



Accreditation and Education France

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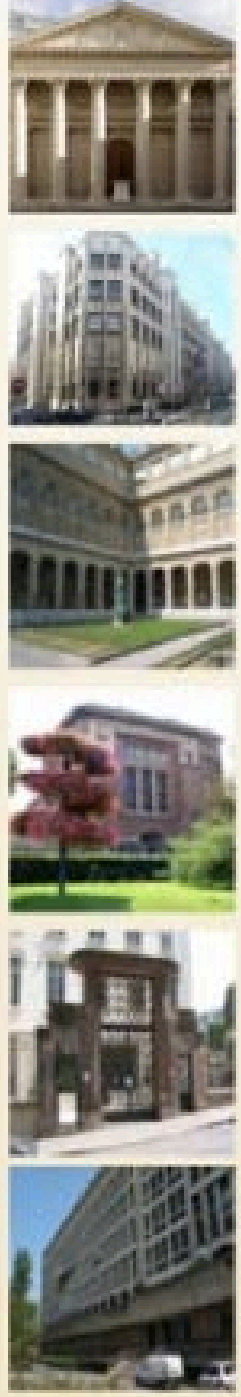
France (66,3 millions)

Law HPST 2009 (modernisation, accessibility, prevention, territorial organization)

264 466 medical doctors (2010); 50 000 pharmacists, 10 000 medical biologists



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



RER A
express regional train

La Défense



Charles de Gaulle - Etoile

Gare Saint-Lazare

Aubert Opéra

Gare du Nord

Gare de l'Est

Musée d'Orsay



Saint-Germain-des-près

Saint-Michel

Châtelet

Nation

Javel



Luxembourg

Gare d'Austerlitz

Gare de Lyon

Porte de Versailles

Tramway T3

Denfert-Rochereau

Cité universitaire

RER C
express regional train

RER B
express regional train

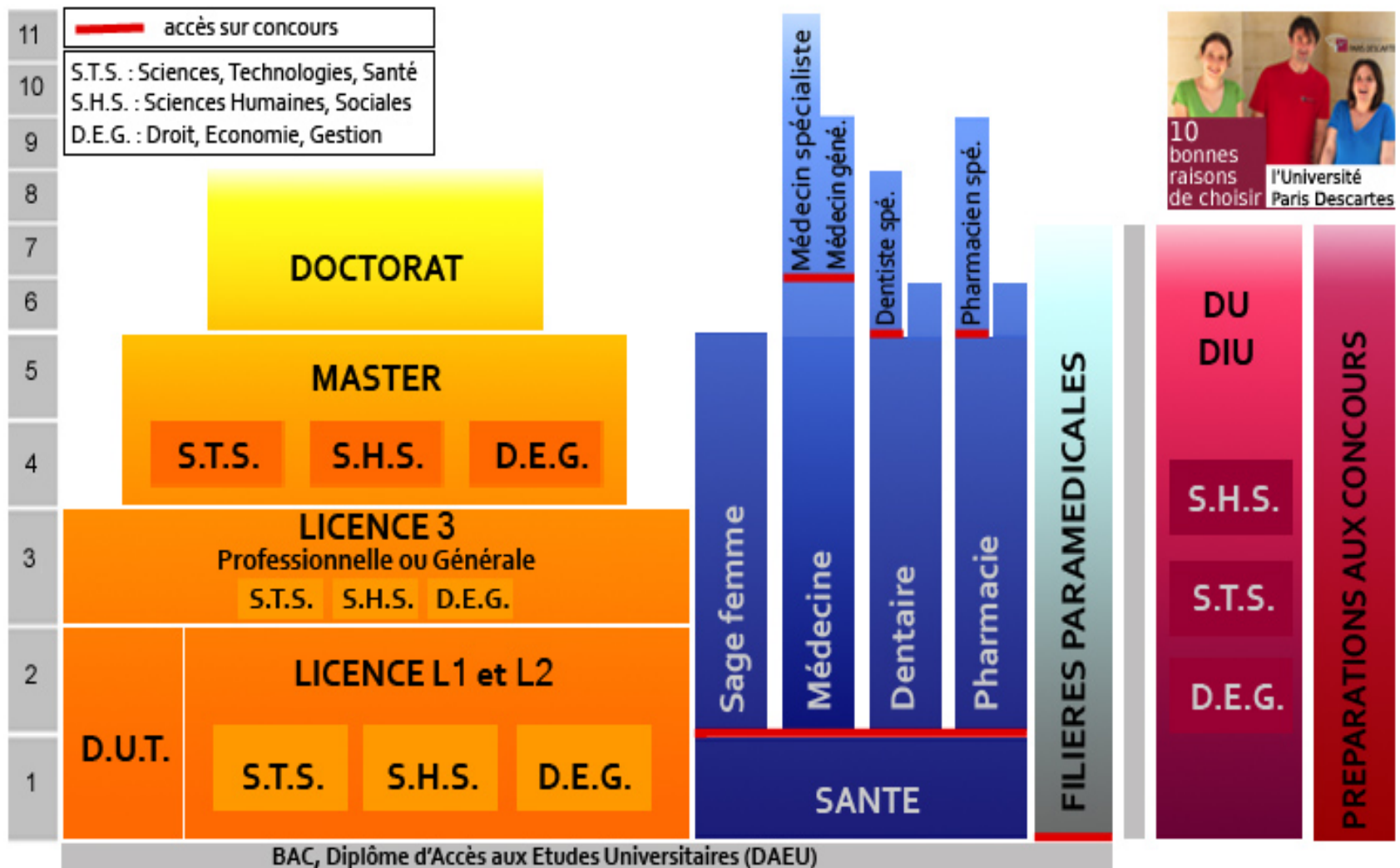
Orly (via Orly VAL)

Roissy Charles de Gaulle



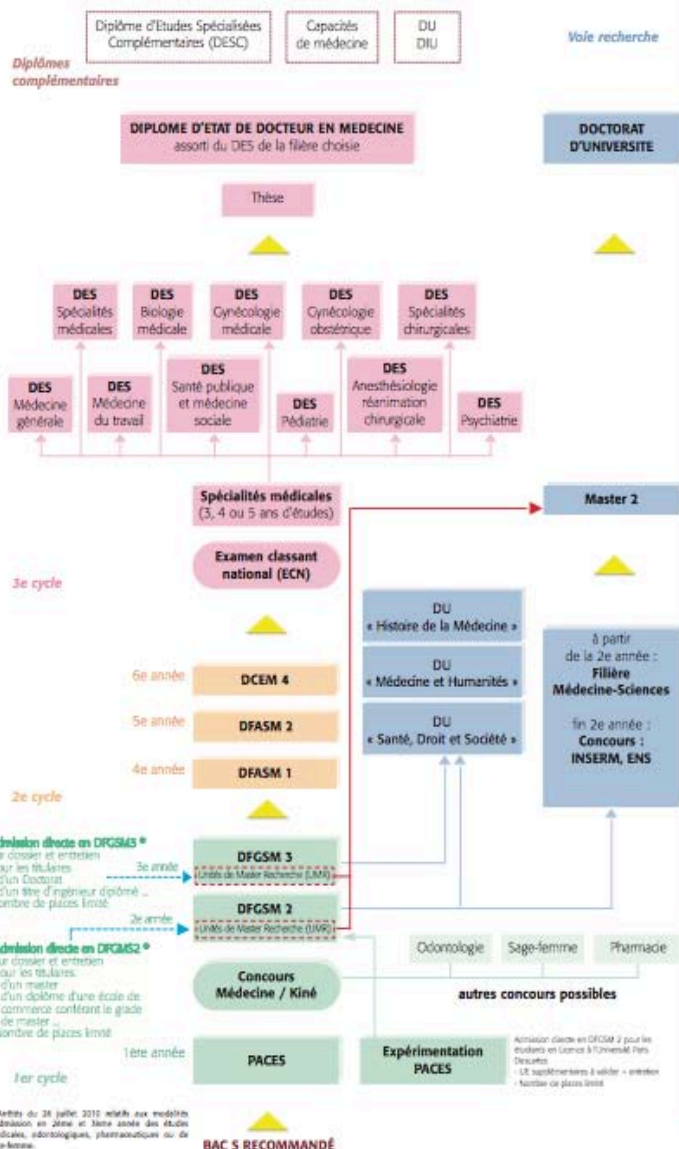
Academic training pathways

University Paris Descartes (France)





