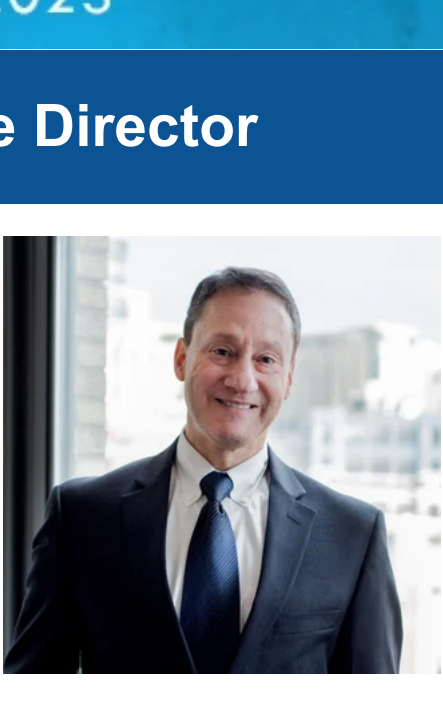
Tufts Center for the Study of Drug Development
TUFTS CSDD INSIDER
August 2023

From the Executive Director



Dear CSDD Friends:

Hard to believe but we are entering into an even more polarized environment for drug development and biomedical innovation. This past month saw a third major pharmaceutical company sue the department of Health and Human Services and Medicare and Medicaid Services for unconstitutional practices in an effort to block drug price negotiations. More companies are expected to follow.

Poor public and lawmaker literacy about the unprecedented risk and complexity of global drug and biologics development, and the mixed and conflicted perceptions about pharmaceutical company pricing and profits contribute greatly to this polarization. Among our many purposes, Tufts CSDD is here to educate and inform government reforms and political discourse. An essential part of our mission is to conduct and share the results of empirical research on drug development trends, economics and operating conditions based on hard data and evidence. Over the years, Tufts CSDD studies have informed congressional inquiries; National Academies and General Accounting Office initiatives; Capital Hill, policymaker and public meetings.

This is an extremely important time for organizations to participate in, and to support Tufts CSDD's mission. We're grateful to our Circle of Supporters and working group companies for your participation and financial support. And we thank the many stakeholder communities that complete our surveys and provide qualitative and quantitative data each year. The work of our center could not be more important or relevant and we encourage your continued collaboration and support.

We have many ongoing studies in our pipeline and many more soon to be launched. This *Insider* and the CSDD website are good places to turn to for updates on projects, publications and presentations. As always, please reach out to me directly with your input, inquiries, ideas and feedback.

