# Belgian Medical Genomics Initiative (BeMGI): genetic testing and reimbursement in Belgium

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# Overview

- Organisation of genetic services in Belgium
    - Reimbursement system

- (Rare Disease Plan)
- (Cancer)

- (Plan for the) introduction of ‘genomics’
    - Prenatal CGH arrays
    - Targeted panels, exomes

- Europe
    - Recommendations on genetic services (Council of Europe)
    - Guidelines for diagnostic NGS testing (EuroGentest)

# Genetic testing in Belgium

- Public healthcare system

- 8 genetic centres (regulated by law since 1987)
  linked to academic hospitals (‘private-non-profit’)
  4 in Flanders, 4 in Wallonia

- Specific reimbursement system for genetic tests since 1988
  wonderfully simple and efficient

# Genetic centres in Belgium

All (8) universities/university hospitals have a "center for human/medical genetics".

Funded in part:

- by the regional governments "for service to the patients and public, and for research (development)"
- by the national health care system on the basis of clinical/diagnostic activities
- by research grants

# Reimbursement

- Specific reimbursement system since 1988
  - Cytogenetic, molecular and biochemical tests
  - Prenatal tests

- Since 2013:
  - Stratified reimbursment of (molecular) genetic tests
  - Reimbursement for consultations (counseling)
  - Reimbursement for samples sent abroad

!!!! Accreditation (ISO 15189) of the lab is an obligation !!!!

"A.R. 22.7.1988" (en vigueur 1.8.1988)

**"SECTION II. Examens génétiques.**

**Art. 33. § 1er.** Sont considérés comme prestations qui requièrent la qualification de médecin visé au § 2 :

Examens génétiques :

| | | |
|---|---|---|
| Caryogramme (autres cas que ceux prévus à la prestation n° 588652 - 588663) **€ 327** | B | 8000 |
| Détermination de la chromatine sexuelle | B | 209 |
| Caryogramme sur culture de cellules amniotiques **€ 327** | B | 8000 |
| Mise en culture de cellules amniotiques en vue d'un caryogramme (prestation n° 588652 - 588663) et/ou d'un dosage d'enzymes intracellulaires (prestation n° 588733 - 588744) (ne peut être portée en compte qu'une fois même si les deux prestations n°s 588652 - 588663 et 588733 - 588744 ont dû être effectuées) | B | 3000 |
| Recherche d'anomalies génétiques par les méthodes d'hybridation de fragments d'A.D.N. **€ 327** | B | 8000 |

# Reimbursement

- The unique reimbursement system has been critized.

