

My RWD *(My RealWorld Data)*

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Policy Solution

My RWD

- Target:
 - Manufacturers of wearable, data-sharing medical devices
- Purpose:
 - More patient control over personal health data
 - Privacy protection
 - Responsible use of RWE

FDA Priority Areas Addressed:

4) Ensure FDA Readiness to Evaluate Innovative Emerging Technologies

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

(United States, Department of Health and Human Services, Food and Drug Administration. "Strategic Plan")

The Problem



- Lack of informed consent for data -sharing
- Risk of re-identification
- Deregulation around non-device software functions
 - Gap: FDA encourages, but does not require, transparency and patient access to data from medical devices

How it Works

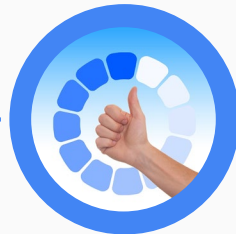
Step 1

Device manufacturers make patient data accessible and provide an opt-out function for data - sharing.



Step 2

Patients control whether or not they share their data with third-parties.



Step 3

Secure data portal for research and development.
Responsible data collection for RWE Program.



Works Cited

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Thank you! Questions?