

April 2020 Newsletter



Finding the Pathways to a Cure

A cure for MS can mean different things to different people. For some, it means alleviating symptoms or regaining lost abilities. For others, a cure would eradicate the disease. As part of a three-year strategic plan, the [National MS Society](#) is working with researchers and clinicians to develop an international consensus defining what are the pathways to cures. By engaging the global research community, the Society will establish a Pathways to Cures research roadmap to identify knowledge gaps, milestones, and accelerators to speed solutions for people living with MS today, as well as preventing MS for future generations. Three distinct Cure Pathways have been identified with significant points of overlap. They include: (1) Stopping disease activity, (2) Restoring function by reversing damage and symptoms, and (3) Ending MS by preventing new cases. ACP and the Society share common goals – speeding the pace of research towards cures for MS and enabling research that enables people affected by MS to live their best lives – and are working in partnership on Pathways to Cures.



The Society is committed to ensuring the Pathways to Cures research plan is informed and influenced by the perspectives of the entire MS community and especially by people affected by MS. [iConquerMS](#) (currently 5,500 members strong and growing every day) is a meaningful resource to gather both data and input from people affected by MS. The



Society and ACP developed a survey to collect the perspectives of the MS community on the initial direction of the Pathways to Cures research plan, and to ensure the current definitions of Stop, Restore, and End resonated. Once approved by the iConquerMS Research committee, the survey was hosted on iConquerMS. One of the advantages of hosting a survey on iConquerMS is that the collected data can be linked to data already collected from network members through [REAL MS™](#), including demographics, disease severity information and other characteristics. All of this information can be used to explore the answers to any survey hosted by the network.

The survey included a number of questions designed to gather the perspectives of people affected by MS related to a cure or cures. Respondents were asked to rank the cure pathways (Stop, Restore, End) in order of importance to them. They were also queried about whether or not they had seen signs of progress toward a cure since their diagnosis and their optimism about having a cure within the next 10 years. Other questions included, “What 5 words come to mind when you think about a cure? What would a cure look like to you? How will we know when we have a cure?”

Over 400 iConquerMS members completed the survey, 56% of whom had relapsing remitting MS and 34% had progressive MS. Results show that 99% of people affected by MS consider a cure to be important. Optimism about a cure within the next 10 years was mixed (44% were somewhat or highly optimistic, 22% were neutral and 34% were somewhat or highly pessimistic). The three key pathways – Stop, Restore and End – resonated with respondents, with restore being ranked most important (especially to those with a higher level of disability). In other words, results show those with more advanced MS want to get back to where they were prior to this disease.

A slight majority of respondents (58%) agreed with the question “In the time since your diagnosis, have you seen any signs of progress toward a cure?” Interestingly, the reason many agreed was because they saw the work of industry as one of the most prominent and well-known elements of research. In other words, the number of effective disease

modifying therapies (DMTs) available are seen by these individuals as an indication that good research toward a cure is being done. Those that disagreed did not view the availability of highly effective DMTs in this way, either in general or because they hadn't found one that worked for them (more than 60% of those who disagreed with the question stated that new treatments did not equal progress toward a cure for them). Data suggest some people with MS (12% of those who disagreed with the question) feel knowing the cause of MS is necessary in order to find a cure. Therefore, more research is necessary toward this end.

When asked what words come to mind when thinking about a cure, iConquerMS members highlighted activities they are eager to get back (those their MS symptoms have prevented them from participating in). When asked what a cure means to them, responses centered on freedom from the disease and painted a picture of a life free from the constraints of MS. Survey results showed the cure definitions of Stop, Restore, and End resonated with survey respondents. Data show 51% of respondents rank Restore as most important and disability drives the desire for restoration (those with higher levels of disability felt restore was most important). Stop was ranked as highest priority by 30% of survey respondents and 20% thought End was most important.



In January, survey results were shared at a Pathways to Cures meeting in Washington, D.C., at which approximately 60 participants, including ACP and Society staff, researchers, people affected by MS and other stakeholders contributed to advancing the initiative.

