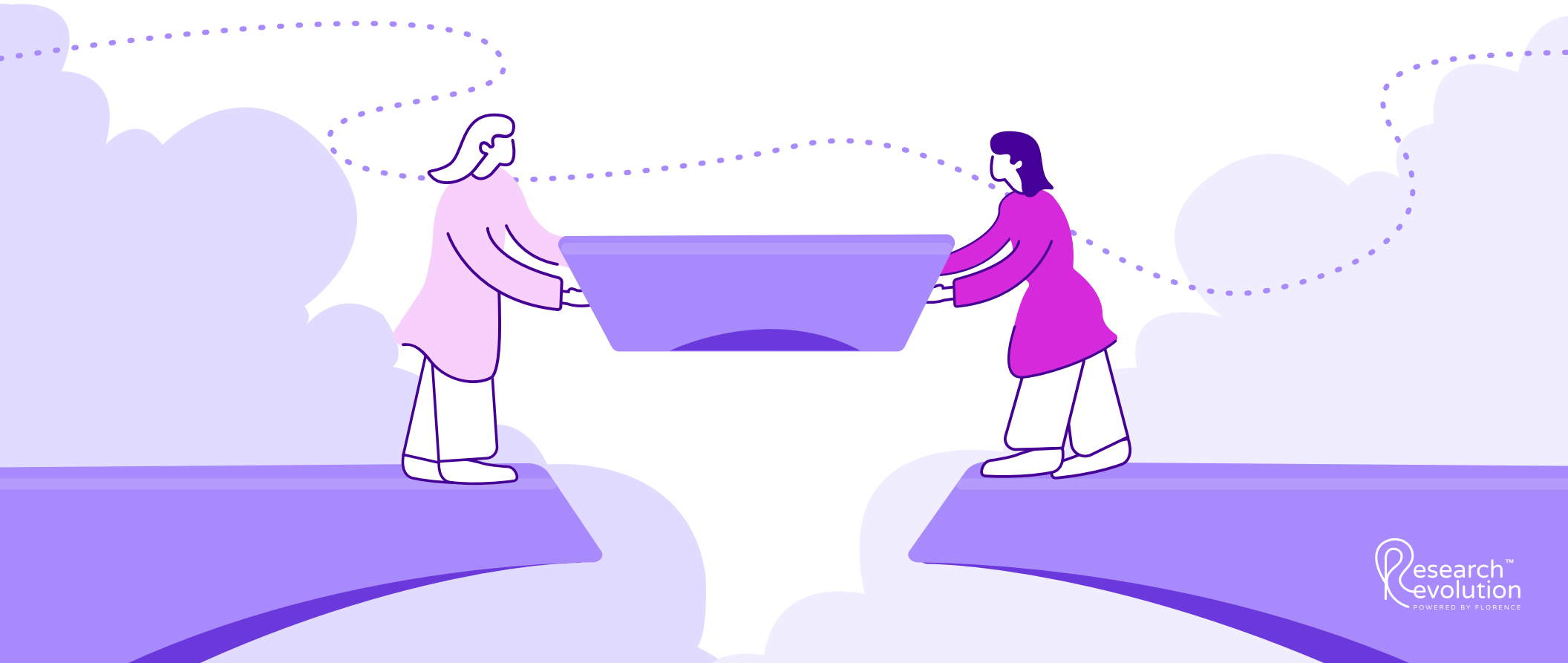
Navigating the Capacity Gap:

Challenges for Clinical Research Sites and Sponsors in the US and Europe

Written by: Kristin Surdam, Keith Wright, Simon Taylor

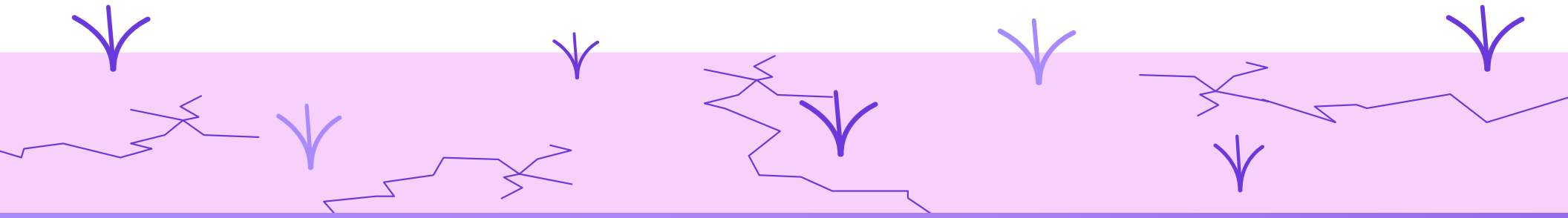


Research Revolution™ POWERED BY FLORENCE

Table of Contents

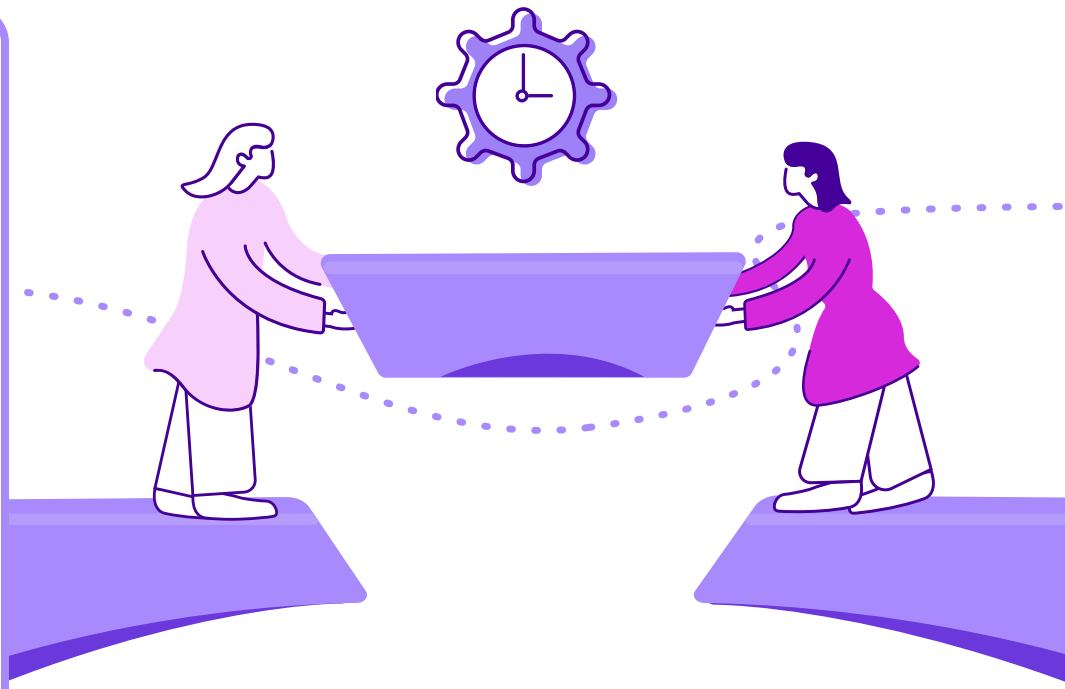
Abstract

The global landscape of clinical research is characterized by a burgeoning demand for studies and fewer resources to conduct them, creating a significant capacity gap that poses challenges for both research sites and sponsors/CROs. Insights into the current capacity gap, challenges facing the industry's various (US and EU) stakeholders, and proposed strategies to mitigate the inherent risks will be explored. Data collected by Florence Healthcare via a survey of 182 site representatives is included to demonstrate the changing needs of clinical research sites.



