DIGITAL HEALTH

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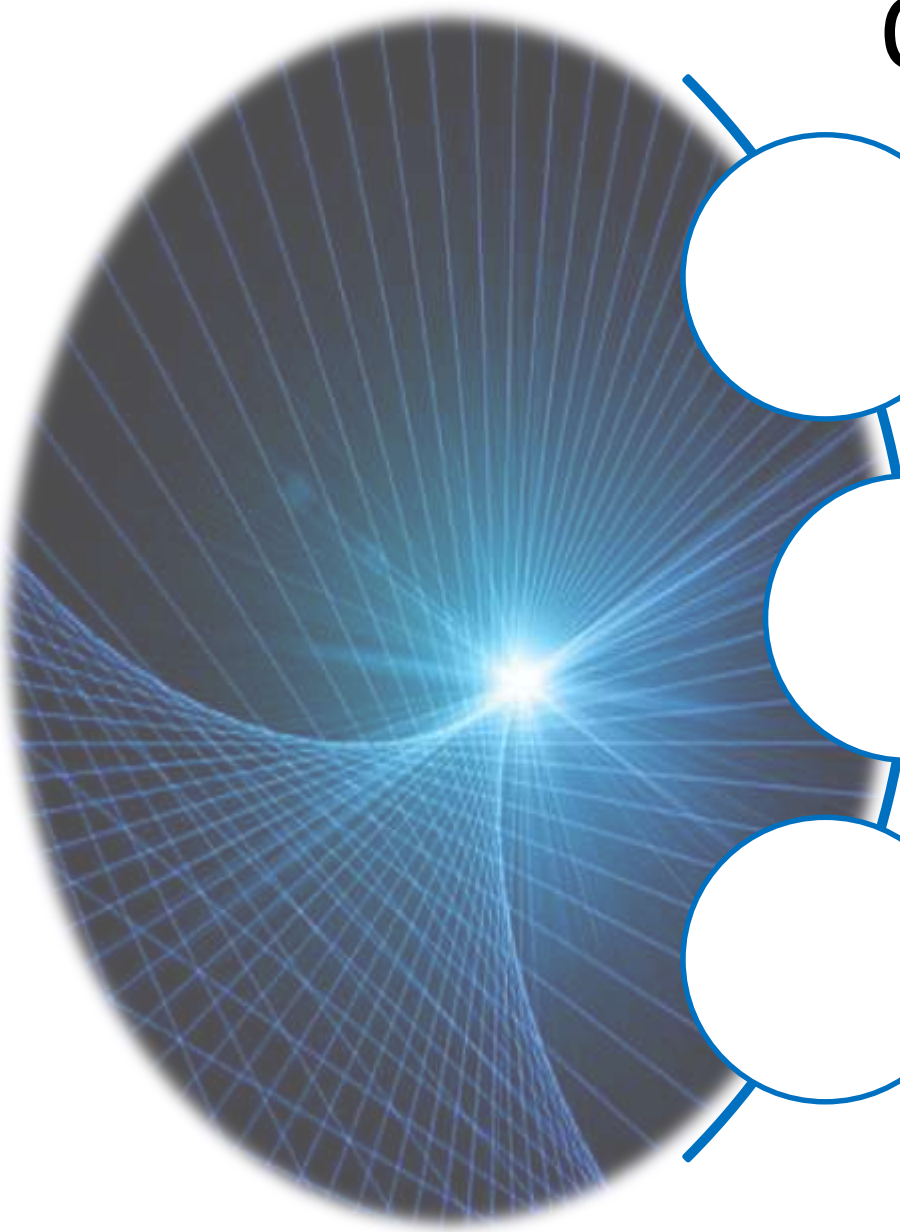
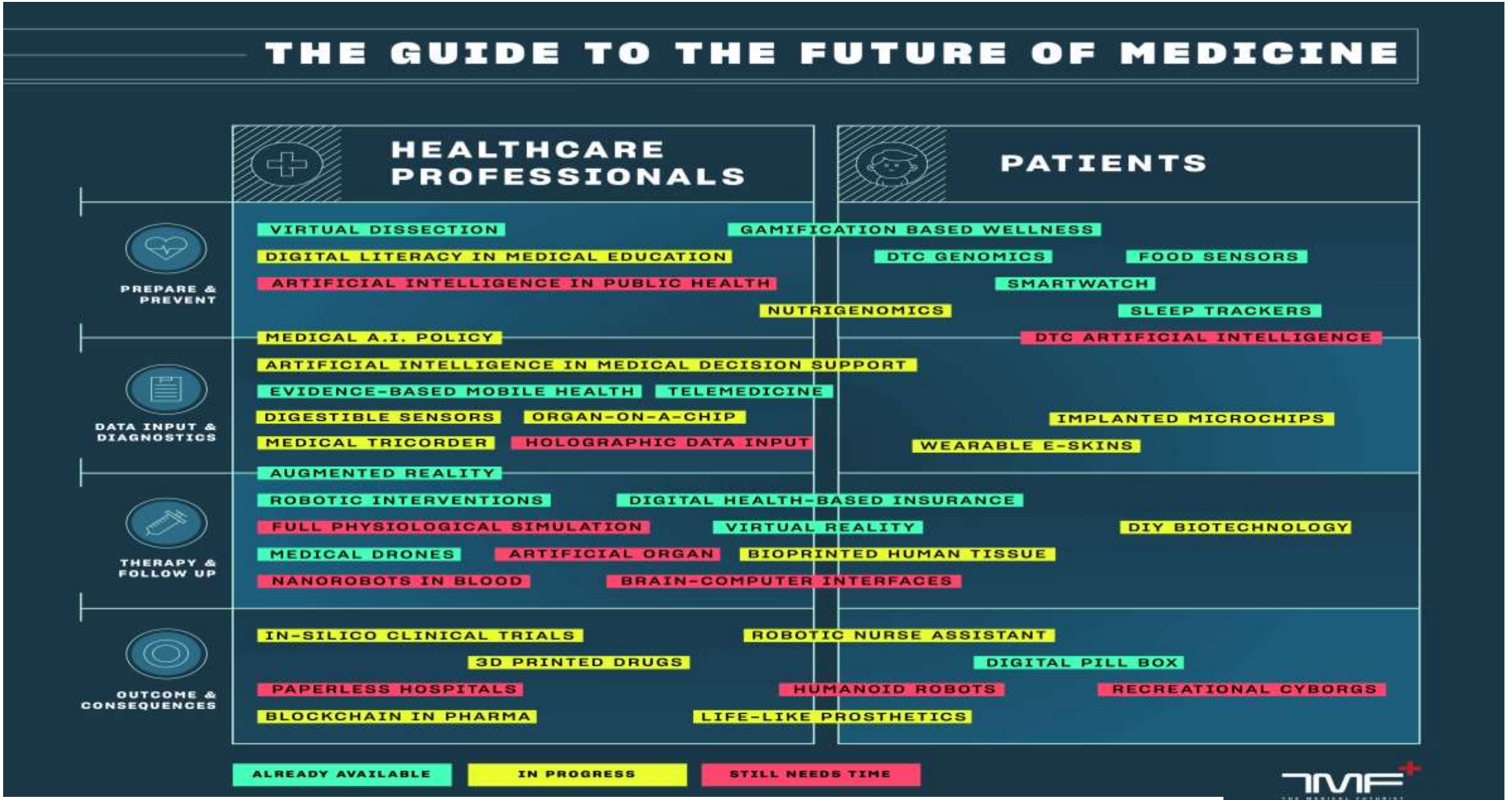
Overview



