

Harnessing Real-time Patient Data to Improve Clinical Outcomes and Research

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Agenda

- Introduction
- Components of MS PATHS
- MSPT (Multiple Sclerosis Performance Test)
- Quantitative MRI Measures
- Biomarkers
- Learning Health System
- Ongoing Challenges
- Conclusion

Introduction

Real World Data (RWD) and Real World Evidence (RWE) are playing increasing roles in health care decisions.

- Currently, a similar initiative – MS PATHS is being sponsored by Biogen. MS PATHS – is a RWD generation initiative, which leverages technology in routine care to produce real-time data. It is a collaboration with 10 leading MS centers in Europe and the U.S. to leverage technology deployed in routine care to generate standardized, high-quality data from a diverse, real-world patient population. Because the information is collected at the patient visit, it will be immediately available for better, data-driven medical decisions; and the data will also be de-identified, transferred out of the individual MS centers, and then deposited into a secure database where it can be analyzed, studied, and applied toward advancing knowledge about MS and its treatment.
- Biogen's goal is to help improve the outcome-based and precision medicine for MS patients.
- This presentation highlights the vision and salient features of MS PATHS. We explore MS PATHS's potential to influence the future Randomized Clinical Trial study designs, how it can shape the personalized medicine initiative and its potential to impact the drug post market activities like label expansion, reimbursements etc

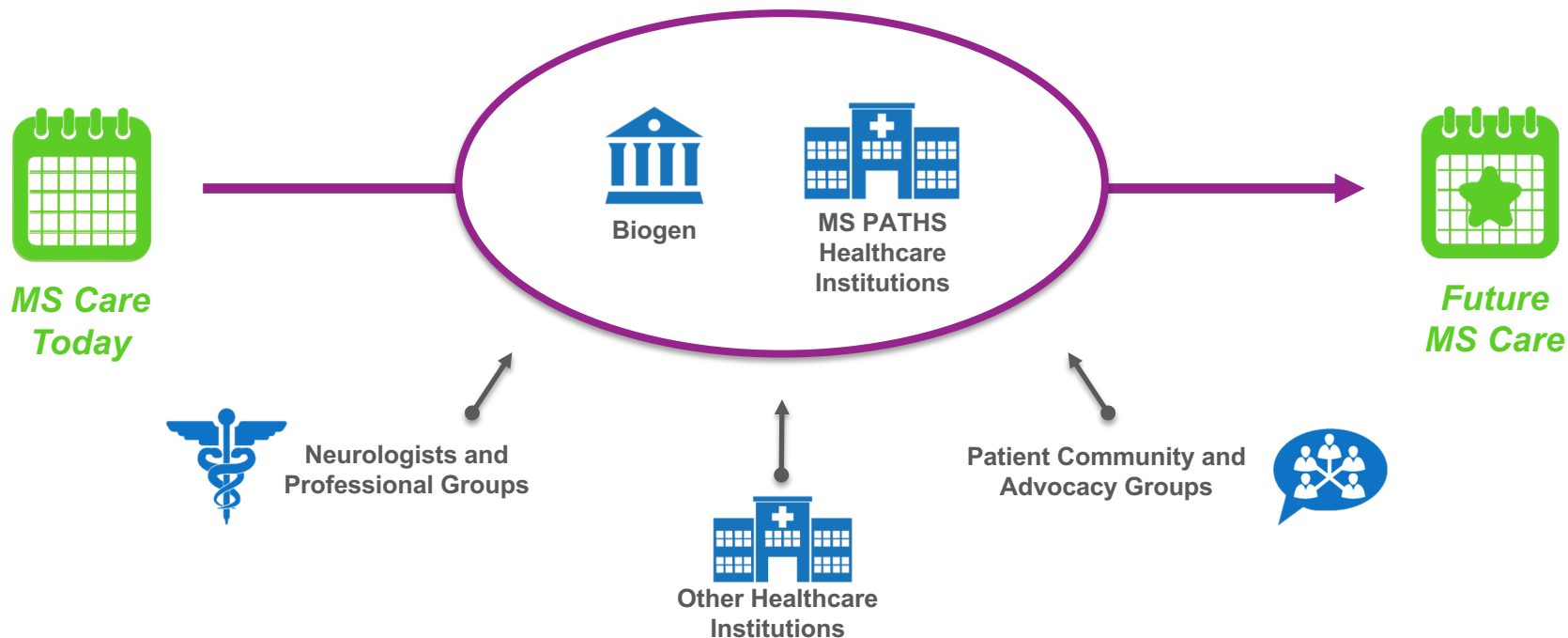
MS PATHS aims to enhance the standard of care through a Learning Health System



