

EUROGENTEST

Network of Excellence

The logo features a solid maroon circle positioned behind the text. The word "Euro" is in blue, "Gent" is in white, and "test" is in blue. A thin blue horizontal line is located below the text.

EuroGentest

Project acronym : Eurogentest

Project full title : Genetic Testing in Europe – Network for test development harmonization, validation and standardization of services.

Proposal/Contract no : FP6-512148

Date of preparation :

- Letter of interest June 2002

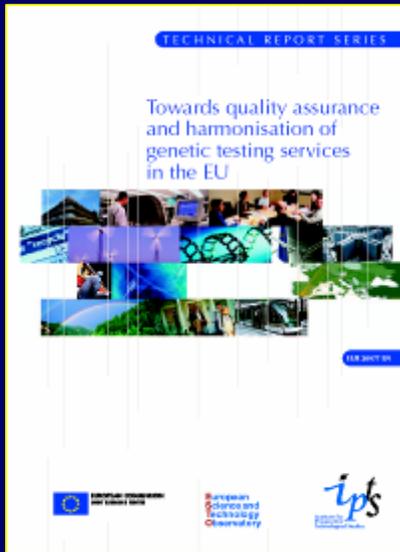
- Genetic Testing in Europe – Integrated Network for test development and harmonization of quality testing services*

