Advances towards Remote Assessment of Disease and Relapse in Multiple Sclerosis

Value Based Medicine

Jane Rhodes

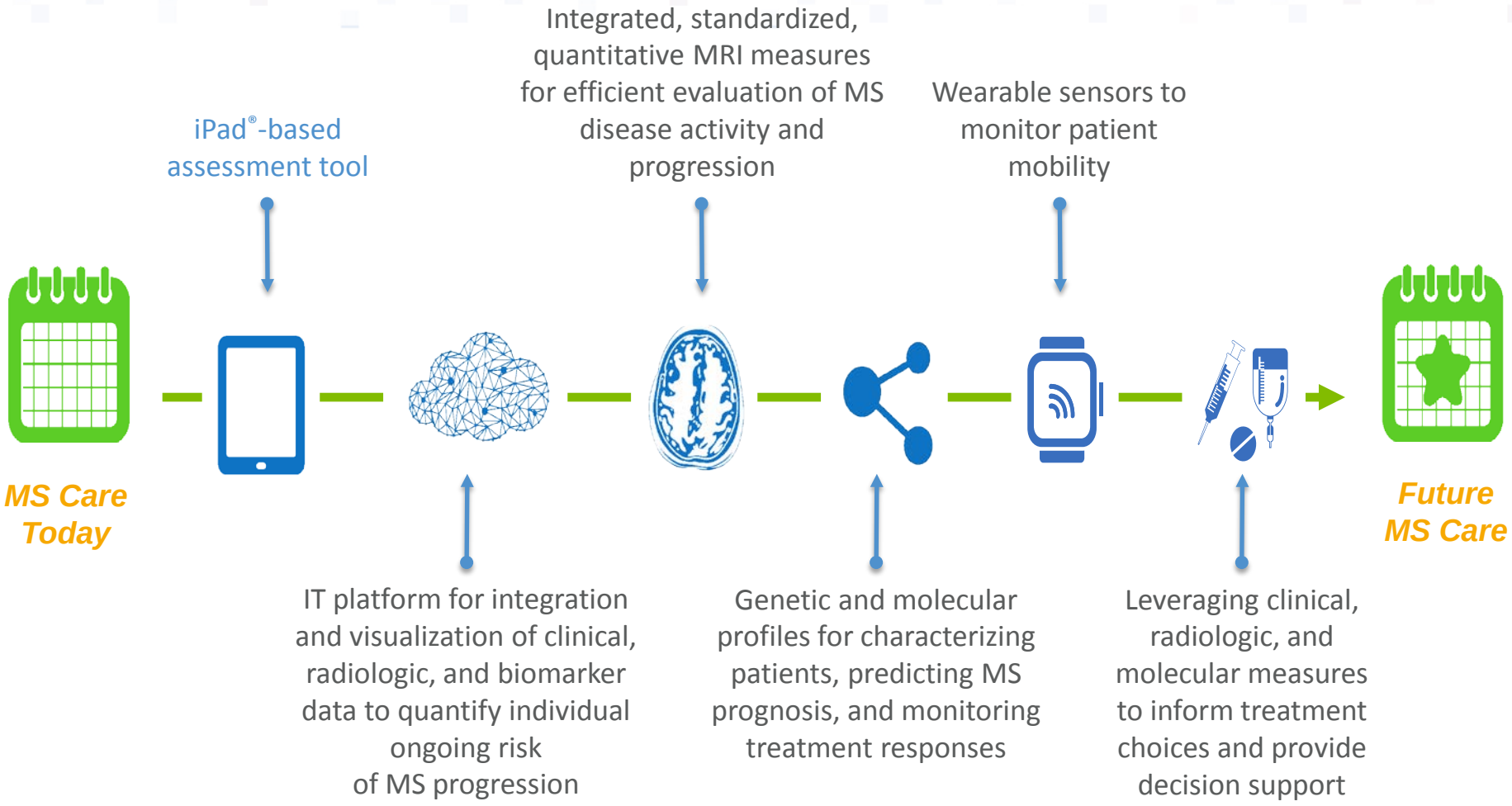
March 31st 2016

CAMD Digital Biomarkers Conference

Baltimore, MD

Biogen

Emerging technology for the enhancement of patient monitoring and assessment



Note: All components are under development and/or being explored.

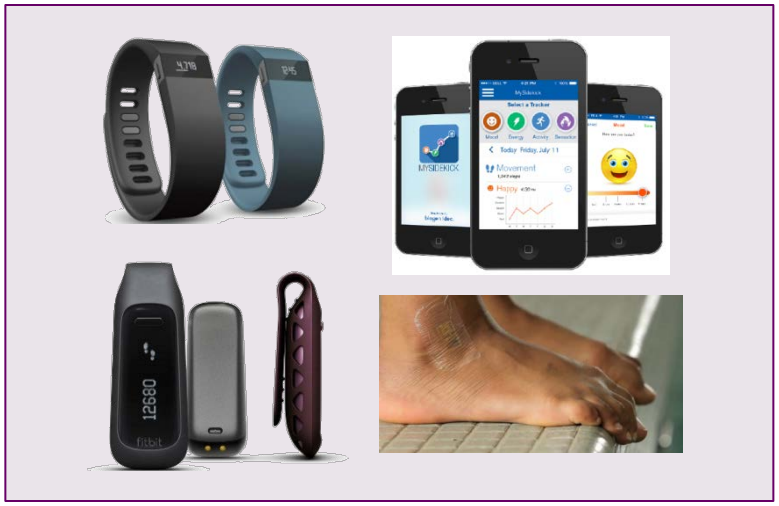
Challenges in using Digital Biomarkers for Assessing Function in Multiple Sclerosis

