

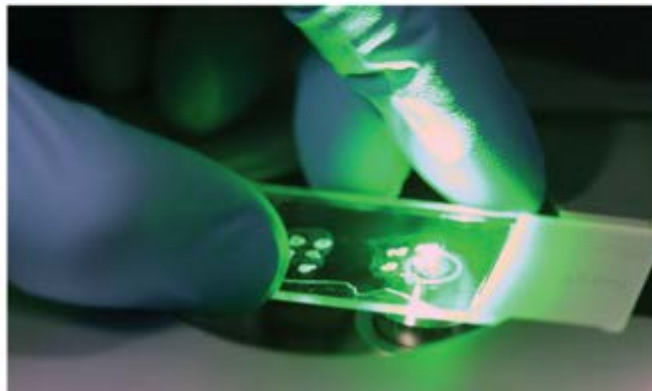
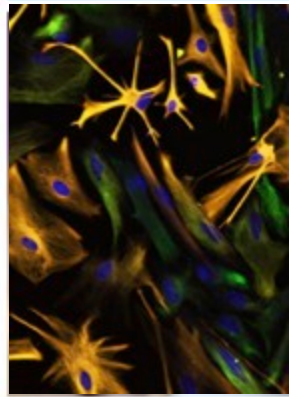


National Institute of
Neurological Disorders
and Stroke

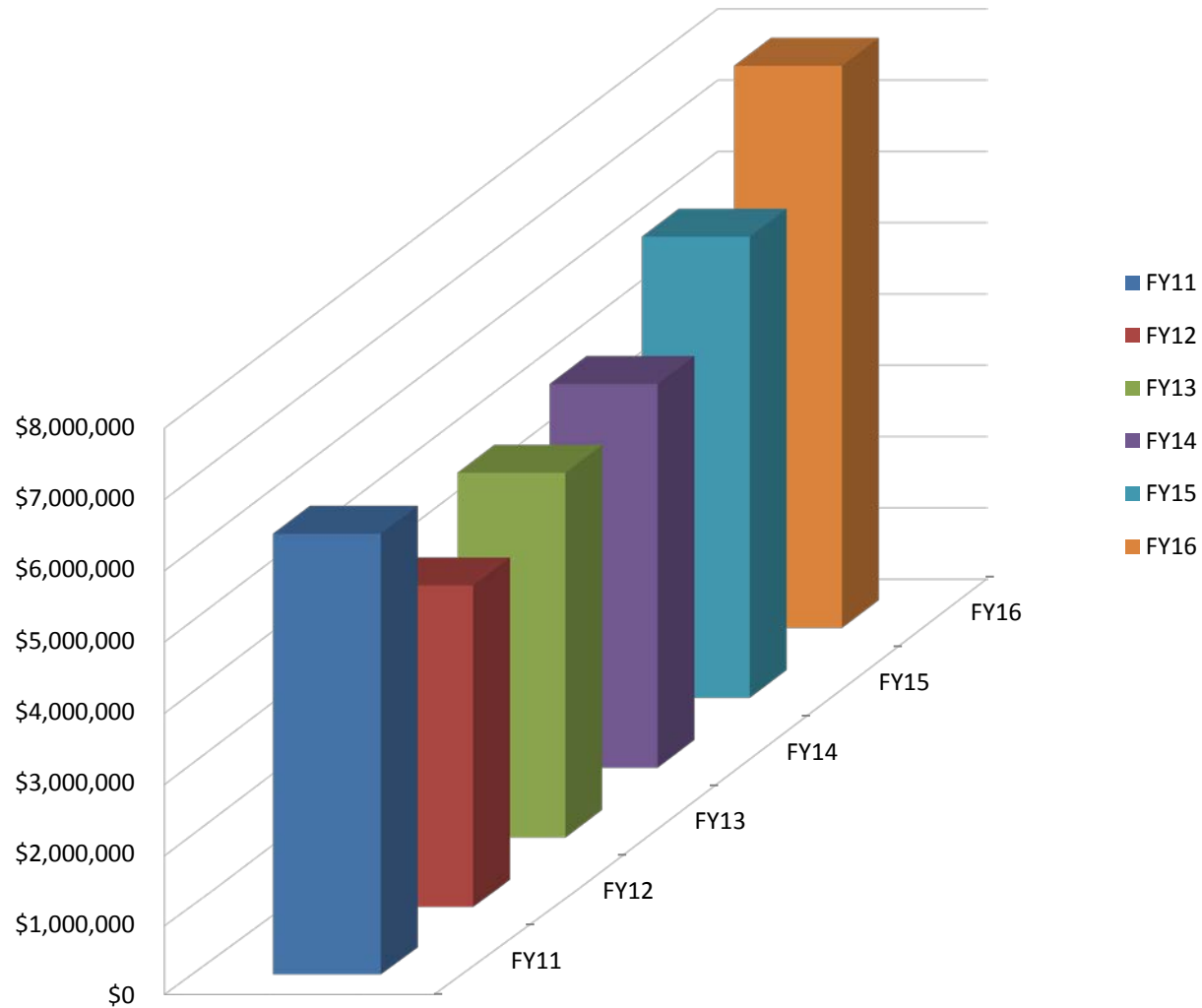
NIH Update CFSAC June 29-30, 2017

Vicky Whittemore, Ph.D.
Program Director, National Institute of
Neurological Disorders and Stroke, NIH

On behalf of the
Trans-NIH ME/CFS Working Group



NIH Funding for ME/CFS Research



NINDS Fellowship Award

- Rakib Uddin Rayhan, MD/PhD Candidate at Georgetown University and Howard University
- 1F30NS103563-01
- “Investigating the neural correlates of fatigue in Myalgic Encephalomyelitis/Chronic Fatigue Syndrome(ME/CFS) “
- Funding Period: 09/2017 – 08/2021
- Sponsor: James Baraniuk, MD



NIH Grant Mechanisms

- Funding Opportunity Announcements

<https://grants.nih.gov/funding/index.htm>

- Parent Announcements

https://grants.nih.gov/grants/guide/parent_announcements.htm

- New Funding Opportunity

Notice of Intent to Publish a Funding Opportunity Announcement for NIH Blueprint for Neuroscience Research: Dynamic Neuroimmune Interactions in the Transition from Brain Function to Dysfunction (R01)

[NOT-AA-17-006](#)

FY2018 President's Budget for NIH

	FY17 appropriations	President's budget for FY18	Difference (FY18 - FY17)
NIH	\$34.1 B (including \$352 million from 21st Century Cures)	\$26.9 B (including \$496 million from 21 st Century Cures)	-7.2 B
NINDS	\$1.784 B	\$1.356 B	-428 million

Comparison of FY17 appropriations vs. President's proposed FY18 budget

Trans-NIH ME/CFS Working Group


- Chaired by Walter Koroshetz, MD, NINDS Director
- Coordinated by Vicky Whittemore, PhD
- Representatives from 24 Institutes, Offices and Centers across NIH
- Continues to meet monthly
- Implementing goals and strategies to stimulate and support research on ME/CFS

Implementing Goals and Strategies

- Stimulate research: 7 Administrative Supplement awards supported by NIAID and NINDS to NIH-funded investigators in FY16
- Identify research priorities: Request for Information provided responses from ME/CFS stakeholders that help to shape research focus and priorities going forward
- Common Data Elements Project initiated together with the CDC

ME/CFS Common Data Elements

[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




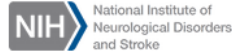

- ▶ Project overview and background
- ▶ Meetings and Presentations
- ▶ Collaboration with developers around the world

[CDEs Now Available](#) [CDEs Under Review](#) [CDEs in Development](#)

[General \(CDEs that cross diseases\)](#)

