

Digital Tools for Post-Marketing Research (Industry Perspective)

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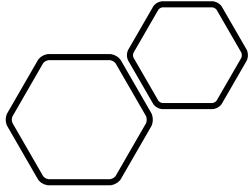
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Key Points of Discussion

- Considerations for what compels industry to conduct post-market research (e.g. regulatory obligations, other incentives).
- How industry may use digital health technologies in post-market research.
- The application of patient-generated data to build insights.





What Compels Industry to conduct Post-Marketing/ Real-World Studies?



PMR for safety
surveillance

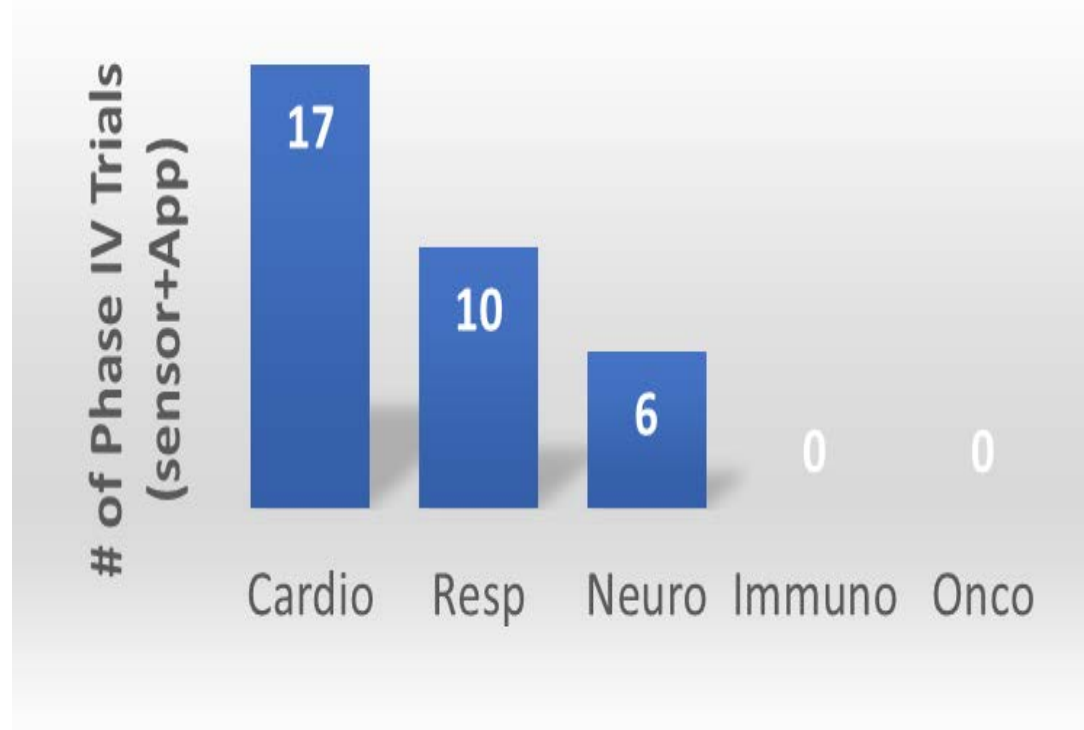


PMC for label
expansion



Real-world Evidence

Exploration of Digital Health Tools



Source: Clinicaltrials.gov



Methodology of RWD Collection



Development of Novel Digital
Endpoint

mHealth tools for RWD collection

2007



2015



2016



2017

2018

2019

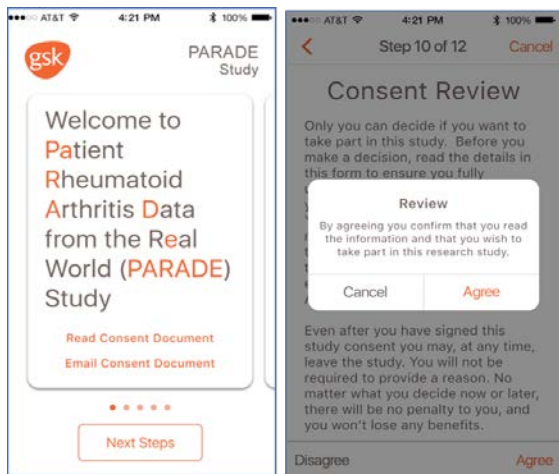


PARADE Study – Industry 1st Apple ResearchKit Study

*PA*tient *R*heumatoid *A*rthritis *D*ata From *RE*al World Study



Patient's Voice



Living with Rheumatoid Arthritis

$N = 399$

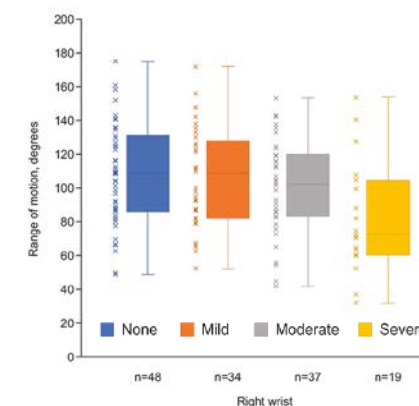
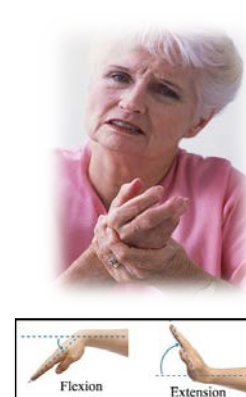
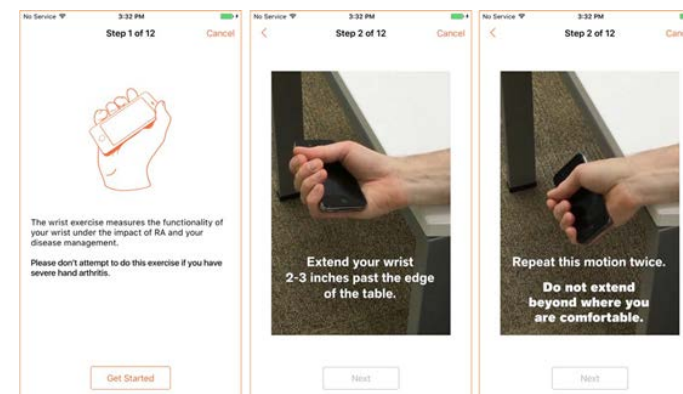
❖ Which RA symptoms bother you the most?

