

Sanguine

Bridging the gap between donor biospecimens and researchers



Accelerating discovery and development

Who we are and what we do

We are your single point of access to a community of more than **70,000 donors** ready to help advance the next scientific breakthrough. Our community is engaged in translational and clinical research studies for a range of conditions as well as healthy donors for matched controls.



DISEASE CONDITIONS



Autoimmune and Inflammatory Diseases



Genetic Diseases



Cardiovascular Diseases



Hematological Diseases



Infectious Diseases



Oncology



Neurological Diseases



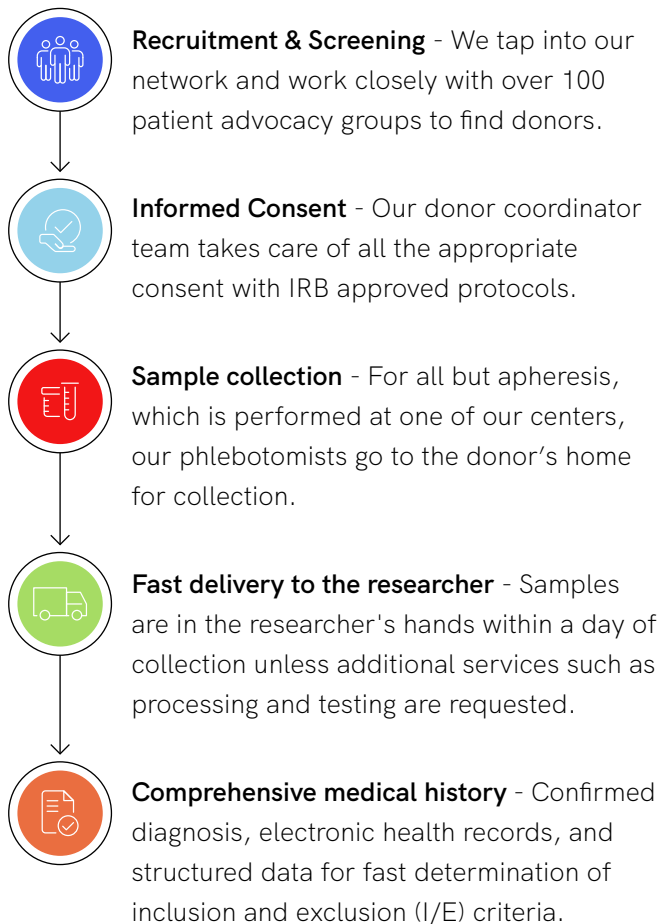
Respiratory and Metabolic Diseases

Our mission is to connect researchers to the biospecimens and associated data they need with our robust donor network. Learn more about our direct-to-donor model and our portfolio of biospecimens.

How our direct-to-donor model works	2
Prospective Collections	4
OnSite Collection	5
Community Access	6
Apheresis Products	7
Biospecimen Inventory	9
Lab and Biorepository Services	10

How our direct-to-donor model works

We have reimagined biospecimen procurement by providing a unique, fully integrated solution. Our model revolves around a direct-to-donor approach that offers comprehensive sample and data collection solutions supported by mobile phlebotomists across the United States. For both the donor and researcher, it is **simple and efficient**.



BIOSPECIMENS WE COLLECT



Blood-Derived Biofluids and Products

- Whole blood
- Serum
- Plasma
- Buffy coat
- Peripheral blood mononuclear cells



Non-Blood Derived Biofluids

- Nasal mucosa
- Non-induced sputum
- Saliva
- Semen
- Stool
- Urine



Integumentary Tissues

- Fingernails
- Hair
- Skin

We collect more than the sample:

Indirect Donor



Biospecimen

Direct-to-Donor

Donor Reported Outcomes



Lab Results



Electronic Health Records (EHR)



Biospecimen



Specify I/E Criteria

Longitudinal Studies

Prospective study design

Recallable participants



The advantage of our direct-to-donor model

As we work directly with the donors, we ensure samples are ethically and appropriately collected. With over 2000 studies completed, we are your partner in study design to accelerate your research.

Event-based sample and data collection

Prospectively collect biospecimens and donor-reported outcome data to monitor response (or lack thereof) to a treatment, before dosing, or other events specific to your study.

