DISCOVERY
LIFE SCIENCES

Science at your Service™

AllCells® Donor Management Case Studies

DISCOVERY LIFE SCIENCES

AllCells®

High Quality RUO and GMP Human Primary Cells

Serving the complete cell and gene therapy continuum

RUO/GMP Mobilized and Non-Mobilized Leukopaks, Isolated Cells, Thousands of Recallable/ HLA-Typed Donors

Genomics

WES, RNA-Seq, Single-Cell, Targeted-Seq, Pan-Cancer, WGS, HiFi LRS, Epigenomics, qPCR

Proteomics

Targeted & Untargeted LC-MS/MS, Luminex, Olink (Explore HT, Explore, Target, Focus, Flex), Multi-omics

Assay-Ready Biospecimens

The World's Largest Biospecimen Inventory Powered by Discovery Partners® Network

Molecular Pathology

IHC, mIF, ISH, Histology, Digital Pathology, Quantitative Gene Expression

***In Vitro* Preclinical Solutions**

Hepatocytes, HLM, Supersomes™, TransportoCells™, ADMET Services, Hematopoietic CFC Assay Services

Clinical Flow Cytometry

Clinical Flow Cytometry, FACS, Dissociations, Single Cell & Spatial Library Prep, *In Vitro* Culture

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The Right Donors for Every Project

Premier Access to our Donor Repository

Discovery has a large, diverse donor pool, with facilities strategically located across the United States. GMP and RUO products are available at our Alameda, CA and Quincy, MA locations, enabling geographic diversity for supply chain risk mitigation. Fresh products for same day delivery are available across sites.

- FDA-registered
- AABB-accredited (Alameda, CA)
- Experienced technical and clinical team
- Strict IRB compliance, regulatory oversight
- Donors meeting FDA 21 CFR 1271 requirements

Serving the Full CGT Development Continuum

Discovery maintains the same high quality material and stringent protocols for both AllCells® RUO and GMP products for a seamless transition.

	PRE-CLINICAL PHASE RESEARCH USE ONLY	CLINICAL PHASES I / II / III GMP USE	COMMERCIALIZATION GMP USE
Donor Assessment and Testing	Donors are subject to infectious disease marker testing for HIV, Hepatitis B, and Hepatitis C. Donors also undergo a physical exam.	Donors are subject to infectious disease marker testing in compliance with 21 CFR 1271, as well as those recommended by CDC and AABB. Donors also undergo a physical exam and must pass the donor health questionnaire.	
Donor Consent (IRB Approved)	For research use only	For research and commercial use	
Operational SOPs	Validated SOPs/e-batch records	Validated SOPs and extensive batch records	
Regulatory Compliance	For research use only	Products are manufactured in accordance with FDA Title 21 Part 1271 Subparts A-C and provisions of Subpart D deemed applicable by Discovery under Section 1271.150(c) and good industry practice.	
Quality	E-documentation, product specifications based on process experience, certificate of analysis	QMS-governed documentation e.g. batch records, equipment and product validation, stability studies, to support product for further manipulation	
Processing Facility	GMP-like collection and processing facilities	ISO 7 cleanroom with Grade A and B zones	
Packaging Protocol and Packaging	Commercial grade	Packaging validated to ISTA standards including temperature logger	

Precision Donor Management for Complex CGT Projects

Recruitment

Ongoing and client-specific donor recruitment efforts

Screening

Standard viral screening and/or client-specific protocols

Monitoring

Premier access to the AllCells® donor database to identify donors with study-specific attributes

Retention

Active donor engagement to foster repeat/recallable donors; maintain minimum client-specific donor pool size

At Discovery, we understand that donors meeting the stringent regulatory criteria is just as critical as meeting the specific project needs for the success of the product and subsequent application. Our proprietary AllCells® Donor Management System (DMS) enables us to optimize our processes from recruitment, screening, monitoring, and retention, ultimately empowering us to provide the right donor for every project with the shortest lead times on the market.

Our diverse, dynamic, and continuously expanding donor pool enables us to provide the match customers need to successfully complete their study.

- Healthy donors
- Recallable or unique donors
- Human leukocyte antigen (HLA) type (low and high resolution)
- Killer Cell Immunoglobulin-Like Receptors (KIR) type
- Cytomegalovirus (CMV) status (negative or positive)
- Blood type
- Demographics (gender, age, ethnicity)
- Specific lifestyle characteristics (BMI, smoking status, and more)
- Additional custom criteria (screening or testing)
- Dedicated donor pools

All collections are from donors who are qualified for participation in accordance with the IRB approved informed consents and meet our quality standards.

