TRANSCRIPT: Finding Treatments Faster via Master Protocols

CHRISTOPH HORNIK: My name is Christoph Hornik. I'm a faculty member at the DCRI in our Pediatric therapeutic area. I joined our faculty in 2013 after a fellowship at Duke in pediatric cardiology and critical care.

Master protocols are certainly an interesting topic in clinical research. They're difficult to do, they're difficult to design, and difficult to execute, but they also have great promise. The FDA actually first issued guidance on the role of master protocols back in 2018, and then last year in the midst of the COVID-19 pandemic, issued updated guidance, specifically to COVID.

In both of these guidance documents the importance of well-designing and well-executing master protocols is highlighted. I think both of these aspects are great opportunity for DCRI to provide significant thought leadership and an operational analytical input to meet, to maximize, the goals of the master protocol and public health impact of these protocols.

So, first of all, master protocol design is complicated, I think, for a number of reasons. First and foremost, they tend to require more scientific input because they try to basically cover more ground, whether that be covering multiple drugs like we've done at the DCRI in master protocols for almost a decade now, with multi-drug clinical trials, or they're trying to cover multiple diseases. They tend to require input from a lot of scientists, clinical specialists, to design the best question and the best approach to answer that question. And I think DCRI has a long, long track record of team science approaches to anything, including protocol design. I think that suits, basically, designing master protocol fits well into our into our skill set.

The second issue, I think, for master protocol design is the operational complexity. Again, DCRI has a long track record of designing protocols that are not just rigorous in terms of answering the key questions for public health, but also are designed with a feasibility lens in mind. I think that's where our strong operational leadership really plays a critical role, allowing us to assess what can and can't be done, basically, and do it, for the difficult things, do them in the best operational manner possible. So the second challenge is the operational complexity of a master protocol.

And then the third challenge, I think, are analytical. Again, when you're bringing in data across multiple therapeutics or interventions and multiple disease areas or populations, it's no surprise that analysis of the data becomes more complex. And, obviously, DCRI again has a track record of analytical expertise where we can bring our innovative thoughts and our experience to designing analytical approaches that maximize the value of the data collected in these master protocols.

And then, once protocols are designed, execution is not easy. I think, obviously, the details affect—all details of the protocol will change how complex protocol execution ultimately will be, but as a general rule, it's fair to say that master protocols, while they have tremendous public health impact and are potentially, ultimately—for sites—beneficial to do, can have challenges in their execution. And I think DCRI is an excellent partner for master protocol execution because we have a long, long record of working with sites very closely across multiple therapeutic areas, in very complex diseases, and very complex protocols in studies. And so our track record of working with these sites, leading networks, having established collaboration can really help us.

So I think as we all, collectively, try to sort of take lessons learned from the pandemic and translate approaches to transform research during a pandemic into approaches to transform research even outside of the pandemic, in my opinion, master protocols are going to continue to have a bright future, and DCRI is in a good position to build on, you know, our experience and expertise in master protocols. I look forward to pushing that envelope further. I foresee that DCRI will continue to play a leading role in designing and executing master protocols for quite some time.