Global Cardiovascular Device Market

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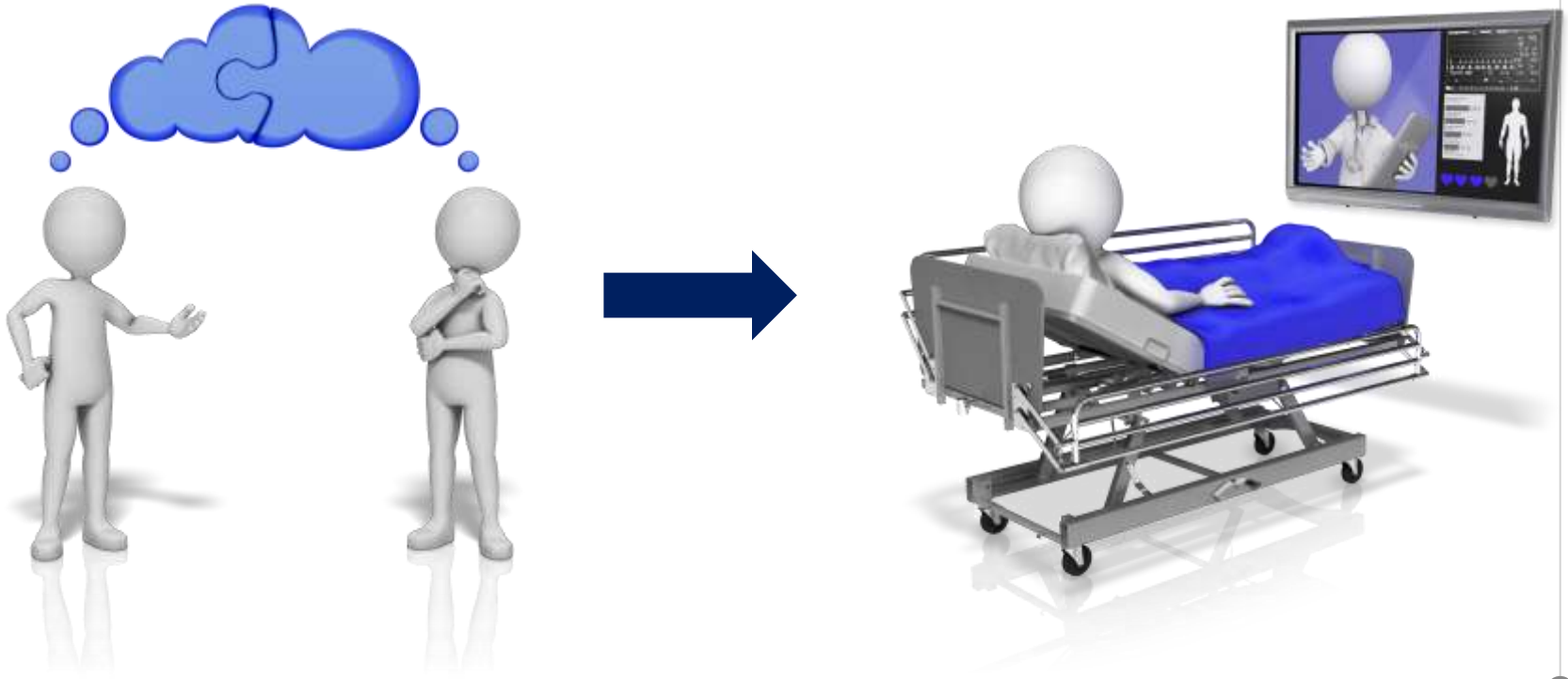
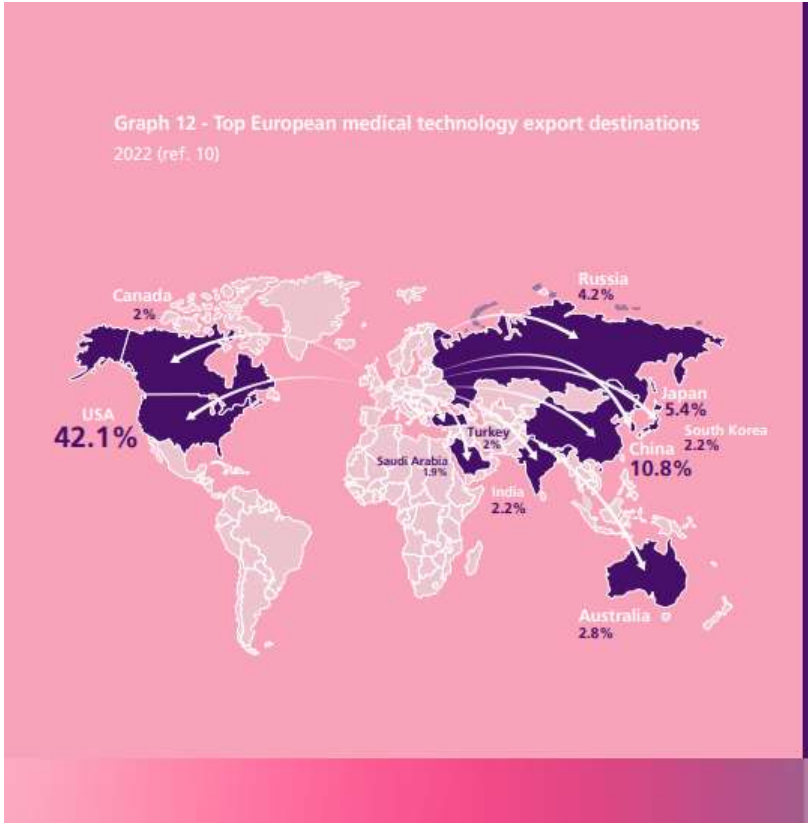
ESC
European Society of Cardiology