Industry Best Collection Deliverability Through a Unique Donor Ecosystem

98%

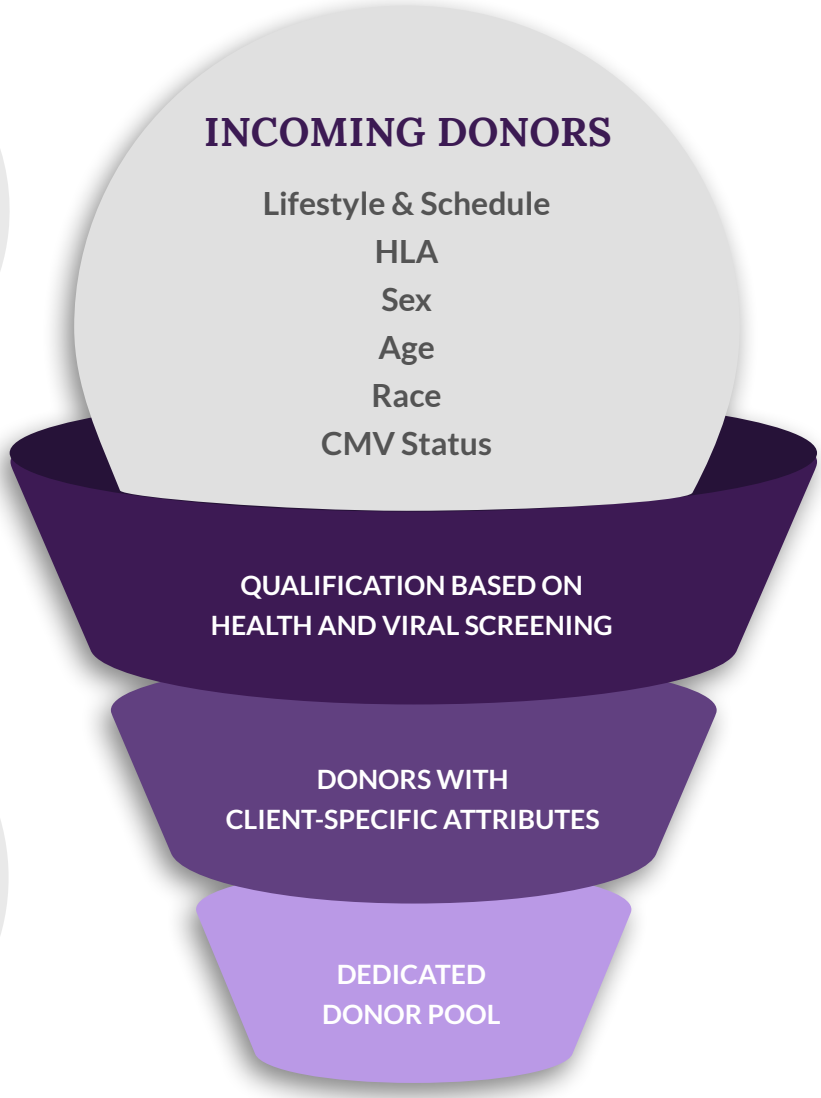
Average Collection Deliverability Rate

- Innovative software targets specific donors to get the right donors for every project
- Collection cadence / timeline specifications
- Recruitment based on demand and forecast
- Dedicated, reserved donor pool options available

Reliability

Recallability

Scalability



Case Study 1:

RUO Leukopaks with HLA Requirements

PROGRAM OBJECTIVE

Client A required a large volume of RUO leukopak collections with complex and specific HLA requirements.

Projects with Simple HLA Requirements	Projects with Complex HLA Requirements
One donor with one allele requirement Example: One donor with A02:01 heterozygous	Multiple donors with complex allele requirements Example: Five donors with all of the following: • HLA Gene A: Specific allele combination • HLA Gene B: Two options for allele • HLA Gene C: Six options for allele combination

OUR SOLUTIONS

Discovery maintains a robust donor pool of well-characterized, HLA-typed, and highly engaged recallable donors from across our US collection sites. Our real-time HLA dashboard and reporting system enables the Donor Management (DM) team to rapidly identify donors by HLA based on specific demographic criteria including, but not limited to, gender, age, CMV status, BMI, race, blood type, and product eligibility (i.e., non-mobilized vs mobilized leukopaks, bone marrow, GMP collections).

