An Introduction to the Medical Device User Fee Program: MDUFA V

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MDUFA Program History

MDUFA I - MDUFMA (FY2003-FY2007)

Authorized FDA to collect user fees for the review of premarket submissions. Enacted to provide additional resources to an under resourced medical device program.

MDUFA II - FDA Ammendments Act (FY2008-FY2012)

Reauthorized user fee collections and established tiered performance goals for 510(k) and PMA.

MDUFA III - FDASIA (FY2013-FY2017)

Reauthorized user fee collections and increased resources for medical device programs. Created more aggressive performance goals and introduced interim performance milestones (RTA, SI).

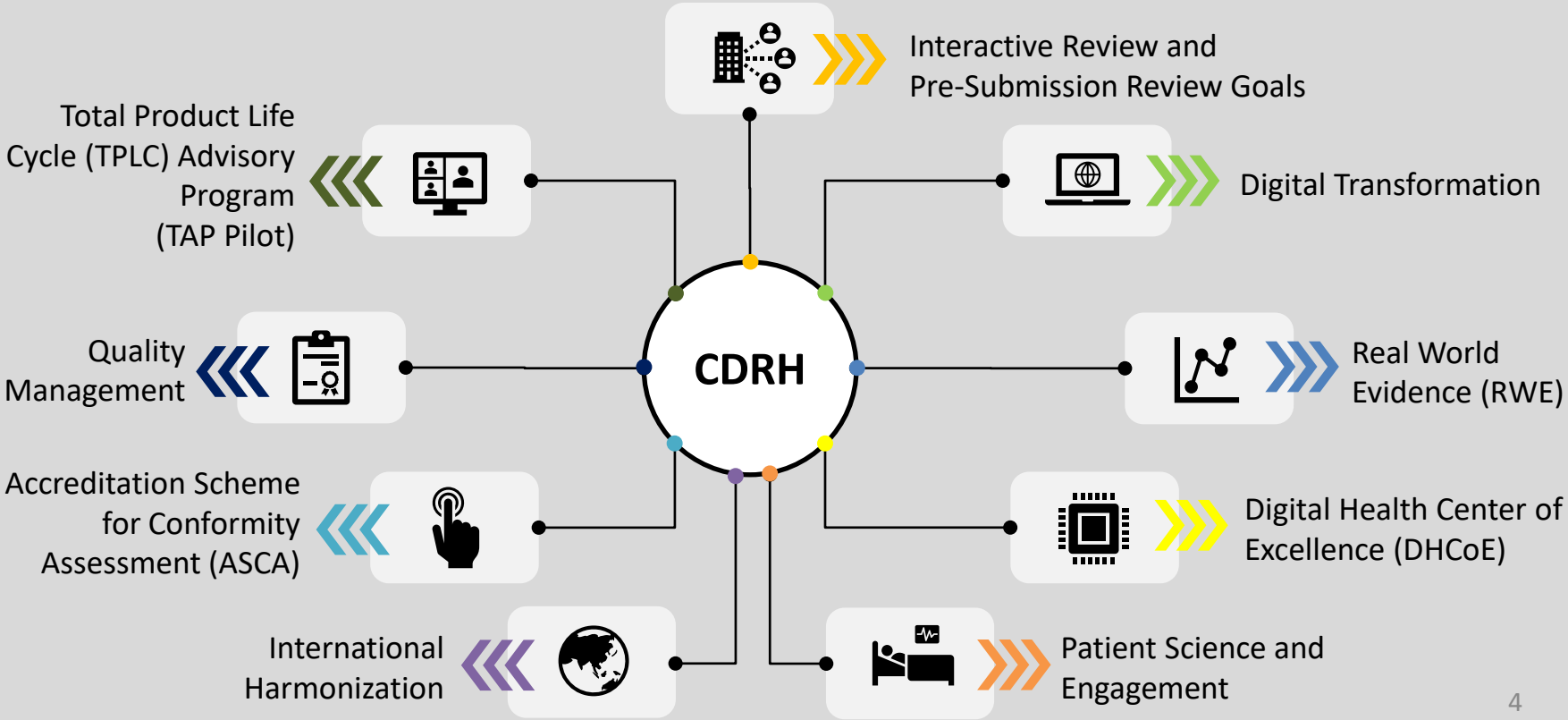
MDUFA IV - FDARA (FY2018-FY2022)

Reauthorized user fee collections, increased resources, created more aggressive performance goals for 510(k) and PMA, introduced new performance goals for De Novo and Pre-Sub. Support for NEST, digital health, ASCA Pilot, and patient engagement.

