# Initiatives to Accelerate Medical Device Access: US Regulatory Perspective

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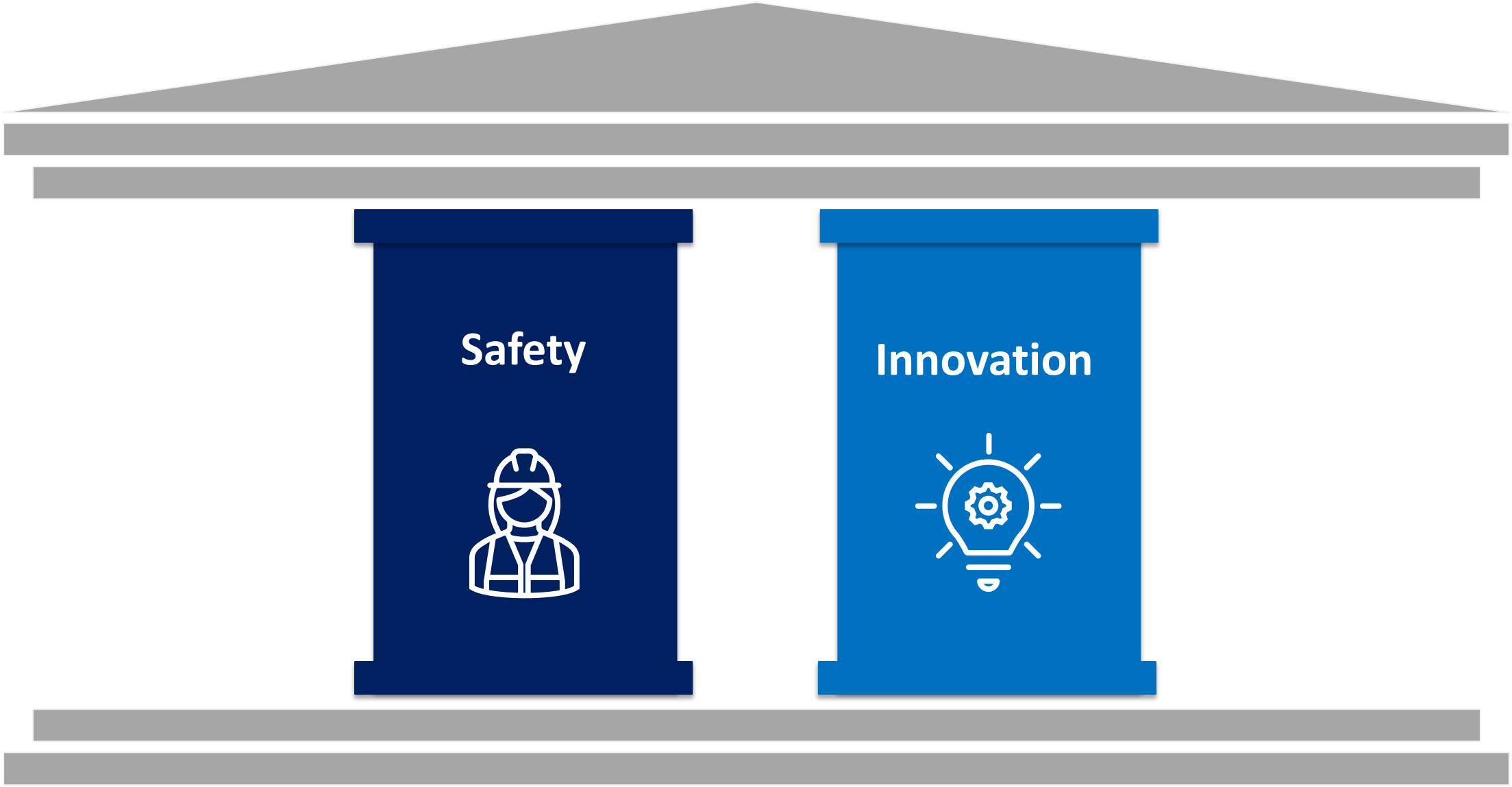
# CDRH Core Pillars