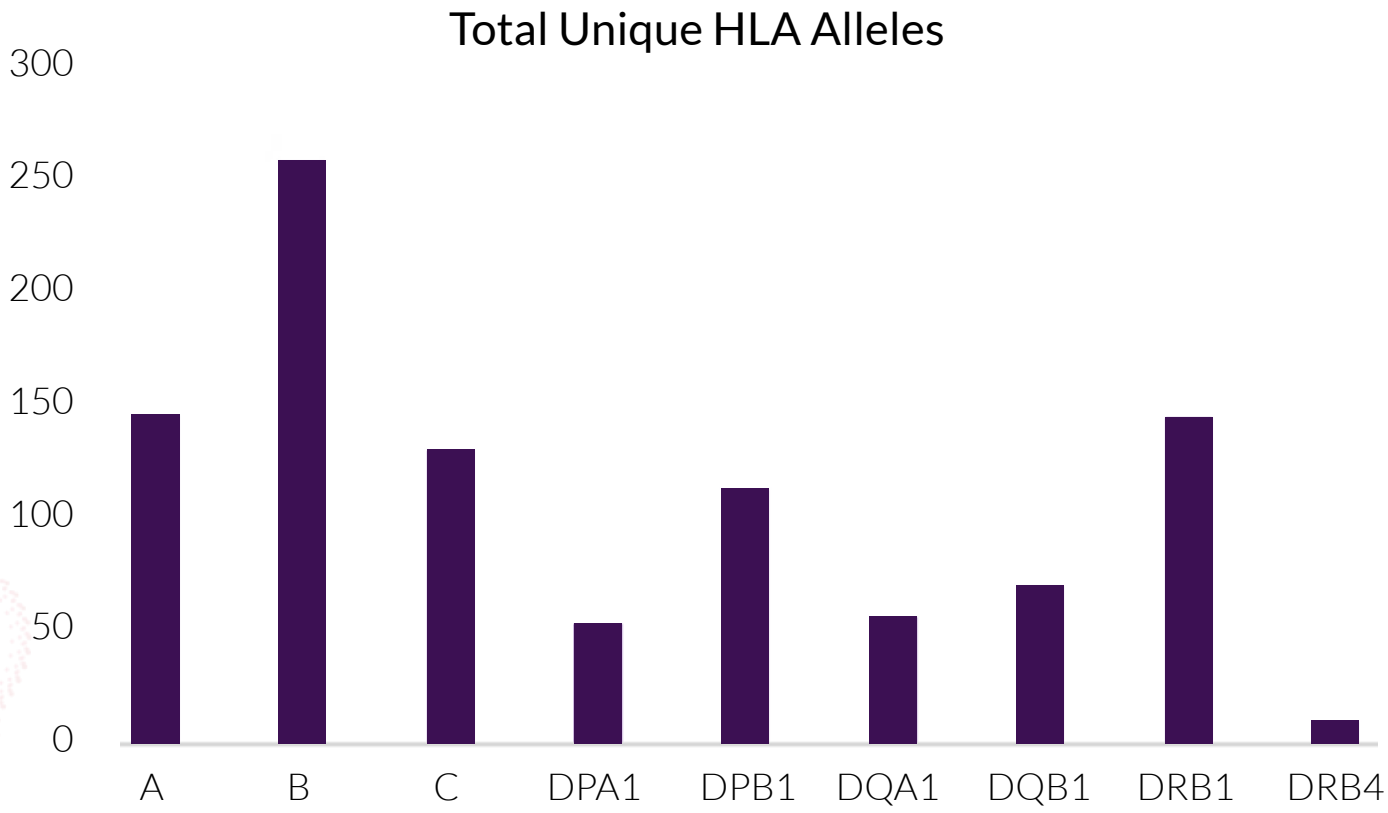


Figure 1. Discovery's robust AllCells® donor network includes donors with a diverse range of unique HLA alleles.

Discovery's AllCells® HLA-typed donor pool can be segmented based on demographic attributes.

Figures 2 and 3 focus on subsets of donors with a common HLA type (A*02:01), segmented by age, gender, and blood type.

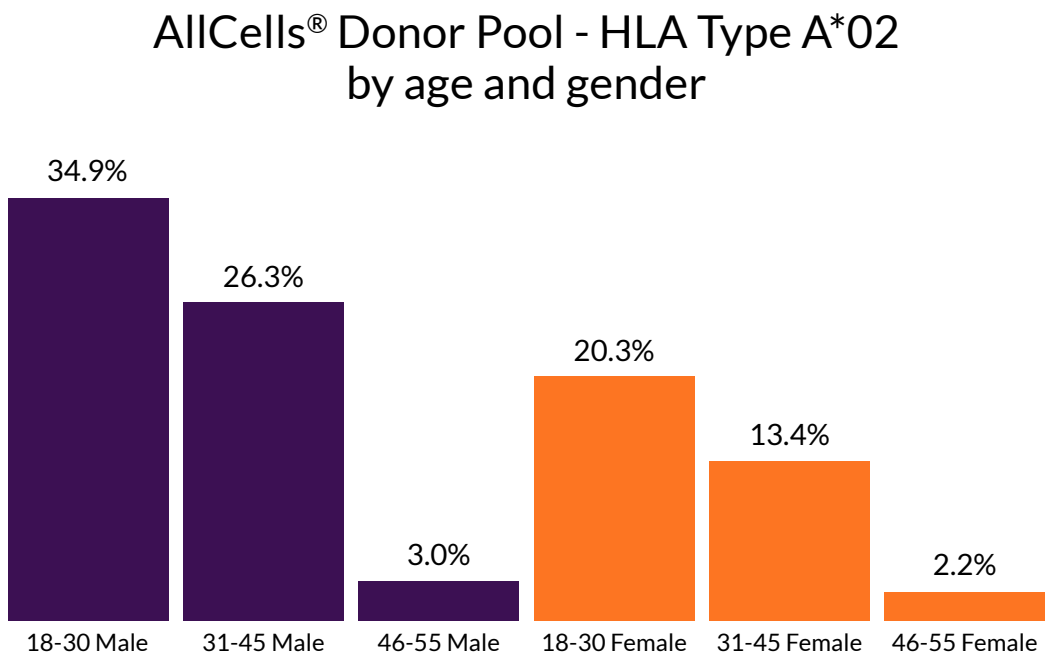


Figure 2. Subset of donors with a relatively common HLA type (A*02:01) segmented by age and gender.

