FDA's Software Precertification Program

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Moderated by **Frederick R. Ball**, Partner, Duane Morris LLP and Treasurer, FDLI Board of Directors

FDA's Software Precertification Program

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FDA'S SOFTWARE PRECERTIFICATION PROGRAM

PRESENTED BY BAKUL PATEL

May 2, 2019

Effects of Moore's Law

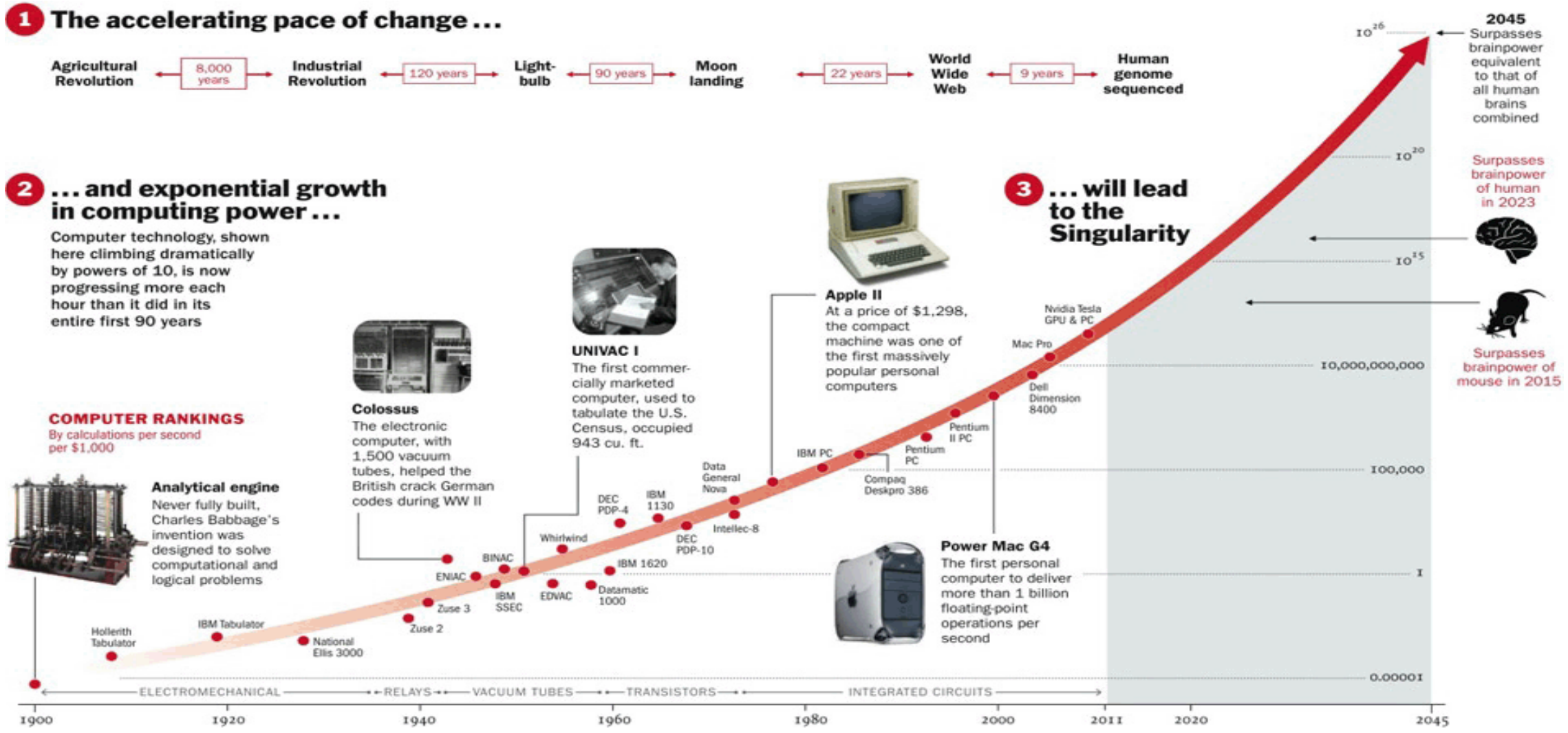

Image Credit: [Time Magazine]

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Novel Digital Health Innovation

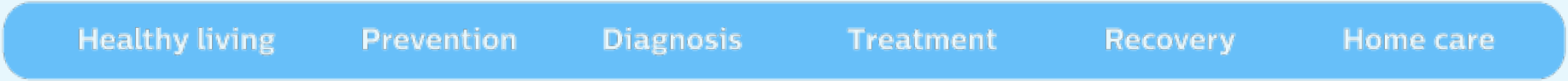
Digital tools can provide consumers with valuable health information.

Consumers who are better informed about health make better decisions.

What qualifies as a digital health product?

What digital health technologies need regulation?

Digital Health Technology



Digital health technology is the convergence of computing power, connectivity, sensors, and software used in healthcare.

→ Used as a medical product;

→ Incorporated into a medical product (include a pharmacologic product);

→ Used to develop a medical product;

→ Used to study a medical product;

→ Used as a companion or adjunct to a medical product, including diagnostics and therapeutics.

