June 2nd, 2013 began like any other day. I could barely lift myself out of bed, yet I knew my life was about to change. “DJ, the catalyst is here, the catalyst is here!! I know it hurts, but today you need to push through it.”

For five years I had been living in an ocean of solitude where no one was like me…Where no one knew me…But something incredible was about to happen—I’d realize that I wasn’t alone.

When I arrived at the Catalyst Café it felt as though I had just entered my Mecca. I was instantly greeted by Dr. Suzanne Vernon. She didn’t know who I was, but I could tell that she already knew my story. As I looked around the room, everyone appeared to be seemingly normal. “Who is sick, who isn’t sick?” The presentation rolled along with bombshell revelations… With every new thing Dr. Vernon discussed, I could feel the optimism transforming into pure empowerment. Mere minutes earlier my life had absolutely no purpose, no meaning. My Kryptonite had been my Achilles heel for far too long.

No longer would I stand in the shadows waiting for the cure to come to me. No longer would I let this horrible disease rob me and millions more of the lives we once had and of all the greatness we have yet to achieve.

“My hope is full of questions My eyes are no longer riddled with doubt My life has such a deeper meaning What’s lost, can always be found I’ve been treading water, But I will never drown Dear World, I’m one of one million We’re still alive and we’re dying to be found Our voice can catalyze crowds Our hope will triumph the doubt Our lives can turn back around And one day… A cure will be found”

Even in our limited capacity, we have the power to make a difference. My name is DJ Gilbert, and I have Chronic Fatigue Syndrome…
There is a big gap in the pipeline that moves basic laboratory research and discoveries into safe and effective treatments. Think of it like railroad tracks that stop at the edge of a canyon... Without a bridge to bring these remarkable discoveries to the clinic, laboratory research rarely becomes more than a science paper.

We recognized the gap between the laboratory and the clinic. We knew the bridge for this gap was a translational research infrastructure—providing the means for basic researchers to move their discoveries through the pipeline. So in early 2012 we launched the Research Institute Without Walls (RIWW)—our translational research infrastructure. ‘Construction’ of the RIWW began in 2010 with the SolveCFS BioBank. It was the perfect way to start, bringing the patient into the research process.

Participatory Data

The SolveCFS BioBank is a popular way for ME/CFS patients to participate in research from anywhere in the world. Today, more than 550 people are consented and enrolled and more than 250 people are in the consent process. The process is secure and connects all the data generated on you and your sample. In the past each study was siloed, collaboration and cross-referencing was a challenge. Our SolveCFS BioBank has eliminated the silos and broken down the walls separating pockets of information, bringing a synergy that is vital to progress.

Experimental Data

Because of this remarkable level of participation over the past 2 years, four investigators are using the clinical data and biological samples from the SolveCFS Biobank for their research.

- Lenny Jason and his DePaul University team are using clinical data for ME/CFS case definition research. It is likely that the SolveCFS BioBank data will help inform as well as refine the ME/CFS case definition.

- Eric Delwart and his team at University of California San Francisco and Blood System Research Institute are cataloging all the viruses in ME/CFS patient’s blood using samples from the SolveCFS Biobank. This study will determine whether there are novel viruses in ME/CFS patients.

- Michael Cooperstock has partnered with Columbia University and University of Oklahoma to look for central nervous system autoantibodies in ME/CFS patient’s blood using samples from the SolveCFS BioBank. This study will determine whether ME/CFS patients are developing antibodies that attack the brain and neurotransmitters.

- Patrick McGowan and his team at University of Ontario are studying the activity of immune cells and determining chemical differences in the DNA from SolveCFS BioBank participants. Preliminary results indicate that ME/CFS patient immune cells function differently in vitro than healthy immune cells.

Our other 2012 funded investigators have made remarkable progress:

- Spyros Deftereos and his team at Biovista have identified a combination drug therapy they believe will be beneficial to ME/CFS patients—we are working with them to design a Proof-of-Concept clinical trial to begin in 2014.

- Peter Rowe and his team at Johns Hopkins are conducting a study of neuromuscular strain. They hypothesize that the movement restrictions are a measurable abnormality that affects the signaling to the brain and may be partly responsible for why some ME/CFS patients are unable to tolerate exercise.
• Dane Cook and his team at University of Wisconsin have partnered with Gordon Broderick, University of Alberta and Kathy and Alan Light, University of Utah to collect physiology, gene expression, brain imaging and clinical data which they will combine using powerful computational methods for a system biology look at ME/CFS.

