Improving Patient Outcomes: eCOA Steps up in the Fight Against Cancer

Breast cancer is the most commonly occurring cancer in women worldwide and the second most common cancer overall. With the World Cancer Research Fund revealing that there were over 2 million new cases in 2018,[1] it seems an appropriate time to shine a spotlight on clinical research into this prevalent disease. According to the World Health Organization (WHO), cancer is the second leading cause of death globally, with around one in six deaths due to cancer. It estimates that the disease has been responsible for approximately 9.6 million deaths in 2018.[2] In 2017, the World Health Assembly passed the resolution Cancer Prevention and Control through an Integrated Approach (WHA70.12),[3] which urges governments and WHO to accelerate action to achieve the targets specified in the Global Action Plan and 2030 UN Agenda for Sustainable Development to reduce premature mortality from cancer.

By developing and bringing new oncology treatments to market, clinical researchers have an important role to play in helping reduce this cancer-related mortality. But trials in this therapeutic area are not without challenges. In fact, research suggests that fewer than one in 20 adult cancer patients enroll in cancer clinical trials.[4] Once enrolled, retaining these participants is therefore vital.

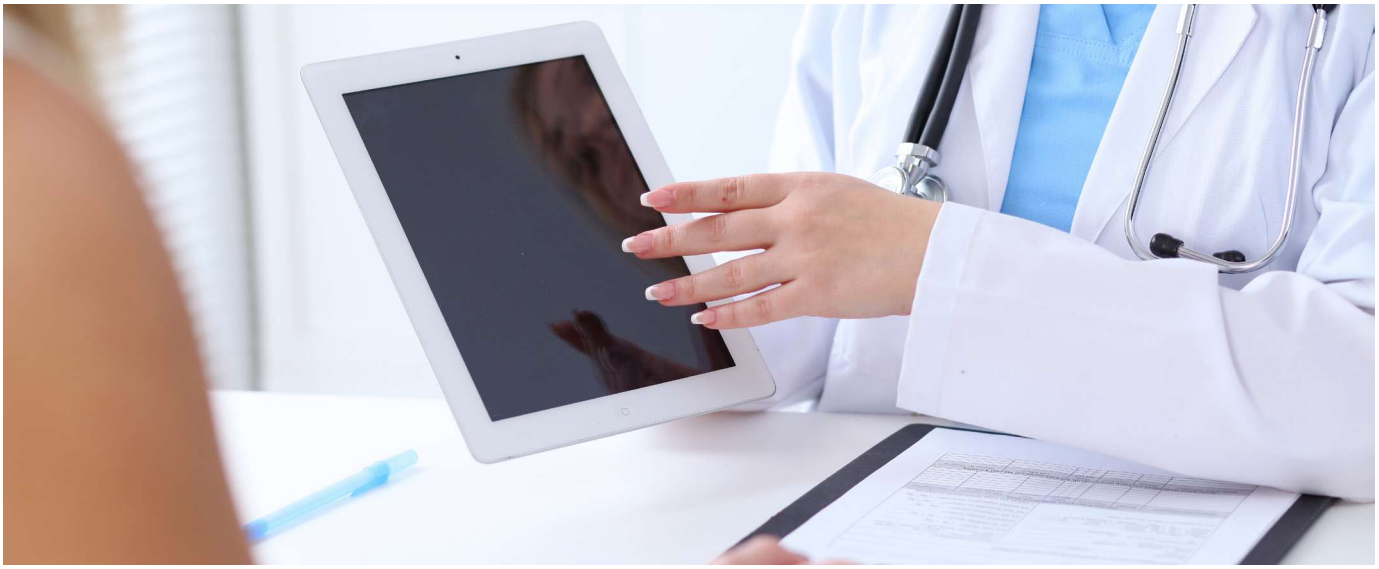
With this in mind, Brad Sanderson from CRF Health, a CRF Bracket company, discusses the current state of oncology clinical research and how researchers can utilise the latest technology to improve the patient experience and improve outcomes.

