## Bridging the Gap Between

# Sanguine

## Patients and Researchers

ACCELERATING INNOVATION THROUGH PURPOSE

sanguinebio.com

## Next-Generation Therapy Research Needs Patients, not Specimens

Successful drug and diagnostics development ultimately depends on deploying pertinent human biospecimens to address the emerging translation gap between laboratory models and real-world patients. Biospecimens in isolation, such as biobank samples collected retrospectively, fail to provide a panoramic view of the patient that is critical to biomarker-driven therapeutic development based on precision medicine principles. At Sanguine Biosciences, we pioneered a direct-to-patient approach to facilitate patient participation in the therapeutic research process. As your single point of contact to our 70,000+ engaged patient community, we provide unparalleled access to the most relevant patients and their corresponding data, accelerating research initiatives across discovery, translational, clinical, and manufacturing. We make it easier for you to deliver on behalf of patients actively impacting their future care.



## One Partner to Integrate Patient Biospecimens and Data into Your R&D

The intrinsic value of any given biomarker centers on its association with phenotypic data and medical outcomes. Accordingly, biospecimens collected from our patient community include the annotations essential for biomarker utility in precision medicine, such as medical records, patient-reported outcome (PRO) documentation, questionnaires, and demographics. In-home biospecimen collections by professional phlebotomists promote patient participation not limited to an individual's geography or mobility, as well as permit biomarker studies that are longitudinal and/or multidimensional. Apheresis operations provide researchers with large volumes of peripheral blood mononuclear cells (PBMCs) from a single donor with minimal disruption to our patient participants. Our biorepository capabilities enable custom preanalytical, analytical, storage, and delivery services by a single provider, reducing variability and streamlining results.



## **Engaging Patients in the Research Process**

Our mission is to develop innovative solutions that empower patients to participate in advancing treatments for conditions that matter most to them, regardless of their location or ability to travel. We work directly with patients and advocacy groups to accelerate research through convenience and transparency while guiding each patient every step of the way. Over 70,000 patients and healthy donors have joined Sanguine's nationwide network of research-ready participants. We actively maintain and grow our patient community through inspiring patient engagement, partnerships with patient advocacy groups, generous compensation, and digital outreach to ensure motivated individuals can impact medical research and therapy development.



## Prospective Study Design: Procure Annotated Patient Specimens Without the Clinic

Prospective study design means you establish biospecimen collection, processing, and delivery parameters according to your therapy program needs from study conception. Factors like inclusion and exclusion criteria, T, B, or NK cell isolation, and storage requirements can mirror proposed clinical trial parameters while controlling variability and safeguarding sample integrity. Biobanks with indirect access to patients usually cannot offer such assurances.

You design the study and receive samples and data. Sanguine handles donor recruitment, consent, scheduling, biospecimen collection, processing, storage, and delivery logistics as an extension of your team. Our protocols are IRB-approved and HIPAA and 21 CFR part 11 compliant.



"Typical specimen collections are just anonymous tubes, and you work with just that sample. Collecting data and performing longitudinal studies, like the study design with Sanguine, **allows us to collect key data points from patients to really understand who they are**. A study design involving questionnaires replicates a phase 0 non-interventional study. It matches clinical information and PROs to biomarker data for an understanding of disease activity." *-Senior Director, Global Biopharmaceutical Company* 

## Accelerate your research with annotated biospecimens directly from patients and customizable post-collection services

	@Home Collection	Apheresis
Description	Patients donate in the comfort of their own homes via mobile phlebotomy. Multiple samples can be conducted concurrently.	Patients donate at a qualified apheresis center to yield a leukocyte-enriched product. An onsite screening visit determines eligibility.
Biospecimens		
IRB-approved collection protocol	Standard	
Leukopak	N/A	Apheresis center collection Additional biospecimens can be collected in-home from recallable donors in a separate visit
Whole blood	In-home	
Serum	In-home or in-lab from whole blood	
Plasma		
Urine, stool, hair, skin tapes, skin swabs, saliva, semen, non-induced sputum, nasal mucosa	In-home	
Buffy coat	N/A	N/A
Peripheral blood mononuclear cells (PBMCs)	Isolated In-tab Horn Whole blood	Further isolation in-lab available
T cells	Isolated in-lab via positive or negative selection	- Isolated in-lab via positive or negative selection
B cells		
NK cells	- N/A	
CD34+ cells		
Patient Data		
HIPAA-protected patient privacy	Standard	
Electronic medical records (treatment history, disease diagnosis, lab results, & infectious disease status)	Standard	
Demographics	Standard	
Vital signs, height, weight, & age	Standard	
Patient Reported Outcomes (PRO or ePRO)	Available	
Study specific surveys & questionnaires	Standard; Custom available	
Wearable digital biomarker devices	Available	
Complete Blood Count (CBC)	Available	Standard
Biorepository Services		
PBMC Isolation	Available	Available, with aliquoting
Lymphocyte isolation (T and B cells)	Available via positive or negative isolation	Available via positive or negative isolation
Serum, plasma, urine processing	Available	N/A
Human Leukocyte Antigen (HLA) typing	Available (NGS 4 field, 11 loci)	
DNA/RNA NGS	Available	
Cryopreservation	Available	
Choose from 130+ clinical tests	Available	
Short- and long-term sample storage	Appropriate -20°C, -80°C, liquid N2	liquid N2
Sample storage volumes	Accommodate liquid volumes > and < 2 mL	Half (100 mL) and full (200 mL) leukopaks
Delivery timeline	Overnight; same-day available	
Delivery temperature	Ambient or temperature controlled dry shipper	Temperature controlled dry shipper