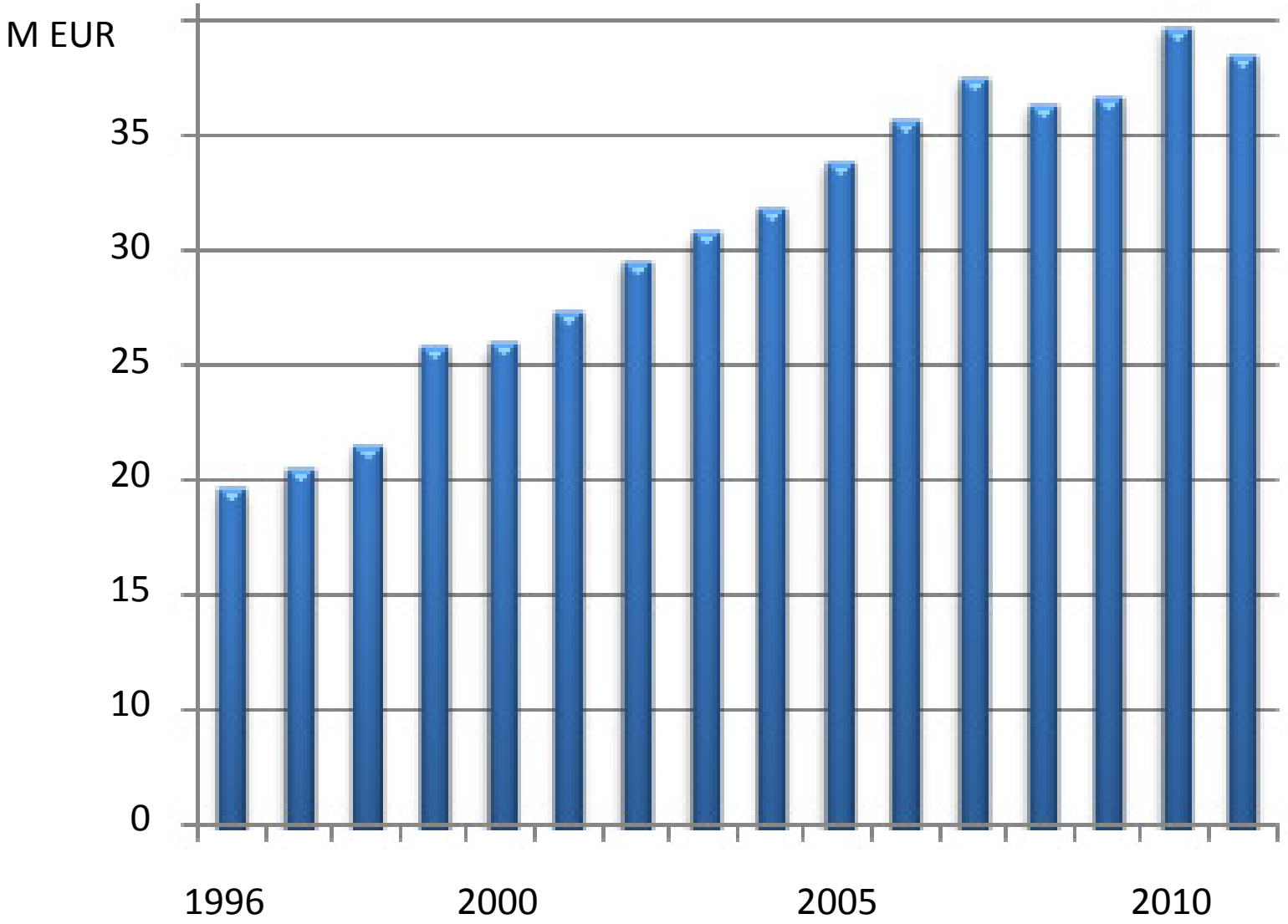
- € 327 ($ 444) for CF-testing ?
- € 327 ($ 444) for BRCA testing !

- 2001: initiative to stratify the tests
- 2013: new regulation in place

Budget: approx. 40 M EUR in 2013 (appox. 54 M USD)

for 11.099.554 inhabitants

## Genetic testing – national costs - Belgium




i'm lovin' it
MENU 4
4 productes
per menys de 4 euros
3,90€
Coca-Cola
zero

# Reimbursement

- Karyotype (€295) , FISH (€184), CGH arrays (€579)
- DNA test: a stratified system

| | | | |
|---|---|---|---|
| Simple | Hemochromatosis | € 78 | $ 105 |
| Frequent | CF, fragile X | € 155 | $ 211 |
| Typical | Duchenne, MD,… | € 357 | $ 485 |
| Complex | hemophilia, LDLR, | € 558 | $ 758 |
| Very complex | BRCA, LQT,… **+ PANELS** | € 1,377 | $ 1,871 |

- Prenatal test (€465)
- Biochemistry (€61 - € 620)

- Patient pays only € 8,68 ($ 12) !
- No reimbursement for exomes/genomes (yet)

# An exemplary system?

- All genetic centres combine clinical and laboratory activities
- Accredited diagnostic labs are closely associated with the academic research centres
- Parsimonious use of the national 'envelope' for testing
- Stratified system allows flexibility
- Development of national guidelines
- Recent initiative for reimbursement of exomes (genomes)
- System challenged by commercial companies
  - Disconnected from the needs (patient and population)
  - No genetic counselling
- Belgian Medical Genomics Initiative (BeMGI)

# Belgian Medical Genomics Initiative

- a network funded by the Interuniversity Attraction Poles (IAP) programme of the Belgian Federal Science Policy Office (BELSPO)
- Research, standardization, education, …



