

## Recruitment

- The current number of participants recruited to 19<sup>th</sup> December stands at **56 – well done all!**
- Recruitment began on 10<sup>th</sup> June 2022 and we now have **12 sites open** to recruitment, and **2 sites** pending SIVs - A very warm welcome to all!
- We are nearing the end of our pilot phase of the study (**31st Jan 2023**). The NIHR stop-go criteria are shown on the next page. If your site is a large site, we are asking for **1 randomization a week** and for smaller sites, every **fortnight**. Sites hitting the milestone figures (60<sup>th</sup>, 75<sup>th</sup>, etc.) will receive tokens of our appreciation. Thank you in advance for your efforts!

## Site Map



## Recruitment per site per month

Site	Open	Jun-22	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Total
Edinburgh	10-Jun-22	2	5	1	3	5	4	3	23
Rotherham	20-Jun-22	1	0	1	1	0	0	1	4
Durham	30-Jun-22	-	3	2	2	2	2	1	12
Lanarkshire	05-Sep-22	-	-	-	1	5	2		8
Glasgow	21-Sep-22	-	-	-	-	0	0	1	1
Oxford	29-Sep-22	-	-	-	-	2	2		4
Borders	31-Oct-22	-	-	-	-	-	0		0
Newcastle	31-Oct-22	-	-	-	-	-	1	3	4
<b>Total</b>		<b>3</b>	<b>8</b>	<b>4</b>	<b>7</b>	<b>14</b>	<b>11</b>	<b>9</b>	<b>56</b>

**Green** – Open  
**Orange** – SIV completed  
**Blue** – SIV pending



**THANK YOU FOR YOUR CONTINUED SUPPORT!**



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**FAQs** - Screening FAQs. This issue will focus on issues sites have raised around the screening process:

**A patient / Next of Kin has declined participation in the study, how do I document this on the screening log?**

Please use Exclusion Criteria 2 "unable to consent" if the below apply:

- a) patient or NoK has declined
- b) unable to reach NoK if have tried to consent
- c) tried to consent, but patient be discharged / transferred prior to consent

If have not attempted to consent the patient, please document in the reason why in reason why patient not pre-consented column with the most appropriate response.

**A patient we are screening has had a blood transfusion clinically, are they still eligible to be included?**

Yes, if the Hb falls again while in the screening period the patient would still be eligible to participate despite having a blood transfusion clinically.

**A patient's Hb has reached the randomisation trigger (Hb <90) but they are not pre-consented to the trial, can I still approach for consent?**

Yes, please approach for consent. If obtained randomise if Hb remains 90 or below.

**During the screening process patient has become covid positive, are we still able to enrol?**

Yes, if acceptable with local policy in regards to sample processing. If enrolled and samples obtained please note on the sample logs which samples are from covid positive patients.

**\*NIHR Red/Amber/Green**

**trial progression criteria**

Sites Open/Recruiting

<5 red; 5 -10 amber; >10 green

Participants randomised

<75 red; 75 -130 amber; >130 green)

Protocol adherence

<70% red; 70-90% amber; >90% green)

Recruitment rate/site/month open

<2.2 red; 2.2 – 3.7 amber; >3.7 green



### **Reminders**

- Please enter your **screening logs** on to the database **weekly**.
- **Data queries** will be sent out to sites at the start of every month – please complete these as promptly as you can.
- If you have any **photos** that we can use in future newsletters, please do send them to us!
- We are registered for the **NIHR Associate PI Scheme** – if your site is interested in having an API, please contact us and we can advise on how to proceed.

### **Contact Information**

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**Trial Twitter:** <https://twitter.com/HipTrial>