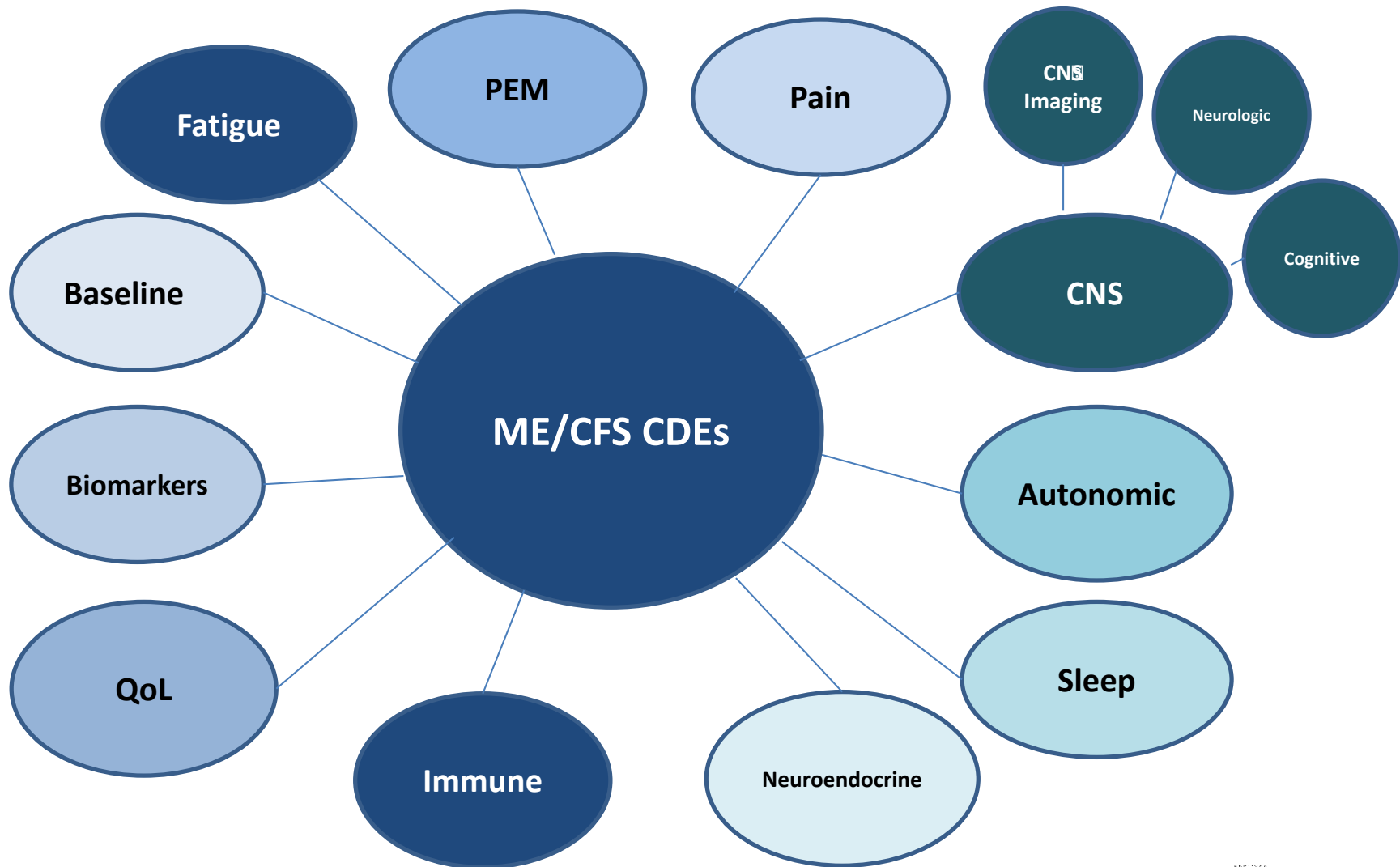
- [Amyotrophic Lateral Sclerosis](#)
- [Epilepsy](#)
- [Friedreich's Ataxia](#)
- [Headache](#)
- [Huntington's Disease](#)
- [Mitochondrial Disease **NEW!**](#)
- [Multiple Sclerosis](#)
- [Neuromuscular Diseases](#)

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Page last updated on August 27, 2015

ME/CFS CDE Project



Timeline for CDE Development

- Health care professionals and researchers were invited to participate in the project
- ME/CFS stakeholders (individuals with ME/CFS and advocates) are critical for the project and are involved in all of the working groups
- Training conference calls were held in January and February 2017
- Working groups were formed and are meeting to discuss specific domains of CDEs
- Finalize CDEs in 10-12 months
- Public comment period to allow input from all ME/CFS stakeholders
- CDEs will be utilized in the ME/CFS Collaborative Research Centers and other NIH-funded research

Implementing Goals and Strategies

- Participation in ME/CFS Conferences:

- BIOMEDICAL RESEARCH into ME COLLOQUIUM, London, UK
- 12th Invest in ME International ME Conference 2017



- Participation in sessions on ME/CFS at professional scientific conferences:

- SLEEP 2017 - A joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society

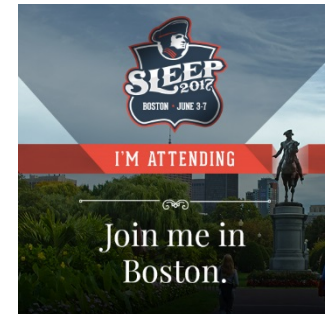
- Included session on fatigue and ME/CFS – Hans Knopp, Janet

