Tufts Center for the Study of Drug Development

TUFTS CSDD *INSIDER*

October 2023

From the Executive Director

Dear CSDD Friends:

Complex and highly risky drug development science & operations, combined with a soft global economy, are presenting an unusually challenging environment at this time. Pharmaceutical, biotechnology and contract services organizations are pursuing four primary strategies to navigate these challenges: cost containment; protocol & operational simplification; capacity & asset augmentation; and, risk reduction.

Newly launched and ongoing Tufts CSDD studies are informing these strategies. We recently embarked on a study looking at how artificial intelligence and machine learning are augmenting drug development planning, execution and reporting. Tufts CSDD is currently conducting several studies diagnosing and identifying opportunities to reduce patient and investigative site participation burden in clinical trials. And we are also conducting research quantifying the return on investment for deploying decentralized clinical trial elements and digital endpoints supporting drug development programs.

Next month, Tufts CSDD will be launching a new study benchmarking protocol data optimization (e.g., reducing the amount of extraneous data supporting tertiary and exploratory endpoints) and another updating benchmarks on the vendor qualification process. Please contact me at **Kenneth.Getz@tufts.edu** if you would like to learn about, and participate in, any of these upcoming studies. This *Insider* and **our website** also provide additional information.

I also wanted to inform you that this month — and next — Tufts CSDD is offering several professional development opportunities that may be of interest to you and your colleagues. Beginning on October 17, we will be holding four interactive sessions for drug development professionals looking to hone their skills managing and leading teams. And on November 8 we will be presenting a new program designed to help drug development professionals build and leverage more diversity within and across functions. Please join us and **register** for these unique and valuable professional development programs.

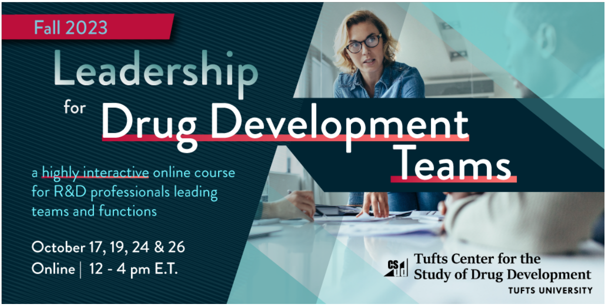
As always, we welcome your feedback and suggestions. My very best regards,

Ken

Kenneth Getz
Executive Director and Professor

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

Professional Development Courses



Fall 2023

Leadership for Drug Development Teams

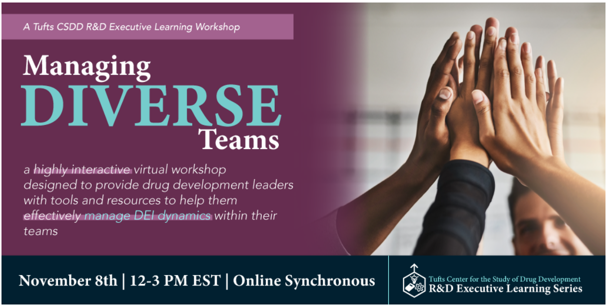
a highly interactive online course for R&D professionals leading teams and functions

October 17, 19, 24 & 26
Online | 12 - 4 pm E.T.

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

On October 17, 2023 Tufts CSDD will begin its fall **Leadership for Drug Development Teams** virtual program. Designed specifically for executives currently managing internal and external teams, the highly interactive program offers new strategies and practical approaches to managing teams in a volatile, complex and ambiguous global operating environment; enhancing remote team productivity and performance; leveraging diversity and inclusion to improve team effectiveness; and optimizing multi-functional and external collaborations and partnerships.

Contact **Sarah Wrobel** or visit the **Tufts CSDD website** for a course agenda and to register for the program.



