EU Medtech Landscape

Latest Trends and Market Dynamics

Presented by:

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Global Commercial Lead | Bridging EU and Asian Healthcare Markets

About me

Expertise:
Business Development | Market Access | Strategic Marketing. Skilled in partnership development, entry strategy, and go-to-market execution across EU healthcare systems

Education:
MSc, International Marketing & Business Development – SKEMA Business School, France

Current Roles:

- Global Commercial Lead, Kreivo Health (France)

Regional Focus & Experience

Extensive experience supporting Asian healthcare and medtech companies entering EU markets through partnership, GTM, and business expansion strategies

The EU Medtech Landscape

Why the EU still matters for Medtech

Europe remains one of the most mature but still opportunity-rich medtech markets

€170B European MedTech Market

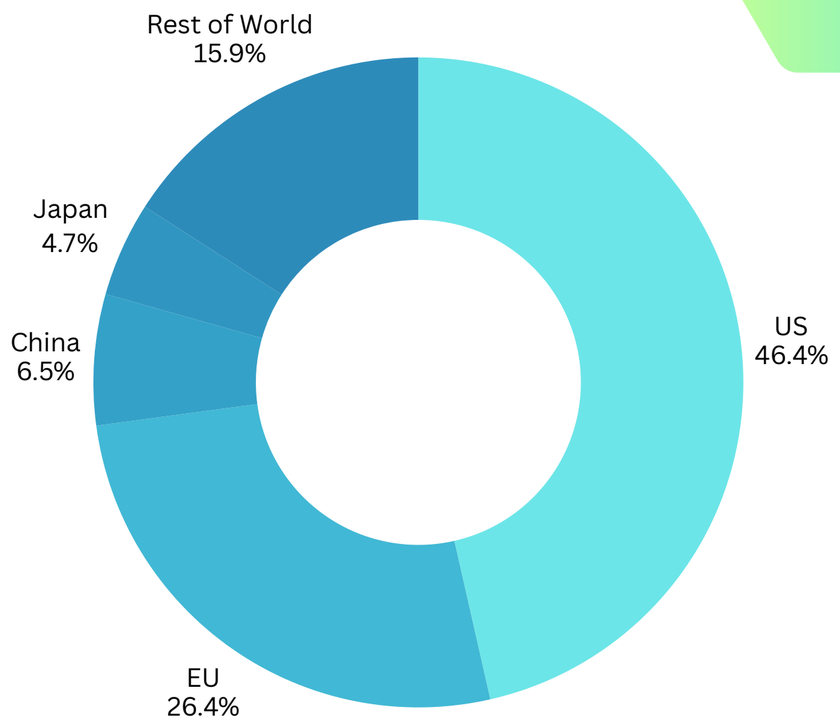
Accounts for 26.4% of global value

2nd Largest Market After the US

Driven by strong innovation and healthcare demand

Top 5 European MedTech Markets

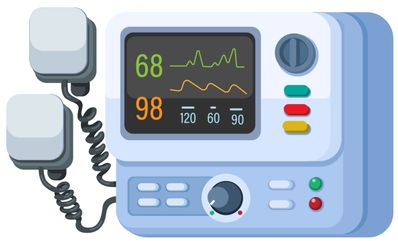
Germany, France, UK, Italy, and Spain lead regional growth



(2024, Medtech Europe)

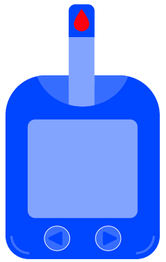
Medtech Market

Medical Devices



Instruments, apparatus, machines, or implants used to prevent, diagnose, monitor, treat, or alleviate disease or injury.

In Vitro Diagnostics

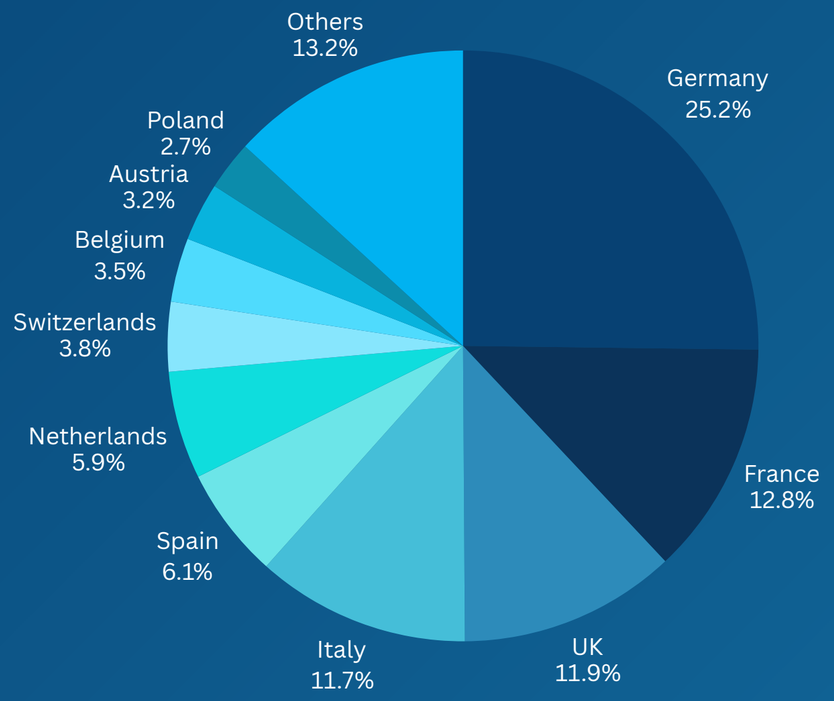


Tests performed on biological samples (such as blood, urine, or tissue) outside the human body to provide information on a person's health status.

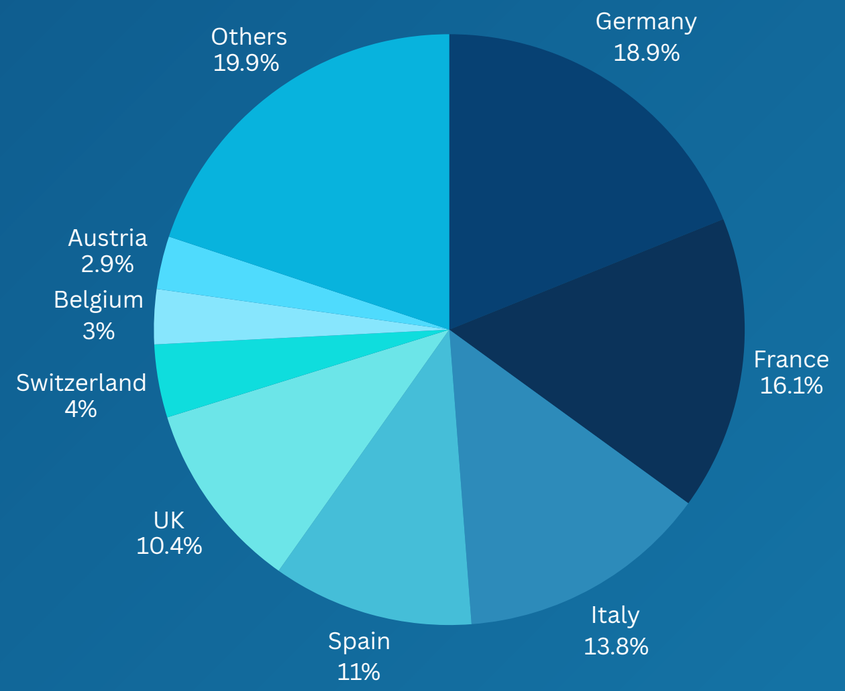
Digital Health

Use of information and communication technologies (ICTs) and data analytics to improve healthcare delivery, monitoring, and patient engagement.

