



CLEAR Newsletter

Welcome to the latest edition of the CLEAR Newsletter!



We're Tweeting...

Follow us on Twitter by visiting twitter.com/TrialCLEAR for important updates and news about the study!

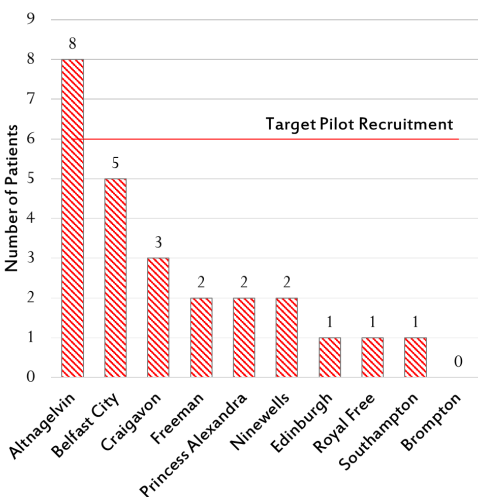


EDITION 4
DECEMBER 2018

We're delighted to say that all 10 pilot sites are open to recruitment and **25 patients** have been recruited to-date.

Congratulations to the following sites who have randomised their **first patient** since our last newsletter:

- ❄️ Craigavon Area Hospital
- ❄️ Royal Infirmary of Edinburgh
- ❄️ Royal Free Hospital
- ❄️ Freeman Hospital
- ❄️ Ninewells Hospital
- ❄️ Southampton General Hospital



A big **THANK-YOU** to all sites!

We really appreciate all of your hard work towards reaching 6 patients each by the end of January!

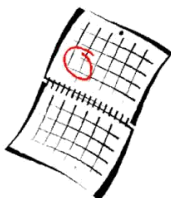


We'd like to say a massive congratulations to the staff of **Altnagelvin Area Hospital** for recruiting a phenomenal **8 patients** to the study by 8th November.

Drs Kelly & Grant, Kathryn, Edmund, Patrice & Amanda - you're all superstars!

Do you have a visit planned?

Please let us know the dates of your scheduled baseline visits so we can ensure that support is available to answer any urgent queries.



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GET IN TOUCH

Please get in touch with any comments, suggestions or queries you may have.

Email the NICTU at: CLEAR@nictu.hscni.net

Or give us a ring on: **02890 635 794**

and ask to speak to a member of the CLEAR Team.



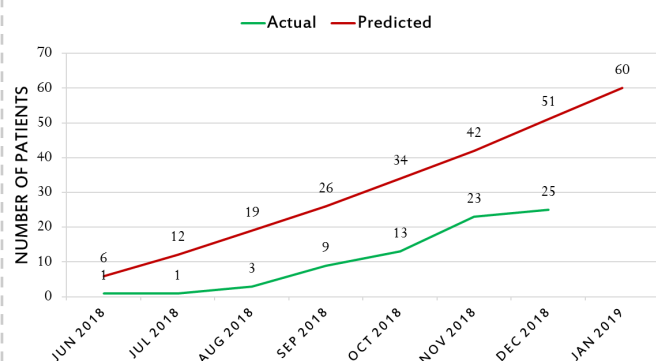


FAQ

PILOT STUDY TARGETS

The 8-month internal pilot study is due to finish at the end of January 2019. The pilot will be used to confirm recruitment rates, protocol compliance and data collection. Recruitment rate will be used to determine whether progression to full trial continues. If we achieve 25-49% recruitment, the study will progress to the main trial with a rescue plan developed by the TSC and agreed with the NIHR HTA secretariat. If we achieve above 50% recruitment, the study will progress to main trial following a review of screening logs and an assessment of any barriers to recruitment. With 25 patients enrolled we have achieved just over 40% of projected recruitment. With your help and support we hope that we can reach the funder target of 60 before the end of the pilot study!

CUMULATIVE RECRUITMENT:
PILOT STUDY
(June 2018-January 2019 Inclusive)



Q: Which spirometry results do I enter?

A: Always enter the spirometry measurements from the green box into the CRF. The green box is the best manoeuvre (the manoeuvre with the largest sum of FEV1 and FVC). If more than three measurements are taken before the data is saved, the best three measurements in the series are shown as follows:

- Best measurement = green
- Second best measurement = red
- Third best measurement = blue

Q: If a patient didn't contact the site at start of exacerbation, but contacts me in the middle/end of an exacerbation do I still complete the RSSQ 'end of exacerbation' version?

A: Yes, please complete the end of exacerbation telephone call. For data entry in MACRO please add a comment to the additional comments section under the first and second telephone calls stating that the patient did not report the exacerbation when it started.

Please keep an eye out in your mailbox for our CLEAR FAQs V3.0

Reminder

Our Data Manager, Una, would like to remind you to enter all screening data onto MACRO by the **first Monday of every month**.

Pilot study screening data is crucial as it allows us to identify any potential barriers to recruitment in the inclusion criteria.

If you have any queries about screening or the MACRO system in general, please contact us *via* the CLEAR mailbox and Una will be glad to help!



We'd like to welcome the following sites which will be participating in the main study, we're looking forward to working with you on CLEAR!

- ❄ Countess of Chester Hospital
- ❄ Queen Elizabeth Hospital, Birmingham
- ❄ John Radcliffe Hospital, Oxford
- ❄ Royal Gwent Hospital
- ❄ Royal Lancaster Infirmary