Les études



VERS QUELS MÉTIERS

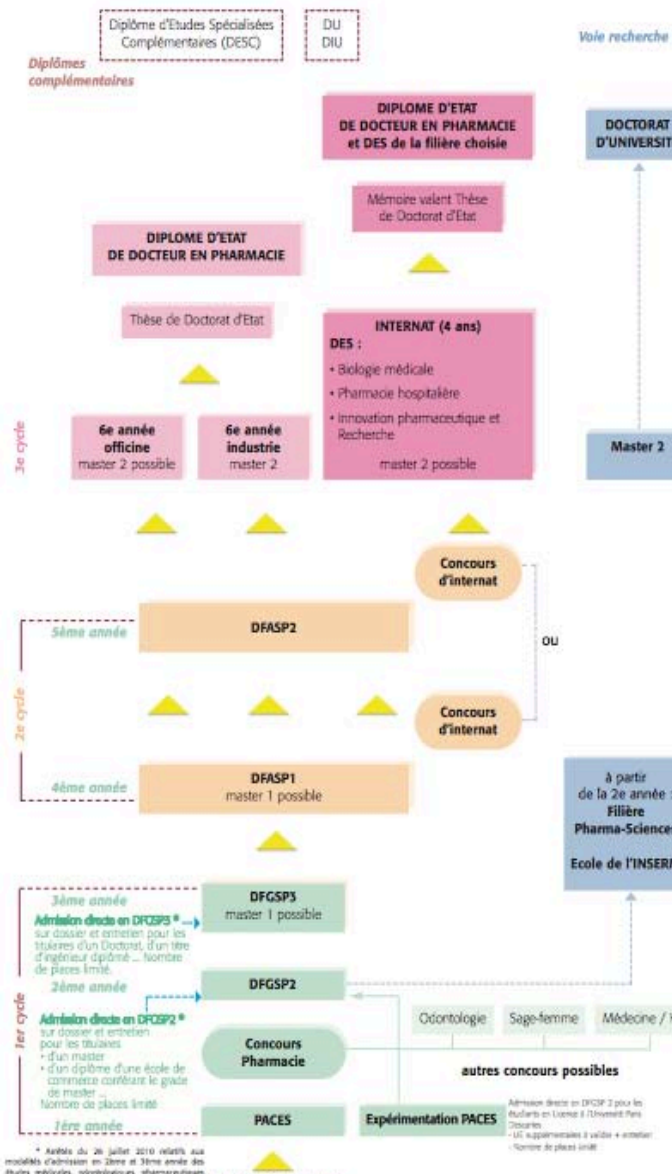
exemples de métiers

- Médecin généraliste
- Dermatologue
- Chirurgien
- Gynécologue
- Médecin du travail
- Ophtalmologiste
- ORL
- Pneumologue
- Psychiatre
- Rhumatologue
- Médecin des armées (filière spécifique)...
- Urgentiste...

modes d'exercice

- **exercice en secteur libéral** (environ 60 % des médecins) : en cabinet ou dans un établissement de soins privé
- **exercice salarié en hôpital** : il s'agit principalement de praticiens hospitaliers. Les praticiens hospitalo-universitaires (voie recherche) dans les CHU, exercent à la fois des activités de soin, d'enseignement et de recherche.
- **exercice salarié dans diverses structures** :
 - collectivités territoriales (sur concours) : médecin de PMI, ...
 - fonction publique d'Etat ou organismes publics (sur concours) : médecin scolaire au Ministère de l'Education Nationale, médecin inspecteur de la Santé Publique, médecin-conseil de Caisse d'Assurance Maladie, médecin chercheur à l'INSERM, ...
 - associations diverses : médecin humanitaire auprès d'une ONG, médecin dans une association de lutte contre le cancer, ...
 - entreprises privées : établissement de soins privé, industrie pharmaceutique (responsable des essais cliniques, directeur marketing, chef de produit), grosses entreprises (médecin du travail), ...

Les études

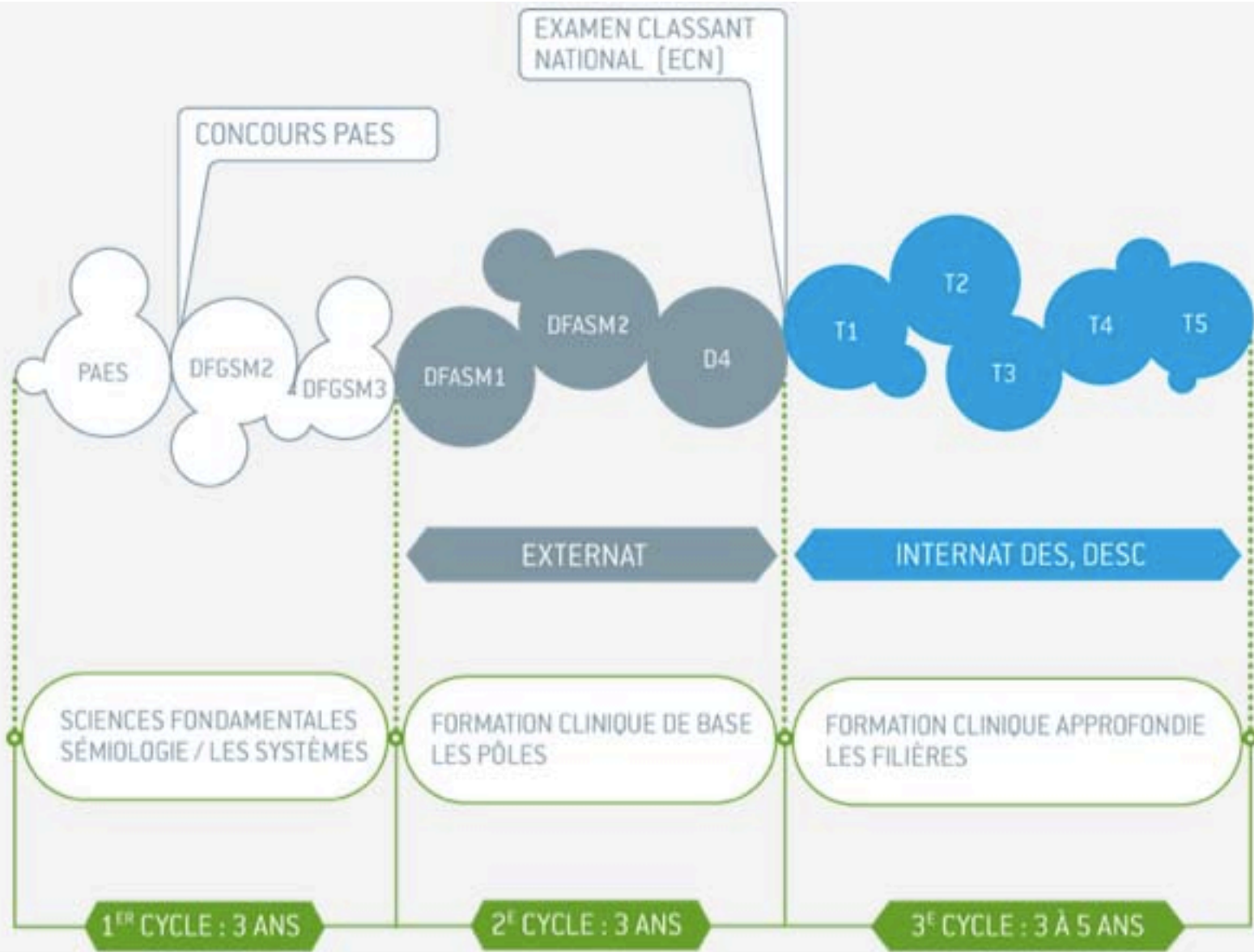


VERS QUELS MÉTIERS

- exemples de métiers**
- Pharmacien d'officine
 - Pharmacien hospitalier
 - Pharmacien en industrie pharmaceutique
 - Biologiste
 - Chercheur
 - Enseignant-chercheur

modes d'exercice

- **exercice libéral ou salarié** :
 - Officine : environ 70 %
 - Laboratoires d'analyses de biologie médicale
- **exercice salarié** :
 - Entreprises des secteurs pharmaceutique, cosmétologique, agro-alimentaire, hydrologique :
 - recherche et développement
 - contrôle qualité
 - production
 - marketing commercial
 - réglementation
 - distribution
 - Centres de recherche publics : INSERM, CNRS, INRA, ...
 - Hôpitaux
 - organismes de santé publique :
 - agences de sécurité sanitaire
 - inspection des pharmacies
 - police scientifique, armée, sapeurs-pompiers



Cursus des études médicales

French Council of Pharmacists / Medical Doctors



Ordre national
des pharmaciens



Conseil national de l'Ordre des médecins



Medical Biology in France : Economic aspects

FR Gross Domestic Product (GDP): 2113 BM€

- Health 11,6%
- Hospital (86,7 BM €)

Medical Biology

- **1,8%** routine health care expenses
- **2,4%** Consumption of care and medical goods
- (**4,3 BM €private sector, 2,9 BM €public**)
- **9,7%** Consumption of ambulatory health care

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 1126 medical labs** (3600 sites) / **359 Hospital Labs** (32 UH)
- There is a movement for concentrating laboratories, increasingly pursued by investment funds.