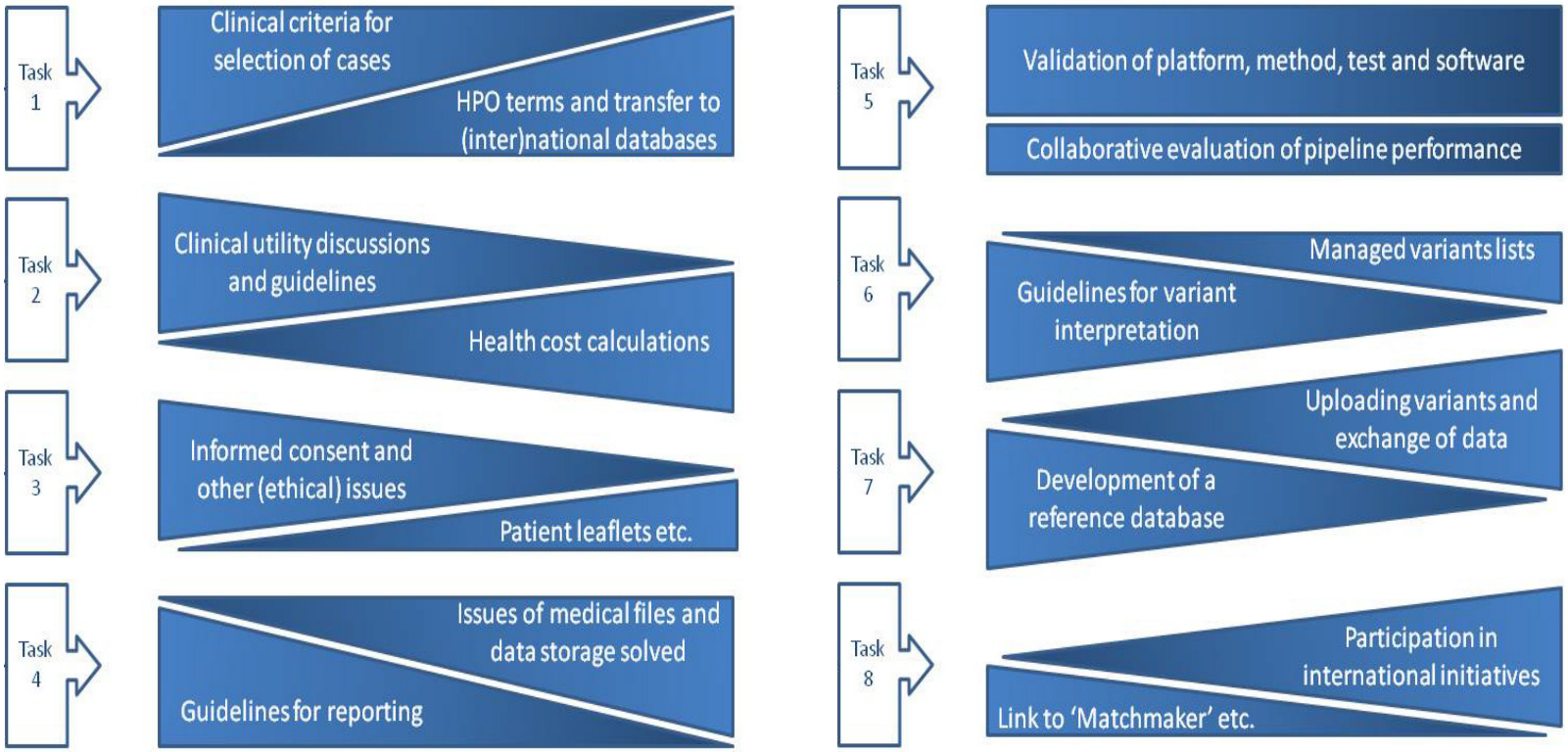




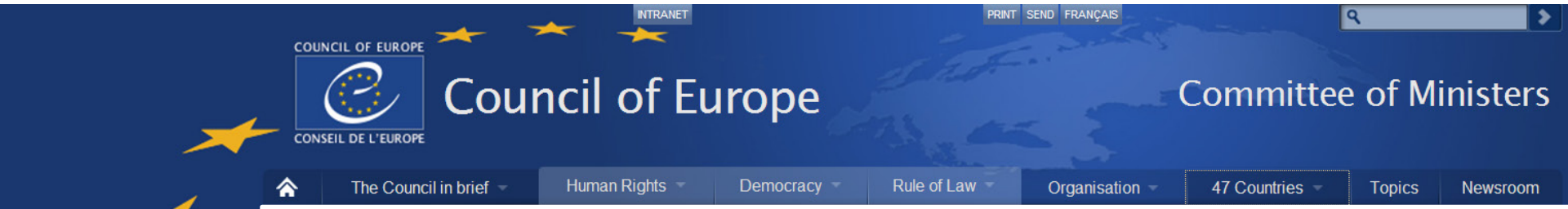


# A national plan for exomes

To create the best possible framework for exome sequencing in a clinical context



