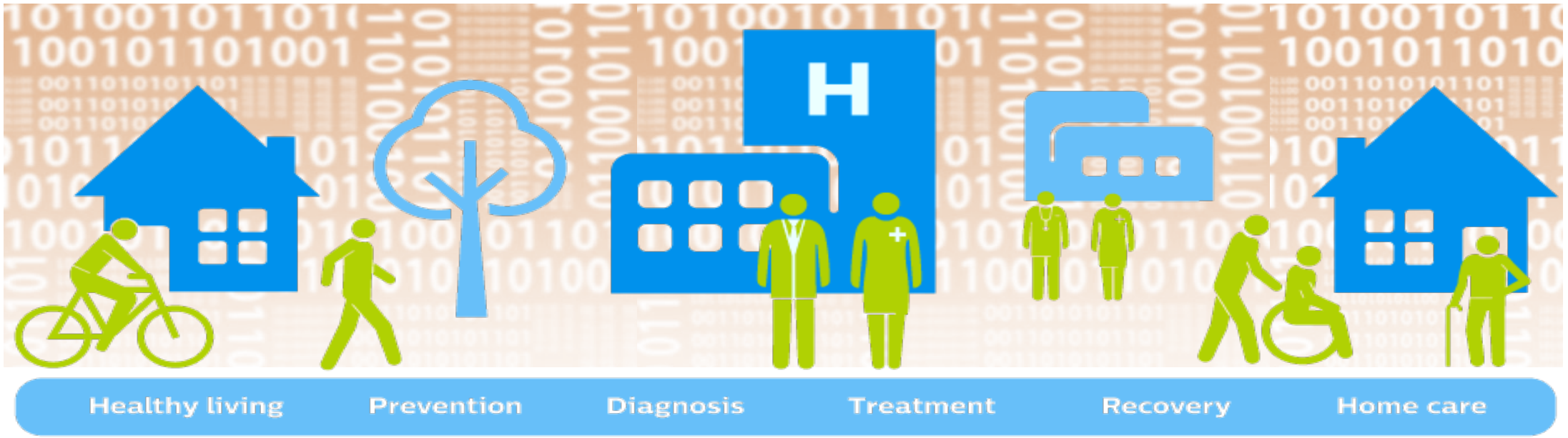
FDA'S SOFTWARE PRECERTIFICATION PROGRAM

Presented by Bakul Patel

Digitalization across the health care continuum



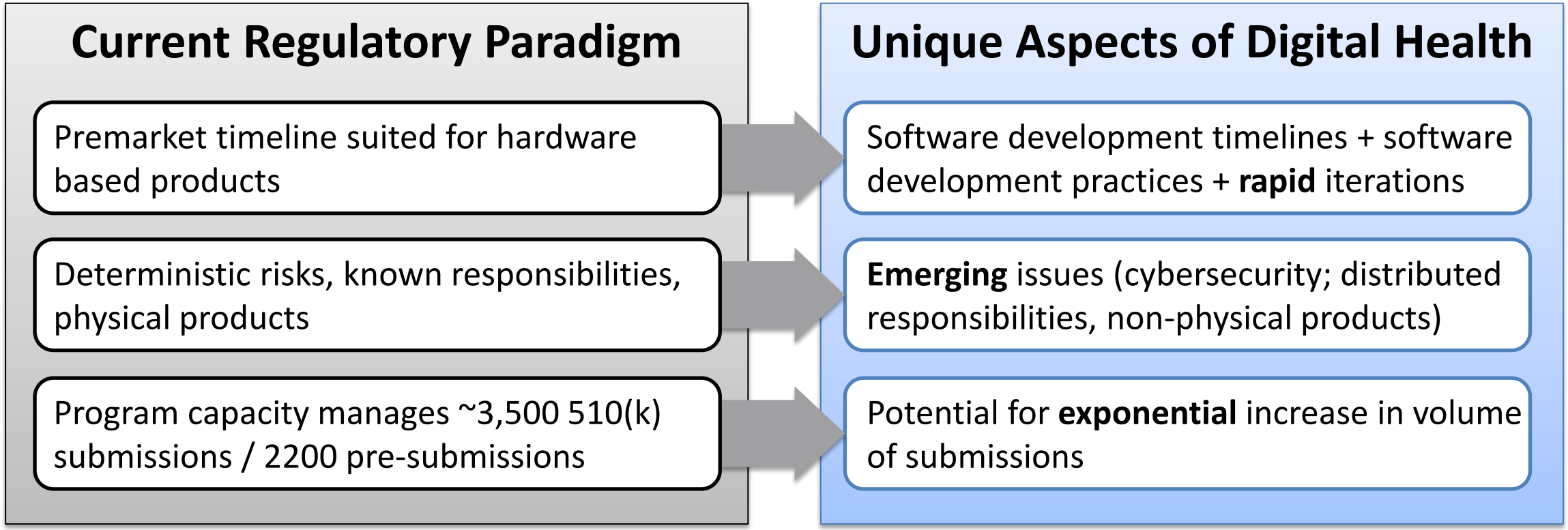
Expanding health care from the Clinic to the Patient.

