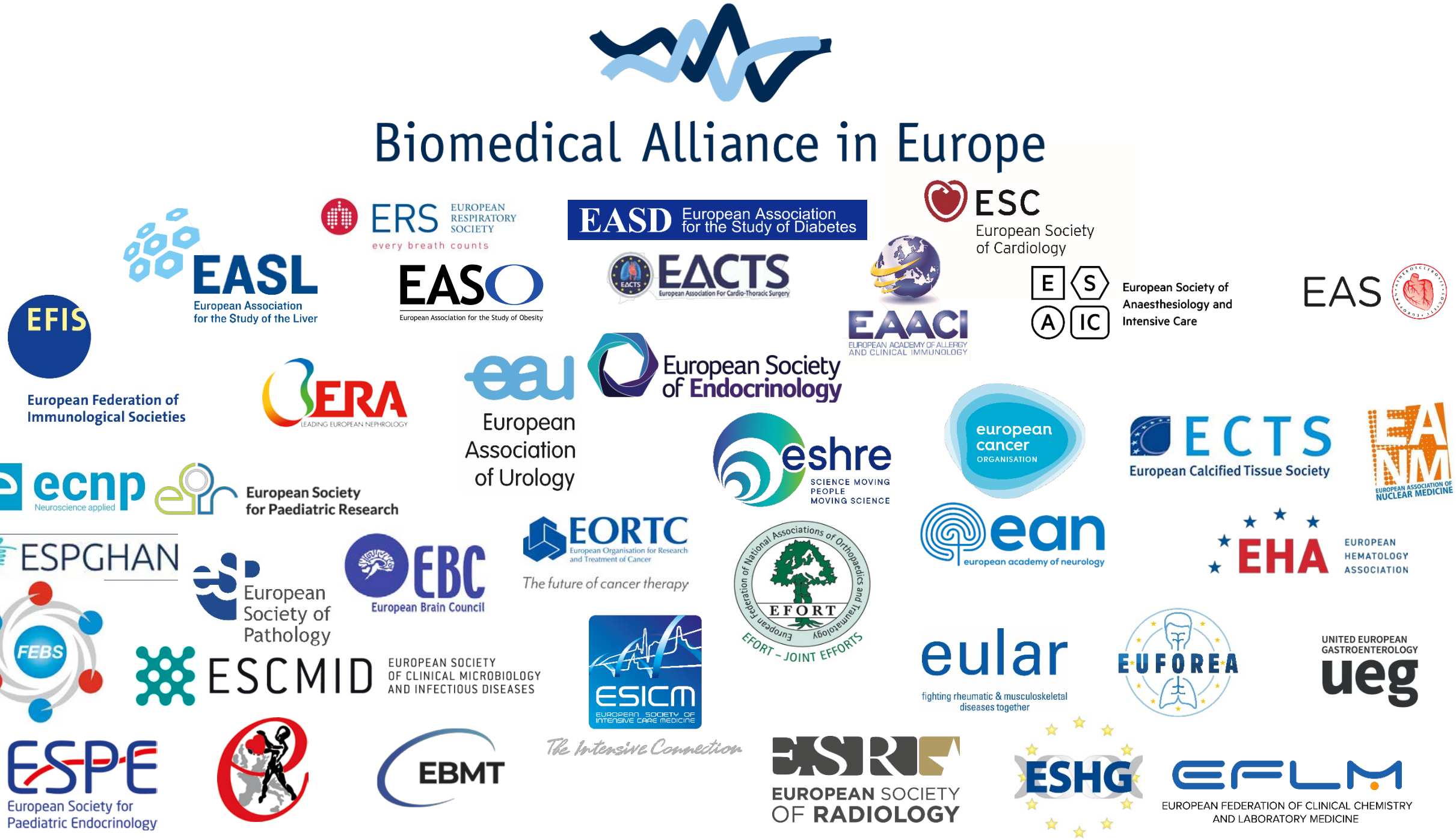
Elizabeth Macintyre, IVDR TF chair and President-elect

