



**THE FORUM**  
For Collaborative Research<sup>SM</sup>

# Liver Forum Project Updates

**Katherine Barradas, MPH**

Forum for Collaborative Research

# Agenda, Today

<b>2:00 PM</b>	<b>Session IV: Liver Forum Updates</b>	
2:00 PM	<b>Liver Forum Project Updates</b>	<i>Katherine Barradas, Forum for Collaborative Research</i>
	<b>Introductory Remarks</b>	<i>Veronica Miller, Forum for Collaborative Research</i>
	Liver Forum Co-Chairs	<i>Arun Sanyal, Virginia Commonwealth University</i>
<b>2:15 PM</b>	<b>Session V: Biomarker Development</b>	
	<b>Moderators:</b> <i>John Sninsky, Independent &amp; Veronica Miller, Forum for Collaborative Research</i>	
2:15 PM	<b>Opportunities in Biomarker Development</b>	<i>Christopher Leptak, U.S. Food and Drug Administration</i>
2:50 PM	<b>NASH Consortia Update</b>	
	<ul style="list-style-type: none"><li>LITMUS</li><li>NIMBLE</li></ul>	<i>Quentin Anstee, Newcastle University</i> <i>Arun Sanyal, Virginia Commonwealth University</i>
		<b>Panelists:</b> <i>Quentin Anstee, Newcastle University</i> <i>Julia Brosnan, LITMUS &amp; Pfizer</i> <i>Lara Dimick-Santos, U.S. Food and Drug Administration</i> <i>Elisabeth Erhardtsen, Nordic Bioscience</i> <i>Céline Fournier, Echosens</i> <i>Eric Huang, Glympse Bio</i> <i>Christopher Leptak, U.S. Food and Drug Administration</i> <i>Arun Sanyal, Virginia Commonwealth University</i> <i>Sudha Shankar, NIMBLE &amp; AstraZeneca</i>
3:35 PM	<b>Panel Discussion</b> Challenges and Opportunities	
<b>5:00 PM</b>	<b>PSC Forum and Liver Forum Evening Reception</b>	

# Agenda, Tomorrow, Abbreviated

<b>8:30 AM</b>	<b>Session I: NASH Combination Therapy</b>	
	<b>Combination Approaches for NASH Patient Populations</b>	
8:30 AM	<ul style="list-style-type: none"><li>• Pre-Cirrhotic NASH</li></ul>	<i>Brent Tetri, Saint Louis University</i>
8:45 AM	<ul style="list-style-type: none"><li>• Cirrhotic NASH</li></ul>	<i>Julia Wattacheril, Columbia University</i>
9:00 AM	<b>Panel Discussion</b> Current Combination Strategies	
<b>10:15 AM</b>		
<b>10:45 AM</b>	<b>Session II: NASH Regulatory Considerations</b>	
10:45 AM	<b>NASH Regulatory Update</b>	<i>Elmer Schabel, BfArM/ European Medicines Agency</i> <i>Yao-Yao Zhu, U.S. Food and Drug Administration</i>
11:15 AM	<b>Innovations in Trial Designs in NASH Clinical Research</b>	<i>Arun Sanyal, Virginia Commonwealth University</i>
11:35 AM	<b>Panel Discussion</b> Challenges & Potential Approaches	
<b>1:00 PM</b>		
<b>2:00 PM</b>	<b>Session III: Parallel Breakout Sessions</b>	
	NASH Cirrhosis Working Group	
	Pediatric Issues in NASH Working Group	
	Biomarker Development: Diagnostics	
<b>3:30 PM</b>	<b>Break</b>	
<b>4:00 PM</b>	<b>Session IV: Reports and Wrap-Up</b>	
4:00 PM	Reports from Breakout Sessions	
4:45 PM	Future Directions & Next Steps	
<b>5:30 PM</b>	<b>Meeting Close</b>	