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^{ème} 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:** 10 avril Commission Mixte Paritaire > **Ratification Jeudi 11 Avril 2013 Sénat (LAW)**

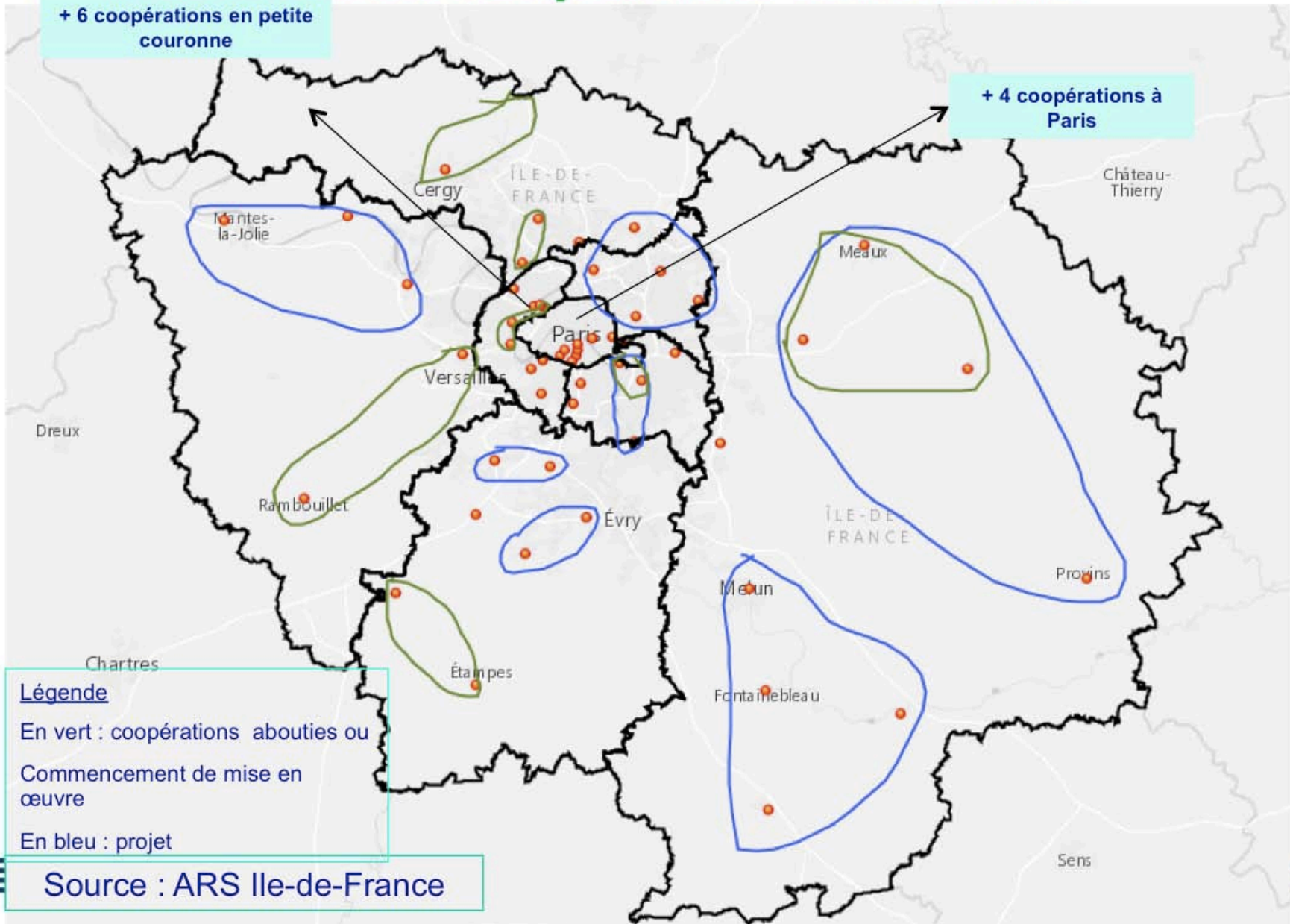
Four major objectives of the new law on Medical Biology (2013)

- **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
- and **slow the Intrusive process** of the finance industry
- to ensure the **quality of medical biology tests**.

périmètres de coopération territoriale laboratoires hospitaliers franciliens

+ 6 coopérations en petite couronne

+ 4 coopérations à Paris



Légende

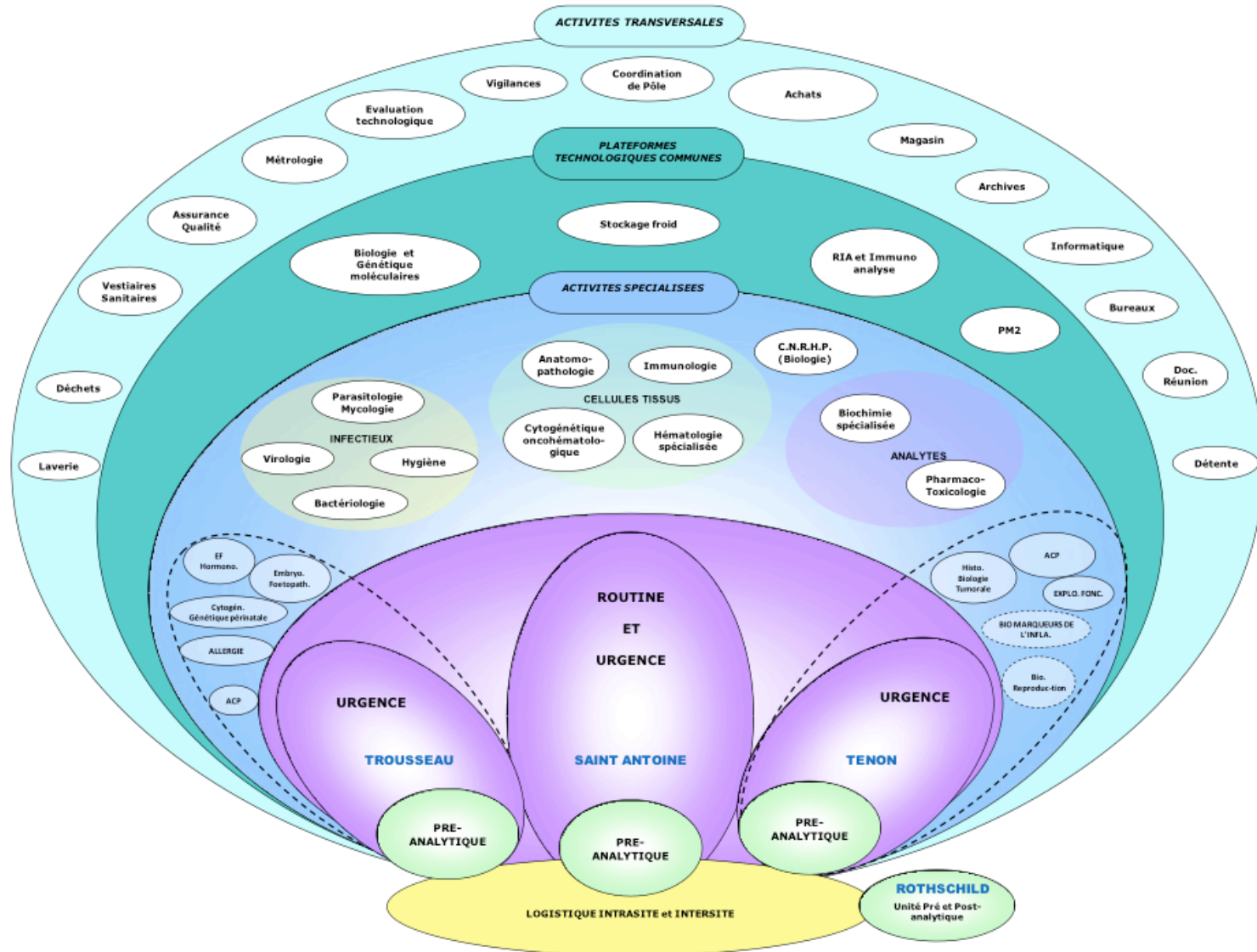
En vert : coopérations abouties ou

Commencement de mise en œuvre

En bleu : projet

Source : ARS Ile-de-France

Biologie médicale GH HUEP



Qu' est-ce que la Haute Autorité de santé?

