

# THE STATE OF MEDTECH STARTUPS

## Exclusive Survey Results

November 2025



# Introduction

The 2025 State of MedTech Startups survey captures the pulse of early- and growth-stage innovators across the medical device ecosystem. Respondents span a wide range of device categories—from implantables and wearables to software-based and diagnostic platforms—offering a multifaceted view of the technical, financial, and regulatory realities shaping today's MedTech landscape.

Despite differences in stage and specialty, a unifying theme emerged: Funding pressures remain acute, timelines are tightening, and the race to demonstrate clinical and commercial viability continues to test even the most disciplined teams.

# Key takeaways

## 1 Capital remains the defining constraint.

Three out of four early-stage companies cite fundraising as their biggest hurdle, with almost forty percent of later-stage firms still struggling to secure growth capital. For many, the fear of running out of money before reaching key clinical milestones overshadows all other risks.

## 2 Political uncertainty compounds risk.

Shifting regulatory priorities and delayed reviews are creating uncertainty in planning and investor confidence. Many founders cited the current administration's FDA leadership changes and recent research funding clawbacks as sources of concern.

## 3 Clinical proof is a top challenge.

For many startups, the greatest execution risk lies in bridging the gap between a promising prototype and a proven product. Sixty percent of respondents identified demonstrating that their technology works as intended as their top technical challenge.

# Key takeaways (cont.)

## 4 AI and biosignals reshape intelligence.

More than two-thirds of respondents either already use or plan to use AI/ML in their products. Nearly half of all startups now collect biosignals, with cardiac and neurological data leading the way and a growing trend toward multimodal sensing to enrich clinical insights.

## 5 Teams & partnerships are key to success.

Many founders pointed to challenges in hiring and retaining skilled talent, managing payroll, and maintaining cohesive teams under financial pressure. Equally important is finding partners who share their standards for clarity, usability, and defensibility—trusted collaborators who can complement internal expertise and accelerate progress without compromising quality.

# What keeps MedTech innovators up at night?

1

Funding & Runway

*"Hitting milestones before funding runs out."*

*"Not securing funding and losing the opportunity window."*

*"How do we navigate through the current government funding cut-off?"*

*"Running out of money before our FIH trial!"*

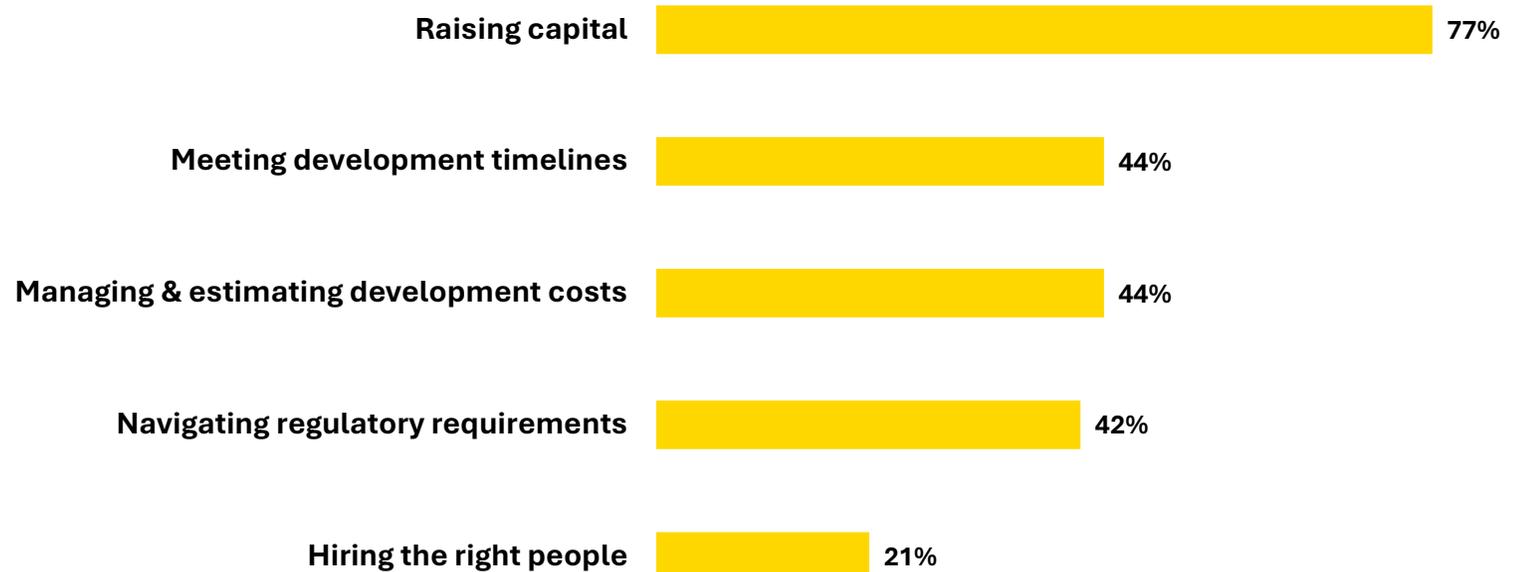
# Top business challenges

Raising capital is the predominant business challenge for medical device startups.

Among early-stage startups (pre-seed to Series A), raising capital was a top challenge for 89% of the respondents.

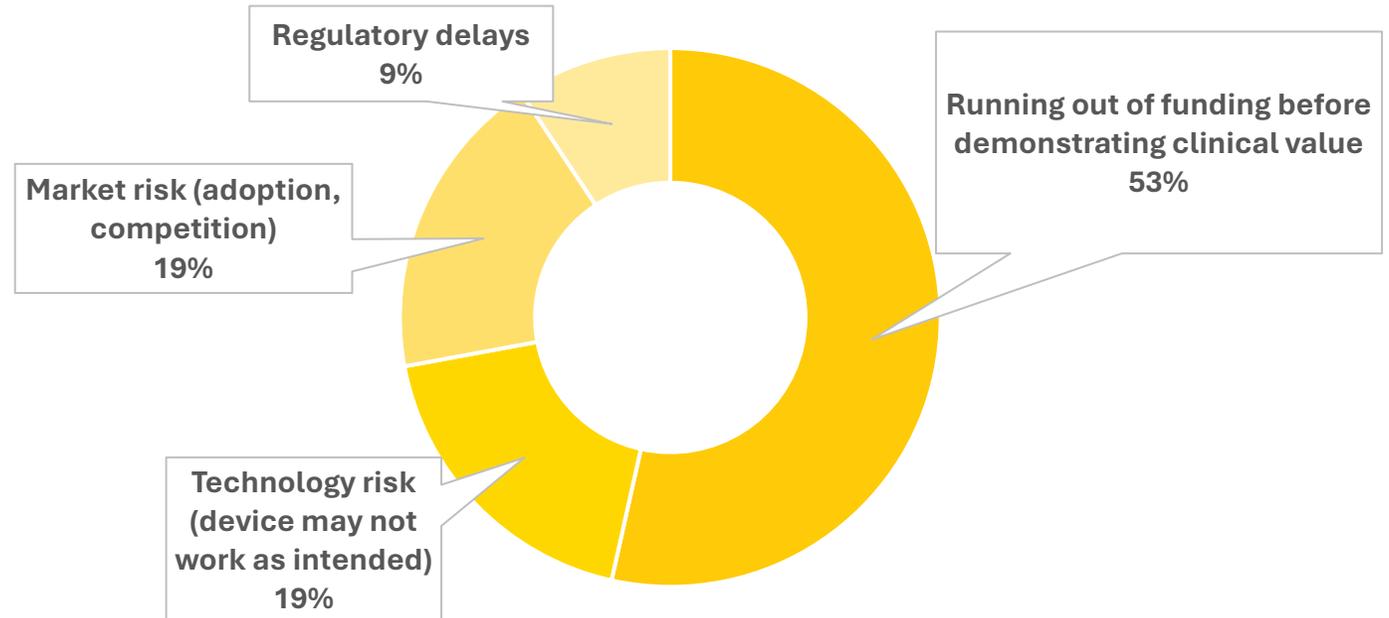
Among later stage companies, it was still a major challenge for 50% of the respondents.

