

The Evolution of Patient Engagement

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At the January meeting of the SCRS Sites NOW Program, Circuit Clinical's CEO and founder Dr. Irfan Khan and (then) SVP of Network and Partnerships Deena Bernstein had the opportunity to lead the discussion on the Evolution of Patient Engagement and Services. The discussion took the attendees on the journey of how patient engagement and services have evolved to support clinical research. The breakout group discussions identified best practices, provided real-world examples of patient engagement success stories, and identified barriers to patient engagement.

An impact report by the Tufts Center for the Study of Drug Development showed that late development studies had an average drop-out rate of 19.1% in 2019, up from 15.3% seven years before. In 2020, COVID-19 caused massive disruption to clinical trials and undoubtedly increased drop-out rates to an all-time high. Unfortunately, as an industry, we have not yet adopted a standardized solution to measure patient engagement to improve retention.

According to a study done in 2017, 0 of 14 sponsors had a consistent, company-wide process for asking for feedback from trial participants. Furthermore, only 1 of 14 sponsors received feedback from patients who declined to participate in a trial, and 3 of 14 sponsors received feedback after a trial ended. We can safely confirm that patient retention is still a critical issue in drug development, but how have we addressed it so far and what is on the horizon?

Patient engagement began when bioethical standards for clinical research were established as a result of the Tuskegee Syphilis Study and the history of Henrietta Lacks. Both examples demonstrate the need for patient rights and are infamous for egregiously failing to take into account the patient perspective. Slowly, the patient perspective has been gaining awareness and traction and being used for trial design and execution. An early advance was the formation of the National Coalition for Cancer Survivorship. This group connected patients with shared experiences and gave them more influence over how cancer care was managed. It wasn't until 2008 that the term patient-centricity became massively popular and was used in over 500 articles on PubMed.

More recently, patient engagement has developed into creating a concierge, white-

glove experience for patients. More and more trials have begun to use cutting-edge technologies and services to enhance the participation experience. For example, the first fully decentralized trial was conducted in 2011 by Pfizer and allowed patients to participate without needing to go to the site location for each visit, therefore giving people more options for how to participate.

Other recent patient engagement services include using Uber Health and Lyft to provide transportation services and faster reimbursement options such as reloadable pay cards instead of checks. Patient engagement has also been improved by providing open discussion forums in Facebook groups and platforms such as Patient Power. Patients are also able to directly leave feedback about their clinical trial experience through ratings and reviews on platforms including TrialScout and Google Reviews. All of these platforms and experiences are giving patients a voice and a seat at the head of the table, empowering choice and offering a direct channel for feedback.

Sponsors, CROs, and sites have been able to use these services and feedback to include the patient perspective during protocol design. These changes have helped mitigate protocol amendments and make adjustments early to save downstream time and cost. Real-world examples of successful patient engagement projects that were shared in the breakout discussions included:

- Financial counselors to help patients navigate medical billing
- 24/7 direct communication channels with trial coordinators for questions or concerns
- Utilizing the TransCelerate BioPharma Patient Experience Toolkit
- Sites measuring patient satisfaction through net promoter scores
- Providing childcare services during trial participation for easier visit scheduling
- Bringing in illustrators to develop informed consent on a pediatric trial
- Sending a birthday message to current/past participants

The largest site networks in the country are using patient engagement platforms to collect participant feedback and make data-driven improvements. Pharmaceutical companies are working on early pilot stages of patient engagement platforms and services. Vendors are supporting patient engagement efforts through the various platforms and services described above. With more virtual and decentralized trials, how do we best engage to keep patients interested and retain them in studies where the in-person connections are hard to create? What does all of this effort lead to through patient engagement?

For patients, it means a white glove experience when participating in clinical trials, better feedback loops with sites and sponsors, and an increased sense of ownership and altruism. For sites, investigators, and sponsors, this means faster patient recruitment, higher patient retention and adherence, and ultimately a lower cost to bring new medicines to market.

References:

Tufts Center for the Study of Drug Development. (2020). New global recruitment performance benchmarks yield mixed results. Impact Report, 22(1). Retrieved from https://static1.squarespace.com/static/5a9eb0c8e2ccd1158288d8dc/t/5e303c3dd4520c015cb8a4b1/1580219453985/JanFeb2020_CropSummary.JPG

TransCelerate Biopharma Inc. (2019). Study participant feedback questionnaire (SPFQ) toolkit. Retrieved from <http://www.transceleratebiopharmainc.com/wp-content/uploads/2020/01/TransCelerate-SPFQ-Socialization-Presentation-Final-Version-1.pdf>

SCRS Sites NOW is a virtual discussion and content project created in response to the COVID-19 pandemic and focused on the changing landscape clinical research sites and industry partners now face. Each session is centered around a singular topic; in January, the topic was the Evolution of Patient Engagement. Attendees benefit from an opening presentation hosted by an industry leader who provides a unique perspective and meaningful metrics on the topic at hand, then break out into groups for a dynamic discussion guided by relevant queries designed to identify areas of opportunity for participants in the clinical research pipeline.

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