

Is a PCT Right for Your Research Question?

Wendy Weber:

So the first question that I often spend a lot of time talking to applicants about is, what is your research hypothesis? I'm often pulling people back from, "Am I designing this the right way or do I have the right control group?" Or those types of questions, to really, initially, "Help me understand what is the hypothesis that you want to test? What's the research question that you want your study to answer?"

And once you have that very clear, then it's much easier to then design the study to answer that question.

Pragmatic trials are not the right design for all clinical research questions. And so it's really important that you're quite clear on the hypothesis you want to test, and not just that you want to do a pragmatic design. It's got to be the right question for pragmatic design to make sense.

I really try to work with investigators and applicants to get very clear about, is their primary question. "Does the intervention work?" We don't even know if it's going to work. So we probably want to first test it in a pretty controlled experiment where we've got a very specific patient population, we have the best chance of being able to determine, does it work or not. And oftentimes we're doing a placebo control with really strict protocols and adherence.

That's a very important question, and often that work needs to be done prior to doing the pragmatic trial. The question is, does this intervention work when it's delivered in routine practice? And these are the more pragmatic designs where you're actually working with a healthcare system. Often, the results of those studies help to inform healthcare systems and payers and other individuals to learn whether or not when you implement or put this intervention into the healthcare system, does it still work? And can you implement it and deliver it in a healthcare setting?

There's slightly different questions, but the design you take to do one versus the other is quite different.