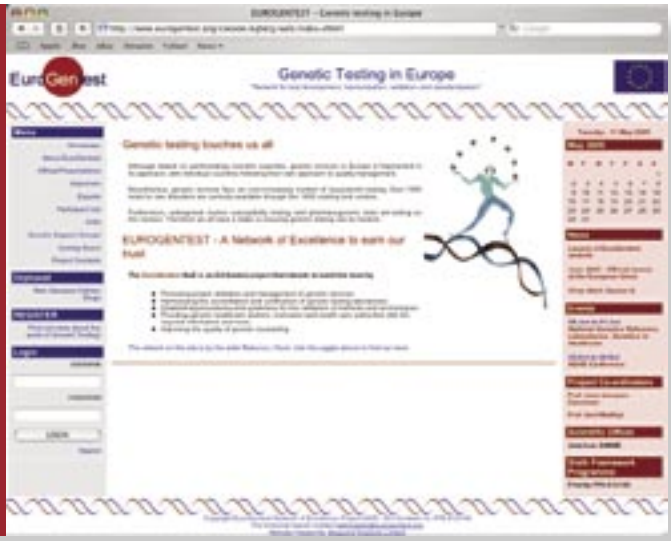
WELCOME to the first issue of the EuroGentest newsletter which contains news from the various Units and other relevant information for all those with both a professional and general interest in this exciting project. At first we will supply the newsletter as a printable PDF but if demand requires will change at a later date to an HTML format. All newsletters evolve over time and we welcome your suggestions and comments.

Jean-Jacques Cassiman

EUROGENTEST NEWSLETTER1/2005

www.eurogentest.org – your direct source for all the latest Information:



The website is the ultimate source of information. Please check regularly for updates and info.

The EuroGentest website has been designed to be a portal of excellence to support the Network of Excellence.

Over the next five years it will grow and develop along with the project.

The website is easy to navigate - as with the intranet the menu bar is located down the left hand side of the screen with content appearing in the middle of the screen.

There is a top "menu" which holds the public domain information available to all interested parties. Once a registered user logs in (using the username and password which has been mailed to them) the "professional" and where applicable "participant" menus will also appear.

The calendar, news and events menus are on the right hand side of the page. These are all areas which will develop over time as the website grows.

Currently the website hosts the following features:

- EuroGentest information including unit deliverables.
- Objectives of the project
- Official presentation (can be viewed via the web as a slideshow)
- Genetic Support Group links
- Access to the project's Intranet
- Latest Research
  - Unit I Abstracts
  - Unit 3 Summary of guidelines for Genetic Counseling
  - Unit 6 EU Educational Initiatives database.

Future developments will include:

- Interactive calendar for conferences and events
- Bioinformatics portal
- Demonstration tool for online EQA
- Deliverables and Milestones from the six units

EuroGentest
Genetic Testing in Europe

Please check the web also for the latest info on the labelling of the Work packages!!!!! and for the deadlines for reporting the progress of the WPs and Units. The next deadline for reporting on progress is JUNE 30

EuroGentest expands NEW PARTICIPANTS RECRUITED

The following persons have been assigned (with or without financial support) by the different participants since the start of the EuroGentest NoE

- **Leuven**
  Iris Rens,
  Administrative Co-worker
  Nick Nagels, IT
  Sarah Berwouts, Unit I
- **Paris**
  I geneticist (master level) with a degree in quality control of biological systems started on March Ist
  I developer (junior) to develop the new features of the database, Unit 2,
- **Geneva**
  Danielle Natale
  Unit I
- **Würzburg**
  Uta Malburg
  project officer
  Unit I
- **Manchester**
  Claudia Validum
  Unit I
- **Basel**
  Dr. Litynski
  Researcher, Unit I
- **NCMG Dublin**
  Christine Brady
  Unit I
- **Geel**
  David Gancberg
  Philippe Corbisier
  Unit I,
- **Prague**
  Dr. Jana Camajova PhD, Unit I

Major achievements (scientific)

