Patient Reported Outcomes for Multiple Sclerosis

The impact of PROMs in developing emerging therapies

12 November 2025 (8:30–13:00 CET)

Agenda

Welcome Session and Introduction

Time	Duration	Session Title	Speakers
8:30-8:45	15′	Welcome	Lydia Makaroff, MS International Federation Xavier Montalban, Centro de Esclerosis Mútiple de Cataluña (Cemcat) Hans-Peter Hartung, Heinrich-Heine University Düsseldorf
		Lived experience perspective The urgent need for relevant PROMs to improve therapy development and access	Helga Weiland PROMS ECT Co-Chair

Welcome Session and Introduction

Time	Duration	Session Title	Speakers
8:45-8:55	10′	**Meeting agenda and aims** Overview of meeting objectives **Context:** the path forward to increase the uptake of PROMs in clinical research in the context of new clinical descriptors without undermining the rigor of EMA PROMs validation and use in decision-making.	Paola Zaratin, Italian MS Society Patrick Vermersch, Université de Lille

Session 1: EMA Reflection Paper on Patient Experience Data in Q2-3 2025

Moderators: Elena H. Martínez-Lapiscina, European Medicines Agency; Mario Alberto Battaglia, Italian MS Society

Time	Duration	Session Title	Speakers
8:55-9:15	20′	**Keynote Speech:** The Value of Patient Experience Data (PED) in Medicines Development and Regulation: An EU Perspective	Juan Garcia Burgos European Medicines Agency
9:15-9:25	10′	**ECT response to the EMA reflection paper**	Meenakshi Nandakumar PROMS ECT
9:25-9:45	20′	**Discussion** Implications of reflection paper for PROMs in MS; When and how to engage EMA (e.g., Innovation Task Force); Differences in evidence standards for various regulatory goals.	
9:45-10:00	15′	**Coffee break**	

Session 2: **Clinical descriptors and new classification - Bridging biological disease mechanisms with different clinical states: the role of PROMs in phenotyping MS**

Moderators: Patrick Vermersch Université de Lille Maria Pia Amato Università di Firenze

Time	Duration	Session Title	Speakers
10:00-10:10	10′	**Lived experience perspective on MS classification**	Marilena Hadjiyianni PROMS ECT
10:10-10:25	15′	**Redefining MS disease descriptors and phenotypes**	Alan Thompson University College London
10:25-10:40	15′	**New clinical descriptors rooted on PROMs: myth or reality**	Giampaolo Brichetto Italian MS Society
10:40-10:55	15′	**Redefining Rating Scale Data Analysis in MS Trials: Report from the PROMS Workshop**	Jeremy Charles Hobart University of Plymouth
10:55-11:15	20′	**Discussion** Role of PROMs in capturing progression beyond relapses; The case for phase-specific and phenotype-specific PROMs; Aligning biological and experiential data; PROMs standardisation has to happen together with their personalized use.	
11:15-11:30	15′	**Coffee break**	

Session 3: **Alignment of stakeholders for PROs for emerging therapies**

Moderators: Xavier Montalban Centro de Esclerosis Mútiple de Cataluña (Cemcat) Nektaria Alexandri Merck

11:30-11:45	15′	**Successful PROs development from rare neurological diseases: the case of Myasthenia Gravis (MG)**	Carlo Antozzi Istituto Neurologico Carlo Besta
11:45-12:00	15′	**Industry perspective on integration of PROs to drug development**	Tammy McIver Roche
12:00-12:15	15′	**Regulatory perspective on alignment of PROs and drug development**	Elena H. Martínez-Lapiscina European Medicines Agency

Session 4: **Potential roadmap and next steps**

Moderators: Lydia Makaroff MS International Federation

12:15-12:25	10′	**Lived experience perspective: call to action**	R van den Bos PROMS ECT
12:25-12:55	30′	**Discussion panel** Moderator: **Daniel Ontaneda** Cleveland Clinic	Panel Members: **Carmen Tur** Centro de Esclerosis Mútiple de Cataluña **Jeremy C. Hobart** University of Plymouth **Patrick Vermersch** Université de Lille **Agnė Kazlauskaitė** Roche **Elena H. M.-Lapiscina** EMA **Alan Thompson** University College London **Paola Zaratin** Italian MS Society **ECT member**

Session 5: **Closure**

Time	Duration	Session Title	Speakers
12:55-13:00	5′	**Closing remarks**	Hans-Peter Hartung Heinrich-Heine University Düsseldorf