- A demonstration project supported by Biogen, in collaboration with a number of healthcare institutions
- Seeking to improve MS outcomes through real-world data and insight generation
- Leveraging technology to enable the creation of a data repository of deeply phenotyped patients
- Exploring new technologies (eg, advanced wearables) to generate and collect patient data outside of the clinical practice setting to be made available at the point of care

MS PATHS Shared Vision: By pooling data, this network of healthcare institutions will create a system of continuous learning—a way to learn from clinical practice and generate insights that can be used to inform decision making at the point of care.

Through collaborations, we aim to generate new insights that may help transform MS clinical practice



MS PATHS guiding principles

- Engage all providers and nearly all MS patients in a healthcare institution
- Standardize, quantify, and maximize data collected as part of standard of care
- Leverage technology to enable data collection in clinical practice
 - Make it possible to collect data on all participating patients, which is too time consuming using traditional methods
- Ensure transparent governance by multi stakeholder group
- Become recognized as meaningful for patients, providers, payers, and other stakeholders



Components of MS PATHS

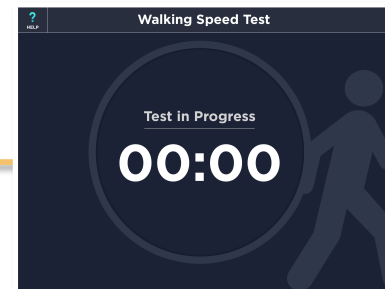
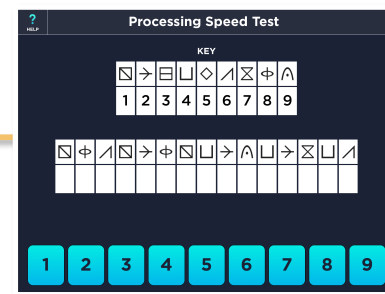
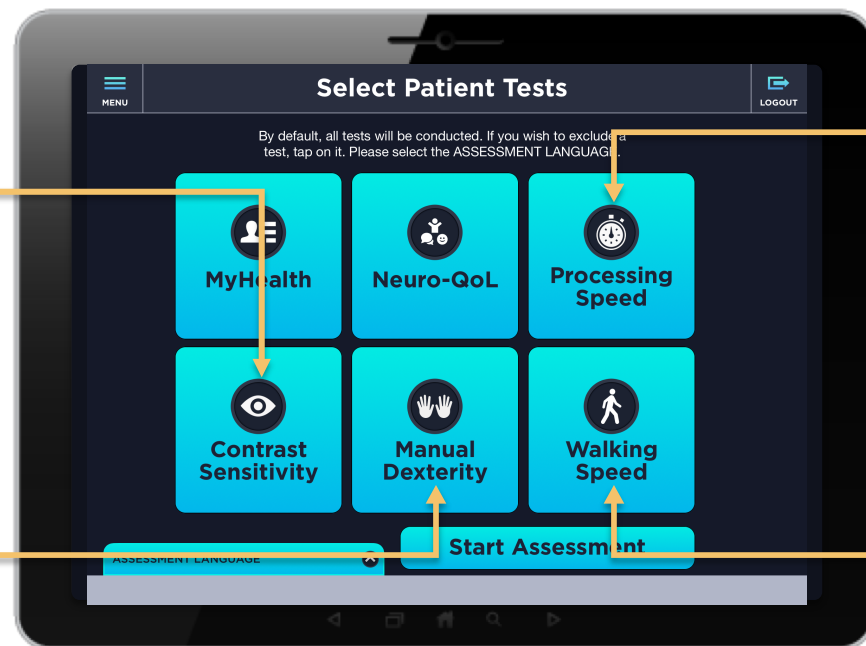
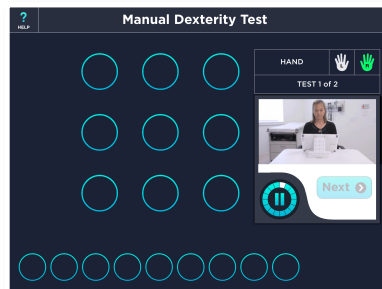
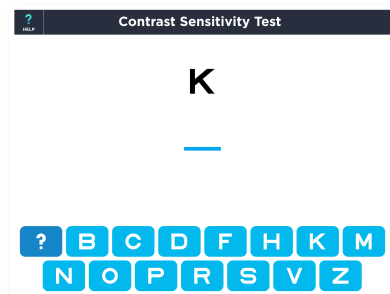
- MSPT • Quantitative MRI measures
- Biomarkers • Learning Health System