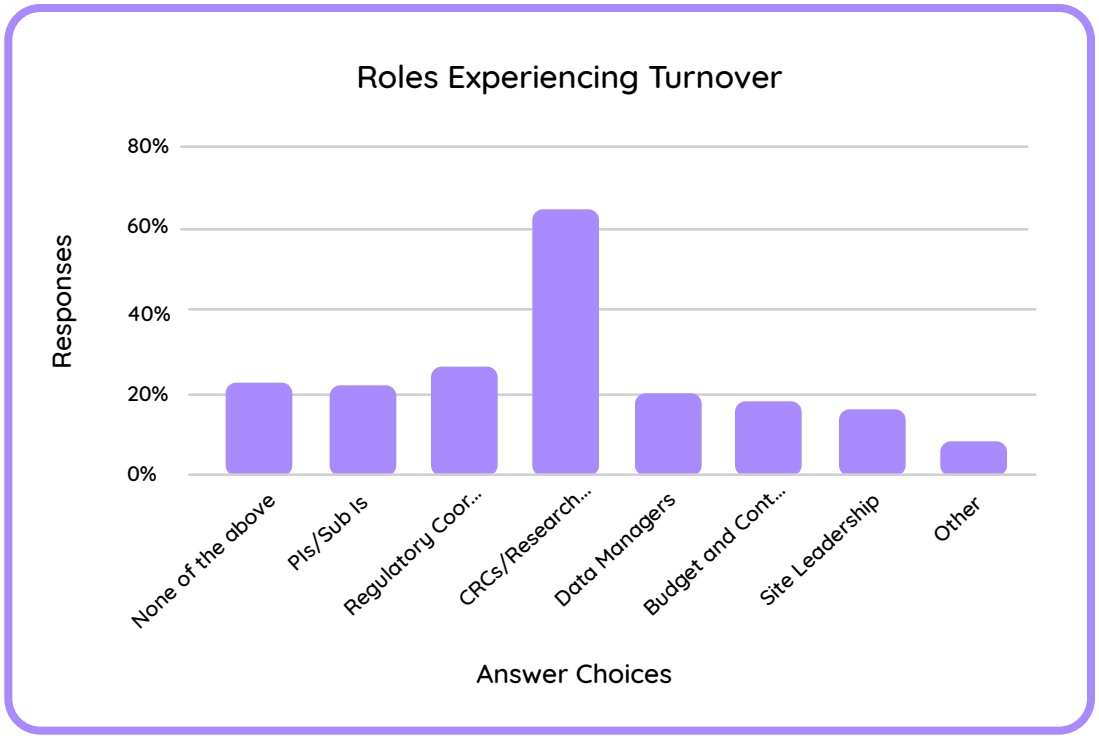
Introduction

Clinical research plays a pivotal role in advancing medical knowledge, public health, and patient outcomes. The growing demand for clinical trials and their increasing complexity per trial has led to a capacity gap, impacting the efficiency with which clinical trials can be conducted, not to mention the longer term timeline and cost effects, which ultimately affect patient options for care. Drug development for one product already takes an average of 10-15 years before it is commercially available. WCG Data Intelligence has reported that 41% of clinical trials now target complex therapeutics. If the current capacity gap is maintained or increased over time, the industry could see this average elongated over time, further delaying the availability of new therapies to patients.



Sites - We Can't Keep Up!

The rise in the number of active studies, as evidenced by a surge in 58% over the past year according to survey respondents, has created an overwhelming workload for clinical research sites. Simultaneously, a 34% increase in experienced turnover has occurred, with 60% of that turnover occurring in Clinical Research Coordinator (CRC) or Research Nurse roles. Since CRCs and Research Nurses are likely to carry the largest workload, it follows that continuity becomes a significant challenge, further increasing the criticality of the capacity gap in clinical research.



Exiting PIs and Sub-Is had an average of 6-10 years in their role, while all other roles averaged 2-5 years. Consequently, these roles are likely to be more difficult to fill at the same level of expertise, further expanding the capacity gap at clinical research sites. Staffing shortages were reported to cause a multitude of challenges. Over 85% of respondents cited staff workload and study startup as the areas most affected by organizational turnover.