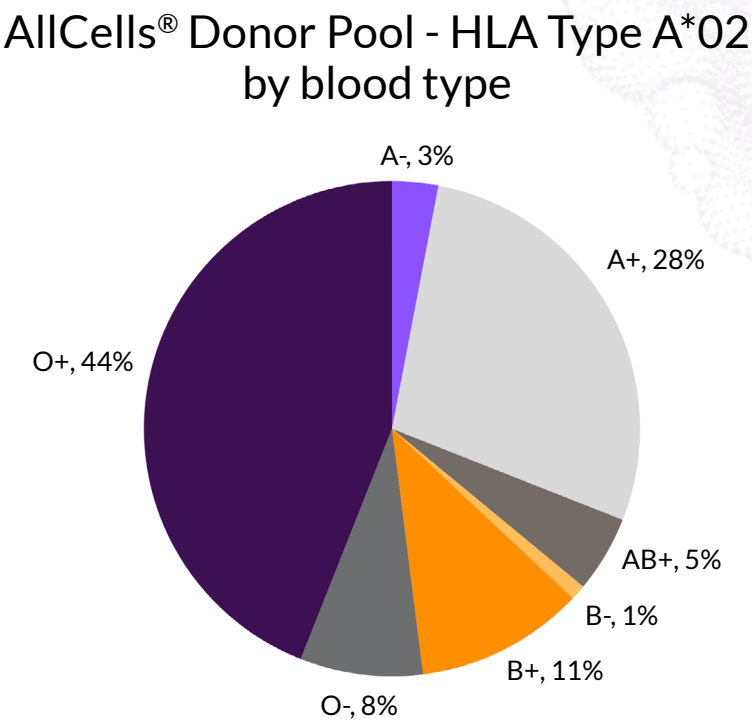


Figure 3. Subset of donors with a relatively common HLA type (A*02:01) segmented by blood type.

PROGRAM RESULT

Within a year, Disocovery successfully delivered 60+ Leukopaks with 30+ different HLA requirements for Client A.

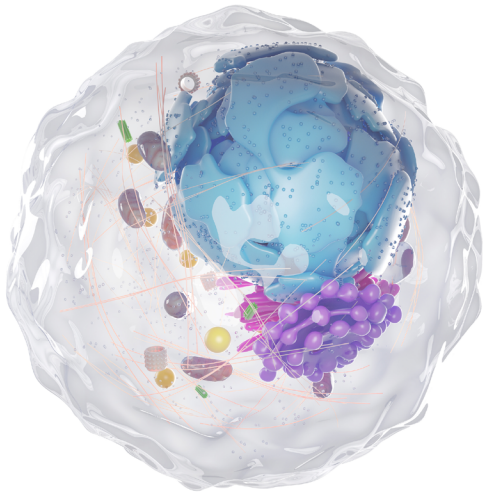
Our diverse, HLA-typed, and well-characterized donor pool, in combination with the real-time DMS dashboard system, enabled the team to identify donors that precisely matched Company A's specific needs.

60+

RUO Leukopaks Collected

30+

HLA Requirements Met



Case Study 2:

GMP Cryopreserved Leukopak Collections with Post-Collection Follow-Up

PROGRAM OBJECTIVE

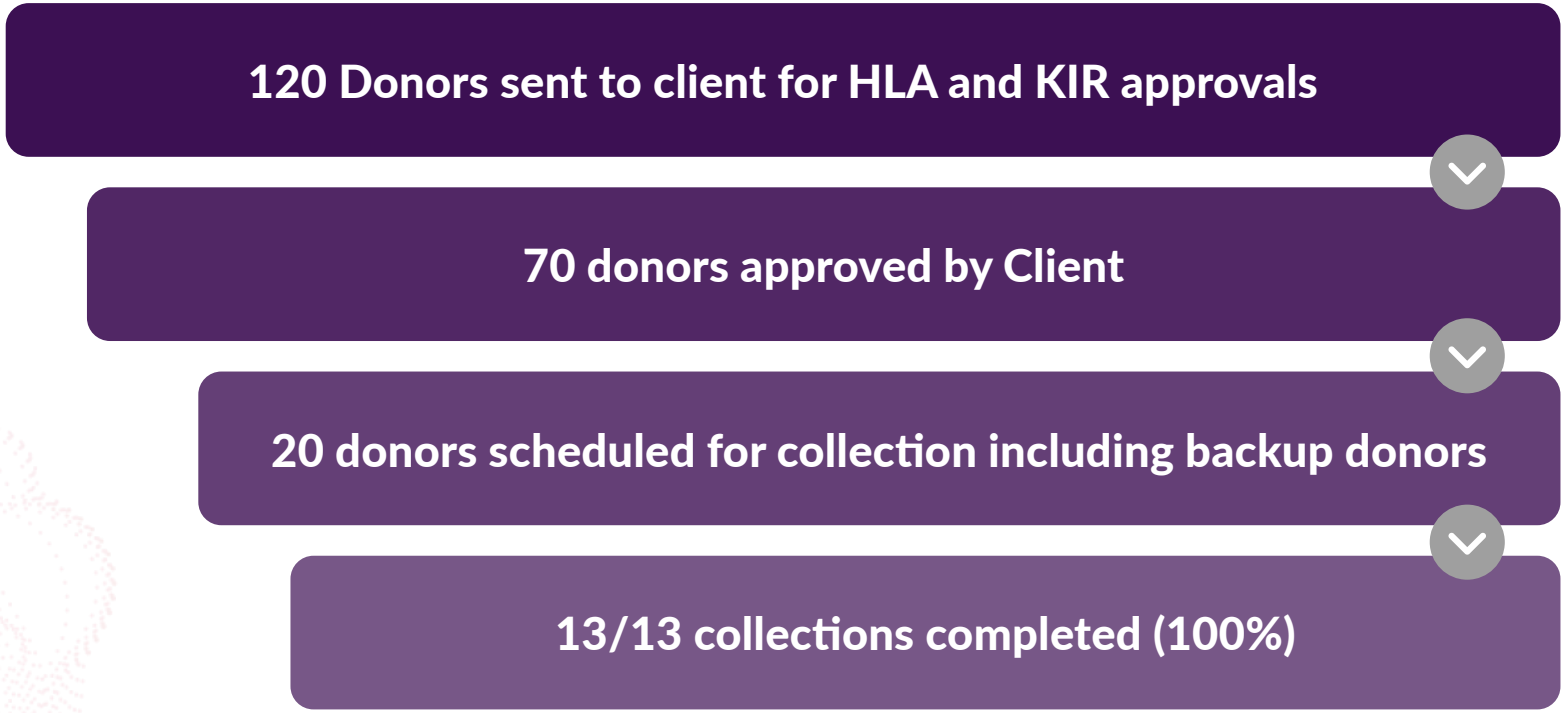
Client B required 13 GMP collections from donors aged 18-45 who were CMV negative. The client had specific HLA and KIR requirements and needed to review donors' HLA and KIR types to confirm eligibility for GMP collections.