Mullington, David Raizen, Mary Harrington, Joseph Breen

Vicky Whittemore

- FOCIS 2017 – Federation of Clinical Immunology Societies

- Session on ME/CFS included speakers: Beth Unger, Mark Davis, Eleanor Riley, W. Ian Lipkin & Jose Montoya
- Organized by Joseph Breen, PhD, NIAID & Vicky Whittemore, PhD, NINDS



Implementing Goals and Strategies

- Foster collaboration and communication regarding research activities on ME/CFS between:
 - USA Federal agencies and non-profit organizations
 - Foreign funding agencies:
 - Canadian Institutes of Health Research (CIHR)
 - Medical Research Council (MRC) in UK
 - National Institute of Health Research (NIHR) in UK

NIH Funding Opportunity Announcements

NIH released FOAs in January 2017

- Multi-disciplinary, multi-site ME/CFS collaborative research centers (CRC) and a data management coordinating center (DMCC)
- Collaborative effort between NIH Institutes, Offices and Centers to support \$6 million in ME/CFS research per year for 5 years
- Foster use of common protocols and common data elements across sites to enable longitudinal studies of large cohorts of individuals with ME/CFS
- Enable and support research at academic centers
- Partner with Clinical Science Translational Awards (CTSAs) where possible to provide infrastructure
- Encourage involvement of young and new investigators (both basic science and clinical)
- Require community engagement and involvement to ensure success
- Discussions underway to partner with international partners to expand network of ME/CFS Collaborative Research Centers

NIH ME/CFS CRCs and DMCC

Overall research areas of interest include, but are not limited to:

- Determining the etiology and pathogenesis in ME/CFS;
- Studies that help to identify subtypes of ME/CFS based on biological markers and/or symptom classifications;
- Longitudinal studies to understand the course of disease over time to better characterize the manifestations of ME/CFS; and develop and validate outcome measures for future intervention trials; and
- Identification of potential treatment targets for ME/CFS.

Timeline for ME/CFS CRCs and DMCC

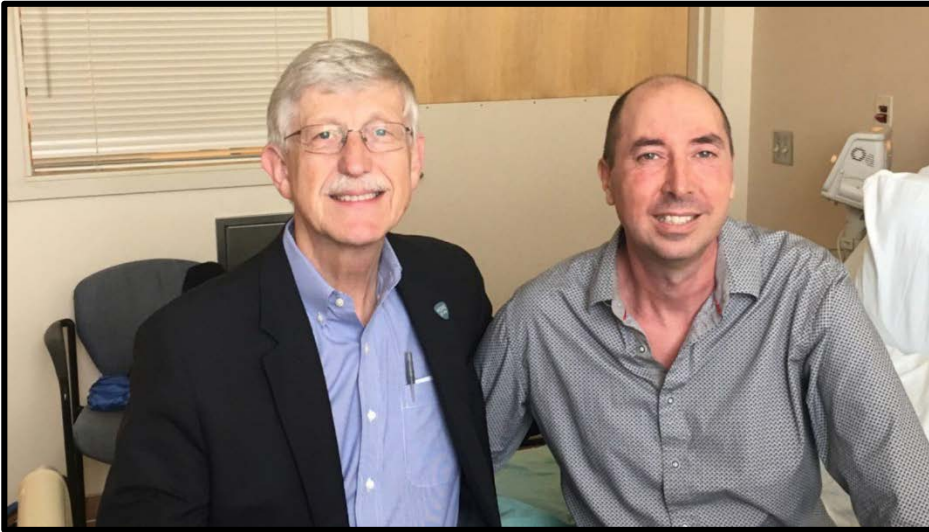
- FOAs released in January 2017
- Letters of Intent received in April 2017
- Full applications received in May 2017
- Application review to be held in July 2017
- Funding recommendations reviewed at appropriate NIH Institute National Advisory Council meetings in September 2017
- Funding to begin in September 2017 (hopefully!)

