

Welcome to the 11<sup>TH</sup> edition of our Newsletter!

As we step into the final month of our recruitment journey, we're looking to wrap things up with the same energy and enthusiasm that got us here!

### 55 Patients successfully enrolled

- 637 Patients screened in total
- 4 Sites actively recruiting





Last chance to be awarded our £50 Amazon gift voucher. The award will go to the site that will recruit the highest number of patients during the following period:

• 1st April - 30th June 2025

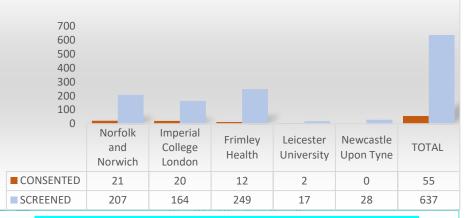
### Focus Group Participation – Reflections and Next Steps

Out of the 28 patients who provided written consent to participate in the Focus Groups, only 2 patients were able to attend .

While participation was lower than anticipated, we are grateful for the valuable insights shared by those who were able to join. To gather deeper insights, more feedback will now be collected through semi-structured informal interviews.

Further details on this process will follow shortly.

## PATIENTS SCREENED vs CONSENTED BY SITE 01/06/2025



#### **ENROLMENT BY MONTH**

#### 6 OCTOBER 2023 - 1 JUNE 2025



#### ON SITE MONITORING VISITS - COMPLETED

As our recruitment phase nears its close, we want to extend a heartfelt thank you to all participating sites for your ongoing support throughout the on-site monitoring visits. Your consistent cooperation plays a key role in keeping everything on track.

# As we move closer to database lock, please ensure the following actions are prioritized:

- Keep the focus on timely and accurate data entry
- Report all Protocol Deviations / Violations / All out of study window visits - in a timely manner
- Make sure all Adverse Events / Serious Adverse Events are being reported swiftly



#### PLANNED DATABASE LOCK 31 OCTOBER 2025

As we approach the planned database lock on 31st
October, our focus remains firmly on timely and
accurate data entry. Please ensure that all REDCap
forms are fully completed and up to date. This is
critical to ensuring a smooth and successful database
lock. If you have any questions or uncertainties,
please don't hesitate to get in touch — we're here to
support you every step of the way. Let's keep up the
momentum and finish strong!

#### QUALITATIVE DATA COLLECTION UPDATE

Following our Trial Management Group (TMG) meeting on 3rd June, we are planning an alternative approach to Focus Groups. Site teams will be encouraged to engage patients through brief, informal telephone conversations. As these interactions do not constitute formal research interviews, no additional ethics approval is required, making this a more feasible and timely method of gathering additional patient feedback.

To ensure consistency in data collection a draft set of guiding questions for use by all sites will be circulated shortly.

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