Additionally, donors were required to return for a post-collection appointment 35-45 days after leukopak collections. The program faced stringent timeline restrictions imposed by Client B's CMO for manufacturing, resulting in a narrow window for donor collections.

OUR SOLUTIONS

Discovery provided Client B with a list of pre-vetted donors to ensure HLA and KIR typing matched the client's specific requirements and implemented an accelerated timeline to accommodate the manufacturing restrictions.

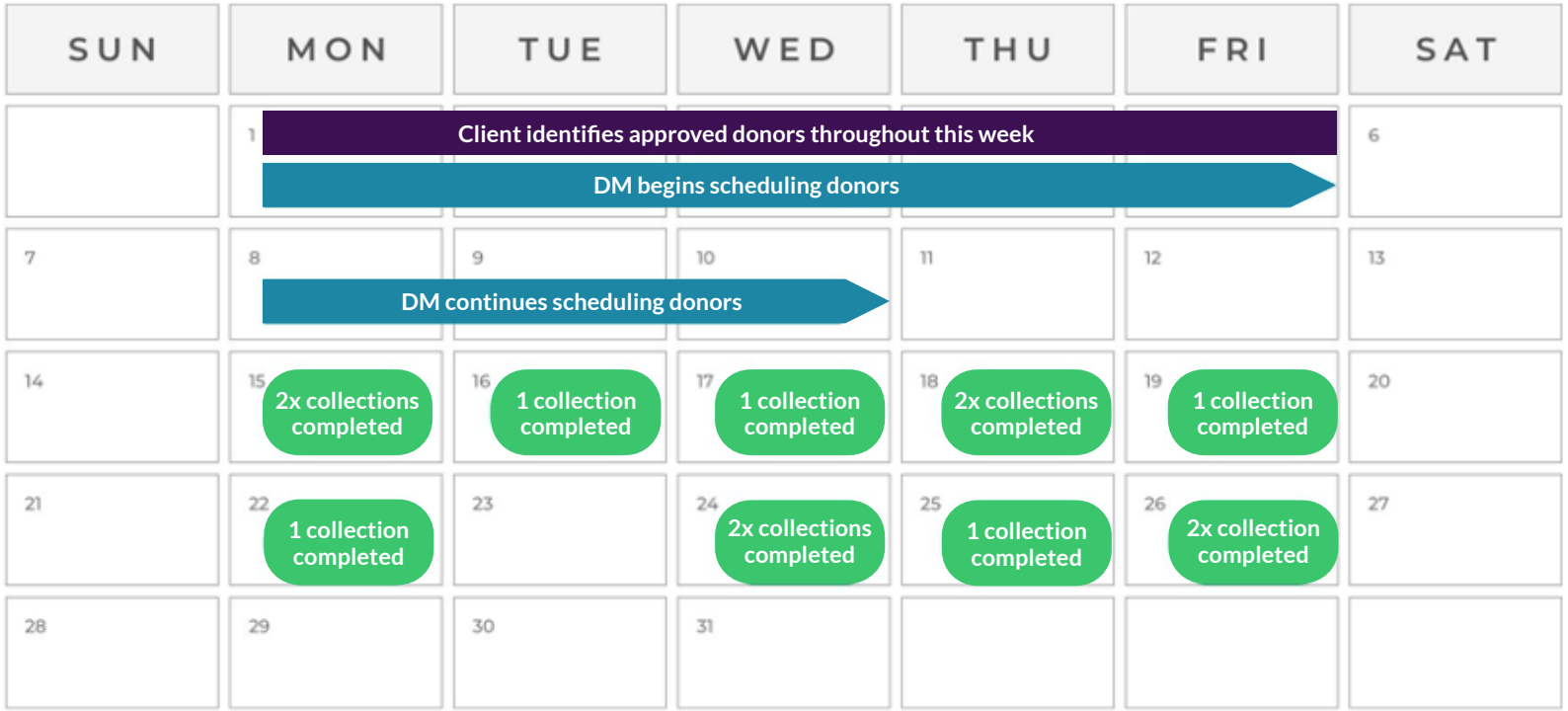
Because we do not use a traditional large donor pool model, we were able to execute a faster workflow to successfully deliver GMP collections to the client. All donors returned for post-collection follow up 35-45 days later.



