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# Lab Medicine: Economics, Financing and organization in the new French / EU environment

**Bernard GOUGET**

SFBC-EFLM representative

Public Health and Medical Biology department FHF

Vice-Président Comité section Santé Humaine COFRAC

[b.gouget@fhf.fr](mailto:b.gouget@fhf.fr)



# French Health care system

general population 66,03 million

## ➤ Based on fundamental principles :

- Solidarity between all citizens
- Universal health coverage
- Diversity in the delivery of healthcare (hospital, outpatient care services)
- Patient's freedom of choice

## ➤ Built on the dichotomy between :

- Public and private sectors
- Hospital and ambulatory care

## **Public hospitals**

**Over 1000**

- 32 UHC
- 519 CH
- 89 SHC
- 324 LH

**8,5 M hospitalisations  
3,8 M outpatient care  
13 M visits to ER**

**Legal persons  
governed by public law  
with administrative and  
financial autonomy**

## **Not-for-profit hospitals**

**1444**

**1,3 M hospitalisations  
4,5 M outpatient care  
830 000 visits to ER**

**Almost the same rules  
as those applied for  
public hospitals**

## **For-profits hospitals**

**1408**

**3,3 M hospitalisations  
1,1 M outpatient care  
1,8 M visits to ER**

**Lots of small  
structures where the  
main activity is  
scheduled surgery**

## ➤ Human resources and ambulatory care :

- **Practising doctors** : 217 000 (3,3 for every 1000 inhabitants), which include over 50 % GPs.  
75 % of GPs and 68 % of specialists are in private practice
- **Dentists** : 40 599 / **Pharmacists** : 73 127
- **Midwives** : 18 800, which 16 % are private midwives
- **Nurses** : 520 000, which 14 % are in private practice

## ➤ Hospital care :

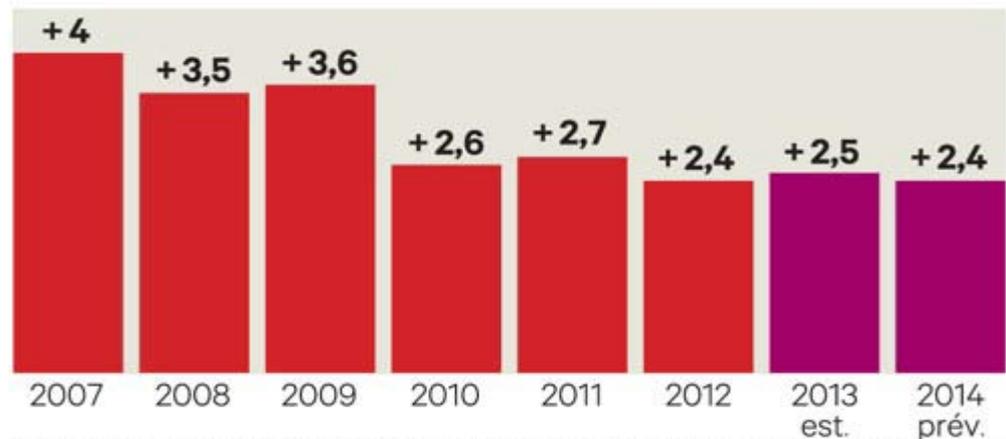
- **1 hospital for 20 000** people versus **1 for 40 000** in Europe
- 6,2 hospital beds for every 1000 inhabitants (average OECD 34 : 4,4 beds)
- 44% of the consumption of care and medical goods / 4% of GDP

**Patients are free to choose the public or the private sector, hospital or outpatient care**

- **Total Health Budget 2014 : 179,1 billion €** Ambulatory care : 81,1 billion €
  - Public and private institutions : 75,5 billion € **(41,8 % of CCMG)**
  - Medico-social : 17,6 billion €
  - Others : 1,7 billion €
- **11,6 % of GDP**
- **3275 € per capita**

## Les dépenses d'assurance-maladie

Evolution annuelle, en %



➤ **99,9% of the population covered**, thanks to the creation of :

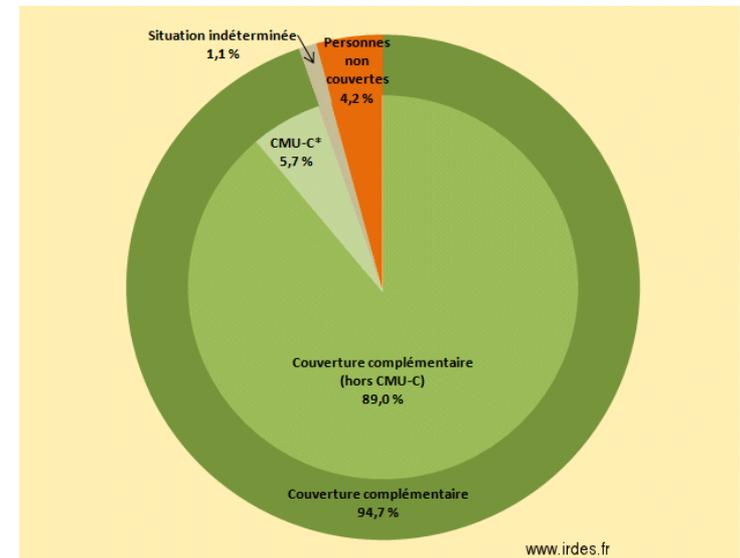
- Universal Healthcare coverage (CMU) in 1999
- Assistance with Purchasing Top-Up Health Insurance (ACS) in 2004

