Research Institute Without Walls
Progress & Promise

All around the country, the Solve ME/CFS Initiative is holding Research Roundtable events, bringing news of progress and promise through our Research Institute Without Walls. At these events, attendees learn how we are using the SolveCFS BioBank to attract the brightest investigators from the best institutions to help us get to the bottom of ME/CFS.

"Last month I attended a Solve ME/CFS Initiative Roundtable. It was the first meeting of this kind that that I have been to in over 15 years. During the presentation I learned more about ME/CFS than I had over the 25 years since being diagnosed in 1989.

Throughout the years I have had glimmers of hope and excitement when reading about the different studies that might help our plight. Yet, most of the clinical trials and studies I read about eventually waned into the shadows of the unknown.... along with any hope of ever finding a cure for what has followed me throughout a good portion of my adult life. Because of this I was left to navigate this struggle on my own.

The Solve ME/CFS Initiative Research Roundtable gave me a renewed hope. The comprehensive multilevel collaborative approach to researching ME/CFS provides a path that takes the best of the best in hopes to create a win for all. Right after the presentation I knew that I wanted to step up and support the efforts of such an incredible team of people. Thank you to the team of warm, compassionate experts that have spearheaded this effort. Hats off to each one of you."

—Lawrie, patient

At the Solve ME/CFS Initiative, we are shifting the paradigm for how nonprofits participate in and support research. Together we will identify ways to diagnosis, treatment and solve ME/CFS.
From our CEO

Friends,

We bring you news about the progress and promise of our Research Institute Without Walls and SolveCFS BioBank. As we continue our effort to **make ME/CFS widely understood, diagnosable, and treatable** we are focused on patient-centered research aimed at identifying safe and effective therapies to eradicate this dreadful and debilitating disease.

As always it’s a busy time for us. We are:

- Holding multiple Research Roundtable events in major cities around the country. At these events, participants hear directly from Suzanne D. Vernon, PhD, our Scientific Director, about the research we are funding, and have the opportunity to ask questions of Suzanne and me. For more information on our Research Roundtables, go to [bit.ly/progresspromise](http://bit.ly/progresspromise). And if you’re not able to attend an event, you can watch it on our YouTube channel at [bit.ly/researchroundtable](http://bit.ly/researchroundtable).

- The work of two of our 2011 funded researchers continues:
  - Dane Cook at the University of Wisconsin continues his research to identify biomarkers for post-exertional malaise.
  - Patrick McGowan at the University of Toronto, is expanding the first ever epigenetic study of ME/CFS to include more SolveCFS BioBank patients and controls and is writing up his intriguing results.

- So many of you have asked that we resume our research webinars and we are responding. In these webinars, open for anyone to view online, researchers using our BioBank and other experts describe their work and results. Online participants have the opportunity to ask questions. Details are available on the back cover of this issue.

- We continue to monitor and participate in work at the federal level—P2P, the IOM and CFSAC.

- We continue to work with BioVista to support their fund raising efforts for a clinical trial. This trial, if funded, would test the drugs they identified using their drug repurposing platform.

I am deeply committed to our evidence-based, research-driven work and am excited about the research we are funding. We know that the road to solving this illness is long and hard. We travel that road together.

The SolveME/CFS Initiative relies on the generous donations of patients and their loved ones to fund our work. We are especially grateful for your financial support. Together we can Solve ME/CFS. Onward.

Carol Head
President & CEO
CEO@SolveCFS.org
Solve ME/CFS Initiative — Just the Facts

Who we are:

- Founded in 1987, the longest standing organization serving ME/CFS patients and advancing rigorous research.
- A national organization with a volunteer board of directors composed entirely of patients and their families.
- Our mission: We will make ME/CFS understood, diagnosable and treatable.
- Our core asset: Research Institute Without Walls and SolveCFS BioBank.

Why we do what we do:

- Despite the fundamental complexity of this illness, we believe that ME/CFS can and will be solved in our lifetimes.

Does SMCI receive any federal funding?

- The Solve ME/CFS Initiative relies on the generous donations of patients and their loved ones—we have not received government funding since 2010.