Comment évalue-t-on les produits
et actes médicaux?

Qu' est-ce que la certification
des établissements de santé?

Pourquoi recommander
les bonnes pratiques médicales?

Qu' est-ce que l'accréditation des médecins?

HAS

Évaluer les
produits de santé

Recommander les
bonnes pratiques

Certifier
les hôpitaux

Accréditer
les médecins

Niveau des actions de renforcement de la qualité
et de la sécurité des soins d'un établissement



4 ans



- 10 000 médecins actifs dans la démarche
- 12 000 événements indésirables analysés / an

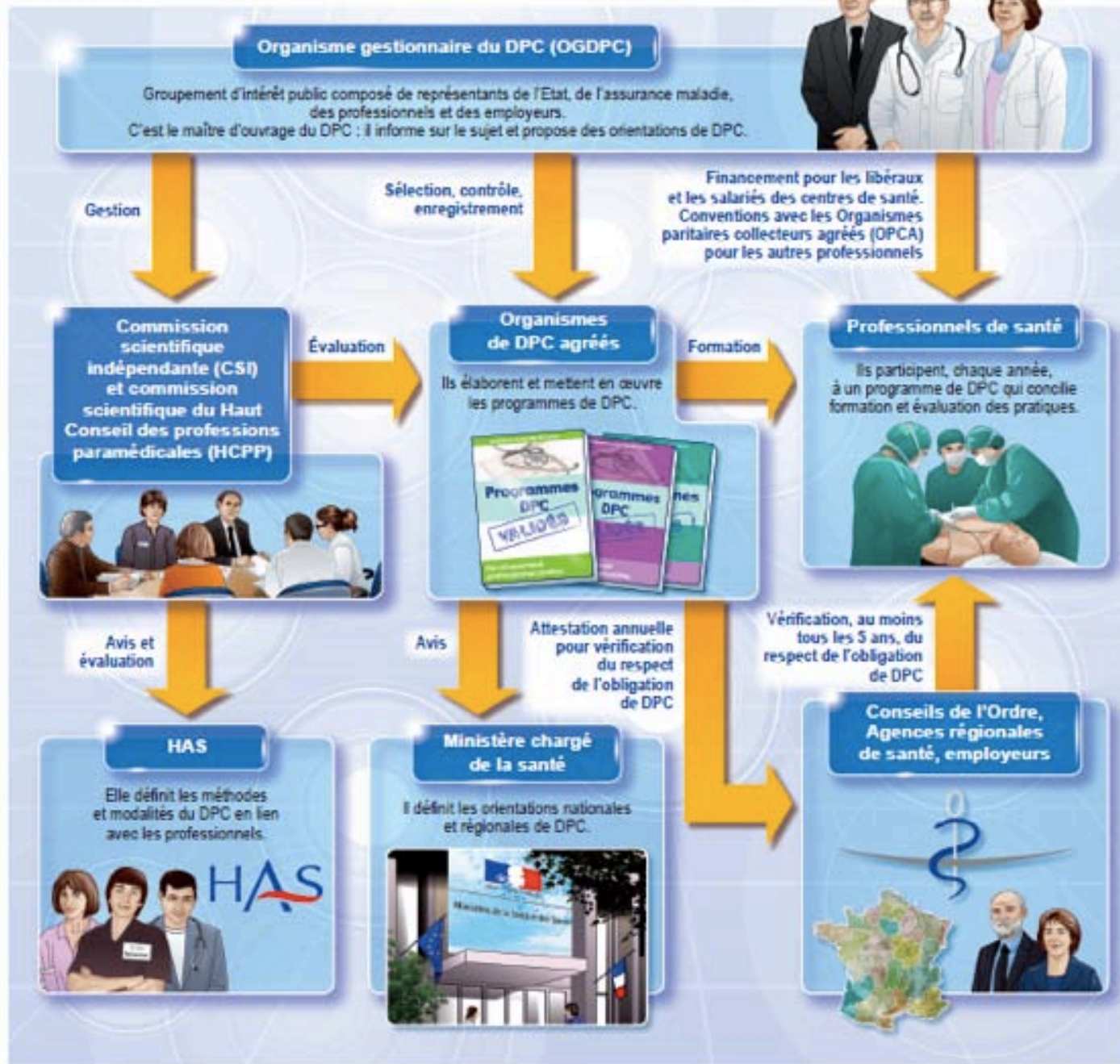


spécialités « à risque »

