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# **New Database for Sharing MS Clinical Trial Data**

April 25, 2016

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## **Sharing Clinical Trial Data for Multiple Sclerosis**

### **Standardized and Pooled Data Available for Secondary Research**

New York and Tucson – April 25, 2016. 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](#).

### **About Multiple Sclerosis:**

Multiple sclerosis (MS) is an unpredictable, often disabling disease of the central nervous system that disrupts the flow of information within the brain, and between the brain and body. Symptoms vary from person to person and range from numbness and tingling, to walking difficulties, fatigue, dizziness, pain, depression, blindness and paralysis. The progress, severity, and specific symptoms of MS in any one person cannot yet be predicted, but advances in research and treatment are leading to better understanding and moving us closer to a world free of MS. Most people with MS are diagnosed between the ages of 20 and 50, with at least two to three times more women than men being diagnosed with the disease. MS affects more than 2.3 million people worldwide.

### **About the organizations:**

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[The National Multiple Sclerosis Society](#) mobilizes people and resources so that everyone affected by multiple sclerosis can live their best lives as we stop MS in its tracks, restore what has been lost, and end MS forever. To fulfill this mission, the Society funds cutting-edge research, drives change through advocacy, facilitates professional education, collaborates with MS organizations around the world, and provides services designed to help people with MS and their families move their lives forward. Last year alone, through our comprehensive nationwide network, the Society devoted \$122.2 million to help more than one million individuals connect to the people, information and resources they need. To move closer to a world free of MS, the Society also invested \$54 million to support more than 380 new and ongoing research projects around the world.

Early and ongoing treatment with an FDA-approved therapy can make a difference for people with multiple sclerosis. Learn about your options by talking to your health care professional and contacting the National MS Society at [nationalMSSociety.org](http://nationalMSSociety.org) or 1-800-344-4867.

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[Critical Path Institute \(C-Path\)](#) is an independent, nonprofit organization established in 2005 with public and private philanthropic support from the Arizona community, Science Foundation Arizona, and the U.S. Food and Drug Administration (FDA). C-Path's mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader in forming collaborations, C-Path has now established twelve global, public-private partnerships that currently include nearly 1500 participants from government and regulatory agencies, academia, patient advocacy organizations, and dozens of major pharmaceutical companies. C-Path is headquartered in Tucson, Arizona. For more information, visit [www.c-path.org](http://www.c-path.org).

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[The Multiple Sclerosis Outcome Assessments Consortium \(MSOAC\)](#) was created jointly with the National Multiple Sclerosis Society to collect, standardize, and analyze data about MS with the goal of qualifying a new measure of disability as a primary or secondary endpoint for future trials of MS therapies. The National MS Society recognized the gap in the MS treatment pipeline and decided to employ a method that has steadily gained support within the research community—consortia science. MSOAC brings stakeholders from industry, academia, MS advocacy groups, and regulatory agencies together to spur development of drug development tools to assess the effectiveness of potential treatments for all forms of MS.

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