



Planning Considerations for oncology studies

It is widely accepted that oncology studies are a breed apart from studies in other therapeutic areas and require specialist in-depth knowledge. Therefore, sponsors can benefit enormously from choosing a CRO with proven expertise in oncology study design, statistical analysis and medical report writing—the right experience can ensure timely and appropriate design, data collection and reporting, thus keeping costs to a minimum and avoiding unnecessary delays. Furthermore, successful and timely reporting will very likely lead to increased shareholder value.

When planning a phase 1 oncology study, experience in this particular phase is paramount. Your CRO needs to have prior experience of running a variety of dose-limiting toxicity [DLT] studies including use of standard designs such as Simon two-stage design and other adaptive designs. These trials need rapid data collection to allow for expedited reporting and data review for decision-making. Electronic Data Capture (EDC) applications with real-time reporting can benefit sponsors by providing this service via web access.

At all phases, given the multitude of data collected, the importance of engaging personnel with experience handling complex data from oncology studies cannot be understated. For example, it is necessary that the team has:

- Expertise to advise on the correct study design for a particular treatment
- Knowledge to design the CRF collection modules to allow for changes to dosing and/or dose regimen
- Understanding of matching concomitant medications and adverse events to the correct treatment cycles in order to provide accurate reporting
- In-depth knowledge and understanding of regulations and guidelines provided by regulatory agencies such as the FDA

EDC is highly recommended for oncology studies due to the higher volume of data being collected—it is much more practical than walking around with an enormous CRF under your arm! Setting up a database for an oncology study using EDC will take about 5 weeks. However, pre-defined eCRF libraries can be used to substantially reduce set-up time, cost and effort.

The increasing use of EDC technologies allows for more sophisticated reporting techniques; not only DLT reporting, but real-time patient profiles allowing sponsors to follow patient progress throughout the study. Centrally collected data, such as blood draws, bio-imaging data, MRI scans and ECGs, can be uploaded within the EDC platform to allow the investigator to comment on-line. Other electronically captured data (such as patient symptom diaries) can also be uploaded; thus, the EDC platform can become a one-stop data repository and reporting hub.

Katherine Hutchinson – Head of Consultancy, Quanticate Ltd.