➤ **77,4% of health expenditures covered by the statutory health insurance**

- GP's consultation : 23 €
- Specialist's consultation : 25 €

➤ **13,8% covered by private insurers**

➤ **8,8 % of rest supported by patients**

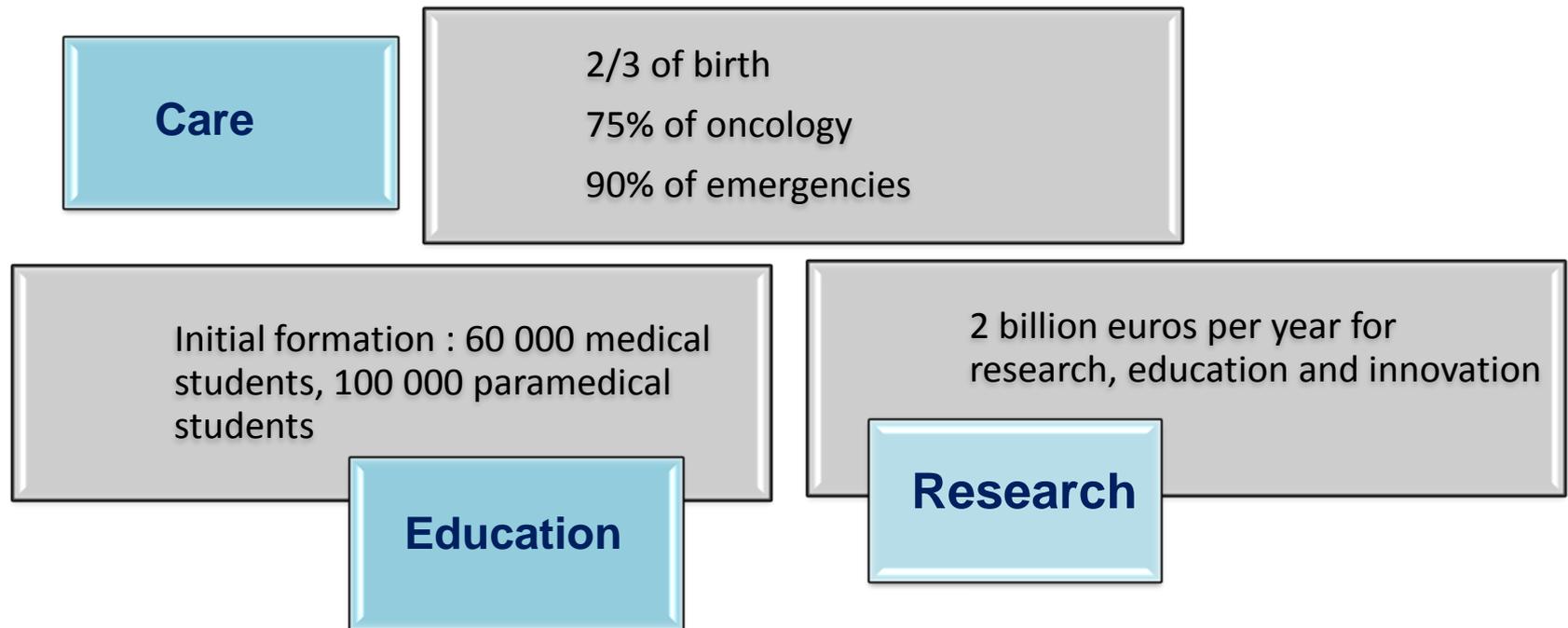


# Public Hospital : an increasing role

## ➤ A major player in economy :

- 4,6% of GDP
- 2 million direct and indirect jobs
- 16 billion euros of purchases per year

## ➤ Threefold mission :



# Public hospital : a dynamic activity

- The hospital activity has increased by 8% on the whole activities of the medical-surgery-obstetrics sphere in a 5 years period
- **Large reorganization movement implemented :**
  - Optimisation of the care pathway, ambulatory development, pooled purchasing, various externalizations
  - Cooperations with public, private and outpatients care services
- Hospital park modernisation has improved patients reception and working conditions of hospital civil servants

# Healthcare reforms : an ideological continuity

➤ For 30 years, healthcare reforms are responding to the same movement :



Redefine public hospital's position in the healthcare system



Rationalize resources to lower health insurance expenditures for public hospitals



Find the ideal management and organization



**Law  
12/18/2003**

- Transition from global budget to activity based payment

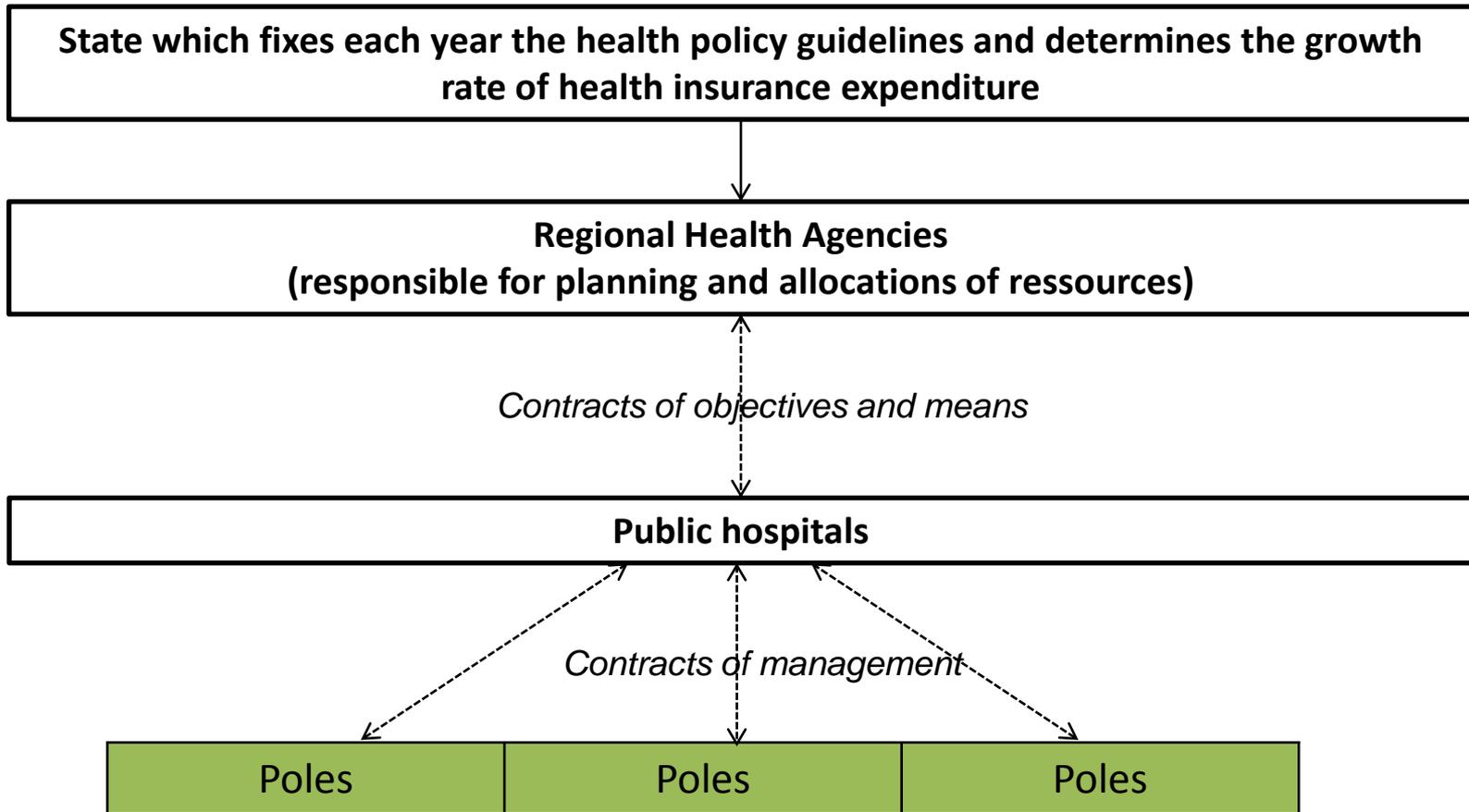
**Ordinance  
05/02/2005**

- Medical pole's setting up in order to decentralize management issues

**Law  
07/21/2009**

- Regional Health Agencies' setting up
- Renew hospital governance and strengthen the hospital director
- Facilitate cooperations

