

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

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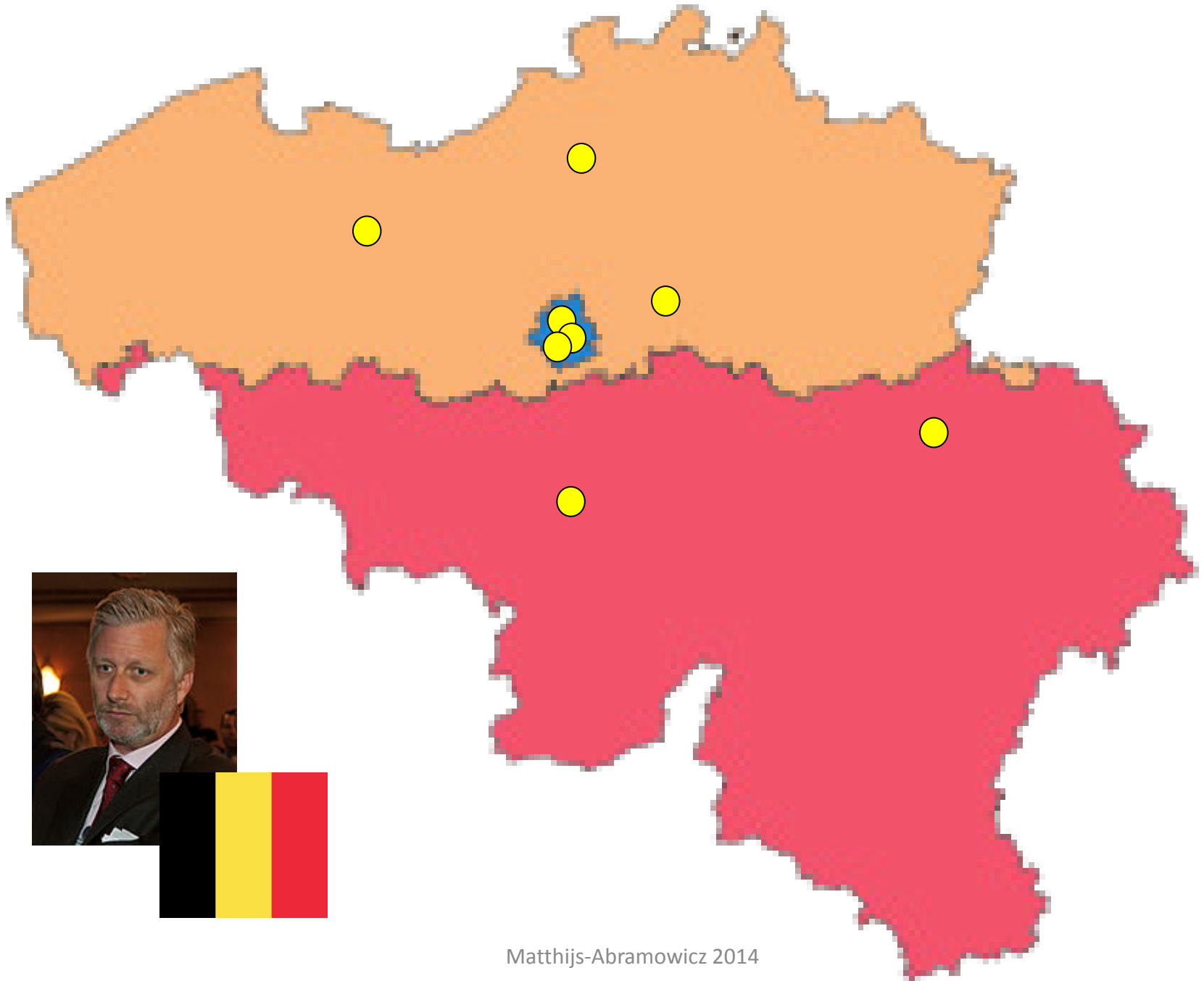
Hôpital Erasme, Université Libre de Bruxelles, Belgium

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



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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 reimbursement 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. § 1^{er}. 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