Goals for a Tailored Regulatory Framework

Fostering Responsible Digital Health Innovation

- Enhance patients access to high quality digital medical products
- Enable manufacturers to rapidly improve software products with minor changes
- Maintain a reasonable assurance of safety and effectiveness
- Minimally burdensome

The Need for a Tailored Approach

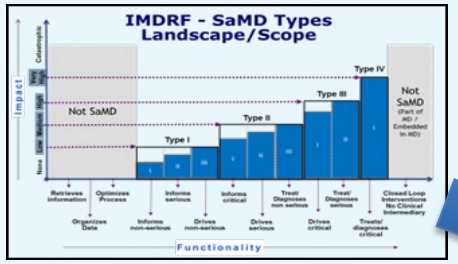
While maintaining reasonable assurance of safety and effectiveness

Today's Device World (Hardware-based)	Digital Health Device World (Software-Based)
Product Development Timeline • Months to years + • Less frequent modifications	**Product Development Timeline** • Weeks to months (**incremental, iterative**) + • Frequent modifications
Postmarket Data • Limited availability and access to real world data (522, PAS, MDRs, MedSun)	**Postmarket Data** • Potential for **high availability** and access to rich real world data (benefits and risks)
FDA Premarket Program Volume: • Stable (~3,500 510(k) submissions / 2200 pre-submissions)	**FDA Premarket Program Volume:** • Potential for **exponential** increase in volume of submissions

FDA Pre-Cert Program

An **organization-based** streamlined regulatory approach
for
Software as a Medical Device (SaMD)
that relies on a demonstrated
Culture of Quality and Organizational Excellence

Concept: A Reimagined Approach Using FDA Pre-Cert



Based on
SaMD Risk +
Pre-Cert level

FDA Pre-Cert level

e.g. lower-risk software, certain modifications

Streamlined Premarket Review

Commercial Distribution & Real-World Use

Real World Data Collection

DH FDA Pre-Cert

FDA Pre-Cert effectiveness feedback

Assessment effectiveness feedback

DH FEEDBACK

Regulatory Science

Real-World Evidence

Clinical Trials

Outcomes research

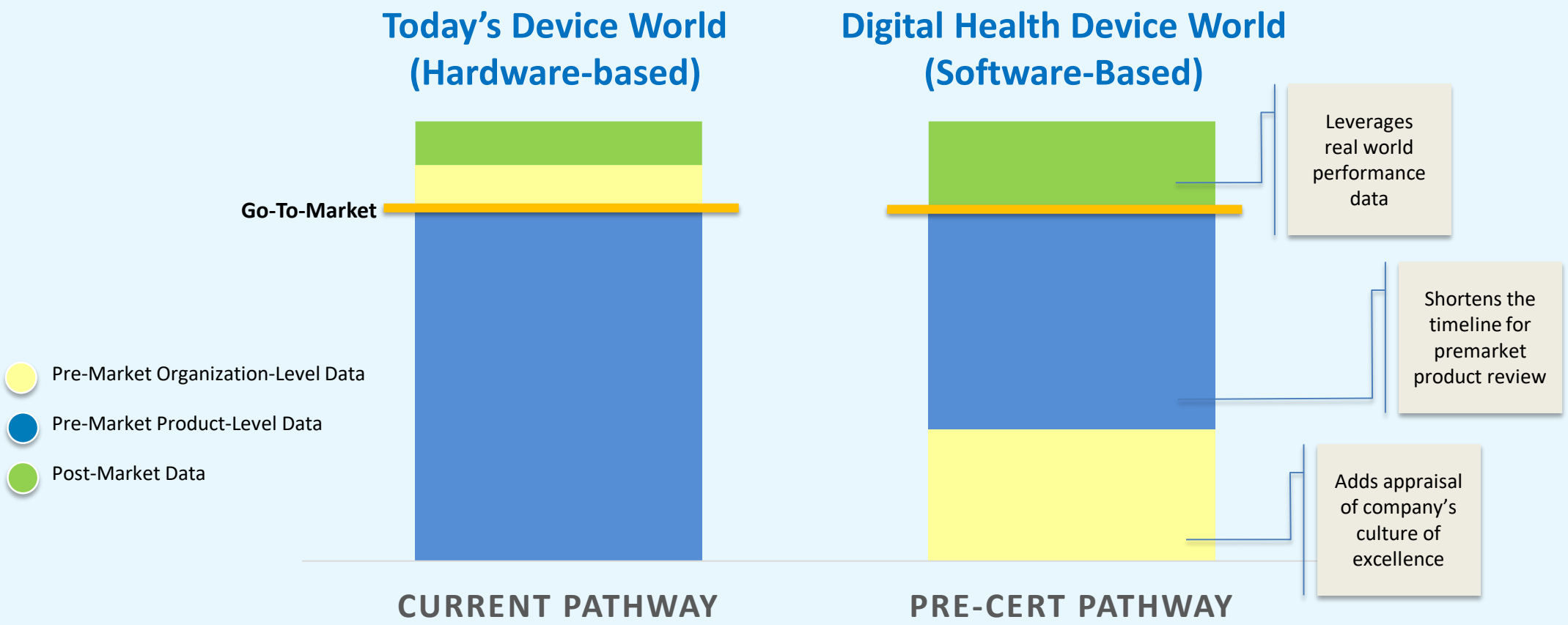
Patient Preference

Five Excellence Principles Proposed

Patient Safety		Demonstration of a commitment to providing a **safe patient experience**, and to emphasizing patient safety as a critical factor in all decision-making processes.
Product Quality		Demonstration of a commitment to the development, testing, and maintenance necessary to deliver SaMD products at the **highest level of quality**.
Clinical Responsibility		Demonstration of a commitment to responsibly **conduct clinical evaluation and to ensure that patient-centric issues** including labeling and human factors are appropriately addressed.
Cybersecurity Responsibility		Demonstration of a **commitment to protect cybersecurity**, and to proactively address cybersecurity issues through active engagement with stakeholders and peers.
Proactive Culture		Demonstration of a commitment to a **proactive approach** to surveillance, assessment of user needs, and continuous learning.

Reimagining the Regulatory Approach

While maintaining reasonable assurance of safety and effectiveness



FDA's Software Precertification Pilot Program

- ✓ Launched pilot program in 2017.
- ✓ **Building** a working model with continuous public input.
- ✓ **Working** with nine participating companies (large and small).
- ✓ **Testing** v1.0 throughout 2019 to ensure the same level of **safety and effectiveness** of products as compared to our traditional approach.

Our Goals For a New Model

How can a pre-certification program address the evolving needs of SaMD products?

