

My RWD *(My Real World Data)*

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My Real World Data

The Process:

- Opt-in/opt-out of data sharing
- Applies to devices that collect RWD
 - Example: Verily Study Watch ¹

Why?

- Increase autonomy over mobile health data
- Responsible collection of RWD for Real World Evidence (RWE) program ²



FDA Priority Areas Addressed:

4) Ensure FDA Readiness to Evaluate Innovative Emerging Technologies ³

5) Harness Diverse Data through Information Sciences to Improve Health Outcomes ³

The Problem

- Deregulation around non-device software functions and medical devices ⁴
 - Gap: FDA encourages, but does not require transparency and patient access to patient-specific information from medical devices ⁵
- Lack of protection for anonymized (de-identified) data ⁶
 - Risk of data re-identification
 - Privacy and confidentiality concerns

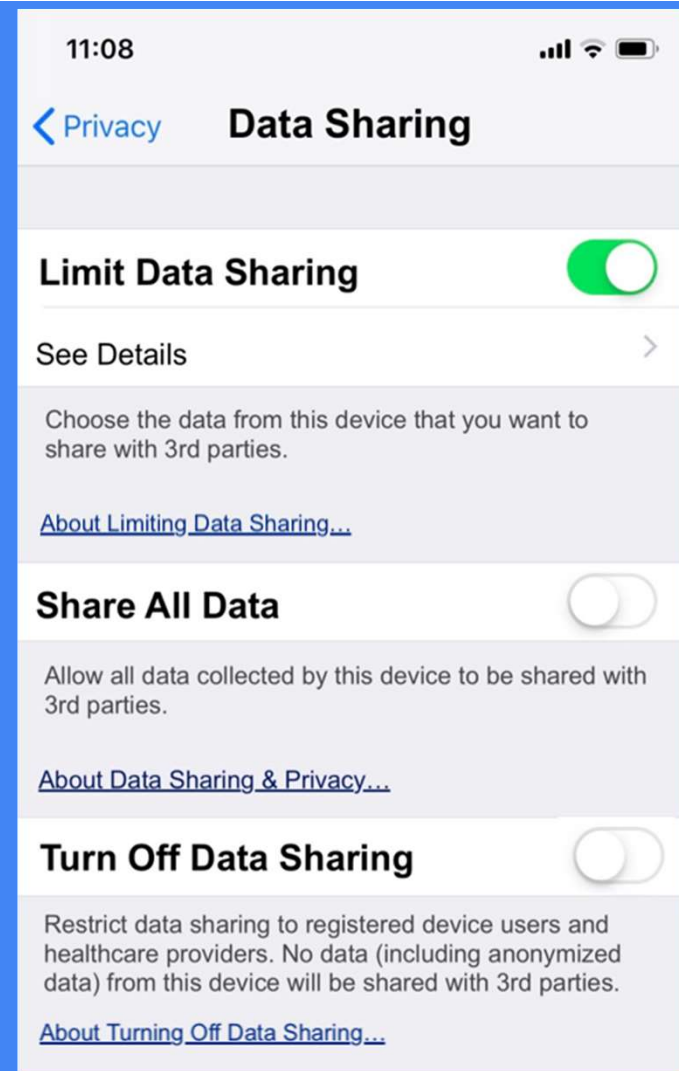
Data Re-identification

*The process of matching de-identified data with publicly available data*⁶

- The Health Insurance Portability and Accountability Act (HIPAA) authorizes the release of de-identified health data to 3rd parties⁶
- 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.

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Thank you!