

HumanoidHealthcare.AI

The Regulatory Software Brain
for Safe Humanoid Care



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The Problem

A Ticking Liability Time Bomb in Healthcare Robotics



**Patient
Safety Risk**



**Catastrophic
Manufacturer
Liability**



Regulation Gap
Unitree R1 @5,900
Soon in Homes

Why Now?

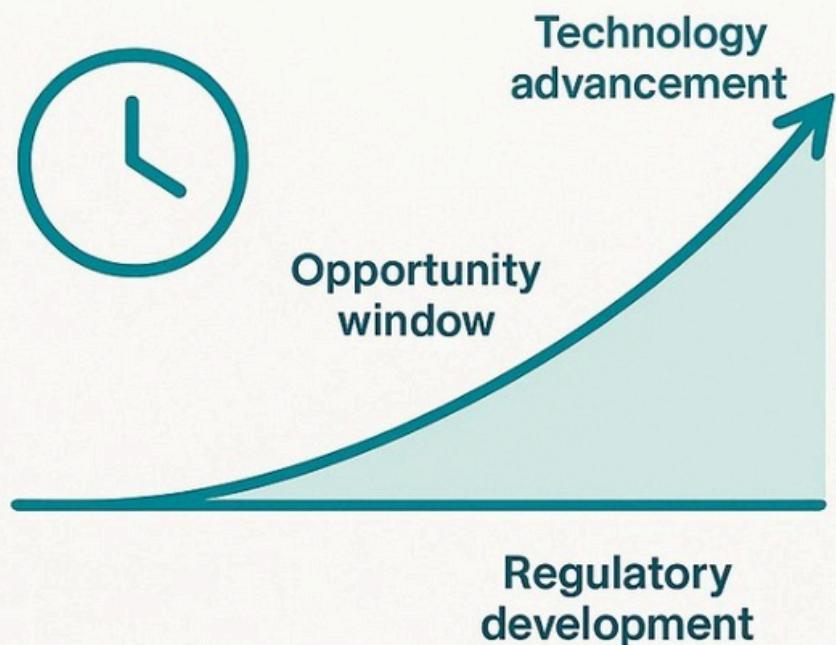
Technology is here. Regulation hasn't caught up.

**1.6B people
aged 65+ by 2050**

 Aging populations & caregiver shortages

 Explosion of humanoid R&D & falling prices

 EU AI Act & FDA SaMD frameworks = compliance inevitable



Medical Robots Market Growth

Medical Robots Market to Reach \$33.8B by 2029

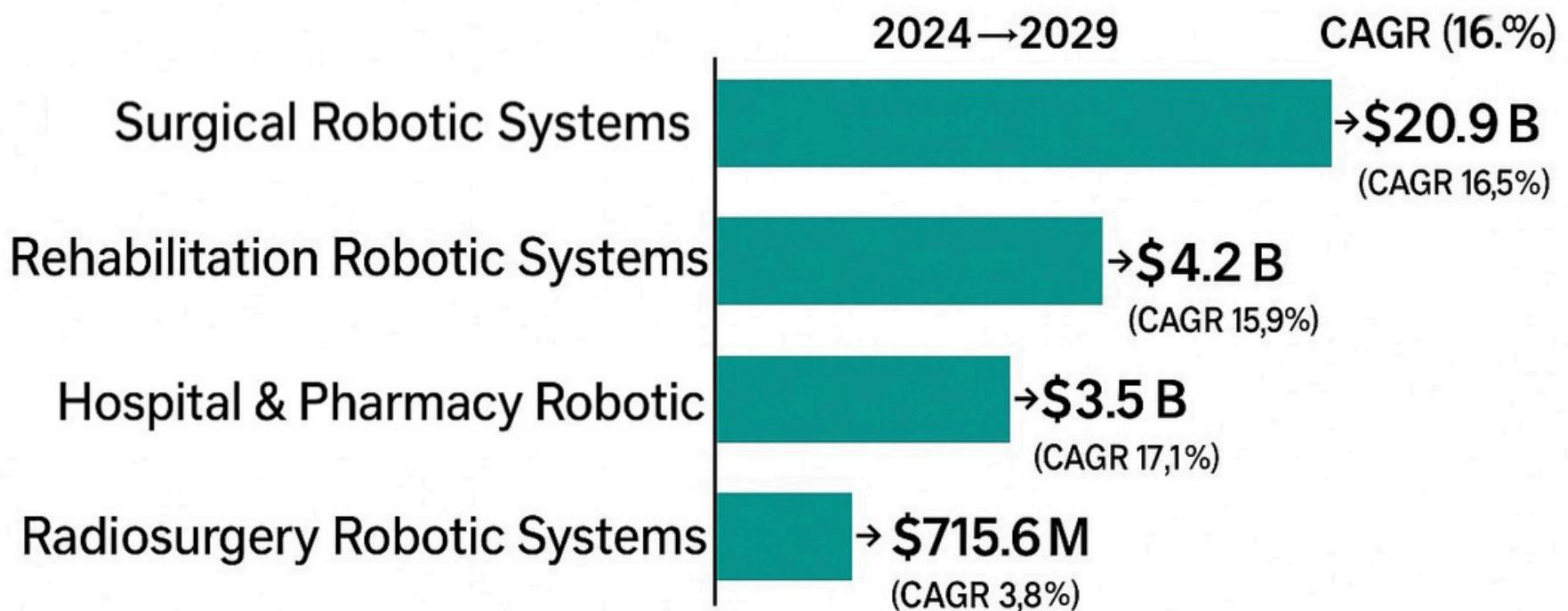
- Market: \$18.0B (2024) → \$33.8B (2029)
- CAGR: 16,1%
- Key drivers: Aging population, chronic disease, workforce shortages, AI-enabled robotics