# Options for Discussion

## ■ Microphones

- 1 mic per table
- Signal moderator
- Introduce self



## ■ Submit Questions

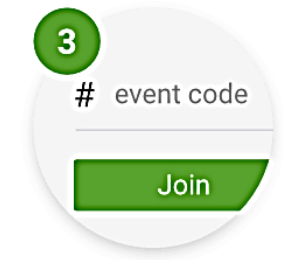
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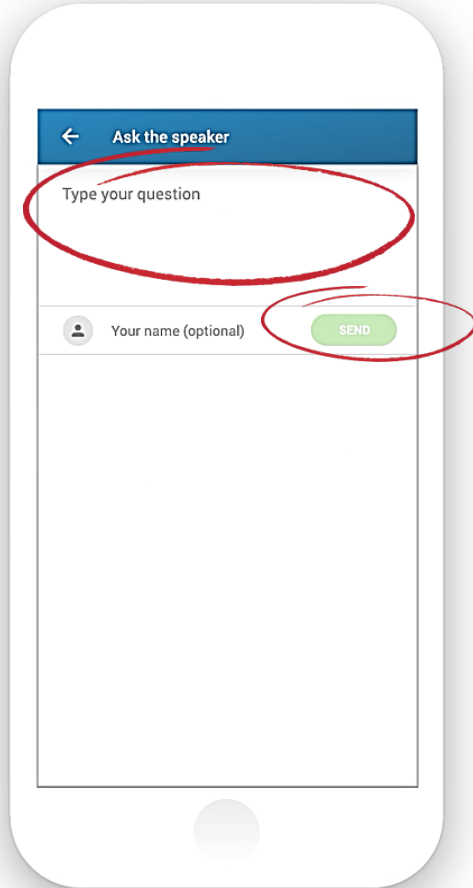
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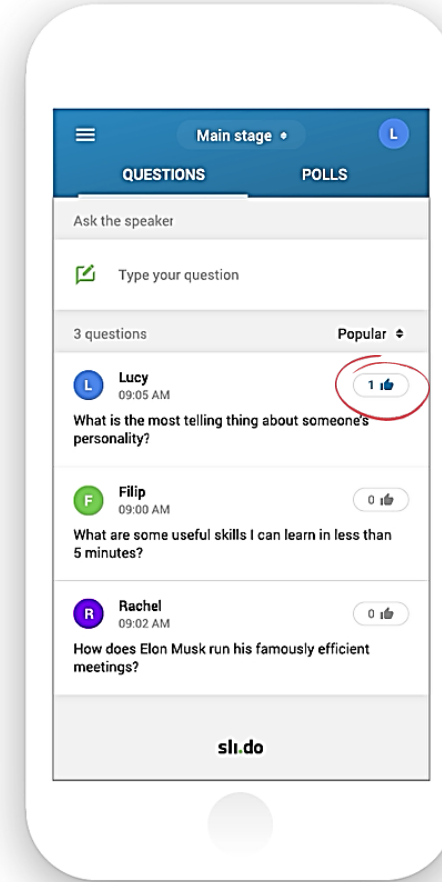
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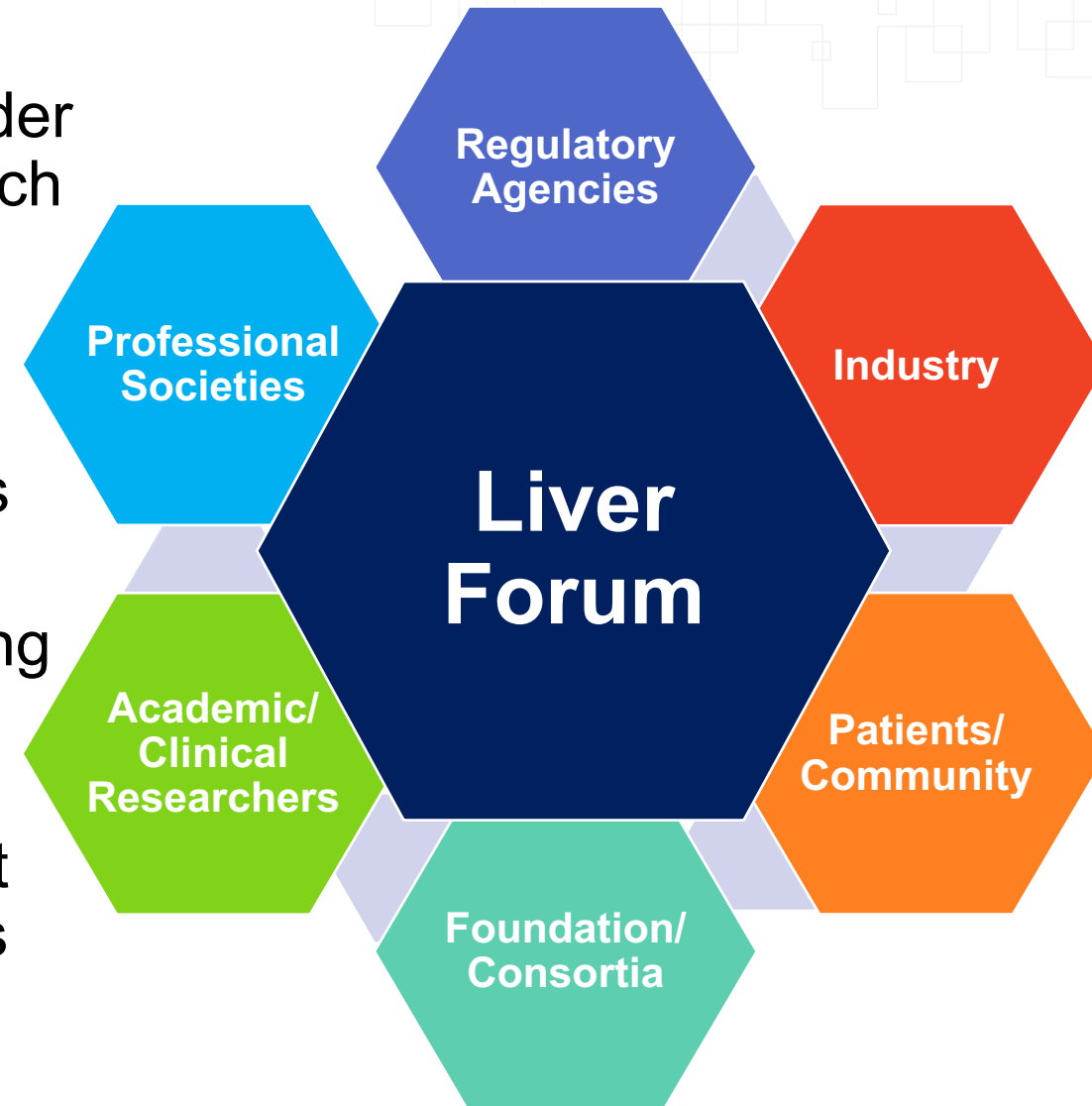
Type questions & submit