# Flow chart of health system



# Tomorrow's challenges

- **Restoring the link between local communities and hospitals**
- **Creating a real territorial public service by reinforcing cooperation between hospitals (hospital group territory)**
- **Refocusing supervisory agencies on their strategical steering mission** : RHA should propose a global viewpoint, support local actors and promote decompartmentalisation
- **Encouraging in this new context the local hospitals**, which ensure coordination with doctors from the liberal sector, medico-social structures

# Tomorrow's challenges

- **Develop alternatives to full hospitalisation** : hospital at home, hospital hotel, ambulatory medicine
- **Build a new human resources management policy** more adapted to care network
- **Improve public hospital funding** through defining a fixed part, which would correspond to public service missions, and a variable part, whose purpose is to valorize the relevant activities and cooperation actions
- **Enhance the information system** to become more efficient
- **Improve health democracy** : build a common culture between patients and professionals through the creation of the Patient Institute

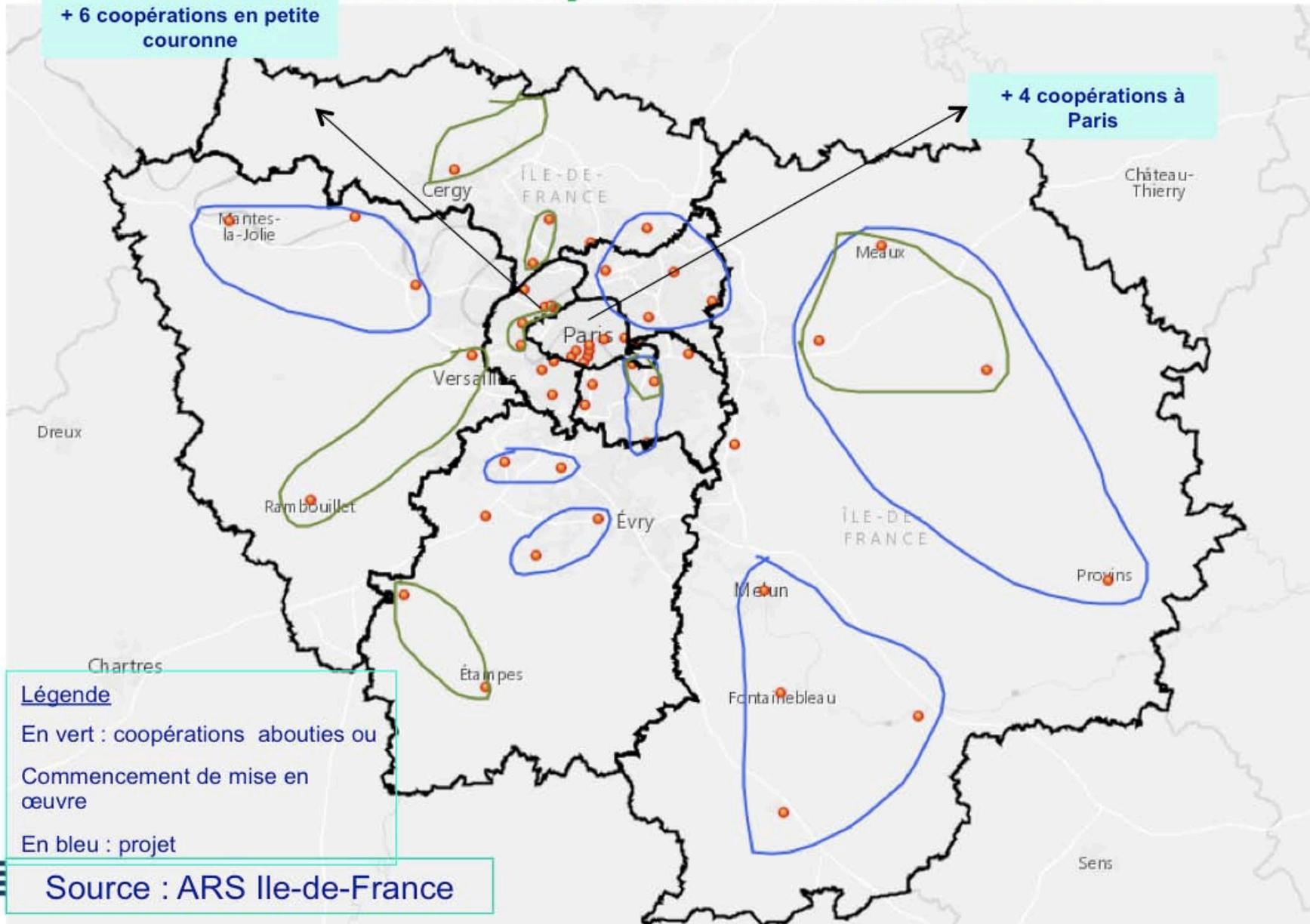


La carte des régions de France au 1er janvier 2016.

# périmètres de coopération territoriale laboratoires hospitaliers franciliens

+ 6 coopérations en petite couronne

+ 4 coopérations à Paris



## Quality Management and patient safety:

- A French procedure, compulsory, managed by the « High Health Authority » « Certification HAS »
- Accreditation of the Medical labs, histo-pathology, imagery.....

