

FLOODLIGHT Open – A Global, Prospective, Open-Access Study to Better Understand Multiple Sclerosis Using Smartphone Technology



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BACKGROUND

Multiple sclerosis (MS) is an insidious and unpredictable disease that can be hard to track and measure. **FLOODLIGHT Open** aims to fill in the gaps and help complete a more holistic picture with the hope to one day help improve care

Smartphone-based active and passive functional measurements may be more sensitive and robust in determining MS disease progression than periodic in-clinic assessments¹

- A 6-month proof-of-concept study (FLOODLIGHT; NCT02952911) showed that frequently collected smartphone-based measures can enhance data collected from in-clinic tests by providing a highly granular assessment of patients with MS in their natural setting²⁻⁵
- These findings demonstrate the need for a better understanding of patterns of use for smartphone-based measurements in the real-world to inform the feasibility of collecting sensor data in the long-term

FLOODLIGHT Open aims to assess adherence to smartphone-based high-yield active and passive assessments in approximately 10,000 participants over 5 years

FLOODLIGHT Open measures the participant's ability to perform simple tasks on a smartphone with the aim of understanding the impact of MS on functioning in the domains of cognition, upper extremity and mobility

- This is a digital monitoring study only, with no clinical measurements and no clinical data collected (e.g. no treatment information)
- Participants will be able to access their own data on their smartphones or through a web portal and share them with others, including their providers
- Each data point from each person will contribute to a unique and open dataset designed to help move MS research forward

OBJECTIVE

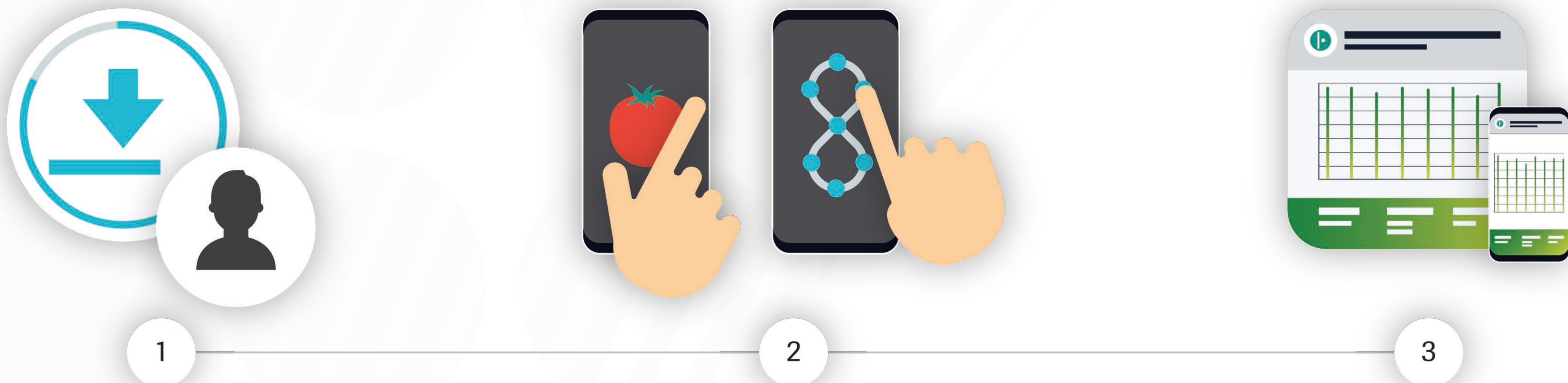
Primary objective: To understand the factors influencing long-term adherence to active and passive data collection on cognition and motor performance in people with MS over a period of 5 years

To create a more holistic view of MS. By engaging with **FLOODLIGHT** on a regular basis, patients generate data for themselves, and join thousands of others to build a unique open-access dataset

METHODS: Study Design, Population and Tests

FLOODLIGHT Open: A 5-year, global, prospective, non-interventional study

The **FLOODLIGHT Open** website can be accessed here and the **FLOODLIGHT Open** App is available here



Participant consents, downloads app and receives a unique identifier

Inclusion criteria

Participants with/without MS can enroll (participants provide baseline demographic information and medical history)

Age: ≥ 18 years

No exclusion criteria for this study

Study size: N≈10,000

Brain: Tests to assess participant's mood and cognitive functioning



Daily Mood Question

Quick daily questions about how the participant feels to help understand well-being and mood