UNIT I: Quality Issues

- A survey concerning harmonization, preparation of quality procedures and the use of positive control materials was conducted.
- Different expert meetings were held: one with a scheme organizer and his team of accredited EQA schemes; one with quality assessors to discuss a quality system for organizing and evaluating EQA scheme; and one concerning the recognition of harmonization of QS and accreditation (e.g. recognition of CPA in UK)
- The required QAu content for pilot survey was defined
- A pilot survey was sent to 244 contacts in Switzerland to evaluate laboratory responses and questionnaires, the data are being analyzed.
- A series of discussions with Unit 2 about the lab database took place.
- Identify needs for EQA materials (cell lines), sources of EQA materials the EMQN database was updated
- The Cytogenetics group organized a series of meetings: a forum meeting in Prague, a Best Practice Meeting on Cytogenetic Guidelines and an Open Meeting to present the EuroGentest Network of Excellence with emphasis on WPI.4 at the ECA conference in Madrid.
- Web System design - some normal and abnormal FISH and other images for EQA have been prepared. UK labs were contacted for EQA images.
- Cytogenetic Guidelines are being written/drafted by Simona Cavani and will be discussed at ECA Madrid Conference.
- A temporary Database was set up with 650 laboratories.
- Database and web site of ERNDIM was updated. A directory of known EU biochemical genetics laboratories completed. First steps made to identify situation in EUI6- 25
- National representatives from EUI5 identified
- Initial best practice meeting with ERNDIM SAB organized
- Control of accuracy and precision guidelines, and Amino Acid analysis guidelines were all posted on the ERNDIM web-site
- First steps were taken towards preparation of the meeting on reference measurement systems including reference materials in Geel, scheduled for November 2005. Contact with the European Commission DG ENTR on the role of the IVD Directive 98/79/EC in human genetic testing: in-house materials and standardization issues
- Work started on a glossary of terms used in Reference Materials and Procedures

UNIT 2: Bioinformatics

- Members of Unit 2 and Unit Isat together during three meetings (Leuven, Paris) to determine how to collect information from all European laboratories on QA under optimal conditions and how to make this information available on the Orphanet website attached to the current information on tests.
  To achieve these goals the type of information to be collected (Unit I + 2) must first be defined, and questionnaires drafted to collect these data (on going Unit 2). A list of labs will also be defined and these questionnaires will be sent to relevant biologists (Unit 2) with a cover letter signed by JJ Cassiman + S. Aymé. The quality of the data collected will be checked before posting on the website
- The following tools will be developed: an on-line questionnaire to fill in automatically as an excel file; new tables in the Orphanet database to accommodate this new information; new screens to enter the new data in the database;and new screens to query the Orphanet database
- Unit I will handle the data collected in the excel file for monitoring and validation purpose (Unit I as soon as the data are defined. To be ready by September at the latest)

UNIT 3: Public Health and Genetic Counseling

- Experts groups to draft recommendations for counseling practices and to establish a EU platform for the clinical validation of genetic tests have been formed, and a joint expert meeting has taken place in mid May 2005.

The Unit has gathered a group of highly respected experts from various fields of genetic counseling, genetic epidemiology and health economics. These experts met in a 2 day experts' meeting in Copenhagen, May 24-26. In total we were 25 persons from Europe, South America and South Africa (see picture). After two introductory sessions covering topics related to both work packages we had 2 brain storming sessions in smaller groups to explore where to put focus for the future work. This was a very successful approach, and we got many valuable ideas for our future work.

NEWS

Workshop on Laboratory Accreditation

The Ist Expert Workshop on Laboratory Accreditation was held in the Centre for Human and Clinical Genetics, LUMC, Leiden on 14-15 April 2005, organized by UnitI (Els Dequeker, Sarah Berwouts and Michael Morris).EuroGentest partner Mieke Gielis (MCR Leuven), a specialist in the "human side of change processes", participated actively in the organization and in the workshop itself. The initial workshop brought together people working either in laboratories that are already accredited or in the process of developing a quality system and working towards accreditation.

A variety of participants (25) were invited, including laboratory directors, scientists, technicians and quality managers, from cytogenetic and molecular genetic laboratories.

The workshop was very interactive, with only brief formal presentations and discussion of three case studies. Structured questionnaires helped participants formulate their opinions, positive and negative, about quality systems and provided a basis for honest discussion.

All participants provided detailed feedback, which will be used for planning future workshops.

Specific topics that were requested for future meetings included IT support for quality management (almost unanimously requested), more detailed information about different accreditation norms, experiences of accredited labs, and specific support for the problems of smaller labs wanting to achieve accreditation. The possibility of expanding participation to more labs while maintaining the active format is under discussion.