Sponsors & CROs - We're Trying to Help!

On the other side of the industry, sponsors and contract research organizations (CROs) also encounter resource challenges in managing the increasing workload and meeting the demands of a growing number of clinical trials. In addition to their own resourcing struggles, sponsors and CROs are greatly impacted by the capacity gap at sites. After all, sites recruit patients to meet study needs. Consequently, sponsors and CROs truly are at the mercy of sites' ability to manage workloads, retain professional resources, and improve workflow efficiency. As such, we have seen an increase over the past 1-2 decades of sponsors/CROs providing sites with tools (i.e., technology) and resources (i.e., staff augmentation) meant to aid sites in these endeavors.

The need for efficient oversight and proactive collaboration with research sites has become paramount across the industry to solve the capacity gap in clinical research.

Increasing Workload and Staff Turnover: EU

European Research Centers - European Trials are Changing Rapidly

Across the ocean, European clinical research is experiencing similar challenges. The rising need for clinical trials in Europe is a significant challenge facing the scientific community. Several factors are contributing to this demand. One of the most notable is the changing demographics of Europe; as an example, the European Union has more than 20% of it's population over 65. More than one-third of citizens in the EU defined themselves as having a chronic health condition; both of these statistics combined place enormous strain on mostly public healthcare systems, making developing new and innovative treatments crucial.

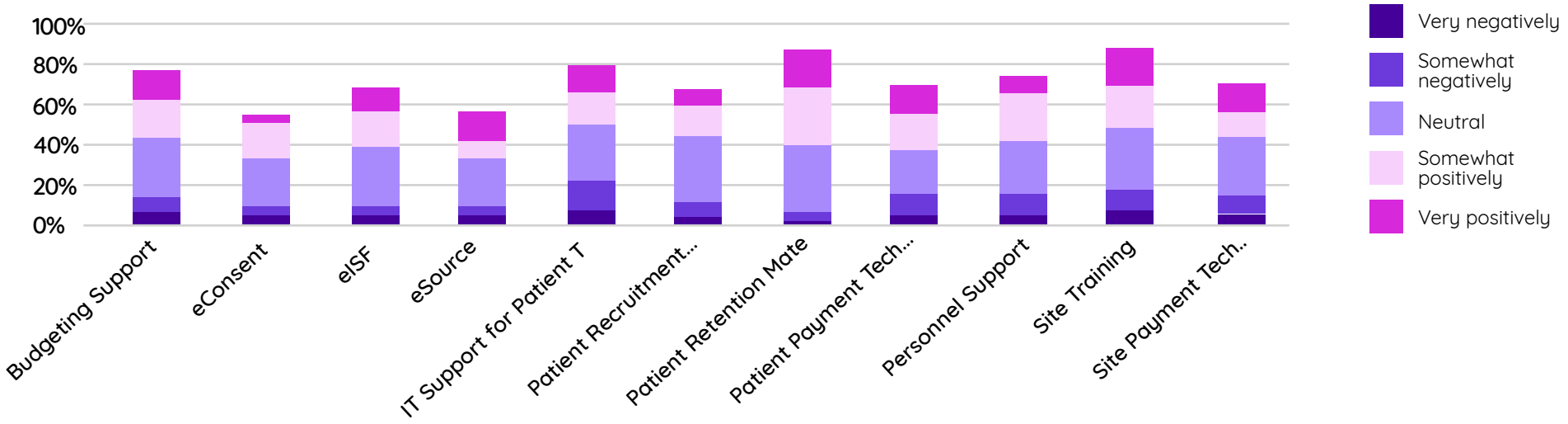
These demands have put a tremendous strain on the limited infrastructure, resources, and personnel involved in clinical research. A continual obstacle is the shortage of qualified research personnel, including clinical investigators and research coordinators - to give a sense, a paper published in the BMJ estimates anything up to a shortage of 1.8 million healthcare workers, one senior leader describing it quite aptly as a medical desert', none of these things paint the healthiest picture of how much capacity there is to run effective high-quality research. These shortages make it difficult to keep up with the demands of the scientific workforce, especially in specialized fields. As a result, there is immense pressure to find new ways to assess the safety and efficacy of cutting-edge treatments.

