Beat Childhood Cancer
RESEARCH CONSORTIUM

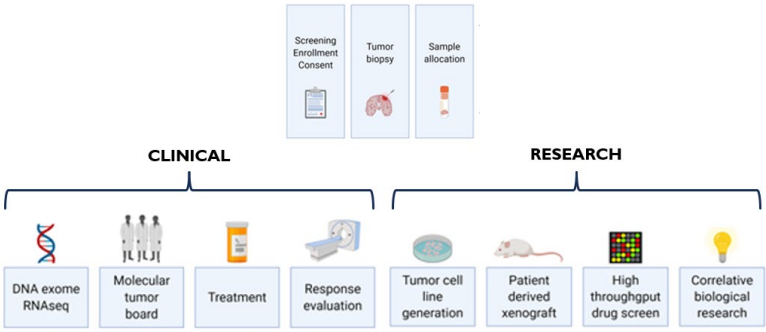
BCC-BIO-001
research.beatcc.org

BCC-BIO-001: Specimen Banking with Clinical and Genomic Data Registry with the establishment of Tumor Models for Pediatric Cancers

Clinical Trials Identifier: NCT04715178

The BCC-BIO-001 acts as the research arm of our Precision Medicine Program. This is an observational data registry study, also referred to as the "IN:Formation Project" of pediatric cancer patients at participating Beat Childhood Cancer (BCC) Research Consortium sites involving specimen banking and data collection.

We hypothesize that large gene panels, sequencing (DNA/RNA), and epigenetics of tumors can identify molecular aberrations in tumors that can be leveraged to offer more effective treatment. There are no age restrictions on this study and all patients with suspected or confirmed pediatric tumors are eligible to enroll. We combine ALL clinical data, genomic data, outcome data, and lab research data into a database usable by all BCC collaborators to study and analyze this data together.



Primary Objective:

- Create a data registry of clinical and molecular/genomic data from cancer patients who have undergone biopsy or surgical resection for clinical care to better understand the relationship between genomic and molecular information and clinical outcomes.
- Define genomic landscape of pediatric cancers through the determination of the number and types of genomic alterations within tumor types/ subtypes, across tumor types, and tumor evolution over time.
- Evaluate the rate of actionable genomic alternations resulting in associated targeted therapies relative to all actionable genomic alterations.
- Evaluate the correlation of baseline genomic alterations with clinical outcome.
- Identify biomarkers that predict risk of adverse outcomes that occur following pediatric cancer therapy.

Secondary Objectives:

- Bank additional specimens available for future research projects
- Create cell line xenograft, and organoid models of pediatric cancers for future research.
- Identify biomarkers that predict risks of disease states in controls.

ENROLLMENT

Scan this QR code with your phone's camera app to learn about inclusion/ exclusion criteria for enrollment.

Study Chair

Giselle Saulnier Sholler, MD, MSc
Penn State University
Hershey, Pennsylvania

Contact Info

BCC: BCCEnroll@pennstatehealth.psu.edu
Study Chair: gsaulniersholler@pennstatehealth.psu.edu

"We are excited to develop a sequencing dashboard to analyze this genomic and clinical data collected from patients enrolled on study to find effective therapies and collaboratively share data while maintaining patient privacy. The samples collected from these patients are also essential for preclinical studies and drug development that can translate to future clinical trials for patient access."

There are 17 Beat Childhood Cancer Research Consortium Sites currently open to enrollment.

PennState College of Medicine

Penn State College of Medicine is home to the Beat Childhood Cancer Research Consortium, a consortium of more than 50 hospitals that offer a worldwide network of childhood cancer clinical trials. Learn more at **research.beatcc.org**.

