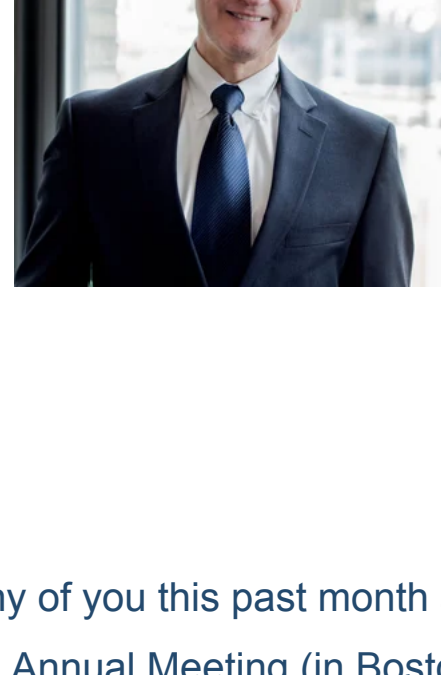


From the Executive Director



Dear CSDD Friends:

It was a pleasure seeing many of you this past month at the DIA China Annual Meeting and the 2023 Global Annual Meeting (in Boston). The programs shared a number of critical themes — protocol optimizations; addressing racial and ethnic disparities in clinical trials; workforce shortages; clinical trial execution and ethics supported by virtual and remote solutions; improving site engagement to maximize clinical trial performance and cost; and AI/ML-enabled data integration and analytics. I was particularly pleased to see many members of the Tufts CSDD team at the Boston meeting sharing the results of, and insights from, their research initiatives informing these themes.

This past month we launched a new consortium to gather, aggregate and analyze actual sponsor and CRO company experience deploying virtual and remote solutions supporting clinical trial planning and execution. Tufts CSDD has received foundation funding for this initiative and 25 companies participated in the launch meeting. We're in discussions with an additional ten companies who wish to join. Please let me know if your organization is interested in learning more and I'll send over details.

We are very busy preparing manuscripts of recently completed studies; managing projects underway; and responding to an unprecedented number of requests for proposals. We have also been giving onsite and virtual presentations and facilitating discussions on our research findings and their implications. Notable active research underway includes a working group study assessing investigative site activation and achievement post-pandemic; a study quantifying the ROI of using digital endpoints in clinical trials; studies assessing how to reduce patient and site burden in protocol execution; and research updating past studies on the capitalized cost to develop a successful drug.

This *Insider* and the CSDD website (CSDD.tufts.edu) are always good places to learn about specific Tufts CSDD projects, publications and presentations. And, as always, please reach out to me directly to discuss new study ideas and results from recently published studies, and to explore ways that we might collaborate.

Please contact [me](#) for information about any of our upcoming and ongoing activities. I also welcome hearing your thoughts on new areas of research inquiry.