On Friday May 27th, a conference on "Gene Patents and Public Health" was organised by Prof. Dr. Geertrui Van Overwalle on behalf of the Centre for Intellectual Property Rights with the focus on gene patents and genetic testing. During the morning session, the different aspects of the situation were reviewed, starting with the experience of a clinical geneticist (Prof. Dr. Gert Matthijs), the philosophical perspective on ethics related to IP and diagnostic testing (Prof. Dr. Tim Baldwin), and the patent-technical side with a review of case-law on diagnostic methods at the European Patent Office (Mr. Daniel Thomas) and the approach from a patent attorney's position (Mr. William Bird). The afternoon session (chaired by Prof. dr. JJ. Cassiman) was then dedicated on how the different stakeholders try to deal with these IP rights, this fragmentation of IP rights and concomitant licensing problems. Dr. Philip De Corte (J&J) shed a light on the big pharma approach and subsequently Diagnostic kit R&D issues with regard to IP were reviewed by Dr. Katrin Vlassak (Innogenetics). Ms. Sampogna gave an overview of the OECD guidelines for best practice in licensing of genetic inventions. Finally, instruments for dealing with IP fragmentation in the sector were explored such as patent pools (Dr. James Simon) or compulsory licensing and its implementation in the French (Mr. Gilles Requena), Swiss (Mr. Christophe Germann) and Belgian (Mr. Jerome Debrulle) legislation.

To conclude the day, a floor debate was setup in which there was a striking consensus on the fact that a lot of the controversy on patents and genetic diagnostic testing is due to the breach of the implicit "social contract" of the patent system in the BRCA1 and BRCA2 story. In order to restore this balance and regain faith in the system, all professionals involved are called upon to find a way of dealing in an appropriate way with the exercise of IP rights in this field.

The EuroGentest project was presented at the following meetings/presentations:

Genetic Testing Advisory Board Gen Probe March, 2005 San Diego E Dequeker (Unit I)

OECD April 18 -19, 2005 E Dequeker (Unit I)

UNIT 4: Ethical and Legal issues

- With the support of the Viwta (Flemish Institute of TA) a first draft of genetic testing documents is being prepared during a preparatory workshop in Brussels (March 2nd 2005).
- In order to support the activities of the Work package 4.1 (ethical issues: guidelines for genetic testing) the technology assessment (TA) part of genetic testing services is looked after by specialists in TA, in this case the Flemish Technology Assessment Institute (viWTA). An Experts Workshop with all the European TA associations was held in Seville May 26th-27th, under the auspices of IPTS.The workshop was entitled: Ethical, social and governance aspects of genetic testing services: what can we learn from the Technology Assessment approach and other recent studies in the field? Fifteen participants attended this Workshop, of which half were TA experts from European countries and Canada. The other half consisted of representatives of Patients Organisations, Bio-industries, Insurance Companies, and specialists in human genetics and medical ethics.The objectives of this Workshop were: mapping a broad variety of viewpoints on TA with regard to genetic testing services; identifying the headlines of findings and hiatusses in research.The Workshop resulted in a shortlist of recommendations that were ranked. The three issues that were listed at the top of this priority list concern governance aspects, underlying ethical norms and health economical aspects of genetic testing services. The results will be available in an extensive report published in September.
- An overview of guidelines on genetic carrier testing of minors is being finalized for publication.
- An initial inventory and update of the relevant literature and the evolution of the implementation of the Convention in the 'old' Member States of the European Union is being finalized

UNIT 5: R & D

- Different working groups, composed of scientists and technicians with hands-on expertise in specific methods or techniques, representatives from the private partners whose methods and technologies are under scrutiny, and at least one expert on quality management, are being set up. They will generate 'generic' method SOPs and validation files on the different methods or techniques which are already in use in some diagnostic laboratories, or which are ready for transfer to a wider range of labs, or for introduction on the market.
- Collection of information on (novel) diagnostic methods and technologies has started. Collaboration is sought with a sister NoE called SAFE which is working on non-invasive technologies for prenatal diagnosis. We like to combine efforts on novel technologies.
- Negotiations are ongoing with potential new partners to evaluate a flow-through array platform to test for copy number changes, a possible start of a first Beta test is being considered.
- A first set of hereditary disorders was used to optimise and test the developed patent search tool. The set of disorders includes Achondroplasia, late onset Alzheimer's disease, Canavan's disease, Gaucher, Familial Breast and Ovarian Cancer, Hereditary Haemochromatosis, HNPCC, Huntington's disease, Neurofibromatosis, Tuberous Sclerosis and Shox. Granted patents and patent applications that could affect the practice of genetic testing were collected.