Managing development timelines and costs were consistently mentioned as a challenge for close to half of the companies across all stages.



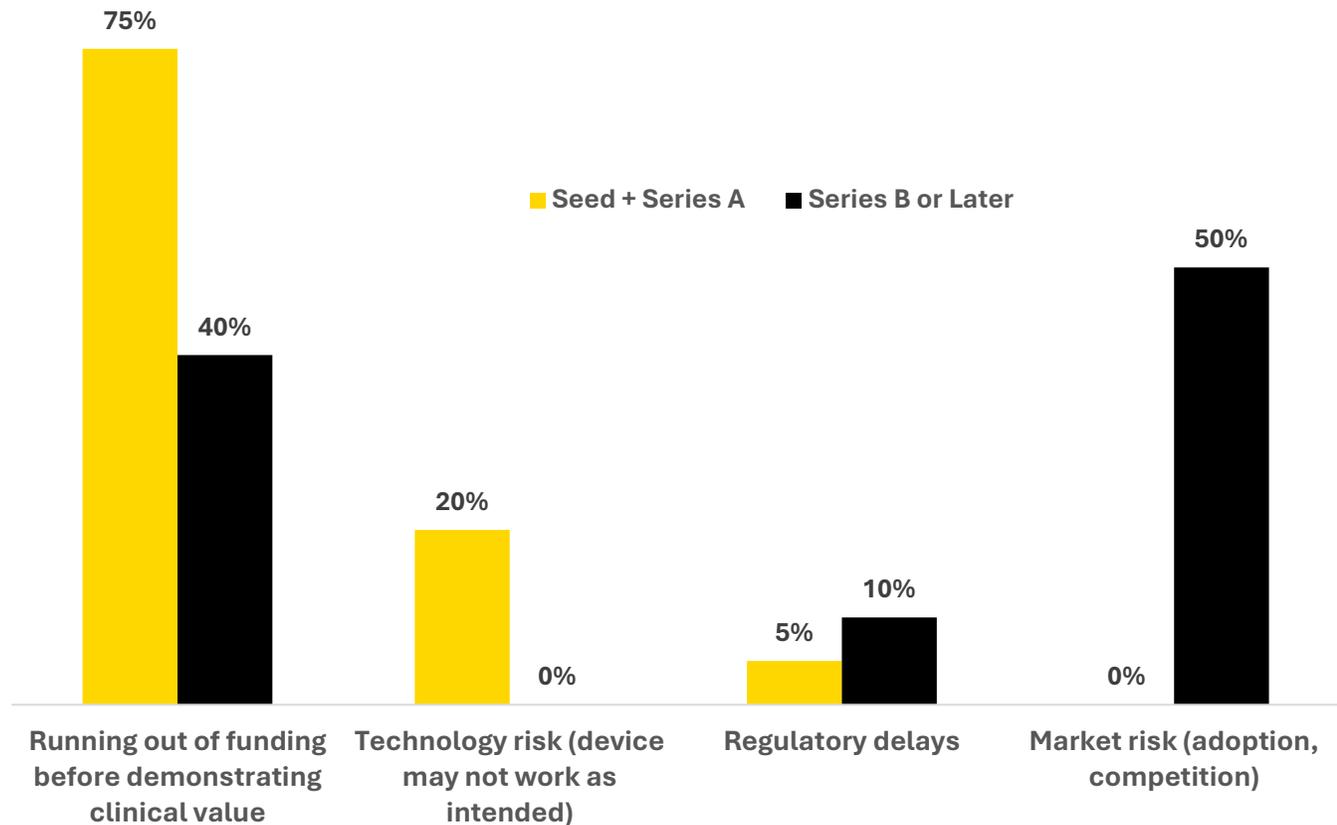
# Greatest risks to MedTech startups

Running out of money before they are able to meet critical clinical milestones is the most dominant risk perceived by MedTech innovators.



# How risks shift as startups mature

As companies mature, funding and technology risks go down, while regulatory and market risks become more prominent.



