Toward a Common Research Agenda in Infection - Associated Chronic Illnesses

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NATIONAL ACADEMIES Sciences Engineering Medicine

Solve M.E.

Co-founders of:

LONG COVID ALLIANCE

Patient-Driven Data: ME/CFS subset of Long COVID

Oved Amitay

President and CEO

solveme.org

Solve M.E.: at the intersection of Science, Patient Empowerment and Policy

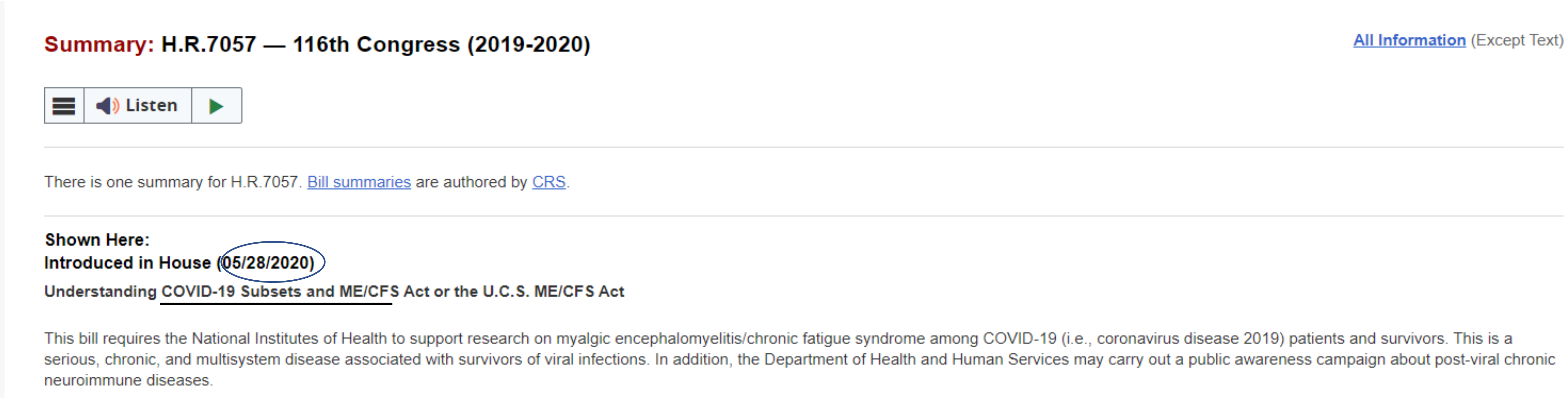
- National non-profit patient advocacy organization, established in 1987
- Co-founder of The Long Covid Alliance
- Long COVID Alliance begun building the foundations for establishing a new Infection Associated Chronic Conditions Patient Advocacy Coalition

Mission

Be a catalyst to make myalgic encephalomyelitis (aka chronic fatigue syndrome; ME/CFS), Long Covid and other infection-associated diseases widely understood, diagnosable and treatable

Policy Guided by Prior Evidence and Experience

- ME/CFS often triggered by an infection [1]
- Previous infection outbreaks led to a chronic condition in some people [2]



Summary: H.R.7057 — 116th Congress (2019-2020)

All Information (Except Text)

There is one summary for H.R.7057. Bill summaries are authored by CRS.

Shown Here:
Introduced in House (05/28/2020)

