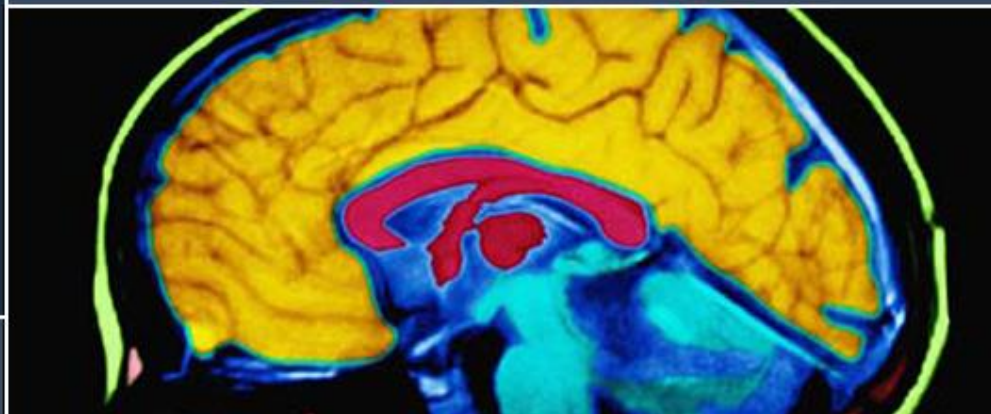
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Institute of Neurological Disorders and Stroke

National Institutes of Health Update

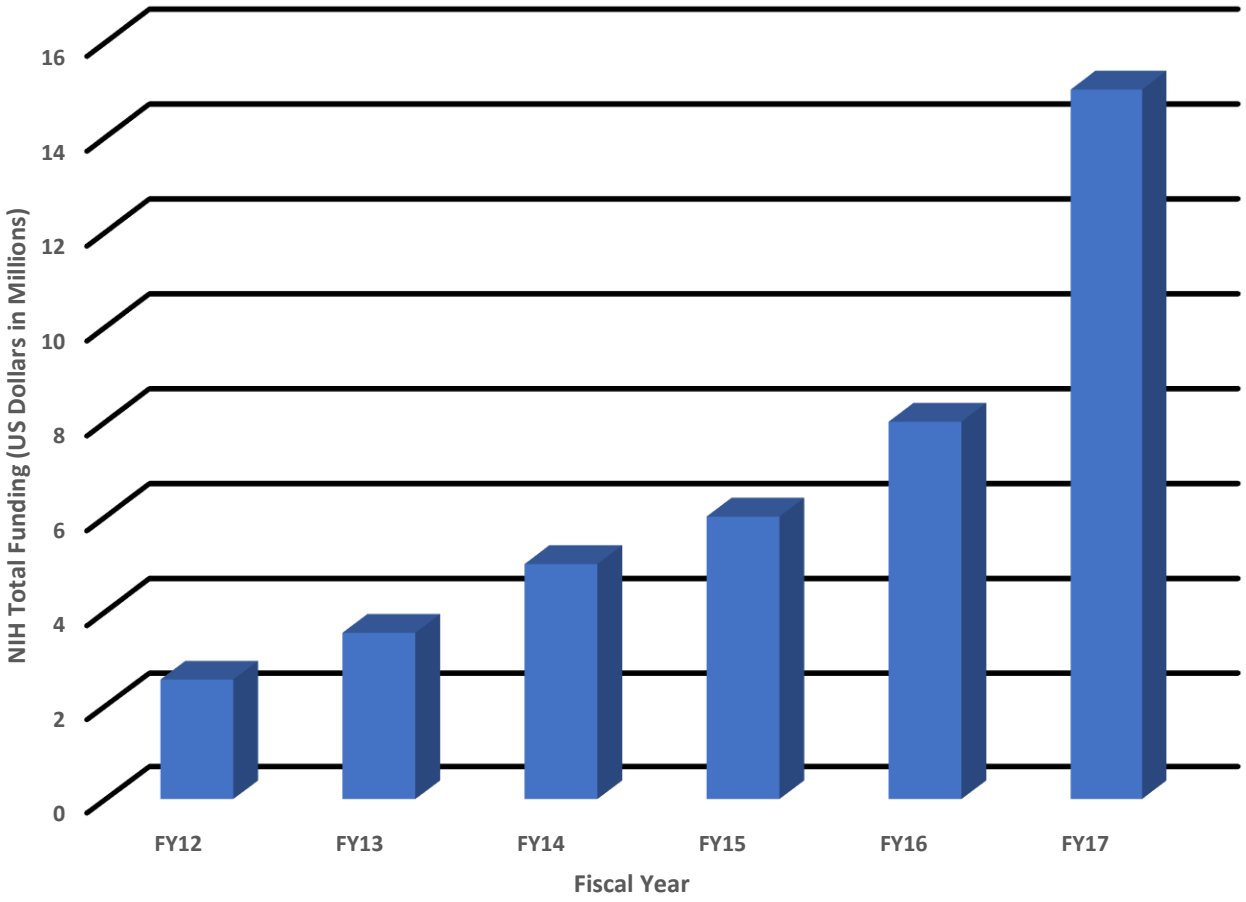
Chronic Fatigue Syndrome Advisory Committee
June 21, 2018

