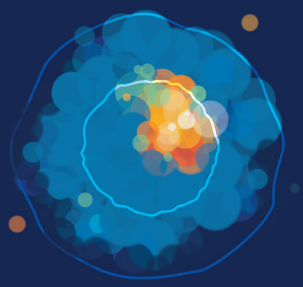
Case Study:

OPERATIONAL STRATEGIES FOR SUCCESS IN CELL THERAPY CLINICAL DEVELOPMENT



A study of intraperitoneally administered allogenic cell therapy in patients with adenocarcinoma

35 PATIENTS

SERVICES PROVIDED

- Clinical Management
- Clinical Monitoring
- Data Management
- Pharmacovigilance
- Biostatistics
- Medical Writing

CHALLENGES

- Cell therapy is not common in the indication and so clinical sites with access to the patient population did not necessarily have established relationships between patient care teams and other groups critical to operational execution, such as the Cell Therapy Lab.
- The handling, preparation, and administration of the investigational cell therapy was complex and outside the standard of care procedures in the indication.
- The just-in-time cell therapy manufacturing approach coupled with a short window between manufacturing completion and expiration of the investigational therapy required detailed coordination of screening and enrollment procedures with manufacturing schedules.

CRITICAL CONSTRAINTS

- The investigational cell therapy product is ready for shipment under quarantine on Monday morning
- The testing results required to release the cell therapy from quarantine are available on Wednesday evening
- The therapy must be administered by end of day Friday otherwise the therapy expires
- The Cell Therapy Lab at some clinical sites cannot accept the therapy until it is released from quarantine

THE SOLUTIONS

- Detailed, 3-part training for clinical sites with Sponsor experts
    1) Didactic training and review of the Cell Therapy Manual
    2) Mock shipment of investigational therapy from manufacturer to site and IRT actions
    3) Mock preparation and administration of investigational therapy
- Support of sites from Medpace Clinical Operations and Medical groups, as well as Sponsor Medical group, in establishment of critical relationships and practices at clinical sites necessary for operational execution of cell therapy handling and administration
- Establishment of detailed, study-specific process led and executed by Medpace for:
    - Assignment of enrollment slots
    - Support of sites during potential subject identification and scheduling of screening procedures
    - Management of scheduling and logistics for investigational therapy transport, including troubleshooting

SUCCESSES

- Cell therapy administration to 9 patients with no logistical issues
- Complementary feedback from sites on training, especially the hands-on portions (parts 2 and 3 above)

GENERAL LESSONS LEARNED

- Robust training for sites led by investigational therapy experts is necessary when handling, preparation, and administration of the therapy is outside the care team's typical scope
- Hands-on, mock shipments and administrations cement learnings from didactic training and mitigate risk of pitfalls during subject enrollment and treatment
- When successful operational execution requires close coordination of schedules and logistics across stakeholders, it is imperative to designate a team member and a substantial portion of that team member's time to acting as a central point of contact for stakeholders and to overseeing the entirety of the process