# What keeps MedTech innovators up at night?

2

Time Pressure and Execution Risk

*"Keeping launch timeline."*

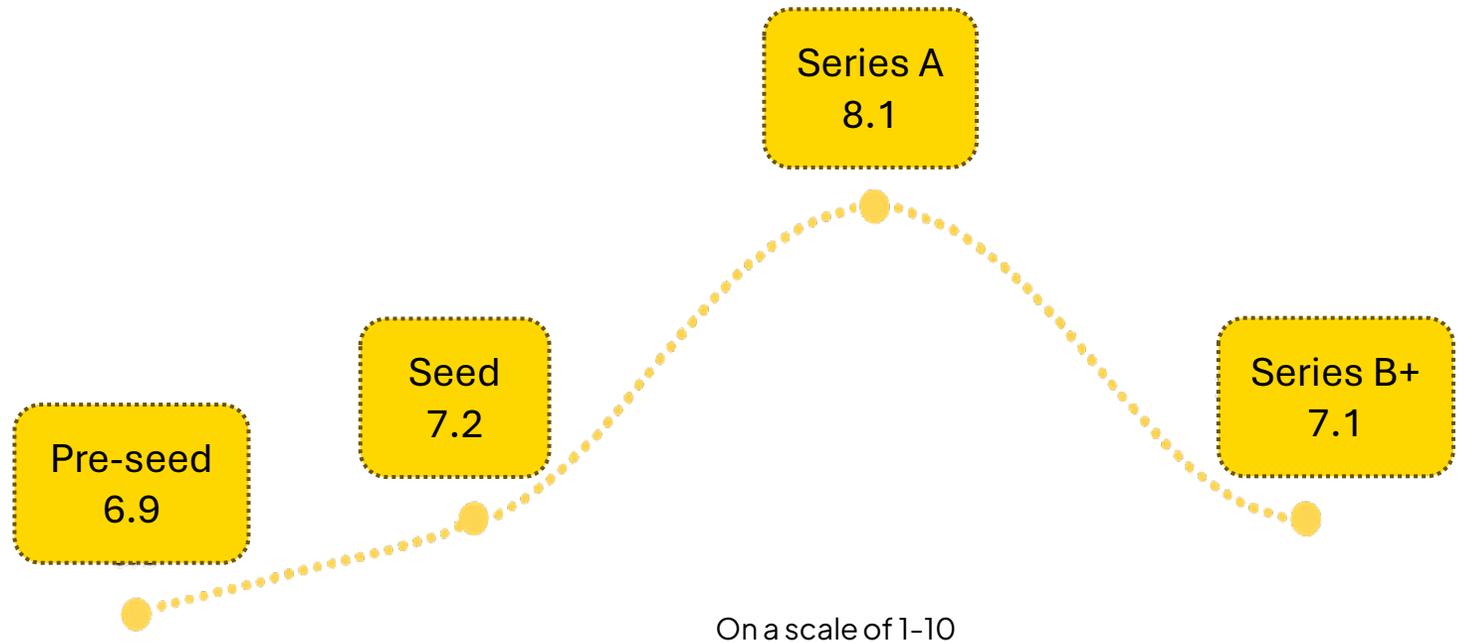
*"Roadblocks preventing a major product milestone."*

*"Balancing speed with rigor."*

*"Delivering value for all stakeholders at a level that drives adoption vs. competitive options."*

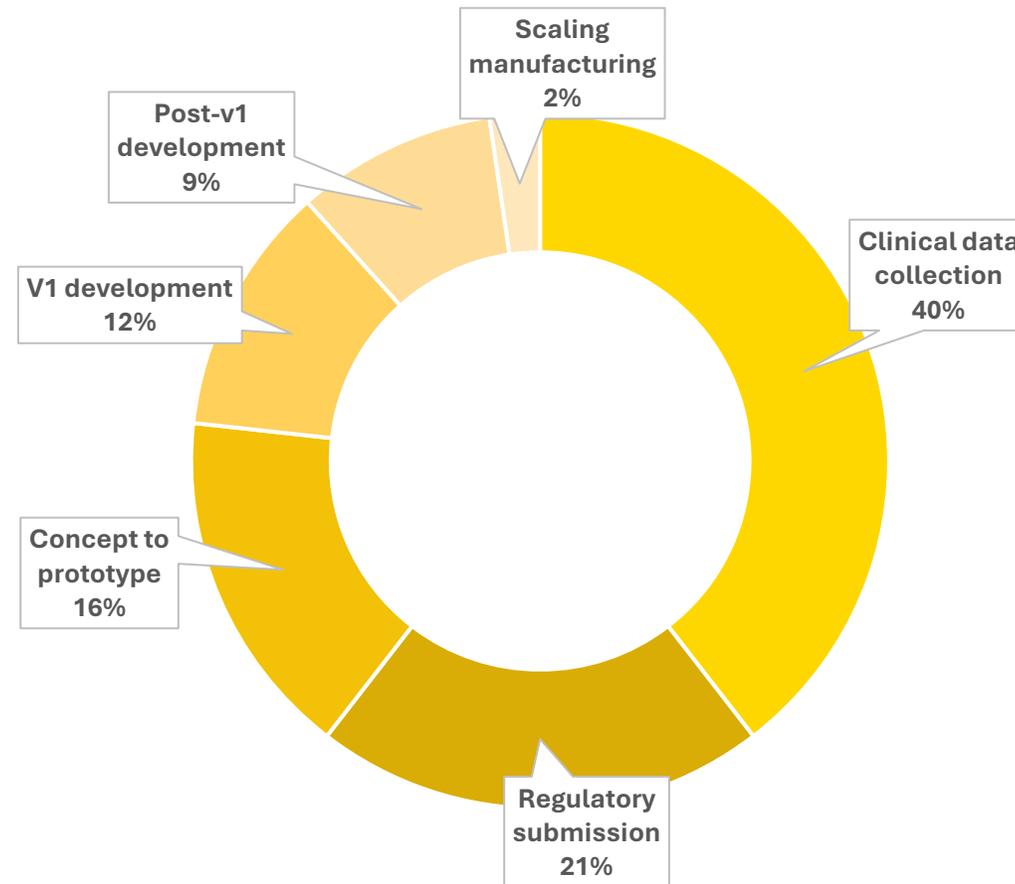
# Confidence in meeting goals for development timeline and budget

Confidence in meeting development timeline and budget goals grows as companies move from pre-seed to Series A, only to hit a reality check when they move to Series B and beyond.



# What part of the development process would you like to accelerate?

Collecting clinical data is the most critical stage of the development process that MedTech innovators would like to accelerate, followed by regulatory submission and prototype development.



