



SOLVE M.E.

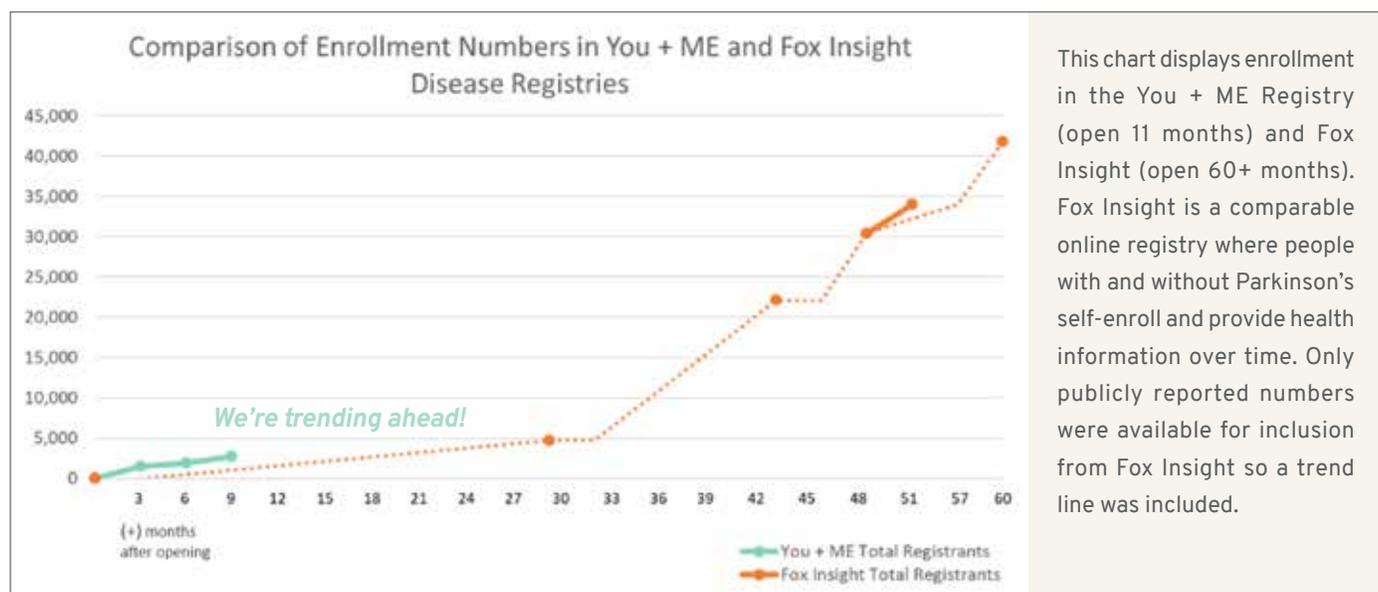
RESEARCH 1st

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Looking into the Future of ME/CFS Research with Fox Insight Parkinson's Disease Registry

By Sadie Whittaker, Chief Scientific Officer, Solve M.E.

It's been a year since we launched the You + ME Registry and we've grown more than we ever imagined! The You + ME Registry is the largest global data repository for ME/CFS—we currently have more than 4,000 participants enrolled and more than one million data points. This is an incredible accomplishment made possible by the support of the ME/CFS community. As the Registry grows it becomes a more and more valuable resource for researchers. The more data we collect, the easier it will be to harness the power of big data to identify treatments and cures as has happened for other complex illnesses.



This chart displays enrollment in the You + ME Registry (open 11 months) and Fox Insight (open 60+ months). Fox Insight is a comparable online registry where people with and without Parkinson's self-enroll and provide health information over time. Only publicly reported numbers were available for inclusion from Fox Insight so a trend line was included.

In December last year, we expanded the Registry to include data from those with Long COVID—enrollment now stands at more than 600 participants. The most prevalent Long COVID symptoms—crippling fatigue, post-exertional malaise and cognitive dysfunction—mirror those of ME/CFS and both are post-viral illnesses. Our hope is that learning more about Long COVID can deepen our understanding of ME/CFS and that what we know about ME/CFS can shed light on Long COVID—and ultimately point to treatments and cures for both.

We also forged partnerships around the world—You + ME is the official partner of the UK's DecodeME, a 20,000 person genome wide association study, and we opened You + ME

Australia in collaboration with Emerge. You can read more about these initiatives in this issue.

One of the key questions we heard over the past year is “*how exactly will the Registry advance ME/CFS research?*” Perhaps the easiest way to explain the immense potential of the Registry is by highlighting a similar resource established for the Parkinson's community.

Launched in 2015, Fox Insight, a Michael J. Fox Foundation for Parkinson's Research initiative, is a registry much like You + ME in which people with Parkinson's disease share health information to help researchers identify treatments and cures.

