



Tufts Center for the Study of Drug Development

**TUFTS CSDD INSIDER**

FEBRUARY 2021

## From the Director



Dear CSDD Friends,

We are witnessing the rare opportunity to show the global public how new vaccines and treatments are developed *and* delivered. During the past 12 months, we've succeeded at the former through demonstrating innovativeness, productivity, passion and commitment. But the latter has not gone particularly well. Distribution challenges, vaccine shortages, inconsistent access, confusion and varying levels of public trust are but some of the most visible conditions witnessed since December.

Late January appears to be a key turning point. Recent global success stories are offering insight into best practices as stakeholders throughout the clinical research and healthcare enterprises refine communication, public education and coordination while they improve and scale operations. Tufts CSDD has been gathering data and monitoring practices and response throughout the pandemic, and we will continue to share insights from our research.

Our recent *Impact Report* on protocol design practices and their impact on clinical trial performance has been generating considerable response. In the coming months, we will continue to share and disseminate findings from this large and ambitious study. Please let us know if you would like to learn more about reviewing and discussing the implications of these new benchmarks.

This past month, we tested and validated a new algorithm that measures study volunteer burden in clinical trials based on protocol design variables. The new algorithm is highly predictive of several key clinical trial performance outcomes. We'll begin sharing these results this month.

The CSDD team is currently assessing remote team effectiveness and efficiency managing drug development activity. This comprehensive global study is a collaboration with the Bill & Melinda Gates Medical Research Institute. Please consider participating. More information is provided below.

In addition to this monthly *Insider*, I encourage you to periodically check our [website](#) for updates on Center activity, to access study results and insights that have been published and presented. And as always, we welcome your ideas, feedback and participation.

Kenneth Getz  
Director and Professor



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TUFTS UNIVERSITY

## Working Group Studies

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

This month, Tufts CSDD is initiating 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 a New 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 be conducting listening sessions among sponsors and contract service providers. [Contact us for more information.](#)

## Global Surveys

### Participate in a New 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



## Tufts CSDD Partnership with The American College of Greece (ACG)

### ACG Professional Certificate in Clinical Pharmacology, Drug Development and Regulation

Tufts Center for the Study of Drug Development is excited to collaborate with The American College of Greece to offer an online version of its highly acclaimed Postgraduate Course in Clinical Pharmacology, Drug Development and Regulation. This new two-week, intensive, live-interactive program offers a Professional Certificate in Clinical Pharmacology, Drug Development and Regulation from the Deree – School of Graduate and Professional Education.

[Learn more and register online](#)

## Research Highlights

### Our Latest *Impact Report*



### *Rising Protocol Design Complexity is Driving Rapid Growth in Clinical Trial Data Volume*

Our January/February 2021 *Tufts CSDD Impact Report* presents results of our study updating benchmarks on protocol design practice. The research was based on 220 recently completed protocols targeting multiple therapeutic areas worldwide.

[Learn more](#) | [Purchase online](#)

**Coming in early March:**  
*Pinpointing Cycle Time Challenges in Clinical Data Management*

**Order your copy today!**

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## Recent Publications

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](#)

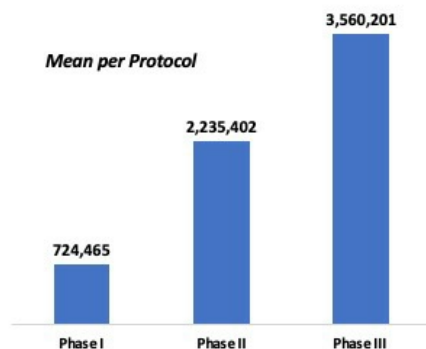
Harper B, Wilkinson M, Indupuri R, Rocchio S, Getz, K. **Evolving Clinical Data Strategies and Tactics in Response to Digital Transformation.** *Ther Innov Regul Sci* 2020; Sep 14. [Access article](#)

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

Cameron D, Willoughby C, Messer D, Lux M, Aitken M, Getz K. **Assessing Participation Burden in Clinical Trials: Introducing the Patient Friction Coefficient.** *Clinical Therapeutics* 2020; 42(8):e150-e159. [Access article](#)

## Data Insights Digest

### Total Data Points Collected per Protocol



- Each phase III protocol collects nearly 3.6 million data points – 60% more than phase II protocols and 400% more than phase I protocols

- The average number of data points collected per phase III protocol is three times greater than collected 10 years ago

For more benchmarks and insights on protocol design practices and performance, check out our most recent [\*Impact Report\*](#).

## 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



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### Upcoming Presentations

*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

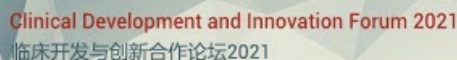


*Anticipating Changes in Clinical Trial Design and Execution Post Pandemic*

**Ken Getz, MBA**

Clinical Development and Innovation Forum 2021

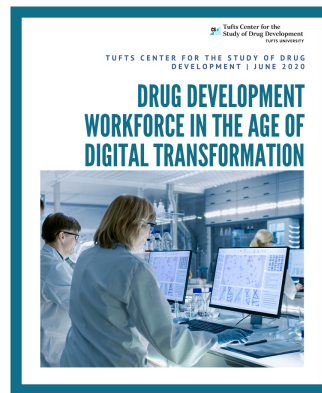
Online | March 10



## Subscriptions, Papers and Books



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**About Tufts CSDD**

**Support Tufts CSDD**

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