Clinical Insight Data

Clinical intuition is the observations, reasoning and opinions of clinicians treating ME/CFS patients. This intuition is largely undocumented yet is often what lies behind the making of a hard to arrive at diagnosis, the design of a successful experiment or the administration of a workable treatment for patients. We believe that ‘clinical intuition’ would help define the core signs, symptoms and decrements in specific functioning caused by ME/CFS. This ‘core’ is currently not defined for development of treatments.

We partnered with Biovista to create a web-based platform to systematically collect, store, maintain and analyze clinical intuition data. Clinicians were able to log on to a secure website, provide information on how they treat ME/CFS and then submit their data for analysis. The analysis of the clinical intuition data indicated that clinicians deal with two predominant ‘types’ of ME/CFS—one with immune system abnormalities and one with predominately autonomic nervous system abnormalities. Clinicians also indicated certain symptoms were effectively managed with existing drugs. Importantly, the clinical intuition data validated the findings of the Biovista funded investigators.

The opportunity to share their experiences and approaches was welcomed by the clinicians. The information they provided is invaluable for helping identify the most safe and effective treatments for ME/CFS. Capturing clinical intuition was successful and proved so important that we are exploring ways for physicians from around the world to use a secure place on the internet to interact, share and contribute to ME/CFS research.

Clinical Trials Data

Our first RIWW clinical trial will begin in 2014. We will collect information and samples before, during and after treatment and all of this will be managed with the SolveCFS BioBank. The clinical data will help us determine the safety and effectiveness of the treatment. We will use the biological samples to identify objective biomarkers in order to evaluate treatment efficacy and discover new targets.

We are also partnering with other investigators conducting clinical research so information and samples can be deposited into the SolveCFS BioBank.

Our Research Institute Without Walls is more than a catchy name, it is a program and a philosophy that will lead to a more collaborative and productive approach to the science of solving ME/CFS. All RIWW projects are linked through us and to the SolveCFS BioBank and position the Association at the center of a multi-spoked wheel of linked research projects directed by leading experts working in diverse disciplines.

Researchers funded through the RIWW must embrace our open approach and the opportunity it affords them to work across institutions and disciplines as a coordinated team. As Alexander Graham Bell once said, “Great discoveries and achievements invariably involve the cooperation of many minds.” The best answers come not from one individual, but from the group. The ultimate solution won’t come from one lab, but from one discovery informing another. This is the bedrock of the Research Institute Without Walls. Together we have changed the landscape of ME/CFS research to accelerate the path for safe and effective treatments, the search for the root cause and the quest for a cure. ●
LogosOmics: Making Sense Out of Scientific Chaos

Imagine an enormous library with millions of books. Then imagine being able to type a few words into a computer and find not only the book you’re looking for, but the text within that book that could answer your questions and give new clues. That’s the way LogosOmics (Logos meaning “word” and Omics meaning “all”) is designed to work.

LogosOmics, an information technology platform, is a “knowledge base” built by an Association partner that will enable us to obtain a greater understanding of ME/CFS. It brings data and information to one place and then translates it into a standard form. This tool enables us to ask LogosOmics questions no matter how the data and information originally looked. It helps us generate specific hypotheses to help describe subtypes, identify biomarkers, and ultimately uncover the root cause(s) of ME/CFS. A major goal of LogosOmics is to identify ME/CFS subtypes so that right treatments can be targeted to the right people.

Overcoming Overwhelming Data

The need for LogosOmics becomes clear when you consider not only the deluge of medical publications available (far more than 20 million) but also the complexity of human beings (we have approximately 50 trillion cells in our bodies). Researchers need to approach ME/CFS from a holistic perspective, focusing on interactions between genes, proteins, cellular function, and diseases—like looking at a detailed highway map rather than a single road. LogosOmics will do the work, making connections that wouldn’t be made otherwise, to empirically generate hypotheses and guide future work.

All information downloaded into LogosOmics is translated into a single, coherent language that can be used across all platforms. Resulting in organized and relevant biological data on everything ME/CFS allowing us to see connections in ME/CFS patients that we never would have made before.