# European context



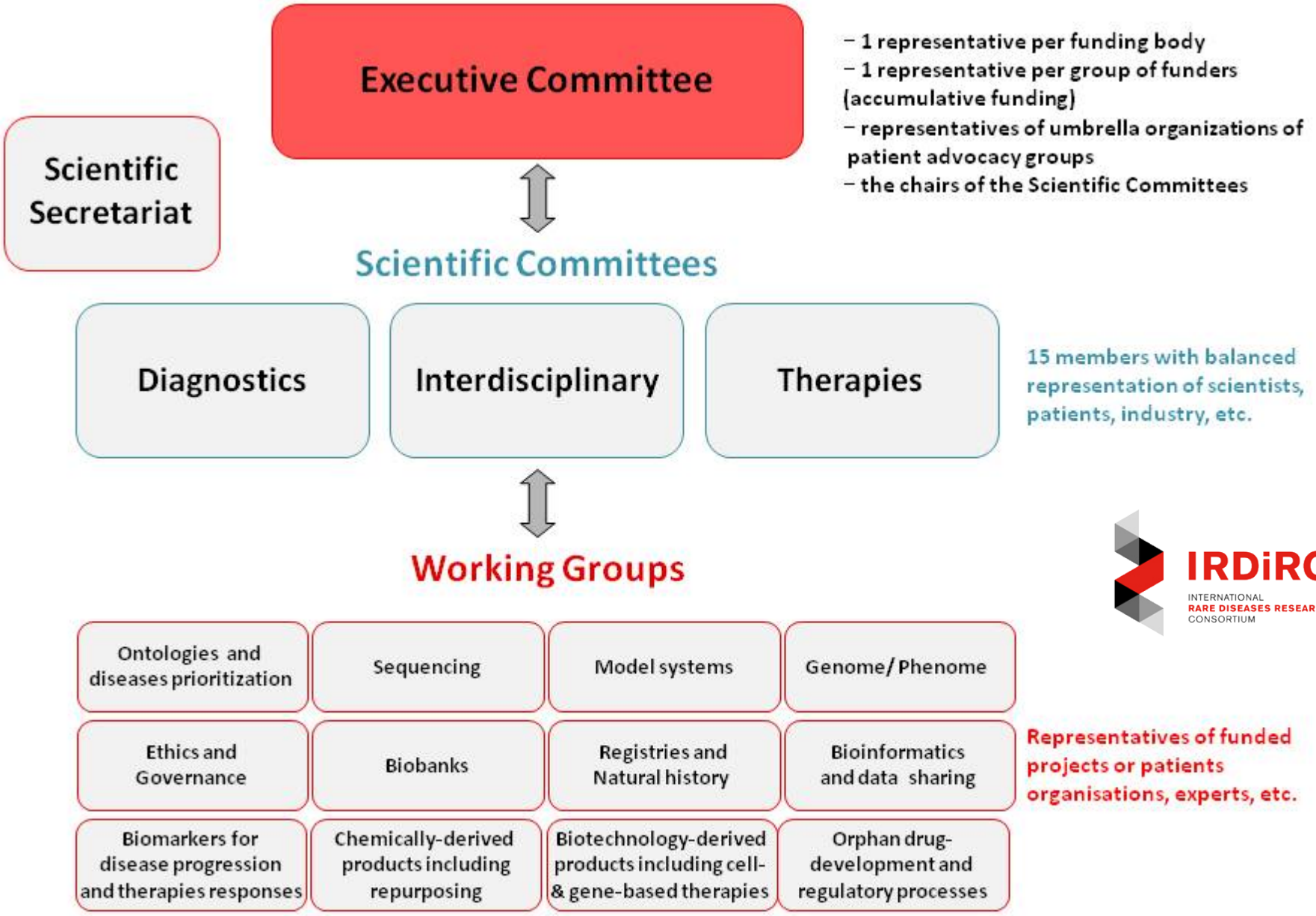

Recommendation CM/Rec(2010)11
of the Committee of Ministers to member states
on the impact of genetics on the organisation of health care services and training of health professionals