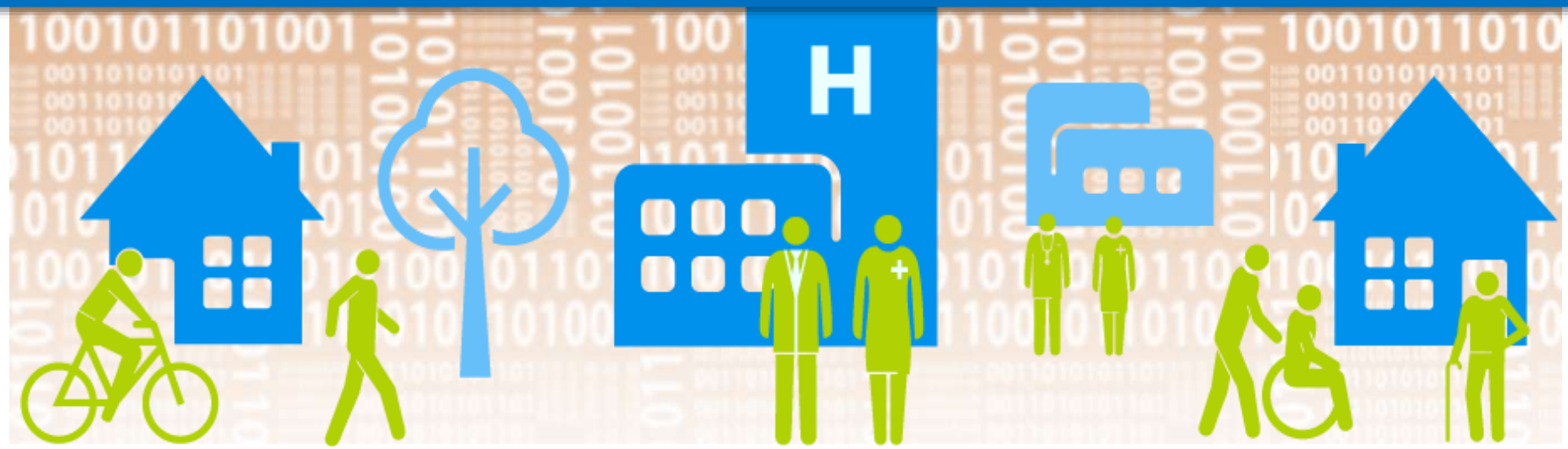
- What is Digital Health?
- Current Digital Health Activities
- Potential Needs to Advance Science



Source: https://medicalfuturist.com/what-would-make-every-doctor-use-digital-health/

Digital Health

The convergence of connectivity, data and computing power for healthcare and related uses across the life of an individual or a patient.



Healthy living | Prevention | Diagnosis | Treatment | Recovery | Home care

Moving healthcare from the clinic to the patient.

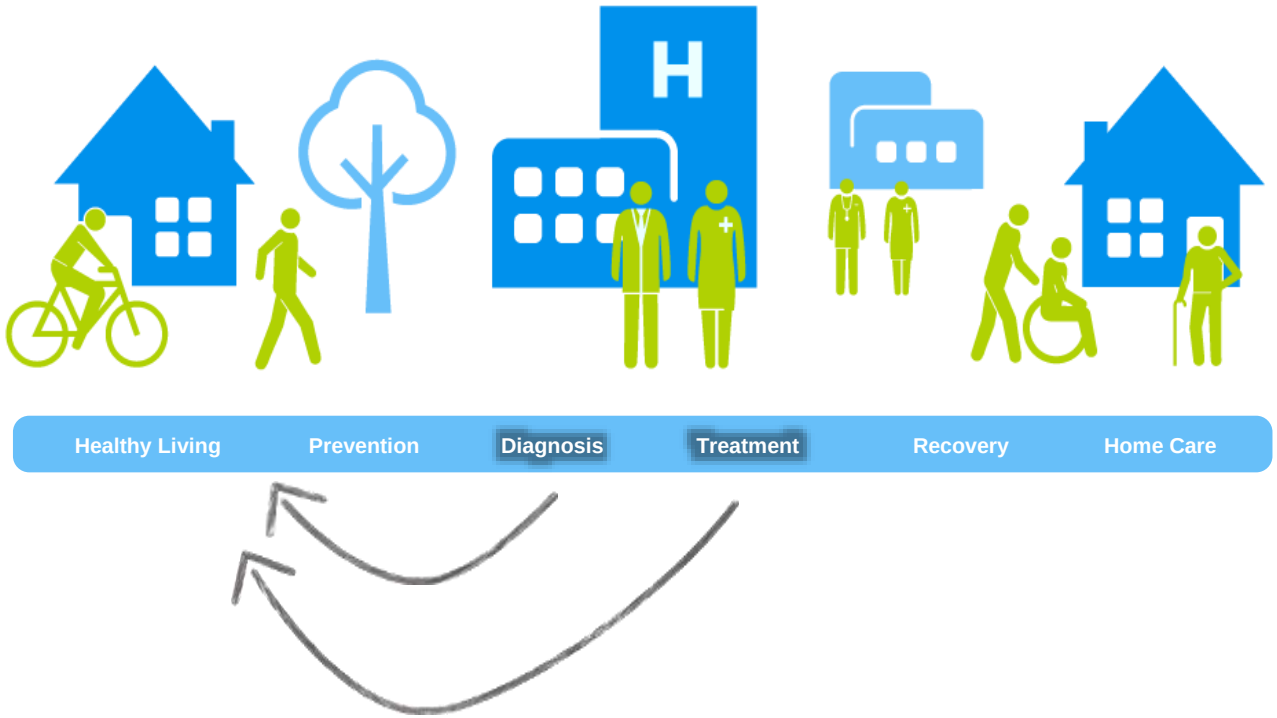
Understanding patient's behavior and physiology *"in the wild."*

Focusing on prevention for early/smaller interventions.