> from page 1

Their community currently stands at 48,000 strong. More than 400 researchers are registered to access the Fox Insight dataset, resulting in 12 publications. Research informed by the data led to two FDA-approved therapies and an additional 35 potential therapies are advancing through clinical trials.

The same is possible for ME/CFS.

You can see from the graph on the previous page that we are already on track to exceed the Fox Insight enrollment numbers but we have some enrollment gaps that you can help us fill:

- We'd like to include more individuals who were infected by COVID-19 with or without long term effects.
- Consistent with historical enrollment of people with ME/CFS in research, the current composition of the Registry is largely white and does not reflect the diversity of our community. We will be making a directed effort to increase Registry inclusivity and participation from members of underrepresented communities.
- We need to boost the number of control volunteers in the Registry. Based on other registries, 30% of our total cohort numbers should be controls. It currently stands at around 10%, so we have work to do.

Of course, we also want to continue to grow the number of participants with ME/CFS overall. So if you haven't yet, please consider signing up today at youandmeregistry.com.

And finally, some exciting news! We have started to analyze the data and plan to share results in coming weeks, so stay tuned!

Thanks for all you do to make the Registry a success. None of this would be possible without you.

Healthy Participants Are Critical to the Success of You + ME!

A healthy control is someone with no known significant health problems who participates in research. To understand what is different for someone with ME/CFS or Long COVID, we need to compare their biology to someone who is healthy.

Joining the Registry as a healthy control is quick and easy, and takes less than 30 minutes. You sign up, fill out a couple of surveys about your health, and you're done!

"I became a control to help my daughter-in-law who has ME and reached out to friends and cousins to join too. It's such a quick, easy and no-cost way for supporters to provide huge value to the fight to cure ME," said Board Member Barbara Lubash.



Emily Taylor, our director of advocacy and community relations, added, *"My mom has ME/CFS so I know firsthand about the importance of being a healthy control. I know I am helping researchers uncover what has gone wrong with my mom's biology. This is a small sacrifice for me but could have a major impact for individuals affected by ME/CFS."*



Please consider joining the Registry as a healthy control or asking your friends and family to join. Visit youandmeregistry.com for more info and to sign up!

Solve M.E. and Action for M.E. Partner to Accelerate Search for a Cure

Solve M.E. is pleased to share its partnership with Action for M.E. and Professor Chris Ponting of the Medical Research Council Human Genetics Unit at the University of Edinburgh on the world's biggest biomedical study of the causes of ME/CFS.



The DecodeME genome-wide association study will enroll 20,000 individuals with ME/CFS living in the UK using the You + ME Registry platform. The goal is to analyze DNA from the saliva of people with ME/CFS to see whether the disease is partly genetic and, if so, help pinpoint its cause. The study should help us understand the disease and ultimately find treatments.

"We are delighted to partner with Action for M.E. This strategic collaboration leverages our individual strengths and catalyzes goals otherwise out of reach," said Sadie Whittaker, chief scientific officer with Solve M.E. *"We are committed to cooperating with changemakers like Action for M.E. and continuing to expand our efforts until there is a cure."*

Learn more about DecodeME by visiting decodeme.org.uk.

You + ME Registry Partners with Emerge Australia to Open Australian ME/CFS Registry

The You + ME Registry and Biobank has partnered with Emerge Australia on a landmark effort to establish the first Australian ME/CFS patient registry and biobank. This significant undertaking will help create the largest possible dataset and harness the power of big data to understand ME/CFS.



The project is an international effort that includes the Australian National University, British Columbia Women's Hospital, CureME, London School of Hygiene and Tropical Medicine, Macquarie University, Murdoch Children's Research Institute Victorian Paediatric Rehabilitation Service, Open Medicine Foundation and University of Melbourne.

"We are delighted to collaborate with Emerge Australia on their efforts to expand ME/CFS research and create the first Australian ME/CFS patient registry and biobank. Our vision is to create the world's largest ME/CFS data repository to help researchers find a cure, and this partnership is another critical step."

—Sadie Whittaker, Chief Scientific Officer, Solve M.E.

Solve M.E. & UCLA ME/CFS Brain Stimulation Study Begins

Excerpted from
"Novel Chronic
Fatigue Syndrome
(ME/CFS) Brain



Stimulation Study Begins" by Cort Johnson
published on healthrising.org.

The Iris Cantor Center at UCLA didn't know much about ME/CFS but when they learned (from Sadie Whittaker, chief scientific officer at Solve M.E.) about the high female predominance, the little funding and the high prevalence, they invited Solve M.E. to apply for the Center's Annual Health Pilot Program. In this program, the Center solicits proposals for UCLA researchers to study a select number of diseases that disproportionately affect women.

Solve M.E. put together a toolkit about ME/CFS and applied to be one of the featured diseases in the program. Their application was accepted—the Center notified UCLA researchers that it was looking for proposals to study ME/CFS—and the proposals rolled in.

