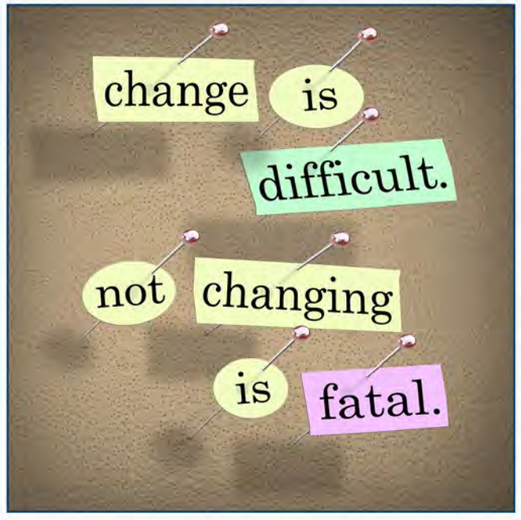
The Changing Face of Clinical Research

Technology is changing the face of the world as a whole, person by person and industry by industry. The introduction of technology in the clinical research space is making sweeping changes in an industry that has remained relatively unchanged for the last 15 years. While change is often difficult to navigate and acclimate to, it generally leads to improvements in processes, especially when experience and science merge to develop methods for overcoming age-old challenges. To quote William Pollard, "To change is difficult. Not to change is fatal."



However, one needs only to examine one's own experience with change to understand that too much change too fast creates chaos. Finding the balance between too much and not enough change is the way to create sustainable growth.

Why Do I Need Technology?

As technology infiltrates most every day activities, today's consumers have come to expect increased convenience in every aspect of their lives. This, combined with the ever-increasing complexity of trials, has made it increasingly difficult to recruit and retain participants for clinical trials due to the time and effort participation requires, often including numerous visits to a physical research site. The barriers are enhanced for sites that conduct trials requiring work with a population that doesn't drive or a demographic in remote areas far from a research site.

Technology as a Solution in the Research Industry

As is the case with general medicine, the emergence of telehealth solutions demonstrates how technology can add convenience to participants' lives by enabling them to connect and converse with their physician without having to travel to and from their office. For some types of visits, patients can obtain a benefit similar to an in-person visit by connecting with their physician on a computer or mobile device. This saves the participant a significant amount of time typically spent commuting to appointments and sitting in waiting rooms.

Telehealth solutions in clinical trials introduce significant benefits to trial sites and sponsors as well. By eliminating or reducing late arrivals, missed appointments, and the transition time between seeing patients, opportunity exists for research sites to increase efficiencies and therefore the number of patients they see each day. This increases productivity and profitability for both the site and sponsor.

A plethora of technology solutions extend beyond telehealth. Electronic data capture (EDC), electronic regulatory binders (eTMF) and electronic source (e-source) have played a significant role in simplifying the collection and exchange of data. Electronic informed consent forms (eICF) provide a means to consent a clinical trial participant remotely on a mobile device or computer, and often includes a video explanation of the study which improves participant understanding of the trial and overall ICF process. The benefits introduced by the adoption of clinical payment solutions are vast within the site community. SCRS VP of global engagement Dan Milam shared, "Whether sponsors and CROs pay sites monthly or quarterly is not just a timing issue. This is an issue of whether or not sites can stay in business."[1] The ability to automate and streamline the management and processing of site payments has dramatically improved study start-up timelines, made delivery of study funds timelier, and increased sites' ability to sustainably conduct work.

The Dangers of an Extreme Shift

While there are undeniable benefits to incorporating technology for all players in the clinical research space, it is important to consider the potential downfalls of making an extreme shift too quickly, utilizing technology in a manner that decreases connectivity, or simply using the wrong technology.

Some technology providers like Science 37 are planning trials in which study materials and drugs are boxed up and shipped directly to the patient for start-to-finish, site-less clinical trials. This approach dictates that patients engage with a central principal investigator (PI) determined by the company and referred to as a "metasite." While we do not dispute the intrinsic benefit of simplifying the clinical trial process, we cannot ignore the fact that using technology to create site-less clinical trials removes an essential element to clinical trial success: the human connection.

No form of technology exists that can replace human connection. Patients trust people. "Of all the interviews I've conducted and people I've talked to in the clinical research field, there is one unmistakable commonality that each industry leader has identified: people need people," said SCRS' senior communications manager Jessica Knott. "There is measurable benefit when patients can hear the voice or shake the hand of the person who is invested in improving their health." Research has shown that:

"…a low quantity or quality of social ties (are linked) with a host of conditions, including development and progression of cardiovascular disease, recurrent myocardial infarction, atherosclerosis, autonomic dysregulation, high blood pressure, cancer and delayed cancer recovery, and slower wound healing."[2]

Strong social connection strengthens the immune system, aids recovery from disease, and leads to a 50% increase in life expectancy.[3]

Connection in other areas of life cannot act as a substitute for a lack of connection when seeking to improve one's health by participating in a clinical trial. "Quality communication and connection are vital components to consistent and successful recruitment and retention," shared SCRS president Casey Orvin. "Unless the day comes when technology can address a patient's social and emotional needs, the quality of clinical trials will not be improved by eliminating sites and severing the human connection that research has proven to be essential to the patient."

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It is critical that patients understand they are participating in a trial for a new medication and that there is a degree of risk involved. They must document their agreement to participate, and the PI must be confident that the person qualifies for the study. These initial interactions are more confidently completed via human interaction as opposed to technology. Many study protocols require that certain visits be conducted in person, in part for this exact reason, such as those that include a physical examination or require an initial dose of study medication to be administered or dispensed.

Clinical Research Sites are Not Optional or Disposable

Technology will continue to emerge in the clinical research industry, and the industry will almost certainly grow and prosper as a result. We should embrace it but also promote the reality that clinical research sites are an absolute necessity to maintain the safety of patients and the validity of clinical trials.

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When introducing technology into clinical trials, it is important to diligently research the providers you are considering. While there are many incredible options available (view SCRS' list of Global Impact Partners who have demonstrated their commitment to site sustainability), they may not all have the same vision for their platform's use, may not all be well-suited to your site's needs, and may not all have a comprehensive understanding of the clinical research field.

Many technology providers take a site-friendly approach to introducing their trial solutions. With goals of enhancing site productivity and reducing patient burden, these technology providers recognize the value of human involvement and independent PIs by promoting a hybrid approach and recommending that a varying percentage of visits be done virtually, with the larger percentage of visits conducted in-person.

Technology is here to stay, and embracing this fact will surely improve clinical trial success. SCRS encourages sites to conduct thorough research to identify the professional solution partners that are best-suited to their needs.

References

1. Miseta, E. SCRS Drives Site Payment Solutions. Clinical Leader. June 7, 2017. Accessed February 27, 2019 from: https://www.clinicalleader.com/doc/scrs-drives-site-payment-solutions-0001

2. Karas Montez, J., Umberson, D. Social Relationships and Health: A Flashpoint for Health Policy. National Center for Biotechnology Information, Department of Health and Human Services. Accessed February 27, 2019 from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3150158/

3. Seppala, E. Connectedness & Health: The Science of Social Connection. Stanford Medicine. Accessed February 27, 2019 from: http://ccare.stanford.edu/uncategorized/connectedness-health-the-science-of-social-connection-infographic/