Leveraging **computing power, sensors, connectivity,** *and* **software.**

Tech allows for early and smaller interventions which can be:

1. Less costly
2. Less Invasive
3. Potentially change the course of a disease before it's onset



Digital Health Technology

Healthy living | Prevention | Diagnosis | Treatment | Recovery | Home care

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

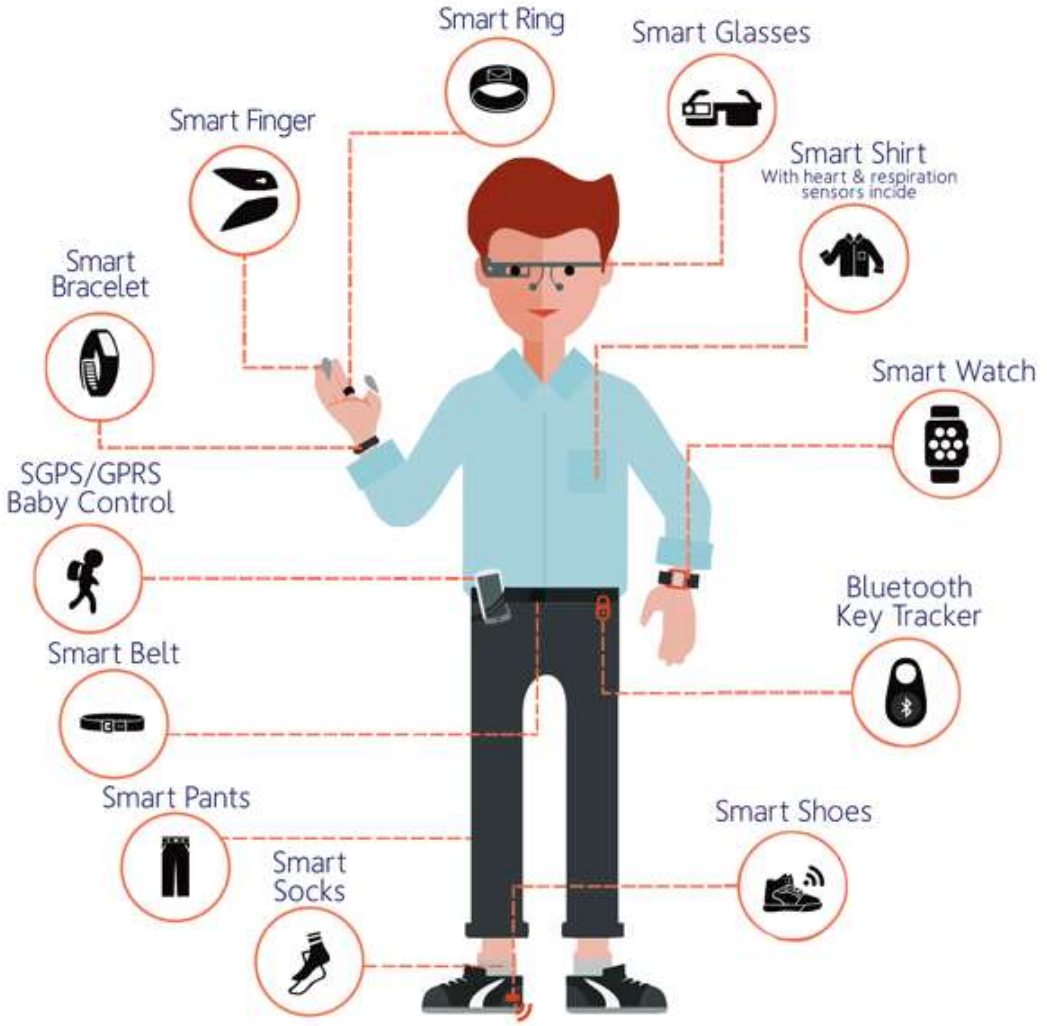

Used to study a medical product


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

Digital Health Solutions

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?

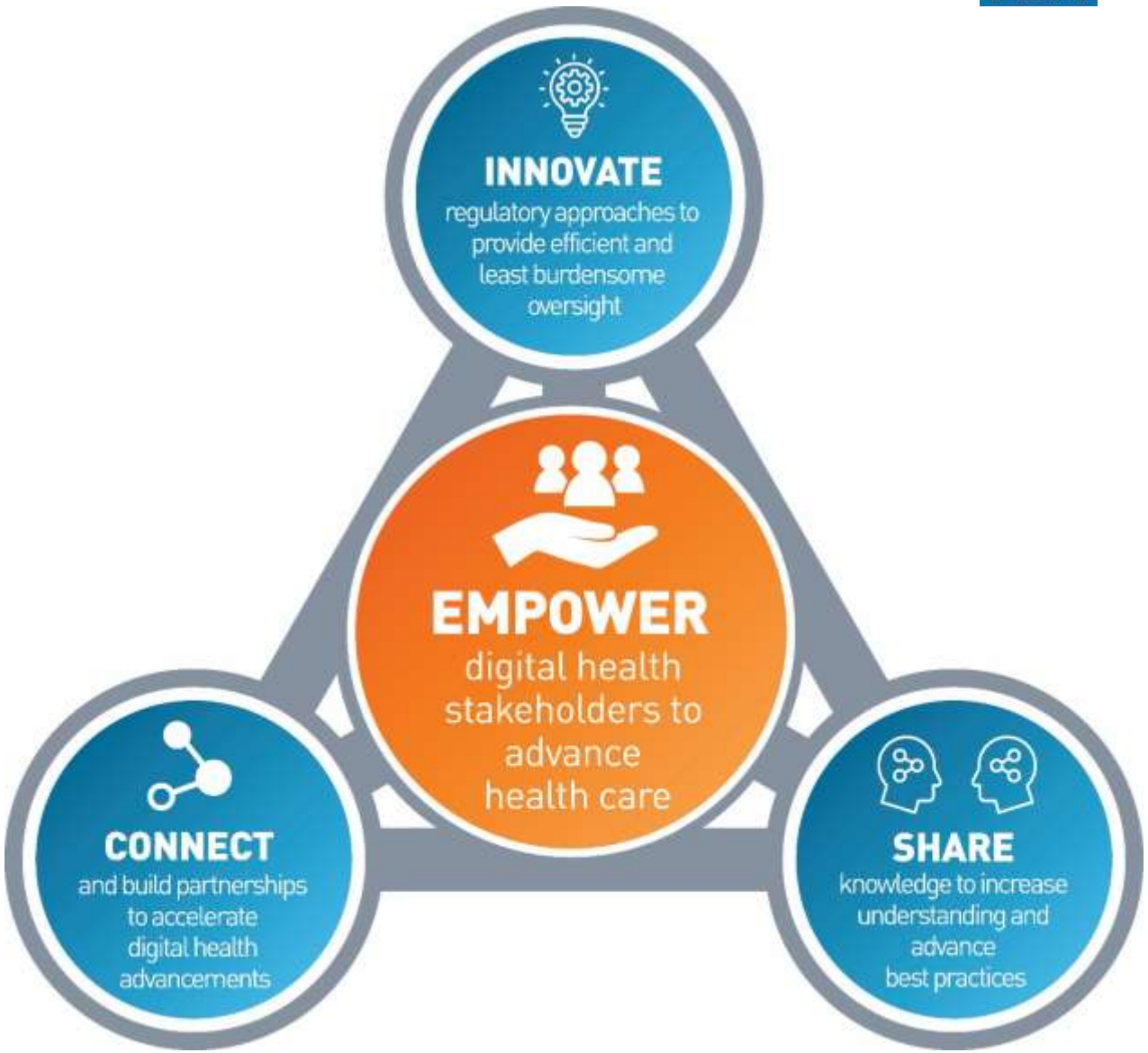
FDA's Digital Health Center of Excellence

Empowering All to Advance Healthcare

Our goal: Empower stakeholders to advance health care by fostering responsible and high-quality digital health innovation that meets FDA standards of safety and effectiveness.