- November 2002 – November 2003, preparation phase*

- 13 November 2003, Submitting project

Start date of contract : January 2005

Quality Issues in Europe



European Molecular Genetics Quality Network

EMQN



The CRMGEN Project
Certified Reference Materials for Molecular
Genetic Testing

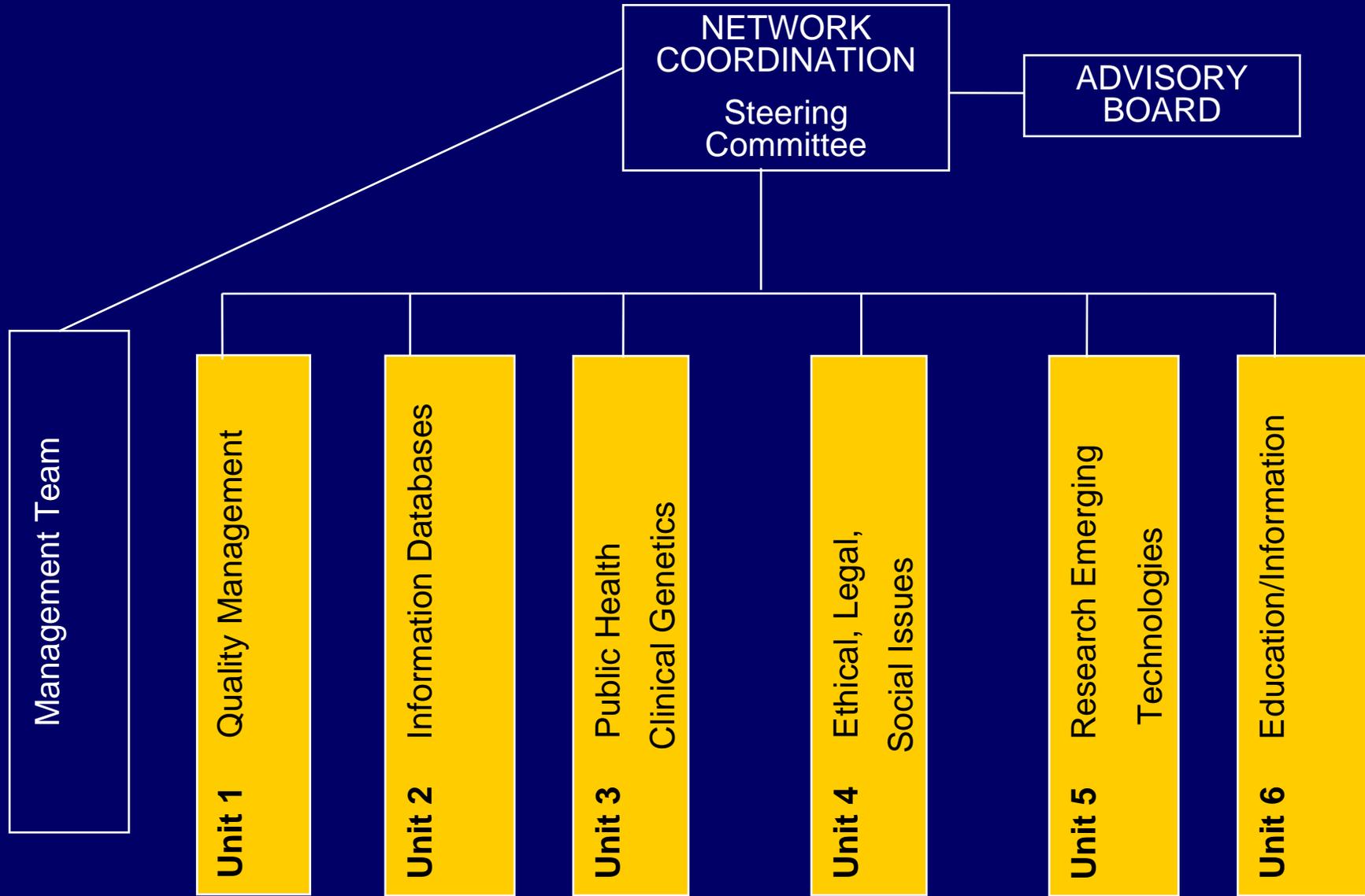


CF Cystic Fibrosis
European
Network

Quality Issues in Europe

- More than 100 laboratories / centers in different settings
- More than 1000 rare diseases can be tested
- Lack of centralized and uniform information about service
- Limited networking
- Lack of harmonized and standardized EQA / PT
- Lack of reference materials
- Limited number of QA accredited labs
- Need for more information / training to lab in QAu issues
- Limited analytical and clinical validation of tests
- Insufficient counseling

Network of Excellence: “EUROGENTEST”



WP Coordination; IPR issues; Fellowships; Health Policy issues; Expert Laboratories Network

EUROGENTEST

coordinator Cassiman JJ (B) / Matthijs G (B)

Unit 1: Quality Management and accreditation / certification of genetic testing
Dequeker E (B) / Morris M (CH)

Unit 2: Information sources and bio-informatics tools.
Ayme S (F) / Dallapiccola (I)

Unit 3: Clinical Genetics, Community Genetics and Public Health
Kristofferson U (Sw) / Schmidtke J (D) / Kaäriänen H (Fin)

Unit 4: Ethical, Legal, Social Policy Issues
Nys H (B) / Sequiros J (P)

Unit 5: Research and Emerging Technologies
Bakker B (NI) / Matthijs G (B) / Macek M (Cz)

Unit 6: Education and Information
Kent A (UK) / Coviello D (I)

List of Participants

Coordination

J-J Cassiman, coordinator, BE
G Matthijs, assist. coordinator, BE

Management

A Vyverman, BE

Unit 1

E Dequeker – coordinator, BE
M Morris – co-coordinator, CH
R Elles, UK
R Hastings, UK
B Fowler, CH
D Barton, IRL
G Matthijs, BE

Unit 2

A Ségolène – coordinator, FR
B Dallapiccola – co-coordinator, IT
L Vanmaldergem, BE
A Devereau, UK

Unit 3

U Kristofferson – coordinator, SE
H Kääräinen – co-coordinator, FIN
J Schmidtke – co-coordinator, DE

Unit 4

H Nys – coordinator, BE
J Sequeiros, P - co-coordinator, PT
K Dierickx, BE

Unit 5

B Bakker – coordinator, NL
G Mathijs – co-coordinator, BE
M Macek – co-coordinator, CZ
G Van Overwalle, BE

Unit 6

A Kent – coordinator, UK
D Coviello – co-coordinator, IT

Developing Countries

D Radojkovic, YU
J-C Ruiz Cabezas, Ecuador

SME's Participants

J Schouten, NL
D Bishop, UK
P Rosseel, BE
F Orfeu, PT
D Atlan, BE
P Stanssens, BE

