The US-First Advantage

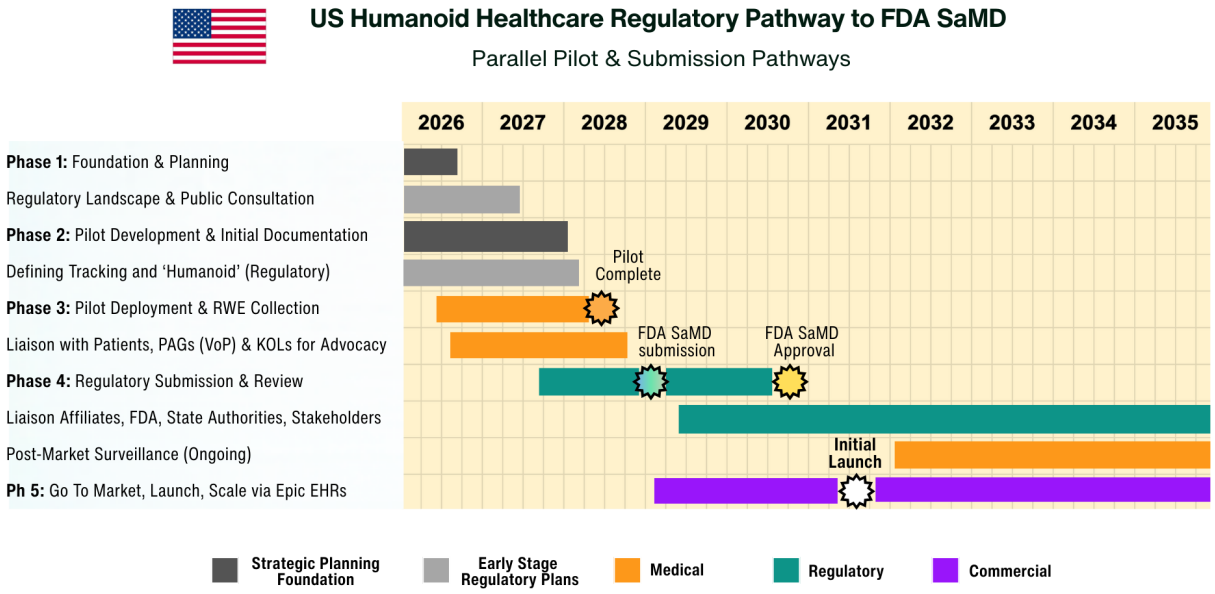
A Faster, More Flexible Path to Market for Humanoid Healthcare Robotics

Confidential Investor Presentation | PatientCentricCare.AI

Executive Summary

For investors, hardware manufacturers, and strategic partners in the advanced robotics space, the choice of a primary regulatory jurisdiction is the most critical decision impacting time-to-market, cost, and innovation potential. This document outlines a compelling case for a **US-First regulatory strategy**, demonstrating a significantly faster, more cost-effective, and flexible pathway compared to the European Union's Medical Device Regulation (MDR).

Our analysis shows the US Food and Drug Administration (FDA) pathway, leveraging the Q-Submission and 510(k) processes, can achieve market clearance for a Class II Software as a Medical Device (SaMD) with **US Launch in 2031** and **EU Launch in 2033**. This accelerated timeline not only reduces burn rate but also secures a first-mover advantage in the world's largest healthcare market.

