



OrganaBio

Corporate Overview
July 2024

Company Overview



OrganaBio

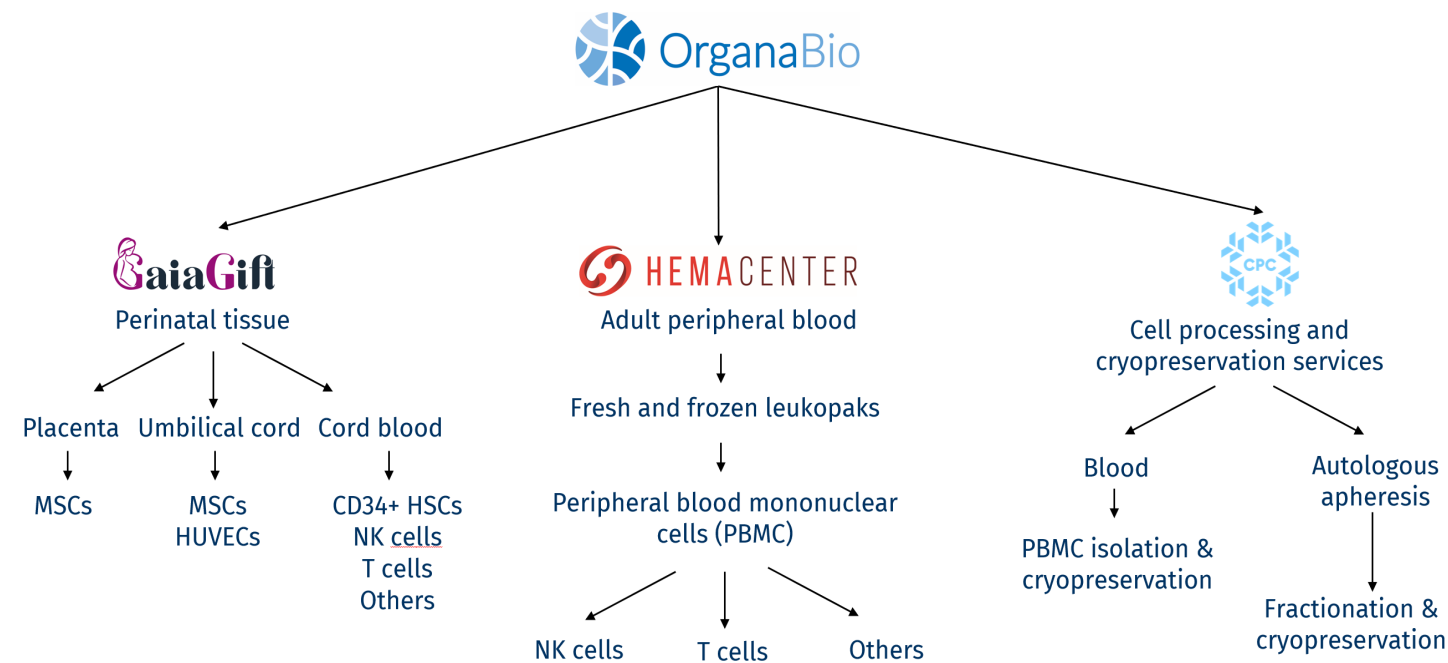
OrganaBio's Tightly Integrated Supply Chain and Cell Processing Solutions Catalyze Cell-Based Therapies for Cancer, Autoimmune Diseases, and Other Indications

MISSION

To become the hub for tissue sourcing, cell isolation, cGMP manufacturing, and clinical sample processing to accelerate cell and gene therapy development and deployment to patients around the globe.

THE COMPANY

- Founded in 2018
- Privately held
- Experienced team uniquely suited to execute plan and deliver results
- Extensive experience in regenerative medicine, tissue engineering, cell biology, cell and gene therapy, drug development and immunology
- FDA registered and inspected blood and tissue establishments

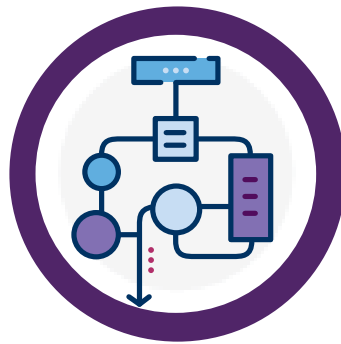


OrganaBio's Core Capabilities Span the Product Lifecycle, from Discovery to Therapeutic Application



Donor Recruitment & Tissue Collection

IRB and FDA approved donor consent, eligibility determination, and collection processes; Ethical tissue sourcing



Cell Isolation & Process Development

Rapidly progress programs from proof of concept to Phase I/II appropriate processes



Technology Transfer & cGMP Manufacturing

Manufacture, store, and distribute human cellular therapy starting materials & products for clinical development and commercialization



Quality Control: Assay Development & Analytical Testing

Develop custom assays for analytical testing of in-process and final product to determine conformation to specifications



Quality Assurance & Regulatory Affairs

Ensure process & product safety, suitability, and compliance with all regulatory standards across all business units



Product Transport & Logistics

Dedicated Project Management & operational oversight result in OTIF delivery meeting all customer specifications

All processes are governed by approved Standard Operating Procedures and Master Batch Records to ensure consistency, traceability, and suitability for use in humans

Business Verticals



OrganaBio



GaiaGift

Birth Tissues & Cord Blood



GaiaGift is committed to the mission of utilizing generously gifted birth tissue-derived products to accelerate the development of life-saving cures. By facilitating delivery of donated birth tissues to medical researchers, GaiaGift enables the discovery of new methods of treating a range of diseases like cardiovascular disease, rheumatoid arthritis, and various forms of cancer.

- FDA registered and inspected
- ~350 birth tissue collections
- 5 hospitals & 50 trained OB/GYN in South FL
- cGMP HSCs from cord blood successfully manufactured for use in clinical trials





HemaCenter

Adult Whole and Peripheral Blood



HemaCenter supplies adult whole blood- and peripheral blood-derived cellular starting materials to cell therapy developers. Each member of the HemaCenter team is driven by a personal mission to improve the human experience and condition. We have spent decades in the regenerative medicine and pharmaceutical industries as medical researchers and lab technicians.

