European networking of Regulatory Procedures

Optimizing Communication between European Medical Specialists and the European Commission

Pr. Elizabeth Macintyre, FRCP, FRCPath UK

Diagnostic hematologist

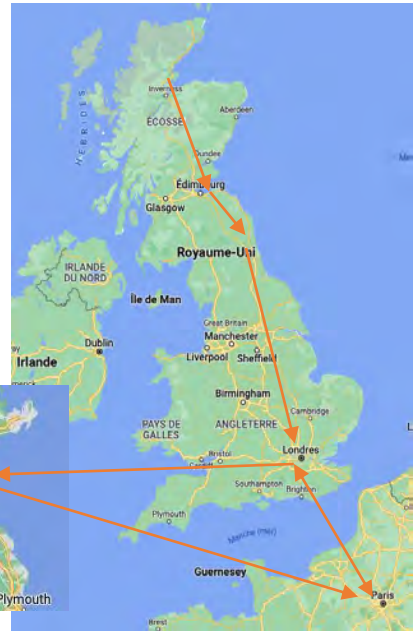
European Hematology Association president 2021-23

Biomedical Alliance president 2024-25

Université Paris Cité

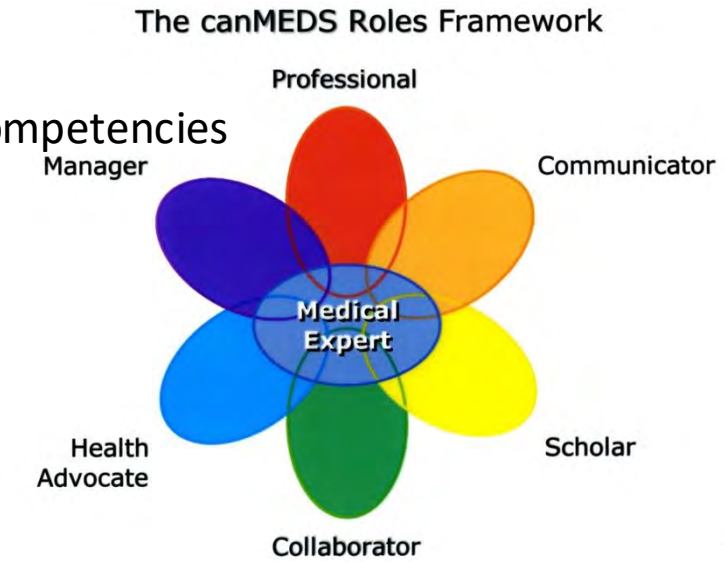
Necker Enfants Malades Hôpital Universitaire

Institut Necker Enfants Malades Centre de Recherche



AWMF 5/12/2025

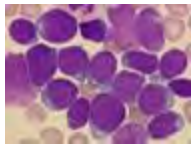
7 competencies

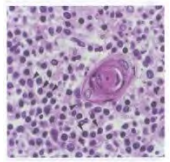


eha

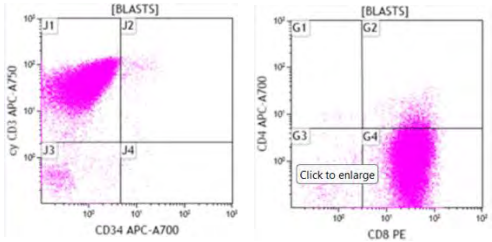
An integrative approach to Hematological Malignancy Diagnostics

Vahid Asnafi et al.

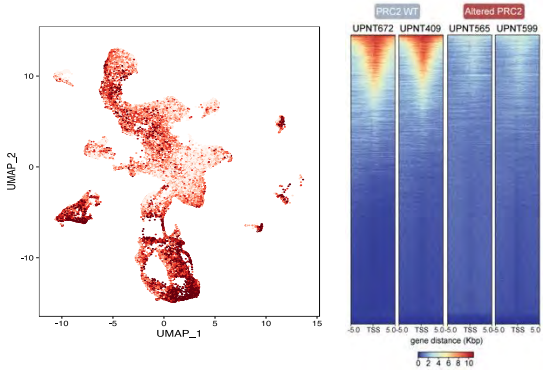




Phenotypic annotations



Multimodal omics



RNA-seq

ChIP-seq

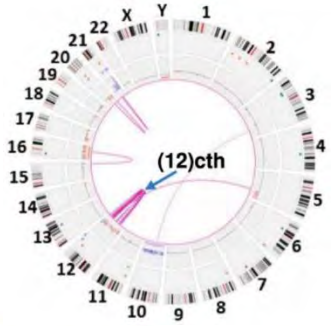
DNA methylation

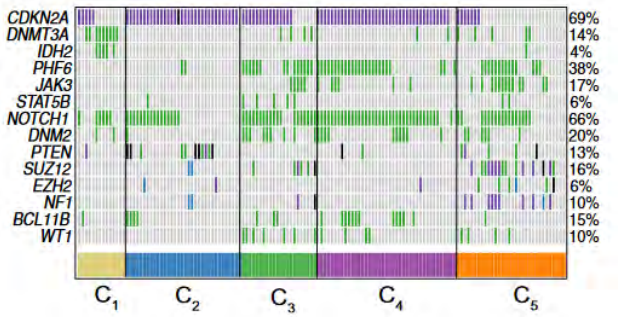
Metabolomics

Preclinical models

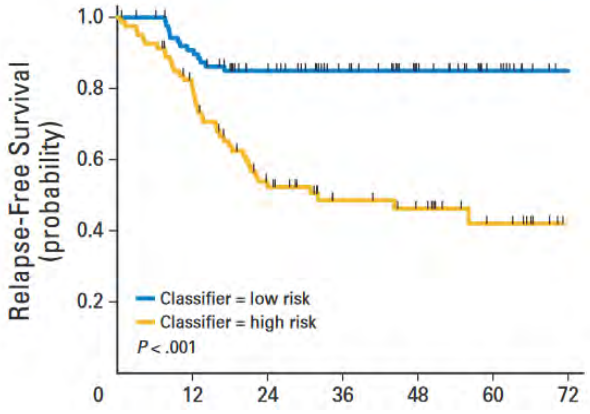
100+ PDX

Molecular annotations

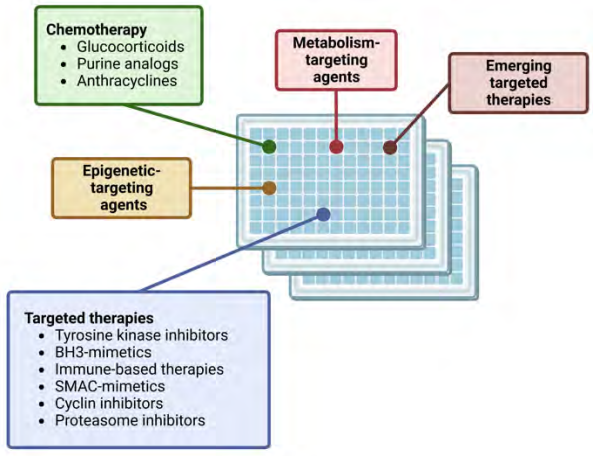


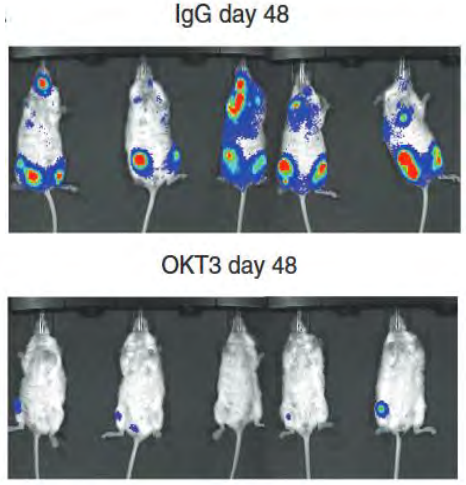


Clinical data



Drug testing

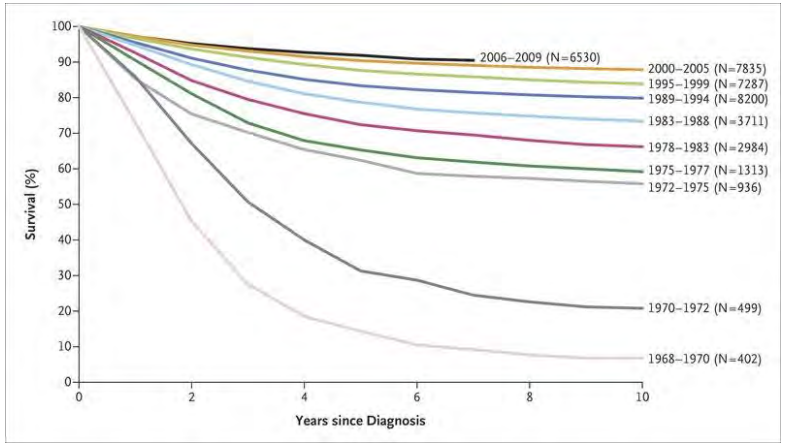




A special responsability for Hematology

- On the frontline of innovation in diagnostics and therapeutics
- Major (potential) benefit for patients and public health systems
- Leukemia: 1st cause of childhood cancer
  - Probably the biggest success story in cancer
  - Long term side effects of treatment problematic
    - Genetic testing allows stratified therapy
    - Precision medicine combining diagnostics and therapeutics