Enable a tailored, pragmatic, and least burdensome regulatory oversight that

1. **Assesses** organizations to establish trust that they have a culture of quality and organizational excellence such that they can develop high quality SaMD products;
2. Leverages **transparency** of organizational excellence and product performance across the entire lifecycle of SaMD;
3. Uses a tailored **streamlined** premarket review;
4. Leverages unique postmarket opportunities available in software to **verify** the continued safety, effectiveness, and performance of SaMD in the real world.

Pre-Cert Update: Working Model v1.0

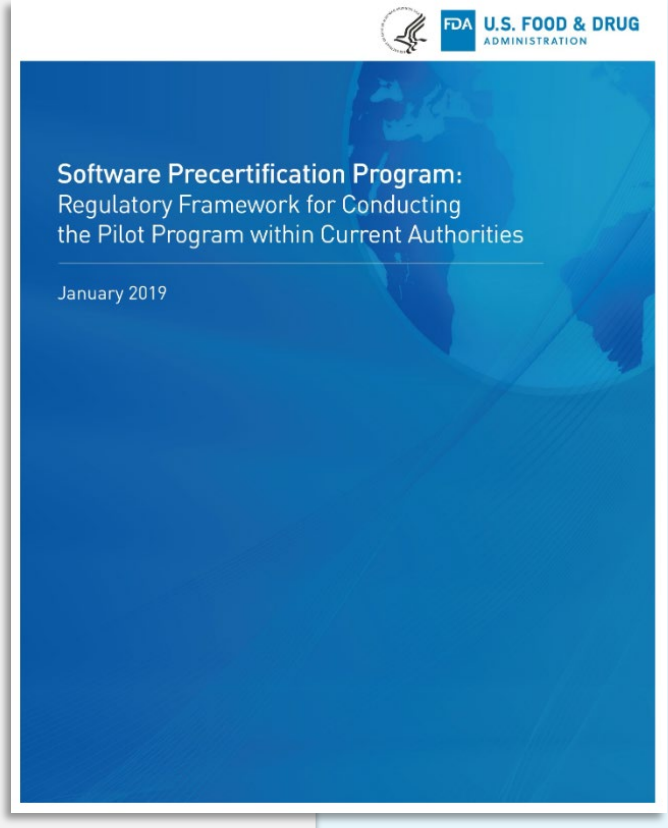
The Software Precertification Working Model v1.0 published on Jan 7, 2019 and included the following changes:

1. A description of the **Total Product Lifecyle approach**
2. Revisions to **Excellence Appraisal** (EA) descriptions for levels of Pre-Cert and FDA's intention to conduct appraisals in 2019;
3. Revisions to SaMD product-level elements for **review determination**;
4. A proposed list and descriptions of review elements for **streamlined review**, and an updated review process to apply to all submission types;
5. An updated description of the process for developing a **Real World Performance** analysis plan, examples of analytic types/sources, and how the types of RWP collected & the duration of collection may vary.

Regulatory Framework

FDA intends to implement Pre-Cert Pilot Program under the De Novo Pathway so that Excellence Appraised sponsors may:

1. **Submit a "Pre-Cert De Novo"** to receive device classifications through De Novo Pathway by submitting all applicable required information to FDA at different times (i.e., during the Excellence Appraisal, Review Determination, and Streamlined Review);
2. **Submit a Review Determination pre-sub** to confirm a SaMD sponsor is excellence appraised and is eligible for 510(k) under device classification created by Pre-Cert De Novo;
3. **Submit "Pre-Cert 510(k)"** under device classification created by Pre-Cert De Novo containing product-level information on modifications while leveraging EA data to satisfy some required elements of a 510(k) submission.



2019 Test Plan

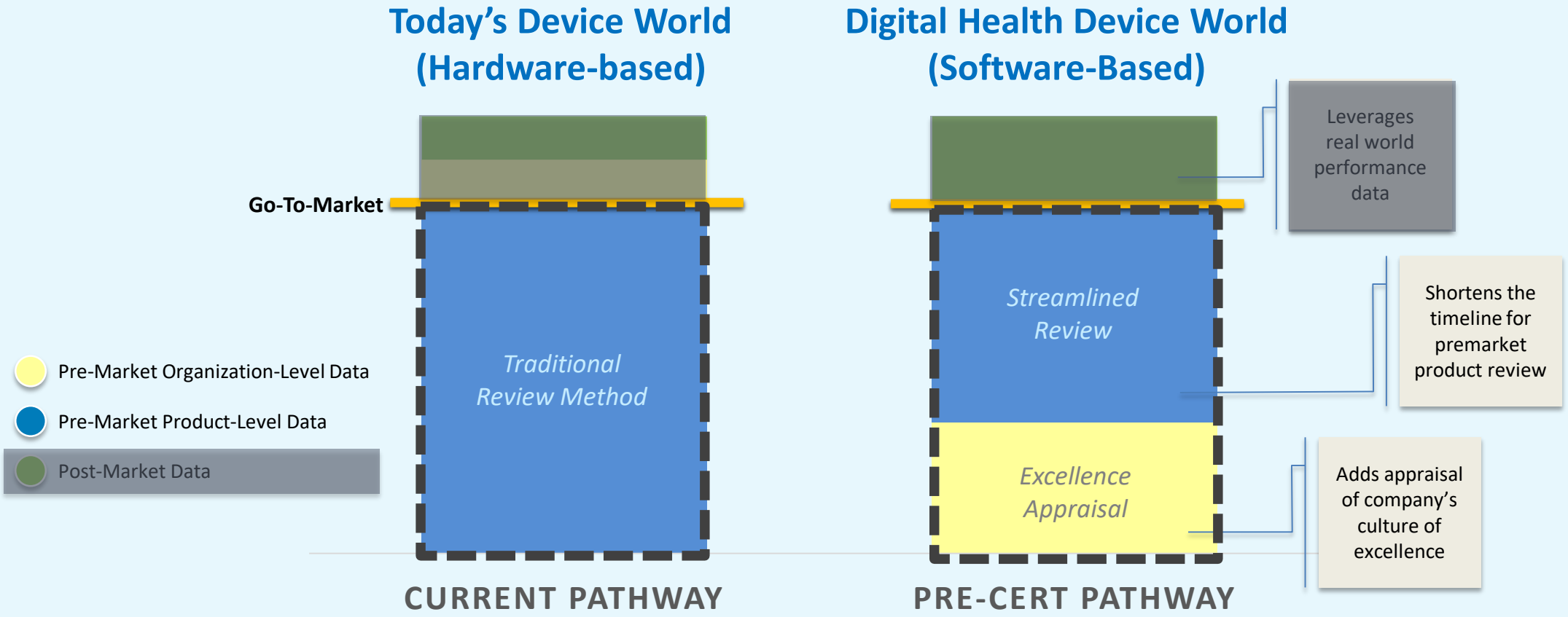
FDA intends to perform testing of the Pre-Cert program model before establishing it as an alterative premarket pathway for SaMD:

The Test Plan will assess whether **Excellence Appraisal** (EA) and **Streamlined Review** (SR) components together produce an **equivalent basis** for a determining reasonable assurance of safety and effectiveness, as compared to the traditional paradigm.

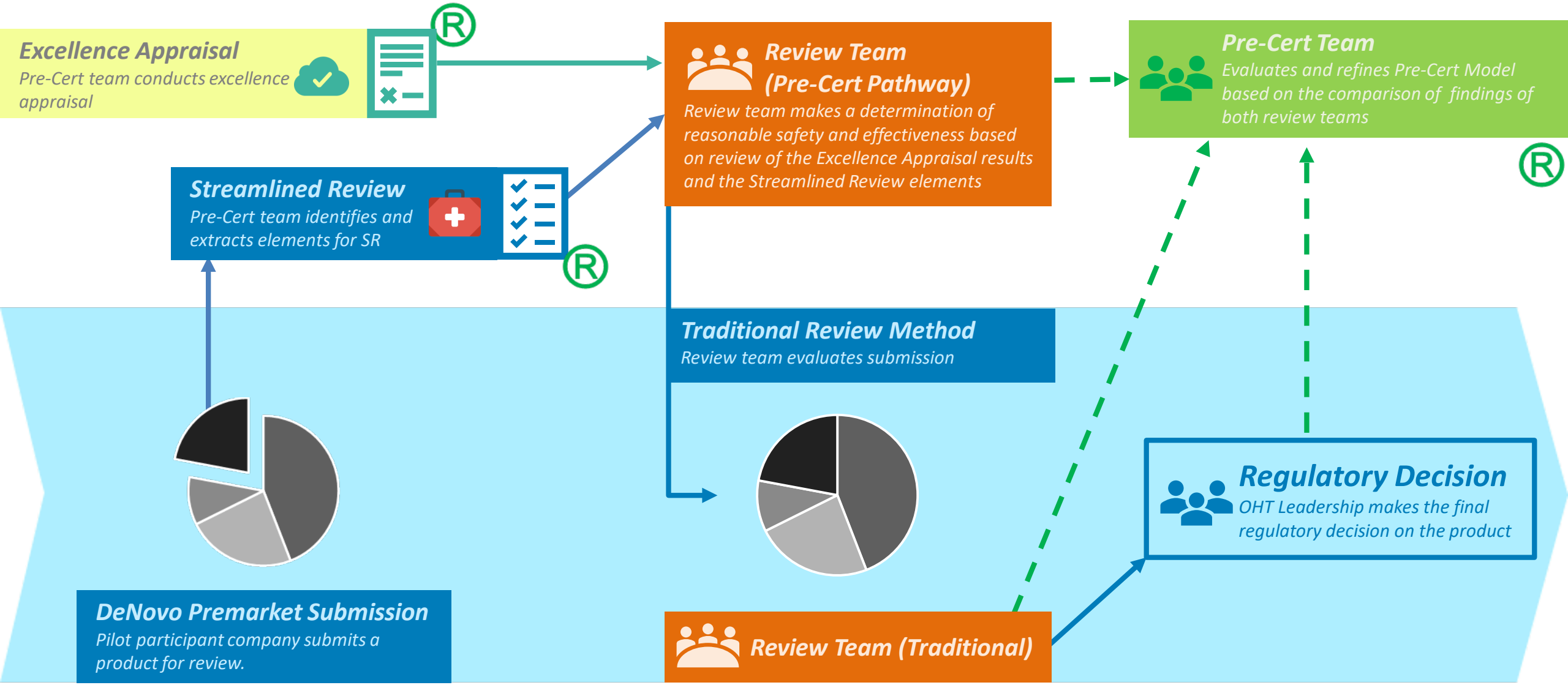
1. **Retrospective Testing:** Internally FDA is conducting retrospective tests of SaMD submissions that FDA previously reviewed.
2. **Prospective Testing:** FDA is working with Pilot Participants who volunteer submissions to apply both the proposed Pre-Cert pathway and the traditional review process;
3. **Evaluation of Findings:** Demonstrate that the evidence collected through EA and SR processes align to satisfy regulatory requirements for safety and effectiveness.

Determining Equivalency

The Test Plan will assess whether Excellence Appraisal and Streamlined Review components together produce an **equivalent basis** for determining a reasonable assurance of safety and effectiveness, as compared to the traditional paradigm.



