Sanguine

Leukopaks and Biospecimens for Cell & Gene Therapy

Healthy & disease-state leukopaks, noninvasive specimens, and comprehensive donor data from our diverse network of 70,000+ participants

1000+ Unique Studies | **70,000+** Patient Community | **100+** Conditions | **140+** Publications

Comprehensive Data from Recallable Donors

- Confidently choose patients with confirmed disease diagnosis and healthy matched controls.
- 95+% recallable rate enables longitudinal study design to uncover real-world biomarkers.

Prospective Study Design

- Specify I/E criteria and link conditions to healthy-matched controls.
- Dictate collection and handling protocols to reduce variability.

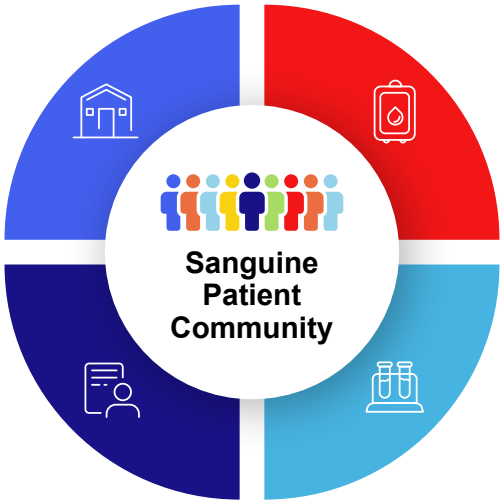
Customization and Communication

- Include immune cell isolation and biomarker services post-collection.
- A dedicated Study Coordinator manages logistics and keeps you in the loop.

The value of a biomarker value depends 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 mononucleated immune cells 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.

@Home Biospecimen Collection
- Whole Blood and Derivatives
- Minimally Invasive Collections
- In-Home Processing

Apheresis
- Healthy Leukopaks
- Disease State Leukopaks
- Rare Cell Collection & Isolation



Patient Data
- Medical Records
- Patient Reported Outcomes
- Surveys & Questionnaires

Biorepository Services
- Biospecimen Processing
- Testing & Analysis
- Sample Storage

Healthy and Disease-State Leukopaks

Apheresis-separated lymphocytes and monocytes (leukopaks) collected from the same donor provide a reliable and consistent source of peripheral blood mononuclear cells (PBMCs) for biomarker, immunology, autologous, and allogeneic cell therapy research. One leukopak can provide up to 10 billion nucleated immune cells in one donation from a single donor (healthy or confirmed disease diagnosis). Combined with annotated medical data and the ability to recall donors, Sanguine leukopaks accelerate the development of diverse therapy programs from discovery to manufacturing.

Use Leukopaks for:

- Assay validation
- Process Development
- Rare cell isolation
- Cell & Gene Therapy

Take advantage of additional services:

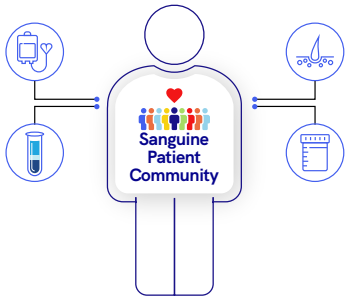
- Mononuclear cell isolation (PBMCs, T, B, and/or NK cells)
- 100+ additional CLIA-certified diagnostic tests
- Prospective collection of additional samples from the same donor

Prospective Biospecimen Collection

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. Collect specimens longitudinally or multiple specimens simultaneously. Our protocols are IRB-approved and HIPAA and 21 CFR part 11 compliant.

Whole Blood & In-home centrifugation
- Serum
- Plasma

Processed Blood (in Lab)
- PBMCs
- Cell Isolations
- Serum/Plasma
- Buffy coat
- RNA/DNA



Skin Tapes, Swabs, & Hair

Other non-invasive specimens
- Stool
- Urine
- Saliva
- Semen
- RNA/DNA

Case Studies: Supporting Advanced Therapy Development from Discovery to Manufacturing

Below are three examples of biopharmaceutical companies working with Sanguine to accomplish research and development initiatives. Please contact us at LearnMore@Sanguinebio.com to discuss a study design and accelerate your research.

David Beidler, Ph.D.
Senior Director, Pfizer

Sanguine Speaker Series

"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

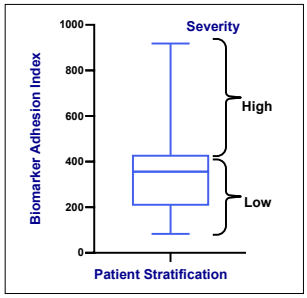
Identify functional and clinically relevant biomakers predictive of Sickle Cell Disease (SCD) symptom onset and progression (ELIPSIS study).

Sanguine Study

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

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. (2022) Br J Haematol. 196: 1052-1058.

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

Disease-state leukopaks for process development: replicating the final product

Challange

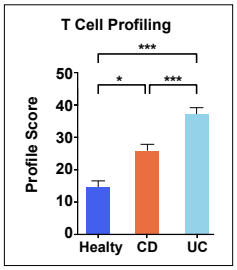
While leukopaks from patients with confirmed disease are preferred for establishing process development parameters, identifying such candidates for apheresis is exceedingly difficult.

Solution

Leukopak donors with confirmed diagnoses were recruited from Sanguine's 70,000+ patient community, in support of CAR-T development programs in two distinct autoimmune diseases (n=5 each condition).

Outcome

Access to leukopaks more closely resembling the final autologous therapy product given to patients enabled the process development team to obtain more accurate data.



adapted from: Bai (2022) *Front Immunol.*

Costumer: CA-based cell therapy company

"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

Leukopaks facilitate the isolation of rare cell types from peripheral blood

Challange

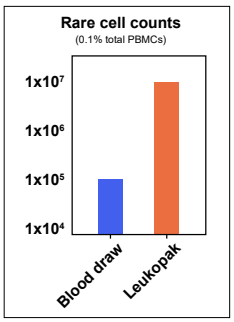
Standard blood draws from patients with chronic viral infections often fail to yield sufficient quantities of rare immune cells harboring viral genetic material.

Solution

Sanguine recruited 20 apheresis donors with confirmed chronic viral infection. Each collection safely yields ~100X more PBMCs in one sitting than a 100 mL blood draw.

Outcome

Leukopaks can more confidently provide adequate rare cells for isolation and analysis, whereas standard blood draws risk yielding inadequate material.



Costumer: UK-based biotechnology company

Search our network of 70,000+ study participants

Discuss a study design

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