- Functional measures are challenging to collect objectively in MS : Currently accepted primary endpoints in MS clinical trials focus on inflammatory events in relapsing forms of disease and are not effective functional measures of chronic progression.
- Validated functional outcome measures, most suited to a digital format, are not routinely used to assess MS patients – hence there is a lack of evidence to support actionable outcomes from digital data
- Construct validity and clinical meaningfulness are frequently overlooked in App and wearable development

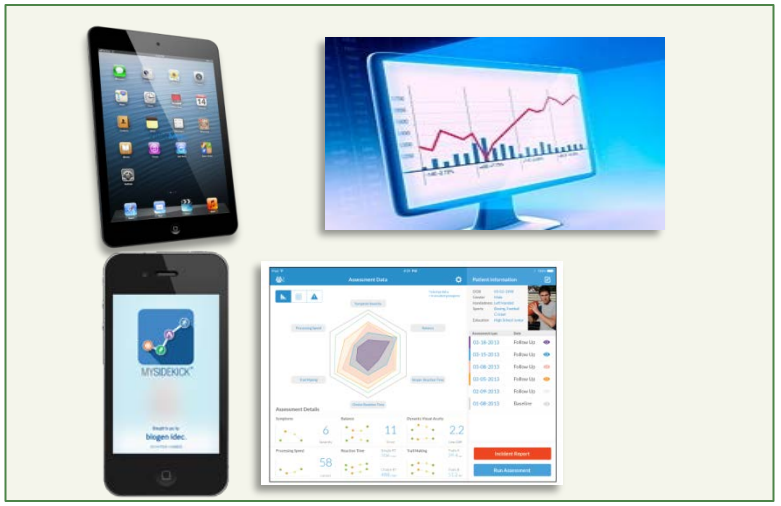
Partnering across Industry and Academia to Develop and Assess Digital Biomarkers in MS

Developing tools to help improve outcomes through passive and active data collection

Consumer Wearable Devices & Sensor Technology for Passive Data Collection



Medical Devices & Apps for Active Data Collection



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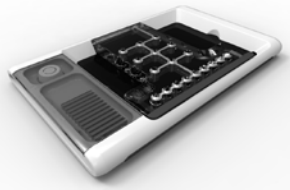
Chronic Disease Management

Leverage emerging patient monitoring tools to generate novel data or extend window of observation with the goal of better disease management at a lower time burden and financial cost



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Deploying Wearable Sensors to MS patients:

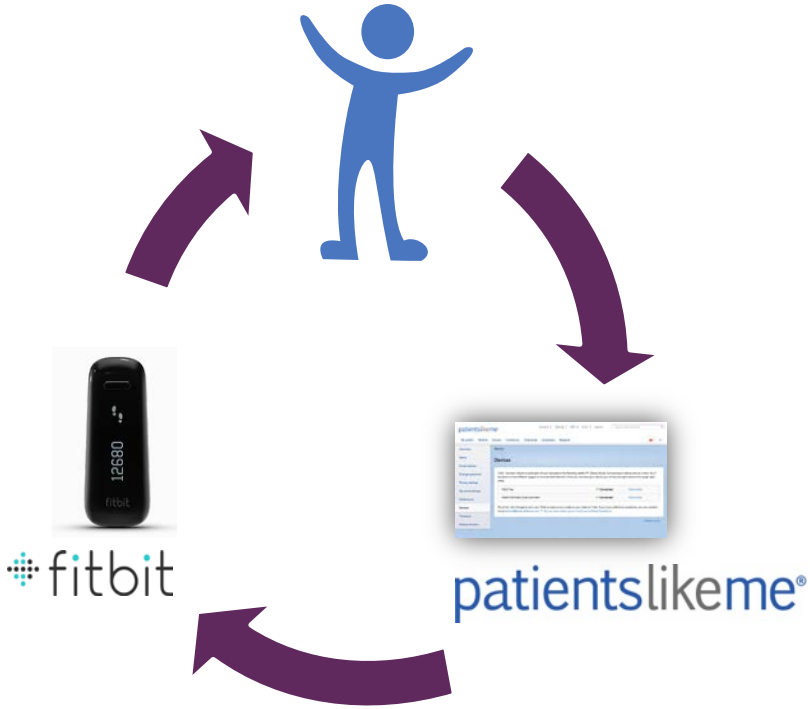
The purpose of the study was to understand the deployment and use of consumer activity tracking devices in the MS population

Objectives:

- Assess likelihood of use of devices
- Assess feasibility of collecting data from patients via devices

