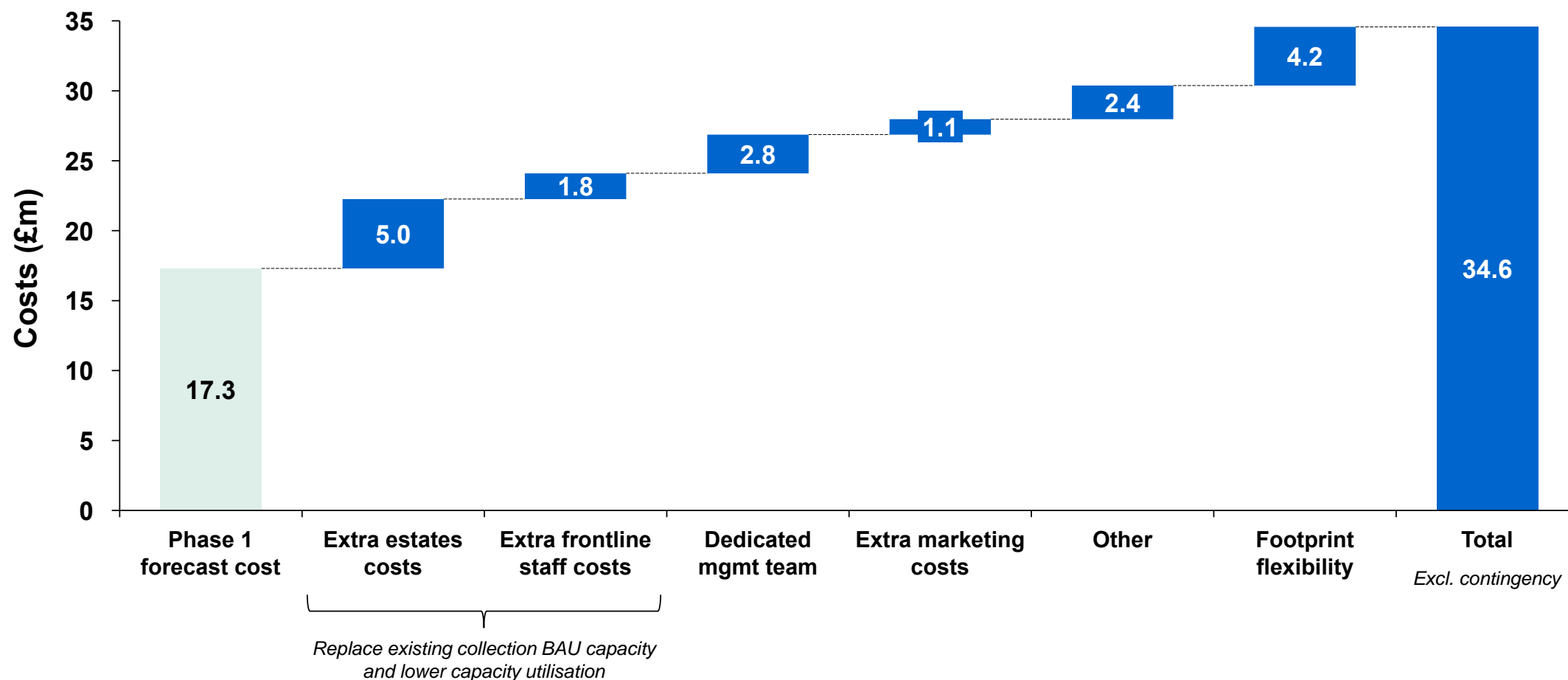
## **Accelerate integration of CP into Donor Experience and ramp up marketing efforts**

Accommodate CP into existing Donor Experience processes, and leverage capacity and skills of the directorate. Tailored marketing required for target segments (e.g. psychological needs)

