MedTech Europe
from diagnosis to cure

MedTech Europe perspective

EMA CV workshop: Emerging and innovative devices

1 July 2026

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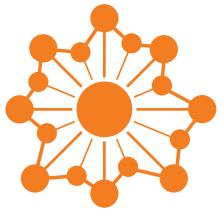
from diagnosis to cure

The European trade association for the medical technology industry including diagnostics, medical devices and digital health

145+ multinational corporations*

*medical devices, diagnostics and digital health



50 medical technology associations

MedTech Europe Cardio Vascular sector group

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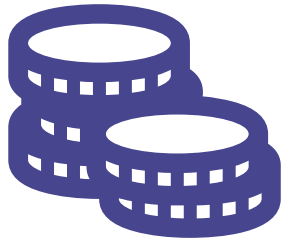
each
European Alliance for Cardiovascular Health

innovative health initiative

Patient pathway

How medical technologies support patient pathway

Screening	Treatment	Monitoring
Blood tests	Implants (e.g. pacemakers)	Implantable cardiac monitors
Imaging	Stents/valves	Home care
➢ **Early detection**	➢ **Fewer complications**	➢ **Fewer hospital visits**



MedTech Europe recommendations

Safe hearts plan: Health check

Systematic screening for high risk populations above 65 years of age every two years

Targeted health checks based on scientific guidelines: e.g. European Society of Cardiology (ESC)

Personalized pathways: Connect screening with coordinated referral systems and integrated care models

Accelerate patient access to life-saving innovations

- by streamlining **regulatory**,
- **procurement**,
- **reimbursement** pathways
- tailored to cardiovascular needs