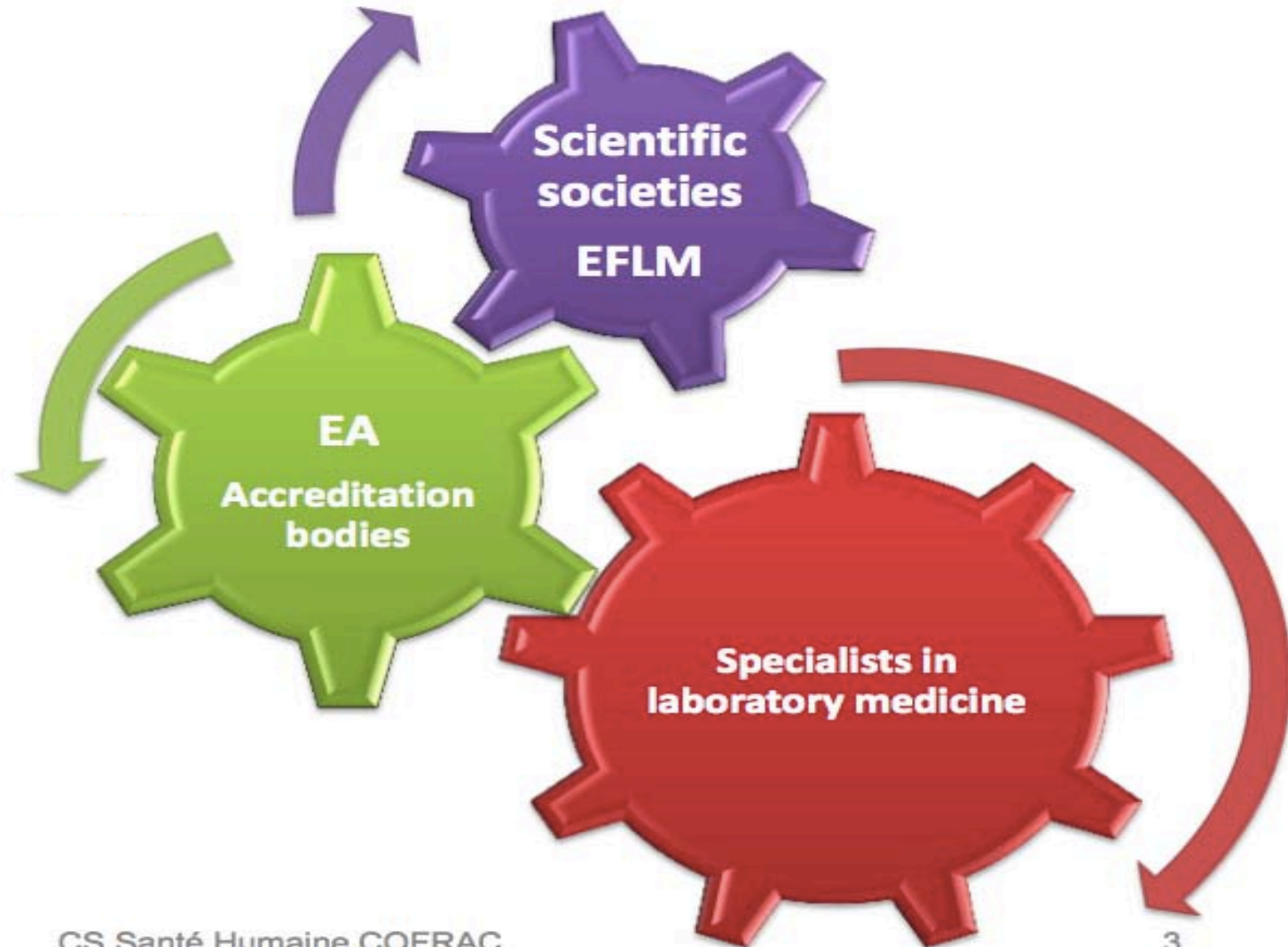
HAS accreditation for medical doctors

- **A accredited physician** is a doctor who is the subject of an assessment of the quality of his work by an approved body.
- **This approach is voluntary and under the responsibility of the High Authority for Health (HAS)**, which states that accreditation "is part of a comprehensive system of quality and safety of care and to improve practices."
- Accredited physicians are necessarily physicians practicing an **activity or a specialty "at risk"** in a public or private institution health.
- **The decree No. 2006-909 of 21 July 2006** lists the medical sectors involved in the accreditation process:
 - Surgery
 - Gynecology and obstetrics,
 - Anesthesia-resuscitation
 - Resuscitation and intensive care,
 - Interventional specialties (dentistry, ENT, ophthalmology, cardiology, gastroenterology, pulmonology)
 - Radiology and ultrasound.
- **Objective** : to reduce the number and severity of accidents that doctors may be responsible during their career.

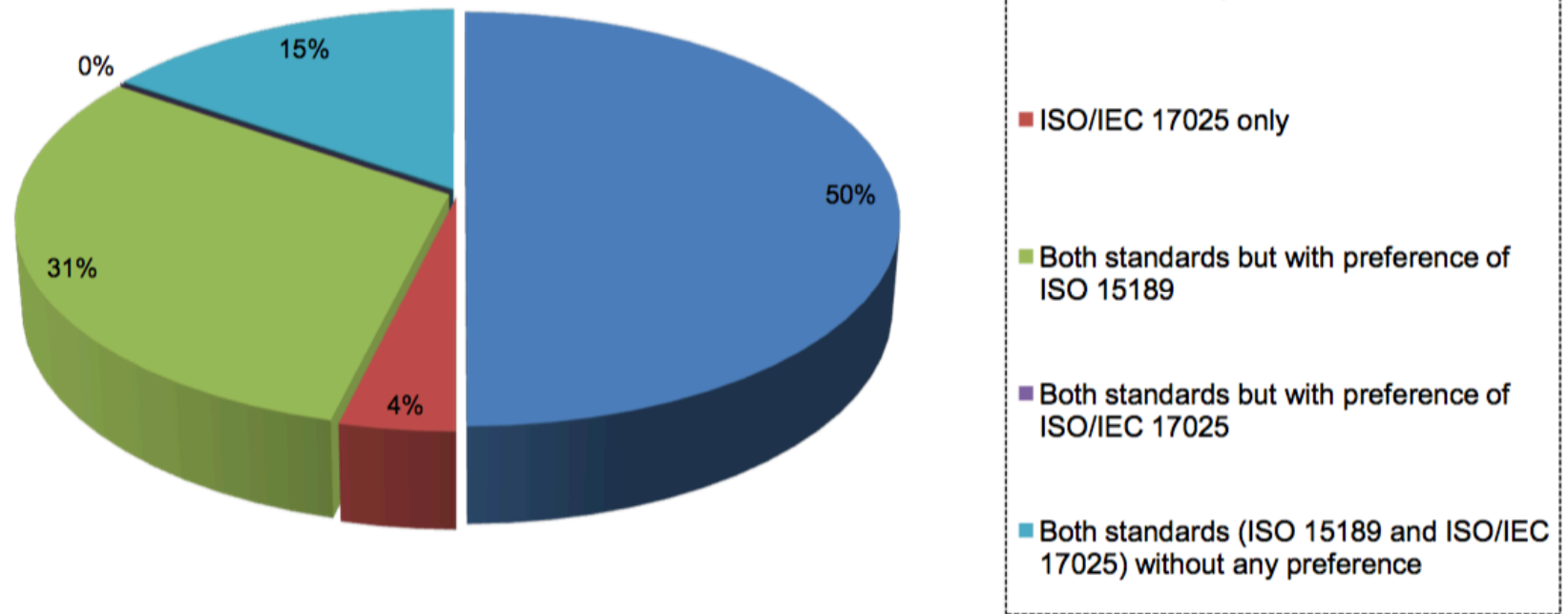
Organisation du DPC : les acteurs et leur rôle



Survey regarding the accreditation of medical labs within EA from Helene Mehay , COFRAC (FR)



Standard used for accreditation for medical laboratories



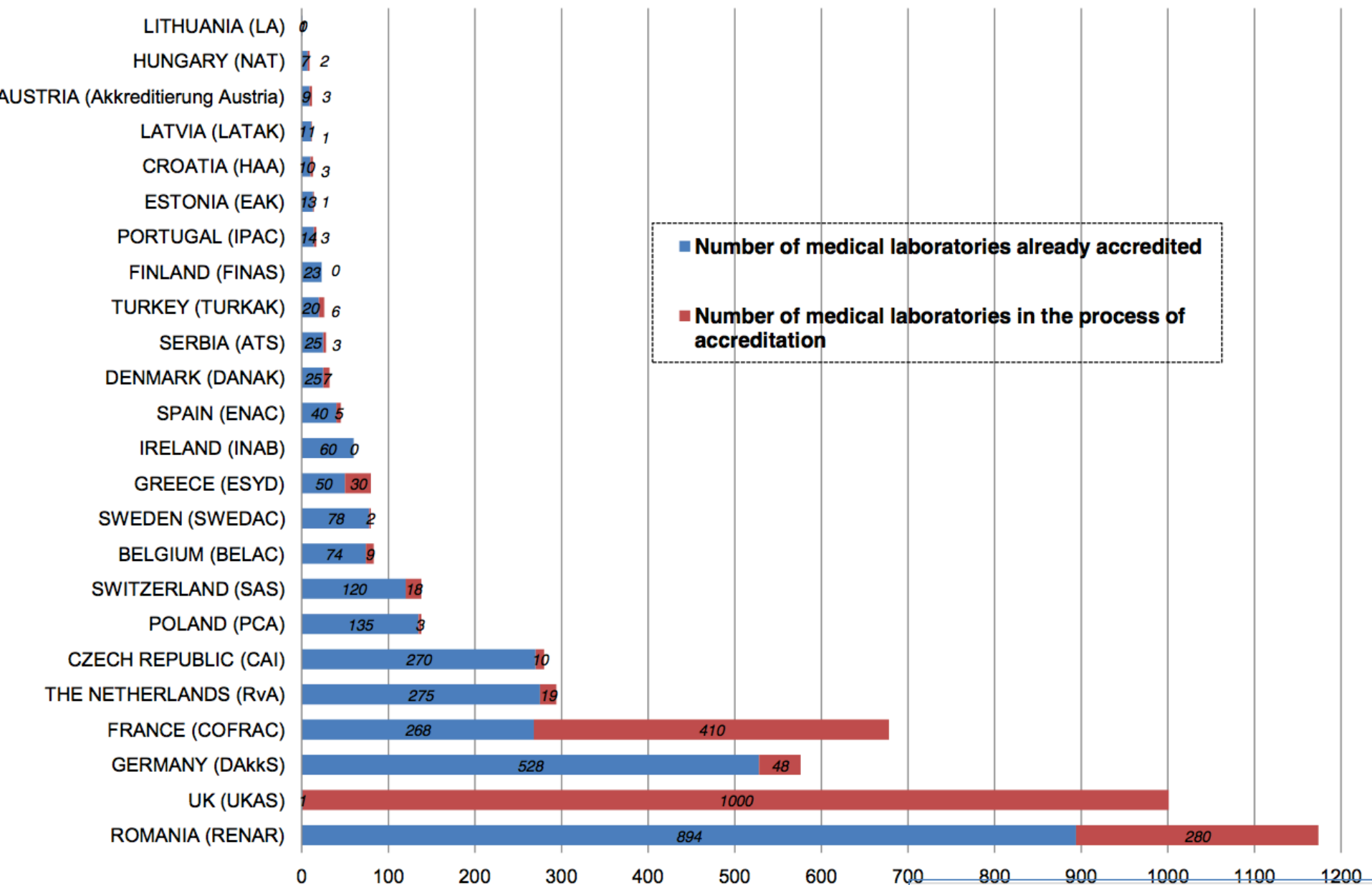
Germany (Dakks) : ISO/IEC 17020 for pathology
Turkey (Turkak) : ISO/IEC 17020 and ISO 15189 for pathology