Longitudinal sampling

Follow donors long-term to evaluate relationships between defined factors, effects of treatment, outcomes and exposures, and other associations.

Case Study: Validation of preclinical pharmacology



Background and Challenge:

Almost 3 million people suffer from multiple sclerosis (MS) across the world. Inhibitors of Burton's tyrosine kinase (BTK) have been of interest as a means to slow progression of MS. Prior to phase I clinical trials, lead candidate inhibitors are tested in mouse and human preclinical models to determine pharmacokinetic and pharmacodynamic properties. A global biopharmaceutical company partnered with Sanguine to identify donors and collect whole blood from people diagnosed with MS who have not had B-cell depleting therapy along with healthy matched controls.



Solution:

Whole blood was collected from donors in the comfort of their homes and shipped to the client's site for analysis. Along with the biospecimens, medical records were obtained and confirmation of meeting the study's "I/E criteria. These samples helped to demonstrate the lead candidate inhibitor maintained high selectivity of inhibiting B-cell activation in MS whole blood - a key finding to move the candidate to phase I clinical trials.

Our Success in Numbers

70,000+

Donor Community

100+

Diagnosed Conditions

93%

Delivered to Plan¹

2000+

Completed Studies

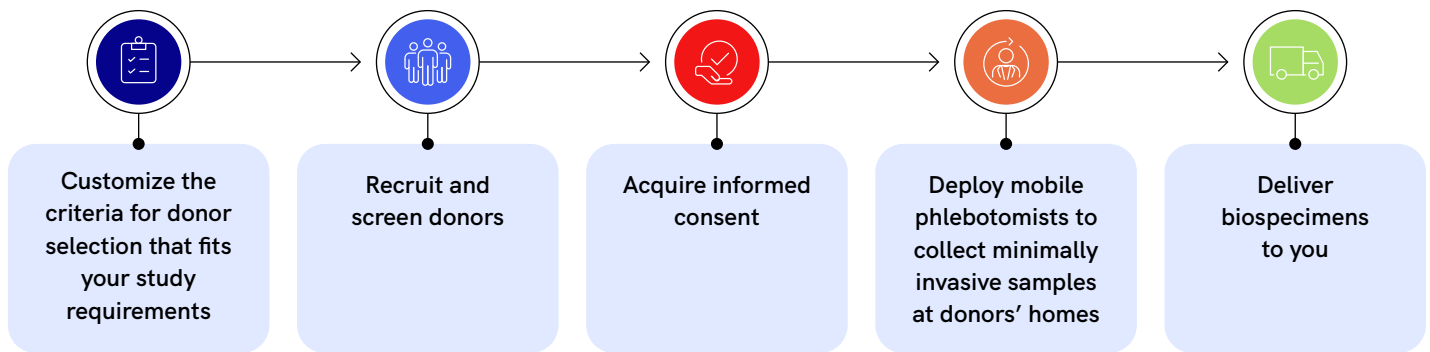
¹ Calculation from all in-home collections initiated from 2021 to 2023 - including rare diseases and highly complex I/E criteria

Prospective Collections



Our donor-powered mobile biospecimen collections is what Sanguine was founded upon. A major challenge for researchers, and what can stunt therapeutic development is access to clinically relevant biospecimens with comprehensive donor data. Our vast and engaged donor network affords us the ability to find the donors that fit your research needs - disease, demographic, "I/E criteria, and other complexities in your study design.

How it works:



Success is in the numbers, with over **2000 studies initiated**, we have successfully **delivered to plan 93%** of the biospecimens requested - including those with highly complex inclusion and exclusion requirements and for rare diseases like Behcet's Disease and Fabry Disease.

Case Study: Microbiome study requiring multiple types of biospecimens



Background and Challenge:

The interplay of microbiota, tumor microenvironment and immune system influence the efficacy of some cancer treatments but the interaction is still not understood. Researchers engaged Sanguine for a complex recruitment as they wanted 250 donors with cancer who were receiving either chemotherapy or immune checkpoint inhibitors, along with 60 unmatched healthy donors. Three separate collection visits for whole blood, urine, stool, and buccal swabs were performed over the course of a four month time period, as well as, medical record-based health status updates six months after the last collection.



