What Are the "Must Dos" of Writing PCT Grant Applications?

Wendy Weber:

These are some suggestions of things to be sure to do when you are putting together your application. We strongly encourage you to carefully read through the funding opportunity announcements, particularly for RFAs and for PARs, those that have special review criteria, because within those, there are special review criteria that have been added in on top of the standard NIH review criteria in many cases, and you want to make sure that your application actually addresses those review criteria.

The other section of the funding opportunity announcement I want to draw your attention to is in Section 4 where there's a whole part of the funding opportunity announcement that gives additional instructions of what we're looking for in response to that particular funding opportunity announcement. So I know it looks like boilerplate information after that beginning section there that describes the science, but there's this whole other section further in the back that specifically says, "In the budget, do this. In the research strategy, make sure you address these issues." So don't forget to look to that part of the funding opportunity announcement.

Certainly we're looking for strong justifications. Definitely you want to include pilot data many times the pilot data for a pragmatic trial will actually include efficacy data of the intervention that was done in the much more controlled setting. It's often helpful to provide a rationale for reviewers of why it's necessary to go beyond the efficacy study that was already done and to test it in the healthcare delivery setting and to just make that explicitly clear in your application.

These studies should be impactful. It should be clear there's a reason to need to do this study to advance the field. One really strong suggestion is to make sure that your data collection and your analysis plan match back to your aims. Occasionally we see an application where there was a study design that happened that didn't get back to the bio statistician, and then the analysis plan no longer matches the aims. That's not going to do well in peer review. So make sure that as you make changes, that you update the other sections that need to be updated.

Certainly with these pragmatic trial designs, we're often looking for people to sort of reduce the complexity. We're often trying to answer kind of a single question in a very complicated healthcare delivery system. And so the more you can streamline the way the intervention is delivered and how you're collecting your data, it will have tremendous help in being able to actually accomplish the trial and get things done. We hear frequently from all of our investigators how challenging it is to add any kind of burden into healthcare delivery. And so the more you can reduce complexity of your research design to be able to just test the hypothesis question that you have, the more likely you'll have success in being able to answer that hypothesis.

And again, that multidisciplinary team, having a track record of working together or doing a small pilot together and publishing that ahead of coming in with your full application really demonstrates to reviewers that this team has worked together. They're going to be able to do this. It's not required that everybody on the team has worked together before, but certainly it is something that we do hear from

reviewers in those summary statements that you all get back after your applications have been reviewed. That is something that they definitely look for in these really often complicated pragmatic trials to implement.

As always, if you're doing multiple sites, we encourage you to provide a strong rationale for the multiple sites and the sample size that you're using. Often these pragmatic trials can include a much broader patient population that's much more generalizable to the U.S. population, which is one of the reasons we really like these types of pragmatic design.