

Initiation and Innovations of Cellular Therapy Research in Multicenter Investigator Initiated Trials

A. Bauchle, J. Kline

Indiana University Melvin and Bren Simon Comprehensive Cancer Center

1. Background

Cellular therapy trials are new and extremely complex. These novel trials have proven both scientifically thrilling and potentially lifesaving for those suffering from Cancer. As we are in the early stages of exploring the risks and benefits of these trials, we can all recognize their extraordinary amount of untapped potential. At Indiana University (IU), we began rapidly expanding this initiative in 2021 with the expansion of our infrastructure and development of cellular therapy experts and supportive teams, including the ability to manufacture our own products. IU prioritizes Investigator Initiated trials (IITs) and has fostered a robust IIT program including a very knowledgeable Protocol Development Team and an experienced Multicenter Program. As our Cellular Therapy program has become a highlight in IU's Cancer Center portfolio, we have opened 3 Multisite Cell Therapy IITs with eight participating sites and have a pipeline of studies currently in varying stages of development.

2. Goals

Our goal at IU is to embark on scientific discoveries and expand access to lifesaving treatments. Cellular therapy has shown great promise, and the support of this program is critical to working toward a cure for cancer. It is important to develop trials and collect data to better understand toxicities, long term effects and allow for the expansion and inclusion of all subjects and disease groups. Developing Multisite IITs allows IU to strengthen its goals of expanding access both inclusively and geographically. The development of Multisite IITs allows for both flexibility and expansion of research initiatives contributing to the overall knowledge and scientific discoveries for all centers and, most importantly, expanding access to subjects and lifesaving treatments.

3. Solutions and Methods

In 2021, the Brown Center for Immunotherapy was established. The Brown Center for Immunotherapy and its staff brought a wealth of knowledge and drive to grow the program to reach as many patients as possible by conducting Multicenter IITs. One of the benefits of Multisite IITs is that our protocols are designed to ensure access to as many subjects as possible while avoiding limiting exclusion factors and allowing for extended follow-up for safety. Another benefit of conducting Multisite research is the natural promotion of collaboration between institutions.

4. Outcomes

At Indiana University, we have successfully opened 3 Multisite Cellular therapy IITs in the last 3 years. To date we have enrolled 15 subjects across these trials. We currently have 3 outside sites open, with another 5 in start-up. Collaborating with other institutions has allowed a diverse portfolio of accruals and data to be analyzed while continuing to expand our knowledge.

5. Lessons Learned and Future Directions

As we continue to fine tune this innovative program, we recognize barriers to both sites conducting this research and participants. These include high costs as well as a lack of trials and opportunities surrounding recruitment. Moving forward, grants and robust investments from the institutions will help with costs and allow the addition of more trials. Expanding into multisite research will allow greater

Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

each of these trials geographically, and education of Investigators and staff alike will hopefully encourage recruitment in this novel and lifesaving field.