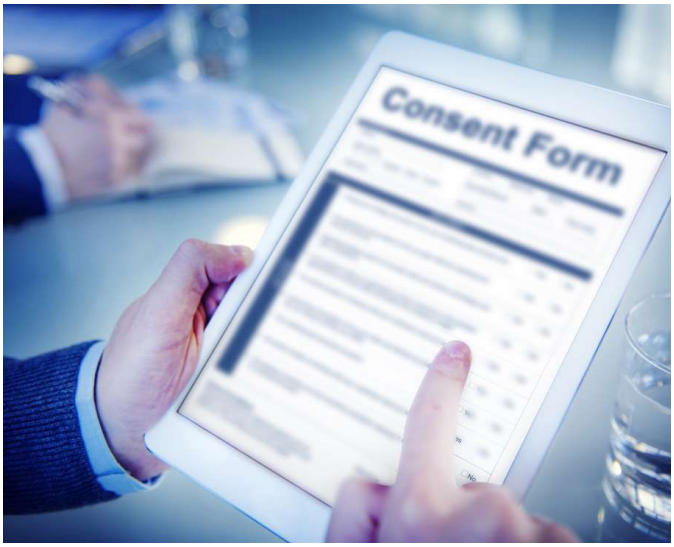
What is the current state of the oncology clinical trials market?
It is a competitive and ever-evolving landscape, meaning it's an exciting time for pharmaceutical companies who want to play their part in creating and advancing therapies that will shape the course of future, much-needed, cancer treatment.

According to recent figures, almost 11,000 cancer clinical trials are underway in the US[5] and with as many as 600 oncology-related treatments in the pipeline, the next decade will hopefully see a number of new medicines introduced to market which will extend the lives of cancer sufferers.

What are the challenges in collection of patient-reported outcomes for patients in oncology clinical trials?
The associated symptoms of the disease, and side-effects of treatment, place a huge burden on cancer patients. These symptoms, such as pain and fatigue, make it at times difficult or impractical for them to provide regular reports on their symptoms, side-effects and ability to conduct activities of daily living, and can make clinic visit attendance difficult. Even if they are able to travel, long journeys and waiting time can prove strenuous for participants, adding considerable burden to their involvement in the trial. For some patients, flexibility around visit dates and the ability to complete certain assessments, such as patient-reported outcomes measures (PROMs) away from clinic may be important.

In addition to this, making sure patients keep track of their concomitant medications and treatments can also be a challenge for oncology researchers. Tracking these medications during a clinical trial is an important element of understanding treatment effects. That said, asking a patient to write down the supplemental medications they take can be problematic as they may not always remember what they take, how often they take it, or its official name. Traditionally, patients are asked about concomitant





medication during site visits but this could be weeks after they have taken the medication. Clearly this could lead to missed and/or incorrect data.

Why is the patient experience so important in oncology research?
While involvement in oncology studies often provides access to latest treatments, drugs, specialist equipment and better access to specialist oncologists that might not otherwise be available, it's important to remember that many of the participants may be very ill, facing reduced life expectancy, or uncertainty around life expectancy. They may also have complex treatment programmed and numerous other medications to take, so it's vital that participation in a clinical trial does not add any additional burden or stress to the challenges they are already facing.

Creating patient-centric trials has been high on the agenda for the pharmaceutical industry for many years now, with researchers realising the benefits to be gained from patient-focused study designs. The FDA are publishing new guidances on patient-focussed drug development in response to the requirements outlined in the US 21st Century Cure Act.[6] By adopting a patient-centric approach to a clinical trial, sponsors and CROs can ensure that the study fits in with the participants' lives and not the other way around, improving their study experience. Understanding the patient perspective and improving their overall study experience sounds obvious but this should be at the heart of the development process. Identifying what would be valuable for the patient by working with them, as well as patient representatives and associations, and incorporating their suggestions into the trial development process is a logical step. It is likely to result in improved compliance and retention which, in turn, will result in higher quality data capture and maximise the value of PROs in a timely and cost-effective manner.