More than half of European sites are taking on an increasing number of trials spread across a stagnant workforce. In public health care systems like the National Health Service (NHS), much time is spent on manual, paper-based processes spread across wide geographical areas, meaning staff too much of their day traveling between locations just to complete tasks. Ideally, this time can be better spent recruiting and caring for patients and conducting study activities. Unfortunately, the current clinical trial climate, particularly in publicly funded healthcare systems, prohibits the continual addition of personnel resources in order to solve the capacity gap. That being said, the National Institute for Health and Care Research (NIHR) does provide NHS sites with access to flexible funding meant to sustain research capabilities at these organizations. This funding is often used to help solve the capacity gap by funding salaries of critical research support staff, as well as funding CPD through basic costs like travel and accommodation.

Supportive Measures to Address the Capacity Gap: Sites

Florence's survey also delved into sites' reactions to the ways in which sponsors/CROs have attempted to support them during this age of the capacity gap. When asked whether sponsors/CROs were adapting positively to site challenges, a resounding 58% of respondents replied negatively. The overall increase in study volume and complexity, coupled with the increased turnover of experienced staff is worsening the industry's capacity gap and sites cannot bear the lift all on their own. Site voices on this and other topics have grown exponentially in recent years and many sponsors and CROs have heard the cry for help. Unfortunately, support solutions are often determined by the sponsor/CRO with little or no input from the sites. This doesn't mean that they've missed the mark entirely, however.

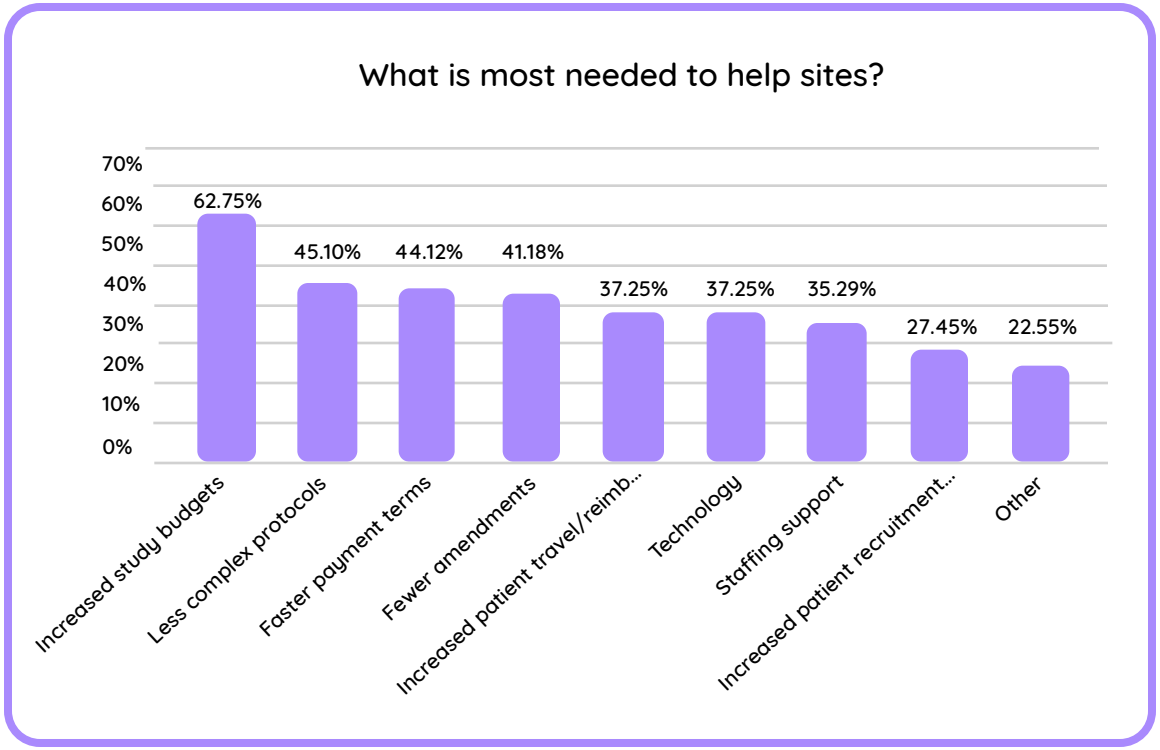
Of solutions provided by sponsors or CROs, a majority of sites found patient retention materials or services to have a positive impact, while patient recruitment services were rated neutrally. Out of the support solutions listed, none were reported as having a negative impact by a majority of sites. When neutral responses were removed, sites most often reported eSource and eISF technologies as having a positive impact, though all options shown did have a majority of respondents reporting positive impacts as compared only to negative impacts.



