Filling the Leukopak Gap

A Blood Center's Unique Position Enabling Cellular Therapy Research

Executive Summary

Navigating the constantly evolving cellular therapy and clinical research landscape can be an ongoing challenge for researchers and therapeutic developers. With significant market growth projected in the next 4-6 years, anticipated limiting factors, including the high cost of leukapheresis and stringent donor recruitment criteria for leukopak collections, pose a unique set of challenges for companies without significant experience in this space. Biomaterial supplier diversity will be essential to meeting market demands, and providers like blood centers with expertise in developing and managing an engaged and diverse donor base will be integral to supporting studies in the forecast period.

Anticipated Market Bottlenecks

The global cell therapy market is projected to expand at a compound annual growth rate (CAGR) of 14.5% from 2021 through 2028. This growth is attributed to a rising number of clinical studies for cell-based therapies.[1] An integral component in the development of cellular therapies is the provision of starting biomaterials from human donors for research. Leukopaks are an industry-standard starting material valued for their high concentration of T cells, monocytes, B cells, NK cells and granulocytes. These components are integral in cell therapy research and the development of new therapeutics, as these cells provide useful insight into various mechanisms of the immune system.

The global leukapheresis products market sub-segment is itself expected to grow at a CAGR of 8.4% to $91 million per year by 2026.[2] However, potential limiting factors to this anticipated growth in the market are the numerous regulatory and logistics considerations involved with leukapheresis, including the high cost of leukapheresis and cellular therapies, stringent donor recruitment criteria, and long procedural time for leukapheresis.[2]

In light of this anticipated growth and the essential nature of these complex and highly regulated leukopak products, biomaterial supplier diversity will be essential to meet market demands tied to supply chain bottlenecks in the next several years. As demand for leukopak products increases with this anticipated growth, researchers may need to identify secondary suppliers to continue conducting research without supply chain-related delays.

A Blood Center's Unique Position

The leukapheresis procedure is a modified apheresis (dual needle) collection involving the removal of a healthy contributor's whole blood and separation of white blood cells. Inherent in the procedure are increased risks to the donor related to the extended procedure duration, larger blood volume processed, and, in the case of mobilized donations, inclusion of the G-CSF administration process.[3]

Identifying, recruiting, screening and managing white blood cell contributors is a multi-faceted process that is integral to collecting Leukopak products to satisfy the needs of researchers around the world. An organization with demonstrated experience in

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blood product collection and donor management is an ideal partner in mitigating these challenges and the increased risks that come with leukapheresis. Maintaining a healthy, engaged contributor bank with diverse characteristics, in tandem with navigating the highly regulated Leukopak collection environment, requires an organization with deep expertise in transfusion medicine and blood collection.

Due to this confluence of factors, blood centers are uniquely positioned to provide leukopaks for clinical research. The provision of biomaterials is an undeniably critical component for clinical research. Access to a diverse, well-characterized, recallable contributor base enables research to proceed without undue delay related to recruiting, identifying, screening and drawing new contributors. In a process with innumerable variables, a contributor bank operating under an IRB-approved protocol helps mitigate risk in early-stage trials by adhering to stringent contributor recruitment criteria, ensuring a safe procedure for the donor, and timely provision of products for researchers.

