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eDiary Problems: Avoidance and Mitigation

By John Lacombe

Any study coordinator who has used an electronic diary device (eDiary) in a clinical study knows they seldom live up to the promises made by vendors or study sponsors. Technical problems, inadequate training, awkward interfaces, unclear data capture questions, and even uncharged batteries can lead to non-compliance, untimely or incorrect answers, lost data, and potentially lost subjects. Otherwise eligible study subjects may be unable or unwilling to cope with the devices during an initial screening/baseline period or during the study. However, with the following strategies, sites can mitigate many common eDiary problems:

1. **Readiness Preparation.** Prior to assigning the first eDiary to the first subject, review the reference manual for the device and the instruction guide for its use during the study. Know confidently how to assign a device to a subject and how to train subjects. Make sure you can log into the devices as an administrator and as a subject, and into the web portal, if any.
2. **Training.** Thoroughly train the subject, not only on the eDiary device itself, but also on the data capture questions. Most eDiaries have a practice mode. Use it with each subject, repeating the process until you are certain the subject understands how to use the device and answer the questions in the likely scenarios. Ensure that the subject knows how to obtain support when an issue arises. Make sure the subject understands that he or she must make daily eDiary entries without fail and the consequences of missed entries.
3. **Missing Data.** Even a single missed entry during the screening/baseline period can prevent a subject from enrolling in a study. Therefore, check each subject's compliance daily — without exception — during this period. Most vendors provide a web portal for monitoring eDiary activity, but information may be available through automatic emails or faxes. Inform the subject that you will check compliance daily. If you notice even a single incident of non-compliance, contact the subject immediately. Never wait until the next day. Document the incident and its resolution, including that you counseled the subject, demonstrating to the sponsor that you are on top of any issues.
4. **Correct Data.** During the screening/baseline period, check each subject's answers daily because they can make mistakes or not quite understand a question. Once the screening/baseline period is complete and you are confident that any problems have been resolved, check their answers periodically, e.g., weekly. Some vendors make this possible through their portal, but others do not. If not, call the subjects and review their answers. This process is especially critical if their data determines eligibility. Most eDiaries prohibit changing answers or entering data after midnight of that day. So, if the subject wants to correct an answer or misses a deadline, record the information in the source documents and ask the sponsor how it would like you to handle the data. Most importantly, make sure the same problem does not occur again.
5. **Follow Up.** Even if you observe 100% compliant and valid answers, call the subject in the first few days to check for potential problems. Ensure the subject has the device plugged in properly and it is charging or fully charged. Uncharged batteries are a common cause of missed entries. A missed entry is a missed entry, no matter the reason. Many devices are now wireless, so make sure subjects can receive the cellular signal in their home for transmission. If not, they might be able to communicate from

another location. The sponsor may also be able to provide a device that communicates through a landline.

6. **Avoid Fridays**. Avoid issuing an eDiary on a Friday. Most problems occur when the device is first assigned, so you do not want to be dealing with issues like replacing a device over the weekend or losing a few days of data because the subject waited until Monday to contact the site. Most protocols do not allow subjects to start over after the bugs have been worked out.
7. **Access to Knowledgeable Staff.** If possible, make sure that subjects can call the study coordinator or other support person directly with problems, including after hours. The study coordinator should know how to troubleshoot most problems. While a vendor's customer help desk is usually available 24/7, the site is in the best position to solve most eDiary issues. While the vendor can often help with device problems, the site is in the best position to help with operator problems and has experience training the subject. The site should provide a cell phone to the study coordinator, who can give that number to subjects. When the protocol requires evening diary entries, it is common for subjects to need help after business hours, when they cannot recall all the training or their eDiary has malfunctioned. While most study coordinators would rather not receive these calls at odd hours, most troubleshooting is not difficult and waiting until the next business day risks missing data entries.
8. **Reset.** Technical issues like the device not turning on or locking up can often be fixed with a simple reset (reboot). Generally, the vendor does not provide this information unless you ask, so ask.
9. **Expect the Unexpected**. Assume that subjects will have problems with compliance, entering data, and malfunctioning devices. Instruct subjects to bring their eDiary to every visit, even if not required by the protocol. Check the device to ensure it is working and charging properly. Also, if the visit turns into an early termination for some unforeseen reason, you can collect the eDiary and will not have to chase it down.
10. **Maintain Spare Devices.** When you get the eDiaries, keep them plugged in at all times using a power strip at a single location. Watch your inventory and always have a few devices on hand for new subjects or in case one malfunctions. eDiaries are expensive, so sponsors try to limit site inventories, but they are usually open to well-justified requests for additional devices.

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