GETTING AHEAD FROM BEING BEHIND:

Collaboration on a Rescue for a Complicated Oncology Program

BACKGROUND

A small privately-held biotech with limited internal resources had contracted with a CRO to conduct its Phase III oncology study for an autologous immunotherapy. Based upon the logistics involved in executing the study and developing and distributing an autologous, complex investigational product to sites and study subjects, the Sponsor required a CRO that had global oncology experience, excellent project management, and solid site relationships. The CRO was selected primarily because of cost and the promise of an integrated, customizable technology platform that would help manage the complex logistics of the trials (collecting, storing, shipping and tracking tumor cells and individual doses for personalized medicine). The study got off to a slow start with the initial CRO, primarily due to the following:

- Lack of global phase III oncology study execution experience, coupled with this study's complexity
- Lack of startup team to lead the initial project phase
- CRO staffing issues including turnover of three lead Project Managers within 12 months of contract and study startup, and the CRO used only contract CRAs
- The integrated system to support CTMS, DM, IVRS had to be built from scratch and customized to the study's needs

BEING BEHIND

Twelve months into the study, there were no active sites, and only 37 out of 120 qualified sites. This included eight months of preliminary start-up and four months of active startup and study implementation.

> ***"After 12 months, we were behind and we knew we needed a different set of resources."***

Given this suboptimal start, the Sponsor had to make the decision to search for and select another CRO who could get the project back on track. After another round of CRO evaluations, Medpace was selected to rescue this study and get it back on track for the following key reasons:

- Experienced in global oncology Phase III studies
- Centralized model for startup, project management, data management
- Proven, highly customizable ClinTrak® technology - CTMS/IVRS/EDC
- Dedicated CTMs, CRAs, regulatory, and start-up team including project management, regulatory, and legal from the outset
- Single-minded dedication to activate 50 sites to ensure accrual began within four months of transition
- Flexible approach to meet evolving needs after study startup and initiation

GETTING AHEAD

After being awarded the rescue study, the two teams immediately came together with a shared commitment and determination to get the project back on track. A key underlying theme to moving the study forward was: Do not let process get in the way of making progress. Medpace had enough flexibility in its systems and enough latitude with its SOPs that allowed for a number of distinct strategies to be developed.

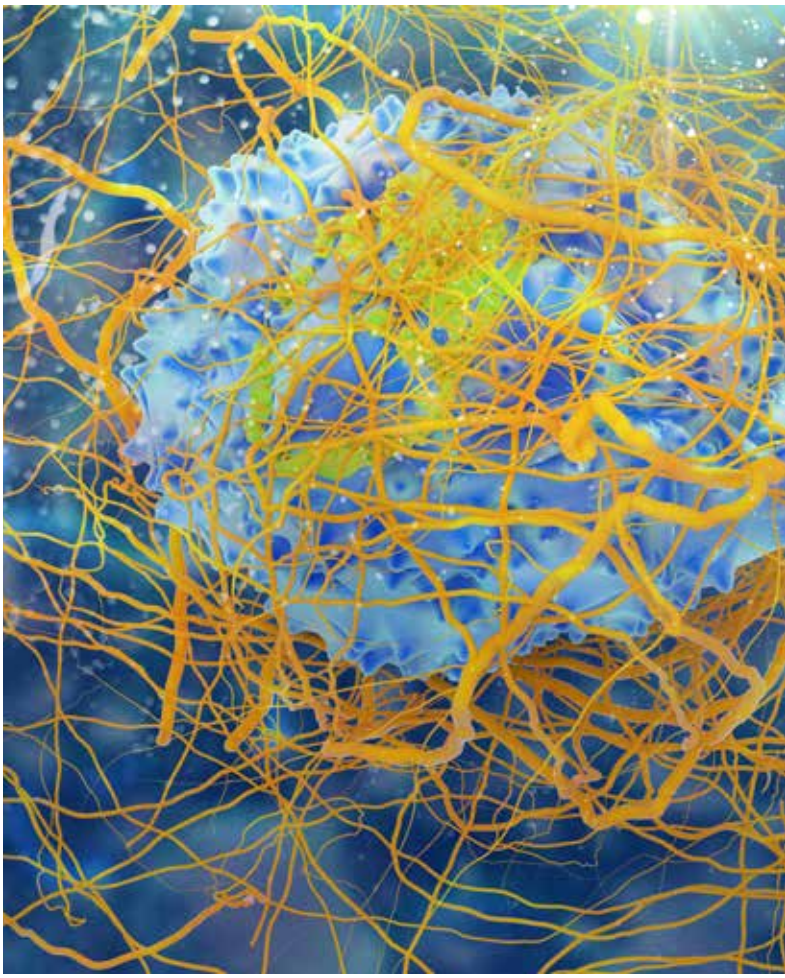
Leverage the knowledge: This was a complicated study, sites were waiting to get qualified, and Medpace did not have the luxury of time to get its in-house CRAs trained. Because the CRAs from the previous CRO were already up-to-speed, Medpace contracted with the existing team. This is outside of Medpace's normal model, but this was a talented team that would be instrumental in rapidly moving the study forward.

