The MS-LINK Outcomes Study Cohort: Study Design and a Descriptive Analysis of Baseline Key PROs, Disease, and Sociodemographic Characteristics

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Disclosures

JE: Creator, partner, and stockholder in Healthcare Impact Partners, LLC, and HIPnation Operations & Solutions, LLC; was on advisory boards and speaker panels for pharmaceutical companies including Biogen-Idec, Teva, Mallinckrodt, Novartis, Genentech, Genzyme, EMD Serono, and Celgene. Medical Director at MS Center of Atlanta (MSCA). **CT**: Has received research funding from Biogen, Sanofi, and EMD Serono and was on advisory boards for Biogen, Genentech, Sanofi, EMD Serono, TG Therapeutics, and Atara. **ER**: Nothing to disclose. **GP**: Has received grants (to the institution) from Biogen, EMD Serono, Roche/Genentech, Sanofi Genzyme, Novartis, Abbvie, and BMS; consultant and/or speaker bureau for Biogen, EMD Serono, Roche/Genentech, Sanofi Genzyme, Novartis, Janssen, BMS, TG Therapeutics, PRIME Education, and MSAA. **LF**: Has received consultancy fees from Genentech, Novartis, Bristol Myers Squibb, EMD Serono, TG Therapeutics, Sanofi and Horizon Therapeutics; has received program sponsorship from EMD Serono; and has grant support from NIH/NINDS, PCORI, Genentech, and EMD Serono. **JS**: was on advisory boards for Biogen, Novartis, and Genentech. **EP**, **CC** and **TL**: Employees of EMD Serono, Rockland, MA, USA.

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- PROs, which help to foster a more complete understanding of the effects of diseases and associated treatments on patients' lives, are currently underutilized
- In conjunction with provider-reported outcomes and healthcare utilization data, PROs can be used to improve our understanding of MS disease progression and treatment, particularly in diverse subpopulations

MS, multiple sclerosis; **PROs**, patient-reported outcomes.

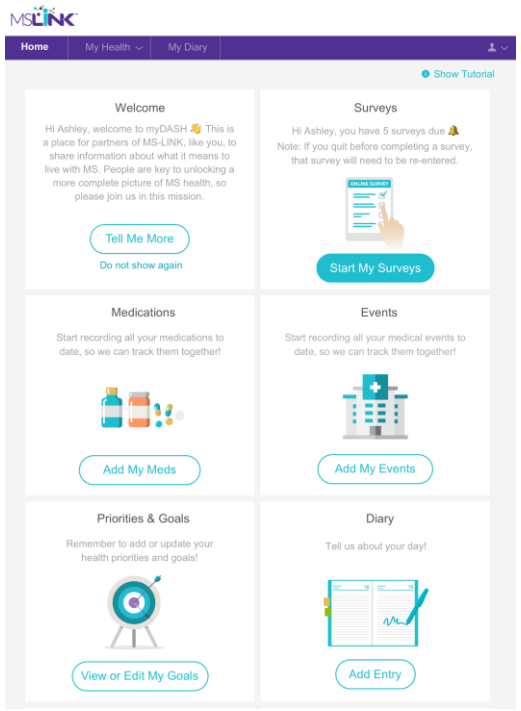
- **To create a comprehensive registry of MS patient data**
- **To examine PROs in diverse subpopulations of people with MS**
- **To correlate PROs with functional and clinical outcomes**
- **To facilitate future substudies**