Even though they aren't using the exact same words, people with MS are thinking in very much the same ways and are on the same page as researchers. When survey respondents were asked, "What would a cure look like to you?", data showed they use the language of Stop, Restore and End in their responses (see below). People affected by MS are able to contribute in significant and meaningful ways to scientific conversations in the development and implementation of the Pathways to Cures as well as other research plans.

What Would a Cure Look Like to You?

"A cure would be that we could **halt MS** in its tracks as soon as its identified."

"Understanding the **cause of MS**, **stopping its progression** then **remyelination and restoration** of function."

"People would know if they were predisposed to develop MS and would know exactly what lifestyle/diet changes to make to **avoid it entirely**."

"**Stop the disease onset** for those without MS at present so no more people get the disease. For those of us with the disease, a cure means **progression stops** and to some degree, symptoms are **reversed or eased**."

"**No more people would have to live with MS** and current MS sufferers would **stop progression** and then start **remyelinating**."

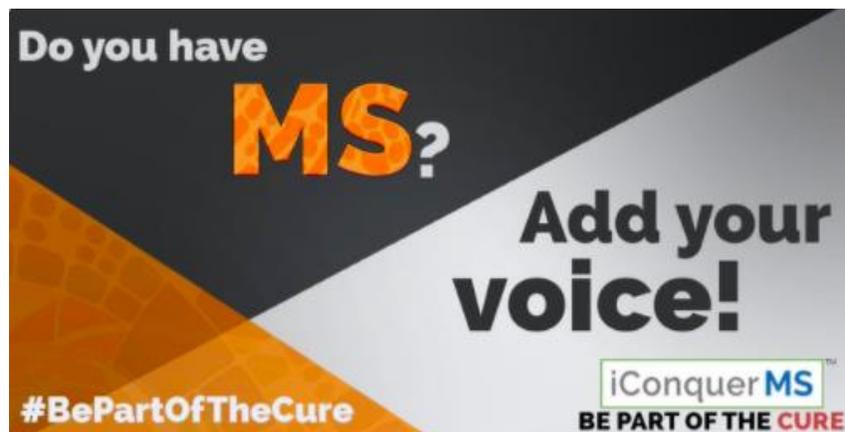
"Those with MS are **healed, no one new contracts MS**."

"**Stopping MS & repairing nerve damage** for the rest of us."

"**Stop** progression completely. Then **repair** the damage already done. If MS can be **prevented** like polio was, even better."

Sample responses from the Pathways to Cures survey

iConquerMS is an innovative platform for alternate or novel study designs. The rich data collected from this research-ready cohort is being used to inform Pathways to Cures activities by providing both quantitative and qualitative feedback from the iConquerMS community, representing the broad perspective of those affected by MS. There are many ways the patient perspective can enlighten the implementation of the initiative moving forward, for example, understanding the best way to communicate work that is being done, or study results, to the MS community. If you are not already a member, please consider [joining](#) iConquerMS, the only people-powered research network for MS. Every person that contributes their data advances MS research forward more rapidly! Already a member? Thank you for adding your voice to others working toward a cure for MS!



Patients Are the Experts

Patients are experts in what it's like to live with their condition and the effectiveness of its treatments. They know the most about symptoms and the quality of life improvements that matter most, as well as what therapeutic benefit/risk tradeoffs an individual with a given condition would be willing to make. People living with MS are the best source of information to help researchers understand the therapeutic context for MS drug development and evaluation. However, this important input hasn't been considered comprehensively in the drug development process throughout the industry until now.



In 2012, the U.S. Food and Drug Administration (FDA) established the [Patient-Focused Drug Development](#) (PFDD) initiative. PFDD is a systematic approach to ensure that patients' experiences, perspectives, needs, and priorities are captured and meaningfully incorporated into drug development and evaluation. The FDA is developing a series of PFDD guidance documents to address how patient and caregiver input can be collected and used in this regard.



