

DCRI THINK TANKS
FROM INSIGHT TO ACTION

**ANNUAL
IMPACT
REPORT**

FISCAL YEAR
2022



Duke Clinical Research Institute

FROM THOUGHT LEADERSHIP
TO CLINICAL PRACTICE

“The Think Tank provides a remarkable opportunity for authentic and frank engagement about challenging problems and creates the milieu for the emergence of creative solutions. It is truly exhilarating to bring together wise stakeholders from diverse background and with common aspirations to make healthcare and research better.”

Harlan Krumholz, MD, SM
Yale University
October 2021 Think Tank

“As the global research community must continue to learn and evolve based on the experiences during the pandemic, the DCRI Think Tank proved to be a timely catalyst for ideation and exploration together”

Craig Lipset
Clinical Innovation Partners
July 2021 Think Tank

DEAR COLLEAGUES:



Although the COVID-19 pandemic posed ongoing challenges in 2021-2022, the DCRI Think Tank series continued to address critically important topics in clinical research.

With input from our Advisory Board, we examined the durable innovations that have emerged from COVID-19, identified ways to increase access to clinical trials and improve community engagement in clinical trial “deserts”, and highlighted opportunities and challenges as more trials shift from a brick-and-mortar approach to a “click-and-mortar” approach. We also tackled the inevitability of a future pandemic and identified strategies to improve pandemic responsiveness based on lessons learned from COVID-19.

We are incredibly grateful to the members of the Think Tank Advisory Board for providing the leadership and expertise that is so crucial to the success of the Think Tank program. We extend our sincerest thanks to our Advisory Board members for their guidance on attendees, framing discussion topics, and contributions to resulting publications.

We look forward to another successful and impactful year.

Regards,

A handwritten signature in black ink that reads "Lesley Curtis". The signature is written in a cursive, flowing style.

Lesley Curtis, PhD

Chair and Professor

Department of Population Health Sciences

Duke University

Think Tank Impact: By the Numbers



102
Meetings



25
Years

60+
Co-Director
Collaborators

250+
Academic Institutions
Represented



148
Publications



3
Alliances



4,700+
Attendees

“It was a delight and an honor to be able to co-direct this Think Tank with Duke’s own Christoph Hornik.

Your team brought together an extraordinary group of individuals from across the globe to have quick-moving, impactful conversations. Even in the virtual format, I was impressed by the insights on how best to approach the opportunities, risks, and barriers to a consumer-oriented digital transformation of clinical trials. I look forward to great things to come.”

Megan Ranney, MD, MPH, FACEP

Brown University

January 2022 Think Tank

Durable Innovations in Clinical Trials and Regulatory Oversight From COVID-19: Emergence of a New Normal

July 28-29, 2021

CO-DIRECTORS:



Emily O'Brien, PhD, FAHA

Associate Professor, Department of Population Health Sciences
Duke University



Craig Lipset

Advisor and Founder
Clinical Innovation Partners

COVID-19 has disrupted the clinical research paradigm in numerous ways. Reallocation of staff, suspension of recruitment activities, movement to virtual intervention delivery and other changes have required unprecedented adaptability of research teams. While efforts to streamline research conduct are not new, the pandemic has broadened awareness of existing inefficiencies and galvanized calls for change. The experiences of the past year offered a unique opportunity to learn where we have made the most progress and what barriers persist.

Identifying innovations with the greatest durability is critical, and three areas were ripe for examination. First, platform trials offer the opportunity to study multiple hypotheses concurrently but were infrequently used prior to the pandemic. The evidence generated by COVID-19 platform trials has improved patient outcomes around the world, yet acceptance of these novel designs faces substantial pre-existing barriers. Second, the promise of decentralized trials has been more fully realized due to limitations on in-person recruitment and data collection throughout the pandemic. However, longstanding obstacles may continue to frustrate implementation. Finally, COVID-19 has had major impacts on the way science is shared and understood. Balancing rapid evidence generation, robust study design and integrity in interpretation is critical in the information age. This Think Tank aimed to identify key opportunities to accelerate innovation from the study design phase (*Focus Area 1: Platform Trials*) through study implementation (*Focus Area 2: Decentralized Trials*) and finally, to rapid uptake of results in practice (*Focus Area 3: Dissemination*).

DISCUSSION FOCUS AREAS:

What innovative strategies from COVID-19 can be used to strengthen clinical research in the following areas?

- How can virtual trials be more “person-centered trials” and answer the questions that matter most to patients?
- How can we leverage new methods to answer research questions reliably?
- What areas are ripe for efficient study conduct?
- How can we appropriately approach digital health data?

Key Takeaways:

1. The past year has brought a shift in mindset from linear or stepwise thinking about clinical trials to ecosystem thinking.
2. Platform trials have come of age over past year, especially outside the United States. Moving away from the status quo will require commitment from a broad group of stakeholders.
3. The promise of decentralized trials and thinking of home as the new site—leveraging things like telemedicine, e-consent, ePROs—is that it can bring research to people rather than the other way around. Regulatory barriers are the key challenge.
4. We have an obligation to disseminate research findings. We should work toward a research culture that rewards team science rather than independent investigators.
5. Rebuilding public trust in science will require resetting people's expectations and being honest about the fact that scientific knowledge is provisional and always changing.
6. The burden of building trust with research participants is with us, not with those whose trust we want. Trust is to be found in involving patients early in the research process, understanding their needs, and sharing what we learn as a result of their participation.

