Impacts of the IVDR for industry

Dr Heather Johnson PhD RAC

8th May 2025

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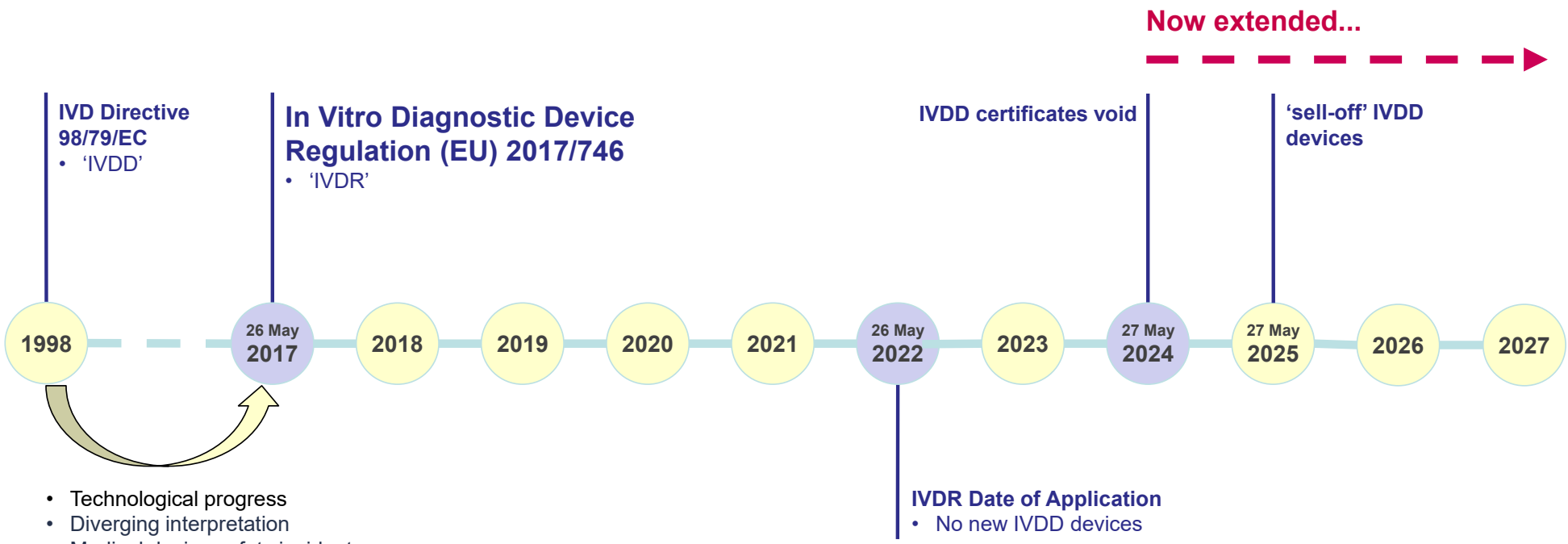
The History



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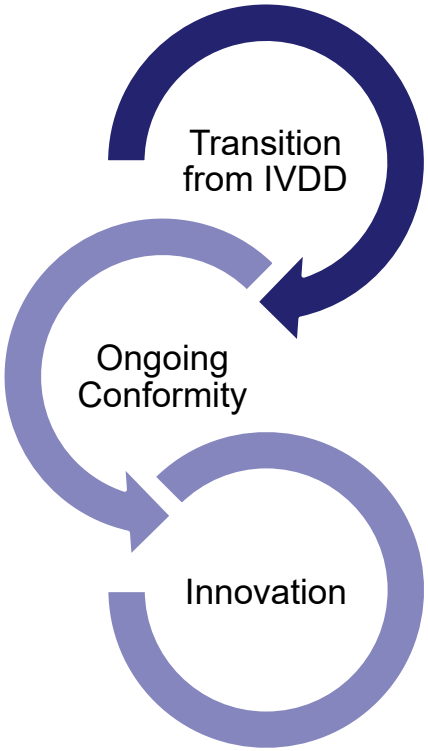
Impacts of IVDR for Industry



