The Clinical Trial Process – a case study

By Andrew Spanyi - January 2024

While clinical trials are essential in advancing the development of new medications for many diseases – especially for cancer – there remain many challenges. Researchers have pointed out that clinical trials are characterized by low patient retention, low recruitment, and are challenging for pharmaceutical companies and subjects alike. Clinical trials are especially hard on participants or subjects. This article represents the perspective of one caregiver on the experience of his wife in a clinical trial for a cancer medication, including observations on the current state and recommendations for improvement.

The Current Approach

The current approach to clinical trial is characterized by an inside-out mental model. In this perspective, participants in a clinical trial are seen as participants or subjects – not as patients. Accordingly, it should not be surprising that recent research found that 90% of patients surveyed would like to participate in medical research, but only around 3% of patients ever do and 85% of all trials are discontinued because of poor retention.

The current approach to clinical trials is driven by sponsors and investigators. It is a linear, rule driven, bureaucratic process. The inside-out view allows study doctors to hide behind sponsors and it enables sponsors to distance themselves from participants – who are seen as subjects in an experiment – not as patients.

The case study below illustrates the following points. Recruitment in clinical trials is challenging, in part due to the minimal use of existing information technology. Many potential patients – especially in outlying areas - rarely learn of them. The screening process is designed totally from the study doctor's and the pharmaceutical team's point of view and is burdensome on patients. The rules around tests are driven once again by the principal investigator's preferences with little regard to what is convenient for the patient. The ongoing participation in the trial is often taxing on patients and when the subject is released from the trail – the transition to the local oncologist is flawed.

A Case Study

My wife had metastatic cancer – originating in the breast. She was originally diagnosed in 2003 and treated in 2003/2004. While she was cancer free from 2004 through 2015, the cancer returned in 2016. She went trough 3 lines of therapy from 2016 to 2020 and was searching for a fourth line of therapy. Even though she had just completed next generation sequencing 2 months prior which identified the PIK3CA-H1047R driver mutation, my wife's local oncologist – in the Niagara area – was not aware of a trial that targeted this condition. The existence of the trial was discovered through a second opinion consult in Toronto.

Once she became aware of the trial, she received a consent form, which was designed totally from the perspective of the principal investigator and the pharmaceutical team. It was not patient friendly. The consent form was 29 pages in length and not particularly well written. Even though my wife had a doctorate and I have a master's degree - we found it somewhat challenging to work our way through it. I wonder what the average person thinks of this document.

The screening process was very burdensome on my wife. Screening visits were lengthy and without consideration of participants' comfort. One visit took 8 hours. On another visit the lab results were inaccurate - indicating that my then 59-year-old wife was NOT menopausal. In just over a month, we made 3 trips from our home in the Niagara region to the trial location in Toronto for screening - and still did not know whether she was accepted in the trial. When she emailed the study doctor, he claimed that the delay was due to the sponsor.

The training of nurses on the administration of intramuscular (IM) injections was poor. My wife had bruises on her buttocks on several occasions due to inept administration of the intramuscular injection. When I wrote to the study doctor that they may wish to take advantage of free training on how best to administer large-volume (≥ 3 ml) intramuscular (IM) injections - his curt email reply was that "If your wife has concerns, she can address them directly to me at her next visit. If he she is unhappy with her care, she can withdraw consent from the trial and return to her local oncologist."

The process during the actual study drug period was not designed from the patient's point of view. A typical visit began at 8am for a blood draw, a doctor visit at around 10am, another blood draw and an ECG around noon, then an injection once the study doctor had revied the results and next get the 4-week supply of the study drug around 2pm. Visit typically took 6 hours or more. While we had the means to book a nearby hotel and I was available to drive my wife back and forth, so she did not have to wait in the hospital, I wonder how other study participants coped with the demanding schedule.

When my wife requested whether some of the required tests might be done locally in Niagara, and thereby ease the burden of the long day at the facility in Toronto, the reply was that the tests had to be done at the study site to minimize potential variation in reading results.

After 2 years in the study, my wife requested time off for a vacation in Hungary to see her mother, the study doctor did little to facilitate the trip. Since the vacation was over a month in duration, the study doctor claimed that the sponsor demanded that various tests be conducted, and the results reviewed by him. Even though there was a similar study being conducted in Hungary, where the leading physician would have been able to assist - the Toronto based study doctor was not able to provide an introduction. We were able to arrange the needed tests ourselves and the trip did take place successfully - but not without stress.

Poor study design. After 27 months in the study, when the tests in October 2022 revealed minor disease progression, my wife was dismissed from the study. There was no dialogue around which of the two drugs in the study stopped working. As my wife had been on the intramuscular injection med for nearly 4 years, I continue to believe it was this drug and not the study drug that had stopped working. The study doctor did not provide a transition to new treatment. He basically suggested that my wife return to the care of her local oncologist. Thankfully, Katalin's local oncologist responded rapidly with medication and treatment. The post-study follow up was not designed from the patient's point of view.

While we had resources to fund hotel stays, the sponsor's offer of $35 per study-related visit for transportation expenses was utterly inadequate for most out of town patient.

There was no consideration whatsoever of the caregiver's experience. As a caregiver, I was never contacted over a 27-month period. I was never asked how things were going.

Opportunities for Improvement

Adopting a patient centric approach has significant benefits in improving clinical trial results. It begins at the beginning – patient involvement in the early phases of clinical trial design will payback substantially later.

Patients can provide valuable input on the clarity and readability of the consent form, and they may advocate for a "cliff notes" version.

Digital technologies can be deployed to broadcast the availability of clinical trials and scanning medical records can pinpoint the most qualified patients.

Patients can also provide valuable input on how the screening process can be made comfortable for patients while meeting the research requirements of the sponsor.

Considering the physical condition of participants, would make it less burdensome on patients.

Allowing patients to use local resources would lessen the burden of study visits for out-of-town patients.

Visibility and transparency into similar trials in other geographies would benefit all concerned.

Consideration of the caregiver's experience may provide sponsors with insights form another perspective.

Upon releasing a patient from the clinical trial, close collaboration between the study doctor and the local oncologist would serve to produce a more effective transition to the next phase of therapy.

Others have pointed out that the entire clinical trial process is designed from the sponsor's point of view - and not that of the patient. Drug companies should note that adopting a human centric approach has significant benefits in improving clinical trial results.