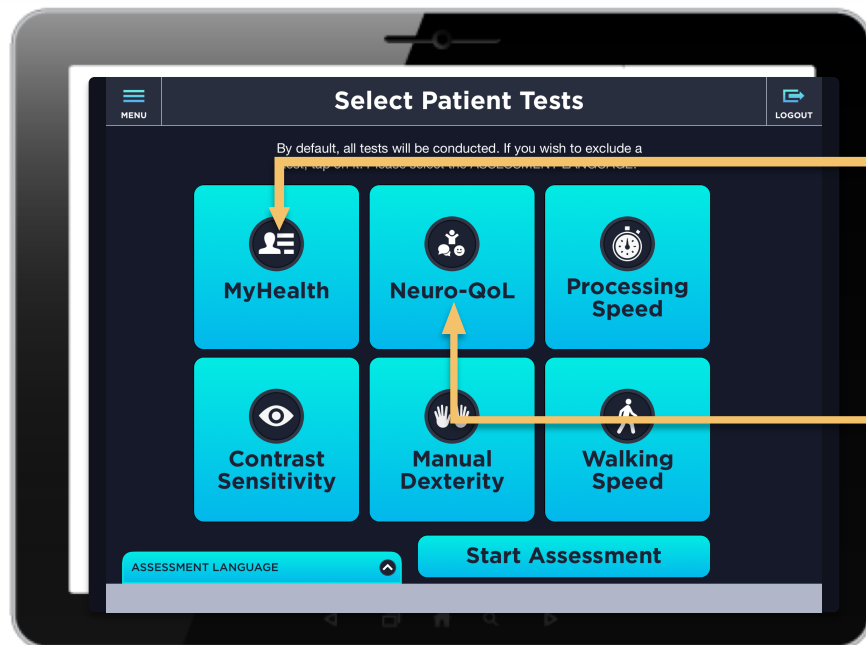
MSPT

An iPad-based assessment tool designed to objectively quantify major motor, visual, and cognitive symptoms and quality-of-life outcomes associated with MS

Neurological assessments of the MSPT



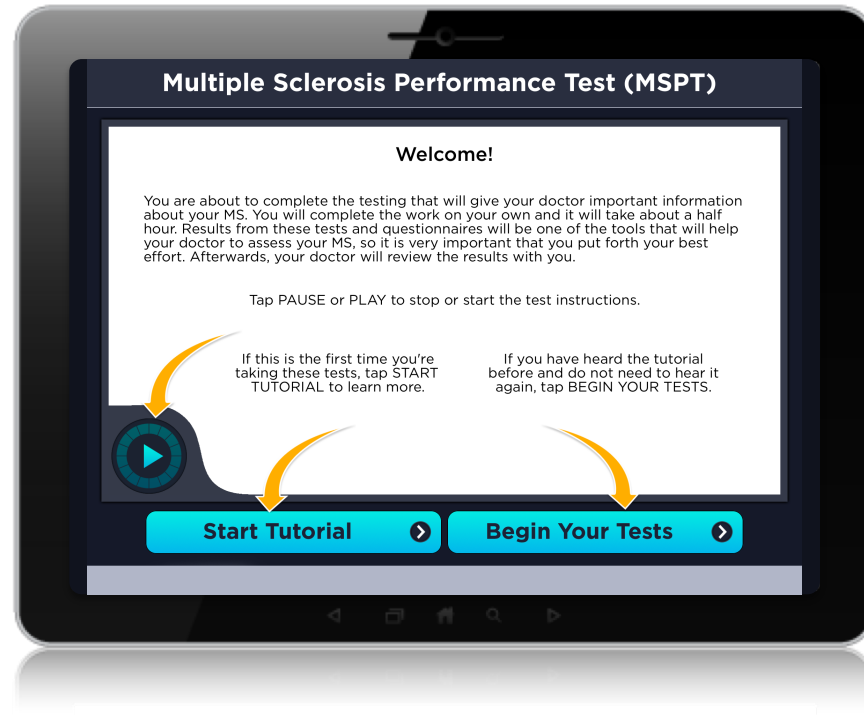
The MSPT includes a structured history and patient-reported outcomes