- FDA registered and inspected
- ~600 successful leukopak collections
- cGMP fresh and frozen leukopaks successfully collected and manufactured for clinical trials





CELL PROCESSING AND CRYOPRESERVATION SERVICES

CPC Services

Cell Processing & Cryopreservation

CPC Services is a multi-center, geographically-distributed clinical sample processing hub with readily available services such as routine cell isolation from whole blood (e.g. PBMC), analytical testing of blood samples and cells, cryopreservation of donor material (e.g. autologous leukopaks), and cold storage solutions.

- Bicoastal operations (FL & CA)
- Work with 8 clinical sites in South FL to process >50% of large pharma's clinical samples
- 2,200+ samples processed with 99.9% success
- 30 minutes average from sample receipt to processing
- Average of 2.94 million PBMC isolated/mL blood with 99.1% viability



OrganaBio's GMP Manufacturing Facility

Manufacturing of Clinical Grade Cellular Starting Materials & Cryopreservation



Facility Information



Location: Miami, FL | Footprint: 19,000 sq. ft

Access and Notable Local Organizations

Airports

International: MIA (10mi.), FLL (19mi.)

Executive: Opa-Locka Exec. (4.5mi.), Miami Exec. (26mi.)

Universities + Hospitals

University of Miami, Florida International University

Cancer Centers

Cleveland Clinic, Sylvester Comprehensive, Baptist Cancer

OrganaBio's Locations

Co-located with areas of high-density for research and clinical trials, OrganaBio is readily capable of commissioning a facility with full-service capabilities within a matter of weeks to service needs within the area.

Additional Locations planned in Houston, Chicago, Detroit, Memphis, Nashville, and Atlanta to create additional capacity for therapeutic developers.



MIAMI

- Birth Tissue Collection Network
- Leukapheresis Center
- Cell Processing
- Cryopreservation
- Process Development Suites
- ISO 7 Cleanrooms for current good manufacturing practices (cGMP) Manufacturing
- QC/Analytical Testing core
- Dedicated Long-Term Storage

IRVINE

- Cell Processing
- Cryopreservation
- Dedicated Long-Term Storage



Birth Tissue Products



OrganaBio



GaiaGift Birth Tissue Sourcing

Ethical Tissue Collections that Meet the Needs of Cell-Based Therapy Development

- **FDA-registered** tissue establishment
- OrganaBio initiates and controls donor relationships
- **Ethical collections** with donor safety and well-being at the forefront
 - Fully-consented donors; IRB approved protocols
 - Follow best practices per ACOG guidelines; Delayed cord blood clamping
- Trained **OB/GYN team** under the supervision of the **Chief of Obstetrics** at Baptist Hospital
- OrganaBio team handles **IRB approvals**, physician training, donor identification, screening, qualification, and relationship maintenance

Umbilical Cord Blood Unit Parameter	Average	Range
Blood volume without anticoagulant	79 mL	50 - 145 mL
TNC count	1.1 x 10 ⁹ cells	5 x 10 ⁸ - 2.3 x 10 ⁹ cells
Viability	97.8%	95 – 100%

OrganaBio Birth Tissue Product Portfolio

Human Placenta, Umbilical Cord, and Foreskin Tissue

- Unique tissue and cell source for regenerative medicine and immunotherapy
- Ethically sourced birth tissue from healthy, full-term births
- Obtained from c-section and non-c-section births

NeoPAC™-PL

- Fresh or cryopreserved placenta tissue
- Unprocessed whole placenta
- RUO and GMP
- Custom processing available

NeoPA C-UC

- Fresh or cryopreserved cord tissue
- Unprocessed whole umbilical cord
- RUO and GMP
- Custom processing available

NeoPAC-PL-UC

- Fresh or cryopreserved placenta + cord tissue
- Unprocessed whole placenta and umbilical cord
- RUO and GMP
- Custom processing available

NeoPAC-FS

- Fresh or cryopreserved neonatal foreskin tissue
- Unprocessed whole foreskin
- RUO and GMP
- Custom processing available

OrganaBio Birth Tissue Product Portfolio

Umbilical Cord Blood Units, Cord Blood-Derived Immune Cells, and MSCs

HematoPAC™-CB



- Human umbilical cord blood from healthy, full-term births
- RUO and GMP
- Rich source of hematopoietic stem cells and immune cells

HematoPAC-HSC-CB



- CD34 positive selection
- Hematopoietic Stem Cells 100,000, 200,000, and 500,000 cryopreserved cells per vial, from a single donor
- RUO and GMP
- Custom formats available

ImmunoPAC™-T-CB



- Obtained through CD3 positive or negative selection
- 5 and 10 million cells per vial
- High CD4:CD8 ratio

ImmunoPAC-NK-CB



- Obtained through CD56 positive or negative selection
- 1 and 2.5 million cells per vial
- Immature NK cell phenotype as shown by CD56:CD16 ratio

