

The Site Landscape Related to New Expectations in a Changing Clinical Research Environment

Diana L Foster*

Chief Executive Officer, Total Clinical Trial Management, United States

***Corresponding Author:** Diana L Foster, Chief Executive Officer, Total Clinical Trial Management, United States.

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The Investigator site landscape and the clinical research sites position within the pharmaceutical and biotechnical industry has been evolving and changing in many aspects over the last five to seven years. The expertise and skillset required by the site research team has taken on more importance in the eyes of industry, therefore, allowing for a more powerful position for the Investigator. Through industry partners such as TransCelerate, The Society of Clinical Research Sites (SCRS), CITI and others, the sites have found a voice and platform, crucial to the viability and sustainability of their ongoing ability to do business.

As little as twenty years ago, almost all clinical trials were conducted in academic settings and much control of study conduct was dictated by Investigators who were thought leaders. In many cases, these Investigators were not necessarily encouraged to enroll expeditiously or to start up studies with the speed we expect today utilizing central versus local IRB requirements.

The evolution of new models in the conduct of trials in the private sector evolved quickly once it was clear the academic center was not the only game in town and occurred in somewhat of a random process of implementation. In today's market, Site Management Organizations (SMO), both global and domestic, academic centers, individual private sites, site networks, hospital-based groups and hybrid models have expanded the options to carry out clinical trials.

Entrepreneurial and business-oriented approaches have replaced the traditional business model used initially by sites. This positive shift in site operations allows for more stable and consistent fiscal viability.

Site networks, in particular, are owned and operated in many cases by sophisticated financial, strategic and industry experienced leaders. The ability to negotiate and place studies with large networks of sites has most certainly changed the landscape and opened the eyes of both Sponsors and Contract Research Organizations to a different style and depth of negotiations. These changes are all a positive direction for the research sites of today and in the future; however, this exerts more pressure on the independent single site who may not have the same level of experience and resources as the larger site networks.

Despite a deeper understanding of the pivotal role the partnership with the site plays, many sites still struggle to find their footing and to maintain cash flow and to make sense of the many changes in technology, expectations and the labor burden required to operate soundly. The ongoing uncertainty of the conduct of clinical trials amidst the challenges and delays resulting from COVID-19 are adding to the questions already in front of the research site community around the globe. With that said, table 1 shows that the site's desire to remain committed to working during the current research environment is strong and necessary to long term success.

•	62% Not had to close or pause operations.
•	38% Merely had to pause to adjust or were put on hold.
•	0% Sites reporting having to close completely.
•	80% Not had to reduce wages.
•	81% Sites that "stayed the course".

Table 1: Sites stay committed during the pandemic.

Source: SCRS Site Solutions Summit 2020.

Recent data presented in October 2020 at the annual SCRS Global Site Solutions Summit point to the burdens sites face related to payment delays, payment terms and uncertain payment structure for new expectations including remote monitoring and virtual processes that will become common practice (Table 2). It is therefore essential that these concerns are addressed by Sponsors and the industry. The independent site will remain hungry for new work assignments but without attention to the new demands of conducting clinical research and new models to support the site environment it will be difficult to meet demand.

<ul style="list-style-type: none">• 90% increase in hybrid/decentralized trials and remote monitoring• 78% report increased workload<ul style="list-style-type: none">• 43% average increase• Increased time requirement around remote monitoring• Not being reimbursed<ul style="list-style-type: none">• 62% of sites request reimbursement• 5% getting what they ask for• 39% are getting some of what they ask for

Table 2: Impact on sites with shift to decentralized model.
Source: SCRS Site Solutions Summit 2020.

The pandemic spurred the utilization of digital innovation and virtual services among clinical trials. It is not surprising that clinical research sites have seen a 90% increase in decentralized trials and remote monitoring. While these advancements will remain critical in the structure of current and future clinical studies, they have resulted in a 78% increase in workload at the site level. Of the sites that responded to the survey, 43% are doing more work to support these digital and virtual technology services. The adaption of these technology interfaces requires changes in site’s processes, integration, and reporting, which equate to additional funds being required to support these services at the site level. Most sites are not receiving the reimbursements they are requesting. Only five percent received what they requested.

Research sites are waiting for the industry to respond and are poised to improve patient availability as well as to modify processes, as necessary. It is clear that these modifications must occur for research sites to remain viable as the critical link in completion of successful clinical studies and new drug development.

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