The Digital Health Center of Excellence aims to:

- **Connect and build partnerships** to accelerate digital health advancements.
- **Share knowledge** to increase awareness and understanding, drive synergy, and advance best practices.
- **Innovate regulatory approaches** to provide efficient and least burdensome oversight .



Current Areas of Focus

Software as a medical device (SaMD)	Artificial Intelligence/ Machine Learning	Wearables	Software in a medical device (SiMD)	Wireless Connectivity
Interoperability	Medical Device Cybersecurity	Virtual Reality/ Augmented Reality	Real-world Evidence and Advanced Clinical Studies	Advanced Manufacturing
	Patient-Generated Data	Digital Biomarkers	Digital Pathology	

Digital Health Center of Excellence Roadmap

Following is our roadmap for bringing the benefits of digital health to all Americans, efficiently and collaboratively:

Raise Awareness and Engage Stakeholders

Phase I: Communication

Fall 2020

- Stakeholder Listening Sessions
- Update and develop resources for FDA staff
- Begin operationalizing the DHCoE and outcome measurement
- Amplify current work being done at FDA in digital health

Build Partnerships

Phase II: Coordinate

Fall and Winter 2020

- Build strategic partnerships for policy, regulatory science, and fellowships
- Develop resources for external stakeholders
- Create a digital health community of practice
- Assemble FDA and CDRH advisory groups

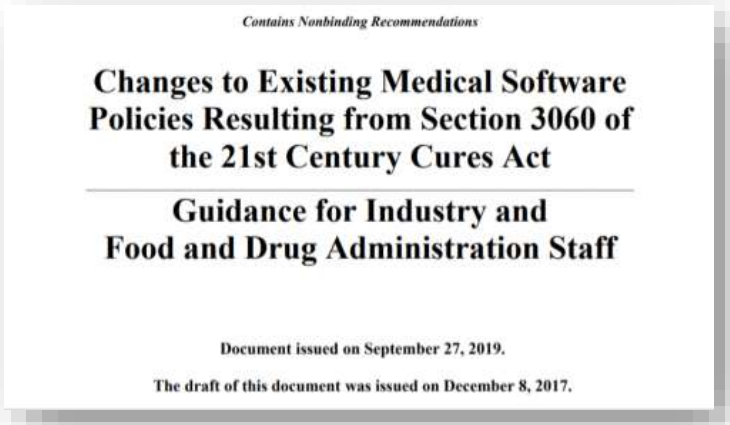
Build and Sustain Capacity

Phase III: Amplify

Winter 2021 onwards

- Continued strategic partnership building and communication
- Update and implement regulatory framework for digital health
- Harmonization with other regulators

Guidances Interpret Cures Act (520(o))



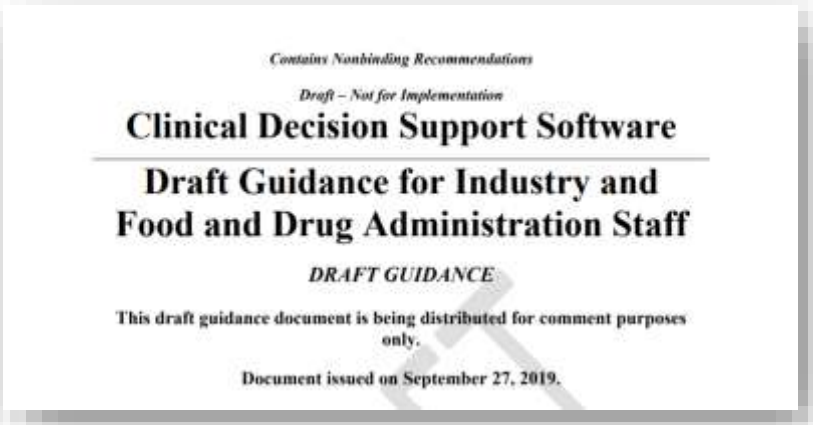
Contains Nonbinding Recommendations

Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 27, 2019.

The draft of this document was issued on December 8, 2017.



Contains Nonbinding Recommendations

Draft – Not for Implementation

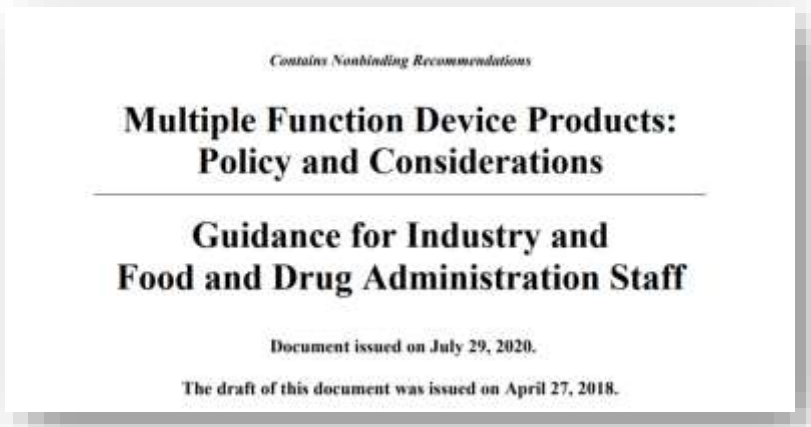
Clinical Decision Support Software

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on September 27, 2019.



Contains Nonbinding Recommendations

Multiple Function Device Products: Policy and Considerations

Guidance for Industry and Food and Drug Administration Staff

Document issued on July 29, 2020.

The draft of this document was issued on April 27, 2018.

Administrative Support

General Wellness

Electronic Patient Records

Transfer, store, convert formats, display

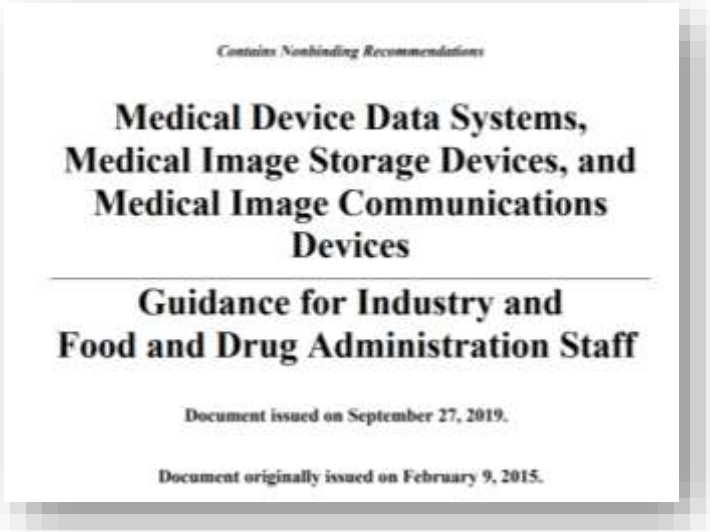
Decision support software intended for healthcare professionals