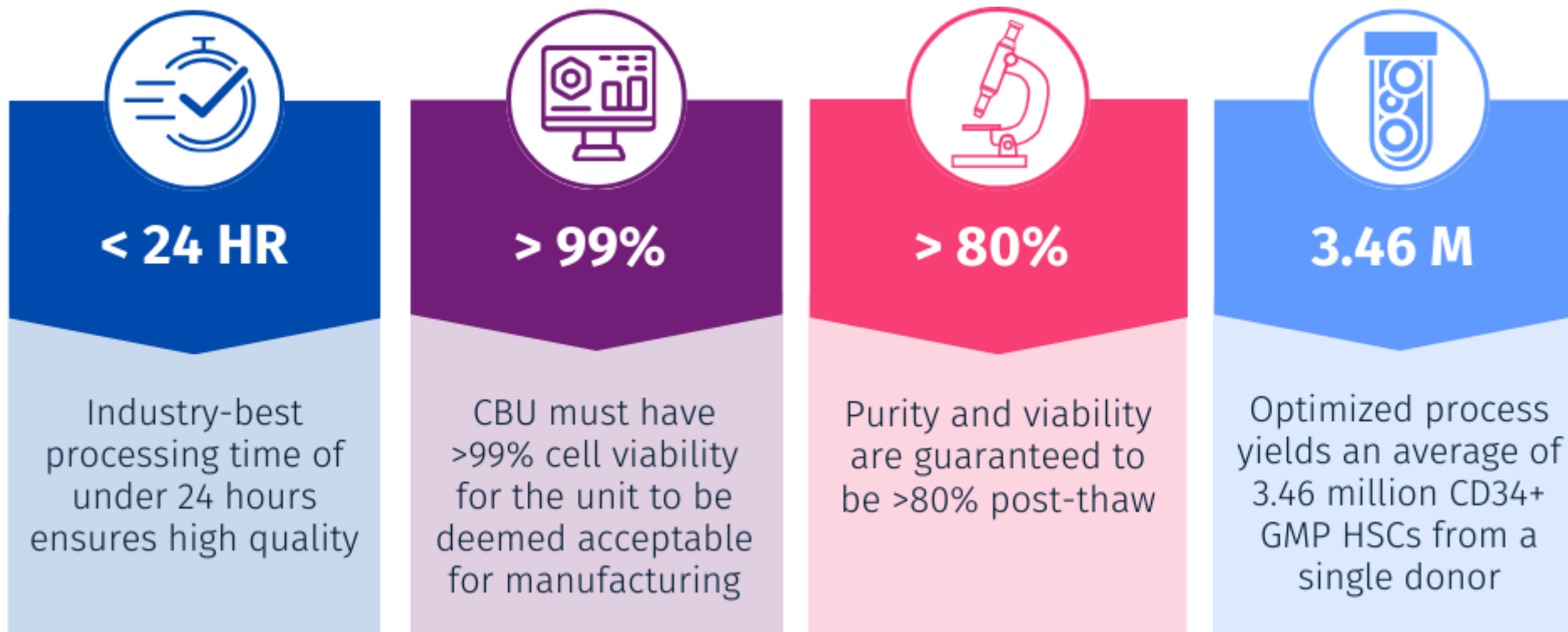
MesenPAC™-MSC



- Isolated from placenta and cord tissues
- 1 and 10 million cells/vial
- Paired with high productivity MSC media system

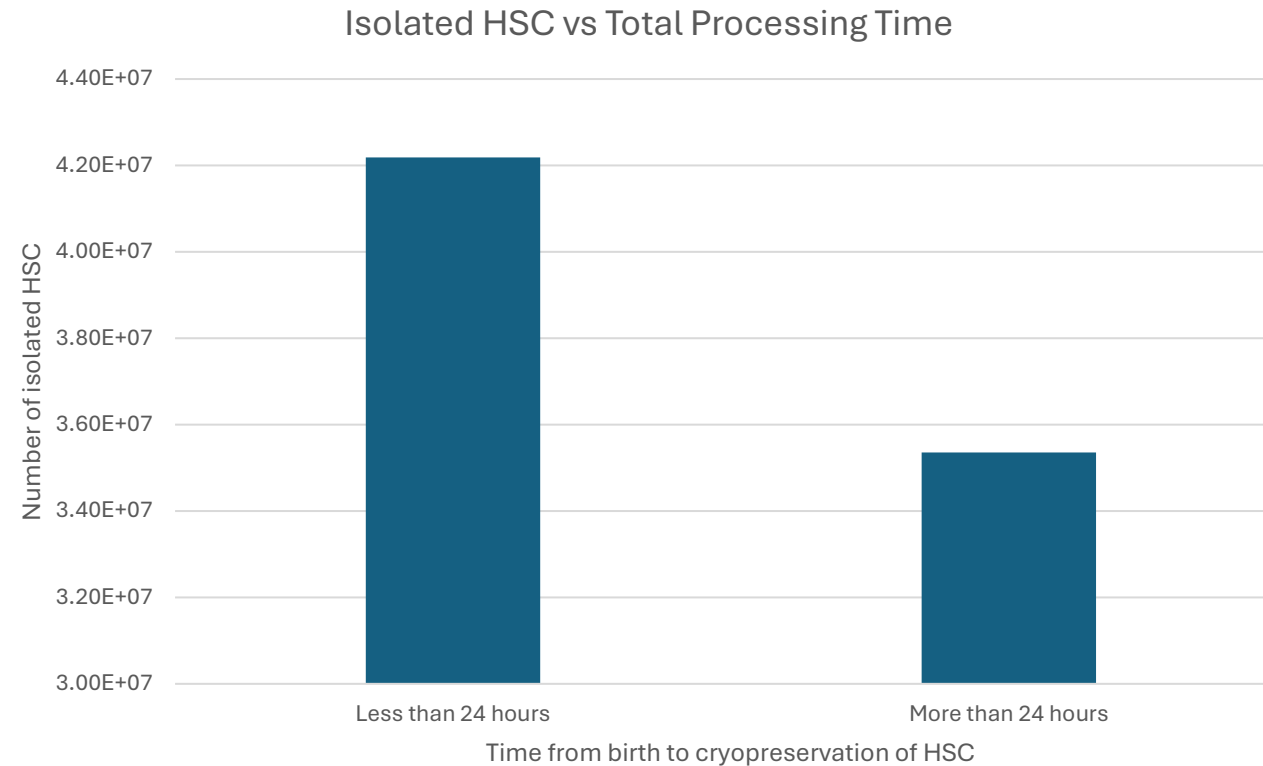
Cord Blood-derived CD34+ HSCs

The OrganaBio advantage: Processing tissues <24 hours after birth significantly impacts HSC recovery, viability, and purity



Industry Best Processing Time for GMP HSCs

HSC isolation under 24 hours yields robust CD34+ recovery



Leukapheresis Products





HemaCenter Tissue Sourcing

Robust Donor Screening Meets US FDA & EU Compliance Requirements

IRB approved screening and collection protocols

- ✓ Strict inclusion/exclusion criteria
- ✓ Informed Consent Form (ICF)
- ✓ AABB Donor History Questionnaire (DHQ)
- ✓ Reviewed and approved by our Quality Department before enrollment

Donor screening and eligibility determination prior to tissue collection

- ✓ Physical assessment
- ✓ Medical history: allergies, meds, and surgery
- ✓ In house Complete Blood Count (CBC)
- ✓ High resolution HLA genotyping (6 genes, digits)
- ✓ Example of Instruments: (Hematology equipment for blood testing)

