CLEAR

Site Newsletter

We're delighted to say that 14 sites are open to recruitment and 134 patients have been recruited to-date.

Congratulations to the following sites who have completed their first patient, first visit since our last newsletter:

well DONE

QUEEN ELIZABETH HOSPITAL BIRMINGHAM

ROYAL GWENT HOSPITAL

SUBSTANTIAL AMENDMENT 12

CLEAR Substantial Amendment 12 was implemented on 07/01/2020.

This amendment included updates to the following documents, current version numbers/dates are listed:

- PROTOCOL V4.0 (29/07/2019)
- PATIENT INFORMATION SHEET V4.0 (07/08/2019)
- INFORMED CONSENT FORM V4.0 (07/08/2019)
- GP LETTER V3.0 (05/08/2019)

The updated participant information should be used for any future patients enrolled at your site.

You should have received SWAT recruitment packs containing these documents. Please discard any previous packs.

We have also created a separate DATA TRANSPARENCY STATEMENT (V1.0, 05/08/2019) in compliance with GDPR. This should be provided to patients previously enrolled on the trial at their next study visit. If this will not be for some time, or if the patient has withdrawn from the study, the statement may be posted to the patient. A COVER LETTER (V1.0, 05/08/2019) has been created for this purpose.

As a result of the amendment we have made some updates to the MACRO clinical trial database. Please see our email correspondence for details on the actions that may be required as a result.

Our new Data Manager, Andrew Jackson (below), will be in touch if required.

Please contact Andrew with any of your MACRO-related queries at: AndrewX.Jackson@nictu.hscni.net.

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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:

028 961 51447

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

SITE TELECONFERENCES

Monthly site teleconferences are continuing throughout 2020, please check your email for the updated schedule.

During these calls we discuss study updates, screening & recruitment, and answer any of your queries.

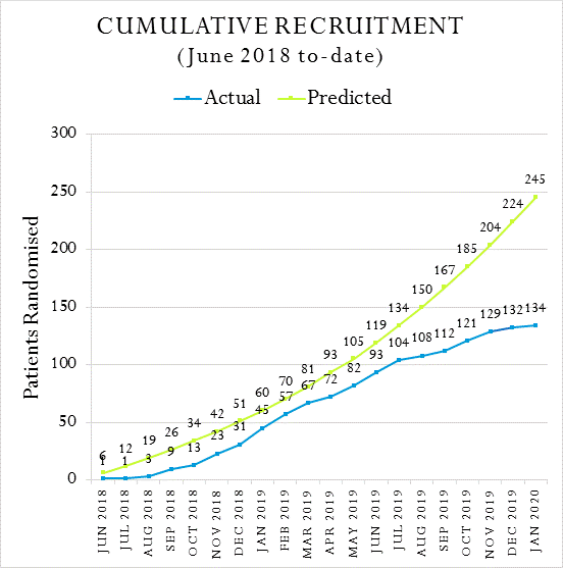
We also offer TRAINING MOMENTS such as: 'capturing optimal exacerbation data', 'RSSQ administration', 'airway clearance', 'spirometry'; 'the year 2 treatment plan', 'safety reporting' etc.

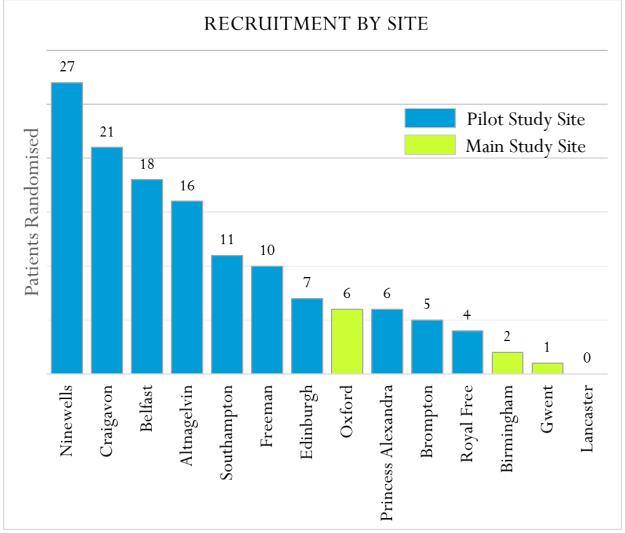
Please get in touch via the CLEAR mailbox (CLEAR@nictu.hscni.net) with any ideas for future calls. If you are new to the study, please also let us know if you'd find it useful for a previous session (see above) to be repeated.

RECRUITMENT UPDATE

We'd like to say a big THANK-YOU to all sites for your ongoing contributions to the study.

Unfortunately, in recent months we have seen a drop in recruitment against our targets. We encourage you to take the opportunity to meet with your PI to discuss your local recruitment strategy for CLEAR, and how you can meet the target of 1-2 patients/month.





MUCOACTIVE WASHOUT: *Quick Facts*

- If required, patients may undergo a 30-day mucoactive washout period if agreed by the patient, the clinical team, and the local PI.
- The patient must sign the informed consent form prior to commencing washout.
- Consent should be re-confirmed verbally and eligibility confirmed prior to randomisation .
- It is essential that patients who agree to a washout understand that there is a 1:4 chance of being randomised to standard care .
- During the washout period, exacerbations should be reported as AEs/SAEs as required.
- There is no maximum time between informed consent and the baseline assessment, but this should be *as close to 30 days as possible.*
- As of 10/2019, 30 patients had completed washout. Of these, only two experienced an exacerbation. We believe that washout is unlikely to affect a patient's clinical status in the short-term (although this needs to be considered by your PI on a case-by-case basis).

PROTOCOL PUBLICATION

We are happy to report that the CLEAR study protocol has been published in *Trials:* *https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-019-3766-9*

We'd like to take this opportunity to thank all of those who contributed to the design of the study and development and review of the manuscript.