Tufts Center for the Study of Drug Development
TUFTS CSDD INSIDER
MARCH 2021

From the Director

Dear CSDD Friends,

Decentralized clinical trial activity has been one of the most notable adaptations since the beginning of the pandemic. Industry observers and insiders have speculated that remote and virtual support — largely piloted initiatives up until 12 months ago — will become the new standard trial execution model. Some have recommended that the drug development enterprise adapt quickly.

Evidence and data on past industry behavior suggests a more nuanced approach. The choice to implement decentralized clinical trials will not be an either/or proposition, but rather part of the long-running trend to hybridize drug development planning, design and execution. Hybrid approaches hold much conceptual promise — streamlining individual tasks, reducing execution burden, lowering costs and improving participant convenience. They also add executional challenges associated with increased levels of complexity and customization.

Several Tufts CSDD studies completed and underway examine strategies and practices to best manage the challenges associated with hybrid and customized drug development activity. Insights to date suggest that agile operational mindsets, staff training, more expansive strategies, new governance mechanisms and reimagined collaborations are essential.

Please send me a note if your organization would like to participate in Tufts CSDD studies informing best practices in accommodating and managing hybrid activity. We will be kicking off a working group study in March where we will draw lessons from other industries on how to best adopt operating innovations. All of our working group studies gather robust and valuable evidence and provide unprecedented opportunities to interact with peers, to network and collectively problem solve.

Tufts CSDD's global survey assessing remote team effectiveness and efficiency managing drug development activity is well underway. Please take a moment to participate in this important study conducted in collaboration with the Bill & Melinda Gates Medical Research Institute. (See below for more information.)

Last month, Tufts CSDD introduced a new algorithm that measures study volunteer burden in clinical trials based on protocol design variables. Several companies have expressed interest in piloting the algorithm, and we are looking for additional organizations. **Please let me know if you would like to learn more** .

As always, we welcome your ideas, feedback and participation.

Kenneth Getz
Director and Professor

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Working Group Studies

Join Our Working Group Study Characterizing and Improving the Innovation Adoption Process

Last month, Tufts CSDD initiated a new working group study looking at how sponsor companies adopt innovations supporting drug development planning, design, execution, data management and logistics. The study will characterize best practices including those associated with pandemic response; apply lessons learned from other heavily regulated industries; and identify opportunities to accelerate innovation adoption. **Contact us for more information.**

Participate in Our Study Exploring Patient-Centric Clinical Trials Oversight

In late January, Tufts CSDD launched a new study looking at the evolution of guidelines to accommodate patients as partners in the oversight of research integrity, issue escalation and remediation. With increasing demand for decentralized activity, study volunteers are becoming more integral to clinical trial oversight. As part of this study, Tufts CSDD will conduct listening sessions among sponsors and contract service providers. **Contact us for more information.**

Global Surveys

Participate in the Tufts CSDD-Gates MRI Global Survey on Remote Teams in Clinical Research

