National Brain Tumor Society

July 24, 2020

Innovating Brain Tumor Clinical Trials: Building on Lessons Learned from the COVID-19 Experience

Roundtable participants include clinicians, researchers, representatives of biopharmaceutical companies, patients, patient advocates, and regulators.

PURPOSE: To understand the barriers and opportunities to advance and improve clinical research in neuro-oncology in a more virtual and/or decentralized environment brought on initially by the COVID-19 pandemic.

Key topics included:

- A review of recent FDA Guidance stemming from the COVID-19 pandemic.
- Considerations, challenges, and opportunities associated with telemedicine for clinical trials from the perspective of a variety of stakeholders.
- A vision for the future of hybrid or decentralized neuro-oncology clinical trials.
- A focus on several specific issues relevant to leveraging the lessons learned from the pandemic to enhance clinical research, including:
    - Electronic consent. o Leveraging the community oncology setting for imaging, lab work, monitoring, drug supply distribution, accreditation, and other trial aspects.
    - Addressing disparities (including lack of access to technology). o Accessing issues including licensing and reimbursement.

Major conclusions included:

- COVID-19 has disrupted the “traditional” approach to brain tumor clinical trials, leading to enhanced regulatory and sponsor flexibility and the opportunity for innovation.
- COVID-19 has exposed new opportunities and challenges for telemedicine, including in the areas of access, reimbursement, and disparities/equity.
- The brain tumor community can focus on advancing hybrid/decentralized trials by:
    - Documenting/publishing the feasibility of conducting virtual neurologic exams.
    - Deconstructing trial elements that can be done remotely/in the community. o

Promoting adoption of the Brain Tumor Imaging Protocol (BTIP). o Defining the expertise/capabilities needed for a brain tumor clinical trial partner.