



Externally-led Patient-Focused Drug Development Meeting
Cardiac Late Effects in Pediatric Cancer Survivors
September 15, 2022

AGENDA

10:00-10:05 am

Welcome: Steve Wosahla

CEO, Children's Cancer Cause

10:05-10:15 am

Opening Remarks: Greg Reaman, MD

Associate Director for Pediatric Oncology
Oncology Center of Excellence, Office of the Commissioner
Office of Oncologic Diseases, Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

10:15-10:30 am

The Etiology and Pathogenesis of Cardiotoxicity in Cancer Survivors

Smita Bhatia, MD, MPH, FASCO

Director, Institute for Cancer Outcomes and Survivorship
School of Medicine
University of Alabama at Birmingham

10:30-10:40 am

Meeting Participation Overview:

James Valentine, JD, MHS
Moderator

Senior Associate, Hyman Phelps & McNamara, P.C.

10:40-10:45 am

Audience & Remote Demographic Polling:

James Valentine
Moderator

10:45-12:30 (includes Q&A)

Topic 1: Living with Cardiac Late Effects

- ***During this panel presentation, survivors and caregivers will share their personal experiences. This will be followed by a moderated live Zoom discussion panel of survivors and caregivers with Q&A. Audience attendees are invited to share their questions and comments via phone and online submissions.***

12:30-1:00 pm Lunch Break

1:00-1:10 pm (includes Q&A)

Cardiovascular Disease in Childhood Cancer Patients and Survivors: Emerging Paradigms to Consider

Saro Armenian, DO, MPH

Chair, Department of Pediatrics
Director, Division of Outcomes Research
City of Hope Comprehensive Cancer Center

1:10-2:40 pm

Topic 2: Perspective on Current & Future Approaches to Prevention and Treatments for Cardiac Late Effects

- ***This panel presentation will feature survivors and caregivers. It will be followed by a moderated live Zoom discussion panel of survivors and caregivers with Q&A. Attendees are encouraged to submit their questions and comments via phone and online submissions.***

2:40-2:50 pm

Meeting Summary

Larry Bauer, RN, MA

Senior Regulatory Health Expert
Hyman, Phelps & McNamara, P.C.

2:50-3:00 pm

Closing Remarks

Steve Wosahla

CEO, Children's Cancer Cause

3:00

Adjourn



Discussion Questions
Externally-led Patient-Focused Drug Development Conference
Reducing Cardiac Late Effects in Pediatric Cancer Survivors
September 15, 2022

Discussion Questions

We will utilize discussion questions to gather input from survivors and caregivers prior to and during the conference. The information gathered from these questions will be incorporated in the “Voice of the Patient” report and shared with FDA and the public.

Topic 1: *Living with Cardiac Late Effects and Daily Impacts That Matter Most to Patients*

- 1) Of all the symptoms/concerns that you experience because from the heart-related effects from cancer treatment, which 1-3 issues have the most significant impact on your life?
- 2) Are there specific activities that are important to you, but that you cannot do at all or as fully as you would like because of your heart condition? (Example of activities may include participation in sports or social activities.)
 - How do these symptoms and their negative impacts affect daily life on the best days?
On the worst days?
- 3) How has the impact of your heart issues changed over time?
- 4) What worries you most about your condition?
- 5) Quality of life for survivors may change significantly due to cardiac late effects. How do parents empower their children to make their own decisions regarding their health and quality of life as they transition to adulthood?

Topic 2: *Patients' Perspectives on Current Approaches and Future Treatments for Cardiac Late Effects*

- 1) Have you been told about or considered any clinical trials that might help with your cardiac issues? If so, how would you describe your decision whether or not to participate?
- 2) What are you currently doing to help treat the condition or its symptoms? (Examples may include prescription medicines, over-the-counter products, and other therapies or interventions.)
 - How has your treatment regimen changed over time, and why?
- 3) How well does your current treatment regimen treat the most significant symptoms of your cardiac conditions?
 - How well do your therapies address specific activities that are important to your daily life?
 - How well have these treatments worked for you as the condition has changed over time? Which symptoms or issues are not addressed as well?
- 4) What are the most significant downsides to your current treatments for your cardiac late effects, and how do they affect your daily life? (Examples of downsides may include bothersome side effects, interacts with other medications, time devoted to treatment, etc.)
- 5) What specific things would you look for in an ideal treatment for your condition?