Dominated by the Big Five: Europe’s 2024 MedTech & IVD Power Map



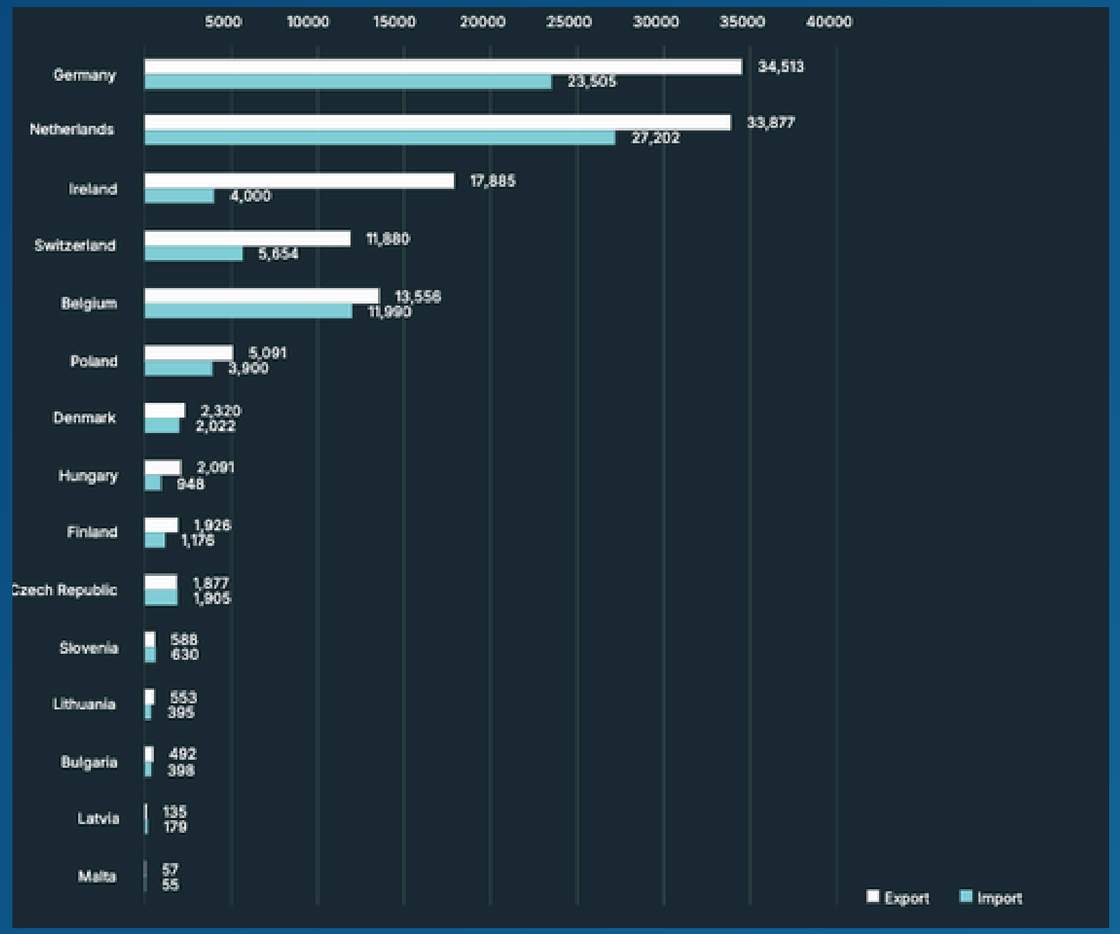
EU Medical Device Market by Country



EU IVD Market by Country

(2024, Medtech Europe)

Netherlands, Germany & Belgium: Europe’s Top Medtech Buyers



(2024, Medtech Europe)

Imports reflect not only demand but also the direction of investment by hospitals, clinics, and distributors in new technologies. Central and Western Europe continue to lead as medtech buyers, while Eastern Europe’s demand is accelerating from a smaller base, with imports maintaining a steady 4.3% annual growth over the long term.

TOP 15 Export & imports of medical devices by country (including European intra-community trade, million euro)

Europe ≠ US — It's 27 Distinct Markets with One Regulatory Framework

Regulatory	One single FDA system	MDR harmonized framework, but each country still requires notification and sometimes local registration before market entry.
Healthcare System	Centralized logic under CMS and private insurers	27 different national healthcare systems — each with its own rules and reimbursement pathways.
Business Culture	English only; consistent branding and labeling.	24+ official languages; marketing and labeling must be localized.
Strategy	Nationwide access after FDA clearance; still requires regional sales execution across major health systems and states.	Localized entry per country or region; starting in one country or focused segment to build traction before expanding across Europe.

From Certification to Commercialization: The Real EU Challenge

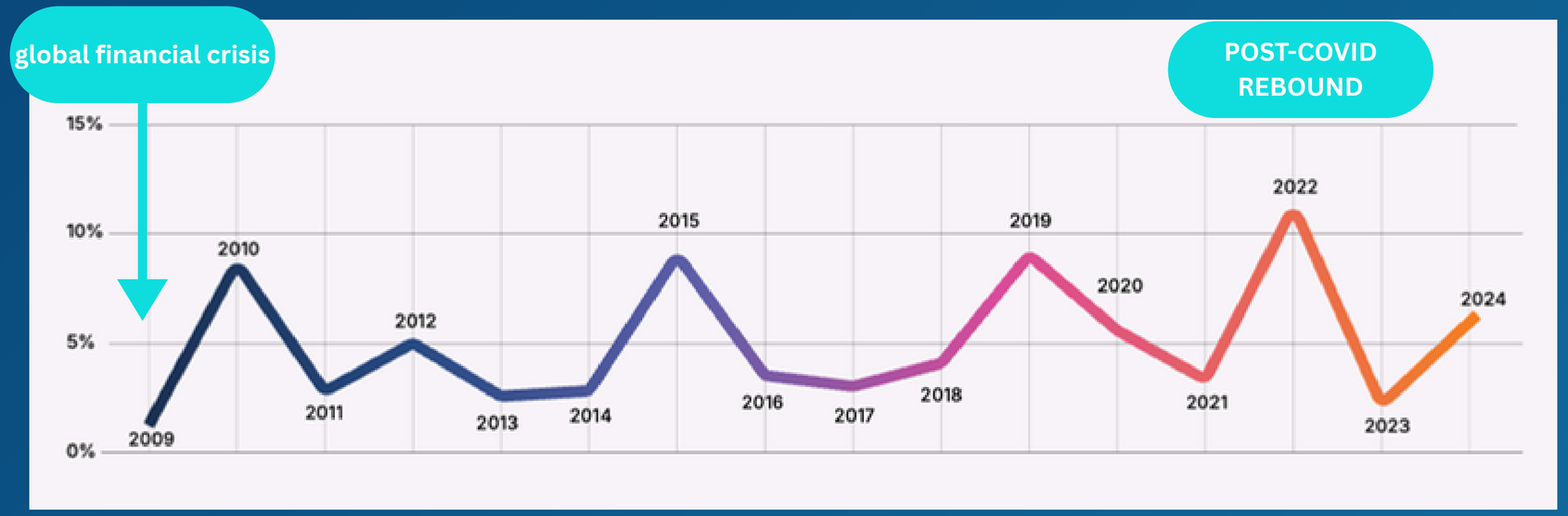
COMMON MYTHS

- One or two strong distributors can cover all of Europe.
- Europe is one single market, just like the U.S.
- We can find a partner to help us pay for MDR or manage the whole process.
- Our existing English materials will work fine
- U.S./Asia clinical data will be enough for EU approval and adoption.
- We don’t need to do market research before entering the EU — we already know the key countries to enter.
- We can finalize our strategy once we start selling.
- Trade shows like MEDICA are for sales.