- Initial challenges
- Resources
- IVD and wider pharma / biotech industries

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Increased Requirements

IVDD – 24 Articles / 37 pages

Notified Body reviews: List A, List B

IVDR – 113 Articles / 157 pages

wider scope Notified Body reviews: Class B, C, D

new Obligations: authorised reps, importers, distributers

increased Quality System and Post-Market requirements

increased Clinical performance requirements

new EUDAMED database - transparency

new Unique Device Identifier (UDI) - traceability

increased scrutiny of Notified Bodies

new EU Reference Laboratory (EURL) testing: Class D

new Competent Authority consultation: companion diagnostics

new Competent Authority performance study authorisation

new Regulation of health institution (“in-house”) assays

Increased Requirements – key challenges

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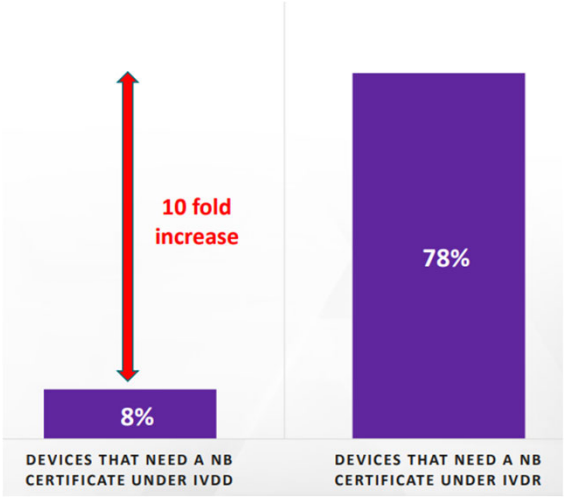
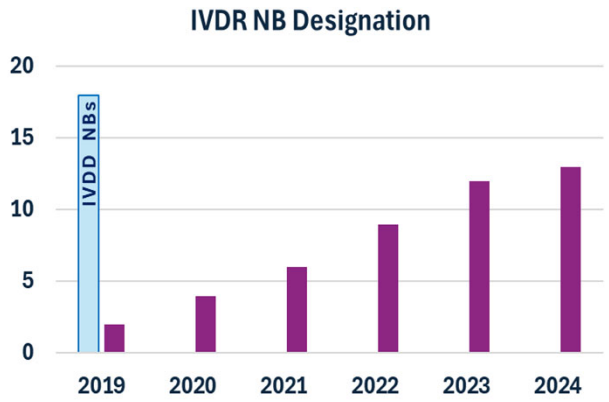
Initial delays





53%

Devices requiring NB Certificate*

NB Re-designation

Manufacturers without a notified body contract in 2021*

* MedTech Europe Survey Report analysing the availability of In vitro Diagnostic Medical Devices (IVDs) in May 2022 when the new EU IVD Regulation applies; 08 September 2021

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European Commission Response

Extended IVDD certificate validity

More time for IVDD now requiring certification

Removed ‘sell-off’

Notification of interrupted supply

EUDAMED go-live in stages

- Regulation (EU) 2022/112
- Regulation (EU) 2023/607
- Regulation (EU) 2024/1860

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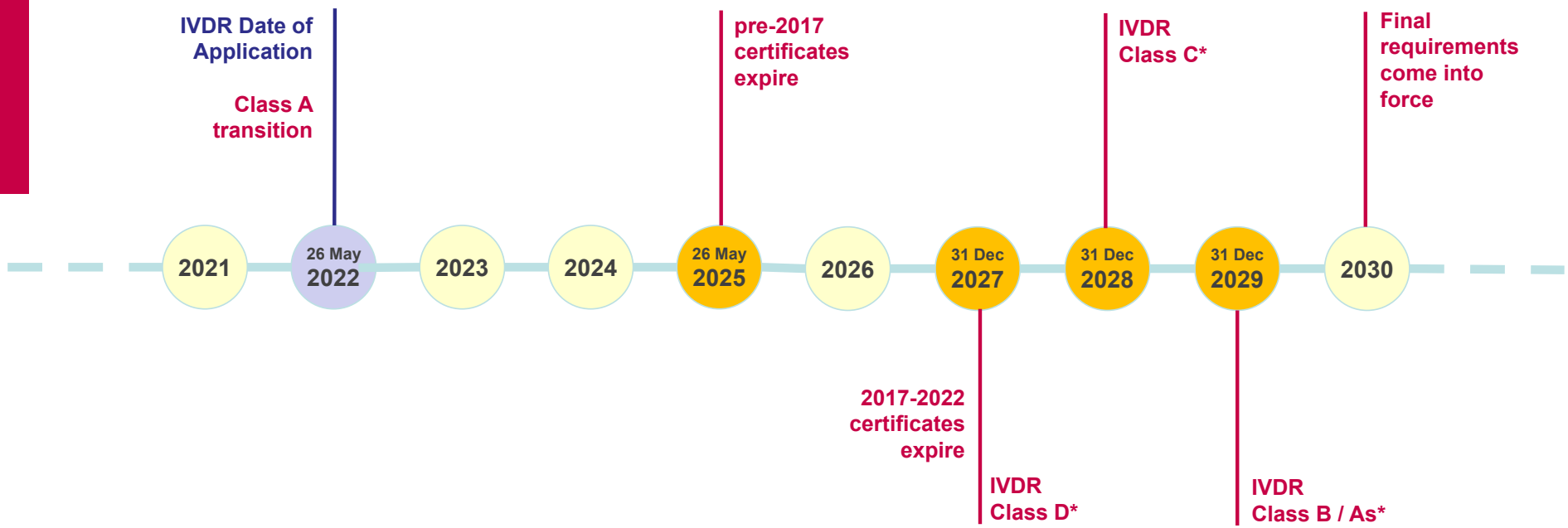
New timelines



