IMDRF International Medical Device Regulators Forum

U.S. FDA UPDATE

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MEDICAL DEVICE SAFETY ACTION PLAN:
PROTECTING PATIENTS, PROMOTING PUBLIC HEALTH

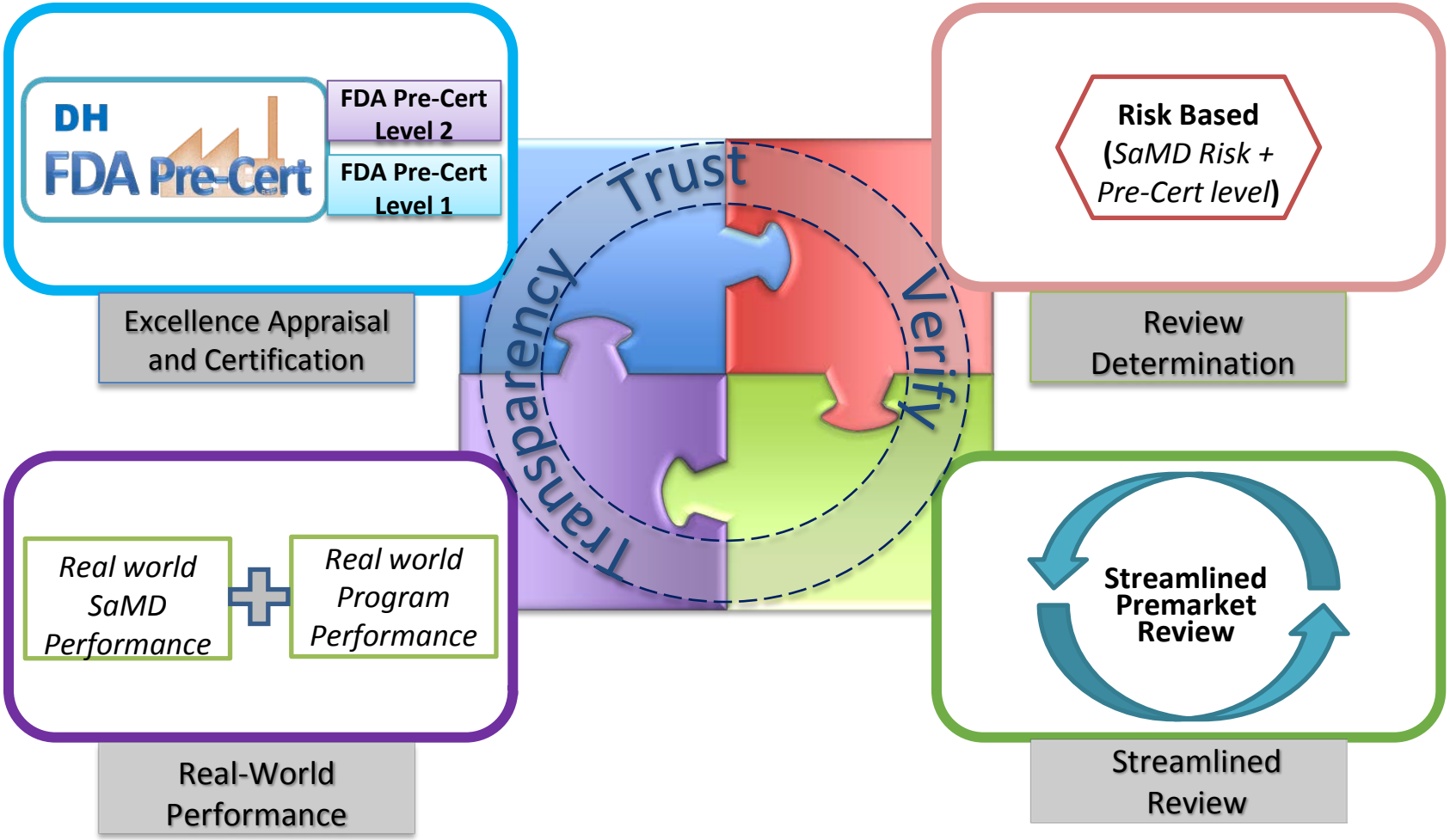
1. Establish a robust medical device patient safety net in the United States
2. Explore regulatory options to streamline and modernize timely implementation of postmarket mitigations
3. Spur innovation towards safer medical devices
4. Advance medical device cybersecurity
5. Integrate the Center for Devices and Radiological Health's premarket and postmarket offices and activities to advance the use of a TPLC approach to device safety

https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM604690.pdf

DIGITAL HEALTH: FDA PRECERTIFICATION PROGRAM GOALS

1. Enable a modern and efficient regulatory framework that allows software iterations and changes to occur in a timely fashion
2. Develop a tailored and pragmatic regulatory oversight that trusts organizations with a demonstrated culture of quality and organizational excellence to develop high quality, safe and effective software products
3. Leverage transparency regarding an organization's product performance across the entire lifecycle of SaMD
4. Use a tailored streamlined premarket review and leverage unique postmarket opportunities available in software to verify the continued safety, effectiveness, and performance of SaMD in the real world
5. Be a program that learns and adapts (i.e., adjusts/tweaks/evolves scorecard elements and key dimensions and measures) and can adjust key elements and measures based on the effectiveness of the program