Risk-based policy for device-CDS, including those intended for patients

Regulation and assessment of software products that contain multiple functions

Guidance applies to ALL medical devices (including hardware-based)

Final Guidances – Cures Act



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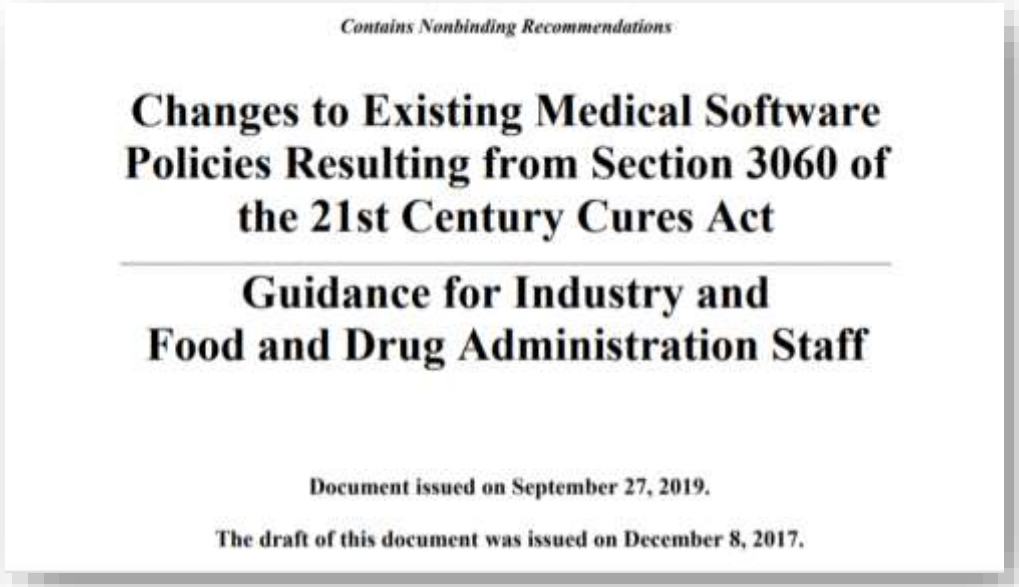
Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 27, 2019.

Document originally issued on February 9, 2015.



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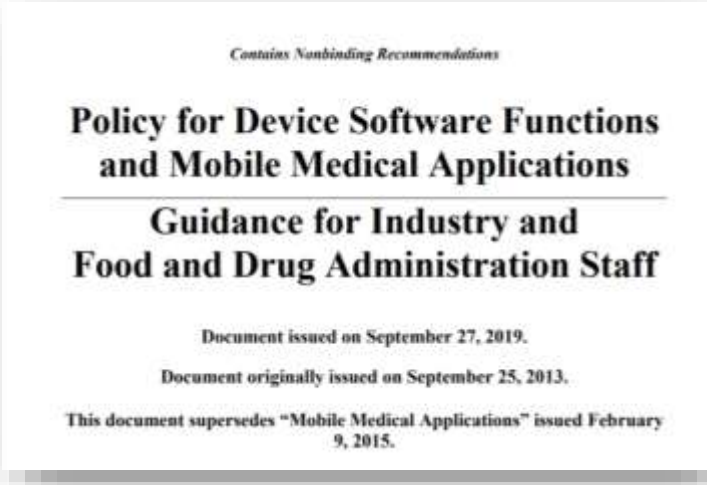


Contains Nonbinding Recommendations

Policy for Device Software Functions and Mobile Medical Applications

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 27, 2019.

Document originally issued on September 25, 2013.

This document supersedes "Mobile Medical Applications" issued February 9, 2015.

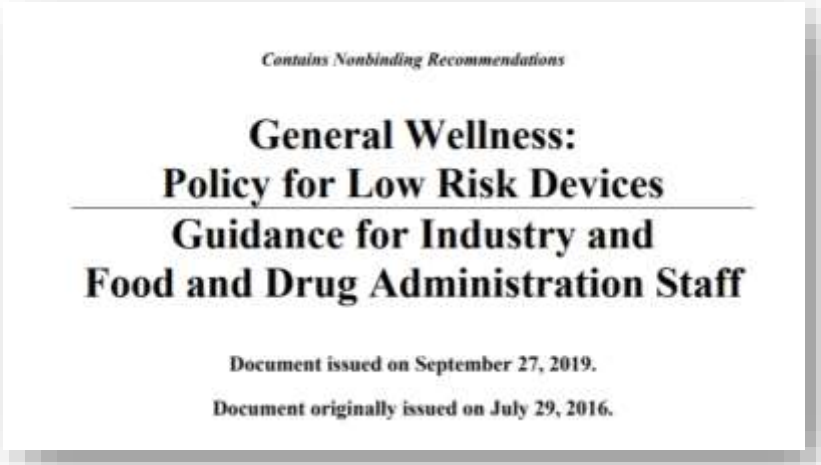
Contains Nonbinding Recommendations

Off-The-Shelf Software Use in Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 27, 2019.

Document originally issued on September 9, 1999.



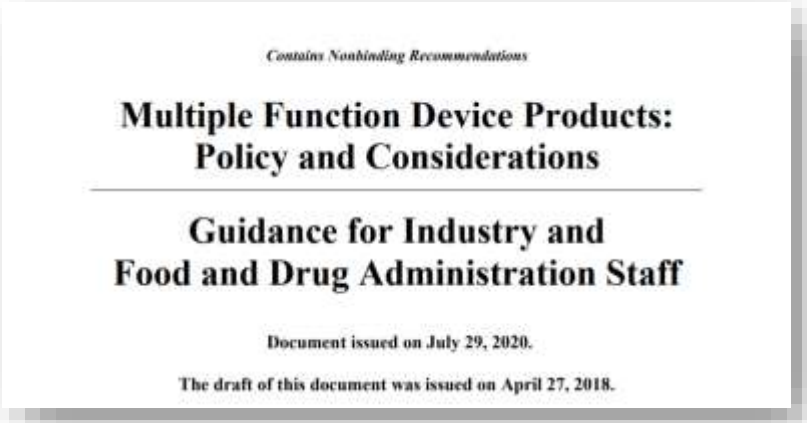
Contains Nonbinding Recommendations

General Wellness: Policy for Low Risk Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 27, 2019.

Document originally issued on July 29, 2016.