From H Mehay COFRAC

Standard used for accreditation for medical laboratories

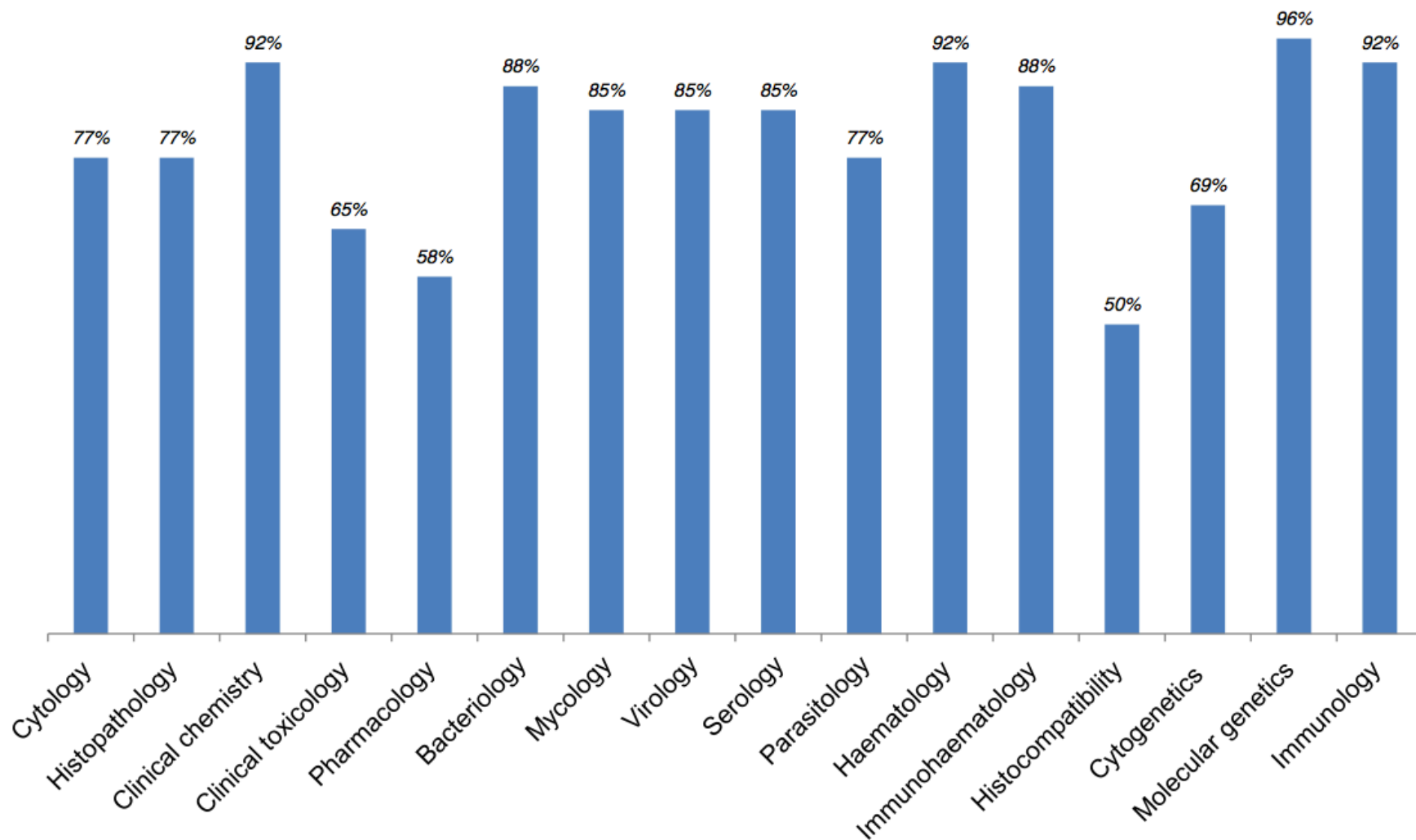
ISO 15189 only	ISO/IEC 17025 only	Both standards but with preference of ISO 15189	Both standards without any preference
Romania (RENAR)	Lithuania (LA)	Poland (PCA)	Switzerland (SAS)
UK (UKAS)		Belgium (BELAC)	Sweden (SWEDAC)
Germany (DAkkS)		Greece (ESYD)	Finland (FINAS)
France (Cofrac)		Denmark (DANAK)	Portugal (IPAC)
The Netherlands (RvA)		Serbia (ATS)	
Czech Republic (CAI)		Estonia (EAK)	
Ireland (INAB)		Latvia (LATAK)	
Spain (ENAC)		<i>Belarus (BSCA)*</i>	
Croatia (HAA)			
Turkey (Turkak)			
Austria (Akkreditierung Austria)			
Hungary (NAT)			
<i>Malta (NAB Malta)*</i>			

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

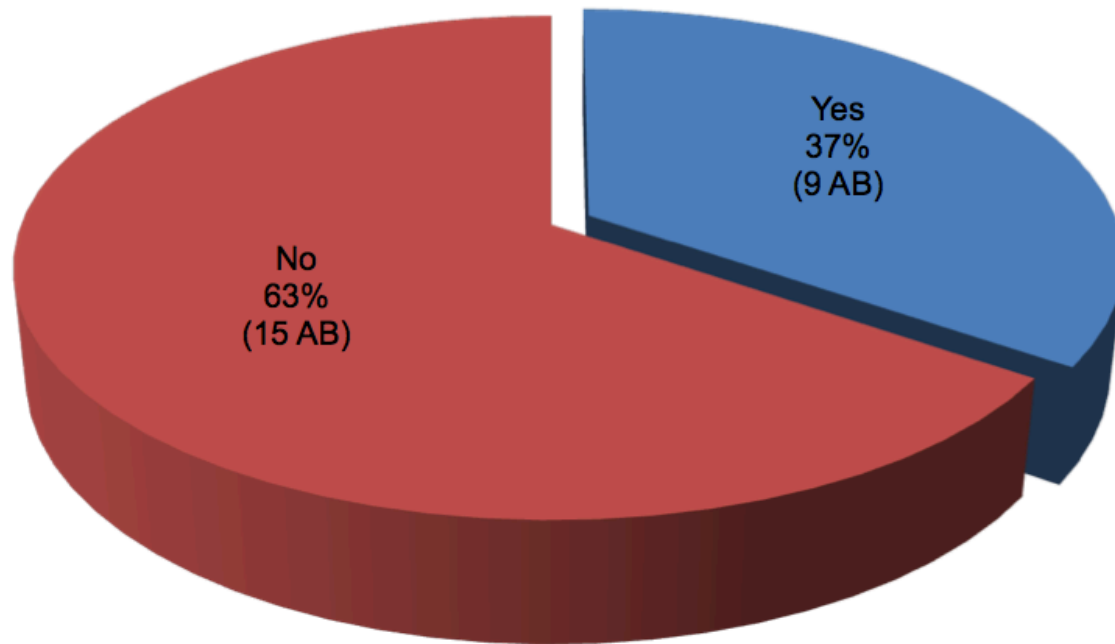
Technical fields in the medical area covered by accreditation