PROGRAM RESULT

Our team successfully scheduled and executed 13 GMP leukopak collections from qualified donors within a two-week span, which met Client B's timeline requirements for downstream manufacturing with their CMO.

EXAMPLE MONTH



13/13 Collections

completed on time

All Collections

completed within two weeks

14/14 Post-Collection

follow-up appointments completed

Case Study 3:

Multi-Year GMP Leukopak Collections

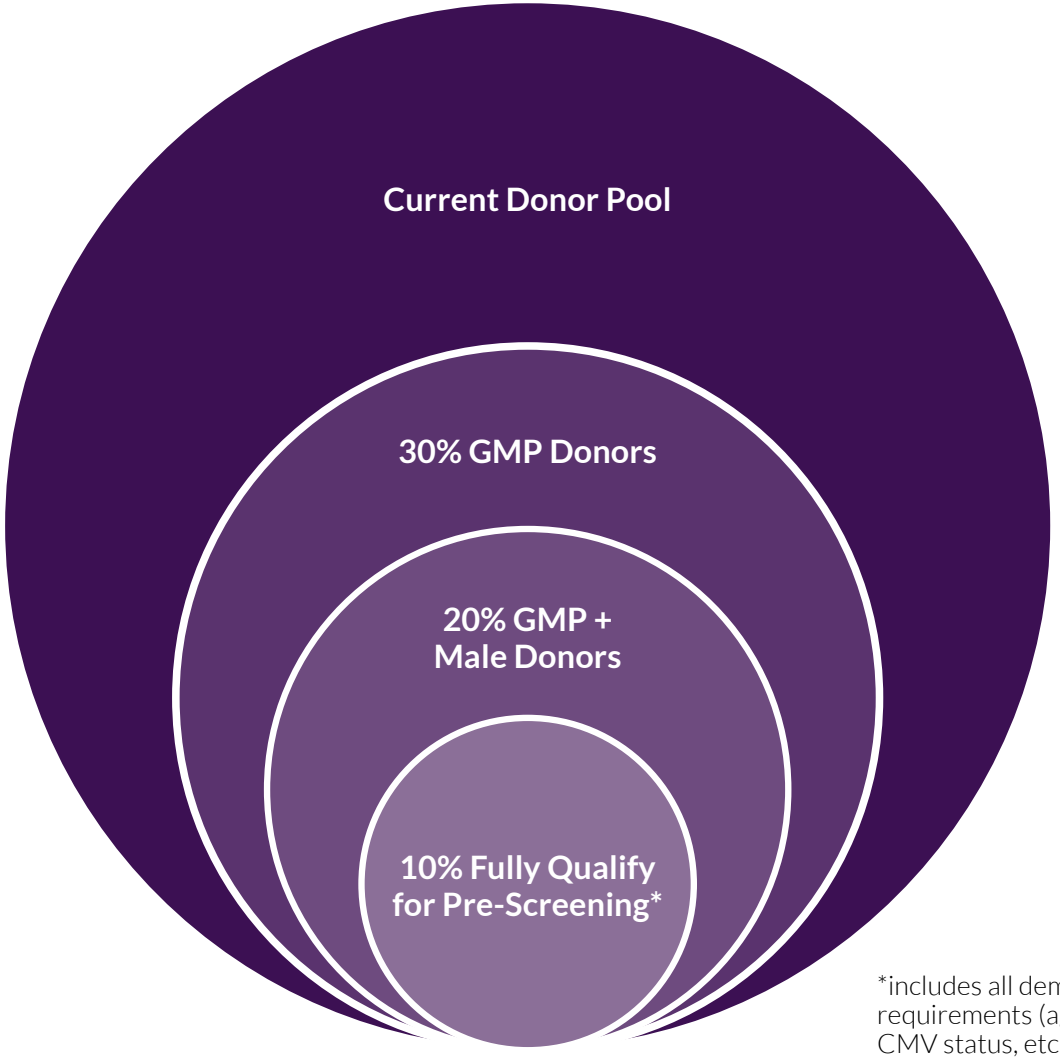
PROGRAM OBJECTIVE

Client C required a high volume of GMP Leukopaks on a predetermined schedule spanning multiple years collected from male donors aged 18-45 with a BMI < 25, CMV negative status, and meeting comprehensive viral and genetic pre-screening criteria.

Client C also faced stringent timeline restrictions, allowing only a narrow window for donor collection to ensure delivery of materials to their CMO for product manufacturing. Given the high downstream cost of failed collections, mitigating this risk was a top priority in program development.

