

CLEAR

Site Newsletter



Study Update

It is now one year since the CLEAR study was given Sponsor Green Light Approval to begin recruitment.



During this time we have completed a successful 8-month pilot study in which 75% of target recruitment was achieved. This would not have been possible without all the hard work and dedication of our 10 pilot study sites so thank-you all!

The main study is now well underway and we'd like to take this opportunity to welcome all new staff who will be working on CLEAR:

12 Royal Lancaster Infirmary:

Dr Gatheral, Rebecca, Jean, Kerry and the team.

13 Countess of Chester Hospital:

Prof Scott, Lynda and the team.

14 Queen Elizabeth Hospital,

Birmingham: Dr Sullivan, Diane, Lulu, Gurpreet and the team.

15 Churchill Hospital, Oxford:

Dr Flight, Tom, Andrea, Mary and the team.

16 Royal Gwent Hospital:

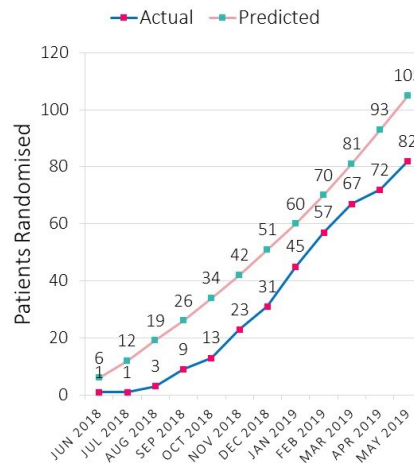
Dr Ionescu, Maxine, Simon, Evelyn and the team.

We appreciate all of your efforts towards getting your sites open to recruitment!

Recruitment

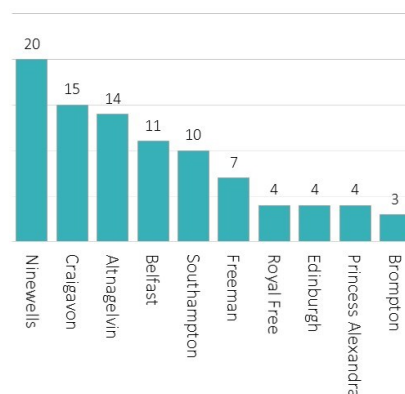
We are delighted to say that as of 18th June, 92 participants have been randomised on CLEAR. We're well on the way to 100!

CUMULATIVE RECRUITMENT
(June 2018-May 2019)



May was a fantastic month for recruitment, with 10 patients recruited across 8 sites. Keep up the good work everyone!

RECRUITMENT BY SITE



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Get in touch

Please get in touch with any comments, suggestions or queries that 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.



Adverse Event Reporting

CLEAR Tips

Do I report exacerbations as adverse events?

For participants enrolled on the study, you are not required to report exacerbations of bronchiectasis as adverse events (AEs), even if these result in hospitalisation. However, please record data on all exacerbations according to the Protocol.

Please note, if an exacerbation occurs between the points of consent and randomisation i.e. during a washout from a mucoactive drug, you should report this as an AE/SAE.

Can multiple symptoms be grouped into one AE?

If an AE consists of multiple associated symptoms e.g. vomiting and diarrhoea, please record these individually (i.e. as different terms) on separate AE forms.

Should I enter SAE data onto MACRO?

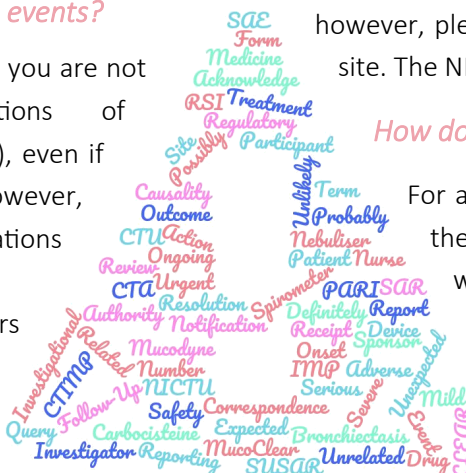
In the event of a SAE at your site, please submit the SAE form as instructed in the Trial Manual Guideline, however, please do not enter this data onto MACRO at site. The NICTU will do this on your behalf.

How do I assess expectedness?

For assessment of expectedness, please refer to the approved Reference Safety Information which can be found in Section 9.1 of your ISF:

- **Hypertonic Saline:** the 'side effects' section of the MucoClear 6% patient information leaflet
- **Carbocisteine:** the Mucodyne Summary of Product Characteristics (SmPC)

Please ensure that you follow-up all AEs until resolution, and respond to any queries on MACRO in a timely fashion. Our Data Manager, Una, will keep you on the right track!



Equipment Issue?

- Email PARI Support (paritrack-support@PARI.com) within 7 working days of becoming aware of an issue, even if you initially contact PARI/NICTU via telephone.
- Always cc the CLEAR mailbox (CLEAR@nictu.hscni.net).
- Add your site name & number, the device affected, and any relevant serial number(s) to the subject title of the email.
- Please quote PARI's internal CLEAR ID (10040) and include as many other details as possible.
- PARI Support will issue a ticket number. This is required for them to process your query and anything else required e.g. device returns.
- PARI will advise if the equipment needs to be returned.
- Device orders should be sent to the dedicated email address (paritrack-supply@PARI.com).

PLEASE LOOK OUT FOR VERSION 2 OF THE GUIDELINE WHICH WE WILL DISTRIBUTE TO YOU SHORTLY.



Thank you to all the pilot site staff who have joined our **MONTHLY TELECONS** and made them such a great success!

Summer telecon details:

JULY: Wednesday 3rd at 9 am & Friday 5th at 2 pm

Monthly Topic: 'Discussing the treatment plan for year 2'

AUGUST: Wednesday 7th at 9 am & Friday 9th at 2 pm

Monthly Topic: 'IMP Compliance'

SEPTEMBER: Wednesday 4th at 9 am & Friday 6th at 2 pm

Monthly Topic: 'mySpiroSense Data Review'

Please look out for agenda and dial-in details in the week preceding the meeting!

Are you a main study site?

We will be offering Refresher Training with Judy and Kathryn prior to your first study visit, and individual calls thereafter until your site is established.

