JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 10, No. 6, June 2014 "Happy Trials to You"

Clinical Research: A Time to Change

By Norman M. Goldfarb

The recent Partnerships in Clinical Trials (PCT) conference provided an excellent opportunity to assess trends in the clinical research industry. To start with, while the PCT conference, historically, has been more of a tradeshow than a forum for education, this edition of the conference was probably stronger on the education side.

We do need trends, and fast. By some estimates, it costs the industry as a whole over $4 billion (including the cost of failed drugs and capital costs) to bring a new molecular entity to market. A panel of senior executives estimated that 30-50% of the money spent on a typical clinical trial is wasted.

Digital Health

Over 5,000 digital health applications, mostly wearable devices and mobile apps, are under development. Venture capitalists are now investing more in digital health ($6.8 billion estimated in 2015) than in biotechnology. Thirty-eight of the Fortune 50 now provide healthcare products or services. The applications are beyond astonishing: breath testing to detect cancer; heart rate, temperature, blood oxygen, respiration and EKG in a wireless patch; blood pressure without a cuff; blood sugar sensing in a contact lens; and that's just scratching the surface. Qualcomm is offering a $10-million X Prize for the best version of a Star Trek tricorder. IRB review anyone?

Risk-Based Monitoring

Major study sponsors have gone all-in on risk-based monitoring (RBM). They are seeing significant improvements in quality, principally by detecting and correcting deviations more quickly. They are also seeing cost savings of 15-30%. The initial TransCelerate white paper of 2013 has evolved into full-scale RBM adoption in 2015.

RBM implementations are managed by a central monitoring office, not to be confused with remote monitoring, that is staffed by a cross-disciplinary team. Commitment by the project manager, advance planning, and flexibility are essential. To be effective, RBM needs proper tools, such as a periodic risk report that highlights issues and an efficient system for escalation.

The role of the field monitor is evolving in the direction of auditing, i.e., a growing focus on site process improvement. With remote monitoring — and often small participant populations — monitors are visiting sites only three times per year. Most monitors love their evolving role; others do not, but there has not been a significant impact on CRA turnover.

Social Listening

Social media emerged a few years ago as an effective way to recruit study participants. The focus has now shifted to social listening — monitoring social media for relevant postings that reveal adverse events, public sentiment, how patients think about their diseases, etc. Although it is often impractical to respond to problematic postings directly, listening to social media can help shape messaging and study conduct.

Precision Medicine

Precision (personalized) medicine will drive the trend toward ever more restrictive eligibility criteria, which works to the advantage of large health systems with detailed EMR data. Genetic analysis is starting in Phase I. Insurers are starting to negotiate drug pricing based on performance — if you want to charge $100,000 for a course of treatment, it better work. As more risk factors are identified, preventive medicines will emerge. Large groups of patients have started sharing health information in what are basically observational trials. A significant number of patients with a narrowly defined profile can answer questions specific to that profile, with statistical significance.

Controlled Access (Transparency)

Pharmaceutical companies have started to accept the authority of independent boards to decide when to release study data and to whom (so far, mostly academic researchers and health groups, not competitors). Cleaning and packaging the data typically takes about 80 work hours. At least some large pharmas "will not hide behind the IP"; the public benefit is too large. Safety data can be combined across multiple studies. Fresh eyes might find new opportunities in failed studies. Patients might be more willing to participate in studies when they know their data will not locked away by the study sponsor.

Author

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.