A Tufts CSDD R&D Executive Learning Workshop

Managing DIVERSE Teams

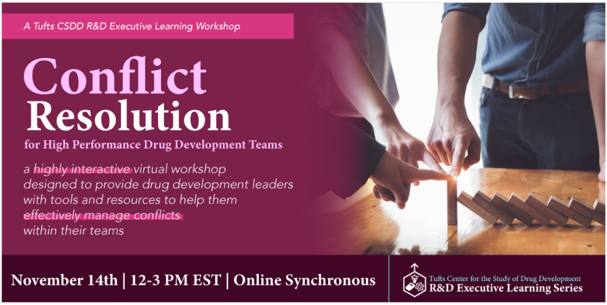
a highly interactive virtual workshop designed to provide drug development leaders with tools and resources to help them effectively manage DEI dynamics within their teams

November 8th | 12-3 PM EST | Online Synchronous

Tufts Center for the Study of Drug Development
R&D Executive Learning Series

On November 8, Tufts CSDD will offer a new and unique virtual program — **Managing Diverse Teams** — for clinical research professionals interested in effectively managing diversity, equity and inclusion dynamics within their functions and teams. Offered in a participatory workshop format, the one-day program blends topics from management and organizational and behavioral psychology applied specifically to companies operating within the clinical research enterprise. Attendees will receive valuable, practical insights on ways to leverage inclusivity to drive team productivity.

To review the program agenda and register for the program, contact **Jennifer Kim** or visit the **Tufts CSDD website**



A Tufts CSDD R&D Executive Learning Workshop

Conflict Resolution

for High Performance Drug Development Teams

a highly interactive virtual workshop designed to provide drug development leaders with tools and resources to help them effectively manage conflicts within their teams

November 14th | 12-3 PM EST | Online Synchronous

Tufts Center for the Study of Drug Development
R&D Executive Learning Series

All drug development teams must be able to resolve disputes in an efficient and constructive manner. TCSDD's **Conflict Resolution for High Performance Drug Development Teams** is an interactive course that will teach participants how to identify, resolve and mitigate conflicts that might arise with team members, functions, or senior management using practical and productive approaches.

The course will examine the latest frameworks, models and strategies for reducing and resolving conflicts, at both the individual and team levels, while sustaining motivation, enhancing productivity and building high performance teams. Participants will also study ways to enhance communication and curb potential disputes before they escalate into conflict. Through case studies and breakout session participants will gain hands on experience with multiple conflict resolution strategies.

For more information, contact **Sarah Wrobel** or visit our **webpage**

Upcoming Studies

Benchmarking AI use in Drug Development and Quantifying ROI

Tufts CSDD has launched a new multi-company study updating benchmarks on AI/Machine Learning use in clinical development planning, design, execution, reporting and oversight. Conducted in collaboration with the Drug Information Association, the study will look at drug development landscape practices, profile specific use cases, and quantify the return on AI investment in drug development. For more information, contact **Mary Jo Lamberti.**

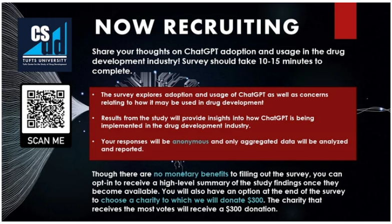
New Consortium Launched to Gather Empirical Data on DCT Deployment Experience and the Impact of DCT

A new multi-company, pre-competitive consortium was formed this past June 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 grant funding from the Reagan-Udall Foundation to support the consortium. Thirty sponsors and CROs are currently participating. Data collection will soon begin. For more information and if you would like to participate, please contact **Ken Getz.**

Updating Benchmarks on the Vendor Qualification Process

Next month, Tufts CSDD will be launching a new working group study updating benchmarks on the vendor qualification assessment process and identifying improvement opportunities. Sponsors, CROs and other service providers dedicate substantial resources and time annually to support this process and to accommodate increasingly complex operating activity. For more information, contact **Zak Smith**

ChatGPT in drug development: How are you using ChatGPT for your job?



NOW RECRUITING

Share your thoughts on ChatGPT adoption and usage in the drug development industry! Survey should take 10-15 minutes to complete.

