



Opportunities and Challenges of Real-World Patient-Generated Health Data

THE ARTHRITISPOWER EXAMPLE

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What is RWD/E?



- 1. Real-World Data (RWD):** Data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources.
 - Data used for decision making that are not collected in conventional randomized controlled trials
 - Data that are collected outside the controlled constraints of conventional randomized controlled trials (RCTs) to evaluate what is happening in normal clinical practice
- 2. Real World Evidence (RWE):** Clinical evidence regarding the usage, and potential benefits or risks, of a medical product derived from analysis of RWD.



Use of patient-generated data for RWE



1. Traditional RCTs may lack information that can be valuable to sponsors and other stakeholders.
2. Data derived from real world sources like patient-reported outcomes (PROs) or registries may be used to support regulatory decisions (pre-market) and assist with post-market assessment.
3. Integration of data from various sources enables a more holistic evaluation of medical devices.



ArthritisPower



- 1. Research registry of >17,000 patient participants with rheumatic and musculoskeletal disease**
 - Created in 2015 with support from PCORI; one of 20 PPRNs and 33 networks within PCORnet
 - Capacity to designate study cohorts and create customized user flows for each new study
 - Novel data collection techniques (passive data)
 - Individual health tracking so patients can view symptom data over time and share with them
- 2. Smartphone App for mobile collection of patient data Patient-Reported Outcome**
 - Measurement Information System (PROMIS®) developed by the NIH
 - Other PRO measures in library that can be quickly updated with new instruments as needed
 - Custom surveys (via HIPAA-compliant SurveyMonkey API)



ArthritisPower mHealth Features



Tracking

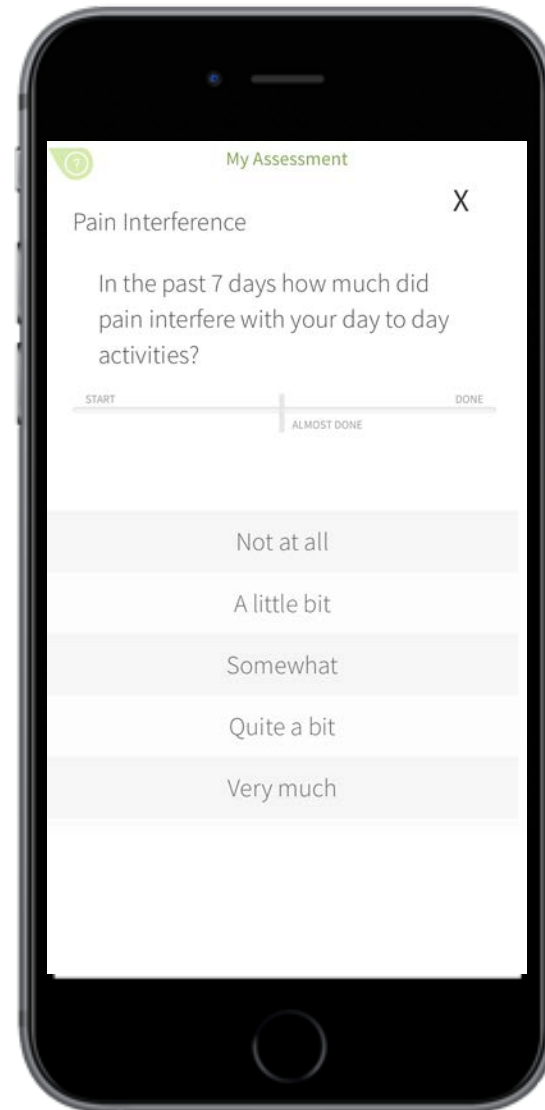
Track your health with customized assessments

Analytics

View results over time / see how symptoms are changing / identify causes of symptom changes

Share

Share results with family / caregivers / healthcare professionals



Medications

Enter / keep track of treatments

Research Opportunities

Participate in paid / unpaid surveys and studies

Education

Access education resources about your condition



Partnerships with other data sources



- Ancillary studies with external investigators:
 - Recruit in clinic, patients join ArthritisPower
 - Data collected in clinic and via mobile app
 - Link ArthritisPower data and EHR/claims data
- Health systems and medical centers (UAB, Vanderbilt, etc.)
- Health plans (Anthem/HealthCore, Optum, etc.)
- Specialty Pharmacy (Walgreens, etc.)



Engagement with patient community



- Education in-app and at CreakyJoints website and social media platforms
- Engagement webinars on research and other topics of interest to patients
- Frequent email contact
 - Monthly reminders to complete PROs and medication data
 - Quarterly newsletter
 - Announcements of special events and milestones
 - Annual summary of participation
 - Webinar alerts



Engagement with patient community



- **EXAMPLE:** Engagement webinar, “Know Your Medical Device”
Terrie L. Reed, US Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH)

Here's what patient participants said they learned from this webinar:

I have had both shoulders and both hips replaced by the same orthopedic surgeon who did a marvelous job on me. In fact, the left hip implant was replaced [when] I fell, fracturing the femur and destroying the implant. All of them have been manufactured by Stryker but that is all I know. When I have a follow-up exam in November, I will ask for the UDI.

Deane F., Patient Participant

I never knew patients had access to all this information about the medical devices that are in them. This information helps us feel more in control.

Jane M., Patient Participant

Here are a few key learnings from CreakyJoints staff:

1. The Unique Device Identification System (UDI) is fundamental to making sure that the devices patients receive are clearly globally unique number for all classes of medical devices that is assigned by manufacturers of medical devices and linked to
2. Information associated with the UDI that is linked to FDA is available publicly for patients to access at [AccessGUDID](#). The database administered by the FDA that serves as a reference catalog for every device with an identifier.

Know Your Medical Device:
Why the Unique Device Identification (UDI) System Should Matter to You



Engagement with patient community



Annual Email Summary of Participation

- “Lyft-style” email to ArthritisPower participants to thank them and highlight their participation



Thank you for being you.

The most important members of ArthritisPower are participants like you. We'd like to take a moment to let you know how you've made a difference.

You are ArthritisPower member **#6** out of more than 15,000 members. Since joining ArthritisPower on **March 23, 2015**, you've done quite a bit.

You've logged into ArthritisPower

88 times

Great Job!



You've completed your health assessment

343 times

Our researchers are



Caveats



1. May need to confirm diagnosis
2. Self-selected population
3. Real world involves unmeasured confounders which we cannot control for
4. Barriers to technology access
5. Privacy Concerns



Opportunities for RWE



1. ArthritisPower:
 - a community of patients interested in research
 - an app for mobile capture of patient data
 - a real-world database of patient-generated data
2. Bi-directional information sharing
3. Linkable with other data sources
4. Uses privacy-preserving methods
5. Provides information that patients and other stakeholders need (moving from anecdotal to RWE)



ArthritisPower Publications



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ArthritisPower Publications



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