ORBIT STUDY – NEWSLETTER
11TH EDITION

Recruitment.

We require another 19 participants in order to reach our target!

For that we need your help

Can we please ask for a final push?

Amendments.
A summary sheet detailing all amendments has been forwarded to all PIs and Point of Contact. All regulatory amendment documentation is also available on the ORBIT webportal. The same naming convention is used as per the summary sheet. Should you have any missing amendment documentation; then please print off your missing documents from the portal and insert in your PI site file.

Changes of PI at sites

Many thanks to Dr Sheeran (Cannock) and Dr MacDonald (Aberdeen) for taking on PI role at your respective sites. Welcome back Dr Nixon. (Chester)

New site.
A big welcome to Dr Morrison and staff (Hairmyres Hospital – Lanarkshire). Thank you for your cooperation in the study!

Capturing the use of study drugs
You will have noticed some changes to the eCRF. Most notably is the addition of the IV Rituximab log. Can we ask you to transcribe all rituximab administration from your paper record to the electronic format.

It is <u>really important</u> that we capture accurate information about the use of the study drugs, using the rituximab log to capture rituximab use, and the Concomitant Medication section of the eCRF to capture TNFi use. An email has been sent to all sites explaining the actions required but don't hesitate to be in contact if you have any queries

Data Query Forms
The data query process is now well underway. The second batch will be forwarded to sites this month.
Can we ask you to insert a copy of your completed Data Query Forms in Section 10 of the PI Site File (Completed data query forms)

New updated Reference Safety information.
The updated Reference Safety Information is available on the ORBIT webportal – Section documents. These documents should be used should be used to assess the "Expectedness" of any serious adverse reactions to the IMPs.

Safety update
To date we have received 49 Serious Adverse Event reports involving 38 subjects. Of these 22 have been assessed as being possibly, probably or definitely related to the Investigational Medicinal Product (7-adalimumab, 13-rituximab, 2-etanercept) with one of these considered being a SUSAR.

STOP PRESS – one patient died on the 22/8/2013 from sepsis secondary to an infected elbow prosthesis, which occurred 5 months after being treated with rituximab.

Serious Adverse Event guidance. An updated SAE guidance sheet has been forwarded to all sites and should by now be in Section 9 of your PI Site File. Please refer to the guidance in the first instance

The Pharmacovigilance Office team (Dr Eleanor Dinnett – PV officer and June Allan – PV Administrator) is happy to answer any questions you may have regarding any aspect of the SAE assessment and reporting process and can be contacted by phone at 0141 330 4744 or by email at: pharmacovig@glasgowctu.org

Cumulative List of SAEs received by the Pharmacovigilance Office to 20/08/2013

Diagnosis	Classification	IMP (if related)
Ankle swelling, sore throat and general tiredness	SAE	
Asthma	SAE	
Urinary sepsis	SAE	
Cerebral infarction –(L)sided hemiparesis, visual/sensory neglect	SAE	
Myocardial infarction	SAE	
Investigations for increased confusion	SAE	
Left groin pain	SAE	
Admitted for analgesia assessment	SAE	
Flare of RA	SAE	
NIDDM (Type 2 Diabetes)	SAE	
(R+TKR) right total knee replacement	SAE	
Grade 2 cancer left breast	SAE	
Urinary tract infection + urinary retention	SAE	
Headache, diarrhoea, abdominal pain (hospitalisation)	SAE	
Pneumonitis	SAE	
Left # NOF	SAE	
Rheumatoid arthritis flare up	SAE	
Elective admission to hosp for decompression and fusion surgery for lumbar spine l4/l5	SAE	
Chest pain	SAE	

Colonic polyps	SAE	
Laminectomy	SAE	
Musculoskeletal chest pain	SAE	
Septic arthritis left 2nd DIP joint	SAE	
Pulmonary embolism	SAE	
Fracture of left femur bone	SAE	
Right hip replacement	SAE	
Admitted with lower abdominal pain and vomiting ?bowel obstruction	SAE	
Chest infection	SAR	Adalimumab
Chest infection	SAR	Adalimumab
Neutropaenia	SAR	Rituximab
Probable cutaneous vasculitis	SAR	Adalimumab
New onset interstitial lung disease	SAR	Etanercept
Neutropenia	SAR	Rituximab
Non specific abdominal pain	SAR	Rituximab
Neutropenic sepsis	SAR	Rituximab
Labyrinthitis (acute)	SAR	Adalimumab
Epigastric pain, fever, vomiting	SAR	Etanercept
Eczema in left foot	SAR	Adalimumab
Chest infection	SAR	Rituximab
Gram negative sepsis	SAR	Rituximab
Urine infection	SAR	Rituximab
Low immunoglobulins (Low IgM)	SAR	Rituximab
Acute urinary tract infection	SAR	Rituximab
Parotiditis	SAR	Rituximab
Acalculic cholecystitis	SAR	Adalimumab
Chest infection	SAR	Rituximab
Probably viral tonsillitis	SAR	Adalimumab
Urticaria, itch	SAR	Rituximab
Abnormal liver function test results	SUSAR	Rituximab

Pharmacy update

A new Master IMP Accountability Log for Rituximab 500mg/50ml vials (v3.0 22.07.2013) has been circulated to all pharmacy contacts via e-mail. Please ensure that this log is now used.

QUERIES.

Should you have any queries then please contact:

- Data queries: ORBITsupport@glasgowctu.org
- PEAC sampling queries:
  - Dr Becky Hands: r.e.hands@qmul.ac.uk
  - Ms Rita Jones: m.r.jones@qmul.ac.uk
  - Dr Vidalba Rocher: v.rocher@qmul.ac.uk
  - Sudeh Riahi: s.riahi@qmul.ac.uk
- For Pharmacy information: please contact Elizabeth on Elizabeth.Douglas@ggc.scot.nhs.uk or R&Dimp@ggc.scot.nhs.uk
- Cost questionnaires, please contact Emma on Emma.Miller@ggc.scot.nhs.uk
- For general information / queries please contact Jurgen on: Jurgen.van-melckebeke@ggc.scot.nhs.uk or Duncan on: Duncan.Porter@glasgow.ac.uk

THANK YOU FOR YOUR SUPPORT IN THE STUDY!

Duncan & Jurgen.