Joint pain	344 (87.5%)
Fatigue	289 (73.5%)
Morning stiffness	226 (57.5%)
Poor sleep	206 (52.4%)
Walk and balance	129 (32.8%)
Mood variations	93 (23.7%)

❖ Top 4 medication use (past and present):

NSAIDs (76%)
Methotrexate (71%)
Painkillers (70%)
Corticosteroids (67%)

Functional Measure



Crouthamel, Michelle, et al. "Using a ResearchKit smartphone app to collect rheumatoid arthritis symptoms from real-world participants: feasibility study." *JMIR mHealth and uHealth* 6.9 (2018).

Developing Smartphone-based Objective Assessments of Physical Function in Rheumatoid Arthritis Patients: the PARADE Study. *Digital Biomarkers* (2020). Accepted.

Key learning



Strength

- Easy access to trials
- Patient insight
- Speed to recruit
- Active tasks

Weakness


- Patient authentication
- IOS bias
- Drop out
- Variability

PMR/PMC Use Considerations

- Telehealth visit+ Study access code + facial + fingerprints
- Researchkit + ResearchStack
- Longitudinal study should include incentives for patients, and human interactions
- Good data > big data

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Exploring mHealth tools for RWD collection

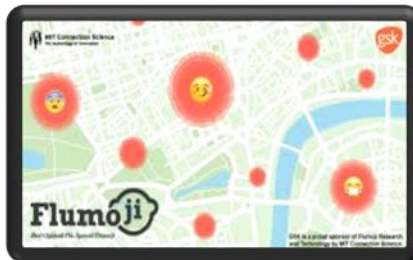
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Re-imaging the PMR, pregnancy registry