“Like” questions



# Overview of the Liver Forum

- **What:** a platform for ongoing multi-stakeholder dialogue to identify barriers, prioritize research and identify solutions to accelerate therapeutic development for NAFLD/NASH
- **How:** provide a neutral, independent, safe space for discussion and deliberation across stakeholder groups
  - Focus on developing consensus, increasing synergy and collaboration, and reducing duplication and uncertainty
  - Ongoing working group activity throughout the year anchored by larger project events
  - Active & engaged participation



# Rules of the Room

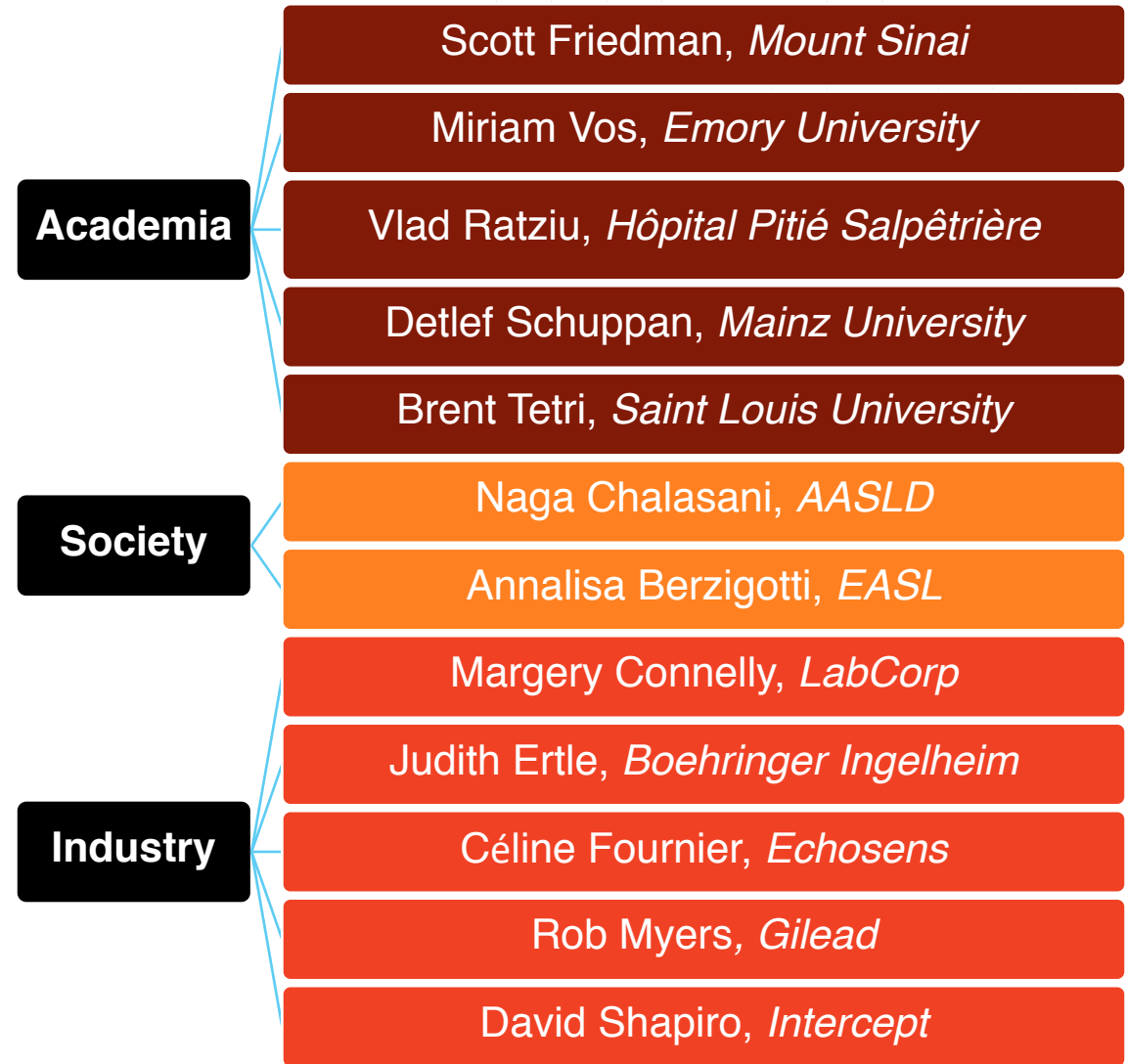
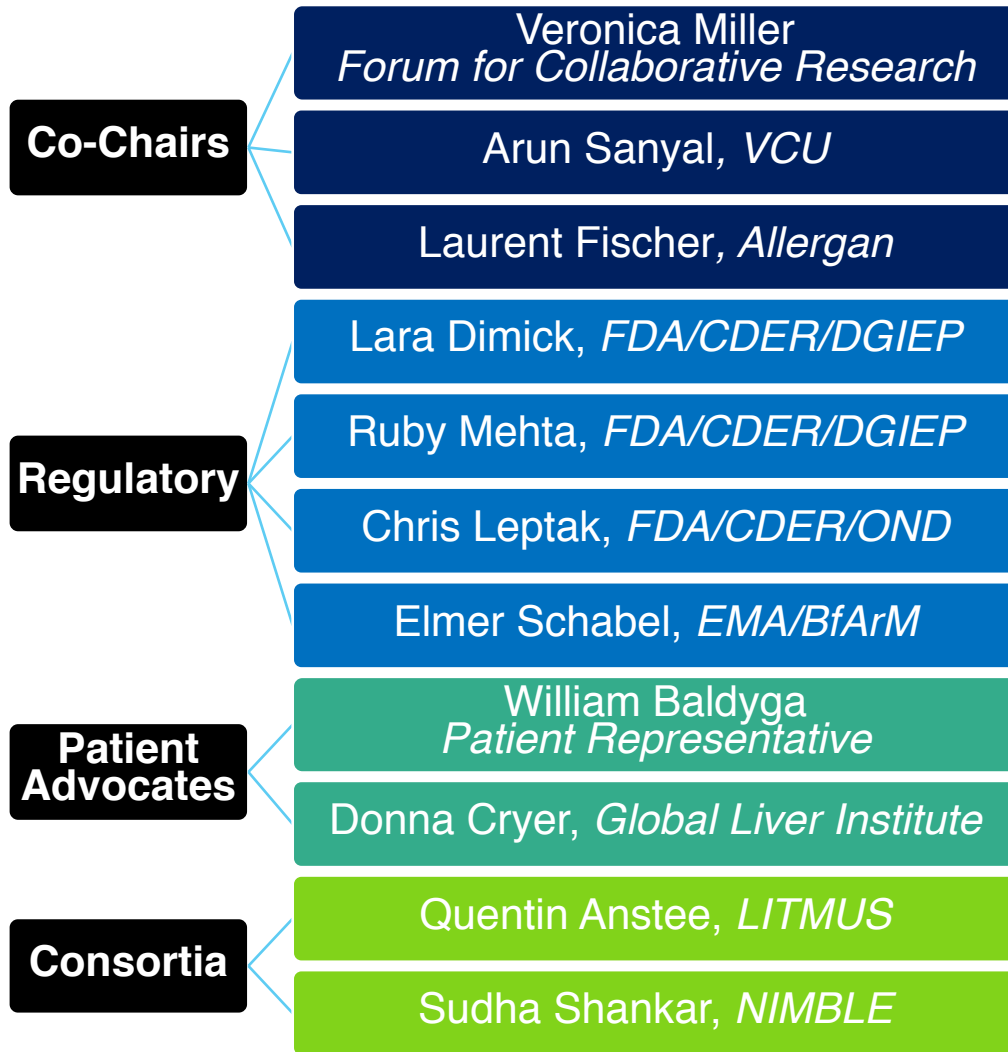
- Presentations, discussions, comments, and questions are not for attribution
  - Participants speak as individuals and express views that may not represent those of their organizations
  - Social Media:
    - ❌ Quotes of speakers/panelists/audience
    - ❌ Detailing meeting proceedings
    - ✅ Photos during receptions
    - ✅ Referencing attendance
    - ✅ Interactions during breaks