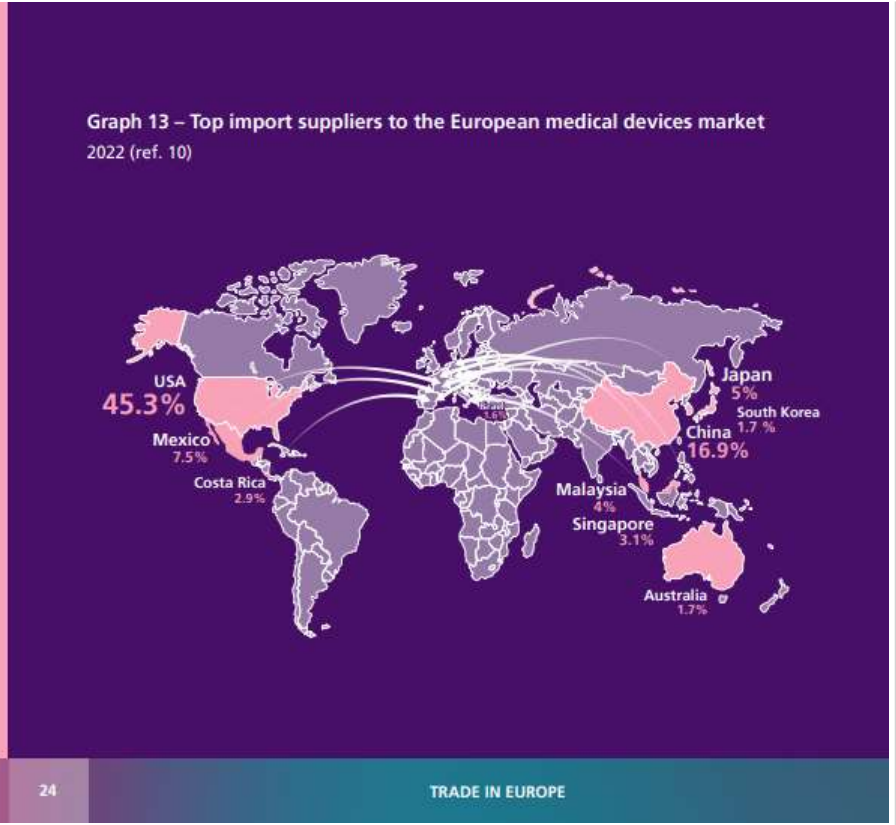
Put Patients First

Regulators and manufacturers are committed to timely patient access to safe, effective, and quality medical devices



Medical technology is a global sector…





Source: MedTech Europe https://www.medtecheurope.org/resource-library/facts-figures-2023/