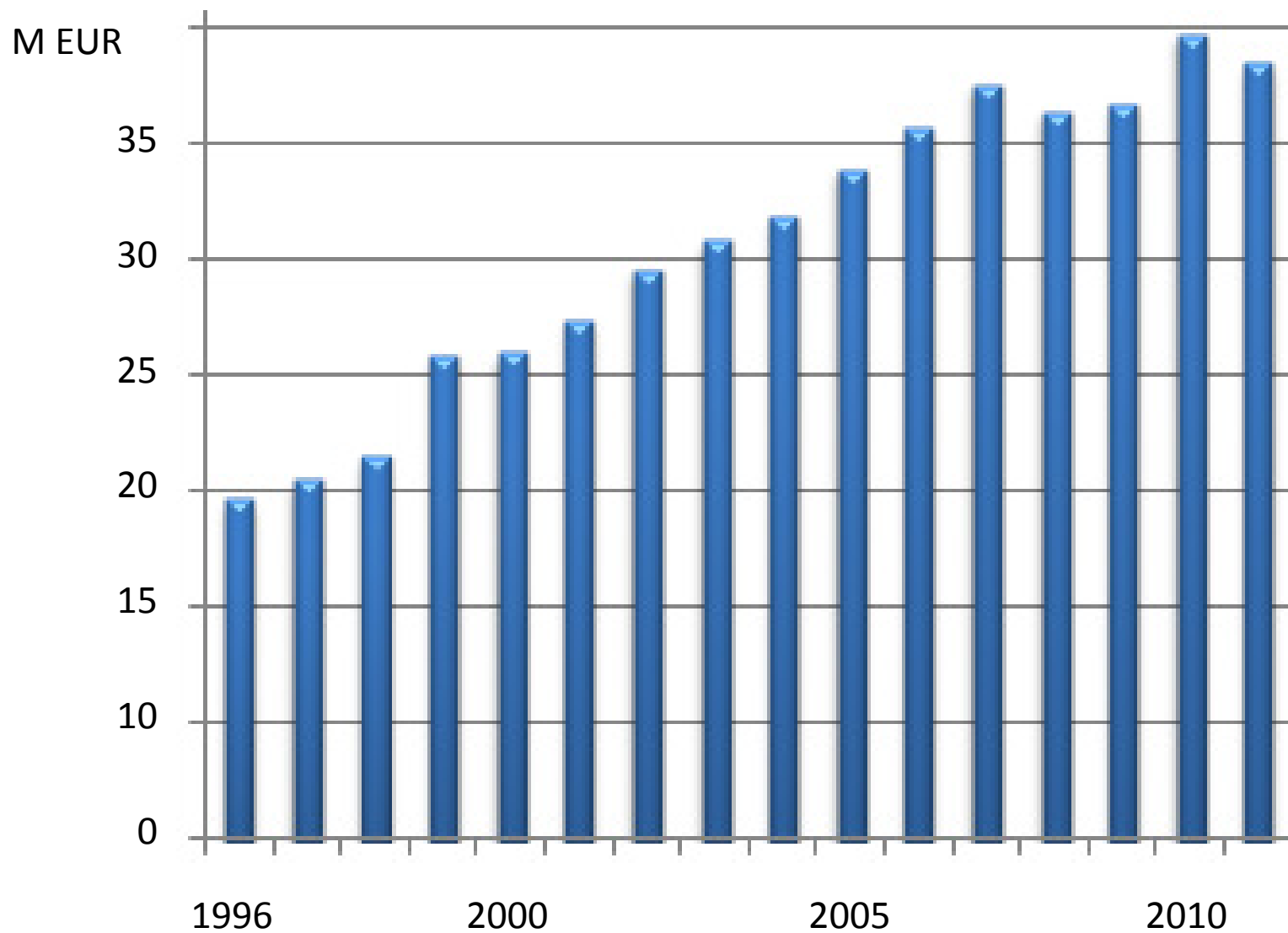
Recherche d'anomalies génétiques par les méthodes d'**hybridation de fragments d'A.D.N.** **€ 327** B 8000

Reimbursement

- The unique reimbursement system has been criticized.
- € 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 (approx. 54 M USD)
for 11.099.554 inhabitants

Genetic testing – national costs - Belgium





MENU **4**

4 productes
per menys de 4 euros



3,90€



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)