**@LIVERFORUM**



# Steering Committee





# Recent Activities & Accomplishments

## ■ Submitted: Responses to Regulatory Guidance Documents

- EMA reflection paper “Regulatory Requirements for the Development of Medicinal Products for Chronic Non-Infectious Liver Diseases (PBC, PSC, NASH)”
- FDA draft guidance “Nonalcoholic Steatohepatitis with Compensated Cirrhosis: Developing Drugs for Treatment”

## ■ Submitted: Standard of Care Lifestyle Manuscript

***Standardization of Diet and Exercise in Clinical Trials of NAFLD-NASH: Recommendations from the Liver Forum***

*Oliver Glass, Claudia Filozof, Mazen Nouredin, Mark Berner-Hansen, Elmer Schabel, Katherine Barradas, Jörn M. Schattenberg, Veronica Miller, Sven Francque, Manal F. Abdelmalek, for the Liver Forum Standard of Care Working Group*

Submitted to Journal of Hepatology

# Recent Activities & Accomplishments

## ■ Pediatric Issues Working Group Manuscript #1

### *Factors to Consider in Development of Drugs for Pediatric Nonalcoholic Fatty Liver Disease*

*Miriam B. Vos, Lara Dimick-Santos, Ruby Mehta, Stephanie O. Omokaro, Johannes Taminiau, Elmer Schabel, David E. Kleiner, Peter Sztanyi, Piotr Socha, Jeffrey B. Schwimmer, Stephanie Noviello, Debra G. Silberg, Richard Torstenson, Veronica Miller, Joel E. Lavine, on behalf of the Liver Forum Pediatric Issues Working Group*