As an organization primarily focused on research, why is SMCI involved in activities on the federal level, like the CFS Advisory Committee, participating in P2P and IOM meetings?

- SMCI is involved in advocacy efforts aimed at improving the research landscape for the early detection, objective diagnosis and effective treatment of ME/CFS. As part of this effort, we work to validate the burden of illness imposed by ME/CFS in agencies where national policy is made and executed. While there is still much work to be done, we are encouraged that ME/CFS is now receiving much attention on a federal level and we are involved to help maintain this positive momentum.

Why is SMCI best positioned to improve the lives of ME/CFS patients?

- We have a deep and longstanding commitment to this disease. Despite our modest budgets, we were the first to fund research into epidemiology, viral causes, immunology, neuroimaging, exercise physiology and the autonomic nervous system.
- Our Research Institute without Walls allows us to fund the brightest researchers from the best institutions, without the cost of a bricks and mortar institute. We have fostered an innovative and collaborative environment.
- Our SolveCFS BioBank provides the means for patients to participate in research without leaving their homes, broadening the base of patients studied.
- We have earned a broad base of support. In 2013, nearly 2,000 individuals “voted with their dollars” and funded our organization, and several businesses offered in-kind goods and services to stretch those dollars. Among them, we received more than $100,000 in pro-bono legal fees. Among other things, this legal support ensured the effective re-branding and re-naming of our organization met all legal standards without taking valuable funds from research coffers.
1987
The CFIDS Association of America (now Solve ME/CFS Initiative) began funding research.

2008
Began a competitive research funding process, with rigorous review; focus on biomarker discovery, biomarker validation and treatment of ME/CFS.

- Awarded 6 grants, engaging 3 researchers who were new to the field of ME/CFS research.
- The first ME/CFS research network was launched, where investigators share data and collaborate.

2008 Funded Researchers

Gordon Broderick, PhD, Professor, NOVA Southeastern, Boca Raton, FL  
**Biomarker and computational biology research focus**
- SMCI introduced Broderick to ME/CFS and was the first to fund him
- First to apply network and control theory to ME/CFS data and analysis
- More than $2.5M in follow-on funding for ME/CFS research as a result of our funding.

Kathy Light, PhD, Professor, University of Utah Health Sciences Center  
**Biomarker research focus**
- Identified potential blood-based biomarkers of post-exertional malaise
- Awarded more than $1.5M in follow-on funding to further study these biomarkers.

Marvin Medow, PhD, Associate Professor, New York Medical College  
**Biomarker research focus**
- Studied mechanisms of postural orthostatic tachycardia syndrome (POTS) in young people with ME/CFS.

Bhubaneswar (Bud) Mishra, PhD, Courant Institute of Mathematical Sciences at NYU  
**Computational biology research focus**
- Created the framework for an ME/CFS knowledge-base.

Sanjay Shukla, PhD, of Marshfield Clinic Research Foundation  
**Biomarker research focus**
- Studied the gut microbiome to determine if it was different in ME/CFS patients and related to post-exertional malaise.

Dikoma Shungu, PhD, professor of physics in radiology and chief of the Laboratory for Advanced Magnetic Resonance Spectroscopy Research at Weill Cornell Medical College  
**Biomarker research focus**
- Used brain imaging to show metabolic and oxidative stress in ME/CFS.
- Awarded more than $1.5M in follow-on funding to validate this findings.
2010

Launched the Research Institute Without Walls, offering a better ‘virtual’ cost-effective infrastructure without the bricks and mortar to support researcher collaboration and data-capture.

Launched the SolveCFS BioBank—a tremendous resource for researchers, that lowers barriers to researchers and enables patients to be at the center of research.

2011

Offered another competitive funding opportunity; funded 4 investigators, bringing 2 new researchers into the field of ME/CFS research.
• Through the structure offered with the Research Institute Without Walls, every investigator now has a means to capture data electronically, access standard measures and share. Now all electronic data is permanently archived!

2012 Funded Researchers

Spyros Deftereos, MD, PhD
Treatment research focus
• Employed Drug Repurposing (DR) and identified a combination of drugs to target key ME/CFS symptoms.
• Raising funds to conduct a “proof of concept” clinical trial to test the combination.

