Newsletter November 2011

Program online for the joint EuroGentest2/TECHGENE Scientific meeting and General Assembly meeting 18-19th of January 2012, Nijmegen, The Netherlands

EuroGentest is organizing a joint Scientific meeting together with another FP7 framework program, TECHGENE. This meeting will take place in Nijmegen, The Netherlands and will encompass topics ranging from Quality in Genetic Laboratories to Next Generation Sequencing technologies and its medical implementations.

The preliminary program is now available on the website.

Preceding this Scientific meeting, EuroGentest will have its General Assembly meeting Wednesday 18th January in Nijmegen. EuroGentest participants are required to be present. More information can be found on the website soon.

Joint EUGT2 and CNAPS workshop report - Madrid (Spain) October 2011

A stimulating session, attended by around 100 delegates from around the world, was organised by EuroGentest2 during the seventh international conference on Circulating Nucleic Acids and Proteins (CNAPS). The objective of the session was to inform the audience of the role of EUGT2 in developing standards for prenatal diagnostic testing across Europe.

EuroGentest2 coordinator, Gert Matthijs opened with an overview of EUGT2. This was followed by a detailed description of how non-invasive determination of fetal sex using cell free fetal DNA in maternal blood has been implemented in the UK. This included a national audit, detailed health economic evaluation which showed that NIPD is no more expensive than invasive testing for serious X-linked disorders and congenital adrenal hyperplasia and development of health professional and patient information following evaluation of their views. Once new tests are implemented there is a need to audit service delivery. Rob Elles described the first EQA of NIPD for fetal sex determination which was performed in the UK, and discussed the plans to deliver this across Europe through the EMON working with EuroGentest2. The session ended with a view from the US when Dan Bellissimo described the steps required to implement and deliver laboratory tests the other side of the Atlantic. He focussed on fetal RHD typing. The message was very similar to that delivered by earlier speakers as he highlighted the need for service delivery from accredited laboratory working to rigorous standards, with careful quality assurance at least twice a year.

Summary of the EUGT French workshop on validation

All medical laboratories in France must, by law, be accredited according to ISO 15189 by November 2016. Since 2009, EuroGentest has organized a series of French-language workshops on accreditation, in partnership with and hosted by the Agence de la biomédecine, the French national agency overseeing genetic diagnostics. The first workshop on validation of diagnostic tests was held on 20-21 October. This workshop was a considerable challenge, notably because validation of methods represents one of the most difficult tasks to achieve in the process of preparation for accreditation. There were 29 participants, mostly molecular and cytogeneticians but also experts in quality. Eleven had already participated in a previous workshop. All had knowledge of ISO 15189 requirements, some had read the recommendations of Cofrac (the French accreditation body) and the EUGT paper (Mattocks et al., Eur J Hum Genet 2010; 18:1276-86), but almost none had real experience in the formal validation of methods.

Despite the challenge, the workshop was a success, with enthusiastic participation and exchange. Participants were particularly impressed by the interactive and didactic aspect of the training. Through practical exercises along with formal presentations, they understood the different categories of tests and the corresponding parameters to evaluate. They declare their intention to implement formal validation/verification of their tests, mostly using the templates and examples of validation provided.

This report can also be found on the website.

Other news

- Connect to EuroGentest on LinkedIn
- November 18th, the EUGT2 steering committee will hold its next meeting by teleconference; a report will be published on the website afterwards.
- 22nd and 23rd of November 2011, a closed workshop on Quality in Genetic Counseling and Best Practice Guidelines for Provision of Clinical Genetic Services will be organized in The Netherlands.
- In the participant section of the EuroGentest website, some interesting general documents from the EC website are highlighted and you can find information on the 18 month reporting and on time recording (participants only).