DIRECTORATE FOR SCIENCE, TECHNOLOGY AND INDUSTRY
COMMITTEE FOR SCIENTIFIC AND TECHNOLOGICAL POLICY

Cancels & replaces the same document of 22 June 2006

Working Party on Biotechnology

OECD EXPERT MEETING ON “THE EVALUATION OF CLINICAL VALIDITY AND CLINICAL UTILITY OF GENETIC TESTS”

DRAFT AGENDA

To be held at the NOWGEN Centre, Grafton Street, Manchester, United Kingdom

on 26-27 June 2006

For further information, please contact: Ms. Elettra Ronchi; Tel: (+33 1) 45 24 18 28; Fax: (+33 1) 44 30 63 36; E-mail: elettra.ronchi@oecd.org
OECD EXPERT MEETING ON “THE EVALUATION OF CLINICAL VALIDITY AND CLINICAL UTILITY OF GENETIC TESTS”

DRAFT AGENDA

To be held at the NOWGEN Centre, Grafton Street, Manchester, United Kingdom

on 26-27 June 2006

BACKGROUND

1. In 2000, the Organisation for Economic Co-operation and Development (OECD) organised an international workshop to review developments in the area of genetic testing. The results of this workshop highlighted the need for an international framework to standardise genetic testing methods and procedures across borders. OECD responded to this finding by organising a survey of its member countries in order to assess molecular laboratory quality assurance and proficiency testing practices. The survey was completed in 2004. The survey assessed laboratory quality assurance and proficiency testing practices associated with DNA-based testing, a rapidly evolving segment of genetic testing. Background, results, conclusions, and recommendations from this survey are available at http://www.oecd.org/dataoecd/25/12/34779945.pdf. The survey shows that molecular genetic testing is provided under widely varying conditions and regulatory frameworks across the 18 participating countries. The limited availability of tests, services and expertise within any one country to deal with many rare diseases means that patient samples and data cross national borders. The report concludes with general recommendations for moving the process forward by developing best practice guidelines and particularly emphasizes that accreditation to a defined standard is the single most important measure to ensure quality.

2. Recommendations also point to the importance of genetic test evaluation, in particular establishing the clinical validity and clinical utility of newly-developed genetic tests and tests for rare disease which may require cross-border referral.

3. Several expert drafting groups have been formed to translate the recommendations into draft guidelines under the responsibility of the Working Party on Biotechnology and the Working Group on Human Health-Related Biotechnology of the OECD.

4. There are considerable challenges in establishing and interpreting clinical validity and clinical utility of genetic tests and these have international relevance.
5. In order to explore and address these challenges, OECD will hold an international expert meeting.

6. The meeting is organised under the auspices of the UK Department of Health and is being supported by the National Genetics Reference Laboratory (Manchester). It will be held on the 26 and 27 June 2006 at the NOWGEN Centre, Manchester. The objectives of the meeting are to:

   - Share international experience of genetic test evaluation and review current frameworks, mechanisms, and practice in selected OECD member countries. Provide a descriptive analysis of roles and responsibilities.
   - Review statements under the ACCE framework and whether these could be translated into internationally agreed principles or recommendations.
   - Investigate a number of the key methodological and operational issues for the evaluation of clinical validity and clinical utility of human genetic tests.
   - Inform policy makers and regulators about the key issues that surround the technical evaluation of genetic tests.

**Format and structure of the meeting**

7. Target audience will include policy makers as well as experts. Participation at the Workshop is by invitation only and limited to a small number of experts (40-50 max). WPB delegations are invited to appoint expert representatives to the workshop, who possess substantial knowledge and experience with respect to the topics to be addressed, and in particular with respect to national experience in evaluation of clinical validity and clinical utility of genetic tests.

8. The meeting will focus primarily on discussions around specific topics of relevance to genetic test evaluation and will be based also on working groups.

