HOW COSTLY ARE YOUR DATA?

Allan Wilson MD PhD

Clinical trial costs are spiralling out of control. Studies generally estimate the cost of bringing an Investigational new drug (IND) to market at $1B although there is considerable variability in such estimates. Data handling and pickup costs related to patient records account for a staggering 30 percent of drug development costs. This is just the beginning of the cost of non-compliance – for more details, refer to "Medication Non-Compliance", "How Valid Are Your Clinical Trials Data?" and "Are Patient Reports Accurate?"

Consider the cost of simply recording dosing times. Then add the inaccuracies inherent in the recording process. Remember that many patients will fill out their diaries retrospectively – often while waiting for their follow-up interviews. Factor in the time spent deciphering illegible and incomplete patient diaries. Finally, pay someone $4.00 per page for the double data entry required to capture that information into an eCRF (Electronic Case Report Form). It adds up quickly.

Are you in doubt as to when patients really take their medication? Are they missing doses or taking doses as irregular intervals? How does this affect your data? Is poor patient compliance adding noise to your study, making it more difficult to detect the signal (therapeutic effect)? If you are a clinician, how does poor compliance affect your ability to make a rational decision about continuing or altering further pharmacotherapy?

A manual query about the dosing regimen can cost $12 to $20 per page of information. The cost could be as high as $2000 to $10,000 per patient per study to record and handle data the reliability of which is suspect.

What if you had a way to identify non-compliant patients early in a study using a short course of a placebo? Non-compliant patients could be excluded from the study or targeted for education on the importance of compliance. Their outcome measures could also be adjusted for non-compliance noise using statistical covariance techniques. This would result in considerable savings as the increased accuracy of data lead to more convincing outcomes.

What if there were a better way? A way to get all your patient compliance information with direct data capture right at the source. A foolproof method of recording the time each tablet or capsule was removed from a blister package. That's Med-ic® state-of-the-art Electronic Compliance Monitoring (ECM©).