- The survey explores adoption and usage of ChatGPT as well as concerns relating to how it may be used in drug development
- Results from the study will provide insights into how ChatGPT is being implemented in the drug development industry.
- Your responses will be anonymous and only aggregated data will be analyzed and reported.

Though there are no monetary benefits to filling out the survey, you can opt-in to receive a high-level summary of the study findings once they become available. You will also have an option at the end of the survey to choose a charity to which we will donate $300. The charity that receives the most votes will receive a $300 donation.

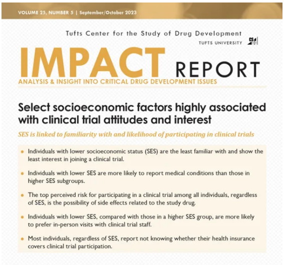
The Tufts CSDD research team invites you to participate in a 15-minute survey about how drug development professionals are using ChatGPT in their everyday jobs. The survey should take no more than 15 minutes. Responses will be anonymous and only aggregated data will be analyzed and reported. Results from the study will inform growing knowledge about AI/Machine Learning in drug development. As a thank you for participating, Tufts CSDD will provide a summary of the study findings once they become available. You will also have an option at the end of the survey to vote on a charity to which we will donate $300.

To complete the survey, please go to: https://tufts.qualtrics.com/jfe/form/SV_bdOKu26xYtk9pVY?Source=CSDDInsider

---

Research Highlights

Our Latest Impact Report



VOLUME 25, NUMBER 5 | September/October 2023

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

IMPACT REPORT
ANALYSIS & INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Select socioeconomic factors highly associated with clinical trial attitudes and interest

SES is linked to familiarity with and likelihood of participating in clinical trials

- Individuals with lower socioeconomic status (SES) are the least familiar with and show the least interest in joining a clinical trial.
- Individuals with lower SES are more likely to report medical conditions than those in higher SES subgroups.
- The top perceived risk for participating in a clinical trial among all individuals, regardless of SES, is the possibility of side effects related to the study drug.
- Individuals with lower SES, compared with those in a higher SES group, are more likely to prefer in-person visits with clinical trial staff.
- Most individuals, regardless of SES, report not knowing whether their health insurance covers clinical trial participation.

Select Socioeconomic Factors Highly Associated with Clinical Trial Attitudes and Interest

The Sept/Oct 2023 issue of the Tufts CSDD Impact Report Series (Vol. 25, No.5) is now available. This issue presents compelling results from a new study looking at the relationship between SES and attitudes, preferences, and perceptions of clinical trials among U.S. patients and the public. The findings suggest new opportunities to inform and recruit prospective volunteers.

Learn more | **Purchase online**

Recent Publications

Smith Z, Botto E, Johnson O, Rudo T, Getz K. **New Benchmarks on Demographic Disparities in Pivotal Trials Supporting FDA-Approved Drugs and Biologics.** *Ther Innov Regul Sci.* Published September 29, 2023. **Access article.**

Zheng W, Kim JY, Kark R, Mascolo L. **What Makes an Inclusive Leader.** *Harvard Business Review*. Published September 27, 2023. **Access article**.

Getz K. **In Search of Attributes Predictive of Collaboration Effectiveness**. *Applied Clinical Trials.* September 2023. **Access article**

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**

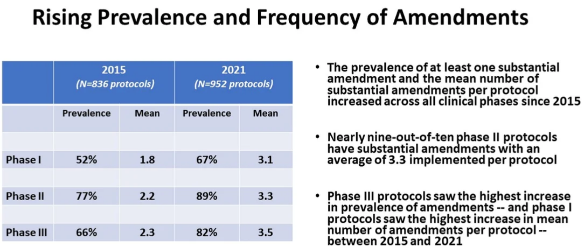
DiMasi JA, Smith Z, Oakley-Girvan I, Mackinnon A, Costello M, Tenaerts P, Getz KA. **Assessing the financial value of decentralized clinical trials**. *Ther Innov Regul Sci*.

