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Resourceful Resourcing: Consolidate Your Technology Providers

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The tenets of clinical development for the modern life sciences industry have been unchanged for decades: we are in pursuit of developing products faster and more cost effectively while retaining efficacious, high quality data with a watchful eye on patient safety. Accomplishing this is the first objective; endeavoring to do it better than the competition is the ongoing challenge. Factoring in the constraints of a changing corporate landscape – mergers and acquisitions, downsizing or reorganizing to meet investor expectations – and a harsher regulatory environment, our industry has been forced to become more strategic and cost conscious in order to meet its goals. One strategy that has proven effective is leveraging technology innovation to streamline the very costly phases of clinical development. Companies that embrace this dynamic approach to technology resourcing will continue to emerge as leaders.

Our industry's approach to resourcing, in particular technology resourcing, has evolved based on how we define and realize efficiencies. Clinical development executives are tasked with developing a best-fit strategy for the organization based on evaluation of internal vs. external resources. To date, we have experienced two technology outsourcing models:

1. Sponsor outsources all technology solutions to a full-service contract research organization (CRO)

What was once a choice to outsource to CROs has become imperative in order to get a product through marketing authorization and into the hands of patients. In the 1990s and early 2000s, Sponsors outsourced primarily to full service CROs, which allowed them the ease of making one provider choice for a given study. These CROs met all functional service needs, including the use of their proprietary technology.

This was a successful model for years, and for some Sponsors is still the best fit, but CROs have generally been unable to keep up with the fast pace of technology development or provide the most current offerings. Most third-party products developed for the clinical development and post-marketing environment are designed to address one functional area. Conversely, CROs' proprietary systems have become less specialized, less user friendly and more cumbersome—all resulting in risk for inefficiencies and loss of competitive edge. Coupled with increasing Sponsor disenchantment with their outsourced experiences – likely due to unclear and often unrealistic expectations – the outsourcing model began to shift towards a more specialized approach.

2. Niche technology providers and the Functional Service Provider (FSP) relationship

We are currently in an environment where Sponsors are favoring the FSP model for technology outsourcing. This shift has occurred for a number of reasons, including the decreased cost of technology, the perceived advantages of specialized providers, and the high degree of flexibility afforded by a la carte outsourcing—allowing sponsors to procure a combination of technology services for an entire compound development program or on a study-by-study basis.

Yet what makes the FSP model so attractive is also its Achilles heel. The breadth of technology needs for any given Sponsor/CRO can be huge, including solutions such as EDC, electronic Trial Master File (eTMF) and Study Start Up platforms, and Clinical Trial Management Systems (CTMS), as well as portals for IVR, Institutional Review Boards (IRBs)/Ethics Committees (ECs), central laboratories, safety and pharmacovigilance, and many others. With most solutions only covering one or two functional areas, the Sponsor/CRO must partner with a variety of providers in order to cover all their requirements. It's the investigative sites that must largely shoulder the burden of these disjointed relationships, as each new system brings a host of separate training and access requirements that must be managed on top of their ongoing clinical responsibilities. Because sites are sensitive to these added requirements, they may question the attractiveness of a particular study if it involves taking on a new vendor/system. Study stakeholders recognize this growing issue and are looking to the industry to reduce the number of different technology solutions utilized to execute a clinical trial.

The full service CRO and FSP technology models need to change. Sponsors should be able to select a single provider to supply technology across several functional areas.

Consider a fluid, integrated solution that ties together several functions: feasibility, site selection, study start-up, subject enrollment and treatment, EDC, eTMF and so on. Training within the Sponsor, CRO and Investigative site is kept to a minimum as all parties develop familiarity with a single system. Transparency, consistency and efficiency are inherent, paperwork is reduced

and cost savings are realized. Providing internal and external transparency will enforce a competitive edge, allowing more visibility for regulators in an environment of increased regulatory scrutiny.

Of course, evolving our approach to technology outsourcing is contingent upon providers developing the consolidated technologies that Sponsors/CROs require always keeping an eye on the future environment when developing these technologies. To date, a handful of providers have realized this need and are working to integrate disparate systems, or are creating solutions that address a broader number of functional areas. But the success of this evolution on an industry level will largely be driven by demand, which means Sponsors and CROs have to buy in to the consolidated approach and take aggressive steps towards adoption. This requires companies to think through their current and future needs, ideally using providers that share their strategic vision for the future. Start-up and virtual organizations have already taken the leap and are reaping the benefits: a lesson for the larger companies trapped in their archaic processes.

Consolidating services and multiple technologies into one solution will be the critical path forward for Sponsors and CROs to keep a competitive edge. This is happening now: solutions exist today that can cut significant costs and provide support at the site level, providing a paperless clinical trial process. Recognizing the impact a shift in technology outsourcing can make, then taking the step forward and embracing that model, is the decision we are facing today. Sponsors receptive to learning the benefits will continue to be the leaders driving the competitive edge and forging the path towards streamlined clinical development and commercialization of products for patients in need of new medical therapies.