



Case Highlight:

Enabling Cellular Therapy Manufacturing

Building a Dedicated Donor Pool

Executive Summary

Versiti, a leader in biomaterials supply and clinical trial services, partnered with a biotech company in support of a phase I clinical trial for the development of gamma delta T-cell therapies. This sponsor's previous supplier was challenged with consistency and availability of leukapheresis products in support of their study, putting the trial at risk. To secure a dependable supply of starting materials, this partner engaged Versiti to identify and obtain a dedicated donor pool to support their trials and eventual product commercialization.

Consultative Approach

Versiti held multi-disciplinary meetings with the client to understand the customer's current experience, challenges, and how Versiti could best design a solution. Through these conversations, it was determined that:

- The existing screening process was not attracting recallable donors; and
- Their experience with their current supplier did not match pre-established project expectations.

Through these conversations, Versiti established a specialized donor selection process with specific criteria and characterization to meet the project's scope.

A Customized Donor Recruitment Solution

The Versiti team built customized donor recruitment campaign strategies to target a specific ethnic demographic and identify dedicated IRB-consented donors for this project. The screening process focused on:

- CMV status,
- Ethnicity and age, and
- Prior confirmation for negative infectious disease markers required by 21 CFR 1271.

Versiti also expanded our in-house testing panels with additional infectious disease markers to support customer IND requirements for human herpes virus (HHV)-6, -7, -8, hepatitis A, Parvovirus B19, and other markers as requested.

Product Collection and Dedicated Donor Pool Protection

Following the identification of prospective donors, Versiti collected half-unit RUO leukapheresis products (leukopaks) at our FDA-registered leukapheresis center, to expand and qualify assays to determine the best possible donor match for manufacturing needs. After identification of the most suitable donors, the donor pool was protected from future recruitment and reserved for this customer's project to ensure recallability to support future manufacturing runs.

By the Numbers

Consultative Approach -> Contributor Screening -> Contributor Selection

37 Identified through marketing and recruitment	37
19 Screened for suitability and project criteria	19
2 Dedicated donors identified	2

Impact and Outcomes

By securing a dedicated donor pool, Versiti stabilized the customer's manufacturing supply chain and ensured access to high-quality starting materials. In addition, due to Versiti's regulatory and quality expertise, our ability to conform to EU regulations enables the customer to expand their trials in other markets internationally to meet demand as the therapeutic development progresses.

Versiti consults with partners to deeply understand their needs and identify custom solutions to meet each unique project's demands.

About Versiti

Versiti's expertise in donor recruitment, apheresis collections and donor management ensure the availability and production of high-quality, well-characterized cellular starting materials and human blood products for research. Our nimble approach and flexibility ensure starting materials are customized to meet your unique study or project needs.

Versiti looks forward to partnering with you to support your research, development and commercial manufacturing programs. To learn more about Versiti's cellular therapy capabilities and starting biomaterial products, visit versiticlinicaltrials.org, or contact us at biomaterials@versiti.org.



For more information about our services, contact: Clinicaltrials@versiti.org