In his role as a clinical psychologist, DCRI’s Scott Kollins, PhD, cares for children with attention deficit hyperactivity disorder (ADHD). He knows firsthand the challenges his patients and his families face. So when an opportunity arose to align his research with what he was seeing in the clinic, he jumped at the chance.

Several years ago, Akili Interactive Labs sought to validate its claim that EndeavorRx, a video game it had developed, would improve attention in children between ages 8 and 12 with diagnosed ADHD. The company asked Kollins and a DCRI study team to design and conduct a clinical trial that would examine the video game’s efficacy.

Fast forward to this year, and that trial, along with other study data generated through DCRI-led studies, contributed to a precedent-setting decision from the U.S. Food and Drug Administration (FDA)—now, for the first time, a video game can be prescribed as a therapeutic.

The decision came after DCRI’s studies not only proved that EndeavorRx compared with standard video games improved attention, but also that it was effective whether or not children were concurrently taking medication for ADHD, and that the effects continued to improve over time.

“All clinicians know that treatment plans are not one size fits all,” Kollins said. “We originally took on this study because we were intrigued by the possibility of expanding treatment options for kids who are diagnosed with ADHD. Now, the FDA has enabled this expansion by approving prescriptions of EndeavorRx. The fact that our study data helped to support this first-of-its-kind decision really underscores the reliance of regulatory bodies on these kinds of clinical data when assessing novel digital therapeutics.”

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Kollins’ work on the Akili studies inspired him to delve deeper into the emerging field of digital therapeutics—and led to the launch of a new research group at the DCRI.

Novel Apps, Clinical Applications

The group, called DCRI Digital Health Solutions, comprises DCRI investigators who partner with
companies of all sizes to apply clinical insights to digital health innovation. Some of these innovations treat a condition, just as EndeavorRx treats ADHD, while others, such as wearables and other technologies, enable novel ways of delivering clinical research.

DCRI’s Satasuk Joy Bhosai, MD, MPH, co-directs the group with Kollins. Bhosai is a hospital medicine physician whose clinical experience equips her with the ability to discern whether an innovative idea will be translatable in a real-world clinical setting.

Both Bhosai and Kollins see great potential for digital health technology to transform the way clinical research is conducted. Potential opportunities presented by digital tools include expanding access to participation in research, streamlining the process for implementing research, improving participant recruitment and retention, and introducing novel types of data that can help answer new research questions.

The work of DCRI Digital Health Solutions can help advance digital health applications to disrupt research and can also help technology companies gain a competitive edge. Competition in the industry is fierce, and companies are beginning to pursue rigorously designed and conducted clinical studies to bolster marketing claims and differentiate themselves from competitors.

“There are thousands of companies acting in the same markets, with new competition emerging daily,” Bhosai said. “Our work helps companies cut through the noise—any company can claim their product helps improve a clinical challenge such as attention span or quality of sleep, but to date, far fewer can back up those claims with clinical data. In the cases where they do have data, it is rarely verified by an unaffiliated, independent party. I see many claims made by companies all the time, but most of the time these claims are based on internal analysis, which obviously is biased.”

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Taking Research from the Lab to the Living Room

Digital health technologies can also help people take more of an active role in managing their own health. In some cases, these technologies enable participation in clinical research from the comfort of a patient’s own home.

iPERSONAL is a direct-to-family DCRI trial testing whether a digital pill bottle cap will improve medication adherence in pediatric patients with lupus. The trial’s remote delivery, which is made possible through telehealth check-ins and in-home visits from mobile nurses, eliminates the need for participants to travel to clinical research sites. As one of the first direct-to-family trials in the industry, iPERSONAL is laying the groundwork for how trials will be conducted in the future, as well as breaking records. Enrollment was completed in an unprecedented 10 days, and the participant response was so enthusiastic that the study team decided to expand enrollment.

“We’re really flipping the traditional site-based research model on its head,” said Lindsay Singler, MPH, project leader for the study, which is being led by DCRI adult and pediatric rheumatologist Stephen Balevic, MD, MHS. “Through our new direct-to-family research offering from the DCRI, we are using technology and mobile research teams to expand access to studies beyond a clinic or site, making it less burdensome for patients and their families to participate.”
While iPERSONAL’s remote delivery was planned from the study’s outset, other DCRI studies adapted a hybrid or virtual model mid-study this year. When the COVID-19 pandemic halted most in-person research activities, some study teams responded to the disruption with a plan to conduct disruptive research.

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One of these studies is testing whether a digital health device made by Sana Health will help alleviate fibromyalgia-related impairment. When the study team realized that the COVID-19 pandemic would necessitate adaptations, they shifted every component of the study to remove all in-person interactions, figuring out everything from how to build an e-consent platform to how to ship the study device or control device directly to participants’ homes.

The study team also relied on technology to automate some study processes; for example, in cases of noncompliance, the app will automatically send reminder text messages rather than a coordinator following up with a phone call. This approach is particularly innovative because it conserves resources, said Anthony Cunningham, manager of DCRI’s small trials program.

“This was already a study testing an innovative product, but now we’ve had to consider ways to innovate the research delivery, as well,” Cunningham said. “For example, now that we won’t be seeing patients face-to-face at a clinical site, we’ve thought of new ways to engage them, such as creating a video and a quick reference guide to help familiarize participants with using their devices.”

Creating Space for Disruptive Discussions

Not only is the DCRI implementing virtual delivery of its own trials, but the Institute is also leading industry-wide discussions on how to best chart the path forward for these kinds of trials through the DCRI Think Tanks program.

DCRI Think Tanks invite executives with clinical, industry, and regulatory expertise to participate in multi-day discussions about challenges and opportunities for the future of clinical research. Takeaways from DCRI Think Tanks are typically published in academic journals, helping to advance the discussion within the scientific community. In July 2020, the DCRI hosted a virtual think tank focused on direct-to-patient, virtual, and hybrid trials—an especially important discussion in the COVID-19 era.

Past DCRI Think Tanks have also focused on research opportunities presented by novel digital tools and the proliferation of real-world data these tools are able to collect. A January 2020 think tank discussed applications for machine learning in research and potential ethical issues.

“Through DCRI Think Tanks, we’ve created this pre-competitive space for not just open exchange of ideas, but articulation of the barriers and pain points, as well as discussion of how to solve them,” said DCRI population health scientist Lesley Curtis, PhD, faculty director for the program. “This environment is ideal to discuss how we will move forward as an industry while smoothly integrating truly disruptive technologies and methods.”