

# US FDA Update

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# Patients are at the Heart of What We Do

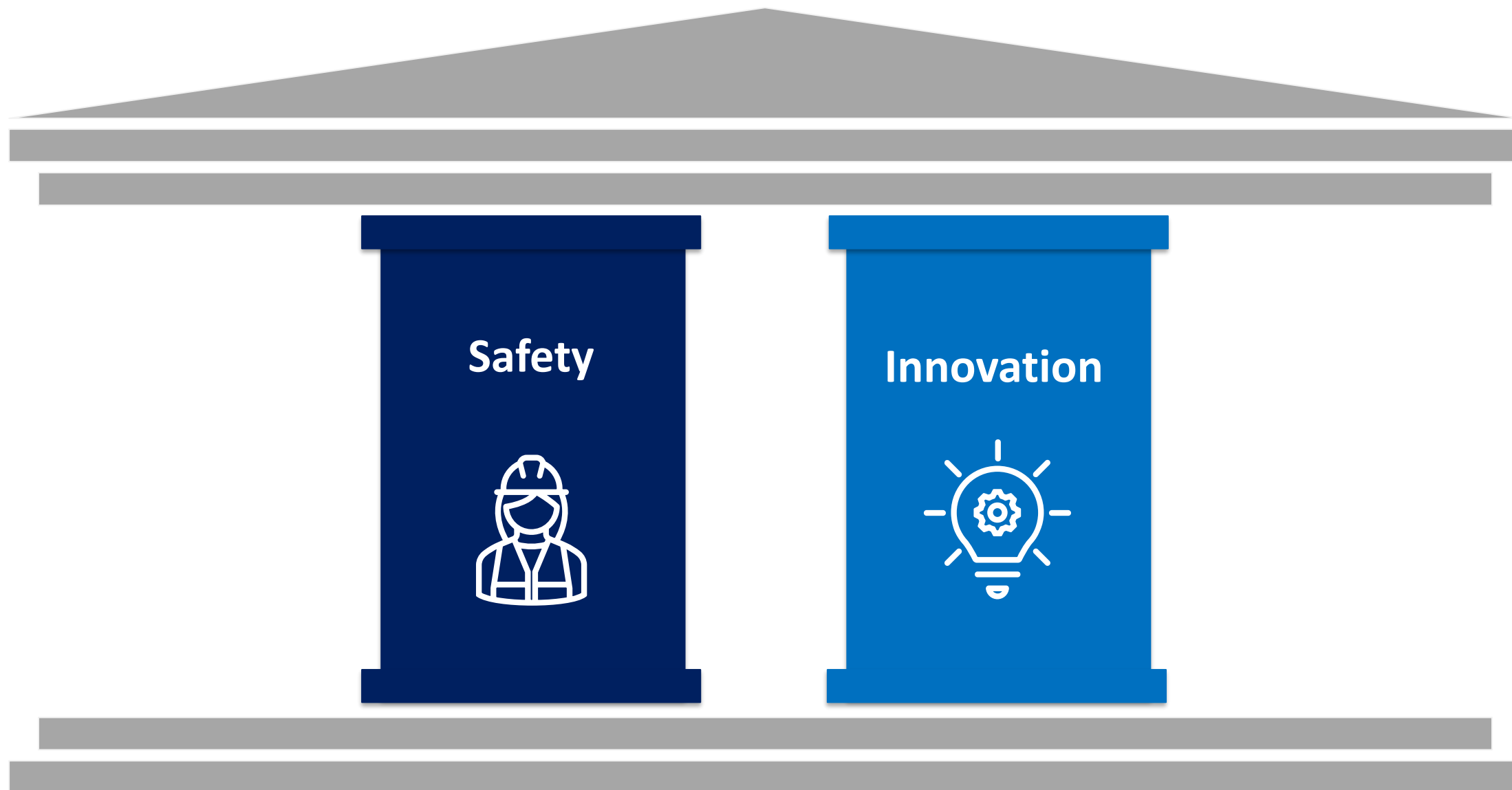


## Center for Devices and Radiological Health (CDRH) Vision

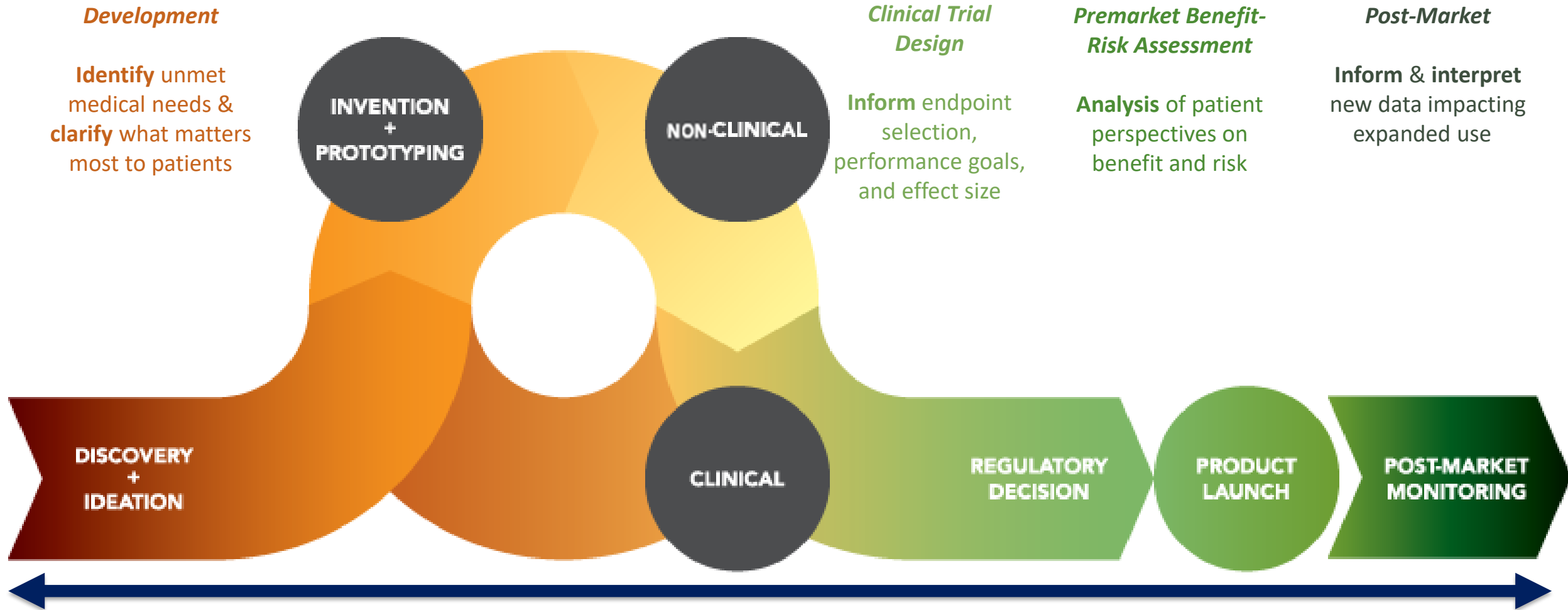
Patients in the U.S. have access to **high-quality, safe, and effective** medical devices of public health importance



# CDRH Core Pillars



# Patient-Centered Development & Evaluation



# Real-World Evidence Program

Use of Real-World Data & Evidence in place of conventional clinical trial data  
to reduce time to answer device questions



## Regulatory Decision-Making

180+ devices authorized using RWE



## Collaboration

Engaged with 100 national or regional  
registries from 45 countries



## Transparency

Updated webpage with reporting adverse events & more  
for medical devices from RWD sources

