Brain Tumor Trials COLLABORATIVE BTTC annual meeting

The Brain Tumor Trials Collaborative held a productive meeting on March 31, 2017 at the National Institutes of Health (NIH). The BTTC is a network with the expertise and the desire to participate in state-of-the-art clinical trials investigating new treatments for malignant brain tumors. At the meeting, which included neuro-oncologists from 26 hospitals across the United States, BTTC members shared information about current and upcoming clinical trials.

A summary of key findings and an overview of each discussion is provided below.

Dr. Gilbert, the Principal Investigator for the BTTC and the Chief of the Neuro-Oncology Branch at the NIH, welcomed attendees. This was the largest BTTC meeting to date, which included 89 attendees and an exciting new breakout session for research staff. This endeavor would not be possible without the Center for Cancer Research (CCR). The CCR at the National Cancer Institute serves as the lead institution and coordinating center for the BTTC.

Dr. William Dahut, Clinical Director of the Center for Cancer Research (CCR), shared an overview of the National Cancer Institute's CCR at the NIH. This organization is a model for cancer research and provides the environment and infrastructure to support innovative, high-impact research that might not be possible anywhere else. Their innovative design allows them to reach patients globally and foster investigator-driven research with an emphasis on emerging research areas, rare cancers and underserved patient populations. The NCI CCR has 235 principal investigators and the clinical research is performed in the NIH Clinical Center, the largest clinical research hospital in the world.

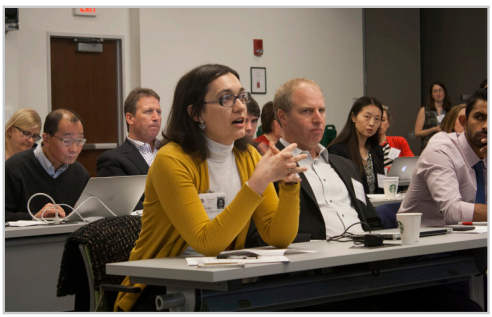
Caryn Steakley, Deputy Clinical Director of the CCR, commends the dedication of the BTTC staff (Katie, Miranda and Jennifer) and emphasized the NIH's Clinical Center and CCR's commitment to providing oversight and support to the BTTC.

Kristin Odom, BTTC Communications Coordinator, gave an update on the external and internal BTTC websites. The current external website will be moved within the Neuro-Oncology Branch's website at the NIH but will still contain these prominent elements: about BTTC, clinical trials, members and institutions. The internal website will be completed soon and shared with institutions. This tool was created to allow one central location for important documents and information for BTTC centers and their research staff.

Michael Pollack, Supervisory Technology Transfer Specialist at the NCI, oversees the BTTC agreements. He discussed the status of current and legacy BTTC trial agreements. Trial information is available online at bttconline.org.

Katie Blackburn, BTTC Project Manager, shared information on the invoicing process.

Dr. Mark Gilbert and Dr. Terri Armstrong, Senior Investigator for the Patient Outcomes Program at the Neuro-Oncology Branch at the NIH, discussed the Rare Tumors Outcomes Program for the Central Nervous System (RTOP-CNS). The Neuro-Oncology Branch of the NCI has already created a rare CNS cancer initiative. With the patient accrual a challenge, they are proposing this rare cancer initiative as part of the Beau Biden Moonshot Program. In turn, they hope to improve the understanding and provide better therapies to patients with rare CNS tumors.



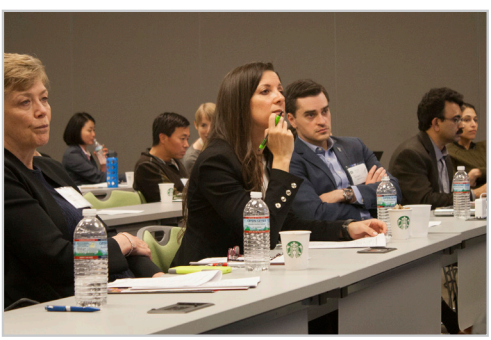
They will use the CERN Foundation model: integrate basic, translational, clinical and patient outcomes research, adult and pediatric collaboration and reach accrual by using awareness tactics such as social media networks. Patients who enroll in the RTOP-CNS registry will be clinically assessed, their tumor tissue analyzed and banked for future studies, blood samples taken and stored and connected to clinical trials if needed. They will utilize the BTTC infrastructure by implementing hypothesis-based clinical trials through the network. There is interest from the group to move forward with this initiative.

