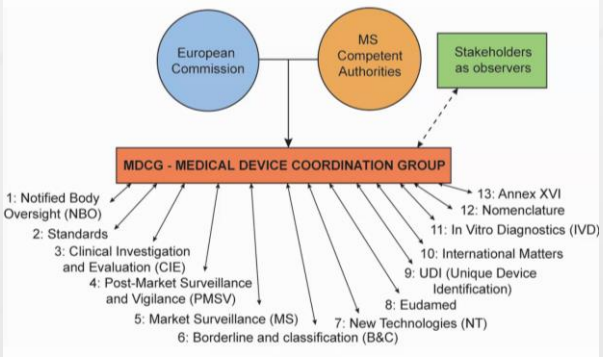
IVDR & Rare Diseases – update on steps taken so far

Prof dr E Dequeker, Belgium
Liaison for the ESHG in the Task Force of IVDR Biomedical Alliance
Head of the Quality Department of Medical Diagnostics – University of Leuven

IVDR 2017/746 (May, 26th 2022) – *Harmonization*

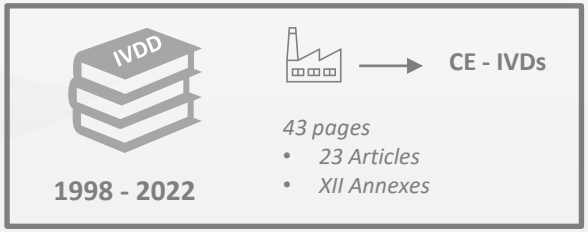
- **European regulation**
  - CE-IVD & In-house (IH)-IVD
  - Industry & Health Institution

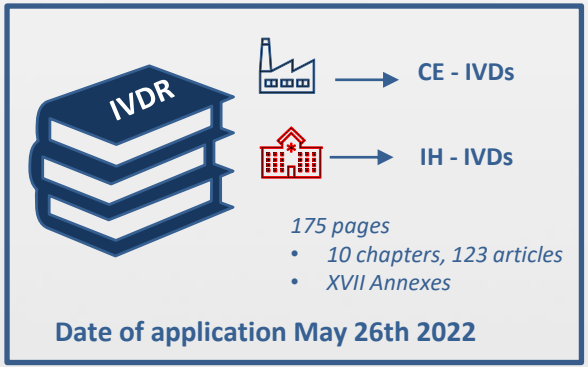
- **EU guidelines / interpretation documents – MDCG**



MDCG 2022-15,
MDCG 2022-22 rev1,
MDCG 2022-9, …

MDCG Guidelines





Initiatives ESHG took to help genetic diagnostic laboratories

Initiatives taken by ESHG

1. Member of Biomed Alliance

Initiatives ESHG took to help genetic diagnostic laboratories

EUROPEAN SOCIETY OF HUMAN GENETICS

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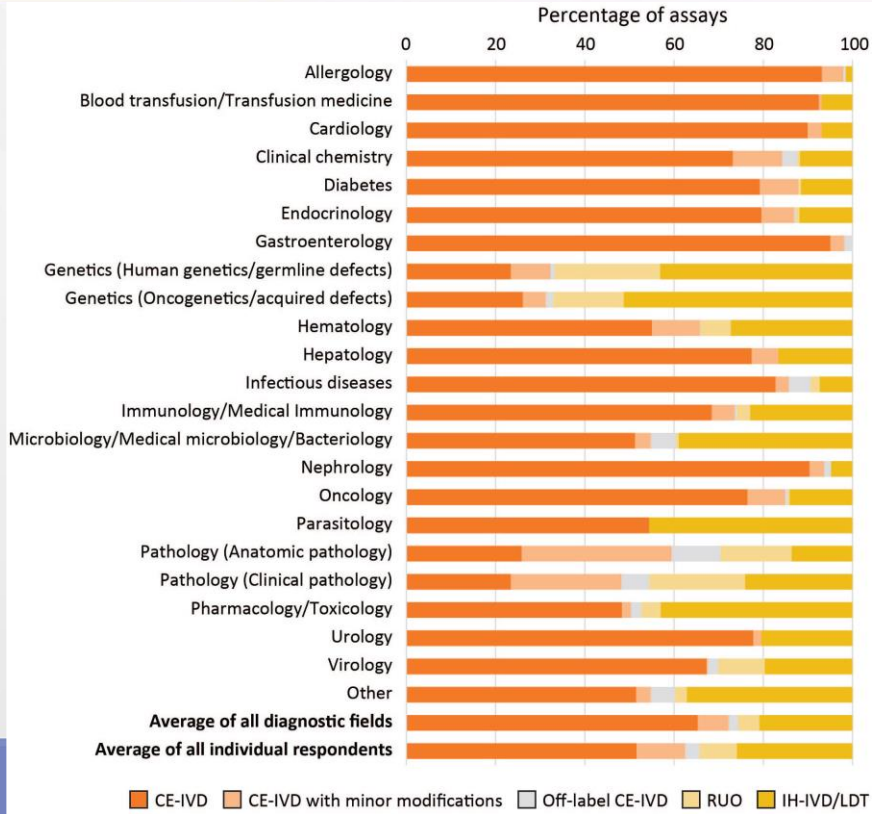
Critical Implications of IVDR for Innovation in Diagnostics: Input From the BioMed Alliance Diagnostics Task Force