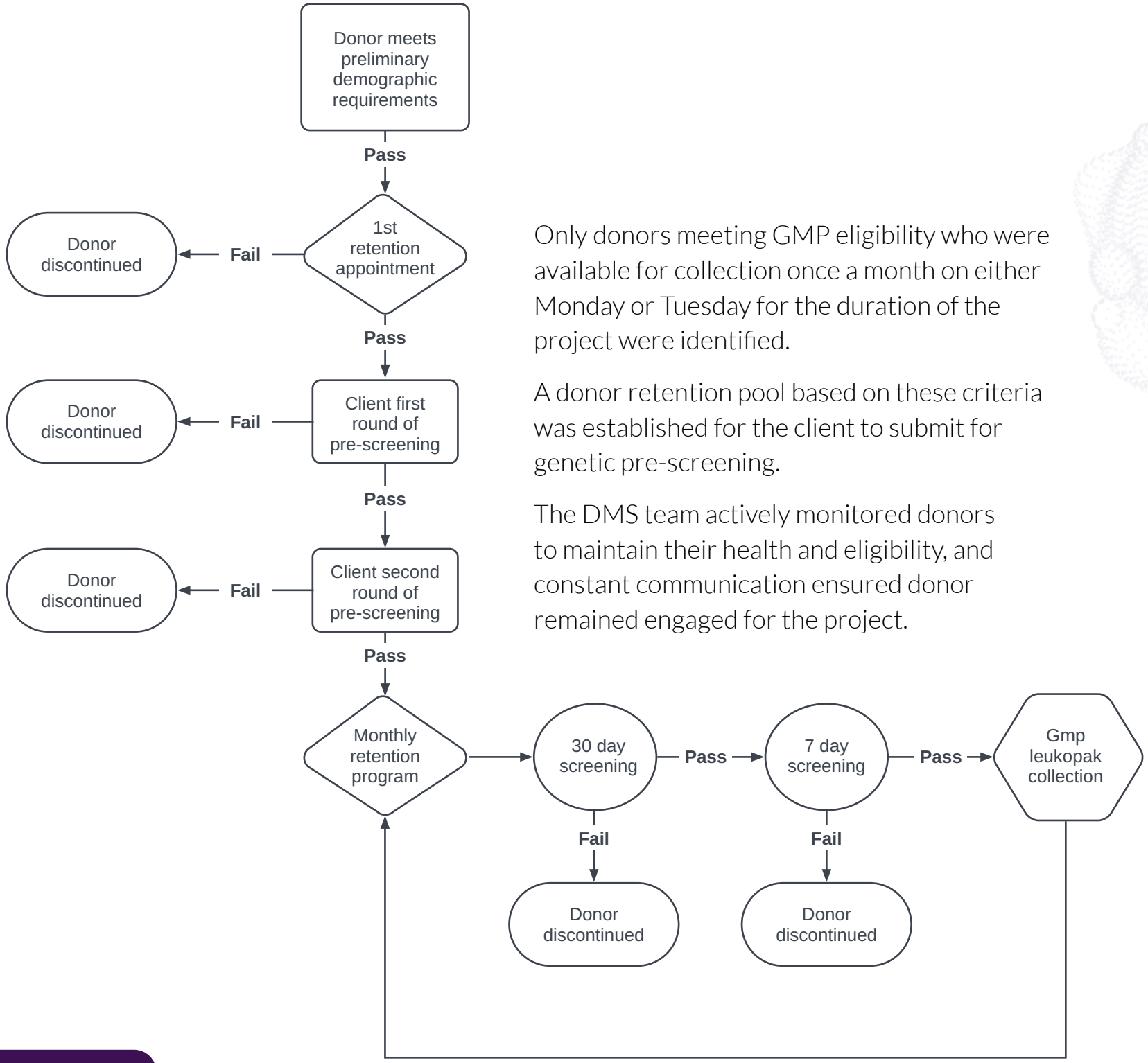
OUR SOLUTIONS

We developed and implemented an active monitoring and retention program to ensure donors meeting collection criteria remained engaged throughout the duration of the client's project. This initiative significantly reduced the risk of donor collection failures and guaranteed the availability of donors with program-specific attributes according to the client's schedule.



*includes all demographic requirements (age, BMI, CMV status, etc)

Figure 4. 10% of the AllCells® donor pool were eligible for Client's C's internal screening



Only donors meeting GMP eligibility who were available for collection once a month on either Monday or Tuesday for the duration of the project were identified.

A donor retention pool based on these criteria was established for the client to submit for genetic pre-screening.

The DMS team actively monitored donors to maintain their health and eligibility, and constant communication ensured donor remained engaged for the project.

PROGRAM RESULT

Our approach ensured donors were always available when collections were required based on the client's collection criteria and cadence, enabling the successful scheduling and execution of 148 GMP leukopak collections for Client C over a five-year period.

Collection Information	In 5 Years
Total number of scheduled collections	153
Successful collections	148
Donor related failures	5

RETENTION PROGRAM SUCCESS

6.4 Months

Average length of time a donor stayed in retention

5.04

Average number of successful collections per donor

Case Study 4:

RUO and GMP Mobilized Leukopak Collections

PROGRAM OBJECTIVE

Client D required a substantial volume of dual RUO mobilized leukopak (mLP) collections and identified a simultaneous need for GMP mLP collections. The injection regimen used in this case study was a dual mobilization of Neupogen and Plerixafor. With stringent timeline restrictions for the GMP mLP collections, donor collections were limited to a very narrow window of time. Additionally, Client D requested us to oversee shipping and logistics to deliver the RUO mLPs to their CDMO for downstream manufacturing.

OUR SOLUTIONS

Mobilization-qualified donors represent a minority of the AllCells® donor pool and the percentage of eligible donors for GMP mLP collections is even smaller.