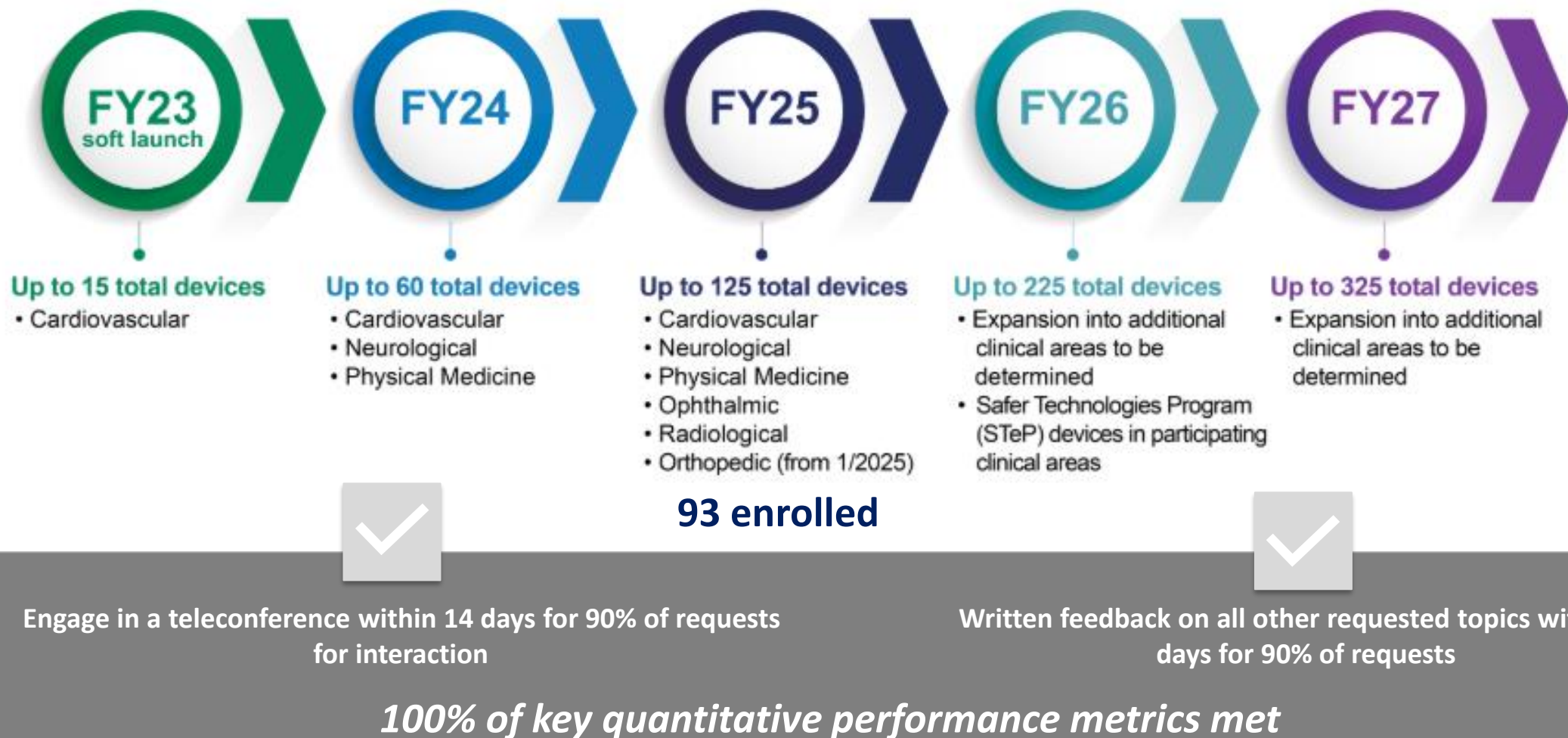


## Knowledge Management

2023 draft guidance including new appendices of  
examples and recommended elements



# Total Product Life Cycle Advisory Program (TAP) Pilot Update



# Digital Health Innovation

*New!*

Regulatory Accelerator – Curated resources to support development of medical device software

## Resource Index



Visual guide to FDA tools and resources available throughout the process of bringing a device to market

## Early Orientation



Best practices for engaging early with the FDA on marketing submissions on medical device software

## Guidance Navigator



Resource for identifying guidances that may be applicable to a device across the development life cycle



# AI in Medical Devices



# Authorized AI/ML-Enabled Medical Devices\*

*Over 1,200 AI-enabled devices have been authorized by FDA*

Search:

Show 

50

 entries

Date of Final Decision	Submission Number	Device	Company	Panel (lead)	Primary Product Code
05/30/2025	<a href="#">K251406</a>	BriefCase-Triage	Aidoc Medical, Ltd.	Radiology	QAS
05/30/2025	<a href="#">K250236</a>	Swoop® Portable MR Imaging® System (V2)	Hyperfine, Inc.	Radiology	LNH
05/30/2025	<a href="#">K243863</a>	Opulus™ Lymphoma Precision	Roche Molecular System	Radiology	QIH
05/30/2025	<a href="#">K243005</a>	AudaxCeph Cephalogram Analysis Software	Audax d.o.o.	Radiology	QIH
05/30/2025	<a href="#">K242830</a>	LensHooke X3 PRO Semen Quality Analyzer; LensHooke X3 PRO SE Semen Quality Analyzer	Bonraybio Co., LTD.	Hematology	POV
05/30/2025	<a href="#">DEN240047</a>	Allix5	Clairity, Inc.	Radiology	SEZ
05/29/2025	<a href="#">K250543</a>	Voluson™ Performance 16; Voluson™ Performance 18	GE Medical Systems Ultr	Radiology	IYN
05/28/2025	<a href="#">K243378</a>	Rapid MLS	iSchemaview Inc.	Radiology	QIH



# AI Use in CDRH's Work



## Meet Elsa: Your AI Assistant

An AI assistant designed by FDA employees for FDA employees



### Save Time

Compare documents in context  
Find and extract information  
Cross-reference regulations