# Certification according to the High Health Authority (V2014)

- Procedure driven by experts (who do not belong to the hospital which asks for procedure)
- Who measure gaps between observed practices in the hospitals and practices which have been defined as optimal
- The aim is to write a public report on the level of quality in the different fields of the hospital



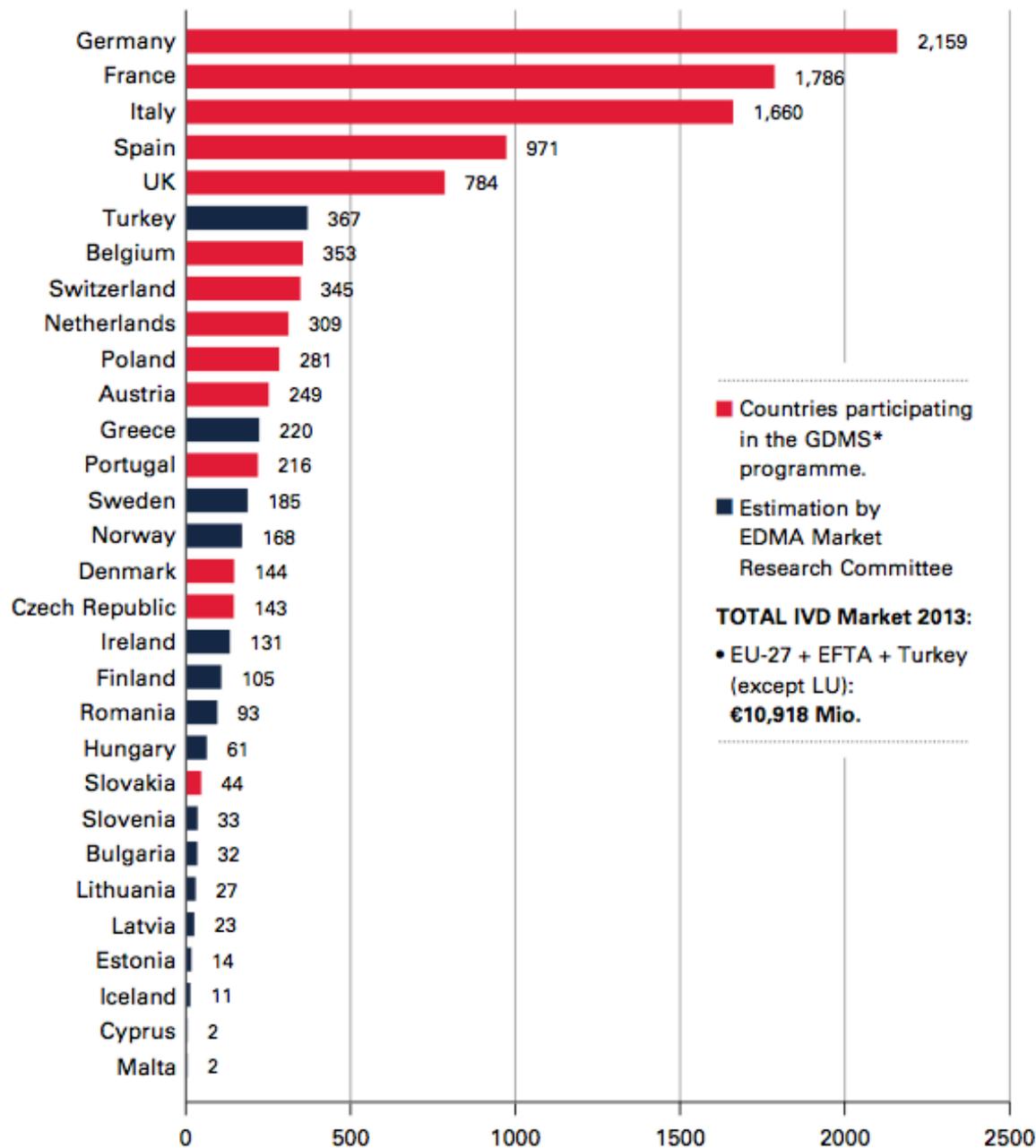
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# The French Lab Med context

- **10 000** medical biologists
- 16,5/100 000 inhabitants vs 5,8 in UE
- **7000** private sector / **3000** hospital
  
- $\frac{3}{4}$  pharmaceutical ;  $\frac{1}{4}$  medical background
- Medical Lab demography is decreasing
  
- **41 000** people are working the the private sector
- Before 2010
  - 3800 private labs
  - 1200 Hospital labs
- Today
  - **In total 1081 medical labs** ( 3600 sites) / **359 Hospital Labs** ( 32 UH)
- There is a movement for concentrating laboratories, increasingly pursued by investment funds.

# European IVD Market 2013 (million €)



Mio €

# Medical Biology in France :

## Economic aspects

**FR Gross Domestic Product (GDP): 2113 BM€**

**Total Health Budget 2014 : 179,1 billion €**

- Health 11,6%
- Hospital ( 86,7 BM €)

### Medical Biology

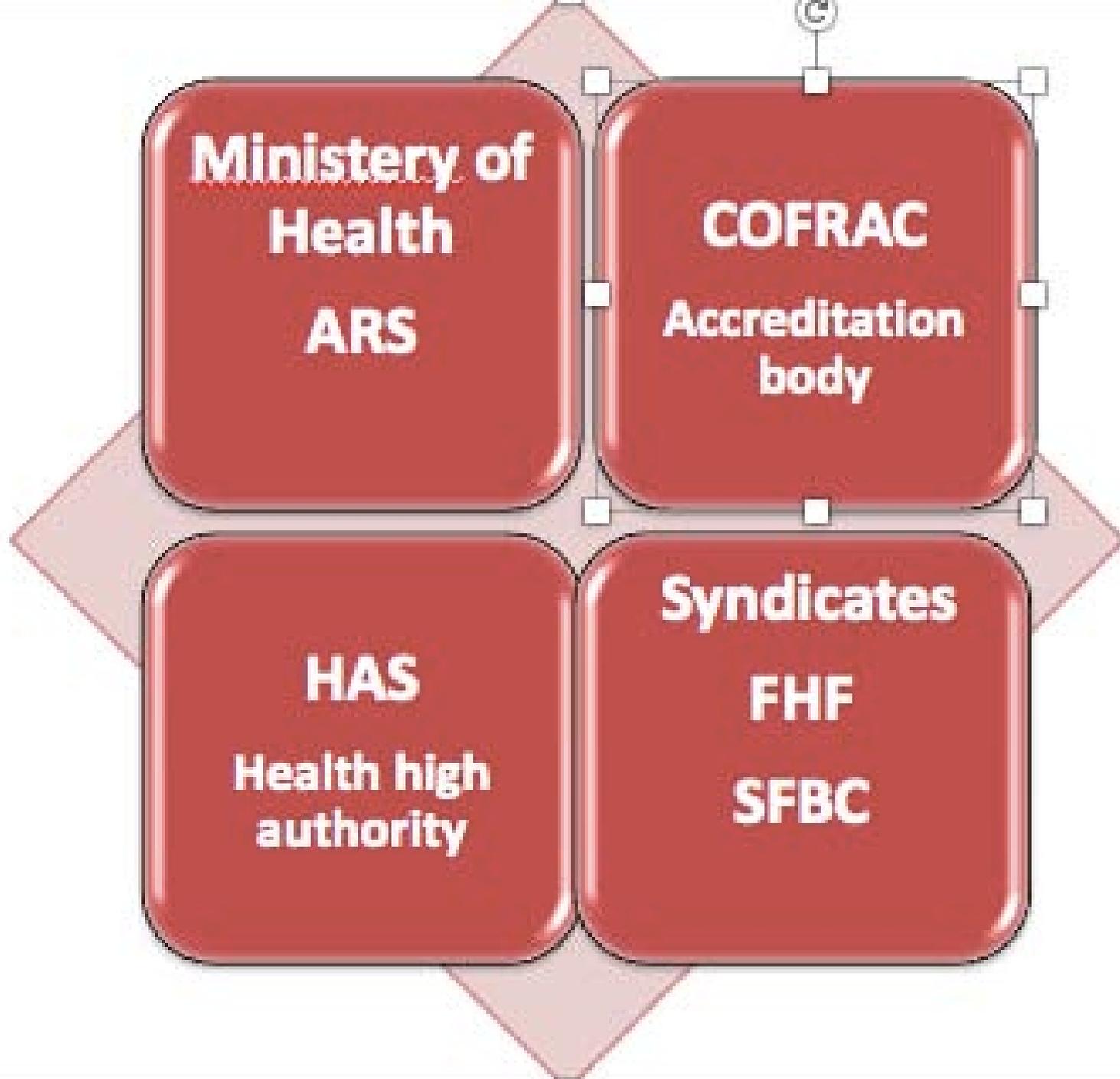
- **1,8%** routine health care expenses
- **3-5% of the Hospital Budget**
- **2,4%** Consumption of care and medical goods
- ( Total: **7,23 Md€** ( 60,5 % private Labs,6,4% clinic, 33,1% Hospital)
- **2,4 Md€ hospital, 4,83 Md€ private sector refundable by the National Health Insurance**
- **9,7%** Consumption of ambulatory health care