Understanding patient's behavior and physiology "*In the wild*".

Focusing on prevention with early/smaller interventions.

Leveraging* computing power, sensors, connectivity *and* software *across the health care continuum.

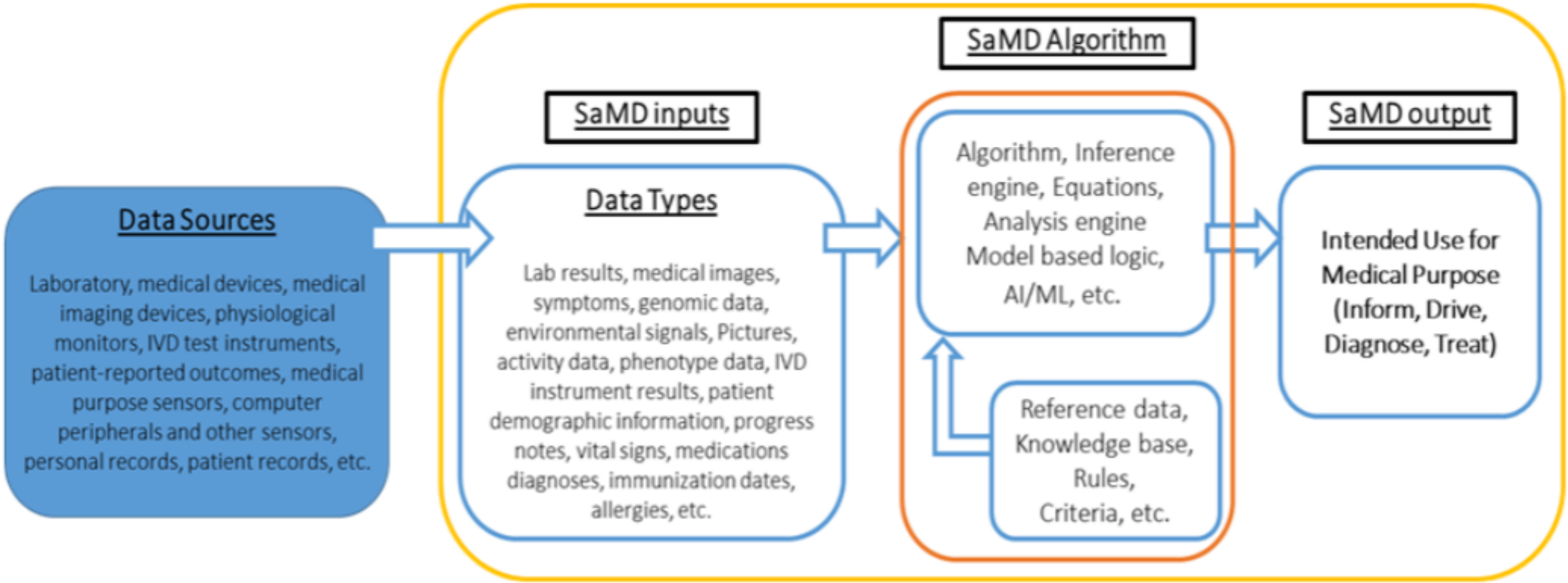
The rapidly evolving nature of digital health is sparking a paradigm shift



*Harnessing the potential of digital health tools can lead to making medical care **truly patient-centric** and to reduce healthcare costs and risks to patients.*

Focusing Initially on SaMD

"Software as a Medical Device" (SaMD) is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.[5]