Members Advisory Board

National Center for Rare Disease, Roma, Italy: **Domenica Taruscio**

EuropaBio, Brussels, Belgium: **Erik Tambuyzer**

EDMA, Brussels, Belgium **Christine Tarrajat**

EFB European Federation of Biotechnology, Delft, Netherlands, **David Bennett**

OECD, Paris, France : **Elettra Ronchi**

PHPPO/CDD, Laboratory systems, Atlanta, USA: **Joe Boone**

KUL, BE: **Koen Debackere**

Hôpital Cochin, Paris, France: **Marc Delpech**

ESHG, Birmingham, UK: **Farndon Peter**

ACMG, USA: **Carolyn Sue Richards Houston**

WHO, Geneva, Switzerland: **Victor Boulyenkov**

EMA, London, UK: **Marisa Papaluca, Patrick Leourtois**

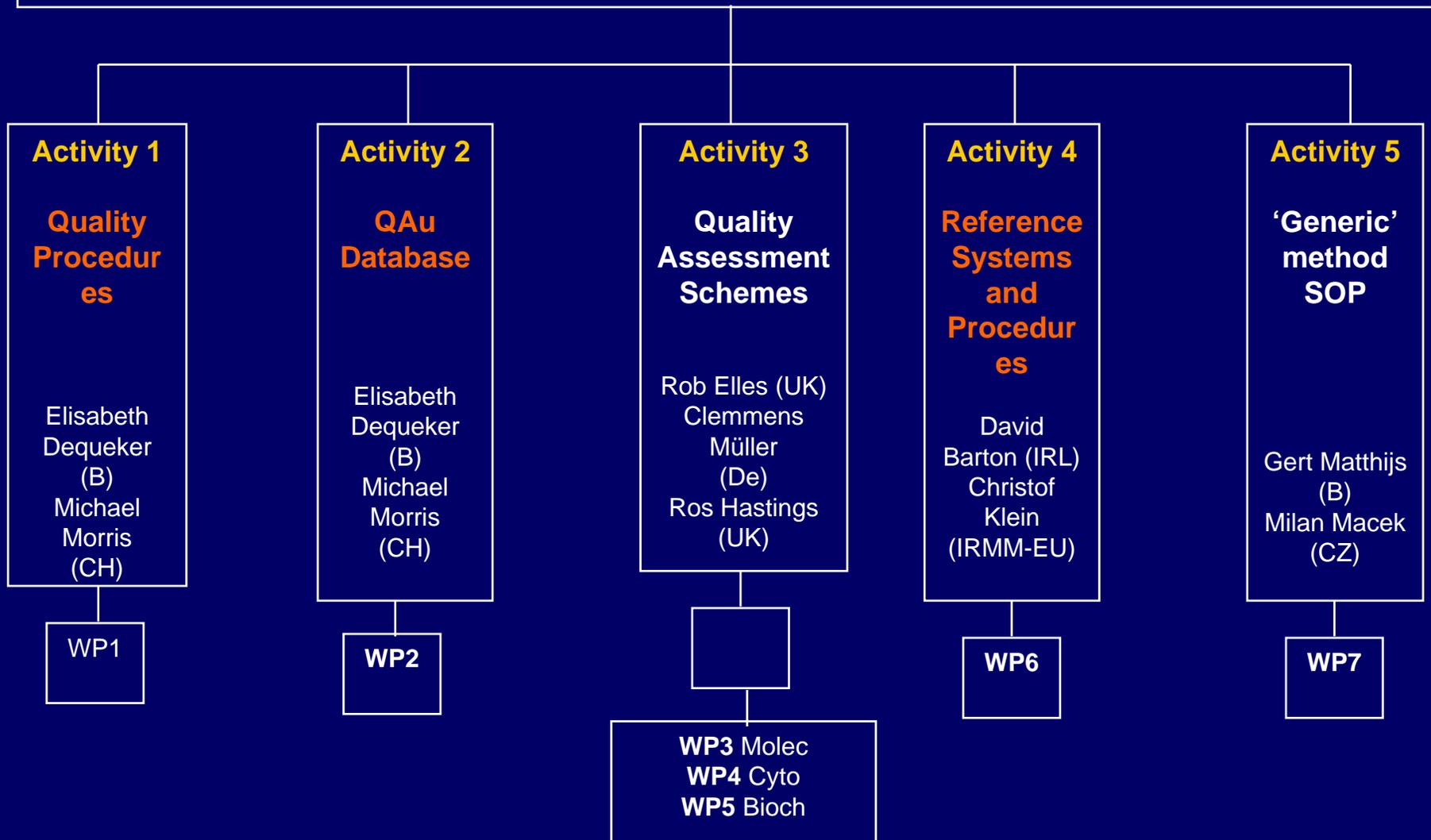
National Societies representative, University of Verona, Italy: **Pier Franco Pignatti,**

Institut für Human Genetik, Heidelberg, Germany: **Claus Bartram.**

Unit 1:

Quality Management and Accreditation/Certification of Genetic Testing

Elisabeth Dequeker (B)/Michael Morris (CH)



Unit 2:

Information sources and bio-informatics tools

Segolene Ayme (F)/Bruno Dallapiccola

Activity 6

**Harmonization of databases
on genetic testing**

Segolene Ayme (F)
Bruno Dallapiccola (I)
L. Van Maldergem (B)
A. Devereau (UK)