9. The meeting is intended to last two days.

**Deliverables**

10. The expected output of the meeting will be a report summarising the debate at the meeting, providing an overview of current international perspectives on clinical validity and utility and – to the extent feasible – a consensus view on core principles necessary for the evaluation of clinical validity of human genetic tests. Elements of the summary report will be published to complement the OECD quality assurance guidelines but will not be included in the material to be submitted to the OECD Council.
DRAFT AGENDA
To be held at: NOWGEN Centre, Grafton Street, Manchester, United Kingdom
DAY 1 – 26 JUNE 2006

08:30-09.00 REGISTRATION

09:00-09:30 OPENING
Welcome remarks by Bénédicte CALLAN, OECD

INTRODUCTORY REMARKS
Rob ELLES, CMMC, United Kingdom; Elettra RONCHI, OECD

09:30-10:00 KEYNOTE ADDRESS
Introduction and Policy Context
Ron ZIMMERN, SRL, United Kingdom

10:00-13:00 SESSION 1 : CURRENT PRACTICE AND DEVELOPMENTS IN OECD MEMBER STATES
Chair: Glenn PALOMAKI, Brown University, United States

10:20-10:40 Speaker: Peter FARNDON, BHAM, United Kingdom

10:40-11:10 Speaker: Glenn PALOMAKI, Brown University, United States

11:10-11:30 Speaker: Ulf KRISTOFFERSON, EUROGENTEST, Sweden

11:30-11:45 COFFEE BREAK

11:45-12:05 Speaker: Cedric CARBONNEIL, French National Authority of Health, France

12:05-12:20 Speaker: Gerardo JIMENEZ SANCHEZ, NIGM, Mexico

12:20-12:40 Speakers: Giuseppe NOVELLI, Domenica TARUSCIO, Italy

12:40-13:00 PLENARY DISCUSSION

13:00-14:00 LUNCH
14:00-18:00  SESSION 2:  EVALUATION OF CLINICAL VALIDITY AND CLINICAL UTILITY OF GENETIC TESTS

Chair: Angela BRAND, DZPHG, Germany

14:00-14:40  Challenges in Genetic Test Evaluation: Clinical Validity and Clinical Utility

Wylie BURKE, University of Washington, United States

14:40-15:10  Testing for rare diseases: The UK Experience

Fiona STEWART, City Hospital, Belfast, United Kingdom

15:10-15:40  Testing for Pharmacogenetics: The US Experience

Al BERG, University of Washington, United States

15:40-16:00  COFFEE BREAK

16:00-16:40  Testing for BRCA: The Canadian Experience

Ingeborg BLANQUAERT, CANADA

16:40-18:00  PLENARY DISCUSSION

19:00  DINNER (to be served at 19:30)

Restaurant: Simply Heathcotes Restaurant, Jacksons Row, Deansgate, Manchester M2 5WD
DAY 2– 27 JUNE 2006

09:00-09:30  Patients’ Perspectives

Alistair KENT, GIG, United Kingdom

09:30-11:15  Working Group Parallel Sessions

Experts will be assigned to four groups and asked to review and discuss issues raised in earlier sessions. Each group will have a Moderator and a Rapporteur, who will be responsible for putting together a summary of main points and a short presentation at the end of the meeting.

11:15-11:30  COFFEE BREAK

11:30-12:30  Workgroup reports

12:30-14:00  LUNCH

14:00-16:00  Roundtable Debate

Implications for Policy

Moderators: Elettra RONCHI (OECD)/ Ingeborg BLANCQUAERT, CANADA

Discussants:

Al BERG, University of Washington, United States
Evans GARETH/Jayne SPINK, NICE, United Kingdom
Dietmar VYBIRAL, Ministry of Health, Austria
Diana PAINÉ, Department of Health, United Kingdom
Ronald TRENT, Human Genetics Advisory Group, Australia
Francois THÉPOT, Agence de la Biomédecine, France

16:00-16:30  Summary of main points from the meeting and recommendations for Policy action

Mark KROESE, SRL, United Kingdom

16:30-17:00  Closing Remarks

Bénédicte CALLAN, OECD
Rob ELLES, CMMC, United Kingdom