Evolution of Overall Survival in pediatric ALL

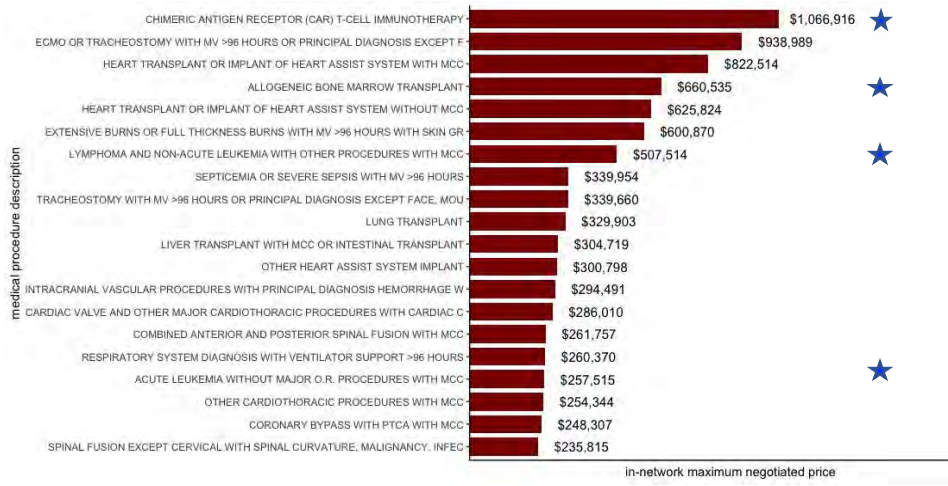


S. Hunger, C. Mullighan NEJM 2015

However, hematology is also a 'troublemaker':

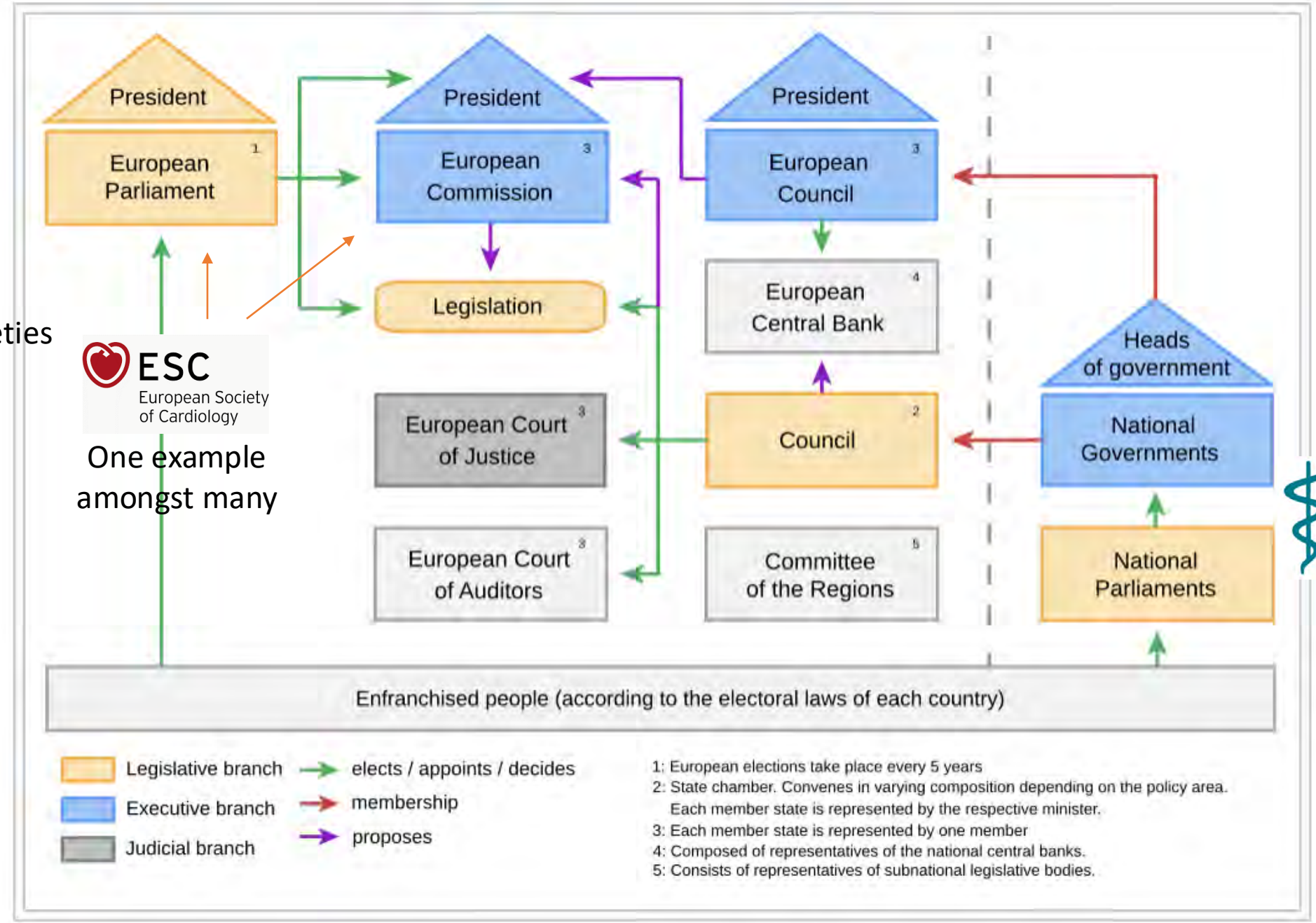
- Expensive therapies, with major impact on patient journey
  - eg. cell therapies, CAR-T… difficult for even the 'richest' countries
- Not in "one box"
  - small populations, adults and children
  - cancer and non-malignant
- Diagnostics are a cost, not a resource
  - novel methodology required for HTA
- Requires adapted regulatory frameworks and structures
  - advocacy within the evolving European Health Space
  - regulations are generic
  - multi-stakeholder communication

Most expensive medical procedures



3 main categories of Advocates in Health Innovation

3 European political institutions



Eu Med Res Societies
Congress
Research
Education
Journals….

ESC
European Society of Cardiology

One example amongst many

Ref. Ares(2025)1416181 - 21/02/2025

AWMF

Equivalents in other Member States?

Origin: 4 societies (*acForum for CEOs*)

EASD European Association for the Study of Diabetes

ECCO European CanCer Organisation

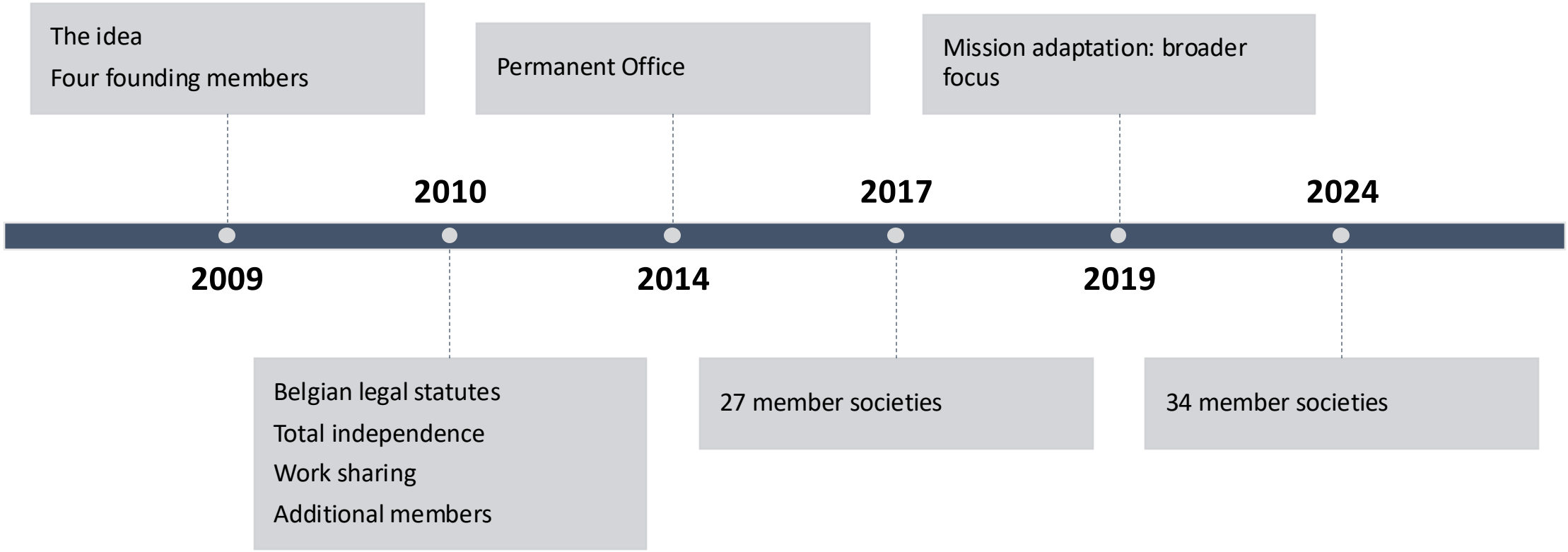
ESC European Society of Cardiology

ERS European Respiratory Society

every breath counts

History

9 Board members, of which 6 are elected
In 2025 Croatia, DK x2, FR, IT, NL, SE, NO, PT
In 2026 AT, Croatia, FR, IT, NL, SE x2, NO, PT