Supportive Measures to Address the Capacity Gap: Sites

In addition to the inquiry regarding common support from sponsors and CROs, respondents were asked what they feel is most needed to positively impact their site. It is no surprise that sites overwhelmingly stated the need for increased study budgets. Other comments received included themes of CRO/CRA training and accountability, technology reduction and optionality, early stakeholder engagement, overall communication, and simplification of protocols and processes. If taken into serious consideration by sponsors and CROs, all of these solutions can help reduce the pressure currently facing sites, leading to better workload management, improved efficiency, less burnout, and increased staff retention, ultimately helping to alleviate the impact of our capacity gap problem.

Sites have spoken and it is clear that we need to work together to solve the capacity gap. There is no single solution that will resolve our workforce issue; cross industry stakeholder collaboration is the way forward.



Supportive Measures to Address the Capacity Gap: Sponsors & CROs

As illuminated in the site survey, there are plenty of opportunities for sponsors and CROs alike to support sites in doing their best work. While technology offers solutions, the adoption does require significant investment and a cultural shift. Ensuring that technology enhances, rather than complicates, trial management is an ongoing challenge. Many sponsors and CROs are currently providing sites with technology infrastructure to run their trials, which inherently leads to another problem: technology overload. Sites work with multiple sponsors on multiple trials being conducted by multiple CROs. The problem with supplying study-specific technology is the lack of optionality and integration among those systems.

Sponsors can play a pivotal role in bridging the capacity gap by investing in comprehensive training programs for site staff. Additionally, providing robust support for the integration of technology can enhance the efficiency of research sites.

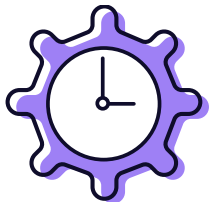
Sites most often reported eSource and eISF technologies as having a positive impact on their workflows (when neutral responses were removed) in our survey. As such, we will focus this section on how an eISF technology can benefit sponsors/CROs while simultaneously helping to solve the capacity gap at sites.

eISF Technologies

Electronic Investigator Site File (eISF) technology addresses the research site resource capacity gap from sponsor and CRO viewpoints by streamlining document management, enhancing real-time oversight, and ensuring efficient collaboration. Through centralized and electronic document systems, sponsors/CROs can remotely monitor site activities, verify compliance with protocols, and make informed decisions swiftly. This not only improves data quality and reduces administrative burden, but also fosters better collaboration between sponsors and research sites. The technology's time-saving features contribute to resource optimization on both sides, allowing sponsors/CROs to focus on more strategic aspects of study management, ultimately facilitating the successful and timely completion of clinical trials.

Benefits of eISF

- **Efficient Document Management:** Sponsors can more efficiently manage and track study-related documents across multiple sites. This ensures that all sites have access to the latest versions of protocols, regulatory documents, and other essential files. It reduces the time and resources spent on document distribution and minimizes the risk of discrepancies due to outdated information. This also ensures that site personnel always have clear access to current documents (no more searching emails to see if there's been a new IB or ICF!).