Dane B. Cook, PhD, University of Wisconsin and the Veterans Administration
Biomarker and system biology research focus
• Uses exercise challenge and combines neuroimaging and blood genomics to identify biomarkers of post-exertional malaise.
• Awarded more than $750,000 in funding as a result of our seed grant.

Patrick O. McGowan, PhD, University of Toronto
Biomarker research focus
• First to conduct a genome-wide methylation study in ME/CFS.
• Awarded more than $850,000 in funding as a result of our seed grant.

Peter C. Rowe, MD, Sunshine Natural Wellbeing Foundation Professor of Chronic Fatigue and Related Disorders, Johns Hopkins University School of Medicine
Treatment research focus
• First to demonstrate that neuromuscular strain and restricted range of motion is associated with ME/CFS.

Solve ME/CFS Initiative is one of the largest and most successful private funders of ME/CFS research.
SolveCFS BioBank
Then, Now and the Next Evolution

The SolveCFS BioBank was approved by the Genetic Alliance for operation in April 2010, launching with a partnership with GlaxoSmithKline (GSK) and several of the top ME/CFS expert clinicians in the U.S. This initial study was very specific—to determine if XMRV could be found. We enrolled 240 cases and 87 healthy controls, collected information about symptoms and collected from each participant four tubes of blood. By August of 2011, it was clear that XMRV was not associated with ME/CFS so this study ended. (Results of the study have just been published in the open access journal BMC Research Notes.) It is noteworthy that GSK, one of the largest pharmaceutical companies in the world, chose to partner with our organization—a testament to the quality of the SolveCFS BioBank as a unique and robust resource for ME/CFS research.

This study seeded the SolveCFS BioBank with an inventory of blood samples from ME/CFS patients being cared for by expert ME/CFS doctors, as well as healthy controls. This inventory of blood samples, combined with the health information we collected and the expert manner that these samples were collected, quickly attracted other researchers to ME/CFS research and gave us a resource of great value to attract new investigators into the field of ME/CFS research.

Over the past 2 years, the SolveCFS BioBank has provided health information and these existing blood samples to 10 researchers—8 of them new to ME/CFS research, most of them specifically recruited into this field of study by Dr. Suzanne D. Vernon, SMCI Scientific Director.

Current research being conducted on the SolveCFS BioBank asks specific questions like,

• Are there autoantibody differences in ME/CFS patients compared to healthy controls?
• Are there immune profile differences in ME/CFS patients compared to healthy controls?
• Are there antibodies to viruses in ME/CFS patients that are different than healthy controls?
• Are there blood biomarkers that distinguish ME/CFS patients compared to healthy controls?
• Are there epigenetic differences in ME/CFS patients compared to healthy controls?

Over the coming months there will be several publications describing the exciting research coming from the SolveCFS BioBank. Typically, researchers work in a silo—each study done in its own lab, results held close and rarely shared with other investigators. Because of the unique and forward thinking design of our Research Institute without Walls and Solve CFS BioBank, we will be able to “connect the dots” on these separate studies. We are not aware of any other ME/CFS organization doing this.

This information and results sharing will also help inform the types of research that should be pursued. This open-collaboration with research results is groundbreaking and a critical ingredient to accelerating progress.

In addition to attracting the brightest investigators from the best institutions to ME/CFS research, the SolveCFS BioBank must include patients that are representative of those affected by ME/CFS. That is why in 2012 we encouraged anyone diagnosed with ME/CFS by their provider and anyone with ME/CFS symptoms to enroll in the SolveCFS BioBank.

Now, nearly 1,000 people strong, the SolveCFS BioBank is evolving into an excellent platform to study the natural history of ME/CFS. Natural history means providing information about your disease over time—what makes symptoms better, what makes symptoms worse. This information is essential to understanding the most meaningful clinical outcomes in ME/CFS, to understand the factors that are key to recovery.
In addition to natural history, the SolveCFS BioBank is growing to be a resource for genetic studies, which will need family members to serve as controls. For some ME/CFS studies, your healthy friends will make great controls because friends are often similar in education and socioeconomic status. In the coming months we will be rolling out resources that may be useful to get your family and friends interested in enrolling in the SolveCFS BioBank.

