DCRI
THINK TANKS
FROM INSIGHT TO ACTION

Technology-Enabled Clinical Trials—Innovations in Trial Design and Conduct

October 3–4, 2018

The lightning speed of innovation in both scientific research and technology over the past few years have quickly compounded to create a dramatic paradigm shift in clinical research. While the clinical research industry has been traditionally slow to adopt and embrace change, new players in healthcare technology have created a more competitive and collaborative environment helping to drive a faster pace. Regulators have also spurred change by embracing and encouraging innovation and technological development, specifically with the promising trial efficiencies offered by pragmatic trials.

This shift is creating a "clinical trial renaissance" in which all clinical trial stakeholders—investigators, patients, pharmaceutical and device industry partners, academic thought leaders, and regulatory authorities—are all considering how to leverage these new scientific breakthroughs and new technologies into the clinical trial continuum for faster, less expensive, and more applicable clinical trials in the future.

Amidst all of the change, regulators are tasked with providing regulations and guidance that balance the leeway and flexibility needed for disruptive change while also continuing to protect quality, safety, and patient privacy.

The emergence of virtual clinical trials that bypass traditional clinical trial sites by recruiting and following patients directly through electronic approaches is an example of how new technologies have challenged the traditional clinical trial model and dogma.

The "Technology-Enabled Clinical Trials" think tank meeting convened by Duke Clinical Research Institute will bring together diverse stakeholders and perspectives to address the emerging perspectives on the evolution of technological solutions that support clinical trials. At this meeting, our aim is to foster the collaborative partnerships needed to ensure the proper oversight and implementation of these technological advances that are positioned to accelerate the assessment of promising new therapies.

MEETING OBJECTIVES

1. Review value-added implications for new technological advances that enhance clinical trial efficiency and streamline trial conduct
2. Discuss the emerging perspectives of clinical trial stakeholders on technology infiltration
3. Delineate innovative trial designs and options facilitated by technological advances and potential barriers to implementation of innovative trials
4. Determine the optimal framework for regulatory oversight and partnerships needed to guide the role of technology in changing clinical research paradigms

DCRI **THINK TANKS**

FROM INSIGHT TO ACTION

POTENTIAL AGENDA

Session 1: Beyond Digital Health—Defining the Scope and Impact of Technology Solutions to Support Clinical Trials

- Overview of technology and software tools being developed to streamline trials
- Machine learning/artificial intelligence approaches designed to enhance trial efficiency (i.e., patient recruitment, remote data surveillance, endpoint ascertainment, etc.)
- Industry and government experience with leveraging technological advances for trial conduct
- Academic and regulatory perspective on evolving clinical trial paradigms

Section 2: Facilitating Innovative Clinical Trial Designs

- Virtual clinical trials with direct-to-patient recruitment and central trial administration
- Pragmatic trials embedded within learning health systems using technology interfaces
- Obstacles encountered by "real world" trials – defining limitations of technological solutions
- Academic, industry, and government perspective on innovative trial designs
- Regulatory policies for oversight of technology solutions utilized to streamline trials

Section 3: Enhancing Evidence Generation with Technology Applications

- Increasing patient access to clinical trials with novel technologies
- Easing the burden on site investigators for participation in trials
- Leveraging big data to inform machine learning and artificial intelligence applications for trials
- Improving trial efficiency with technology advances—an industry and government perspective

Section 4: Framework for Assessment and Dissemination

- Evolving quality by design considerations for technology-enabled trials
- Partnerships needed to guide the evolution of methodological approaches for analyzing results from innovative trial designs
- Options to promote continuous learning opportunities across trial stakeholder groups to disseminate experiences with leveraging novel technology solutions