OrganaBio

CASE STUDY

OrganaBio's Hub Processing Model: A Proven Solution for the Cell Processing Needs of Today and in the Future

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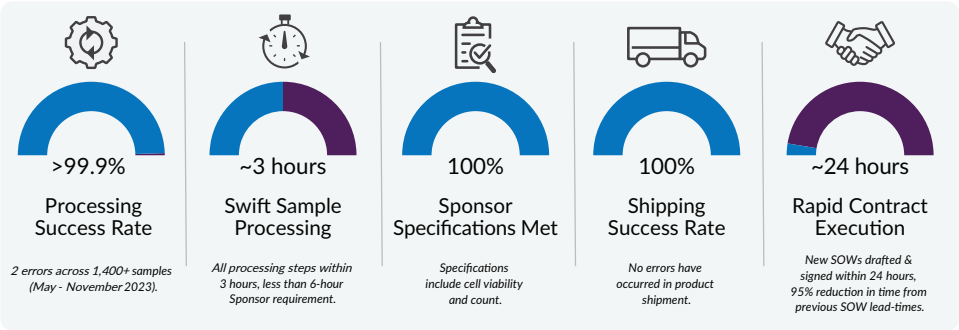
OVERVIEW

In 2022, OrganaBio forged partnerships with two prominent multinational pharmaceutical companies ("Sponsors") that were conducting multiple mRNA vaccine studies for the development of next-generation therapeutics for COVID-19, influenza, and RSV. The Sponsors were conducting their clinical trials with consenting participants from the greater Miami, Florida metro region, which necessitated the collection of participant blood samples at specific intervals and over a rolling period. The Sponsors also required extremely stringent sourcing and processing criteria, with tight timelines associated with these efforts. Given the trial requirements, the Sponsors demanded an experienced cell processing solutions provider in the region.

Sponsors initially approached contract research organizations (CROs) to perform the required function. However, CROs are not typically known to provide cell isolation and cryopreservation with efficient processes to scale up production to economies of scale, which was an additional critical point of consideration for a cell processing partner. The most important requirements from the Sponsors during their supplier selection process consisted of three main aspects: 1) Maintain stringent 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.

Examined within this case study was how OrganaBio was able to successfully utilize its unique Hub Processing Model to achieve all three critical requirements, in addition to fully realizing key time and cost-savings for the Sponsors. First, OrganaBio maintained a near-flawless processing success rate of 99.9% over 1,400+ donors' samples processed of different volumes, signifying that nearly all samples successfully met the stringent quality control requirements prior to release and shipment to the Sponsors – only 2 out of 1,400+ samples did not pass. Second, OrganaBio accomplished a sample turnaround time of less than three hours

from sample collection at clinical sites to processed, cryopreserved peripheral blood mononuclear cells (PBMCs) – this turnaround time represented a best-in-class achievement when compared to the industry standard of 24 hours and the Sponsor's requirement of six hours. Finally, OrganaBio was able to successfully integrate the Sponsor's sample requirements into its internal processing network to ensure full compatibility and tech transfer of information within the OrganaBio network, guaranteeing that all Sponsor specifications were met through the sample processing stages.



CUSTOMIZED AND EFFICIENT SERVICES

OrganaBio implemented a dedicated Project Management (PM) team to collaborate closely with Sponsors, clinical sites, and couriers, optimizing project milestones and the execution of time-sensitive deliverables. Leveraging the expertise of OrganaBio's PM and manufacturing teams in collecting and processing PBMCs, OrganaBio collaboratively developed customized workflows and standard operating procedures (SOPs) for each Sponsor and their specific clinical trials. This partnership approach includes, but is not limited to, technical transfers of complex workflows, sourcing of raw materials and trial-specific reagents, adherence to stringent sample documentation and data capture policies, and maintenance of rigorous processing timelines. Each of these aspects were meticulously designed to meet each Sponsor's unique needs. The development of bespoke SOPs, covering aspects from quality control to logistics, further accentuated OrganaBio's commitment to meeting Sponsor requirements.

Over an 18-month period, OrganaBio collected and processed over 1,400 samples for the Sponsors while maintaining a >99.9% success rate.