Our intention is to evolve the SolveCFS BioBank into the most sought after resource for ME/CFS research in existence. In order to achieve this, we must grow in a rigorous and strategic manner. If you are already signed up, you are our research-ready momentum leaders. Your registration already makes you part of the solution, and we’ll be engaging you in the months and years ahead.

If you haven’t yet signed up, what are you waiting for? Please contact Gloria Smith at BioBank@SolveCFS.org or by phone at 704-362-2343.

The Importance of a Representative Patient Population for Research

Over the past 4 years, the SolveCFS BioBank has become a sought after resource for ME/CFS research. Ten of the brightest investigators from the best medical institutions have used the samples and information from the SolveCFS BioBank to conduct research in the following areas:

- case definition
- patient-reported outcomes
- autoimmunity
- viral pathogens
- epigenetics
- immune function
- biomarker validation

Importantly, 8 of these 10 researchers are new to ME/CFS research, most of them recruited to the field by our organization. And ours is an illness which NEEDS more researchers…and much more research.

Why did we create the SolveCFS BioBank? The Solve ME/CFS Initiative recognized that in order to recruit the best and brightest into ME/CFS research, the researchers would need access to ME/CFS patients and controls. If we could offer researchers access to the right type of biological specimens for their experiment—access to ME/CFS patients with demographic and clinical characteristics that represent the full range of people affected with ME/CFS—it would remove one of the hurdles all researchers face. By creating the biobank we lowered one of the most important barriers to research—providing scientists with access to patients.

So what is the ideal representation of patients and controls in any biobank? An ideal biobank contains patients that reflect the population of all those affected by a disease. We know that certain diseases can occur more frequently in women, children, or a specific race. There are some diseases where a representative patient population is not known, either because population-based epidemiology studies have not been done or because many groups are historically underrepresented in medical research (e.g., because of race/ethnicity, access to care, socioeconomic status, gender, severity of illness).

Fortunately, this is not the case with ME/CFS. There have been several epidemiology studies that have clearly demonstrated that ME/CFS does not discriminate. Community-based research has shown that ME/CFS can strike anyone. For example, Dr. Leonard Jason of DePaul University found that in Chicago, ME/CFS occurred at higher rates in

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SolveCFS BioBank
Get Ready for Research!

The SolveCFS BioBank is the Solve ME/CFS Initiative’s innovative approach to patient-centered research; it’s how we collect the “big data” we need to solve ME/CFS. Unlike conventional biobanks that collect samples and medical information waiting for a researcher to use it, we’ve designed the SolveCFS BioBank as an “on-demand” research system to give scientists access to the right patient and the right sample when needed.

We urge you—whether an ME/CFS patient or not—to sign up for the Solve CFS BioBank. Currently anyone in the world is able to join the SolveCFS BioBank. It is free and takes only a few minutes. When you decide that you are interested in participating, we will send you a consent form. Once we have your consent, we will send you questions that help us create your “Research Ready” profile.

Here are the simple steps to follow to become a Research Ready SolveCFS BioBank participant:

1. Contact our SolveCFS BioBank Coordinator by email or phone to receive a brochure that tells you about the SolveCFS BioBank along with an informed consent document. Contact Gloria at BioBank@SolveCFS.org or 704-362-2343

2. If you want to become a Research Ready SolveCFS BioBank participant, sign the informed consent, make a copy and return the original to the SolveCFS BioBank Coordinator. Mail to SMCI, Attn. BioBank Coordinator, PO Box 49527, Charlotte, NC 28277

3. When we receive your consent, we will send email with a link to a short survey for you to complete. This allows us to generate a code that is unique to you and helps to protect your private information.

4. Some time thereafter, you will receive another email with a link to a survey that collects more detailed information about you and your health. This information lets us match you with the right ME/CFS research study.

5. When you are a match for a specific research project, you will be sent a kit to collect the specific type of sample needed for the research. This could be saliva, blood or other types of body fluids. Everything you need to ensure the sample is collected properly and returned to the SolveCFS BioBank is provided.