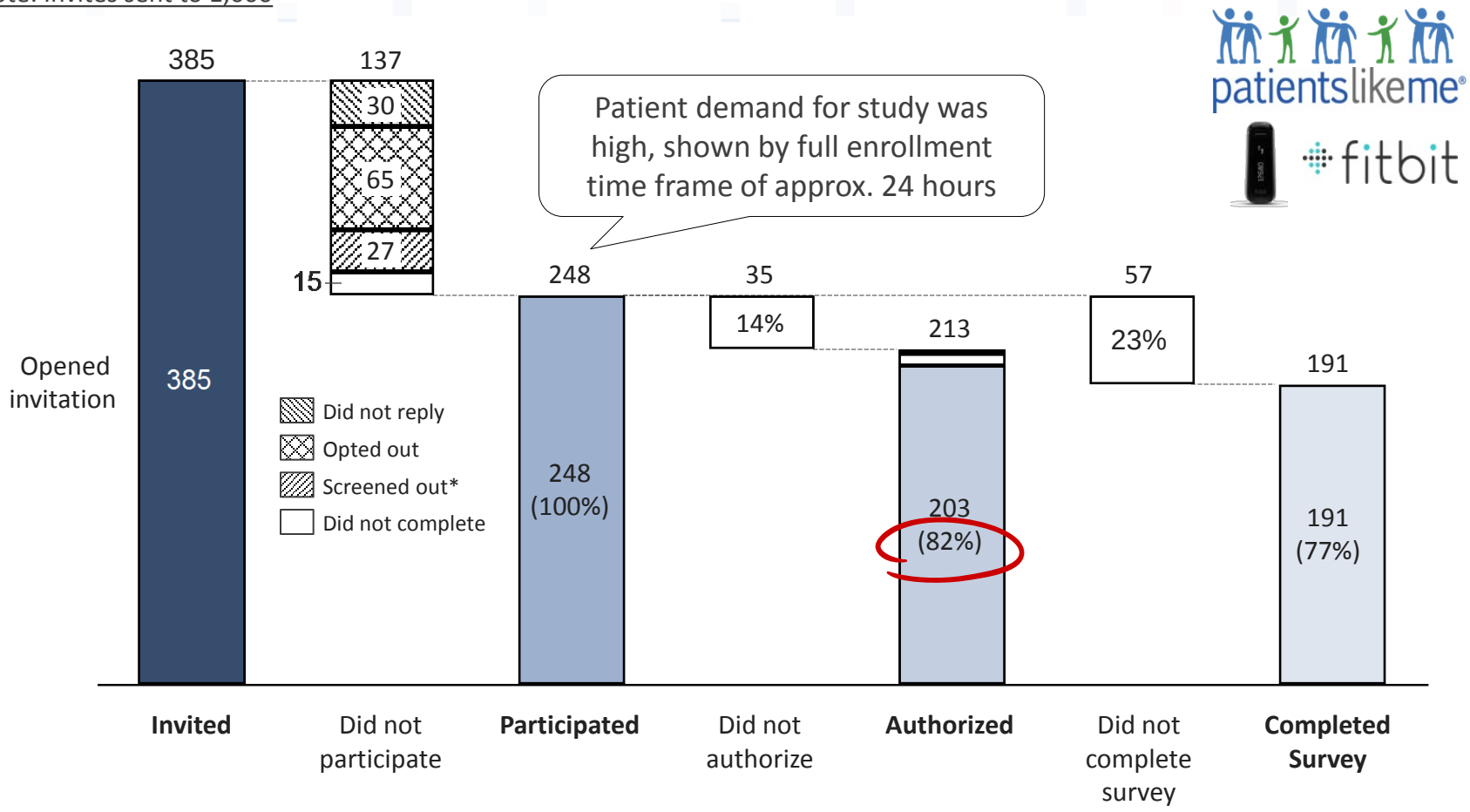
Additional questions

- What features do patients want in a patient-centric device/app?
- Does a wearable device impact patient behavior, patient-provider relationship, disease understanding?
- How does social and peer-to-peer connectivity affect utilization of wearables by patients?



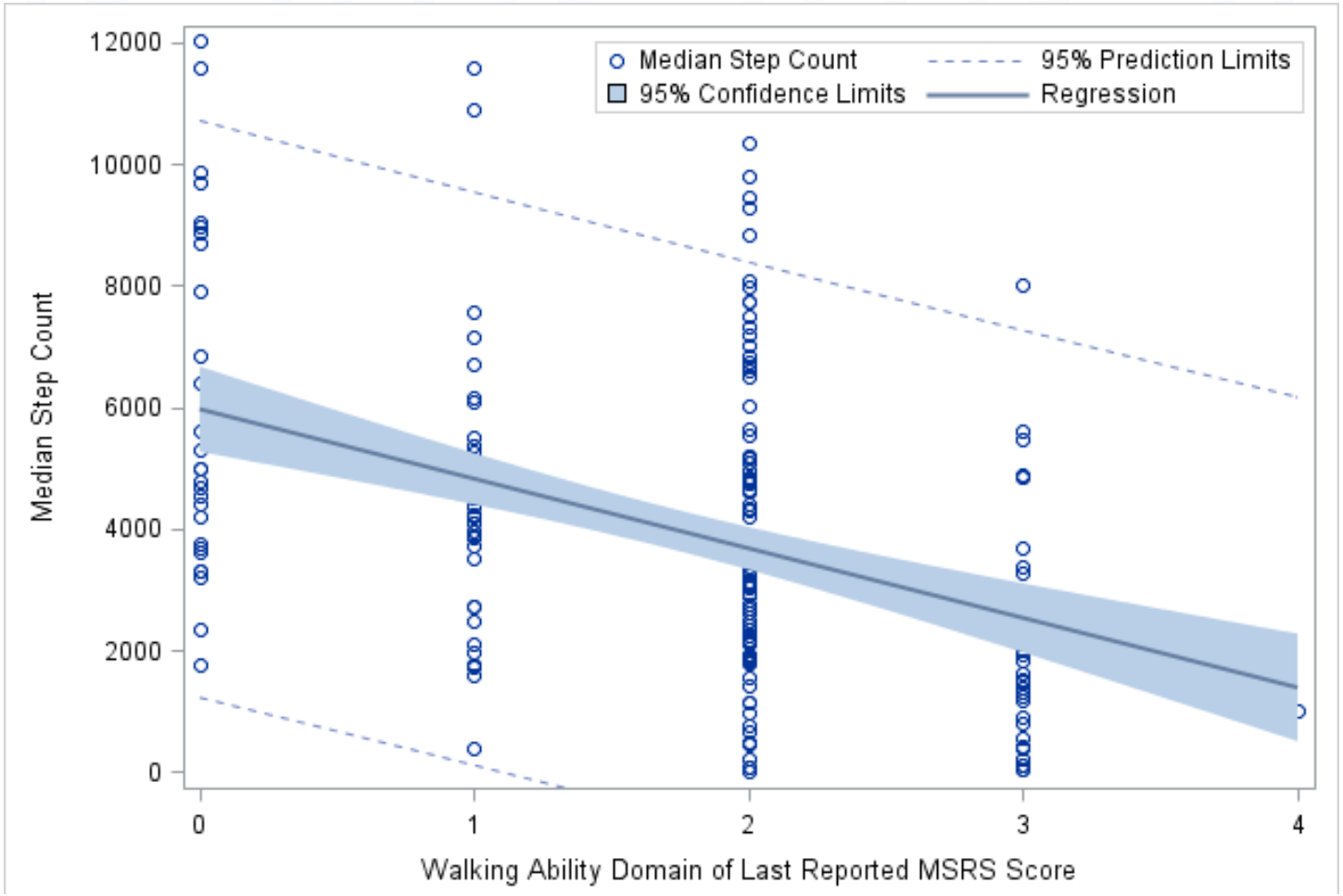
Study engagement rates observed were very high, likely the result of high patient interest and value