Source: MarketsandMarkets, March 2025

Medical Robots Market Segments

Rehabilitation & Hospital Robots Among Fastest Growing



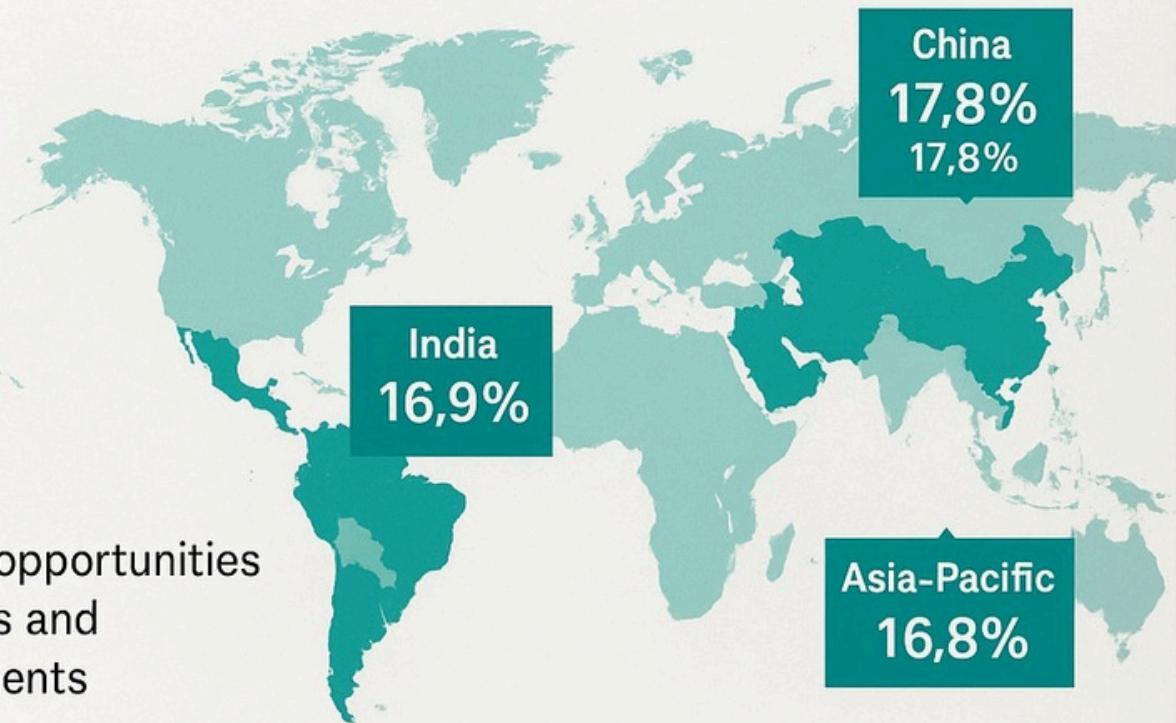
Source: MarketsandMarkets, March 2025

Geographic Opportunities & Trends

Global Growth Led by Asia-Pacific and Emerging Markets

Key geographic insights

- China: Highest CAGR (17.8%) 2024–2029
- India: Strong growth (16.9%)
- Developed markets (US, Germany): Steady growth at lower rates
- Emerging economies: Key opportunities through lower-cost devices and lighter regulatory requirements
- Asia-Pacific & Latin America: Fastest growth in telemedicine and automation-focused applications