Understanding COVID-19 Subsets and ME/CFS Act or the U.C.S. ME/CFS Act

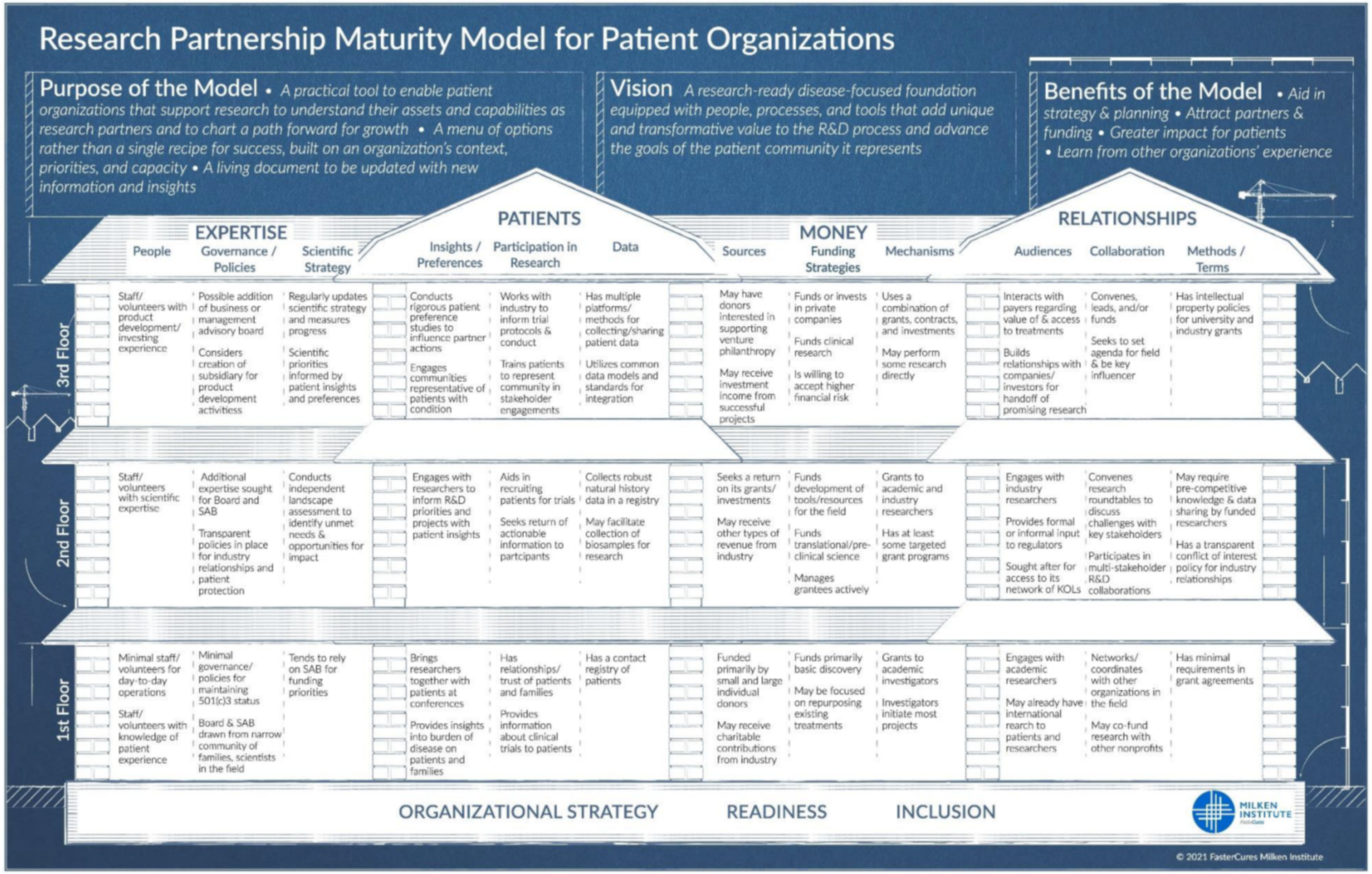
This bill requires the National Institutes of Health to support research on myalgic encephalomyelitis/chronic fatigue syndrome among COVID-19 (i.e., coronavirus disease 2019) patients and survivors. This is a serious, chronic, and multisystem disease associated with survivors of viral infections. In addition, the Department of Health and Human Services may carry out a public awareness campaign about post-viral chronic neuroimmune diseases.

