

2015 SCORE Half-Day Seminar - Session 4:

Let's Make It Real – Critical Decision-making using a Workplace Scenario Exercise & Interactive Discussions

Protocol: A Phase 2 study to examine the Safety and Efficacy of Drug "X" in Children Diagnosed with Chronic to Severe "ABC" Condition.

Study visit 4 - Week 6 visit activities: subject/parent questionnaire, physical exam, blinded assessment, vitals, height and weight, and assessment of: health changes, adverse events (AEs), concomitant medications and medication changes; use of the interactive voice response system (IVRS) with study drug dispensation from pharmacy, blood and urine collection, and subject payment.

Today is a typical study visit: The coordinator scheduled all of the related study team members for the required study procedures and will coordinate the subject's visit today, documenting activities performed, completing the electronic data collection forms, processing and shipping lab samples, and completing financial aspects of the visit.

The Related Study Team Members:

Study Coordinator, a 46 year old experienced research nurse. She's the "glue" that holds the research team together and enjoys her job. Lately she finds herself in continually "sticky situations," with a lack of fellow team member's support. She feels her career is being stalled. For the last 2 months she has accepted a new role as drug administration educator for the PI's ambulatory clinic (3, ½ days a week). To maintain her Research Coordination Certification, she participates in continuing educational opportunities when possible. She continues to have challenges in her work due to some of the dynamics in her group, Ex. Lack of response to emails from PI and inability to schedule training for Blinded Assessor. To accommodate ever changing schedules, subject visits seem to be re-scheduled more often than not. She is getting frustrated with the annoyed looks from various team members when she enters a room to obtain their signature(s), to set-up a meeting, or to discuss results from an assay.

Study Subject, a 10 year old child who arrives with his 35 year old mother, a pleasant lady who is quite chatty and often needs redirection by the coordinator to stay on task with visit activities. The mother is chronically 15 min late for visits; she usually remembers to *bring* her son's diary card which documents study drug dosing, AEs, and medication changes, but often doesn't remember to *record* changes on the diary card. The Mom consults her pocket calendar, but doesn't remember dates without significant prodding from the coordinator during diary card review.

Blinded Assessor (Sub-Investigator), a 32 year old new medical doctor and is also new to the study team. He meets the minimum requirements to serve in the assessor role, but lacks research study experience. The assessor needs significant prompts by the coordinator during the visit. To assist the Assessor, the coordinator will document the assessment as the physician calls out findings. At the conclusion of the assisted assessment, the assessor reviews and signs the coordinator-prepared source document. The assessor will do a blinded assessment. Assessor has agreed to see the subject between his morning meeting and a class he is instructing. The window of open time is 1.5 hours.

Principal Investigator (PI), a 61 year old experienced researcher and doctor who works on bench science, oversees clinical trials and maintains clinic hours 2.5 days a week. She enjoys a busy career, has great rapport with her patients, and has worked "successfully" with the coordinator for the past 12 years. She is known to boast that her coordinator always "dots her Is and crosses her Ts." The PI is unexpectedly "on-service" this week to cover for a colleague, which takes up an extensive amount of time, and needs to perform a physical at

today's visit. As the PI has two other study visits for another study with another coordinator today, the PI emailed the coordinator this morning telling that she'd like to do the physical in the early morning so she can "round" in mid-morning.

Laboratory Associate – is a 38 year old PhD who performs, as needed, blinded lab assays for research studies. Running these assays is not seen as a priority for the Lab Associate. The assay takes one hour to run. The Lab Associate must read and record the result, within an exact time frame, fax results and place results in a sealed envelope. The envelope is then added to the rest of the subject's processed samples which are then shipped to an external laboratory. Today, the Lab Associate just informed the coordinator that she needs the subject's blood sample ASAP as she has a lab meeting later and that she is also working on a poster presentation for a major meeting. This conversation with the coordinator did not go well, with both parties stressed.

Think-n-Talk

Session 1: Ann Michael Henry (10 minutes)

1. Explore the tension experienced by the Coordinator when balancing the need to be highly organized to meet study requirements, while also meeting needs of multiple stakeholders, who all require flexibility due to multiple time schedules and competing priorities?
2. How does the PI's request to be accommodated affect the situation?
3. What self-imposed workload might be affecting how the coordinator is functioning?

Session 2: Carol Shuherk (10 minutes)

4. How can the communication with the Lab Associate improve study processes and team dynamics?
5. Are the Coordinator and Lab Associate really listening to each other? Recognizing needs?
6. What power struggle might there be going on for the PI and the coordinator (between them or independent of each other).

Session 3: Maria Marconi (8 minutes)

7. Describe how the multigenerational differences may be affecting dynamics among the coordinator, child's mother, and Assessor.
8. Describe possible sources of conflict between the Mother, the PI and the coordinator. How might these be addressed?