* IVDs self-certified under IVDD

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Impact for Manufacturers - Certification

18 months

Average QMS or TDA Certification
(not including CDx consultation)

↑70%

Cost of recertification over 5 years

* MedTech Europe IVDR & MDR Survey Results 2024; published Jan 2025

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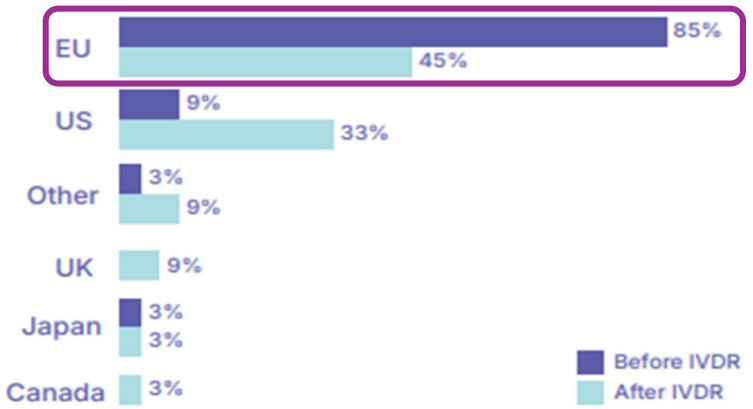
Impact for Manufacturers - Innovation

26.6%



Manufacturers transitioning <5% Orphan Devices to IVDR

Choice of first launch market

* MedTech Europe IVDR & MDR Survey Results December 2024

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IVD Performance Study Requirements

- Competent Authority Submission / Authorisation:
  - All interventional IVD Performance Studies
  - Including all non-CE IVDs in medicinal product Clinical Trials
- No coordinated IVDR review across Member States
- No harmonized CTA / IVDR combined trial submission

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IVD Performance Studies – Current status

3275

(based on 849 CTAs)

Estimated # PS submissions in next 3 years

137 days

(range 45-267)

Mean time for PS Authorisation (excluding ethics)