Market Opportunities

Four forces shaping Europe’s medtech future

Europe’s Medtech Growth Engine Keeps Running Strong

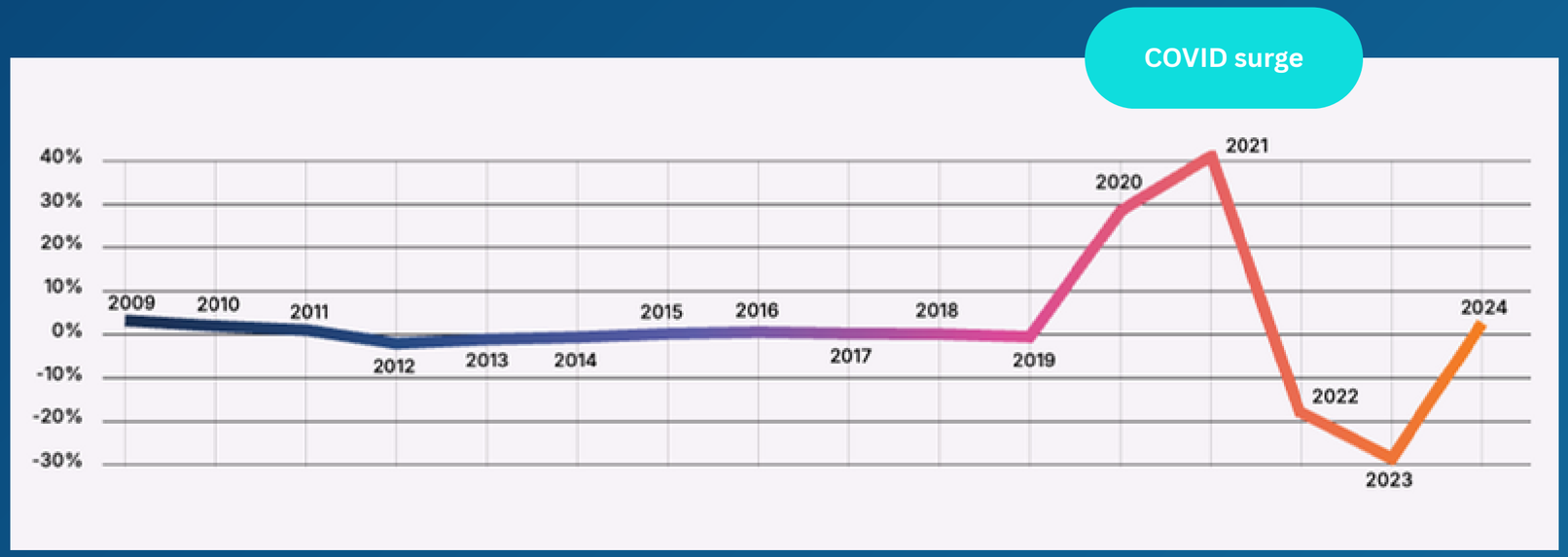


EU medical device market growth rate (2009-2024)

Europe’s medtech market holds steady at 6% growth — powered by innovation, demand, and resilience

(2024, Medtech Europe)

40% Growth and Counting — IVD Leads Europe’s Medtech Momentum.



EU IVD market growth rate (2009-2024)

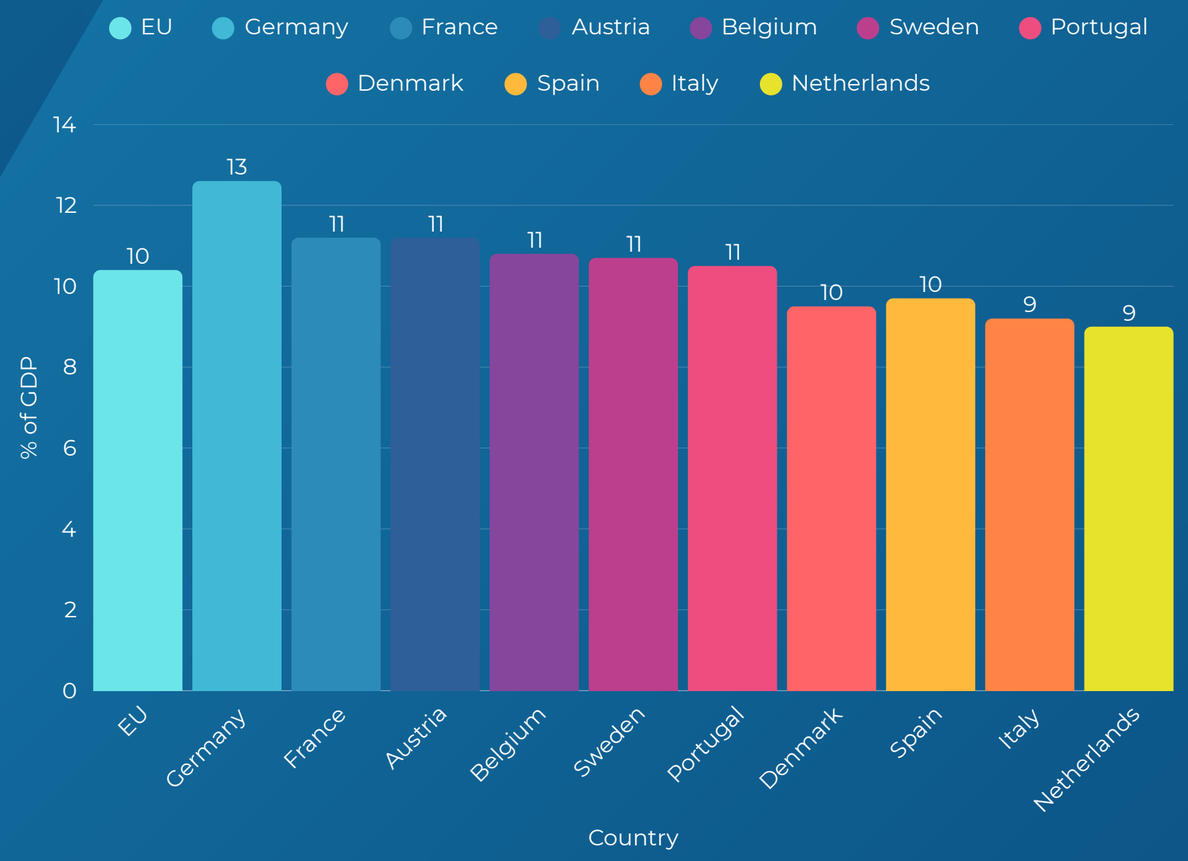
IVD demand spiked 40% in 2021 amid COVID, yet maintained a solid long-term 4.3% annual growth

(2024, Medtech Europe)

Rising Healthcare Spending Fuels Europe's Medtech Opportunity

Major EU economies consistently allocate > 10 % of GDP to healthcare — sustaining long-term medtech investment

The higher the national healthcare spending ratio, the more demand for innovation, chronic-care solutions, and digital health adoption



Universal Coverage and Social Investment: Europe's Competitive Edge in Health

- Europe offers larger opportunities for MedTech companies.
- Emphasis on community-based care and health equity encourages collaboration between MedTech firms and healthcare providers to develop targeted local solutions.