Diagnostic Hematologist, Necker Hospital and Université Paris Cité, FR

European Hematology Association past-President (2021-23)

CORE-MD, 10/7/2023

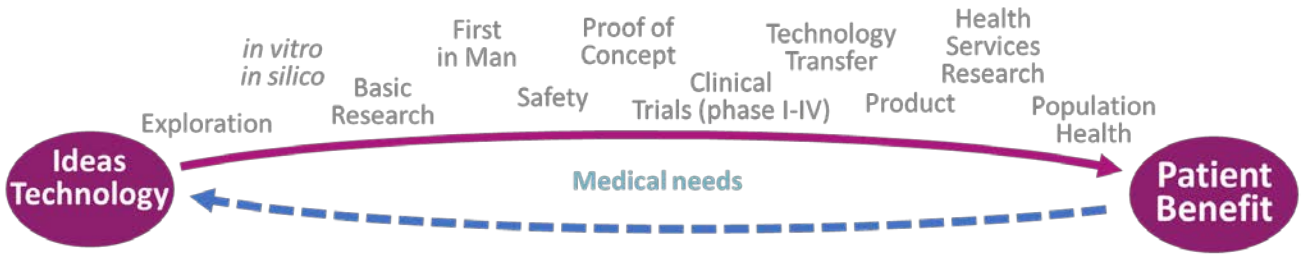
Biomedical Alliance in Europe



Mission

Improve the health and wellbeing of citizens in Europe

- a **unique initiative** of 36 European medical societies that together include more than 400,000 researchers and health professionals
- Speaks as a **common voice** for all its members
- Represents the **translational value chain** from basic research to clinical treatment
- Promotes excellence in European biomedical research and translation for the **benefit of patients**



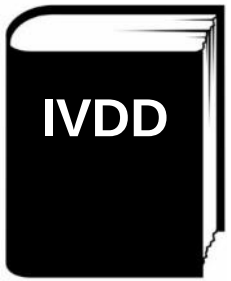
Committees, Task Forces & Working groups

- CME Experts Permanent Committee
- Regulatory Affairs Committee
  - In Vitro Diagnostics Task Force
  - Medical Devices Task Force
  - Health data Task Force (European Health Data Space)
- Research Committee
- Academic Clinical Trials Task Force
- Policy Officers Committee

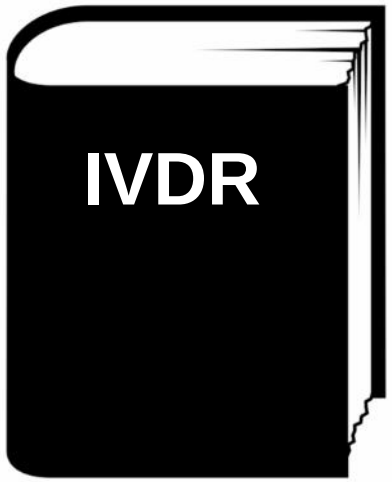
IVDR: What impact for health care professionals & laboratories?