Naess et.al., Postinfectious and chronic fatigue syndromes: clinical experience from a tertiary-referral centre in Norway. *In Vivo*, 2010
Islam et.al., Post-viral fatigue and COVID-19: lessons from past epidemics, Fatigue: Biomedicine, Health & Behavior, 2020

“Research-ready” Patient Organization

Adding distinctive value to the R&D process to address the needs of the patients it represents

- Expertise
- Patients
- Money
- Relationships



Research Partnership Maturity Model for Patient Organizations

Purpose of the Model • *A practical tool to enable patient organizations that support research to understand their assets and capabilities as research partners and to chart a path forward for growth • A menu of options rather than a single recipe for success, built on an organization’s context, priorities, and capacity • A living document to be updated with new information and insights*

Vision *A research-ready disease-focused foundation equipped with people, processes, and tools that add unique and transformative value to the R&D process and advance the goals of the patient community it represents*

Benefits of the Model *• Aid in strategy & planning • Attract partners & funding • Greater impact for patients • Learn from other organizations’ experience*

	EXPERTISE			PATIENTS		
	People	Governance / Policies	Scientific Strategy	Insights / Preferences	Participation in Research	Data
3rd Floor	Staff/ volunteers with product development/ investing experience	Possible addition of business or management advisory board Considers creation of subsidiary for product development activitiess	Regularly updates scientific strategy and measures progress Scientific priorities informed by patient insights and preferences	Conducts rigorous patient preference studies to influence partner actions Engages communities representative of patients with condition	Works with industry to inform trial protocols & conduct Trains patients to represent community in stakeholder engagements	Has multiple platforms/ methods for collecting/sharing patient data Utilizes common data models and standards for integration
2nd Floor	Staff/ volunteers with scientific expertise	Additional expertise sought for Board and SAB Transparent policies in place for industry relationships and patient protection	Conducts independent landscape assessment to identify unmet needs & opportunities for impact	Engages with researchers to inform R&D priorities and projects with patient insights	Aids in recruiting patients for trials Seeks return of actionable information to partcipants	Collects robust natural history data in a registry May facilitate collection of biosamples for research
1st Floor	Minimal staff/ volunteers for day-to-day operations Staff/ volunteers with knowledge of patient experience	Minimal governance/ policies for maintaining 501(c)3 status Board & SAB drawn from narrow community of families, scientists in the field	Tends to rely on SAB for funding priorities	Brings researchers together with patients at conferences Provides insights into burden of disease on patients and families	Has relationships/ trust of patients and families Provides information about clinical trials to patients	Has a contact registry of patients

	MONEY			RELATIONSHIPS		
	Sources	Funding Strategies	Mechanisms	Audiences	Collaboration	Methods / Terms
3rd Floor	May have donors interested in supporting venture philanthropy May receive investment income from successful projects	Funds or invests in private companies Funds clinical research Is willing to accept higher financial risk	Uses a combination of grants, contracts, and investments May perform some research directly	Interacts with payers regarding value of & access to treatments Builds relationships with companies/ investors for handoff of promising research	Convenes, leads, and/or funds Seeks to set agenda for field & be key influencer	Has intellectual property policies for university and industry grants
2nd Floor	Seeks a return on its grants/ investments May receive other types of revenue from industry	Funds development of tools/resources for the field Funds translational/pre-clinical science Manages grantees actively	Grants to academic and industry researchers Has at least some targeted grant programs	Engages with industry researchers Provides formal or informal input to regulators Sought after for access to its network of KOLs	Convenes research roundtables to discuss challenges with key stakeholders Participates in multi-stakeholder R&D collaborations	May require pre-competitive knowledge & data sharing by funded researchers Has a transparent conflict of interest policy for industry relationships
1st Floor	Funded primarily by small and large individual donors May receive charitable contributions from industry	Funds primarily basic discovery May be focused on repurposing existing treatments	Grants to academic investigators Investigators initiate most projects	Engages with academic researchers May already have international rearch to patients and researchers	Networks/ coordinates with other organizations in the field May co-fund research with other nonprofits	Has minimal requirements in grant agreements