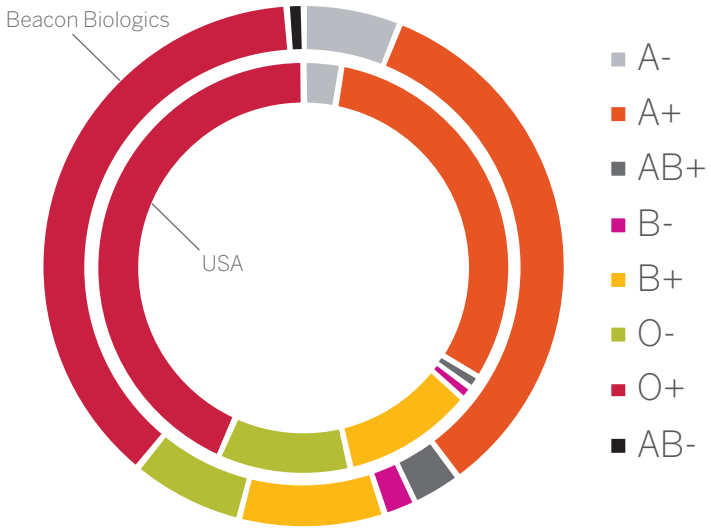
As a leading blood provider with 75 years of experience serving local communities through the provision of blood products for transfusion, Versiti performs over 115,000 apheresis procedures annually. In 2020, Versiti added the provision of leukopak products to support emerging cellular therapy research to its comprehensive suite of services. Our established leukopak contributor bank operates under an IRB-governed protocol, ensuring both the contributor experience and resulting blood products meet strict quality and regulatory standards. To ensure product quality, Versiti provides a certificate of analysis and independent review with every product, ensuring that each collected leukopak meets strict quality standards and study requirements.

Benefits of Contributor Bank Characterization

In addition to seasoned donor recruitment and management capabilities, Versiti further offers in-house characterization and infectious disease testing of our leukopak products. With our foundation as regional blood centers, HLA typing for bone marrow transplant, routine ABO characterization, and FDA-mandated infectious disease screening are cornerstones of Versiti's services. These vertically integrated services remove logistical considerations tied to shipping and testing products that other biomaterial providers must outsource to other laboratories.

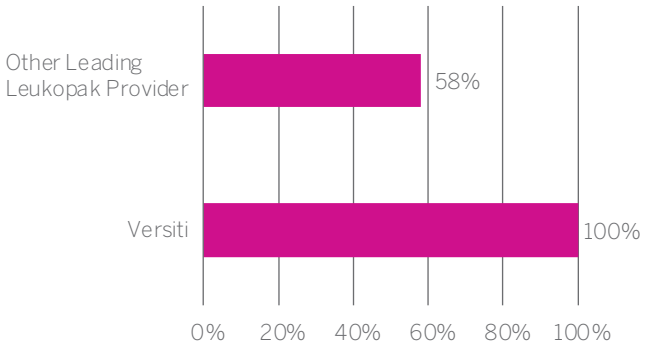
All of Versiti's leukopak products receive high-resolution HLA by NGS characterization, ABO typing and infectious disease testing, including CMV, hepatitis C, hepatitis B, HIV and West Nile virus.

ABO Rh Breakdown: Beacon Biologics vs. USA



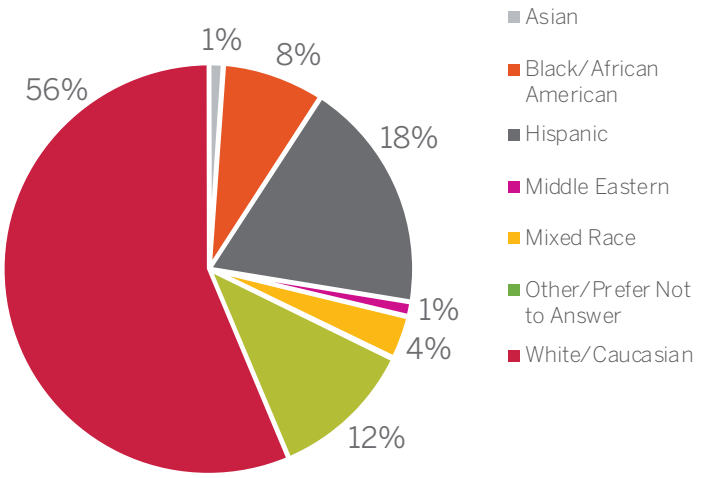
Blood type breakdown of Beacon Biologics' contributor bank as compared to U.S. population data[4]

