Dear Dr. Collins,

We are just a few of the millions of people with myalgic encephalomyelitis (ME) who are missing from our own lives. We are their caregivers, loved ones, friends and allies. We are researchers, clinicians, and the students who aspire to join this field.

As you know, people with ME have for decades been neglected by our governments, mischaracterized by the research community, and treated with disdain by our doctors. Last year, you began to address these problems, saying, “The NIH is committed to unraveling the underlying biologic cause(s) of ME/CFS as swiftly as possible, and promoting research that will inform the development of effective strategies for treatment and prevention of this devastating condition.” And you’ve followed up on this with the Collaborative Research Centers and the NIH Intramural Study. But the reality is that the current portfolio of initiatives will take decades to produce results that will make a meaningful difference in the lives of patients.

Science does take time, as you’ve explained—but it doesn’t have to take that much time. And the last thirty years have proven that time isn’t enough. Commitment, funding, and a well-considered strategy are also essential to scientific progress. With creativity and political will, and leveraging what disease experts have already learned about patient selection, diagnostic tests, and treatments, the time needed can be substantially decreased. We don’t need to lose another generation of people to ME.

We are writing to request an in-person meeting to discuss a plan of action that will speed up the existing approach and make it more effective for our disease. We must start by setting aggressive but realistic goals. By leveraging existing opportunities and working in collaboration with the NIH’s partner agencies, the following outcomes can be reached:

Diagnostics:

- Within 3 years, validate one or more clinically viable ME biomarkers to increase diagnostic accuracy.
- Within 10 years, develop one or more FDA-approved, commercially available diagnostic biomarkers for each identified subtype within the CCC and/or ICC-ME diagnostic criteria.

Trials:

- Within 1 ½ years, start NIH-funded clinical trials of one or more drugs as treatments for ME.

- Within 10 years, start at least one clinical trial of a disease-modifying drug for each identified subtype of ME.

Treatments:

- Within 3 to 5 years, secure FDA approval of at least one treatment for specific usage in ME.
- Within 10 years, secure FDA approval of multiple disease-modifying treatments for ME.

To achieve these outcomes, NIH will need to use all of the tools at its disposal. Therefore, we demand the NIH carry out the following actions within the next 12 months:

1. **RFAs:** Provide substantial funding for multiple, multi-year RFAs for biomarkers, treatment trials, and validation and further refinement of the data collection instruments recommended as part of the Common Data Elements initiative. Such dedicated funding is needed to encourage researchers to enter the field and to rapidly address key issues that are impeding progress.
2. **Case definition:** Create a collaborative initiative that leverages existing expertise to rapidly reach consensus on the research case definition and case ascertainment methods. Until this is completed, patient selection in NIH-funded research must use CCC and/or ICC-ME and must use the NIH CDE approved DSQ to assess symptom profiles.
3. **Program announcements:** Create additional ME-specific Program Announcements, supported by multiple NIH Institutes, for investigator-initiated studies.
4. **Intramural study:** Accelerate the ongoing intramural study by identifying and addressing all barriers to achieving rapid results and dissemination of findings, for instance by providing additional funding, staff, and physical resources that would allow multiple study participants to be seen at the Clinical Center at one time.
5. **Administrative supplements:** Fully fund the existing Collaborative Research Centers (CRCs) and the Data Management and Coordinating Center (DMCC) for the next four years and increase Center funding by issuing an RFA for Administrative Supplements.
6. **New collaborative research centers:** Issue a new RFA for U54 grants to fully fund at least three additional Collaborative Research Centers.
7. **Strategic plan:** Establish an initiative to create a cross-agency, fully-funded strategic research plan that lays out activities and coordination necessary to understand, diagnose, treat, and prevent ME. This plan should include efforts to delineate possible disease subtypes, as well as be informed by input from key stakeholders including, but not limited to, people with ME, ME disease experts, caregivers, researchers, ME organizations, organizations for common comorbidities (i.e., POTS, MCAS, EDS, fibromyalgia, SFN, etc.), and representatives from government agencies including NIH, CDC, and the FDA.
8. **Outreach & engagement:** Formulate and enact an aggressive outreach plan designed to increase engagement of researchers, major academic centers, the pharmaceutical industry, and major medical societies. This includes sponsoring scientific conferences targeted at clinicians and at researchers studying ME and comorbid conditions, NIH staff presenting at many more scientific and medical conferences not specifically focused on ME, and NIH working on the development of private-public partnerships with pharmaceutical companies.

9. **Data repository & biobank:** Finalize a clearly articulated plan to establish and maintain NIH-funded centralized data and biospecimen repositories, which can store anonymized clinical and research data, including imaging data; and biospecimens collected from well-characterized patients in past, current, and future research studies. These repositories should be fully operational within two years and accessible by outside researchers. The repositories can be extensions of existing repositories that are storing ME/CFS data and biospecimens or built from scratch.
10. **NINDS home & funding policy:** Formally house NIH's ME/CFS program in the National Institute of Neurological Disorders and Stroke while also including ME/CFS in the strategic goals of the National Institute of Allergy and Infectious Diseases. Maintain the Trans-NIH working group to coordinate across all relevant institutes. Exclude all ME/CFS-related FOA's from any policy that limits funds or limits paylines for grants to well-funded investigators.
11. **Clinical Care.** To accomplish the NIH mission of doing research in this disease, the agency must tackle a problem that would ordinarily be outside its domain: the crisis in clinical care. So few physicians have expertise in ME that it is difficult for studies to enroll sufficient numbers of accurately diagnosed patients that reflect the diverse community affected by the disease. As research accelerates, this problem will become more acute. The NIH, in partnership with other federal agencies, must work with the medical community to address this as an urgent priority, before any more expert clinicians retire.

Obviously, driving these initiatives and achieving these outcomes will require a significant investment from the NIH. Therefore, within three to five years, NIH funding must become commensurate with disease burden, estimated to be at least $190-$250 million a year.

While this is a significant increase from the current level of $13 million, it's fair, reasonable, and doable. In the last two years overall NIH funding increased by $5 billion, including $3 billion in this March's omnibus bill. While we understand that some of this money is earmarked, this is still a significant increase in the total resources NIH has available to achieve its mission. Dr Koroshetz, who has acknowledged that there are too few ME Collaborative Research Centers, said last year, "We've got to move this field... It's going to take a lot of money. The budget's going to have to be 10 or 20 times what it is now." There is clearly agreement that funding for research needs to increase by more than an order of magnitude if we are going to get to where we need to be.

With strong leadership, a substantial increase in funding and resources, and a resolve to finding creative ways to accelerate progress, these initiatives are achievable within the next 12 months. We want to help you make this happen. The NIH must act with the urgency that this long-neglected and staggeringly debilitating disease demands. We cannot delay; we need meaningful, life-altering outcomes for all people with ME now.

Signed,