Note: Invites sent to 1,600



Note: "Authorization" refers to connecting Fitbit profiles with PLM profiles. "Sync" refers to uploading data from device to Fitbit.com (so that data can be imported into PLM). *the reasons for the screen out of 10 members could not be identified

Clinical Correlation: Participants with lower MSRS-R walking scores also had lower activity



Higher walking ability ⟷ Lower walking ability

Note: Data presented is last reported Walking Domain of MSRS; 15 members did not report MSRS

Source: PatientsLikeMe profile data for study participants, Fitbit data as recorded on PatientsLikeMe; PatientsLikeMe analysis

Clinically meaningful or actionable ?

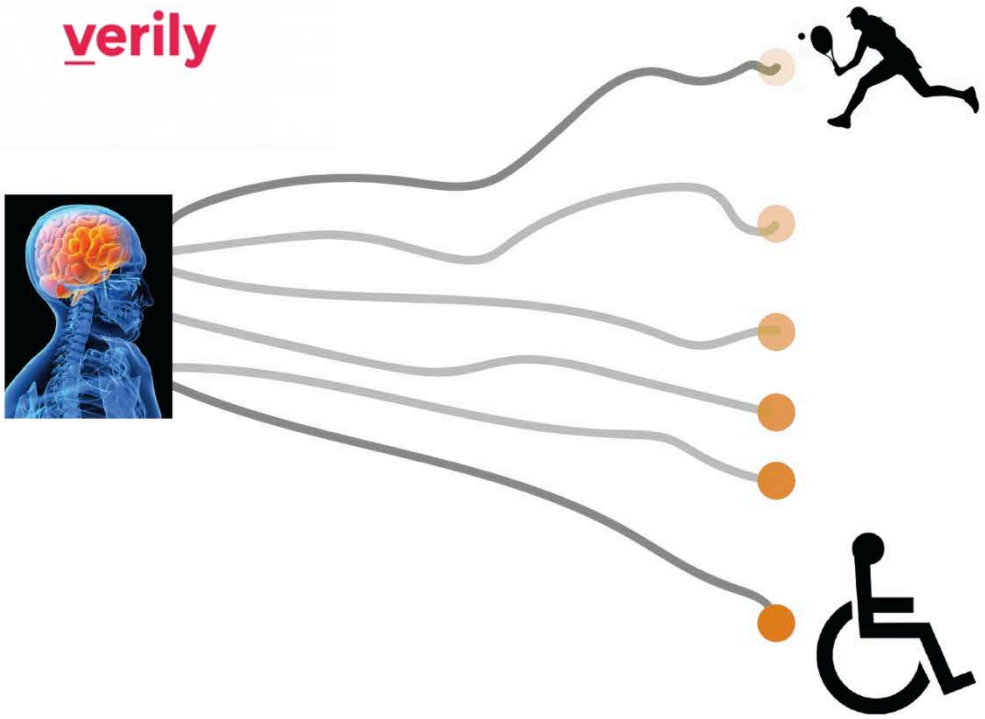
*"This is going to be a **big help** for me to prove that if I change my ways and take better care of my **health** my **MS will be manageable**."*

Quote from actual patient that participated in the study; stock photo used to protect patient identity

Systems Biology Study of Multiple Sclerosis

Google

verily



GOAL:

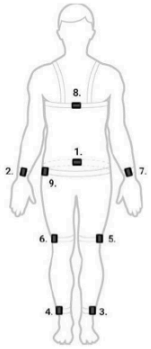
To identify clinical, radiological, biological, behavioral and environmental factors that associate with and drive disease severity in multiple sclerosis (MS) patients.

Molecular and Digital Biomarker studies underway

Two pilot studies currently in progress

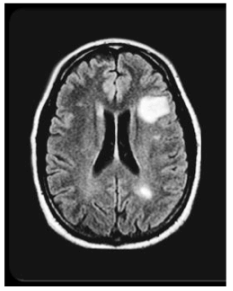
DEVICE PILOT (GMSSM)

- Assess feasibility of using devices to measure features of mobility, dexterity, balance and gait for sub-stratification of MS disease phenotypes.