Isabel Dombrink[1–3], Bart R. Lubbers[1,4,5], Loredana Simulescu[1], Robin Doeswijk[1,5], Olga Tkachenko[6], Elisabeth Dequeker[1,7,8], Alan G. Fraser[1,9], Jacques J. M. van Dongen[1,4,5,10,11], Christa Cobbaert[1,12,13], Monika Brüggemann[1–3,5], Elizabeth Macintyre[1,5,14]

Hemasphere. 2022 May 20;6(6):e724



Initiatives ESHG took to help genetic diagnostic laboratories

Initiatives taken by ESHG

1. Member of Biomed Alliance
2. Task Force IVDR – ESHG

June 2022:
Online webinar - “IVDR – beneficial or just an expensive straitjacket?”

June 2023:
Get2gether - IVDR is a challenge for all of us, the greatest challenge is keeping "orphan" diagnostics available

"IVDR – Beneficial or just an expensive straight-jacket?"

June 22, 2022, 10:00 – 16:30 hrs

The **new IVD EU regulation (IDVR 2017/746)** has major implications on the use, availability and associated costs of in vitro diagnostic tests. But on the other hand, it also builds in many ways new assurance points to improve and monitor the quality of our diagnostic services.

To help laboratories prepare for the IVDR, including compliance with IVDR requirements for in-house devices, the ESHG is hosting a free of charge full-day webinar on IVDR, providing the basics and latest updates on implementation, as well as tips and tricks for working towards compliance.

During these webinar presentations we invite speakers from the EU Commission, Notified Bodies, Compent authorities, national IVDR working groups, lab people working on the implementation of the IVDR will share their knowledge and experience.

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Program – 8 speakers & discussion sessions

- Introduction on IVDR
- Role of different organisation: EC, CA, NB, Reference labs, observers
- IH-IVD's and hospital exemption
- MDCG guidelines and the guideline of in-house devices

Participation is free of charge, registration is necessary !

High attendance > 300 persons

Get2gether : IVDR is a challenge for all of us, the greatest challenge is keeping "orphan" diagnostics available

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Monday June 12, 2023 - Room Boisdale – 15:00-16:30

Speakers

- **Insight into the main elements of IVDR and initiatives ESHG took to help genetic diagnostic laboratories**
  Els Dequeker, University of Leuven, Liaison for the ESHG in the Task Force of IVDR Biomed Alliance
- **Process for CE-marking of a genetic test**
  Alex Laan, Head of the IVD Notified Body BSI The Netherlands
- **Where can genetic diagnostic laboratories help industry and vice versa**
  Maurizio Suppo, Co-owner/VP QARAD

Panel discussion

With persons a laboratory, clinician, a diagnostic company, a Notified Body and a consultant

Initiatives ESHG took to help genetic diagnostic laboratories

Initiatives taken by ESHG

1. Member of Biomed Alliance
2. Task Force IVDR – ESHG
3. Conference on Rare Diseases – CZ Presidency Council of Europe

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Conference on Rare Diseases - October 25-26, 2022

Call to Action

from the Expert Conference on Rare Diseases

Towards a new European policy framework on rare diseases:

"Building the future together for rare diseases"

On 25 and 26 October 2022, in Prague

EU2022.CZ

Czech Presidency of the Council of the European Union

Message:

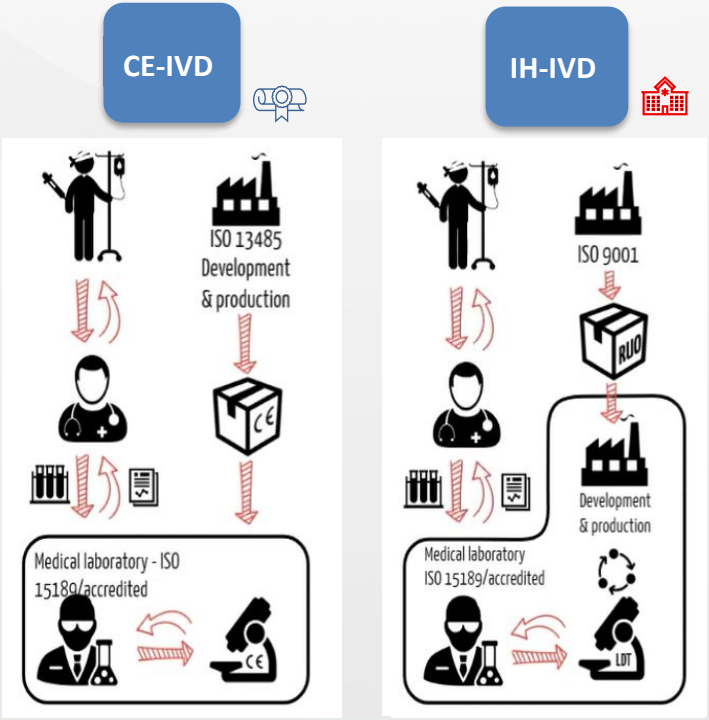
a realistic incubation period for 'orphan' diagnostics *to encourage continued to innovate and truly help families and patients with rare disease*

