

CASE STUDY

Optimizing Kitting for Cell Therapy Trials in Pediatric Oncology

Introduction

In a Phase I multicenter pediatric cell therapy trial for relapsed or refractory solid tumors, the stakes were high: without viable, sterile tumor tissue collected at the right time and under the right conditions, manufacturing the autologous therapy would be impossible.

Precision for Medicine's Kitting team played a pivotal role in solving this challenge—designing and delivering custom kits that ensured sterility, compliance, and successful sample transfer to the manufacturing site.

Background & Study Overview

Therapeutic Area:

Pediatric Oncology (Solid Tumors)

Phase:

Phase I (First-in-Human)

Primary Research Goal:

Evaluate safety and tolerability of autologous TIL therapy, with secondary and exploratory endpoints assessing clinical response and immune activation.

Trial Complexity:

Dose escalation, multi-site, viable tumor resection required, short turnaround times, regulatory sensitivity due to pediatric cohort.

(Note: This study progressed to Phase II, which is mentioned in the conclusions but not detailed in this case study.)

Challenge

Unlike standard tumor collections preserved in fixatives, this study required collection of viable, sterile tumor tissue to be shipped immediately and uncompromised to a manufacturing facility for processing into a personalized cell therapy, heightening the importance of effective kitting and sample collection.

Key Issues:

- Sterile media preparation and aliquoting with antifungals and antibiotics.
- Aseptic handling of temperature-sensitive reagents.
- Ensuring sterility during both production and transit.
- Compliance with manufacturing standards and site-level collection protocols.

Precision's Kitting team played a pivotal role in solving this challenge—designing and delivering custom kits that ensured sterility, compliance, and successful sample transfer to the manufacturing site.

Impact If Unsolved:

- Without a viable tumor sample, the patient could not receive treatment—there was no second chance.
- A contaminated sample would compromise manufacturing and increase risk to patients.
- Long transit times could reduce cell viability and product potency.

Unique Constraints:

- Pediatric population = limited blood volume, heightened sensitivity.
- Tumor resections occurred only once.
- Strict sterility and temperature control required for reagents.

Solution

Precision for Medicine implemented a precision kitting approach that combined custom media preparation, aseptic technique, and real-time logistics oversight:

Sterile Media Aliquoting:

Precision for Medicine compounded sterile reagents with antifungal/antibiotic components and aliquoted them under laminar flow conditions.

Aseptic Handling with Human Oversight:

Trained personnel with validated aseptic technique ensured compliance and batch consistency.

Inventory Management & Sample Tracking:

Automated systems tracked kit inventory, expiration dates, and transit milestones.

Co-Located Regulatory Support:

Kitting was performed within an ISO13485/15189 CAP/CLIA lab environment, ensuring strong QMS alignment.

Real-Time Shipment Coordination:

Teams coordinated same-day or next-day shipments, using time-sensitive tracking for viable tissue delivery

Results and Key Outcomes

- **Rigorous Compliance & Quality Assurance**

All kit components used in this trial were managed according to GLP guidelines, and every assembled kit underwent a thorough QC process. As a result, no errors were recorded in kit component configuration or kit type delivery throughout the duration of the study.

- **Reduction in Site-Level Errors**

By providing custom-labeled, pre-prepared kit components tailored to the protocol's specific needs, Precision for Medicine significantly reduced prep time and minimized opportunities for error at the clinical sites—ensuring kits were ready for immediate use upon arrival.

- **Reliable, Temperature-Controlled Delivery**

Precision's logistics team successfully delivered a range of kit types—including ambient, refrigerated, and frozen kits—using controlled packaging methods to maintain the required conditions. All kits arrived at the correct temperature and on schedule, streamlining the site experience and supporting sample viability.

- **Regulatory Alignment with Zero Deviations**

Across all kitting activities related to this study, no deviations were cited under any regulatory or ethical guidelines, reinforcing the strength of Precision for Medicine's internal quality systems and operational excellence in high-stakes pediatric research settings.

Key Takeaways and Lessons Learned

Early kitting involvement prevents catastrophic failure:

This trial had no room for error, and Precision for Medicine's early planning avoided logistical pitfalls.

Custom sterile media prep is rare in CRO settings:

Precision for Medicine filled a gap few providers could manage.

Automation + Human Expertise = Advantage:

Precision for Medicine's inventory and tracking systems paired with trained hands-on staff created a scalable, reliable solution.

Non-Standard Requests Are a Strength, Not a Deterrent:

Precision for Medicine's flexibility to meet custom needs built client trust and ensured trial success.

Kitting as a Manufacturing Enabler:

This wasn't just assay prep; the kits made treatment possible.

Conclusion

Precision for Medicine's ability to deliver sterile, compliant, customized kits for a complex pediatric cell therapy trial demonstrates why precision kitting is mission-critical to trial success.

While this case study focuses on Phase I, the success of this approach contributed to the trial's progression into Phase II, expanding its impact further.



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