Site start-up - get out in front: To get the study back on track, Medpace had to accelerate site start-up. When a new site was identified, Medpace would disseminate the necessary regulatory and regulatory startup documents, and contract and budget when authorized by the Sponsor, so these processes were underway in parallel with site qualification to support more rapid activation. This approach helped on the IRB front as well because the various committees, such as safety and protocol review, could begin their critical review and approval processes earlier.

Embrace the sites: Because of the complex protocol and personalized therapy, it was critical to fully partner with the sites. Medpace and the Sponsor recognized that the study coordinators at the sites were doing the heavy lifting. To bring these professionals together, multiple centralized study coordinator meetings were hosted where open communication was facilitated. These meetings proved to be highly effective in collectively resolving issues and keeping the sites engaged. Medpace and the Sponsor also stayed tightly connected with the Principal Investigators with quarterly teleconferences and routine site visits from personnel from both project teams.

Use what's working. Modify what's not: Medpace took existing templates and modified the areas that needed improvement. There was an enormous amount of data that already existed. Medpace set-up an FTP study site that provided access to all team members who needed it. By enhancing what was working, adjusting what was not working, and making data readily available, Medpace was able to improve quality and communication from day one.

Follow a map, not a plan: The study required flexibility, not rigidity. A shared understanding that there was more than one way to get to the end destination created a team dynamic that allowed both companies to not only accept changes, but to realize that they could and should continuously make improvements. Both teams recognized that they wouldn't get it all right from the onset but making adjustments based on learning got them to the end goal.



LESSONS LEARNED FROM THE SPONSOR

Work with a partner that aligns with your organization: In our case, we are a highly personalized company, from our culture to our product. Once we made the decision to move the project to Medpace, we rolled up our sleeves as a collaborative team and we started approaching this as a true partnership.

Do not let process get in the way of making progress: Accelerate and short-circuit processes when it makes sense. The best example is the work we did with sites. We didn't have a single investigator meeting. It doesn't mean we ignored them; we kept consistent communication with the PIs through direct, personal engagement of our target sites. But we chose to engage with the study coordinators and site startup personnel at a deeper level and this proved to be the formula for success.

Keep it simple: As complex as our product is to manufacture on a patient by patient basis, we learned that we needed to minimize the operational complexities. Selecting a partner with a centralized approach who was sized for us and had the right resources made the most sense.

Be flexible: Go into the partnership with the understanding that your CRO will not have all the answers and that you need to work collaboratively to continue to learn, adapt, and improve throughout the study. Flexibility and open communication have been central keys to the successful partnership we have forged with the entire Medpace team.

It's about the relationships: In the end, what makes a successful partnership is open communication and transparency at every level – including finance, operations, project management, labs, and sites. You need to communicate and get to know one another. It is these relationships that matter. You can leverage technology but you can't replace the communication that results from building solid relationships with the team.

Don't be afraid to make that switch and don't be afraid to do it early: Switching CROs early in the life of our pivotal phase III study was the most critical decision we made to get our trial back on track. We are now on schedule to complete this complex trial in less than two years, from the time we had the initial sites activated, first patient randomized, to the time we expect to conclude enrollment. I think that's quite remarkable and represents a true testament to the partnership we forged and embraced with Medpace along this challenging but rewarding journey.

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.