

VIP Customer Questions & Answers

– Medical Director, US Pharmaceutical Company

Q: Why did you choose eDiaries over paper diaries, and how did you come to select CRF Box E-Diaries to help you in your clinical trial process?

We had used paper diaries in the past, and we felt that eDiaries would provide us with more accurate data. We also hoped that the patients would become more enthusiastic and compliant in filling in the diary, if we could give the patients a device that they wanted to use, such as the PDA.

Based on our experience, the problems with paper diaries depend a lot on the complexity of the questionnaires. We hadn't had too many problems with very simple Yes-No questions. But if the diaries required more input from patients, they many times forgot to fill them out. For example, in one urinary incontinence trial, the patients needed to measure the volumes of their produce, and that information was difficult to record and collect on paper.

When we had made the decision to go for eDiaries, we wanted to find the right trial, and this seemed like a perfect one, mainly because the patient population was a younger population, which we thought would be a little more tech-savvy. The reason why we picked CRF Box was that we were really impressed with the presentation and product demonstration CRF Box gave compared to the other companies we had seen.

Q: What role did CRF Box e-Diaries play in this protocol?

This diary data that we collected is actually very important safety data. It is not going to be used in the analysis of efficacy, but there is an important safety issue with this drug: So the eDiaries enabled us to capture more reliably one of the main safety issues we wanted to follow.

Q: You have now been using the e-Diaries for several months. Tell us about how you internally participated into the deployment process and what departments were involved?

In the set-up phase CRF Box project management would send our clinical team the specifications of the eDiaries for our review, and in the beginning there was a lot of back and forth commenting of the documentation. Once the diary prototypes were available, we distributed 4-5 eDiaries within our clinical team and 4-5 to the CRO team. The different departments that were involved were mostly clinical and a few people from the biostatistics and data management.

Q: What do you consider most important issues in making the E-Diary deployment a success at the site and patient level?

We faced most of our challenges in the beginning of the deployment process. We did not anticipate the time and effort we had to spend on ensuring QA (Quality Assurance) and QC (Quality Control) of the product. Fortunately the recruited patients didn't start filling in the diary for the first month, so that gave us some extra testing time to make sure that eDiaries worked flawlessly. The more QA performed early in the developmental process, the fewer glitches you end up having.

Q: How did you handle training and support issues?

It seemed that once the diaries got to the sites, the live Helpdesk and telephone support provided by CRF Box was successful. In the beginning there was some frustration at the site level with data transmission, but after the first 3-4 weeks of the trial the issues became less important and more random. Training took place at the Investigators' Meeting, and support overall for both the patients and the sites was crucial because it helped to manage some of the frustrations with the site personnel and the patients.

Fast response times of the CRF Box support personnel was also vital. If the sites didn't get fast response to their issues, their level of frustration would grow fast.



Q: Oftentimes Electronic Patient Diaries are still considered “techy gadgets” that may create confusion for individual patients. How have your sites and patient accepted them, in general?

The average age of our patient population was around 31 years, and we completed 294 patients in total. 290 of these patients used the eDiary to record data. The four patients that didn't use the eDiary missed it due to misunderstandings with their sites.

In terms of patient acceptance we were surprised to find out that instead of keeping the devices after the trial, they preferred to turn in the device and take cash instead. Overall, the patients accepted the EPD technology very well.

Q: To increase data accuracy, CRF Box online Review Tool sent automatic email reminders to sites whose patients were missing their diary data for certain days. How did the sites experience this, and did these “extra reminders” provide any benefits?

Yes, I think we did get a business benefit from the “extra reminders”. We had some overlap, though, with the reminder process, because when the sites called the patients after receiving the email, the Review Tool was updated only with some lag. This led to our CRO further reminding the sites for missing data, which led to some frustration with the site personnel.

However, because the coordinators were able to remind the patients in real-time, this enabled us to capture and collect more data, which is clearly a business benefit for us. With the paper diaries, that wouldn't have been possible.

Q: Aside from improved quality of data, what other benefits have CRF Box e-Diaries provided for the sites and for your organization?

I think one of the added benefits was that our CRO in this study was able to be more effective in managing the sites thanks to the real-time information provided by the online Review Tool.