Source: MarketsandMarkets, March 2024

Market Barriers & SaMD Opportunity

The Barrier is Not Demand — It's Compliance

Current Challenges

-  High Upfront Costs (\$0.3-2.5M per system)
-  Regulatory Hurdles (long, uncertain timelines)
-  Training & Adoption (limited programs)
-  Patient/Provider Acceptance (safety concerns)



SaMD Solution Unlocks Market



HumanoidHealthcare
SaMD

Explosive adoption in
home rehab & eldercare
humanoids

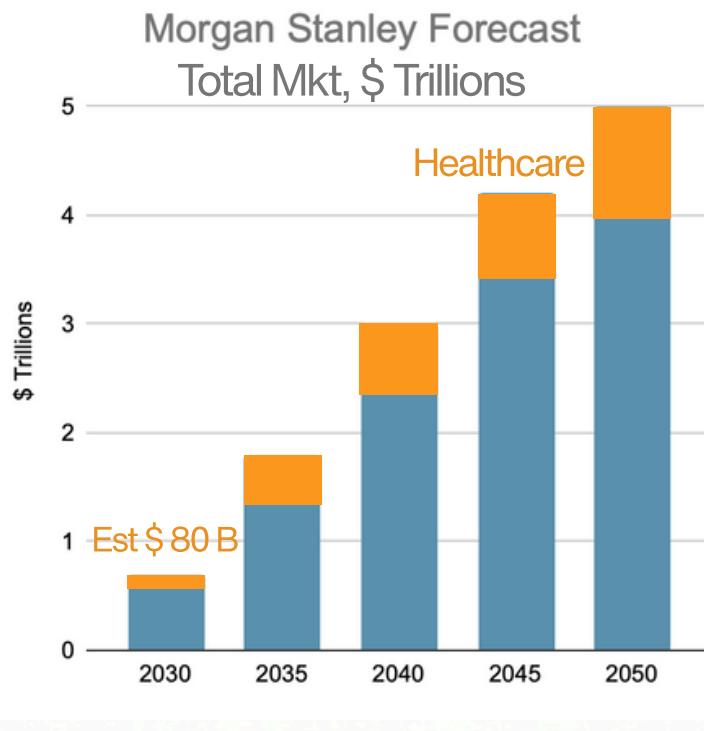
Source: MarketsandMarkets, March 2025

Long-Term Market Outlook

Humanoids: A \$5 Trillion Market by 2050

Key takeways from Morgan Stanley research

- The humanoids market could surpass \$5 trillion by 2050, including sales from supply chains and networks for repair, maintenance and support
- Adoption of humanoids is likely to accelerate in the late 2030s with improved technology as well as greater regulatory and societal support
- Although humanoids are still under development, there could be more than 1 billion by 2050, with 80% used for industrial and commercial purposes



Source: Morgan Stanley, May 14, 2025

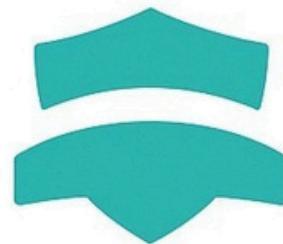
Note: This forecast was made BEFORE the new Unitree R1 general purpose Home Humanoid competitive price of \$5,900 - likely to **accelerate adoption**

Our Solution

The SaMD Software Brain:



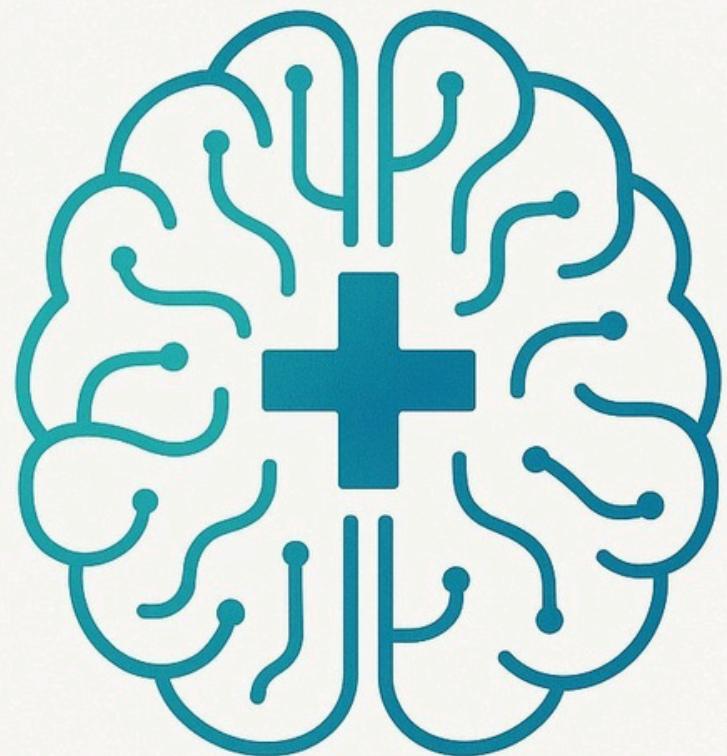
**PROTECT
PATIENTS**



**SHIELD
OEMs**



**INDUSTRY
STANDARD**



Product & Technology

Regulation-first architecture, built to scale

- Modular: integrates with any humanoid platform
Follow [TOGAF](#) Enterprise Architecture
For Sensor / EHR data - [HL7 FHIR](#)
- Compliance-ready: ISO 13485, IEC 62304, FDA, EMA
- Patient-centric by design



Patient/Clinician



SaMD Safety Layer



Robot Hardware

Regulatory Advantage

**Regulation is not a barrier.
It's our moat.**

- ⚠️ Competitors avoid regulation → exposed
- ✅ We turn compliance into defensibility



Data-Driven Business Model (DDBM)

Platform orchestrator of the entire humanoid healthcare ecosystem



Partnership Revenue

Joint ventures with OEMs, white-label deployments



Third-Party Licensing

APIs and IP licensing for app developers/insurers



SaMD Licensing

Per-unit licensing for compliance & safety layer



DaaS (Data as a Service)

