

# SUPREMO, an MRC phase III randomised trial to assess the role of adjuvant chest wall irradiation in 'intermediate risk' operable breast cancer following mastectomy



**SUPREMO Newsletter**

**December 2016**

Dear Supremo colleagues,



We have had another busy year on the Supremo trial. We have now reached a significant milestone where a number of patients have now completed their 10 year follow up and have finished the study.

Since our last newsletter we have joined up with some members of the data management team at SCTRU. Michael, Ashleigh, Ian & James will be processing all trial data and can be contacted via [NSS.isdsupremo@nhs.net](mailto:NSS.isdsupremo@nhs.net) if you have any questions regarding data submission and prompts.

## Supremo Website

Due to the increase work around publications and presentations at major conferences we have decided to update the Supremo website where you will find information relating to trial updates, publications, conference slides, up to date work instructions, current and past newsletters and current contact details.

The website address is [www.supremo-trial.com](http://www.supremo-trial.com)

If you have any suggestions on what we could include or improve on then please get in touch.

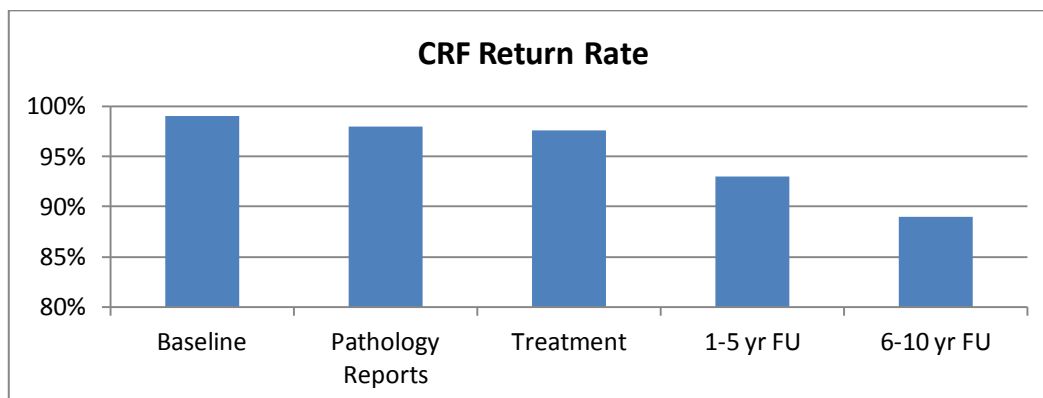
## Follow up & CRF completion

Missing CRFs and data queries are continually sent to all Supremo sites every 4 months via a data prompt and therefore it's important we send them to the correct site contact.

Please can you ensure you notify the Supremo team of any changes to the PI/site staff by sending an updated signed delegation log as soon as they occur.

The data compliance across most sites is excellent and there are only 4% of expected CRFs outstanding. The graph below shows the expected CRF return rate as of November 2016. If your site has any outstanding CRFs, they will be highlighted to you via our latest data prompt last month.

Please also remember to send in all original Mastectomy Pathology Reports and any subsequent surgery reports.



## **\*\*Updated Work Instructions\*\***

Along with this newsletter you have been sent an updated copy of the updated site work instructions (Version 4.0). Please can you distribute to staff and file a copy within your site file. There have been minor changes throughout but we would like to highlight the additions made on page 14 'Termination CRF'.

As we have mentioned already some patients have reached Month 120 and have completed the trial. In-order to capture this information we ask that along with completing the month 120 follow up you also complete a Termination CRF to confirm the patient has completed study. In this instance, please follow the steps below;

- 'Has the patient withdrawn early' - Please tick 'No'
- PI signature and date (this must be completed in wet ink by the PI only).

If the Termination page is not submitted along with the 120 month follow up this will be highlighted as 'missing' at the 4 monthly data prompt.

## **Monitoring**

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As some of you are aware we have started remote monitoring visits across all sites where there have been no previous visits.

We will look to monitor 8 different sites per year focusing on the follow topics;

- Outstanding CRF/queries
- Site contacts
- ISF checklist review
- Pharmacovigilance
- Outstanding site documents.

A common request is for sites to send an updated CV and GCP certificate for the PI. The PI should sign and date their CV on review. Both CV & GCP should be renewed every 2 years (unless NHS trust policy is every 3 years).

## **Contact details**

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Professor Kunkler and the SUPREMO team would like to take this opportunity to thank you all for your hard work and support throughout the year.

Please do not hesitate to contact us by email or telephone if we can be of any assistance.

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### **Individual contact details;**

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**From all the staff at SCTRU we wish you a Merry Christmas and best wishes for 2017!!!**