MDUFA V - FDASLA (FY2023-FY2027)

Reauthorizes user fee collections, increases resources, improves goals for PMA and 510(k) Total Time to Decision, Pre-Sub and De Novo, introduces new goal structure with "add-on" payments, support global harmonization, creates TAP Pilot.

MDUFA V Supported Programs



Enhanced Use of Consensus Standards:

Accreditation Scheme for Conformity Assessment (ASCA)

MDUFA V Commitments

- MDUFA IV pilot program intended to streamline conformity assessment aspects of device review and improve quality of testing
- Will transition from a pilot to a permanent program during MDUFA V
- Work with stakeholders to identify program enhancements and expansion criteria
- Provide training to FDA staff, industry, accreditation bodies and testing labs
- Track and report performance measures

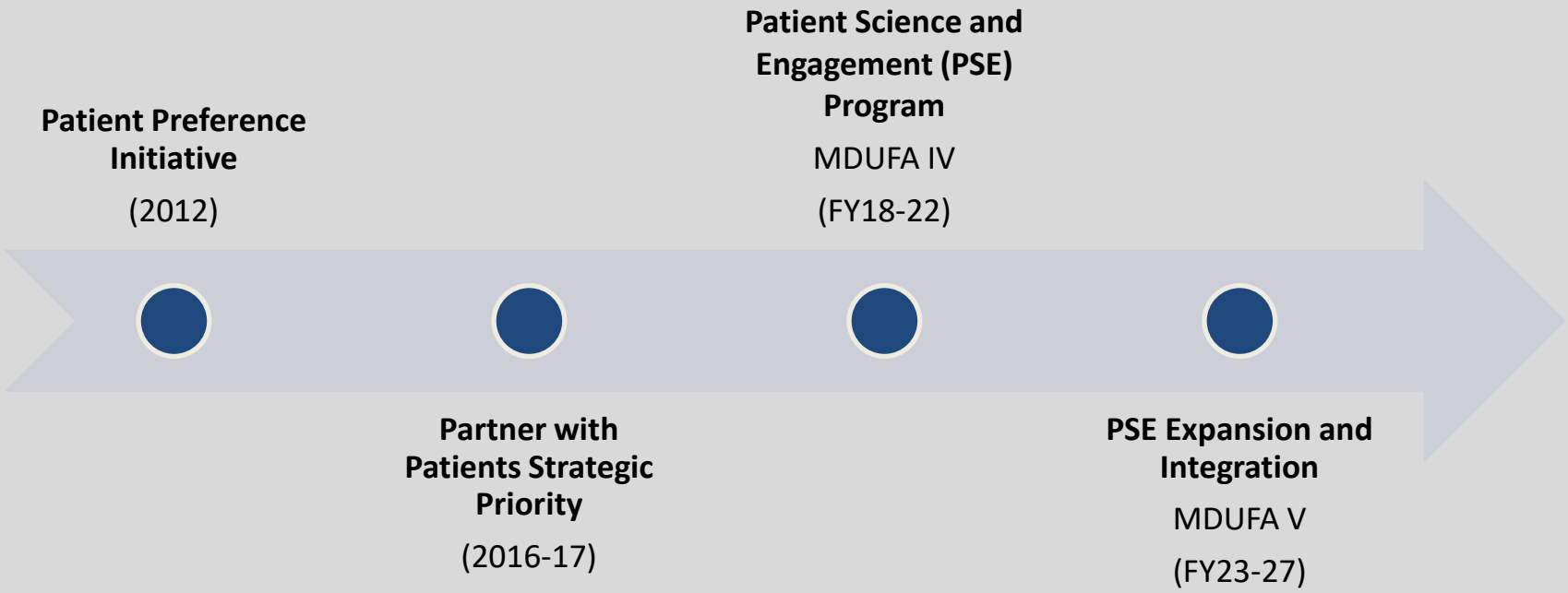
International Harmonization MDUFA V Commitments

- Expand engagement in international harmonization and convergence efforts
- Create a mechanism for working with regulatory partners with whom we have confidentiality commitments
- Assess extent of CDRH implementation of IMDRF technical documents
- Support creation of a forum to identify opportunities for regulators to leverage one another's approaches to decision making
- Participate in outreach activities to other regulators that encourage harmonization
- Issue a draft strategic plan in FY23, begin annual assessments in FY24

