Integrating Digital Health Technology into Regulatory Applications

CDRH Patient Engagement
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Overview

Value of Data Collected by Digital Health Technology (DHT)

Study Designs Enabled by DHT

J&J Studies Using DHT for Regulatory Purposes

Collect Current Data Faster and Better with DHT

- Collect patient-reported outcomes by questionnaires on smartphones
  - Pain, patient function, other PROs

- Improve patient follow up in registries
  - Loss to follow up reduced by patient data from app instead of follow up clinic visit

- Improve clinical trials with fewer clinic visits and more frequent app assessments
  - Geographic proximity to clinical trial sites less of a constraint

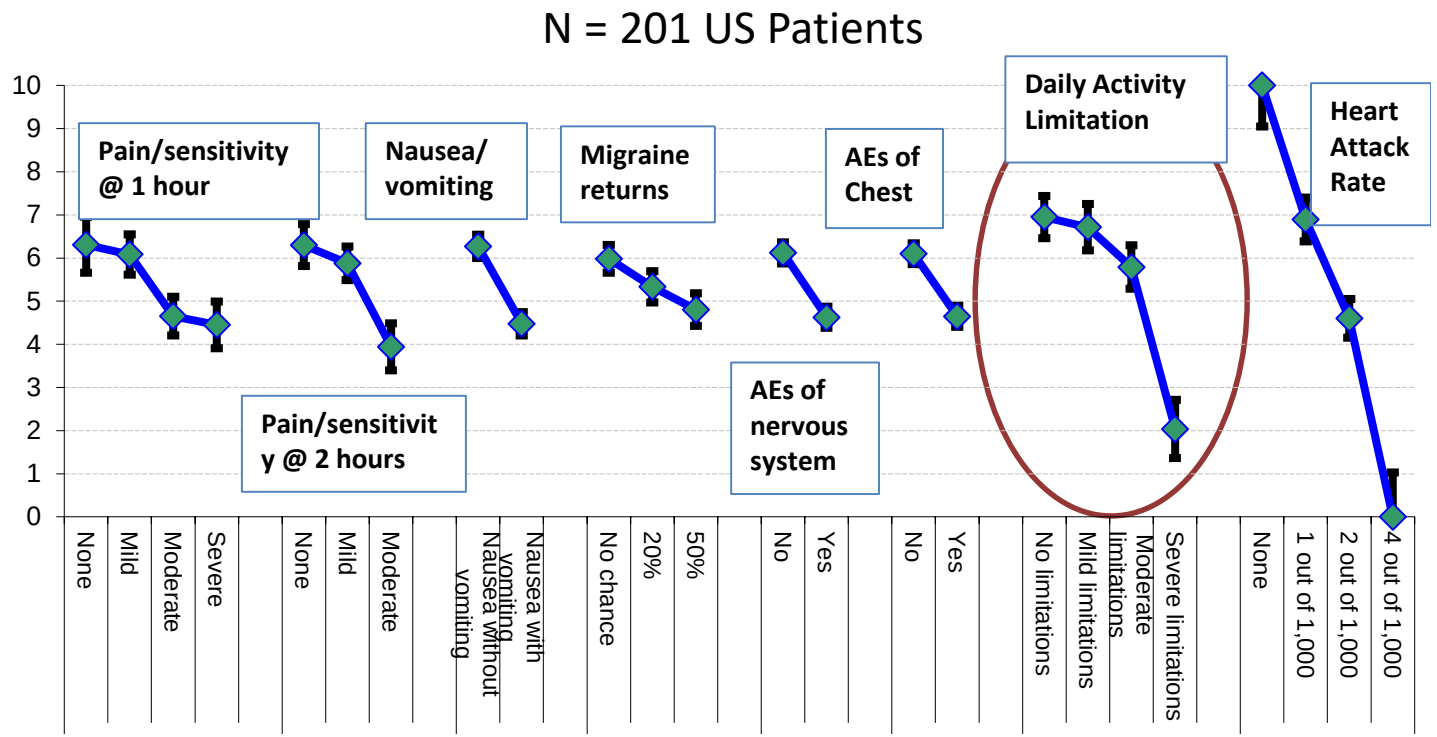
Collect New Types of Data with DHT

- Collect joint range of motion and physical activity through wearable sensors
  - Apps to measure joint range of motion, daily steps, and rigorous exercise
- Collect patient-centered longitudinal EHR and laboratory data
  - Aggregate patient data across insurance plans or tertiary care/primary care networks
  - Patient benefits from comprehensive, longitudinal integrated medical history
- Linkages of data streams from EHRs, labs, PROs, wearable sensors
- Faster safety and quality data from EHRs for proactive postmarketing surveillance
- Integrate device generated data with patient-generated data

Study Designs Enabled by DHT

- Long-term patient follow up studies, eg, registries, long-term clinical studies
  - Patients followed through app instead of follow up clinic visit
- Patient function as primary study endpoint vs. patient recall as secondary PRO
  - Wearable or phone sensors measure function, steps, exercise
- Pragmatic randomized trials within EMR systems with function, pain, PRO outcomes
  - Patients identified through large databases and randomized to devices
- Hybrid studies combining retrospective database comparative effectiveness study with imbedded prospective patient reported pain, function, activity, etc.
  - Patients identified through large databases and matched on propensity scores
  - App to collect PROs without clinic visit
- Proactive postmarketing surveillance

Patients Value Functional Ability: Migraine Patients' Preferences for Benefits & Risks of Triptan Treatment in Conjoint Analysis



