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

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ABSTRACT

Real World Data (RWD) and Real World Evidence (RWE) are playing increasing roles in health care decisions. Currently, a similar initiative – MS PATHS 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. MS PATHS collects clinical, MRI and biologic data from all patients in real-time, at the point of care, to better understand the disease and ultimately improve the lives of those living with MS. We are able to collect a robust set of real-world data that is unprecedented in scale and will contribute to a more precise approach to managing patients by supporting providers in real-time to meet the diverse needs of people living with MS.

This paper highlights the vison and salient features of MS PATHS. We explore MS PATHS's potential to influence the future Randomized Clinical Trial study designs - endpoint selections, patient population selection etc. How it can shape the personized medicine initiative and it's potential to impact the drug post market activities like label expansion and reimbursements.

INTRODUCTION

There's been a deep urge for creation of a learning healthcare system in the U.S. to improve public health. Such systems rely on real-world evidence to maximize the safety, effectiveness, and value of medical care, and to create continuously improving patient outcomes. Yet, that type of approach requires a reevaluation in how we merge patient care and research to generate evidence within the healthcare environment. Biogen's goal is to help improve that approach by paving the way for outcome-based and precision medicine for MS. Patient outcomes, is how well a treatment works to lessen or eliminate disease. Personalized or precision medicine, a new era in which disease-modifying therapies can be selected for individual patients based on scientific data that predicts the likelihood of benefit — the right medicine, at the right time, for the right patient. Biogen's effort is a demonstration project to create a learning health system in MS known as **MS PATHS** (Partners Advancing Technology for Health Solutions). Biogen has collaborated with ten leading MS centers across the U.S. and Europe to collect comprehensive, quantitative medical information directly from thousands of patients and their providers. Using technology and enhanced patient engagement, we are standardizing and collecting comprehensive clinical and imaging data on every MS patient who agrees to share de-identified data. 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. With MS PATHS, a goal is to effectively merge patient care and research — a key component of a learning health system

MS PATHS

MS PATHS is a one-of-a-kind collaboration between Biogen and healthcare institutions to create an integrated, efficient data collection system to conduct research and potentially improve clinical care. It's aimed to leverage data in aggregate and collaborate across centers to learn more about MS through standardized neuro performance testing, patient-reported data and imaging. Its efforts are focused on information-sharing via a learning health system to which leading healthcare institutions in the U.S. and Europe will contribute standardized patient-reported data. MS PATHS takes the best aspects of clinical trials — standardized data collection and imaging, rigorous data collection — and apply them to large numbers of patients in clinical care. Hope is to gain fundamental insights about MS itself and how to best use treatments — and to do so much more quickly, less expensively and with data from many more patients than is possible with traditional clinical trials. MS PATHS emphasis on learning from pooled clinical practice. Through research, this network of technology-enabled healthcare centers intends to create a way to learn from clinical practice and generate insights to one day inform point-of-care decision-making, with the goal of improving outcomes.

MSPT

At the heart of MS PATHS is the **MSPT** (Multiple Sclerosis Performance Test) a suite of iPad-based assessments. MSPT is an iPad based, commercial-ready Class I medical device. It represents a new approach to quantify MS related disabilities. It takes advantage of advances in computer technology, information technology, biomechanics, and clinical measurement science. Based on, but extending the Multiple Sclerosis Functional Composite (MSFC), the MSPT provides precise, quantitative data on walking speed, balance, manual dexterity, visual function, and cognitive processing speed. The MSPT allows for patient data collection to be integrated directly into the MS visit workflow. The data go right into the clinical and research database and can be accessed for research purposes as soon as patients see their provider.

Taken by patients before routine appointments

MSPT has the electronic adaptations of the MSFC to provide quantitative assessments of motor, visual and cognitive performance. It objectively quantifies motor, visual and cognitive symptoms associated with MS.
MSPT comprises of six modules. Of which four are performance modules taken by patients – PST (Processing Speed), Vision (Contract Sensitivity), MDT (Manual Dexterity, WST (Walking Speed). Other two are questionnaires base modules – MyHealth (Demographic and treatment history questionnaire) and Neuro-QoL (Neurological and quality of life questionnaire).

MSPT also permit visualization of clinical data at the point of care. It enables comparison of patient clinical status to longitudinal and normative patient data. It can also generate clinical data for aggregation and analysis.

IMAGING DATA AND BIOLOGIC DATA
A vital component of MS PATHS is the sharing of MRIs under which all MRIs will be aggregated. Imaging activities include quantitative assessment of new or enlarging T2 lesion counts and brain volume changes. Standardized MRI acquisition and image analysis will result in comparable MRI data from all patients across multiple institutions, which could lead to more rapid and reliable treatment decisions. MS PATHS combine assessments from the MSPT with standardized MRI acquisition sequences. Data can also be linked to biosamples collected under a companion research protocol.

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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