I wouldn't say that we were better able to monitor the patient recruitment. We got that information directly from the sites. But I would say that the Review Tool was very helpful in that every other week when we had our teleconferences, the CRO would go over what “subjects have more than 6 days missing data”. CRF Box was then able to follow-up with the sites and the data was closely monitored resulting in enhanced patient compliance. So I would say that the Review Tool was actually very helpful.

In terms of the data quality, we haven't yet analyzed the final dataset, so I can't give any concrete figures there.

Q: How did you benefit from the web-based online Reviewer Tool? And did the sites benefit from it at all?

We actually didn't give the sites the information to access the Review Tool. The reason was that we felt that it really should be the CRO managing it. If the sites had one more thing to do, that may have distracted them. I just felt like that the management was much better being controlled by the CRO, and with the communication between the CRO and CRF Box.

I think that if the data were a little bit different, and if the sites would have wanted to know how the patients were doing, we might have allowed the sites to use and benefit from the Review Tool. And also if there had been fewer patients per site; some sites ended up recruiting more than 50 patients, so I can't imagine one site having to track all of those patients. I just felt that in this trial it would be just another aspect the sites would have to track, and if we could take that responsibility away from them, they would be more receptive in accepting the eDiaries.

Q: In this trial there was also a CRO involved. How did that affect the deployment of E-Diaries (if at all)?

Our CRO did a really good job with eDiaries. In the end I guess they had more work than they imagined, so they just added an extra member to their team. That person's main responsibility was to track the missing or unreported data from the eDiaries. So they were responsible for using the Review Tool once a week to find out which patients were missing data or having a problem with transmission of data, and then they would share this at our teleconference. This way we could proactively follow up and notify the sites.

I think the deployment process of the eDiaries together with CRF Box went very smoothly. The communication, e.g. regarding the replenishment of eDiaries to some high-recruiting sites, worked well. The CRO was also very involved in the User Acceptance Testing process, which was very helpful and made a big difference. Overall, I think our CRO did a very good job with the eDiaries.

Q: E-Diaries typically involve very special clinical benefits that are dependent upon the applied therapeutic area. What therapeutic area are you working on, and were there some special elements in the clinical protocol that lent themselves well to the use of E-Diaries?

The therapeutic area that we were working on was prevention of contraception. In this particular protocol eDiaries were mainly used for two things: to track safety events as they occurred since patients were seen once a month, and as a reminder to tell the patients when to take their medicine. With this particular class of drugs the therapeutic window for when they have to take their medication is crucial: So I think it was very good to remind these patients so that they could be more compliant. And secondly, the eDiaries helped us to gain information on the safety of the product. I wouldn't say that privacy was a big issue in this case, I can see that being a bigger benefit with other adverse side effects e.g. sexual dysfunction.

eDiaries have alarms that alert the patients when to take the drug, and they alarm the patients to answer the questions at a certain time every day. With the paper diaries patients sometimes forget the answers, and they take a week to complete them, which obviously has an impact the accuracy of the data.

Q: Were there any regulatory concerns that you faced when making a decision to deploy electronic patient diaries instead of paper diaries?

I think for us in this particular trial, as we were only capturing safety information, we didn't feel that there was so many regulatory risks as there maybe would have been if we had been collecting primary efficacy data.

The feedback from our regulatory department was that eDiaries really weren't an issue, and we felt that this data would be accepted as well – if not better – than paper diary information.

I think that we are moving more towards an electronic era. Patient records are becoming electronic, case report forms are becoming electronic, and also new submissions are becoming electronic. It is all going hand in hand.

However, with the tightened HIPAA regulations going into effect in April 2003 some things may become more difficult such as tightly regulating how many people have access to patient's information. This would affect things like having patient's contact the help desk directly for assistance with the eDiaries..

Q: How have you been able to justify CRF Box e-Diaries' return on investment for upper management?

There wasn't actually any return on investments analysis done, but I have to say that the budget was approved for two reasons: again we just felt that this was a perfect trial to test the benefits of Electronic Patient Diaries, and also we wanted to improve our internal process of managing the diary data. In the past when using paper diaries, it was our data management department who had to enter the data electronically from paper, which, of course, costs us money because it costs man-hours. And I think in the end we feel that it was probably "a wash": the costs and generated savings balance each other due to the increased accuracy of data and the reduced amount of internal data handling and cleaning.