**Accepted at Gastroenterology**

<https://doi.org/10.1053/j.gastro.2019.08.048>

Tentatively scheduled for December 2019 issue



# Working Group Details

Working Group	Chairs	Status
Data Standardization	Joanne Imperial & Andrew Muir	Completed
Case Definitions	Stephen Harrison & Sophie Megnien	Completed
Standard of Care: Lifestyle	Manal Abdelmalek, Sven Francque	To be Assessed
Estimands in NASH	Peter Mesenbrink & Veronica Miller	Active/ Closed
Standard of Care: Comorbidities	Raluca Pais & Vlad Ratziu	Active/ Open
Pediatric Issues	Joel Lavine & Miriam Vos	Active/ Open
NASH Cirrhosis	Naga Chalasani, Jean Chan, & Arun Sanyal	Active/ Open

All **ACTIVE/ OPEN** working groups welcome additional members!

To join, email me at [kgreene@forumresearch.org](mailto:kgreene@forumresearch.org)

# Liver Forum Manuscript Status

Working Group	Title	Status
Data Standardization	Baseline Parameters in Clinical Trials for Nonalcoholic Steatohepatitis: Recommendations From the Liver Forum	<b>Published</b> <a href="https://doi.org/10.1053/j.gastro.2017.07.024">https://doi.org/10.1053/j.gastro.2017.07.024</a>
Case Definitions	Case Definitions for Inclusion and Analysis of Endpoints in Clinical Trials for Nonalcoholic Steatohepatitis Through the Lens of Regulatory Science	<b>Published</b> <a href="https://doi.org/10.1002/hep.29607">https://doi.org/10.1002/hep.29607</a>
Case Definitions	Defining Improvement in Nonalcoholic Steatohepatitis for Treatment Trial Endpoints: Recommendations from the Liver Forum	<b>Accepted</b> <a href="https://doi.org/10.1002/hep.30672">https://doi.org/10.1002/hep.30672</a>
Pediatric Issues	Factors to Consider in Development of Drugs for Pediatric Nonalcoholic Fatty Liver Disease	<b>Accepted</b> <a href="https://doi.org/10.1053/j.gastro.2019.08.048">https://doi.org/10.1053/j.gastro.2019.08.048</a>
Standard of Care	Standardization of Diet and Exercise in Clinical Trials of NAFLD-NASH: Recommendations from the Liver Forum	Submitted
Standard of Care	Management of Comorbidities in NAFLD Clinical Trials	Under Development
NASH Cirrhosis	Attribution of NASH as an Etiology of Cirrhosis for Clinical Trials Eligibility: Recommendations from the Liver Forum	Under FDA Review

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# THANK YOU!

## **The Forum for Collaborative Research**

Executive Director: Veronica Miller

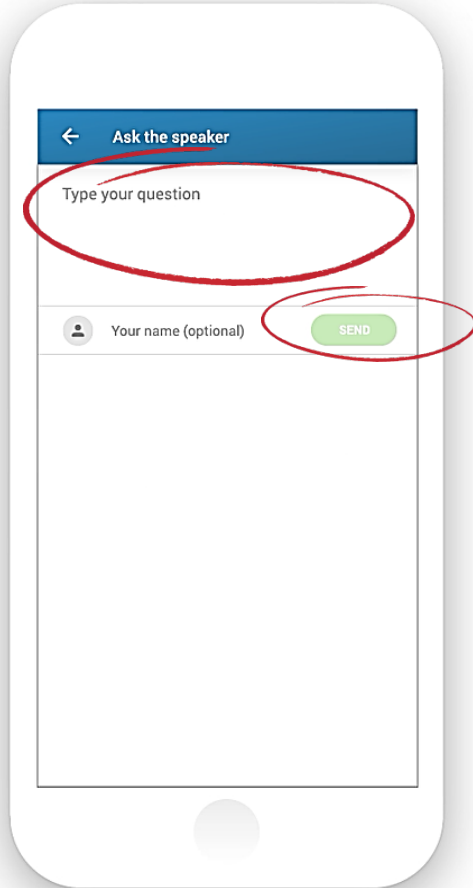
- Jessica Weber
- Brenda Rodriguez
- Luis Javier Hernandez
- Terry Daniels
- Vin Keane

## **Prism Event Management**

- Paula Blay
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