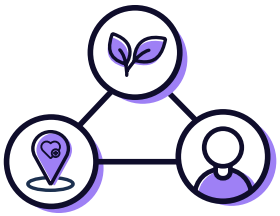


- **Real-time Oversight:** eISF technology allows sponsors to have real-time visibility into site activities. Through secure and remote access, sponsors can monitor the progress of studies, track enrollment rates, and identify potential issues promptly. This proactive oversight helps sponsors and CROs address challenges quickly, ensuring the smooth execution of the trial. While this is a change for sites, it benefits them as well. With earlier identification of errors, sites are able to undergo retraining or corrective actions before that same error turns into a trend of deviations.

- **Compliance Assurance:** Sponsors/CROs can more easily verify site compliance with regulatory requirements and study protocols. Most eISF platforms include built-in audit trails, making it easier to demonstrate compliance to regulatory authorities. This can result in faster regulatory approvals and reduce the risk of delays. For the sponsor, it's an insurance policy improving your confidence in your inspection readiness! This also applies to the site - staying inspection ready at all times is becoming increasingly difficult with the capacity gap, as document based tasks are always deprioritized over patient related tasks.

Benefits of eISF

- **Resource Optimization:** Sponsors can work more efficiently with research sites by reducing administrative burdens associated with document handling and tracking. This allows sponsors to allocate their resources more effectively, focusing on strategic aspects of trial management rather than dealing with logistical challenges. Sites benefit from streamlined and automated workflows, reducing manual processes and giving those hours back to their day.



- **Improved Collaboration:** eISF technology facilitates seamless communication and collaboration between sponsors/CROs and research sites. Shared access to study documents and real-time updates promote transparency and enhance the overall partnership between sponsors and investigators.

- **Cost Savings:** While there may be an initial investment in implementing eISF technology, sponsors and CROs can realize long-term cost savings. Electronic systems reduce the need for paper, storage, and manual processes, leading to operational efficiencies and cost-effectiveness over the course of the trial.

Overall, electronic Investigator Site File (eISF) technology offers industry stakeholders a comprehensive method of reducing the site capacity gap. The technology's role in resource optimization allows sites to focus on strategic trial management aspects, ensuring successful and timely clinical trial completion with the same staffing model. Successful trials are based on successful sites. To allow our sites to do their best work, we must come together in order to fill the current capacity gap across our industry. Despite having fewer staff and coordinators with less experience, we are asking them to achieve more than ever before. By adopting an eISF of record, you will optimize your staff's efficiency and shrink the capacity gap!

European Research Centers

European research centers rely heavily on manual and paper-based processes. The good news though, is that the landscape is changing. We're seeing more innovative strategies, digital platforms, and partnerships with patient advocacy groups. Sponsors and CROs overseeing global research can maintain the same benefits described above when implementing technical solutions in European sites. However, that is easier said than done considering the degree of change management that needs to occur for e-solutions to be fully embraced in many European countries.

While we do not currently have insight into European sites' preferred method of support in solving the capacity gap, we do know it exists. Sponsors and CROs should utilize lessons learned, be receptive to novel support methods, and listen carefully to their global sites to identify ways they can effectively support them (and remain in compliance with GDPR and other applicable regulations).