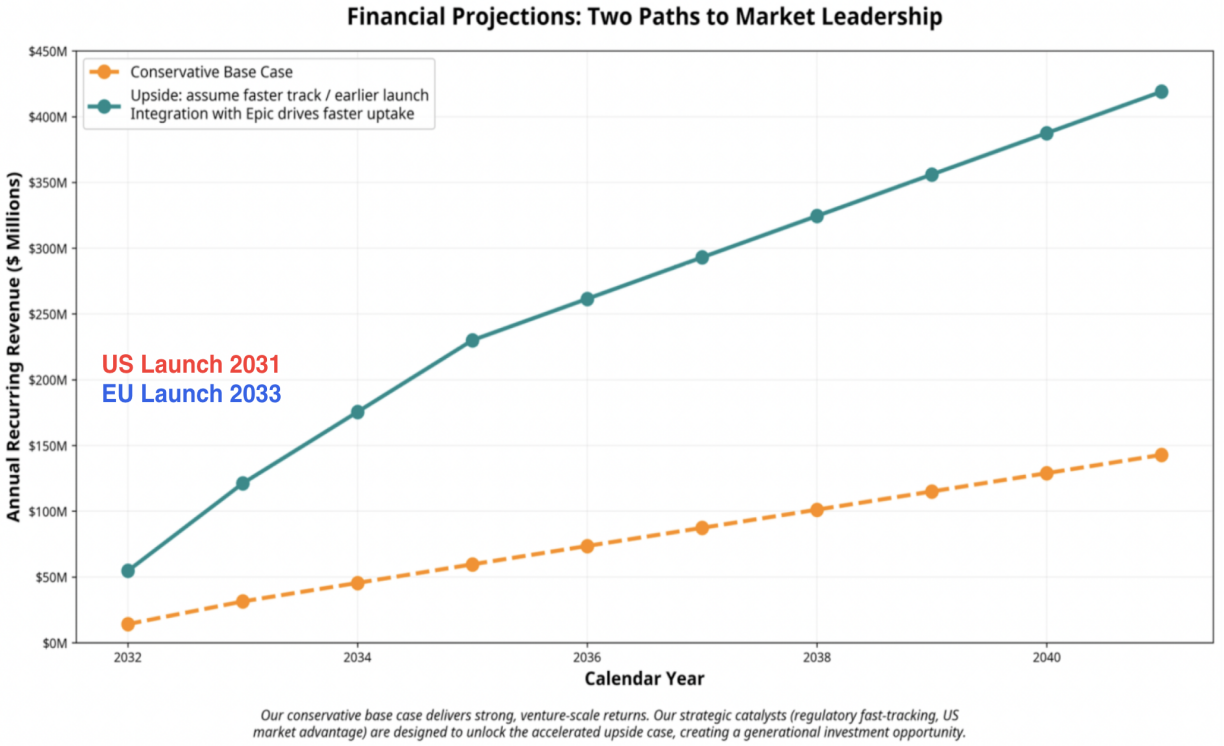


Key Comparison: US vs EU

Metric	US FDA Pathway	EU MDR Pathway	US Advantage
Time to Market	2026-2031 (5 years to launch)	2026-2033 (7 years to launch)	2 years faster
US Launch Year	2031	N/A (EU first)	First-mover advantage
EU Launch Year	2033	2033	Parallel expansion
Regulatory Cost	30-40% lower	Higher (Notified Body fees)	Significant savings
AI/ML Flexibility	Adaptive algorithms supported (PCCP)	More prescriptive	Innovation friendly
Market Access	$4.5T US healthcare market	Fragmented (27 member states)	Largest market first
Regulatory Engagement	Q-Submission (early FDA feedback)	Limited pre-submission options	Risk mitigation

Financial Projections: Two Paths to Market Leadership

Our conservative base case delivers strong, venture-scale returns. Our strategic catalysts (regulatory fast-tracking, US market advantage) are designed to unlock the accelerated upside case, creating a generational investment opportunity.



Key Milestones:

- **US Launch 2031:** Initial market entry in the world's largest healthcare market
- **EU Launch 2033:** International expansion following US validation
- **Conservative Base Case:** $10M (2032) → $145M (2041)
- **Upside Case:** $56M (2032) → $420M (2041) with Epic integration and faster regulatory track

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The US Advantage: Speed, Cost, and Flexibility

The US regulatory environment, guided by the FDA's Center for Devices and Radiological Health (CDRH) and its Digital Health Center of Excellence, is uniquely positioned to support innovation in humanoid healthcare robotics. The key advantages are:

1. Speed to Market: The 510(k) and Q-Submission Pathways

The FDA's 510(k) premarket notification pathway allows for clearance based on "substantial equivalence" to an existing legally marketed device (a "predicate"). For our SaMD platform, we can leverage existing cleared devices in robotic surgery, remote patient monitoring, and clinical decision support.