[Read the executive summary.](#)

Addressing Clinical Trial Deserts

October 6-7, 2021

CO-DIRECTORS:



Harlan Krumholz, MD, SM

Harold H. Hines, Jr. Professor of Medicine, Department of Internal Medicine
Yale University



Charlene Wong, MD, MSHP

Assistant Professor, Department of Pediatrics
Duke University

Clinical trials are intended to generate evidence on whether treatments are safe and effective- ideally evidence that is generalizable beyond those who participated in the trials. For many populations, however, participating in clinical trials is hindered by their inability to access sites that are enrolling participants. On the other hand, other populations are over-represented in clinical trials, such as people in close proximity to academic medical centers.

The October 2021 Think Tank session on “Addressing Clinical Trial Deserts” brought together thought leaders from academia, clinical practice, the FDA, industry, and clinical trial participants to share first-hand and expert perspectives on how to achieve more diverse and expanded coverage of sites where people can participate in clinical trials. The Think Tank focused on increasing access to clinical trials that require in-person interactions through the engagement of community-based health care providers, such as clinical practices, health systems, and pharmacies not traditionally heavily involved in research. Other approaches to increase clinical trial access including virtual and decentralized trials are important considerations but beyond the scope of this Think Tank. The meeting was hosted virtually due to the on-going COVID-19 pandemic.

DISCUSSION FOCUS AREAS:

- What are the barriers for health care partners to enter the clinical trial ecosystem? These barriers were explored in listening sessions with clinical practices and health systems who are new entrants or have not yet been able to operationalize clinical trial participation.
- What is the role of technology to facilitating more diverse and expanded clinical trial sites that lack the research infrastructure available at academic medical centers?
- What are the best practices for developing streamlined partnerships with sites in clinical trial deserts to increase access to clinical trial participation?
- How can expanded and more diverse clinical trial sites promote more equitable participant recruitment and retention?

Key Takeaways:

Top DO WISHES Submitted by Meeting Attendees

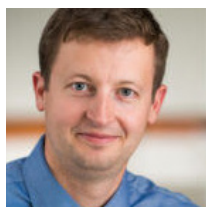
1. Establish a federal clinical trials coordinating body.
2. Identify policies that would support a national system for conducting rapid research based on the RECOVERY trial on critical topics for the country, including generating data for underserved/vulnerable populations on these key topics.
3. Quickly create a proposal for developing a prototype network of community practice trial sites among primary care practices in an underserved city or region of the United States organized by leading academic medical centers
4. Include mentoring of at least 1 research-naïve or less experienced PI/site in sponsor contracts with a National Lead/Coordinating Investigator (NCI). The mentee PI/site would preferably be in a clinical trial desert and/or rural area. The NCI or the sponsor would collaborate on selection of the PI/site(s).
5. Reauthorize AHRQ (or create an NIH primary care research office) to fund a coordinating/resource center and infrastructure support for community/rural practice-based research networks. These networks could more readily pivot to participate in NIH/industry-contracted research (public-private partnerships).
6. Build a more effective national network of networks in community settings; apply what can be learned from other nations.
7. Develop and easily identify networks of care between academic centers and community care.

[Read the executive summary.](#)

Consumerization and Digitization of Healthcare: Where Marketing Meets Clinical Trials

January 26-27, 2022

CO-DIRECTORS:



Christoph Hornik, MD, PhD, MPH

Professor of Pediatrics
Duke University



Megan Ranney, MD, MPH

Associate Dean, School of Public Health
Brown University

Consumerization is inexorably taking hold of healthcare, driven by technological advancements and generational expectations, and accelerated by the COVID-19 pandemic. This trend is also transforming the clinical research landscape: novel digital consumer-driven methods for trial recruitment, retention, and interventions are increasingly commonplace. In this workshop, we discussed novel partnerships, opportunities, risks, and barriers to a consumer-oriented, digital transformation of clinical trials.

DISCUSSION FOCUS AREAS:

- How are novel technologies and digital partnerships (e.g., social media; wellness companies) currently involved in clinical trials? What could/should their future role be?
- How can a consumer-driven model enhance the flow of information about clinical trials?
- What novel strategies for recruitment and retention should be considered “best practice”?
- What ethical concerns exist regarding identification, enrollment, and retention of trial participants in a consumer-driven, digitized clinical trial? What mitigation strategies exist?
- How can consumerization and digital engagement help overcome access and equity issues and engage hard-to-reach populations in clinical trials?
- What is the role of regulatory bodies and funders in facilitating effective, ethical, and equitable consumer-driven digital trials?