	Overall Rank	Access	Equity	Outcomes
1	Norway	Netherlands	Australia	Australia
2	Netherlands	Norway	Germany	Norway
3	Australia	Germany	Switzerland	Switzerland
4	UK	UK	UK	Netherlands
5	Germany	New Zealand	Netherlands	Sweden
6	New Zealand	Sweden	Sweden	France
7	Sweden	France	France	Germany
8	France	Australia	Norway	New Zealand
9	Switzerland	Canada	New Zealand	UK
10	Canada	Switzerland	Canada	Canada
11	US	US	US	US

Europe APAC North America

(2024, Deloitte)

Key Growth Drivers

Europe’s medtech market is growing quietly but powerfully — fueled by aging care needs, digital transformation, and regulation that turns quality into competitive advantage.

Chronic Disease & Aging Population → Persistent, Structural Demand

Digital Health Transformation & Hospital-to-Home Shift

R&D Investment and Innovation Momentum

Government & EU Funding Programs

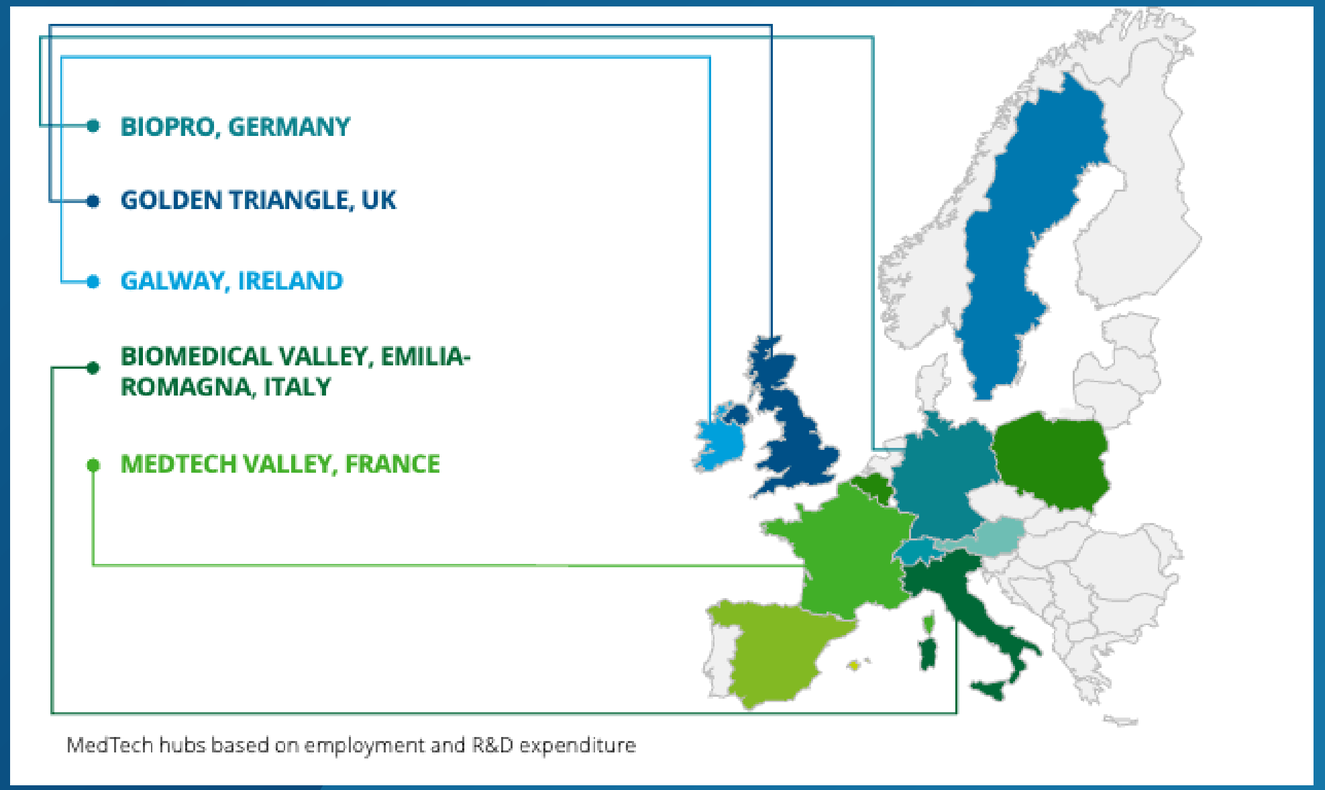
Key Opportunites

For Taiwanese companies entering the EU medtech market, it's crucial to strategically choose the right countries based on market demand, regulatory environment, potential partnerships.

- **Leverage Innovation & Niche Technologies**
- **Entering the Market Through EU-Funded Projects**
- **Access Mature Healthcare Systems with Good Budgets**

EU has strong ecosystem & hubs

- ~2,000 MedTech startups across Europe, supported by **strong academic–industry networks.**
- Europe leads globally in MedTech IP, filing **42% of patents** vs. 35% in the U.S.
- Top innovation hubs: Germany, Switzerland, Ireland, France, Netherlands, Scandinavia.
- **Active public funding**: Horizon Europe, EIT Health, and EU4Health foster R&D and cross-border collaboration.



MedTech hubs based on employment and R&D expenditure

Europe's innovation ecosystem is one of the world's most vibrant — combining academic excellence, established industry players, and an active start-up landscape.

(2024, Deloitte)

Key Challenges

While the overall market entry process in the EU can be slow, it offers a safer environment with steady, long-term growth potential for those who succeed in overcoming these challenges.

- **Complex & Stringent Regulatory Landscape**
- **Fragmented Market & Localisation Needs**
- **High Competition & Need for Strong Differentiation**

Shifting from Products to Solutions — Competing on Value in the EU.

- Price competition is less intense than in Asia; **differentiation, quality, and sustainability drive success.**
- Procurement is shifting from product-based to **solution-based**, integrating service, software, and outcomes.

Not just devices, but integrated solutions locally

Procurement decisions increasingly favor vendors who can prove:

- Clinical effectiveness (measurable patient outcomes)
- Operational value (reduces procedure time, staff workload, or total cost of care)
- Digital integration (connects with hospital IT, EMR, or analytics systems)

Europe Is Bringing Manufacturing Closer

EU Reshoring Momentum

- Countries like Ireland, Poland, and Czechia are attracting new MedTech manufacturing sites.
- Swiss and German firms are relocating partial assembly to reduce logistics risk.