HLA-Typed Donor Frequency

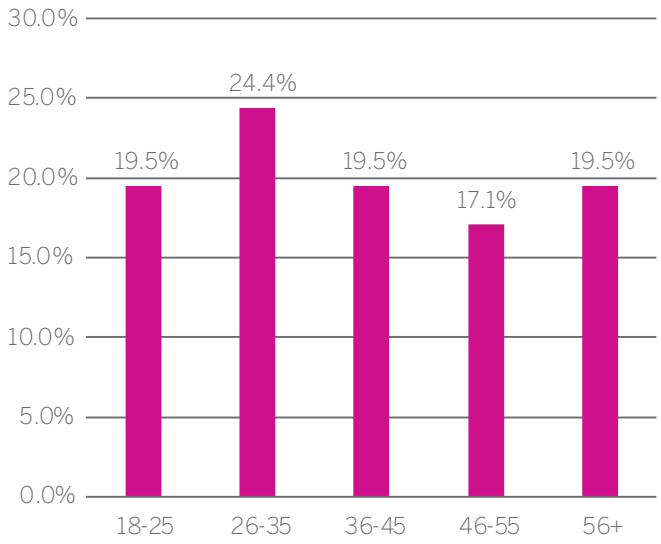


Versiti performs HLA typing on 100% of white cell donors, as compared to 58% of donors from another leading leukopak provider.

Race/Ethnicity Breakdown



Contributor Age Breakdown



Additional infectious disease testing or characterized leukopaks may be available upon request to meet specific study requirements. High-level characterization of the donor bank helps to ensure diversity in white blood cell contributors, and the ABO Rh breakdown of our contributor bank largely reflects the national population, ensuring a wide array of contributors are available to meet the need of any given research study. Versiti's contributor bank also hosts a broad array of races, ethnicities and ages.

Demand for HLA-typed cells can be attributed to market growth in preclinical studies related to personalized cellular therapies and immunotherapy development.[5,6] Versiti has a 30-year history of performing HLA typing and supports more than 800 bone marrow transplants annually through our transplant services. Through this infrastructure, we perform HLA characterization by next generation sequencing (NGS) on 100% of our white cell donors. Typing includes HLA class I - A, B, C and class II - DRB1/3/4/5, DQA1, DQB1, DPA1 and DPB1. With this combination of capabilities and streamlined services, Versiti is an ideal partner for starting biomaterial services.

Top 10 Most Common Class 1-A	% of Bank	Top 10 Most Common Class 1 - B	% of Bank	Top 10 Most Common Class 1 - C	% of Bank	Top 10 Most Common Class II - DRB1	% of Bank
02:01	26%	07:02	9%	04:01	13%	03:01	9%
01:01	12%	08:01	8%	07:02	13%	15:01	8%
11:01	9%	15:01	7%	07:01	12%	07:01	8%
24:02	9%	35:01	6%	03:04	10%	13:01	7%
03:01	8%	40:01	6%	05:01	8%	11:01	6%
26:01	5%	44:02	6%	06:02	6%	04:01	5%
32:01	4%	44:03	6%	01:02	5%	14:01	5%
23:01	3%	51:01	5%	16:01	5%	01:01	4%
31:01	3%	18:01	5%	03:03	5%	13:02	4%
68:02	3%	14:02	3%	12:03	5%	11:04	4%

Snapshot of the frequency of the top 10 HLA types for class I - A, B, C and class II – DRB1 in the Beacon Biologics contributor bank.

Conclusion

There are many elements to consider in the process of collecting leukopak for the cellular therapy market. Significant quality and regulatory considerations for the collection and sale of leukopak are designed to ensure a compliant contributor base and collection procedure, and ultimately yield high-quality white cell products. Maintaining a diverse contributor base enables studies to categorize and access specific product types to meet their unique needs. When executed seamlessly, a well-characterized, diverse and engaged bank is the greatest asset in provision of biomaterials for clinical research. Versiti's 75+ year history of blood product collection and donor management uniquely positions us to help bridge this emerging gap in the cell therapies market – ultimately enabling the translation of research into lifesaving cellular therapy solutions and treatments.

References:

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