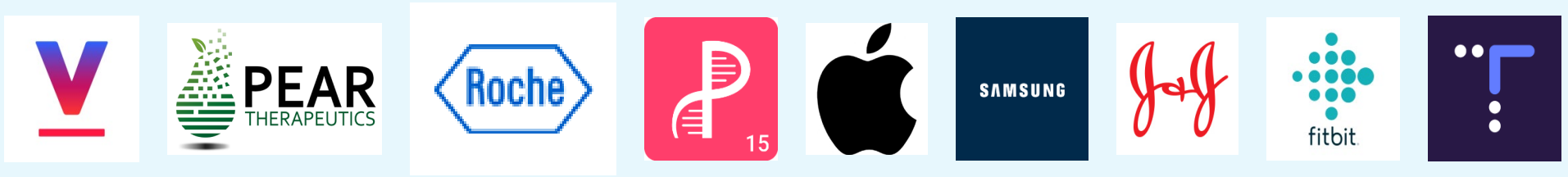
2019 Test Approach



Developing the Program with Stakeholder Input

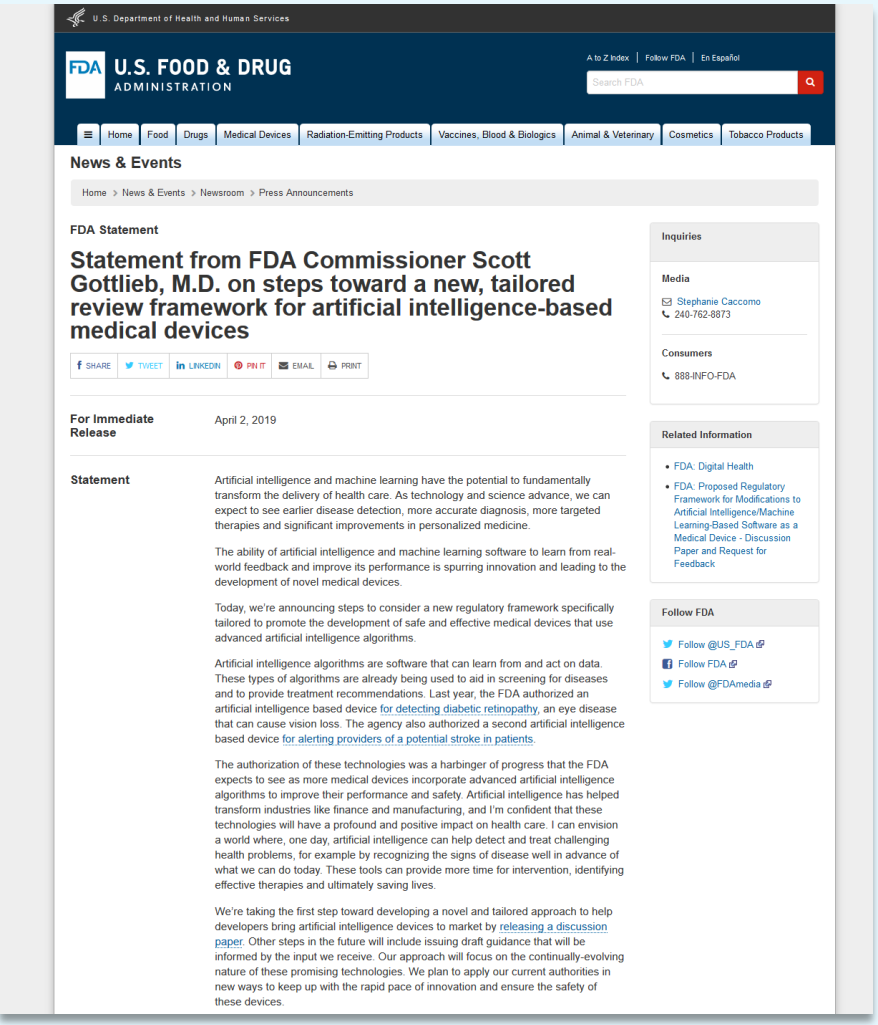
All stakeholders

+



The FDA continues to **seek input** on the Pre-Cert working model from the public through the public docket.
*Your input will **help shape the next steps** that we take to build the Pre-Cert program.*

Digital Health Center of Excellence



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FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D. on steps toward a new, tailored review framework for artificial intelligence-based medical devices

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

For Immediate Release April 2, 2019

Statement

Artificial intelligence and machine learning have the potential to fundamentally transform the delivery of health care. As technology and science advance, we can expect to see earlier disease detection, more accurate diagnosis, more targeted therapies and significant improvements in personalized medicine.

The ability of artificial intelligence and machine learning software to learn from real-world feedback and improve its performance is spurring innovation and leading to the development of novel medical devices.

Today, we're announcing steps to consider a new regulatory framework specifically tailored to promote the development of safe and effective medical devices that use advanced artificial intelligence algorithms.

Artificial intelligence algorithms are software that can learn from and act on data. These types of algorithms are already being used to aid in screening for diseases and to provide treatment recommendations. Last year, the FDA authorized an artificial intelligence based device for detecting diabetic retinopathy, an eye disease that can cause vision loss. The agency also authorized a second artificial intelligence based device for alerting providers of a potential stroke in patients.

The authorization of these technologies was a harbinger of progress that the FDA expects to see as more medical devices incorporate advanced artificial intelligence algorithms to improve their performance and safety. Artificial intelligence has helped transform industries like finance and manufacturing, and I'm confident that these technologies will have a profound and positive impact on health care. I can envision a world where, one day, artificial intelligence can help detect and treat challenging health problems, for example by recognizing the signs of disease well in advance of what we can do today. These tools can provide more time for intervention, identifying effective therapies and ultimately saving lives.

We're taking the first step toward developing a novel and tailored approach to help developers bring artificial intelligence devices to market by releasing a discussion paper. Other steps in the future will include issuing draft guidance that will be informed by the input we receive. Our approach will focus on the continually-evolving nature of these promising technologies. We plan to apply our current authorities in new ways to keep up with the rapid pace of innovation and ensure the safety of these devices.