Still Dependent on Asia

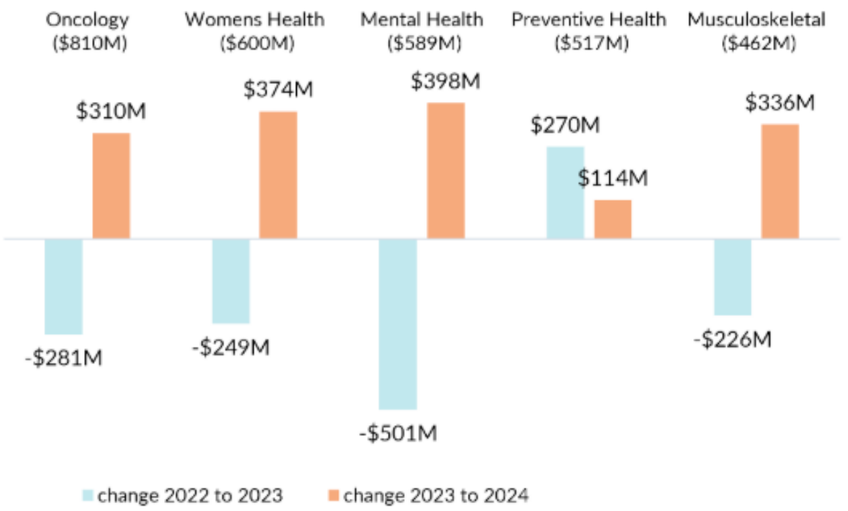
- Over 60% of MedTech electronics & precision modules are sourced from Asia.
- Taiwanese firms supply critical subsystems and contract manufacturing.

MedTech Investment & Innovation in Europe

Top Emerging Investment Areas (2025)

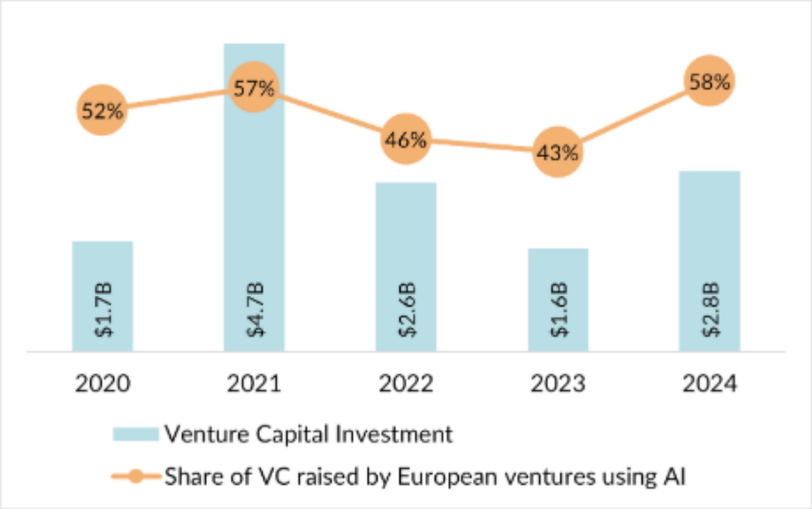
Medical Device

Therapeutic funding rebounded sharply in 2024, led by **Oncology, Mental Health, and FemTech** — signaling renewed investor confidence in scalable, evidence-backed MedTech solutions



Change in venture funding for the top 5 Therapeutic Areas (by funding value)

Digital Health

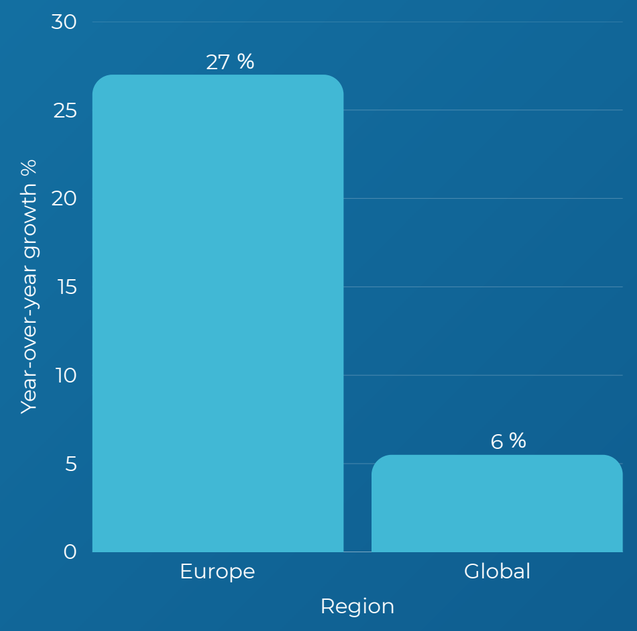


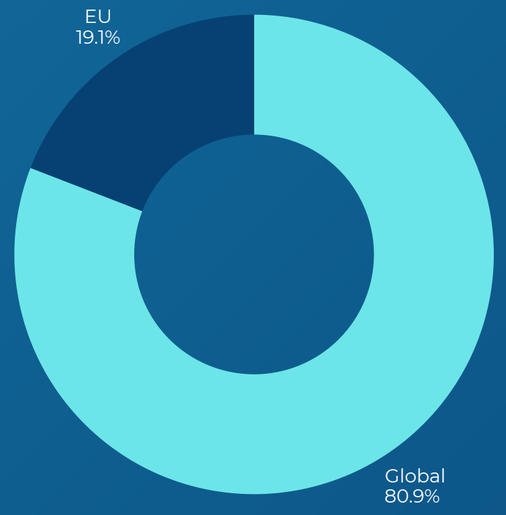
2024 Funding for European ventures using AI in healthcare

Investors now favor AI solutions with clinical validation and regulatory readiness over speculative "hype tech."

Europe’s Digital Health Funding Hits Record Highs

- Fastest-growing digital health region globally — fueled by AI, oncology, and TechBio.
- Public-private investors like Bpifrance, Octopus Ventures, Cathay Innovation drive momentum.
- Mature ventures attract larger rounds; early-stage firms face tighter funding.





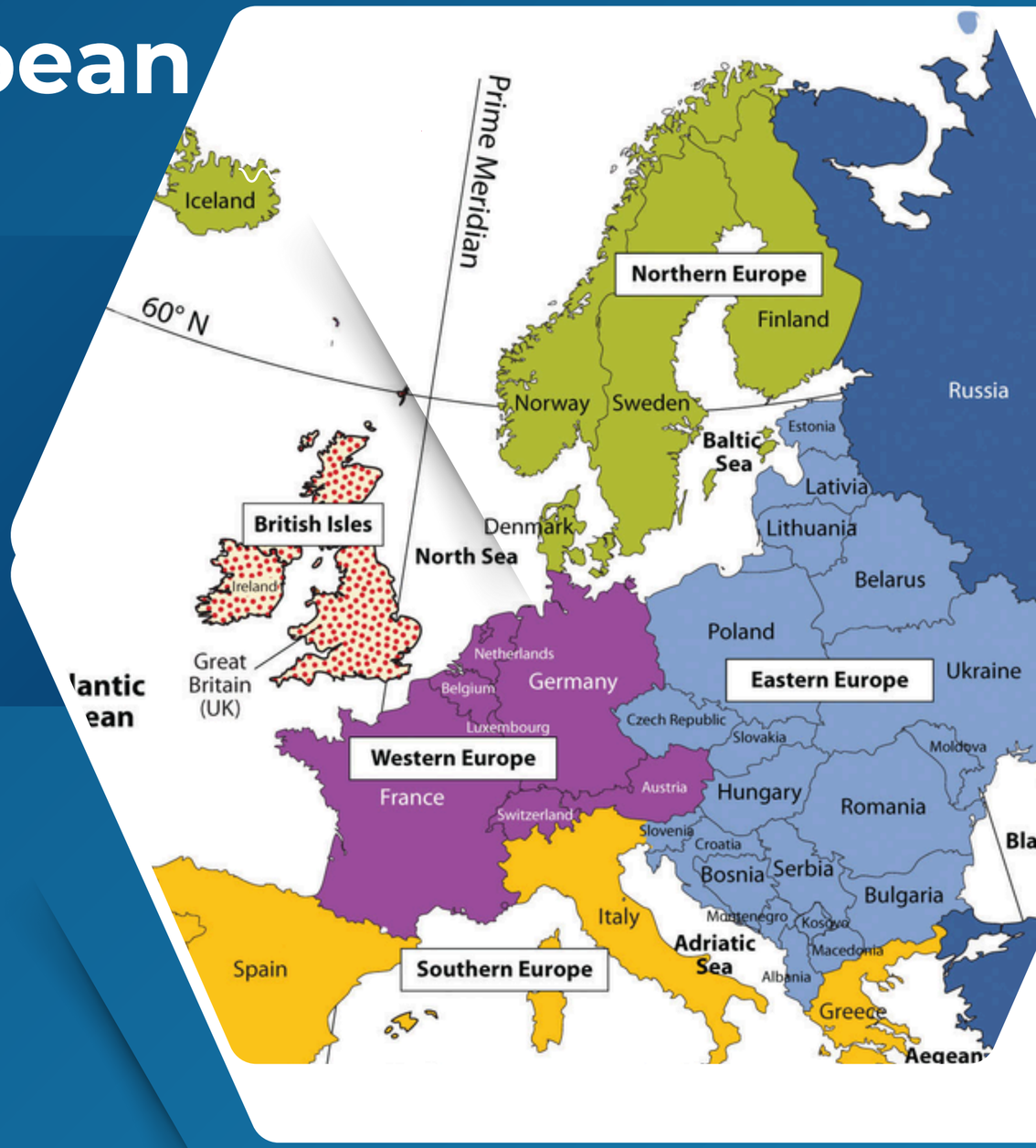
Europe secured $4.8B in digital health funding in 2024, representing 19% of the global $25.1B total, and achieved the fastest regional growth at +27% YoY.