In recent years, the FDA has made progress on its goal to obtain the patient perspective on certain disease areas and incorporate patient input in its drug review process. They conducted a number of [PFDD meetings](#) in order to more systematically obtain the patient perspective on specific diseases and their treatments. These diseases included chronic pain, autism, breast cancer, chronic fatigue syndrome, fibromyalgia, lung cancer, Parkinson's disease and psoriasis (among others). These meetings provided key stakeholders, including FDA staff, patient advocates, researchers, drug developers, healthcare providers, and others, an opportunity to learn more about what matters most to individuals and caregivers impacted by each condition. Attendees learned about such topics as the impact of symptoms on daily life and the effectiveness of different treatments, as well as the challenges or barriers to accessing them. A main take-away lesson from these meetings was that patients, in general, want to be engaged in the drug development process.

At the end of 2019, EMD Serono initiated a global Phase III clinical trial ([EVOLUTION RMS 1](#)) studying the efficacy and safety of evobrutinib, compared to interferon beta-1a, in adult patients with relapsing remitting MS. Recruitment for the study is currently underway with an enrollment goal of 1,900 subjects and a planned target completion date of June 2023. Prior to the initiation of the trial, ACP entered into a year-long partnership with EMD Serono that was well aligned with the FDA guidance. The purpose of this partnership was to ensure the patients' complete MS experience was captured and meaningfully incorporated into the design and implementation of this trial. As part of this collaboration, eight members of the iConquerMS community were invited to participate in a PFDD Council. The Council worked closely with the iConquerMS project team and team members from EMD Serono, attending face-to-face meetings and periodic conference calls over the course of the collaboration. They drew from their own experience to provide feedback and insights on the choice of PROs, patient-facing materials, and endpoints in the trials (specifically regarding the relevance of PRO measures to the real-world patient experience).



The collaboration between iConquerMS and EMD Serono is the first of its kind in MS drug development research. Feedback from the Council has had a lasting effect in the whole spectrum of what is important in drug development throughout the industry (how the success of a drug is measured, what is said about it). Input from the Council changed the way the project team at EMD Serono thought about what is important to people living with MS, for example the impact of symptoms or relapses on daily life, and the way



information is presented on drug labels. Active listening and feedback on follow-up actions by EMD Serono helped reinforce mutual respect and a partnership spirit in the collaboration and an overall positive experience by council members. The Council members expressed a desire for more frequent communication.

Two members of the PFDD Council, Laura Kolaczkowski and Margot Bjoring, shared their perspective on the experience at a recent meeting with EMD Serono. According to Laura, “When it comes to what life with MS is like, Margot is the expert, I’m the expert. It’s together we can all get onboard and pull that expertise together... All aboard, not just some, not just a few, but all of us aboard on this journey towards getting drugs approved that are going to improve our lives.” In Margot’s words, “It’s really challenging to bring together people with such different domains of expertise. The first thing we had to do was establish a common language, establish communication between all of these different groups... We talked about a relapse versus a flare-up. If you asked a clinician, they might say those mean the same thing. But, for people with MS, those actually mean very different things. That becomes very important when you’re talking about patient reported outcomes. To know what the words you’re using mean to the people who are going to be reading them... We navigated those language barriers and over the course of the year of our work, it was really incredible to see the how comments and discussions we made in the early meetings began to be incorporated into the design of the trial, the structure of the PROs, the kinds of questions that were being asked, even labelling language, patient education material... It was really rewarding and, from the point of view of the council members, a huge success. It felt like a true collaboration.”



The movement to include the patient voice in drug development and evaluation is growing. More and more, patients and caregivers are being recognized as partners in the drug development process not just in MS, but across many conditions. For example, according to a recent [article](#) in the American Society of Clinical Oncology Educational Book, including patient perspectives in the trial design, regulatory approval and assessing the effectiveness of cancer treatments is critical. Oncology patients must often choose between treatment regimens with different balances of efficacy and toxicity. Therefore, it is essential for all stakeholders in the drug development process to keep in mind what constitutes meaningful benefit to cancer patients and the best source of this information are the patients themselves.