FDA Pre-Cert Program

Organization-based streamlined regulatory approach for

Software as a Medical Device (SaMD) that relies on a

a demonstrated Culture of Quality and Organizational Excellence

Based on 5 Excellence Principles

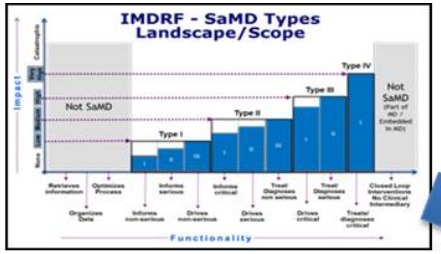
Patient Safety		Demonstration of a commitment to providing a **safe patient experience**, and emphasizing patient safety as a critical factor in all decision-making processes.
Product Quality		Demonstration of a commitment to the development, testing, and maintenance necessary to deliver SaMD products at the **highest level of quality**.
Clinical Responsibility		Demonstration of a commitment to responsibly **conduct clinical evaluation and ensure that patient-centric issues** including labeling and human factors are appropriately addressed.
Cybersecurity Responsibility		Demonstration of a **commitment to protect cybersecurity**, and 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.

Our goals for a new model

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.

A Reimagined Approach



Based on SaMD Risk + Pre-Cert level

FDA Pre-Cert level

DH FDA Pre-Cert

e.g. lower-risk software, certain modifications

Streamlined Premarket Review

Commercial Distribution & Real-World Use

Real World Data Collection

Regulatory Science

Real-World Evidence

Clinical Trials

Outcomes research

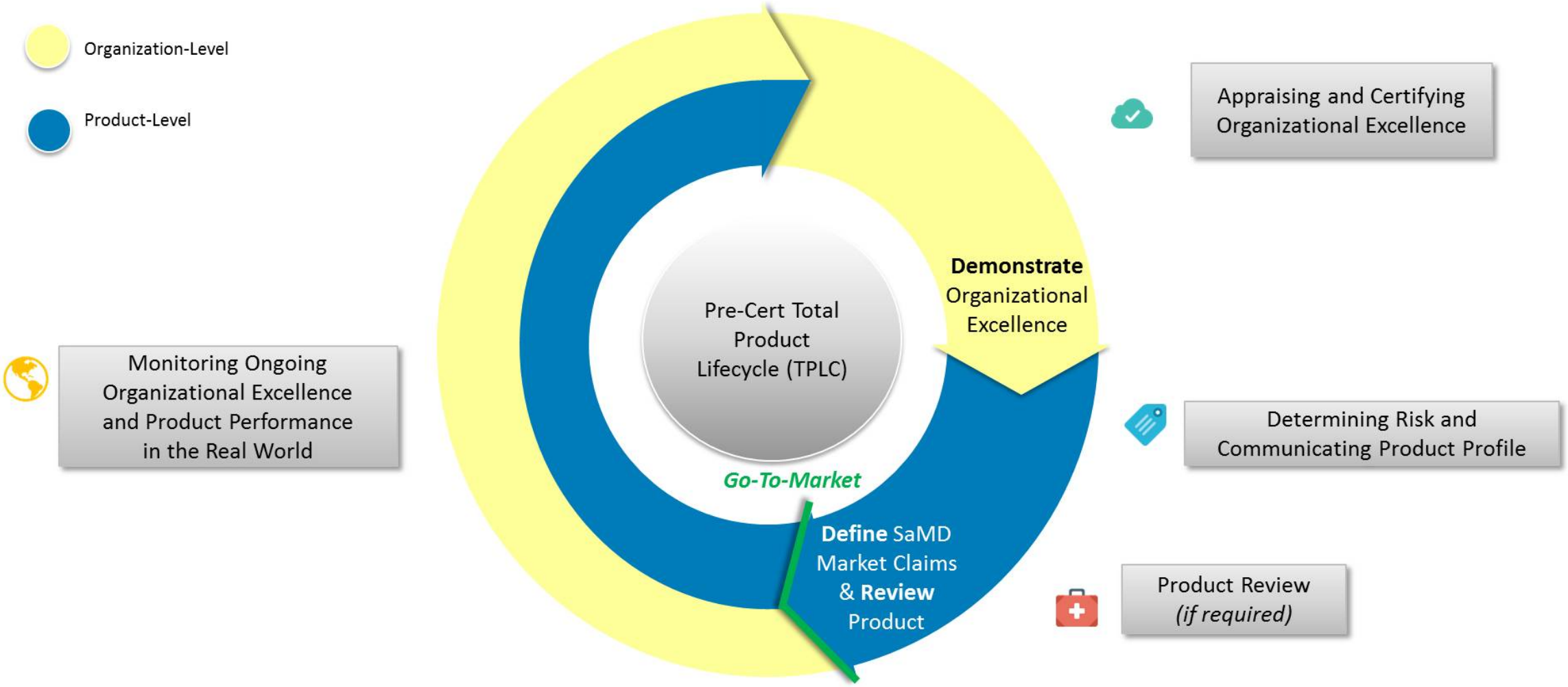
Patient Preference

DH FEEDBACK

Assessment effectiveness feedback

FDA Pre-Cert effectiveness feedback

A Least Intrusive
Ongoing Reasonable Assurance of Safety and Effectiveness



More Details on Excellence Appraisal

1. Develop the **process for precertification** of a company anc
2. Determine the **elements necessary for appraisal:**
    - Eligibility
    - Pre-Cert application
    - Appraisal
    - Pre-Cert status determination
    - Maintenance and monitoring of precertification status