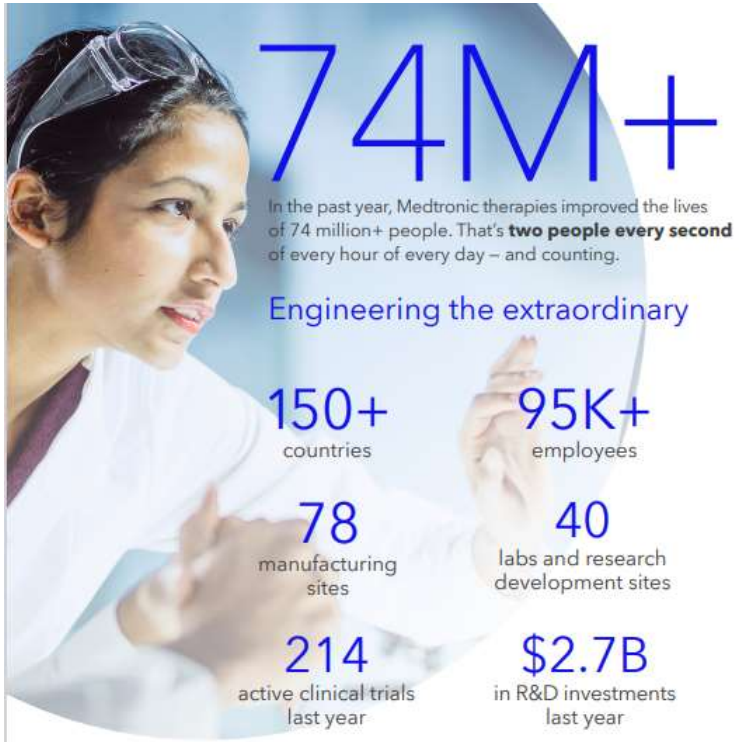
Globally regulated…

IMDRF International Medical Device Regulators Forum

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

With global companies



74M+

In the past year, Medtronic therapies improved the lives of 74 million+ people. That's **two people every second** of every hour of every day – and counting.

Engineering the extraordinary

150+ countries

95K+ employees

78 manufacturing sites

40 labs and research development sites

214 active clinical trials last year

$2.7B in R&D investments last year

12.4K+ scientists and engineers

46K+ active patent matters

Our dedication to transforming lives starts here

- Better outcomes for our world
- Life-transforming technologies
- Experiences that put people first
- Insight-driven care

Beyond products: Integrated health solutions (IHS)

We partner with hospital management and medical leaders to transform care pathways and clinical operations, with a shared goal of:

- Improving efficiency and outcomes
- Increasing patient and staff satisfaction
- Optimizing cost

With our extensive experience across and within regions, we provide proven and highly effective solutions that can be quickly tailored to providers' specific needs and generate value now – and for the future.

In 2023, IHS celebrates a decade of transforming healthcare, delivering value for patients and healthcare professionals, and improving access to high-quality care while optimizing costs and capacity.

Positive impact on complex and challenging conditions

70+ **conditions** in the human body treated with our therapies

2 **people every second** have their lives improved – and counting

Public-private partnerships

Increasing patient access in multiple communities aligns with the core of our Mission. These public private partnerships – with outcome-oriented business models – create mutual benefits by making the most of Medtronic skills, expertise, and assets through the appropriate transfer of risk. They drive our globalization strategy and actively contribute to the international push for universal health coverage. With jointly defined objectives, they address health system challenges efficiently by increasing access to therapy innovation, raising quality, and delivering improved outcomes.

Learn more at Medtronic.com

Medtronic
Engineering the extraordinary

Understanding global patient access from a global manufacturer's perspective

Initial markets

- ✓ Transparent and predictable regulatory environment
- ✓ Leverage of international best practices and standards

International Market Expansion Strategy

Following markets

- ➢ Jurisdiction-specific testing & standards
- ➢ Jurisdiction-specific inspections
- ➢ Jurisdiction-specific labeling requirements
- ➢ Jurisdiction-specific device classification
- ➢ Jurisdiction-specific clinical trial/ evidence requirements
- ➢ Jurisdiction-specific dossier formats
- ➢ Country of Origin requirements (COO)

EU's rules proving too cumbersome to implement
=> EU risks becoming a following market

Our EU MDR challenges

Notified Body **Capacity**

Predictability of review process/timelines

Medicinal Reviews – capacity & review times

Maintaining outside EU registrations – Historical reliance on CE Mark

Minimizing **Supply Disruptions**

Impact **Innovation** in Europe

3 Key Areas

Efficiency

An Efficient CE Marking System: We need a more efficient and resource-effective CE marking system that improves predictability, reduces administrative burden, and adapts to external changes

