The Open Medicine Foundation (OMF) invests in accelerating collaborative medical research to find effective treatments & diagnostic markers for Neuro-Immune Diseases including ME/CFS, MS, Lyme, Autism and others.

In following its mission, the OMF is currently raising funds for the **OMI-MERIT Initiative** (Open Medicine Institute- Myalgic Encephalomyelitis Roundtable on Immunology and Treatment*) lead by the Open Medicine Institute (OMI). Donate now and help support the cause: http://www.openmedicinefoundation.org/donate*

What is the OMI-MERIT Initiative?

OMI-MERIT is a strategic initiative of the Open Medicine Institute (OMI) and its collaborators to put the best science and people together in an organized, collaborative plan to discover and apply diagnostic and treatment solutions for ME/CFS.

Who are the OMI-MERIT Participants?

Led by the Open Medicine Institute and the MERIT Chair, Dr. Andreas Kogelnik (Open Medicine Institute/Private practice, US), the OMI-MERIT Signators are leading scientists and clinicians from around the globe with expertise in immunology, virology, genomics, informatics, molecular biology, epidemiology, infectious diseases, oncology, pathology, and clinical medicine.

What is ME/CFS?

A debilitating disease affecting a range of body functions including: neurologic function, metabolism, hormonal regulation, circulation and blood pressure, mental health, and overall well being; ME/CFS affects over 8 million patients worldwide. It has few options for accurate diagnosis and treatment.

Why is OMI-MERIT important?

Patients with ME/CFS desperately need answers. We are convinced that these answers are readily available if we apply the best resources available in a large-scale concerted effort. The right tools with the right people, delivering practical, actionable results are an idea that has been long-coming to this field. For the first time in the field of ME/CFS, OMI-MERIT has built a plan, a team, and the critical mass to deliver on that plan. OMI-MERIT is ready to deliver on those results.

How was the OMI-MERIT list of Priority Projects arrived at?

The Open Medicine Institute convened a limited group of interested, established scientists and clinicians for 3 days in New York City in late June 2012. The OMI-MERIT meeting was held as a round table forum for identifying and addressing practical issues in ME/CFS with an eye toward projects that deliver practical results for patients in the shortest amount time. We continue to expand the list of OMI-MERIT collaborators and will add additional projects as funds allow.

The OMI-MERIT Priority Projects

(Approximate budgets below totaling $13.5M)

1) Treatment: Phase 1: A large-scale, randomized, placebo-controlled trial of *rituximab and valgancyclovir*

Goal: This rigorous, four-armed study will examine and further validate two of the most promising therapies in the field by comparing: placebo, rituximab alone, valgancyclovir alone and combination therapy of valgancyclovir plus rituximab. Exceptional measurements of physiologic, genomic, virologic, and immunologic markers will be made throughout the course of the trial.

Importance: A large-scale, rigorous trial is needed to confirm the initial findings of earlier smaller studies and move ME/CFS to molecularly trackable disease. Success of such a trial could move ME/CFS to a mainstream process for additional diagnostic and treatment trials.

Cost: **$7.65 million** for a 150 patient study with options for expanding to an **$11.7 million**-300 patient study as funds allow (The majority of the budget goes to the purchase of Rituximab which may be provided at a reduced fee.)

2) An International Neuro Registry and Biobank

Goal: Supporting and expanding the largest and most comprehensive, longitudinal ME/CFS information source for research and collaboration will be the result of this project. We will collect longitudinal data and biological specimens from ME/CFS patients and controls and characterize the ME/CFS population by patient symptoms, laboratory and molecular profiles through crowd-sourced informatics and cutting edge tools in immunology, genomics and molecular biology. Comprehensive, standardized, sampling will include blood, CSF, urine, stool, brain/CNS, and other tissues. Samples will be available for additional studies in the MERIT list and beyond.

Importance: There has been no large-scale, chronologic characterization effort across the ME/CFS population. The Registry and Biobank will help establish clinical and biologic clusters in the population, paving the way for diagnostic biomarkers and cluster specific treatments. In addition, this will provide a community resource for patients and is central to additional collaborative projects.