Predictive algorithms, real-world evidence to hospitals/payers/pharma

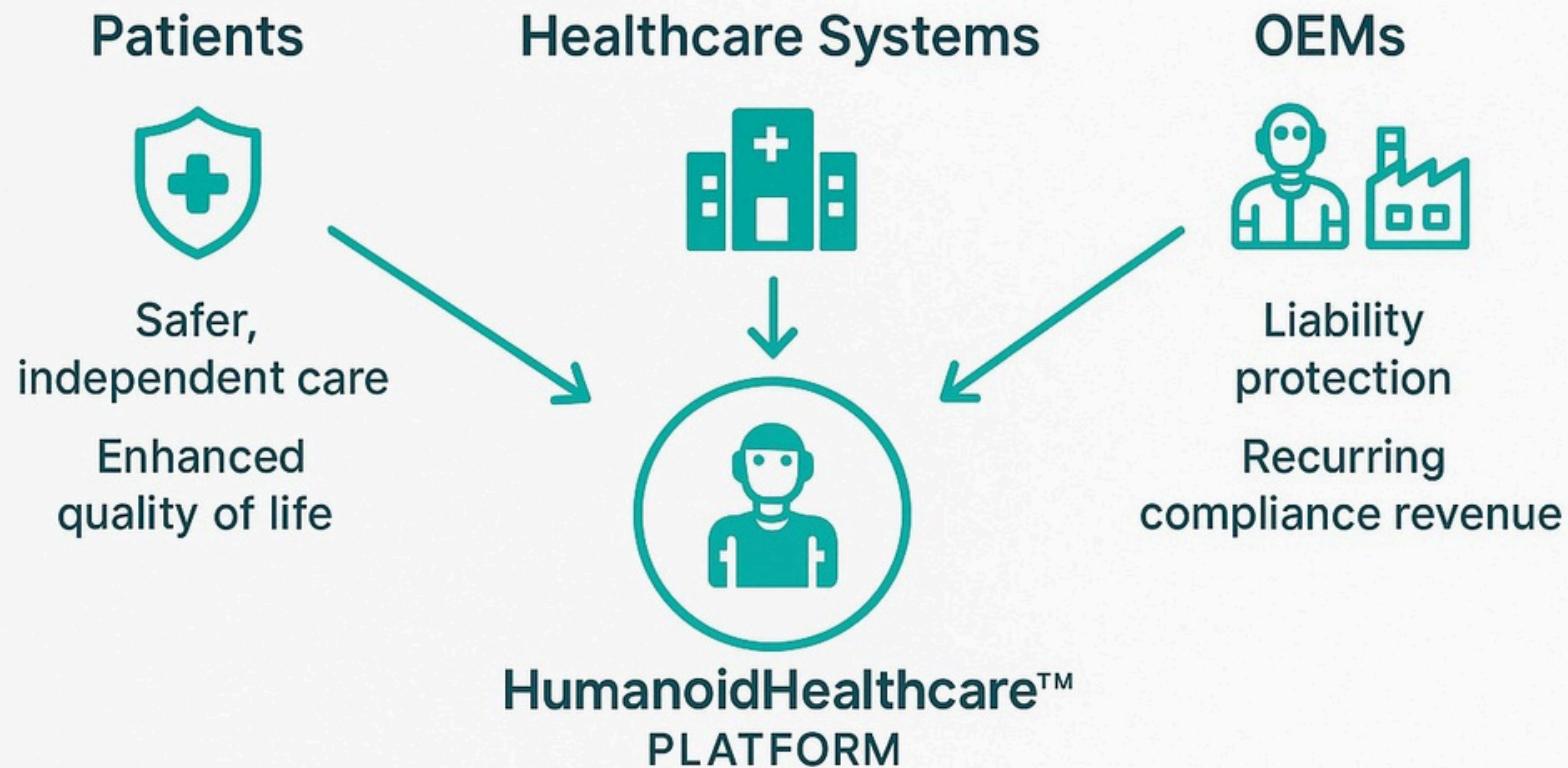


HaaS (Hardware as a Service)

Rental/maintenance partnerships with OEMs

High-margin recurring revenues built on regulatory lock-in

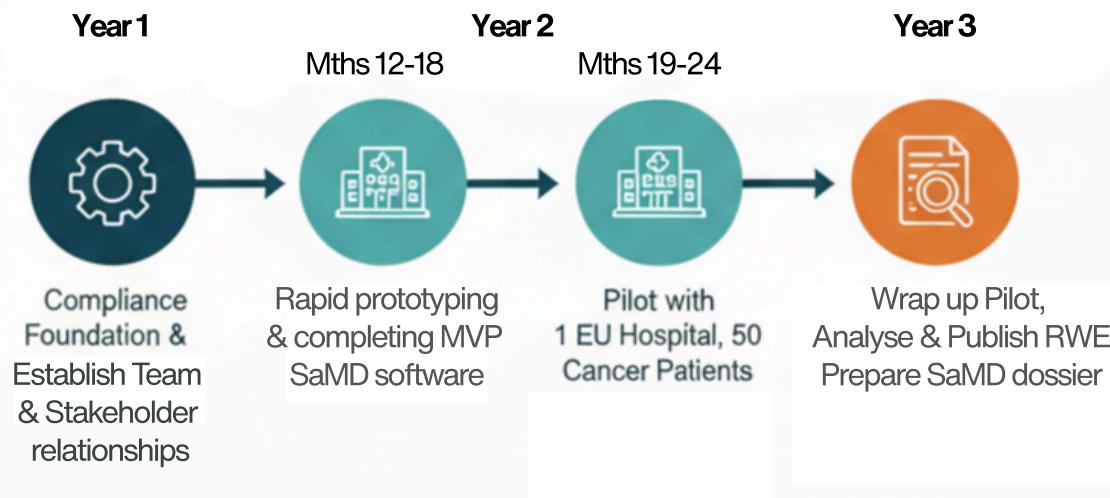
Triple Win Ecosystem



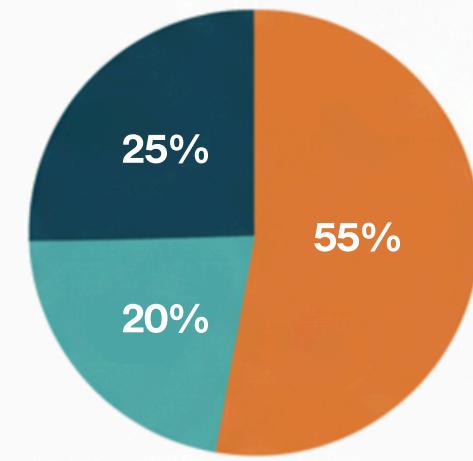
We are the orchestrator and central nervous system of humanoid healthcare.