Biomedical Alliance in Europe

Biomedical Alliance in Europe

List of members

Association for European Paediatric and Congenital Cardiology (AEPC);
European Academy of Allergy and Clinical Immunology (EAACI);
European Academy of Neurology (EAN);
European Alliance of Associations for Rheumatology (EULAR);
European Association for Cardio-Thoracic Surgery (EACTS);
European Association for the Study of Diabetes (EASD);
European Association for the Study of Obesity (EASO);
European Association for the Study of the Liver (EASL);
European Association of Urology (EAU);
European Calcified Tissue Society (ECTS);
European Cancer Organisation;
European College of Neuropsychopharmacology (ECNP);
European Federation of Clinical Chemistry and Laboratory Medicine (EFLM);
European Federation of Immunological Societies (EFIS);
European Federation of National Associations of Orthopaedics and Traumatology (EFORT);
European Forum for Research & Education in Allergy & Airway Diseases (EUFOREA);
European Hematology Association (EHA);
European Renal Association (ERA);
European Respiratory Society (ERS);
European Society for Blood and Marrow Transplantation (EBMT);
European Society for Clinical Cell Analysis (ESCCA);
European Society for Paediatric Endocrinology (ESPE);
European Society for Paediatric Gastroenterology, Hepatology & Nutrition (ESPGHAN);
European Society of Anaesthesiology and Intensive Care (ESAIC);
European Society of Cardiology (ESC);
European Society of Clinical Microbiology and Infectious Diseases (ESCMID);
European Society of Endocrinology (ESE);
European Society of Human Genetics (ESHG);
European Society of Human Reproduction and Embryology (ESHRE);
European Society of Intensive Care Medicine (ESICM);
European Society of Pathology (ESP);
European Society of Radiology (ESR);
Federation of European Biochemical Societies (FEBS);
United European Gastroenterology (UEG).
European SocieTy for Radiotherapy & Oncology (ESTRO)

Our work

BioMed Alliance represents its members at EU level and acts as a platform for information and knowledge sharing on EU health policies

We inform member societies, healthcare professionals and researchers on cross-disciplinary health policy developments through workshops, events, a monthly newsletter and other internal meetings

We allow medical & research societies to speak with one single voice at EU level to ensure the expertise of healthcare professionals is considered in EU policy making and in the regulatory files that impact their work

We also raise awareness among policy makers on key health issues that are of high relevance for its members

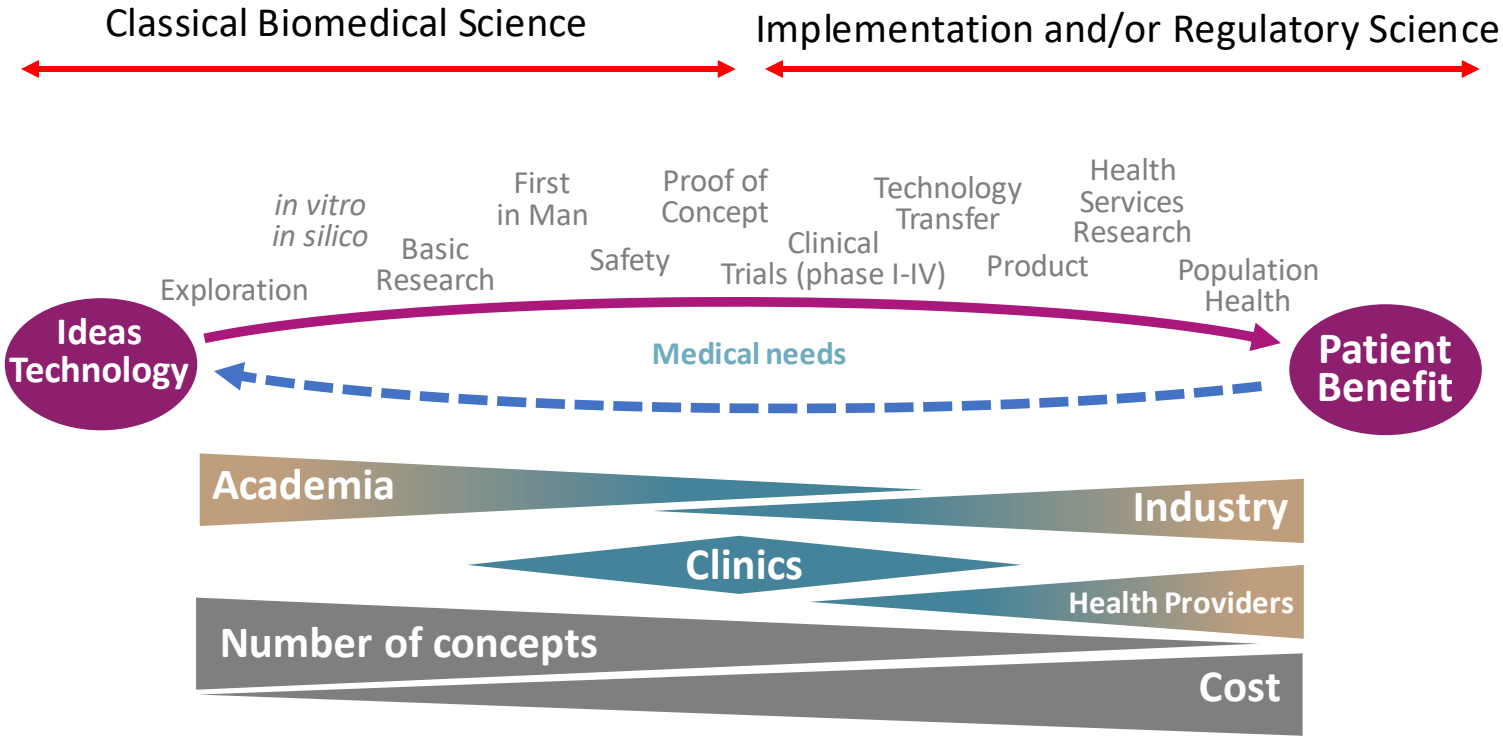
In 2024, BioMed Alliance was supported by EU4Health with an operating grant for the EXHALE project (BioMed Alliance EXpertise in Health Across Legislation at EU level) under grant agreement 101176496

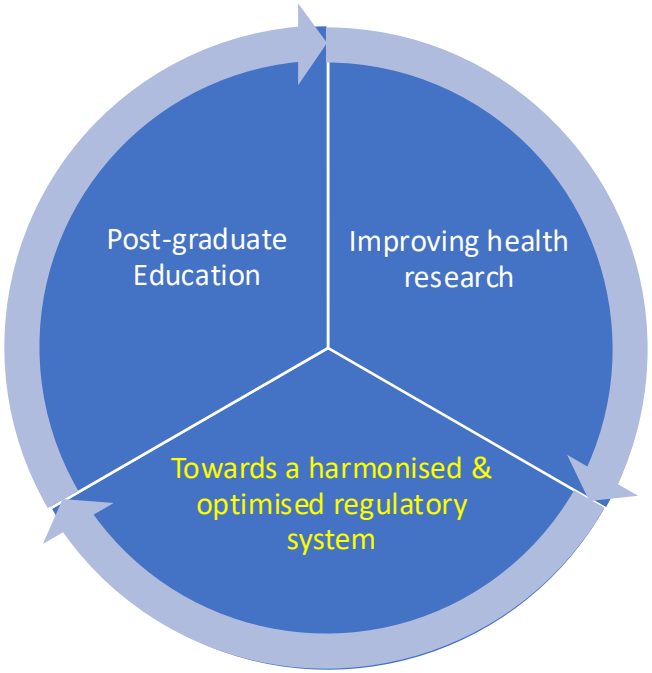
Contacts with Policy makers & Stakeholder group member*

Policy	Industry	Patients	Others	Stakeholder Coalitions/Fora
• European Commission / MDCG* • European Parliament • EMA* • Permanent Representations • HERA Civil Society Forum*	• EFPIA • MedTech Europe • COCIR • EUCOPE	• EPF • EURORDIS	• FEAM • UEMS • EIT Health	• EU Health Coalition • Coalition on Reducing Bureaucracy in Clinical Trials* • OEGH* • TEHDAS/EHDS* • BeWell • CORE-MD

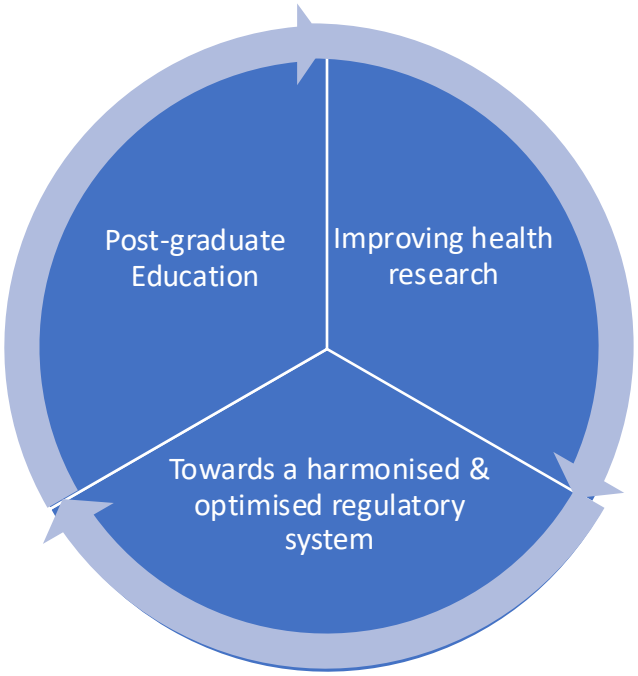
Mission - Improve the health and wellbeing of citizens in Europe