Go-To-Market

How EU MedTech market entry is evolving

How to Look at the European Market

The EU isn't a single, unified healthcare market like the U.S. — it's a mosaic of 27 systems, each with its own rules, reimbursement logic, and buying behavior.
Success depends on choosing the right entry points, not covering all countries.



- Western Europe (DACH + Western EU)
- Nordic Region
- Southern Europe
- Eastern Europe

Europe’s Trust Gate — Validation Before Volume

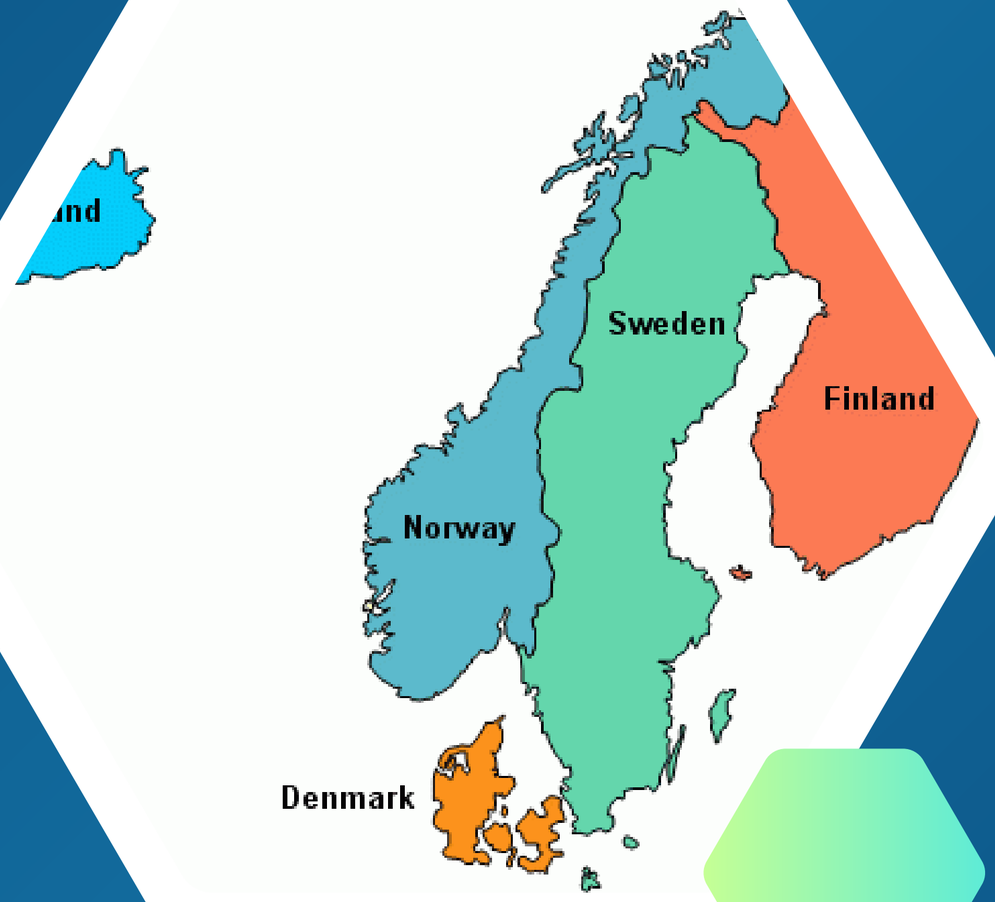
Ideal first step for companies with proven products, regulatory readiness, and a need for long-term credibility.

- Home to the largest MedTech markets — Germany, France, Benelux, Switzerland.
- **Procurement is centralized** and evidence-driven: hospitals, GPOs, and HTA (Health Technology Assessment) bodies decide together.
- **MDR compliance, clinical validation, and post-market data are must-haves** — not optional.
- Success depends on clinical partnerships and reference hospitals.

Nordics Lead Europe’s Leap Toward Digital and Sustainable Care

Best region to test and validate digital health, telemedicine, or AI solutions before scaling to larger EU markets.

- Among the most tech-forward regions in healthcare.
- Public systems are **open to pilots, innovation partnerships, and data-sharing.**
- Strong focus on sustainability, efficiency, and population health.
- Small populations but **high per-capita spending** and **early adoption curves.**



