Redesigning Oncology Clinical Trials

By Andrew Spanyi February 2024

Oncology clinical trial performance is by far the worst performer across all therapeutic areas. The probability that a cancer drug will make it from phase I to final approval stood at some 2.4 percent, according to a study published in March 2020. Consider that the same statistic for cardiovascular clinical trials stood at 25.5% and infectious disease clinical trials were at 25.2%.

The problems are widely known. As a caregiver for my wife, I observed that:

- The informed consent form was lengthy, unduly technical, and difficult to navigate.
- The screening process was very taxing on patients.
- The process during the actual study period was also taxing. A typical visit lasted 6 to 7 hours.
- There was no option to have some tests done locally for out-of-town patients to ease the burden of lengthy trial visits.
- There was no consideration whatsoever of the caregiver's experience.
- Transparency was lacking in the handoff from the study doctor to my wife's local oncologist upon release from the trial.

Nor was our experience unique. Researchers have identified similar issues; including but not limited to, the following (1):

- Poor study design
- Ineffective site selection
- Poor recruitment
- Patient burden/safety issues
- Poor trial execution
- Budget and other constraints

Patient advocacy organizations have promoted the need to engage patients in both trial design and recruitment. Organizations such as the Decentralized Trials & Research Alliance (DTRA) are promoting the need for decentralized clinical research to ease the burden of participation on out-of-town patients.

This is all good news. But it may not be enough and the necessary changes are slow in coming. A new way of thinking is needed by both scientists and clinicians to accelerate the improvement of oncology clinical trial performance.

The first and perhaps most important shift in thinking is that participants in oncology clinical trials are **patients** – NOT subjects. Oncology clinical trials often represent the last hope for many participants. Sponsoring companies need to recognize this fact and engage patients at each stage of the oncology clinical trial process- design, recruitment,

conduct, and reporting. Patients need to be treated with compassion and respect – not like guinea pigs.

The next needed shift in thinking is that data needs to be shared – not hoarded. Transparency is needed in managing and organizing clinical trial data. Only when data is shared will it be possible to maintain high standards of data integrity and accuracy in clinical trials. This is needed to take full advantage of advances in digital medicine with artificial intelligence (AI) and natural language processing (NLP).

Perhaps the most challenging needed shift in thinking is that incremental improvements in the oncology clinical trial process – while perhaps necessary – are not sufficient. More radical change is needed. This shift in mindset is equally a challenge in several industrial sectors other than pharmaceuticals. Many sponsors have opted for small, incremental improvements inside organizational boundaries as this approach fits with the traditional paradigm for project ownership and frankly the success rate is greater. However, that's short-term thinking. Reducing the cycle time of oncology clinical trials by 10% is not going to beat cancer. More ambitious goals are needed. It's possible to radically reduce cycle time as was evident during the pandemic with infectious disease clinical trials.

However, the method to employ in redesigning oncology clinical trials is far from clear. The pharmaceutical sector has not widely embraced reengineering. Perhaps because reengineering has had a poor track record and has been associated with downsizing and cost cutting? Perhaps it is because of the mental model that many physicians embrace? In my experience, the method that is most likely to produce desired results has to be one of facilitated redesign of the end-to-end oncology clinical trial process, involving both a cross functional project team and a cross functional steering team, and sponsored by the company's CEO.

In the short term, sponsoring pharmaceutical companies are invited to consider the following actions:

- Engage patients in the design of clinical trials and in drafting the text of the ICF.
- Incorporate decentralized testing into clinical trial design.
- Ensure that each arm of a clinical trial provides some benefit to patients.
- Structure the screening and the study process with attention to patient comfort.
- Focus on data quality and integrity. Share data.
- Integrate digital health technologies.
- Focus on transparency in reporting.
- Appoint principal investigators not just on the research abilities – but also on their patient centric approach.
- Advocate increased attention to patient education with medical schools.

Mindset matters! As @CraigLipset posted a couple of weeks ago, it’s time to stop “tinkering at the edges.”

(1) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6092479/