Only the SolveCFS BioBank has access to your personal information. The code that we generate for you using your personal information (this code is called a GUID—Global Unique Identifier) allows us to share your health information and sample with other researchers WITHOUT sharing your name or any other personal information.
women, Latinos, middle-aged individuals and people of middle to lower socioeconomic status. Centers for Disease Control and Prevention (CDC) found that even in their epidemiology study with 86% Caucasian participants, rates of ME/CFS were higher in the non-white study participants. The CDC also found the rate of ME/CFS in men and women varied depending on whether one lived in a major metropolitan area or a rural area. There are many more epidemiology studies on ME/CFS. While none are without flaws, these studies clearly indicate that ME/CFS affects individuals of all ages, genders and race.

Looking forward to our goal, a treatment approved by the FDA, it is important that studies are done using a representative patient population. Therefore, it is important that researchers have access to representative patient populations so that their results can be generalized to the affected population as a whole. For example, if research is only done on women, then these results may not be relevant to men. This is not to say that research cannot ask specific questions about ME/CFS in women, for example, but the limitations of studying only women must be made clear. And access to a representative patient population provides researchers the opportunity to conduct very specific research on sub-groups AND research that can be generalized to the population as a whole.

As a national organization, reaching patients online rather than in a clinic in a specific location, we have the unique and important ability to engage a broad, diverse population of patients.

Over the past year our SolveCFS BioBank has grown to 1,000 strong. Patients, family members and friends have signed up to participate in research that will help us Solve ME/CFS. Over the coming months, BioBank participants will receive a survey that will help us determine how representative our SolveCFS BioBank is. If we find that some patient groups are underrepresented, we will reach out to these groups to increase their enrollment.

We are fortunate to have received from Google, access to $10,000 per month in in-kind online AdWords support. With that new tool, we look forward to reaching even more patients and controls and further strengthening our BioBank.

The Importance of a Representative Patient Population for Research (continued)

So it is as easy as that. By sharing your health information in this private, protected way, you are participating in research and helping solve ME/CFS.

Note: The Solve ME/CFS Initiative is a member of the Genetic Alliance whose institutional review board responsibility is to ensure that the regulations governing the protection of human subjects in research are followed. The Genetic Alliance reviewed and approved the SolveCFS BioBank for operation in 2010 and validates our procedures each year.
NIH Pathways to Prevention Workshop (P2P)

The goal of the National Institutes of Health (NIH) Pathways to Prevention program, is to identify research gaps in a selected scientific area, identify methodological and scientific weaknesses, suggest research needs, and move the field forward through an unbiased, evidence-based assessment.

It is very significant that among the many diseases vying for precious federal attention, the NIH has designed ME/CFS as one of the few illness to be studied in the P2P program. Dr. Suzanne Vernon serves as a member of the P2P Working Group, a small group of volunteers that helped frame the initial agenda.

Earlier this summer, there was an opportunity to submit unpublished research for the evidence-based review. SMCI submitted information we felt was important for their consideration and also encouraged others in the research field to do the same—especially as it relates to post-exertional malaise. And at the same time, we have concerns about the P2P process and have formally asked P2P Leaders at NIH to alter some of their practices.

The work of the evidence-based review group is underway and the P2P workshop will be held December 9–10, 2014. A report will be released upon the conclusion of the workshop. Stakeholders—patients, advocates, and researchers—will have an opportunity to offer feedback.

Watch our Research 1st blog to get information as important developments unfold and to know how you can participate in the process.

The Work of the Institute of Medicine (IOM) Continues

In late 2013, it was announced that an Institute of Medicine (IOM) committee had been formed to comprehensively evaluate the current criteria for the diagnosis of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS). The work of the committee is underway with results scheduled for spring 2015.

Specifically the ME/CFS IOM committee is charged to:

• Conduct a study to identify the evidence for various diagnostic clinical criteria of ME/CFS using a process with stakeholder input, including practicing clinicians and patients;

• Develop evidence-based clinical diagnostic criteria for ME/CFS for use by clinicians, using a consensus-building methodology;

• Recommend whether new terminology for ME/CFS should be adopted;

• Develop an outreach strategy to disseminate the definition nationwide to health professionals.

