PRECISION for medicine

CASE STUDY

Process and communication: navigating logistical complexity in matched cellular therapy trials

Situation

Autologous and other matched cellular therapies hold tremendous promise for oncology and other indications, yet the development of these transformational personalized investigational products can be operationally and logistically complex. They may require collecting a range of samples from each patient, shipping those samples to a manufacturing facility for analysis and as raw material for investigational product manufacturing, creating a patient-specific product, and then shipping that product back to the investigative site for administration. An issue during any of these 4 steps creates a ripple effect that can impact outcomes not only for the individual patient, but for the entire study. Sponsors count on Precision to avoid such issues.

Challenges

Sponsors of cellular therapy trials face enormous complexities coordinating site and manufacturing schedules and standards. The challenges are multifold:

- **Multiple samples with unique collection requirements:** Each patient may need to provide varied specimens to serve as raw material for the manufacturing process: tumor tissue, whole blood, apheresis, saliva, and others
- **Pressure to coordinate collection timing:** Sites need to schedule all collections within specific and potentially short timeframes to allow the manufacturing process to begin. In some instances, collection must occur before new or additional anticancer therapies can be administered, placing patient outcomes at risk. In all instances, collections must be coordinated with manufacturing capacity and slot availability
- **Disparity among each site's institutional standard practices and procedures:** Typically, each site across a study has unique processes for collection, scheduling, and communications, causing logistical challenges for the sponsor and potential issues with raw materials for manufacturing. This can be particularly problematic when techniques for raw material collection, such as PBMC processing, apheresis, tumor tissue, etc, vary from site to site
- **Workload pressure on individual sites:** Individual sites can become overwhelmed with the demands of cellular therapy studies. To ensure proper adherence and quality for critical processes such as collection, labeling, shipping, and preparation of investigational product, it is best if the study-specific processes allow sites to follow their standard process as much as possible

"Each site has specific internal processes related to cellular therapy management that can be quite complex and nuanced. Ensuring that both site personnel and department processes are cohesive and able to accommodate the protocol-specific requirements is key to successful study execution."

– Megan Liles, Executive Director, Operational Strategy and Feasibility

Solutions

Clear and consistent communication among the sponsor, sites, manufacturing facilities, and your CRO partner is a key factor for success. A well-defined plan drives critical operational processes and serves to mitigate risks. These critical operational considerations include:

- **Selection confirmation:** We begin each engagement by discussing a site's internal standard processes and the sponsor's specific protocol requirements. With this, we can establish the suitability of the site, as well as the feasibility of the study's raw material collection, processing, and shipment requirements
- **Customized manufacturing methods:** We work with sponsors to identify areas of manufacturing specification and modification to enhance site collection and shipment success
- **Site operations database:** We gather a detailed understanding of operational norms and key success factors for each site. Examples include apheresis algorithms, cellular product thaw protocols, etc
- **Clear timeframes:** We develop patient (and donor, as applicable) timelines from consent to infusion to facilitate site and manufacturing availability to accommodate key procedures
- **Chain of custody forms:** We gain written consensus on which party is responsible for every step of the process within the site, where and how it happens, and related communications, creating an agreed-to workflow and paperwork trail
- **Chain of communication:** Through phone call and email communication we track every step from sample collection through treatment infusion

Results

By clearly aligning both procedures and expectations, we have been able to streamline sample collection and processing, as well as help sponsors and sites mitigate any issues. We develop patient (and donor, as applicable) timelines from consent to infusion to facilitate site and manufacturing availability to accommodate key procedures.

"By understanding these nuances at the site we can help troubleshoot potential issues. Ultimately, this allows for a higher likelihood of successful raw material collection, proper processing, and timely shipping, which in turn increases the likelihood of better raw materials for manufacturing."

– Megan Liles, Executive Director, Operational Strategy and Feasibility

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