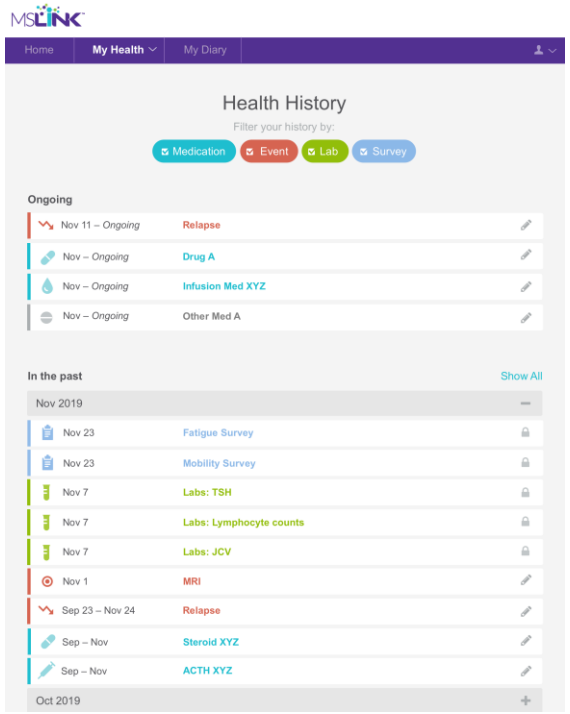
MS, multiple sclerosis; **PROs**, patient-reported outcomes.

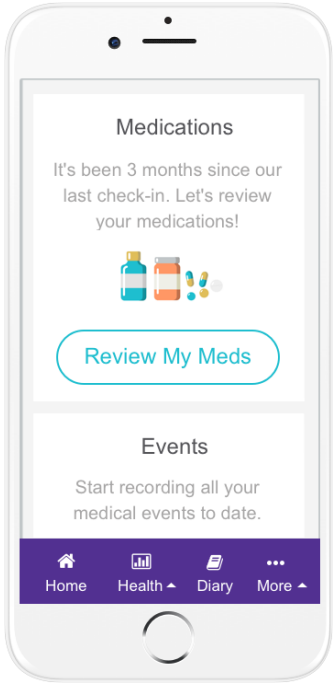
- The MS-LINK Outcomes Study is a prospective, longitudinal, multi-center observational study focused on collection of PROs
- The study aims to enroll ≥2000 patients from 8 to 10 sites in North America
  - Sites are encouraged to recruit and enroll all eligible and interested patients in their practice
- Participants will be followed for 3 years
- The following PROs will be collected at study entry and periodically during follow-up:
  - PROMIS - Fatigue MS
  - PROMIS - Physical Function MS
  - PROMIS - Anxiety
  - PROMIS - Cognitive Function
  - PDDS
  - PHQ9
  - Wasson Health Confidence Scale
  - HRQoL
  - WPAI-MS
  - MSTAQ
- In addition to PROs, patient medical history, demographics, and both clinical and functional outcomes are digitally collected at baseline and at subsequent regular intervals
  - Digital, decentralized data collection is intended to build comprehensive data on different aspects of patient experiences both at and outside of specific points of care

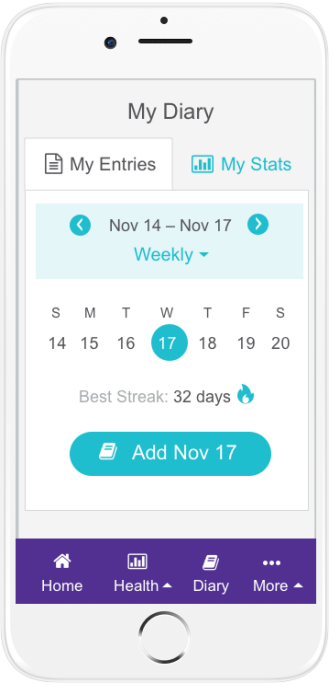
HRQoL, health-related quality of life; **MS**, multiple sclerosis; **MSTAQ**, Multiple Sclerosis Treatment Adherence Questionnaire; **PDDS**, Patient Determined Disease Steps; **PHQ9**, Patient Health Questionnaire, Question 9; **PRO**, patient-reported outcomes; **PROMIS**, Patient Reported Outcome Measurement Information System; **WPAI-MS**, Work Productivity and Activity Impairment Questionnaire.