Patient Science and Engagement Program in CDRH

Voice of Patients

CDRH's Journey Incorporating Patient Perspectives



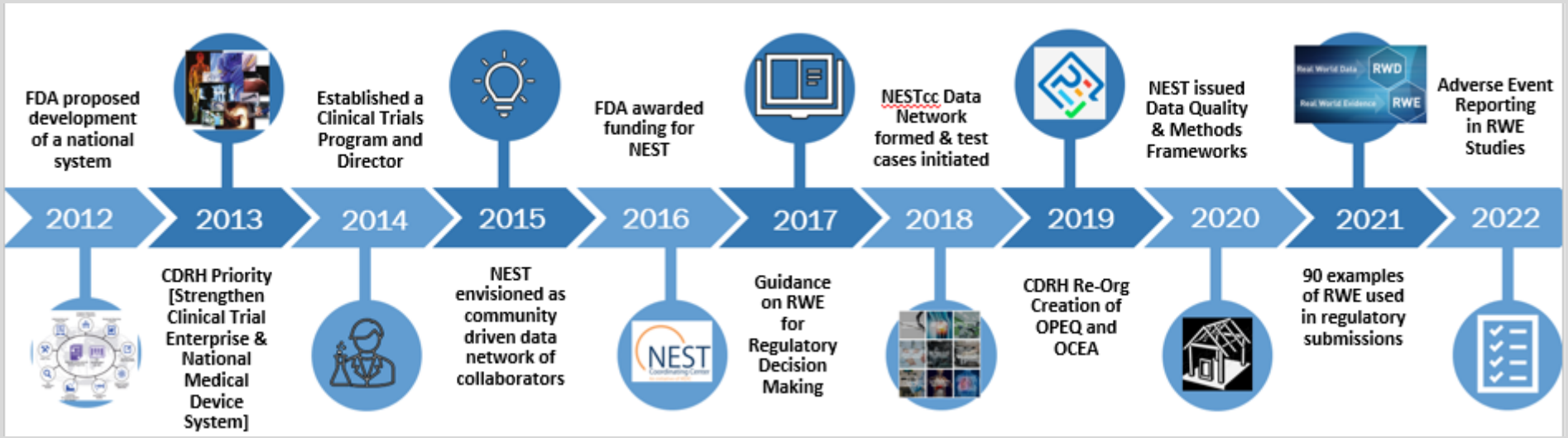
Patient Science and Engagement MDUFA V Commitments

- Facilitate patient engagement through patient-friendly educational content
- Explore ways to advance health equity by incorporating data and perspectives from diverse patients
- Expand patient science review expertise and capacity
- Improve regulatory predictability and impact of patient science, including new research case examples
- Hold public meeting on patient-generated health data (PGHD) for collecting clinical outcome assessment (COA) data and for remote clinical trials
- Issue guidance on incorporating COAs into premarket studies and update patient preference information (PPI) guidance