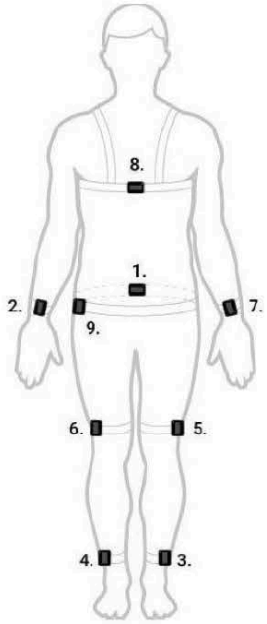
MOLECULAR ASSAY PILOT (SysteMS MRI)

- Conduct deep phenotypic analysis on a small cohort identified as being at low risk or high risk of MS progression based on MRI metrics



Device signals

Aim: Develop a sensitive objective measurement of features of mobility, dexterity, balance and gait to allow sub-stratification of disease phenotypes



Each devices record accelerometer and gyroscope in all 3-axis (50Hz)

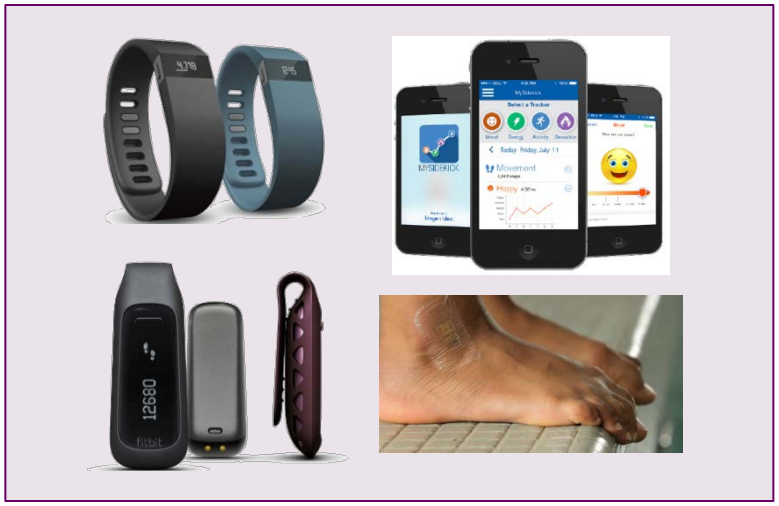
Initial data collection from 9 body locations with the goal of identifying the optimal # of sensors for the take home

- Process raw signals to extract the following motion and gait features at each body location
  - Step rate
  - Step regularity
  - Jerkiness
  - Spectral edge (50%, 75%, 90%, 99%)
  - Standard deviation of pitch, roll and yaw
- Symmetry of motion is also computed at the ankles and wrists
- Postural sway
- Turning Angular Velocity

Method: Digital signals being compared against traditional measures (EDSS) and validated functional outcome measures (MSFC).

Developing tools to help improve outcomes through passive and active data collection

Consumer Wearable Devices & sensor technology for Passive Data Collection



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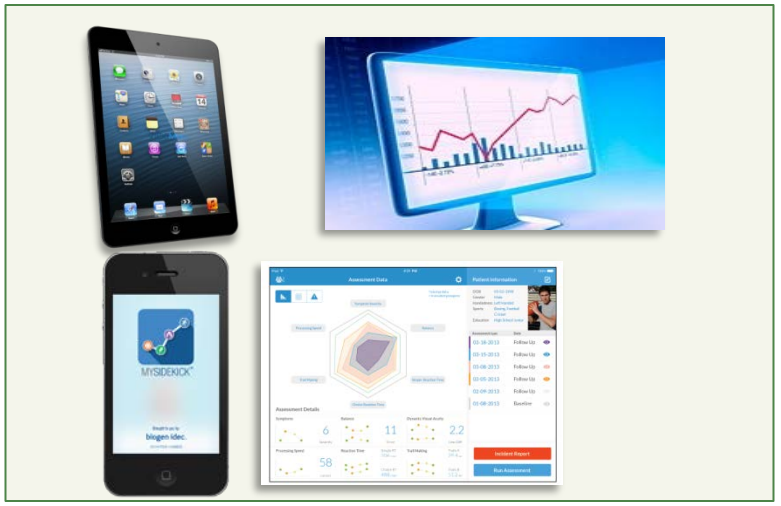

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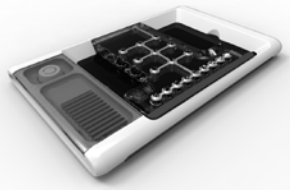