Furthermore, the Q-Submission (Pre-Submission) program is a game-changer. It allows for early, collaborative engagement with the FDA to gain clarity on regulatory expectations, testing protocols, and submission requirements. This de-risks the entire process and prevents costly delays.

2. Lower Costs and Reduced Burn Rate

The US pathway avoids the significant costs associated with EU Notified Bodies. These private entities, required for EU MDR compliance, add layers of complexity and fees that can run into hundreds of thousands of dollars annually.

By achieving market clearance 2 years earlier (US Launch 2031 vs EU Launch 2033), we significantly reduce our pre-revenue burn rate and accelerate the timeline to profitability.

Simplified 5-Phase US Regulatory Pathway (2026-2031)

Our US-First strategy is broken down into five clear, manageable phases, designed for rapid execution and minimal friction.

Phase 1: Foundation & Planning (2026)

- Device Classification: Confirm Class II SaMD classification
- Predicate Identification: Identify suitable predicate devices for 510(k)
- Q-Submission Preparation: Prepare comprehensive briefing documents for FDA meeting
- Regulatory Strategy Document: Finalize overall regulatory strategy

Phase 2: Pilot Development & Initial Documentation (2026-2027)

- Defining Tracking and 'Humanoid' (Regulatory)
- Q-Submission Meeting: Collaborative meeting with FDA reviewers
- Feedback Incorporation: Update development plans based on FDA feedback
- Finalize Test Plan: Lock in clinical and non-clinical testing requirements

Phase 3: Pilot Deployment & RWE Collection (2027-2028)

- Liaison with Patients, PAGs (VoP) & KOLs for Advocacy
- Clinical Validation: Conduct clinical studies to demonstrate safety and effectiveness
- Usability & Human Factors: Perform usability testing
- Cybersecurity Documentation: Develop comprehensive cybersecurity documentation

Phase 4: Regulatory Submission & Review (2028-2030)

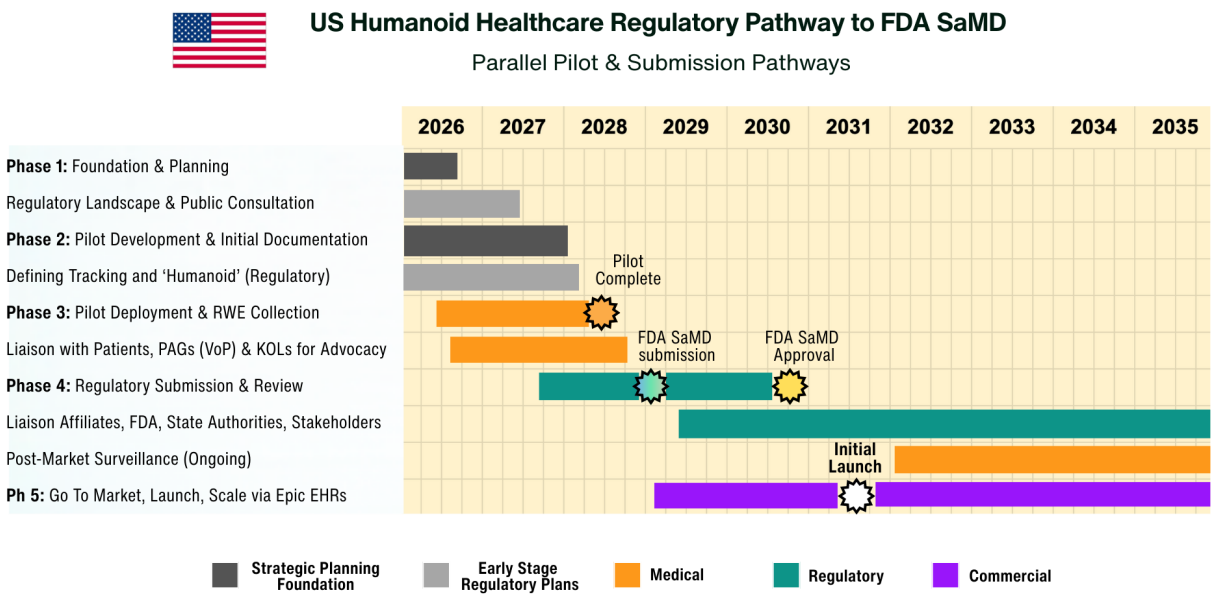
- Liaison with Affiliates, FDA, State Authorities, Stakeholders
- 510(k) Submission: Submit complete dossier to FDA
- Interactive Review: Respond to FDA requests for additional information
- FDA Decision: Receive clearance decision (target: 2030)
- Post-Market Surveillance (Ongoing)

