At the last NIH Collaboratory Steering Committee meeting in Bethesda, MD, we talked with three Demonstration Project Principal Investigators—Lynn DeBar, PhD, of PPACT; Laura Dember, MD, of TiME; and Jerry Jarvik, MD, MPH of LIRE. We asked them to share tips and advice for investigators preparing to conduct their first pragmatic trial. We also wanted to know what was the most enjoyable aspect of their involvement in the Collaboratory.

Advice for New PCT Investigators?

**Debar:** Integrate really well with the key stakeholders from your sites. It is critical to make sure you have buy-in from the very top through all levels, depending on your trial. Also plan that this engagement will not be “one and done”—you will need to continue it throughout the entire trial. It’s been interesting to see how much turnover there is in staffing and leadership across sites. You’re starting anew with a lot of those folks, and that can be rewarding.

**Jarvik:** I have a variation on that theme, which is not only engaging key stakeholders at the sites, but also engaging with senior mentors and people who have gone down this road before. There are so many unexpected events that one has to deal with in a pragmatic trial that having access to somebody who has been through this is critical. I’ve been lucky to have had the mentorship of people like Rick Deyo, Judy Turner, Patrick Heagerty, and others.

**Dember:** My number one piece of advice is to engage at all levels. The key levels may differ from one trial to another, but it is impossible to overstate the importance of this. It is also important to recognize that the perspectives of these key stakeholders may be different than anticipated by investigators. If one has not worked with health systems before in the context of research, there are a lot of new things to learn and unexpected views.

Regarding mentorship and getting advice from others, there are often mentors locally who do research who we can learn from, but in addition to traditional mentors, seeking input from whomever you need to get it is helpful. For example, we had some prominent regulatory issues early on and had to go to multiple people to try to get answers to questions for which there are not necessarily clear-cut answers. When different people have different interpretations, it’s helpful to keep pushing until you feel comfortable that you’ve gotten the information you need.

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“Integrate really well with the key stakeholders from your sites.”

— Debar
My other piece of advice is try to have fun. There are a lot of unexpected things that happen in pragmatic trials, and there is a lot of hard work, but it can be a lot of fun.

**Jarvik:** Don’t get discouraged. You’ll experience pain early on and encounter problems, but the pain will go away and you’ll be able to focus on the fun and rewarding aspects of this research.

**DeBar:** I don’t know that I was as thoughtful and sophisticated about thinking with the end in mind, such as some of the hybrid designs and thinking about how you design for dissemination. Some of us did that more than others, but I think that would be a helpful thing to be more aware of as you are designing or working through some of the refinements in the first planning phase of your trial.

“Involvement in the NIH Collaboratory

**Jarvik:** The most enjoyable part has to do with the people I’ve been involved with both at the University of Washington as well as our site partners and the NIH Collaboratory partners.

“Unexpected things happen and there is a lot of hard work, but it can be a lot of fun.”

– **Dember**

**Dember:** I think the best part has been learning from so many other people who are trying to do the same thing and have had similar but also different struggles and experiences.

**DeBar:** It’s great to work with your colleagues who do similar work, but there’s something enriching about hearing about the different ways people work that are in quite different endeavors. For me, it’s enriched how I think about the way I approach the work. It was nice to have the Collaboratory’s Core structure for early support while working out the trial’s methodology.

“Engage with senior mentors and people who have gone down this road before.”

– **Jarvik**