# Patient-Centered Development & Evaluation

***Development***

**Identify** unmet medical needs & **clarify** what matters most to patients

***Clinical Trial Design***

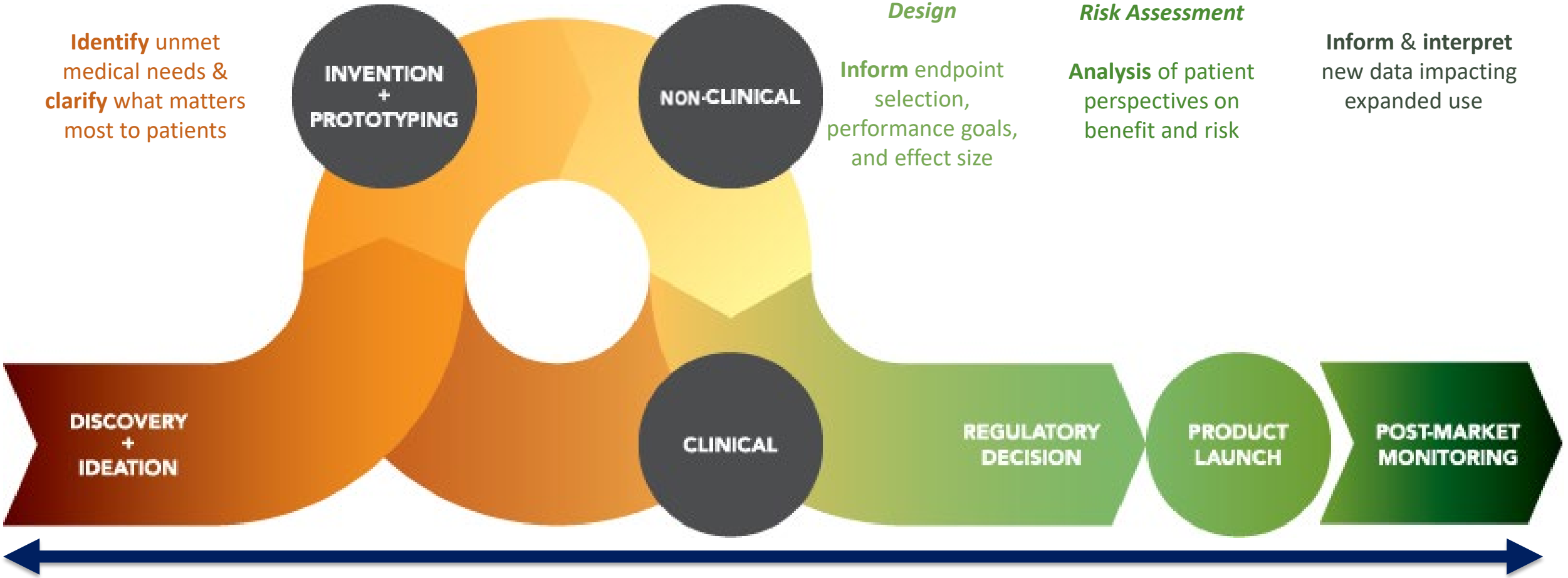
**Inform** endpoint selection, performance goals, and effect size

***Premarket Benefit-Risk Assessment***

**Analysis** of patient perspectives on benefit and risk

***Post-Market***

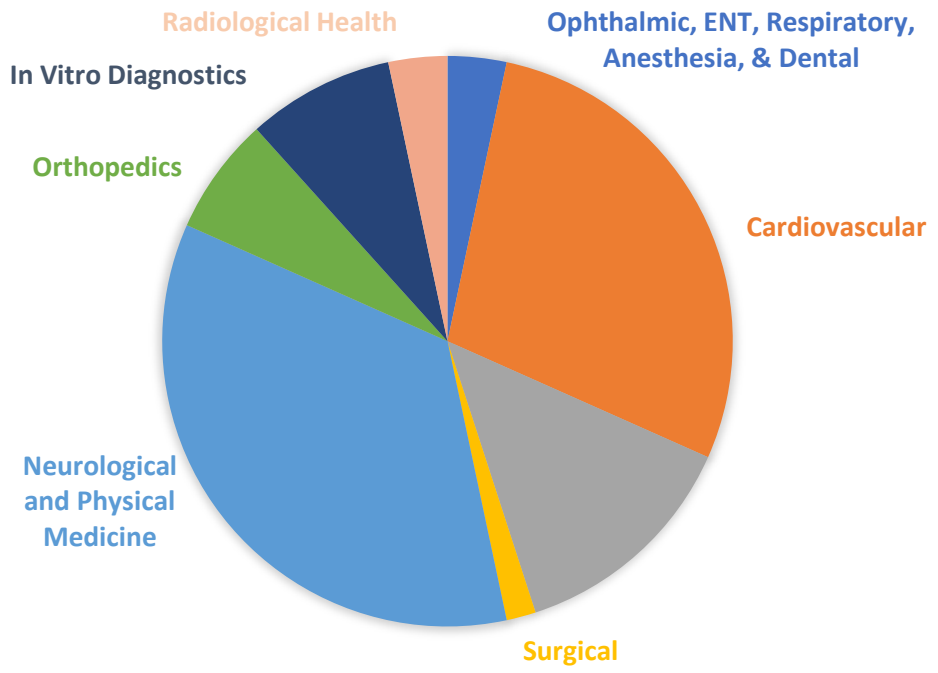
**Inform** & **interpret** new data impacting expanded use