# Guidelines for diagnostic next generation sequencing

EuroGentest

- Diagnostic routing, diagnostic utility
- ‘Scoring system’ for gene panels and exomes
- Instructions for ‘incidental findings’
- Etc.

EuroGentest2 is a Coordination Action founded by the 7th Framework of the European Community (contract HEALTH-F4-2010-261469)

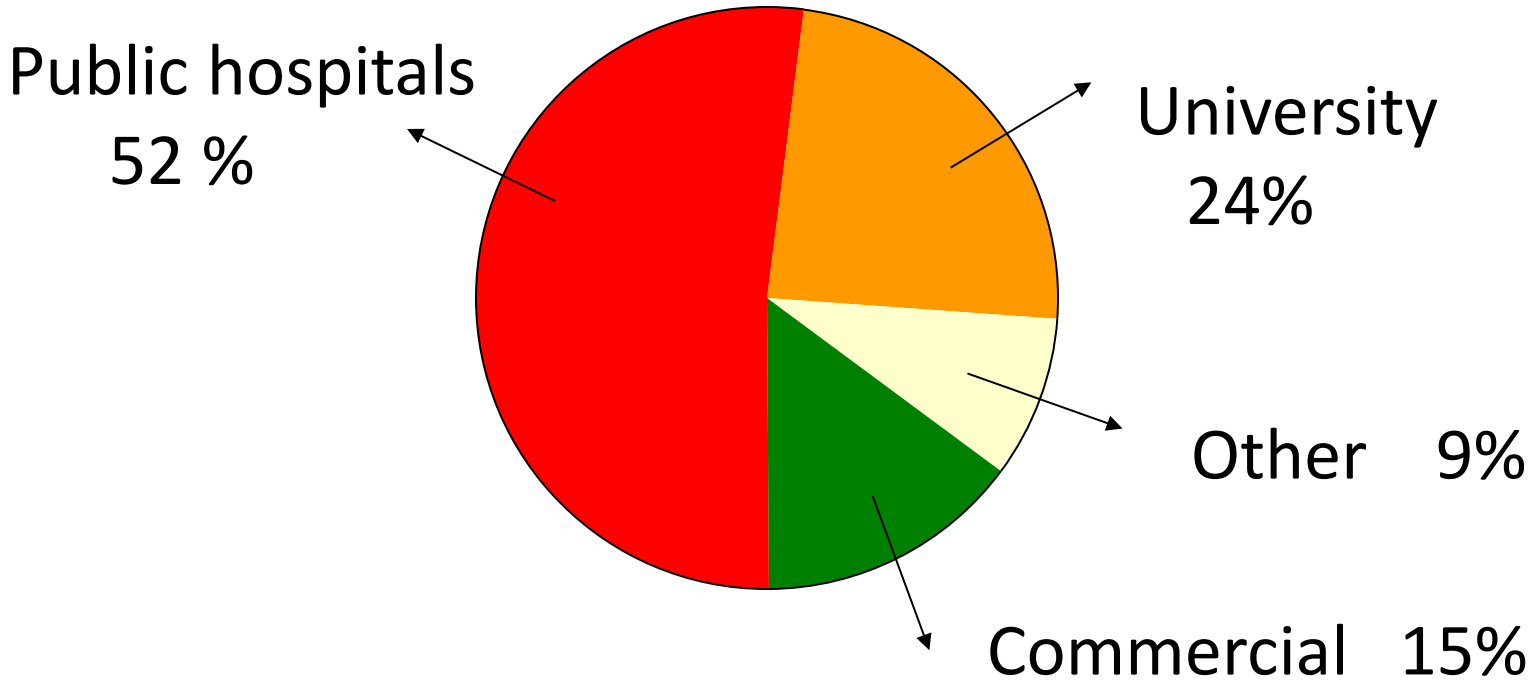

Executive Committee
– 1 representative per funding body
– 1 representative per group of funders (accumulative funding)
– representatives of umbrella organizations of patient advocacy groups
– the chairs of the Scientific Committees
Scientific Secretariat
Scientific Committees
Diagnostics
Interdisciplinary
Therapies
15 members with balanced representation of scientists, patients, industry, etc.
Working Groups
IRDiRC
INTERNATIONAL RARE DISEASES RESEARCH CONSORTIUM
Ontologies and diseases prioritization
Sequencing
Model systems
Genome/ Phenome
Ethics and Governance
Biobanks
Registries and Natural history
Bioinformatics and data sharing
Biomarkers for disease progression and therapies responses
Chemically-derived products including repurposing
Biotechnology-derived products including cell- & gene-based therapies
