Volume 5, Issue 2

PEXIVAS

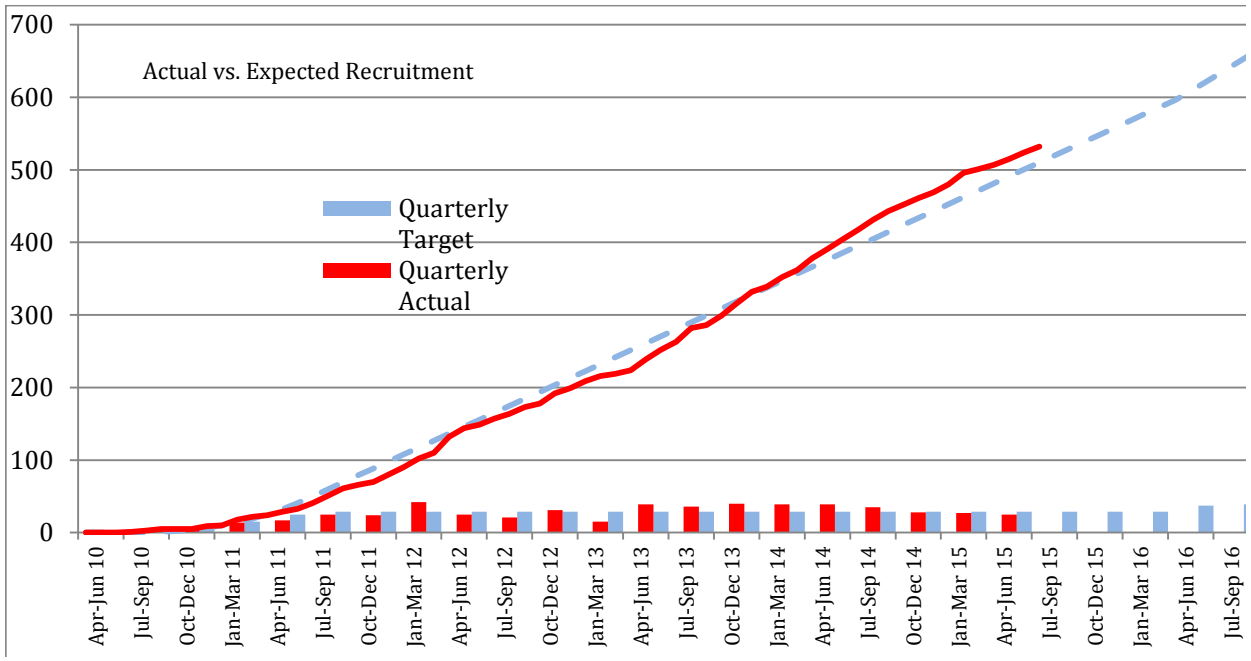
Recruitment Update

- 602 patients have now been enrolled as at 15th December 2015
- Welcome to our new centres:
  Centre Hospitalier de Mulhouse, France
  Leicester General Hospital, UK
  Jagellionian University Medical College, Poland
  Hopital de Bicetre, France
  Hopitaux Universitaires de Strasbourg, France
- The UK has 1 site in set up (Dorset County Hospital) and France are setting up further sites
- We are aiming to complete enrollment during 2016 and trial follow-up one year later with results in early 2018

Thank you all for your continued effort and support!

Christmas 2015 edition

Contents:



Minor Amendment 11 Summary

Protocol V3.1

We have updated contact details in the protocol; made the title consistent across documents; made the inclusion/exclusion criteria consistent in both the synopsis and main section and the study schedule footer now reflects the consent form and states sites may opt out of specimen collection.

Patient information and consent forms V3.1

Correction to study title, amendment to recruitment figures clarifying that we are now recruiting 700 participants. (UK only documents have also removed the non-EU data item).

SF-36 Version 2.0

Please ensure you are using the current SF-36 Version 2.0 Form. Translated versions can also be obtained by emailing: pexivas-trial@contacts.bham.ac.uk

Serious Adverse Event (SAE) Reporting

SAEs **MUST** be reported as soon as possible and within 24 hours of the investigator learning of their occurrence. **SUSARs** (suspected unexpected serious adverse reactions) are SAEs that are suspected to be due to oral glucocorticoids or plasma exchange that are not described in the protocol or drug packaging. SUSARs **MUST** be reported within **24 hours** of learning of their occurrence. If you are unsure if an adverse event is a SAE or a SUSAR, please contact David Jayne, Michael Walsh or Peter Merkel to discuss before reporting the event.

FAX or scan/e-mail the completed SAE form to +44 1223 586767 or **add-tr.pexivastrial@nhs.net**

US centers: please also report SAEs to the Vasculitis Research Consortium office: Peter Merkel (pmerkel@upenn.edu) and Carol McAlear (cmcalear@upenn.edu); Tel No: +1 781 321 4567.

Australian/New Zealand centers: please also report SAEs to the Australasian Kidney Trials Network: Donna Reidlinger/Peta-Anne Paul Brent (pexivas@uq.edu.au) Tel No: +61 73176 5817.

Canadian centers: please also report SUSARs to Dr. Michael Walsh (lastwalsh1975@gmail.com) and Andrea Mazzetti (amazzett@stjoes.on.ca) Fax No: +1 905 521 6153

Please note that it is a Sponsor expectation that SAE will be reported to the coordinating team in Cambridge within 24 hours of the Investigator becoming aware of the event.

CRFs' top tips from our data management centre in Birmingham (BCTU)!

Please download and use the new version 2.1 of the SAE Form!

Reminder from the PEXIVAS team that any approved staff member can use the PEXIVAS online system to input the patients' data after an assessment using their unique username and password which they were given when they were approved to work on the PEXIVAS study.

Assessments can be entered at https://www.trials.bham.ac.uk/PEXIVAS/Login.aspx

All forms except SAE forms can be entered online (including Infection and ESRD forms etc.). The event forms are listed after the 60 Month assessment forms, so please use the scroll buttons to navigate through all available forms.

If you are unsure of your username or password you can get a reminder/change your password at: https://www.trials.bham.ac.uk/Password/

Quick reminder that ESRD is defined as 12 weeks on dialysis or renal transplant.

Any Queries please contact the BCTU-pexivas-trial team on: pexivas-trial@contacts.bham.ac.uk

PEXIVAS Samples

Please be reminded to store your samples at -80°C. Current Blood Biomarker SOP Version 6 available from Elizabeth Broadhurst (add-tr.pexivastrial@nhs.net).

The PEXIVAS team would like to thank you for all your help and support with the PEXIVAS study throughout 2015.

Birmingham Clinical Trials Unit, data management, will be closed from 16:00 22-Dec-2015 (Tuesday) to 09:00 04-Jan-2016 (Monday). The telephone randomisation line will be closed at 13:00 on the 22-Dec-2015 but the online randomisation will continue.

Please continue to report any SAEs/SUSARs to **add-tr.pexivastrial.nhs.net**

Merry Christmas and a Happy New Year!