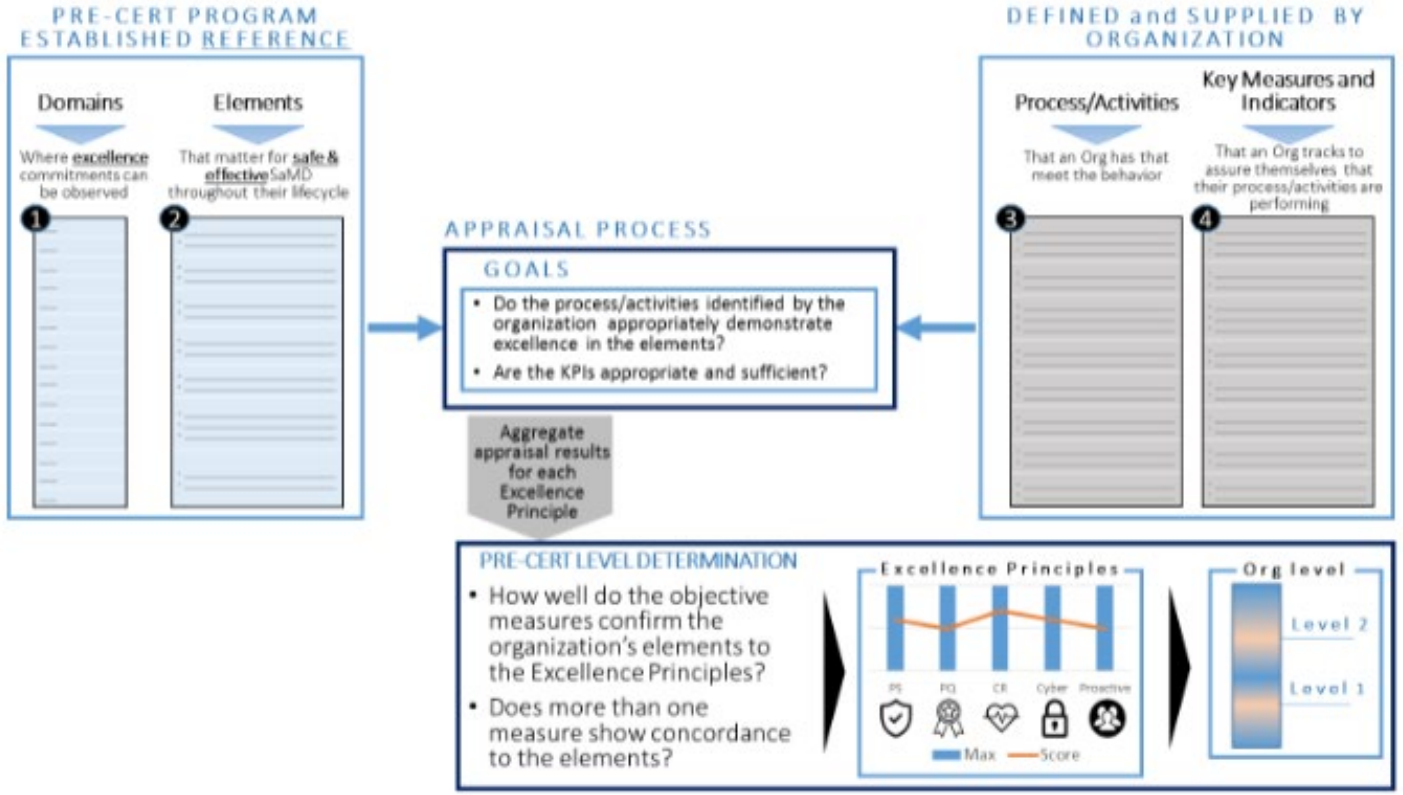
