



Busting the Patient Engagement Myth

Challenging commonly held beliefs or myths about clinical study participation has become increasingly important in an industry that is moving and innovating so rapidly

Aaron Fleishman at
BBK Worldwide

There is no shortage of opinions on how to enrol a clinical study and engage participants. Some may be based on experience, while others may be based on preconceptions, and, in an industry that continues to expand with new players and offerings, it can be hard to differentiate fact from myth. Without methods for challenging or debunking them, these myths can easily be perpetuated, and, for some, they provide an easy and satisfying solution because they are consistent with what they want to believe is true. For others, they are a convenient option when pressed for a solution. However, within the clinical trials arena, relying on myths can be risky when so much is riding on the investment. Developing a process to challenge them can seem daunting, but, with a little insight and a data-driven approach, those working within the industry can feel empowered to do so, creating a solid foundation for clinical trial success.

The Patient Engagement Myth

Patient engagement in clinical trials continues to generate a lot of debate. Some argue in support of its effectiveness in removing obstacles to participation, enhancing the patient experience, fostering compliance, and helping achieve enrolment goals on time and on budget. Others argue that it is too hard to track and measure its success, putting its value in jeopardy.

Over time, a common myth has emerged that patient engagement is too difficult to define and cannot be measured in a way that demonstrates a return on investment (ROI). Despite this, clinical trial sponsors still recognise the need to employ engagement support, such as patient travel programs, reimbursement programs, and study apps, to retain study participants in an increasingly pressure-filled and competitive marketplace. While sponsors embrace patient engagement and recognise its role in fostering a positive study experience, the lack of measurable or consistent data has proved challenging and led to the myth that ROI cannot be measured properly.

There is no better way to challenge the myth than by going to the heart of the matter to the very members of the study community who can provide first-hand insight: patients, site study staff, physicians, study sponsors, and CROs. Their experiences and perspectives will provide the key data points necessary to challenge the myth.

Firstly, it is important to look at the definition of patient engagement. A quick Google search will not help as there are many definitions and many companies positioning themselves as patient engagement specialists.

Subtle differences between how each audience defines patient engagement are clear. Patients and sites are closely aligned by an emphasis on the importance of communication and relationships; their keywords relate to the clinical trial experience and personal journey. However, clinical trial sponsors and CROs focus on the tools and initiatives that help reduce patient burden and increase compliance.

While the definitions do not match across the board, that does not mean that individual groups cannot define them for their own purposes, and, in fact, the data will show they are more closely aligned than it may initially appear.

Patient Engagement

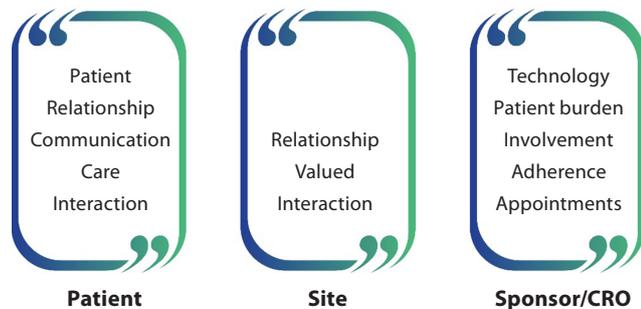


Figure 1: Patient engagement defined by audience

Identifying the Metrics

While clinical trial sponsors recognise the need for patient engagement and have seen positive signs of their efforts, identifying the metrics that prove impact and ROI can be difficult. Understanding sponsor perspectives on what constitutes effective study engagement is a good place to start. The 2018 BBK Study Voices survey, which included responses from 453 study sponsors, provides key insight (see Figure 2). 44% of the respondents indicated they associated a decrease in withdrawal rates with effective study engagement, while 28% associated quantitative data to demonstrate patient satisfaction with effective study engagement. Both are measurable data points that can be assessed as part of the ROI analysis.

Diving deeper into the myth, let's turn to the study community again and, in particular, to the Patient Voice survey to see if there are any measurable insights that can inform the value of patient engagement. As patient satisfaction is one of the most important indicators of a positive experience, findings relating to satisfaction levels will be most relevant.

Of the 5,185 patients surveyed, 2,484 had participated in a clinical trial. Of these, 64% rated their experience an eight or higher on a scale of one to 10 (one representing lower satisfaction), and 36% rated their experience a seven or lower (see Figure 3).

