Welcome to…

The BHF SENIOR-RITA Trial Newsletter

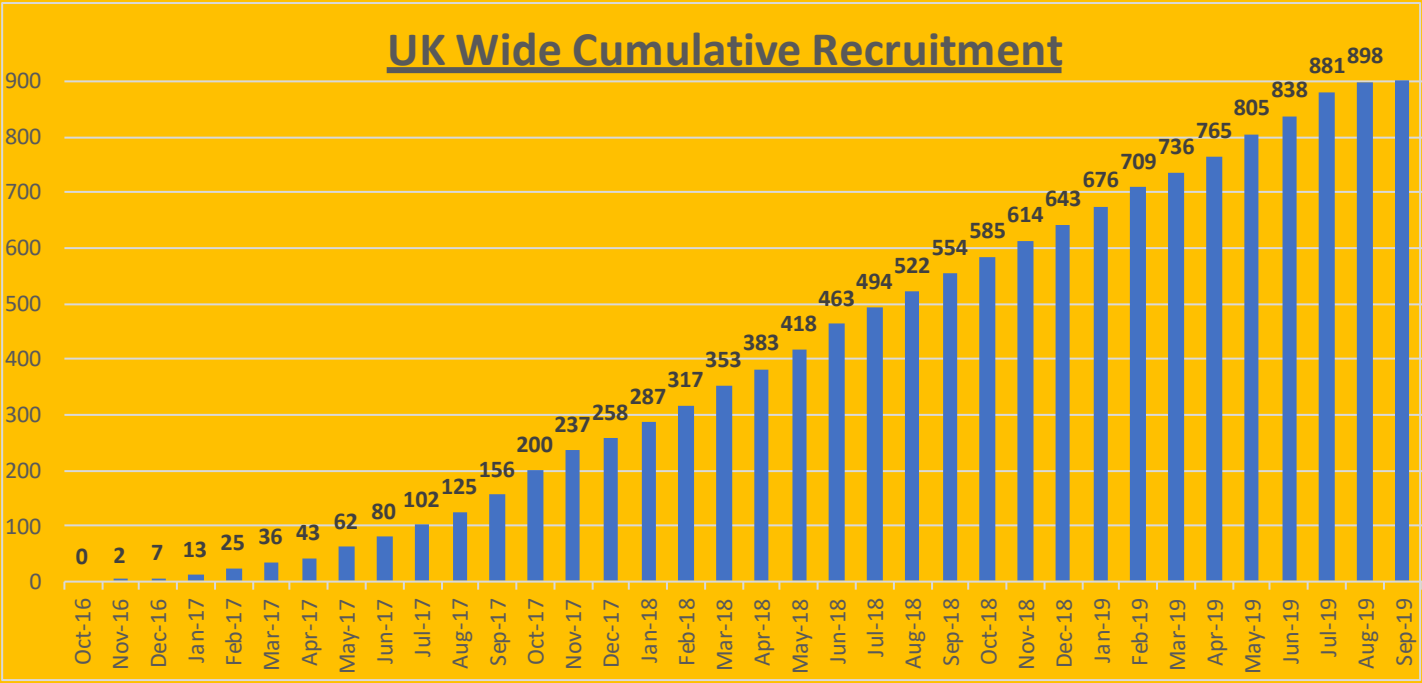
Issue 13: September 2019

TOTAL RECRUITMENT: 901 PARTICIPANTS

Thank you to everyone for your commitment and dedication

Congratulations to **Dr John Irving & team at Dundee** for randomising our **900th participant**!

Special thanks to the teams at **North Tees and Northumbria** who have recruited **over 75 participants each**.



Our goal for 2019: 1000 participants!!!