# Early Feasibility Study (EFS) Program

- Promote early-stage clinical research in the US using just-in-time testing principles
- Elements that define an early feasibility study:
  - Small number of subjects
  - Device intended for a specific indication that may be early in development, typically before the device design has been finalized
  - Does not necessarily involve the first clinical use of a device

*Early Feasibility Studies in several clinical areas across CDRH; highest volume in neurological and cardiovascular spaces*



# Breakthrough Devices Program

**1157** Designated Devices

**154** Marketing Authorizations

- **46** PMAs
- **66** 510(k)s
- **42** De Novos

The Breakthrough Devices Program facilitates timely access to life-saving devices by expediting regulatory review

**Enables** Interactive & Timely Communication

**Promotes** Pre/Post-market Balance

**Facilitates** Flexible Clinical Study Design

**Engages** Senior Management

**Qualifies** for Priority Review

Data as of 7/1/2025

# Applying Real-World Evidence

- Post-market data suitable for providing:
  - Device safety surveillance
  - Additional evidence supporting effectiveness
  - Learning curve assessments
- Post-market surveillance studies (Section 522)
- Post-approval studies imposed as a condition of device approval
- Providing or supplementing the total evidence required for clearances/approvals
- Expansion of indications for use or labeling updates
- Public health surveillance
- Real-world long-term technology performance - need for iterative changes
- Define/identify new study populations - hypothesis generation
- Concurrent or historical control for studies - new or iterative devices
- Development of performance criteria and performance goals

# Qualifiers for Registry Data: The 5 A's

- ❑ Accrual
- ❑ Adequacy
- ❑ Assurance
- ❑ Acceptability
- ❑ Aggregation and analysis

**Reliable:** Are the data adequate the answer the question at hand?

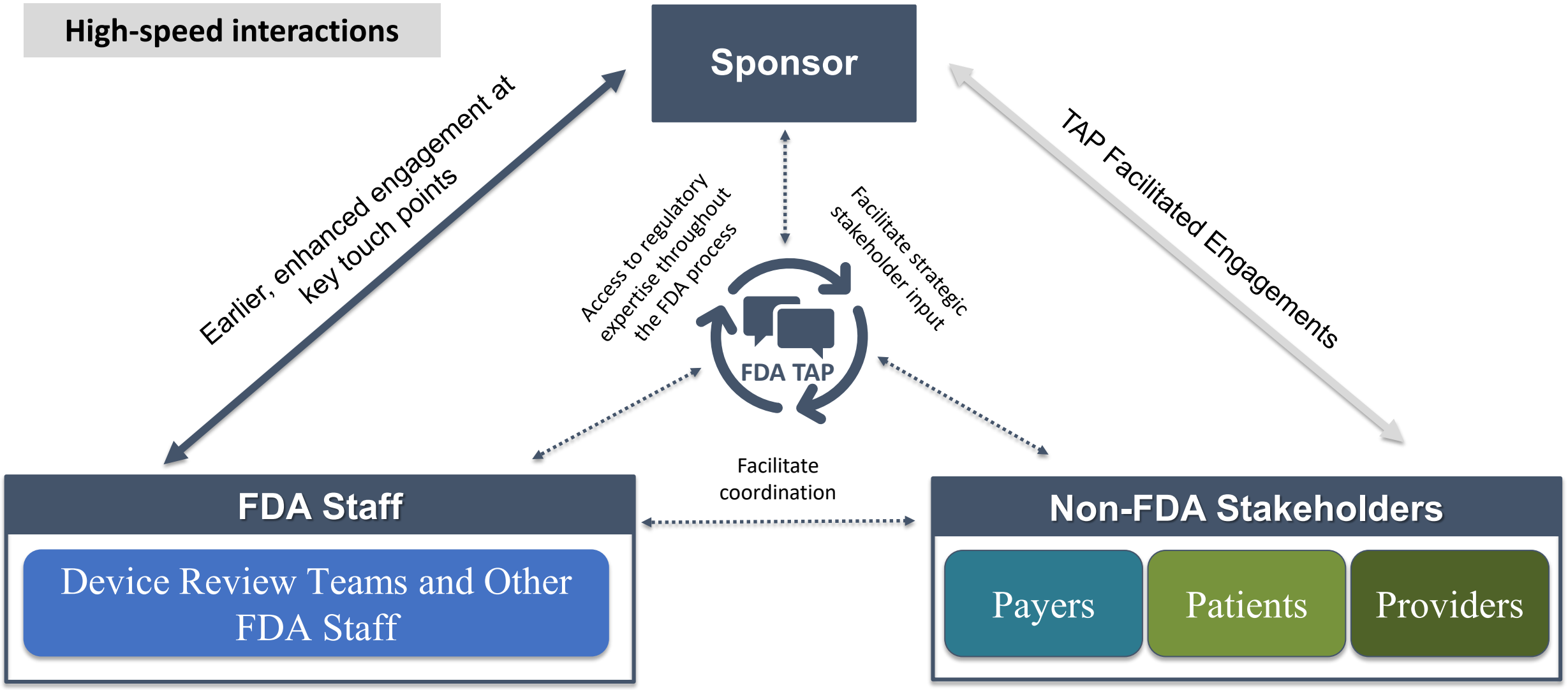
- Population
- Data checks
- Monitoring/auditing
- Patient protections