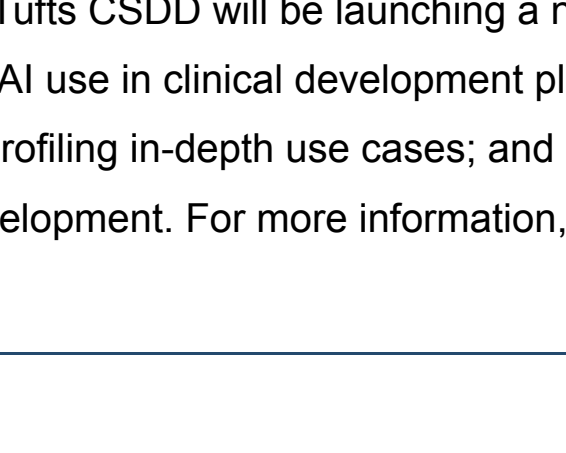
My best regards,

Kenneth Getz
 Executive Director and Professor

Tufts Center for the Study of Drug Development
 TUFTS UNIVERSITY

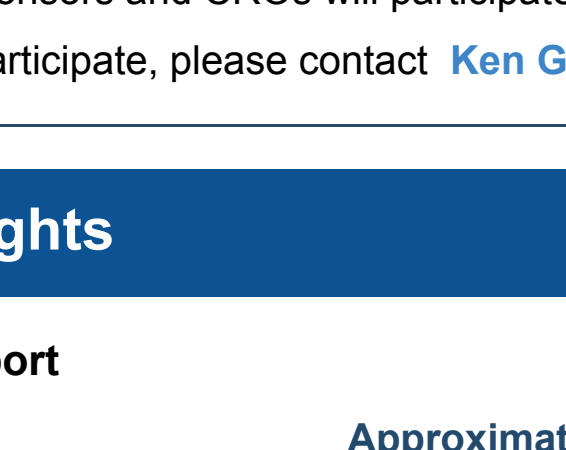
Upcoming Studies

Benchmarking AI use in Drug Development and Quantifying ROI



This coming September, Tufts CSDD will be launching a new multi-company study updating benchmarks on AI use in clinical development planning, design, execution, reporting and oversight; profiling in-depth use cases; and quantifying the return on AI investment in drug development. For more information, contact [Mary Jo Lamberti](#).

New Working Group Study Gathering Rich Data on the Impact of DCT Deployments on Clinical Trial Outcomes



In June, Tufts CSDD launched a new multi-company, pre-competitive consortium to gather and analyze empirical data on company experience with the deployment of virtual and remote solutions supporting clinical trial planning, design, and execution. Tufts CSDD has received a major foundation grant to establish this consortium. We anticipate that 18 – 20 sponsors and CROs will participate. For more information and if you would like to participate, please contact [Ken Getz](#).

Research Highlights

Our Latest Impact Report



Approximately Half of Clinical Trials Use Risk-Based Quality Management Components

The July/August 2023 issue of the Tufts CSDD Impact Report Series (Vol. 25, No.4) is now available. This issue provides new and comprehensive benchmarks on the current adoption of, and implementation challenges associated with RBQM. The ongoing shift to decentralized clinical trial solutions and the introduction of draft ICH E6 R3 guidelines make this new Impact Report particularly timely.

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

Recent Publications

- Getz K. **Optimizing the Process for Adopting DCT Solutions**. Applied Clinical Trials. June 2023. [Access article](#)
- DiBiasi V, Getz K, Miller B, et al. **Introducing Paladin**. Applied Clinical Trials. June 2023. [Access article](#)
- Kim, J. Y., & Botto, E. (2023). **What is hindering the drug development industry from achieving diversity, equity and inclusion in its workforce?** *Nature Biotechnology*, 41(6), 878–879. [Access article](#)
- Kim J, Bautista Acelas MP, Granville C, Getz K. **Benchmarking patient engagement capabilities and preparedness of drug development sponsors**. TIRS. June 19, 2023. [Access article](#)
- DiMasi JA, Smith Z, Oakley-Girvan I, Mackinnon A, Costello M, Tenaerts P, Getz KA. **Assessing the financial value of decentralized clinical trials**. *Therapeutic Innovation & Regulatory Science* 2023 57:209-219 [Access article](#)
- Smith Z, Botto E, Getz K. **Racial and ethnic disparities in pivotal trials supporting FDA-approved and European Commission-approved drugs**. BioPharm Report. Spring 2023; 30(1): 6-8. [Access article](#)
- Getz K. **Assessing investigative site personnel diversity and its relationship with patient enrollment diversity**. BioPharm Report. Spring 2023; 30(1): 9-12. [Access article](#)
- Kim J. Y., Botto E. **Examining the Impact of Exclusionary Behaviors on Team Dynamics**. Applied Clinical Trials. March 24, 2023. [Access article](#)
- Kim J. Y., Shang Z. **Research: How Anti-Asian Racism Has Manifested at Work in the Pandemic**. Applied Clinical Trials, March 13, 2023. [Access article](#)
- Dirks A., Harper B., Getz K. **Assessing Investigative Site Outlook and Operating Experience Post-Pandemic**. Applied Clinical Trials, March 7, 2023. [Access article](#)
- Getz K. **Rebooting the statistic that 5% of eligible patients participate in clinical trials**. Applied Clinical Trials, March 2, 2023. [Access article](#)

Data Insights Digest



Subscribe today to get your copy of the **Tufts CSDD Impact Report**.

