Setting Expectations

As with any change effort, it is good to set expectations all along the journey. Below are some expectations gathered from others implementing QbD that may be helpful as you shape your QbD process within your organization.

- Expect to question/challenge every aspect of the trial, and look for better ways of running it.
- Recognize that changes to your protocol and/or operational plans may result from the QbD exercise and allow adequate time for those to occur
- Expect to implement activities proactively well before trial initiates
- Expect challenging discussion to identify the key Critical to Quality factors for which resources should be dedicated.
- Expect to remove unnecessary processes and checks.
- Expect CtQ mitigations to require more than routine controls and that these mitigations will provide advanced warning for problems with CtQ trial components
- Expect to simplify the protocol.
- Expect to review QbD approach throughout the study and following study closure in order to ensure improvement for current and future trials. Expect to scale the approach for different study types
- Expect to formulate how you will measure effectiveness for your organization
- Expect to start slower and finish quicker and better. Go slow to move fast.

Below are some quotes shared by QbD workshop participants that may also provide some helpful insights.

- "The biggest barrier [to implementation] is time and the perception that this takes extra time...Get people to step back and think about "going slow to go fast" or take time now to benefit in the end."
- "If you take the time to design better up front, you save time by having to do less clean up."
- "Integrating quality early on can save a lot of re-work at the end. Integrating quality early doesn't have to be a lot of work. It can be done in an efficient way."
- "It's a very interactive process. It's been my experience that it's not what one person throws up there but through that exchange, e.g. one person says we may have a problem here and three other people then contribute regarding how to best address it. The value is in the interaction."
- "Design better trials, be more specific, [don't] get lost in data, and errors that don't matter. We need to focus on what is going to make or break the trial."
- "Without buy in from the team, it doesn't work. Power comes from the cross-functional approach."
- "The dialogue is the most important thing. As you start to work with the principles document and work with a draft protocol, the dialogue is increasingly important. If people start to talk about the principles and look for things they'd mitigate during the trial, they find that they'd write the protocol differently."