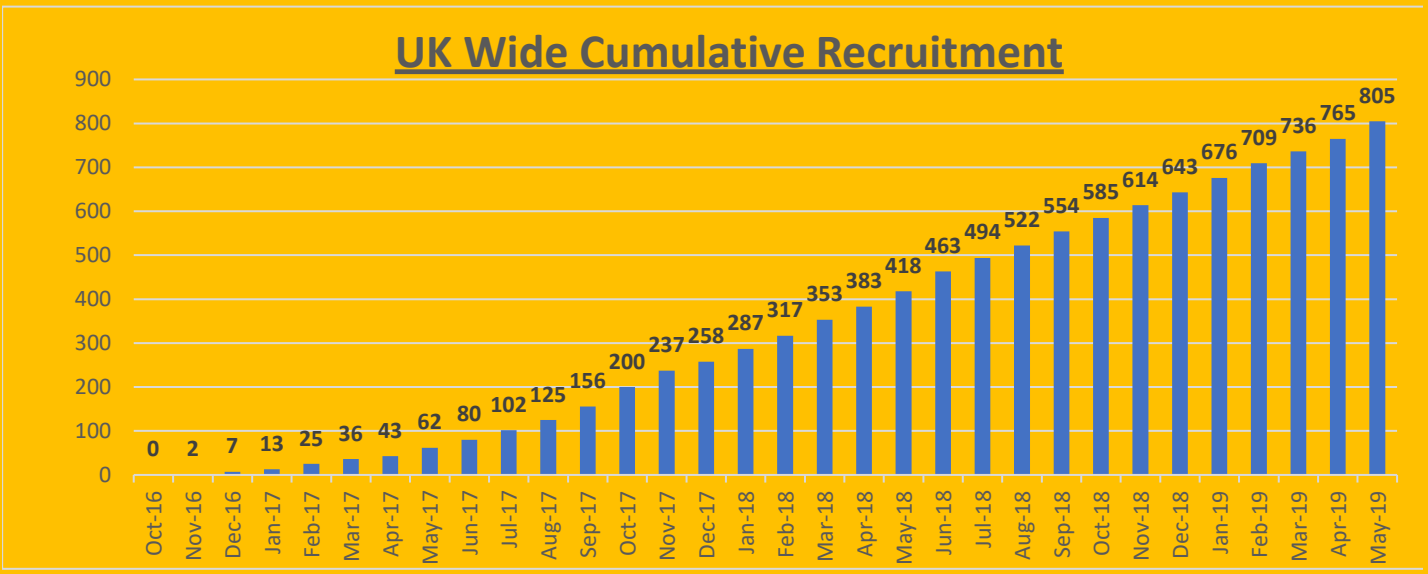
Welcome to…

The BHF SENIOR-RITA Trial Newsletter

Issue 12: May 2019

TOTAL RECRUITMENT: 805 PARTICIPANTS

Thank you to everyone for your commitment and dedication



- **We are pleased that the British Heart Foundation (BHF) have supported our request to extend the recruitment period for the study by another two years.**
- **Recruitment will now continue <u>until September 2021</u> to reach a target of approximately <u>1668 patients.</u>**
- **This can be achieved with your valuable and much appreciated ongoing support in continuing to recruit patients into SENIOR-RITA.**

Highlights…..

SENIOR-RITA is a challenging trial to recruit to but we are all so grateful for your fantastic efforts so far!

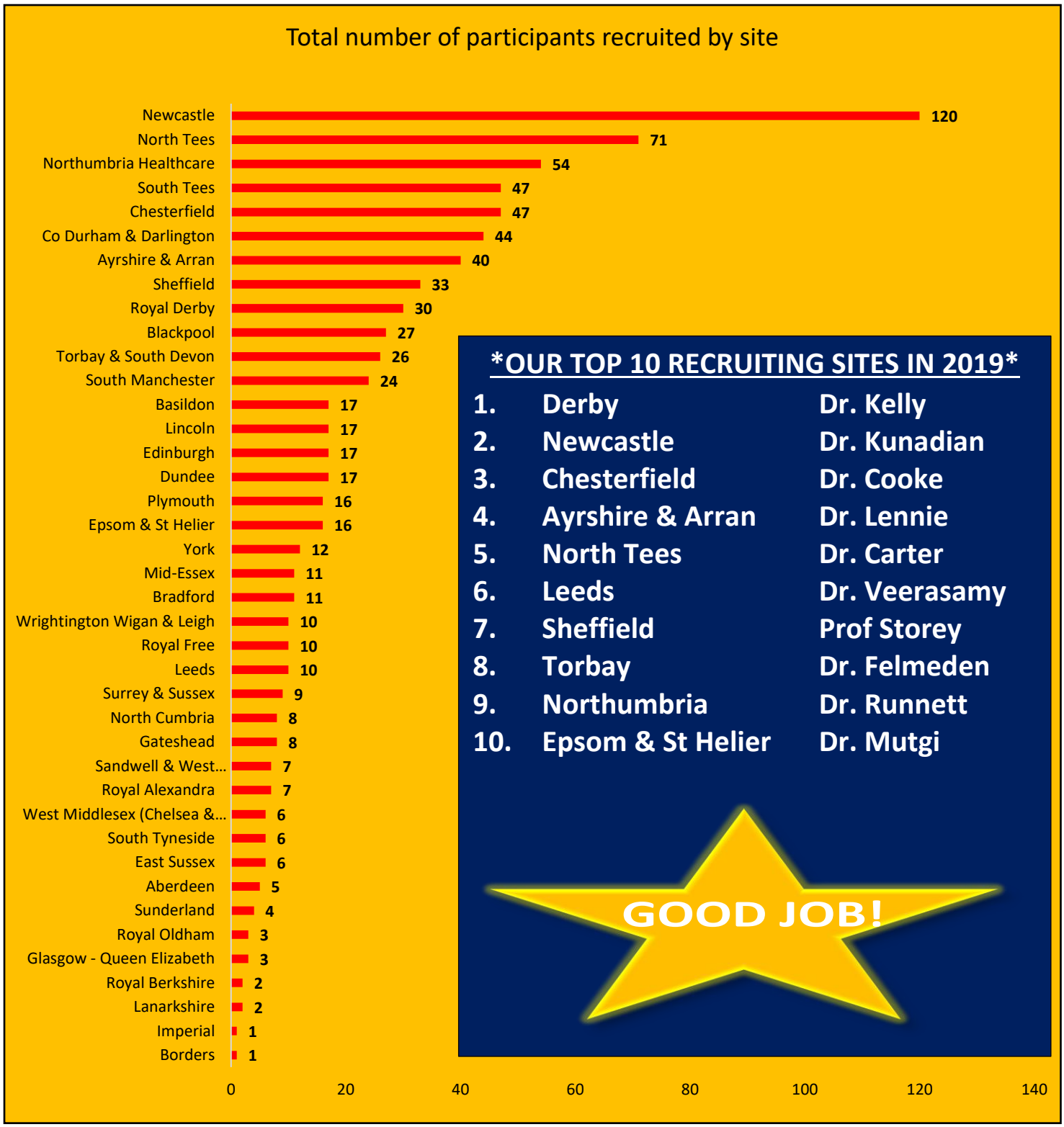
- Our oldest patient is <u>103 years old</u>
- We are recruiting exactly the sort of patients we need for SENIOR-RITA:
  - Median age <u>83 years</u> with 72% of patients ≥80 years of age
  - Women 47%
  - Frail by Rockwood scale in 28%
  - Median MOCA score 24
  - Median Charlson Index 5

