

## **NATTINA NEEDS YOU! - Recruitment update**

After a great finish to 2016 we have seen a considerable reduction in recruitment since the start of 2017. We have 292 recruited participants today and we need every effort to meet our 2017 recruitment targets. There are 9 months of recruitment left and every effort is needed to keep recruitment on track during this time.

To help with recruitment, we have prepared a summary letter for patients which will be submitted to REC approval. We will also be preparing a recruitment handbook for site staff with top tips. If you have any tips for other site let us know and we are happy to include these in the recruitment handbook!

A breakdown of recruitment by site is shown below.

### **STAR Database Update**

The STAR system update has been tested and has just received HRA approval. The Clinical Trials Unit will be writing to all participants to let them know about the changes.

If participants are going to submit STAR Questionnaires electronically they must have an email address registered with us. We will let sites know which participants we do not have an email address for to see if this can be collected. Sites should continue to hand out paper questionnaires to participants at enrolment. New STAR instructions are attached to this email.

### **Safety Reporting**

A brief reminder to all site staff assessing causality and expectedness of AE/SAEs, section 16.6 of the protocol lists expected AE/SAEs which should be used as a reference.

### **DCRs and Missing data**

There will be a data download on 3<sup>rd</sup> May. Prior to this can site staff please make sure they have answered an open DCRs (instructions are attached) and addressed any missing data (marked  in MACRO). If data is not available please right click and change the status to 'not available' to help minimise the need for queries to be raised.

### **New Sites**

We are happy to welcome a new site to the study; Oxford University Hospital

Recruitment by site to 31/03/2017:

| Site                                | Opened     | Total 2015 | Jan-16    | Feb-16    | Mar-16    | Apr-16    | May-16    | Jun-16    | Jul-16    | Aug-16    | Sep-16    | Oct-16    | Nov-16    | Dec-16    | Jan-17    | Feb-17   | Mar-17    | Total      |
|-------------------------------------|------------|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|----------|-----------|------------|
| <b>Newcastle</b>                    | 14/04/2015 | 8          | 1         | 3         | 0         | 3         | 2         | 3         | 0         | 2         | 2         | 2         | 3         | 2         | 2         | 0        | 0         | <b>33</b>  |
| <b>Aberdeen</b>                     | 07/05/2015 | 17         | 1         | 0         | 0         | 0         | 2         | 1         | 2         | 2         | 1         | 4         | 0         | 1         | 1         | 1        | 1         | <b>34</b>  |
| <b>Glasgow</b>                      | 12/05/2015 | 14         | 4         | 2         | 0         | 2         | 3         | 5         | 4         | 2         | 4         | 0         | 0         | 3         | 3         | 2        | 0         | <b>48</b>  |
| <b>Bradford</b>                     | 20/07/2015 | 11         | 4         | 1         | 1         | 1         | 1         | 3         | 1         | 2         | 3         | 4         | 6         | 4         | 1         | 1        | 1         | <b>45</b>  |
| <b>Sunderland</b>                   | 28/07/2015 | 0          | 0         | 1         | 1         | 1         | 0         | 0         | 1         | 0         | 0         | 0         | 3         | 0         | 1         | 0        | 0         | <b>8</b>   |
| <b>Guys</b>                         | 19/10/2015 | 7          | 1         | 2         | 4         | 3         | 0         | 3         | 3         | 1         | 3         | 2         | 4         | 1         | 0         | 0        | 0         | <b>34</b>  |
| <b>Dundee</b>                       | 21/10/2015 | 2          | 2         | 1         | 3         | 2         | 2         | 1         | 0         | 4         | 1         | 1         | 2         | 1         | 1         | 1        | 0         | <b>24</b>  |
| <b>Wigan</b>                        | 08/02/2016 |            | 0         | 1         | 2         | 2         | 0         | 1         | 3         | 2         | 0         | 1         | 1         | 2         | 0         | 2        | 0         | <b>17</b>  |
| <b>Cumberland</b>                   | 15/02/2016 |            | 0         | 0         | 0         | 2         | 1         | 0         | 0         | 0         | 0         | 0         | 0         | 0         | 0         | 0        | 0         | <b>3</b>   |
| <b>Dorset</b>                       | 16/02/2016 |            | 0         | 0         | 0         | 0         | 0         | 0         | 0         | 0         | 0         | 1         | 0         | 0         | 0         | 0        | 0         | <b>1</b>   |
| <b>Birmingham</b>                   | 17/02/2016 |            | 0         | 0         | 0         | 1         | 1         | 0         | 0         | 0         | 0         | 1         | 0         | 2         | 0         | 0        | 4         | <b>9</b>   |
| <b>Frimley</b>                      | 11/03/2016 |            | 0         | 0         | 0         | 1         | 0         | 0         | 1         | 0         | 0         | 0         | 0         | 0         | 0         | 0        | 0         | <b>2</b>   |
| <b>Sheffield</b>                    | 24/03/2016 |            |           | 0         | 0         | 0         | 0         | 0         | 0         | 0         | 0         | 0         | 0         | 0         | 0         | 0        | 0         | <b>0</b>   |
| <b>Nottingham</b>                   | 18/07/2016 |            |           |           |           |           | 0         | 0         | 2         | 0         | 2         | 0         | 1         | 0         | 3         | 0        | 0         | <b>8</b>   |
| <b>Newport</b>                      | 12/07/2016 |            |           |           |           |           | 0         | 0         | 0         | 1         | 0         | 2         | 1         | 0         | 0         | 0        | 0         | <b>4</b>   |
| <b>Salisbury</b>                    | 18/08/2016 |            |           |           |           |           |           | 0         | 0         | 0         | 0         | 0         | 0         | 0         | 0         | 0        | 0         | <b>0</b>   |
| <b>Worcester</b>                    | 26/08/2016 |            |           |           |           |           |           | 0         | 0         | 2         | 0         | 1         | 0         | 0         | 0         | 0        | 0         | <b>3</b>   |
| <b>Blackburn</b>                    | 13/09/2016 |            |           |           |           |           |           |           | 0         | 0         | 1         | 0         | 1         | 0         | 1         | 0        | 0         | <b>2</b>   |
| <b>West Suffolk</b>                 | 26/09/2016 |            |           |           |           |           |           |           | 0         | 1         | 1         | 2         | 1         | 2         | 1         | 1        | 1         | <b>8</b>   |
| <b>Plymouth</b>                     | 29/09/2016 |            |           |           |           |           |           |           | 0         | 0         | 0         | 0         | 0         | 0         | 0         | 0        | 0         | <b>0</b>   |
| <b>Lancashire</b>                   | 30/09/2016 |            |           |           |           |           |           |           |           | 0         | 0         | 0         | 0         | 0         | 0         | 0        | 0         | <b>0</b>   |
| <b>James Paget (Great Yarmouth)</b> | 05/10/2016 |            |           |           |           |           |           |           |           |           | 0         | 0         | 0         | 0         | 0         | 0        | 0         | <b>0</b>   |
| <b>Middlesborough</b>               | 14/10/2016 |            |           |           |           |           |           |           |           |           | 1         | 0         | 0         | 0         | 0         | 0        | 0         | <b>1</b>   |
| <b>Pilgrim Hospital (Boston)</b>    | 13/02/2017 |            |           |           |           |           |           |           |           |           |           |           |           | 0         | 0         | 0        | 0         | <b>0</b>   |
| <b>Lister Hospital</b>              | 02/03/2017 |            |           |           |           |           |           |           |           |           |           |           |           | 0         | 0         | 0        | 0         | <b>0</b>   |
| <b>Ayrshire</b>                     | 02/03/2017 |            |           |           |           |           |           |           |           |           |           |           |           | 0         | 0         | 0        | 0         | <b>0</b>   |
| <b>Total</b>                        |            | <b>59</b>  | <b>13</b> | <b>10</b> | <b>10</b> | <b>14</b> | <b>16</b> | <b>18</b> | <b>12</b> | <b>17</b> | <b>18</b> | <b>23</b> | <b>20</b> | <b>21</b> | <b>14</b> | <b>7</b> | <b>12</b> | <b>284</b> |