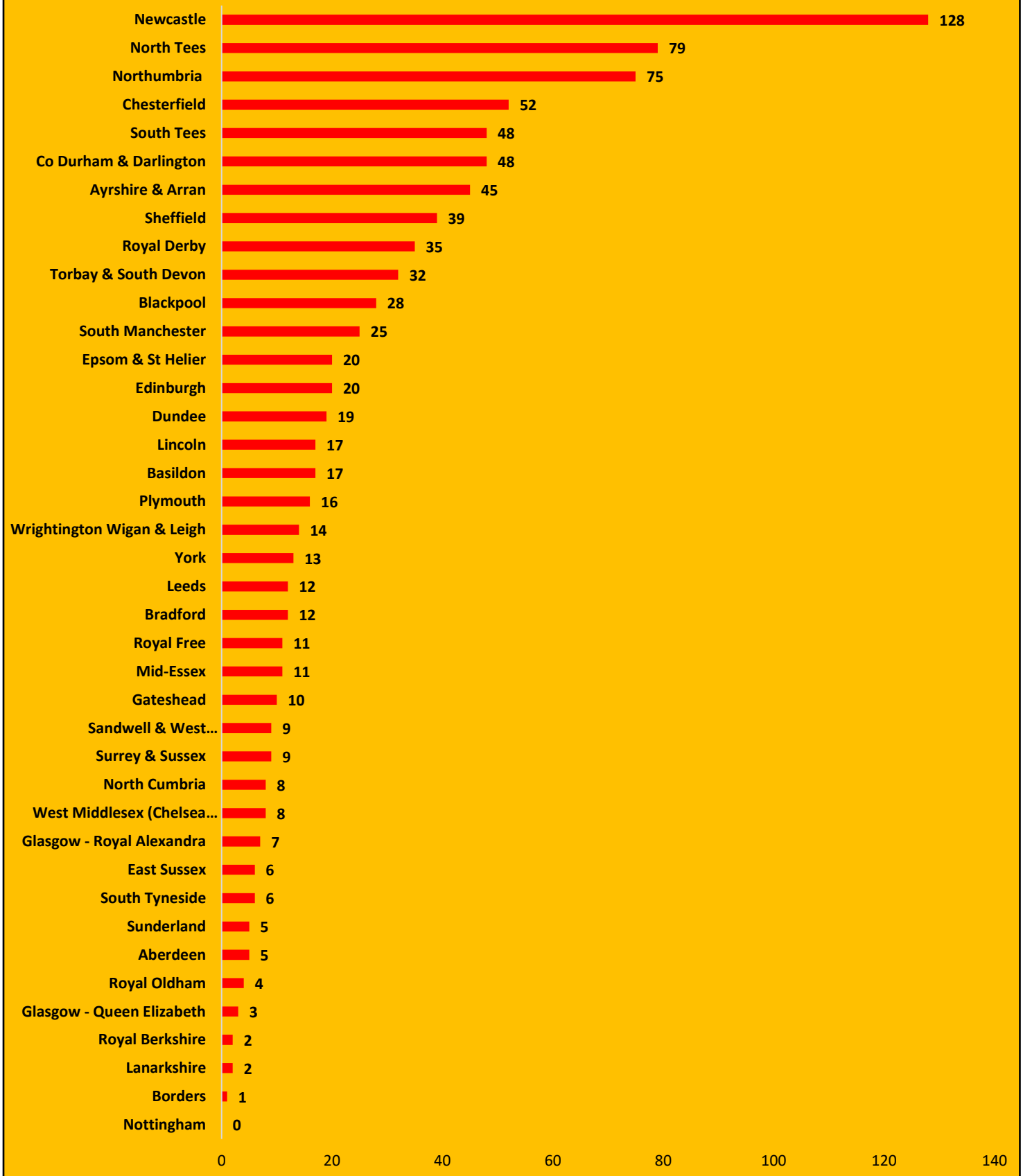
100 more to go….

Top Tips for recruitment…

- **Approach patients at the time of diagnosis BEFORE a clinical decision is made**
- **Have all teams including junior doctors on board (Cardiology, MAU, A&E)**
- **Receiving a report from the lab of all raised troponins each morning so potential participants can be identified and screened**
- **Use lay summary documents and explain that both treatment strategies are standard of care**

Thank you…..

Total number of participants recruited by site



Many thanks for all your hard work and please keep up the great work!

RANDOMISATION DOCUMENTS

Sites should send copies of the completed Consent form, Eligibility Criteria checklist and Participant Contact details form (plus Carer, if applicable) **within one week of randomisation** to the Newcastle Clinical Trials Unit (NCTU) using one of the following methods of transmission:

- via the following SOHO66 fax number - **0191 580 0987**
- Alternatively, you may transmit the information from an **nhs.net email** address to another **nhs.net email**. For SENIOR-RITA, the following **nhs.net email** account must be used – nctu.seniorrita.conf@nhs.net
- **Please do not send Personal Identifiable Data (PID) to Newcastle University email addresses**
- Where site staff do not have access to an ***nhs.net email*** address and the site does not have a ***fax*** facility for transmission of **PID**, you may transmit the information via a standard ***nhs.uk/ac.uk email*** address provided that the information is **encrypted and password protected** prior to transmission. Sites should contact their local IT department for advice on the encryption method to use.