Interesting Links

FP6: LIFESCIENCES

STRATEGIC SPECIFIC SUPPORT ACTIONS: may contain possibilities for conferences, training,....
Deadline: November 2005
Budget: 6 M€
See document: "Opportunities Lifesciences: 2004 call and roadmap".

www.cordis.lu/fp6/lifescihealth.htm

4TH AND LAST CALL LIFESCIENCES.

Expected: June 2005
Deadline: 9 November 2005-05-25
Budget: 533 M€
SME – STREP call: special effort to support Research Intensive SMEs in the Health/Biotechnology Sector.
Budget: 171 M€ (as part of the total budget of 533 €)
Workshop on "SME call" by EBE (Emerging Biopharmaceutical Enterprises).
Date: 28 June

www.ebe-efpia.org/Conferences/6FPWorkshop_2005.htm

www.ebe-efpia.org/Conferences/pdf/4th_call-SME_leaflet.pdf

FP6: MARIE CURIE

CONFERENCES AND TRAINING COURSES
Deadlines: 17/05/06
Budget: 12,25 M€ (each year)
Conditions:

- max 4 weeks
- participants<150
- must start > 6 months after deadline
- essentially early stage researchers

EARLY STAGE TRAINING FELLOWSHIPS:
Deadline: after summer 2005

INTRA EUROPEAN FELLOWSHIPS
Deadline: 15 February 2006

RESEARCH TRAINING NETWORKS
Deadline: 8 September 2005
Budget: 220 €
See document: "Opportinities in Marie-Curie" actions and roadmap.

FP6:INCO

No possibilities at this stage.

www.cordis.lu/fp6/inco.htm

FP6: D PROMOTION OF COORPERATION WITH ASSOCIATED CANDIDATE COUNTRIES

No possibilities at this stage.
In 2004 the following possibilities existed:
To support 20 excellent research centres in 3 ACCs (Bulgaria, Romania and Turkey)

- contribute to RTD capacity building in the country
- enhanced participation of the country in the 6FP
- workshops, conferences
- training in MS or ACCs for PhDs

www.cordis.lu/fp6/spl_wp.htm

INTAS

Collaboration with NIS countries. INTAS seeks to provide incentives for NIS to remain in science by awarding fellowship grants. This programme is open to all NIS scientists of 35 years of age or less (YS) in all fields of science to enable them to:

- Advance their careers via international collaboration;
- Stabilise their position and continue their research in the NIS;
- Establish contacts with INTAS research teams and NIS research teams and create collaborations for future research.

Two categories of young scientist fellowships are available: the PhD and the Post-doctoral fellowship. Call for fellows in April 2005. Somewhat similar to the MC fellowships approach.

www.intas.be

UNIT 6: Education – Website – PR

- A list of national chairs and web sites of genetics societies, gynaecologists, pediatricians, midwives, nurses, ethicist societies was collected.
- A questionnaire was drafted about the information received during counseling to be sent to the Education Committee of the European Society of Human Genetics and then to the Chairmen of the Genetics Societies of EC countries to create a panel of national contact persons and to collect information about institutional courses at different levels in genetic education.
- The lists of national chairs and web sites of Educational and informational web-based material have been collected.
- Various evaluation tools that exist within the UK are being collated and evaluated.
- Various educational and informational web-based materials have been collected from the UK Department of Health, National Health Service and National Institute of Clinical Excellence guidelines re genetic testing services and screening services and patient information.

Website

- Purchase and configuration of the server.
- Design, architecture, development, testing and hosting of Intranet.
- Design and Implementation of databases for the intranet information.
- Dissemination of Participant's usernames, passwords and user manual for intranet.
- System Specification for the website version 1 written and sent out for comment.
- Website development plan agreed by the development team.

PR

- Key European specialist journalists were briefed in the aims of the project at ESHG in Prague and
- EuroMedLab in Glasgow
- Additional key journalists are being invited to the proposed June 15th launch in Brussels
- A journalist database is nearing completion
- A project brochure and poster were produced

Miscellaneous

- Jobs / training offered: EuroGentest has budgeted for a series of short term fellowships for students or post docs to train at the site of participants. Applications can be made through the website

EuroGentest
Genetic Testing in Europe