**Robust:** Are the data supported by the medical community?

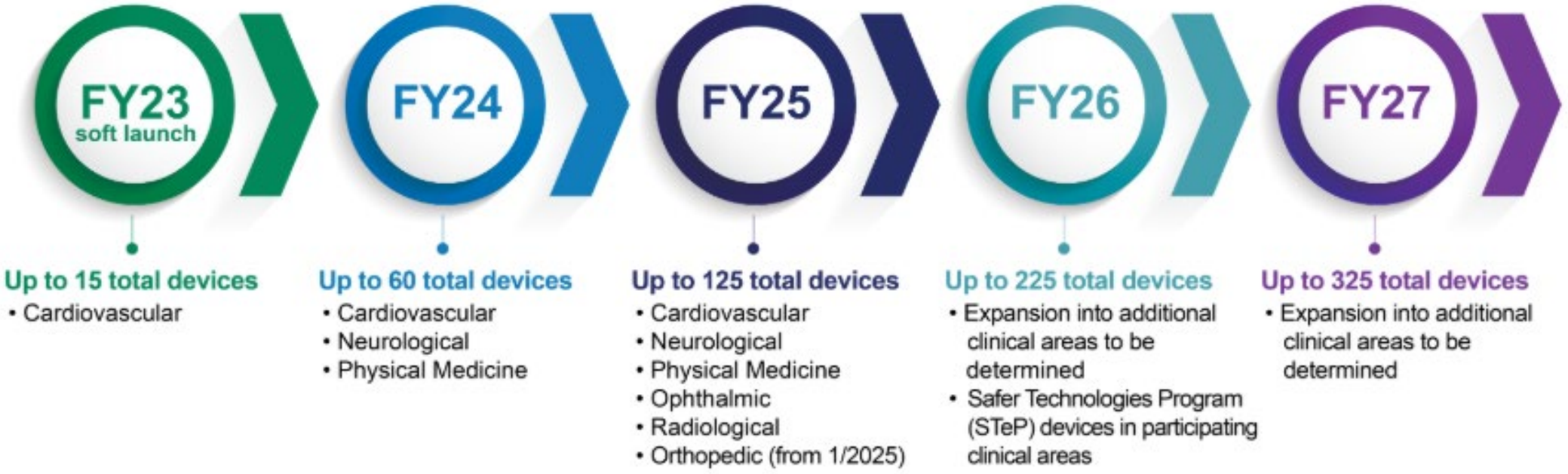
- Benchmarking and performance
- Set practice guidelines
- Generates peer reviewed publications
- Allows validated predictive risk modeling
- Sufficient for signal recognition and assessment