# What keeps MedTech innovators up at night?

3

Technical and Data Challenges

*"Developing efficient algorithms."*

*"Function design and specification document update."*

*"uncertainties around the clinical data."*

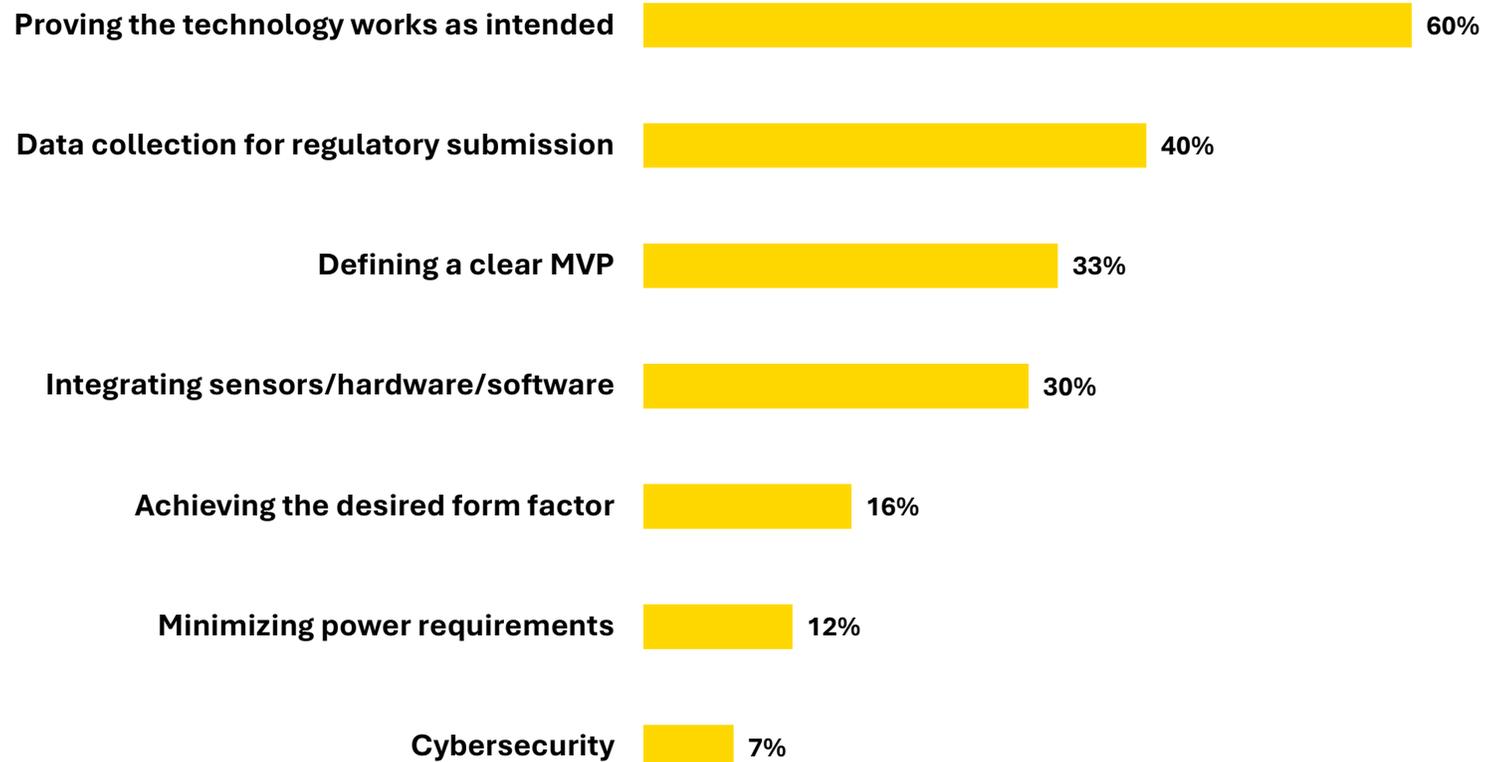
*"Poor design controls."*

# Top technical challenges

Proving the technology works as intended is the leading technical challenge facing medical device startups.

Proving the technology is especially challenging for surgical device companies, mentioned by 100% of these respondents.

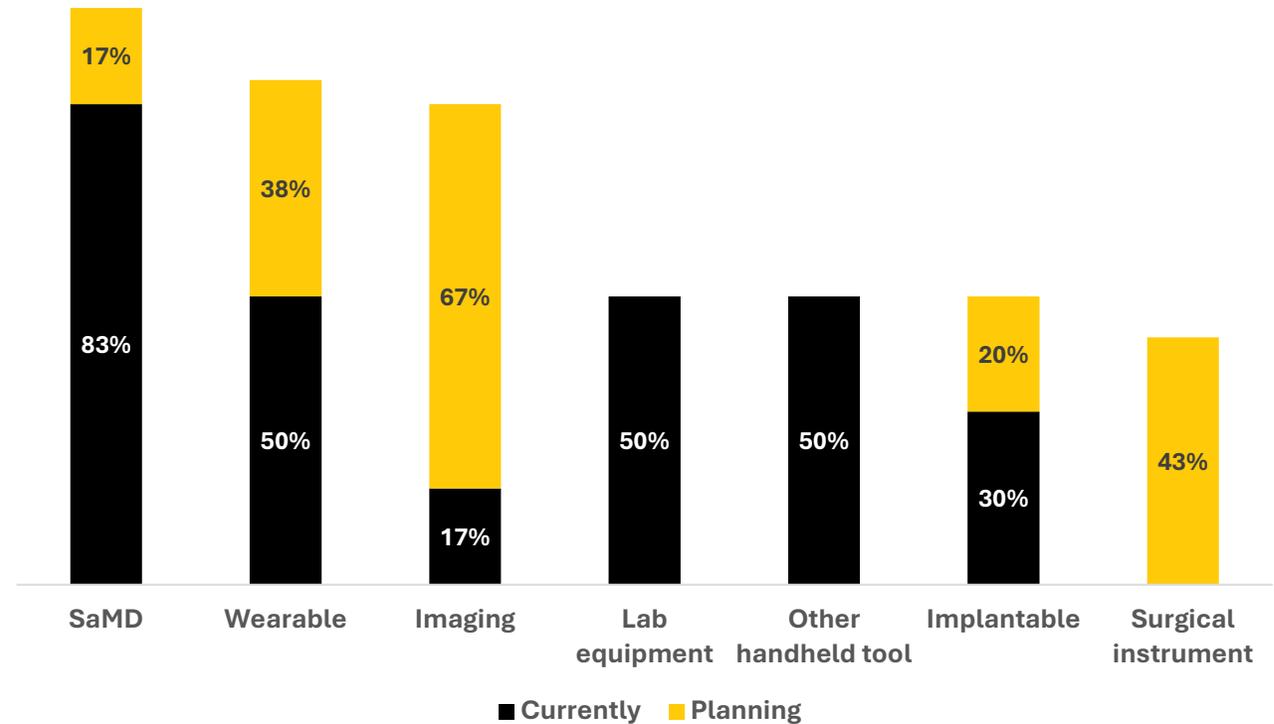
For therapeutic devices, defining a clear MVP is a similarly tough challenge (mentioned by 56% of the respondents).



# AI adoption

Across all device types, 37% of the respondents currently incorporate AI/ML algorithms in their devices, and 32% plan on adding such functionality.