- a **unique initiative** of 35 European medical societies that together represent over 400 000 **researchers and health care professionals (HCPs)**
- Speaks as a **common voice** for all its members on transversal topics - > **Policy representation**
- Promotes excellence in European biomedical research and translation through the **full translational value chain** for the **benefit of patients**





The Scientific panel for health 2016-20 with DG-RTD



CORRESPONDENCE · Volume 388, Issue 10047, P865-866, August 27, 2016 Download Full Issue

Scientific Panel for Health: better research for better health

Karin Sipido [a] · Laurent Degos [c] · Richard Frackowiak [d] · Detlev Ganten [e] · Hans Hofstraat [f] · Ildiko Horvath [g] · Frank Luyten [b,h] · Michael Manns [i] · Wolfgang Oertel [j] · Tomáš Zima [k] Show less

Affiliations & Notes · Article Info

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Show Outline

Health is a human right, with research underpinning every advance in health care. Even if political Europe is under siege, health research must remain high on the agenda of all stakeholders. The Scientific Panel for Health,[1] created under the Horizon 2020 Framework Programme for Research and Innovation of the EU, was born out of concerns of the European biomedical research community.[2,3] Too often, high-quality research is not translated into innovation. European strengths and values are not embedded in or supported by research policies. Challenges in regulations and research management accumulate to the detriment of research outcomes, limiting their impact on health. As a science-led expert group with broad vision and stakeholders' representation, the Scientific Panel for Health has been mandated to provide a comprehensive view on how to advance biomedical research in support of improving health in Europe, and to formulate recommendations to policy makers.[1]

a Department of Cardiovascular Sciences, Division of Experimental Cardiology, KU Leuven, B3000 Leuven, Belgium
b Skeletal Biology and Engineering Research Centre, KU Leuven, B3000 Leuven, Belgium
c University Institute for Haematology, University of Paris Diderot, Hospital Saint Louis, Paris, France
d Department of Clinical Neurosciences, CHUV University Hospital, University of Lausanne, Lausanne, Switzerland
e World Health Summit, Berlin, Germany
f Philips Research, Eindhoven, Netherlands
g National Koranyi Institute for TB and Pulmonology, Budapest, Hungary
h University Hospitals UZ Leuven, Leuven, Belgium
i Department of Gastroenterology, Hepatology and Endocrinology, Hannover Medical School, Hannover, Germany
j Department of Neurology, Philipps University, Marburg, Germany
k Charles University in Prague, Prague, Czech Republic

Towards a "EU NIH"?

First, what we can do, then what we should be doing +/_ reimbursing

Implementation Science in health

- The study of methods to promote the adoption and integration of evidence-based practices, interventions and policies into routine health care and public health settings.

https://www.fic.nih.gov/ResearchTopics/Pages/ImplementationScience.aspx

Interventions and evidence based practices that are poorly implemented – or not implemented at all – do not produce expected health benefits. Even when effectively implemented, interventions and practice changes still might not produce expected health benefits if effectiveness is lost during implementation, or if the intervention or practice was never effective in the first place.

Implementation science is the scientific study of methods and strategies that facilitate the uptake of evidence-based practice and research into regular use by practitioners and policymakers.

The field of implementation science seeks to systematically close the gap between what we *know* and what we *do* (often referred to as **the know-do gap**) by identifying and addressing the barriers that slow or halt the uptake of proven health interventions and evidence based practices.

https://impsciuw.org/implementation-science/learn/implementation-science-overview/

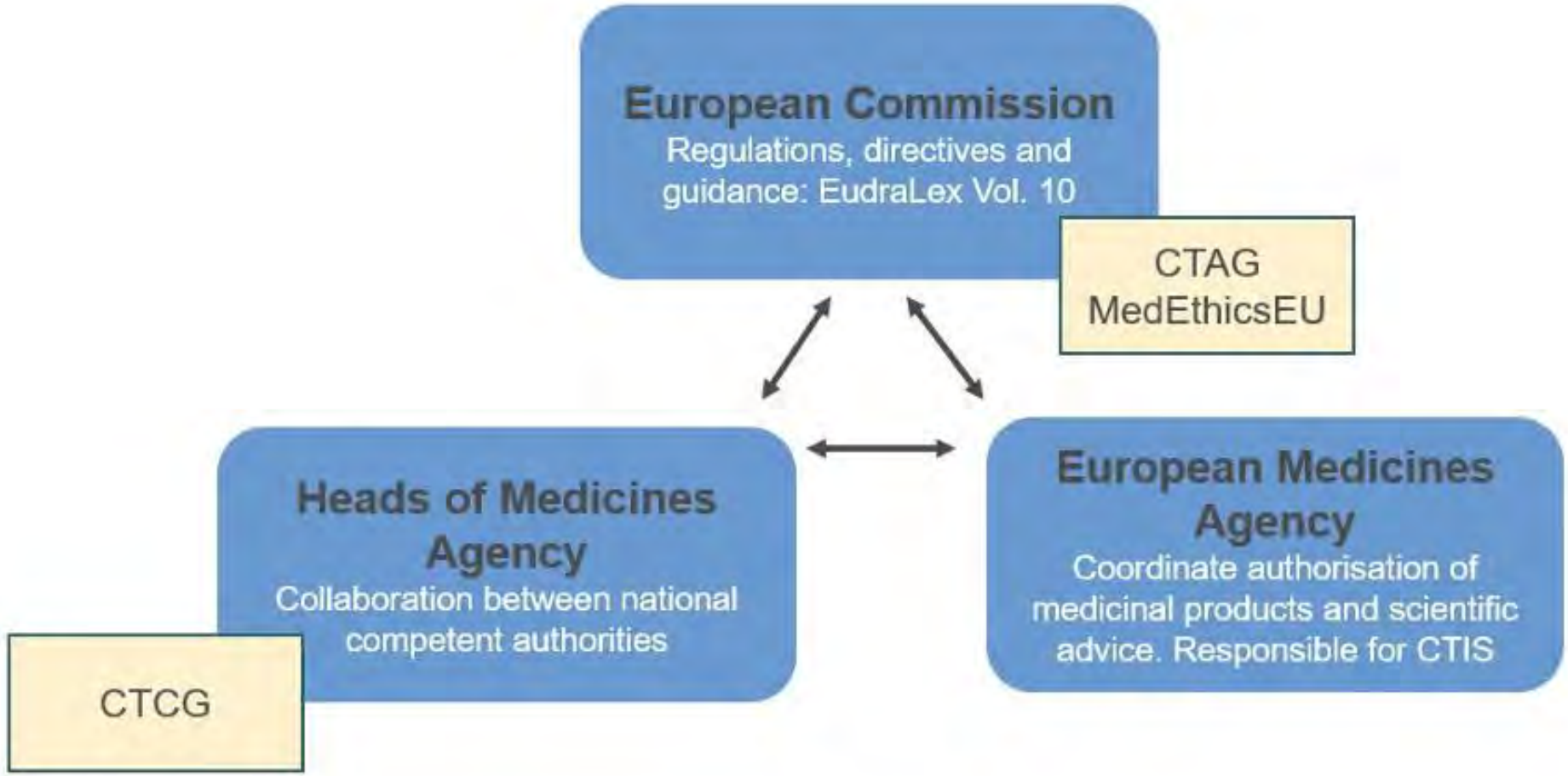


Figure 2: Structure of the EU Medicines Governance relevant to clinical trial authorisation. The clinical trial advisory group (CTAG) and the clinical trial coordination group (CTCG) consists of Member State clinical trial experts from the competent authorities. The MedEthicsEU consists of Member State representatives from the Ethics Committees secretariats of Research Ethics Committees (RECs) and cover both medicines and devices.