Vicky Whittemore, PhD
NINDS/NIH



National Institute of Neurological Disorders and Stroke

NIH Funding for ME/CFS Research



NIH funding for ME/CFS research increased from $8 million in Fiscal Year 2016 to $15 million in Fiscal Year 2017.

NIH Funding by Institute/Center/Office

NIH Institute/Center/Office	Fiscal Year 2016 (Institute funding and percent of total NIH funding)	Fiscal Year 2017 (Institute funding and percent of total NIH funding)
National Institute of Allergy and Infectious Diseases	$4,284,029 (56%)	$5,870,859 (45%)
National Institute of Neurological Disorders and Stroke	$1,628,014 (21%)	$3,558,666 (27%)
National Institute of Nursing Research	$839,560 (11%)	$460,376 (4%)
Office of the Director, NIH	$599,036 (8%)	$1,000,000 (8%)
National Institute of Mental Health	$294,315 (4%)	$250,000 (2%)
National Heart, Lung, and Blood Institute		$500,000 (4%)
National Human Genome Research Institute		$300,000 (2%)
National Institute of Drug Abuse		$250,000 (2%)
National Center for Advancing Translational Sciences		$200,000 (2%)
Eunice Kennedy Shriver National Institute of Child Health and Human Development		$400,541 (3%)
National Center for Complimentary and Integrative Health		$250,000 (2%)

ME/CFS Collaborative Research Centers (CRCs) and Data Management Coordinating Center

Cornell ME/CFS Collaborative Research Center
Cornell University, Ithaca, New York
Principal Investigator: Maureen Hanson, Ph.D.
1U54NS105541-01

Center for Solutions for ME/CFS
Columbia University, New York, NY
Principal Investigator: W. Ian Lipkin, M.D.
1U54AI138370-01

Topological Mapping of Immune, Metabolomic and Clinical Phenotypes to Reveal ME/CFS Disease Mechanisms
The Jackson Laboratory
Farmington, CT
Principal Investigator: Derya Unutmaz, M.D.
1U54NS105539-01

Data Management and Coordinating Center (DMCC) for the ME/CFS Collaborative Research Centers
Research Triangle Institute
Research Triangle, NC
Principal Investigator: Rick L. Williams, Ph.D.
1U24NS105535-01

Each ME/CFS CRC will carry out independent research projects and participate in the collaborative research project(s), and will collaborate with the Canada Institute for Health Research-funded ME/CFS Center in Canada.

Cornell ME/CFS CRC

Identify biological mechanisms underlying ME/CFS by analyzing blood samples/brain scans on individuals with ME/CFS before and after exercise- induced PEM

Test the role of genes, inflammation and the immune system in ME/CFS

Center for Solutions for ME/CFS at Columbia University

Utilize an existing collection of biological samples from people with ME/CFS and healthy controls to look for microbial agents (viruses and bacteria) that may play a role in the disease

Comprehensive genetic analyses used to identify metabolites that are present in the samples

Topological Mapping of Immune, Metabolomic and Clinical Phenotypes to Reveal ME/CFS Disease Mechanisms at Jackson Laboratories

Detailed look at how the immune system, the microbiome and metabolism interact in ME/CFS

ME/CFS Working Group of NINDS Advisory Council Announced

- ME/CFS Working Group announced at NINDS Advisory Council Meeting on May 24, 2018
- Will be chaired by Steve Roberds, PhD, CSO at the Tuberous Sclerosis Alliance and NINDS Advisory Council Member
- Additional members will be invited by Walter Koroshetz, MD, NINDS Director
- The Working Group will provide scientific guidance to the NANDS Council, Dr. Koroshetz, and the Trans-NIH ME/CFS Working Group on how best to advance research on ME/CFS

PROJECT OVERVIEW | CDE SEARCH | CRF SEARCH | FORM BUILDER | CONTACT

NINDS Common Data Elements

Harmonizing Information. Streamlining Research.