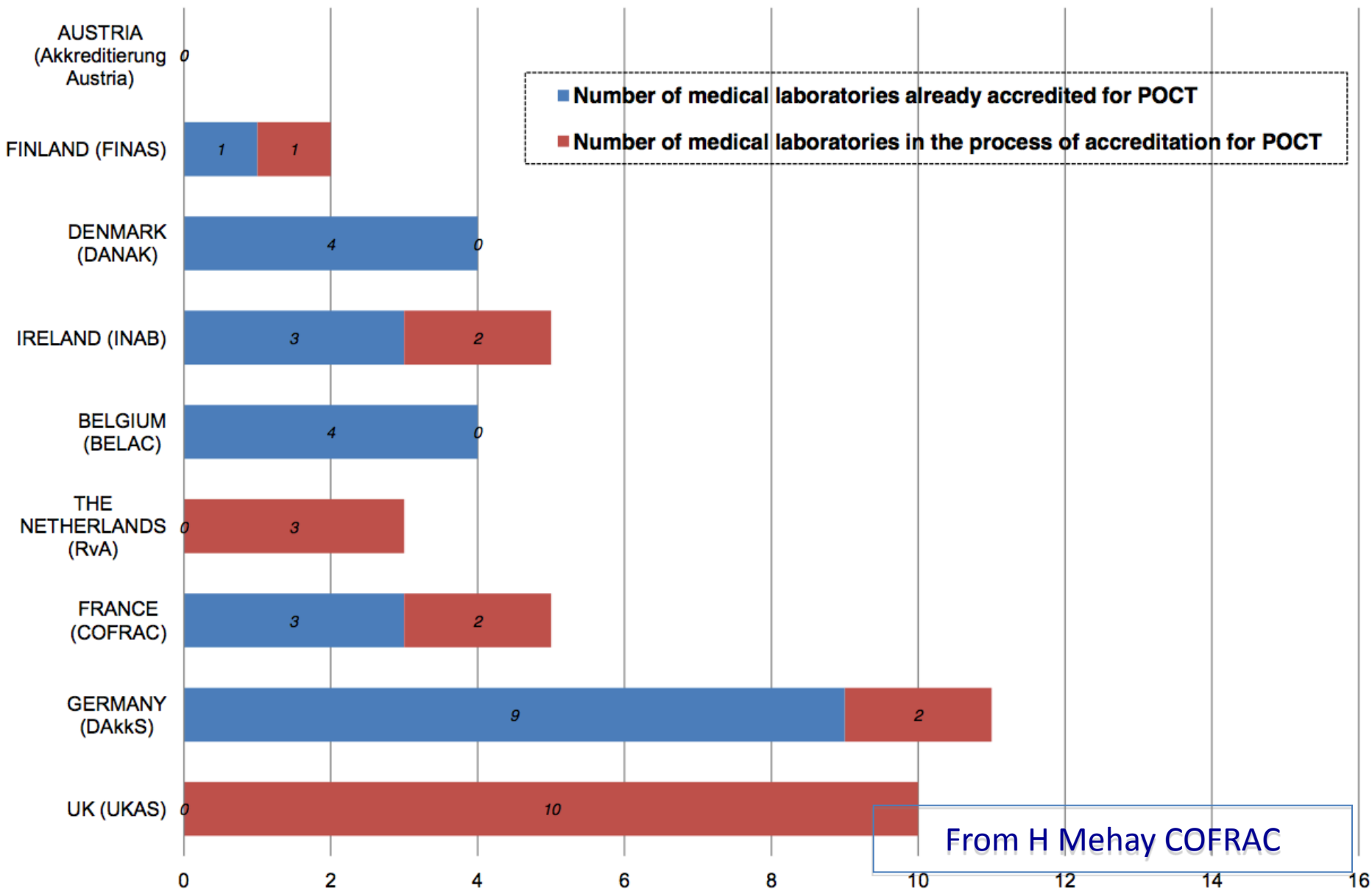
Other : Research and imaging services (biometrics), clinical neurophysiology, isotope medicine, clinical physiology, Radiology; Neurophysiology, Nuclear Medicine, Doping, IVF, molecular pathology, in-situ techniques in pathology

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How many AB accredit for Point of care testing (POCT) (according ISO 22870)?

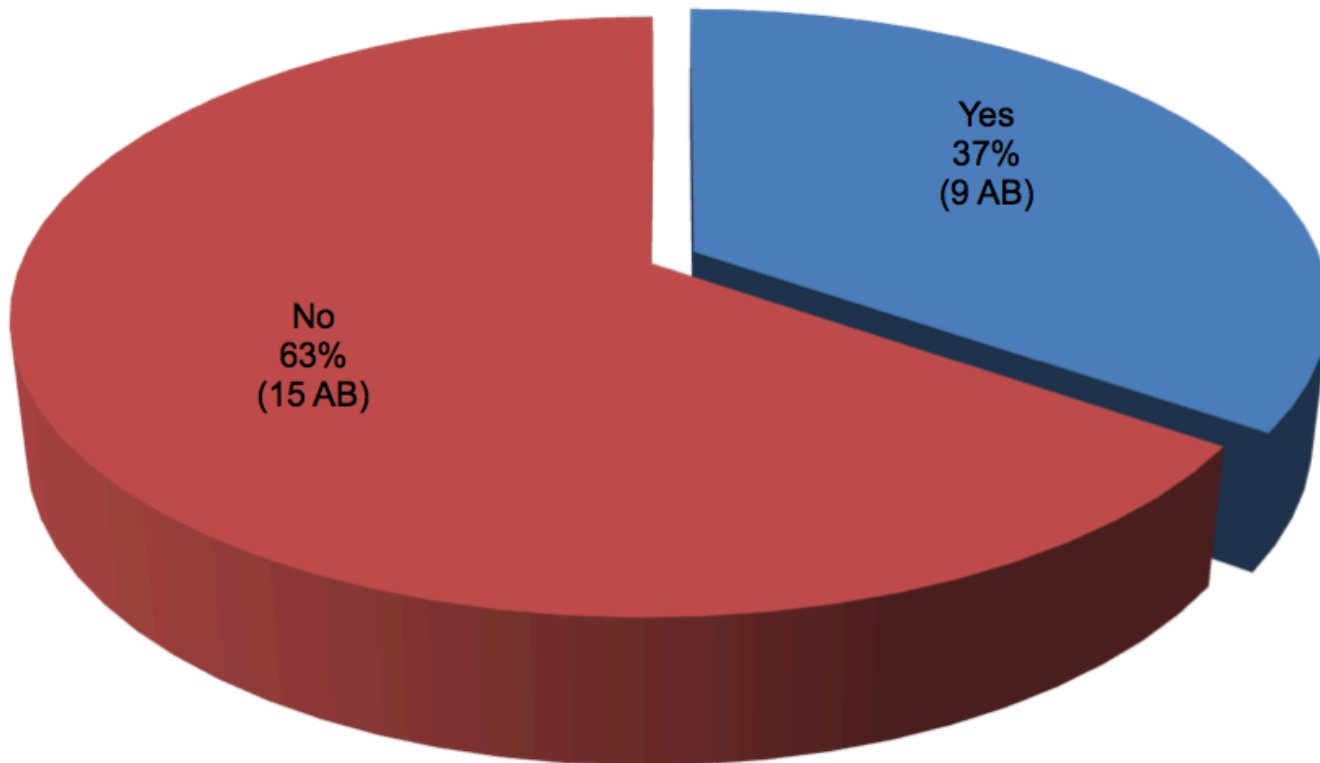


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Is accreditation of medical laboratories mandatory?



