TRACKING CRF DATA

TOPICS COVERED

- TRACKING PAPER CRF DATA
- TRACKING e-CRF DATA
- TRACKING CHALLENGES

EDC CRF

- All EDC software systems have built-in reports on the number of subjects enrolled and the number of EDC electronic CRFs (eCRFs) completed for each site
- The one area in which problems can arise is that the EDC system only knows about subjects that have been enrolled through the software If the site has not yet performed that step, the system has no way of identifying subjects who have been seen but for whom data has not yet been entered
- If the subjects are enrolled through an interactive voice response system (IVRS, or IxRS if it is not purely voice driven), a software integration may be able to automatically load all enrolled subjects into the EDC system so that an accurate status is always available
- When IVRS is not used or an integration with the EDC is not possible, the status relies on the sites

- and monitors to ensure that all subjects are made known to the system in a timely way—not that this is much different from what is done with paper trials
- Historically, it has been a data management responsibility to report on the status of the data to the clinical team and to provide details to each CRA With built-in reports available in the EDC system, each CRA can get a report at any time without going through data management, and the clinical project team can also obtain a cross-site summary at any time
- The CRAs will be comfortable with the EDC application (and have access to see the data) because they use it to monitor The clinical team lead should also have an account to view site and subject status

PAPER CRF MONITORING DATA COLLECTION

- When data is received on paper CRFs, it becomes critical to ensure that all the CRF pages make it from the sites to the data entry group, and then that all the data makes it from the CRF pages into the database
- Today, many companies use imaging systems to scan paper on arrival (or scan after processing), and while this provides a reliable backup to the paper page and makes pages available for entry down the hall or across the globe, it adds yet another place where a page could be misplaced

- Tracking can be performed successfully entirely on paper and by hand
- But the most useful tracking systems are those integrated with the data management system
- The benefits of a good tracking system are surprisingly high and can result in a considerable reduction in the time spent on annoying administrative tasks associated with shuffling paper
- The primary goal of any tracking method is to assure that data is not lost, and this goal must be met

TRACKING CHALLENGES

- Tracking systems and their associated processes need to be able to manage a set of typical situations that arise with CRFs:
- Repeating pages with the same page number
- Pages with no data
- Duplicate pages
- Pages with no page number

REPEATING PAGES

- These are pages such as those for concomitant medications or adverse events where the sponsor may not know how many copies are required to capture all the information obtained from each subject Sometimes the CRF designer will guess an upper limit and repeat those pages—each with its own page number

PAGES WITH NO DATA

- Some pages in a CRF booklet will not have data to enter into the database Some, such as pages designed to hold copies of specimen labels, are designed to have no data, but the sponsor does expect to receive them as part of the study In other cases, a subject may miss an entire visit or the study design may call for alternate pages to be used in specific circumstances In those examples, the site is frequently instructed to send in the empty pages or not-applicable pages with a line drawn through them and "not done" or "no data" written on them If pages are being tracked through initial data entry, repeated double-checking of why data from those pages is missing (because it has no data) can be avoided by tracking the pages as no data pages when they are received or when they arrive at first entry (This would require a database field or cross-check with the tracking system)

DUPLICATE PAGES

- No matter how well designed the CRF or how carefully monitors instruct the sites, sites seem to find ways to send in duplicate pages for a subject Some actual examples help illustrate what can happen:
- The site notices they filled out a form incorrectly, but it was already collected So they fill out a new one transcribing much of the data but correcting some of it and then send that in
- The site sends in a page marked as having no data and realizes they made a mistake, but the page has a line through it, so they fill out a new one The monitor collects both

STUDIES WITHOUT PAGE NO

- Historically, not all studies had page numbers on all the CRF pages Some of these studies did not follow the typical structure where visits happen in a predefined sequence ending with a termination page
- Studies with repeated applications of a treatment or dosing cycles (possibly by the subject at home) are one example In other cases, the CRF pages were not numbered to reduce the number of unique page templates needed for printing, which used to reduce the printing cost significantly
- In some of those studies, a page template name identified the kind of page (e g , Demog page, PE page, Lab page, and so forth) and the pages repeated in visits or cycles In others, a unique document identifier was deemed sufficient to uniquely identify and track the page

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