WP 8

WP 9

WP10

Activity 7

**Updating the
EDDNAL
database**

L. Van
Maldergem
(B)

WP 11

Unit 3:
Clinical Genetics, Community Genetics and Public Health

Ulf Kristoffersson (S) / Joerg Schmidtke (D) / Helena Kaariainen (FIN)

Activity 8

**HTA and
Clinical
validation**

Ulf Kristoffersson
(S)
Joerg Schmidtke
(D)

WP 12

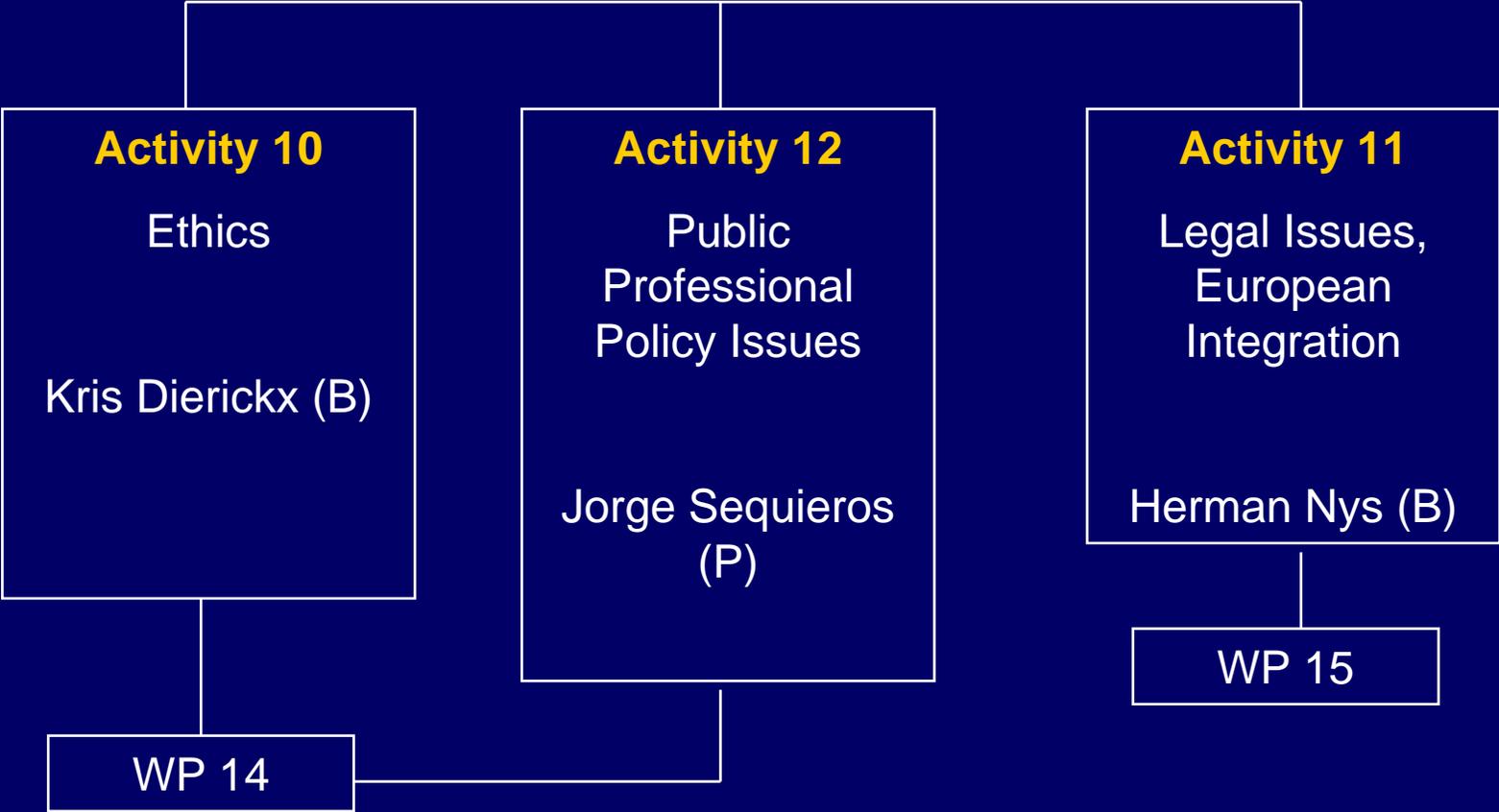
Activity 9

**Quality
Genetic
Counseling**

Helena
Kaariainen
(Fin)
Jörg Sequeiros
(P)

