

## Workshop on Product Development for CNS Metastases

Co-Sponsored by the FDA and National Brain Tumor Society  
In Collaboration With  
Accelerate Brain Cancer Cure, American Brain Tumor Association,  
Friends of Cancer Research, Kidney Cancer Research Alliance,  
LUNgevity Foundation, Melanoma Research Alliance  
Metastatic Breast Cancer Alliance,  
Response Assessment in NeuroOncology, and  
Society for NeuroOncology

March 22, 2019  
8:00am to 4:00pm  
FDA White Oak Campus Building 31, Great Room  
NBTS Meeting contact – Sarah O'Connor, Tel: 617.393.2851

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- 8:00 - 8:30AM**      **Registration**
- 8:30 - 8:35AM**      **Opening Remarks:**  
David Arons, National Brain Tumor Society  
Richard Pazdur, US Food and Drug Administration  
Wendy Selig, WSCollaborative
- 8:35 - 8:45AM**      **Presenting the Challenge**  
Joohee Sul, Workshop Co-Chair, US Food and Drug Administration  
Patrick Wen, Workshop Co-Chair, Dana Farber Cancer Institute
- 8:45 - 9:45AM**      **Session I: Defining the Problem of CNS Metastases**  
*Laleh Amiri-Kordestani, Co-Chair, US Food and Drug Administration*  
*Greg Riely, Co-Chair, Memorial Sloan Kettering Cancer Center*
- Discussant Presentation:**
- **Clinical Management of CNS Metastasis, 2019: Current Strategies, Investigations, and Key Challenges**  
Mike Davies, MD Anderson Cancer Center
- Panel:** Laleh Amiri-Kordestani & Greg Riely, Moderators  
Manmeet Ahluwalia, Cleveland Clinic  
Mike Davies, MD Anderson Cancer Center  
Victoria Ebiana, Merck  
Derrick Queen, Patient  
Luke Walker, Seattle Genetics



**9:45 - 11:00AM**

**Session II: Key Issues for Clinical Development for Brain Mets**

*Nancy Lin, Co-Chair, Dana Farber Cancer Institute*

*Chana Weinstock, Co-Chair, US Food and Drug Administration*

**Discussant Presentations:**

- **Identifying Targets for Brain Mets Clinical Studies**  
Priscilla Brastianos, Massachusetts General Hospital
- **Selecting Drug Candidates for Brain Mets**  
Nancy Lin, Dana Farber Cancer Institute
- **Issues with Conducting Brain Mets Clinical Trials**  
Kim Margolin, City of Hope
- **Standardizing Brain Mets Response Assessment**  
Ben Ellingson, University of California, Los Angeles

**Q&A**

**Session Recap:** Chana Weinstock, US Food and Drug Administration

**11:00 - 11:15AM**

**Break**

**11:15 - 2:30PM**

**Session III: Clinical Benefit in Patients with Brain Mets**

*Carey Anders, Co-Chair, Duke University*

*Tatiana Prowell, Co-Chair, US Food and Drug Administration*

**11:15-12:30PM**

**Discussant Presentations:**

- **Regulatory Definition of “Clinical Benefit”**  
Paul Kluetz, US Food and Drug Administration

Designing an Endpoints Framework for CNS Metastases

Panel: Carey Anders, Moderator

Terri Armstrong, National Cancer Institute

Shelly Engfer-Triebebach, Patient

Chitkala Kalidas, Bayer Pharmaceuticals

Ben Levy, Sibley Memorial Hospital

Jeff Wefel, MD Anderson Cancer Center

Arvin Yang, Bristol-Myers Squibb

**Q&A**

**Panel Recap:** Carey Anders, Duke University

**12:30 - 1:00PM**

**Lunch**

**1:00 - 2:30PM**

**Discussant Presentations:**

- **Regulatory Challenges for CNS Metastases**  
Shanthi Marur, US Food and Drug Administration

**Rethinking Trial Designs for Stimulating Product Development for CNS Metastases**

Panel: Tatiana Prowell, Moderator  
Michael Atkins, Georgetown University  
Kim Blackwell, Eli Lilly and Company  
Vinai Gondj, Northwestern Medicine  
Pallavi Mishra-Kalyani, US Food and Drug Administration  
Hussein Tawbi, MD Anderson Cancer Center  
Lynda Weatherby, Patient

**Q&A**

**Panel Recap:** Tatiana Prowell, US Food and Drug Administration

**2:30 - 3:30PM**

**Session IV: Therapy Development: Challenges & Opportunities**

*Joohee Sul, Co-Chair, US Food and Drug Administration*  
*Patrick Wen, Co-Chair, Dana Farber Cancer Institute*

**Defining Strategies to Advance Product Development**

Panel: Joohee Sul & Patrick Wen, Moderators  
Lauren Abrey, Novartis  
Caroline Chung, MD Anderson Cancer Center  
Nancy Lin, Dana Farber Cancer Institute  
Kim Margolin, City of Hope  
Tatiana Prowell, US Food and Drug Administration  
Greg Riely, Memorial Sloan Kettering Cancer Center  
Peggy Zuckerman, Patient

**Q&A**

**3:30 - 3:40PM**

**Overview of the American Brain Tumor Association's Metastatic Brain Tumor Initiative**

Ralph DeVitto, American Brain Tumor Association  
Nicole Willmarth, American Brain Tumor Association

**3:40 - 4:00PM**

**Summary & Next Steps**

David Arons, National Brain Tumor Society  
Joohee Sul, US Food and Drug Administration  
Patrick Wen, Dana Farber Cancer Institute

**4:00PM**

**Adjourn**