Donor Pool Maintenance

- ✓ Punctual, prepared, follow lifestyle advice for healthy collection
- ✓ Project-specific donor reservations are available upon request
- ✓ Call donors every 8 weeks to maintain eligibility & recallability

Infectious disease marker testing and serology are in accordance with US FDA 21 CFR 1271, which exceed industry standards

- ✓ HIV 1/2 plus O
- ✓ Hepatitis B Surface Antigen
- ✓ Hepatitis B Core
- ✓ Hepatitis C Virus
- ✓ HIV/HBV/HCV NAT
- ✓ HTLV-I/II

1,000+

Qualified donors
within an ethnically
diverse and reliable
donor pool

Robust, Independent Leukapheresis Donor Pool

Enables Meeting Unique Donor Criteria and Specifications Quickly

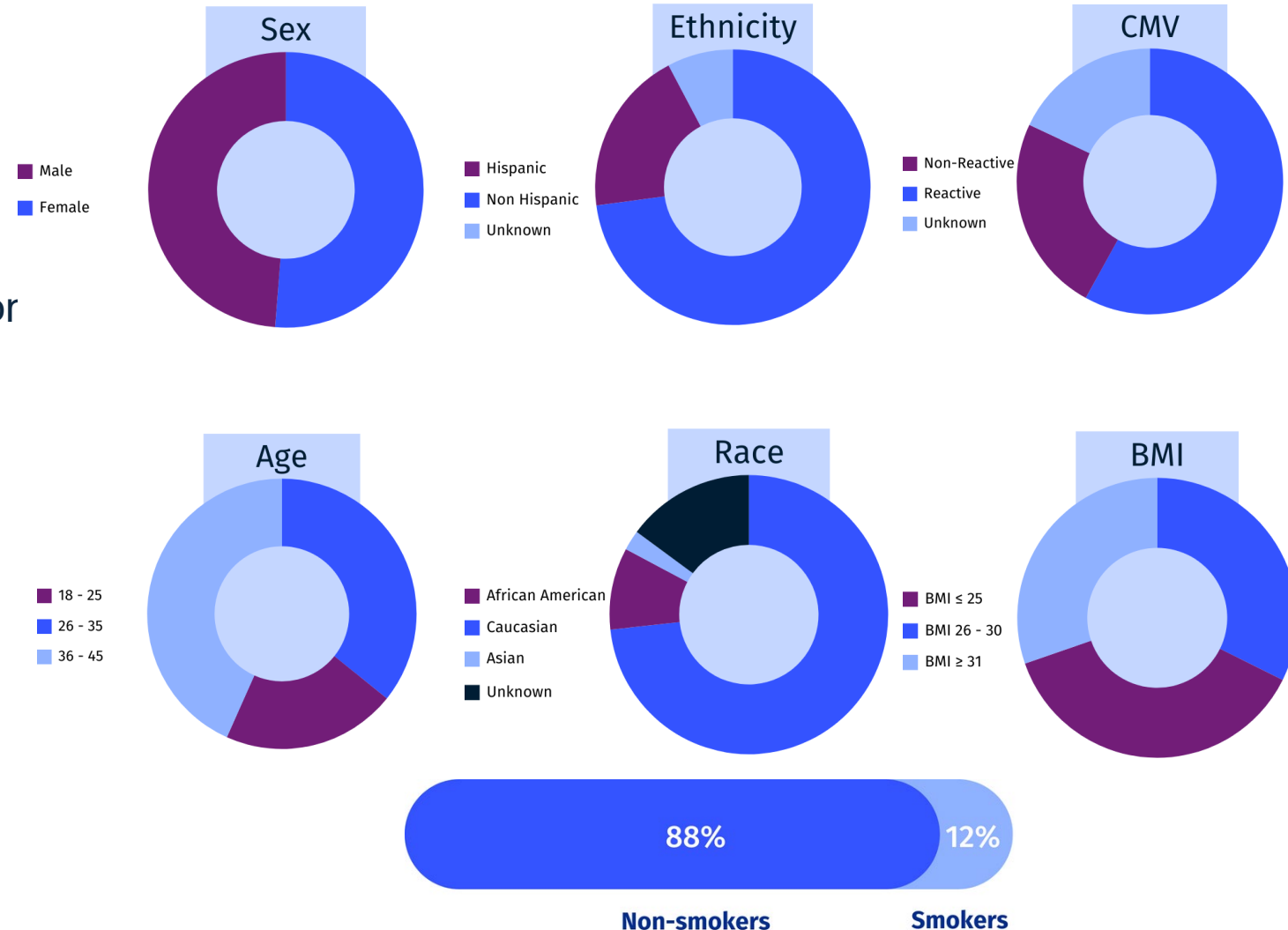


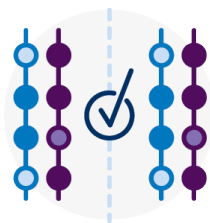
Size and diversity of pool continues to grow:

- Pre-screening new donors every week
- Ethnically diverse Florida population

Customers have access to a comprehensive donor database for identifying matches based on:

- Demographics
- Medical History
- HLA Genotype
- Immunophenotype
- CMV and EBV Status
- Smoking Status





HLA Genotype is Provided for Every Donor

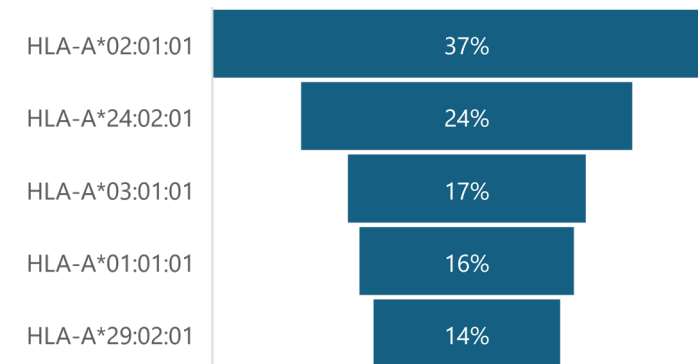
Allogeneic Cell Therapies Require Immunohistocompatibility

Homozygous donors in OrganaBio's database:

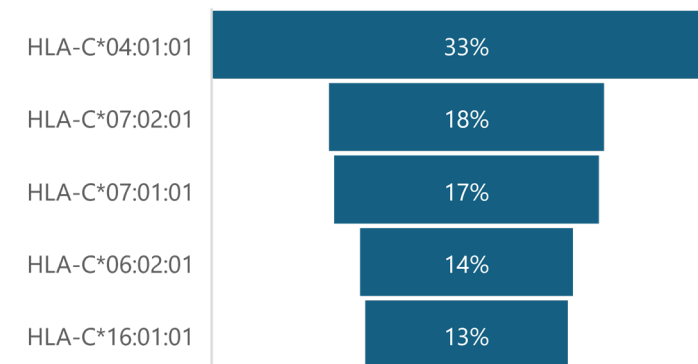
- 9.2% HLA-A
- 3% HLA-B
- 8% HLA-C
- 5% HLA-DRB1

Donor HLA Alleles	Heterozygous Donors	Homozygous Donors
HLA-A*02:01	37%	3%
HLA-B*44:03	16%	1%
HLA-C*04:01	33%	4%
HLA-DRB1*07:01	25%	2%

HLA-A Typing of Donor Pool



HLA-C Typing of Donor Pool



Collection Parameters and Targets

Processes and Procedures Follow US FDA 21 CFR 1271

Leukapheresis Procedure

- Terumo BCT Spectra Optia
- FDA-approved Continuous MNC collection protocol
- Automated Interface Management (AIM) system
- Real time monitoring by apheresis nurse

Products

- Processed within hours of collection
- Cryopreserved using BioLife Solutions Cryostor10 and a Thermo Scientific CryoMed 7452 Controlled Rate Freezer
- CBC is performed using Sysmex automated hematology analyzers (XW-100 and XN-330)

LeukoPAC™ Parameters	
	Target
Body Volume Processed*	1.5 - 2X
TNC Count	1 - 2 x 10 ¹⁰
Hematocrit	2 - 3%
Viability (pre-cryopreservation)	≥98%
*Collection parameters can be adjusted to meet customer specifications	

OrganaBio Leukapheresis Product Portfolio

Leukopaks and Leukapheresis-Derived Mononuclear Cells

LeukoPAC™-FRSH



- Fresh leukopak
- RUO and GMP
- Multiple formats available: whole, half, quarter, and custom

LeukoPAC-FRZN



- Cryopreserved leukopak
- RUO and GMP
- Multiple formats available: half, quarter, and custom

LeukoPAC-PBMC



- 10, 25, 50, and 100 million cryopreserved cells per vial, from a single donor
- Entire build of 100 million cell vials

LeukoPAC-T-PB



- Negatively isolated
- 10 and 25 million cells per vial, from a single donor
- Entire build of 25 million cell vials

LeukoPAC-NK-PB



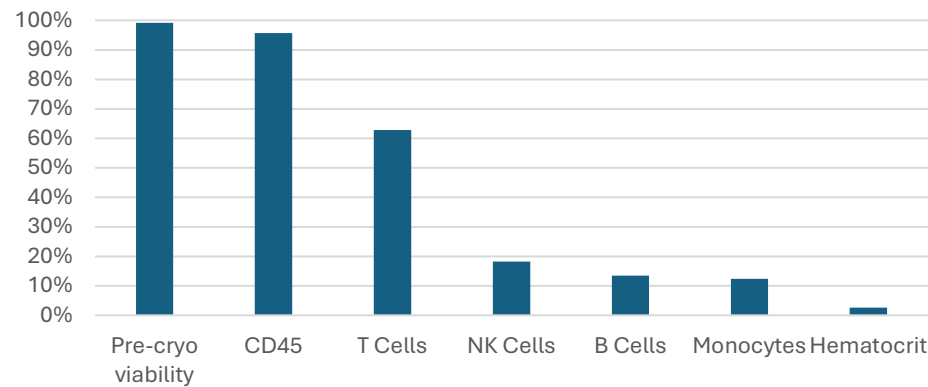
- Negatively isolated
- 5 and 10 million cells per vial, from a single donor
- Entire build of 10 million cell vials



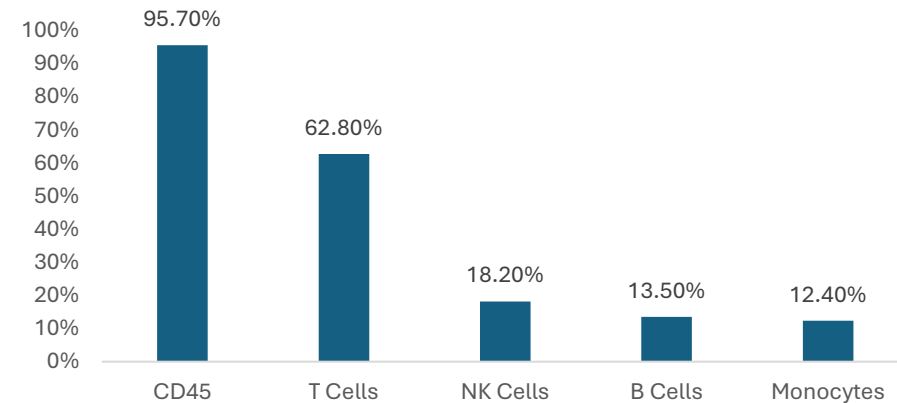
LeukoPAC™ Products with Exceptional Yield

High viability, low RBC contamination, and consistent immunophenotype

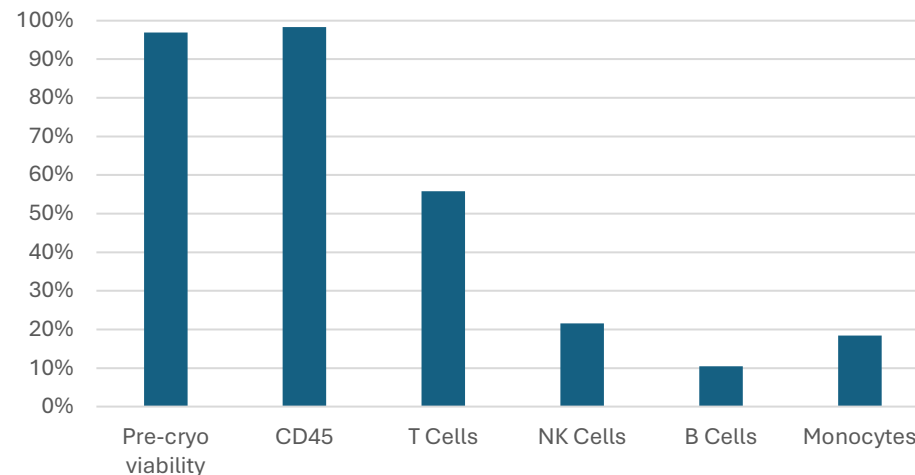
LeukoPAC™ with High Viability, Low RBC Contamination, and Consistent Immunophenotype (n=368)



