DCRI **THINK TANKS**

FROM INSIGHT TO ACTION

Realigning Incentive Structures to Accelerate Evidence Generation Meeting Brief

BACKGROUND AND CONTEXT

The DCRI Think Tank is an interactive meeting that engages diverse perspectives and key stakeholders to address crucial issues in clinical research, policy, and practice to improve health.

On October 25-26, 2023, a DCRI Think Tank session on "Realigning Incentive Structures to Accelerate Evidence Generation" brought together leadership from academia, industry, government agencies, and nonprofit organizations to explore how different entities and influencers in drug development and healthcare can realign incentive structures to efficiently accelerate evidence generation that addresses the highest public needs. This meeting brief provides an overview of the key themes and discussions that took place during the session.

KEY TAKEAWAYS AND THEMES

1. Misalignment of incentives and priorities:
Incentives and priorities in the healthcare system, allocation of resources, determination of outcome measures, and consensus on areas of highest public health needs are not currently aligned toward common goals to improve public health. The COVID-19 pandemic catalyzed a clear alignment of incentives among all stakeholders, leading to accelerated evidence generation; however, as the pandemic subsided, incentives shifted back to individualistic priorities among stakeholders. There are many challenges in defining priority areas of research with distinctions between top-down approaches that involve identifying research priorities from a centralized or authoritative perspective versus bottom-up approaches, which involve grassroots efforts and community engagement in escalating areas of greatest need. Ultimately, a consensus developed that both bottom-up and top-down approaches are valuable in determining areas of greatest need. Achieving a successful alignment of priorities among various stakeholders will necessitate changes in financial and policy incentives. These incentives can take the form of direct mechanisms like value-based care models or indirect mechanisms such as public reporting of a health system's participation in clinical trials.

2. Patient-centered approaches:
The need for patient perspectives and involvement emerged as a significant theme. There was a call for greater engagement of patients in clinical research, inclusion of measures of patient experiences, and minimizing burdens imposed on clinical trial participants to improve the overall patient experience in trial participation. Patients have an important role in advancing clinical care through trial design and participation, building trust with underrepresented or disadvantaged patient populations, and grass root or bottom-up approaches to engage all stakeholders in determining areas of greatest need. Furthermore, patient advocacy groups are also key with their ability to drive policy changes and maintain long-term engagement with legislation to help define priority areas of research.

3. Transparency and accountability in research:
Transparency is crucial, not only in reporting results, but also for understanding allocation of funding and ensuring quality of outputs. Central to transparency is the clear communication of results to regulatory bodies and the public, with an emphasis on excluding unnecessary data that may cloud interpretation of the results. Additionally, there is a need to disseminate not only successes but also failures in order to prevent recurrent and costly errors. This approach underscores the importance of learning from past experiences of the entire clinical research community. Finally, there are opportunities to improve reporting metrics related to patients' clinical trial experience and efficient use of resources at an institutional level to support trial enrollment and follow-up.

4. Efficiency and streamlining clinical trials:
There are needs to optimize recruitment and data collection, streamline study design, and efficiently leverage existing trial and care infrastructure. While technology serves a valuable role in accelerating enrollment and patient engagement in trials, careful consideration should be made so as not to inadvertently exclude underrepresented populations through over-use of technology. Streamlined trial design should be leveraged to ensure ease and accessibility for clinicians who serve as gatekeepers between patients and clinical trials and there needs to be more effective utilization of available resources, infrastructure, and technology to enhance clinical trial efficiency. Electronic health records should continue to transform to facilitate research and data collection, early cessation of the clinical development of drugs or other interventions that show early signs of failure, and identification of patient allocation to one study that may curtail opportunities for that patient to participate in other trials.

5. Public-Private Partnerships:
Alignment of priorities requires the need to collaborate more effectively across different industry sectors, regulatory bodies, healthcare systems, and academic organizations to accelerate the generation of evidence. Industry partners frequently embrace a risk-averse approach in anticipation of regulatory challenges to drug approval. This caution often results in adoption of rigid, standardized research protocols. Such protocols potentially burden patients and research sites by collecting unnecessary data and by relying on less efficient clinical trial procedures. Maximizing the benefits of these partnerships and streamlining research processes requires a more balanced, redistribution of risk and control. Initiating such changes entails reevaluating roles, responsibilities, and expectations of all stakeholders so as to distribute risks related to the process of regulatory drug approval process and influence of trial design more equitably.

ACTIONABLE ITEMS

1. Define research priorities and align financial incentives with impact on population health outcomes:
Develop a *health agenda* with input from academia, industry, government, patient advocates, and payer groups to align public health priorities across stakeholders. Critical to the success of this endeavor will be to align these priorities with financial incentives that reward the impact of outputs and outcomes. A shift towards more pay for performance/ value-based care models and public reporting of performance metrics of clinical trial enrollment and health system participation in clinical trials has the potential to support these goals.

2. Implement initiatives to increase patient involvement and reduce patient and clinician burden in clinical trials:
Successful clinical trial design must address and alleviate patient and clinician burden in trial participation. To do so, create programs to educate patients about the importance of their roles in research design and conduct, address barriers to participation, and elicit feedback from clinical trial participants to ensure that research is designed with patients' needs and experiences in mind.

3. Enhance accountability in research participation and transparency in research progress:
Develop patient- and center-specific performance metrics of research participation and success. This includes capturing information on patient recruitment numbers and diversity as well as information related to the success of clinical trials and their ability to robustly answer clinical questions. Invest in public reporting mechanisms that provide information on the quantity and quality of research outputs aimed at incentivizing high-quality clinical trials while discouraging those that fall short. Share organizational experiences, positive and negative, to promote vicarious learning and reduce resource waste.

4. Redistribute risk and decision-making ability in public-private partnerships:
Continue multi-stakeholder dialogue to redistribute risk allocation and influence trial design within public-private partnerships to allow for more mutually beneficial relationships for the ultimate well-being of the public.

For more information, please visit https://dcri.org/think-tanks/.