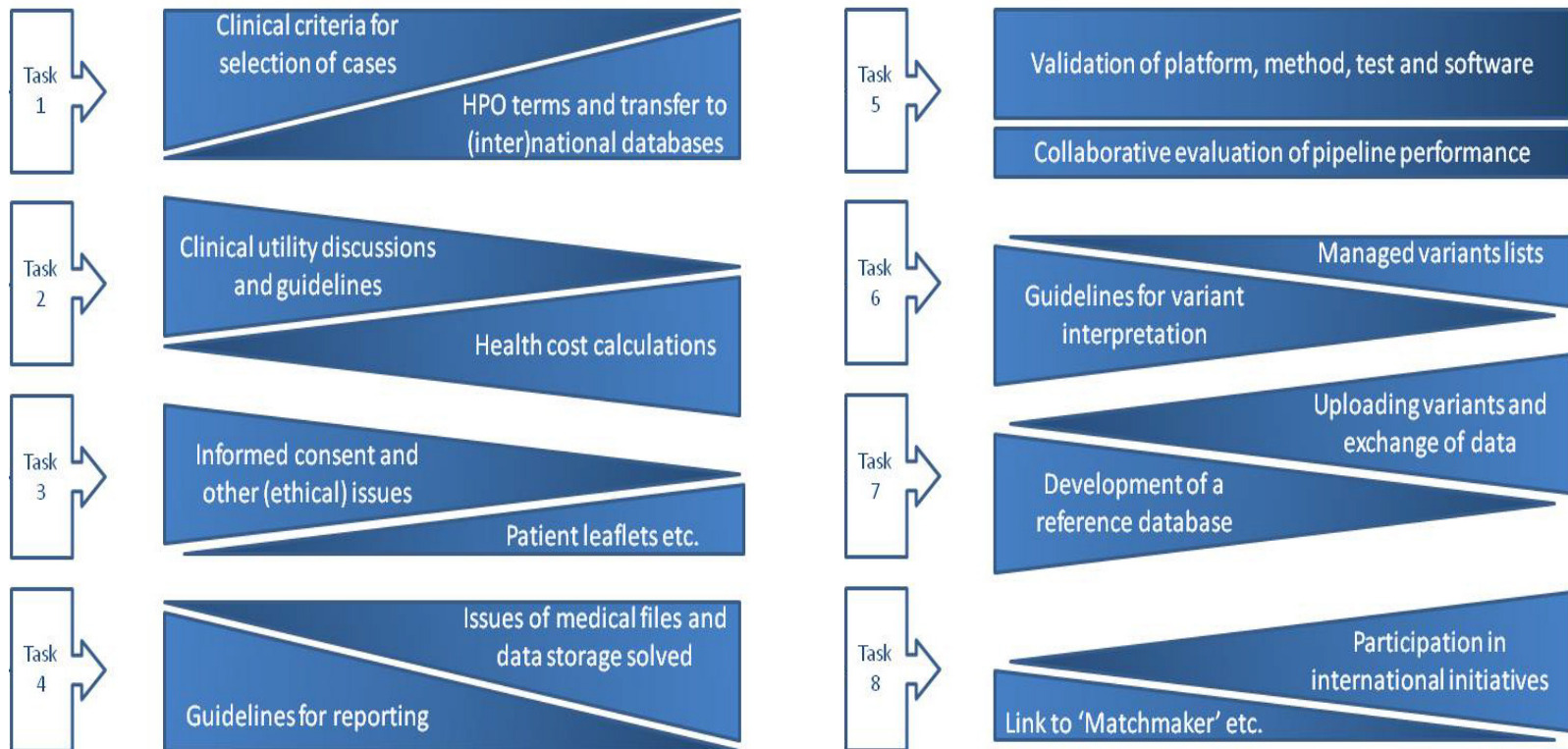
Belgian Medical Genomics Initiative

- 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



- 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



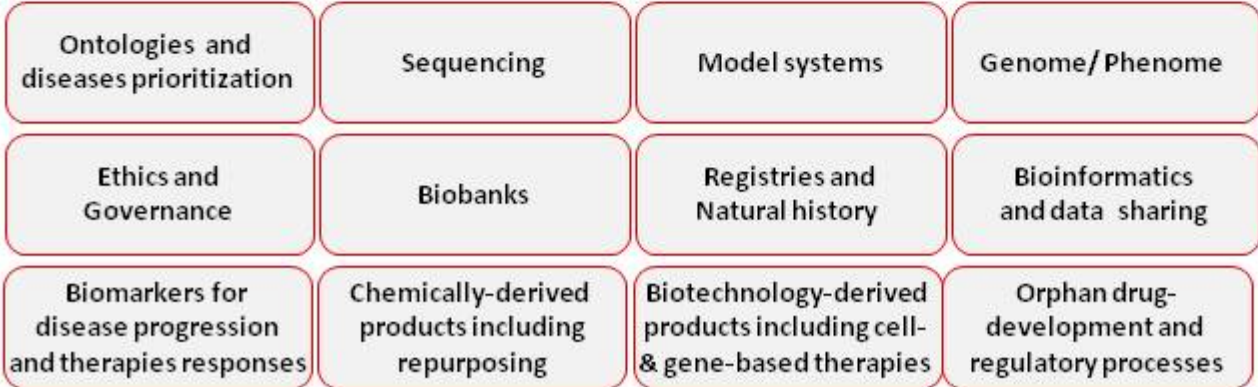
Scientific Committees



15 members with balanced representation of scientists, patients, industry, etc.



Working Groups



Representatives of funded projects or patients organisations, experts, etc.