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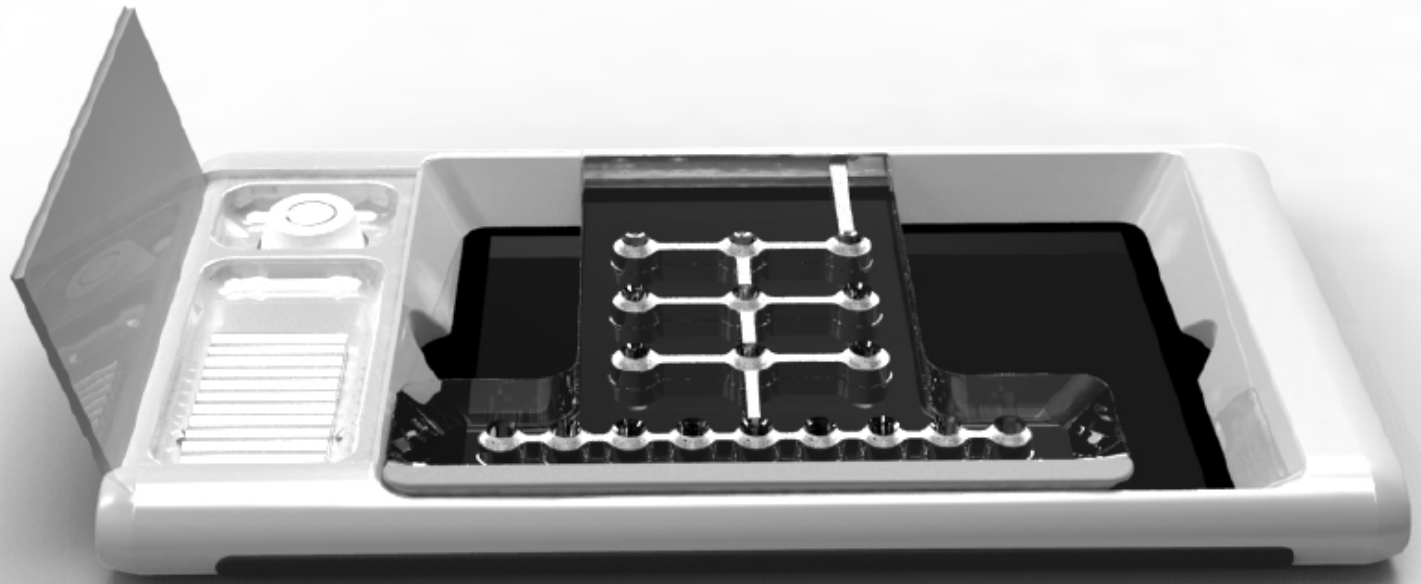
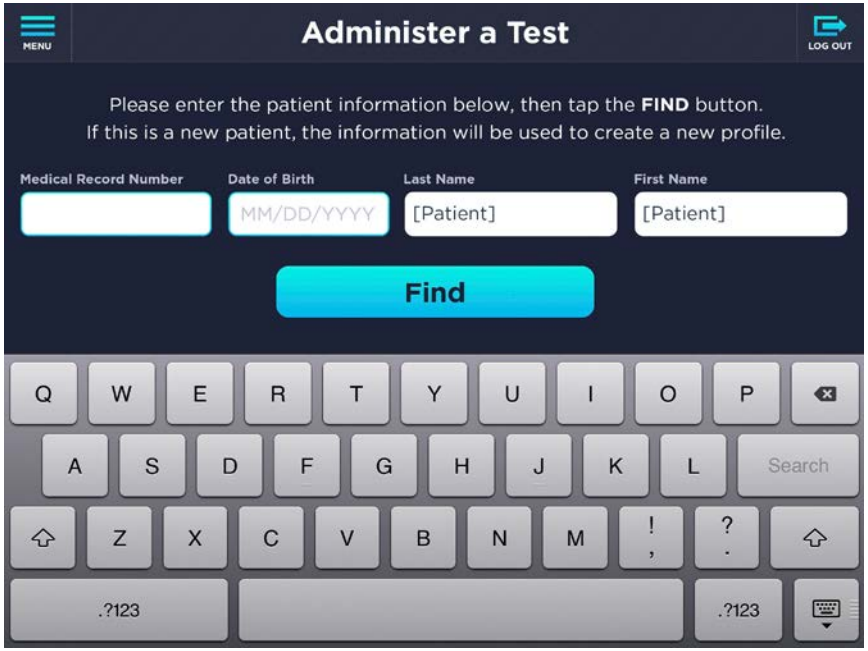
to collect, analyze and visualize clinical data

