



ORBIT STUDY – NEWSLETTER

Dear all

Welcome to the second edition of the ORBIT newsletter!

The purpose of the newsletter is to provide you with ORBIT updates and will be circulated on an ongoing basis.

Update on approval of sites.

Most of the Scottish sites have been fully initiated and we are delighted to announce that some sites have started recruitment and therapy. It is envisaged that all Scottish sites will receive local management approval by end September 2010. For our English colleagues, we have global permission from CSP and the trial has been adopted by CLRN. The information is displayed on UKCRN portfolio. We hope local approval will be granted shortly. If you are eager to commence recruitment at your site and do not yet have management permission, please contact your local R&D representative.

New Sites.

Professor John Isaacs (Newcastle Upon Tyne Hospital NHS Foundation Trust), Professor Jaap Van Laar (South Tees NHS Hospitals Foundation Trust), and Dr Allister Taggart (Belfast Health and Social Care Trust) have agreed to participate in the study. This is good news – the more sites we can enroll the sooner we will reach our recruitment target. All the new sites will be contacted by Jurgen to set the scene and provide information regarding the study. In addition Elizabeth Douglas (Clinical Trials Pharmacist) will contact the respective pharmacies to conduct pharmacy initiation visits.

Recruitment

Thank you for all your help so far – now the key is to recruit participants into the study! The holiday period has now ended and we are confident that recruitment will increase significantly. Congratulations to Vinod and all participating staff at Dundee for recruiting the first participant out-with Glasgow into the study!

ORBIT Webportal training.

For the new sites and the sites that were unable to attend the investigator meeting; ORBIT web portal training can be provided. When you receive your initiation visit, Jurgen will provide you with the demo version of the web portal for staff to familiarise with the eCRF. If after this you feel that additional training would still be beneficial, training can be provided. In this case please contact Jurgen who will organise training.



IV Rituximab log.

For the sites already participating in the study; an IV Rituximab log is required to be completed for all participants randomised to receive Rituximab. Please retain this log in the study booklet. For some sites; this form was not supplied in the Study Site File at initiation visit; it is however available for use in the ORBIT webportal – study documents. Jurgen will forward copies to all sites that have been initiated.

Summary of Product Characteristics.

A recent change in the Summary of Product Characteristics (SmPC) means that all rheumatoid arthritis patients treated with Rituximab must be given the Roche '**Patient Alert Card for Rheumatoid Arthritis**'. Other alert cards can still be used in addition to the Roche card as per site local practice. Copies of the Roche card are available either direct from Roche or from Elizabeth Douglas. Elizabeth.Douglas@ggc.scot.nhs.uk

There will be no requirement to retain a paper copy of the current SmPC for Rituximab, Etanercept and Adalimumab within the local Study Site File and Pharmacy Site File. The SmPCs can be accessed via the ORBIT web-portal and relevant study staff will receive an e-mail alert when these are updated. The sponsor will continue to retain copies of all SmPCs. It is hoped that this will cut down considerably on the ORBIT paper mountain! A file note indicating the location of the SmPC will be sent to all sites that are already initiated for inclusion in the Study Site File to cover this change. For the sites that are awaiting the initiation visit the necessary changes will be made in the Study Site File.

Re-ordering of clinical packs – study booklets.

All sites are supplied at the initiation visit with 6 clinical packs and 6 study booklets. Should you require more packs or booklets, please contact Jurgen as soon as reasonably possible in order to ensure timely delivery at your site.

Good Clinical Practice training.

The Sponsor requires that all study staff members – inclusive of pharmacy staff - have completed GCP training within the last two years of participation into the study. For the sites that are awaiting initiation, could you please ensure that all your study staff members have attended and have a valid GCP certificate available. If study staff require GCP training, please contact your local R&D Department who should organise, alternatively please contact Jurgen who could organise either training provided by Greater Glasgow and Clyde or web based GCP training.

CONTACT DETAILS.

Username and passwords will be supplied to gain access to the ORBIT website <http://www.glasgowctu.org/ORBIT> Could we please ask you to supply Jurgen with an up to date list of all study staff, inclusive of email addresses and phone numbers, who will be working on the ORBIT study as soon as reasonably possible.

QUERIES.



Should you have any queries then please contact:

- For SSI information please contact Ann on: Ann.Tierney@ggc.scot.nhs.uk
- For general information please contact Jurgen on: Jurgen.van-melckebeke@ggc.scot.nhs.uk or Duncan on: Duncan.Porter@ggc.scot.nhs.uk

THANK YOU FOR YOUR SUPPORT IN THE STUDY!

Duncan & Jurgen.