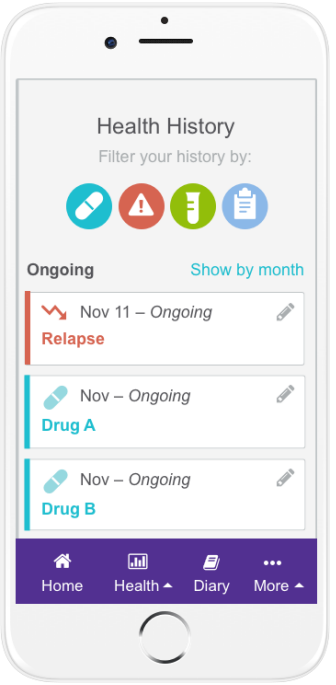
Figure 1. The digital data collection portal











Demographics

- As of January 2023, we report on 1,029 participants
- The mean age of the cohort is 50.8 years, 80.8% are female, and most of the cohort (90.5%) have a diagnosis of RRMS
- Overall mean disease duration was 14.9 years
- The study population demographics are diverse with regard to race, ethnicity and sociodemographic characteristics, with approximately 24% of patients self-reporting as non-white and 17% self-reporting as Hispanic or other ethnicity
- Approximately 50% of the sample were employed for wages or self-employed

RRMS, relapsing-remitting MS.

Table 1. Key sociodemographic characteristics of the Outcomes Study participants (n = 1029)

Characteristic	
Age, years	
Mean (SD)	50.8 (11.8)
Median (range)	51.0 (20–82)
Sex at birth, n (%)	
Female	831 (80.8)
Male	198 (19.2)
Race, n (%)	
White or Caucasian	723 (70.3)
Black or African American	204 (19.8)
Asian	6 (0.6)
American Indian or Alaska Native	6 (0.6)
Two or more races	33 (3.2)
No response	*57 (5.5)*
Ethnicity, n (%)	
Not Hispanic	768 (74.6)
Hispanic	30 (2.9)
Other	145 (14.1)
Do not wish to disclose	28 (2.7)
No response	*58 (5.6)*

Characteristic	
Employment status, n (%)	
Employed for wages	453 (44.0)
Self-employed	64 (6.2)
Homemaker	65 (6.3)
Military	2 (0.2)
Student	5 (0.5)
Out of work and looking for work	22 (2.1)
Out of work but not currently looking for work	22 (2.1)
Retired	153 (14.9)
Unable to work	184 (17.9)
No response	*59 (5.7)*

SD, standard deviation.