Roadmap & Use of Funds

\$3M Seed builds compliance foundation & validates SaMD



Use of Funds



- Clinical Pilot & RWE Analysis Development (MVP)
- Regulatory Affairs & Quality Systems
- Development, IT, Operations & Legal

PATIENT-CENTRIC CARE AndySquire.AI Home Forms Consulting Humanoid Healthcare Collaboration

Humanoid Healthcare

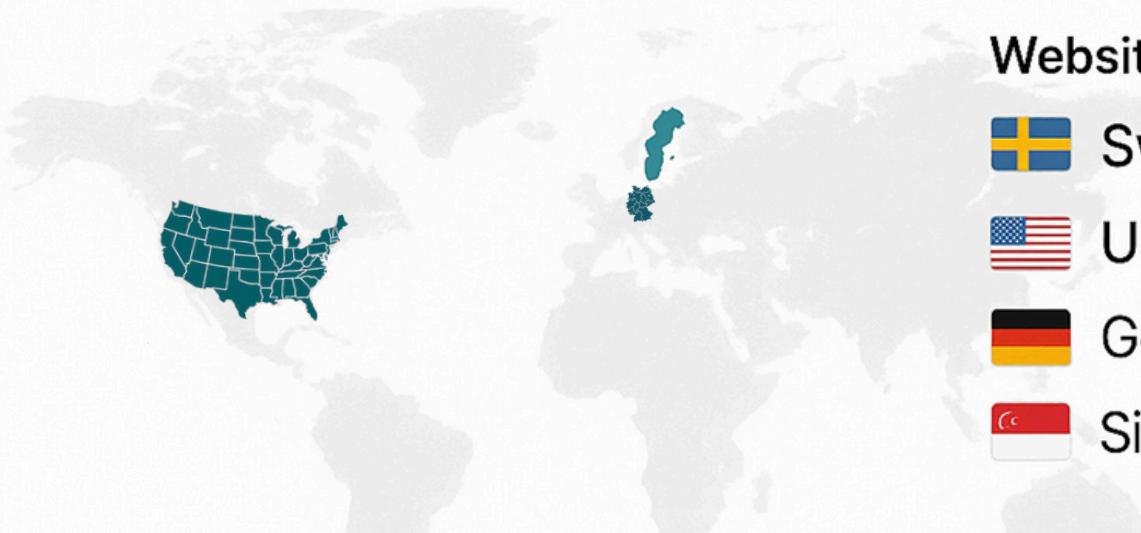
Download Pitch to Manufacturers

Download Ecosystem Architecture Blueprint

Regulatory Hurdles & Possible Pathway Forward

Traction/Proof

Global interest, early momentum:



Website traffic (last 30 days):

| | | |
|--|-----------|--------|
| | Sweden | 34,5 k |
| | USA | 27,7 k |
| | Germany | 21,2 k |
| | Singapore | 9,2 k |

- Research validation: Chalmers, Luleå, ROBERT® rehabilitation robot
- Regulatory pathway defined

Regulatory Hurdles for Humanoid Healthcare: US (FDA) vs. EU (MDR)

General Challenges for Both Regions

Newly and Previously, humanoid caregivers represent a novel challenge for regulators, requiring new pathways. This includes highly complex software, sensors, and actuators, which are potentially subject to rapid obsolescence and degradation.

Safety and Reliability: Ensuring that the humanoid is safe for intended purposes, and does not pose a risk to patients or healthcare providers. This includes software reliability, preventing unintended cybersecurity risks, and ensuring robust protection against potential threats such as hacking or viruses.

MDR (Medical Device Regulation): Special attention is required for the interaction between the device and the patient, or for its role in personal care or medical treatment. This may include clinical trials, regulatory submissions, and post-market surveillance.

Regulatory Hurdles &
Possible Pathway Forward





PatientCentric
Care.AI

Team & Advisors



Andy Squire – Founder

35 yrs **Pharma Insights, Digital CX, Business & IT**
2x cancer survivor & independent Advocate

Advisory Network:



Regulatory Affairs
Medical SaMD, MDR



Robotics Engineers
HRI Hardware & Software



Clinical Oncology
Hospital IT



Ethics & Patient
Advocacy & CX

andy@PatientCentricCare.AI

15th Sept, Basel Switzerland