# Expected costs of Option 2: Optimise and Sustain for 6 months



# Incremental costs of extending existing capacity for additional 6 months (i.e. Phase 2, Option 2 vs Phase 1)





# What Option 3 ('Scale Up') could look like

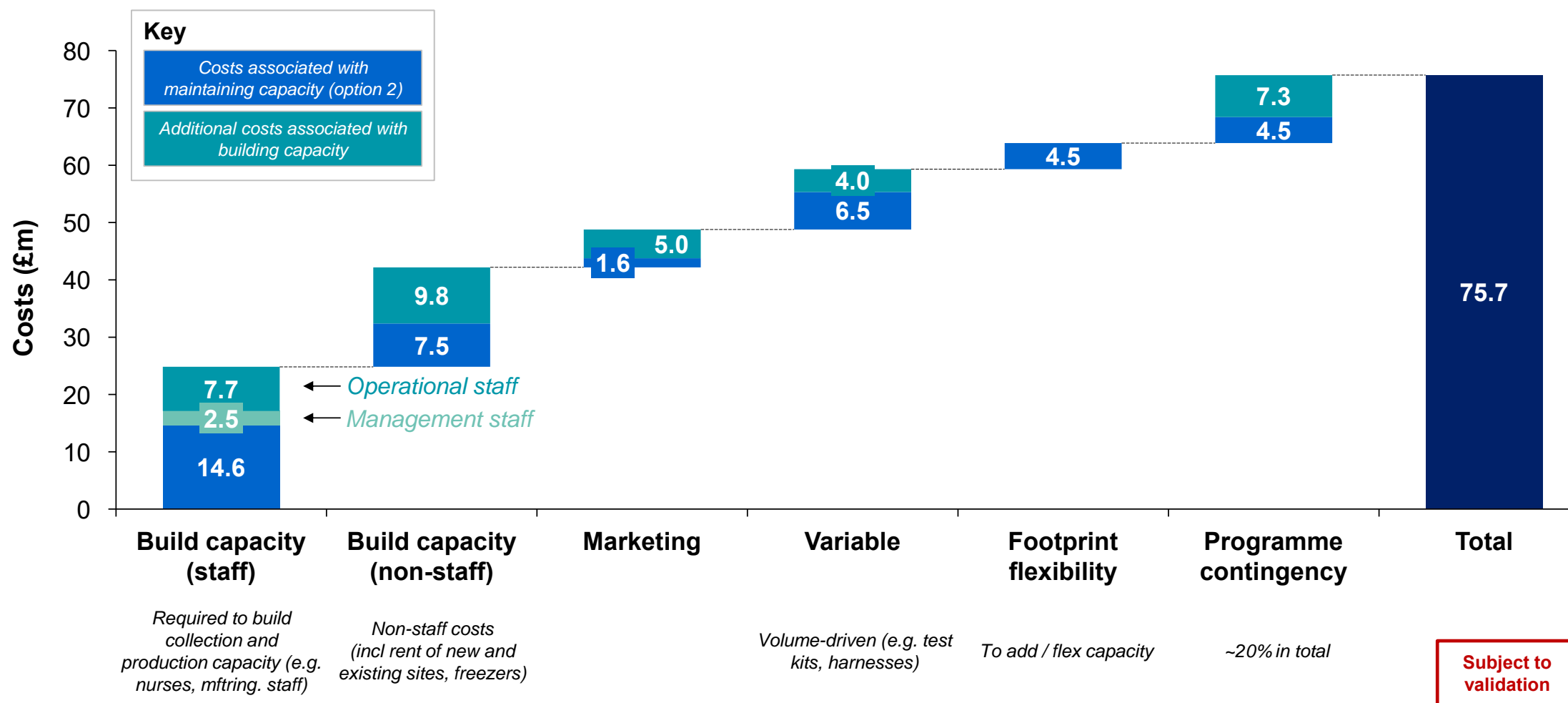


**Option 3 : Extend the programme for 6 more months at approximately double the existing collection capacity (i.e. doubling 'size of pipe')**

- ① **Secure additional ~100 apheresis machines** – ideally machines more suitable for plasma only collections (i.e. not required for platelets / other multicomponent donation)
- ② **Open 10 new donor centres to collect plasma only** – assumes each centre 9 chairs; other sizes could be considered
- ③ **Recruit and train 210 extra WTEs to staff additional new donor centres** (~60 Nurses, ~140 Donor Carers, 10 DCM), and **recruit additional training and management staff**
- ④ **Staff Manufacturing and Logistics and Donor Outreach to approx. double supply chain capacity**

