HOW COSTLY ARE YOUR DATA?

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Clinical trial costs are spiralling out of control. Studies estimate the cost of bringing an investigational new drug (IND) to market at over $1Bn, 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-adherence – for more details, refer to “Medication Non-Adherence”, “How Valid Are Your Clinical Trials Data?” and “Are Patient Reports Accurate?”

Consider the cost of simply recording dosing times and then add the inaccuracies inherent in patient recorded outcomes (PROs). 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 erratically? How does this affect your data? Is poor patient adherence adding noise to your study, making it more difficult to detect the signal (therapeutic effect)? If you are a clinician, how does poor adherence affect your ability to make rational decisions about continuing or altering your patients' 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-adherent patients early in a study using a short course of a placebo? Poorly adherent patients could be excluded from the study or targeted for education on the importance of adherence. Their outcome measures could also be adjusted for non-adherence noise using statistical techniques. This would result in considerable savings, as increased accuracy of data leads to more convincing outcomes.

What if there were a better way? A way to get all your patient adherence 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©).