LeukoPAC™ with Consistent Immunophenotype



LeukoPAC-PBMC (n=77)

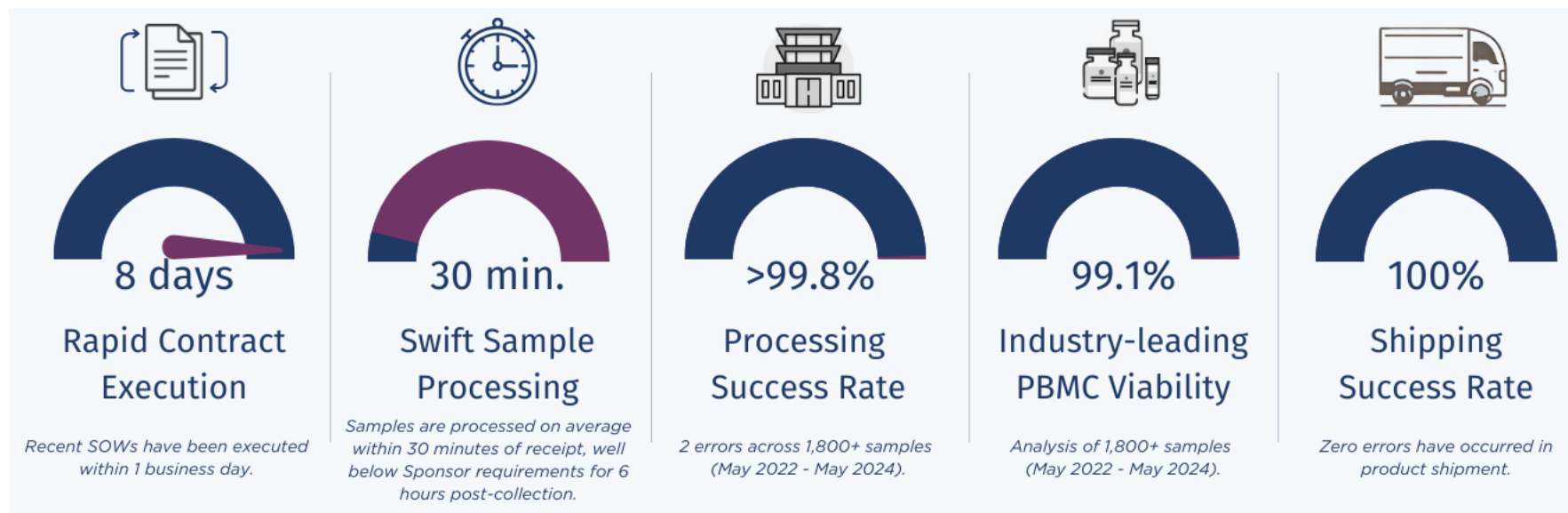


Cell Processing & Cryopreservation Services



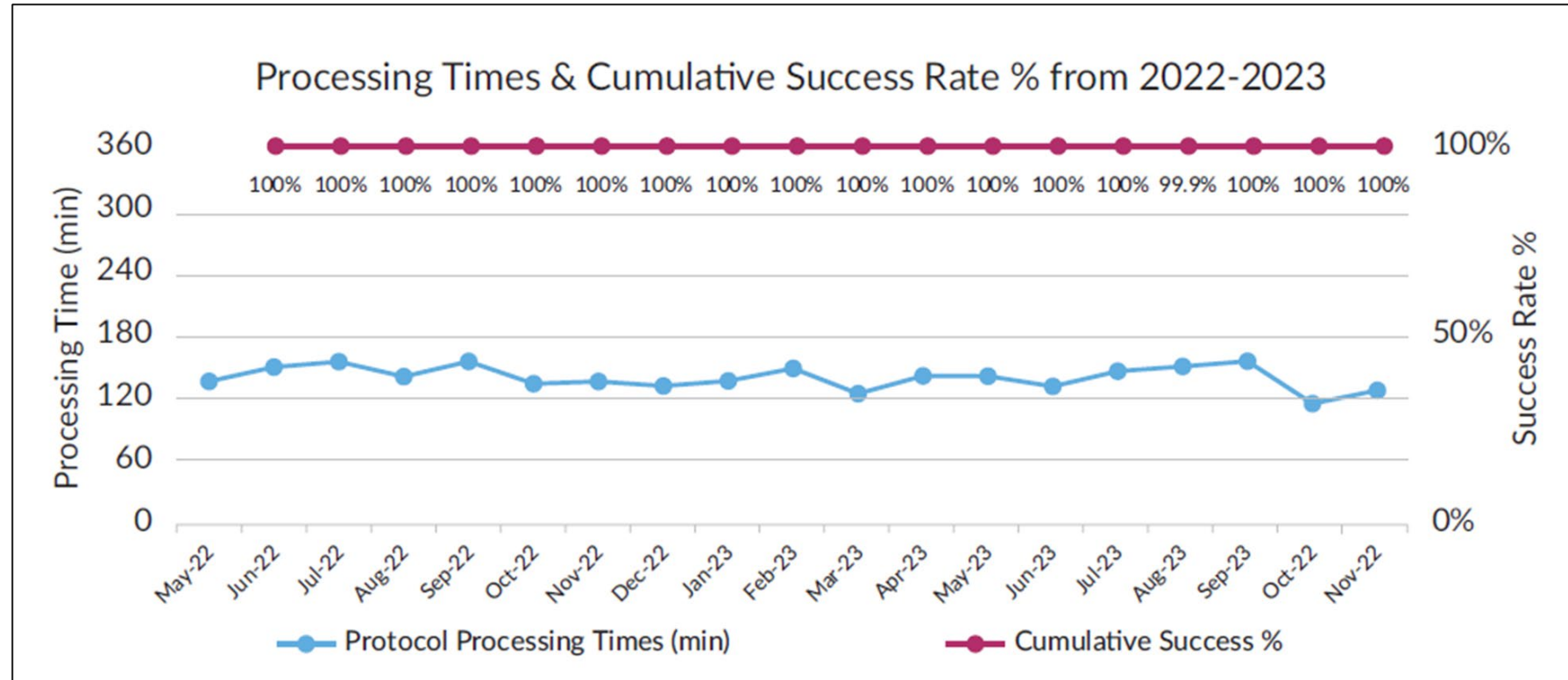
End-to-End Cell Processing At A Glance

Across all OrganaBio business units