Solution:

Sanguine was able to use the existing healthy donor network for the 60 healthy controls but performed significant recruitment and screening of over 600 potential donors diagnosed with cancer to enroll the required 250 individuals. All relevant redacted medical information was collected. The multiple collection days and collection of health status updates six months post collection was possible with the ease of in-home collection and relationships with our donor network.

OnSite Collection

Our OnSite Collection Program provides healthy whole blood samples on-demand and ready for use almost immediately after collection from donors at your research organization. Your organization provides a space and Sanguine takes care of the rest.



Informed consent



IRB, HIPAA, and other regulatory compliance



Donor recruitment from your organization



Biospecimen request portal



Pre-screening eligibility



Sample collection

By recruiting from your own organization, a Sanguine OnSite Collection Program offers your team the opportunity to contribute to on-going research and provides fast, fresh samples.



Convenient

Samples ready for pickup almost immediately after collection.



Customizable

You specify I/E criteria and other collection requirements.

Case Study: Understanding a drug's unique mechanism of action



Background and Challenge:

Adalimumab (ADA), but not other anti-TNF therapeutics has shown to be effective in treating moderate-to-severe hidradenitis suppurativa. This suggests a distinct mechanism of action of ADA that the pharmaceutical team sought to elucidate.



Solution:

The team was able to leverage their OnSite program to obtain healthy blood samples from their own community. Monocytes were isolated from peripheral blood of the healthy donors ex vivo to develop and use as an assay to assess the role of TNF and anti-TNF agents in macrophage differentiation.



Community Access

We have found that often after a first prospective collection for a translational study, planning for the next one commences soon after. For organizations with multiple expected studies across one or many indications, Sanguine is excited to design a Community Access agreement to accelerate start-up. These contracts provide access to a dedicated Project Manager who will help connect you with the best fit segments of our donor community, decreased study start-up times, and more flexibility on minor changes to protocols. Our Community Access agreement is an advantage for both **researchers** and **procurement officers**.



Researchers - As study design can be dynamic, longitudinal, and with a variety I/E criteria - Community Access provides flexibility.



Procurement Officers - Reduces the administrative and financial requirements to save time and budget, and reduces redundancy with a single agreement for multiple research stakeholders.



Case Study: Community Access agreement saves time and money



Background and Challenge:

A global pharmaceutical company focusing on multiple autoimmune diseases had nine unique translational studies across research group. The logistics for setting up each study was becoming time consuming and costly.



Solution:

The organization partnered with Sanguine to build a Community Access agreement before initiating the nine projects. They needed access to two distinct donor communities over the year. The result was a decrease in time to start each study as start-up logistics were already in place and a 50% cost savings across the nine studies compared to each study being initiated independently. Further, there was ease in altering study design as needs shifted with the Community Access agreement in place.

Connect Community Access with OnSite Program for even faster means for collecting both healthy and disease-state biospecimens.

Apheresis Products

Obtaining billions of white blood cells from a single donor is achievable with apheresis. This overcomes a major challenge in therapeutic development for many diseases as large quantities of cells from a single donor removes variability, increases reproducibility, and can provide sufficient quantities of rare cell types.

Healthy and Disease-state leukopak



Over 30 diagnosed conditions



Available fresh or cryopreserved



LeukoLots are a batch of PMBCs isolated from a leukopak, aliquoted, and then cryopreserved. LeukoLots have a few distinct advantages.

Isolated PMBCs may be more desirable for your research.

Aliquots of 100 million cells limit freeze-thaw cycles, thus maintaining viability and function.

Screening vials are available to analyze multiple LeukoLots to identify the ideal donor(s) PMBC composition.

Case Study: Functional cells in mouse model



Background and Challenge:

A group at a biomedical research organization is injecting human immune cells into immunodeficient mouse models. They adhere to strict quality control parameters and thus need to ensure the cells meet their specific requirements. In addition, each batch of cells may behave differently in their models so being able to test before committing to the lot offers a distinct advantage.



Solution:

LeukoLots allowed the team to do their own screening and functional testing before determining which LeukoLots best fit their needs. They now have a large supply of PMBCs that fit their exact criteria - saving time from additional screening and money by limiting the purchase of cells not ideal for their research efforts.