RAPID AND RELIABLE SAMPLE PROCESSING

Over an 18-month period, OrganaBio collected and processed over 1,400+ samples for the Sponsors, successfully achieving a >99.9% success rate through the processing stages. The processing success rate was determined by evaluating the number of samples that were successfully completed and sent to the Sponsors, divided by the total number of patient samples delivered to OrganaBio for processing. The key to this success stemmed from OrganaBio's capability to quickly begin processing each incoming sample within an average of 30 minutes of receipt of sample. This was one of the driving factors for the success rate due to the well-documented issue of sample degradation if the time between collection and processing becomes elongated. The dedicated OrganaBio PM and logistics team collaborated closely with the clinical sites, couriers, and industry-leading logistics partners to effectively manage all aspects of sample deliveries to ensure the processing team's operational readiness, further mitigating any risk of the incoming samples being damaged or delayed during the transportation process.

Across the entire portfolio of five different sample protocols, with volumes ranging from 5ml to 130ml, and samples coming from different collection sites, OrganaBio was able to achieve and maintain a nearly 50% reduction from necessary processing time, as outlined within the project requirements, and achieved an average time of

three hours from receipt to QC completion across all 1,400+ samples. While speed does not always translate to quality, OrganaBio developed an efficient, repeatable, and accurate process, all while sustaining a high-level of sample integrity and adhering to the Sponsor's requirements of less than six hours for sample processing.

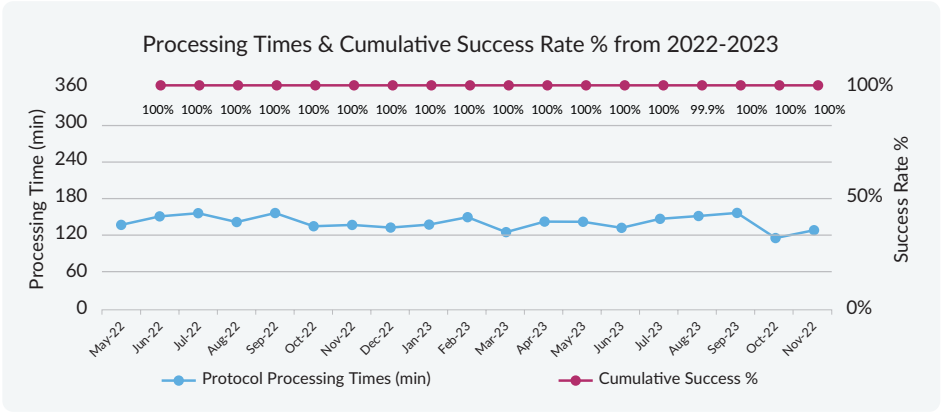
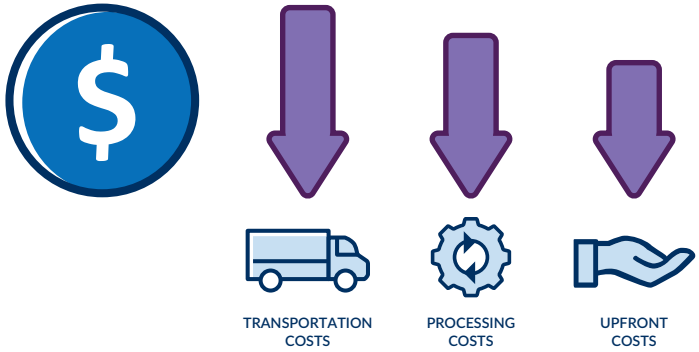


Figure 1: Processing time (including transit time) (in minutes) correlated with success rate (as a %). The Sponsor's requirement for processing was set at less than six hours, or 360 minutes, post-collection. OrganaBio achieved an average processing time of ~150 minutes, while maintaining a cumulative 99.9% success rate of the samples positively completing all steps per the Sponsor's QC and manufacturing requirements. (N = 1,400+)

ACCURATE AND ROBUST DATA MANAGEMENT

OrganaBio's robust data management involved meticulous tracking of processing time, cell yields, viability, and potential deviations/observations upon sample receipt and processing. Beyond specific Sponsor requirements, OrganaBio implemented a comprehensive, electronic database to track all sample data passing through OrganaBio's manufacturing facility. This electronic database contained not only sample data, but also real-time forecasting plans to assist in tracking participant data and site trends. Over the course of this project, this comprehensive database provided the ability for OrganaBio to be fully-confident in the quality of sample processing data, which further contributed to the timeliness and readiness at sample processing stage.