# History of the French reform of the medical labs

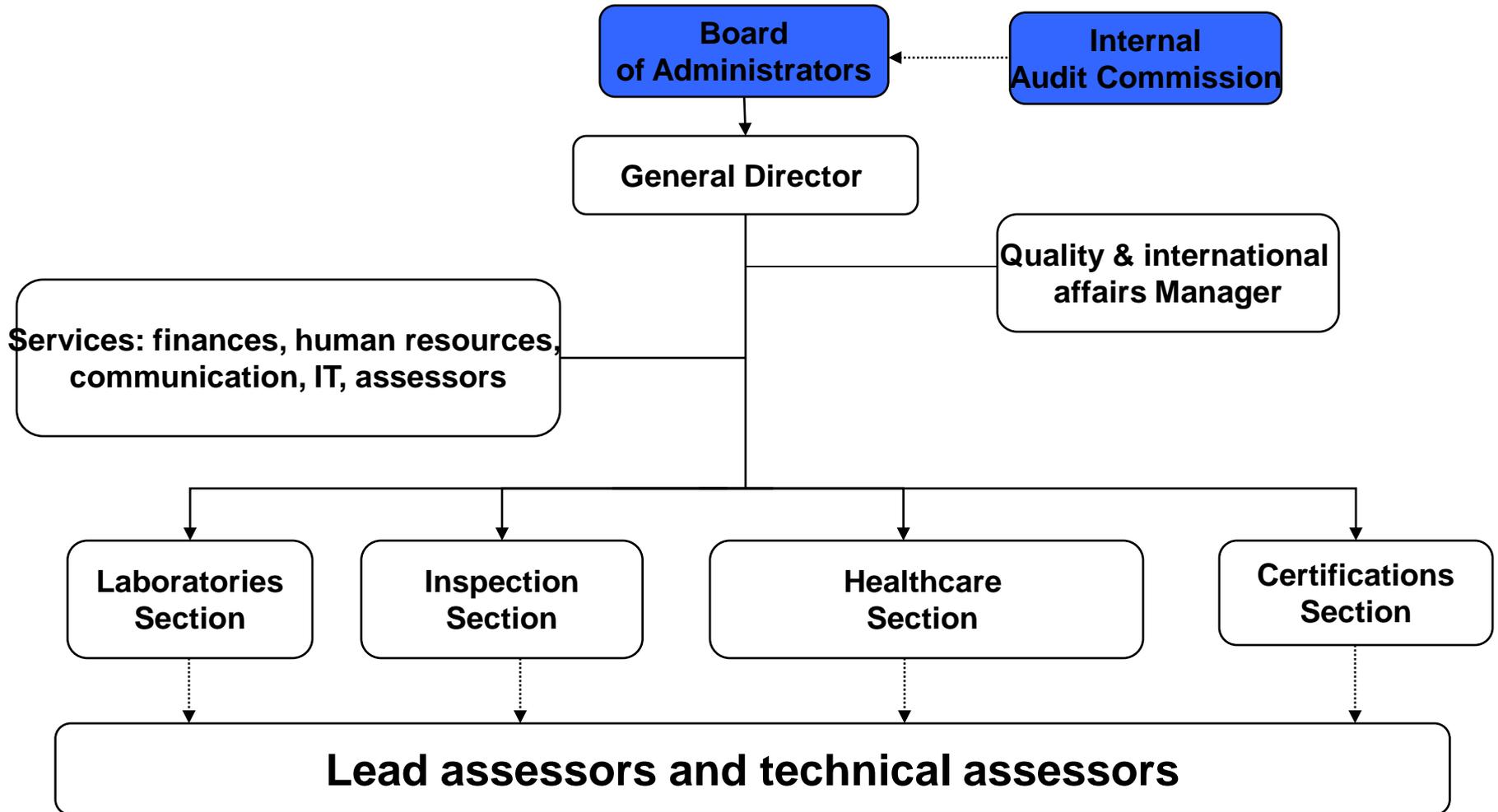
- **2009:** HPST: Art 69 de la loi n° 2009-879 du 21 juillet 2009 portant réforme de l'hôpital et relative aux patients, à la santé et aux territoires
- **2010:** Ordonnance Janvier 13 2010 (REGULATION)
- **2011:** Proposition de loi de M. Jean-Pierre Fourcade modifiant certaines dispositions de la loi n° 2009-879 du 21 juillet 2009 portant réforme de l'hôpital et relative aux patients, à la santé et aux territoires (n° 65, 2010-2011), **censurées par le Conseil constitutionnel.**
- **2012:** l'Assemblée nationale le 26 janvier 2012, Une proposition de loi de Mme Valérie Boyer, M. Jean-Luc Prével et plusieurs de leurs collègues portant réforme de la biologie médicale (n° 3989, AN XIII<sup>ème</sup> législature), reprenant le même texte, a été adoptée
- **2012:** Sénat fev 2012, **sans toutefois être inscrite à l'ordre du jour** avant la fin de la législature.
- **2013:** LOI n 2013-442 du 30 mai 2013 portant réforme sur la biologie médicale

# Four major objectives of the new law on Medical Biology (2013)

- **to ratify the 2010 ordinance** regarding laboratory medicine
- to enhance the **medicalization** of the profession.
- to harmonize the **public and private** sectors
- to **define the organization** of laboratory medicine
- to ensure the **quality of medical biology tests**.