We believe that each of these four issues is quite important to forward progress in our disease. The committee will produce a consensus report with recommendations in early 2015.

SMCI will bring you news of any developments as they arise.
Gift Registry for a Cure
An inspiring way to support the Solve ME/CFS Initiative (SMCI)

When the sister of our board member Aaron Paas, Danielle, became ill with ME/CFS six years ago, like so many patients she went from vibrant and busy to severely ill and debilitated almost overnight. “It left me completely bed-ridden for the first few months,” said Danielle. “I could barely even lift a bite of food to my own mouth.”

It took Aaron a couple of years to really zero in on what was going on with Danielle. In his search for information and answers he stumbled on Solve ME/CFS Initiative (then the CFIDS Association of America) and became interested in the work the organization was doing to improve the lives of people with ME/CFS. “I love the focus that SMCI puts on funding the research that will solve ME/CFS” Aaron said.

So when Aaron and his fiancé, Haley, were setting up a registry for their wedding, the Boston couple wanted to find a powerful way to get people to understand a little bit about what Danielle’s life is really like. “She’s such a positive person that most people have no idea what she’s actually going through,” explained Aaron. “I was confident that by making the disease real, people would be compelled to do something about it.”

Excited by the concept, when the couple set up their wedding website, on the registry page they included a link to Danielle’s painful ME/CFS story and extended an invitation for guests to give the gift of hope by donating to SMCI.

“There is no cure for ME/CFS and no treatment available within the medical system, a fact that can make the future seem bleak at times,” Danielle wrote to her brother’s wedding guests. “However, I am able to have hope for my future because of the knowledge that the people at Solve ME/CFS Initiative are working tirelessly to solve ME/CFS. Because of SMCI, I have hope that there will one day be a cure for ME/CFS.”

As their Aug. 2 nuptials approached, Aaron and Haley were elated to be tying the knot. “It’s so exciting to think that the work that SMCI is doing right now through the funding we’re helping raise could unlock the key to giving Danielle back the physical strength to match the strength of her spirit.”

And their excitement has been bolstered by a far-reaching outpouring of support. “One of the cool parts of putting it on our wedding registry site was that it was right around international awareness day in May, so a few of us asked people on our social networks to share the story,” explained Aaron. “It travelled a lot more than we expected and we got over 5,000 people that week to visit the site and read the story, a ton of whom wrote back to Danielle telling her that it was the first time they really understood the power of ME/CFS, even some friends she’s known for 20 years.”

Aaron and Haley’s powerful network of support for Danielle through the SMCI is encouraging both to the Paas family and to our organization. With this kind of support, we really are one step closer to a world without ME/CFS.

To join the vital group of patients and family members fighting ME/CFS through gifts to SMCI, please visit SolveCFS.org/donate or send a tax-deductible donation to: Solve ME/CFS Initiative, P.O. Box 36007; Los Angeles, CA 90036-0007 using the envelope included in this publication.

Want to include SMCI in your own registry or have an idea for a personal fundraising campaign? We’d love to talk to you about it. Contact Erin E. Parsons-Wright, Director of Development, at eeparsonswright@solvecfs.org or call 704-364-0016.
2014 Webinar Series

Solve ME/CFS Initiative (SMCI) is bringing you a free, monthly webinar series.

Research Institute Without Walls—Progress and Promise
held on Thursday, July 31, 2014
(video available)

Investigator Report: Epigenetics of ME/CFS with Patrick O. McGowan, Ph.D.
held on Thursday, August 21, 2014
(video available)

Investigator Report: Deciphering Post-Exertional Malaise with Dane B. Cook, Ph.D.
Thursday, September 18, 2014

Investigator Report: Decoding the Human Immune Response with Derya Unutmaz, MD
Wednesday, October 1, 2014

Investigator Report: Neuromuscular Strain in ME/CFS with Peter Rowe, MD
Thursday, October 23, 2014

Learn more, access videos, and register online at bit.ly/2014webinarseries.

We’ve Moved!
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