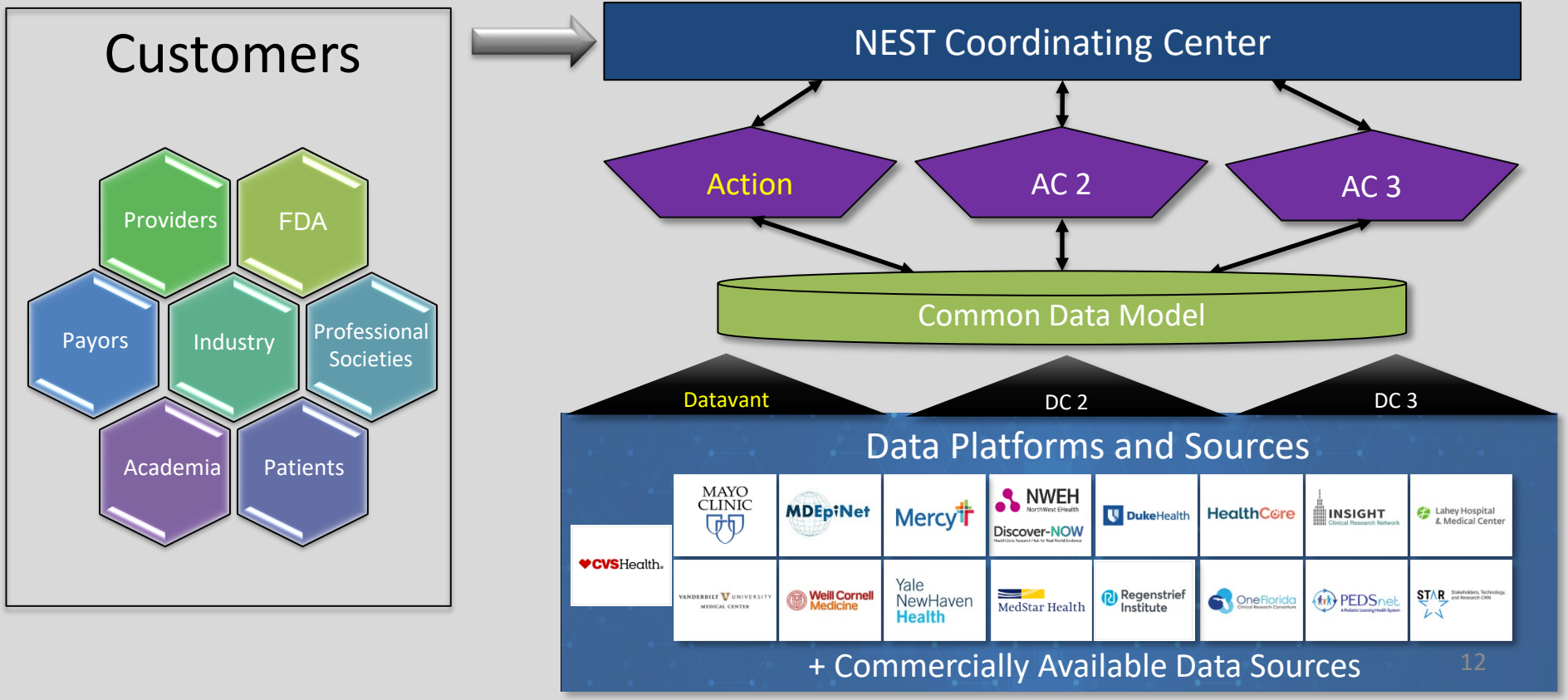
Real-World Evidence (RWE) Program in CDRH

Assess Technology When Used in Clinical Practice

RWE: 2012 to Current State



NEST - Infrastructure



Real World Evidence
MDUFA V Commitments

- Expand or develop RWE methods and policies for premarket submissions
- Update 2017 RWE Guidance
- Continue RWE training of review staff
- Transparent program updates, user-fee accounting
- Option for continued support for the National Evaluation System for Health Technology (NEST)

Digital Health Program in CDRH

Advance Innovation

CDRH's Digital Health Journey

In early days of digital health, CDRH developed changes to its approach to and policy for digital health, and we built on that over time.

Mobile Medical Applications

The Mobile Medical Applications guidance clarified that **FDA did not intend to regulate every health-related app**, and take **a platform-independent approach.**

2013

21st Century Cures Act

The 21st Century Cures Act **took our approach to digital health and built much of it into law**.

2016

MDUFA IV

MDUFA IV helped us expand our Digital Health capabilities and supported the creation of **CDRH's Digital Health Center of Excellence**.

2017-2022

Digital Health Precertification Pilot

Through the "Pre-Cert" Pilot Program, we explored innovative **tailored total product lifecycle approaches** to medical device software.

2017-2022

Final Guidance Implementing "Cures"

Several guidance documents were updated or newly published as final to further implement the Cures Act, including the **function based approach.**

2019-2022

AI/ML Initiatives

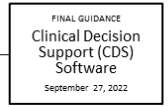
We led stakeholder engagement, shared a discussion paper, and an **AI/ML action plan** to further a total product lifecycle regulatory framework.

2019+

CDRH's Digital Health Center of Excellence

continues momentum in digital health to support FDA's public health mission.

