CELL PROCESSING & CRYOPRESERVATION SERVICES

OrganaBio

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OPTIMIZING CLINICAL RESEARCH OUTCOMES THROUGH A DISTRIBUTED CELL PROCESSING AND CRYOPRESERVATION NETWORK FOR CLINICAL SAMPLE PROCESSING

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OVERVIEW

- Sponsors conducting clinical trials require the collection of participant blood samples at specific intervals and over a rolling period, necessitating an experienced cell processing solutions provider in the regions the trials are conducted.
- CROs and clinical sites often lack the laboratory infrastructure and staff to support sample processing and cryopreservation capabilities, limiting clinical site selection for Sponsors.
- Extended transport times lead to process uncertainty, exacerbating risk for Sponsors.
- Sponsors typically de-risk their clinical trials by stringent supplier selection criteria, including:
  1. Maintain robust quality and process controls within the required processing times.
  2. Scale processing capacity to accommodate dynamic supply and demand schedules.
  3. Reduce risk via client-centric project management teams to actively manage complexities.
- OrganaBio established a novel bi-coastal Hub Processing Model - in Miami, FL and Irvine, California – to support clinical trials of two large cap, global pharmaceutical companies.

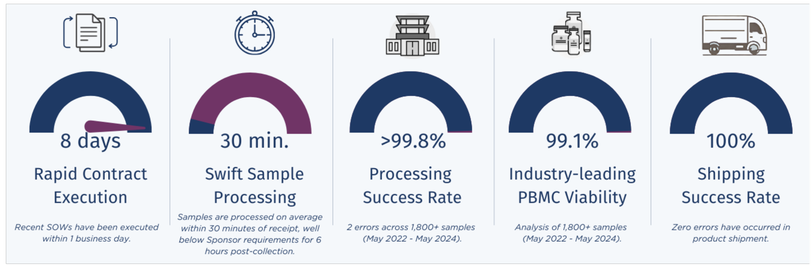

***Figure 1**: Key metrics surrounding performance since May 2022. OrganaBio's Cell Processing and Cryopreservation (CPC) Services has been able to efficiently and rapidly process samples, exceeding Sponsor requirements.*

REDUCED COMPLEXITY, LOWER COSTS, SPEED

- Co-located and integrated processing and cryopreservation capabilities reduce complexity.
- OrganaBio's cell Isolation and cryopreservation (CPC) services team collaborates closely with Sponsors, clinical sites, and couriers, optimizing clinical outcomes and the execution of time-sensitive deliverables.
- Sample batch-shipment reduces shipping costs.
- New sites (geographies) can be operationalized within 6-12 weeks, under a unified eQMS, with standardized operator training and qualifications and transfer of SOPs and protocols internally from one site to another.

COMPREHENSIVE DATA MANAGEMENT

- The OrganaBio sample database recorded process steps beyond Sponsor requirements.
- Additional databases analyzed clinical site behaviors, enabling robust forecasting plans to track participant data and efficient, real-time communication with sites, and for allocation of dedicated resources to each study.
- The additional data capture enabled tracking and trending of KPMs, assisted the quality department in reviewing any deviations or observations, and enabled automated process implementation, adding speed and efficiencies.

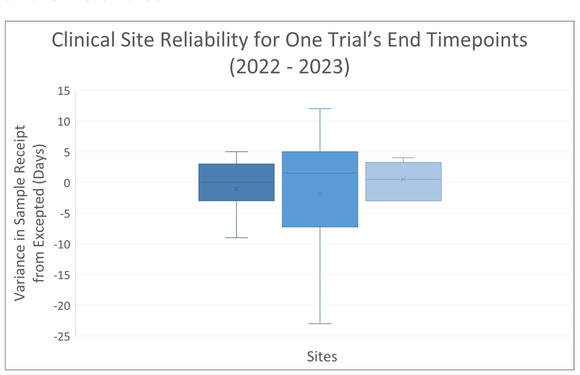

***Figure 2**: Site trends for trial end-point variance data. Upon receiving a participant's first time-point sample, an extrapolated schedule is populated and compared to actual receipt dates, for demand planning and resource allocation, enabling process efficiencies.*

NEAR FLAWLESS AND RAPID SAMPLE PROCESSING

- Over a 24-month period, nearly 2,000 samples were processed, culminating in OrganaBio being the preferred partner for one large pharma sponsor, processing >70% of clinical samples in South Florida.
- Samples were processed with >99.9% success rate (only 2/2000 experienced a processing error).
- The Sponsor's requirement for processing was set at less than six hours, or 360 minutes, post sample collection / blood draw. On average, OrganaBio's processing time was 150 minutes post-sample collection.
- SOWs for new trials were executed within a week (sometimes 24 hours) for rapid response to Sponsor needs.

