How eConsent can improve your trial bottom line

The key business drivers for implementing eConsent include, increasing participant satisfaction and reducing attrition, improving regulatory compliance and the enablement of remote eConsent and real-time monitoring. An effective eConsent process will provide participants with educational content in an easily digestible format and in a language they can understand, while also validating the participant's comprehension and providing a method of providing feedback to the investigator or site and by raising and resolving participant queries and concerns.

In these days of cost cutting big pharma would not be implementing eConsent if these were the only benefits, the bottom line is eConsent is being implemented because it has been proven to reduce overall trial costs. A CenterWatch report found that by using eConsent rather than a paper consent system sites could enrol 25% fewer participants to reach the same study goals. For that to happen the eConsent process needs to move from a medico/legal document to a participant centric education process using learning modalities and language that the participant understands. A well designed eConsent environment can be multi-lingual and include animations, videos or diagrams to enhance the participant learning experience.

The primary identified benefits come from increasing the number of participants that consent to joining a trial and lowering the number of participants that leave the trial prematurely for non-clinical reasons.

Industry research indicates that for every 100 participants identified for a trial, only 31% pass pre-screening and only 13% consent to join the trial, 9% are screened and 7% complete the trial. If we look at these figures from the perspective of meeting the recruitment target, for a trial requiring 200 subjects, 2,757 participants need to be identified. If we take an average pre-screening cost of $1700 per participant, the pre-screening costs for a 200 subject trial would be $4,688,600. By reducing the total number of pre-screened participants, the trial costs will be significantly reduced.

Industry research indicates that eConsent can increase the number of participants consenting to join a trial by between 30-50% and reducing the number of participants that leave the trial for non-clinical reasons by around 20% to 25%. This also effectively reduces the number of participants that need to be identified to meet the recruiting target.

If we just look at pre-screening costs, we can get a really good idea of where the cost benefits lie. For instance if we could achieve a 15% increase in participants consenting to a trial that requires 200 subjects, we would only need to identify 2,032 potential participants. This is a reduction of 726 participant that need pre-screened. The cost saving would be 726 x $1,700 = $1,234,200.

The number of subjects leaving a trial prematurely for non-clinical reasons has a similar affect, but the costs can be more pronounced as not only do you have the pre-screening but also the screening and trial costs up to the point the subject leaves the trial as that subject will need to be replaced. Reducing participant attrition by having better informed participants will significantly reduce trial costs.

However, implementing eConsent will increase the costs when compared with a paper base consent process. The cost will depend upon the type and nature of the trial and whether the same educational content can be re-used for multiple trials. Some of the costs of implementing eConsent include: the eConsent platform, creation of the relevant educational content, training and implementation of cultural change. The selection of the eConsent platform will be driven by the size and complexity of the trial. Currently the available eConsent platforms range from simple standalone Apps to comprehensive integrated trial management systems.

Transcelerate and Signant Health research indicates that with any significant change to the clinical trial process that it usually takes 2-3 trials before the benefits of eConsent are fully realised. The larger the trial the quicker the cost benefits will be realised.

While every trial will be different, with different costs and participant demographics the evidence is clear that for trials of greater than 50 subjects, eConsent will provide a significant cost saving.

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