Study Participants with Low Clinical Trial Satisfaction Rates

The study participants that rated their experience a seven or lower were asked if they were offered any engagement tools or support (see Figure 4, page 16). Surprisingly, 81% were not offered any of these.

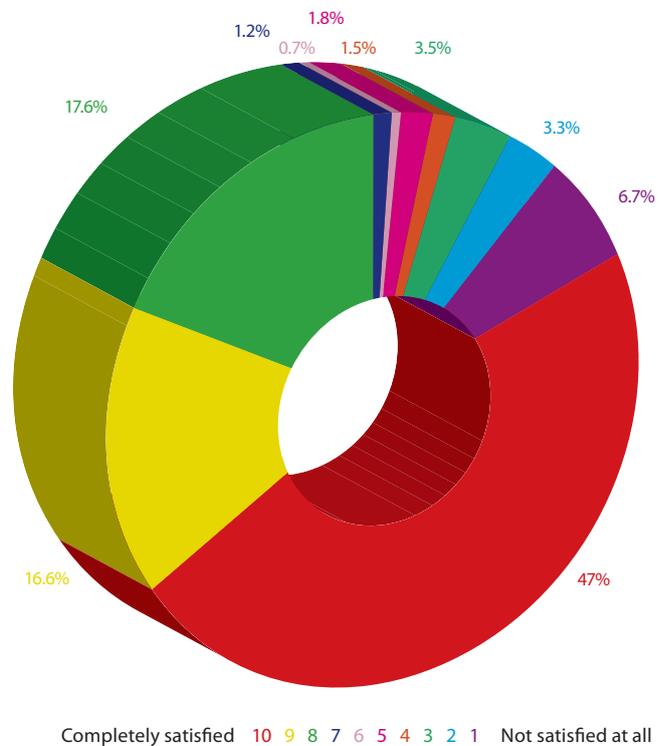
Those that were not offered engagement tools or support were asked to indicate which they think would have helped improve their overall satisfaction (see Figure 5, page 16).

The percentage starts to rise in favour of specific engagement tools and support. None of the study participants were offered any post-study data, and, when asked what would help with their overall study satisfaction, 10% selected post-study data. As another example, only 4% of study participants were offered travel, yet 11% of those not offered tools or support indicated that travel would have increased their overall satisfaction. These results point to the potential for engagement tools and support to impact overall study satisfaction.



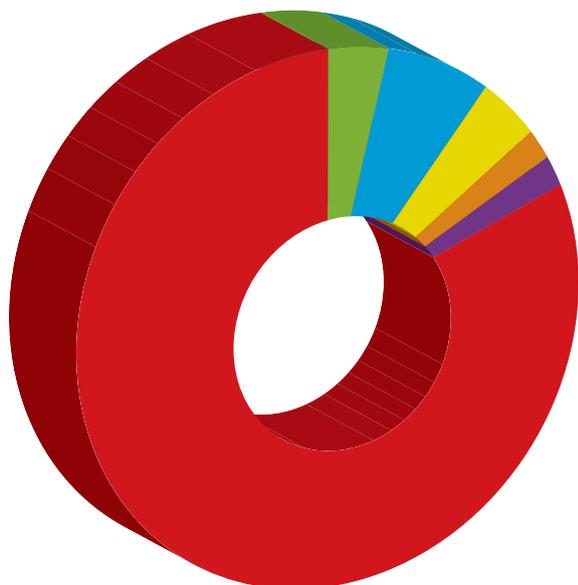
12% Qualitative data to demonstrate site satisfaction
 44% Decrease in withdrawal rates
 16% Increase in site retention for additional clinical trials
 28% Qualitative data to demonstrate patient satisfaction

Figure 2: Sponsors' perspectives on metrics most closely aligned with effective study engagement



Completely satisfied 10 9 8 7 6 5 4 3 2 1 Not satisfied at all

Figure 3: Study participant satisfaction levels



Travel, 4%
 Reimbursement, 7%
 Study app, 4%
 Caregiver program, 2%
 Home visits, 2%
 Post-study data, 0%
 None of the above, 81%

Figure 4: Engagement tools offered to study participants (low rating)



Travel, 11%
 Reimbursement, 13%
 Study app, 8%
 Caregiver program, 4%
 Home visits, 6%
 Post-study data, 10%
 None of the above, 48%

Figure 5: Engagement tool preference

“ There is a dramatic difference in satisfaction rates between those who were offered engagement tools and those who were not ”

It is important to recognise that 48% of respondents indicated that none of the engagement tools or support would be helpful in improving their overall study satisfaction. While this is a relatively high percentage, several factors could be involved, including adverse events, complex visit schedules, and general study burden. It could also be speculated that patients are not aware of engagement tools and support and, if they are, they do not associate them with clinical trial participation.