Keep going….

Top Tips for recruitment…..

- Approach patients *before a clinical decision* is made
- Make it clear to patients and family that we do not know what the best treatment is
- Both treatments are standard of care
- Randomise patients as soon as consent is obtained
- Make sure everyone at your site is aware that you are recruiting to SENIOR-RITA
- Keeping the momentum is key for ongoing success with recruitment

Thank you…..



Our goal for 2019: 1000 participants!!!

SCREENING

Each person **eligible** for SENIOR-RITA, whether or not recruited, must be recorded on the **MACRO Screening log: BHFSRita_Screen.** Screening numbers are manually allocated and consist of six numbers in the following format: the first two digits are your site number and the next four digits follow sequentially starting with 0001. We ask that the screening database be updated as soon as possible after each screening takes place.

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 controlled** 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

MACRO DATABASE AND DATA ENTRY

Please ensure all data is entered onto the SENIOR-RITA MACRO database in a timely manner.
The one-year follow-up visit is the primary outcome for the study and **it is vitally important that this data is input as a matter of priority.**
All missing data and responses to Data Clarification Requests (DCRs) **must** be completed within 1 month of DCR or request from NCTU.

- For any questions where the data is not available, right click the mouse and select 'change status' then 'not available'. This will prevent this question from being flagged as missing.
- In order to close a DCR after you have resolved the query simply right click on the DCR you have responded to and select 'respond to DCR' – you will then be able to place a comment on the DCR and clarify how the DCR has been addressed in the dialog box. Select OK and close the DCR browser before saving the subjects visit page. After the data has either been changed, verified or marked as 'not available' the red flag will change to blue. A member of the NCTU team will then be able to check all blue responded to DCRs and close them. Unless they are showing as blue flags, we will not know that you have responded.
- **Death Form eCRF** – please ensure the primary cause of death is provided and all subsequent data entered. 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.**

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**.

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 some of you are already aware, we are requesting additional source data from you in relation to all deaths reported at your site. As detailed in Section 12 of the SENIOR-RITA Protocol, the Clinical Events Committee (CEC) need to adjudicate important clinical events including those listed as primary outcome measures.

- To enable them to adjudicate all deaths, **we require additional source data such as admission notes, progress/consult notes, discharge/death summary and death certificates**.
- 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.**
- All references to PID or the SENIOR-RITA recruitment arm must be fully redacted before being sent to us, so to assist with the process we will be sending all sites permanent marker pens and correction fluid solely to be used for this purpose.

Warm welcome to team Nottingham our new site!

Welcome…

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

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E-mail: seniorrita.support@newcastle.ac.uk

Database queries e-mail nctu.database.support@newcastle.ac.uk

Special thanks to SENIOR-RITA teams at

Ayrshire & Arran, Blackpool, Chesterfield, Durham & Darlington, Royal Derby, Sheffield, South Tees, and Torbay & South Devon who have all recruited over *25 patients* so far

Northumbria and North Tees who have recruited over **50 patients to date**

Newcastle who have recruited over ***100 patients***

Chesterfield who recruited the *800th participant*

Leeds who have recruited *10 patients* in a short period

Top 3 recruiting teams in 2019

1st place Royal Derby

Derby Teaching Hospitals NHS Foundation Trust

Dr. Kelly & Research Team

Top recruiting team in 2019!

2nd place Newcastle

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Drs. Haq and Bailey, Research Nurses Jenn and Pamela pictured

Overall top recruiting team in UK!

3rd place Chesterfield

NHS Chesterfield Royal Hospital NHS Foundation Trust

Dr. Cooke, Research Nurses Amanda, Rachel and Heather pictured

Recruited 800th Participant Many congratulations!