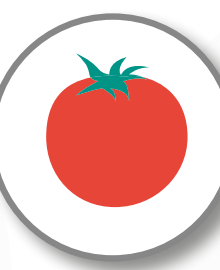


Matching Symbols

Matching symbols to digits measures how quickly information is processed



Hand: Hand Motor Function tasks designed by providers to measure manual dexterity, strength and precision over time



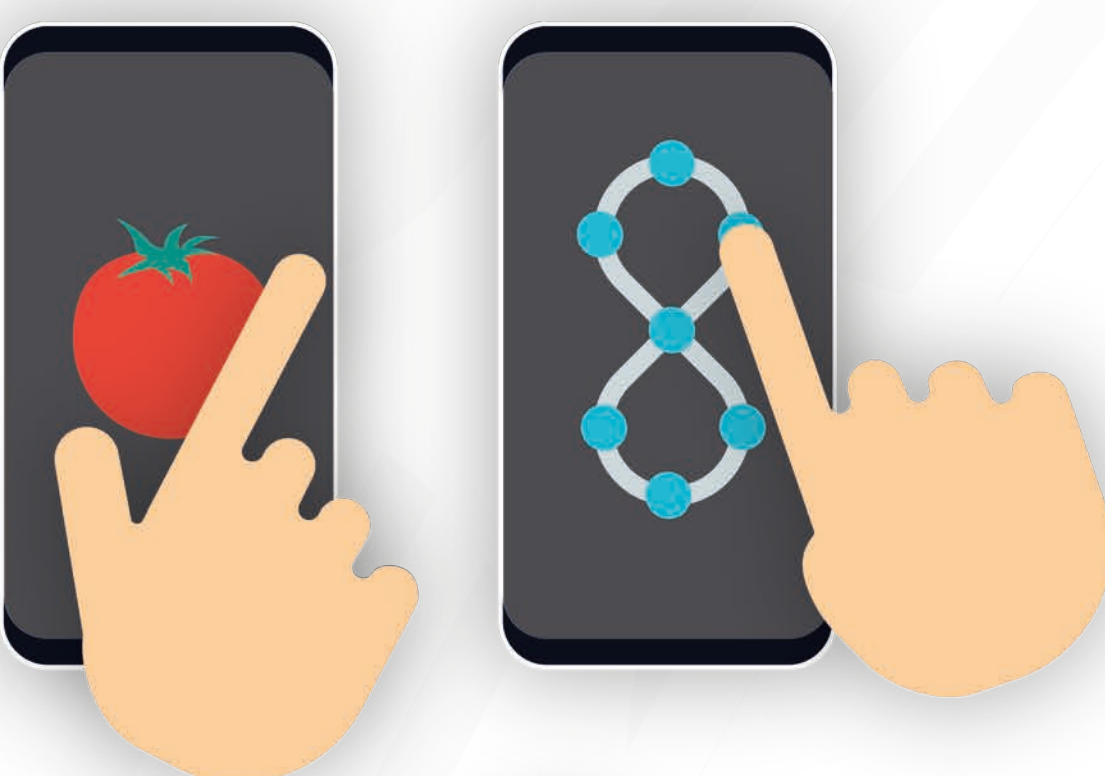
Squeeze a Tomato

Designed to measure changes in hand-eye coordination and fine motor skills



Draw a Shape

Measures the speed and accuracy of hand and finger movements



Participant performs daily assessments (tasks) and tracks performance

Active tests

Tests for cognition and hand motor function (5–10 minutes to complete in total)

Passive monitoring

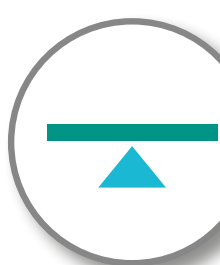
A continuous collection of metrics on mobility throughout the day

Mobility: Walking and posture tasks measure changes in participant's mobility, stability, speed and balance



Two-Minute Walk

Walking quickly for two minutes measures stamina and mobility



Balance

Standing still for 30 seconds measures posture and stability



U-Turn

Task measures how the participant walks and the ability to change direction



Passive Monitoring:

Passive Monitoring

Measures incremental changes in the way participants move throughout the day
Gathering information through the smartphone sensor on step counts/duration and asymmetry