https://health.ec.europa.eu/medical-devices-topics-interest/combined-studies_en

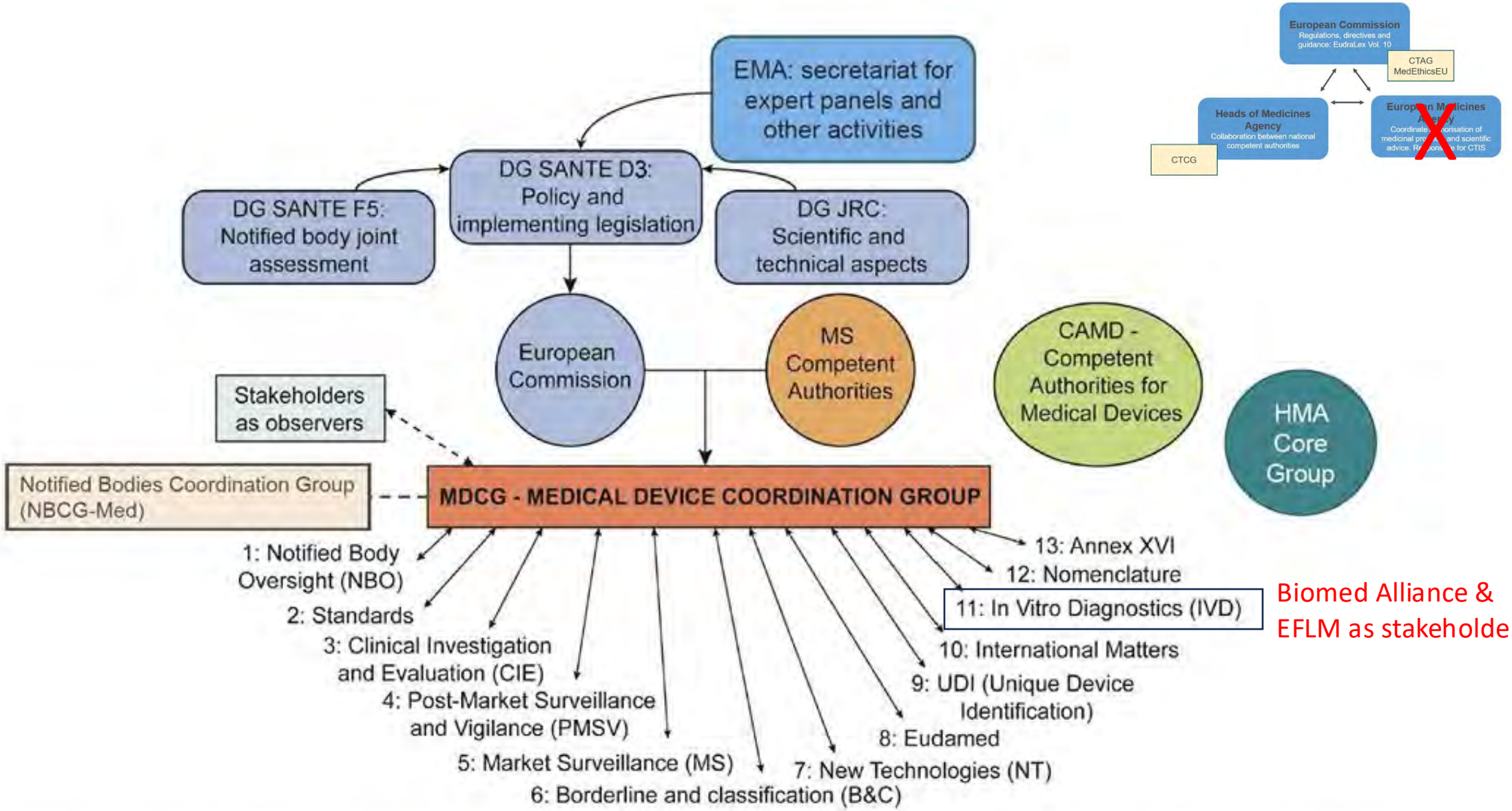


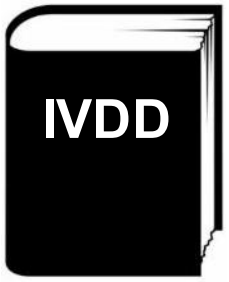
Figure 1: Structure of EU medical devices governance. The MDCG and related expert working groups consists of experts and representatives from the relevant Competent Authorities in the Member States and are hosted by the European Commission.

Biomed Alliance & EFLM as stakeholders

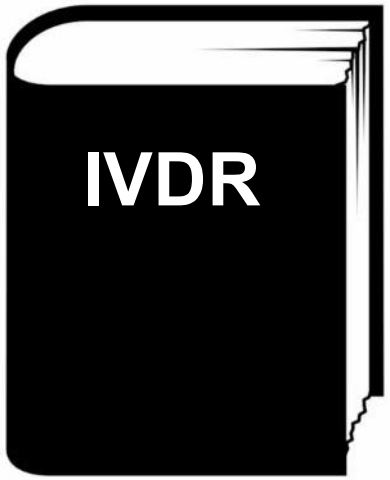
https://health.ec.europa.eu/medical-devices-topics-interest/combined-studies_en

IVDR: What impact for health care professionals & laboratories?

- IVD**D** regulated commercial IVDs (CE-IVDs)
- IVD**R** regulates CE-IVDs and IH-IVD (LDT)
- Intention to improve clinical value of IVD use, including with **post-market surveillance**
  - Managed similarly to Medical Device regulation (MDR) and Digital Health (EHDS)



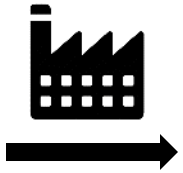
1998 - 2022



Entry into force: 2017

5 years for Implementation

Initial Date of application: May 26th, 2022



CE-IVDs

LDTs/IH-IVD

Laboratory-developed tests (FDA) /

In-House in-vitro devices (EU) IVDR Art. 5.5

25-50% of tests by academic labs, Dombrink I. et al. 2023

Overseen by

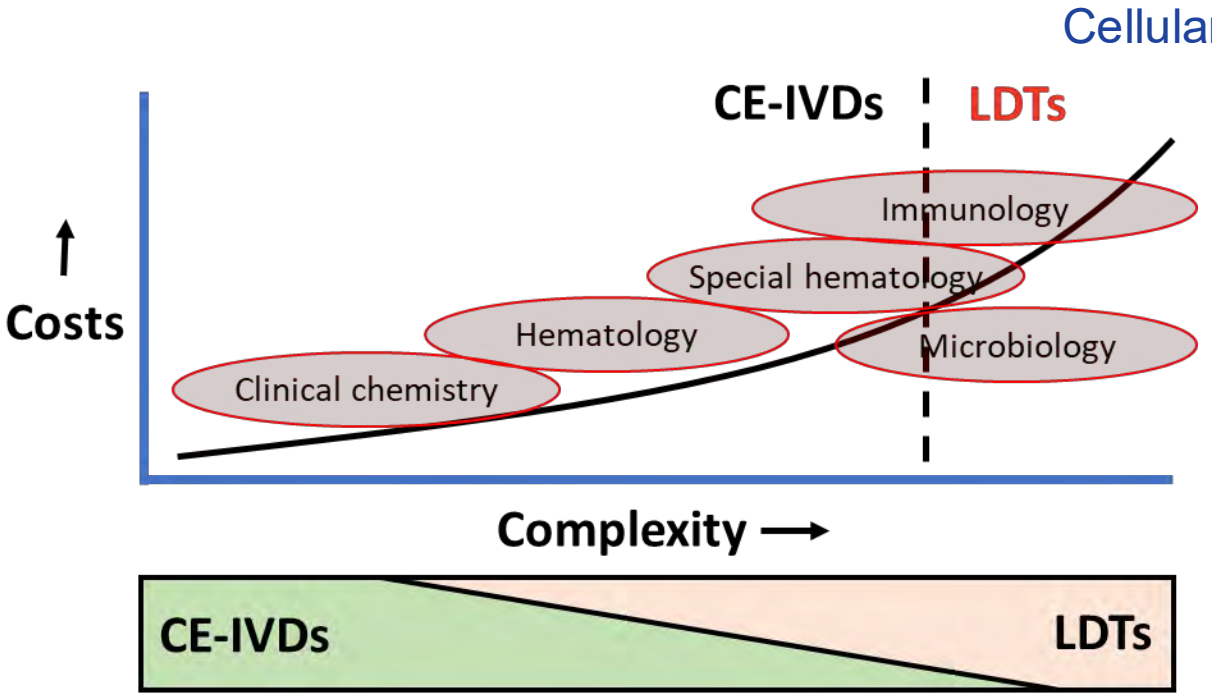
Notified bodies (NB)

National competent authorities

Slide adapted from Van Dongen, 9th ESLHO Symposium, Zoom webinar, 5 November 2020

In-House IVDs (EU IVDR) ≃ Laboratory Developed Tests (USA FDA/CLIA)

High complexity assays are frequently In-House IVDs



RISKS of IVDR

- NB system needs adaptation
- EUDAMED registry of MD/IVD delayed
- Loss of CE-IVDs, esp. from SMEs
- Increased cost of CE-IVDs

- Fragility of the translational diagnostic value chain
- Difficulty in maintainance of innovative diagnostics
- Risk of monopolies (Article 5.5d)
- Implications for Clinical Trials (alongside CTR)
  - Loss of European competitivity

- Assays with higher complexity are more difficult to commercialize
- To provide optimal healthcare, diagnostic laboratories depend on development of LDT/IH-IVDs for many (complex) applications
- This dependence differs significantly per diagnostic field

ESLHO european scientific foundation of laboratory hemato oncology

Slide from Van Dongen, 9th ESLHO Symposium, Zoom webinar, 5 November 2020

Update on MDR/IVDR targeted revision

The initiative aims to:

- reduce administrative burden, including reporting obligations
- enhance the predictability and cost-efficiency of notified body conformity assessment and certification processes
- make the conformity assessment requirements more proportionate, especially for low and medium risk devices and those for special patient needs (e.g. orphans, breakthrough, pediatric, in-house)
- enable further digitalisation
- streamline procedures, including governance
- enable the EU medical device sector to benefit from international reliance
- better align with other relevant EU legislation

★441 contributions submitted through call for evidence (deadline was 6 October 2025)

MDCG IVD group 18/11/25

Concerns (Biomed, MTE, EFPIA, NBs..) on definition of:
a Health Institution (MDCG 2023-1)
Orphan/rare/niche IVD

★

Position documents from (i.a.)
AWMF
Biomed Alliance
ESMO …

Update on MDR/IVDR targeted revision

Adoption planned by December 2025

Proposal to amend MDR/IVDR → ambitious, but targeted revision building on evaluation results and ongoing consultations with member states and stakeholders supported by:

Staff Working Document on the results of the targeted evaluation

Staff Working Document on the Cost-Savings analysis

Consensus MD/IVD position* for regulatory revision in 2025

- Biomed Alliance proposes extension of EMA to include Medical Devices (‘EMDA’)
- Manage IVDR independently/distinctly from MDR
- Modifiy Art 5.5 in order to protect/optimise IH-IVDs, including in clinical trials
- Extend EQA to IH-IVDs & beyond laboratory to test evaluation
- ISO 15189 accreditation should be sufficient & avoid confusion
  - Will require (minor?) adaptation and harmonisation at European level
  - Reputedly, similar but more exacting than CLIA (USA Clinical Laboratory Improvement Amendments)

submitted 6/10/25

https://www.biomedeurope.org/news/biomed-alliance-response-to-the-call-for-evidence-on-medical-devices-and-in-vitro-diagnostics-targeted-revision-of-eu-rules/

Clinical Laboratory Improvement Amendments (CLIA)

- Resulted from public and congressional concerns about the quality of clinical laboratory testing in the United States and set standards designed to improve quality.
- Goal of improving and maintaining quality.
- CATEGORIES OF TESTS BY COMPLEXITY (Categories 1-3)
- CERTIFICATION
- PROFICIENCY TESTING
- PATIENT TEST MANAGEMENT (assures optimum integrity and identification of patient specimens)
- QUALITY CONTROL
- PERSONNEL
- QUALITY ASSURANCE
- INSPECTIONS

Kahles A et al. ESMO open 2025

FDA regulation of LDTs (=IH-IVDs)… or not

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REGULATORY UPDATE: FDA RELEASES NEW FINAL RULE DESCRIBING NEW APPROACH FOR ENFORCING LABORATORY-DEVELOPED TESTS

April 30, 2024

The U.S. Food and Drug Administration (FDA) issued a **final rule** yesterday establishing a regulatory framework for laboratory-developed tests (LDTs).