Additional information captured in these databases allows OrganaBio's PM team to track supplemental performance metrics and assist the OrganaBio quality department in quickly reviewing any deviations or observations, as well as aid with efficient communication with clinical sites. The vertical integration from collections to processing enabled the creation of a robust plan, strengthening the relationship between donor sites and the Sponsors, and enhancing the data needed for clinical study readouts.



COST ECONOMIES AND TIME SAVINGS

Leveraging OrganaBio's vertically integrated processing network provided Sponsors with three major cost efficiencies and two significant time-savings. Firstly, post-processed PBMC samples were stored on site and batch-shipped, reducing overall shipping costs

for the Sponsors. Secondly, the high-quality of OrganaBio's outgoing products translated into high-yield scenarios for the Sponsors, enabling them to spend less on processing costs. And thirdly, through the translation of the Sponsor's protocols across OrganaBio's vertically integrated manufacturing network, the Sponsor was able to reduce upfront costs and capture additional cost-savings through the initial scale-up and production processing steps.

With OrganaBio's integrated manufacturing processes, time-savings realized by the Sponsors was twofold. All cell processing steps, from the first processing step post-sample receipt to the final step of preparing the samples for shipment, were finished within an average of 150 minutes. When combined with the 30-minutes reserved for sample intake and documentation, the start-to-finish sample processing time averaged 180 minutes. This 3-hour turnaround time was significantly lower than the requirements set forth by the Sponsor. This additional time allowed OrganaBio to maintain a critical supply of samples at a high on-time delivery (OTD) schedule for the Sponsors, further streamlining the manufacturing process. The extra time buffer allowed for any delays by external couriers, shipping from the collection sites, and patient or collection site delays to be mitigated without affecting the overall processing and project timelines.

The speed at which new project SOWs are executed has decreased from a 21-day period from the initial SOW to a rapid turnaround time of ~24 hours from first draft receipt to full execution.

The second time-savings is the speed that OrganaBio has been able to execute new project SOWs with the Sponsors. Through diligently maintaining full, continuous, and equivalent processing capabilities within OrganaBio's GMP manufacturing site in Miami, Florida and at its satellite site in Irvine, California, OrganaBio has been able to ensure that all technical and scientific transfers occurred near instantaneously, regardless of client location or requirements. Coupled with the added benefit of the close partnership between OrganaBio's main business contact, Priya Baraniak, PhD, MBA, Chief Business Officer with the Sponsor's legal team to ensure alignment, the overall speed of new project SOWs, from first draft receipt to full execution, has been optimized from the initial 21-day turnaround time to an improved, rapid turnaround time of 24 hours. Once the contract has been executed, OrganaBio can begin executing and producing per project specifications within two weeks post-contract execution, attributing to the speed, execution, and wealth of expertise from its entire commercial and operations teams within its vertically integrated processing network.

CONCLUSION

OrganaBio's vertically-integrated processing hub model, supported by dedicated and trained teams, offers an efficient and cost-effective solution for processing the Sponsors' clinical trial participant samples. The integrated business model, encompassing healthy donor materials for training, robust processing, and analytical testing capabilities, provides a comprehensive one-stop shop solutionfor all cell isolation, cryopreservation, and analytical testing and QC release needs.

Through establishing and operating the hub processing model, OrganaBio has proven its excellence and experience in alleviating complexities and reducing costs associated with clinical sample analyses and cell processing. OrganaBio has plans to quickly expand upon the current network of vertically-integrated processing hubs with planned, strategic expansions into major metropolitan cities, co-located as epicenters for clinical trials, like Houston, Chicago, and Atlanta. As demonstrated within the outcome of the Sponsor cell processing project, each of OrganaBio's current hubs are fully-equipped with rapid, high-quality, low-cost solutions for cryopreservation of patient autologous apheresis material and in compliance with regulatory and certification requirements. OrganaBio plans to institute the same blueprint of manufacturing efficiency and processing excellence into each future location, offering extensive options for Sponsors and clients to process, cryopreserve, and store patient-derived materials at-scale, along with cell sourcing services for clients that require ethically sourced, high quality starting materials. Through its current and future hubs, OrganaBio remains committed to delivering results for drug developers across the US and the globe.

For consultations, please email hello@organabio.com or the contact OrganaBio's team at https://www.organabio.com/contact/.

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