Mobile Devices

Things to know

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Market Overview

- Clinical Research Software
  - Global eClinical Solutions market to reach $7.61B by 2022.
  - Electronic Data Capture (EDC) and clinical data management systems (CDMS) largest share of the market in 2016
  - Electronic clinical outcome assessment (eCOA) is expected to grow the most
    - Driven by demand for eDiaries and use of mobile technologies
- Wearables
  - Wearables Market expected to grow 15.1% in 2018, worth ~$30.5B
    - Driven by fitness devices
    - Leaders: Apple, Fitbit, Xiaomi, Garmin, Huawei
  - Smartwatches make up 32.8% of the wearables market, worth ~$9.3B

Foundational Concepts and Definitions

- Digital Health
  - Umbrella term encompassing mHealth, health information technology (HIT), wearable devices, telehealth, telemedicine, and personalized medicine.
- mHealth
  - Mobile Health – “Medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices”.
- Mobile Devices vs Wearable Devices
  - Mobile Device - portable computing device such as tablets, mobile phones, or other compact and lightweight device that can detect, receive, and or transmit data
  - Wearable (also “wearable technology” or “wearable devices”) - Electronic technologies incorporated into clothing or accessories that can be comfortably worn on the body
- BYOD
  - Bring Your Own Device – the idea that people use their personal devices (smartphone, tablet, etc.) to run software
- Clincal Wearables vs. lifestyle wearables (or medical device vs. fitness device)
  - FDA says – if the wearable is “encouraging a general state of health or healthy activity” then it is a fitness/lifestyle device
  - If the wearable is intended for clinical use for chronic illness or a specific ailment, then it is a medical grade device (and must attain FDA Class II approval)
- eCOA – electronic clinical outcome assessment
  - Technology (smart phones, tablets, laptops, etc.) allowing patients, clinicians, and caregivers to directly report outcomes
- ePRO – electronic patient reported outcomes
  - Effectively the ‘patient’ part of eCOA
- eDRO – electronic device reported outcomes
  - Using technology built into smart phones (accelerometer, camera, microphones, etc.) to capture data directly

mHealth

- Ultimate Goal:
  - Improve data quality and study efficiency
- Two Prevailing Paradigms
  - One: use mHealth within the traditional clinical trial model.
    - Apply devices/technology where clinically appropriate
    - Supplement current practices for data collection
    - Focus on validating wearables for feasibility in subject populations
  - Two: use mHealth to overhaul the traditional model.
    - Apply technology to run virtual, site-less studies
    - Focus on adoption of wearables

Paradigm One: Validation

- Gather information from mHealth technology providers
- Develop best practices for using the technology
- Is the device effective at capturing the needed data
  - Device selection should occur after deciding that a mobile based outcome assessment would be valuable
  - Perform small scale studies to build experience with the mobile device
  - Compare device collected data to traditionally measured data or a gold standard
- Is the device practical for the target population
  - Test to understand the challenges users may have with the technology
  - Conduct user acceptability and feasibility testing
- Is the data from the device available for transfer
  - Pilot test data collection and transfer platforms

Paradigm Two: Adoption

- Create an adoption plan
- Establish tangible goals
- Identify the process and timelines to meet the objectives
- Form a dedicated innovation team
  - Research all available options
  - Validate options internally

Best Practices for Devices on Studies

- Have a clear plan in place before using wearables on trials
  - Know what you want to measure: How will the device help you answer a specific research question or study endpoint?
  - Find a fit for purpose sensor: Make sure the device meets the needs of the study.
  - Support the sensor on the study: Have the infrastructure in place to support the device, including distribution, training, and set up. How will participants report problems with the device?
  - Get the data off the sensor: Identify the data flow from device to study database. Identify how to verify the integrity of the data (i.e. check sums, reviewing timestamps, using multiple timestamps, etc.)
  - Plan for analytics: Know what to do with the different types of data generated by the devices.

Some mHealth Benefits

- Continuous real-world data from participants
  - Richer participant health profiles
- Improved PRO accuracy
  - Time stamped data entry
  - eSource
- Improved recruitment, retention, and compliance
  - Richer communication through prompts and messaging
  - Increased convenience for participants and easier access to information
  - Gamification
- Reduced clinic visits
  - Reduced costs

Some mHealth Challenges

- External
  - Validation of devices
  - Cost of devices
  - Data security and privacy
  - Data attribution questions
  - Regulatory acceptance
- Internal
  - Lack of experience with wearable tech
  - Lack of mobile development experience
  - Dedicated effort

Are mHealth Devices Effective?

- 93% of physicians believe that mobile health apps can improve patient's health.
  - http://www.greatcall.com/greatcall/lp/is-mobile-healthcare-the-future-infographic.aspx
- "We don't have enough evidence that they consistently change clinical outcomes in a meaningful way."
  - Looking at interventions & outcomes
  - Due to lack of evidence; very few randomized trials
  - https://www.nature.com/articles/s41746-017-0002-4

Common Regulatory Certifications

- CE (*Conformite Europeene)*
  - Awarded to certified medical devices in the EU
- 510(k)
  - Clearance granted by the FDA to market a device as a medical device
- MDEL (Medical Device Establishment License)
  - Awarded to medical devices in Canada

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