Please note: PID should never be transmitted to NCTU when reporting SAEs. Please continue to report SAEs as previously via fax 0191 5800866 or email as a password encrypted file to soho66seniorrita@newcastle.ac.uk

DELEGATION LOG

Following any additions or removal of personnel on your site delegation log, the NCTU must be sent a copy of this updated delegation log as soon as the PI signs off the log. For new staff, we will also require a copy of their current signed and dated CV, GCP certificate, plus study specific training log (Nurse Consent Training log too, if applicable).

MACRO DATABASE AND DATA ENTRY

Please ensure that all data is entered onto the SENIOR-RITA Screening database and main MACRO database in a timely manner.
All missing data and responses to Data Clarification Requests (DCRs) **must** be completed within 1 month of DCR or request from NCTU.

- **Death Form eCRF** – please ask the PI to review the notes and then record the primary cause of death on the MACRO Death Form eCRF. The relevant Clinical Endpoint eCRF must also be completed to reflect the death.
- **Study Withdrawal** – please ensure the question asking 'has the patient withdrawn from follow-up' is completed and if yes, select the option to show what they have specifically withdrawn from. We appreciate that participants may wish to withdraw from this trial; **however we would appreciate your assistance in explaining the value of allowing routine data to be used after withdrawal.**
- Please enter the **BM taken on admission** into the baseline laboratory assessment eCRF page for the glucose result.
- **Follow-up Visits –** Please ensure that follow-up visits take place in a timely manner.

ELIGIBILITY CRITERIA CHECKLIST

The Eligibility Criteria checklist must be signed by the PI or appropriately delegated clinician included on the site delegation log. Research Nurses are not permitted to sign off this document.

SERIOUS ADVERSE EVENTS

Due to the nature of the study population (high-risk older patients with multiple co-morbidities) only serious adverse events which are causally related (i.e. possible, probable or definitely related) to the study intervention (coronary angiography and/or PCI) occurring within 7 days of the procedure will be reported in **patients randomised to the invasive arm only**. We really need to understand and capture the procedure related events, therefore if need be, please chase up with centres where the actual procedure was carried out.
Events occurring in participants randomised to the optimal medical therapy will not be reported as SAEs but will be recorded as an outcome measure in the eCRF.
Unexpected events related to the procedure should be reported on an SAE form whenever they occur.

DEATH AND MI ADJUDICATIONS

Our SENIOR-RITA Trial **Clinical Events Committee (CEC)** are working hard to review and adjudicate the primary endpoints (**death, myocardial infarction**). As detailed in Section 12 of the SENIOR-RITA Protocol, the CEC need to adjudicate important clinical events including those listed as primary outcome measures.

- To enable them to adjudicate all deaths, **we will be requesting additional source data such as admission notes, progress/consult notes, discharge/death summary and death certificates**.
- If a participant dies outside of the hospital environment, please try to obtain some source data regarding the death from the GP practice if available, in addition to obtaining a death certificate for the participant. This will assist the adjudicators with understanding the patient's condition leading up to the time of death.
- We are also starting to request additional source data to enable the CEC to adjudicate all non-fatal myocardial infarction (MI) too. The source data for these events includes **documentation of chest pain/ischemic symptoms, baseline and peak troponin values, lab reports, ECGs, drug charts, discharge summary and any procedure reports.**

Please remember to keep checking The SENIOR-RITA website
https://research.ncl.ac.uk/seniorrita/
Also, don't forget to follow us on Twitter @SNR_RITA_Trial
Be sure to check our weekly update emails on Monday mornings

The BHF SENIOR-RITA Trial Team, Newcastle Clinical Trials Unit,
1-4 Claremont Terrace, Newcastle upon Tyne NE2 4AE
E-mail: seniorrita.support@newcastle.ac.uk
Database queries e-mail nctu.database.support@newcastle.ac.uk