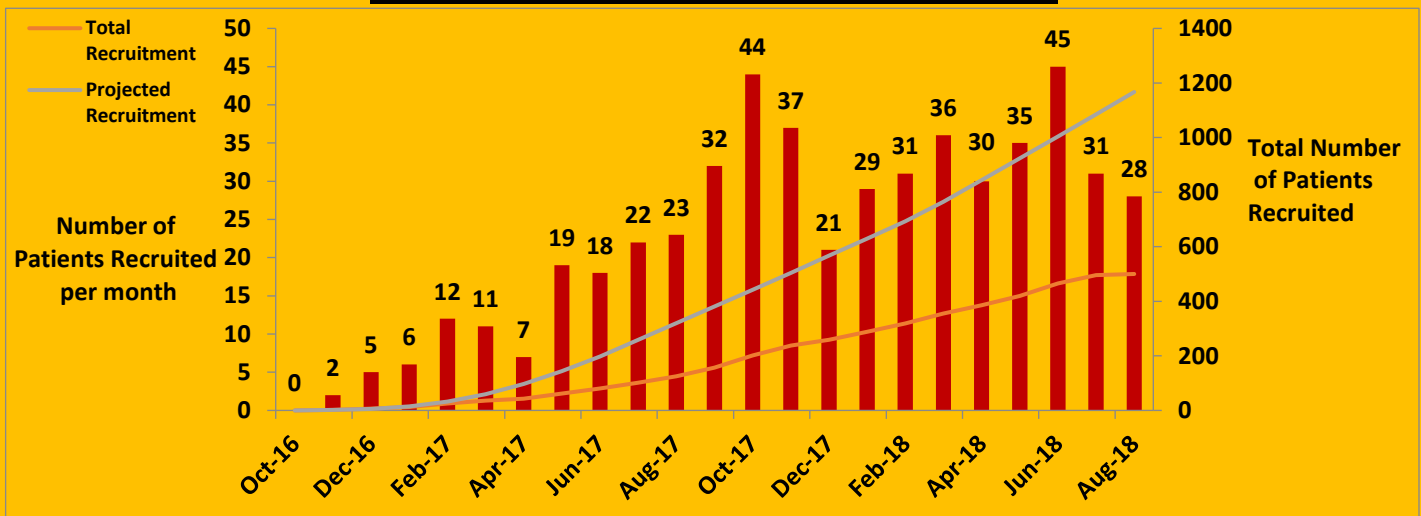


## TOTAL RECRUITMENT: 524 PARTICIPANTS

- ♥ Thank you to everyone for your commitment and dedication to SENIOR-RITA
- ♥ We have recently passed the 500<sup>th</sup> participant milestone however we are still a long way from reaching our target which is 2300 participants
- ♥ Now that we have opened our 40 sites, it is crucial that all our sites are active and recruiting
- ♥ Our weekly target is **16-20 patients** and with 40 sites recruiting this is achievable with all your ongoing enthusiasm and support!

### UK wide BHF SENIOR-RITA recruitment



- ♥ **We ask that you continue to keep up the enthusiasm and continue with the recruitment- EVERY PATIENT COUNTS! Here are the reasons why:**
  - ✚ Lack of data on the best care of older patients with NSTEMI persists as we are now continuing to see an ever-increasing older patient.
  - ✚ We in the UK have done so far so well compared to any other previous studies; let's keep up the great work!
  - ✚ Did you know from across all our sites we actually have come in contact with and screened **2362 eligible patients** (total sample size needed for SENIOR-RITA) during the life of SENIOR RITA so far - *so patients are out there!*
  - ✚ When we look at the screening log data, for eligible patients screened and not randomised, there is almost a **50:50 split** of those receiving invasive: conservative treatment. Patients not randomised due to **CLINICIAN DECISION**, the treatment strategy was **60%:34% (invasive: conservative)** compared to **31%:51% (invasive: conservative)** where **PATIENT DECISION** was the barrier to recruitment.