MyHealth: 
Demographic and
treatment history
questionnaire

Neuro-QoL: 
Neurological
and quality-of-life
questionnaire

Patient self-administration designed to integrate into routine care



Patient progress is displayed on the MSPT dashboard

Comparative normative data is displayed for processing speed test*

A more detailed view of the data is available by selecting the data points

Print functionality allows for generation of hard-copy report

This dashboard view allows clinicians to visualize data at the point of care



*Comparative normative data will be available on future versions of the device.



Quantitative MRI measures

Developing a solution for quantitative measures in routine clinical care



Biomarkers

Seeking to develop a clinically useful molecular test to optimize outcomes for individual MS patients



Learning Health System

Leverages technology to collect and aggregate longitudinal data for a large volume of diverse patients in order to provide a more three-dimensional view of MS

MS PATHS: Core data elements collected and available at the point of care



Background Information

- Demographics
- MS disease-modifying medications
- Disease type and duration
- Patient-Derived Disease Steps ($\cong$ EDSS)



Quantitative MRI

- New and enlarging T2 lesion number*
- Brain volume and brain volume change*

*Technology for point-of-care metrics is under development.



Neuroperformance Testing

- Walking Speed Test – time
- Processing Speed Test – number correct
- Manual Dexterity Test – time
- Contrast Sensitivity Test – number correct



Patient Reported Data (Neuro-QoL)

Physical

– *Function/Health:*

- Upper Extremity Function (Fine Motor, ADL)
- Bowel Function
- Urinary/Bladder Function
- Lower Extremity Function (Mobility)

Physical

– *Symptoms:*

- Fatigue
- Sleep Disturbance

Mental

– *Emotional Health:*

- Depression
- Anxiety
- Stigma
- Positive Affect and Well-Being
- Emotional and Behavioral Dyscontrol

Mental

– *Cognitive Health:*

- Applied Cognition-General Concerns
- Applied Cognition-Executive Function

Social:

- Satisfaction with Social Roles and Activities
- Ability to Participate in Social Roles and Activities

These data will be collected on every patient at each visit as part of routine care.

Ongoing challenges...

- From a clinical statistical analyst perspective while transitioning from a Randomized Clinical Trial (RCT) to an RWE environment.
- Challenges include but are not limited to –
 - Project, resource management
 - SAS to non-SAS software environment
 - Statistical analysis
 - Data management
 - Known unknowns Vs unknown unknowns

Conclusion

Patients FIRST.

MS PATHS seeks to

- Improve MS outcomes through the real-world data and insight generation.
- Explore new/innovative technologies (eg, advanced wearables).
- Generate and collect patient data outside of the clinical practice setting to be made available at the point of care.
- Facilitate early disease detection, predict disease progression and start treatment with the most effective medication.
- Monitor disease course and activity and to monitor success of a specific treatment (individualized treatment response).
- Support neurologists in clinical decision making and enhance quality of care and enhance the standard of care through a learning health system.

MS PATHS offers opportunities for healthcare institutions to enhance clinical practice through evidence-based research. Patients are able to contribute to MS research during the course of a regular office visit and at the same time healthcare institutions are collecting the most advanced data about the status of disease. Patients can be confident they are helping to advance a greater cause.

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