A new global multistakeholder initiative on Patient Reported Outcome for MS
Members of the panel

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MSIF 2017-2021 STRATEGY

Aim: GREATER SCIENTIFIC UNDERSTANDING & MORE TREATMENTS

Measure impact
Search for treatments
Increase funding
Support more researchers

Improve data sharing

“Global collaborations for registries or databases in relation to Patient Reported Outcomes”
MS SOCIETIES AND CURRENT IPRO PARTNERSHIP
MSIF LEAD AGENCY: ITALIAN MS SOCIETY
AISM Lead Agency

• Contributing to the Patient Registry Initiative promoted by EMA

• PROs for MS research and healthcare. AISM is working on an international project to standardize and harmonize PROs between their own PROMOPRO-MS database and iConquerMS (Accelerated Cure Project) network.

• International experience in applying framework for Multistakeholder Research Initiatives (coordinator of EU H2020 Responsible Research Innovation MULTI-ACT project)

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Aim

To explore ways of increasing use of patient registries by supporting a more systematic and standardised approach to their contribution to the benefit-risk evaluation of medicines


Patient Representatives to:

“Advise on appropriate patient reported outcomes that might feasibly be collected and included in registries”
The Accelerated Cure Project and the Italian Multiple Sclerosis Society Collaborate to Advance Patient-Reported Outcomes in MS Research, Patient Care and Product Development

This project will explore standardization of PRO measures between “patient-powered” research initiatives and will enable improved health, healthcare and quality of life for people affected by MS.
15th May, 2018

The MULTI-ACT project calls for continued work towards multi-stakeholder EU Research and Innovation pathways, striving for:

- **Sustained Responsible Research and Innovation ("RRI") in future framework programmes past Horizon 2020**
- **A new model allowing for improved effective cooperation of all relevant stakeholders involved along the entire research and innovation pathway, with the involvement of all stakeholders included below**
- **Improved shared measurements of impact and supporting infrastructures to enable true alignment of efforts and accountability of results**

**The MULTI-ACT Solution: A Multi-Stakeholder Approach**

Patients are the ultimate recipients of MS research findings and, therefore, key stakeholders. MULTI-ACT foresees patients and patient organizations as key in the Responsible Research Innovation (RRI) process and will use Multiple Sclerosis as its first case study.
Impact of Research on People with MS

The Mission: The Explicit Driver
…What began as an extension of patient advocacy is now evolving into an emerging scientific discipline aimed at understanding and incorporating patient needs and perspectives into the processes of developing, regulating, and delivering new therapies as well as improving care….
PATIENT-PROVIDED INFORMATION (PPIN)

- All information regarding a patient regardless of source
- A range of input or data that is collected from the patient
- A subset of PPIn that is reported directly by a patient without amendment or interpretation by a clinician, researcher, or any other entity
- A subset of PPIn that is produced (i.e., created, recorded, or gathered) by the patient or caregiver

Figure 1. Types of Patient Information

(https://www.nationalhealthcouncil.org/sites/default/files/NHC_Patient_Engagement_Rubric.pdf)
THE FUTURE OF PATIENTS: “EMPOWERING EXPERIENTIAL KNOWLEDGE”

(Adapted from David Somekh, European Health Management Association, 2016)
HIGH LEVEL OUTCOME

• Several global initiatives are defining and shaping this developing field

• However, despite differences in viewpoint, the different stakeholders agree that PRO and PROMs have not reached their full potential of delivering benefits to patients
STAKEHOLDERS ATTENDING LERICI MEETING, JULY 2018
MULTI-STAKEHOLDER MEETING – LERICI, JULY 2018
RESEARCH, VALIDATION AND DEVELOPMENT:
STRATEGIC OBJECTIVES

• To identify functional domains that matter most to people with MS that will lead to the prioritization of functional domains. This is particularly important for ensuring content validity.

• To fill critical gaps in the knowledge base that are hindering progress toward the development of a clear roadmap for research needs and progress.

• To research, validate and develop relevant PROMs.
MULTI-STAKEHOLDER MEETING – LERICI, JULY 2018
CLINICAL MANAGEMENT: STRATEGIC OBJECTIVES

• To identify current PROs and PROMs to be used in clinical care and collected in registries and advice relevant regulatory agencies and clinicians.
• Meet regulatory agencies position on PRO and PROMs (e.g. MSOAC EMA document)
• To promote, coordinate, implement and support initiatives aiming at validating and harmonizing PROs across cultures

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MULTI-STAKEHOLDER MEETING – LERICI, JULY 2018

e-HEALTH: STRATEGIC OBJECTIVES

• To establish current e-Health return of investment for all the stakeholders engaged

• To enable the long-term benefits afforded to patients (active versus passive), clinicians and other stakeholders by e-Health

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MULTI-STAKEHOLDER MEETING – LERICI, JULY 2018

HEALTH CARE SYSTEM: STRATEGIC OBJECTIVES

• To translate standardized data into a performance measure (PRO-PMs) that captures the results most important for improving long-term wellness.

• To enable PRO-PM in innovative reimbursement models, regulatory frameworks well as their clinical decision support algorithms.

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Global PRO Joint Initiative
MISSION

• To maximize impact of Science with and of Patient Input on the health, healthcare and quality of life of people affected by MS.
• To represent a unified view on PROs for MS to Healthcare Providers, Regulatory Agencies and Healthcare Technology Assessment Agencies (HTAs).
Global PRO Joint Initiative
MULTISTAKEHOLDER INITIATIVE INITIATIVE PRINCIPLES

• The PROMS Initiative recognizes the crucial importance of a framework to guide effective Multistakeholder engagement.

• As such, it will operate with respect for the values of ECF and MSIF, and will learn from best practice of other relevant initiatives (e.g. ECF Multistakeholder Initiative; Progressive MS Alliance and H2020 RRI MULTI-ACT project).
Global PRO Joint Initiative

KEY PRINCIPLES OF THE PROMS INITIATIVE

• **Clarity of purpose**: the mission of the initiative is clearly defined, with people affected by MS at its heart.

• **Inclusivity**. The initiative will aim to engage all parties/organizations from across the globe that have an interest in furthering the mission of the PROMS Initiative, and will:
  • Learn from their relevant experience and work to date.
  • Give them opportunity to shape the overall scientific agenda of the initiative.

• **Ensure that all stakeholders**, including people with and affected by MS, **have an equal voice**.

• Use a **co-creation approach** where possible.
1. Fill gaps: new validated PRO and PROMs
2. Uptaking PRO into clinical practice
3. Validation of active and passive remote control
4. Increase value of PRO in health care: relevance for the economic dimension

MEASURING IMPACT ON OUTCOMES THAT MATTER MOST TO PATIENTS
PROMS KEY STEPS

ECF - MSIF - AISM MOU signed
June 2019

First SSC Meeting Proposition Paper: Landscape and setting strategic priorities
Alongside ECF Annual Meeting, Baveno
November 2019

Consensus & Dissemination
July 2022

ECF - MSIF - AISM Kick Off Meeting Milan

Public Announcement ECTRIMS Stockholm

Strategic WGs Meeting To define WGs agendas and composition
Spring 2020
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Questions?
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