



OrganaBio

CPC Services Overview
July 2024

Company Overview



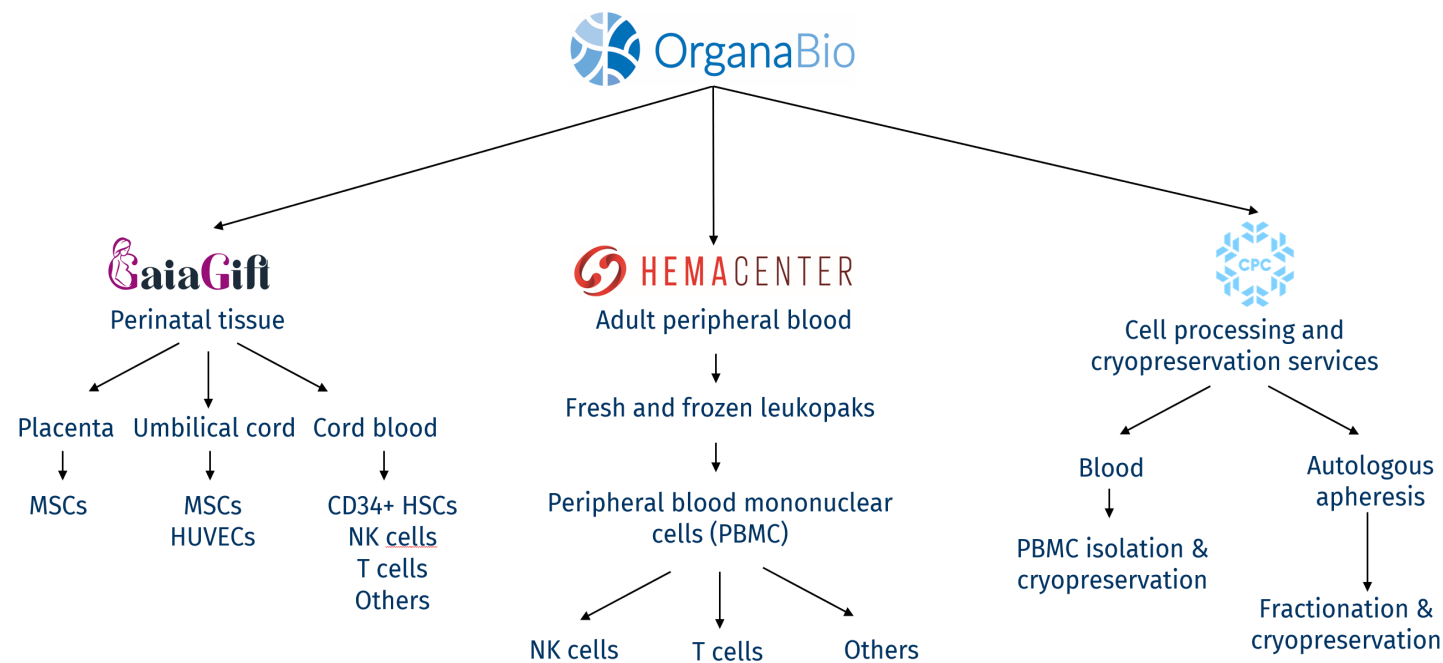
OrganaBio's Tightly Integrated Supply Chain and Cell Processing Solutions Catalyze Cell-Based Therapies for Cancer, Autoimmune Diseases, and Other Indications

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

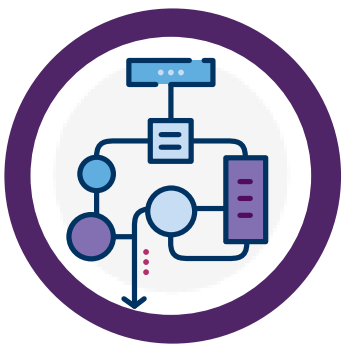


OrganaBio's Core Capabilities Span the Product Lifecycle, from Discovery to Therapeutic Application



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



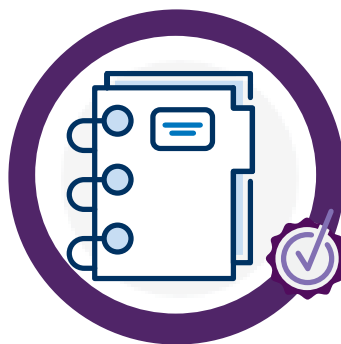
Technology Transfer & cGMP Manufacturing

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

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





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 ~10 clinical sites in South FL to process >50% of large biopharma's clinical samples
- ~2,500+ samples processed with 99.9% success
- 30 minutes average from sample receipt to processing
- Average of 2.93 million PBMC isolated/mL blood with 99.1% viability
- 0 shipping deviations