CONCLUSIONS

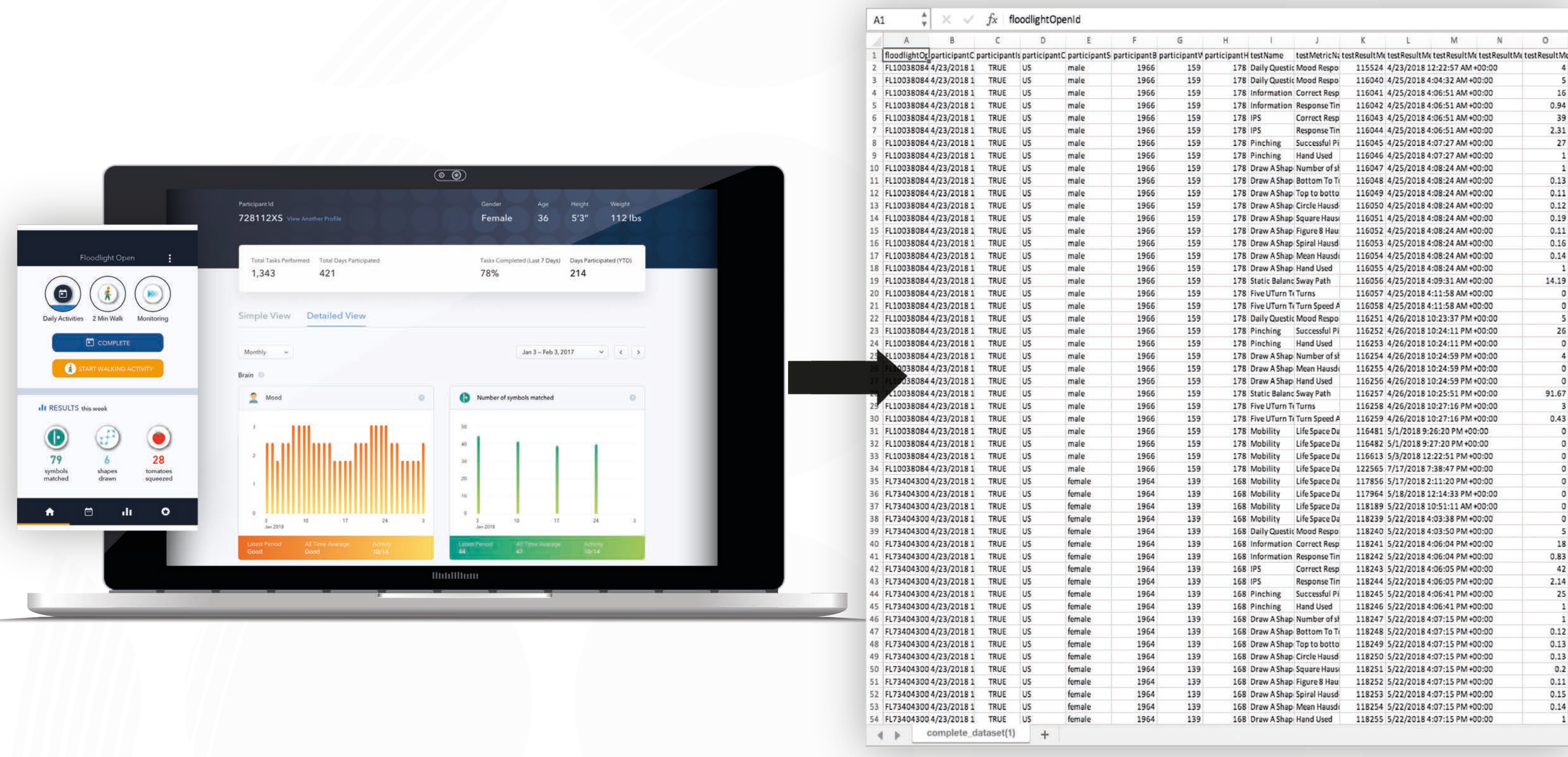
The **FLOODLIGHT Open** study will provide further understanding of long-term adherence to smartphone-based data collection to assess cognition, hand motor function, gait/posture and mobility in people with MS in a real-world setting

Sensor data collected from **FLOODLIGHT Open** will support other secondary research and facilitate the understanding of MS by the broad and collaborative community of MS researchers

