My RWD  *My Real World Data*

Sarah Hackley

*America’s Got Regulatory Science Talent Student Competition*

*University of Rochester Class of 2019, Bioethics*
My Real World Data

The Process:
- Opt-in/opt-out of data sharing
- Applies to devices that collect RWD
  - Example: Verily Study Watch

Why?
- Increase autonomy over mobile health data
- Responsible collection of RWD for Real World Evidence (RWE) program
FDA Priority Areas Addressed:

4) Ensure FDA Readiness to Evaluate Innovative Emerging Technologies

5) Harness Diverse Data through Information Sciences to Improve Health Outcomes
The Problem

- Deregulation around non-device software functions and medical devices
  - Gap: FDA encourages, but does not require transparency and patient access to patient-specific information from medical devices
- Lack of protection for anonymized (de-identified) data
  - Risk of data re-identification
  - Privacy and confidentiality concerns
Data Re-identification

The process of matching de-identified data with publicly available data

- The Health Insurance Portability and Accountability Act (HIPAA) authorizes the release of de-identified health data to 3rd parties
- Risk of re-identification is increasing
  - Era of Big Data
  - Advancing Classification Algorithms
Examples of Medical Devices that Transmit Data Wirelessly:

- Wearable heart monitors and implanted pacemakers
- Continuous Positive Airway Pressure (CPAP) machines
- Blood glucose monitors (glucometers)
Future Directions (Open Data Portal)

- Open data portal for research and development purposes
  - For patients who opt-in to sharing their health data with 3rd parties
- FDA could consider creating or using an existing Public Private Partnership (PPP) for this purpose
  - Examples: The Reagan-Udall Foundation and C-Path (Critical Path Institute)
You should not have to give up your right to privacy to participate in a technological society.
References

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5. United States, Department of Health and Human Services, Food and Drug Administration. "Manufacturers Sharing Patient-Specific Information from Medical Devices with Patients Upon Request Guidance for Industry and Food and Drug Administration Staff." [Link]


Images:


2. Smart Watch. [Image]. [Link]

3. Christoph Scholz (2016) BIG DATA [Image]. [Link]

4. Data Privacy [Image]. [Link]
Thank you!