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Wasteful Clinical Research Processes

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Eliminating wasteful and inefficient processes from clinical research requires study sponsors, CROs and sites to work together. A process improvement that sounds like a great idea to a CRO might create practical issues that actually reduce efficiency at sites. Other processes are not wasteful but do transfer work to the sites without corresponding compensation. In either case, a site might conclude that the CRO is unfair, self-serving or incompetent — not a good basis for a productive relationship. A healthy discussion among sponsors, CROs and sites could resolve misunderstandings and reduce waste and inefficiencies.

The following problems, much more common with CROs than with study sponsors, appear to have been created without consulting with sites:

Patient Recruitment Budgets & Materials

In a growing trend over the past year, CROs often withhold a patient recruitment budget from sites until after the sites have exhausted their internal, "free" patient resources. When the CRO submits regulatory documents to the IRB on behalf of a site, it does not include the site's patient recruitment materials, on the basis that there is no site patient recruitment advertising budget, even though IRBs typically do not charge extra to review patient recruitment materials that are submitted with the regulatory package (and some of these materials are needed for internal recruiting). Later, when a site submits its patient recruitment materials directly to the IRB, the sponsor incurs an extra charge. Only six to eight weeks later, after the CRO's centralized patient recruiting program comes up short, do the sites obtain a budget and approval for site-specific recruiting materials.

Participant Out-of-Pocket Expenses

Some CROs have recently started requiring study participants to provide receipts for parking, tolls and meals, perhaps to reduce false charges or in connection with the Sunshine Act. Assuming the receipts are even available, it is easy for participants to neglect to obtain them, to lose them, or to forget to bring them to the visit or mail them to the site after they return home. The site then needs to spend time following up with the participant to obtain the receipts or explain to an irritated participant that reimbursement will not be forthcoming. When participants are not reimbursed according to their understanding of the informed consent form or perceive they are not being treated with respect, they will be less motivated to stay in a study or to participate in a future study. In addition, processing the receipts is time consuming and delays reimbursement from sponsors.

Central ECG Service Providers

In the traditional ECG process, a nurse or study coordinator starts by taking the ECG. If the study participant moves or there is an artifact, it might take two or three tries to obtain a suitable ECG without defects. The investigator then reads the ECG and documents his or her findings on the thermal paper recording. The site monitor then copies or scans the recording to collect the data for the sponsor.

Many trials now use a central radiology lab to read ECGs (and other lab tests, images and studies). ECG data is transmitted directly to the central service to be read. In theory, centralized reading improves consistency. However, there can be several wasteful aspects:

- The site might not have the required technology in place (e.g., an analog telephone line) to transmit the data. The site might not learn of the incompatibility until it tries to set up the equipment.
- An ECG may not transmit properly, creating additional work for both the site and the central service to deal with technology issues, retransmitting data, etc.
- If there are multiple ECGs and the site cannot or does not know how to delete the defective ones, the central service might read them all, including the ones with recording defects, creating additional, uncompensated work for the site, additional charges to the sponsor from the central service, and more work for data managers.
- The sponsor might want both the investigator and the central service to read the ECGs. It makes sense for the investigator to read the local ECGs to monitor participant safety (and be compensated for doing so if it's not a standard of care reading), but, if his or her readings are collected by the sponsor, along with the readings from the central service, there may be inconsistencies that will need to be reconciled or adjudicated, often weeks or months after a study visit, creating more, uncompensated work for the site.

Fluid Collection and Processing

Fifteen years ago, subject lab testing typically required three tubes of blood and one of urine during a study visit. The research site spun and separated one tube of blood and put it into a vial, left the other two tubes of blood as-is, and put the urine into a shipping vial. It then shipped the two tubes and two vials to a central lab.

Now, the average visit requires the collection of about 11 tubes of blood and urine. Usually one or two are not separated, but the rest of them need processing of some kind, often yielding 15-24 tubes and vials that are frozen or shipped to multiple destinations. Much of the pretest processing work that used to be completed by a central lab is now completed at the site. The average time for collecting, processing, documenting and shipping samples has increased from 15 to 90 minutes or more, not counting the time required to deal with deviations or problems with couriers. Dry ice might also be required, an additional cost for the site. However, even though the volume of work has expanded several-fold, the site fee for collecting and processes the samples is still about the same as it was 15 years ago.

Screening and Baseline Kits

At the end of a study, the central laboratory often has an inventory of visit kits that are not needed. Assuming the study sponsor doesn't want the kits, the central lab should destroy or otherwise dispose of them. But often it doesn't work that way. After enrollment is complete, the sponsor (or CRO) notifies the sites to stop screening patients. Sites then receive a shipment of kits for screening and baseline visits that cannot possibly be used. (The dates on these kits sometimes indicate they were newly made.) When the sites ask the lab for instructions to return the kits, the lab informs them to destroy the kits or throw them away. Site personnel then need to break down the kits and dispose of the contents (e.g., sharps) appropriately — just what the lab would have done before spending the time and money to ship the kits to the sites. One can only speculate on the reason for this wasteful process that causes additional costs for sites and, presumably, sponsors.

Other

Sites should not have to put their investigators and study coordinators through redundant GCP training, especially when TransCelerate has been working on this problem for some time.

Sites should not have to request instructions for an EKG machine or Holter monitor when the equipment arrives without instructions or the instructions are in the wrong language. Nor should they have to untangle leads, clean off bodily fluids, or buy batteries.

Sites should not have deal with a lab kits that are missing tubes or have the wrong ones.

Sites should not have to provide copies of master file documents to the CRO more than once.

Sites should not have to guess which protocol an incoming email relates to, especially when the email comes from an anonymous sender like "In-House Team at..."

Sites should not have to deal with an obsolete EDC system on a new protocol, especially when the system is incompatible with its up-to-date computer.

Sites should not have to provide free replacement copies of documents that FedEx or UPS has confirmed were delivered to the CRO.

Sites should not have to print hard copies of regulatory documents, such as investigator CVs and IRB correspondence, that are easily accessible on a computer (e.g., in an eRegulatory Binder) by the site monitor.

Sites should not have to spend three or four hours providing a CRA with secure access to their EHR system, without being able to charge for time.

Sites should not have to incur extra, uncompensated time and expense to support central monitoring that is higher than that for equivalent on-site visits.

Sites should not have to reconcile payments from CROs to individual line items of activity, especially when the remittance advice is missing or not detailed.

Conclusion

Since most of the input for this article came from only a few sites (and no sponsors or CROs), it is not clear how widespread the above practices are. There may be misunderstandings or valid reasons why these practices are not, in fact, wasteful or do not, in fact, impose uncompensated burdens on the sites. When a CRO is involved and does not adequately explain the rationale for what appears to the sites to be a wasteful process, it is easy for the sites to assume an ulterior motive. (It is a common belief among sites that CROs keep any money they do not pay to the sites.) Study sponsors might want to discuss these practices with their CROs and sites to clear up any misunderstandings and determine whether it is possible reduce waste and inefficiencies in these and other areas. Sites do not like wasting time, especially when it comes as a surprise or is uncompensated; they are more likely to accept a lower budget and enroll more study participants when they can rely on the CRO to minimize waste. Paying sites even a small amount for wasting their time would help identify problematic processes for improvement and measure progress in reducing waste.

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