* European Commission COMBINE CTR-IVDR-MDR Analysis Phase Report, May 2024

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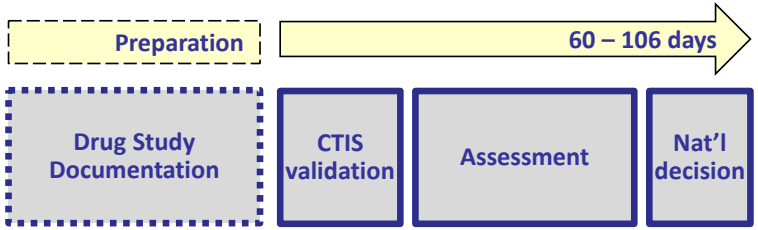
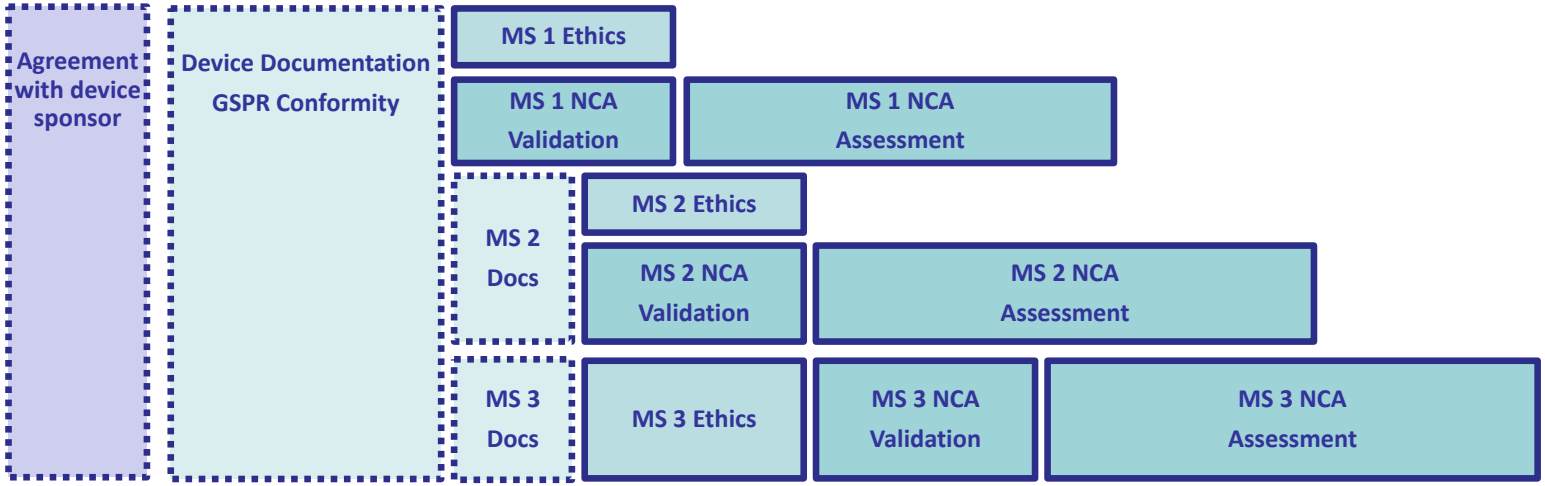
Impact on Medicinal Product Trials

Medicinal Product
Clinical Trial Regulation
(EU) 536/2014



! Complex interface
Inconsistent interpretation
Delays to clinical trials

Clinical Trial Assay
IVDR
(EU) 2017/746



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EU COMBINE Programme

make the European Union an attractive region to conduct combined studies

ultimate goal to support availability of innovative treatments for patients

Phase 1: Analysis of Root Causes, May 2024

Phase 2:

- Programme Strategy, December 2024
- Solutions 2025-2028


Coordinated Assessment


Alignment


Communication & Dialogue

European Commission Combined Studies website

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PS Coordinated Assessment Pilot

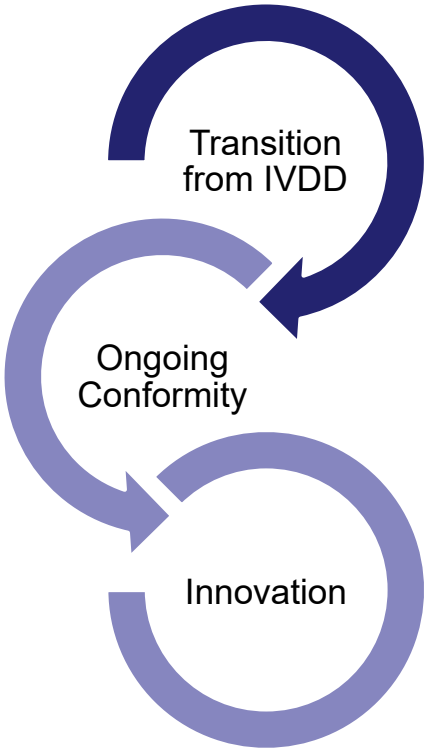
- European Commission pilot announced February 2025
- Single application for ≥2 Member States
  - interventional and CDx
    IVD Performance Studies
  - 19 participating Member States

+ Reduced documentation
+ Efficient communication
+ Transparency
+ Consistency across MS
+ Simplified RFI
+ Faster

- Ethics
- National requirements
- MS fees
- No alignment with CTIS

Call for expression of interest:
MDR - by 30th June 2025
IVDR - not yet open

Impacts of IVDR for Industry - Recap



- Increased requirements
- Notified Body bottlenecks
- EUDAMED delays

- Costs / resources
- Product discontinuation

- Clinical evidence requirements
- Predictability of costs and timelines
- Performance study and clinical trial assay authorisation

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Any questions...

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