Table 2: Use of DMTs among Outcomes Study participants (n = 913)*

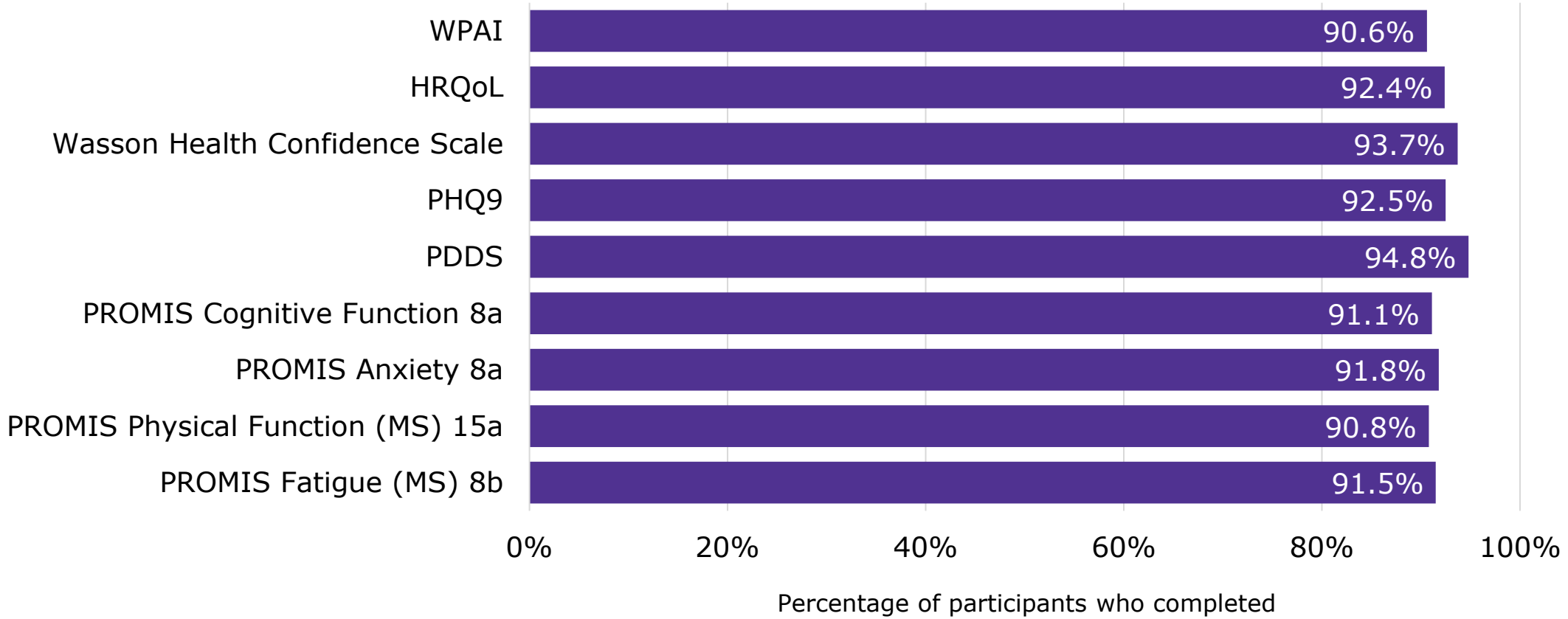
DMT Use	n (%)
Current DMT	
Ocrelizumab	230 (25.2)
Natalizumab	88 (9.6)
Dimethyl fumarate	59 (6.4)
Teriflunomide	58 (6.4)
Fingolimod	42 (4.6)
Glatiramer acetate	37 (4.1)
Diroximel fumarate	36 (3.9)
Ofatumumab	33 (3.6)
Cladribine	28 (3.1)
Interferon beta-1a IM	24 (2.6)
Ozanimod	15 (1.6)
Intravenous immunoglobulin	11 (1.2)
Siponimod	10 (1.1)
Leflunomide	9 (1.0)
Peginterferon beta-1a	8 (0.9)
Interferon beta-1a SC	7 (0.8)
Interferon beta-1b	4 (0.4)
Rituximab	4 (0.4)
Alemtuzumab	4 (0.4)
Methylprednisolone	2 (0.2)
Monomethyl fumarate	1 (0.1)
Methotrexate	1 (0.1)
No Current DMT	198 (21.7)

- Participants reported current use of many different DMTs
- Approximately 22% of participants reported no current DMT use
- Baseline mean PDDS score is 1.9 (SD = 2.1)
- Mean baseline PROMIS Fatigue (55.5, SD = 10.3) and Anxiety (52.3, SD = 10.0) scores are slightly elevated relative to the general population, while PROMIS Physical Function (42.6, SD = 11.4) and Cognitive Function (45.2, SD = 10.3) scores are slightly depressed

*As reported by HCP when available; otherwise, self-reported by patient.
DMTs, disease-modifying therapies; **HCP**, health care professional; **IM**, intramuscular; **PDDS**, Patient Determined Disease Steps; **PROMIS**, Patient Reported Outcome Measurement Information System; **SC**, subcutaneous; **SD**, standard deviation.

Figure 2. Baseline PRO completion rates (n = 1029)

- Baseline PRO completion rates greater than 90% indicate high patient engagement



HRQoL, health-related quality of life; **MS**, multiple sclerosis; **PDDS**, Patient Determined Disease Steps; **PHQ9**, Patient Health Questionnaire, Question 9; **PRO**, patient-reported outcome; **PROMIS**, Patient Reported Outcom urement Information System; **WPAI-MS**, Work Productivity and Activity Impairment Questionnaire