Miranda Brown, BTTC Research Nurse, and Jennifer Reyes, BTTC Protocol Coordinator, organized several breakout sessions which were attended by study coordinators from BTTC sites. Miranda led the morning breakout session which focused on key reportable events (adverse events, protocol deviations, unanticipated problems) and changes to reporting requirements and timeframes now that the BTTC Coordinating Center has transitioned from MD Anderson to NCI CCR. In the afternoon, Jennifer provided an overview of maintaining regulatory files for BTTC protocols and the new process for BTTC site activation. Study coordinators discussed the implications of these changes as well as their preferences and best practices as they launch new BTTC trials at their site later this year. Dr. Armstrong introduced her patient outcomes research program and her research team, Alvina Acquaye, Elizabeth Vera and Dr. Tito Mendoza. Alvina and Elizabeth co-presented an informative session about the MDASI-BT survey, the research findings from this patient-reported data and new tools to collect survey data electronically. Dr. Mendoza, Associate Professor at MD Anderson, who was part of the development team for the MDASI-BT, provided historical perspective on the surveys and how best to collect this data. This session generated a lot of thoughtful questions from participants about best practices for administrating the MDASI-BT survey to patients. As a result, BTTC sites can anticipate more study-specific resources to support their work in the near future.

Dr. Emanuela Molinari of the Queen Elizabeth University Hospital in Glasgow, Scotland, emphasized the importance of international collaborations. “By combining talents and resources, we achieve additional value and benefits,” says Dr. Molinari. This collaboration will help overcome the recruitment barrier.

Dr. Patricia Steeg, Deputy Chief of the Women’s Malignancies Branch at the CCR, talked about pregnancy associated with breast cancer patients and how pregnancy can increase aggressiveness. In breast cancer, brain cancer metastasis continues to increase and chemotherapy proves to be ineffective because of the blood-brain barrier. She highlighted the importance of evaluating the risk of pregnancy in glioma patients utilizing information collected from Dr. Schlomit Yust-Katz’s research. There is interest from the group to move forward on this project, including tissue collection and analysis.

Matt Anthony, Founder and Chairman of the Head for the Cure Foundation, gave an update on Head for the Cure (HFTC): headforthecure.org. HFTC has provided funding to the NCI in support of BTTC activities. He also revealed the newly-developed Brains for the Cure (BFTC) site: brainsforthecure.org. The BFTC site is designed to meet patients wherever they are in their journey and present them with the knowledge needed to help guide them through their care. Patients are directed to doctors who are committed to treating brain tumors – the BTTC.



Dr. Mark Gilbert shared information on the different types of immunotherapy that are being tested for malignant gliomas. He announced the BTTC will be launching a new cutting-edge protocol – the GBM Pembro HSPPC study. This is the very first study to evaluate the combination of a personalized cancer vaccine made from the patient’s own tumor tissue (HSPPC-96) and a PD-1 inhibitor (Pembrolizumab) in newly diagnosed glioblastoma patients. The group talked about trial logistics such as the consent process. This trial is launching at the NIH first and will open soon after at other participating BTTC sites. A total of 108 patients will be enrolled, and the MDASI survey will be completed for each participant to determine if this treatment adds to symptom burden. “This study will take BTTC to the next level. We will now be able to do correlative science,” shares Dr. Gilbert.

Afternoon sessions continued with protocol concept ideas proposed to the group. The BTTC showed enthusiasm for the following concepts and plans are underway to move forward:

- Measurement of 2-hydroxyglutarate Enantiomer Levels for Use as a Biomarker in Management of Patients with IDH Mutant Gliomas

  Dr. Morris Groves of Texas Oncology

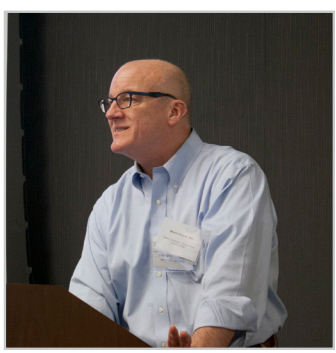
  Note: This protocol concept will be developed into a two-site collaboration between Texas Oncology and the NIH. It will not be initiated across the BTTC network at this time.

- TGO2 Phase II Study

  Dr. Jing Wu of the Neuro-Oncology Branch at the CCR, NCI

- Factorial Design Study in Newly Diagnosed GBM, Stable Post ChemoXRT: Using TMZ + Tumor Treating Fields (TTF) +/- Metformin, Mefluoquine and Valganciclovir

  Dr. Morris Groves of Texas Oncology



Members left the annual meeting recharged and determined to advance treatments for patients with brain tumors.