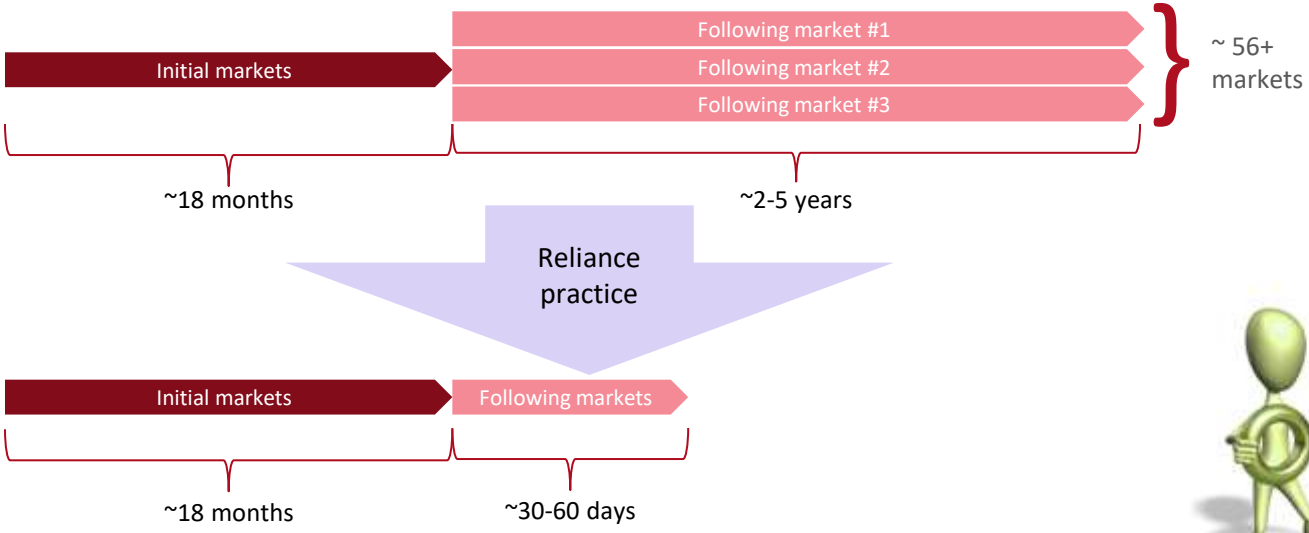
Innovation

A System that Works for Innovation: We propose the inclusion of an innovation principle that swiftly connects the latest medical technologies to European patients and health systems through dedicated assessment pathways and early dialogues with developers.

Governance

An Accountable Governance Structure: We suggest the establishment of a single, dedicated structure to oversee and manage the regulatory system, including the designation and oversight of Notified Bodies, with the authority to make system-level decisions.

The future of medical technology is in convergence, harmonization, trust, and reliance[1]



1 "The future of medical products regulation is in convergence/ harmonization, collaboration, and networking based on reliance and trust." Azatyan, S., MD, PhD (2020, November 3). WHO Activities: focus on reliance [Conference Presentation], 10th Asia Regulatory Conference. https://arc.ifpma.org/wp-content/uploads/2016/05/ARC_2020_S.Azatyan-WHO-01-11-2020.pdf, page 16.

The call for regulatory convergence and reliance for all regulators

Enhance gov efficiency through collaborative regulation: share audits, exchange info & leverage experiences

Increase safety and quality of products by adopting international best practices and standards

Meet regulatory and public health policy objectives whilst under constrained budgets

Increase patient access to innovative medical devices and improve patient outcome

81+

Medical Devices Regulatory Agencies around the world

A globally harmonized approach benefits all stakeholders

1 Patients

- Timely access to life saving medical technology
- Confidence in safety and quality of medical technology
- Swifter access to the latest in innovation

2 Health Authorities

- Patient safety
- Pandemic preparedness
- Fostering innovation
- Leverage resources
- Collaboration
- Efficiencies
- Postmarket monitoring
- Facilitates reliance

3 Industry

- Promotes a transparent, efficient, and predictable regulatory environment
- Supports innovation driven by patient needs
- Reduces regulatory redundancy that pulls resources away from research & development

Concluding remarks

- Put patients first
- Cardiovascular disease is global as too are the technologies and innovations needed to treat cardiovascular disease
- The future of medical technology regulation is in convergence, harmonization, trust, and reliance
- Keep regulatory requirements as globally standard as possible and as local as necessary
- Europe needs to re-set its regulation or risk being a following market

- Today = awareness that global harmonisation of regulation matters for patients
- We welcome ideas on how we can collaborate with ESC on that