Emerging Hubs for Affordability & Aging Care

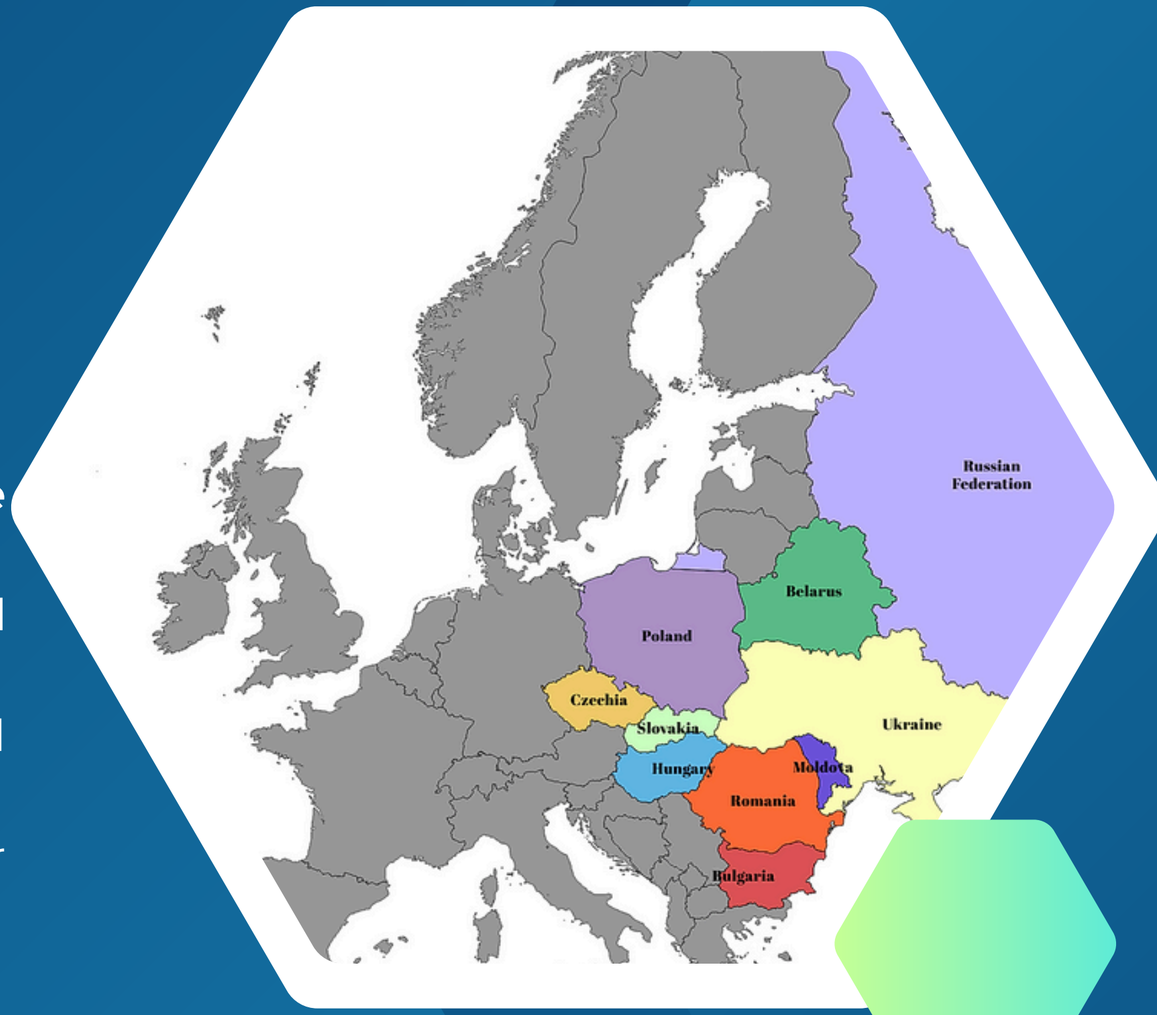
Best region for cost-efficient production, elderly care innovation, and public-private partnerships in chronic disease management.

- Healthcare systems under cost pressure — strong demand for affordable MedTech and home-care solutions.
- Aging population drives innovation in remote monitoring, cardiovascular, and rehabilitation devices.
- Governments and regional clusters promote digital health transformation through EU4Health and regional innovation funds.
- High potential for clinical collaborations and pilot studies in elderly and chronic care due to dense hospital networks.

Europe’s Fastest-Growing Medtech Frontier

Strategic opportunity for Taiwanese manufacturers to build B2B and OEM pipelines — not just export products.

- Fastest-growing region for **private healthcare** investment.
- Strong appetite for **affordable innovation and OEM/ODM** collaboration.
- EU recovery funds boosting hospital modernization and equipment upgrades.
- **Price-sensitive** but open to cross-border manufacturing partnerships.



Key Success Factors

Clear Clinical Positioning

Define exactly which clinical problem your product solves — and how it fits into the local current healthcare pathway.

Target Market Selection

Focus 2-3 countries with proven demand, supportive payers, and clear clinical fit.

Entry Strategy

Align your EU entry with MDR approval timelines and notified body capacity.

Local Validation & KOL Support

Build credibility via pilot sites, user cases, and reference hospitals with KOL endorsement.

Health Economic Evidence

Collect data proving cost-effectiveness or ROI for payers and hospitals

Case study A: Singapore CGM Company Expanding into Europe

Challenges

- **Highly saturated market** — established players with strong brand loyalty and reimbursement coverage.
- **Complex reimbursement pathways differing by country**
- **Fragmented distribution landscape** — strong local distributors, but limited access without EU credibility.
- **Need for localized clinical validation** to compete with strong competitors nd payer expectations.

Approach

- Market Research & Opportunity Mapping
- Competitive & Reimbursement Landscape Analysis
- Localized Positioning & Clinical Evidence
- Strategic Partner Identification

Case study B: Indian Portable Fundus Camera — Using EU Pilots to Validate Market Fit

Challenges

- **Evidence gap** — APAC and U.S. data didn't align with EU patient flow or public-sector care delivery.
- **Reimbursement mismatch** — EU systems reimburse screening primarily under specialist care, not GP-led programs.
- **Adoption friction** — Needed to prove value in primary care, where screening accessibility remains a bottleneck.
- **Funding constraint** — High cost to generate EU-specific evidence without guaranteed market access.

Approach

- Ecosystem Evaluation & Market Mapping
- Proof of Concept: GP-Led Screening Model
- Evidence & Reimbursement Alignment
- Partnership Development

Q&A

Business Development Requirements in EU

COMMERCIALIZATION IN EU MARKET

Understanding the European Preferences

Importance of Local Data

- **For Trust and Credibility:** Local data is crucial for building trust with both consumers and partners in the EU, proving the product's effectiveness in the local context.
- **Lead Users and Validation**: Engaging with local lead users helps validate the product and adapt it to the market.

Business Culture Norms

- **Well-Designed Presentations:** Business Development materials should be logically structured, clear, visually appealing, reflecting professionalism and attention to detail.
- **Know your market:** business model, and value proposition in detail for EU market
- **Transparency:** Clear, honest communication is essential

Pathway to Success

Product Development and Readiness

- Product Localization
- Technology Integration
- GDPR-compliant data protection

Regulatory Navigation

- Navigating the MDR Pathway, GDPR
- Strategic Approaches to Regulatory Compliance

Market Research

- Prioritize countries that serve as strategic entry points for broader EU expansion.
- Focus on markets with high adoption
- Competitive Landscape

Market Entry Strategy

- Choosing the Right Market Entry Model
- Leveraging Government Incentives and Support
- Building Strategic Partnerships

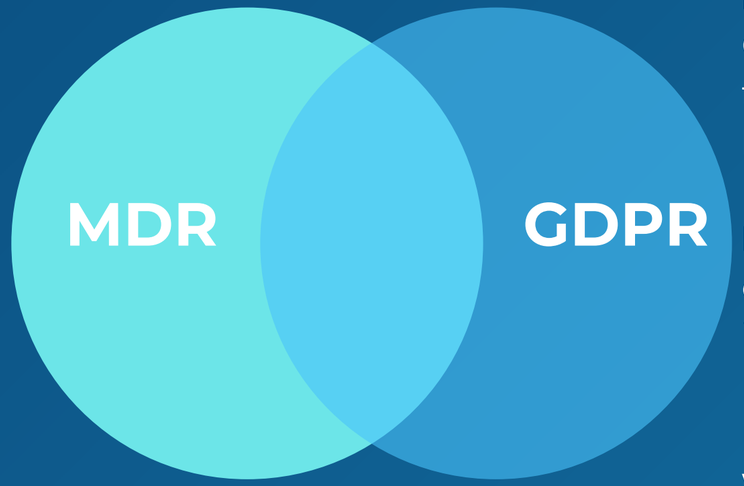
Go-to-Market

- Form strategic partnerships to share resources, reduce entry barriers, and accelerate market penetration

EU Regulations Overview

Importance: For the products classified as medical devices, MDR compliance is mandatory.