Orphan drug-development and regulatory processes
Representatives of funded projects or patients organisations, experts, etc.

# Additional slides

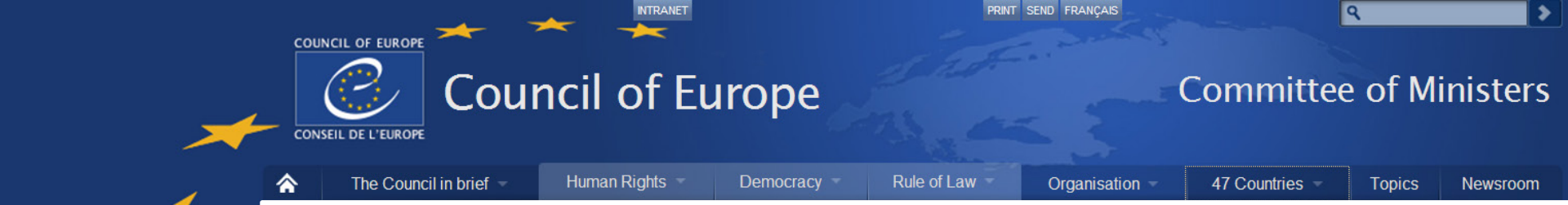
Not for presentation, for information only

# Molecular diagnostics in Europe

- Genetic testing laboratory affiliations




Source: IPTS/JRC-EC (Ibarreta et al. Towards quality assurance and harmonization of genetic testing services in the EU. Report EUR20977, 2003)




# Recommendation of the Committee of Ministers to member states.

CM/Rec (2010)11

"from specialised genetic services to genetics as an integral part of general health services"

"strengthen genetic services to maximise the benefits of genetic applications in health care for all patients"

"genetic services should incorporate clinical and laboratory facilities"

# Recommendation of the Committee of Ministers to member states.

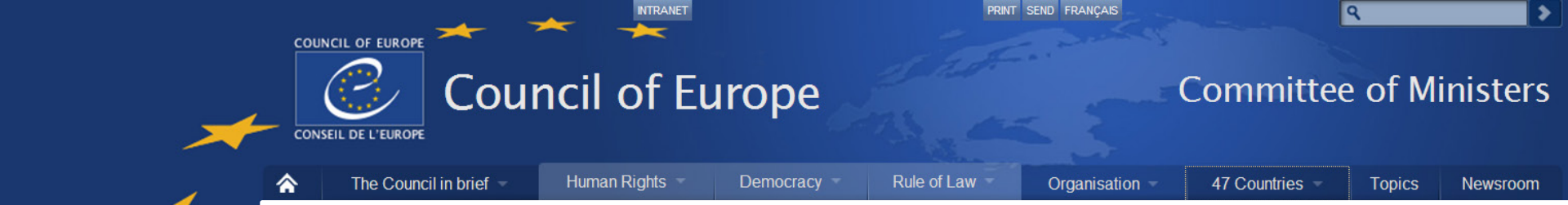
CM/Rec (2010)11

…

5. Primary care providers should have the necessary skills to assess the family history, recognise genetic risks, discuss with patients and relatives the implications of genetic disorders and to appropriately refer them to genetic services.

