

# A phase IV open-label study of clinical outcome assessments to facilitate patient-HCP interaction in MS: study design and rationale

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## Introduction

- It was identified decades ago that better healthcare provider (HCP)–patient communication results in significantly better physiological, behavioral, and subjective health outcomes in chronic disease states.<sup>1</sup>
- The relationship between communication and outcomes may result from HCPs developing more personalized disease management strategies, and/or patients improving their medication compliance and taking a proactive role in managing their disease.<sup>2</sup>
- Patient-centric mobile technologies provide a possible means to facilitate communication between HCPs and patients, and ultimately improve outcomes in chronic diseases such as multiple sclerosis (MS).

## Objective

- To report the design of, and rationale for, a new mobile- and web-based technology platform to enable completion of clinical outcome assessments (COAs) and facilitate HCP–patient communication.

## Methods

### Study design

- The design and technology platform of the 48-week, phase IV, open-label, single-arm COAMS (Clinical Outcome Assessments in Multiple Sclerosis) study are currently being developed using a grassroots approach that will incorporate input from both HCPs and patients with MS.
- This study will enroll patients with any form of MS, who are 16–65 years of age, are being treated with a Food and Drug Administration-approved disease-modifying drug (DMD) as directed by their physician, and have self-reported stable disease.

### Technology platform and COAs

- Patients will use a newly developed technology platform to complete a panel of COAs that will include:
  - Patient-reported assessments of various domains such as quality of life, fatigue, physical pain, and mental health (Table 1).

Table 1. Proposed patient-reported assessments.

Domain	Proposed assessment	Number of questions
MS-specific quality of life	MS International Quality of Life (MSiQoL)	31
Fatigue	Modified Fatigue Impact Scale (MFIS)	5
Mental health	Mental Health Inventory (MHI-5)	5
Social support	MOS Modified Social Support Survey (MSSS)	5
Cognition	Perceived Deficits Questionnaire (PDQ-5)	5
Physical pain	MOS Pain Effects Scale (PES)	6
MS disability	Patient-Determined Disease Steps (PDDS)	9-point scale
Adherence behavior	Morisky Medication Adherence Scale (MMAS-8)	8
Work productivity	Work Productivity and Activity Impairment in MS (WPAI-MS)	6
Relapse	Assessing Relapse in Multiple Sclerosis (ARMS)	14
Ambulation	Multiple Sclerosis Walking Scale (MSWS-12)	12

The panel of assessments will be defined using input from healthcare providers and patients with multiple sclerosis, based on the benefit each possible assessment could provide to the routine care of patients. The selection of patient-reported assessments will be customizable for each patient. MOS, Medical Outcomes Study; MS, multiple sclerosis.

- Functional assessments of ambulation, upper-limb function, manual dexterity, visual function, and cognition (Table 2).

Domain	Proposed assessments
Ambulation	<ul style="list-style-type: none"> <li>Timed 25-Foot Walk (T25FW)</li> <li>6-Minute Walk (6MW)</li> </ul>
Upper-limb function and manual dexterity	<ul style="list-style-type: none"> <li>Nine-Hole Peg Test (9-HPT) and finger-tapping test (FTT) under consideration</li> </ul>
Visual function	<ul style="list-style-type: none"> <li>Amsler Grid Eye Test</li> <li>Color vision test</li> <li>Near vision cards (standard and inverted)</li> <li>Low-contrast visual acuity</li> </ul>
Cognition (processing speed)	<ul style="list-style-type: none"> <li>Symbol Digit Modalities Test (SDMT)</li> <li>Stroop test</li> </ul>

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- The panel of COAs will be defined using input from HCPs and patients with MS, based on the benefit each possible assessment could provide to the routine care of patients.
- Patients will be able to complete the patient-reported assessments using a mobile app on a smartphone or tablet. The selection of patient-reported assessments will be customizable for each patient.
- Patients and their HCPs will be able to review the results of the patient-reported and functional assessments via a web-based interface (Figure 1).

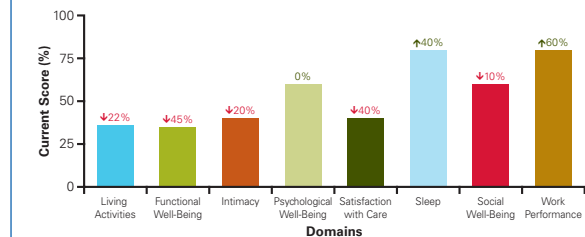
Figure 1. Screenshot of patient trend chart – one of the reports that will be available to HCPs via the web interface.

The Patient Trend chart gives a holistic view of patient outcomes over time, with a focus on changes since the previous visit. Charts for individual assessments provide a more detailed view, with the ability to drill-down into instrument domains and patient responses.

Percent Change since last visit at a glance:

Assessment Name	Compliance	Last Score %	Current Score %	Change in Score %
Patient-Determined Disease Steps	80%	0.00 %	39.50 %	↓ -39.5 %
MOS Pain Effects Scale	95%	33.33 %	80.00 %	↑ 46.67 %
Multiple Sclerosis International QOL	65%	75.48 %	37.42 %	↓ -38.06 %

PERCENT CHANGE BY DOMAIN

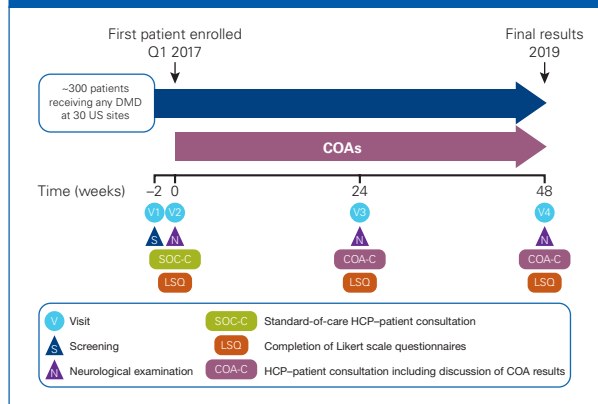


HCP, healthcare provider; MOS, Medical Outcomes Study; QOL, Quality of Life.

