The Multiple Sclerosis Outcome Assessments Consortium (MSOAC) is a public-private partnership which aims to accelerate the development of new therapies for MS by generating new tools for measuring outcomes in clinical trials. It is collecting, standardizing, and analyzing data about MS with the goal of qualifying new measures of disability for the disease. MSOAC is the newest of the eight consortia of Critical Path Institute (C-Path), a nonprofit organization that is dedicated to accelerating drug development by delivering on the mission outlined by FDA’s critical path initiative.

Mission

Multiple Sclerosis Outcome Assessments Consortium (MSOAC) has a mission to develop improved clinical outcome measures for Multiple Sclerosis (MS) trials. The overarching goal of MSOAC is to develop a sensitive, clinically meaningful, and reliable clinician-reported outcome (ClinRO) measure that can be qualified by the regulatory agencies for use as a primary endpoint in clinical trials aiming to reduce, stop, or reverse MS disability progression. In order to achieve its aim it is:

- Creating data standard for MS, which will be developed in collaboration with the standards
setting organization Clinical Data Interchange Standards Consortium (CDISC).

- Creating a database of MS trials in which the legacy data is remapped to the CDISC standard so that studies can be pooled for analysis and submission to the FDA and European Medicines Agency (EMA) in partial support of new measure qualification.

The consortium focuses on sharing precompetitive patient-level data from the control arms of legacy clinical trials, developing new tools to be submitted to the regulatory agencies, and developing consensus data standards. The specific goals include:

- Establishing a mechanism for the various participants in the MS drug development to engage with patients and patient advocates.
- Generating a data standard for MS starting with the National Institute of Neurological Disorders Stroke (NINDS) Common Data Elements that have already been developed for MS.
- Developing a mechanism for data sharing, and analysis of data already collected but largely unanalyzed.
- Establishing a pathway for qualifying better outcome measures for use in future MS clinical trials.
- Contributing to international harmonization of methods and standards, which could improve the efficiencies of world-wide drug development for MS.
- Ensuring that those aspects of disability that are of most importance to patients and families are taken into consideration.

2012 - The National Multiple Sclerosis Society and Critical Path Institute (C-Path) came together to launch the Multiple Sclerosis Outcome Assessments Consortium (MSOAC).

2013 - MSOAC held its first annual workshop with the US FDA and the EMA on 1st April in Maryland. The meeting was launched by Dr. Janet Woodcock, Director of FDA’s Center for Drug Evaluation and Research.
MSOAC published its Initial project plan which was published in Multiple Sclerosis Journal.

The consortium submitted their letter of intent to the FDA and EMA for developing clinical outcome assessment tool for future MS clinical trials.

**Structure & Governance**

Multiple Sclerosis Outcome Assessments Consortium, MSOAC, is a consortia of Critical Path Institute (C-Path) and is governed by C-Path’s Executive Committee. Similar to other C-Path institutes, the Executive Director of MSOAC is a staff member of C-Path and has subject matter expertise. In addition to the Executive Director, C-Path also employs an Associate Director, Project Manager, Project Coordinator, Data Managers and the resources are provided by the sponsoring organizations.

MSOAC also has a liaison from the FDA and EMA to advice on issues relating to qualification of a clinician-reported outcome measure. Like other C-Path consortia a coordinating committee develops the global mission, values, and objectives for the consortium and provides oversight and high-level guidance for all activities. Its membership is composed of representatives of each member organization. This committee is responsible for overseeing the priorities and resources of the consortium and sets both short and long term objectives to be carried out across the disease state initiatives.

MSOAC coordinates their research activities through several working groups that provide advice, support and review across multiple activities and project teams.

**Financing**

As the umbrella organization for the Multiple Sclerosis Outcome Assessments Consortium, MSOAC, the Critical Path Institute’s (C-Path) revenue is generated mostly from membership dues and grants. C-Path also receives financial support through a contract with the FDA.

**Intellectual Property**
The output of the collaboration is within the precompetitive space and intellectual property created is owned by the consortium as a whole. According to the membership agreement, the content and information from the consortium is deemed confidential to MSOAC members and all external disclosures are approved by members.

**Patent Engagement**

External non-profit patient groups interact with each of the Multiple Sclerosis Outcome Assessments Consortium (MSOAC) working groups to help set priorities for gathering and interpreting data, providing information to aid patient care and clinical trial enrollment, and play a prominent role in the external communications. The National Multiple Sclerosis Society is a founding partner of the consortium and its members include Alberta Multiple Sclerosis Research Foundation, Consortium of Multiple Sclerosis Centers, Fast Forward, Italian Multiple Sclerosis Society (AISM), Multiple Sclerosis Society UK, Multiple Sclerosis Society of Canada and the National Multiple Sclerosis Society.

As an effort of Critical Path Institute (C-Path), Multiple Sclerosis Outcome Assessments Consortium (MSOAC), positions itself as a trusted and neutral third party that is able to convene consortia of industry, academia, patient stakeholders, regulators and government in precompetitive collaborations. The iterative involvement of the FDA and EMA for guidance and official recognition of Clinician Reported Outcome (ClinRO) through formal qualification of the marker is a hallmark of C-Path/MSOAC.

In addition, MSOAC also publishes papers in peer-reviewed journals that reflect the lessons learned during each stage of the project.

**Data Sharing**

As a recently created organization, MSOAC has outlined its plans to work with its various members to share, collect and analyze historical as well as newly generated data. The consortium has also made data sharing a priority by specifying that the development of a data sharing mechanism is a success measure for the consortium.
Points of Contact

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Sponsors & Partners

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U.S. Food and Drug Administration
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