



Monday Morning Practice Pearls #4

What does building “wobble room” into your protocol procedure time points really mean?

Without *wobble room* for protocol specific procedures, including drug administration, you may end up with multiple protocol deviations that need to be submitted to the IRB. It is not always possible to build *wobble room* into a protocol as the specific time of the procedure is critical to patient safety and efficacy. Many of our protocol procedures have rigid time points that a procedure must be completed in, but many can safely allow for some compromising or *wobble room*. Below are some examples you can suggest to your PI so that you ultimately avoid having a protocol deviation.

- Protocol states that labs are to be collected on a specific day for example Day 8. Can you add a +/- 2 days so that it would be CBC on Day 8 +/- 2 days allowing the CBC to be collected anytime between Day 6-10?
- If the patient is taking their own daily BP, must it be collected every day or is there room to allow for a few missed time points? What is considered being compliant? For example: patient will take their own BP daily while at home allowing for 15% missed reading.
- The study drug is self-administered by the patient. At what point will the PI consider the patient non-compliant with medication administration (e.g., missing <20% of the doses in a given cycle)?
- Your protocol states that screening labs and PE will be done 7 days prior to starting therapy. Your protocol states that Day 1 labs and PE are needed, but your PI says these aren't needed since labs and PE were done 7 days ago. Amend protocol to remove the Day 1 procedures.
- Avoid giving exact times (e.g., 8 AM) when multiple drugs or pre-medications/hydration is part of your protocol. Instead, indicate the number of minutes or hours in between the drugs, pre-meds and/or hydration and include a +/- times.
- For study medications given on multiple days, indicate the start time of each study medication can be within a certain amount of time (e.g. study medication start times for drugs given once daily should be given within 2 hours of the scheduled time or study medication start times for drugs given more than once daily should be given within one hour of schedule time).
- Consider building in room for non-AE treatment delays (e.g., weather, vacation) during a cycle or delay in starting the next cycle. Maybe +/- 1 week for vacation and +/- 3 days for weather.