Harnessing Big Data & Wearable Technology to Advise Clinical Readouts

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Disclaimer: Opinions presented are my own
Our world is changing!
The healthcare ecosystem: Current situation

- **20%** US adults living with 2 or more chronic health conditions
- **77%** US adults ages 65+ with at least 2 chronic conditions
- **85%** Expected US population growth among individuals 65+ between 2000 & 2030
- **30%** Average increase in cost per case for individuals with 2 chronic conditions
- **20%** of pts living in areas with insufficient primary care doctors
- **19.5d** average wait time for appt to family practitioner Nationwide
- Only **55%** of pts receiving recommended preventive care
Technology could change the current Healthcare paradigm: from clinical research to everyday care

New technologies support real time, continuous, self care/monitoring

Traditional models are being disrupted with new solutions
WEARABLE TECH TIMELINE

The evolution of wearable technology (Source: Raccourteur)
Beyond the FitBit era….

“The global healthcare wearable devices market earned revenues of **$5.1bn** (£3.5bn) in 2015 and estimates this to reach **$18.9bn** (£12.98bn) in 2020….medical and clinical grade wearables are expected to grow at a CAGR of **32.9%**”

Source: Frost & Sullivan
Wearables & Applications

Applications of wearables in the fitness and clinical research context (Source: Biotaware)
Wearables in the New World

• Value-based healthcare

• Empowered patient:
  • emphasis on preventive health choices
  • expansion in home health options

• Advances in technology
Big Data and Challenges

• Non reliable sources of data
• Too much data, too much noise but so little time
• The paradox of the non-personalized approach
• Tracking parameters and desired outcomes (relevant?)

• Interoperability
• Regulatory hurdles
• Reimbursement
• Compliance
There is an immediate need for disruption in the clinical development paradigm in Neurodegenerative diseases

The Cost of Clinical Trials

- **NO OBJECTIVE MEASURE**
- **3-6 MONTHS BETWEEN PHYSICIAN VISITS**
- **CHANGES ARE SLOW AND HARD TO DETECT**

- **COST OF TRIALS** are in the scales of **$M**
- **VERY SMALL** number of patients contribute to research
- **AVERAGE TRIAL SIZE** < 100 PATIENTS
Many of our current outcome measures are subjective and suboptimal

Characteristics of 20th vs 21st century studies Clinical Trials

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>20th Century</th>
<th>21st Century</th>
</tr>
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<tbody>
<tr>
<td>Study design</td>
<td>Randomized, double-blind, parallel-group, placebo-controlled trial</td>
<td>Randomized, double-blind, parallel-group, placebo-controlled trial using adaptive designs</td>
</tr>
<tr>
<td>Study population</td>
<td>All comers with a given disease</td>
<td>Individuals selected based on phenotypic and genetic results</td>
</tr>
<tr>
<td>Study recruitment</td>
<td>Clinical practices</td>
<td>Global clinical trial registries and social networks organized by individuals affected by the disease</td>
</tr>
<tr>
<td>Trial visits</td>
<td>In person and audio calls</td>
<td>In person and audio and video calls</td>
</tr>
<tr>
<td>Data management</td>
<td>Paper and electronic forms</td>
<td>Electronic forms</td>
</tr>
<tr>
<td>Participant feedback</td>
<td>Limited, delayed</td>
<td>Almost universal, approximately real time</td>
</tr>
<tr>
<td>Outcome measures</td>
<td>Insensitive</td>
<td>Sensitive</td>
</tr>
<tr>
<td></td>
<td>Episodic</td>
<td>Frequent or continuous</td>
</tr>
<tr>
<td></td>
<td>Subjective</td>
<td>Objective</td>
</tr>
<tr>
<td></td>
<td>Provider centered</td>
<td>Patient centered</td>
</tr>
<tr>
<td></td>
<td>In clinic</td>
<td>Remote</td>
</tr>
<tr>
<td></td>
<td>Unidimensional</td>
<td>Multidimensional</td>
</tr>
</tbody>
</table>

Big Data Analytics - R&D Success

• Accelerate drug discovery
• Enhance and improve the development of novel therapies
• De-risk later stage drug development
• Gain insights on drug performance and adverse events in real time
The adoption of technology creates new opportunity in clinical research