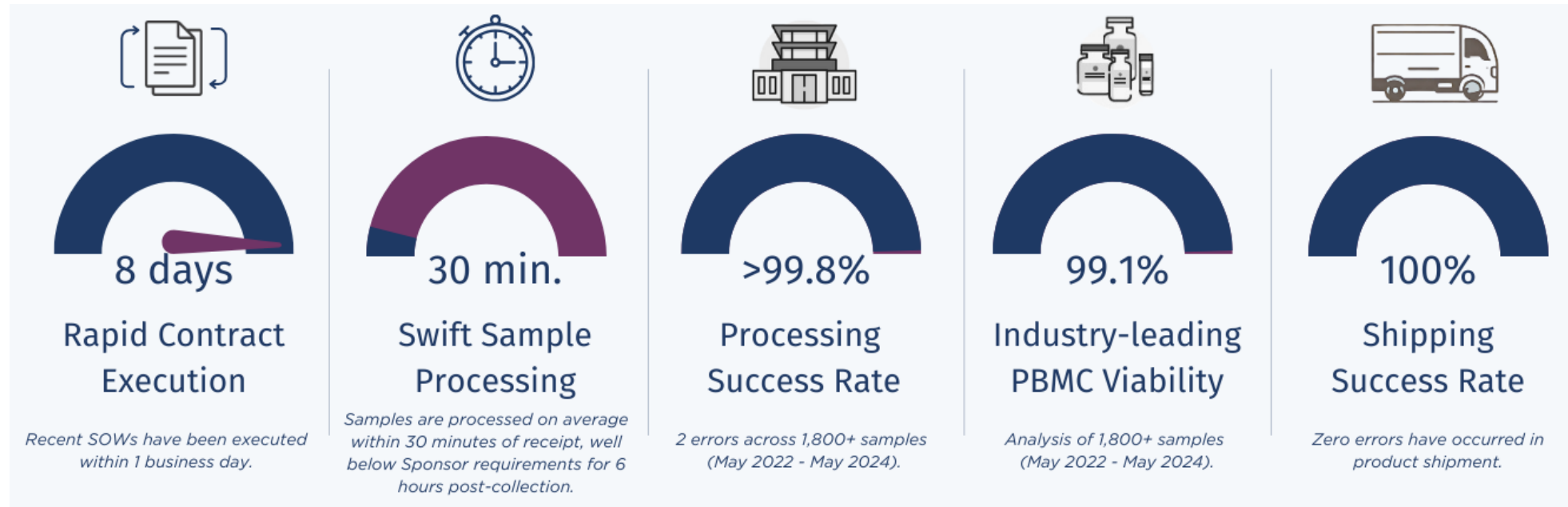
Business Performance Metrics



OrganaBio

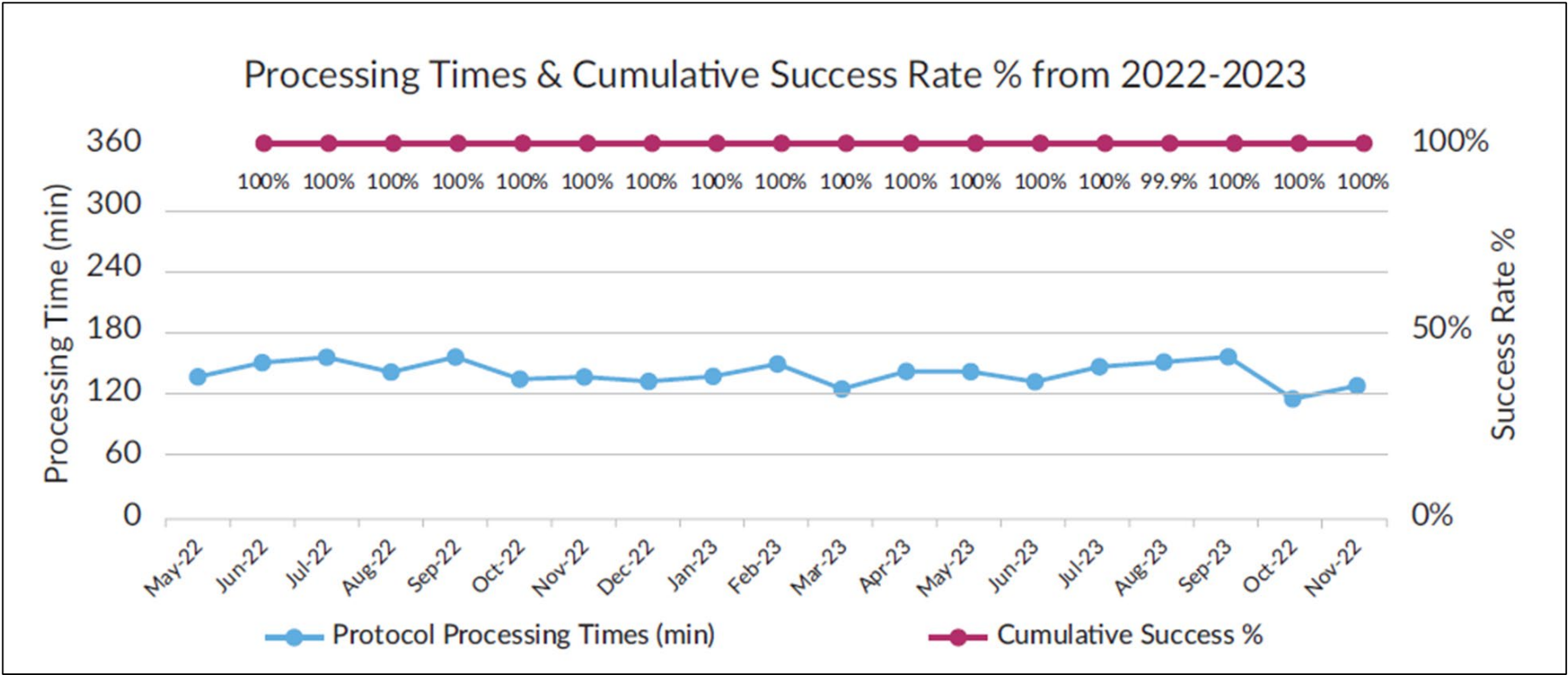
End-to-End Cell Processing At A Glance

Across all OrganaBio business units



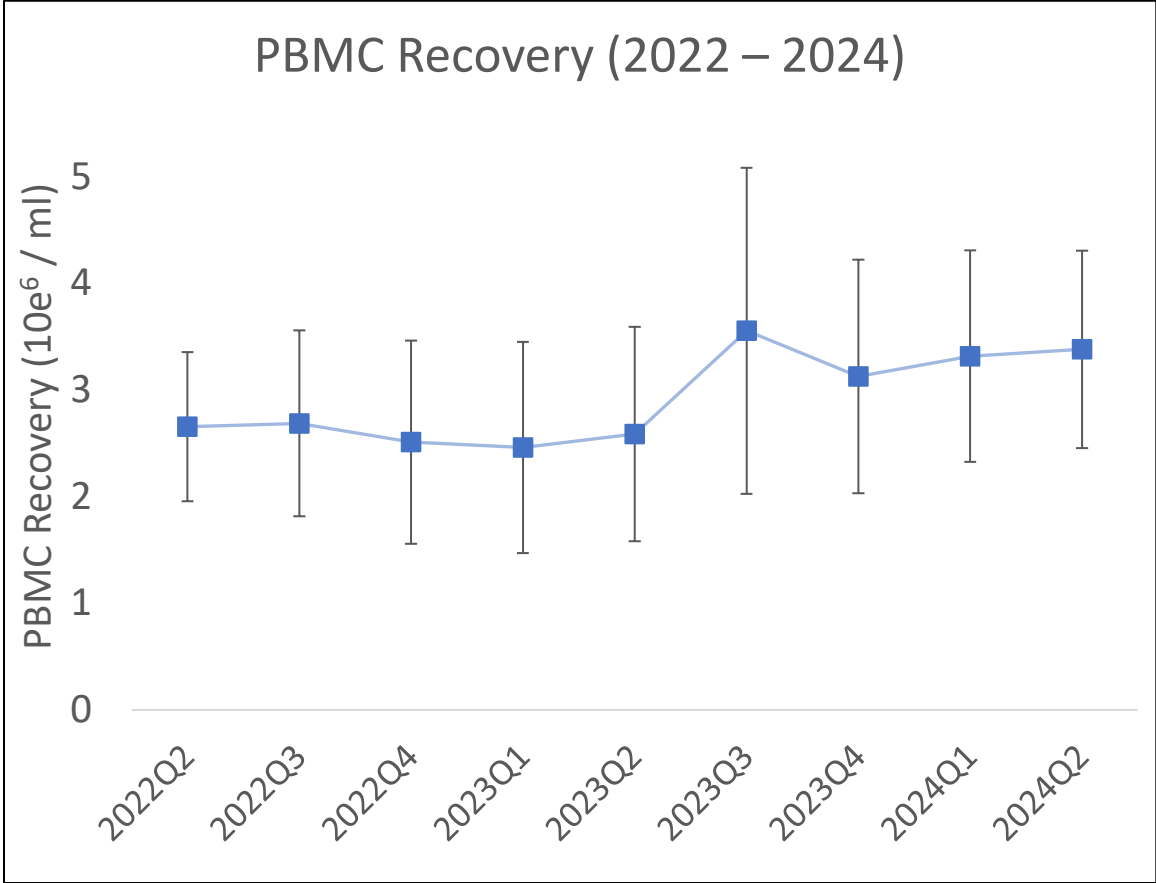
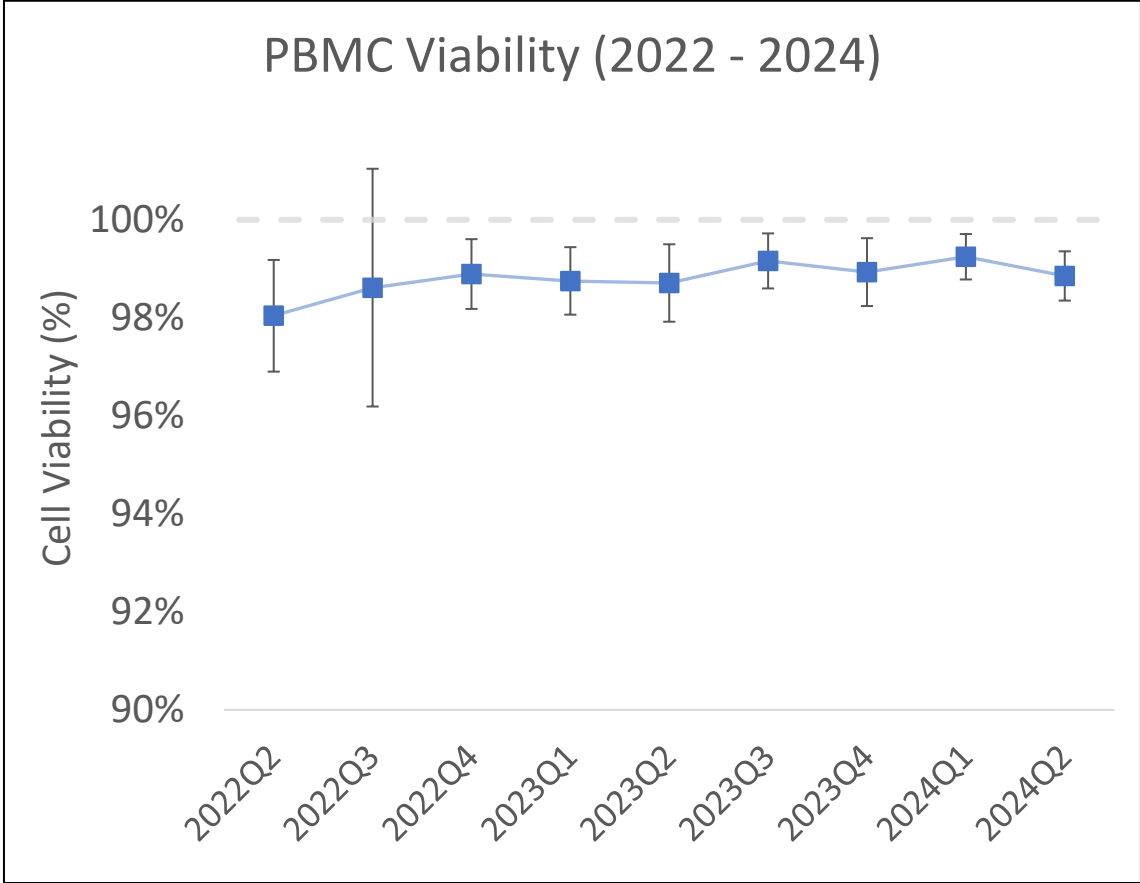
- ~2,500+ samples processed for PBMCs for small biotechs through large pharma
- Industry-leading viability of 99.1% (vs. competitors at marketed 90% and 97% viabilities)
- Rapid processing TAT of **30 minutes** vs. industry standards of 24 hours

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.*

US Processing Lab Overview

	ORGANABIO	COMPETITOR #1	COMPETITOR #2	COMPETITOR #3	COMPETITOR #4	COMPETITOR #5
Processing TAT	30 minutes	Same-day or next-day	24 hours	24 hours	24 hours	8 - 24 hours
Viability	99.1%	90.6%	97%*	Undisclosed	Undisclosed	Undisclosed
Recovery (per mL)	2.9e6	1.7e6	Undisclosed	Undisclosed	Undisclosed	Undisclosed
In-House Apheresis	Yes	Yes	No	No	No	No
US Labs	2	4	3	3	1	10**
Direct Southern FL coverage	Yes	No	No	No	No	No
Direct Southern CA coverage	Yes	No	Yes	Yes	No	No

*Competitor references a harmonized SOP vs. OrganaBio’s data on varying protocols.