The final rule modifies the definition of in vitro diagnostic products (IVDs) to explicitly include LDTs. Since IVDs are defined as devices, all LDTs will now be subject to the regulatory framework governing devices, which includes adverse event reporting, establishment registration, device listing, labeling requirements, investigational use requirements, quality system requirements and premarket review.

Until now, FDA has exercised enforcement discretion and has not enforced applicable requirements for most LDTs. The final rule includes an approach to phase out enforcement discretion for most LDTs, which include "IVDs that are manufactured and offered as LDTs by laboratories that are certified under CLIA and meet the regulatory requirements under CLIA to perform high complexity testing, and used within such laboratories, even if those IVDs do not fall within FDA's traditional understanding of an LDT because they are not designed, manufactured, and used within a single laboratory."

April 2024

Consolidated lawsuits filed by the American Clinical Laboratory Association (ACLA) and by the Association for Molecular Pathology (AMP)

June 2025

•CLIA/CAP* remain the core quality and personnel standards for LDTs, which benefit from FDA enforcement discretion.
•Hospitals & health systems can continue to develop, validate and use LDTs within a single CLIA lab for direct patient care

•CLIA=Clinical Laboratory Improvement Amendments/
•CAP=College of American Pathologists

What is the European equivalent of CLIA?

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FDA DECLINES TO APPEAL LDT COURT RULING

June 04, 2025

The Food and Drug Administration declined to appeal a recent district court ruling that overturned the agency's final rule regulating laboratory-developed tests (LDTs). The 60-day window to file an appeal expired this weekend, effectively ending the agency's effort to expand its regulatory authority over LDTs.

In a March 31 ruling, the U.S. District Court for the Eastern District of Texas determined that the **final rule issued by FDA in April 2024**, which established a regulatory framework for LDTs, exceeded the FDA's authority and was, therefore, unlawful. The ruling was in response to consolidated lawsuits filed by the American Clinical Laboratory Association (ACLA) and by the Association for Molecular Pathology (AMP).

AABB has long supported an alternative approach to regulating LDTs. In previous public statements, AABB noted that LDTs play a critical role in diagnosing and treating conditions such as cancer, rare diseases and infections – and that regulations set forth in the final rule could jeopardize this. AABB also cautioned that the final rule could lead to financial burdens on laboratories, stifle innovation and compromise patient care.

UNIVERSITÄTS
KLINIKUM
HEIDELBERG

Institute of Pathology Heidelberg

IVDR: AWMF views

Courtesy of Albrecht Stenzinger

Member of The AWMF's Ad Hoc Committee for In Vitro Diagnostics (Lead: Michael Vogeser)

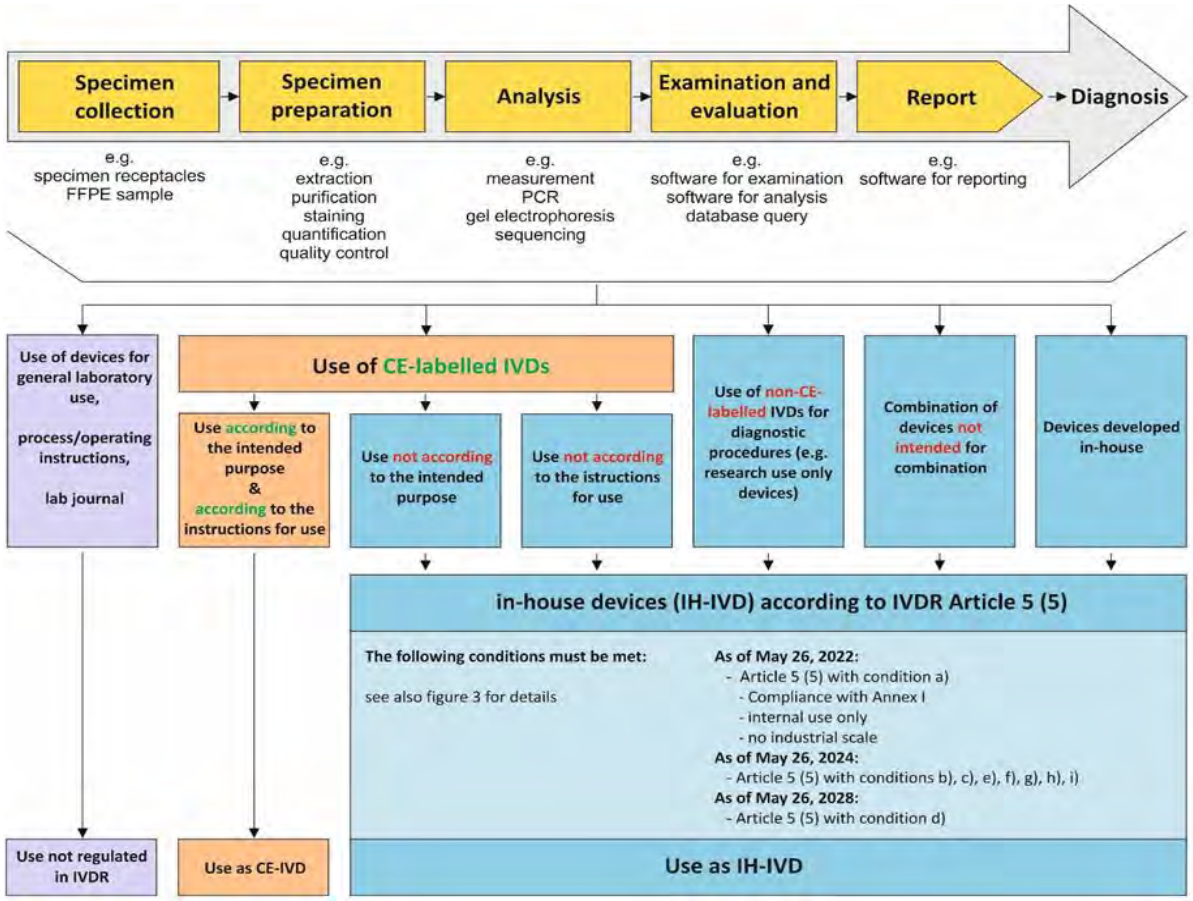
Monika Brüggemann, member of both AWMF and Biomed Alliance IVD groups

Institute of Pathology
Center for Molecular Pathology

UK HD

Process chain for analytics in health institutions

Ref. Ares(2025)1416181 - 21/02/2025



Each link in the process chain from specimen receipt to diagnostic findings may contain devices that can be assigned to either general laboratory use (purple), CE-marked *in vitro* diagnostic devices (CE-IVD, orange), or in-house developed IVDs (IH-IVD, blue)

AWMF argues that :

- IH-IVDs, because they are developed by a health care provider and are only used by this institution, are neither marketed nor made available on the EU market and should therefore not be in the scope of EU-IVDR.
- In accordance with Article 168 of the Treaty on the Functioning of the EU, responsibility for medical care lies with the EU member states. Consequently, the regulation of medical services should fall under national law….

Ref. Ares(2025)1416181 - 21/02/2025

EU CLIA equivalent instead of IVDR Art. 5?

