

Technology in the hands of the CRO

In recent years, the pharmaceutical and biotechnology industry has called for CROs to take a greater role in IT management, and industry analysts are projecting that IT decision-making will move away altogether from the sponsor into the care of the CRO.

CROs are already finding that more often, clients are looking to them as a service provider of data management solutions and are basing their decisions on the capability and robustness of the electronic systems chosen by the CRO.

This has become especially vital for the regulatory submission process. "There is an increasing need for regulatory statistical support, advanced statistical design, statistical validation of biomarkers for use in the clinic and cost-effective and integrated electronic data capture solutions," confirms IDDI CEO Damien Tremolet.

The competitive pressure to shorten the clinical trial cycle by collecting quality data more quickly and accelerating the availability of the data have led to the growth of electronic data capture (EDC) and other systems. As a result, CROs are playing a key role in providing solutions that are imperative for time-controlled

data collection during many early-stage clinical studies.

"This is one of the most significant changes I've seen in the industry," says founder and CEO of Iris Pharma, Pierre-Paul Elena, PhD. "After designing a

compound, clients want to know if the compound is active in humans. They want to be in the recruitment stage, onto Phase II as soon as possible; you have to have electronic data capture technologies set in place." ■

A case study in electronic data capture

A new ophthalmic drug entered a Phase I trial to assess its safety and tolerability in dry age-related macular degeneration. Per the sponsor's requirements, IDDI designed the paper CRF and set up its Oracle-based data management system to collect clinical data using a full proof double data entry process. As the collection of CRFs impacted heavily on the study logistics at site and delayed the data entry process while several patients were already enrolled, the sponsor challenged the data management team to switch the data collection process to electronic data capture.

Since IDDI's Data management suite allows a hybrid deployment (paper or EDC), the changes were limited to the enhancement of existing entry forms and edit checks for a user-friendly remote data entry process and the design of additional tracking reports. A date for stopping paper forms usage was defined. IDDI trained the sites and monitors and enabled the electronic data capture feature five weeks after the request, when all paper CRFs were collected.

Client response: "Switching from paper CRFs to EDC not only significantly reduced the time taken to issue and respond to queries, it also allowed us to lock our database two weeks after the last patient visit. This would not have been possible with paper CRFs. IDDI made the process of switching from paper to electronic CRFs mid-study easy for us and easy for our sites." ■

CROs reduce development time at equal quality

According to an independent study by Tufts Center for the Study of Drug Development, clinical outsourcing results in faster development times at comparable quality. The study's key findings show that:

- According to sponsors, projects with high CRO usage stay closer to schedule: in general, high CRO usage projects are submitted more than 30 days closer to their projected submission date than are low CRO usage projects.
- Median time from projected to actual submission date for low CRO usage projects was 130.5 days.
- Median time for high CRO usage projects was 98.3 days. Although pivotal trials involving high CRO usage tend to be larger than those with low CRO usage, they are completed faster, especially during the study close-out period.

- While CRO usage is associated with faster development speed, performance quality is comparable between low and high CRO users.
- No statistically significant differences between low and high CRO usage were found when comparing time from new drug application submission to approval.
- There was no difference in investigative site compliance with good clinical practice guidelines between high and low CRO usage projects.

For the purpose of this study, low CRO usage is defined as drug sponsors spending less than 40% of their total clinical program budget on CRO services; high CRO usage is defined as drug sponsors spending more than 60% of their total budget on CRO services. ■

