



Newsletter February 2006

No. 2

Dear Colleague, there remains no doubt that a DNA collection from a large group of well described sepsis patients, such as proposed in GAinS, will be the source of invaluable information for the understanding of pathogenesis and the future treatment of our patients. The UK seems to specialise in undertaking high quality, high value critical care studies on meagre budgets. We are indebted to all the participating centres for making this collection possible.

41 patients recruited! The Royal Victoria heads the league table with a remarkable recruitment drive overtaking Oxford by the end of February. Well done everyone. All the DNA blood samples have been safely delivered to the Barts Genome Centre.

Site	No. patients recruited
Royal Victoria	12
Oxford	11
Royal London	4
Reading	3
Norwich	3
Southend	2
Worthing	2
Aberdeen	2
Ipswich	2
Homerton	0

Updated 27/02/06

10 sites now live! So recruitment is likely to accelerate. Twelve more sites have their local Ethics and R&D applications in progress and are awaiting final approval to start recruitment. So far,

we have 39 sites that have registered as interested in participation in GAinS. It's likely that the number of centres expressing interest will continue to grow. If you'd like to spread the word, put us in contact, we'll do the rest.

UKCCG Meeting The next meeting of UK Critical Care Genomics will be in Oxford, on the 29th March 2006 at the Wellcome Trust Centre for Human Genetics, Oxford. The programme will include presentations from Investigators and Collaborators and a review of the progress of GAinS. There will be a dinner in the evening at Magdalen College for those who are able to stay on. You should have received an invitation email from Chris Garrard and a formal invitation from Eli Lilly who are sponsoring the meeting. There is no registration fee and the dinner is free! If you've missed out, our apologies, but please let us know and we'll make sure you get an invitation.

GAinS and GenOSept Each GAinS centre will have the opportunity of also participating in GenOSept (for 1 year). There is no additional work involved other than claiming 100 euros for each study subject recruited. Unlike GAinS, which will recruit only community acquired pneumonia and faecal peritonitis patients, GenOSept will also recruit acute pancreatitis and meningococcal disease patients. GenOSept will probably start in the UK in April 2006. We plan to use just one set of information sheets and consent forms common to both GAinS and GenOSept. There will be an electronic

web-based Clinical Report Form (eCRF) for GAINs/GenOSept and for centres wishing to participate in GAINs alone (see below). The GAINs centres will also have the option of continuing with the paper CRF if preferred.

If you are interested in participating in GenOSept please fill in the unit profile form which is accessed from the ESICM website and return it to Professor Charles Hinds at c.j.hinds@qmul.ac.uk or the ESICM office

eCRF (electronic Case Report Form)

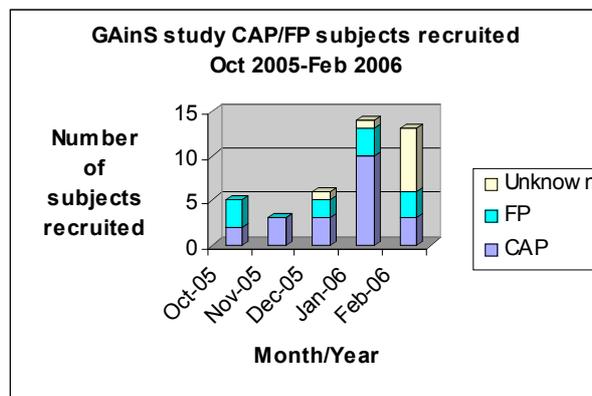
The eCRF for GenOSept/GAINs is almost ready to go live. For those sites participating in both GAINs and GenOSept we will be able to use the eCRF for data entry for both studies with no duplication of effort. Until then we will continue to use the paper CRF for data collection for GAINs. Those sites that are participating in the GAINs study only, will have an identical eCRF hosted on a separate server.

Recruitment of patients

Please remember it is feasible to recruit patients at any time during their ICU stay, so don't give up if you've missed the first few days! The DNA sample can be taken at any time and the data can be extracted from the medical record retrospectively as necessary.

Approx 51% of the subjects recruited have had CAP and 27% had FP (another 22% have yet to be classified by the co-ordinating site – awaiting CRF returns). The ratio of CAP to FP recruitment is a little different than the predicted targets, but this does not include the 'as yet unknown' diagnosis subjects.

There are still some sites (13), which have not commenced the application process yet. We do appreciate that you are all very busy juggling many commitments but the worst part really is the application process - it's all plain sailing from there on!



Patient recruitment packs

Well done to those sites who have already recruited their first 10 patients. We will use the 7th blood sample received at the Genome centre as the trigger for sending sites replacement packs. If you think you will need more than 10 packs per mailing or if recruitment is rapid please inform Paula Hutton or Charles Mein c.a.mein@qmul.ac.uk

CRF questions Completion of the CRFs has raised some questions. These queries were addressed and a table of questions and answers sent out to all active sites. Please continue to ask for clarifications and explanations whenever needed, your comments are always appreciated. If you have not been sent a copy of these Q&A's please e-mail Paula Hutton: ICUgeneticresearch@orh.nhs.uk

Completed CRFs Once Part 1 has been completed please photocopy it and send the original to Paula Hutton in Oxford. Part 2 (Final discharge and outcome data) is retained at the local site until the 6-month follow-up unless the patient dies while still in hospital. If the latter applies Part 2 may be sent to Paula as soon as completed.

UK GenOSept study

status The UK ethics application for GenOSept has been submitted to MREC. The committee meets on 23rd March 2006. We will let you know as soon as we have approval.

GAInS website A website for the GAInS study is in the process of being designed and the URL should be available very soon. This will contain information about the study, membership of the group and contact details, links to other websites (e.g. GenOSept), recruitment rates, questions and answers etc. Once the website is published we'd welcome further suggestions to add to the website such as additional links.

Thank you to you all for your continued support and participation.

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