

Updating Labels for Generic Oncology Drugs

Hosted by the National Cancer Policy Forum
In Collaboration with the Forum on Drug Discovery, Development, and Translation

Keck Center of the National Academies
Room 100
500 Fifth Street, NW
Washington, DC 20001

AGENDA

March 26, 2019	
7:30 am	Registration and Breakfast
8:00 am	<p>Welcome and Opening Remarks Harold L. Moses, Vanderbilt-Ingram Comprehensive Cancer Center Planning Committee Chair</p> <p>Richard Pazdur, Food and Drug Administration</p>
8:15 am	<p>Session I: Background and Overview of the Goals of the Meeting Moderator: Andy Bindman, University of California, San Francisco</p> <p>FDA overview of Project Renewal and regulatory requirements for labeling updates (15 mins)</p> <ul style="list-style-type: none"> • Paul Kluetz, Food and Drug Administration <p>Evidence review processes for clinical practice guidelines/compendia in oncology: lessons learned and how they could inform evidence review process for updating labeling (15 mins)</p> <ul style="list-style-type: none"> • Ethan Basch, University of North Carolina, Chapel Hill <p>Case examples of how outdated labeling affects clinician prescribing and patient care (15 mins)</p> <ul style="list-style-type: none"> • Donald Harvey, Emory University <p>Panel Discussion Include speakers and Lia Gore, University of Colorado & Children's Hospital Colorado Rajeshwari Sridhara, Food and Drug Administration</p>

9:15 am	<p>Introduction to Small Group Discussions Overview of the format and plans for small group discussions Identify moderators/note takers for each table Harold L. Moses, Vanderbilt-Ingram Comprehensive Cancer Center Planning Committee Chair</p>
9:30 am	<p>Session 2: Sources of Information <u>Objectives:</u></p> <ul style="list-style-type: none"> • In small groups, discuss what sources of information could be used to update labels for generic oncology drugs, as well as the challenges and considerations that should be considered when using different information sources (e.g., clinical trials data, meta-analyses, real world evidence). • Reconvene at 10:30 am to report out main points for broader discussion. <ul style="list-style-type: none"> ○ S. Gail Eckhardt will moderate the report back discussion.
11:30 am	Lunch
12:15 pm	<p>Session 3: Evidentiary Standards for Information Sources <u>Objectives:</u></p> <ul style="list-style-type: none"> • In small groups, discuss what the evidentiary standards should be for different sources of information discussed in the prior session. • Reconvene at 1:15 pm to report out main points for broader discussion. <ul style="list-style-type: none"> ○ Richard L. Schilsky will moderate the report back discussion.
2:15 pm	Break
2:30 pm	<p>Session 4: Evidence Considerations for Select Populations <u>Objectives:</u></p> <ul style="list-style-type: none"> • In small groups, discuss how the strength of evidence and sources of evidence may differ depending on the population being considered (e.g., pediatric populations, patients with comorbidities, those with rare cancers, biomarker-defined population subsets).

	<ul style="list-style-type: none"> • Reconvene at 3:30 pm to report out main points for broader discussion. <ul style="list-style-type: none"> ○ Katherine Warren will moderate the report back discussion.
4:30 pm	<p>Session 5: Advancing Progress on Updating Generic Oncology Drug Labeling Moderator: Harold L. Moses, Vanderbilt-Ingram Comprehensive Cancer Center Planning Committee Chair</p> <p><u>Objectives:</u></p> <ul style="list-style-type: none"> • Review key messages from the meeting discussions, including identifying potential next steps, promising areas for future action, and opportunities for collaboration to revise outdated labeling for generic oncology drugs. <p>Panelists (each with 5 minutes for opening remarks, followed by open discussion among the meeting participants)</p> <ul style="list-style-type: none"> • Andy Bindman, University of California, San Francisco • S. Gail Eckhardt, The University of Texas at Austin • Susan Halabi, Duke University School of Medicine • R. Donald Harvey, Emory University • Ishmael Jaiyesimi, William Beaumont Hospital • Rebecca Miksad, Flatiron Health • Richard L. Schilsky, American Society of Clinical Oncology • Steven Sun, Janssen Inc. • Josephine M. Torrente, Hyman, Phelps & McNamara, P.C. • Katherine Warren, National Cancer Institute
6:00 pm	Adjourn