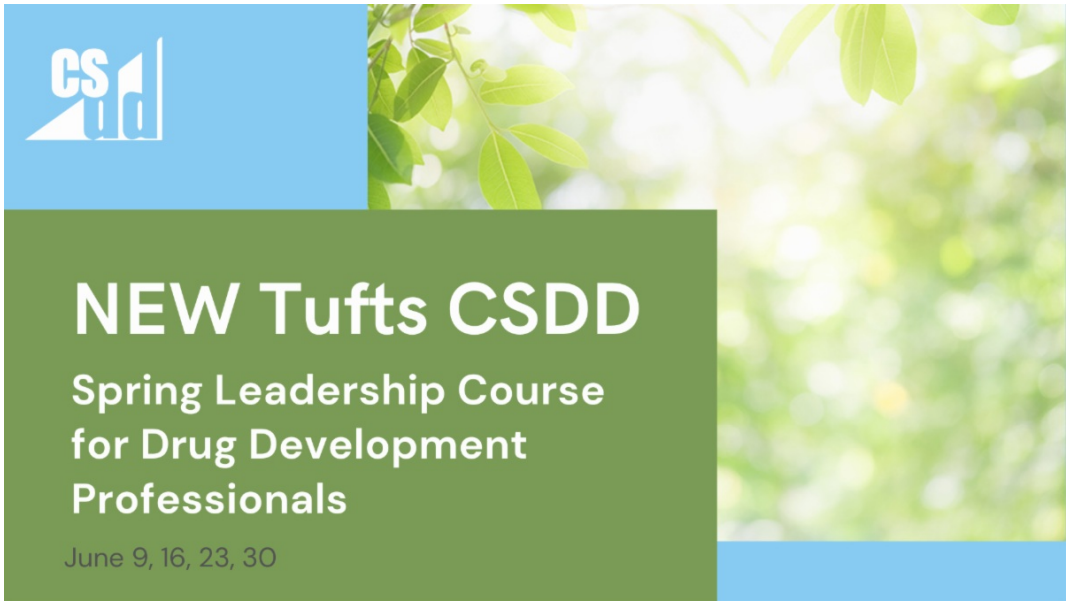
Tufts CSDD — in collaboration with the Bill & Melinda Gates Medical Research Institute — is conducting an ambitious and comprehensive global study examining how remote teams are managing clinical research activity. Study findings will identify trends and key practices and gather critical baselines to compare against future results. We encourage the clinical research community to take part in this important survey. In appreciation for your participation, Tufts CSDD will send you a brief summary of the results. **Complete the CSDD-Gates MRI Survey.**

Professional Development Courses

May 10, 2021

Grab n' Go course: *Enhancing Productivity and Performance of Remote or Distributed Teams (Online)*

This half-day program is provided to small groups and offers concise, practical ideas, insights and focused discussion. For more information, **contact Sundé Daniels**.



June 9, 16, 23 & 30, 2021

Spring Leadership for Drug Development Teams (Online)

Back by popular demand, the course is designed to build leadership skills, improve cross-functional performance and enhance R&D productivity. Delegates meet online in large and small groups over the course of four weeks beginning in early June. For more information, **contact Sundé Daniels**.

Research Highlights

Our Latest *Impact Report*

Planned and Unplanned Mid-study Updates Challenge Clinical Trial Timelines

Our March/April 2021 *Tufts CSDD Impact Report* presents results of recent research examining how the clinical data management function is managing unprecedented challenges as clinical trial data volume and data diversity continue to grow.

Learn more | **Purchase online**

Coming in Early May: *Development Performance by Company Size*

Order your copy today!

Individual subscription | **Corporate subscription**

Recent Publications

Harper B, Smith Z, Snowdon J, DiCicco R, Rezzan H, Getz K. **Characterizing Data Management Challenges and their Impact**. *Applied Clinical Trials* 2021; 30 (1/2). **Access article**

Getz K. **Public Trust and the 'Last Mile' for COVID-19 Vaccines.** *Applied Clinical Trials* 2020; 29 (12): 11 – 12. **Access article**

Gottlieb, N, Byrne, J, Getz, K. **Investigative Site Placement Practices to Support Operation Warp Speed**. *Applied Clinical Trials 2020*; 29 (12): 26-28. **Access article**

Raj Indupuri, Sheila Rocchio, Kenneth A. Getz, Beth Harper, Michael Wilkinson. **Enabling Digital Transformation: Managing External Clinical Data Sources to Advance Drug Development.** *Applied Clinical Trials* 2020; November 13. **Access article**

Stephen LeBreton, Mary Jo Lamberti, Adam Dion, Kenneth A. Getz. **COVID-19 and Its Impact on the Future of Clinical Trial Execution.** *Applied Clinical Trials* 2020; October 22. **Access article**

