

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


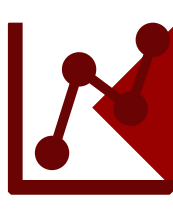

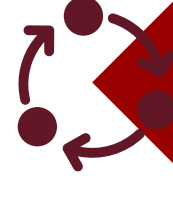
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Background

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.

Goals

-  Embark on scientific discoveries and expand access to life saving treatment
-  Develop trials and collect data to better understand toxicities and long-term effects
-  Expand access both with inclusivity and geographically
-  Expand research initiatives contributing to overall knowledge and scientific discoveries

Solutions & Methods

In 2016, the IU Brown Center for Immunotherapy was established. By 2021, the Brown Center for Immunotherapy and its staff have 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.

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.

Lessons Learned and Future Directions

Barriers include high costs as well as a lack of trials available to patients 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 reach of these trials geographically, and education of Investigators and staff alike will hopefully encourage recruitment in this novel and lifesaving field.