Implement an adapted Art. 5.5 towards a European CLIA equivalent for IH-IVDs

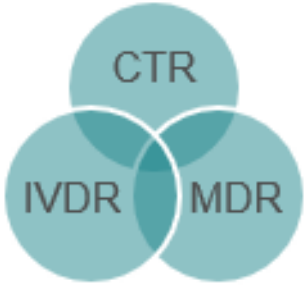
Kahles A et al. 2025

COMBINE – optimising the regulatory environment for combined studies

Courtesy of Ditte Zerlang Andersen, PhD, COMBINE Programme Manager
Danish Medicines Agency (DKMA),

- CTR applicable since 21 January 2022: **Coordinated in CTIS**
- MDR applicable since 21 May 2021:
- IVDR applicable since 21 May 2022:

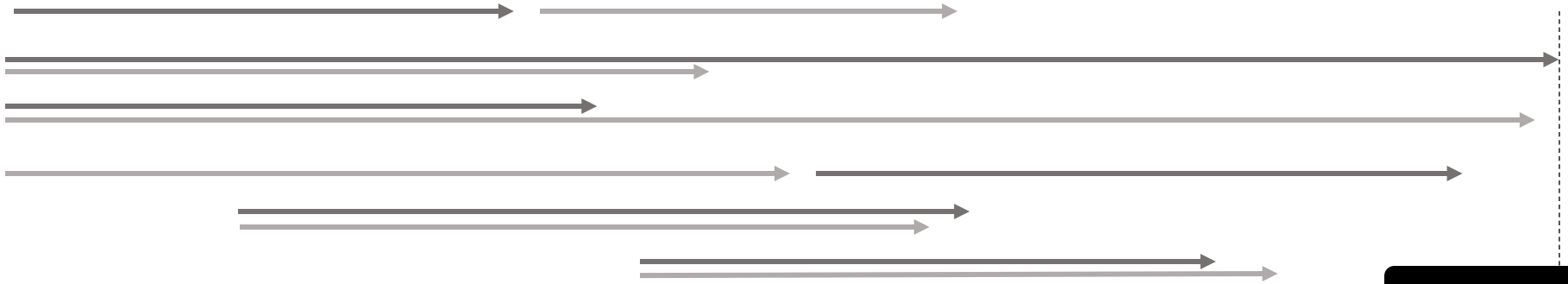
Not yet coordinated.
Eudamed in the future (excl ethics)



Performance Study (PS) of IVD for inclusion of patients

Clinical Trial (CT) with a medicinal product

CT: CTIS – one entry with coordinated CA and ethics assessments



PS/CI: National procedures by competent authorities (CAs) and ethics committees

delay of CT initiation

Broad EU regulatory network collaboration

Commission and EU Expert groups of volunteer national competent authorities and ethics committees representing assessors involved with authorisation of combined studies

Clinical trials of medicines

- HMA* Clinical Trials Advisory Group (CTAG)
- HMA* Clinical Trials Coordination Group (CTCG)

Medical devices

- Medical Device Coordination Group (MDCG)
- 2 of its 13 subgroups: IVD and CIEPSE

Ethics

- MedEthics EU - Voluntary coordination between national ethics committees

Stakeholder reference group: Biomed Alliance, ECRIN, EHA, EORTC, ESMO…..

ACRO (Association of Clinical Research Organizations)
AMDM (Association of Medical Diagnostics Manufacturers)
Biomedical Alliance in Europe
COCIR
Conect4Children Stichting
EAN (European Academy of Neurology)
EATRIS (European Infrastructure for Translational Medicine)
ECRIN (European Clinical Research Infrastructure Network)
EUCOPE (European Confederation of Pharmaceutical Entrepreneurs)
EuropaBio
EAAR (European Association of Authorised Representatives)
EFPIA (European Federation of Pharmaceutical Industries and Associations)
EHA (European Hematology Association)
EORTC (European Organisation for Research and Treatment of Cancer)
ESMO (European Society for Medical Oncology)
MedTech Europe
MPP Association
NBCG-Med (Notified Body Coordination Group)
TEAM-NB (European Association of Medical Devices Notified Bodies)
VE (Vaccines Europe)

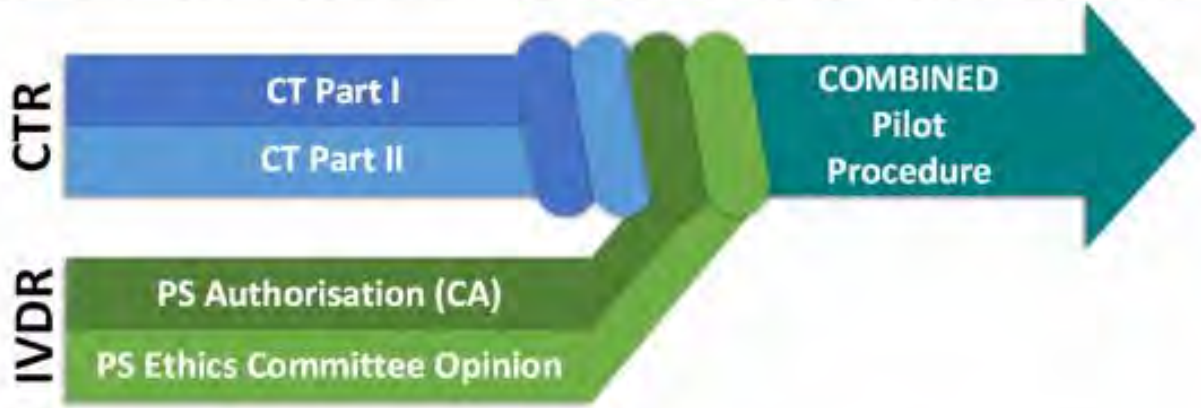
*HMA= Heads of Medecines Agencies of EU Member States

P1 – All-in-one coordinated assessment

Cross-sector project 1: 'All in one coordination' – across Member States and medicine/device sectors - analysis and pilot

***Project 1*: 'All in one coordination of assessment procedures under CTR/IVDR/MDR'**

Purpose to explore coordinating Member State assessments of applications for studies among Member States (including competent authorities and ethics committees) and across the CTR and IVDR or MDR. Focus on CT of a medicinal product combined with PS of a companion diagnostic IVD.

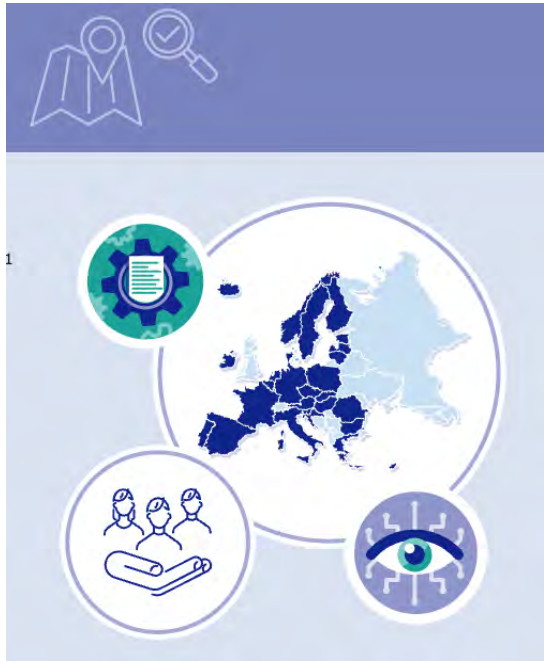


- First phase: single sponsor for CT and PS
- Pilot launched June 2025 - ddl for expressions of interest: Sept 2025
- 8 expressions of interest received and accepted
- First applications start in Nov 2025, last ones to start in March 2026
- Preparatory work for phase 2 ongoing
- Project 1 stakeholder meeting - 19 November 2025

European Commission

Communication between EU data platforms

CTR EU 536/2014 obligatory from 30/01/2025 via Clinical Trials Information System (CTIS).



European Commission | EN

Public Health

Home > Latest updates > The EUDAMED four first modules will be mandatory to use as from 28 May 2026

NEWS ANNOUNCEMENT | 27 November 2025 | Directorate-General for Health and Food Safety | 1 min read

The EUDAMED four first modules will be mandatory to use as from 28 May 2026

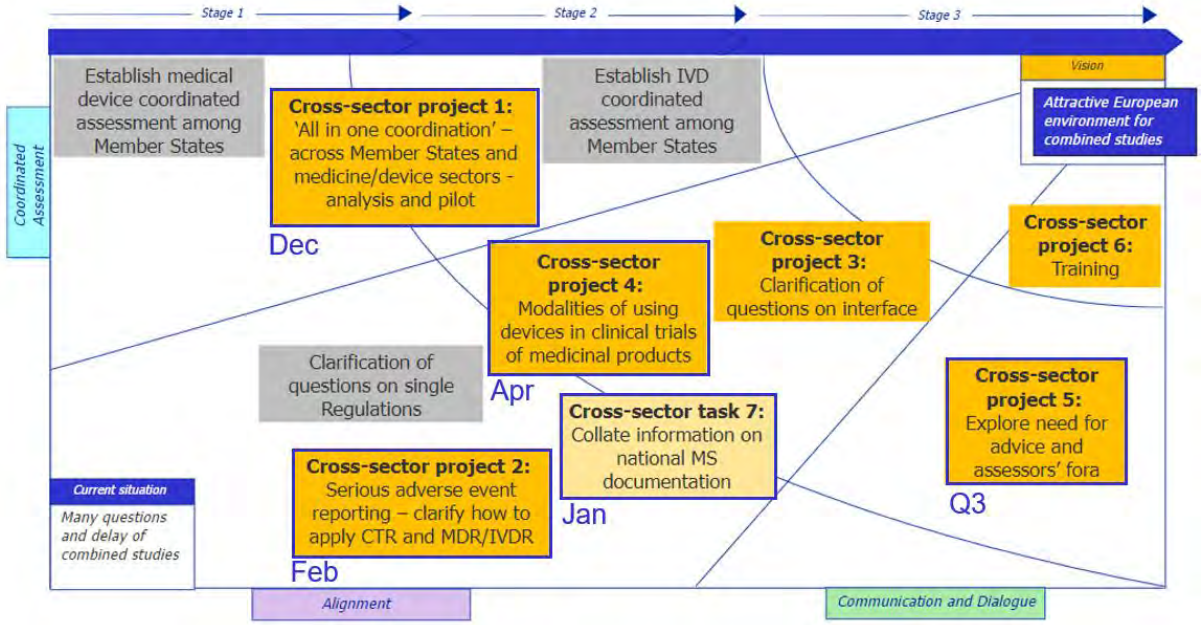
The Commission Decision (EU) 2025/2371 of 26 November 2025 on the notice regarding the functionality and the fulfilment of the functional specifications of certain electronic systems included in the European Database on Medical Devices declaring the functionality of the first four modules has been published in the OJEU of 27 November 2025.