Inquiries

Media

Stephanie Caccomo
240-762-8873

Consumers

888-INFO-FDA

Related Information

- FDA: Digital Health
- FDA: Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning-Based Software as a Medical Device - Discussion Paper and Request for Feedback

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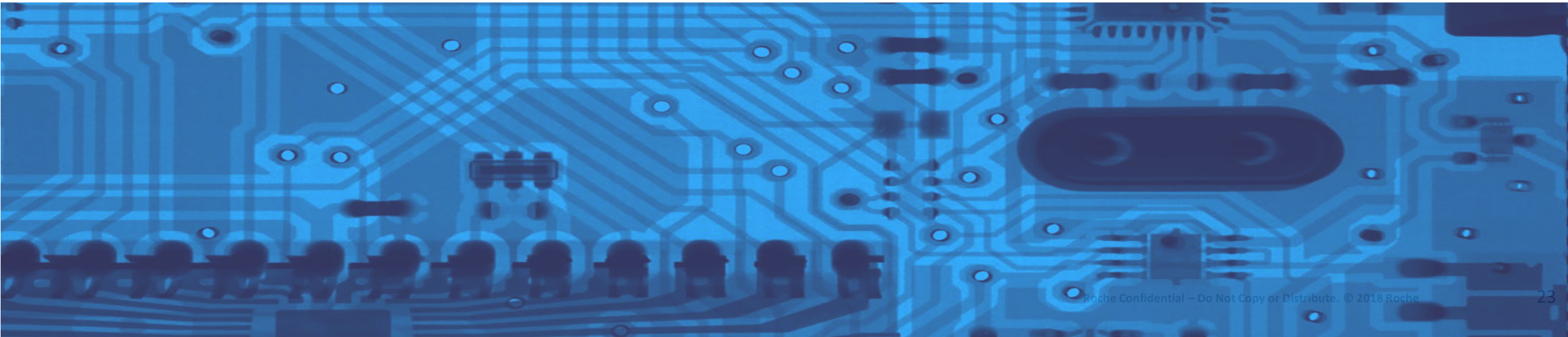
> *"We're building our Digital Health Center of Excellence to develop more efficient ways to ensure the safety and effectiveness of technologies like smart watches with medical apps. Our Software Precertification Pilot Program is allowing us to test a new approach for product review."*
>
> *Dr. Scott Gottlieb, FDA Commissioner*
> *April 2, 2019*

www.fda.gov/digitalhealth

Q&A

2019 FDLI Annual Meeting

Lesley R. Maloney, Pharm.D.
Head, U.S. Regulatory Policy, Roche Diagnostics



FDA Software Precertification Pilot Program

Perspectives From A Pilot Participant

FDA Software Precertification Pilot Program
Perspectives From A Pilot Participant

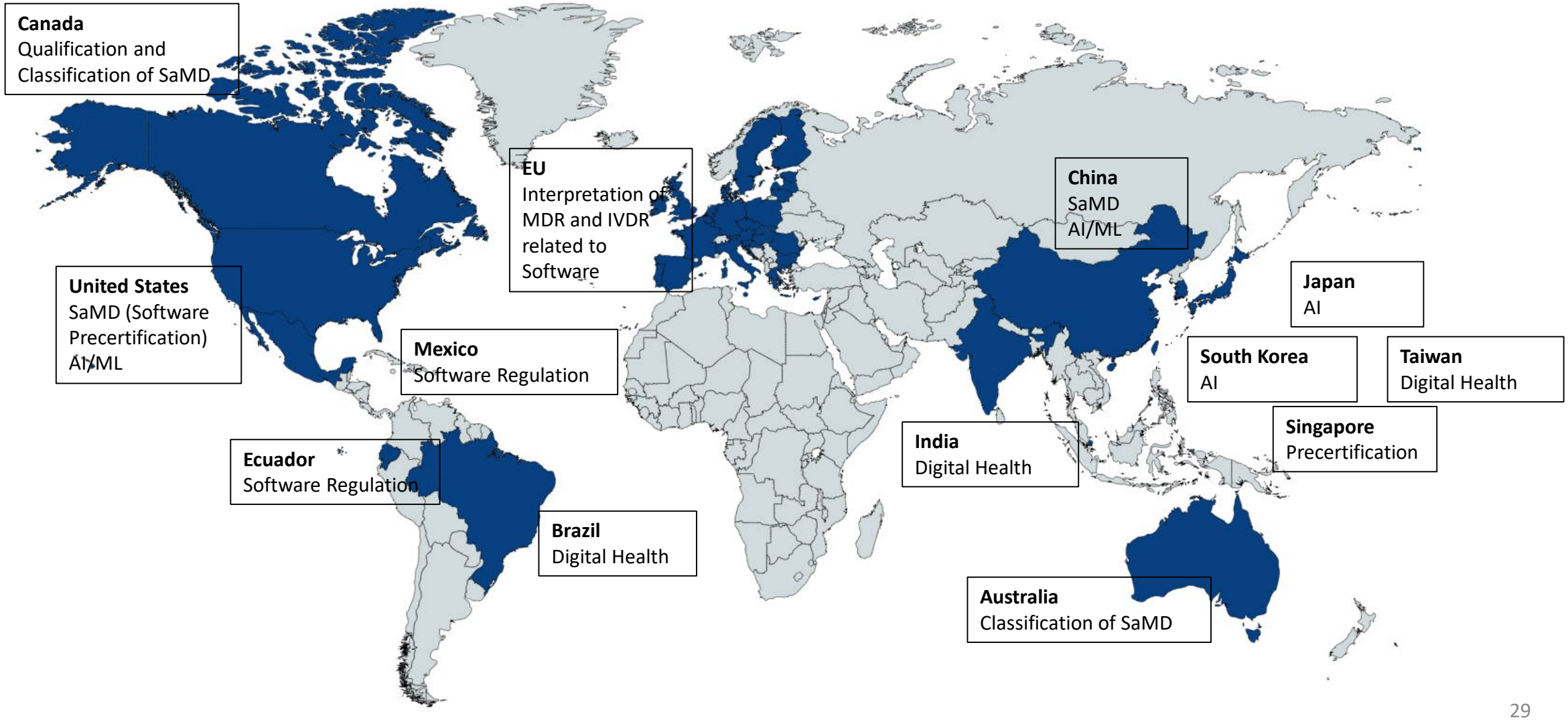
- **2018**: Focused on providing input to the draft Working Models
  - Review Determination
  - Streamlined Review

FDA Software Precertification Pilot Program
Perspectives From A Pilot Participant