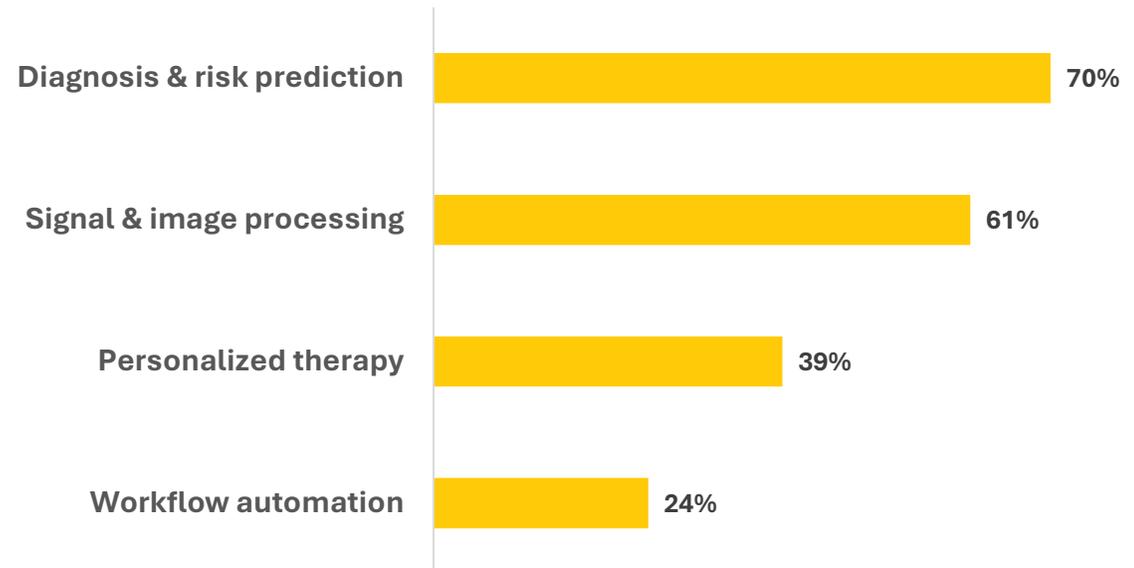
While Software-as-Medical Device and wearables are the leading early adopters of AI, significant levels of adoptions are reported across all device types.



# AI applications

AI is primarily used for diagnostic, risk prediction, and prioritization.

A close second application of AI is signal and image processing, followed by therapy personalization and workflow automation.

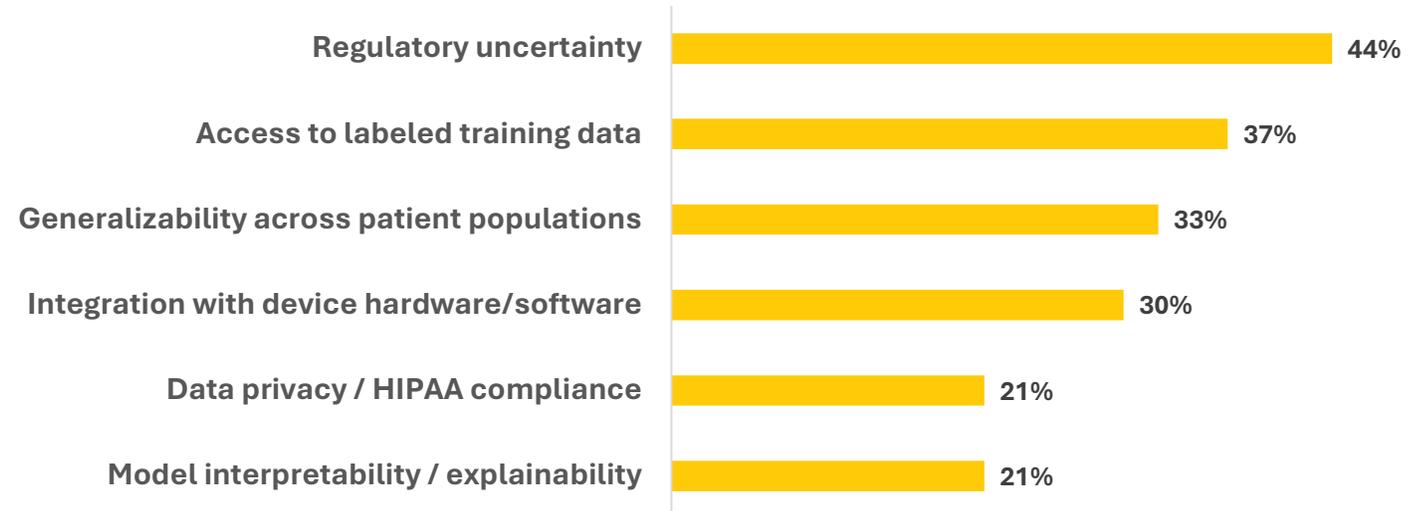


# AI challenges

Uncertainty around the regulations of AI is the top challenge for MedTech startups adopting AI.

Collecting labeled training data is a second major obstacle, as well as the ability to generalize models across patient population and integration with device hardware and software.

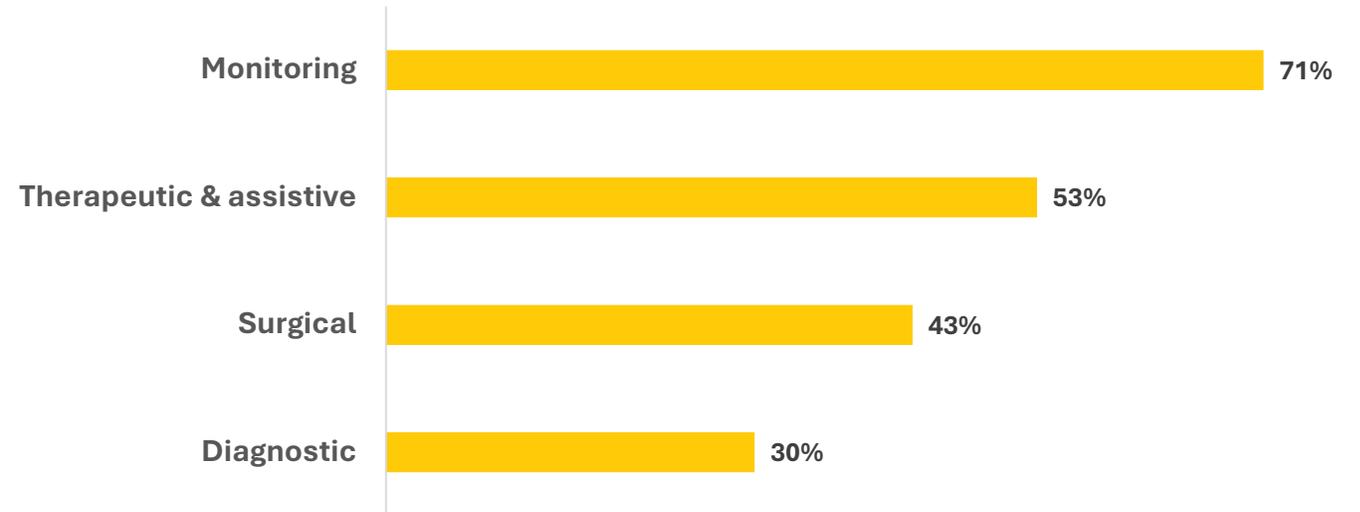
Privacy and model explainability concerns are less of a challenge for most startups at this time.



# Biosignal applications

Biosignals are collected and processed by almost half of all the companies surveyed (47%).

Monitoring devices are the primary users of biosignals, followed by therapeutic and assistive devices.



# Biosignal collected

Cardiac signals are the most common types of signals collected, followed closely by neurological signals.