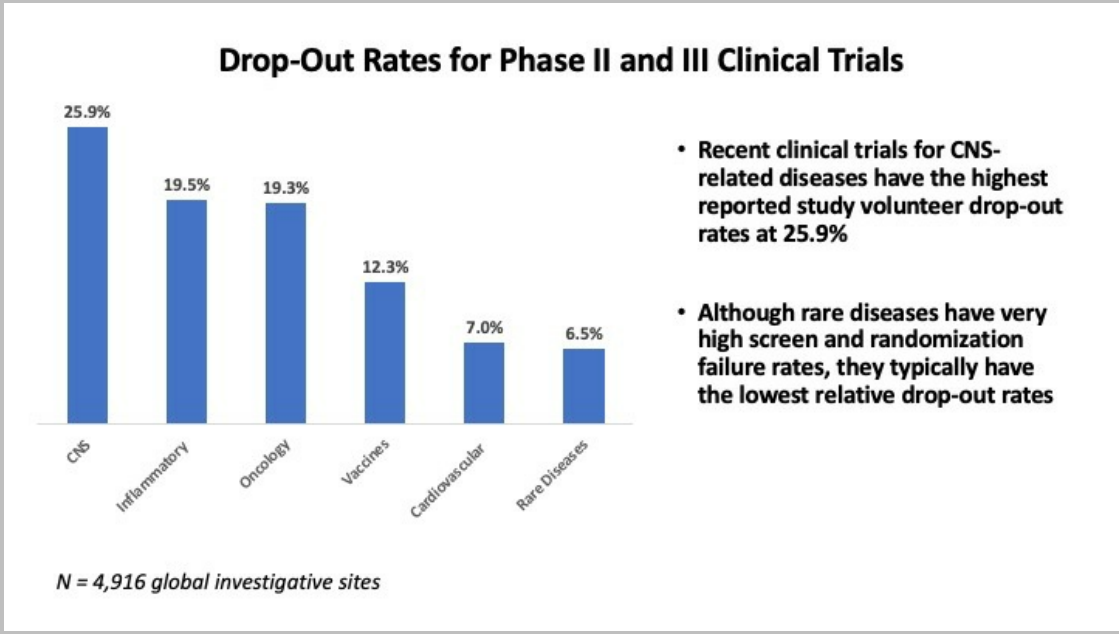
Galson S, Austin C, Khandekar E, Hudson L, DiMasi J, Califf R, Wagner J. **The Failure to Fail Smartly.** *Nature Reviews Drug Discovery* 2020; Sep 23. Published online: **Access article**

Harper B, Wilkinson M, Indupuri R, Rocchio S, Getz, K. **Evolving Clinical Data Strategies and Tactics in Response to Digital Transformation**. *Ther Innov Regul Sci* 2020; Sep 14.

Access article

DiMasi, J.A. **Research and Development Costs of New Drugs [Letter to the Editor].** *JAMA* 2020; 324(5):517. Access article

Data Insights Digest



For more patient recruitment and retention benchmarks and insights, contact CSDD.

Faculty and Staff Presentations

Recent Presentations

Leveraging Patient and Participant Input to Optimize Protocol Design
Ken Getz, MBA
Trial Innovation Network
Online | January 4

The Economics of Pharmaceutical Drug Development & Regulation
Kenneth I Kaitin, PhD
Symposium on the Economics and Law of Pharmaceutical Regulation
Online | January 28

Phase 0/Microdosing Approaches: Time for Mainstream Application in Drug Development?
Joseph A. DiMasi, PhD
American Association of Pharmaceutical Scientists
Online | February 4

Leveraging Predictive Dosing to Reduce Clinical Trial Risk
Ken Getz, MBA

xTalks
Online | February 10

Accelerating Drug Development During the Pandemic - Lessons Learned and Their Implications
Ken Getz, MBA
SCOPE Virtual Summit for Clinical Ops Executives
Online | March 2

Upcoming Presentations

Anticipating Changes in Clinical Trial Design and Execution Post Pandemic
Ken Getz, MBA
Clinical Development and Innovation Forum 2021
Online | March 9

New Benchmarks on Protocol Design Practices and Their Impact on Clinical Trial Performance and Efficiency
Michael Wilkinson, MPH, Zak Smith, MS, Ken Getz MBA
MCC Study Quality Trailblazer Group Meeting
Online | March 10

New Strategies to Balance Protocol Complexity, Customization and Executional Feasibility
Ken Getz, MBA
Reuters Pharma: Clinical 2021
Online | April 7

Examining Strategic Implications of Pandemic Response on the Global Investigative Site Landscape
Ken Getz, MBA
SCRS EU Summit
Online | April 22

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About Tufts CSDD **Support Tufts CSDD**

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