- **2018**: Focused on providing input to the draft Working Models
  - Review Determination
  - Streamlined Review
- **2019**: Individual companies test Working Model v1.0
    - Preparing for FDA to conduct an Excellence Appraisal
    - Fit-for-purpose quality management system (QMS)
    - Continued development of our SaMD for traditional submission

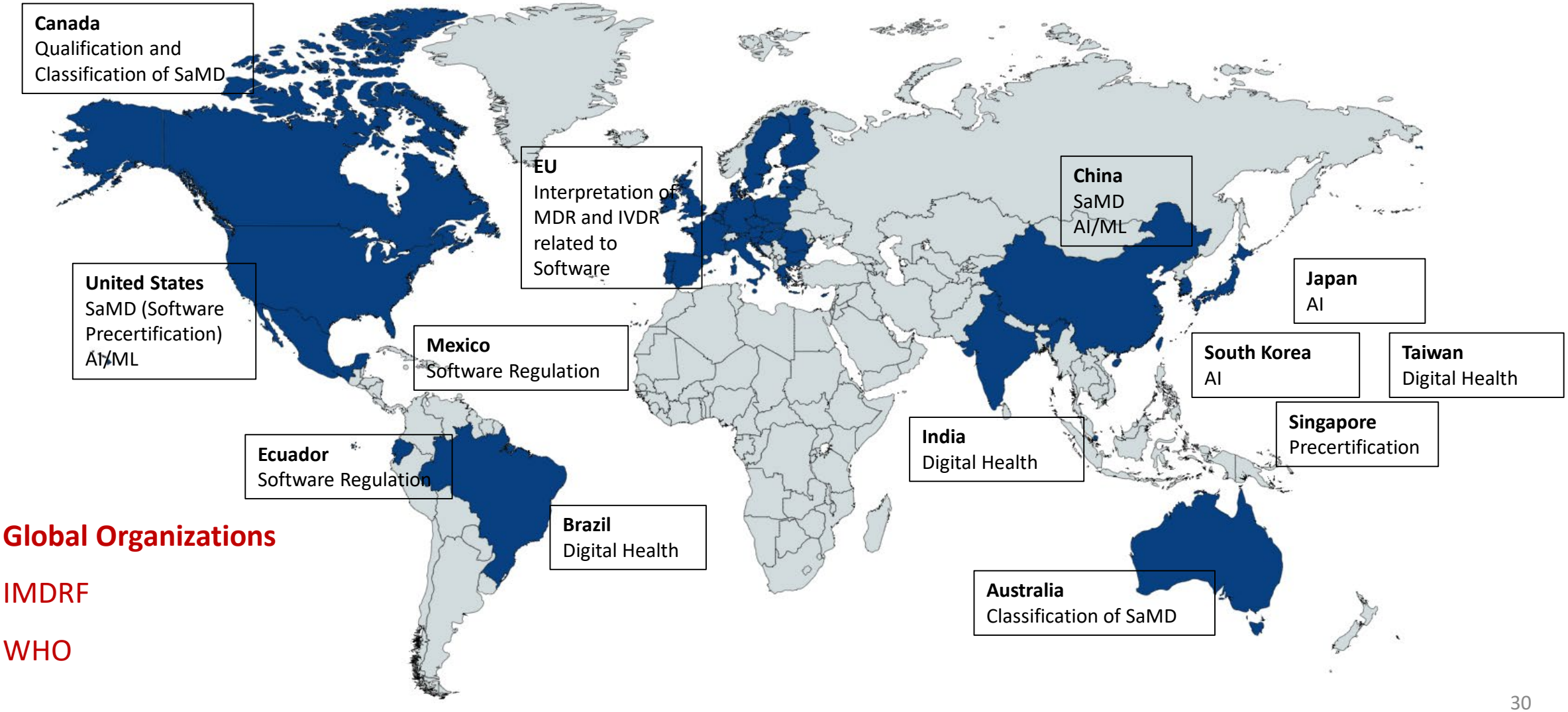
Global Interest in Software Regulation

Driving Toward Global Convergence



Global Interest in Software Regulation

Driving Toward Global Convergence



Global Organizations

IMDRF

WHO

Challenges

- Confusion between qualification and classification
- Mapping IMDRF risk classifications to local jurisdictions
- How to appropriately review software in a streamlined manner
- Extent of FDA's legal authority

Digital health solutions connect the dots...

creating an ever-expanding healthcare ecosystem to support more informed health decisions and improved patient outcomes.

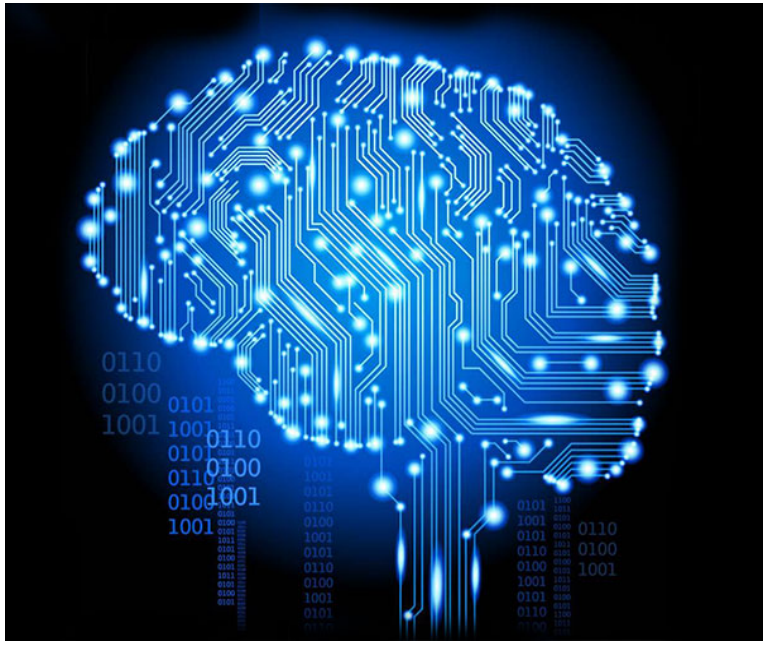
FDA's Software Precertification Program

Ian Pearson, Senior Associate, Jones Day

FDA Software Pre-Cert: Startup Perspective

Mobile Medical Apps

Medical Software



Artificial Intelligence

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New Regulatory Paradigm

Traditional Device Regulation

- Medical Device Amendments added to FDCA in 1976
- Meant to address hardware-based products at the time
- Slower development cycles and technology design changes

Unique Aspects of Digital Health

- Digital health has brought new market participants
- Software development differs from hardware
- New safety issues (e.g., cybersecurity, data privacy, connectivity, AI, etc.)

