

Patient Reported Outcomes: A key to Compliance Success Factors

Subject compliance is a hot topic in the industry right now. Some of the discussions out there can be a little misleading since ‘compliance’ means different things to different people / companies. Many eDiary vendors focus on a subject’s compliance with data entry, whereas sponsors are more interested in the subject’s compliance with the study procedures, and clinicians are interested in the subject’s compliance with their medication / treatment.

I think it’s important that we define what we mean when we use the term compliance, because it can mean any of the above items. It is also important that we carefully define the reports and metrics that are collected in clinical studies. I see many studies attempting to come up with a single metric for ‘total compliance’, which includes a number of different things, such as compliance with different medications, diary entry, etc. By doing this they are actually hiding some important details. Individual metrics for individual items would most likely be much more useful. If a subject is having issues with their medication compliance, it should be addressed separately from their compliance with the entering of information into their eDiary.

CRF Health has been collecting eDiary compliance metrics for many years now, and our compliance database is getting quite extensive, and becoming more useful as we collect more data. Every single CRF Health eDiary device automatically collects project specific eDiary compliance for every subject. While it is sometimes difficult to define a reliable compliance metric for every study (OAB and other event-driven diaries are difficult, for example), there are some interesting trends that are starting to emerge:

Africa is the Leading Geographic Region, with 94.5% Compliance

Personally, I find this surprising. However, we only have a limited amount of data for Africa – only 2% of our subjects are from Africa (n=1785). Africa is followed by Eastern Europe (92.8%) and Asia (92.1%).

Adult Populations have the Lowest Compliance

This is another surprise, since most people would expect the ‘tech-savvy’ groups to be high on the list, but the statistics are almost the opposite. Infants (e.g. care-givers) lead with 93.9%, elderly subjects are close behind with 92.3%, and adults are well below the average with 88.5%.

Healthier Populations Perform Better than Sicker Populations

This is not surprising at all. Our vaccine studies have 93.8% compliance with a standard deviation of 10.9, compared

to 86.1% / 15.7 in pain, and 86.3% / 18.2 in COPD. What is interesting is that there are studies within some of the ‘difficult’ indications that have very good compliance, and there are studies that are not doing so well. It proves that it is possible to get very good results even within the difficult indications. This actually raises some interesting questions – what are the key success factors in these studies and what can we learn from the studies that are not doing so well?

Compliance Success Factors

The space allotted for this article is not enough to discuss the details, but here’s my shortlist of what I personally consider to be the key points:

- Subject focused eDiary design that will proactively guide the subject AND study sites through the study
- Efficient compliance management tools for sites and CRAs – online reports, email notifications, etc
- Active study team from the sponsor / CRO who will use the compliance monitoring tools and stay on top of everything

These are all generic concepts that can be adopted in virtually every study. There are obviously many protocol / disease specific best practices that can be utilised. Study sponsors should expect the eDiary vendor to be able to proactively guide them through the design process to ensure best results for each study. This is exactly what the CRF Health teams are used to doing – we actively use our existing experience and best practices and provide these recommendations to our sponsors.



Kai Langel has worked with CRF Health since the company’s inception in 2000 and is one of the pioneers in the ePRO industry. During this time, Kai has been involved in all aspects of ePRO operations from system design to deployment and support. Kai spent 5 years in the United

States where he was responsible for building CRF Health’s technical delivery team. He is currently based in Europe in a consultative role providing advice and guidance to both customers and CRF Health’s internal teams on technical, operational and regulatory issues. Kai is a true global ePRO expert, having worked both in the United States, Europe and more recently in Japan and Asia.

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