"Access to disease state leukopaks, specifically for the conditions we are developing treatments, helps produce much more accurate data for our process development team. Compared to leukopaks from healthy donors, **these leukopaks are much closer to the incoming products we will be receiving for our clinical trials**."

- Director, Cell Therapy Company

## Facilitating novel therapy development across diverse disease conditions

Sanguine's ability to recall donors for longitudinal studies, incorporate patient data crucial for biomarker discovery, and customize specimen post-collection processing enable complex and cutting-edge medical research. The disease states investigated in these studies reflect the diversity of Sanguine's Patient Community (see chart).

 RESEARCHER SUCCESS WITH SANGUINE

 700+
 140+

 STUDIES SINCE
 PEER-REVIEW

 2021
 PUBLICATIONS

Several biopharmaceutical companies have instituted healthy on-site programs, whereby Sanguine phlebotomists and data management are leveraged to build healthy cohorts for therapeutic and specimen research utility. Such studies have led to publications detailing best practices for clinical specimen processing, comparing competitor drug properties *ex vivo*, and exploring new indications for approved therapies.



#### David Beidler, Ph.D.

2000

STUDIES SINCE

2010

Senior Director, Pfizer



"We are trying to bring in these more patient-centric endpoints and create a tool that can capture these in a future interventional study. We [have] the ePRO monitoring, actigraphy, and [longitudinal] blood collections regardless of where they are. This is where Sanguine comes in again, they were basically our operations group on the ground in Detroit."

#### Describing the patient experience in biomakers with longitudinal, in-home collections

### **Objective**

Identify functional and clinically relevant biomakers predictive of Sickle Cell Disease (SCD) symptom onset and progression (ELIPSIS study)

### Sanguine Study

Blood samples and patient reported outcomes (PROs) were longitudinally collected in-home (at least every 3 weeks) for 6 months.

## ्ग्रें Insight

A biomaker panel predictive of symptom onset and duration correlated strongly with SCD severity and treatment status. The assay may be clinically useful in stratifying patients for evaluating SCD therapies.



White J, et al. (2002) Br J Haematol. 196: 1052-1058.

Pittman DD, et al. (2021) Blood. 137: 2010-2020.

#### Immunogenicity benchmarking to recovered individuals in COVID vaccine trials



Provide a benchmark convalescent sera cohort that represents COVID-19 recovered individuals.

### Sanguine Study

Sera from individuals aged 18-83 years who donated blood in their homes at least 14 days post-diagnosis and were asymptomatic at the time of collection.



Immunogenicity of the lead vaccine candidates in preclinical and clinical studies could be compared directly against COVID-19 recovered individuals without needing clinical site biospecimen collection.



Sahin U, et al. (2020) Nature. 586: 594-599. Mulligan MJ, et al. (2020) Nature. 586: 589-593. Walsh EE, et al. (2020) N Engl J Med. 383: 2439-2450.

Vogel AB, et al. (2021) Nature. 591: 283-289. Sahin U, et al. (2021) Nature. 595: 572-577.

#### Daniela Weiskopf, Ph.D.

Assist. Professor, La Jolla Institute for Immunology



"We wanted to make sure there are representatives of different disease severities, ethnicities, and, most importantly, the different HLA phenotypes in our population. That is something we used Sanguine's help to fill in the holes... to provide a comprehensive picture of the T cell response."

**Contact Us** 

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For more information or to discuss a study design, please contact:

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