Regulatory access barriers

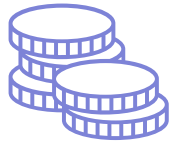
Regulation impact

Absence of 'formal' early access for breakthrough

MDR/IVDR complexity & regulatory burden

Horizontal legislations impact

Companies are **relocating** first launches away from Europe



- Unpredictability
- Resources diverted to compliance

1 in 2 clinicians

clinicians has experienced device availability issues since MDR introduction

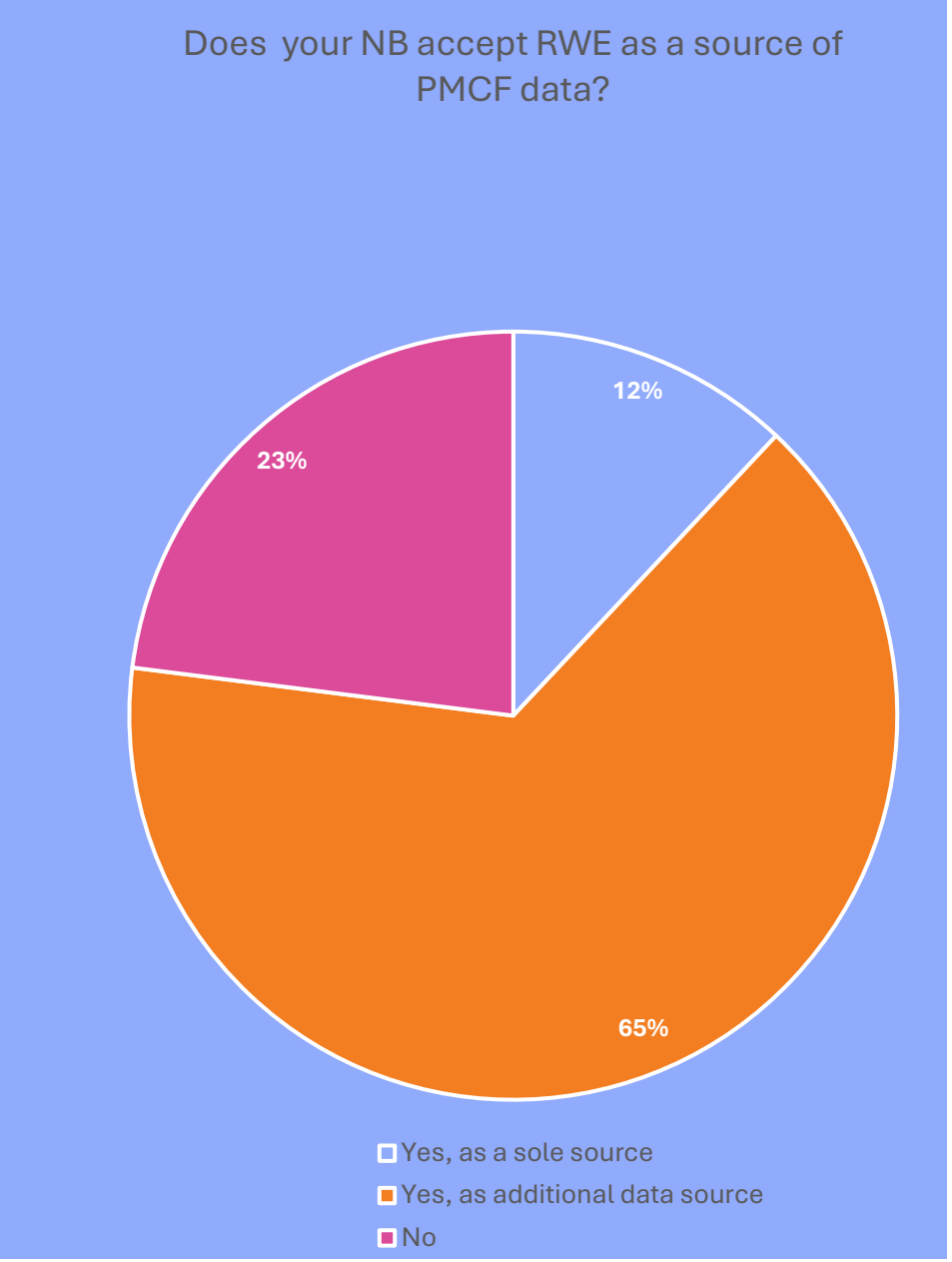
(Clinical) evidence

- **Diverse data sources**
  - Pre-clinical
  - Non clinical data
  - Early feasibility studies

HEU EFS

HARMONISED APPROACH TO EARLY FEASIBILITY STUDIES FOR MEDICAL DEVICES IN THE EUROPEAN UNION

- **RWE:** goal
  - A supportive source for CE marking
  - Recognised post market activity
- Heterogeneity in data quality
- European Health Data Space (EHDS)
- Registries



RWE acceptance for PMCF: 2024 MTE survey

- 65 % indicated RWE was accepted as an additional source
- 12% could use RWE as a sole source
- 23% indicated RWE was not accepted

* ***Registries as the most accepted source***

Solutions: Short term

Recent breakthrough developments

MDCG Breakthrough guidance

Dec. 2025

EMA Pilot on breakthrough

Apr. 2026

Dec. 2025

MDR/IVDR revision proposal

Breakthrough pilot

Incorporate lessons learned

medtech-europe_special-pathways-position-paper.pdf

Breakthrough prioritization

Predictability through secondary legislation – a timeline

(Clinical) evidence

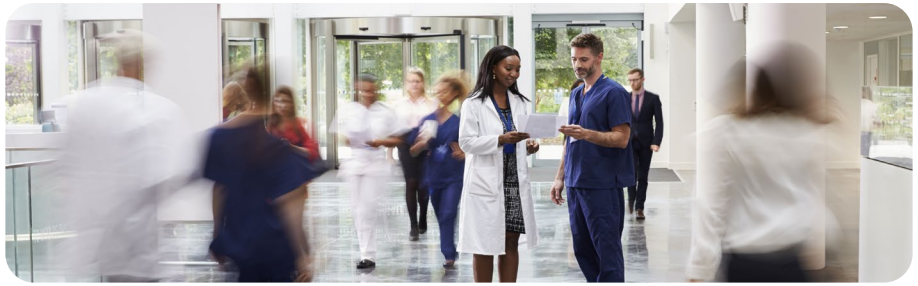
MDCG Clinical evaluation guidance – RWE: e.g. PMCF from outside of EU

Consider adoption of a harmonised EU methodology for Early Feasibility Studies (EFS)

Wider acceptance of diverse data sources

Solutions: mid term

A revised MDR/IVDR Regulatory Framework …



MedTech Europe's Position on the Proposal

WELCOME

Simplification measures
Risk-based certification, streamlined reporting, digitalization

International cooperation
EU participation in MDSAP

STRENGTHEN

Innovation pathways
include paediatrics, align orphan IVD thresholds

Cybersecurity
avoid triple reporting under MDR, NIS2 and CRA

AI
operationalise reflection through delegated acts within one year

Blood draws
in studies should not be subject to requirements designed for high-risk procedures

Health institutions
should use CE-marked device when an equivalent exists

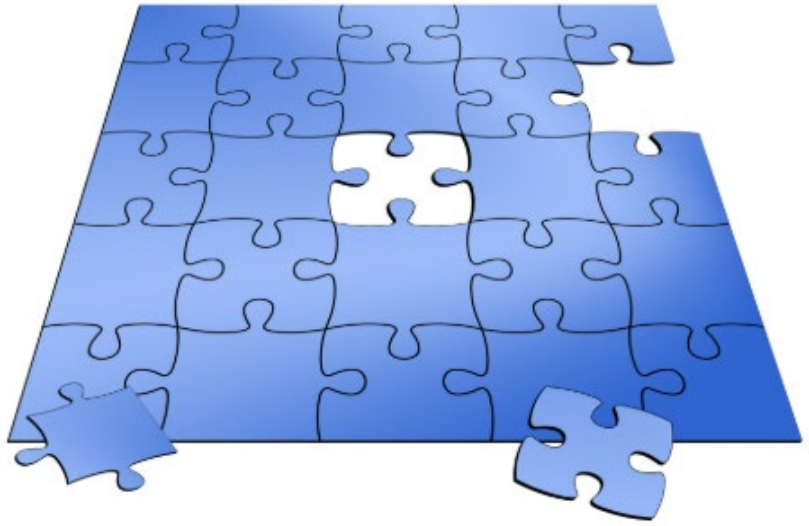
RETHINK

Reprocessing of single-use devices
should not be the regulatory default

The Commission's own evidence highlights major safety and effectiveness gaps

MDR/IVDR revision: Building a simpler, more predictable framework for patient access and innovation - MedTech Europe

Accelerate patient access to CV innovation: Big picture



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Thank you