WP 13

Unit 4:
Ethical, Legal, Social Policy Issues
Herman Nys (B)/Jorge Sequieros (P)



Unit 5:
Research and Emerging Technologies

Bert Bakker (NL) /Gert Matthijs (B) /Milan Macek (CZ)

Activity 13

**Analytical/
Technological
Validation**

Gert Matthijs
(B)
Milan Macek
(CZ)

WP16

Activity 14

**Technical
Evaluation/
Implement
Network**

Bert Bakker
(NL)

WP17

Activity 15

IPR Issues

Geertrui
Van Overwalle
(B)

WP18

Unit 6: Education

Alastair Kent (UK) / Domenico Coviello (I)

Activity 16

**Education
Training of the
public**

Alastair Kent (UK)
Domenico Coviello
(I)

WP19

Activity 17

**Education
Training of the
professionals**

Alastair Kent (UK)
Domenico Coviello
(I)

WP20

Work package

Objectives

Description of work

Deliverables

Milestones and expected results

WP1 Quality Procedures

Objectives related to QC material project CDC

Harmonize the quality systems and accreditation / certification requirements for genetic testing services and EQA / PT schemes in Europe:

- Determine the specific requirements for accreditation of genetic testing services.
- Develop and disseminate guidelines.
- Organize Training Courses and Workshops for genetic testing services undertaking accreditation, scheme organizers and quality assessors.

WP1 Quality Procedures

Description of work

Organize meetings and teleconferences with representatives of EA, national accreditation organizations (SWEDAC, SAS, BELAC, CPA, CCKL, etc) and other interested parties (ISO, ESHG, OECD, CAP, CDC, HGSA)

- to review the existing standards and guidelines for laboratory accreditation and for certification;
- to determine the specific requirements for accreditation of genetic testing laboratories and for certification of EQA schemes.

Develop draft guidelines for accreditation of genetic testing services, to harmonize standards and the criteria applied by auditors:

- disseminate the guidelines to accreditation and genetic testing services.

WP2 QAu database

Objectives related to QC material project CDC

Determine the current status of Quality Assurance (QAu) in European Genetics Laboratories.

Make QAu information of European laboratories publicly available:

- To disseminate information to potential partners and/or consumers (patients, doctors, laboratories, support associations, companies) to facilitate informed choice of a medical genetics laboratory.
- To encourage participation in QAu by providing added value for participating laboratories.
- To increase public confidence by increasing transparency and public awareness of the investment in quality assurance.

WP2 QAu database

Description of work

Research current QAu status in European laboratories

Existence of SOP's and internal quality control

Participation in EQA / PT

Create and maintain a database with QAu information of European Laboratories

WP6 Reference Systems and Procedures

Objectives (1)

1. To identify and describe the present and future needs for Reference Materials (RM) and Reference Measurement Procedures (RMP) for genetic testing.
2. To set priorities for the development of new Reference Materials and new Reference Measurement Procedures (which combine to define Reference Measurement Systems)
3. To support implementation of traceability for routine diagnostic methods to described RMs and/or RMPs.
4. To support implementation of traceability for In Vitro Diagnostic Devices (IVDs) to described RMs and/or RMPs with the respective manufacturers

WP6 Reference Systems and Procedures

Objectives (2)

5. To support improvement of quality and harmonization of genetic testing by definition of guidelines for the development of Reference Measurement Procedures and Reference Materials in this field.
6. To build an enduring network, involving all the key stakeholders in Reference Measurement Systems development.
7. To disseminate and leverage the knowledge gained during the CRMGEN project into practical applications in diagnostic molecular genetics.

WP6 Reference Systems and Procedures

Description of work

Networking of stakeholders in RM's development

Sharing of knowledge, experience and expertise in DNA based RM development via three types of actions:

1. Series of symposia on RM Development
2. Focused meetings of technical sub-groups
3. Co-operation in focused RM development projects.

Main deliverables EUROAGENTEST

- ✓ Guidelines and recommendations for quality assurance of genetic testing and counseling.
- ✓ Availability of quality reviewed information (what, how, where) about genetic testing
- ✓ Training of laboratory, medical, non-medical personell
- ✓ Structuring and harmonization of testing in Europe
- ✓ Networking and reference laboratories
- ✓ International collaboration (OECD, ACMG, IFHGS)
- ✓ Evaluation of impact of procedures on society (economic, social, legal)

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More information available after starting date
www.eurogentest.org