**Relevant:** Is aggregate data sufficient to make a regulatory decision?

# Total Product Lifecycle Advisory Program (TAP)



# TAP Pilot Update




**93 enrolled**

**Engage in a teleconference within 14 days for 90% of requests for interaction**

**Written feedback on biocompatibility and sterility topics within 21 days for 90% of requests**

**Written feedback on all other requested topics within 40 days for 90% of requests**

***100% of quantitative performance metrics met***

# Fostering reliability and validity

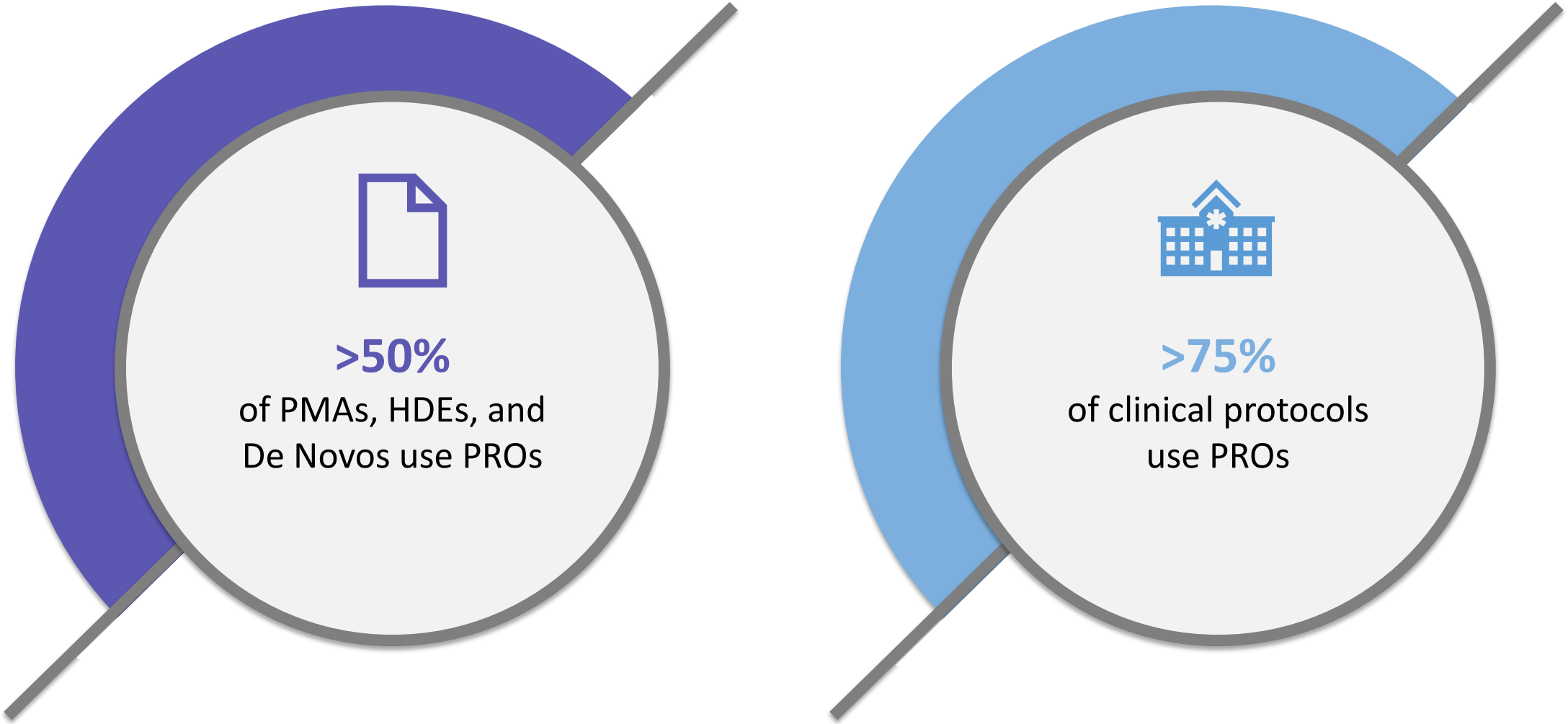
## Patient-Focused Device Guidances

**Patient Engagement in the Design and Conduct of Medical Device Clinical Studies**

**Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle**

**Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation**

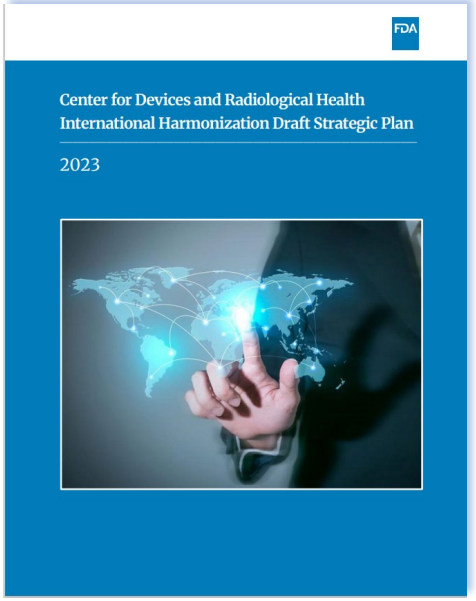
# More than 50% of submissions with clinical data use PROs



