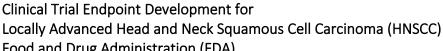
Clinical Trial Endpoint Development for Locally Advanced Head and Neck Squamous Cell Carcinoma (HNSCC) Food and Drug Administration (FDA) FDA U.S. FOOD & DRUG ADMINISTRATION
ONCOLOGY CENTER OF EXCELLENCE

Oncology Center of Excellence (OCE) Public Workshop (Virtual)

Date: November 3, 2021

Time: 12:00 PM to 5:00 PM (ET)

	Agenda
	Introduction
12:00 PM	Introduction and Welcome
12.00 1 111	Paz Vellanki, MD, PhD, FDA
12:05 PM	Opening Remarks
	Julia Beaver, MD, FDA
	Session I: Clinical Trials in Non-Metastatic HNSCC
	Moderator: Paz Vellanki, MD, PhD, FDA
12:15 PM	Landscape Analysis of Clinical Trials in Non-Metastatic HNSCC
	Barbara Burtness, MD, Yale School of Medicine
50	ssian III Defining Farly Endnaints and Issues Regarding Management After Definitive Therapy
36	ssion II: Defining Early Endpoints and Issues Regarding Management After Definitive Therapy Moderator: Liza Stapleford, MD, MPH, FDA
12:30 PM	Definitions of Event Free Survival (EFS) and Locoregional Control (LRC) for Locally Advanced HNSCC
12.30 1 101	Sue Yom MD, PhD, University of California, San Francisco
12:45 PM	The Surgical Perspective
	Robert Ferris MD, PhD, University of Pittsburgh Medical Center
1:00 PM	Panel Discussion
	Panelists: Session II speakers and the following additional panelists:
	Nabil Saba, MD, Emory University
	Jared Weiss, MD, University of North Carolina
	Loren Mell, MD, University of California, San Diego
	Objectives:
	Review current definitions and harmonization of EFS and LRC endpoints.
	Discuss variability in imaging and management paradigms after completion of concurrent
	chemoradiation.
	Session III: Patient Perspective on Clinical Trials for Locally Advanced HNSCC
	Moderator: Gautam Mehta, MD, FDA
1:40 PM	Panel Discussion
	Panelists:
	Jeffrey Shoop, Patient Advocate
	Stephen Cassidy, Patient Advocate
	Amanda Hollinger, Executive Director, Head and Neck Cancer Alliance
	Mary Ann Caputo, Executive Director, Support for People with Oral and Head and Neck Cancer
	Objectives:
	 What makes head and neck cancer unique compared to other cancers?
	Discuss the importance of clinical trials for patients with HNSCC.

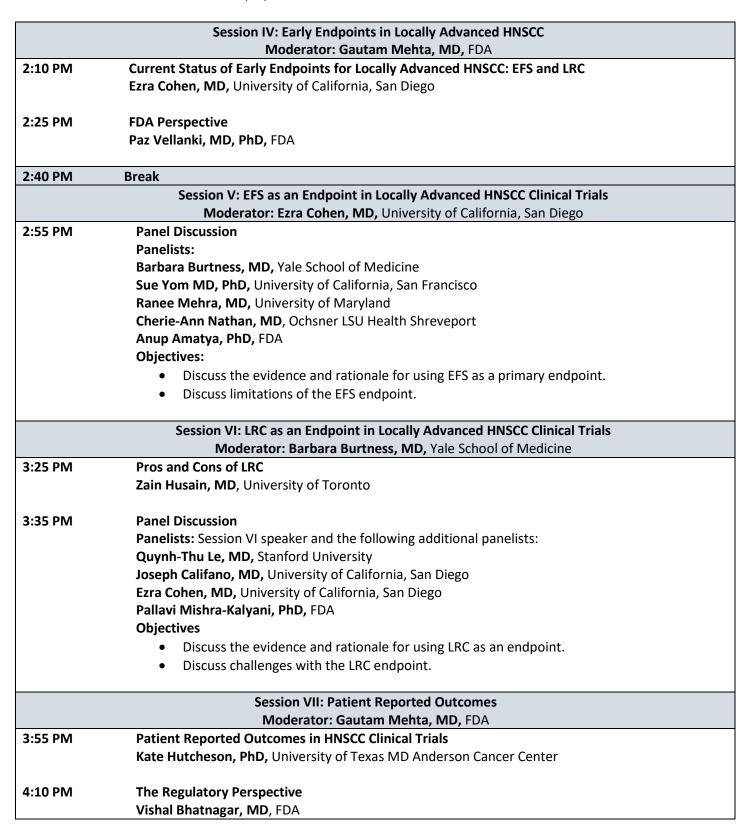


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	Workshop Summary and Conclusions
	Moderator: Erin Larkins, MD, FDA
4:25 PM	Panel Discussion
	Panelists:
	Barbara Burtness, MD, Yale School of Medicine
	Ezra Cohen, MD, University of California, San Diego
	David Pfister, MD, Memorial Sloan Kettering Cancer Center
	Sharon Spencer, MD, University of Alabama at Birmingham
	Objectives:
	 Review key findings from workshop.
	 Prioritize next steps for early endpoint development for HNSCC.
4:55 PM	Preview of Part 2 of Workshop and Closing Remarks
	Gautam Mehta, MD, FDA
	Liza Stapleford, MD, MPH, FDA
	Paz Vellanki, MD, PhD, FDA
5:00 PM	Adjourn