**Competitor utilizes outsourced, second-hand labs. 10 may be inclusive of these labs.

Partnership Roadmap



- NDA execution
- Near-term trial information sharing

- Automations for monitoring upcoming trials
- Near-to-long term trial information sharing

- Lab services contract execution ahead of FSFV

- CPC handbook provided
- Communication pathways established
- Trial key dates relayed

- First blood drawn
- First samples processed
- Periodic review for process improvements

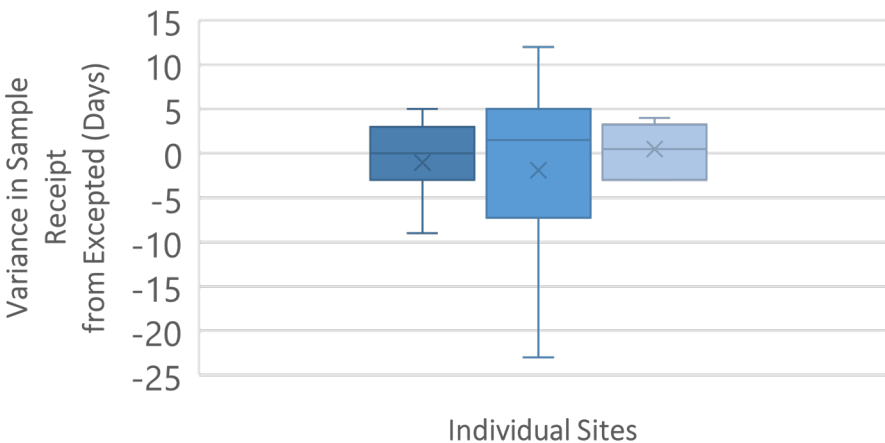
Partnership-Focused and Customer-Centric Approach

OrganaBio is focused on partnership and communication, both critical stressors for Sponsors.

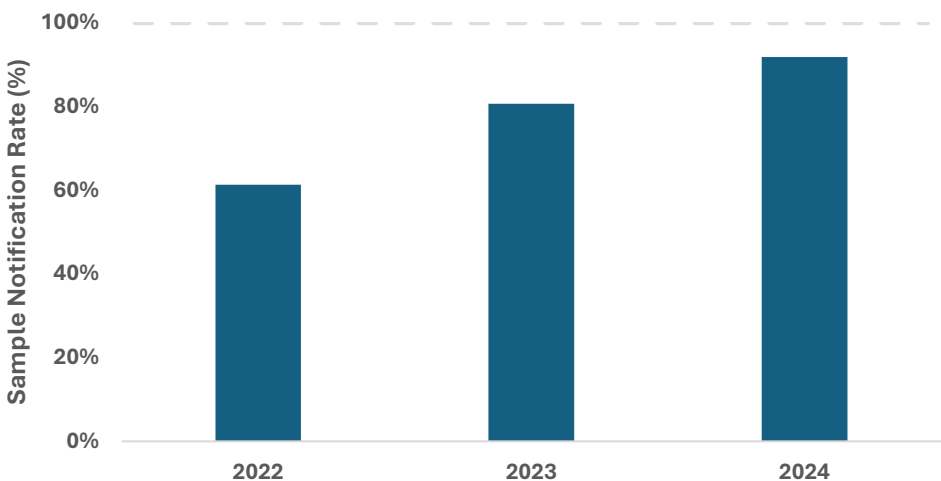
- Business Development shares upcoming trials that may be good fits for institutions
- For Sponsors with custom-fit trials, OrganaBio may lend their QA, QC, PD, Regulatory, etc., departments to aide selection
- Upon project initiation:
 - Introductions to relevant departments as needed
 - Lab flyer and manual shared containing:
 - Lab specifics (receipt cutoff time, address, etc.)
 - Communication escalation pathway
 - Additional flexible communication pathways can be explored
 - Teams chat integration
 - Text messages
 - Phone calls
 - Discussions with sites / institutions for process improvements

A +31% increase was observed in successful sample communication rate over 2 years, reaching 92% in 2024.

Clinical Site Variability for One Trial’s Final Time Points (2022 - 2023)



Clinical Site Sample Communication Rate YoY





OrganaBio

COMMITTED TO ACCELERATING
MEDICINES OF THE FUTURE

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