How can new technologies, such as eCOA and eConsent, help improve the patient experience?
The advantages of using new technologies such as electronic data collection methods during oncology clinical trials are very clear, with industry leaders among the first to adopt eCOA. Inside the primary care environment, oncology patients believe that the use of eCOA to report symptoms positively affects their clinical care.[7]

Improving the patient experience is one of the biggest benefits eCOA solutions provide. Firstly, eCOA lends itself to daily life more than traditional paper-based questionnaires. It is cumbersome to carry around paper and a pen for the duration of the study, and it is easier to misplace or forget about. This can often result in what we'd call the 'parking lot syndrome' – when patients fill out the questionnaire in the parking lot just before an appointment. eCOA provides helpful reminders, alerting patients as to when to input data and notifying them if they miss anything. It also provides alerts to sponsors and site teams if there is data missing from a participant, meaning they can follow up and ensure it is obtained promptly. By completing data entry in a timely manner, data quality is improved as patients are less likely to forget or mis-report activity. By improving the timeliness of data entry, sponsors can also ensure the data is contemporaneous, helping them meet the ALOCA principles as required by the FDA in its PRO Guidance.[8]

As previously mentioned, as their condition progresses or during certain cycles of treatment, patients may experience increasing burden due to the disease and its treatment. For studies utilising eCOA, patients unable to complete the questionnaire at the site can use the technology to reschedule visits, re-activate incomplete or interrupted visits so that patients can pick up where they left off, and also add unscheduled visits for patients who may need additional time at the site due to a change in their diagnosis.

In addition, eCOA allows patients to elect a caregiver role on their device, meaning that if necessary, a caregiver can input data on their behalf using observer-reported outcomes (ObsRO), and this user-entry clearly marked within the eCOA data. Caregivers will be provided with on-device training to ensure they feel comfortable with the process and are able to report the data confidently in line with the study protocol, in order to maintain compliance.

eCOA solutions are also intuitive and extremely user-friendly, delivering an outstanding user experience compared to traditional paper-based collection methods. By transforming the way patients submit their data, making it easy and time-efficient for them, they stay invested in the study, improving retention rates and increasing compliance.

Without these options provided via eCOA, which all reduce burden for the patient, the likelihood of poor data quality, participant drop-outs, or site challenges greatly increases. In turn, study teams put at risk their ability to collect high quality, defensible data that they can feel confident about.

How do you feel technology will influence oncology clinical trials over the next 5–10 years?
New solutions will continue to evolve and impact on the speed and accuracy with which oncology clinical trials are able to be conducted. Paper-based processes really are no match for e-solutions in terms of

speed, simplicity and cleanliness of data collection.

Perhaps the biggest opportunity within patient onboarding in the coming years is the advent of eConsent within the clinical trial environment. eConsent provides a huge opportunity to improve patient comprehension of study procedures before embarking on a clinical study which may reduce the risk of drop-out. Additionally, eConsent enhances the traceability of consent across clinical studies and provides a clear and secure QA trail that provides robust support for GCP regulatory requirements. Furthermore, specifically relevant to oncology trials, is the flexibility with which eConsent can manage the completion of multiple consent forms with relative ease. This could include consent forms for biopsy, imaging, etc, which, if not appropriately signed, may result in a sponsor not being able to use the data as planned.

The continued introduction of innovative wearable technologies will also play its part, as these solutions offer new means of data capture by allowing researchers to passively monitor and collect information about a person's physical activity and movement, such as step-count or sleep patterns.

All stages of a clinical trial, from recruitment through to monitoring, will benefit from the adoption of electronic solutions. Not only will communications be much smarter and faster but by utilising technology which is familiar with patients and fits in with the participants' everyday lives, outcomes will be of higher quality, resulting in lower cost for sponsors and CROs, and much quicker time to market for new treatments in the fight against cancer.

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