CDEs | Tools | Learn

Streamline Your Neuroscience Clinical Research using content standards that enable clinical investigators to systematically collect, analyze, and share data across the research community.

The NINDS strongly encourages researchers who receive funding from the Institute to ensure their data collection is compatible with these common data elements (CDEs). Learn more about the CDE Project.

Launch Your Own Studies Faster
- Case report form modules
- Standardized data element definitions
- Instrument recommendations

Incorporate CDEs Into Systems
- Search for current CDEs
- Download CDE metadata
- Download Case Report Forms

Learn About the CDE Project
- Project overview and background
- Meetings and Presentations
- Collaboration with developers around the world

CDEs Now Available | CDEs Under Review | CDEs in Development

- General (CDEs that cross diseases)
- Amyotrophic Lateral Sclerosis
- Epilepsy
- Friedreich's Ataxia
- Headache
- Huntington's Disease
- Mitochondrial Disease NEW!
- Multiple Sclerosis
- Neuromuscular Diseases

Privacy Statement | NeuroQOL | NIH Toolbox | PROMIS

NINDS Common Data Elements | NIH National Institute of Neurological Disorders and Stroke | NIH National Institutes of Health Turning Discovery Into Health | USA.gov

Page last updated on August 27, 2015

What is the CDE Project?

- NINDS initiated the development of Common Data Elements (CDEs) as part of a project to develop data standards for funded clinical research in neuroscience.

- NINDS recently partnered with the CDC to develop ME/CFS CDEs.

- The CDEs are content standards that can be applied to various data collection models and are intended to be **dynamic** and **may evolve** over time.

- CDEs are **not** a database.

What are the objectives of the CDE Project?

- Identify CDEs used in clinical research
  - (age, gender, race, etc.)
- Present data elements in a standard format available to all
- Identify common definitions
  - (including permissible values, range checks, etc.)
- Standardize CRFs, when needed, and instruments
- Provide information to researchers for clinical data collection and sharing