Market Entry: It's crucial for Taiwanese medtech companies to thoroughly navigate the MDR pathways, either by leveraging available resources or by making strategic decisions such as forming partnerships or pursuing licensing agreements.



Importance: Compliance with GDPR is essential for handling the personal and health data of EU residents.

Market Access: For Taiwanese digital health companies, it's important to understand that all potential partners, healthcare providers, and clients in the EU will expect full compliance with GDPR.

Market Entry Models

Licensing

- Lower Entry Costs
- Quicker Access to Market

Requirements:

- **Strong IP: enforceable in EU**
- **Well-Defined Partner Profile: choose a licensee with a strong market presence, relevant experience, and a genuine interest in your technology, ensuring alignment with your business goals**

Distribution

- Regulatory Responsibility
- Established Networks

Requirements:

- **MDR compliant**
- **Distributor Selection: Select distributors with a strong track record in commercialization and local reputation**
- **Distributor Management**

Joint Ventures

- Shared Resources and Risks
- Combined Expertise

Requirements:

- **Cultural and Strategic Alignment: outlining each partner's contributions, roles, responsibilities, and profit-sharing structure to avoid conflicts.**
- **Clear Agreement Terms**
- **Exit Strategy**

Direct Investment

- Total control over operations
- Higher Profit Potential

Requirements:

- **Adequate financial and operational capacity**
- **Deep understanding of local regulations, market, and culture**
- **Critical to have strong local connections and market knowledge**

Innovation and Funding in the EU

EU Innovation Ecosystem

Strengthen and connect innovation ecosystems across Europe to enhance collaboration among startups, SMEs, researchers, and policymakers.

Focus Areas: Healthcare, Digital transformation, green transitions, inclusiveness, and scaling innovation across the EU.

Opportunities for Startups

- Collaboration: Engage with diverse stakeholders for collaborative projects.
- Support: Access funding, networks, and resources to drive innovation and growth.

EU Funding Opportunities

The Digital Europe Programme

Supports digital transformation across Europe by funding projects in key areas such as supercomputing, AI, cybersecurity, and digital skills.

- Budget: Over €7.9 billion.
- Objective: Shape Europe's digital transformation by 2030

Participation in EU-Funded Projects

Engaging in EU-funded R&D projects provides access to resources, networks, and advanced technologies, facilitating innovation and market entry.

EU Innovation Funding Pathways

The EU actively funds innovation that strengthens strategic technologies, healthcare resilience, and digital transformation.
Through **STEP** (Strategic Technologies for Europe Platform), companies — including non-EU collaborators — can access grants and partnerships to validate and scale medtech solutions within Europe.

Potential Pathways

- Join EU consortia as a technology or OEM/CDMO partner to access funding indirectly.
- **Co-develop clinical data pilots with European hospitals** under Horizon or EU4Health.
- Use the STEP Seal ecosystem to scale validated innovations across multiple EU markets.

Building Local data for Market Entry

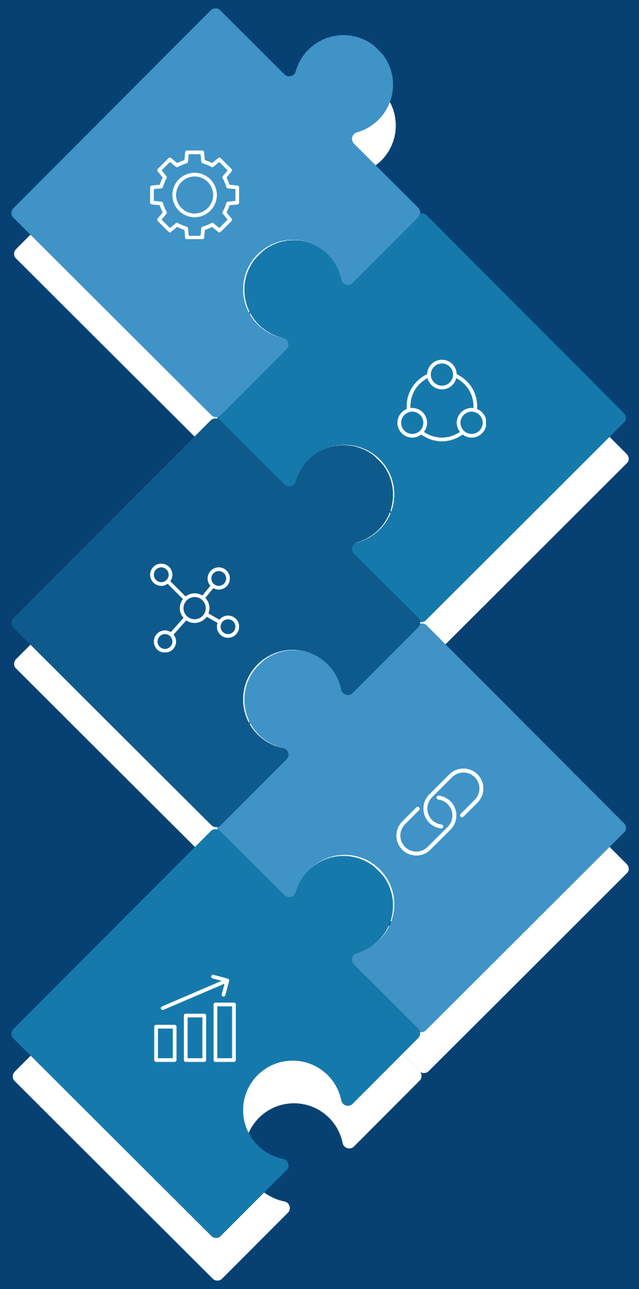
Frame your device or platform as a data-enabling solution that improves EU clinical or operational workflows

Partnership model:
Work with an EU research institute or digital-health integrator to join existing grant consortia or form new ones targeting calls under.

Outcome:
Use resulting EU-generated datasets, pilot outcomes, and ethics-approval track record as proof for the market entry

Practical Steps & Resources for Entering the EU Market

Product Readiness



- MDR/IVDR Compliance Plan Ready
- IP & Freedom-to-Operate
- Local Data/ User Cases
- Quality Systems
- Localization & Technical Adaptation

Strategic Readiness

Navigate expansion stages for sustainable business model scaling

Alliance Management

Partnering

Identify and evaluate strategic partners — distributors, research institutions, and clinical sites — based on market coverage, regulatory capability, and cultural fit.

Engage Key Stakeholders Early

Build relationships with KOLs, reference hospitals, and clinical champions — their validation boosts credibility and strengthens your leverage in distributor negotiations.

Go-To-Market Strategy

Choose the right path — distributor, hybrid, or subsidiary — based on your product's regulatory class, service needs, and market insights.

Pricing & Reimbursement Strategy

Build clinical-economic evidence to ensure the feasible pricing strategy

Market Research

Understand market size, reimbursement models, clinical fit, local competition and user adoption (HCPs & patients)

Enter smart, not wide — validate before you invest

Checklist

- Thorough market research to identify demand and competition
- EU regulation navigation
- Market entry strategy
- Funding and resources allocation
- Go-To-Market Strategy

Key External Resources

Regulatory Bodies: EU regulatory bodies for guidance on compliance with MDR, IVDR GDPR, and other relevant regulations.
Local Consultants: Work with local consultants to navigate the complexities of market entry, cultural adaptation, funding seeking, and the local network.

Thank You

For Your Attention

More questions about EU market entry
Contact: vesper@kreivohealth.com