Faculty and Staff Presentations

Upcoming Presentations

- Patient preferences for virtual and remote clinical trial services**
[Ken Getz, MBA](#)
 DPharm
 Live | September 22
- Benchmarking Patient Enrollment and Use of Patient Recruitment Tactics**
[Mary Jo Lamberti, PhD](#)
 Outsourcing in Clinical Trials New England
 Boston, MA | November 1
- Optimizing clinical trial performance**
[Ken Getz, MBA](#)
 OCT New England
 Live | November 2
- Measuring patient and site burden in clinical trials**
[Ken Getz, MBA](#)
 DIA Annual Meeting Japan
 Live | November 5 - 8
- Recent Presentations**
- Clinical Trials for Small Biotechs**
[Ken Getz, MBA](#)
 STAT News
 Online | June 12
- The Impact of the last 5 years on investigative sites**
[Abigail Dirks, MS](#), and [Ken Getz, MBA](#)
 ACRP
 Online | June 14
- The Impact of Patient Engagement on Drug Development Performance**
[Ken Getz, MBA](#)
 DIA China
 Online | June 17
- Maximizing Diversity in Clinical Trials**
[Ken Getz, MBA](#)
 Finn Partners
 Boston | June 20
- Performance, Interrupted: Examining DEI dynamics that can impact team performance in drug development.**
[Jennifer Kim, PhD](#)
 DIA Annual Meeting
 Boston | June 26 - 29
- Measuring Impact of Patient Engagement Across Research and Development**
[Jennifer Kim, PhD](#)
 DIA Annual Meeting
 Boston | June 26 – 29
- Sponsor-CRO Collaborations and the Impact of Decentralized Clinical Trials**
[Mary Jo Lamberti, PhD](#)
 DIA Annual Meeting
 Boston, MA | June 26
- Managing Protocol Complexity to Optimize Clinical Trial Performance**
[Ken Getz, MBA](#)
 Linking Leaders
 Boston | May 10
- Innovation in the pharmaceutical industry: New estimates of R&D costs**
[Joe Dimasi, PHD](#)
 PhRMA R&D Roundtable
 Boston | May 11
- Innovation in Clinical Research: Why it Takes So Long to Adopt a New Solution**
[Ken Getz, MBA](#)
 MAGI East Conference
 Philadelphia | May 21 - 24
- Sponsor-CRO Collaborations and the Impact of Decentralized Clinical Trials**
[Mary Jo Lamberti, PhD](#)
 DIA Annual Meeting
 Boston, MA | June 26
- State of the Drug Development Industry**
[Ken Getz, MBA](#)
 Chief Medical Officers Summit
 Boston, MA | April 3 - 4
- Quantifying the Value Proposition of DCT Deployment**
[Ken Getz, MBA](#)
 Informa Decentralized Clinical Trials
 Boston, MA | April 18 - 20
- The Impact of DCT Use on Sponsor-CRO Relationships**
[Mary Jo Lamberti, PhD](#)
 Informa Decentralized Clinical Trials
 Boston, MA | April 19
- The Economics of Implementing Phase 0 Techniques – Methods for measuring Financial Value**
[Joseph Dimasi, PhD](#)
 4th International Phase-0/Microdosing Stakeholder Meeting: Intra-Target Microdosing (ITM): Revolutionizing Clinical Pharmacology and Drug Development
 Boston, MA | April 24
- Assessing Patient Engagement Capabilities and their Impact**
[Ken Getz, MBA](#)
 DIA Europe
 Basel, Switzerland | March 23
- Examining Current Patient Engagement Activities and Investments within Sponsor and CRO Companies**
[Ken Getz, MBA](#)
 DIA Europe
 Basel, Switzerland | March 22
- The Impact of Decentralized and Hybrid Trials on Sponsor-CRO Collaborations**
[Mary Jo Lamberti, PhD](#)
 SCOPE Summit
 Orlando, FL | February 8
- Panel Discussion - Navigating Global Crises: Pandemic War, Hyperinflation and Supply Chain**
[Ken Getz, MBA](#)
 SCOPE Summit
 Orlando, FL | February 7
- Remote Teams in Clinical Research During the COVID-19 Pandemic**
[Maria Florez, MA and Mary Jo Lamberti, PhD](#)
 Clinical Research Webinar
 Online | January 26-27
- Clinical Operations and Clinical Outsourcing Roundtables**
[Ken Getz, MBA](#)
 Linking Leaders
 New York, NY | January 17 - 18

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