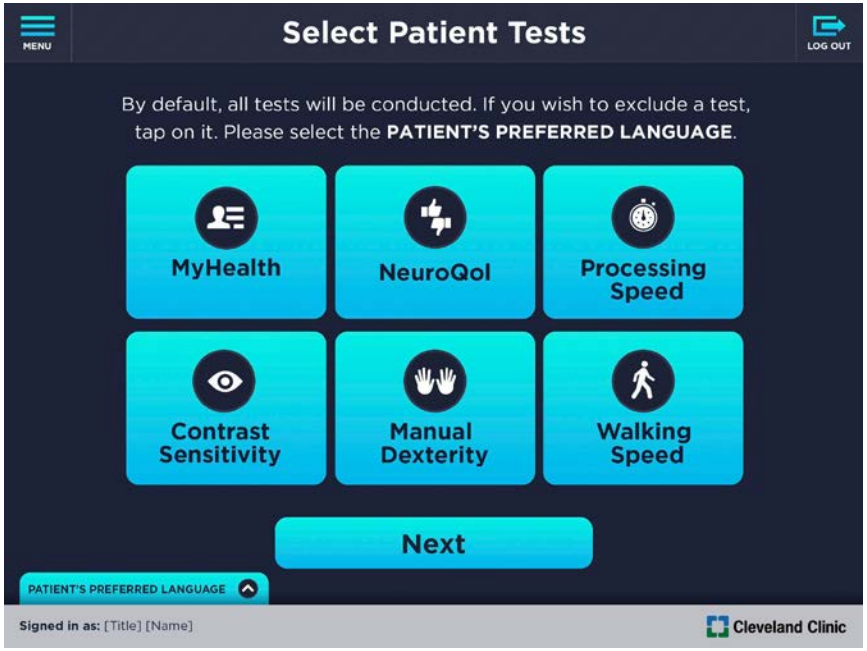


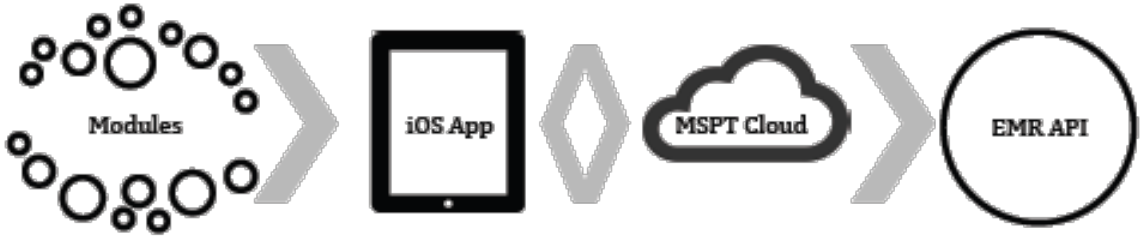
Patients can use this iPad-based medical device to **Conduct self-administered neurological tests that quantify walking ability, dexterity, vision, and cognition**

Developed in Partnership with Cleveland Clinic

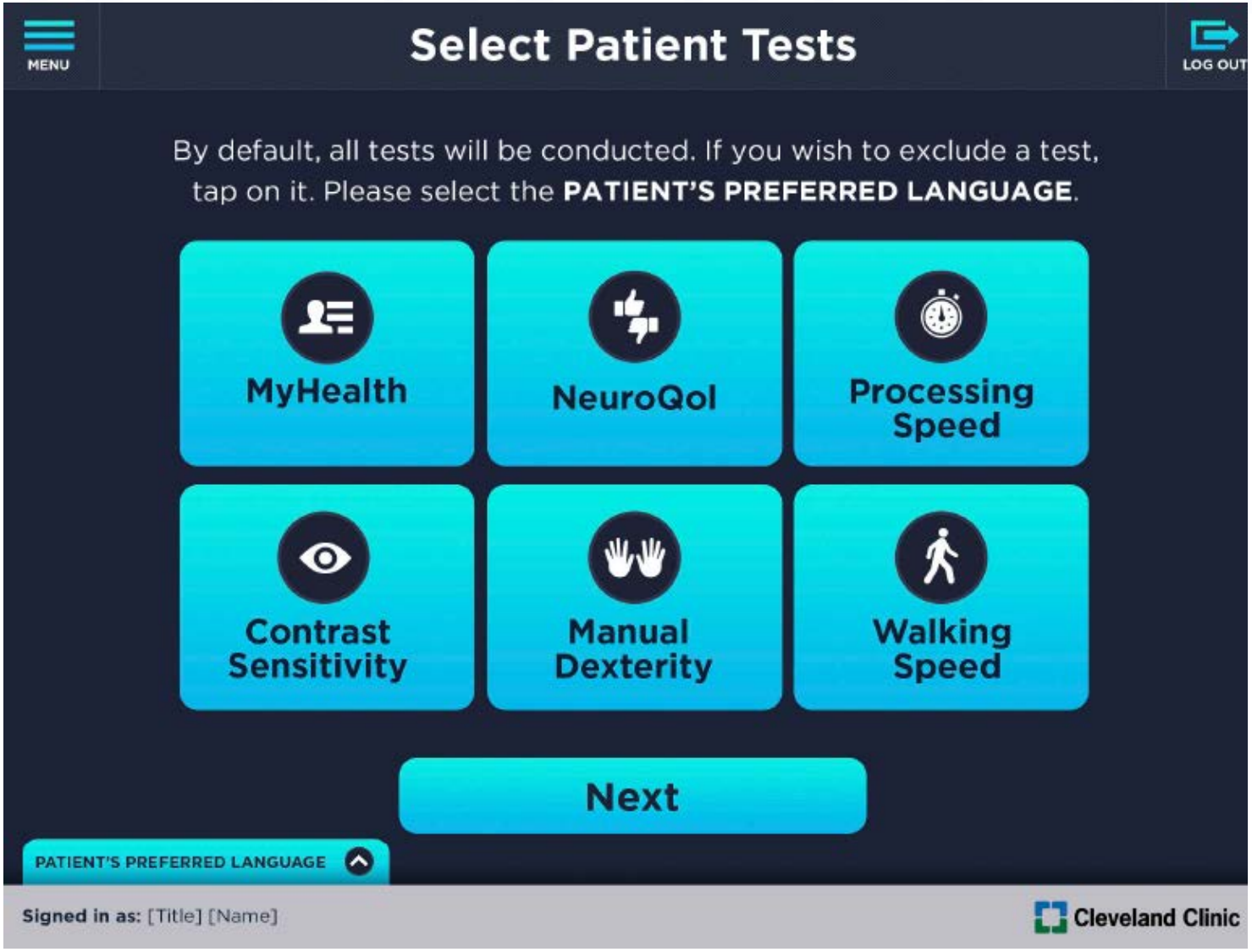
Clinical data collection device designed to be used in routine practice for comprehensive patient assessment