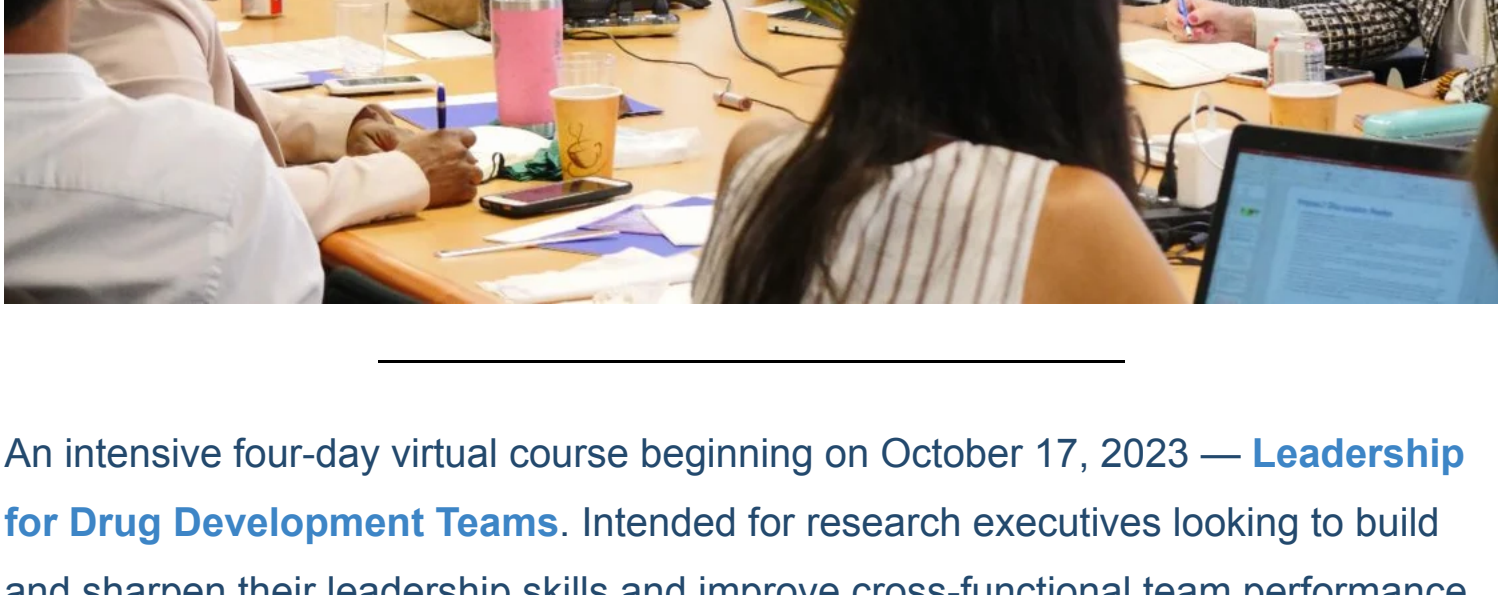
My best regards,

Ken

Kenneth Getz
Executive Director and Professor

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

Professional Development Courses



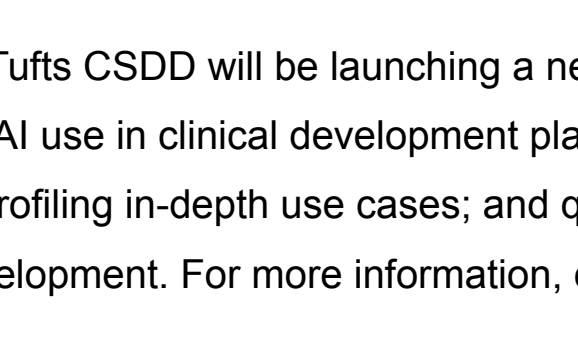
An intensive four-day virtual course beginning on October 17, 2023 — **Leadership for Drug Development Teams**. Intended for research executives looking to build and sharpen their leadership skills and improve cross-functional team performance and productivity, this internationally-recognized program is facilitated by Dr. Robert Franco with an outstanding faculty. Course enrollees will have ample opportunity to interact with faculty and colleagues. To learn more about the course, receive the course agenda, or to register — contact **Sarah Wrobel** or visit the Tufts CSDD **website**.

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**.

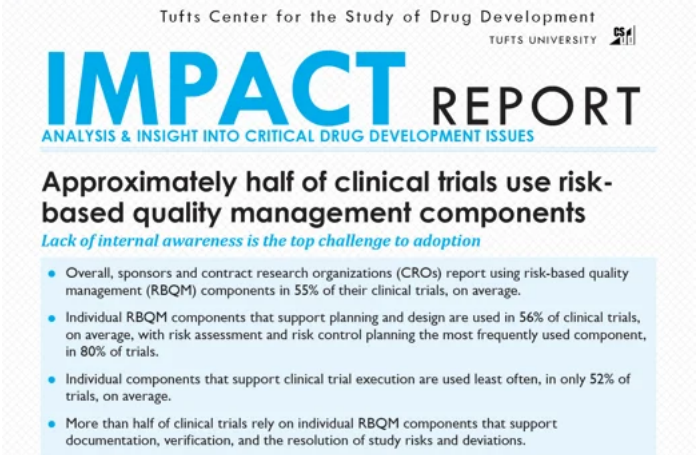
New Working Group Study Gathering Rich Data on the Impact of DCT Deployments on Clinical Trial Outcomes



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


VOLUME 25, NUMBER 4 | July/August 2023
Tufts Center for the Study of Drug Development
IMPACT REPORT
ANALYSIS & INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES
Approximately half of clinical trials use risk-based quality management components
Lack of internal awareness is the top challenge to adoption

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

Kim JY, Maria Paula BA, Granville C, Getz KA. **Benchmarking Organizational Patient Engagement Capabilities in Clinical Research.** Ther Innov Regul Sci. Published online July 2023. **Access article**

Kim JY, Dirks A. **Is Your Organization's Remote Work Strategy "Working"? Exploring the Impact of Employees' Attitudes Toward Flexible Work Arrangements on Inclusion and Turnover Intention.** *Ther Innov Regul Sci.* Published online July 17, 2023. **Access article**

Betcheva L, Kim JY, Erhun F, Oraiopoulos N, Getz K. **Applying Systems Thinking to Inform Decentralized Clinical Trial Planning and Deployment**. Ther Innov Regul Sci. 2023 Jun 30. **Access article**

Getz K. **Optimizing the Process for Adopting DCT Solutions**. Applied Clinical Trials. June 2023. **Access article**

DiBiaso 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**

Data Insights Digest

Oncology and Non-Oncology Clinical Trial Durations
(from Protocol Ready to Database Lock -- 2014-2019)

Mean Days and (Coefficient of Variation)	Non-Oncology Drugs and Biologics	Oncology Drugs and Biologics
Phase I	573.1 (.57)	1,018.3 (.35)
Phase II	991.4 (.66)	1,481.7 (.62)
Phase III	1,214.3 (.46)	1,769.3 (.49)

