

Improving the Evidence Base for Treatment Decision-Making for Older Adults with Cancer: A Virtual Workshop

Workshop Agenda

**Part 2: Monday, January 25, 2021
Eastern Time Zone**

<https://www.nationalacademies.org/event/01-25-2021/improving-the-evidence-base-for-treatment-decision-making-for-older-adults-with-cancer-a-workshop-part-2>

1:00 pm	Welcome from the National Academies and plans for this session (5 min) Monica Bertagnolli, Brigham and Women's Hospital and Dana Farber Cancer Institute
1:05 pm	Session 3: Study designs and policy opportunities to benefit older adults: Approaches to clinical trials designed for registrational intent (85 minutes) <i>Co-Moderators:</i> <i>Eric Rubin, Merck Research Laboratories</i> <i>Monica Bertagnolli, Brigham and Women's Hospital and Dana-Farber Cancer Institute</i> <p>PART I: STUDY DESIGNS</p> <p>Overview of the 2020 FDA Draft Guidance for Industry, Inclusion of Older Adults in Cancer Clinical Trials (15 minutes)</p> <ul style="list-style-type: none"> • Rajeshwari Sridhara, Food and Drug Administration • Harpreet Singh, Food and Drug Administration <p>Examples of study designs/drug development strategies that could help improve the evidence base for older adults</p> <ul style="list-style-type: none"> • EA2186: A Randomized Phase II Study of Gemcitabine and Nab-Paclitaxel Compared with 5 Fluorouracil and Liposomal Irinotecan in Older Patients with Treatment Naïve Metastatic Pancreatic Cancer (GIANT) (10 minutes) <ul style="list-style-type: none"> ○ Efrat Dotan, Fox Chase Cancer Center • Inclusion of Older Adults in the TeseTaxel Development Program (10 minutes) <ul style="list-style-type: none"> ○ Kevin Tang, Odonate Therapeutics • Acute Myeloid Leukemia Trials in Older Adults (10 minutes) <ul style="list-style-type: none"> ○ Richard M. Stone, Dana Farber Cancer Institute

	<ul style="list-style-type: none"> • Capmatinib in <i>MET</i>ex14 NSCLC (10 minutes) <ul style="list-style-type: none"> ○ Monica Giovannini, Novartis • Trial Design in Older Adults: European Perspective (10 minutes) <ul style="list-style-type: none"> ○ Hans Wildiers, University Hospitals Leuven, Belgium <p>Panel discussion (20 minutes)</p>
2:30 pm	Break
2:45 pm	<p>Session 3: Study designs and policy opportunities to benefit older adults: Approaches to clinical trials designed for registrational intent (90 minutes)</p> <p>PART 2: POLICY OPPORTUNITIES</p> <p>Policy opportunities to improve the evidence base How Ethical Principles Apply to this Workshop (10 minutes)</p> <ul style="list-style-type: none"> • Rebecca Pentz, Emory University <p>ASCO Policy Perspective (10 minutes)</p> <ul style="list-style-type: none"> • Richard L. Schilsky, American Society of Clinical Oncology <p>Incentives for Drug Development: Learning from the Experience of Pediatric Drug Development (10 minutes)</p> <ul style="list-style-type: none"> • Aaron Kesselheim, Harvard Medical School <p>Patient Advocacy Perspective on Policy Opportunities (10 minutes)</p> <ul style="list-style-type: none"> • Sue Peschin, Alliance for Aging Research <p>Policy Change to Improve Evidence Development for Older Adults with Cancer: If not us, who? If not now, when?</p> <ul style="list-style-type: none"> • Stuart Lichtman, Memorial Sloan Kettering Cancer Center <p>Panel Discussion (40 minutes)</p>
4:15 pm	Wrap up (15 min)
4:30 pm	Adjourn Day 2