September 2022



Issued Final Guidance on Clinical Device Support Software

Launched Digital Health Policy Navigator

October 2022

Updated List of AI/ML-Enabled Medical Devices

Spotlight on Digital Health Regulatory Science Research Opportunities

December 2022

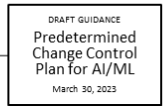
Held joint Public Workshops on Medical Devices for OUD

Published List of Medical Devices that Incorporate AR/VR

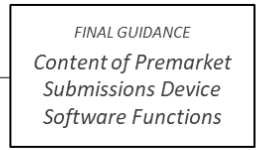
March 2023

Report on Risks & Benefits of Non-Device Software Functions

Draft Guidance on PCCP for AI/ML-Enabled Devices



COMING SOON



Final Guidance on Content of Premarket Submissions for Device Software Functions

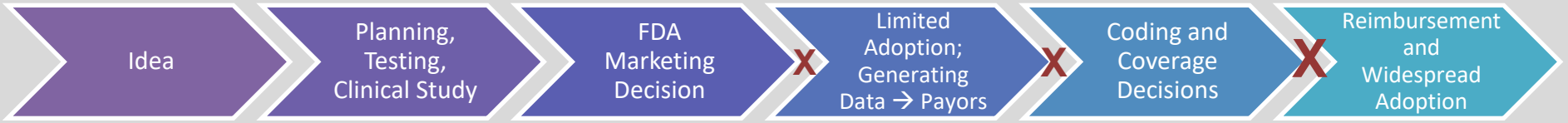
Digital Health
MDUFA V Commitments

- Build software and digital health technical expertise
- Streamline and align review with software lifecycles
- Participate in international harmonization and convergence
- Finalize guidance for device software functions
- Publish draft guidance on evaluating change control plans

Total Product Lifecycle Advisory Program (TAP)