Sanguine's apheresis RUO portfolio

	Full Leukopak	Half Leukopak	LeukoLot™
Size	8-10 billion cells	4-5 billion cells	40 vials PBMCs + screening vial
Healthy	✓	✓	✓
Diseased	✓	✓	✓
Fresh	✓	✓	✗
Cryopreserved	✓	✓	✓

Deliverables with our apheresis products:



Donor demographics



Comprehensive medical records (disease-state only)



Infectious Disease Status



HLA typing



Complete Blood Count



Certificate of Analysis*

Leverage our lab services for additional processing and analysis including



PBMC or further cell isolation



HLA typing and testing



Aliquoting



200+ additional CLIA-certified diagnostic tests

*available for select products

Biospecimen Inventory

We appreciate that searching for the right biospecimen for your research slows progress. We have a diverse biorepository of samples ready to ship from our freezer to yours including PBMCs, serum, and plasma. Our inventory has over 30 diagnosed conditions and is continually growing. These samples are collected by our team and thus adhere to the same ethical standards of our prospective collection services. In addition, as these biospecimens are from our donor network, we have significant information about the samples including:



Donor demographics

Age, gender assigned at birth, and ethnicity



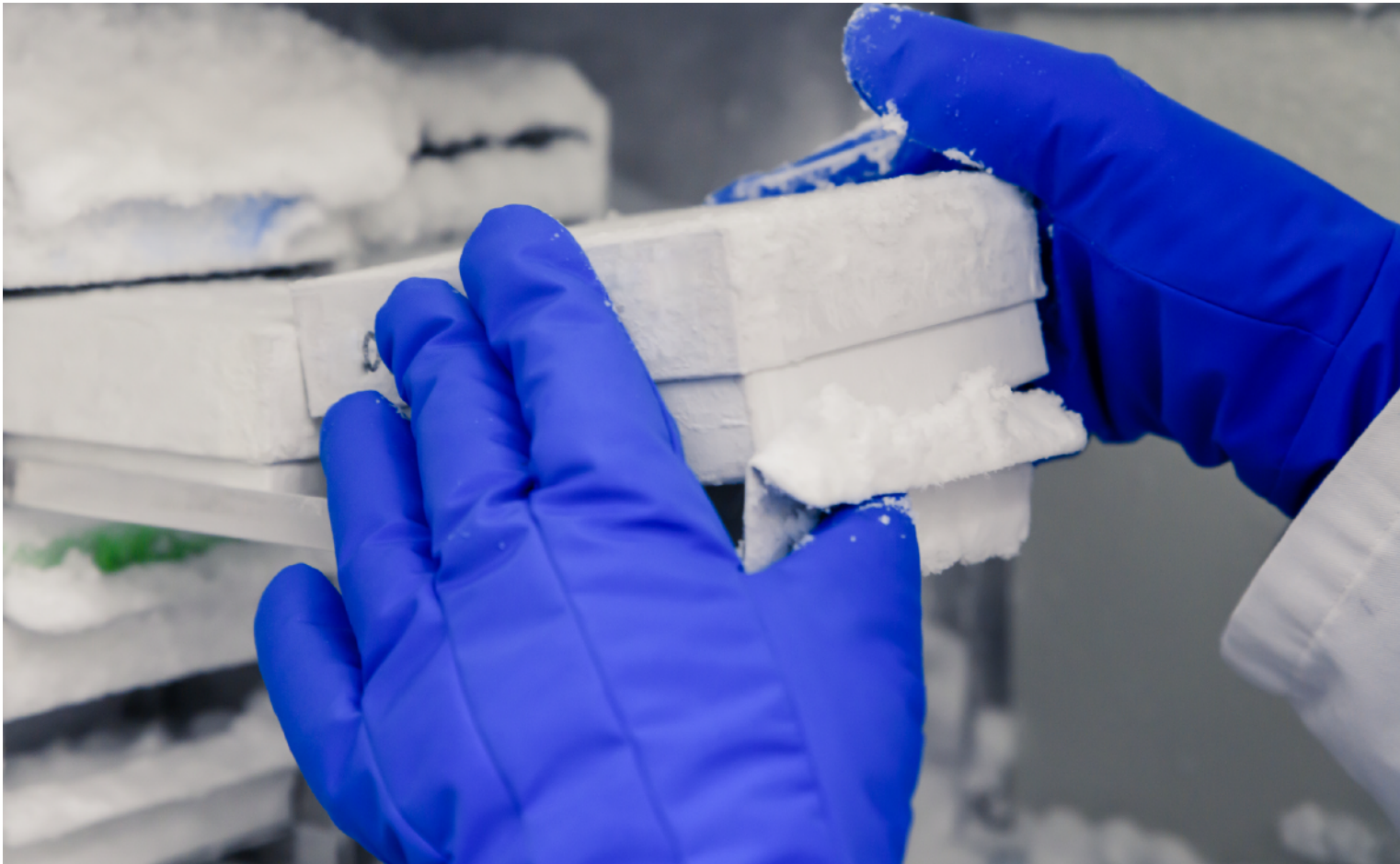
Health Status

Diagnosis and BMI



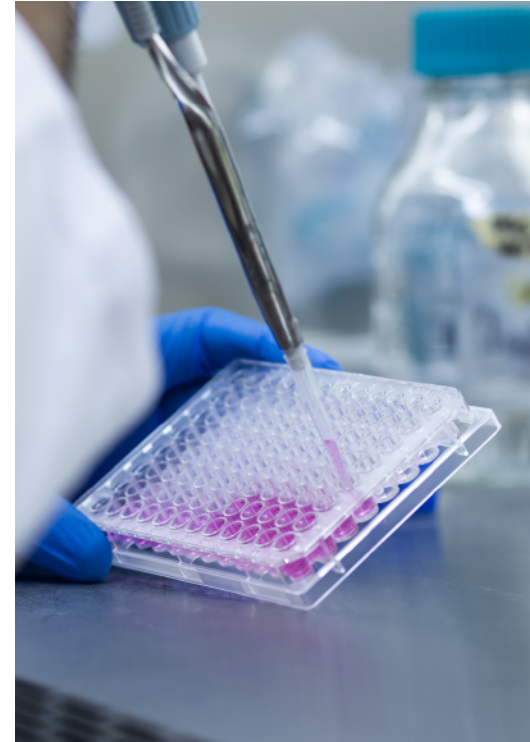
Donor reported information

Current medications, infectious disease status, and allergies



Lab and Biorespository Services

Further processing is often necessary for the biospecimens we have collected. We are happy to continue to be your partner with flexible and customizable capabilities. Our lab is an extension of your lab, with expertise and flexibility on maintaining the high quality we demonstrate with sample collection for your critical projects.



Biospecimen Processing Services



Whole blood-derived samples - Serum, Plasma (including platelet-rich and platelet-poor), Buffy Coat, and nucleic acids



Immune cell isolation - PBMCs, B cells, T cells, and NK cells