In accordance with the transitional provisions set out in Regulation (EU) 2024/1860, this publication triggers a transition period of 6 months;

Therefore, as from 28 May 2026 the first four EUDAMED modules will be mandatory to use:

- Actor registration
- UDI/Devices registration
- Notified Bodies & Certificates
- Market Surveillance

COMBINE program outlook



- Brings parties together across sectors
- Active participatory roles, intended to address needs
- Aims to facilitate implementation
- Tests **new ways of working**
- Will inform possible future policy development

More information:
Combined studies - European Commission (europa.eu)

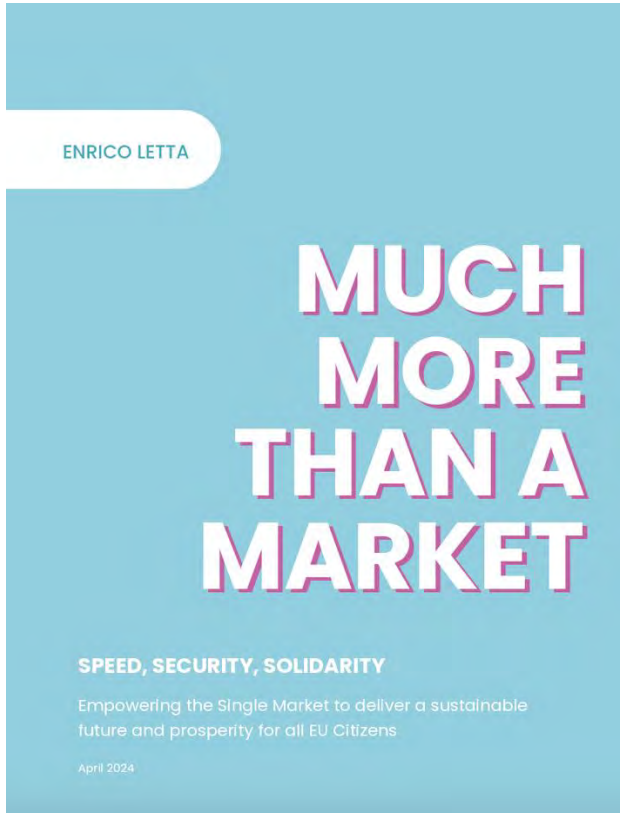
Conclusion 1: European Health Space advocacy in 2026

- If we want a “certain degree of” fit-for-purpose, appropriate, competitive Europe Health Space, we need to contribute to building it
- This needs scientific innovation, but also Implementation scientific accompaniment and advocacy
  - There are 3 main categories of advocates in health
    - Industry, Patients and Health Care Professionals
- A small number of European regulatory scientists within medical specialties is required, now
  - This requires community acceptance, training and academic recognition
- It is important for European and national advocates to communicate
- The European Life Sciences strategy is starting…

The current European climate in research in 2024

The DRAGHI report: 9th Sept. 2024
Evaluation One year on: 16th Sept. 2025

HEITOR report on Horizon programs
https://data.europa.eu/doi/10.2777/9106236



LETTA,
president Institut Jacques Delors

Biomed general meeting 25/11/25

Flagship Innitiatives

Reinforcing European R&I

- Clinical Research Investment Plan
- Network of ATMP Centers of Excellence
- Life Sciences career development through Choose Europe

Unlocking the power of data and AI for breakthrough innovation

- European Life Sciences R&I Data Assembly

Promoting innovation-responsive regulation

- EU Biotech Act
- Regulatory simplification for medical devices and in vitro diagnostics

Promoting a holistic approach to the life sciences

- One Health approaches in research and innovation
- One Health Microbiome Initiative
- Climate Change and Health R&I Agenda

Life Science Coordination Group

Unlocking public and private investment

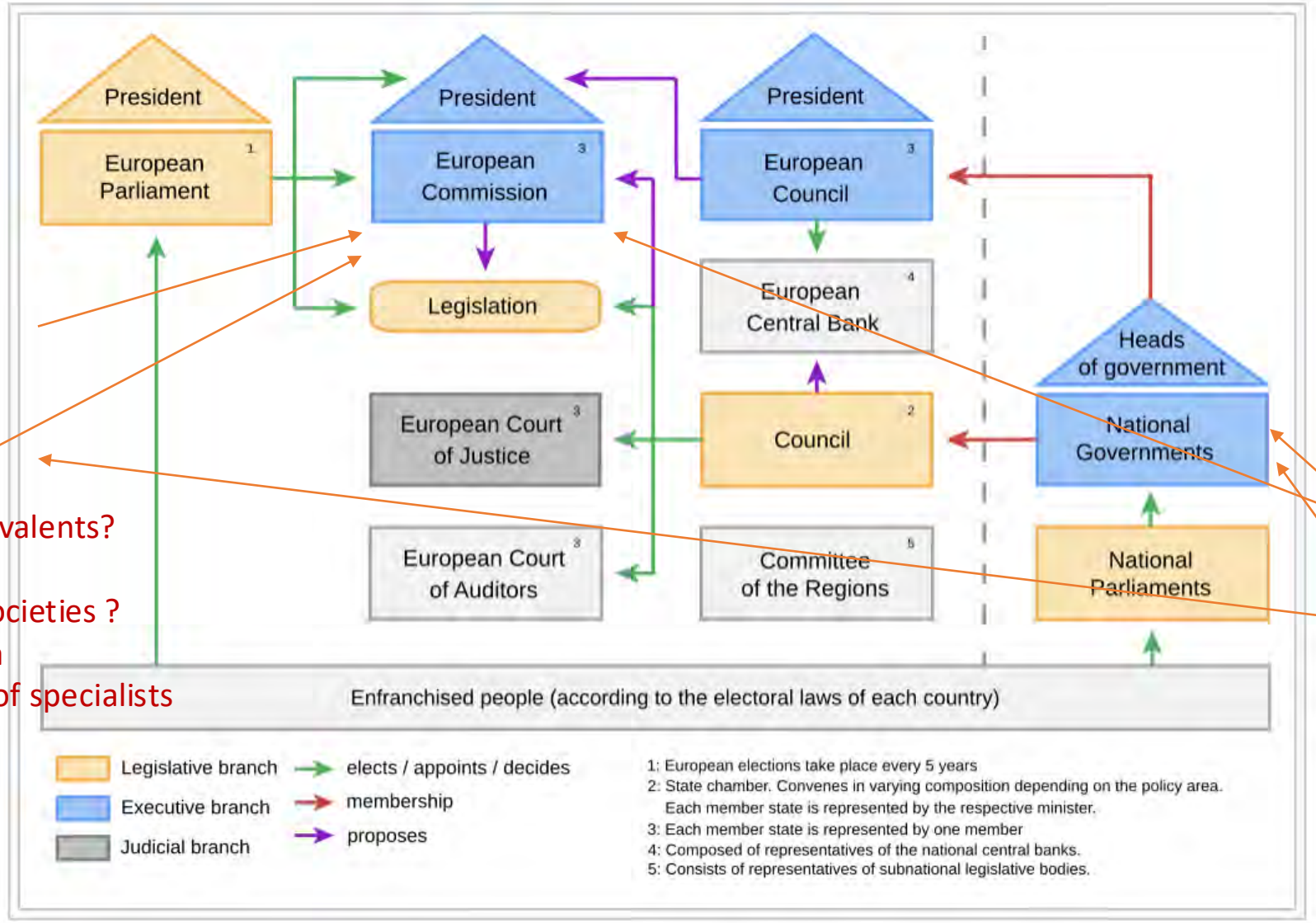
- Life Sciences Investors & Corporates Interface
- Procurement of life science innovations

Choose Europe

Optimizing Communication between European Medical Specialists and the European Commission

e.g. eha

An Alliance of AWMF equivalents?
FEAM?
Academies vs. Medical societies ?
Ensure communication via
overlapping membership of specialists



Ref. Ares(2025)1416181 - 21/02/2025
AWMF
DGHO DEUTSCHE GESELLSCHAFT FÜR HÄMATOLOGIE UND MEDIZINISCHE ONKOLOGIE
e.g.

Advocacy requires an alliance of medical and political science knowledge/skills & sufficient representation

"Everything is possible if we communicate clearly and respectfully"

EUROPEAN MCL NETWORK

GRAALL
LALA GOELAMS SAKK

NGS EuroClonality

EuroMRD

Lysa
THE LYMPHOMA STUDY ASSOCIATION

Société Française de lutte contre les Cancers et les Leucémies de l'Enfant et de l'adolescent
SFCE

GBMHM
Groupe des Biologistes Moléculaires des Hémopathies Malignes

sfh
Société Française d'Hématologie

Biomedical Alliance in Europe

Vahid Asnafi and the « Home team »

Necker ENFANTS MALADES HÔPITAL UNIVERSITAIRE

Université Paris Cité

Institut Necker Enfants Malades
Centre de Recherche

eha

Why the Germans do it better: Notes from a Grown-up Country

John KAMPFNER (Aug 2020)

The last paragraph

Countries that struggle with the present take comfort from the nostalgia of past glories, real or imagined. Germany, because of its history, cannot. Germany is Europe's best hope in this era of nationalism, anti-enlightenment and fear.

Britain was always seen as a beacon, America too, but both countries have abrogated much of their responsibility to the wider world. Who will represent European values in a fast-changing world? Who will stand up to authoritarian regimes? Who will make the case for liberal democracy?

Germany can, because it knows what happens when countries fail to learn the lessons of history.