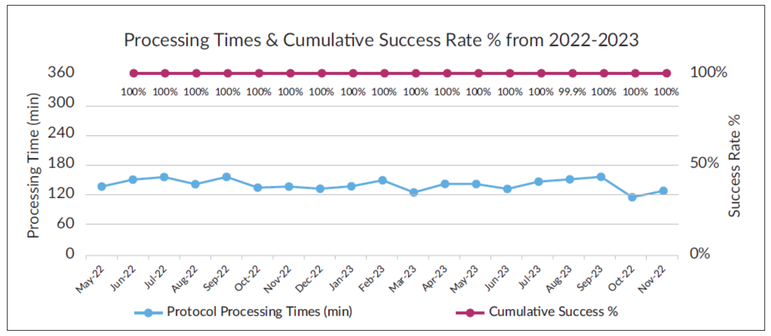

***Figure 3**: Processing time (including transit time), in minutes, correlated with success rate (as a %). OrganaBio achieved an average processing time of ~150 minutes, a nearly 50% reduction from the maximum allowable time, while maintaining a >99% success rate of the samples positively completing all processing and storage steps, per the Sponsor's QC and manufacturing requirements. (n=1,400+ from May 22 to Nov 23)*

CONSISTENTLY HIGH PBMC RECOVERY AND CELL VIABILITY

- Over a 24-month period, nearly 2,000 samples were processed with average PBMC viability of 99.1%
- PBMC yield from nearly 2,000 participant blood samples was consistent, averaging 2.93 e6 cells/ ml.

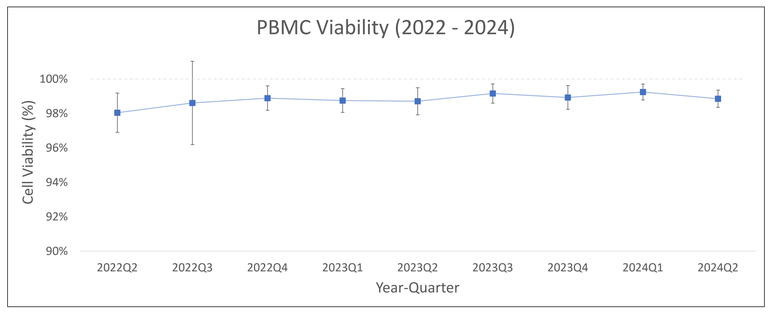

***Figure 4**: Average percent viability for PBMCs over a 25-month period. OrganaBio has achieved an exceptional average viability of over 99.1% in 2024 and tighter process control, reducing standard deviation by a factor of four since 2022 measures. (n=1,802)*

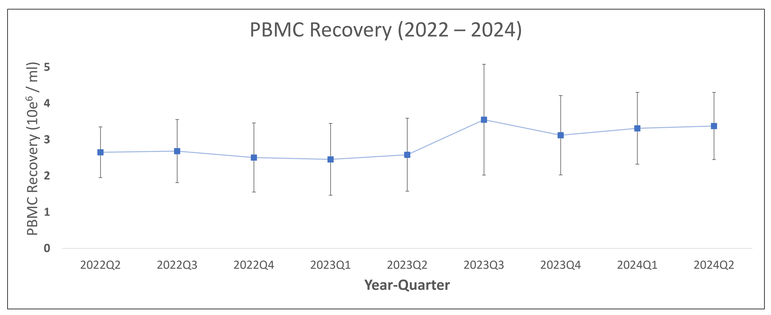

***Figure 5**: Average PBMC recovery has increased over a 25-month period. OrganaBio has achieved an industry-leading PBMC recovery of 2.93 e6 / ml. (n=1,802)*

CONCLUSIONS

- A unique and novel hub processing model performs more efficiently and faster than the required four- to six-hour sample processing window, ensuring consistency and validity of sample data.
- Bi-coastal operations allow for timely coverage across the continental United States, with expansion facilities planned for even greater geographic coverage.
- OrganaBio's CPC Services has successfully scaled processing and cryopreservation capacities to fulfill initial and growing demand to cover the lifespan of the trials.
- OrganaBio's client-centric and data-driven approach enables seamless operation and timely processing and delivery of crucial clinical trial participant samples.