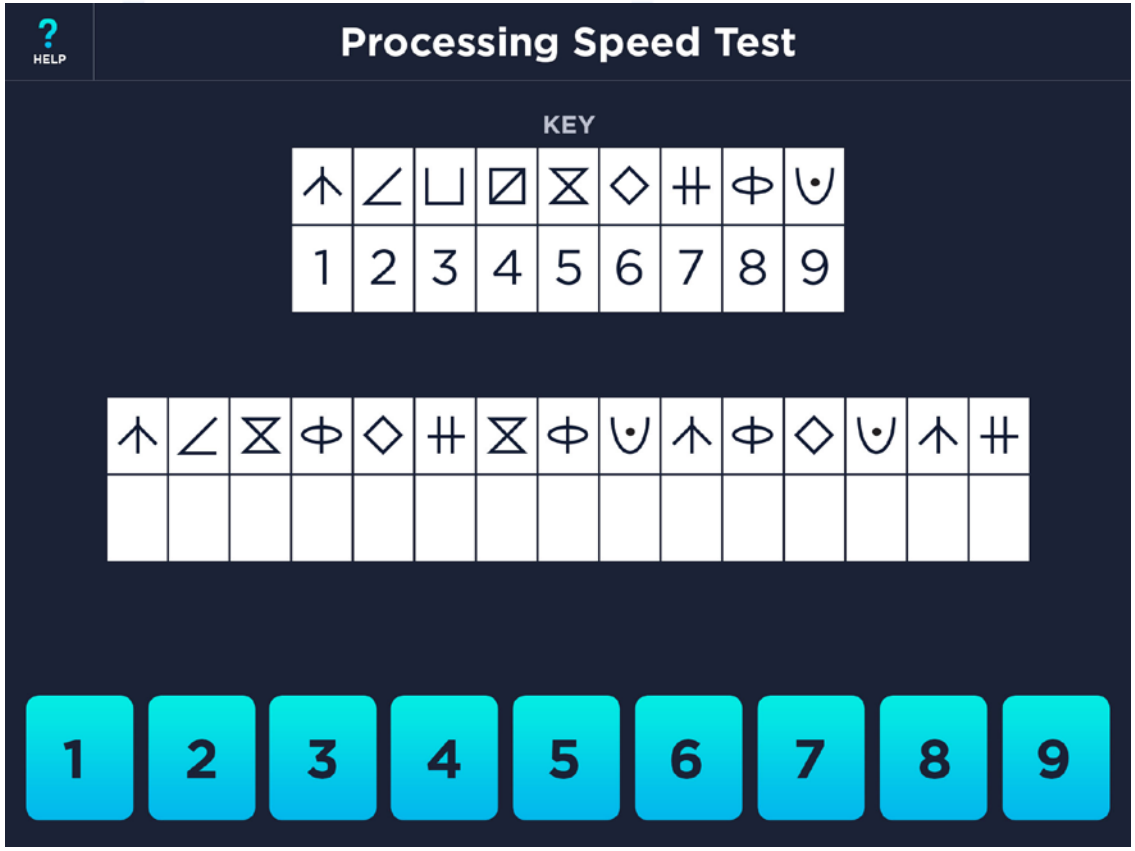




MS Performance Test domains



Processing Speed Test – based on the symbol digit modalities test



Patient will be instructed to match the numbers and symbols according to the key provided. The trial lasts 120 seconds using audio and visual instructions

Instructional videos are embedded in the app to facilitate the user experience

Data Dashboard for Physician use

Applications to help patients living with chronic disease

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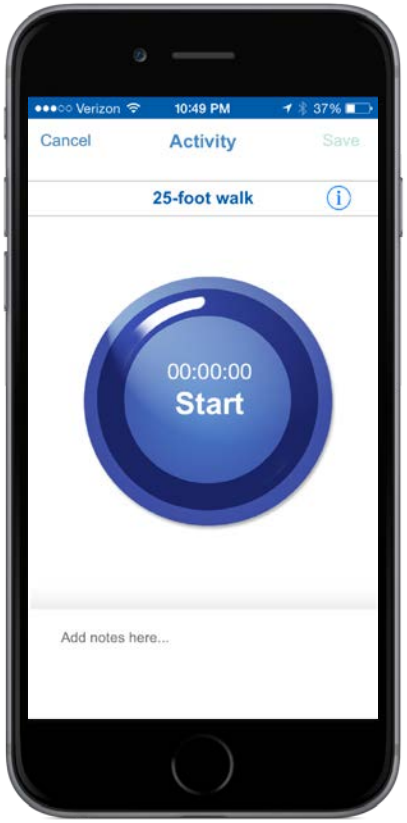
Mood

Energy

Activity



Sensation

Barriers that impede advancement of digital biomarkers in MS

- Clinical validity: Correlation with conventional measures
- Clinical meaningfulness: Actionable or useful output
- Standardization of ‘Minimal Viable Product’ attributes for clinical use
- Sensitivity to change over time
- Sensitivity/utility in the patient’s own environment
- Differentiation between non-clinical and clinically relevant digital tools
- Physician acceptance

Back up slides

Biogen

Partnering to assess digital biomarkers in MS

"Biogen…gave out 250 Fitbit bands to MS patients in the U.S. last spring to track their level of activity and sleep patterns. Biogen says collecting data on a daily basis—about **how much and how fast MS patients walk** — could yield data about the progression of the disease and lead to better treatments."
– Bloomberg, Dec 2014

Biogen partners with Altas 5D to evaluate the use of in-home sensor technology to monitor MS patient symptoms.

"Precise measurement of neurological and neuropsychological i**mpairment and disability** in multiple sclerosis is challenging. We report methodologic details on a new test, the Multiple Sclerosis Performance Test (MSPT), a computer-based platform for precise, valid measurement of MS severity."
– Rudick et al, "MSPT: An iPad-Based Disability Assessment Tool", June 2014

"Google will join Biogen Idec to study **environmental and biological contributors** to the debilitating disease's progression. Using sensors, software and data analysis tools, the companies will collect and sift through data from people with the disease. The goal is to explain why multiple sclerosis progresses differently from patient to patient."
– Bloomberg, Jan 2015

IMI2 initiative to develop and test a transformative platform of remote monitoring of disease in CNS disorders including MS

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