Phase 5: Go To Market, Launch, Scale via Epic EHRs (2031-2035)

- **Initial Launch 2031:** US market entry
- US Market Launch: Begin commercialization in the US
- Post-Market Surveillance: Implement required post-market surveillance activities
- PCCP Implementation: Begin implementing planned algorithm updates
- International Expansion: Leverage US FDA clearance for EU launch (2033) and other markets

Detailed US FDA Regulatory Roadmap (2026-2035)

The Gantt chart below provides a detailed visual representation of the US FDA regulatory pathway, showing the parallel and sequential activities across the five phases.



Key Milestones:

- **2026:** Foundation & Planning Complete
- **2028:** Pilot Complete, FDA SaMD Submission
- **2030:** FDA SaMD Approval
- **2031:** Initial US Launch
- **2033:** EU Launch (following US validation)
- **2035:** Full commercial scale via Epic EHR integration

Why This Matters for Our Partners

For Investors

Faster ROI: Achieving US market clearance in 2031 (vs EU 2033) means earlier revenue generation and a quicker path to profitability. A 2-year acceleration represents an additional $20 million in cumulative revenue during the investment horizon.

Lower Risk: The Q-Submission program and early FDA engagement significantly de-risk the regulatory pathway.

Higher Valuation: First-mover advantage in the US market, combined with FDA clearance as a validation point, positions the company for a higher valuation at subsequent funding rounds or exit events.

For Robotic Hardware Manufacturers

Platform for Innovation: Our FDA-cleared SaMD platform provides a regulatory pathway for your hardware to be integrated into a medical device system.

Access to US Market: Partnering with us provides a clear path to deploying your robotic hardware in the US healthcare market, the largest and most lucrative market globally.

...represents an additional $50+ million...

Conclusion: The Clear Choice for Market Leadership

The choice is clear. A US-First regulatory strategy provides the fastest, most cost-effective, and flexible path to market for our humanoid healthcare robotics platform. By embracing the FDA's collaborative and innovation-friendly approach, we can achieve commercial success years ahead of an EU-first strategy, delivering value to patients, providers, and investors at an accelerated pace.

The combination of:
- **2 years faster time-to-market** (US 2031 vs EU 2033)
- **30-40% lower regulatory costs**
- **Access to the $4.5 trillion US healthcare market**
- **Flexibility for AI/ML innovation through PCCPs**
- **Collaborative FDA engagement through Q-Submissions**

...makes the US-First strategy not just a viable option, but the **optimal strategic choice** for achieving market leadership in humanoid healthcare robotics.

We invite you to join us on this exciting journey to revolutionize healthcare, starting with the world's most important market.

About PatientCentricCare.AI

PatientCentricCare.AI is developing the next generation of humanoid healthcare robotics, combining advanced AI/ML algorithms with state-of-the-art robotic platforms to deliver safer, more effective, and more accessible healthcare. Our US-First regulatory strategy positions us to be the first-to-market with FDA-cleared humanoid healthcare robotics, capturing a significant share of the $4.5 trillion US healthcare market.

For more information or to discuss partnership opportunities, please contact:

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