EMERGING DIGITAL HEALTH TECHNOLOGIES

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Increasing digitization across the healthcare continuum

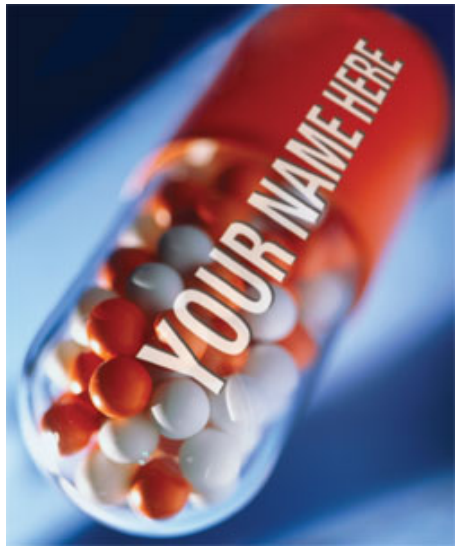
Moving health care from the clinic to the patient.

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

Focusing on prevention for early/smaller interventions.

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

Wide range of products under the broad label of digital health technologies



FDA regulation of digital health products

- Tailored, risk-informed regulatory oversight

- FDA oversight limited to digital health products that meet the definition of a medical device
  - Recent legislation excluded medical device data systems and general wellness apps from definition of a medical device

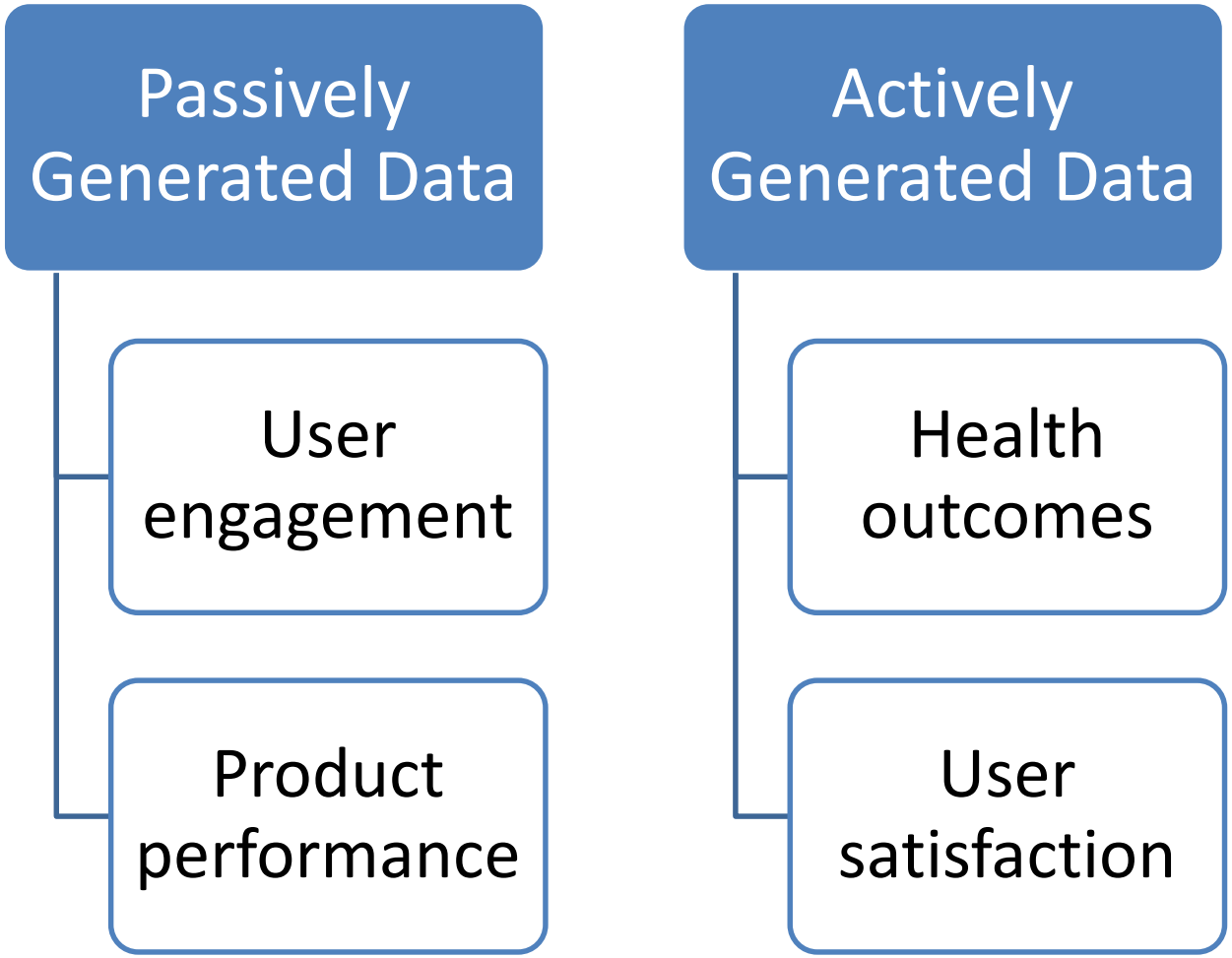
- Focus on digital health products that may pose a risk to patient safety if the product does not function as intended
  - Enforcement discretion for lower-risk mobile medical applications and decision support tools

Sensor-based digital health medical devices

Considerations for Sensor Design

- Location of use and intended duration of use
- Device storage capacity and connectivity
- Frequency of updates – OS, sensor, algorithm
- Feedback to the device user

Types of data generated by sensor-based digital health products



Sensor Data Considerations

Analytic Validity

- Are the data reproducible?
- Are the data accurate?
- Are the data precise?

Clinical Validity

- Is the sensor capturing a clinically meaningful outcome?
- Does the sensor output have a reliable relationship to a “gold standard” measurement?

The digital health paradigm shift

Current Regulatory Paradigm	Digital Health Paradigm Shift
Lengthy premarket development of a final product	**Rapid** premarket development, frequent iterations
Passive postmarket surveillance (522, PAS, MDRs, MedSun)	Software capable of **actively tracking and analyzing** data from all users
Stable program volume: ~3,500 510(k) submissions / 2200 pre-submissions	Potential for **exponential** increase in volume of submissions

Goals of harnessing digital health sensor data

Develop benchmarks and standards for emerging technologies

Generate clinical evidence to support public health interventions through the development of patient-driven registries

Provide insight into real-world digital health product performance

Foster continuous improvement of digital health medical devices by incentivizing manufacturers to collect a range of real-world data types

Challenges to harnessing digital health sensor data

Privacy

Do patients get to control how and when their data are used?

Security

Is there a process to ensure that patient privacy is protected? Can data be accessed or manipulated by third parties without consent?

Interoperability

Can data from one device be understood by another, so that data from multiple sources can be pooled?

Data Integrity

Are the data generated by sensors reliable? Accurate? Is any data missing?

Generalizability

Does the data reflect the full population of patients with a disease state? Is it skewed by socioeconomic status or other factors?

Governance

Who owns the data generated from digital health sensors? Who determines the best practices for gathering, analyzing, and sharing data?

The Path Forward

- Collaborative development of governance standards with input from patients, governments, academia, and industry
- Regulatory pilot programs to incentivize adoption of best practices by digital health product manufacturers

https://www.fda.gov/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/default.htm

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