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



Rising Prevalence and Frequency of Amendments

	2015 *(N=836 protocols)*		2021 *(N=952 protocols)*	
	Prevalence	Mean	Prevalence	Mean
Phase I	52%	1.8	67%	3.1
Phase II	77%	2.2	89%	3.3
Phase III	66%	2.3	82%	3.5

- The prevalence of at least one substantial amendment and the mean number of substantial amendments per protocol increased across all clinical phases since 2015
- Nearly nine-out-of-ten phase II protocols have substantial amendments with an average of 3.3 implemented per protocol
- Phase III protocols saw the highest increase in prevalence of amendments -- and phase I protocols saw the highest increase in mean number of amendments per protocol -- between 2015 and 2021

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

Faculty and Staff Presentations

Upcoming Presentations

Examining the Vendor Qualification and Selection Process

Ken Getz

CORE East

Live | October 4-6

Overcoming Barriers Slowing the Adoption of Disruptive Technologies

Maria Florez

Disruptive Technologies in Clinical Trials

Boston, MA | October 10

Adopting Technologies that Enable Digital Transformations

Maria Florez

Precision in Clinical Trials Summit

San Diego, CA | October 16

Envisioning the Future Landscape: Preparing the Future Workforce for Drug Research & Development - A Workshop
National Academies
Mary Jo Lamberti, PhD
Washington D.C. | October 16-17

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

Assessing the Net Financial Benefits of Employing Digital Endpoints in Clinical Trials
Joseph DiMasi, PhD
4th Annual Digital Biomarkers & Digital Measurements East Summit
Boston, MA | 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

Adoption Cycle for Technologies that Support DCTs
Maria Florez
Webcast Series: Effectively Adopt a Decentralized Approach, DCT Week
Virtual | November 7

Understanding and Overcoming Barriers to Technology Adoption in Clinical Trials
Maria Florez
Clinical Trials Innovation Programme US

Brooklyn, NY | November 17

Leveraging Patient Engagement Strategies to Optimize Protocol Performance

Ken Getz

Evolution Summit

Live | December 4

Site Activation and Patients Enrollment Benchmarks Among Sponsors and CROs

Mary Jo Lamberti

Summit for Clinical Operations Executives (SCOPE)

Orlando, FL| February 11-14

Workshop: Upskilling for Successful Digital Transformations in Europe

Maria Florez

DIA Europe

Brussels, BE | March 12-13

Recent Presentations

Increasing R&D Productivity to Sustain Biomedical Innovation

Ken Getz

IQVIA Institute Life Sciences Innovation Forum

Virtual | September 26

Patient Preferences for Virtual and Remote Clinical Trial Services

Ken Getz, MBA

DPharm

Live | September 22

Quantifying the Impact of DEI: Making DEI Stick in Drug Development

Jennifer Kim, PhD

EMD Serono

Live | September 13

Speaker Series: DEI

Jennifer Kim, PhD

Massachusetts Department of Revenue

Live | September 11

How Lack of Inclusion Can Impact Women In STEM

Jennifer Kim, PhD

Cornell School of Medicine

Live | August 31st

Silence is Not Always Golden: Impact of Leader Intervention Against COVID-19

Microaggressions

Jennifer Kim, PhD

Academy of Management

Boston, MA | August 8

Methods in Organizational Change Research: Dialogue on the Past, Present, and Future of Organization

Jennifer Kim, PhD

Academy of Management

Boston, MA | August 7

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

Subscriptions Papers and Books

IMPACT REPORT

Biotech R&D spending grew by more than 3X the rate of total industry spend in 2001-20

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

Become a Corporate Sponsor or donate to support our critical mission of providing data-driven analysis and strategic insight to improve the efficiency and productivity of pharmaceutical development.

About Tufts CSDD

Support Tufts CSDD

Tufts CSDD, 145 Harrison Ave, Boston, Massachusetts 02111, United States, (617) 636-2170

Unsubscribe Manage preferences