ACP and iConquerMS are leaders in the growing PFDD movement. iConquerMS members recently played a key role in ensuring the voice and experience of people living with MS is incorporated into the development of a new MS therapy. PFDD Council

members were selected from network participants who provided their data by logging into the [portal](#) and completing their surveys. iConquerMS empowers everyone affected by MS to participate in research. Data from people with MS, caregivers and family members are essential to helping researchers better understand the impact of MS and its treatments. Be a part of the growing PFDD movement! If you haven't already done so, please consider [enrolling](#) in iConquerMS. Already a member? Please [log in](#) and complete your open surveys today! Whether you have MS or not, every piece of data expands the pool of information that investigators can draw from.



April 2020 Research Spotlight

EVENTS



A New Podcast Series for People with MS – Your 15 Minutes of Fame?

Accelerated Cure Project (ACP) has entered into an agreement to collaborate with EMD Serono on a 5-part, non-product related, educational podcast series focused on reproductive and hormonal considerations for people living with MS (female and male). The research questions and topics submitted by iConquerMS participants were key information for EMD when considering what topics the podcast should center around.

We're looking for people living with MS to participate as patient advocates in each of three remaining podcast episodes, including:

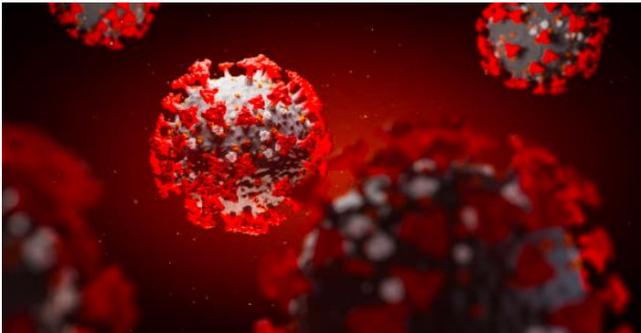
1. Third trimester postpartum planning for people living with MS (one female guest)
2. Impact of sexual dysfunction in lives of people living with MS (two guests, one male, one female)
3. Effects of menopause and andropause on MS disease course (two guests, one male, one female)

Each podcast will be approximately 15-20 minutes in length and include a brief interview between the host and the person/people living with MS, and a separate brief interview between the host and a health care provider. No travel is required. You would be required to participate in a 1-hour pre-recording call to discuss the questions that will be asked and to review technical logistics and an additional hour for the recording. Each

podcast will be available through the ACP website and the EMD Serono YouTube page. It is our understanding that there will be compensation for this but as contracting will be done between the guest and EMD, we're not privy to the amount or details.

Are you interested in being considered for one of the podcasts as a person living with MS? Do you have suggestions for others who should be considered or would be good candidates? Please email Sara Loud at sloud@acceleratedcure.org for more information, or to indicate which podcast you would like to be considered for and/or provide the details of the person you think would be a good fit. Thank you!

RESEARCH OPPORTUNITIES



Share your experience with COVID-19

As a supporter of Accelerated Cure Project, you know one way to deal with the uncertainty of MS is to **act** – to be proactively involved in research and to contribute your insights, expertise, and information so that key questions about MS may be answered.

The COVID-19 crisis has added an additional level of complexity and urgency for those affected by MS.

In response, we have just launched a survey on iConquerMS to learn more about how people affected by MS are dealing with the COVID-19 pandemic and what their personal experience has been with COVID-19.

We are interested in responses from all – those with and without MS – and hope the information gathered through this survey will help people affected by MS and their doctors during the current pandemic and in the case of future viral outbreaks.

Participating in the COVID-19 in MS study is easy. If you are not already a member, please consider [joining iConquerMS](#). Your voice matters! Already a member? Please [login](#) to your account and complete your COVID-19 survey. Thank you for your participation!



UsAgainstAlzheimer's

What Matters Most: Caregiving Challenges

Study Purpose:

Living with MS takes a toll on families due to both the intensity of care and long disease progression. This study will help shed light on how caregiving affects one's health and quality of life. We've partnered with a sister organization supporting families coping with Alzheimer's disease on a survey about the challenges and concerns of providing care to a loved one with MS. We will use what we learn to create new materials to educate caregivers about best practices, and resources for caregiving and self-care.