- Given **lead times** and the **additional effort**, we would need to be **instructed asap** to be able to **make the capacity available from November**
- Likely to **require external help** (i.e. DHSC) to achieve these targets and / or do things differently

# Expected costs of Option 3: Scale Up at approx. double the capacity for 6 months



# Key risks for Option 3

Risk	Mitigation
<b>Unused / excess plasmapheresis capacity</b>	<ul style="list-style-type: none"> <li>Excess capacity could be utilized for                             <ul style="list-style-type: none"> <li>✓ Plasma for fractionation (subject to MRHA approval and new tender for machines/harnesses)</li> <li>✓ Stock build ahead of Brexit Jan'21</li> <li>✓ Accelerate delivery of some BAU projects e.g. Session Solution</li> </ul> </li> <li>Demand for RBCs and plasma likely to go up as hospitals ramp up BAU activities</li> </ul>
<b>Recruit / retain &amp; train additional staff (front line and mgmt team)</b>	<ul style="list-style-type: none"> <li>Recruitment – collaborate with NHS and partners to source suitable and qualified personnel</li> <li>Training – transform and modernise the approach to training, train additional Trainers</li> <li>Secure external management consultant support immediately</li> </ul>
<b>Finding and retaining high titre donors</b>	<ul style="list-style-type: none"> <li>If second wave occurs there may be large collection opportunity</li> <li>Continue to review approach to segmentation and to secure loyalty</li> <li>Implement targeted marketing plans</li> </ul>
<b>Finding and securing new venues</b>	<ul style="list-style-type: none"> <li>Leverage existing large mobile sessions (if suitable) as much as possible</li> <li>New venues could be set up as whole blood donor centres and existing repurposed for CP (if suitable)</li> <li>Collaborate with Government and commercial estate specialists (as required)</li> </ul>
<b>Secure machines and harnesses</b>	<ul style="list-style-type: none"> <li>Early orders to secure machines and harnesses, due to expected high global demand</li> </ul>
<b>Demand increases unexpectedly, which we may not be able to meet</b>	<p><i>For example, RECOVERY trial finishes early, or data from US studies influences clinicians in UK – which could lead to CP being approved for use in UK or more units being assigned for compassionate use</i></p> <ul style="list-style-type: none"> <li>NHSE to design clinical protocol for patient populations</li> <li>Potential to use “medium titre” units if evidence shows patient populations could benefit</li> </ul>

# Key messages



## Phase 1 progress and targets

- **Collected 15k units**, of which **3.5k are HT** and **issued 300+ units** across the trials
- Aim to collect a total of **55-65k units**, of which **15-18k are HT** by **end-Oct 2020**



## Phase 2 funding

- Use the **£80m approved by DHSC** for Phase 2 to start with Option 2 and work towards Option 3 (£40m for Option 2, £40m for Option 3) that is allocated until **end-Apr 2021**



## Phase 2 objectives

- **Scale up capacity** to collect up to **~7,500 units per week** (i.e. providing no donor supply constraints), to increase our ability to treat patients during a potential second wave



## Key requirements

- **Increase capacity** by securing **~100 apheresis machines**, opening **10 new plasma donor centres**, and **recruiting additional staff** in collection sites and across the supply chain



## Activities underway

- **Recruit collection staff** (incl. Nurses, DCs and DCMs)
- **Progress training plans** by recruiting Trainers and Training Managers, and setting up training rooms in Tooting and Barnsley
- Seek to **extend leases in London sites** (incl. potential for Stratford as a more permanent donor centre)

# Appendix

# Key assumptions for current Phase 1 forecast

Number of Slots Available	3000 / week
Average Fill Rate	80%
Yield (average units collected per donor)	1.93
% of available slots used for sample-first	20%
Assumed national roll out of sample-first complete	31 <sup>st</sup> Aug 2020
% Tested Males with High-Titre (HT)	38%
% Untested Males and Tested Females with High-Titre (HT)	14%
% of returning HT Donors who retain High-Titre (HT)	50%
% of available slots filled with returning HT donors	20-30%

# Key assumptions to define max capacity