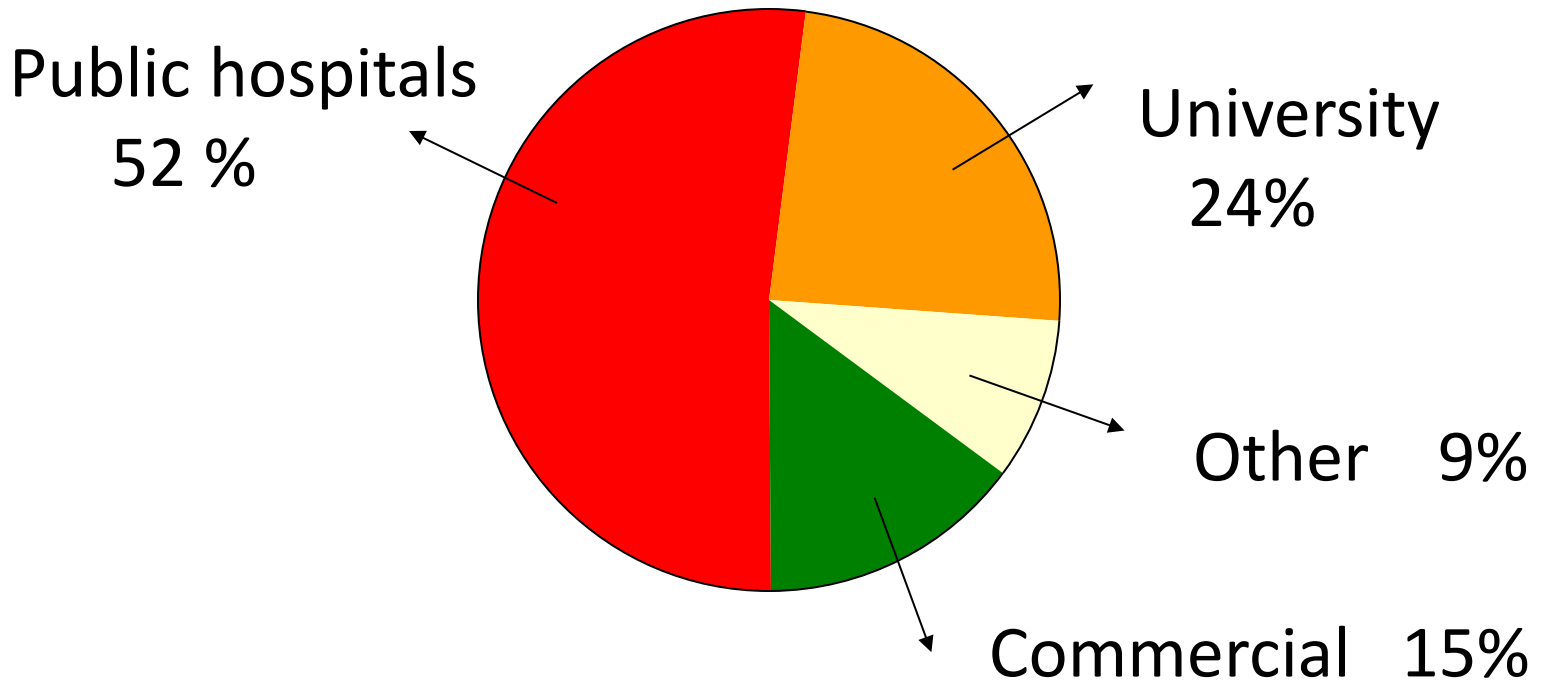


Additional slides

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.”

...



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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



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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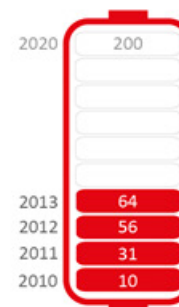
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Petition requesting amendments to the draft on Data Protection Regulation

To sign the petition click here

NEW THERAPIES



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...

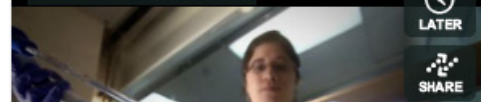
Call 44746

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SPOTLIGHT ON IRDiRC

In search of IRDiRC

from Emakina.EU **PLUS**





*There is no disease so rare
that it does not deserve attention*

Rare diseases	Orphan drugs	Expert centres	Diagnostic tests	Research and trials	Patient organisations	Professionals and institutions	Other information
Search	EuroGentest	Register / Update your activity					

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Selecteer een taal ▼

Print

Mogelijk gemaakt door Google Translate

SIMPLE SEARCH

- * Disease name
 Gene name or symbol

→ OK

(*) mandatory field

Country All countries ▼

- Accredited laboratories
 EQA participating laboratories

OTHER SEARCH OPTION(S)

- > Search by city
- > Search by laboratory
- > Search by professional



::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