

FDA-NBTS Public Workshop

Product Development for Central Nervous System (CNS) Metastases

March 22, 2019 | FDA White Oak Campus

Co-Sponsors



There is a paucity of effective treatments for patients with central nervous system (CNS) metastases. Moreover, there are few clinical trials and a need for more attention to this high unmet medical need. One impediment to product development for CNS metastases is uncertainty on the optimal clinical trial endpoints and study designs for evaluating products. This unique workshop will bring key stakeholders together to evaluate what is needed to advance development of effective products and consider optimal endpoints and clinical trial designs related to this topic.

Agenda

Speaker Biographies

Workshop Committee

Workshop Goals and Objectives

- Provide a forum for open discussion among FDA, clinicians, researchers, patient advocates, and industry in neuro-oncology product development on clinical trials for patients with brain metastases
- Discuss and work toward identifying endpoints for clinical trials for patients with brain metastases
- Educate researchers and product developers about relevant regulatory science and policy issues important to CNS metastasis product development
- Accelerate the development of products for the treatment of CNS metastases
- Facilitate open discussions among major stakeholders in the field of CNS metastases

Presentations

- Opening Remarks and Presenting the Challenges
- Clinical Management of CNS Metastases - Current Treatments and Investigations
- Identification of Targets Brain Metastases Clinical Trials
- Selecting Drug Candidates for the Treatment of Brain Metastases
- Issues in Conducting Clinical Trials for Patients with Brain Metastases
- Standardizing Brains Mets Response Assessment
- The Multiple Facets of Clinical Benefit
- Regulatory Challenges with Trials Seeking CNS Efficacy Claims
- Overview Am Brain Tumor Assoc Metastatic Brain Tumor Initiative
- Summary and Next Steps- Discussion Only
- NBTS Meeting Condensed Transcript with Index
- NBTS Meeting Full Transcript

Webcast Information

- Opening - Session II
- Session II - Lunch
- Post-Lunch Session III
- Session IV - Adjourn

Collaborators