IVD's under the IVDR

Main goal:
Regulating medical devices' quality, safety and reliability

Impact:

- More demanding requirements for manufacturers and health institutions
- Use of IH-IVDs will be restricted
- Discouraging innovation for diagnostics



Conformity assessment is needed before use of the device

IH-IVD article 5.5

Competent authority

Justification of use of IH-IVD

Quality Management System

General Safety Performance Requirements

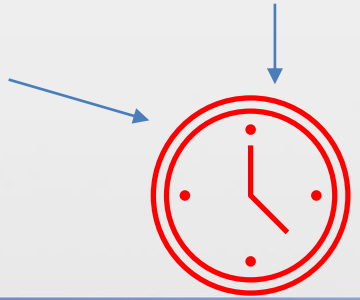
- Risk management
- Performance evaluation studies
  - Scientific validity
  - Analytical validity
  - Clinical validity
- Post market surveillance studies

CE-IVD

Notified Body

175 pages

- *10 chapters, 123 articles*
- *XVII Annexes*



'Orphan' diagnostics

Flexibility will be the key

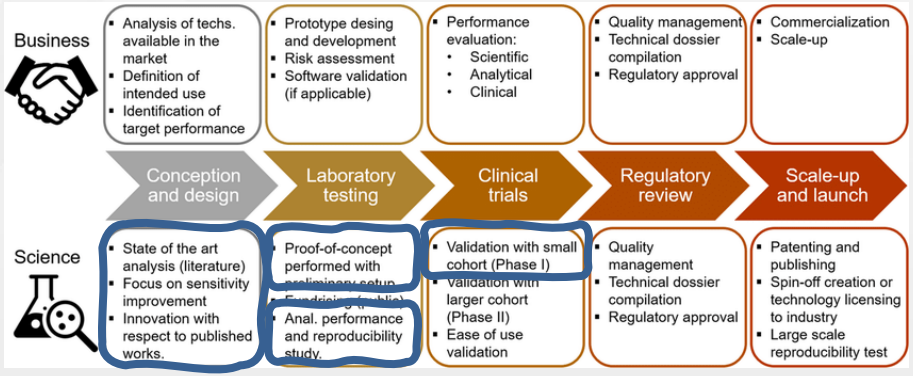
“Orphan” IVD devices - before and after implementation of IVDR

		
Before IVDR	RUO	Under validation according ISO 15189
After IVDR	CE-IVD	IH-IVD

discourage investment in technological and medical innovations

- jeopardize patient health

- reverse all the initiatives of Europe to reduce the diagnosis time



Development process of a diagnostic device

G Rosati et al, ACS Nano 2021, 15, 11, 17137–17149

EPSCO Council Meeting - December 9, 2022

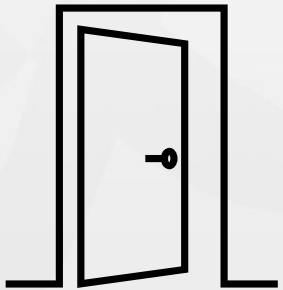
EURORDIS
RARE DISEASES EUROPE

Press release

21 Member States endorse Czech EU Presidency's Call to Action on rare diseases at EPSCO Council Meeting.

9 December, Brussels – The Czech Presidency of the European Union Council has today presented their Call to Action in the area of rare diseases at the EPSCO Council. The call received endorsement from 22 Member States, including the Czech Republic, representing 81,6% of the EU population. This is a strong indication of the support from across the European Union towards a new comprehensive rare disease strategy.

- ESHG member of Biomed Alliance = stakeholder EU
- Call for action > 80% EU population



Marieke Meijer likes this

Biomedical Alliance in Europe
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Today we are presenting at the European Commission's MDCG on issues around the availability of orphan #medicaldevices & #IVDs under #MDR and #IVDR

Urgent action is needed to improve the availability of these essential devices, read more in our recent press release: https://lnkd.in/ehzddrQ4

Elisabeth Dequeker, Marc Gewillig

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European Commission

‘Orphan’ IVD’s – possible solutions

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And keep focus on IVDs’ quality, safety and reliability

Importance: Keep harmonization in EU and protecting the aim of the IVDR

Article 54:

Derogation from the conformity assessment procedures

54.1: …level of member state to bring a product on the market or putting into service

54.2-4: … possibility to make derogation European wide for the device

Article 54 of the IVDR provides that the national authorities may authorise the use of a specific device even though the conformity assessment procedures have not been carried out if the use of the device in question is in the interest of public health or patient safety or health. The European Commission has the possibility of extending national derogations to the entire territory of the Union.

Article 5.5

Annex I: General safety and performance requirements

General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? Yes/No	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/ comment in case of deviation
CHAPTER I, GENERAL REQUIREMENTS				
1. Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of				