LogosOmics has been loaded with 20 million abstracts from PubMed and approximately 500,000 full text articles on ME/CFS, common overlapping conditions, and other relevant diseases. The database also includes searchable links to other publicly available databases that contain information about proteins, genes and pharmacogenetics (i.e., what drugs work best in which individuals based on genetic variations).

The more information that is fed into LogosOmics, the smarter it becomes. Patient data is critical. LogosOmics will integrate all data with the Association’s SolveCFS BioBank, but in the future we foresee even more. Patient-powered, patient-reported details about diet, activities, symptoms and more can be fed into the platform right from your home computer. Experimental data from researchers can be shared and integrated with SolveCFS BioBank and patient self-reported information, strengthening the power of the platform to generate new discoveries. Filtering in all clinical trial data is equally important; it breaks down the “lab walls” that have traditionally separated results and segmented answers. Finally, we hope to build a portal for doctors to share their de-identified clinical insight to fully round out the information. Our Research Institute Without Walls, coupled with the power of LogosOmics, brings collaboration that would never have been possible before and is what will ultimately deliver the answers to solve ME/CFS.
Drug repurposing has grown in importance recently due to significant advantages over traditional drug development. The approach is to find new uses for “old” drugs that have either been shelved or are being used for other diseases. A repurposed drug has already passed a significant number of toxicity and other tests, its safety is known and the risk of failure for reasons of adverse toxicology are reduced. More than 90% of drugs fail during development, and this is the most significant reason for the high costs of pharmaceutical R&D. In addition, repurposed drugs can bypass much of the early cost and time needed to bring a drug to market.

Recognizing the need to speed the discovery process for ME/CFS patients, the CFIDS Association took a bold step forward into the drug repurposing arena.

In 2012 the Association awarded a grant to Biovista, a biotech with expertise in drug repurposing. Biovista used their state-of-the-art computational platform to evaluate more than 90,000 compounds together with 25,000 clinical outcomes and the more than 6,000 biomedical publications on ME/CFS. This approach looks for correlations in information leaving no stone unturned. The goal was to find one or more compounds that could be repurposed to safely and effectively treat ME/CFS.

As a result of their search, Biovista has identified two candidate therapy approaches including a drug combination treatment.

The next step is to design a clinical trial to test if this drug combination is safe and effective in ME/CFS patients. This is called a “proof-of-concept” clinical trial. When used alone these drugs have been shown to be safe and effective in the diseases they are indicated for; this proof-of-concept clinical trial is required to establish the safety and effectiveness of using these drugs in combination in ME/CFS patients. Biovista, the CFIDS Association of America and a clinical collaborator have begun designing the clinical trial by submitting the necessary documentation to the FDA—an essential part of the regulatory process for drug development. This gives us the opportunity to ask questions of the FDA so that we can optimize the clinical trial design for the best possible outcome before we submit our request for FDA’s approval to conduct the trial.

Upon approval from the FDA, we are hoping to begin this proof-of-concept clinical trial in 2014. In just over two years we went from funding a new study to partnering in sponsoring a clinical trial. This is a perfect example of how drug repurposing can slash the time and cost to bring new therapies to the patients who need them most.

This is a first for ME/CFS and a sign of things to come—safe and effective treatments for ME/CFS. The CFIDS Association of America is uniquely positioned to foster the translation of scientific knowledge into meaningful impact for patients more quickly than ever before. With your support, we will be able to shorten the path to safe and effective treatments for ME/CFS.
ME/CFS “In The Know”

**Better Communication** Have you noticed some changes? We’re working hard to bring you more simple, easily digestible information and resources. You’ll see cleaner designs, clearer messaging and shorter publications. Coming soon—a whole new website! (Made possible through a generous donation that has underwritten the entire process.)

**Groundbreaking FDA Meeting** Recently the FDA spent two days listening to dozens of patients and doctors talk first-hand about their experiences with ME/CFS. Through the agency’s Patient-Focused Drug Development Initiative 20 focused workshops will be held quarterly over the next 5 years—and ME/CFS was the focus for the first meeting of its kind.

FDA’s new initiative is designed to collect information and perspectives directly from patients, their caregivers and advocates. Thanks to your support, the CFIDS Association was able to be there to represent your voice in the proceedings.

The Association wanted to make sure as many patients as possible had an opportunity to provide input. Using questions posed by the FDA and others we believed were important, we conducted an online survey asking questions about the impact of ME/CFS on lives, symptoms experienced and treatments used. We reported these results at the meeting to represent the patient voice during the proceedings because understanding patients’ perspectives is critically important for drug development.