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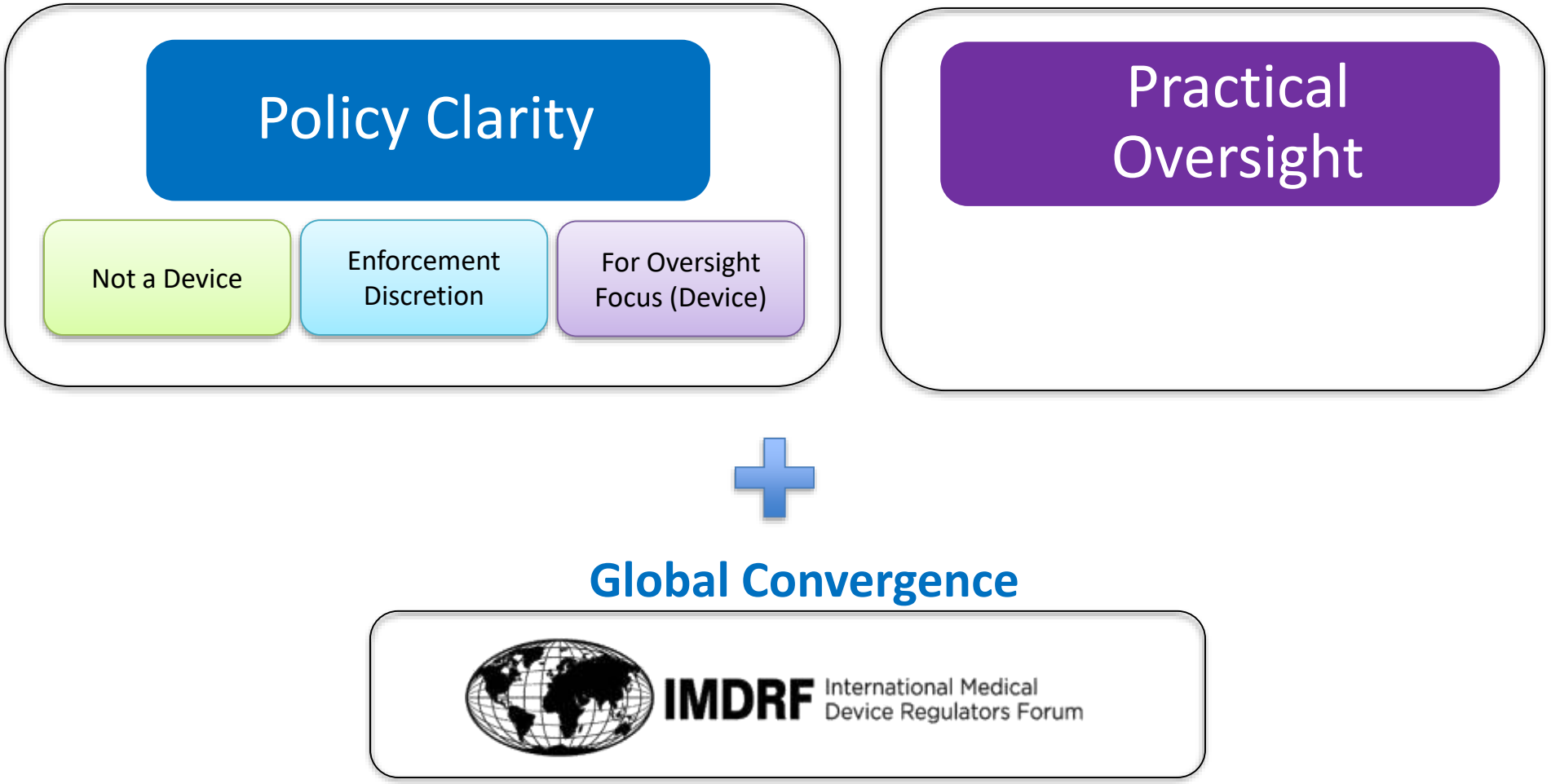
Digital Health Policies Related to COVID-19

- Cites examples of software functions that are not regulated as medical devices that may be useful in the response to COVID-19.
- Cites examples of lower-risk device software functions for which the FDA does not intend to enforce requirements.
- Clarifies how manufacturers of higher-risk digital health devices that are outside the FDA's COVID-19 policy may leverage the Emergency Use Authorization Process.

See Digital Health Policies and Public Health Solutions for COVID-19

Domains of Digital Health Work



The Need for a Tailored Approach

Current Device World		Evolving Digital Health Device World
Product Development Timeline • Months to years + • Less frequent modifications	→	*Weeks to months +* (incremental, iterative) and potentially *frequent modifications*
Postmarket Data • Limited availability and access to real world data (522, PAS, MDRs, MedSun)	→	*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)	→	*Potential for **exponential** increase in volume of submissions*