*\*This is the exact reason why we are doing SENIOR-RITA and it would be great to have these screened patients randomised to gather valuable data to inform care\**

#### BEST PRACTICE IN RECRUITMENT

- ✚ Let your entire team (Junior doctors, MAU, Wards, CCU, COE team) know about SENIOR-RITA
- ✚ Use the posters and stickers to publicise the study at your site
- ✚ Use the recruitment video and share with your patients and colleagues
- ✚ Make contact with patients early before a decision is made
- ✚ Regular reminders, education sessions, prominent presence of SENIOR-RITA research staff on the wards

## THE BHF SENIOR-RITA TRIAL SITE LEVEL RECRUITMENT UPDATE AS AT 31 AUGUST 2018

Site	Principal Investigator	Opened to recruitment	Monthly Site target	Recruited to Date
Aberdeen	Dr Awsan Noman	04-Dec-17	3	5
Ayrshire & Arran	Dr Vera Lennie	22-Mar-17	2	23
Borders	Dr Paul Neary	02-Jun-17	2	1
Dundee	Dr John Irving	13-Nov-17	3	9
Edinburgh	Prof Dave Newby	01-Dec-16	4	13
Fife	Dr Mark Francis	01-Dec-17	1	0
Glasgow - Royal Alexandra	Dr Keith Robertson	28-Feb-17	2	5
Lanarkshire - Hairmyres	Dr Ross McGeoch	30-Mar-17	1	2
Basildon	Dr Rajesh Aggarwal	02-Dec-16	1	9
Birmingham	Dr Kaeng Lee	22-Nov-17	3	0
Blackpool	Dr Gavin Galasko	15-Nov-16	2	20
Bradford	Dr Steven Lindsay	19-Jun-18	2	2
Chesterfield	Dr Justin Cooke	30-Nov-16	2	25
Co Durham & Darlington	Prof Jerry Murphy	23-Jun-17	2	30
Derby	Dr Damian Kelly	22-Sep-17	2	12
East Sussex	Dr Robert Gerber	21-Feb-17	1	6
Epsom & St Helier	Dr Sanjay Mutgi	04-Aug-17	5	5
Gateshead	Dr Ray Meleady	09-Dec-16	4	5
Imperial	Dr Rasha Al-Lamee	22-Aug-17	1	3
Lincoln	Dr Kelvin Lee	27-Jan-17	1	10
Mid-Essex	Dr Gerald Clesham	30-May-17	1	8
Newcastle	Dr Vijay Kunadian	31-Oct-16	8	86
North Cumbria	Dr Louise Buchanan	31-Jul-17	2	8
North Tees	Dr Justin Carter	23-Feb-17	2	50
Northumbria Healthcare	Dr Craig Runnett	27-Mar-17	2	41
Plymouth	Dr David Sarkar	15-May-17	1	12
Royal Berkshire	Dr Charlie McKenna	03-Jul-17	3	2
Royal Free	Dr Roby Rakhit	03-Jul-17	1	6
Royal Oldham	Dr Jolanta Sobolewska	13-Mar-18	3	0
Sandwell & West Birmingham	Dr Vinoda Sharma	09-Jul-18	4	2
Sheffield	Prof Rob Storey	25-Jan-17	4	22
South Manchester	Dr Hussain Contractor	15-Mar-17	2	19
South Tees	Dr David Austin	02-Dec-16	1	39
South Tyneside	Dr Abdul Nasser	16-Dec-16	0.5	6
Sunderland	Dr Shahid Junejo	15-Mar-18	2	1
Surrey & Sussex	Dr Shrilla Banerjee	02-Jun-17	0.33	9
Torbay & South Devon	Dr Dirk Felmeden	12-Jun-17	2	13
West Middlesex	Dr Sukhjinder Nijjer	26-Apr-18	1	5
Wrightington Wigan & Leigh	Dr Ayyaz Sultan	21-May-18	2	1
York	Dr Chris Gale	31-Aug-17	1	9
<b>TOTAL</b>				<b>524</b>