This Study Involves:

This study involves completing an anonymous survey. We'll use these data to better inform care practices and health care provider education. Let us know your biggest challenges, what resources or services you use or wish you had. What advice would you share with other caregivers?

Study Contact Information:

If you're interested in participating in this study, you can access the survey [here](#). Thank you for helping us make life better for all caregivers and their loved ones with MS!

The logo for iConquerMS, featuring the text "iConquerMS" in a blue sans-serif font, with "i" and "MS" in a smaller size than "Conquer". The text is enclosed in a thin blue rectangular border.A light blue rectangular box with a subtle gradient, containing the text "A Research Study EVERYONE can join!" in a blue sans-serif font. "EVERYONE" is in all caps and a larger font size than the other words.**Real MS™ (Research Engagement About Life with MS)**

In the summer of 2016, the iConquerMS initiative launched REAL MS, a longitudinal study of MS. REAL MS participants complete questionnaires online twice each year on a variety of subjects, including health history, diet, exercise and their experience with MS. An eighth round of REAL MS surveys are now available through the iConquerMS portal. Completing these surveys is one of the simplest ways you can accelerate MS research. The information collected will play a pivotal role in helping scientists and clinicians gain a better understanding of the health and quality of life over time for people with MS. REAL MS is just one of the many ways iConquerMS is facilitating research on topics of importance to people affected by the disease. If you are not already a member, please consider [joining](#) iConquerMS, the only people-powered research network for MS. Already a member? Please [log in to your account](#) and complete your open surveys!



New Year, New You

Study Title: Step for MS (Supervised versus Telerehab Exercise Program for People with Multiple Sclerosis)

Study Purpose:

New research shows that exercise is good for people with MS and may decrease symptoms and improve health and walking ability. An exercise study called *STEP for MS* will compare the outcomes of a 16-week exercise program conducted at home to a program conducted in a gym. The researchers conducting the study hope that the findings will make exercise and its benefits more available to people with MS who have problems walking.

This Study Involves:

Participants will exercise two times per week for about one hour each session for 16 weeks. A trained “coach” will help participants learn how to exercise and will provide encouragement throughout the program. Participants will take assessments before starting the program, two months into the program, at 16-weeks when the program ends, and at 6 and 12 months after starting the program.

Eligibility:

If you are between the ages of 18 and 65 years and you have Multiple Sclerosis you may qualify if you:

- Can **walk** but you have **some difficulty**, with or without a device
- **Do not exercise** regularly

- Have not had a **relapse** in the past month
- Can commit to **train 2 times a week for 16 weeks**
- Can **drive to study site** for assessments and potentially for exercise training
- Have reliable **internet access**

Participating Locations:

- Massachusetts General Hospital, Boston, MA (new site for the New Year!)

Contact: Dr. Plummer 617-724-3103/ PPlummer@MGHIHP.EDU

- Shepherd Center, Atlanta, GA

Contact: Erica Sutton at 404-367-1305

- Cleveland Clinic, Mellen Center, Cleveland, OH

Contact: Darlene Stough at 216-445-5877/ stoughd@ccf.org

- University of Colorado, Denver

Contact: Alexa Vareldzis: neurologyresearchpartners@cuanschutz.edu / 303-724-4644

- University of Alabama, Birmingham

Contact: Petra Silic at 205-975-1306/ petra09@uab.edu

- University of Georgia, Athens

Contact: Megan Ware at 423-260-5045/ megan.ware20@uga.edu

- Marquette University, Milwaukee, WI

Contact: Heidi Feuling at 414-288-6209/ Heidi.feuling@marquette.edu

- University of North Carolina, Chapel Hill

Contact: Rachel Keen at 704-877-5636/ rayray@live.unc.edu

For more information, please visit our

website: <https://www.iconquerms.org/welcome-step-ms>