Source: Tufts CSDD

- **The duration of clinical trials for oncology drugs and biologics in each phase are considerably longer – by 12 to 18 months on average - than non-oncology.**
- **The coefficients of variation around mean clinical trial durations for oncology and non-oncology drugs and biologics are comparable.**
- **Despite longer trial durations by phase, the average overall clinical duration for oncology development programs is only five months longer than non-oncology due to more parallel and phase II-III combination activity.**

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

Faculty and Staff Presentations

Upcoming Presentations

Methods in Organizational Change Research: Dialogue on the Past, Present, and Future of Organization
Jennifer Kim, PhD
Academy of Management
Boston, MA | August 7

Silence is Not Always Golden: Impact of Leader Intervention Against COVID-19 Microaggressions
Jennifer Kim, PhD
Academy of Management
Boston, MA | August 8

Patient Preferences for Virtual and Remote Clinical Trial Services
Ken Getz, MBA
DPharm
Live | September 22

Increasing R&D Productivity to Sustain Biomedical Innovation
Ken Getz
IQVIA Institute Life Sciences Innovation Forum
Virtual | September 26

Examining the Vendor Qualification and Selection Process
Ken Getz
CORE East
Live | October 4-6

Clinical Trial Disruptions During Disasters and Public Health Emergencies
Ken Getz
CTTI and FDA public meeting
Virtual | October 18 - 19

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

Diversity and Representation in Oncology Trials
Zachary Smith, MA
Cancer Immunotherapy Summit
Boston, MA | Nov 6 - 8

Leveraging Patient Engagement Strategies to Optimize Protocol Performance
Ken Getz
Evolution Summit
Live | December 4

Recent Presentations

A Site Perspective: The Impact of the Last 5 Years
Abigail Dirks, MS
Clinical Operations in Oncology Trials East Coast
Boston, MA | July 11

Performance, Interrupted: Examining DEI Dynamics that can Impact Team Performance in Drug Development.
Jennifer Kim, PhD
DIA Annual Meeting
Boston, MA | June 26 - 29

Measuring Impact of Patient Engagement Across Research and Development
Jennifer Kim, PhD
DIA Annual Meeting
Boston, MA | June 26 – 29

Sponsor-CRO Collaborations and the Impact of Decentralized Clinical Trials
Mary Jo Lamberti, PhD
DIA Annual Meeting
Boston, MA | June 26

Maximizing Diversity in Clinical Trials
Ken Getz, MBA
Finn Partners
Boston, MA | June 20

The Impact of Patient Engagement on Drug Development Performance
Ken Getz, MBA
DIA China
Virtual | June 17

The Impact of the Last 5 Years on Investigative Sites
Abigail Dirks, MS, and **Ken Getz, MBA**
ACRP
Virtual | June 14

Clinical Trials for Small Biotechs
Ken Getz, MBA
STAT News
Virtual | June 12

Innovation in Clinical Research: Why it Takes So Long to Adopt a New Solution
Ken Getz, MBA
MAGI East Conference
Philadelphia | May 21 - 24

Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs
Joseph Dimasi, PHD
PhRMA R&D Roundtable
Boston | May 11

Managing Protocol Complexity to Optimize Clinical Trial Performance
Ken Getz, MBA
Linking Leaders
Boston | May 10

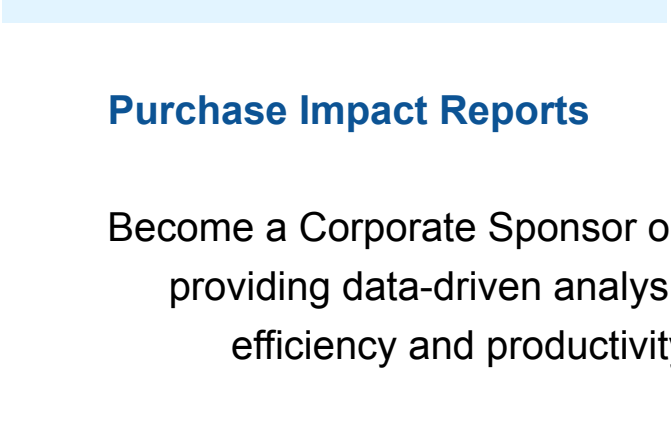
The Economics of Implementing Phase 0 Techniques – Methods for Measuring Financial Value
Joseph DiMasi, PhD
4th International Phase-0/Microdosing Stakeholder Meeting: Intra-Target Microdosing (ITM): Revolutionizing Clinical Pharmacology and Drug Development
Boston, MA | April 24

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

State of the Drug Development Industry
Ken Getz, MBA
Chief Medical Officers Summit
Boston, MA | April 3 - 4

Subscriptions Papers and Books



Purchase Impact Reports


Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY
BENCHMARKING AND OPTIMIZING THE PROCESS FOR ADOPTING INNOVATIONS SUPPORTING CLINICAL TRIAL EXECUTION
Tufts CSDD White Paper
Fall 2022
Kenneth Getz, Maria Florez and Beth Harper

Download White Paper

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