Getting Ready for the Digital Future

Goals for a Tailored Regulatory Framework

- 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

Move from

episodic oversight to

continuous oversight

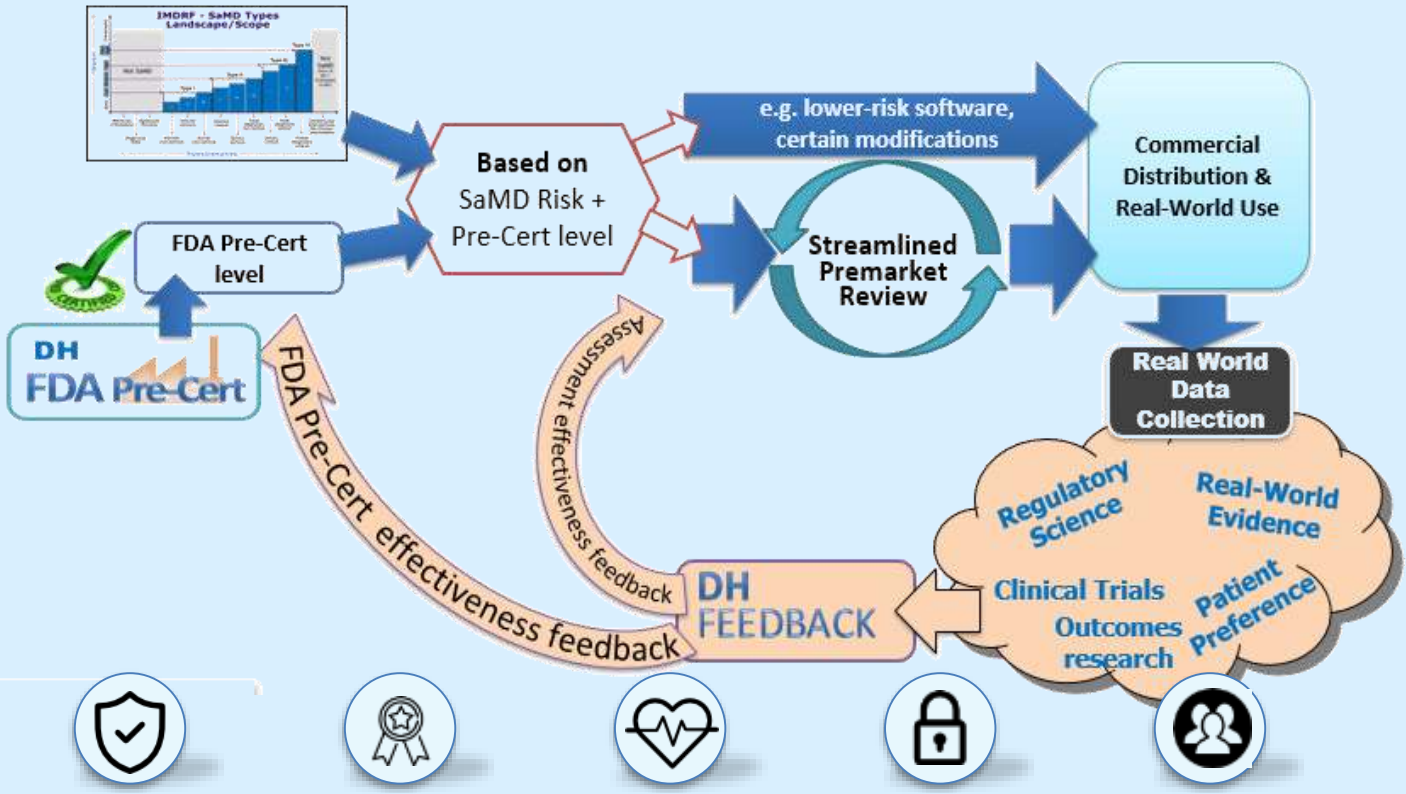
that **enables trust**

in the organization using a

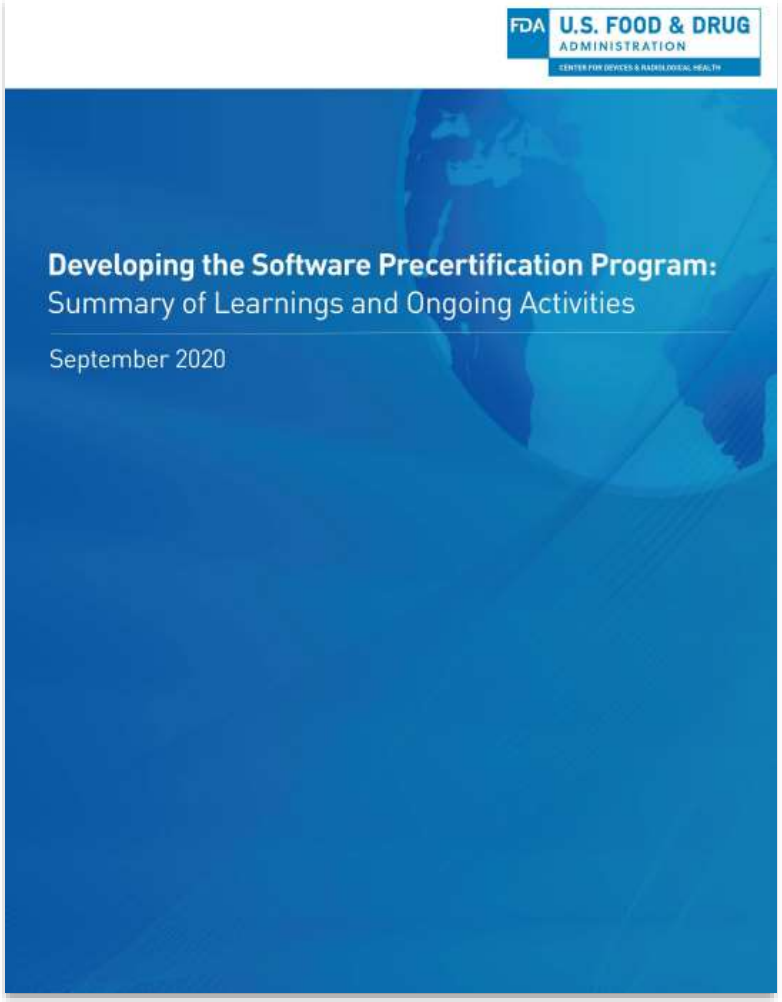
pragmatic check-in with

real-world performance

data.

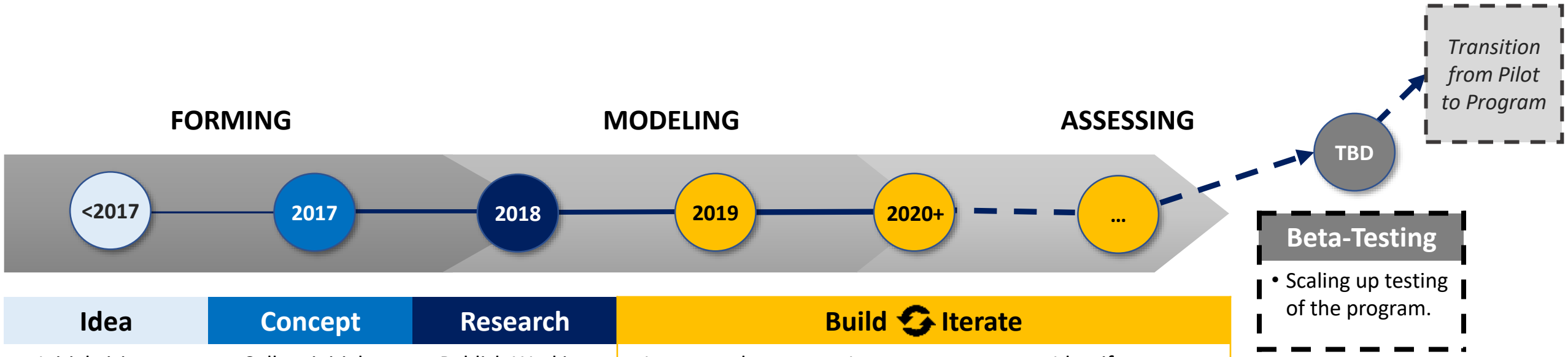


2020 Update on “Pre-Cert”



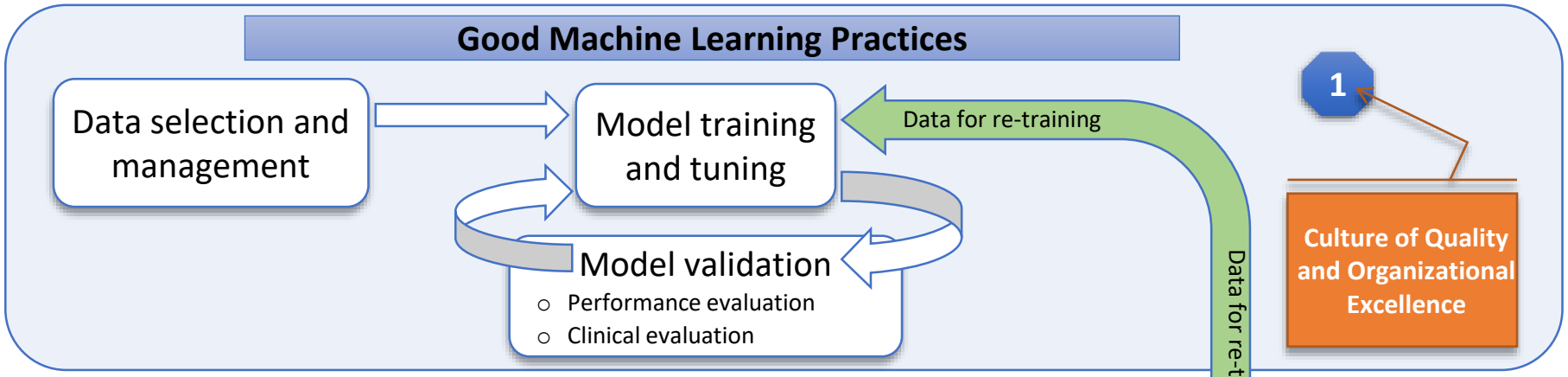
- Released 2020 Update on Software Precertification (Pre-Cert) Program in September 2020.
- Highlights learnings to date from the ongoing building / testing of the Pre-Cert Program.
- Depicts phases of Program development.
- Outlines how Pre-Cert is leveraging learnings for the next iteration of testing including simulations.