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

Biomedical Alliance in Europe



1998 - 2022



Entry into force: 2017

5 years for Implementation

Initial Date of application: May 26th, 2022

CE-IVDs

LDTs

Laboratory-developed tests / In-house devices

EFLM EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

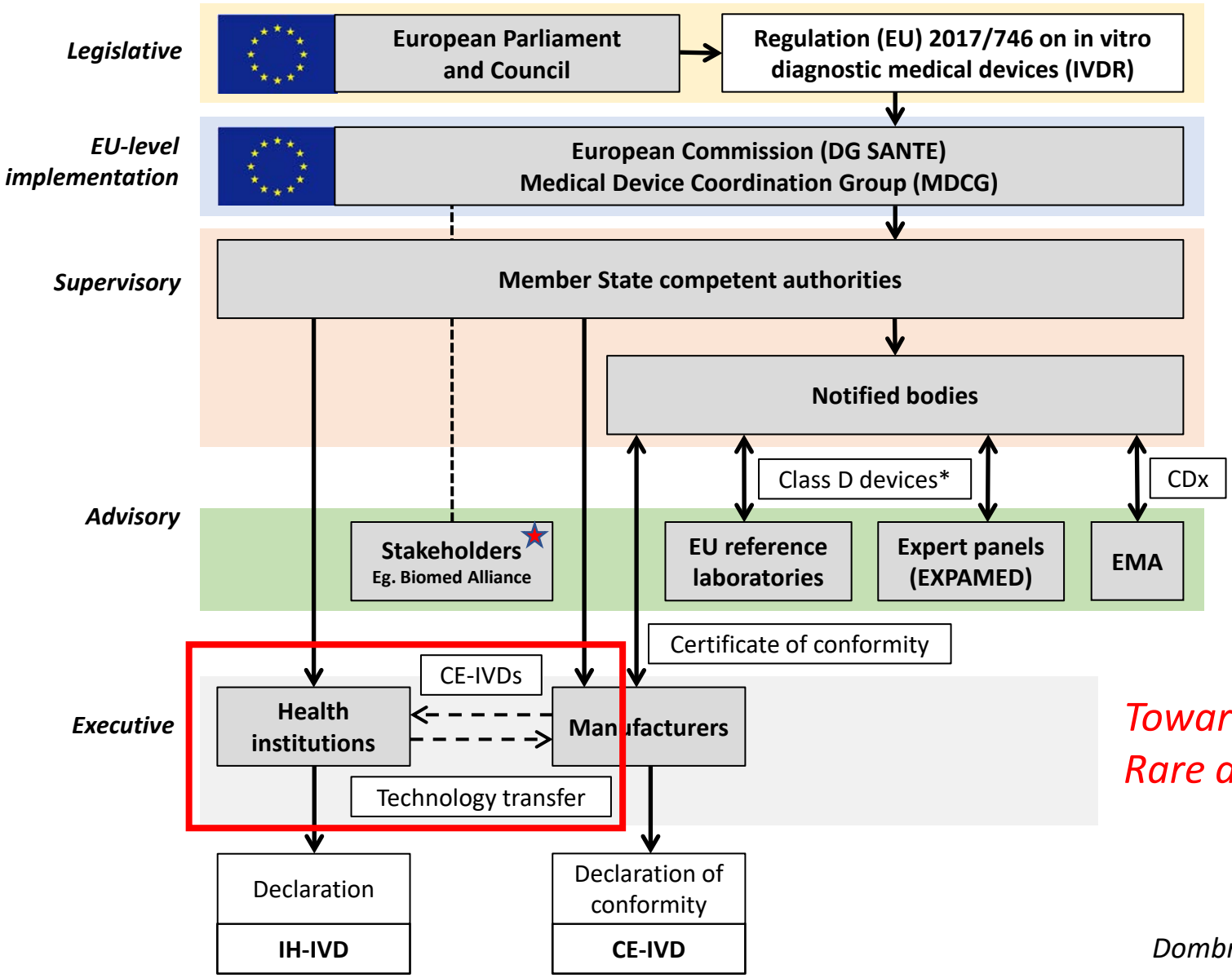
ESHG

EHA EUROPEAN HEMATOLOGY ASSOCIATION

ESLHO european scientific foundation of laboratory hemato oncology

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

Inclusion of IH-IVDs into the EU IVDR Regulatory Framework



Towards ERN-like/linked Rare diagnostic networks ?

Dombrink I. et al. HemaSphere 2022

Examples: how can healthcare professionals contribute to regulatory affairs

- Reporting adverse events
- Participation in clinical trials
- Contributions to Health Technology Assessment
- Participation in stakeholder panels including EXPAMED panels, European Reference Laboratories and MDCG
- Working as a clinical expert in notified bodies
- Developing new CE-IVD tests, in house devices or other medical devices
- Applying knowledge on the regulatory system in their day to day work in clinical care

What form should the training take for HCP

- Flexible form of education adapted to the day-to-day work of healthcare professionals
- Short training modules on regulatory affairs in undergraduate training
- Sessions at medical congresses
- Short training courses/preceptorships
- Webinars and e-learning
- Targeted and flexible master programmes that can be combined with their job