# The Cofrac

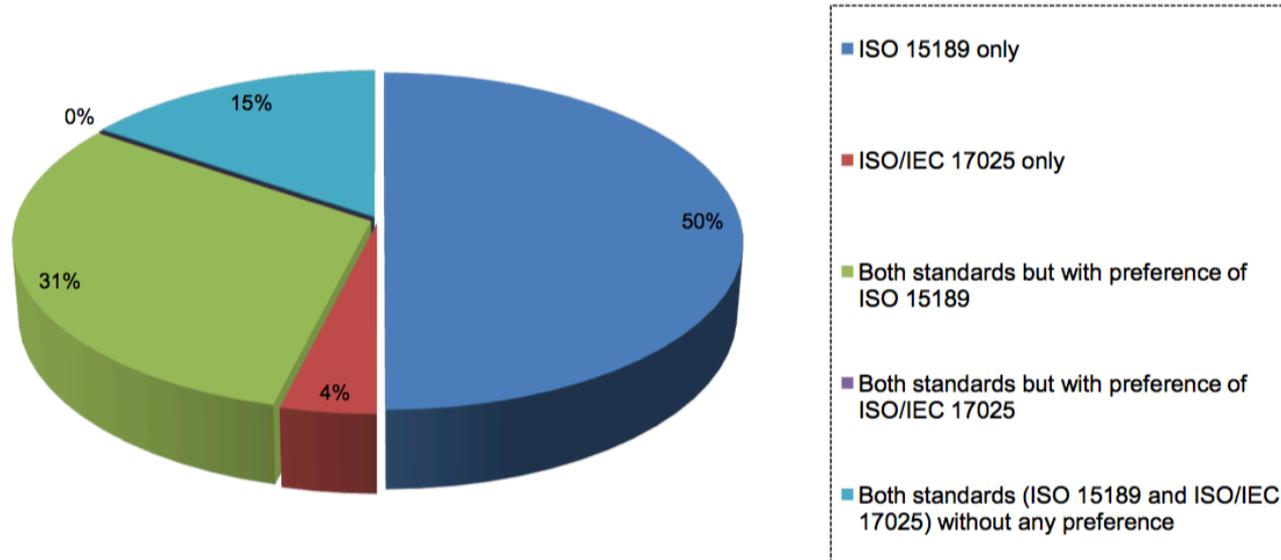


# Survey regarding accreditation of medical Labs within EA

( sent to 30 ABs received from 26 ABs)

H Mehay Cofrac (FR)

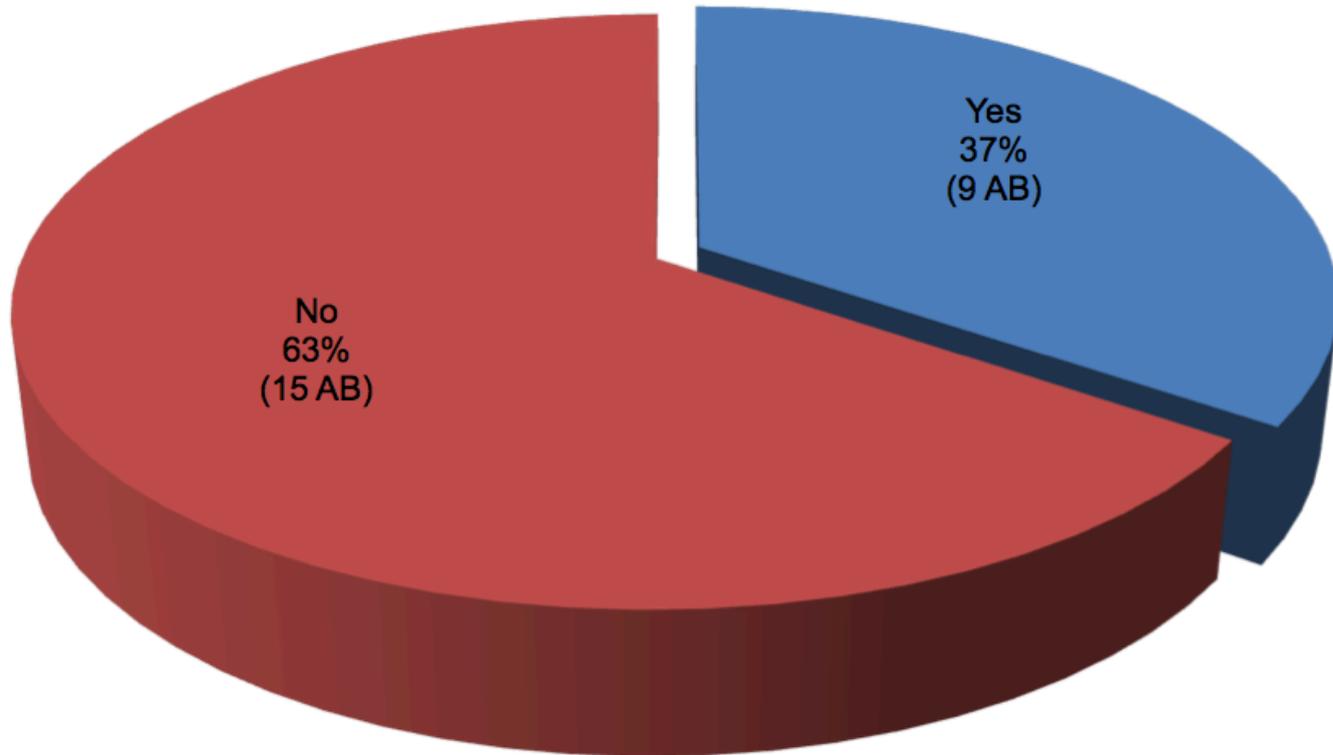
## Standard used for accreditation for medical laboratories