NIH ME/CFS Intramural Study Update

- Led by Dr. Avi Nath, Clinical Director at NINDS
- Studies conducted at the NIH Clinical Center
- Recruiting 40 individuals with ME/CFS, 20 healthy controls, and 20 individuals who have recovered from Lyme's Disease
- Protocol includes detailed phenotyping, neurological and immunological studies (Visit 1)
- Exercise testing and PEM evaluation (Visit 2)
- Both healthy controls (5) and study participants (5) with ME/CFS have been enrolled and completed Visit 1
- Extensive analyses and biospecimen collection
- <http://mecfs.ctss.nih.gov/>



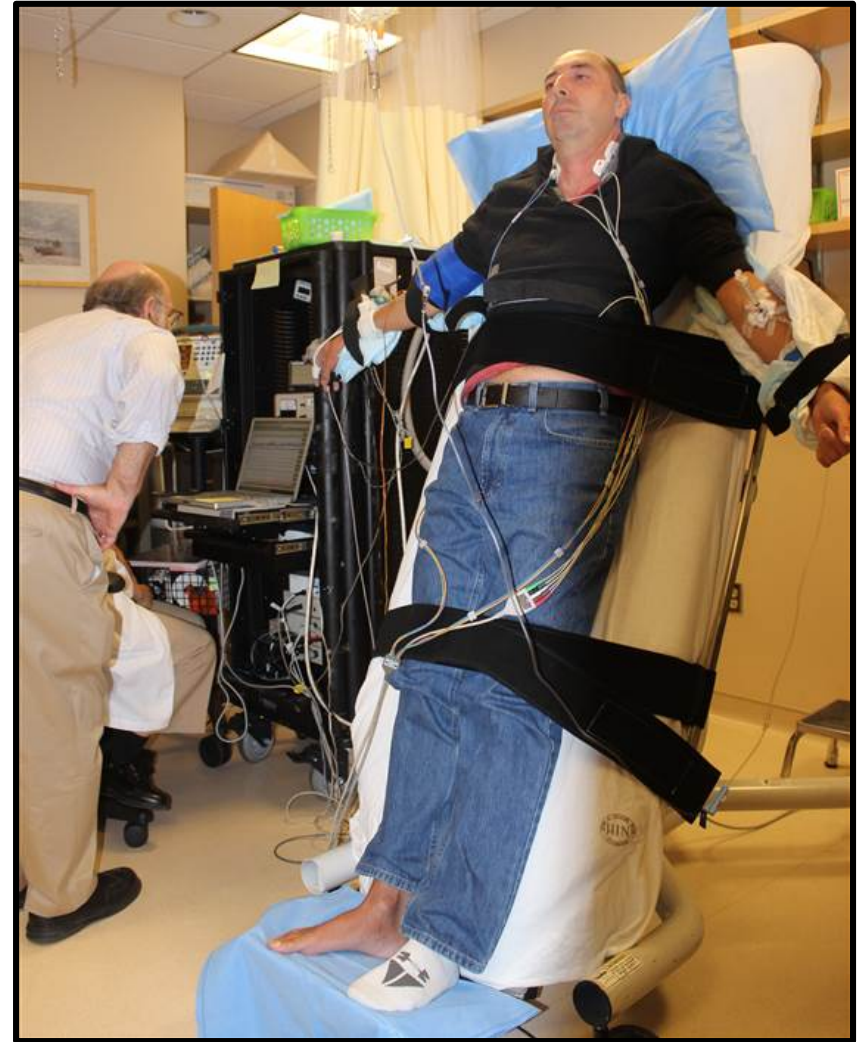
NIH ME/CFS Intramural Study



Above: NIH Director Francis Collins, MD (left) and Brian Vastag at the NIH Clinical Center
Statnews

Right: Dr. David Goldstein of the NINDS tests Brian Vastag for autonomic nervous system dysfunction as part of a myalgic encephalomyelitis study.

NBC News/Picture by Beth Mazur



ME/CFS Special Interest Group (SIG)

- Seminars organized by NIH intramural investigators
- Designed to educate and provide perspective about the clinical and research issues in ME/CFS for intramural staff and extramural program staff
- W. Ian Lipkin and Sonya Marshall-Gradisnik & Don Staines will present in July 2017
- Information at:
<http://mecfs.ctss.nih.gov/sig.html>

Plans for 2017

- Stakeholder conference call on July 10, 2017
- Complete CDE Project
- Launch the ME/CFS Collaborative Research Centers and Data Management Coordinating Center
- Foster collaboration and communication with foreign and USA agencies and organizations funding research on ME/CFS

Long-term Goals

- Stimulate and support research on ME/CFS
- Grow the pipeline of ME/CFS investigators
- Support and expand ME/CFS collaborative research centers as funding allows
- Support the development of new therapies and treatments for ME/CFS
- Support clinical trials for ME/CFS
- Ultimately, to improve the quality of life for all individuals with ME/CFS

For More Information

NIH ME/CFS Website:
<https://www.nih.gov/mecfs>

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