Development Phases for Pre-Cert



Idea	Concept	Research	Build Iterate		
• Initial vision on how Pre-Cert would create value with a lens towards patient safety and digital health innovation.	• Collect initial insights from stakeholders • Select 9 pilot participant companies to help inform development.	• Publish Working Model, v0.1 for public input from stakeholders. • Iterate Working Model with public input	• Iterate and publish Working Model, v1.0 and Test Plan. • Expand stakeholder test cases to help test for a reasonable assurance of safety and effectiveness.	• Integrate Program workstreams, iterating to a Total Product Lifecycle (TPLC) approach. • Develop objective measures.	• Identify infrastructure needs for statutory authority.

FDA's Proposed TPLC Approach Overlaid on AI/ML Workflow



Legend

- AI Model Development
- AI Production Model
- Proposed TPLC Approach
- AI Device Modifications

Artificial Intelligence / Machine Learning

Background

FDA published a Discussion Paper on April 2, 2019 seeking early stakeholder input on a potential regulatory approach to medical devices that use artificial intelligence ("AI") and machine intelligence ("ML"). A statement from then Commissioner Scott Gottlieb, M.D., outlined the following goals for a new, tailored review framework:

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

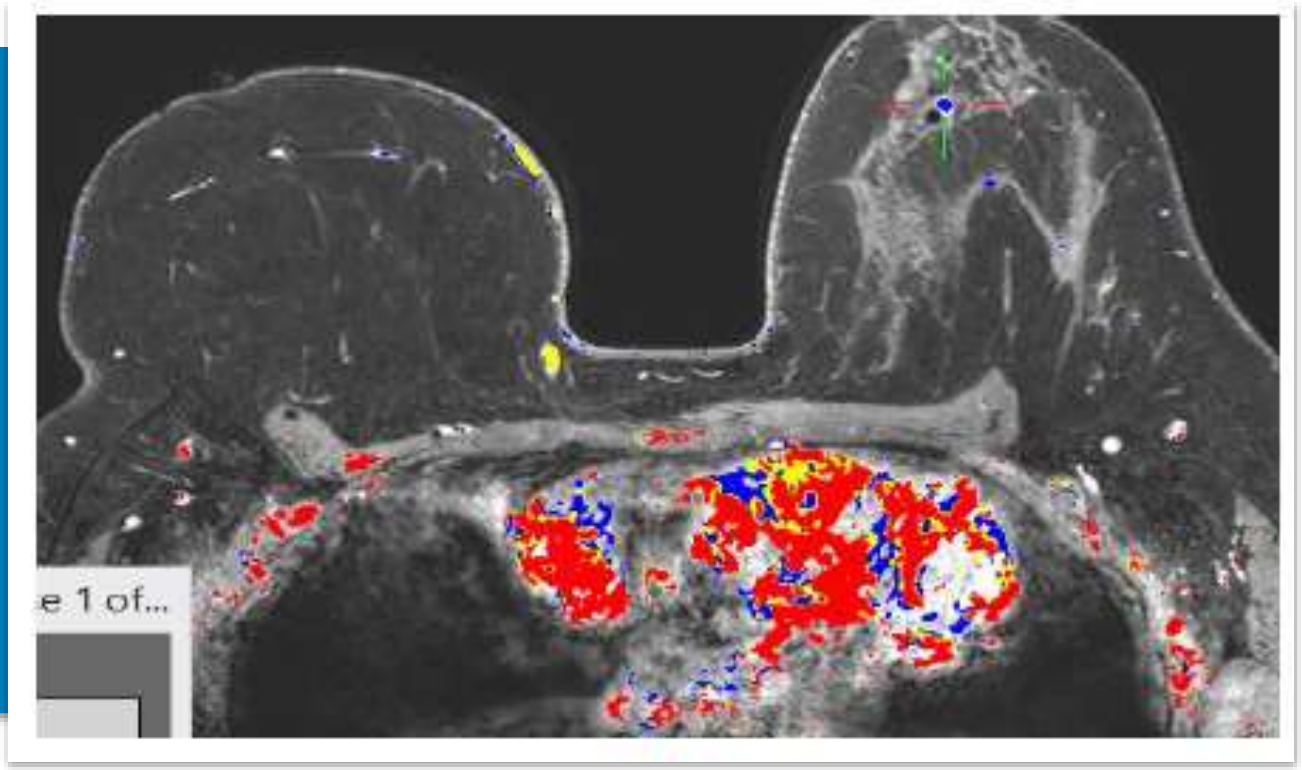
979 Comments Received To Date

Summary of Comments

- General support for idea of Good Machine Learning Practices (GMLP)
- Outline what a Real-World Performance plan looks like for AI/ML-based SaMD
- Calls for FDA to encourage harmonization through consensus standard efforts
- Received lots of suggestions on proposed ACP/SPS and Focused Review content
- Received suggestions for additional modification categories
- Calls for FDA to support a public-facing policy on transparency

AI/ML-Based Medical Devices: Challenges

- Need for large, high-quality, well-curated data sets
- Explain-ability of these "black box" approaches
- Identifying and removing bias



QuantX

Open Questions

Coexistence of multiple products in rapidly evolving conditions—for example, rapid approval of DH products for EUA considerations—how to ensure RASE when our current review paradigm is blind to presence of other products in the real-world.

Hidden bias in AI can negatively impact decision-making. But transparent bias (e.g. tuning a model trained on a national population to align with local factors) can improve personalized medicine and have lessons for tweaking national models.

- How can we used biased AI/ML to improve our decision-making?
- How can we use digital health approaches to address knowledge gaps related to co-morbidities and poly-pharmacies.
- Opportunities for standards creation:
  - To ensure interoperability within the complete ecosystem: EHR, Clinical Devices, Personal devices?
  - Ensure safe and effective autonomous AI systems in healthcare?

Opportunities and Challenges

Identifying key measures at an individual and ensemble level

Enabling user-centric labeling

Developing a common vocabulary for connecting data

Decision-making between multiple AI systems with competing interests

Consumer technology in healthcare and clinical trials

Longitudinally learning AI systems as digital clinical trials

Get More Information

www.fda.gov/digitalhealth

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