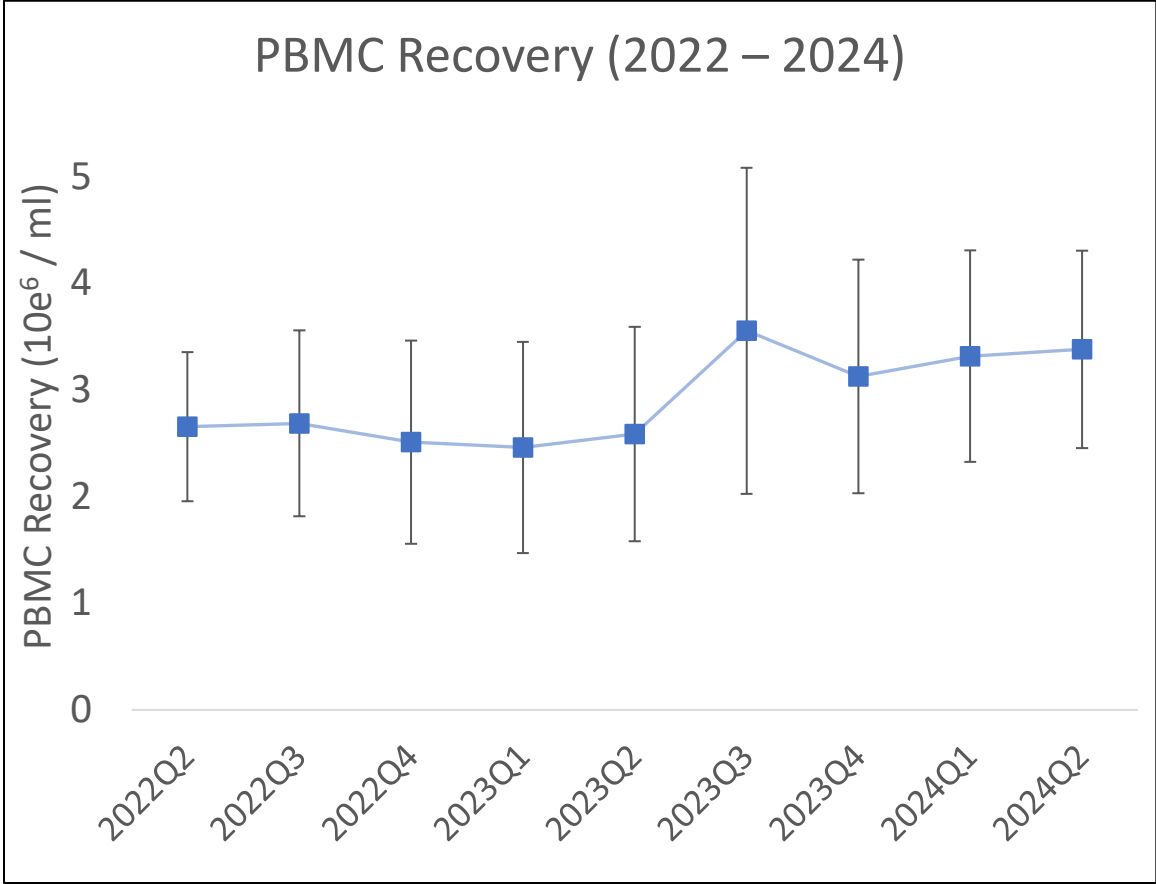
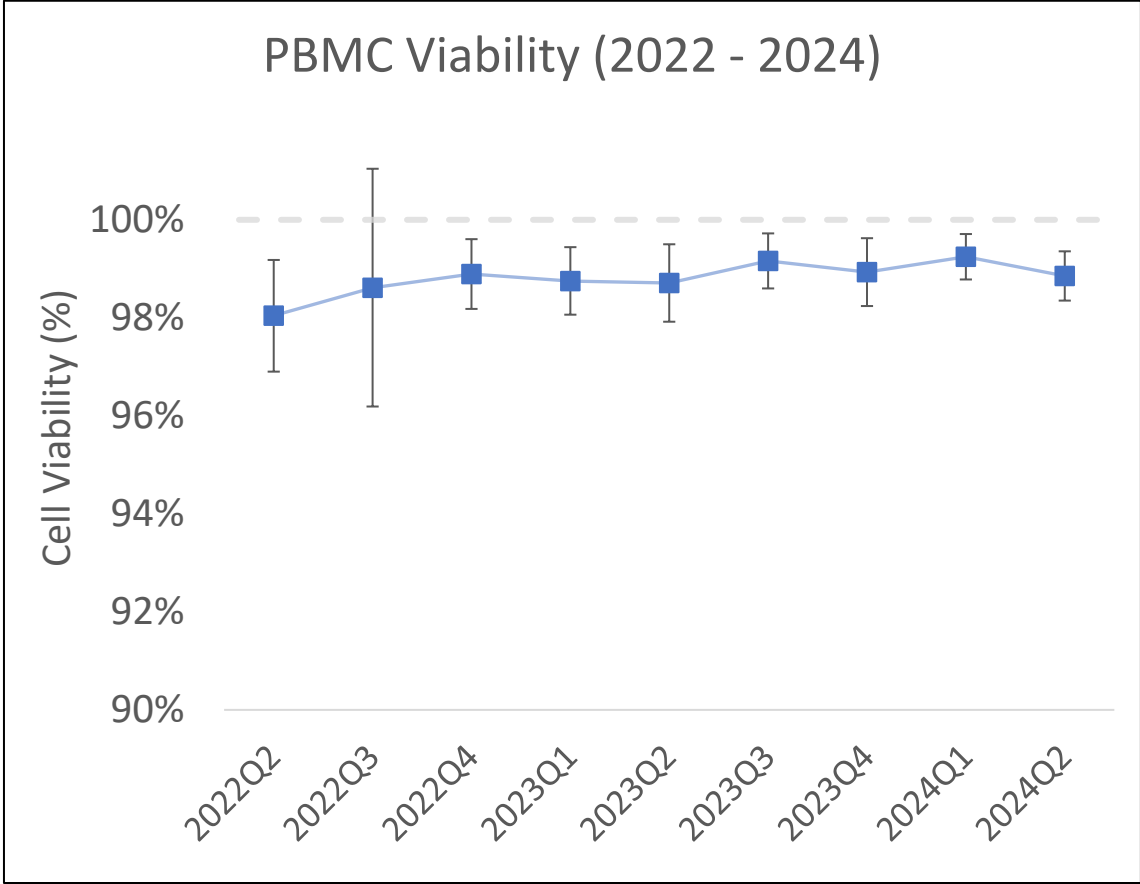
- ~2,500 PBMCs processed for small biotechs through top-5 large pharmas.
- Industry-leading viability of 99.1% (vs. competitors – Precision for Medicine: 90% viability)