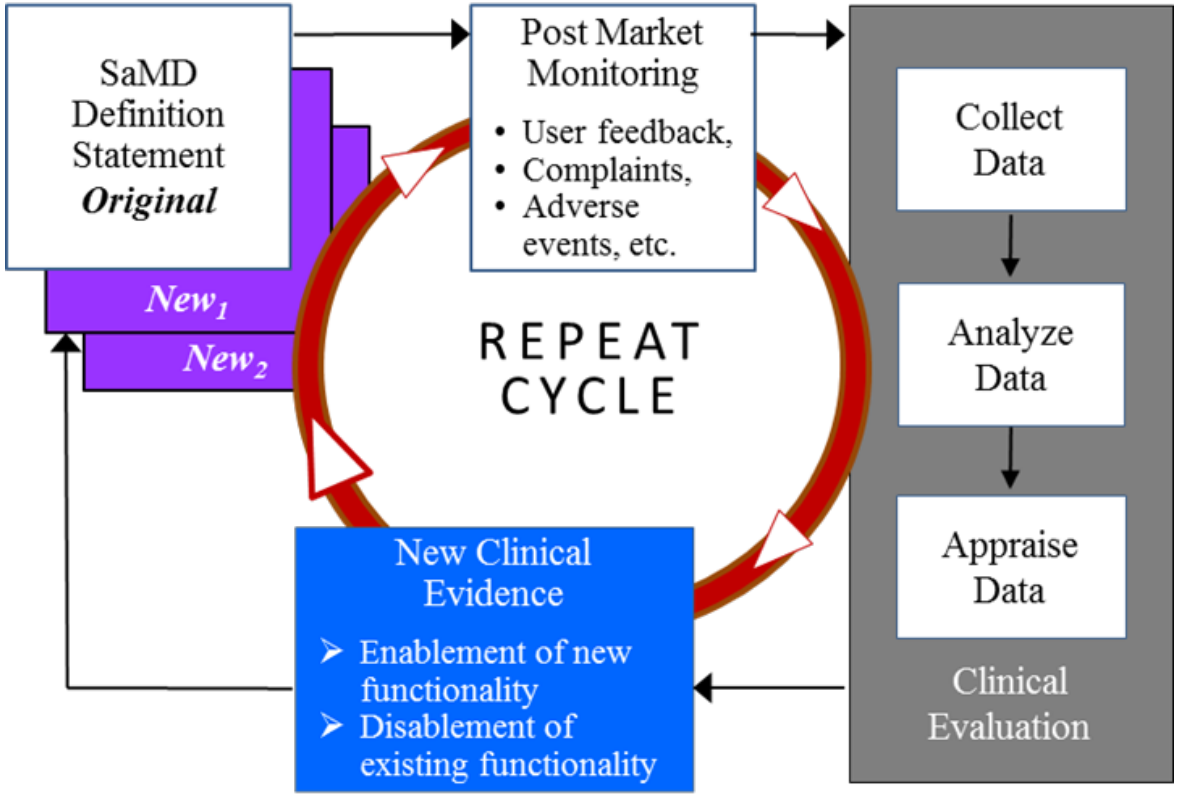