### Schedule of assessments

- At the baseline clinical visit, patients will have a standard-of-care consultation with their HCP. After the baseline visit, patients will begin using the technology platform to complete the COAs, and results will be incorporated into HCP–patient discussions during the clinical visits at 24 and 48 weeks (Figure 2).
- Throughout the study, patients will take their prescribed DMD as directed by their physician.
- The primary endpoint will be to evaluate the change in satisfaction with HCP–patient communications due to the regular completion and discussion of a defined set of COAs.

Figure 2. Proposed COAMS study design.



COA, clinical outcome assessment; COAMS, Clinical Outcome Assessments in Multiple Sclerosis; DMD, disease-modifying drug; HCP, healthcare provider; Q, quartile.

- The satisfaction with HCP–patient communications during the standard-of-care consultation (at baseline) and during consultations that incorporate COA results (at 24 and 48 weeks) will be assessed both by patients and by HCPs using Likert scale questionnaires.
- Patients and HCPs will also report on the perceived utility of each individual COA, facilitating further development of the technology platform.

Table 3. Likert scale questionnaire for assessment of the primary endpoint by patients.

Thinking about satisfaction with your healthcare communications as of today, please mark the best response based on how you feel about it today.						
	Very strongly disagree	Strongly disagree	Disagree	Agree	Strongly agree	Very strongly agree
1. I receive the information I need from my medical team (doctor, nurse) about what to expect from my MS condition in the future						
2. Communication with my medical team (doctor, nurse) is always efficient and focuses on what I need during that time period						
3. I am able to express all of my MS-related healthcare needs at my medical appointments (such as doctor office visits)						
4. Conversations with my doctor during office appointments provide me with information for how to manage my MS condition						
5. My medical team (doctor, nurse) helps me understand the changes in my MS condition since my last medical appointment						
6. I feel that my medical team (doctor, nurse) understands my individual needs for health and quality of life						
7. I feel confident that my medical team (doctor, nurse) has enough information about my MS condition when treating me						

MS, multiple sclerosis.

Table 4. Likert scale questionnaire for assessment of the primary endpoint by HCPs.

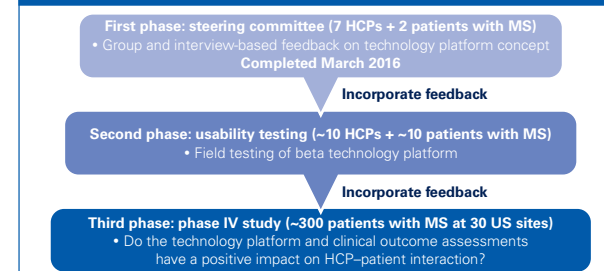
Thinking about satisfaction with your healthcare communications as of today, please mark the best response based on how you feel about it today.						
	Very strongly disagree	Strongly disagree	Disagree	Agree	Strongly agree	Very strongly agree
1. I have the information I need about how my patients' MS condition is affecting their day-to-day life						
2. I find that my communication with patients is efficient						
3. My patients feel comfortable communicating their needs during their office appointments						
4. I get reliable information I need about my patients' health status from medical records, reports, and office appointments						
5. I have everything I need to understand my patients' MS-related health in order to provide him or her with the best care possible						

HCP, healthcare provider; MS, multiple sclerosis.

## Results

- Development of the COAMS platform and study design is proceeding using a three-phase grassroots approach based on a collaborative effort between HCPs and patients (Figure 3). The first phase was completed in March 2016 and included input from seven HCPs and two patients with MS on the development of the technology platform, and psychometric interviews to develop the study primary endpoint.
- To minimize the burden on patients, the majority of the proposed patient-reported assessments each contains only 5–6 questions (Table 1).

Figure 3. The three-phase grassroots approach to develop the COAMS study design and technology platform.



COAMS, Clinical Outcome Assessments in Multiple Sclerosis; HCP, healthcare provider; MS, multiple sclerosis.

- The Likert scale questionnaires that will be used to assess the primary endpoint have been developed (Tables 3 and 4).
- The first patient enrollment is expected in Q1 2017.
- The final study results are expected in early 2019.

## Conclusions

- Innovative patient-centric technologies have the potential to improve HCP–patient communication and, ultimately, patient outcomes.**
- The COAMS study will evaluate the regular use of a mobile- and web-based platform, and incorporation of COAs into HCP–patient communication.**
- The study results will help to define a minimal set of key platform features to improve HCP–patient communication without imposing an additional burden on patients or HCPs.**
- Maximizing the quality of communication between HCPs and patients has the potential to improve disease management, therapy compliance, and patient quality of life.**
- The results of this study may have a substantial impact on streamlining the clinical assessment of patients with MS, and thus may have potential utility in future trials in MS.**

## References

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## Disclosures

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