Solve M.E. picked the winner. It turned out to be a rarity for this disease—a small clinical trial no less—to assess the effects of repetitive transcranial magnetic

stimulation (rTMS) in ME/CFS. Karl Zeile, a Solve M.E. board member, and Dian Zeile stepped up to support it.

I talked with Dr. Juliana Corlier, PhD and Dr. Andrew Leuchter, MD about their upcoming study.



Dr. Juliana Corlier, PhD and Dr. Andrew Leuchter, MD

The procedure is remarkably easy on the patients: the participants are awake during the procedure and are able to drive themselves home afterwards. The 20-person trial will begin shortly and is open to women with ME/CFS.

Corlier and Leuchter reported, "We anticipate that rTMS treatment will significantly improve many of the symptoms of ME/CFS. Positive results from this study will provide proof-of-concept evidence for a novel rTMS treatment approach for ME/CFS to be validated in a future double-blind, randomized control trial."

That would be a nice step forward for a disease which has had all too few clinical trials.

Read more at healthrising.org.

YOU CAN HELP!

Research on ME/CFS continues to be underfunded.

Expanding support is critical and one of our most important initiatives.

Our efforts include funding research at UCLA, co-funding a postdoctoral fellowship with Action for ME and expanding our Ramsay Grants for which we received a record number of applications this year.

To learn how you can help us find treatments and a cure for ME/CFS, please visit solvecfs.org/donate/youandmeregistry.

The Path to Diagnostics for ME/CFS: Can Long COVID Pave a Short-Cut?



By Oved Amitay, President and CEO, Solve M.E.

It is often said that there are no biomarkers for ME/CFS. In fact, a number of objective measurable biological differences between people with ME/CFS and healthy individuals have been observed over the years. Yet we are missing diagnostic biomarkers that can be readily used to make a diagnosis and manage the disease. What could clinically useful biomarkers for ME/CFS look like, and can they be developed and ultimately be used to define and track success in treating people with ME/CFS? Achieving that has been eluding us in ME/CFS for many years. Could the tragic SARS-Cov-2 pandemic lead us on a path to finally address these unmet needs for our community?

WHAT IS A BIOMARKER?

A biomarker is a characteristic that is objectively measured. It can be evaluated as an indicator of normal biologic processes, disease (pathogenic) processes or the responses to a therapeutic intervention (NIH Biomarkers Definition Working Group. Atkinson et.al., *Clin Pharmacol Ther* 2001). Therefore, biomarkers can be obtained by any number of methods and technologies looking at genetic, biochemical, functional or other dimensions of what is actually measured in the body. Obviously different biomarkers can provide different types of information, and can be used in a number of ways.

TYPES OF BIOMARKERS	
Susceptibility Biomarkers	Evaluate the risk of developing the disease
Diagnostic Biomarkers	Indicate the presence of disease
Monitoring Biomarkers	Reflect the burden of disease, ideally can be used to see changes over time
Prognostic Biomarkers	Project the severity of the disease
Treatment Biomarkers	Detect a positive response to specific treatments and alert to safety or toxicity concerns

COVID-19 CAN HELP US DEVELOP DIAGNOSTIC BIOMARKERS FOR ME/CFS

The first step in the research and development of a diagnostic biomarker is to identify a measurable characteristic that is different in the people with the disease compared to those without the disease. Ideally, this is achieved as early as possible before other changes take place that make this comparison more difficult. The challenge in the past has been that most individuals with ME/CFS don't get the right medical attention until many months or even years after the onset of symptoms. The COVID-19 pandemic provides the scientific opportunity to study people shortly after infection and follow their recovery over time. This should make it a lot easier to identify differences between those who recover and those who don't. The immune system is a great place to detect

those early differences. Indeed, preliminary reports identified a measurable "immune profile" predicting a "Long COVID" course of disease (Patterson et.al. 2020). While a lot more research is still necessary to confirm these initial findings, these immune abnormalities are consistent with some of the changes seen in people with ME/CFS after EBV infection. So, it is possible that specific immune profiles will emerge that could be used to diagnose Long COVID and ME/CFS early.

One of the key challenges of developing susceptibility and diagnostic biomarkers for a dynamic disease like ME/CFS or Long COVID is the need to follow people over time. Longitudinal studies are important to collect biological samples

(e.g., blood, saliva) and collect information about symptoms people experience. The You + ME Registry and Biobank is one such longitudinal study. Using this research platform, individuals with ME/CFS and Long COVID can capture their experience with the disease online and via a mobile symptom tracking app. Biological samples can be collected remotely. These data will be invaluable in the development of biomarkers and allow us to take the experiences of the Long COVID community and apply them to advance biomarker development in ME/CFS.

STAY IN TOUCH!

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Humans of ME/CFS: HOMECFS.SolveCFS.org



**THANKS
TO YOU**

the Registry is making an impact and fueling progress toward better diagnosis, better treatment and a cure.

To learn more or to donate, visit solvecfs.org/donate/youandmeregistry