ORGANIZATIONAL STRATEGY READINESS INCLUSION

MILKEN INSTITUTE

The Milken Institute

Patient Organizations Play Unique Role

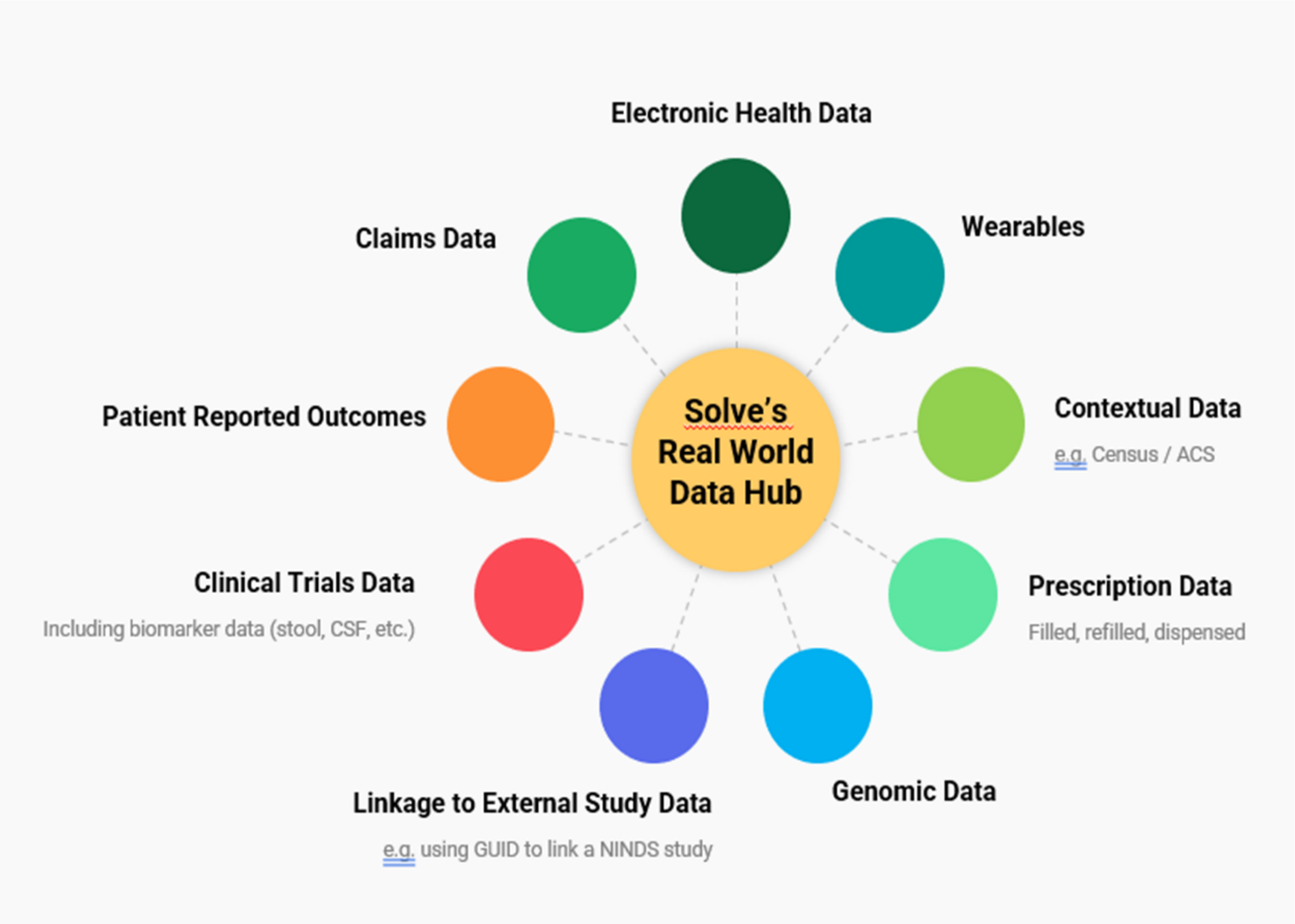
- Insights
- Preferences
- Participation in research
- Collection of patient-driven data