JOINING A COMMUNITY

Participants joining **FLOODLIGHT Open** become part of something bigger: a group of people contributing to a growing dataset of invaluable information and potentially paving the way for future breakthroughs

Anonymized sensor data will be available to the broader MS research community to download for secondary research purposes



For Scientists and Providers

By **enrolling patients** in **FLOODLIGHT Open**, you can use the data for your own research

FLOODLIGHT Open data integrates with independent research and existing clinical data. Researchers will have **open access** to the complete dataset, opening up new fields of study and collaborations

References: 1. Bove R, et al. *Neural Neuroimmunol Neuroinflamm* 2015;2:e162. 2. Mulero R, et al. *CMSC* 2017;Poster QLI19. 3. Mulero R, et al. *EAN* 2017;Poster EP2169. 4. Mulero R, et al. *ECTRIMS* 2017;Poster P1226. 5. Montalban X, et al. *AAN* 2018;Poster 382. **Disclosures:** J van Beek is an employee of F Hoffmann-La Roche Ltd. R Freitas is an employee of F Hoffmann-La Roche Ltd. C Bernasconi is a contractor for F Hoffmann-La Roche Ltd. X Montalban received speaking honoraria and travel expenses for scientific meetings, has been a steering committee member of clinical trials or participated in advisory boards of clinical trials in the past 3 years with Biogen Idec, Merck Serono, Genentech, Genzyme, Novartis, Sanofi-Aventis, Teva Pharmaceuticals, F Hoffmann-La Roche Ltd, Celgene, Actelion, NMSS and MSIF. H Butzkueven's institution (Monash University) has received funding from Biogen, F Hoffmann-La Roche Ltd, Merck and Novartis; has carried out contracted research for Novartis, Merck, F Hoffmann-La Roche Ltd and Biogen; has taken part in speaker's bureaus for Biogen, Genzyme, F Hoffmann-La Roche Ltd and Merck; H Butzkueven has received personal grants from OxfordPharmagenesis and Biogen. L Kappos's institution (University Hospital Basel) received in the last 3 years and used exclusively for research support at the Department: steering committee, advisory board and consultancy fees from Actelion, Alkermes, Almirall, Bayer, Biogen, Celgene/Receptos, df-mp, Excedem, GeNeuro SA, Genzyme, Japan Tobacco, Merck, Minoryx, Mitsubishi Pharma, Novartis, F Hoffmann-La Roche Ltd, Sanofi-Aventis, Santhera, Teva, Vianex and license fees for Neurostatus-UHB products; the Research of the MS Center in Basel has been supported by grants from Bayer, Biogen, Novartis, the Swiss MS Society, the Swiss National Research Foundation, Innoswiss, the European Union and Roche Research Foundations. J Oh has received personal compensation for consulting or speaking from EMD Serono, Sanofi Genzyme, Biogen Idec, F Hoffmann-La Roche Ltd, Celgene and Novartis; and has received research funding from the MS Society of Canada, National MS Society, Brain Canada, Biogen Idec and Sanofi Genzyme. G Giovannoni has received honoraria from AbbVie, Atara Biotherapeutics, Bayer HealthCare, Biogen, Carbox Therapeutics, F Hoffmann-La Roche Ltd, Five Prime Therapeutics, Genzyme, GlaxoSmithKline, GW Pharmaceuticals, Merck, Merck Serono, Novartis, Protein Discovery Laboratories, Synthon, Teva, UCB and Vertex; research grant support from Biogen, Ironwood, Merck Serono, Merz and Novartis; and compensation from Elsevier. R Bove has received consulting fees from F Hoffmann-La Roche Ltd, Genentech, Novartis, Sanofi Genzyme and Pear Therapeutics, received research support from Akili Interactive and is funded by the NMSS, CIAPM and Hilton Foundation. L Julian is an employee of Genentech, Inc., and a shareholder of F Hoffmann-La Roche Ltd. M Baker is an employee and shareholder of F Hoffmann-La Roche Ltd. M Lindemann is an employee of F Hoffmann-La Roche Ltd. **Acknowledgments:** We would like to thank all patients, their families, and the investigators who participated in this trial. This research was funded by F Hoffmann-La Roche Ltd, Basel, Switzerland. Writing and editorial assistance for this presentation was provided by Articulate Science, UK, and funded by F Hoffmann-La Roche Ltd, Basel, Switzerland.