- Read the workshop review by Association President and CEO, Kim McCleary at [www.Research1st.com/2013/05/17/FDA-Workshop-Summary](http://www.Research1st.com/2013/05/17/FDA-Workshop-Summary).
- Read the summary of survey results by Association Scientific Director, Suzanne Vernon, PhD. at [www.Research1st.com/2013/05/29/FDA_Survey_Results](http://www.Research1st.com/2013/05/29/FDA_Survey_Results).

**CFS Advisory Committee Meeting** On May 22 & 23 the Chronic Fatigue Syndrome Advisory Committee met in Washington DC. In one of her final roles as President and CEO, Kim McCleary sat at the table to represent the Association in the proceedings, while Leigh Reynolds, Association Engagement Manager, was in attendance as a public attendee and gave testimony on day two. Several board members took part as well.

- Read more about it and access the session’s video recordings at [www.Research1st.com/2013/06/25/CallForUnity-CFSAC](http://www.Research1st.com/2013/06/25/CallForUnity-CFSAC).
A Note From Interim CEO Maryam Aghamirzadeh

I am honored and jazzed to have the privilege of serving as your interim CEO.

When I reflect on this opportunity I think of several things… First, the goal of the organization to “Make ME/CFS Understood, Diagnosable, and Treatable.” Of my personal stake in driving toward these goals. The extraordinary team that has dedicated themselves to this organization; with their innovative and collaborative three-year plan, this team will change the way we approach ME/CFS in the future. And, finally, I think of you—the dedicated community of individuals facing a life with ME/CFS.

You may be wondering why I am here? Personal stake; my family has been touched by this condition. Just like you, my world was turned upside-down as I watched the most energetic, vivacious person I know become confined to home. After years of feeling desperate and useless I had to jump at a chance to DO MORE.

By education and temperament I am a technologist, I’ve never worked in a related field, I have no medical training, and I’ve never worked in a not-for-profit organization, so what could I possibly offer? The answer came from a member of the board. Bring what you have! I have extensive background in running organizations of all sizes, from start-ups in the Silicon Valley to fortune 50 companies. So I must offer what I can to accelerate discovery of safe and effective treatments and aggressively expand funding for treatments and cures.

Although I am but a bridge I will venture to be the strongest, most effective bridge I can to serve the community and to ensure long term success and perseverance of this organization. Please join me. DO MORE. Offer what you can in striving for a world free of ME/CFS. You can help us through:

- Lend financial support—any level of investment fuels the path forward. You can give online at www.CollaborateFindSolve.org or use the enclosed envelope to mail a check.
- Sign up for the SolveCFS BioBank—contact Gloria Smith, GESmith@cfids.org.
- Stay engaged on social media—add your voice to the dialogue.

Tell us what you think, help me be the best bridge I can be. Write to me at CEO@cfids.org.

Sincerely,

Maryam Aghamirzadeh
Interim CEO, CFIDS Association of America
Catalyst Café on the Road  The CFIDS Association has an exciting story to tell—one of science and collaboration, seeking and finding new ways to engage the patient, and a road map that we believe will ultimately lead us to a solution for ME/CFS—so we’re taking our show on the road! So far in 2013 we have held 5 Catalyst Café events from Dallas to California and more are in the works. We are meeting in loaned offices, living rooms and public meeting spaces. The goal is to connect with the ME/CFS community in a very real way, share our story, and invite everyone to become a part of it.

You heard from one Catalyst Café attendee, DJ Gilbert, in our cover article. We are encountering similar reactions all across the country and we hope to be bringing a Catalyst Café event to your town. To make sure you receive regular news from the Association and Catalyst Café invitations, should we make it to your neighborhood, be sure and sign up for email updates. Simply send an email to CatalystsInAction@CFIDS.org with “subscribe” in the subject line.

Invest in Progress  The reality is, progress takes investment. Who is more motivated to fuel this progress than those most impacted by ME/CFS? We need your involvement and your support. The staff and board are fully committed to doing all they can to ensure progress and maximize your investment.

Any level of investment fuels the path forward. Our secure online donation form is ready and available 24/7 at www.CollaborateFindSolve.org or you can use the envelope in this issue to mail your gift. Thank you for your continued support!