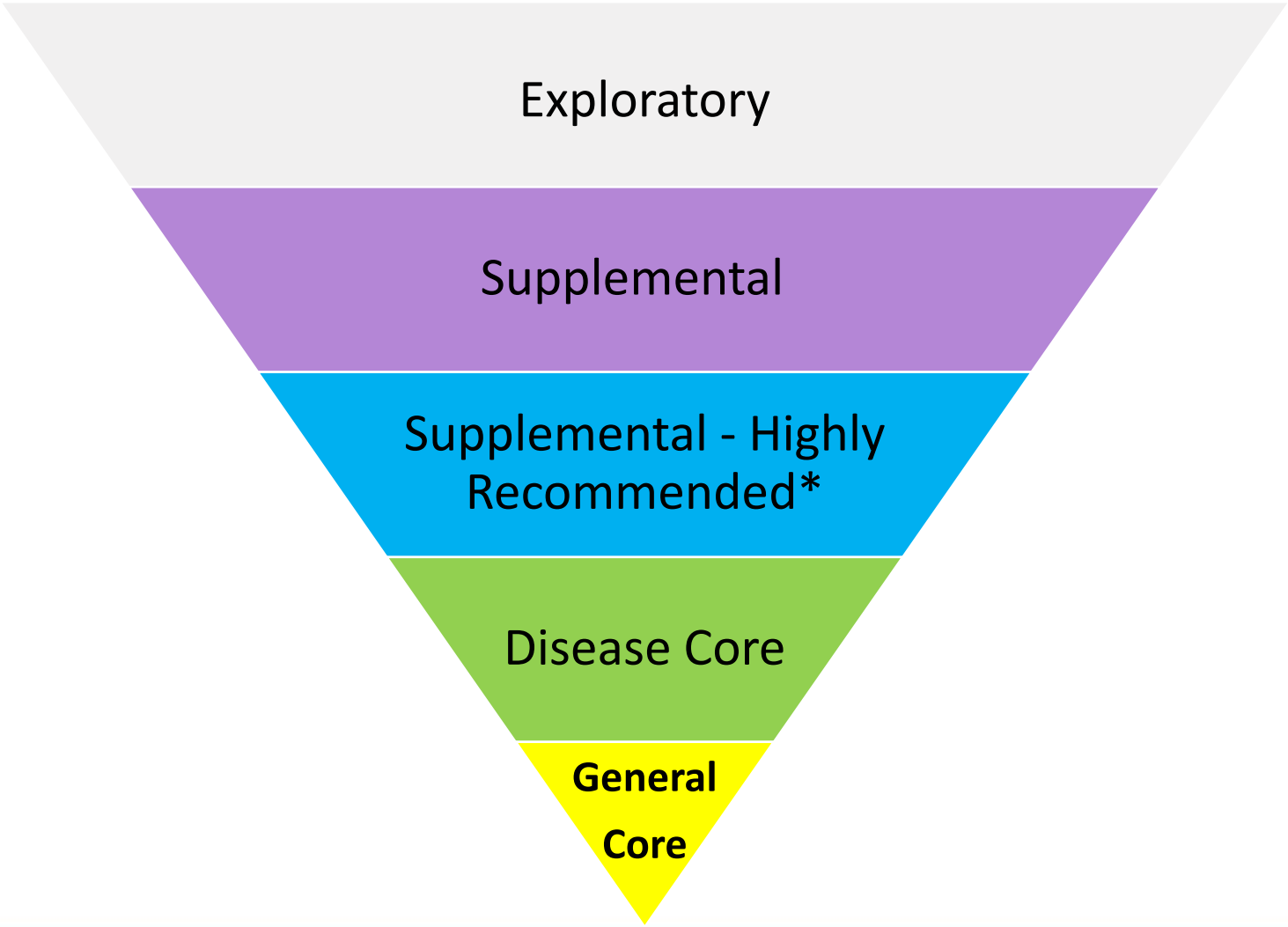
Methods and Timeline

- **December 2016**: Researchers, clinicians and patient advocates from the world-wide ME/CFS community invited to join the working group.
- **February 2017**: All members split into 11 subgroups.
- **March – October 2017**: Regular subgroup meetings were held to discuss their purview, review forms and instruments within their domain currently used in ME/CFS research and applicable CDEs from other NINDS CDE disease recommendations.
- **October – December 2017**: Internal review – draft recommendations reviewed across subgroups.
- **December 2017– January 2018**: Public review – draft recommendations posted for feedback.
- **February 2018**: Posting of ME/CFS CDEs on the NINDS CDE website.
- **Ongoing:** Review and revision of CDEs and writing publication.

Domains and Sub-Domains for ME/CFS CDEs

- Baseline/Covariate Information
- Fatigue
- Post-Exertional Malaise
- Sleep
- Pain
- Neurologic/Cognitive/ CNS Imaging
- Autonomic
- Neuroendocrine
- Immune
- Quality of Life/Functional Status (CPET)/Activity
- Biomarkers
- Pediatrics

CDE Terminology – Classifications



Thank you to all who participated in the working groups to develop ME/CFS CDEs!

- Jim Baraniuk
- Cindy Bateman
- Jonas Bergquist
- Alison Bested
- Italo Biaggioni
- Simon Carding
- David Cella
- Dane Cook
- Lily Chu
- Ron Davis
- Mary Dimmock
- Emmeline Edwards
- Mary Ann Fletcher
- Fred Freiburg
- Maureen Hanson
- Neil Harrison
- Carol Head
- Drew Helmer
- Nathan Holliday
- Mady Hornig
- Len Jason
- Ben Katz
- Betsy Keller
- Nancy Klimas
- Tony Komaroff
- Rachel Korinek
- Eliana Lacerda
- Gudrun Lang
- Sue Levine
- Jin-Mann Sally Lin
- Denise Lopez-Majano
- Anna-Louise Midsem
- Jose Montoya
- Christopher Mullins
- Luis Nacul
- Benjamin Natelson
- Lubov Nathanson
- Martina Nicholson
- Elisa Oltra
- David Patrick
- Katherine Rowe
- Peter Rowe
- Leo Saligan
- Richard Simpson
- Christopher Snell
- Staci Stevens
- Kim Sullivan
- Mark VanNess
- Terri Wilder
- Jared Younger
- Michael Zeinah
- Marcie Zinn

Project Leads:

- Beth Unger
- Vicky Whittemore

With support from:

- Andrew Breeden
- Emmes Staff
- NINDS Division of Clinical Research

Funded by:

- NINDS Contract to Emmes
- CDC

Accessing the NINDS/CDC CDEs

NINDS Common Data Elements Website

www.commondataelements.ninds.nih.gov

For more information on the NINDS/CDC ME/CFS CDEs, please contact:

Vicky Whittemore vicky.whittemore@nih.gov

NINDSCDE@emmes.com

For more information, go to NIH ME/CFS Website:

https://www.nih.gov/mecfs

Save the Date!

Accelerating Research on ME/CFS
April 4-5, 2019

Masur Lecture Hall, Clinical Center, Building 10
National Institutes of Health
Bethesda, MD

In partnership with Solve ME/CFS Initiative