Patient-driven data platforms

- Patient empowerment
- Democratizing research
- Decentralizing tools, removing barriers
- Increase inclusivity and equity
- Converging traditional and innovative research

Solve's Patient-Driven Platform

- IRB governed, online, observational longitudinal study [1]
- 7,000 Participants: people with ME/ CFS, Long COVID, and controls
- ME/CFS launched May 2020
- Covid-19 launched December 2020
- Transitioning to a new platform towards a larger and more diverse cohort
- Enable recruitment to nested clinical studies
- Expedite diagnostic and therapeutic progress



Ramiller et. al., The Facilitation of Clinical and Therapeutic Discoveries in Myalgic Encephalomyelitis/Chronic Fatigue Syndrome and Related Diseases: Protocol for the You + ME Registry Research Platform. *JMIR Res Protoc*. 2022

Demographics

Characteristic	ME/CFS (n=4410)	Long Covid >12months (n=270)
Female	83%	83%
Median Age (yrs.)	50	46
White/Caucasian	92%	82%
Working Fulltime	16%	31%
Disabling symptoms*	31%	22%
Onset	40% Infection trigger	59% +PCR

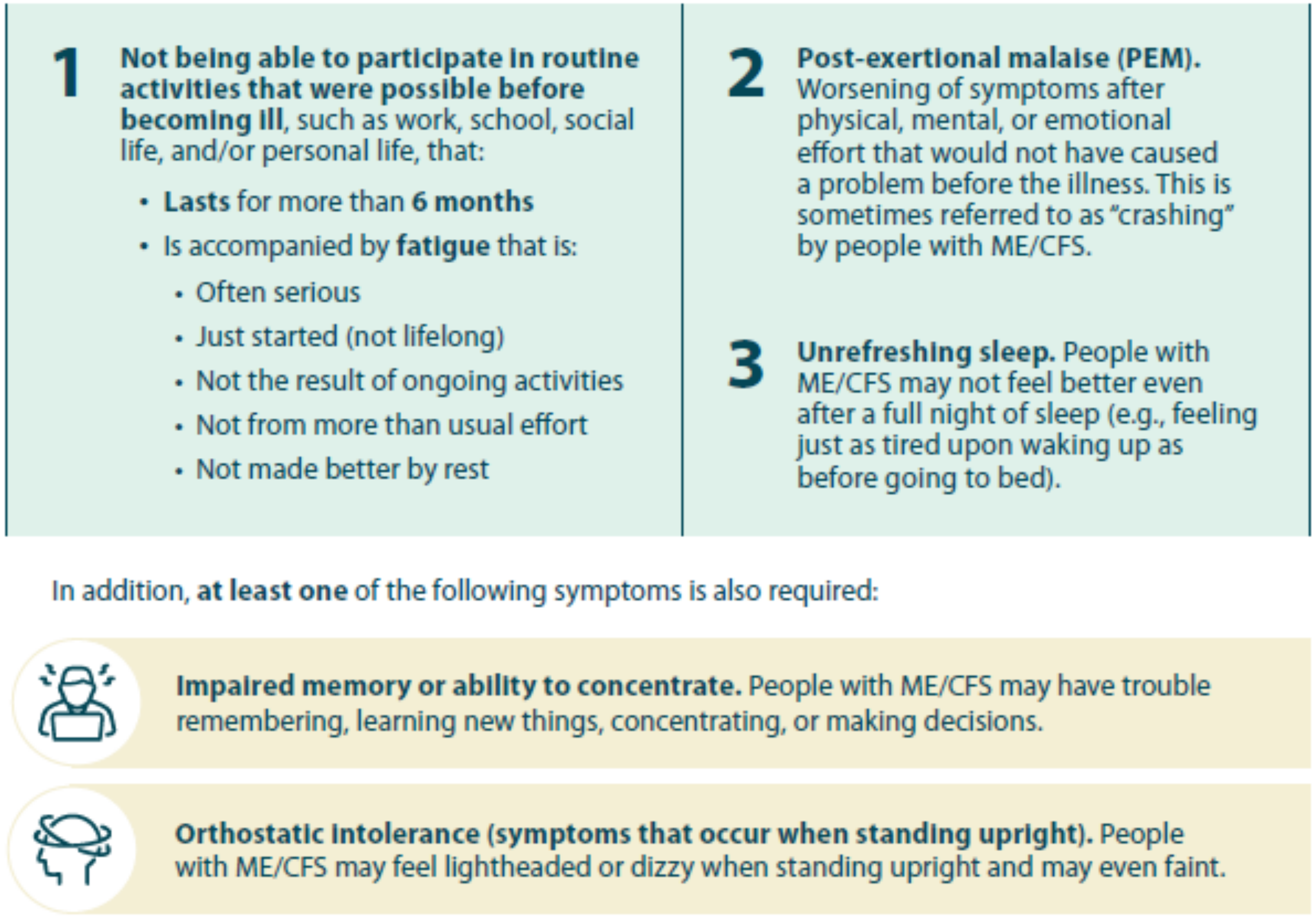
*independent of whether receiving disability benefits or not

