

Customized Starting Materials for Manufacturing: Client Highlight

Versiti supports a client with a therapeutic in phase 1 clinical trials sought to identify and maintain a unique contributor pool eligible to support future manufacturing and commercialization. Through a collaborative partnership, Versiti's vertically integrated services helped identify and incubate that contributor network for future collections.

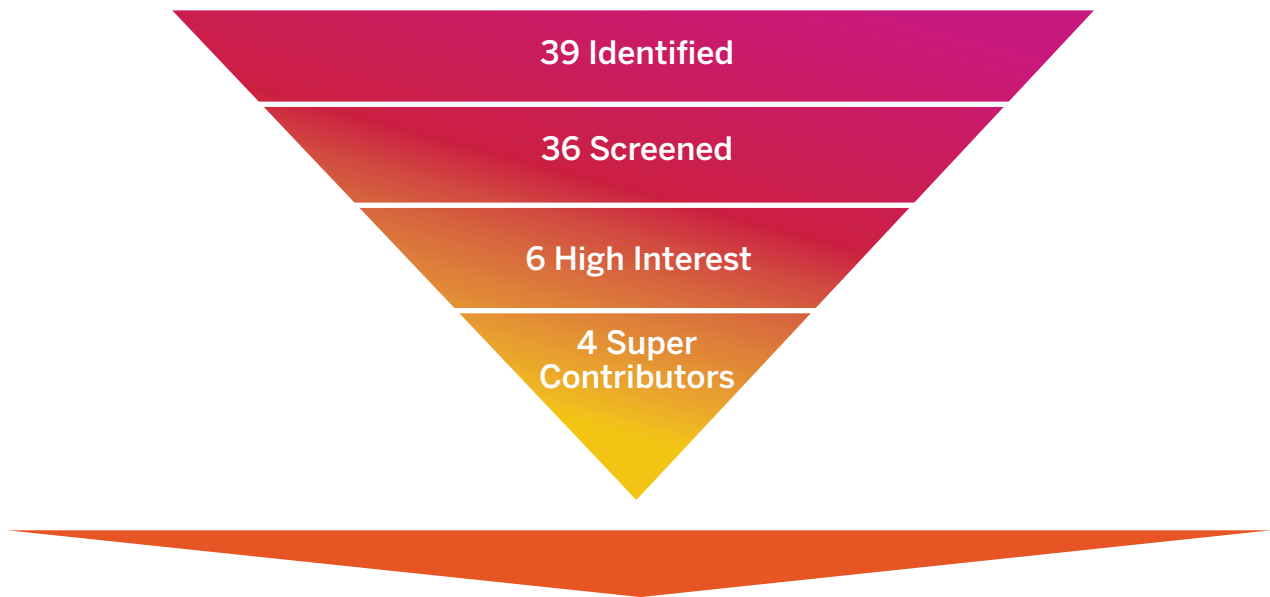


Through our consultative approach, we held multi-disciplinary meetings to understand the contributor profile required in order to develop a custom process for our client. We built a long-term-use donor base of selected contributors characterized by CMV status and genotype and phenotype highly specific to the client's project. Our client received dedicated project management services to support onboarding and project timelines, which were maintained throughout all phases of their project.

Using a customized donor screening approach based on our client's needs, we quickly queried our existing, highly characterized contributor base for matches. We interviewed the selected contributors under an IRB-approved protocol to determine their willingness to participate in our client's project long-term. Our team drew whole blood tubes to perform PBMC isolations, which were frozen and sent to a third-party lab for testing. Versiti saved time and effort for our client through in-house lab services and logistics solutions by isolating and freezing the PBMCs on-site rather than contracting another lab to perform the service.

Based on the project scope and required donation frequency, we identified final contributors to support our client's project. Contributors were recalled as needed for expansion studies. To date, Versiti identified 39 contributors of which 36 were screened. This led to six contributors identified as high interest, four of which were identified as "super contributors." These contributors matched client genotype and phenotype donor characterization profiles and were tested in expanded testing to produce quality product in a trial manufacturing run. Versiti's expertise in donor management was used to segment and incubate the contributor pool for the client.

Contributor Selection



For this client, Versiti collected both RUO-grade and GTP leukopak products, depending upon specific need. Our process included expanded infectious disease testing panels at our FDA-registered collection center and in-house flow cytometry for quantification of collected GTP leukopak products. We customized our collection and testing schedule to align with the client's manufacturing schedule. Versiti optimized logistics by creating custom labels, certificates of authorization, and logistics processes to meet client need and align to their unique project protocol.

Versiti's consultative approach and partnership with the client established a process for a recallable and usable contributor bank committed to the project, providing quality starting materials for manufacturing.

About Versiti

Versiti's expertise in donor recruitment, apheresis collections and donor management ensures the availability and production of the highest-quality, most well-characterized 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/or commercial manufacturing processes. To learn more, contact us at biomaterials@versiti.org.