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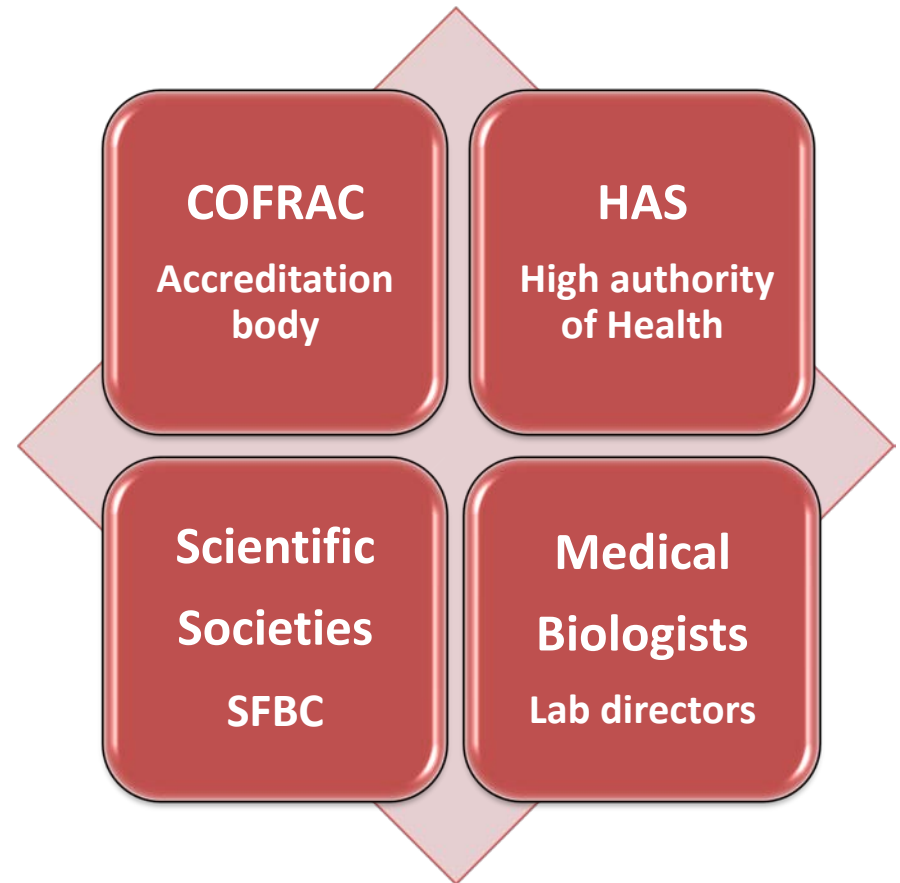
Accreditation of medical laboratories mandatory ?

Romania (RENAR)	NO
UK (UKAS)	NO
Germany (DAkks)	YES : Only mandatory for newborn screening (2010) and PID – 9/4
France (Cofrac)	YES : all labs and technical fields (2020) – 268/410
The Netherlands (RvA)	NO
Czech Republic (CAI)	YES : genetic test of human genom only (2012) – 50/2
Poland (PCA)	NO
Switzerland (SAS)	NO
Belgium (BELAC)	YES : molecular biology tests (oncology, virology)
Sweden (SWEDAC)	NO
Greece (ESYD)	YES : private laboratories providing primary healthcare services (2013) – 35/24
Ireland (INAB)	YES : blood transfusion (immunohaematology) (2009) – 50/0
Spain (ENAC)	NO
Serbia (ATS)	YES : determination the damage caused by the action of ionizing radiation and other mutagenic agents in the human genome – 2/0
Turkey (Turkak)	NO
Denmark (DANAK)	NO
Finland (FINAS)	NO
Portugal (IPAC)	NO
Estonia (EAK)	NO
Croatia (HAA)	NO
Latvia (LATAK)	YES : all medical laboratories (2015) - 11
Austria (Akkreditierung Austria)	NO
Hungary (NAT)	YES : all technical fields (2018) - 7
Lithuania (LA)	NO

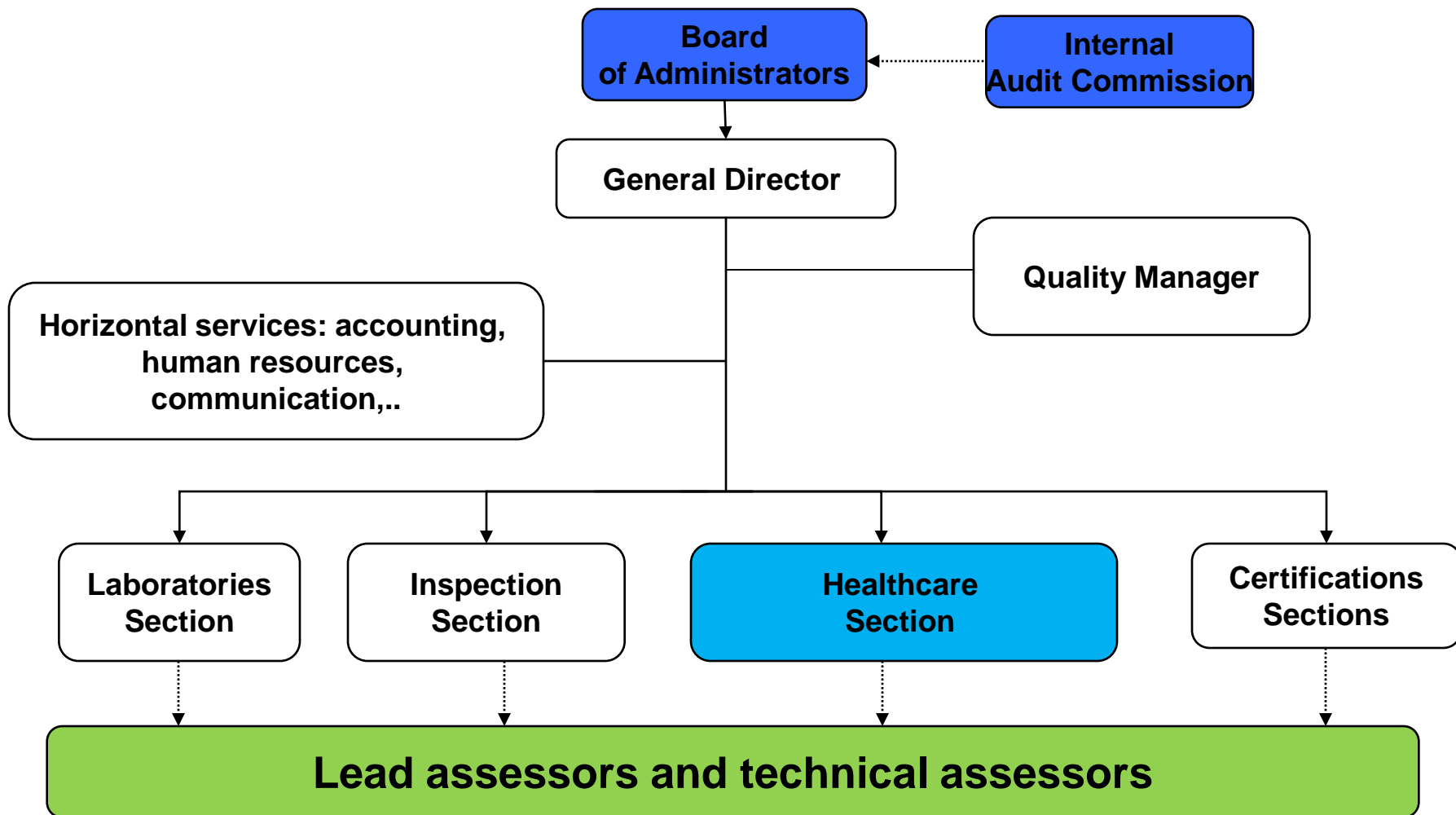
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French Lab Med Accreditation

- **NF EN ISO 15189**
- **NF EN ISO 228 70**



The Cofrac



The Healthcare Section

- This section is ***totally dedicated to human health issues***
- ***The section committee*** participates in the elaboration of the strategy for accreditation of medical laboratories as well as in the working of the documents useful to evaluation and accreditation
- ***The technical commission for accreditation*** studies evaluation reports and looks at the candidatures of technical evaluators and experts
- These two instances are composed of:
 - ***representatives*** from the ministry of Health, its permanent offices in regions, the High Authority of Health, medical biologists, patients, prescribers, accredited medical laboratories.

The evaluators

- ***Accreditation*** is based upon evaluations undertaken by ***peers***
- Selecting a candidate to become a technical evaluator consists in ***validating his capability to evaluate*** as well as the adequacy of his technical competence to our needs
- The selected technical evaluators are ***working in medical laboratories accredited or on the way*** to be accredited.

COFRAC: Section Santé Humaine

- **Permanent team:** 31 members
 - + 1 medical biologist FTE
- **Assessors (31/03/2015)**
 - Quality assessors : 88
 - Technical 207 + 47 in process
 - Only 37 from hospital



Avancement de la démarche

	Accréditations effectives au 01/04/15	Demandes d' accréditation (voie A)	Demandes d' accréditation Recues (voie B)	Total	Nb total de LBM au 31/10/13
Nb de LBM	501	108	188	806	1384
(nb de sites)	(1892)		//		
dont pour des EBMD (POCT)	5		//		
LBM hospitaliers*	153	41	61	255 (32%)	359
LBM « privés » et « autres publics »	357	67	127	551	1025

* CH, CHU, GCS, HIA, CLCC



EUROMEDLAB PARIS 2015

21-25 JUNE



REVOLUTION IN LABORATORY MEDICINE