6. The recommendations set out in point 5 also apply to specialists in other fields of medicine.

…




# Recommendation of the Committee of Ministers to member states.

CM/Rec (2010)11

…

"…systematic assessment of the quality, effectiveness and efficiency of genetic services.

- developing and sharing standards
- clinical practice guidelines
- clinical protocols at the European level."

…

EUCERD
European Union Committee of Experts on Rare Diseases

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EUCERD

The **European Union Committee of Experts on Rare Diseases** is charged with aiding the European Commission with the preparation and implementation of Community activities in the field of rare diseases, in cooperation and consultation with the specialised bodies in Member States, the relevant European authorities in the fields of research and public health action and other relevant stakeholders acting in the field. Read more


2013 edition of the State of the Art of RD Activities report now online


8th EUCERD meeting: New recommendations adopted

IRDiRC delivers a successful and inspiring conference: a common


New EUCERD Recommendation on RD European Reference

EuroGentest

# HARMONIZING GENETIC TESTING ACROSS EUROPE



Season's greetings and best wishes for 2014 from the EuroGentest team.

## What is EuroGentest?

EuroGentest is a project funded by the European Commission to harmonize the process of genetic testing, from sampling to counseling, across Europe. The ultimate goal is to ensure that all aspects of genetic testing are of **high quality** thereby providing **accurate and reliable results for the benefit of the patients.** More...

## For specific groups

- **Genetic Laboratories**
- **Health Professionals**
- **Patients, Public & Policy**

## Workshops

Prepare for accreditation or improve your current quality management system by participating in our interactive workshops.

## Clinical Utility Gene Cards

Clear and concise documents with good practice information for disease specific genetic tests.

## Patient Leaflets

Download leaflets with information on genetic testing for patients and their family in your own language.

## Newsletters

Monthly highlights of news and events on quality and genetic testing.

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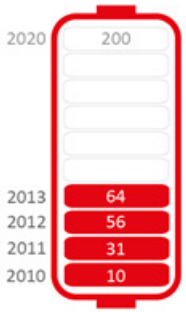


**Objective 2020: 200 new therapies**

**Disclaimer:** the numbers do not reflect IRDiRC initiatives only

More information

## SPOTLIGHT ON INITIATIVES

### FDA awards USD 14 million to 15 rare disease projects

The U.S. Food and Drug Administration (FDA) announced it has awarded 15 grants worth more than $14 million altogether which will aim to improve the course of development of products that will be valuable to patients with rare diseases. The grant applications were reviewed by...

*Full Article*

## SPOTLIGHT ON IRDIRC


orphanet
The portal for rare diseases and orphan drugs
Languages: FR EN ES DE IT PT NL
There is no disease so rare that it does not deserve attention
Homepage
Help
Contact us
Inserm
Rare diseases
Orphan drugs
Expert centres
Diagnostic tests
Research and trials
Patient organisations
Professionals and institutions
Other information
Search
EuroGentest
Register / Update your activity
Homepage » Diagnostic tests » Search
Selecteer een taal
Print
Mogelijk gemaakt door Google Google Translate
SIMPLE SEARCH
(*) mandatory field
Disease name
Gene name or symbol
OK
Country All countries
Accredited laboratories
EQA participating laboratories
OTHER SEARCH OPTION(S)
> Search by city
> Search by laboratory
> Search by professional
EuroGentest
::Help
Simple search: This screen gives access to lists of expert laboratories through a query by disease name or by gene name/symbol. You may optionally specify the country and the type of quality management (accreditation, EQA) required for the laboratory. Enter your request in the query zone, select additional desired criteria, and click on OK to validate.
You may use truncated names. A list of all names matching your query will appear. Select the one of interest to you.
Search by city: This screen provides access to lists of expert laboratories through a query by disease name or by gene name/symbol restricted to a specific city.
Search by laboratory: This screen provides access to lists of expert laboratories through a query by laboratory or institution name or EUGT number, optionally restricted to a geographical area. To define the area, select a country in the drop-down list. You may also define the services that the laboratory should provide by clicking the appropriate boxes. You may also restrict your search by medical