

CASE STUDY:

NORMAL ISOLATED IMMUNE CELLS

Custom Sourcing for a 30 Patient, Matched Monocytes and Pan T-cells Study



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BACKGROUND:

The client in this case study is a recognized and respected researcher in the hematological oncology discovery group of a major biopharma company. The researcher has been investigating interactions of novel therapies within the microenvironments of multiple hematological malignancies.

Discovery Life Sciences has been a human biologics partner to this discovery group for over 5 years, providing diseased bone marrow and peripheral blood samples, but had not previously provided any healthy isolated immune cells. The discovery group typically sourced isolated cells from two well-known vendors, but has often had challenges with accrual timelines as well as the post-thaw quality and viability of the cells.

The name of the client and their company could not be disclosed for this case study due to the sensitive nature of their research.

REQUEST:

For this study, the researcher intended to procure matched monocytes and pan T-cells from 30 apheresis patients and then culture in-house. The cells would then be combined with a novel immuno-oncology therapy and monitored for cell death and cell activity in response to the drug. Access to these matched samples was an urgent need, and **the client was investigating many potential vendors** seeking a quick accrual of the samples.

STUDY PARAMETERS:

- 30 healthy apheresis patients
- Match sets of monocytes and pan T-cells from the same patient
 - 30 CD14+ monocytes, 20MM cells
 - 30 CD3+ pan T-cells, 20MM cells
- Quick accrual timeline





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CONSULTATION:

In early 2018, the research group reached out to multiple healthy isolated immune cell vendors, including Discovery Life Sciences, desperately trying to source samples for this project. Upon receiving this inquiry, our VP of Global Accounts and Senior Research Scientist scheduled a call with the researcher to discuss the details and challenges of their study. Our feasibility team was able to approve the project and **a quote was provided within two business days**. The initial accrual timeline estimated that the accrual would be complete within 6 weeks. The researcher was pleased to receive a quick response and excited by the accrual estimate for the matched CD14+ and CD3+ cells from the same patient. Their only reservation about starting the project was that they had not previously validated the quality of isolated immune cells from Discovery Life Sciences. Our scientific team then reviewed our quality and validation processes with them.

The researcher and their discovery team chose Discovery Life Sciences to source this project, and let us know that our proposal was selected because we had the **quickest response, shortest estimated accrual, and could provide the match samples from the same patients**. They also mentioned that the competing proposals could only provide one cell type per patient within a reasonable accrual timeframe and that sourcing patient-matched samples would require much longer accrual timelines.

CHALLENGE:

During the fulfillment of the project, the researcher began experiencing issues with the survival of the cells in culture. In particular, the monocytes, which were used as the target cell population for T cell-mediated cytotoxicity, had a very high level of background death, making interpretation of the data problematic. At the research group's request, the fulfillment was put on hold until a solution could be found. Our Senior Research Scientist, who is a trained immunologist, **conducted a consultation to optimize results** for culturing the cells.

After reviewing their protocol, he suggested modifications to the culture media and the growth factors, **which significantly aided in cell survival**. The research team was pleased with the outcome and requested that the remaining samples be fulfilled.

FULFILLMENT:

Deliveries were coordinated with the research group by the project's dedicated project manager and **no delays or logistics issues took place**. The research group did validate that the quality, purity, and viability of the Discovery Life Sciences samples did exceed the requirements for their assay and they were pleased with the samples they received. All of the matched cells from the 30 unique patients were delivered within 9 weeks of the project initiation. While the actual accrual timeline did exceed the initial estimate, this was largely due to the hold placed on the project fulfillment while a solution was sought for the cell culturing issue.



SUCCESS:

The heme discovery research group was pleased with the outcome of this project and was able to move their research forward and evaluate their therapy's impact on healthy human immune cells. Since the close of this project, many other custom projects have now been requested by members of the same research group.

This study was successful because the discovery group was:

- Provided a quick accrual timeline for a large custom study with 30 unique patients
- Delivered both monocytes and pan T-cells from the same patient in sufficient quantities. (Custom Leukopak processing and isolations)
- Assured that the cells had high quality and post-thaw cell viability
- Presented with scientific solutions for challenges in culturing the cells.
- Provided quick and clear communication throughout the project, from the initial consult through to fulfillment.



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