- Greater accuracy, sensitivity of collected data/ efficacy measure
- Enables much richer data sets through the addition of more contextual information
- Improved protocol patient compliance, less missing data, out of window events
- Greater flexibility with user inputs (participants have more choice over input devices)
- A new avenue to connect with Investigators, study personnel and subjects
- Real-time quality tracking
- Decrease in-person clinic visits, while maintaining high quality care and engagement
- Reduce study costs
- Enable new type of research protocols if combined with eVisits
Technology (wearables & mobile applications)- Challenges

- Data accuracy and validation
- Data security and privacy
- Regulatory acceptance
- Long term engagement
- Proving ROI
- Global scale implementation
Lessons Learned:
The road to digital success is through partnerships.
Lessons learned?

Biogen idec explores use of wearables to track MS patient activity

March 10, 2015 8:29 pm by Stephanie Baum | 10 Comments

As part of an effort by Biogen idec to explore ways to use wearables with MS patients to help physicians quantify patient activity, it recently completed a study of 250 patients in collaboration with PatientsLikeMe, Naomi Fried, vice president of medical information and innovation at Biogen, referenced the study as part of a keynote presentation on digital health at the MidAmerica Healthcare Venture Forum in Chicago this week.

This is the problem that Biogen idec wants to solve. Impaired mobility affects more than 90 percent of people with MS, but the quantified assessment of their walking ability tends to be limited to clinical settings. Sensors could give physicians a more accurate assessment of the level of activity of these patients if they were willing to wear activity trackers between appointments.

The study of 250 people with MS sought an answer to the questions: Would patients actually use wearables as part of their daily lives and be willing to share that information with physicians?

The initial takeaway from the study is that it needs to use devices with more sophisticated sensors to quantify movement accurately and consistently. “Current technology is not built to provide consistent and validated data in MS. We are early in the process, but hope to have progress in the coming months,” according to an emailed statement about the study from Biogen. It also noted that it was encouraged by the “overwhelming positive participation” from MS patients. It took the response as a sign of encouragement as it explores using wearables in the future.
Number of clinical trials to use wearables nears 300

by Nick Paul Taylor | Sep 16, 2015 7:58am

Boehringer Ingelheim, Propeller Health to enroll 2,500 'smart' inhaler patients in evidence-generation program

Mar 23, 2016 7:32am

Why Partners and Daiichi Sankyo partnered on an AFib remote patient monitoring pilot

By Jonah Comstock | March 03, 2015

Teva, Intel to develop wearable technology for Huntington's disease

Major partnerships struck with AZ, GSK, BI, Novartis, Vectura, Philips, Aptar within last 12 months
## Current technology-related activities in Parkinson’s Pharma perspective

<table>
<thead>
<tr>
<th>Pharma Company</th>
<th>Technology</th>
<th>Focus/Project</th>
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<tbody>
<tr>
<td>Pfizer</td>
<td>IBM</td>
<td>Internet of things</td>
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<tr>
<td>Roche</td>
<td>Mobile application (Dr. Little)</td>
<td>Clinical Development (measurement of disease and symptom severity)</td>
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<tr>
<td>AbbVie</td>
<td>Google</td>
<td>Age related disorders</td>
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<tr>
<td>Janssen</td>
<td>Multi-organization</td>
<td>Brain Disorders</td>
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<tr>
<td>UCB</td>
<td></td>
<td>Intervention in PD</td>
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<tr>
<td>Radboudumc</td>
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<td>ParkinsonNet will be first tested in Kaiser Permanente’s Southern California Region, which has more than 7,000 Parkinson’s patients</td>
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Sunovion taps Empatica for Phase 4 drug trial and two other digital health projects targeting epilepsy

- Embrace watch is a new wearable device for epileptic patients and can provide notifications to caregivers and family
- We are planning to demonstrate how effective the Embrace and the Alert app are in seizure detection in real world conditions in Aptiom Phase IV study
Main Key Take Aways

- Medical grade wearables
- Patient centricity
Thank you!
Questions?