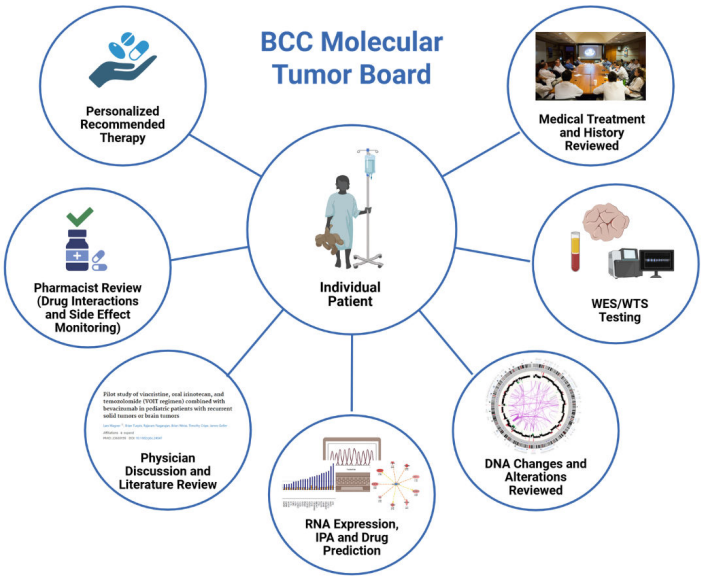
Beat Childhood Cancer
RESEARCH CONSORTIUM

Precision Medicine Program

No two tumors are the same. In fact, they vary greatly among patients with the same diagnosis. Many times, tumors may share characteristics with other types of cancer – cancers that may have different targets and different treatments.

In 2021, the Beat Childhood Cancer Research Consortium (BCC) launched an international Molecular Tumor Board (MTB) for therapeutic recommendations based on Whole Exome/Whole Transcriptome (WES/WTS) genomic sequencing for pediatric solid tumors. This program was launched based on NCT021627321 which showed 65% patient benefit with acceptable safety profile. The MTB is a dedicated group of medical experts aimed to provide personalized options based on unique genetic characteristics of each patient's tumor. The majority of patients presented have extensive histories of high-risk, relapsed, and/or refractory cancers.

If patients are presented at a clinical BCC MTB, their treatment data and response is captured through the BCC-BIO-001 study to further evaluate patient benefit.



How the BCC MTB is different:

- WES/WTS is performed by Caris Life Sciences as a clinical test. The genomic data is analyzed through capturing mutations and structural events across the genome including translocations/ inversions, copy number changes and tumor mutation burden.
- Gene expression in patients' tumor cells are compared to references of other cancers (CRC score) and normal whole-body samples (NRZ score) to generate relative expression scores.
- Ingenuity Pathway Analysis (IPA) software is used to identify significant pathways, regulators or networks.
- Literature review is performed by clinical reviewers and pharmacists to ensure safe combinations of personalized treatment recommendations.
- Each patient presented is enrolled on BCC-BIO-001 trial (NCT04715178) to collect biological correlates, follow clinical outcomes, and create a data repository for future research.

Scan this QR code with your phone's camera app for the clinical trial (NCT021627321) publication that led to the creation of this clinical MTB program.

Contact Info

BCC: BCCEnroll@pennstatehealth.psu.edu

Frequently Asked Questions

Q: I had sequencing already done on my tumor, how is this different?
A: Most tumor sequencing only looks at DNA from a smaller subset of genes pulled from adult cancers. The WES/WTS testing through the IN:Formation Project looks at DNA and RNA in 20,000+ genes and the medical team will provide a deeper dive into options than a typical commercial report.

Q: What samples are needed for this DNA/RNA testing?
A: We will need Tumor (available from previous or most recent biopsy), associated Pathology Reports and Separate Consents, and if interested in liquid sequencing may include blood sample(s). A patient can submit a sample for genomic sequencing at any point during their treatment (For example: diagnosis, surgery in real time, or from a past surgery where tissue is available.)

Q: Do I need to travel to a BCC Site to participate?
A: Yes, you would need to travel to a BCC site to enroll on BCC-BIO-001 as that is how we receive the raw data for analysis. The amount of ongoing travel will depend on your home care hospital's ability and willingness to deliver recommended therapy. Each patient's care plan is individualized regardless of location.

Q: Are there any added risks with combining multiple agents that are not approved for pediatric patients?
A: All of the drugs recommended by the molecular tumor board are FDA approved medications. A licensed pharmacist participates in the molecular tumor board to provide insight on drug interactions and monitoring assessments needed for patient information and safety.