

## Cellular Therapies

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**STANDARDIZED TRANSCRIPTIONAL PROFILING FOR OPTIMIZING CELLULAR THERAPIES: A MULTI-CENTER PICI-NANOSTRING COLLABORATION**

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**Background** The field of cellular therapy remains one of the most promising areas for the development of new cancer treatments. To further these improvements, it is imperative to broadly understand cell therapy products at the molecular level and to identify factors that contribute to their efficacy. NanoString and the Parker Institute for Cancer Immunotherapy (PICI) have established a ground-breaking collaboration to characterize up to 1,000 apheresis and cellular therapy infusion products with the primary goal to dissect and study molecular pathways that correlate with optimal cellular therapies.

**Methods** Using a large and diverse sample cohort collected from eight PICI network Cell Therapy Centers the team will aim to study gene expression profiles (GEP) that correlate with optimal apheresis and downstream cellular products, identifying biomarkers and signatures for clinical response or toxicity and further explore unique cancer-specific and shared characteristics that make an optimal and effective chimeric antigen receptor (CAR) T cell. As shown here, this first of its kind study will include samples that target dozens of different antigens covering both primary and metastatic hematological and solid tumors. Samples will be characterized using the standardized set of genes included in the nCounter CAR-T Characterization Panel and will measure essential components of CAR-T including: metabolic fitness, phenotype, TCR diversity, toxicity, activation, persistence, exhaustion and cell typing along with individual transgene expression.

**Results** Presented here are initial questions that will be asked as part of this study. Meta-analysis will be performed as an aggregated set of data and individual site-specific analysis. Data will further be analyzed across individual cancer types, target types, outcome and manufacturing conditions as examples. We anticipate this information will prove useful across many aspects of the development, manufacturing and clinical applications for cellular therapies and further hypothesize that these findings will promote the understanding of pathways affecting safety and efficacy that may help optimize the therapy.

**Conclusions** The project is anticipated to begin Fall of 2021 with work continuing in phases through 2022 with periodic data reports to be shared through scientific conferences. All data and findings will be made publicly available to the scientific community through PICI's Cancer Data and Evidence Library analysis platform (CANDEL).

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