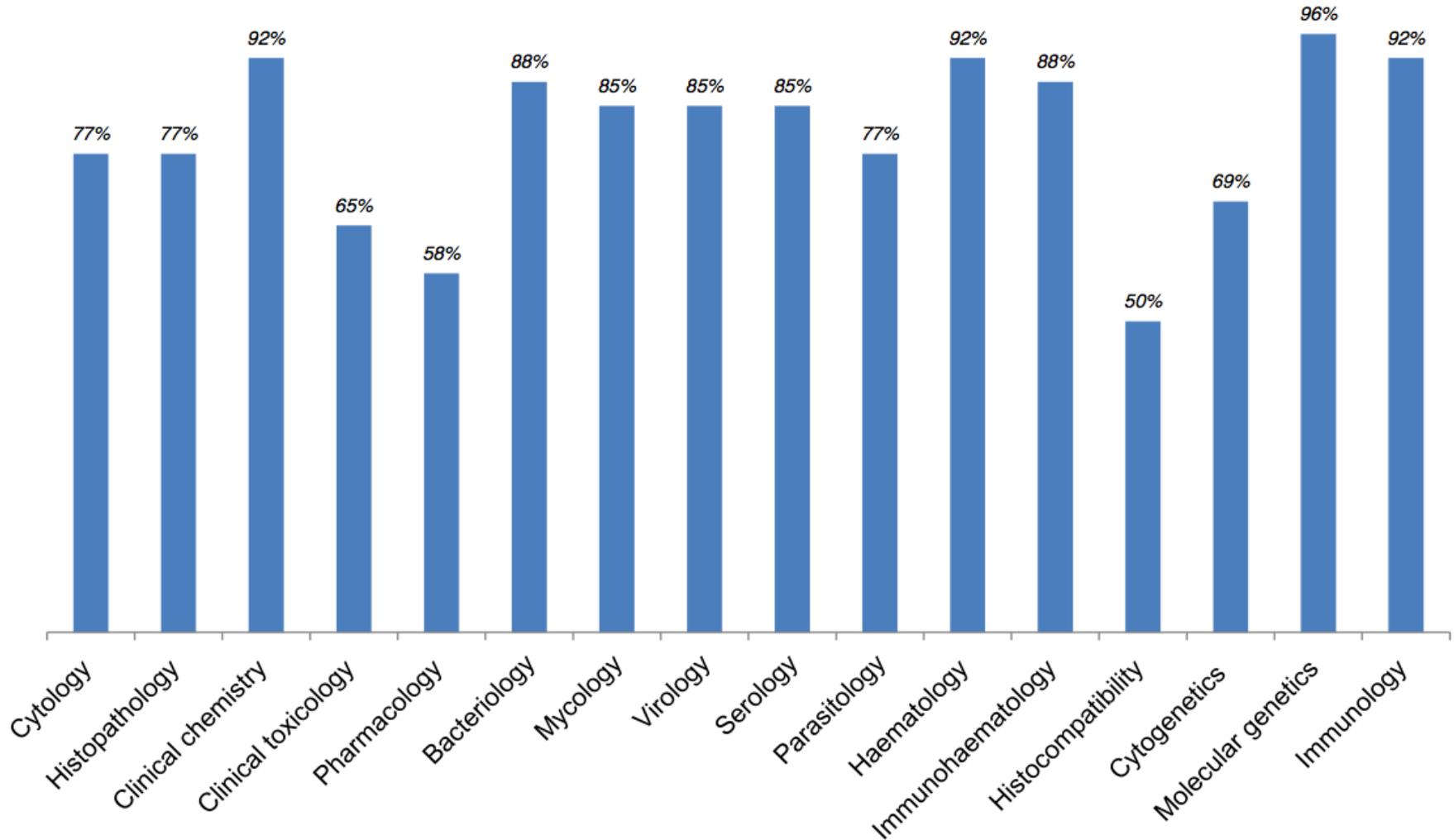
Germany (Dakks) : ISO/IEC 17020 for pathology

Turkey (Turkak) : ISO/IEC 17020 and ISO 15189 for pathology

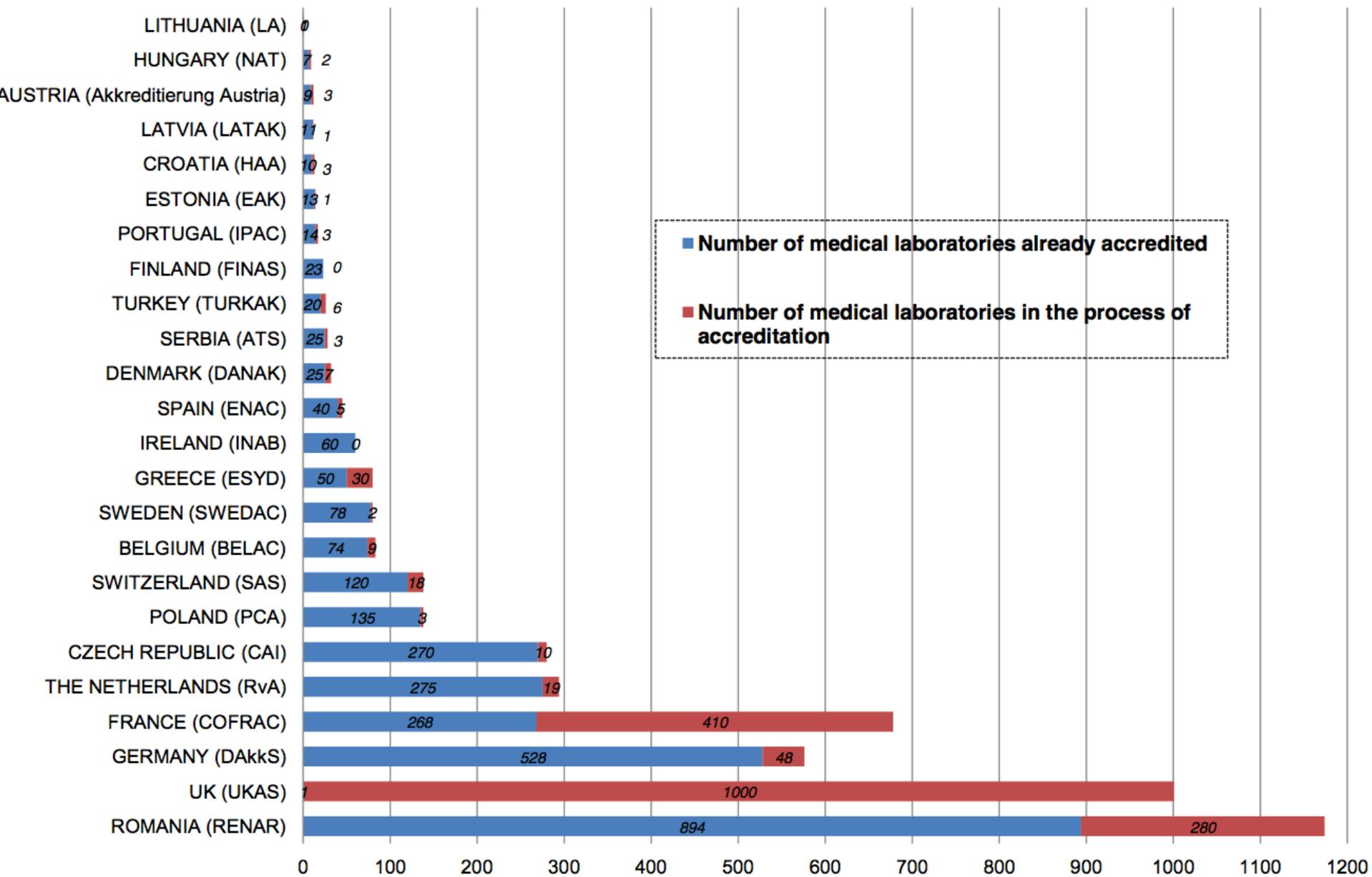
## Is accreditation of medical laboratories mandatory?