Leukopak processing - PBMC isolation, PBMC aliquoting, T, B, and NK cell isolation

Biospecimen Testing and Analysis Services



Over 200 diagnostic test offerings, including infectious disease status, toxicology, and complete blood count.



CLIA-certified testing available



HLA typing

Advantages of Sanguine Processing Services



Configurability - Format your biospecimens to your criteria



Speed - Process upon arrival for fast turnaround



Equipped - Ready with reagents and equipment for processing



Safety - Eliminate exposure and contamination in your lab



Case Study:



Background and Challenge:

Although many people who contract hepatitis B virus (HBV), are able to clear the infection; others have chronic infection that can result in developing liver disease. A virology biotech company sought to better understand viral infection in people with HBV over the course of a year to monitor biomarkers.



Solution:

The team sought to have 100 donors willing to have weekly blood draws over the course of year. In addition, when recruited, they were free of viral coinfections and advanced liver disease. Sanguine partnered with Hepatitis B Foundation and other independent recruitment initiatives to identify more than 1,000 donors and ultimately enrolled 106 who met the criteria. Beyond biospecimen collection, Sanguine screened for levels of two antigens - HBsAg surface antigen and HBeAg secreted antigen - to provide additional information about current infection and whether the virus was actively replicating. The study success is in the numbers with continuing into year three (originally planned for only one year) and 95% of donors still participating.

Sanguine Biosciences strives to accelerate research and discovery by bridging the gap to obtaining biospecimens with a robust donor network. By directly engaging with donors, we can identify and collect the biospecimens necessary for advancing discovery. Our portfolio includes in-home prospective collections, apheresis product offerings, retrospective biospecimen collections, and a suite of biorepository services.

[Explore Sanguine Biosciences](#)

