

The Patient Experience in Clinical Studies

By Norman M. Goldfarb

PanAgora Pharma’s recent Clinical Trials Patient Experience Summit offered 140 attendees numerous perspectives from industry leaders on how to improve clinical research by improving the experience of study participants.

The patients’ experience in a clinical study affects the likelihood that they will stay in the study and adhere to study requirements. Improving their experience is well worth the effort since, in a typical clinical study, retention is only about 70%. According to conference chairman Moe Alsumidaie, drug (IP) adherence typically drops by 40% by day 200. Drug nonadherence of even 20-30% requires a 50% increase in sample size to maintain statistical power.

In addition to improving retention and adherence, studies that offer a positive patient experience can speed recruitment and avoid the protocol amendments needed to facilitate enrollment, at a typical cost of \$250,000 per amendment. In addition, a technique that proves effective in one study might prove useful in others.

Leading pharmaceutical companies (and CROs) are conducting a variety of initiatives to improve the patient experience. While the impact of these initiatives appears very positive — in some cases, astoundingly so — calculating ROI is a challenge, since both the costs and benefits can be hard to measure, especially in the absence of controlled, scientific experiments, e.g., splitting a study into two halves, one with and one without the innovation.

While it is necessary to measure the benefit of patient-experience innovations for the study sponsor, a patient-centric perspective suggests that the benefit to study participants should also be measured. Some of these metrics overlap. For example, higher retention and adherence reduce sample size, saving the sponsor time and money, and they also eliminate risks, discomforts and inconveniences for the people who do not enroll in the study. Quality-of-life (QoL) research can provide fairly accurate estimates of the value of avoiding injury, discomfort and inconvenience.

Some study sponsors have started to ask a patient panel their opinions about a protocol. One might assume that the sponsor’s physicians (on staff, consultants and prospective investigators) would have a deep knowledge of the patients, but, apparently, this is often not the case. The reasons for this disconnect are not entirely clear. In some cases, physicians might not fully appreciate the patients’ experience. In other cases, they might be aware of the patients’ issues but not their priorities or how they look at the world.

A good example of an insight into the patients’ perspective is that patients are more likely to record data that interest them. For instance, if patients are interested in their own eating habits, they will be more likely to accurately record this information in their diaries. Study sponsors can turn this preference to their advantage by creating diaries that collect this information and promising to return it — with charts, graphs and comparisons to other people — to study participants. Even if the data is unrelated to any statistical study outcome, it will motivate patients to use their diaries.

Many patient recruiting firms pride themselves on their ability to determine what patients really want, in terms the patients understand. For example, some people with arthritis might place great weight on being able to open a beer bottle. Some patients with

emphysema might highly value being able to talk to their grandchildren on the phone. These firms can assist sponsors in study design, not just recruitment marketing.

Nevertheless, one might ask how many patient panels for a particular condition in a particular population are needed to develop a very full understanding of the patients' perspectives (and why this information is not already available)?

Of course, different patients can experience a given disease differently and have their own priorities and preferences. For example, some patients might prefer one long visit, while others prefer two shorter visits on consecutive days. Sensitivity to these differences is key to delivering positive patient experiences — one size might not fit all. For instance, it might be possible to offer patients the option of one long visit or two shorter visits. Also, since patients vary, sponsors should not over-react to the views of a single patient.

A few sponsors have tried running patients through a simulation of key parts of a study, and discovered significant practical and perceptual problems. For example, instructions might be ambiguous, packaging difficult to open, or a measurement difficult to obtain consistently.

Some studies survey participants to gain insights for future studies. However, asking participants for feedback *during* the study can help improve the patient experience in *that* study and, in effect, create a dialog with the participants.

Some study sponsors have discovered the power of patient stories. These stories can reveal useful insights of which not even the patients were aware. Stories humanize study participants — they are real people with real lives outside the study — and help study personnel appreciate the important of their own contributions to the study.

Patient experience data can also be persuasive to the FDA, to formulary managers, to advocacy groups, and, eventually, to real patients. If we want to improve patients' lives, shouldn't the patients be able to contribute?

References

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