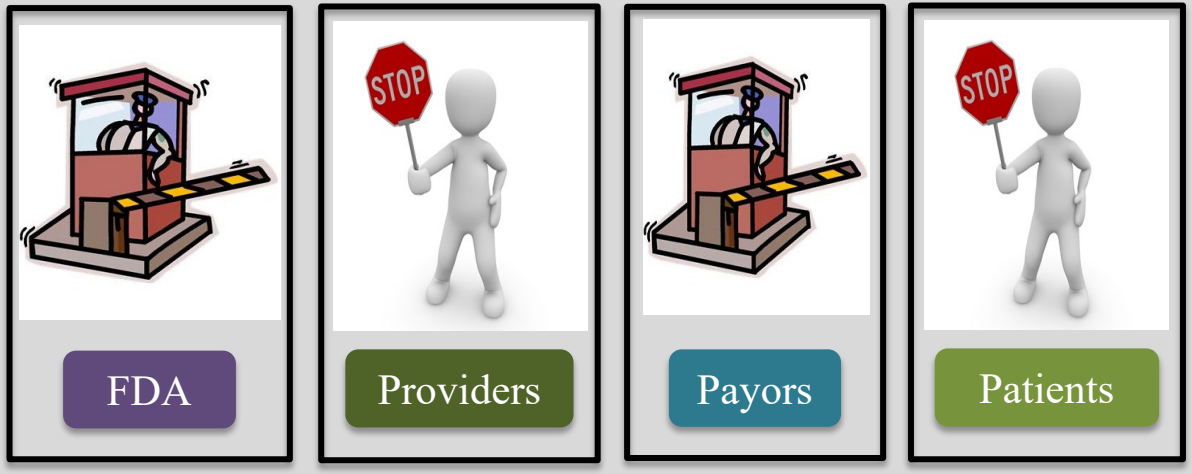
Engagement with Device Developers

Limits of Current Developer Engagement Opportunities



→ No single stakeholder has ownership of total process

→ It's not laying blame; it's just the way the system evolved

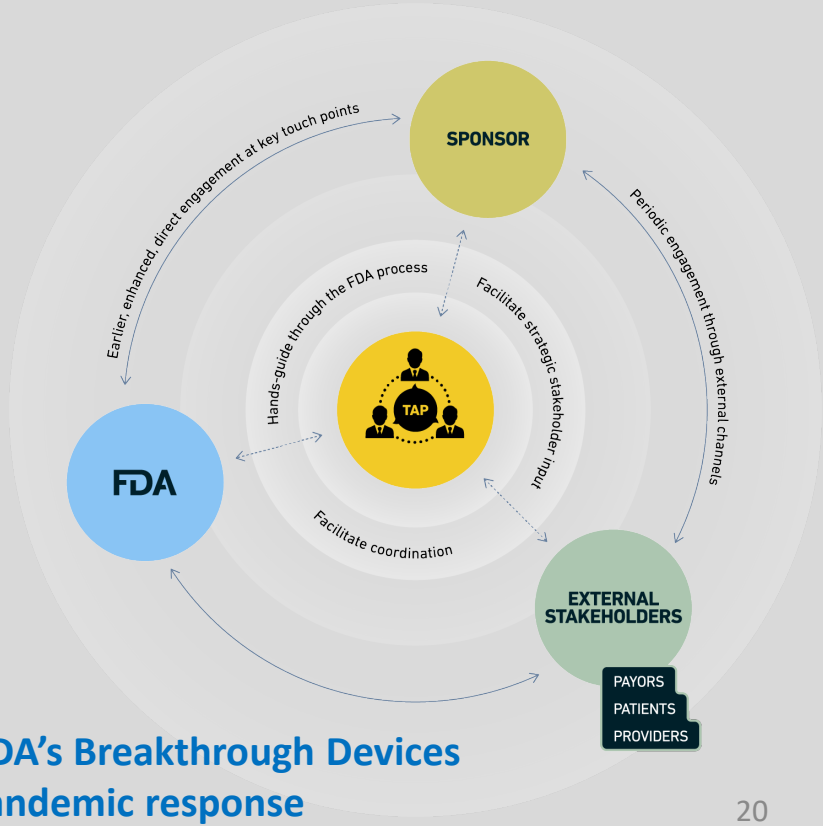


TAP Pilot

Long-term Vision | Help spur more rapid development and more rapid and widespread patient access to safe, effective, high-quality medical devices of public health importance.

Voluntary Pilot in MDUFA V

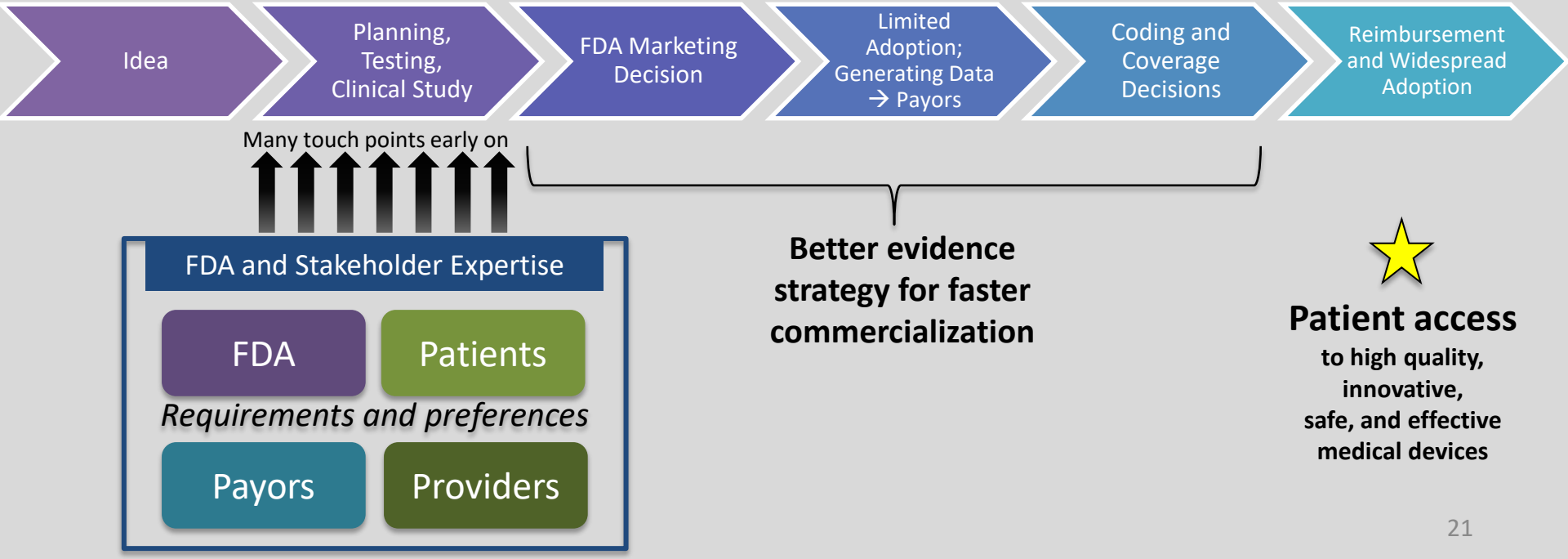
- Provide earlier and more frequent interactions with FDA, as well as facilitate coordination of earlier and more strategic stakeholder input, with a focus on Breakthrough and STeP devices.
- Begin with "soft launch" of up to 15 products in one CDRH OHT in FY 2023, and expand to enroll up to 325 products across multiple OHTs by end of MDUFA V.
- FDA will conduct an assessment of the TAP Pilot using an independent third party and include a participant survey and quantitative and qualitative success metrics.