Figure 3. Conceptual Framework for Excellence Appraisal

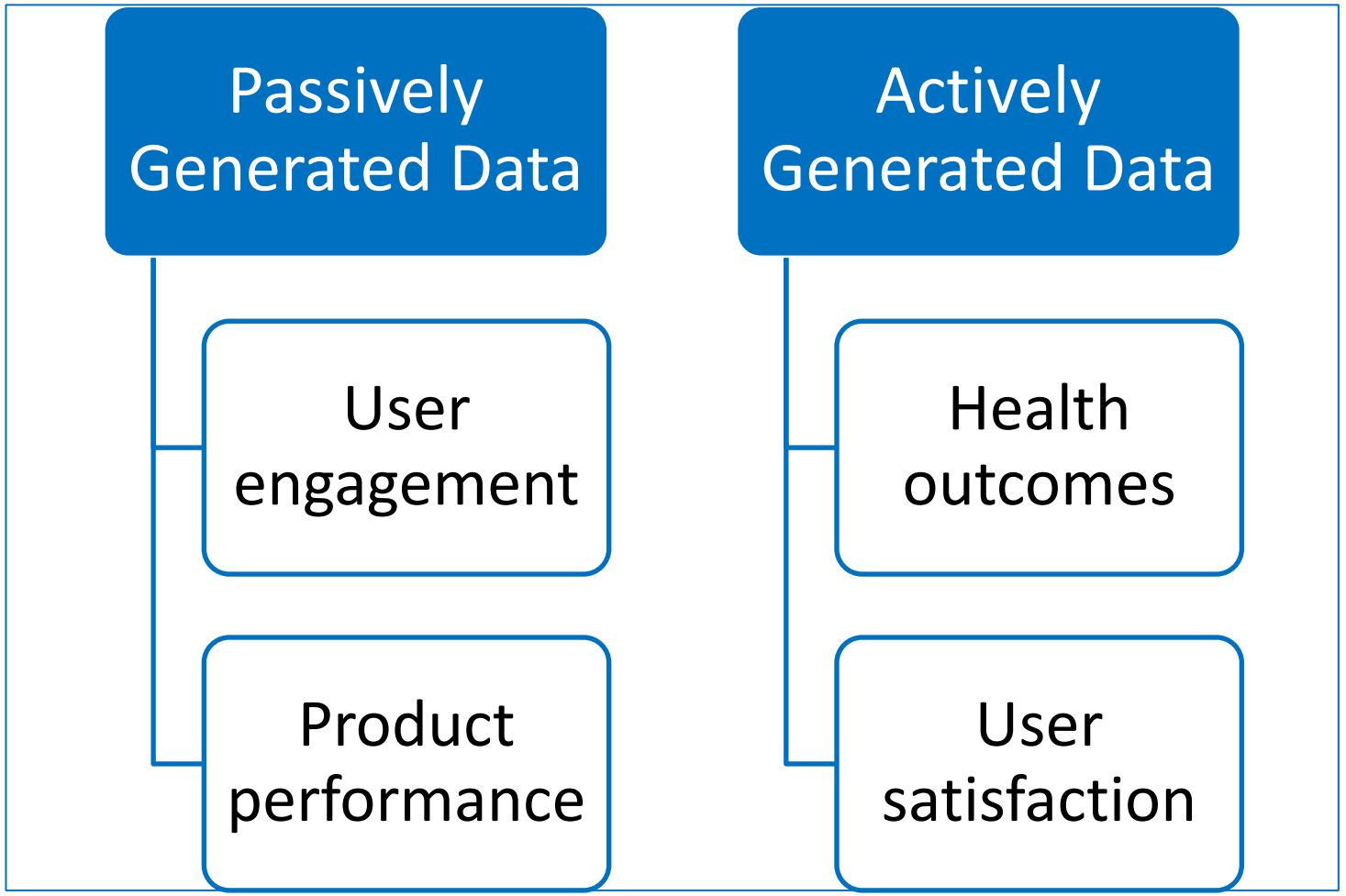
Enabling Continuous Learning from Real World Performance Data

SaMD manufacturers are encouraged to leverage SaMD's technology capability to capture real world performance data to understand user interactions with the SaMD, and conduct ongoing monitoring of analytical and technical performance to support future intended uses.