Study Participants with High Clinical Trial Satisfaction Rates

When taking a closer look at the study participants who rated their clinical trial experience an eight or above, a different trend emerges. Those patients were offered more of the standard engagement programs than those who rated their experience below eight. Of the patients in this category, 50% were at least offered reimbursement, 30% were offered home visits, and 28% were offered a study app.

Here, only 23% indicated they were not offered engagement tools or services (compared to 81% of those with lower study satisfaction rates) (see Figure 6).

Of these patients who were offered engagement tools and support, over 50% of them indicated they greatly or moderately contributed to their overall clinical trial satisfaction and decision to participate in the study (see Figure 7).

There is a dramatic difference in satisfaction rates between those who were offered engagement tools and those who were not. The data clearly shows that engagement tools and services can have a positive effect on patient satisfaction and the decision to participate and remain engaged in a clinical study.

For sponsors, that is a clear indicator of ROI. What also emerged was a clear correlation between engagement tools and support and their effectiveness in enhancing the relationship between study participants and site study staff (see Figure 8).

The Site Perspective

As part of the data-driven research, sites were asked to rate the aspects that had the greatest positive impact on their job. Patient engagement tools were rated the highest. Going back to the earlier definition of patient engagement, these are the very tools that impact the relationship, confirming that tools can be provided to enhance satisfaction. By ranking patient engagement tools



Travel, 18%
 Reimbursement, 50%
 Study app, 28%
 Caregiver program, 4%
 Home visits, 30%
 Post-study data, 2%
 None of the above, 23%



10.7% Did not contribute
 9.2% Slightly contributed
 36.9% Greatly contributed
 17.3% Somewhat contributed
 25.9% Moderately contributed

Figure 6: Engagement tools offered to study participants (high rating)

Figure 7: Impact of engagement tools and services on decision to participate

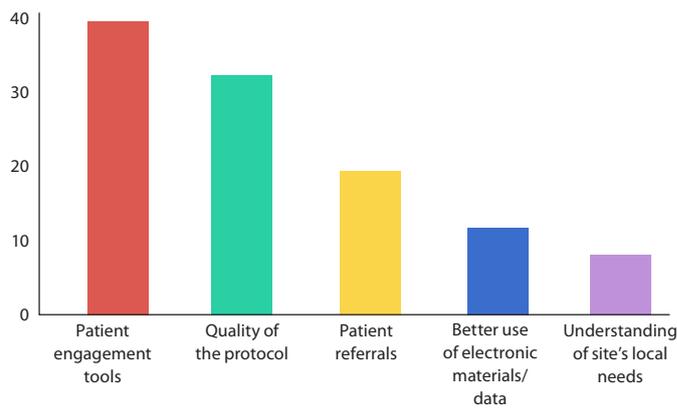


Figure 8: Study staff on the clinical study aspect, experience, or service that has made the greatest positive impact on their job

as having the greatest impact, it also confirms that site study staff are aware of them and their potential to impact the relationship with patients and facilitate study participation.

Opportunities Ahead

Clinical trial sponsors are closer than they think in terms of identifying and quantifying the value of patient engagement. The data is there, it's just connecting the dots. As the industry works to create a uniform way to measure ROI, sponsors can independently analyse the information they have through surveys, focus groups, and other research initiatives throughout the course of a clinical trial or at its conclusion. With first-hand insights and relevant data in hand, they will be empowered to challenge other commonly held beliefs and set a course for clinical trial success.

About the author



Aaron Fleishman, Director of Market Development at BBK Worldwide, helps pharmaceutical sponsors, advocacy organisations, and patient thought leaders to create and

deploy award-winning, innovative strategies that generate awareness and engagement surrounding clinical research. Aaron's efforts have resulted in the development of new educational and interactive resources to help improve the overall study participation experience while ensuring that patients and caregivers remain at the centre of every campaign. In 2018, Aaron launched BBK's Pharma15 Live! web series, a dynamic new format for dialogue within the clinical R&D industry addressing numerous burning issues, including travel services, the patient experience, and disruptive innovations.

Email: afeishman@bbkworldwide.com