Build upon lessons learned from FDA's Breakthrough Devices Program and COVID-19 pandemic response

TAP Pilot: Intended Impact

A shorter, happier journey



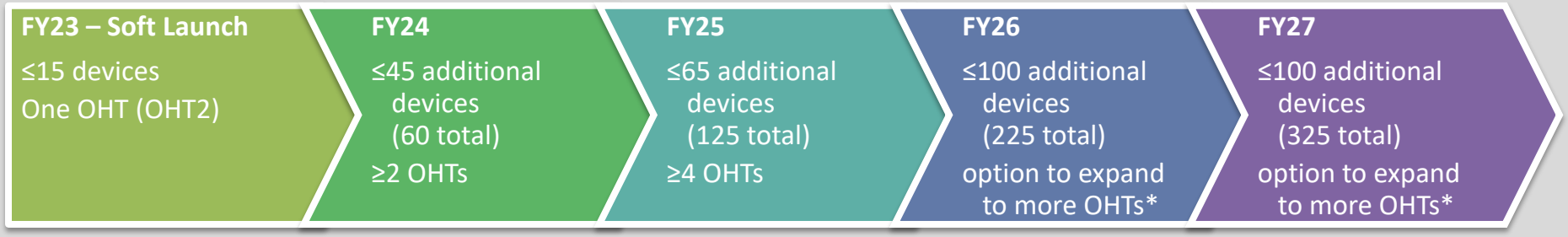
TAP Pilot

Implementation

- Starting w/OHT-2 (Cardiovascular)
- 15 companies with new Breakthrough Designation
- Teleconference within 14 days (90%)
- Biocompatibility/Sterility written feedback within 21 days (90%)
- Written feedback for other requests within 40 days (90%)

Assessment

- Independent third party
- Quantitative metrics
  - Time from BDD/STeP to Marketing Submission
  - Time from Submission to Marketing Authorization
  - Requests for additional info during review
- Company satisfaction of interactions w/FDA and non-FDA Stakeholders



Acronym Glossary

AI/ML	Artificial Intelligence/Machine Learning	**OCEA**	Office of Clinical Evidence and Analysis
ASCA	Accreditation Scheme for Conformity Assessment	**OHT**	Office of Health Technology
BDD	Breakthrough Device Designation	**OPEQ**	Office of Product Evaluation and Quality
COA	Clinical Outcome Assessment	**OUD**	Opioid Use Disorder
DHCoE	Digital Health Center of Excellence	**PCCP**	Predetermined Change Control Plan
FDARA	Food and Drug Administration Reauthorization Act	**PGHD**	Patient-Generated Health Data
FDASIA	Food and Drug Administration Safety and Innovation Act	**PMA**	Premarket Approval
FDASLA	Food and Drug Administration Safety and Landmark Advancements Act	**PPI**	Patient Preference Information
FY	Fiscal Year	**PSE**	Patient Science and Engagement
IMDRF	International Medical Device Regulators Forum	**RTA**	Refuse to Accept
MDUFA	Medical Device User Fee Amendment	**RWE**	Real-World Evidence
MDUFMA	Medical Device User Fee and Modernization Act	**SI**	Substantive Interaction
NEST	National Evaluation System for health Technology	**STeP**	Safer Technologies Program
NESTcc	National Evaluation System for health Technology Coordinating Center	**TAP**	Total Product Lifecycle Advisory Program

Summary from CDRH

Lessons learned from previous cycles have informed the size and scope of today's MDUFA program

User fees collected as part of the MDUFA V legislation will allow us to meet the needs of our customers while driving innovation

Industry Education

1. **CDRH Learn – Multi-Media Industry Education**
   - over 200 modules - videos, webinars, presentations, software-based “how to” modules
   - accessible on your portable devices: **www.fda.gov/CDRHLearn**

2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information across the device total product life cycle: **www.fda.gov/DeviceAdvice**

3. **Division of Industry and Consumer Education (DICE)**
   - Email: DICE@fda.hhs.gov
   - Phone: 1-800-638-2041 or (301) 796-7100 (Live Agents 9 am – 12:30 pm; 1 – 4:30 pm ET)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