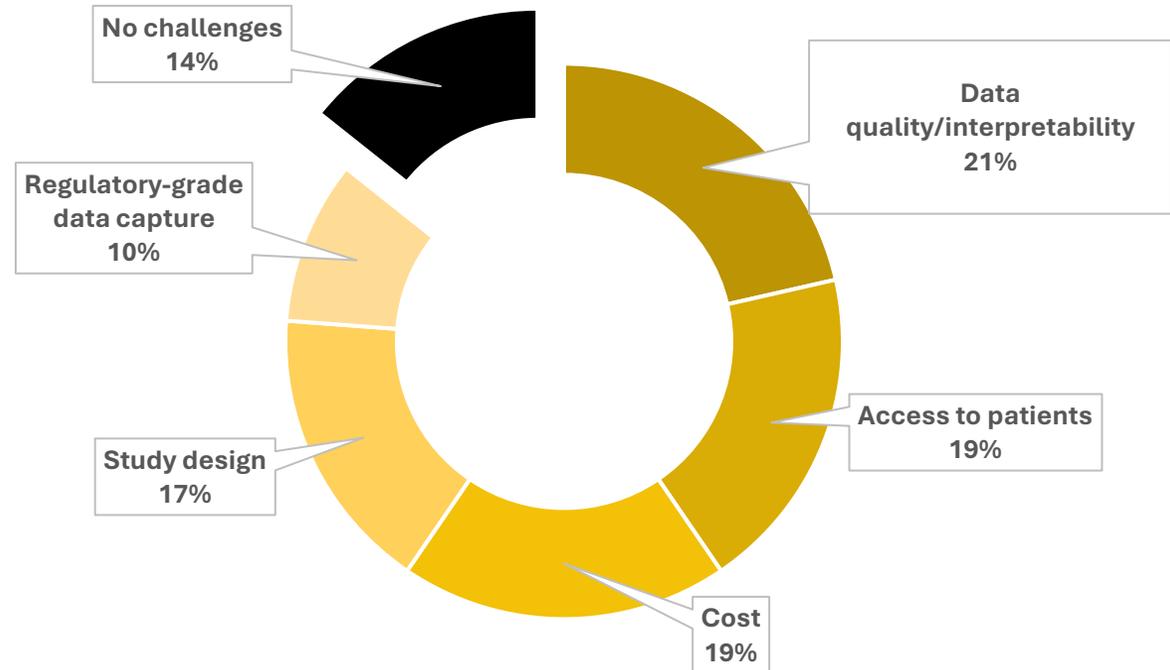
The use of multimodal sensing is an emerging trend, with several startups combining electrical, optical, and mechanical signals for richer data (e.g., ECG + SpO<sub>2</sub> + motion).

Signal Type	Frequency	Signals Collected
Cardiac		ECG, Heart Rate, HRV, Central Venous Pressure (CVP)
Neurological		EEG, EMG, ECoG, epileptic seizure detection
Oxygenation		SpO <sub>2</sub> , SO <sub>2</sub>
Movement / Motion		Movement / Motion sensing
Pressure / Gas / Fluid		ICP, pressure, gas
Other		Electromagnetic field strength, saliva, audio, image

# Data challenges

A great majority of the startups surveyed face challenges related to clinical data collection.

Data quality and interpretability are the top challenges, followed closely by cost, access to patients, and study design.



# What keeps MedTech innovators up at night?

4

Talent and Team

*"Employees' salary."*

*"Finding partners who share our standards for clarity, usability, and defensibility."*

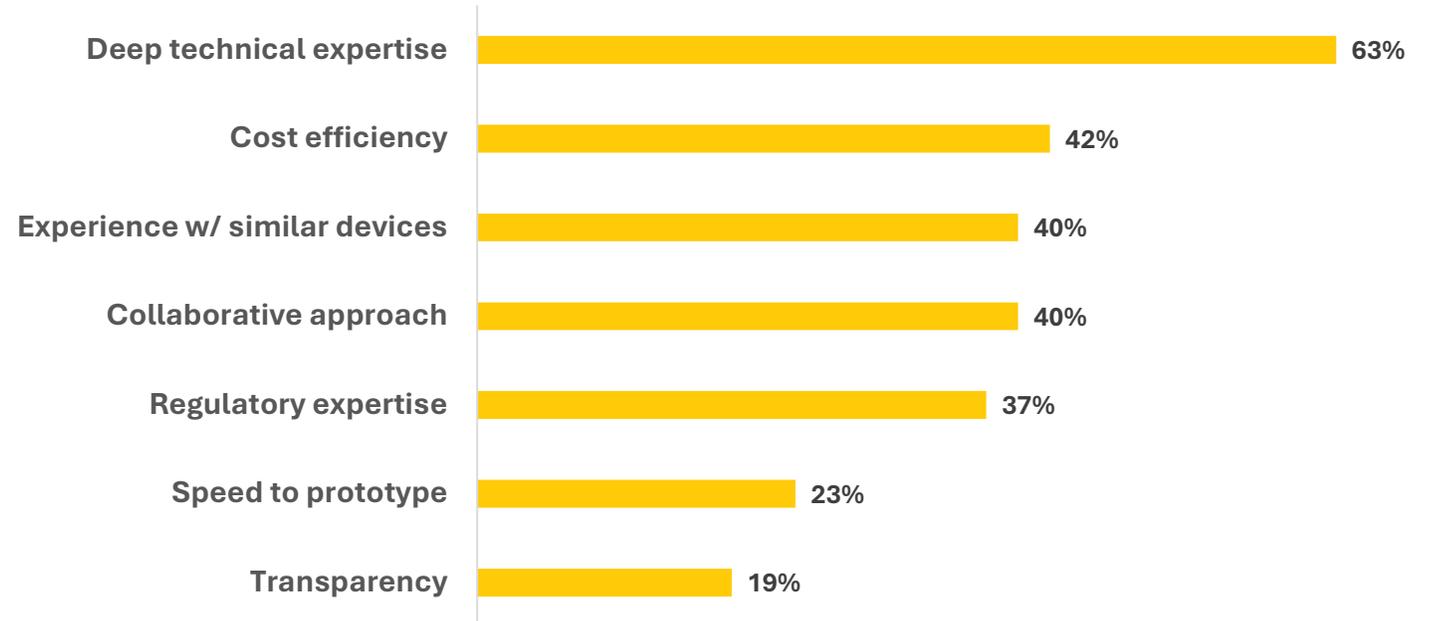
*"Recruiting and managing employees."*

*"Inexperienced staff."*

# What startups look for in a development partner

Deep technical expertise is decidedly the top consideration for startups when engaging a development partner.

While cost efficiency is important, relevant experience, regulatory expertise, and a collaborative approach are equally top of mind for startups in their evaluation of development partners.