Digital Health: Four Key Program Components in Proposed Framework



Digital Health Precertification Working Model

	Content Highlights	Feedback

v0.1 April 2018	• Program outline & abstract
	  • Excellence appraisal and certification level
	  • Review pathway determination
	  • Streamlined premarket review and
	  • Real world performance (RWP)
	• Challenge questions for public input
		• Strong support for shift in regulatory paradigm to address digital health technologies
		• Public seeking greater clarity on:
		  • Vision, goals and objectives of the program
		  • Scope and eligibility and
		  • How program components intersect

v0.2 June 2018	• Detail on precertification program process and components:
	  • Proposed appraisal criteria
	  • Proposed review pathway determination leveraging IMDRF framework
	  • Proposed possible premarket review elements and
	  • Proposed elements of post market RWP analytics
		• Recommendations include:
		  • Easing into the program using a continuous learning process to ensure program success, improving outcomes, and productivity
		  • Adequately ensuring the safety and effectiveness of specific SaMD submissions via a combination of streamlined review and RWP and
		  • Balancing desire to tailor the program to individual companies with a framework that is predictable for potential participants and minimizes complexity

ACCESSORIES

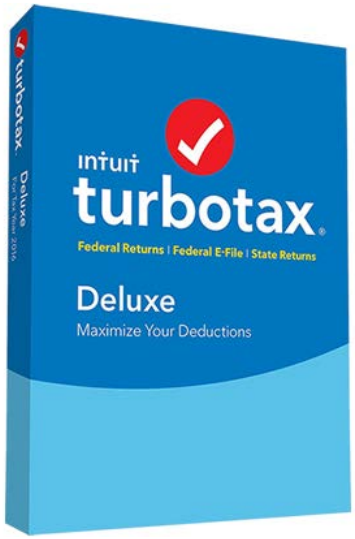
- FDA Reauthorization Act of 2017
  - Better benefit-risk-based regulation of accessories by de-coupling accessory classification from classification of the parent device
- Enables accessories to be used with a wider range of devices
- Streamlined process for classifying accessories into Class I via FR Notice:
  - https://www.federalregister.gov/documents/2018/08/17/2018-17731/medical-devices-classification-of-accessories-distinct-from-other-devices-proposed-list-of

VOLUNTARY SUMMARY MALFUNCTION REPORTING PROGRAM

- MDUFA IV Agreement
  - Expand the number and types of devices for which malfunction reports (MDRs) could be submitted summarily rather than individually
- Allows FDA to focus postmarket oversight on devices with greatest risks to public health
- Eligible: Procodes FDA explicitly identifies
  - https://www.federalregister.gov/documents/2018/08/17/2018-17770/medical-devices-and-device-led-combination-products-voluntary-malfunction-summary-reporting-program
- Ineligible:
  - Procodes in existence <2 years
  - Procodes FDA finds reason to exclude
  - Companies FDA finds reason to exclude

Streamlining Premarket Review: Quality 510(k) (QuiK) Review Program Pilot

- "Turbotax" for 510(k)
- Sponsor completes formatted eSubmission
- In return, CDRH will:
  - Skip RTA phase
  - Commit to interactive review without hold
  - Reduce FDA review time by 1/3



Launched Pilot (selected product codes) September 2018

Streamlining Premarket Review: Expanded Abbreviated 510(k)

- For certain well-understood device types that FDA would identify, substantial equivalence determinations could be made based on comparisons to safety and performance criteria
  - Criteria: FDA-recognized national and international standards, FDA final guidance documents, special controls, or a combination
- Maintains FDA's clearance standard while providing patients and healthcare professionals with greater confidence that devices meet performance standards that reflect the complexity of more modern products
- Can drive innovation of safer devices
- Opportunity to harmonize with other jurisdictions and support the establishment of a Medical Device Single Review Program

Streamlining Premarket Review: Consideration of Uncertainty in Benefit-Risk Determinations

- Some degree of uncertainty generally exists around benefits and risks for regulatory decisions
- The regulatory standard is **reasonable** assurance of safety and effectiveness – not absolute assurance
- Flexible, patient-centric approach

- Uncertainty is a critical factor in Benefit-Risk decision making, as described in our original 2012 B-R framework
- CDRH draft guidance provides details to provide greater scientific rigor in the consideration of uncertainty in certain premarket decisions
- CDRH draft guidance describes circumstances where FDA is more likely to accept greater uncertainty:
  - Breakthrough Devices subject to PMA
  - PMAs with small patient populations, e.g., pediatric populations
- Opportunity to harmonize with other jurisdictions and support the establishment of a Medical Device Single Review Program

THANK YOU