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New database for sharing MS clinical trial data

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A new database containing nearly 2500 patient records from the placebo arms of nine multiple sclerosis (MS) clinical trials is now available for research by qualified investigators. This is just one of the tools generated through the Multiple Sclerosis Outcome Assessments Consortium (MSOAC), a global effort launched by the National MS Society and Critical Path Institute (C-Path). MSOAC is striving to develop an outcomes measure that addresses the critical need for a more sensitive way to detect the benefit of potential treatments that slow or reverse progressive disability in people with MS.

"Key to the success of every C-Path consortium is the sharing of expertise and data," stated Lynn Hudson, PhD, C-Path's Chief Science Officer and Executive Director of MSOAC. "The sharing of both treatment and placebo arm data by MSOAC member companies is unparalleled."

Nearly 15,000 records from active treatment and inactive placebo arms, a rich source of performance measures and related clinical information, are currently being analyzed for regulatory qualification of a new instrument to measure disability and progression in MS. The measurement tool, which will also incorporate the viewpoint of people living with MS, will be submitted to the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) for regulatory qualification, a step toward validating its acceptance for use as a primary outcome measure in clinical trials.

"We're pleased to enable investigators around the world to access previously unavailable data through the new placebo data platform, which should increase our understanding of MS," notes Bruce Bebo, PhD, Executive Vice President, Research, at the National MS Society. "MSOAC is the latest in a long line of special initiatives undertaken by the Society to enhance the conduct of MS clinical trials and thereby speed the development of new therapies for all forms of MS. By bringing multiple stakeholders to the table, including people with MS, we have been able to achieve broad support for our goal of better and faster trials."

Prior to pooling data, standardization is essential. The consortium began by developing another tool—a data standard for MS—in collaboration with the leading global standards organization the Clinical Data Interchange Standards Consortium (CDISC). Released in 2014, this therapeutic area standard allows data from multiple MS trials to be grouped for reporting, analysis, and regulatory submissions. As another advantage for the MS community, the MS data standard will help drug sponsors meet next year's FDA requirement for implementation of CDISC data standards in individual submissions.

The MS data is housed at C-Path's Data Collaboration Center (DCC), which was founded to provide large-scale data solutions for scientific research in a neutral, non-competitive environment. Currently, DCC's data platform securely hosts data from 83 clinical trials, representing over 49,000 subjects, over 100 million data points, and six different therapeutic areas. The DCC's policies around individual patient-level data meet or exceed data privacy and human subject research protection requirements.

A review board will screen requests for access to the MS placebo arm database, using the process established for another successful C-Path effort in sharing placebo data, namely, the Alzheimer's disease database.

Investigators may apply by supplying a brief description of the research plan and agreeing to the terms and conditions; details and forms are available on the MSOAC website.

Provided by The Critical Path Institute (C-Path)