Cost: **$1.93 million** for an (unlimited) international registry and detailed 1000 specimen survey.

3) Protein Panels in Treatment and Naïve Patients

Goal: Performing in-depth, cutting edge protein analysis of selected specimens from the Biobank to identify bacteria, viral, hormonal, antibody, cytokine and other protein-based substances that might be present in patient specimens. Specimens will be selected based on expected yield from clinical data and then discoveries confirmed in the larger patient population.

Importance: This project aims to apply cutting-edge protein detection systems with specific, ultra-sensitive ME/CFS related targets identified. Protein markers are key in identifying potential biomarkers and many new advanced technologies have never been applied to ME/CFS before.

Cost: **$658,000** for over 250 samples to be run on a detailed array of protein platforms.

4) Treatment: Phase 2: Other therapy mono and combination pilots

Goal: To assess the effect of other touted treatments that are currently available in the field and establish immunologic and molecular parameters for measuring the efficacy of such treatments. Treatments assayed will include: Ampligen, Etanercept, Rifaximin, Issentris, Famvir, and possibly others.

Importance: To determine a direction and baseline for other potential drug therapies in the field and assess which should receive additional allocation of funds for research.

Cost: **$984,000** for 2 case-control studies and 3 pilot studies.

5) Immunologic Biomarker Exploration Studies

Goal: These exploratory studies will examine B-cell, T-cell and Natural Killer cell responses to disease and treatment groups using comprehensive, rigorous methods many of which have never before been applied to ME/CFS. It will seek to establish immunologic baselines and variants from that across the patient population.

Importance: For a disease that appears to have a solid immunologic component to it, this study will provide the most advanced, longitudinal characterization of immune changes in critically implicated cells over selected treatment and control patients.

Cost: **$447,000** for 3 pilot studies.

6) DNA Genetics

Goal: Use the most advanced methods to sequence key areas of the human genome in a set of patients and controls and affected families and unrelated individuals. Utilizing advanced Human Genome Project technologies, this project will undertake HLA and other regional sequencing of areas of interest for selected patients and families.

Importance: Establishing or refuting a role for genetics and potential heritable risk in ME/CFS.

Cost: **$592,000**

7) Mass Spectroscopy/Environmental Measurements

Goal: This exploratory study will search patient samples for unknown compounds, toxins, proteins and other substances that may be implicated in the genesis of the disease or otherwise contribute to immune dysfunction.

Importance: This would be the first systematic examination of samples by the most reliable substance identification techniques to begin to establish an understanding of the contribution of nutritional and environmental factors to ME/CFS.

Cost: **$232,000**

8) Comprehensive Viral Testing

Goal: Establish a core of viral testing methodologies that are useful and could be useful clinically. Testing will include blood, urine, and saliva and other tissues where available for specific viruses such as EBV, HHV6, CMV, Parvovirus, HSV1, HSV2, and additional panel type testing for novel viral identification and high throughput methods.

Importance: This project will set the standard for clinical viral testing in ME/CFS and establish a guideline for evaluation and treatment directions for patients. Priority will be given to assays that have already yielded promising clinical results in partner labs.

Cost: **$406,000**

9) Advanced Immunologic Biomarker Study 2

Goal: This secondary immune study will look at additional cell types that complement project #5 above, such as monocytes, macrophages and dendritic cells.

Importance: This study extends our immunologic understanding of the disease and its extent.

Cost: **$187,000**

10) Treatment: Phase 3: Natural and Over-the-Counter substances

Goal: Examine the potential benefit of several over the counter/natural therapies in a vetted scientific setting. Substances examined will include: Moringa oleifera, GcMAF, Vit B12, and Artemesinin.

Importance: This project will be a first application of vetted scientific method and molecular science to non-pharmacologic substances that have had anecdotal benefits reported, thereby setting a standard for mainstream measurement of ME/CFS.

Cost: **$416,000** for 2 small studies and 2 pilots