

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Gastroenterology Regulatory Endpoints and the Advancement of Therapeutics VI (GREAT VI)
Workshop on Eosinophilic Gastrointestinal Disorders Beyond EoE

Virtual meeting
July 21, 2021

AGENDA

The goal of today's workshop is to discuss the disease characteristics, natural history, and endpoints to assess treatment benefit in patients with eosinophilic gastrointestinal disorders (EGID) beyond eosinophilic esophagitis (EoE) to provide a forum for open discussion between stakeholders to facilitate drug development.

10:00 a.m.	Opening Remarks	Erica Lyons <i>(10 min)</i>
10:10 a.m.	Session 1: Diagnosis and natural history of EGID <u>Moderators: Matthew Kowalik and Marc Rothenberg</u>	
	EGID pathogenesis and nomenclature	<i>(15 min)</i>
	<i>Speaker: Evan Dellon</i>	
	Histopathologic characteristics of EGID: a pathologist's perspective	<i>(10 min)</i>
	<i>Speaker: Margaret Collins</i>	
	Clinical symptoms/signs and natural history of EGID	<i>(20 min)</i>
	<i>Speaker: Nirmala Gonsalves</i>	
	Alternative etiologies for gastrointestinal mucosal eosinophilia	<i>(20 min)</i>
	<i>Speaker: Nicholas Talley</i>	
11:15 a.m.	Break	<i>(10 min)</i>

- 11:25 a.m. Panel Discussion and Q&A* (40 min)
Panelists: Seema Aceves, Margaret Collins, Evan Dellon, Glenn Furuta, Robert Genta, Nirmala Gonsalves, Ikuo Hirano, Erica Lyons, Veronica Mas Casullo, Macie Smith, Nicholas Talley
- 12:05 p.m. **Lunch** (55 min)
- 1:00 p.m. **Session 2: Assessing clinical benefit in EGID**
Moderators: Erica Lyons and Ikuo Hirano
- Living with EGID and goals of treatment: a patient perspective (15 min)
Speaker: Macie Smith
- Defining clinical benefit in clinical trials for EGID: An FDA perspective (20 min)
Speaker: Sarrit Kovacs
- Clinician perspective on the assessment of meaningful benefit (20 min)
Speaker: Kathryn Peterson and Calies Menard-Katcher
- 1:55 p.m. Break (15 min)
- 2:10 p.m. Panel discussion and Q&A* (40 min)
Panelists: Mirna Chehade, Evan Dellon, Glenn Furuta, Sandeep Gupta, Sarrit Kovacs, Veronica Mas Casullo, Calies Menard-Katcher, Kathryn Peterson, Marc Rothenberg, Macie Smith, Jonathan Spergel, Juli Tomaino
- 2:50 p.m. **Closing Remarks** **Matthew Kowalik** (10 min)
- 3:00 p.m. **Adjournment**

***To facilitate discussion, please submit all questions for the panel prior to the session break**