

### Welcome to...

# The BHF SENIOR-RITA Trial Newsletter

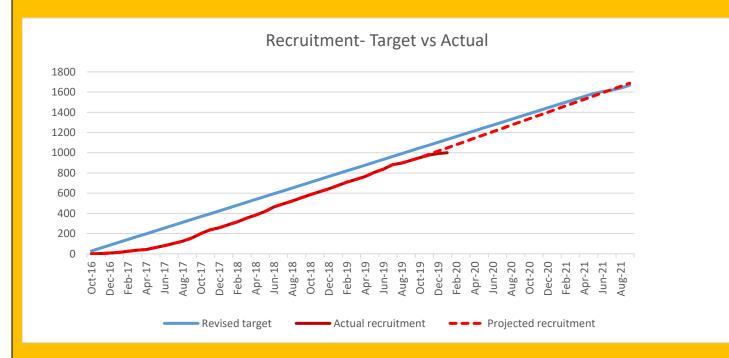


Issue 14: January 2020

## TOTAL RECRUITMENT: 1000 PARTICIPANTS

Thank you to everyone for your commitment and dedication

Congratulations to **Sheffield – Prof. Rob Storey and team** for randomising our **1000**<sup>th</sup> **participant**!



We ask that all our sites continue to offer eligible patients the opportunity to take part in SENIOR-RITA. We really need to keep up our continued efforts, momentum and enthusiasm to ensure we achieve our required revised target of 1668 participants by the end of September 2021.

We all agree that we need to complete this trial successfully to answer a number of unanswered questions in this growing older patient cohort with NSTEMI and we still do not have any other trial that will address this other than SENIOR-RITA - so let's please keep going!

We are really grateful for all your hard work, and ask that you continue your fantastic efforts.

#### **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. The Data Monitoring Committee will be meeting soon and the data we present to them must be as complete and accurate as possible. The Screening database is a record of all the work you are doing to try and recruit participants so please keep it updated.

All missing data and responses to Data Clarification Requests (DCRs) <u>must</u> be completed within 1 month of DCR or request from NCTU.

- The easiest way to find DCRs is by clicking on the red flag short cut button on the home page toolbar. You can then view and respond to every DCR raised by right clicking on each DCR and selecting 'Respond to DCR', entering any suitable text and then clicking 'OK'. The red flag will then change to a blue flag and this indicates to the NCTU that you have responded to the DCR. If we are happy with the response, we will close the DCR and this will change the flag to green. Please ensure that as well as making any required changes (if applicable) you do respond to the DCR otherwise the red flag will never disappear!
- ▼ When you see the orange sun against a data point on MACRO, this indicates there is missing data. If you know that this data is definitely not available, instead of leaving the question unanswered please right click on that particular answer box and choose 'Not Available' from the menu.

#### **SUBSTANTIAL AMENDMENT – data collection**

We are aware that the protocol does not currently allow sites to contact participants' GPs in order to follow them up or obtain data. We are currently working on a substantial amendment to the protocol that will include a change to this to make it easier for sites to follow up participants even if they do not want to be contacted directly.

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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