Long COVID Cohort: Selected Symptoms

Characteristic	>12 months (n=270)
Fatigue	96%
Brain Fog	87%
Headaches	83%
Marked physical or mental fatigue/exhaustion after minimal activity that lasts for a long time	74%
Muscle pain	67%
Dizziness or faintness when standing up	61%
Shortness of breath	57%

Meeting Diagnostic Criteria for ME/CFS

48% of people living with Long COVID symptoms persisting for more than one year meeting Institute of Medicine criteria



1 **Not being able to participate in routine activities that were possible before becoming ill**, such as work, school, social life, and/or personal life, that:

- **Lasts** for more than **6 months**
- Is accompanied by **fatigue** that is:
  - Often serious
  - Just started (not lifelong)
  - Not the result of ongoing activities
  - Not from more than usual effort
  - Not made better by rest

2 **Post-exertional malaise (PEM).** Worsening of symptoms after physical, mental, or emotional effort that would not have caused a problem before the illness. This is sometimes referred to as "crashing" by people with ME/CFS.

3 **Unrefreshing sleep.** People with ME/CFS may not feel better even after a full night of sleep (e.g., feeling just as tired upon waking up as before going to bed).

In addition, **at least one** of the following symptoms is also required:

Impaired memory or ability to concentrate. People with ME/CFS may have trouble remembering, learning new things, concentrating, or making decisions.

Orthostatic intolerance (symptoms that occur when standing upright). People with ME/CFS may feel lightheaded or dizzy when standing upright and may even faint.

IOM Criteria: www.cdc.gov/me-cfs

Conclusion

- A looming crisis: nearly half of people living with Long COVID symptoms persisting for more than one year, meet the diagnostic criteria for ME/CFS

- Form Follows Function: a common research agenda should inform a complementary NIH structure

- A common research agenda supports a stronger advocacy voice

- Taking first steps to establish a broader patient coalition

Get Involved

A new coalition is being formed to bring together U.S. patient advocacy organizations, patient partners (IACC patients, caregivers, and those interested in IACC healthcare) and community-based organizations to collectively champion for the needs of the infection-associated chronic condition community — and we're inviting you to get involved!

This coalition is being developed by Long COVID Alliance, with support from CDC Foundation, Solve ME, COVID-19 Longhauler Advocacy Project, Patient-Led Research Collaborative, and Dysautonomia International.

Learn more: **contact@iaccpac.org**

THANK YOU!

Oved Amitay
President & CEO

oamitay@solvecfs.org
Cell: 508-685-6738