Source: Coplan PM, Mohamed AF, Hauber AB, Johnson FR, B Levitan. ISPE 2010

J&J Studies Using DHT for Regulatory Purposes

- Feasibility assessment: patient engagement, EHR data linkage, longitudinal follow up, PRO questionnaire completeness
- Postmarketing registries: improved efficiency and patient retention
- Label extensions:
  - Comparative effectiveness studies using patient-reported function, pain, PROs, sensor activity (joint motion, EKG) and EHR safety data
  - Pragmatic trials using same outcomes
- Predictive analytics: improving patient benefit by predicting better devices or procedures using patient-generated and EHR data

NEST Demonstration Project: FDA-Yale-Mayo-Hugo-J&J

GOAL: Use mobile-health app (Hugo) for post-market surveillance

DEVICES: Bariatric surgery, catheter ablation for atrial fibrillation ablation

CO-FUNDING: FDA Center for Excellence in Regulatory Science and Innovation (CERSI) and J&J

DESIGN: 60 patients use mHealth app to merge 4 data sources into a research-ready database

1. EMR data from Yale and May
2. Patient Reported Outcomes (PROs)
3. Pharmacy
4. Wearables: Fitbit, AliveCor Kardia Mobile (arrhythmia), weight

PROJECT LEADS: Joe Ross at Yale, Nilay Shah at Mayo

PROGRESS: 59/60 enrolled patients

Interim Results from NEST Demonstration Project

- Completeness of PROM reporting
  - 81% (383/475) “short” PROMs sent out were completed
  - 85% (34/40) “regular” 8-week PROMs sent out were completed
  - Only 9 (1.6%) of PROM questionnaires were incomplete
- Enrollment depends on participant’s comfort/familiarity with smartphone and limited to patients with a smartphone/tablet
- Participants like using the app and didn’t report a burden

Planned Pragmatic Trial to Evaluate Device to Treat Joint Osteoarthritis using Mobile App (Hugo)

Goal

- Use mobile app to assess patient-generated outcomes in patients randomized to device vs corticosteroid injection treatment

Design

- Randomized pragmatic trial (unblinded) embedded in health care system(s)
- Use electronic health record (EHR) database to identify and follow patients

Outcomes

- Patient-generated measures of pain, patient function, joint range of motion
- Safety assessment from EHR

Duration

- 6 month duration post-randomization & treatment
- Monthly measures of patient-generated outcomes
- Safety assessment within 30 days