# Promoting *Global* Device Access

Five broad CDRH commitments related to international harmonization efforts:

1. Expand engagement in international harmonization and convergence efforts through participation with international regulators and other key stakeholders in forums, working groups, projects, and committees
2. Further support regulatory convergence by creating a mechanism for FDA to work with regulatory partners
3. Assess the extent of CDRH implementation of IMDRF technical documents and make this information publicly available
4. Support the creation of a forum to engage with relevant stakeholders to identify opportunities for regulators to leverage one another's approach to decision making
5. Participate in outreach activities to other regulatory authorities that encourage harmonization




Strategic plan with additional details and timelines associated with achieving these international harmonization objectives

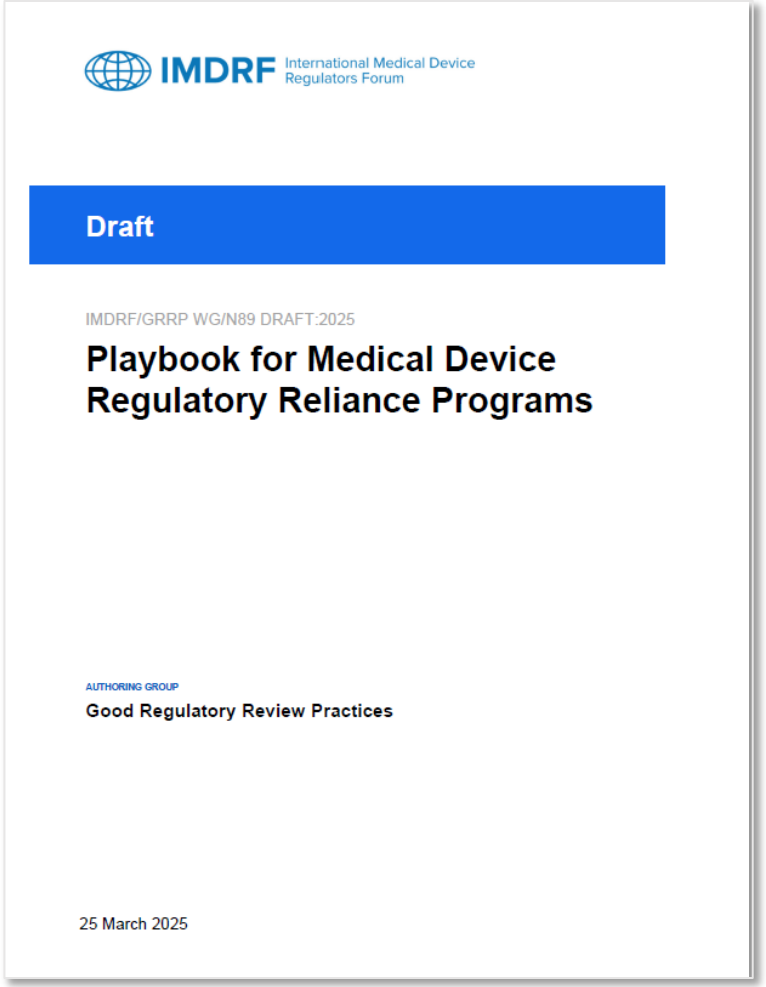
- Publish an annual assessment of our international harmonization activities

# Regulatory Reliance?

- Maximize resources by relying on the decision-making of other regulatory authorities to facilitate multi-regional regulatory strategies and expand global device access

- IMDRF developing a *Playbook for Medical Device Regulatory Reliance Programs*
  - Outlines general strategies and specific considerations for developing and implementing regulatory reliance programs within and across regulatory jurisdictions
  - Expected publication in early 2026

- Opportunity to promote trust and collaboration among like-minded regulators



# Summary

- Promoting the availability of safe, effective, and innovative devices is an important part of CDRH's mission
- CDRH initiatives to promote access can synergize well with evaluation and marketing strategies in other regulatory jurisdictions
- Further global engagement is an important component of CDRH's strategic planning over the coming years

Thank you!

ご清聴ありがとうございます！