# What keeps MedTech innovators up at night?

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Regulatory and Compliance

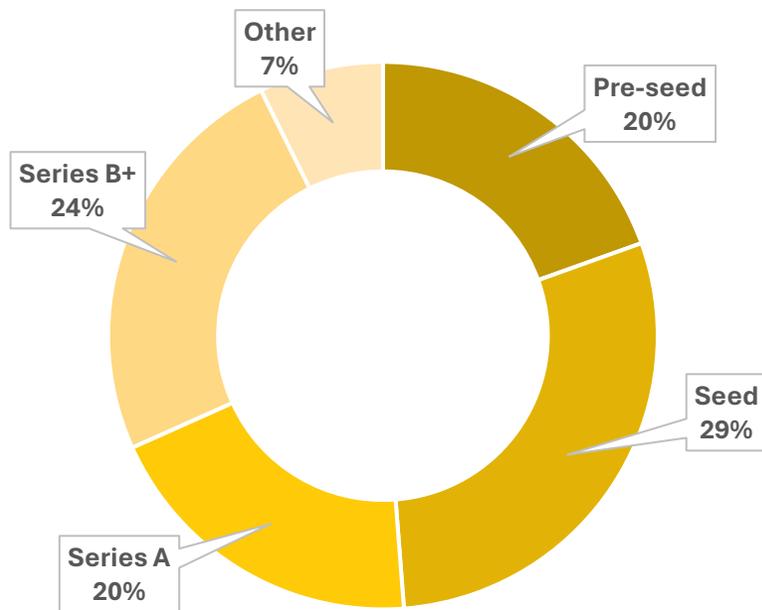
*"Risk management and FDA approval."*

*"Changing MedTech regulatory landscape."*

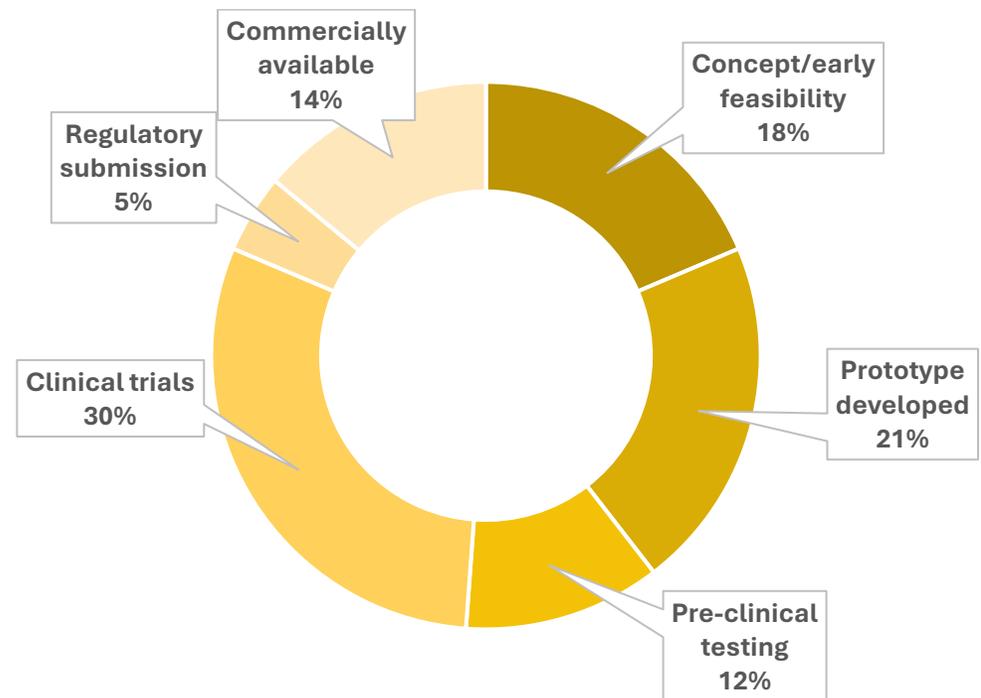
*"FDA changes in staffing"*

# Respondents' demographics - Funding and development stage

Funding Stage

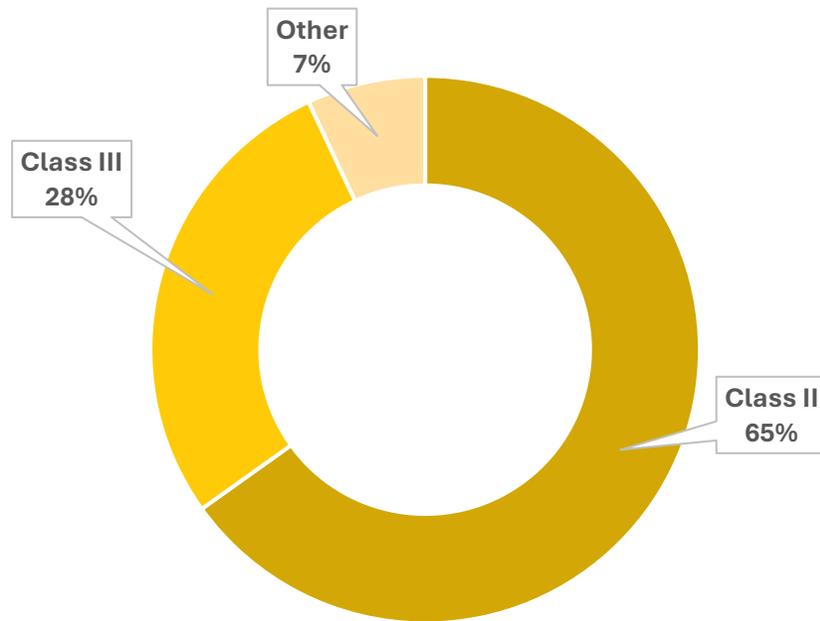


Development Stage

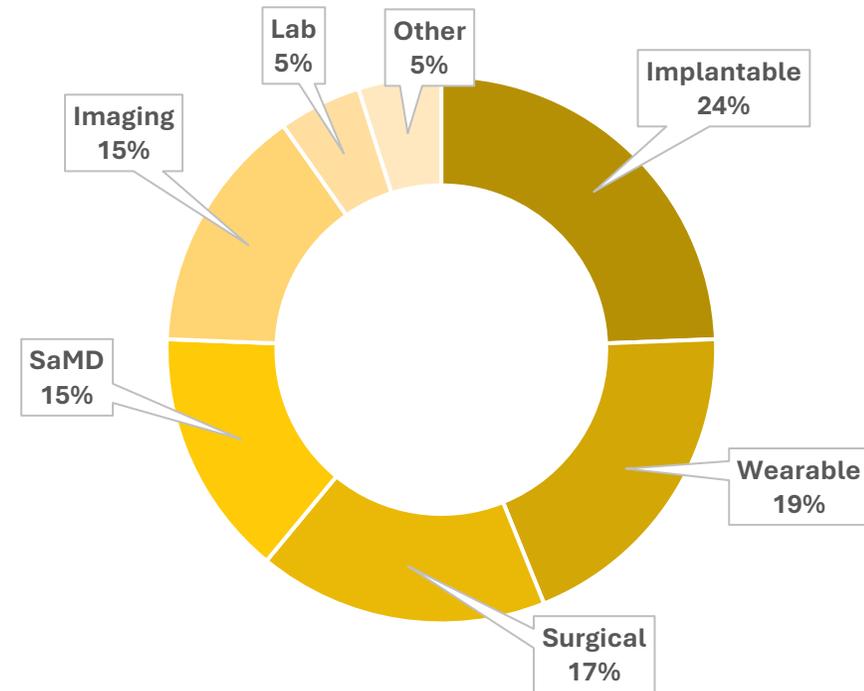


# Respondents' demographics - Device class and category

Device Class

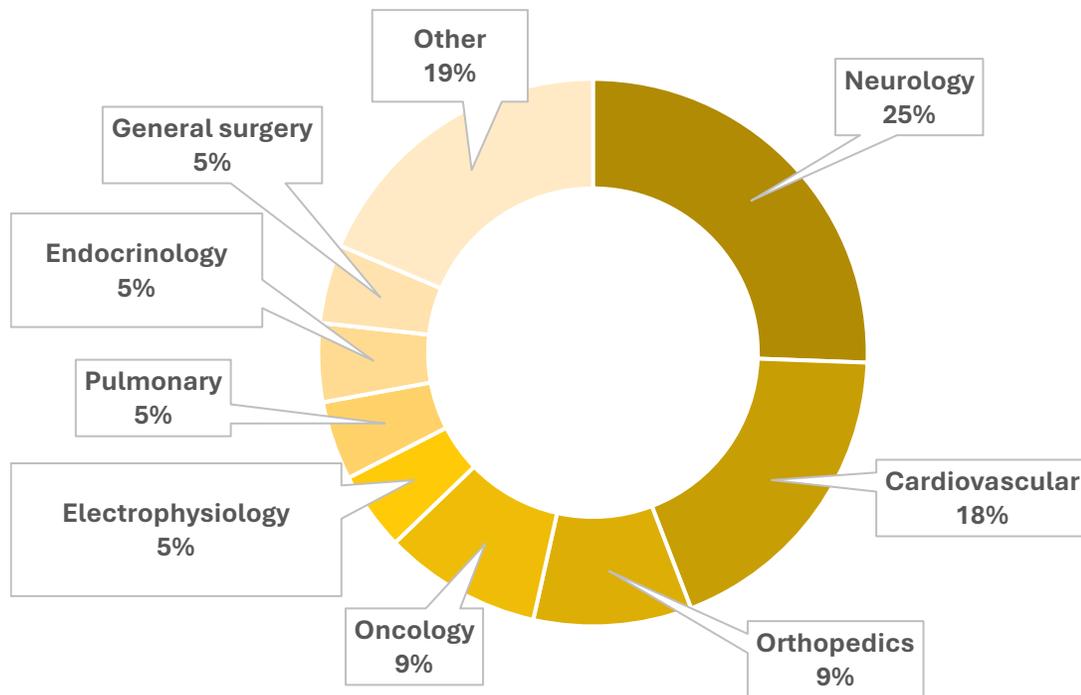


Primary Device Category

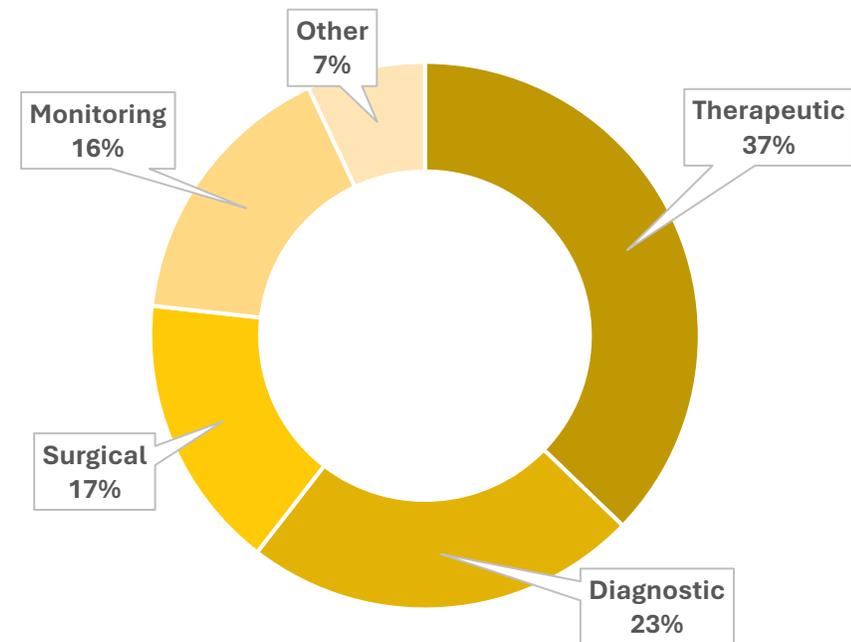


# Respondents' demographics - Device target and function

Primary Clinical Target



Primary Device Function



# Methodology and disclaimer

This report is based on an online survey conducted in October 2025 among founders, executives, and technical leaders from early- and growth-stage medical device startups.

The survey combined quantitative and qualitative questions to capture both metrics and sentiment. Based on 44 responses, not all findings may be statistically significant. At the same time, they provide meaningful directional insights into current industry dynamics shaping the MedTech startup landscape.

# This survey is provided courtesy of



**nocturnal**

Nocturnal specializes in the design and development of Class II and Class III implantable and wearable medical devices, with a track record of accelerating time to market for early-stage companies.

Nocturnal offers a milestone-based engagement model aligns the company's success with client outcomes, ensuring transparency and accountability that help startups reach funding milestones with speed and confidence.



**QuickVault**  
by **Veeva**

QuickVault unifies design, submission, and production to accelerate your MedTech journey from concept to market. The platform simplifies regulatory compliance, streamlines quality management, and eliminates inefficiencies, so medical device innovators can focus on creating transformative healthcare solutions.

Using the QuickVault platform, medical device companies get a jumpstart on an ISO 13485 quality management system that they can grow with and make their own with a click of a button.

# Additional resources for MedTech startups

## NAVIGATING MEDICAL DEVICE FUNDING CYCLES

How to meet critical product milestones,  
increase investor confidence, and accelerate  
device path to commercialization.



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## MEDICAL DEVICE DESIGN CONSIDERATIONS FOR THE CASH STRAPPED STARTUP

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Optimizing device design  
for AI-driven outcomes



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