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 **October 2020**

Dear Supremo Colleagues,

On behalf of the Chief Investigator, Professor Ian Kunkler we would like to express our appreciation for everyone's dedication in the face of recent challenges to our normal mode of working.

Supremo Interim Analysis

On behalf of the SUPREMO trial team we would like to thank you for your continued support to the SUPREMO trial. We are aware of the increased pressure and prioritisation of work due to the Covid-19 outbreak, as well as the challenges for sites to get the follow-up done and sending by post wet ink CRFs when many staff are working remotely from home.

In the current circumstances due to Covid-19, we would also like to take this opportunity to update you all on some changes to data collection and the interim analysis.

The Data Monitoring and Ethics Committee (DMEC) has recommended an interim analysis should be performed before the end of the trial ~ August 2023. The Trial Management Group (TMG) and the Trial Steering Committee (TSC) have discussed, agreed and accepted the advice given by the DMEC. The trial committees have a duty of care to the trial participants and clinicians worldwide to get the data published sooner in the event of potentially changing patient care pathways and it would not be in the patients' interest to wait until the end of the trial.

In preparation for this, the SUPREMO team have started cleaning the data; checking and validating each individual CRF page/s for subsequent QC of the data as per our SOP. This is an exciting stage for the study. As you are aware, SCTRU team have now adopted a new process for sending sites data queries and/or requests outstanding Case Report Forms (CRFs) via a spreadsheet/email on a 3-4 monthly basis and the last data prompt was sent out in February 2020. Due to Covid-19 some sites have still outstanding queries' responses and outstanding CRFs **including early baseline CRFs**. The individual sites will be contacted separately to chase for these as a matter of urgency.

The study median follow-up is now at 9.1 years and we are now receiving a large number of 10 year follow up CRFs. This is fantastic news and as such it is important that you continue to send us all the correct and up to date patient trial CRFs/data in real time, and respond to data queries and complete the sign off sheet in a timely manner.

Your cooperation will greatly help in the smooth processing of the CRFs, data queries, data cleaning and subsequently allow the performance of timely analysis. Please contact us if you require further clarification or any help with this.

In order to expedite follow-up reporting in real time and also to make it easier for sites to send vital data/completed CRFs to SCTRU without any delay, please find the two changes below;

1. The Health Research Authority has issued guidance for changes to studies due to Covid-19 restrictions for face to face contact, as safety of patients remains a priority. The current Protocol version 29.1 11th June 2019, states the patients' follow-up is by clinic visits. Therefore, to reduce the risk of potential exposure to Covid-19, patients can also now be followed up by telephone, video consultation, or sites can contact the family doctor/ GP. The SUPREMO trials team will be submitting a Non Substantial amendment to inform the Research Ethics Committee of this update.

2. Please send, by post, wet ink signature completed CRFs using the contact address below. SCTRU will accept PDF's of the completed CRFs by email to; phs.supremo@phs.scot if it is not possible to post them in real time. The PDFs should be sent from an **NHS email address**. Please retain wet ink copies at your site to send on by post once the site will be able to do so or when staff have been allowed to return to the office. Currently SCTRU team are working very hard on the data cleaning and sending out data queries so that we can work towards the interim analysis. Therefore, completing CRFs and sending them out in real time would be very helpful.

International sites please use a SECURE email to send PDF copies of completed CRFs to SCTRU.

Please also note that SCTRU have changed area and contact address, see below;

Scottish Clinical Trials Research Unit, Partners in CaCTUS
Public Health Scotland
Area 143A
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

SAE Reporting
Please be aware that we no longer have a fax machine. Please send all SAE forms or follow up forms to phs.sctru@phs.scot and not to phs.supremo@phs.scot. Any questions, then please get in touch at phs.supremo@phs.scot.

Please note that SCTRU have moved from NHS National Services Scotland to Public Health Scotland. We will be submitting a Substantial Amendment in due course and subsequently updating the Site Work Instructions soon with the change to sponsor and new email address

The Chief Investigator, Professor Ian Kunkler and the SUPREMO team would like to take this opportunity to thank you for your continued support.

Any questions please do not hesitate to contact a member of the SUPRMEO team at phs.supremo@phs.scot.

With kind regards,

Yours sincerely,

Professor Ian Kunkler

Contact details

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

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