Discovery's experienced team of project managers actively evaluates the existing donor pool and ongoing complex projects to ensure optimal donor allocation and utilization. This active support and management are crucial to ensure donor reliability within the limited pool of eligible GMP mLP donors.

PROGRAM RESULT

We achieved 97% and 100% success rate of RUO and GMP mLP collections, respectively, for this program.

Collection Information	RUO mLP	GMP mLP
Total number of scheduled collections	169	16
Successful collections	164	16
Donor related failures	5	0

Customer Excellence: During this project, we encountered multiple unexpected adverse weather conditions. Our multidisciplinary team was able to provide thoroughly vetted shipping options to the client. Proactive risk management and strong internal and external communication throughout the entire process led to the safe and timely receipt of the product to the CDMO.

Case Study 5:

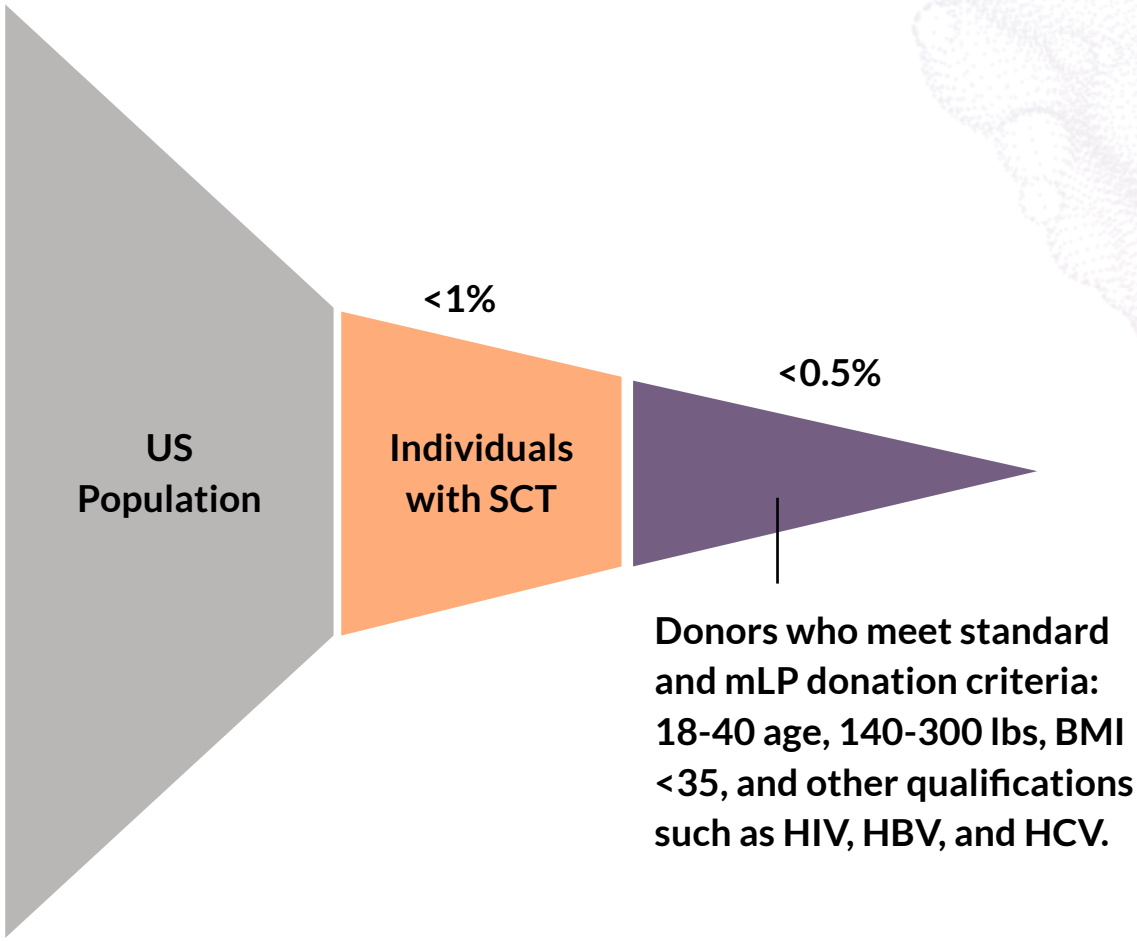
Donor Recruitment for Sickle Cell Program

PROGRAM OBJECTIVE

Client E needed to recruit donors that have the sickle cell trait (SCT) who also qualify for mobilized leukapheresis collection for their autologous cell therapy to treat sickle cell disease.

The frequency of donors with SCT in the US population is < 1.0% and even fewer are eligible for mLP collections.

Using a mass recruitment approach, the potential conversion rate to a successful mLP collection is **<0.5%**



OUR SOLUTIONS

We created a customized IRB-approved donor recruitment campaign using both print and digital media for this client to attract and onboard potential donors with rare SCT willing to undergo mLP collection.

Because of our decades of proven expertise in the industry, our team understands the approaches that resonate with the target demographic for recruitment campaigns and these tactics have become part of our proprietary process that compared to mass recruitment, achieves a high success rate of collections.

PROGRAM RESULT

We successfully recruited SCT donors for Client E's sickle cell program delivering a high conversion rate for successful mLP collections.

10%

Conversion Rate of SCT Donor mLP Collections

(50-fold increase in success over mass recruitment tactics)

100%

Successful mLP Collections

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