PRO Results

Figure 3: Comparison of key PROs across patient groups by sex at birth

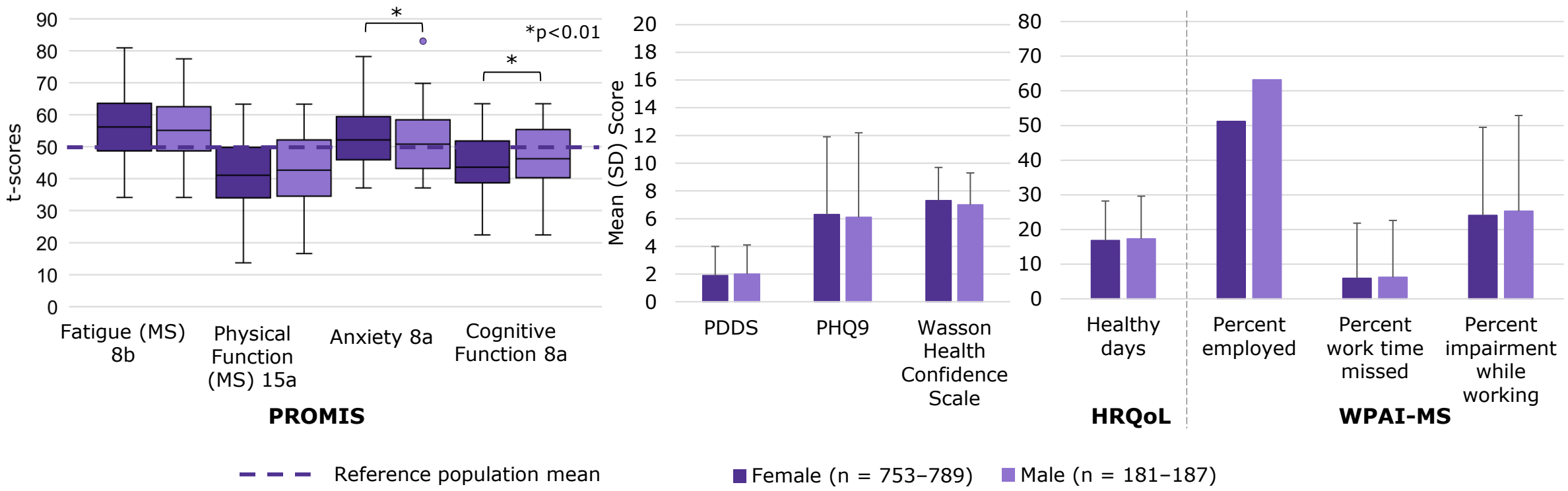


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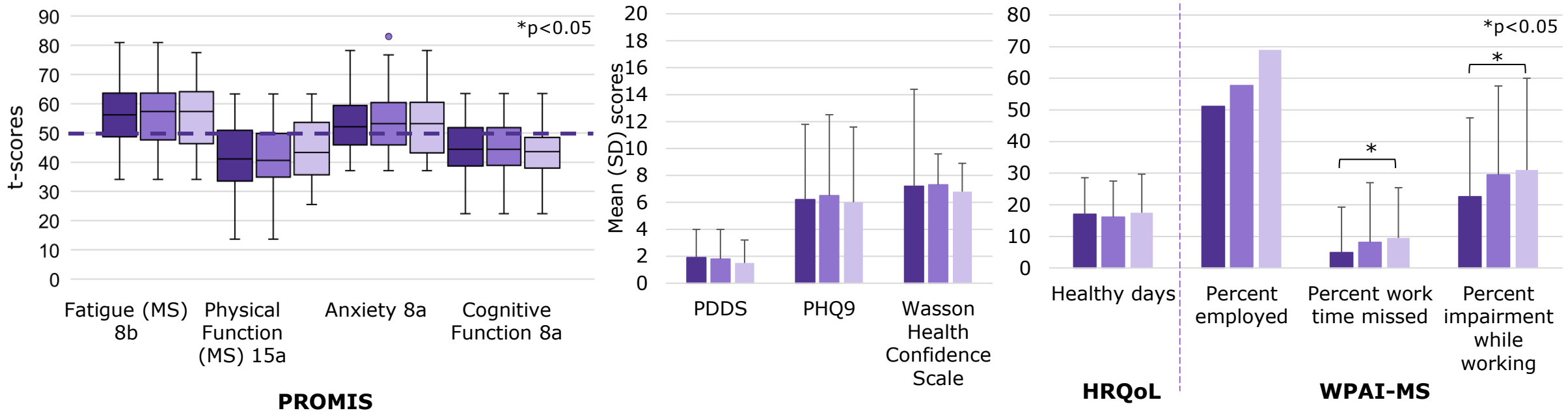
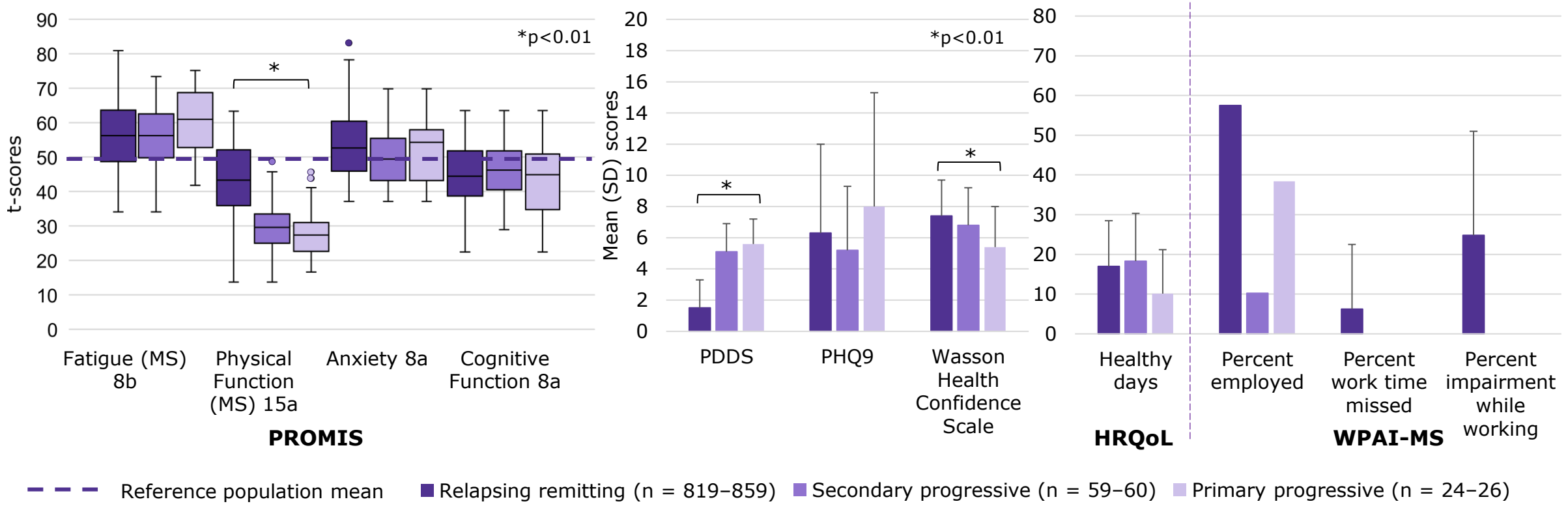
Figure 4: Comparison of key PROs across patient groups by race[a]



- Significant differences were not observed between ethnicities on any measure

[a]Groups with ≤10 members excluded from reporting.
HRQoL, health-related quality of life; **MS**, multiple sclerosis; **PDDS**, Patient Determined Disease Steps; **PHQ9**, Patient Health Questionnaire, Question 9; **PROs**, patient-reported outcomes; **PROMIS**, Patient Reported Outcomes Measurement Information System; **SD**, standard deviation; **WPAI-MS**, Work Productivity and Activity Impairment Questionnaire.

