

Clinical Trial Endpoint Development for
 Locally Advanced Head and Neck Squamous Cell Carcinoma (HNSCC)
 Food and Drug Administration (FDA)
 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 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
Session 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 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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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Session IV: Early Endpoints in Locally Advanced HNSCC	
Moderator: Gautam Mehta, MD, FDA	
2:10 PM	Current Status of Early Endpoints for Locally Advanced HNSCC: EFS and LRC Ezra Cohen, MD, University of California, San Diego
2:25 PM	FDA Perspective Paz Vellanki, MD, PhD, FDA
2:40 PM	Break
Session V: EFS as an Endpoint in Locally Advanced HNSCC Clinical Trials	
Moderator: Ezra Cohen, MD, University of California, San Diego	
2:55 PM	Panel Discussion Panelists: Barbara Burtness, MD, Yale School of Medicine Sue Yom MD, PhD, University of California, San Francisco Ranee Mehra, MD, University of Maryland Cherie-Ann Nathan, MD, Ochsner LSU Health Shreveport Anup Amatya, PhD, FDA Objectives: <ul style="list-style-type: none"> • Discuss the evidence and rationale for using EFS as a primary endpoint. • Discuss limitations of the EFS endpoint.
Session VI: LRC as an Endpoint in Locally Advanced HNSCC Clinical Trials	
Moderator: Barbara Burtness, MD, Yale School of Medicine	
3:25 PM	Pros and Cons of LRC Zain Husain, MD, University of Toronto
3:35 PM	Panel Discussion Panelists: Session VI speaker and the following additional panelists: Quynh-Thu Le, MD, Stanford University Joseph Califano, MD, University of California, San Diego Ezra Cohen, MD, University of California, San Diego Pallavi Mishra-Kalyani, PhD, FDA Objectives <ul style="list-style-type: none"> • Discuss the evidence and rationale for using LRC as an endpoint. • Discuss challenges with the LRC endpoint.
Session VII: Patient Reported Outcomes	
Moderator: Gautam Mehta, MD, FDA	
3:55 PM	Patient Reported Outcomes in HNSCC Clinical Trials Kate Hutcheson, PhD, University of Texas MD Anderson Cancer Center
4:10 PM	The Regulatory Perspective Vishal Bhatnagar, MD, FDA

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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: <ul style="list-style-type: none">• 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