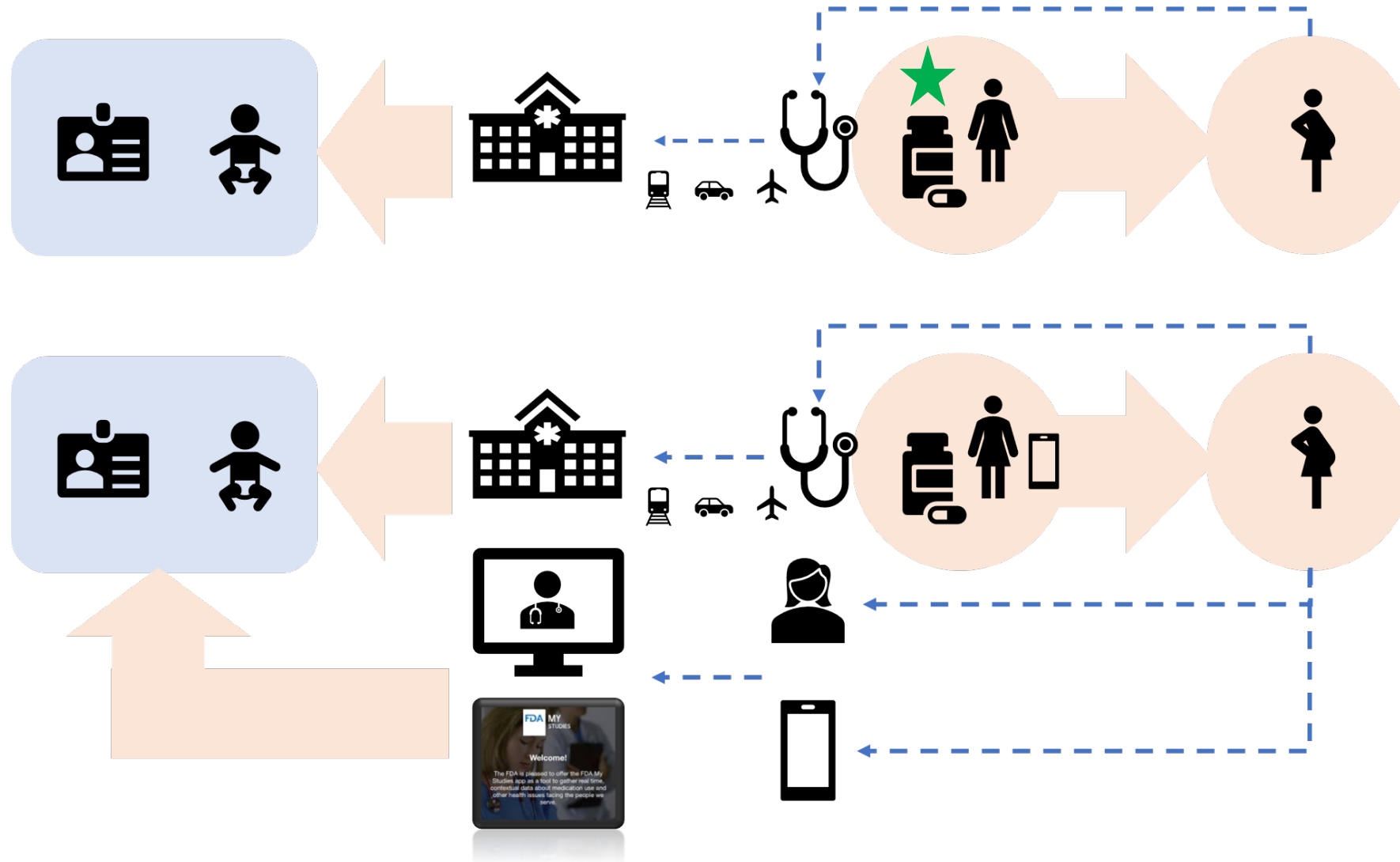
Impact on pregnancy such as miscarriage or birth defect are important to patients and all stakeholders.



TARGET

Traditional design and approach will take 10 years to collect results. Can we shorten it by half using digital tools?

Maximize (Digital) Touch Points



Summary

Post-Marketing research has become a very active space for digital trials.

Sponsors should leverage digital platforms to re-design traditional PMR, PMC and RWE studies to collect better quality data in a more efficient manner.

Thank you!

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