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The 21st Century Cures Act

- Enacted in December 2016, Section 3060 of the Cures Act removes certain types of medical software from FDA's regulatory jurisdiction, including software intended to:
    1. Support administrative functions;
    2. Encourage a healthy lifestyle;
    3. Serve as an electronic patient record;
    4. Transfer, store, convert formats, or display device data and findings; or
    5. Provide clinical decision support
        - See FDA draft guidance 2017 : Clinical and Patient Decision Support Software https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm587819.pdf

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FDA Software Pre-Certification Pilot Program

- The Pre-Cert Pilot Program is intended to be a tailored approach to regulating software by focusing regulatory oversight on developers rather than the product
  - Will allow manufacturers to "demonstrate a culture of quality and organizational excellence"
  - Leveraging of real-world data and regulatory history
- If adopted, this developer-targeted review would be a significant departure from FDA's historic approach of a evaluating each individual product
- Pilot participants include:

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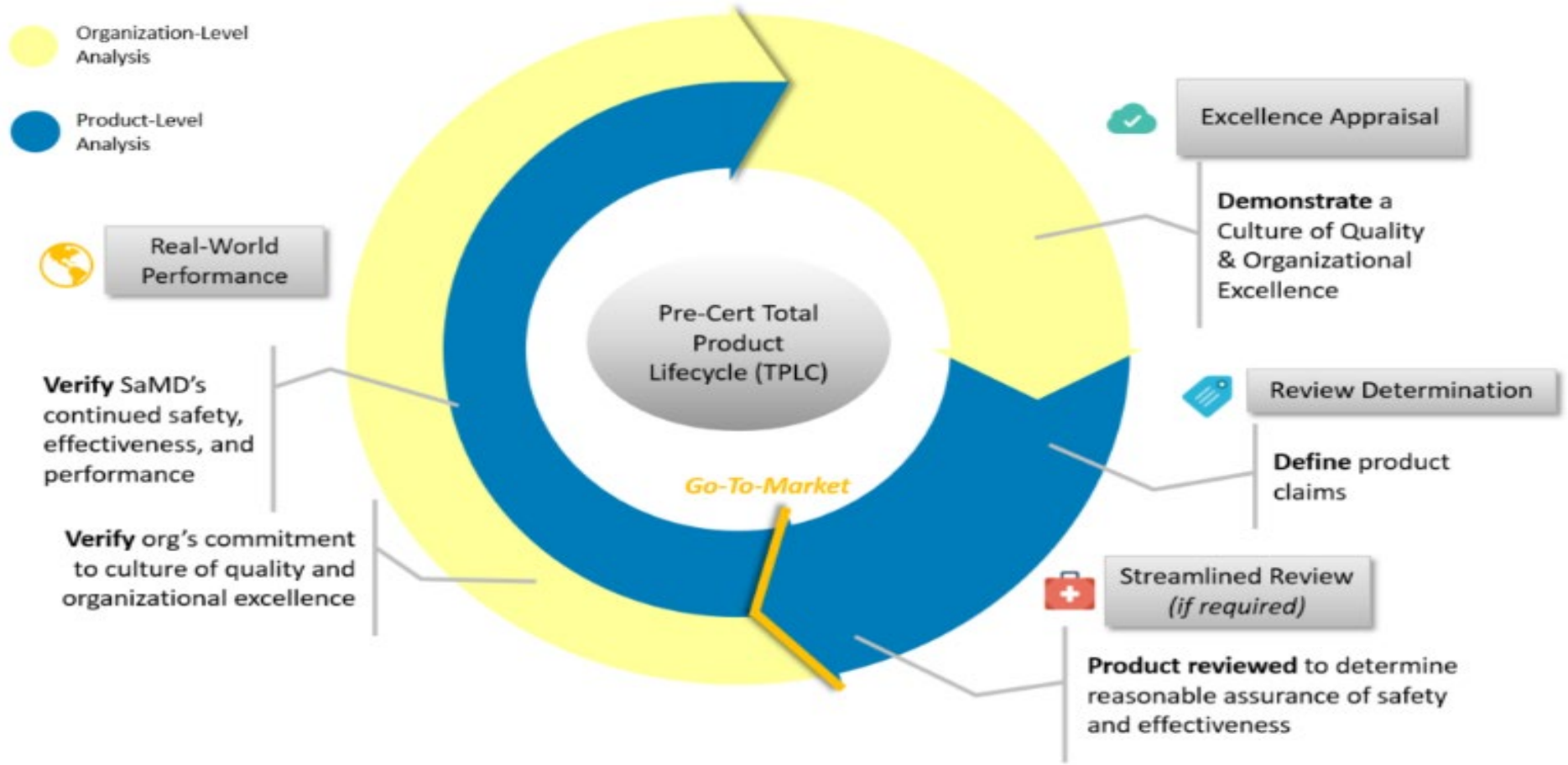
Software Pre-Cert: Program Outline



Source: FDA.gov

Startups: Unique Concerns

The Startup Perspective

LIKES

Acknowledgment
Agency Responsiveness
Focused Review
Shorter Timelines

CONCERNS

Legal Authority
Scalability
Burden
Information Sharing
Staffing
Cost

The Path Forward


ANY
QUESTIONS
?