



eSolutions: A CUSTOM FIT

A collaborative approach to building a program mixed with superior customer support will yield more efficient data collection and management, and in return the sponsor will be more inclined to work with that vendor again.

Patient reported outcomes, patient data capture, case report forms, document and content management — if there's a process for it, chances are, there's an electronic solution for it. With the rapid explosion of eSolution offerings, trial sponsors are inundated with choices of products from vendors who are more than happy to showcase all the new bells and whistles. In theory, this is fantastic — a plethora of tools and companies dedicated to process refinement, innovation, and optimization: in many ways, a microcosmic reflection of the pharmaceutical research industry in general. Also in parallel with the industry lies the reality that any new product does not come without its own set of challenges.

Customization and Collaboration Key to Success

In the same way that no two trials or studies are identical, neither are any two builds of an IWR, ePRO, or EDC platform. eSolutions require a substantial amount of customization, and it's important for sponsors to choose a vendor that will design a program to work with all of their needs. Rather than creating an "out-of-the-box" program and pushing for a faster install, vendors should be focusing on the sponsor's needs and developing a program that will provide quality results and good customer service while maintaining an affordable cost and reasonable timing.

It should come as no surprise that the complexity of eSolutions cause sponsors and vendors to spend a vast amount of time and money making sure everything is right before implementation. Often times the people signing the contracts are not accustomed to the technical jargon written in the contract and do not understand all of the details they are agreeing to. This can cause a dissonance between the sponsor and vendor and can amount to significant time lost between customizing and implementing the software. Vendors should be

working directly with the sponsors and collaborating on what needs to be done to make the program work for the trial. Cutting back on the amount of change orders can save time and money and ultimately the sponsor will feel that their requests are being heard and executed.

An IRT program, for example, typically takes about 10 to 12 weeks to go from sponsor signing to user acceptance testing because of the extensive amount of change orders made. With a collaborative build, vendors can cut that time in half and sponsors can stay ahead of schedule in their trial. While customization permits sponsors to integrate their specifications, it's important that the vendor also maintains the basic structure of the IRT program. Having a balance between customization and configuration allows sponsors to get the functions they need built in while preserving the core function of the program. There is no "one size fits all" program to work with every trial, and sponsors should be looking for the vendor that will utilize a visually collaborative process during the specifications gathering.

Managing the Relationship

Once a program is built and implemented, the service from vendors should not stop. Sponsors and vendors should have a close relationship throughout the entire trial to eliminate the possibility of error. Should a vendor leave after the installation process, the sponsor will be left to find a solution to their problem if one should arise, forcing them to turn to an external consultant resulting in additional costs they may not have budgeted for. To further exacerbate the problem, the sponsor then runs the risk of the consultant not understanding the program as well as the vendor, and thus being ill-equipped to provide the proper assistance.

Customer Service

Trials can occur anywhere around the world, and vendors need to provide 24/7 service. If a

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sponsor knows one of their trial sites will be in a location that may not have an adequate internet connection, they should make sure the eSolution they are using can accommodate for the environment. An ePRO system, for example, should be able to collect patient forms and send them back to the master database no matter where the patient is in the world and what their connectivity is like. Dependable customer service gives sponsors the satisfaction and security in knowing their trial is running as smoothly as it possibly can.

A collaborative approach to building a program mixed with superior customer support will yield more efficient data collection and management, and in return the sponsor will be more inclined to work with that vendor again. Sponsors looking for a quality clinical trial results are going to select a vendor that can provide them with the customization they desire and the service that can back them up once the program goes live. It's important for sponsors and vendors to develop a strong relationship to ensure that the sponsor's needs are taken care of in the most efficient and preeminent way possible. This relationship not only achieves the greatest results, but it provides a blueprint for sponsors to reuse in future clinical trials. **PV**

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