PBMC Processing Times



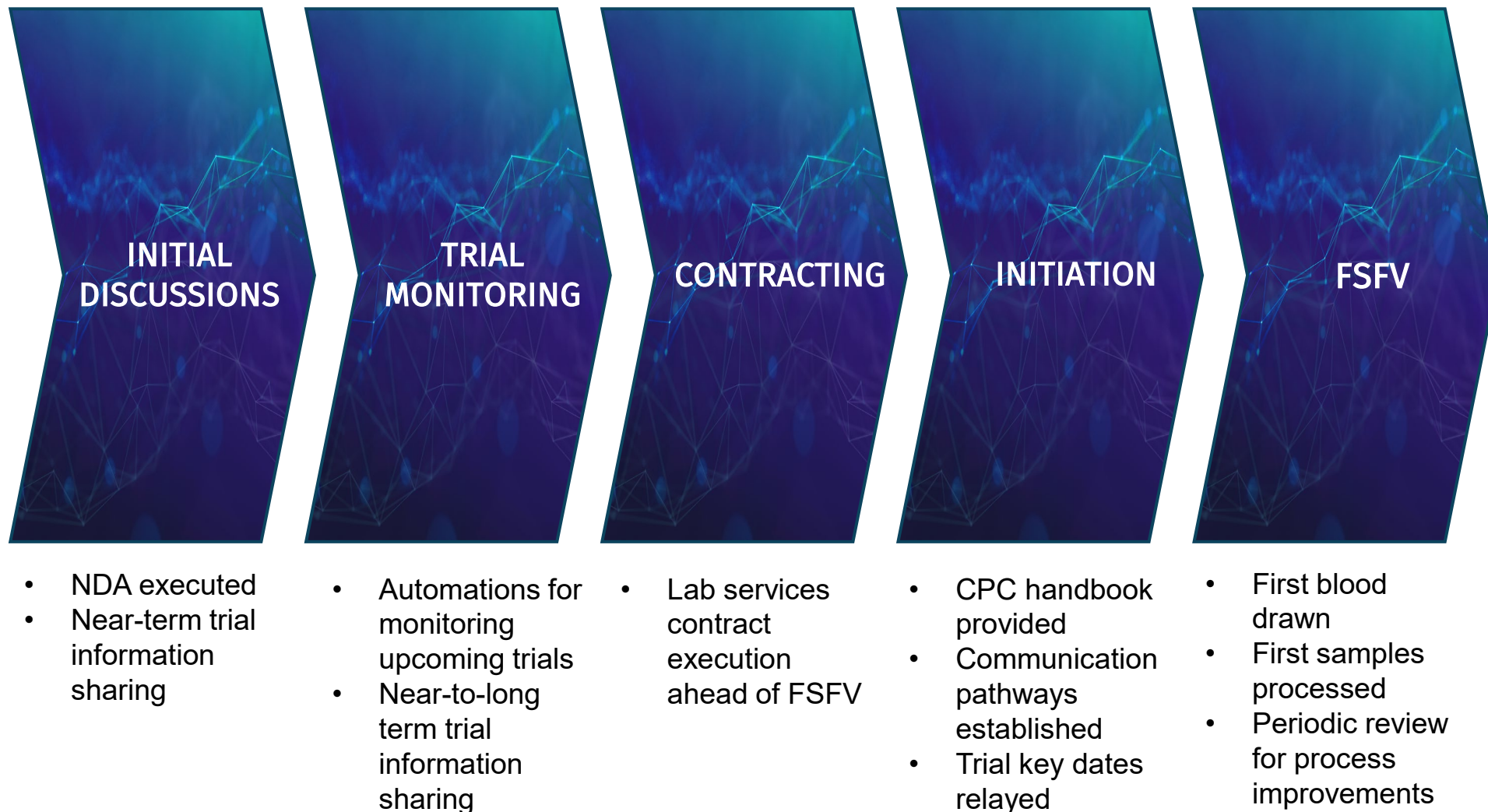
Processing time (including transit time), in minutes, correlated with success rate (as a %). OrganaBio achieved an average processing time of ~150 minutes, a nearly 50% reduction from the maximum allowable time, while maintaining a >99% success rate of the samples positively completing all processing and storage steps, per the Sponsor's QC and manufacturing requirements. (n=1,400+ from May 22 to Nov 23)

PBMC Viability and Cell Recovery Q/Q



Q/Q trends for OrganaBio’s PBMC viability and recovery. OrganaBio has achieved an exceptional average viability of over 99.1% in 2024 and tighter process control, reducing standard deviation by a factor of four since 2022 measures. This is accompanied by an industry-leading PBMC recovery of 2.93 e6/mL.

Partnership Roadmap





OrganaBio

COMMITTED TO ACCELERATING
MEDICINES OF THE FUTURE

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