



CSRC Think Tank: CV Safety in Oncology Clinical Trials: Providing Clarity for a New Era of Cancer Therapeutics

December 1st, 2021

12:00pm - 2:00pm (EST/New York Time)

Meeting Goal Discuss how cardiovascular events are currently captured in clinical trials of cancer therapies and to consider whether current processes can be improved.

Meeting Moderators **Mark Petrie, MBChB** (Univ. of Glasgow, UK)
James Januzzi, Jr, MD (Harvard Medical)
Marc Bonaca MD, MPH (CPC Clinical Research – University of Colorado)
Ninian Lang MBChB, PhD (Univ. of Glasgow, UK)

12:00 – 12:10 Welcome and Introductions

Jonathan Seltzer, MD, MBA, MA (Executive Director, Cardiac Safety Research Consortium)(10 min)

12:10 – 12:55pm Presentations

Session 1: There is a problem with CV endpoints in oncology trials

- Pros: **Marc Bonaca, MD, MPH** (CPC Clinical Research – University of Colorado) (5 min)
- Cons: **Leslie Lipka, MD, PhD** (Merck & Co, Inc.) (5 min)

Session 2: Perspectives, CV endpoints in oncology trials

- Regulatory Perspective: **Laleh Amiri-Kordestani, MD** (US FDA)(5 min)
- CTCAE Perspective: **Alice Chen, MD** (US NIH)(5 min)
Over- and under-counting of CV events: experience of miscalculation of CV events in oncology trials– **James Januzzi, Jr, MD** (Harvard Medical)(5 min)

Session 3: Problems with Current Methods of Endpoint Capture

- Problems with current methods of endpoint capture: **Ninian Lang, MBChB, PhD** (University of Glasgow, UK)(5 min)

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12:55 – 1:35pm Session 4: Breakout Groups

Breakout A: Event Definitions (40 min)	Breakout B: Adjudication Strategies (40 min)
<p>Moderators:</p> <ul style="list-style-type: none"> ▪ Marc Bonaca MD, MPH (CPC Clinical Research – University of Colorado) ▪ Ninian Lang MBChB, PhD (Univ. of Glasgow, UK) <p>Faculty:</p> <ul style="list-style-type: none"> ▪ Laleh Amiri Kordestani (FDA) ▪ Ana Barac (US) - Cardiology ▪ Sigrid Klaar (EMA) ▪ Alice Chen (US) –Oncology, CTCAE ▪ Shanda Finnigan (US) Oncology, CTCAE ▪ Leslie Lipka (US) – Merck & Co, Inc ▪ Joerg Herrmann (US) - Cardiology ▪ Brian Rini (US) – Oncology ▪ Tom Neilan (US) - Cardiology ▪ Peter van der Meer (Netherlands) - Cardiology ▪ Morten Schou (Denmark) – Cardiology 	<p>Moderators:</p> <ul style="list-style-type: none"> ▪ Mark Petrie, MBChB (Univ. of Glasgow, UK) ▪ James Januzzi, Jr, MD (Harvard Medical) <p>Faculty:</p> <ul style="list-style-type: none"> ▪ Judith Hsia (US) - Cardiology ▪ Javid Moslehi (US) – Cardiology ▪ Jonathan Seltzer (US) - Cardiology ▪ Tom Flaig (US) – Oncology ▪ Rudolf de Boer (Netherlands) - Cardiology ▪ Mike Fradley (US) – Cardiology ▪ Lavanya Kondapalli (US) - Cardiology ▪ Anita Deswal (US) – Cardiology ▪ Rob Jones (UK) - Oncology

1:35 – 1:55pm Session 5: Report Back Breakout Groups

<p>Report for Breakout Session A (10 min)</p> <ul style="list-style-type: none"> ▪ Marc Bonaca MD, MPH (CPC Clinical Research – University of Colorado) ▪ Ninian Lang MBChB, PhD (Univ. of Glasgow, UK)
<p>Report for Breakout Session B (10 min)</p> <ul style="list-style-type: none"> ▪ Mark Petrie, MBChB (Univ. of Glasgow, UK) ▪ James Januzzi, Jr, MD (Harvard Medical)

1:55 – 2:00pm Closing Remarks