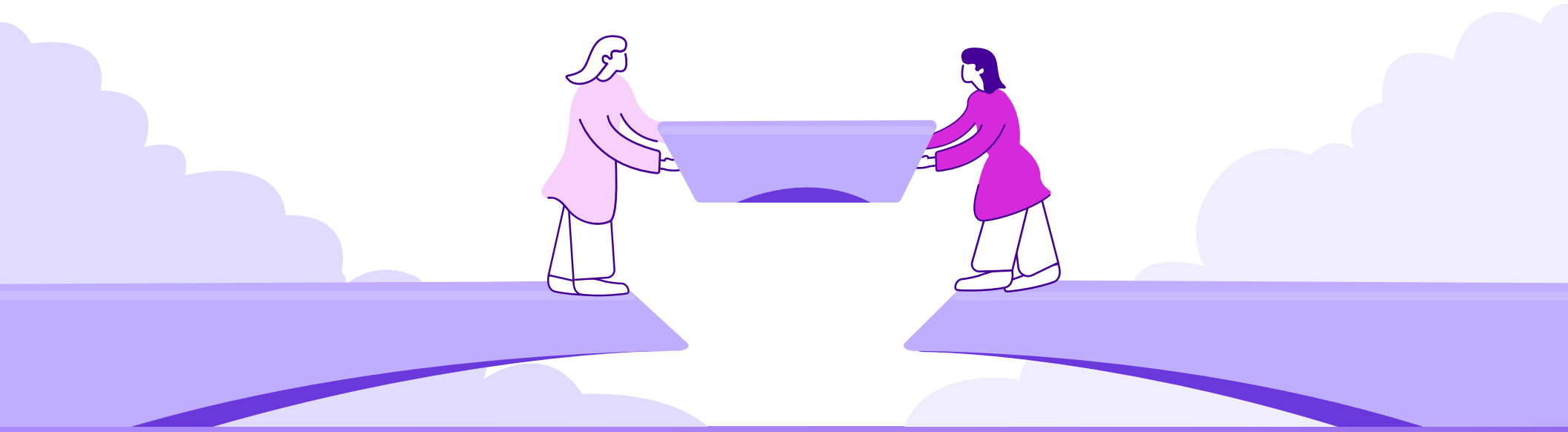
These approaches are helping us to overcome recruitment challenges and optimize research capacity across the continent.

Conclusion

The capacity gap in clinical research poses substantial challenges for both research sites and sponsors/CROs in the US and Europe. Building stronger relationships between research sites and sponsors/CROs will only help to propel solutions forward. This involves addressing issues related to budgeting, contracting, technology, and communication to foster trust amongst all parties.

Addressing these challenges requires collaborative efforts, investment in training and technology, and a commitment to streamlining processes. By focusing on these solutions, stakeholders can collectively navigate the capacity gap and ensure the continued advancement of clinical research on a global scale.

Finally, effective use of technology, including built-in tech optionality and integrative abilities, will be pivotal for streamlined operations. Since sites often face barriers in adopting and integrating new technologies, sponsors, CROs, and vendors will all need to get on board for the greater good. Again, collaboration seems to be the answer.



Writer's Bios

Kristin is a Certified Clinical Research Professional with more than 15 years of experience in phase I - IV multi-center clinical trials, at both the site and sponsor/CRO levels. She has experience in various industry roles, types of organizations, and therapeutic areas. Kristin has earned industry certifications as both a Clinical Research Coordinator and a Project Manager, demonstrating her proficiency and commitment to the industry. Kristin is a Key Opinion Leader and Subject Matter Expert leading the Thought Leadership department at Florence Healthcare. She is passionate about driving the industry forward through clinical research technology, streamlining study operations, and ultimately condensing the time to market for new therapies.

Simon is a Clinical Technology veteran with more than 10 years working across all facets of the eClinical Spectrum. Based in the UK he has detailed working knowledge on European/UK Regulations and works collaboratively with the ICH, MHRA and the EMA to forward the position of technology further with those in the know. His role at Florence centers on leading our European Site Business with a particular focus and passion for digital transformation within the NHS through vital infrastructure like eISF, eTMF and eConsent.

Keith is a Certified Clinical Research Professional with 10 years of experience ranging from nearly every position at a site to leading a team focused on Study Start-Up in a top 5 pharma company. Keith helps dozens of clinical research sponsors and CROs optimize their site enablement strategies through people, processes and technology. Keith now lends his expertise to other organizations looking to digitize their operations with study sites as the Director of Industry Strategy at Florence Healthcare.

Research™ Revolution
POWERED BY FLORENCE