# Technical fields in the medical area covered by accreditation



Other : Research and imaging services (biometrics), clinical neurophysiology, isotope medicine, clinical physiology, Radiology; Neurophysiology, Nuclear Medicine, Doping, IVF, molecular pathology, in-situ techniques in pathology



The Netherlands : 260 accredited and 17 in a process of accreditation by CCKL  
 UK : 1000 in a process of transfer from CPA-UK

## Law No. 2013-442 of 30 May 2013 which amended Ordinance No. 2010- 49 of 13 January 2010 :

- Accreditation of all Medical Labs
  - 100 % of their tests to 1 November 2020;
- two steps to organize the scalability of accreditation:
  - On October 31, 2016 : all LBM are accredited on 50 % and at least one test by « family »
  - On October 31, 2018 : all LBM are accredited on 70%.
- All labs have crossed the entry into the accreditation process in 2013 :
- On 31 October **2013**: **1380**, private and public ( 359) LBM referenced in the BIOMED information system



# Le portail de l'accréditation en France

- Tout sur l'accréditation
- Tout sur le Cofrac
- Domaines d'activités**
- Contactez-nous
- Espace évaluateurs

Choisissez votre profil  
Vous êtes un...

Rechercher... un document

- DOMAINES D'ACTIVITÉS
- Comparaisons inter-laboratoires
  - Laboratoires
  - Organismes de certification
  - Organismes d'inspection
  - Santé Humaine

## Santé humaine

### Actualités de la section Santé humaine

- [Cliquer ici](#) pour consulter les dernières actualités liées à la section Santé humaine.
- [Cliquer ici](#) pour consulter la documentation liée à la section Santé humaine.

## LES LABORATOIRES DE BIOLOGIE MÉDICALE (LBM) POURSUIVENT LEUR DÉMARCHE D'ACCRÉDITATION !

	Accréditations effectives au 01/09/15	Processus d'accréditation en cours (évaluation initiale réalisée) au 31/08/15	Demande initiale d'accréditation reçue au 31/08/15*	Total
Nombre de LBM	573	64	431	1 068
Dont LBM «hospitaliers» (CHU, CH, GCS, CLCC, HIA)	173	26	123	322
Dont LBM «privés» et «autres publics»	400	38	308	746

\* Après recoupement avec les informations détenues par les ARS, notamment en lien avec les restructurations en cours, le nombre de dossiers déposés en application du décret du 23/02/15 a été réévalué.



# Challenges of Accreditation of medical labs according to NF EN ISO 15189 ( DGS: Sept 4, 2015)

- To ensure a level of **proven quality** for the patient and clinician for public health reasons,
- To **accelerate the Consolidation of Med Labs** to increase their expertise and skills and **to reduce the operating costs**,
- To Contribute to the **control of volumes and prices** in the context of a medical accreditation : lower costs for health insurance to support sustainability ;
- To facilitate participation in **international biomedical research**
- To Encourage the **international competitiveness** of French medical services . All obligations of means ( provided by LABM Act 1975 ) were replaced by the mandatory accreditation

# Lessons to be learned..

- 60% of LBM are already accredited or in the process of being:
  - it is a remarkable result achieved through the efforts and the mobilization of all parties
  - A development of accreditation of LBM consistent and slightly ahead of the international development of accreditation in medical biology in the world: an asset for France;
  - A drive-related effect "to pass a course in 2016";
- Positive feedback on the added value of accreditation in efficiency and safety, and the continuous improvement process that it implies,
- Mutual understanding between the COFRAC and the professionnal still need to be corrected,
- But a slow and gradual entry into the process leading to:
  - Less than 10% of accredited LBM meet at this stage, the two criteria to achieve 31 October 2016 with 50% of the tests, one test by a family
  - less than half accredited LBM meet at this stage the sole criteria of 50%

# • With very important consequences.....

- **A considerable effort remains to be done in 1 year**, to carry out initial assessments and extension (one thousand evaluations), which implies strong resources available evaluators, including medical biologists
- **Available resources** remain worrying despite better mobilization in recent months, particularly in hospital;
  - Quality assessors **91** (70 external)
  - **231** medical biologists Technical Assessors (45 are from Hospital, 19%) - - - 79 candidates of Assessors under examination techniques (of which 27 are from hospital medical biologists, 34%)
- **Still clearly insufficient number of technical evaluators to pass the "cap" end October 2016**

# Actions Ministry of Health and COFRAC: 4 priorities

- To achieve and to implement , by the end of 2015, **the optimization measures of the accreditation process** to provide flexibility and to save time for technical evaluators



- To optimize the process and **reduce the time for qualification** of candidates technical assessors



- To redefine prioritization assessments by adapting **the scope of initial accreditation** if needed and to maintain a dynamic extension of the scope of accreditation



- To continue actions **to increase the number of technical assessors** in a collaborative approach with all stakeholders

# New proposals from the COFRAC

under discussion...

- Prioritize assessment of the **431 unaccredited LBM without an initial assessment**. The extension visits will wait...
- **Setting a more limited scope to achieve the objective of accreditation** : 
  - **Suppression the condition of 50%** and one test per family ( 1 November 2016 ) ;
  - **Suppression the condition of 70% Accreditation** ( 1 November 2018)
  - Accreditation 100 % of all LBM (1st November 2020 )
  - Referral to
    - Legal affairs at the Ministry level
    - the Constitutional Council
    - In order to declassify a part of the Law 2013 > decree of The French Conseil d'état

## In summary

- The Law 2013 is far too detailed > any change is difficult., but...
- The concept of accreditation is accepted by all the Health professionals (**+ 60% of accredited labs**) > patient safety and wellness
- But still Complex relationships between:  
Ministry, Syndicates, Cofrac
- Med Lab reform, restructuring and geographical reorganisation, medical demography and evolution of the profession encourage stereotypes
- **Future >Precision medicine:** a challenge for the Lab medicine

