How would you describe the first 5 years of the Biostatistics Core?

From my perspective, it’s been an amazing 5 years in terms of the collegiality and collaboration and especially the multidisciplinary integration of the various Cores. Since the beginning, I’ve been impressed with the UH2/UH3 process whereby pilot studies are not only provided a budget but also have access to resources from the various Cores. As these pilot studies are being implemented, input from a broad range of perspectives is incorporated to ensure high probability of a successful implementation with UH3 funding.

With respect to the Biostatistics and Study Design Core, I’ve found the collegiality and learning environment to be marvelous. I’ve personally learned a lot and have great respect for the statisticians on the individual trials, who have not only developed excellent statistical methods for their own trials, but also contributed substantively to the Core.

What accomplishments of your Core are you most proud of?

I’m most proud that the Core has been effective in three different ways. When we were first established, we were tasked with two aims: engage with the various trials to provide input as they are being developed and implemented, and contribute information that would be accessible to researchers as they think about initiating pragmatic trials. I believe we have accomplished both missions, but the group also wanted to work on contributing new knowledge to the literature. Among us, we have produced manuscripts that address methodological issues related to pragmatic trials, and one group, led by Patrick Heagerty, was awarded a grant to further study such issues.

“I’m hoping the Biostatistics Core will continue to push the boundaries of statistical methods.”

– DeLong
What do you view as the biggest impact of your Core to date?

Probably the biggest impact has been working with the individual trials to provide a sounding board to discuss statistical issues that have arisen. For example, after discussing the actual proposed operation of one of the trials, it became evident that there was risk of contamination if the randomization were at the physician level, as originally planned. Different physicians in the same clinic all had access to the same resources and the same processes, so the patient outcomes would likely be correlated—more so than across clinics. So they changed the design to randomize at the clinic level, which had implications for power and sample size and hence required them to recruit more clinics.

Interestingly, another trial had the reverse situation. They had intended to randomize at the clinic level, but preliminary data indicated minimal correlation among patients in the same clinic but who saw different physicians. Hence they were able to randomize at the physician level.

What do you view as important for the Biostatistics Core to tackle going forward?

It goes without saying that it will be important to engage the new trials that will be funded soon for their pilot phase. Of course, other initiatives will be decided by the group, but I'm hoping that we will continue to push the boundaries in terms of statistical methods.