



## Newsletter January 2007

## No. 4

### Dear Colleagues,

There has been a bit of a delay in getting the Newsletter out primarily due to the great effort that has gone into getting GenOSept up and running and integrated with GAinS. **205 patients** with faecal peritonitis and community-acquired pneumonia have now been recruited to GAinS. So we've continued to recruit successfully but not at a rate we'd like to see. Never the less, well done everyone. Recruitment rates into GAinS and GenOSept, for individual centres are shown below:

Site	Total no. Patients recruited GAinS/GenOSept
Oxford	32
Royal Victoria	30
Aberdeen	27
Norwich	23
Southend	20
Reading	19
Worthing	14
Swindon	13
Chelmsford	11
Royal London/Bart's	8
Ipswich	4
Royal Hallamshire	3
Cardiff	3
Antrim	2
Chelsea & Westminster	1
Cheltenham	2
QE Birmingham	1
King's Lynn	1
Homerton	0
Leeds General	0
St Jame's Leeds	0
Medway	0
Frimley Park	0
UCL/Middlesex	0
<b>TOTAL</b>	<b>215</b>

### 24 sites are now live for

**GAinS!** So far **32** sites have received local Ethics approval, **31** have obtained R&D approval, **26** sites have been visited and had their patient recruitment packs delivered. As more sites go live so recruitment is expected to accelerate. Over the next few months we will be contacting centres where recruitment has been slow to see if there is anything we can do to help. We are all too well aware of the obstacles to recruitment and the difficulties you face, particularly in centres not supported by research nurses.

### GenOSept

We have started recruiting to the EU funded, ESICM sponsored GenOSept study. **24** centres have LREC approval and **22** of these are R&D approved. We are be recruiting the same diagnostic groups of patients as GAinS (community acquired pneumonia and faecal peritonitis) with the addition of pancreatitis and meningococcal disease. Recruiting centres will receive 100 euros for every patient recruited to GenOSept!!

An electronic case report form (eCRF) is available for patients recruited to both GenOSept and GAinS. Log onto the eCRF at: <https://www.genosept.eu/index.ecrf/> Your username and password will be provided by the GenOSept central office. If there are problems getting passwords email Paula Hutton at [ICUgeneticresearch@orh.nhs.uk](mailto:ICUgeneticresearch@orh.nhs.uk)

Most centres have elected to recruit to both GAinS and GenOSept (requires no extra work since the consent forms cover

both studies). The eCRF must be completed for patients recruited to GAINs/GenOSept. Those few centres that only wish to recruit to GAINs should continue to use the paper CRF. Some centres have found that using the paper CRF is a useful way of collecting data before entering data into the eCRF. Completion of the paper CRF is optional but if used it must be photocopied and the original sent to Oxford (as for GAINs).

Please would all those who wish to participate in GenOSept complete their LREC and R&D applications so that you will be ready to commence recruiting as soon as you receive the recruitment packs and your password for the eCRF.

Please note the Financial Agreement Form must be completed and one copy kept at your site, the other copy must be returned to Professor Stuber in Bonn: this is essential in order to receive payments for patient recruitment. When GenOSept is completed (1 year recruitment) GAINs will have a further 18 months to 2 years to run; we will continue to use the eCRF for these patients.

Could you also 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](mailto:c.j.hinds@qmul.ac.uk) and to the ESICM office at [public@esicm.org](mailto:public@esicm.org)

There will almost certainly be some teething problems with the eCRF, and many questions as we move to the joint GAINs/GenOSept recruitment process. We plan to rigorously test the eCRF with the first batch of patients recruited to GAINs and GenOSept.

GenOSept sites have been asked to complete screening logs. You will be contacted monthly for updates on screening, which will be relayed to the GenOSept team in Brussels.

**Completed CRFs** We appreciate the time you spend completing the CRF's – this information is vital to the success of our project (inadequate definition of "phenotype" has been a frequent and serious problem with previous association studies). Thanks to your efforts the CRF's have generally been completed fully and accurately. Please do contact us if anything needs clarification. Our team in Oxford will contact you if there are any data queries to resolve.

**CRF questions** CRF questions and answers can now be found on the UKCCG website <http://www.ukccg-gains.org/> – select 'technical information', then 'frequently asked questions'. This is periodically updated and may well already have the answer to your question! Alternatively call CH, CG or PH.

**Grant applications and funding** Thanks to the generous support of the Sainsbury Family Charitable Trusts to fund the National Coordinator, Paula Hutton, we've achieved much in the last year. Other submissions and re-submissions are planned to support GAINs and related projects. Without the enthusiasm and support of all the recruiting centres, none of this could have been achieved, so our thanks to you all.

**GAINs website** Just a reminder of the website for the GAINs study. The URL is: <http://www.ukccg-gains.org/> This contains information about the study, membership of the group and contact details, links to other websites (e.g. GenOSept), recruitment rates, questions and answers etc.

**UKCCG Meeting** The next UK Critical Care Genomics group meeting will be held in the Spring of 2007 in London

**Thanks** Once again, thank you for your continued support and participation.

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