### Tailor Communications

Summarize large communication threads  
Accelerate drafting of communications

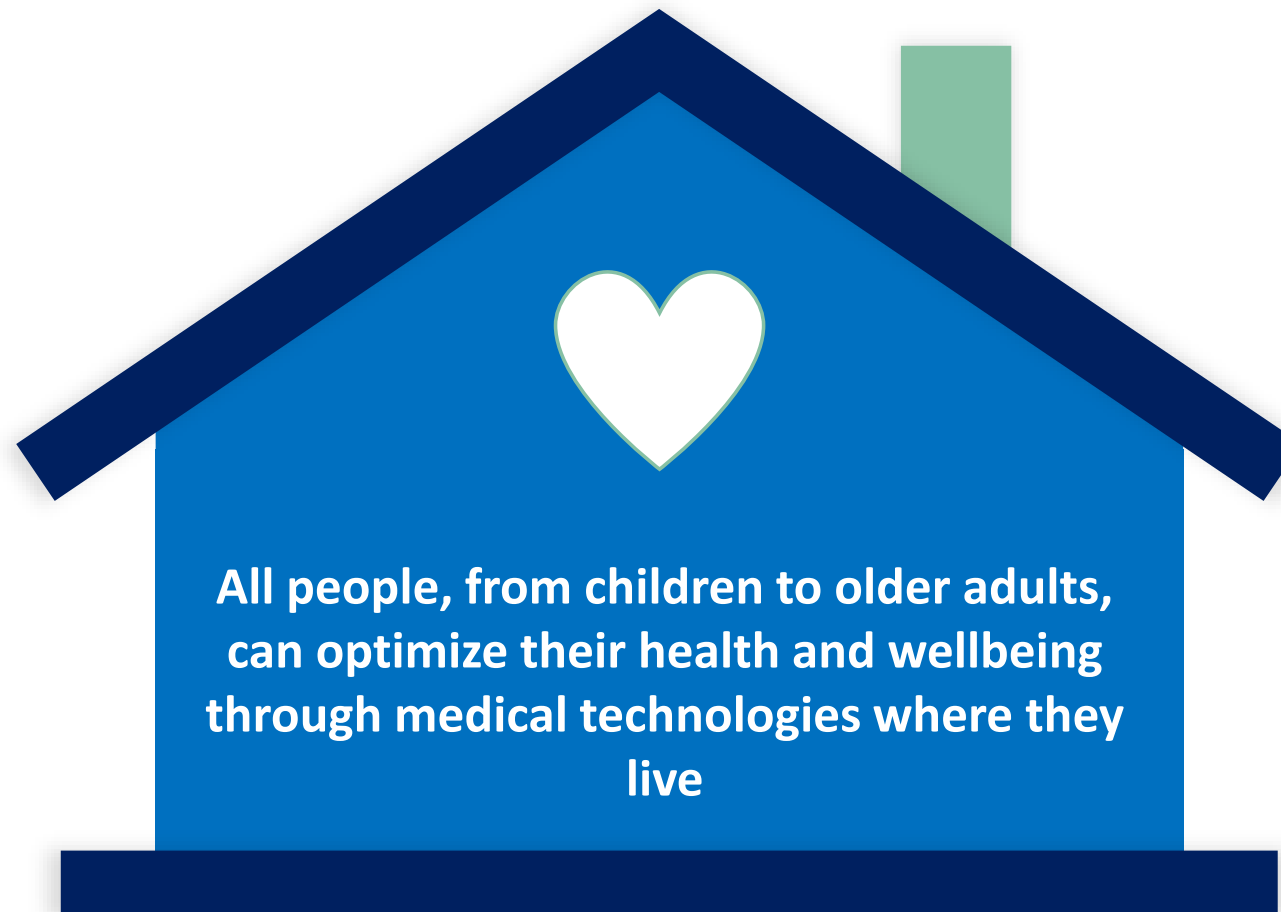


### Accelerate Discovery & Understanding

Analyze large files for content  
Provide context and insights on new topics

# Home as a Health Care Hub Initiative

**Reimagine the home environment as an integral part of the health care system, with the goal of advancing access to better health outcomes for all people in the U.S.**



# The Idea Lab

Imagine *Home as a Health Care Hub* through  
**The Idea Lab**



Fictional  
Personas



Virtual Reality  
Prototype



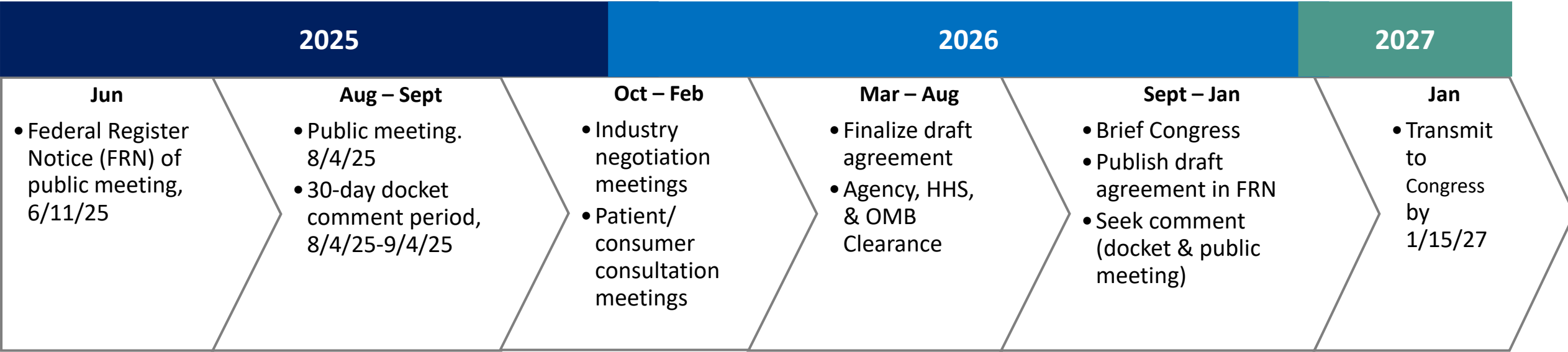
Considerations  
for Innovators



Research and  
Insights

*Fueling innovation in home use of medical  
devices through person-centered design*

# MDUFA VI Reauthorization Timeline





# CDRH Vision

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**Patients in the U.S. have high-quality, safe, and effective medical devices of public health importance**



**U.S. FOOD & DRUG**  
ADMINISTRATION