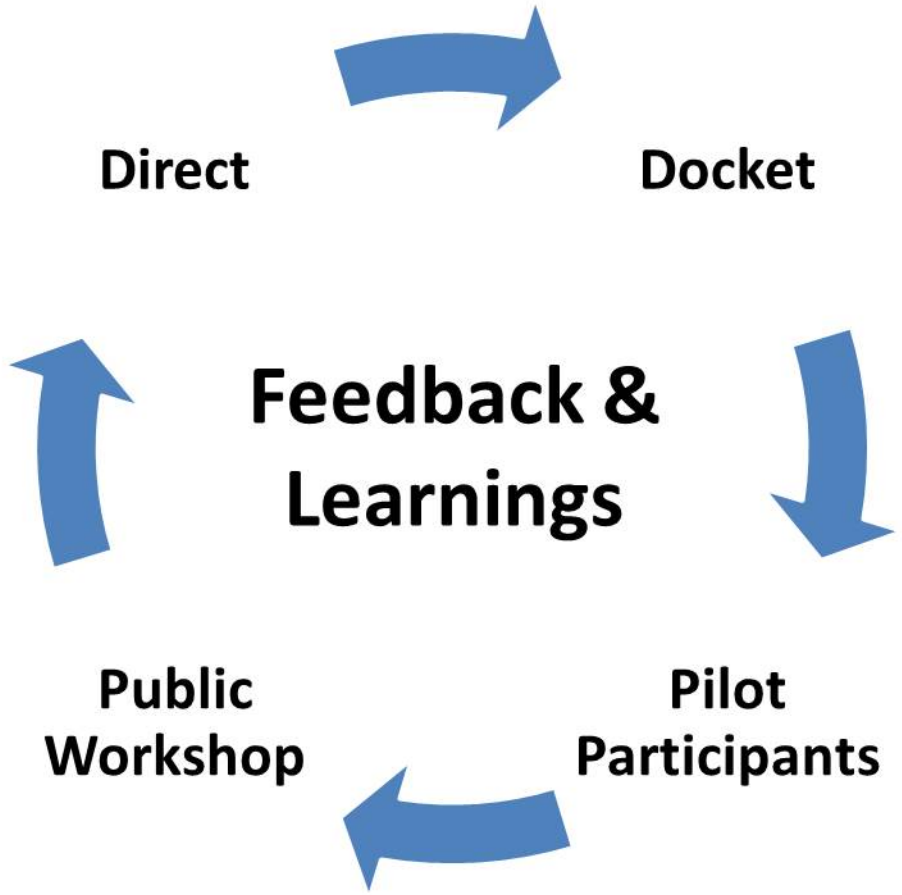
1. Additional clinical data is gathered.
2. The data may create and support new intended use(s).
3. The SaMD manufacturer will update the clinical evaluation and generate a new definition statement.
4. Then the cycle repeats.

Types of data generated by sensor-based digital health products



Building the Program with Continuous Public Input

- Release working model updates throughout 2018, with each update **incorporating comments and learnings**.
  - April 2018: Working Model v0.1 released
  - June 2018: Working Model v0.2 released
  - Dec 2018 / Jan 2019: Working model v1.0 scheduled release
- Focus on being **collaborative** and **transparent**
- Ensure development process meets federal guidelines:
  - Federal Advisory Committee Act (FACA)
  - Paperwork Reduction Act (PRA)
  - Federal Register



Our Most Recent Working Model Release

Working Model v0.2 – June 2018

- Clearly stated **program vision** and **goals**.
- Clarity on who is **eligible** for precertification and which product type review pathways are the **focus** for 2019.
- Outline of **each program component**:
  - *Excellence Appraisal*
  - *Review Determination*
  - *Streamlined Review*
  - *Real World Performance*
- Description of **interdependencies** between components.
- Noted where we incorporated comments.

Looking Ahead: Our Next Release

- **Next release** anticipated for December 2018 or January 2019
- Release will include
    - **Working Model v 1.0**:
        - Refine and clarify program components and intersections
        - Respond to and incorporate comments from the federal register
    - **Test Plan** for Phase 2 of the pilot:
        - A plan to confirm that products reviewed via the software precertification program maintain the same level of safety and effectiveness as products reviewed via the traditional pathway.

Pre-Cert Roadmap

Overall Roadmap

2017 – Select pilot participants; develop program timeline

2018 – Develop a working model **collaboratively** with public input

- ✓ Year-long: Receive and review docket comments
- ✓ April: Released Working Model v.1
- ✓ June: Released Working Model v.2
- ❑ December (or Jan '19): Release Working Model v1.0; and Test Plan for phase 2 of the pilot.

2019 – Phase 2 of pilot

- ❑ Midpoint Update
- ❑ December: Release Working Model v2.0

Work to Complete in 2018 and 2019

Now thru December 2018

- → Incorporate comments from public docket
- → Finalize specifics for phase 2 of the pilot
- → Release working model v1.0

Throughout 2019

- → Conduct excellence appraisal using the criteria and methodologies designed in 2018.
- → Conduct streamlined review and provide premarket authorization based on current authorities.
- → Create mechanisms to access real world performance data from pilot participants, perform analysis, and identify benefits and risks of SaMD products.
- → Refine or confirm types of SaMD products that require review prior to marketing.
- → Work with pilot participants to quickly correct adverse events related to products cleared through the model.
- → Transparently share test results with the public and ongoing revisions to the model.

Q&A

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