***To assist newly opened sites and as a refresher to all other sites, please find below information to assist you in conducting this trial***

### **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 SYSTEM – Password resets**

Site staff with access to the NCTU Randomisation Service are able to reset their passwords themselves. On the Log In page there is a 'Forgotten your password?' link that will request the users email address and then ask them to click **RESET PASSWORD**. A reset link will be sent to the users email account where they are requested to enter their email address and a new password. Please note the user is required to change their password within 15 minutes of receiving the email.

### **PERSONAL IDENTIFIABLE DATA (PID)**

- Sites should send **PID** i.e. completed Consent forms, Eligibility Criteria checklists and Participant Contact details forms (plus Carer, if applicable) **within one week of randomisation** to the SENIOR-RITA trial to the NCTU via the following SOHO66 fax number - **0191 580 0987**.
- Alternatively, they 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](mailto:nctu.seniorrita.conf@nhs.net) Please do not send 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**, they 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](mailto:soho66seniorrita@newcastle.ac.uk)**

### **ELIGIBILITY**

The role of confirming the eligibility criteria for participants must only be assigned to the PI, a sub-investigator or another medically qualified person on the delegation log. The Eligibility Criteria Checklists must only be signed off by these delegated persons and not by the Research Nurses.

### **MACRO DATABASE AND DATA ENTRY**

Please ensure all data is entered onto the SENIOR-RITA 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.

- ♥ 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.

## **MACRO DATABASE AND DATA ENTRY (cont'd)**

- ♥ 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 will then be able to check all blue responded to DCR's and close them. Unless they are showing as blue flags, we are not aware that you have responded.
- ♥ Death Form eCRF – please ensure the primary cause of death is provided and all subsequent data entered.
- ♥ 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. Please do not use the Study Withdrawal eCRF to record that a participant has passed away.

## **SITE STAFF**

- ♥ All new site staff must undertake study specific training and this must be recorded on the study specific training log. A copy of this training log together with a current signed and dated CV, GCP certificate, and updated and authorised delegation log must be forwarded to the SENIOR-RITA support team.
- ♥ Every time your site delegation log is updated, please ensure we are forwarded a copy.
- ♥ Once you renew your GCP training, please forward us a copy of your new GCP certificate together with a signed and dated CV reflecting your updated Research training.

## **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 (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 a SAE but will be recorded as an **outcome measure** in the eCRF.

SAE forms should be faxed to 0191 5800866 or emailed to [soho66seniorrita@newcastle.ac.uk](mailto:soho66seniorrita@newcastle.ac.uk)

## **EQ-5D-5L QUESTIONNAIRES – 30 DAY AND 3 MONTH**

The 30 day and 3 month questionnaires are sent to the participants by the SENIOR-RITA support team, NCTU. The data from these returned forms is entered by the NCTU on to MACRO.

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](https://twitter.com/SNR_RITA_Trial)

Here is the link to the BHF Heart Matters news on the SENIOR RITA Trial

<https://www.bhf.org.uk/heart-matters-magazine/research/heart-attack-treatments-for-older-patients>

Be sure to check our weekly updates on Monday mornings

The BHF SENIOR-RITA Trial Team, Newcastle Clinical Trials Unit, 1-4 Claremont Terrace, Newcastle upon Tyne NE2 4AE

Telephone: 0191 208 4591 (Philippa), 0191 208 5825 (Denise) or 0191 208 3825 (Carol)

E-mail: [seniorrita.support@newcastle.ac.uk](mailto:seniorrita.support@newcastle.ac.uk) Clinical Queries: 0191 282 6710

Database queries e-mail [nctu.database.support@newcastle.ac.uk](mailto:nctu.database.support@newcastle.ac.uk)