Key Takeaways:

1. The distinction between traditional “brick and mortar” clinical trials and digital trials is artificial. Traditional and digital strategies are best used in a combination, “click and mortar” strategy. The optimal strategy is trial- and intervention-specific. The session presented several examples of successful approaches and their challenges. Trialists have an opportunity to learn new skills in applying digital approaches while bringing their expertise to test which combinations of approaches work best.
2. Trialists need to better understand the risks to data privacy and confidentiality in clinical trials conducted in virtual spaces, as well as strategies for protecting data in these trials. Trialists should understand the features of the software used in their studies to ensure the tools can be trusted. Digital trials offer trialists opportunities to build partnerships with groups outside of the traditional clinical trials realm to assess and address digital risks.
3. Digitization of clinical trials has important implications for equity. The funnel for recruitment is much wider in digital trials. This creates new opportunities for reaching more participants, but it risks missing certain groups during recruitment and may pose challenges for retention of some groups. More research is needed to understand differences between participants who are retained in digital trials and those who are lost to follow up.

[Read the executive summary.](#)

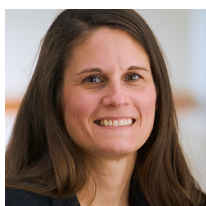
Preparing for the Next Pandemic: From EUA to Beyond

May 11–12, 2022

CO-DIRECTORS:



Rajesh Gandhi, MD
Director, HIV Clinical Services and Education
Massachusetts General Hospital



Susanna Naggie, MD, MHS
Vice Dean for Clinical Research
Duke University

The Emergency Use Authorization (EUA) mechanism is central to the US response to global pandemics, such as COVID-19. It allows the US Food and Drug Administration (FDA) to respond quickly to novel threats by approving a new drug, device, or diagnostic or allowing for unapproved use of an approved drug through an accelerated authorization process, when no approved alternatives exist. To obtain authorization, evidence must support that a drug or product “‘may be effective’ to prevent, diagnose, or treat serious or life-threatening diseases or conditions,” and the known or potential benefits of the product must outweigh known or potential risks. Since the declaration of a public health emergency due to the COVID-19 pandemic by the Secretary of Health and Human Services in February 2020, 3 preventative interventions, 400 diagnostics, and 15 therapies have received EUA and of these, 3 (less than 1%) have received FDA approval.

DISCUSSION FOCUS AREAS:

- Review the experience with EUA during COVID-19 pandemic and the proportion of requests coming from federal versus industry sponsors and success rate
- Summarize the quality and number of clinical trials contributing to EUA for COVID-19
- Discuss the need for additional evidence or studies post-authorization and the timeline that should be expected for the provision of the additional evidence to FDA or to advance the drug/device to approval
- Review potential incentive structures that might need to be established to conduct large trials and studies following EUA
- Discuss streamlined approaches for getting to the highest quality data the fastest, particularly for actively approved drugs

Key Takeaways:

1. Collaboration among industry, academia, government, and community partners – at national– played a huge role in the accelerated development of vaccines, therapeutics, and clinical trials over the course of the pandemic. How can we strengthen these public-private partnerships? How can we utilize platform trials?
2. Keep things warm. Implementing an infrastructure/s that sustains readily available resources (testing, community engagement/partnerships, funding, etc.) will help us ensure a prepared response in a timelier matter.
3. Prioritization is key when it comes to clinical trial efforts, resource availability, sustaining our workforce, and determining where government funding will be allocated.
4. We need to consider creating some sort of centralized network with streamlined processes of sharing critical data to enable learning across domains and cut back on time and redundancy/overlapping. How can we develop a global infrastructure to harmonize processes?
5. The flexibility, adaptability, and agility of EUAs was extremely beneficial.
6. Ensuring diversity, equity, and inclusion in our clinical studies is critical to fostering trust, sustaining community engagement, and receiving accurate study results to adequately meet the needs of our communities, especially at-risk and underserved populations. We also need to be aware of the economic, social, and political climates that are affecting our staff, clinicians, patients, and their families.
7. Sustained community engagement built on long-term relationships, transparent communication, and commitment to meeting community needs is imperative to building and maintaining trust.
8. Utilize creative, nontraditional opportunities and strategies to both engage and teach our communities about clinical research to eliminate mistrust, gaps, and misinformation.

[Read the executive summary.](#)

DCRI Think Tanks Advisory Board



Advisory board partnerships with industry leaders help the DCRI Think Tanks program address the right topics, at the right time, with the right people. Our partners provide crucial insight and connections that go beyond DCRI's clinical and operational expertise. From guidance on attendees, framing discussion topics, and contributions to resulting publications, our advisory board members are players in the lifecycle of every event.

DCRI Think Tanks Leadership



Lesley H. Curtis, PhD

DCRI Think Tanks Faculty Lead
Chair and Professor, Department of Population Health Sciences



Jennifer Gloc

DCRI Think Tanks Program Manager

“It was an honor to be invited to co-direct this DCRI Think Tank. The co-director and DCRI faculty were terrific and brought a remarkable depth of expertise to the event. The participants were top-notch and the discussion was broad-ranging and insightful. The DCRI staff is tremendous, and the organization of the Think Tank could not have been better. All in all, this was a phenomenal experience, and I look forward to participating in future DCRI initiatives!”

Rajesh Gandhi, MD
Massachusetts General Hospital
May 2022 Think Tank