Figure 5: Comparison of key PROs across patient groups by MS subtype[a]



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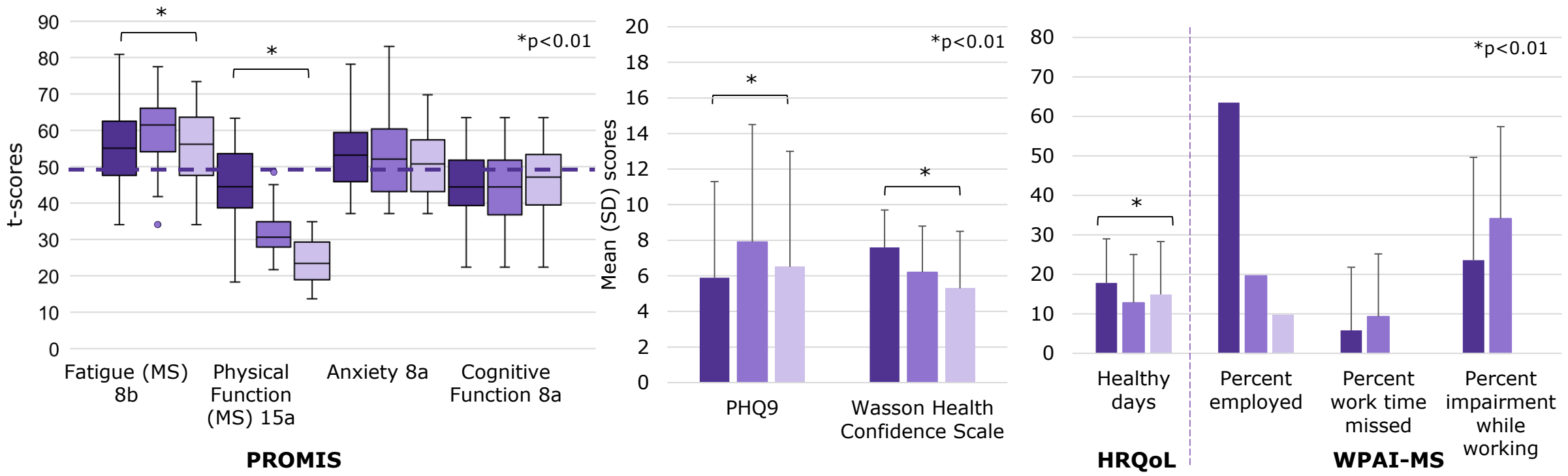
HRQoL, health-related quality of life; **MS**, multiple sclerosis; **PDDS**, Patient Determined Disease Steps; **PHQ9**, Patient Health Questionnaire, Question 9; **PROs**, patient-reported outcomes; **PROMIS**, Patient Reported Outcomes Measurement Information System; **SD**, standard deviation; **WPAI-MS**, Work Productivity and Activity Impairment Questionnaire.

Figure 6: Comparison of key PROs across patient groups by PDDS score[a]

- Participants were grouped by PDDS scores into mild (0-3), moderate (4-6), and severe (>6) categories.



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The MS-LINK Outcomes Study uses a unique, decentralized approach to gathering data about the real-life experiences of people with MS.

- The study was designed to enroll a more representative sample of the wider US patient population than clinical trials or other patient registries

The diverse patient population improves the generalizability of study findings and facilitates both subgroup analyses and potential future substudies.

The overall objectives of the Outcomes Study are to understand PRO changes over time, to identify PRO correlations to clinical and functional outcomes in MS, and to develop a comprehensive data source on patients with MS.

The digital dashboards, also known as digital data collection portals, provide patients and providers real-time tracking of outcomes and a comprehensive view of the patient experience.

As of January 2023, baseline PROs are largely similar between patients grouped by sex, race, and ethnicity. There are numerous significant differences in PROs by patient subtype and disability, as determined by PDDS score.

- The design of the study allows long-term examination of changes over time in both PROs and provider-reported outcomes, reflecting rates and extent of disability accumulation in the full study population as well as subgroups

MS, multiple sclerosis; **PDDS**, Patient Determined Disease Steps; **PROs**, patient-reported outcomes; **US**, United States.