The Center for the Study of Drug Development
TUFTS CSDD INSIDER
September 2021

From the Executive Director

Dear CSDD Friends:

Faculty and staff are gearing up for a very busy fall. Several studies underway—and some we've begun—focus on interesting and decisive factors that contribute to patient and investigative site participation burden in clinical trials. We will soon be launching a study that explores the "why" behind the use of patient recruitment and retention incentives in global oncology and rare disease clinical trials, and other drug development activities. More then thirty pharmaceutical and biotechnology companies + one prominent funder to the Regulatory Focused Foundation — will soon begin collecting hard data on CT patient solicitation deployments and their impact on clinical trial performance outcomes. Meanwhile, Tufts CSDD will be revisiting its assessment of, and improvements to, the vendor qualification process.

This theme extends the CSDD website present more details on not only what and soon to be launched studies, but also a comprehensive listing of peer-reviewed and trade journal articles related to our recently completed study.

In October, Tufts CSDD is offering its internationally recognized Leadership for Drug Development Teams program. This virtual interactive program is ideal for pharmaceutical and biotechnology R&D teams and their business partners. Presentations and discussion by or substantiating faculty will focus on practical and actionable strategies and solutions designed to optimize collaborative effectiveness and efficiency and sensor higher levels of team performance. Please visit our website or contact Sarah Wenger at sarah.wenger@tufts.edu for more information.

Later this fall we will be holding our next Research Priority Council meeting among drug development executives from nearly two dozen sponsor and CRO companies. The purpose of the council meeting is to identify and prioritize the most critical of evidence-based, industrial analysis study in 2023. Please contact me at Kenneth.Getz@tufts.edu, if you would like to learn more about participating in the meeting.

As always, we welcome your ideas, input, and collaboration.

Wishing you the very best,

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, 2021 — 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. Stephen Francis with an outstanding faculty. Course enrollees will have ample opportunity to ask questions, share ideas, and learn from others. To learn more about the course agenda, or to register — contact Sarah Wenger or visit the Tufts CSDD website.

On November 4th, Tufts CSDD will offer a NEW virtual program — Managing Diverse Teams — designed to provide leaders with tools and resources to help them effectively manage DEI dynamics within their teams. This highly interactive, interdisciplinary workshop features faculty from management, organizational psychology and behavior, constituted within the drug development industry. Participants will learn how to manage diverse teams, how to ensure participants can manifest in teams and learn how to spot and address these behaviors in both psychological safety, reduce burnout, and ultimately increase team productivity. The workshop incorporates interactive exercises among industry practitioners to make the insights relevant to a drug development audience, ranging from sponsors and CROs to research centers and beyond.

For more information, contact Jennifer Kim or visit our website.

Upcoming Studies

Benchmarking AI use in Drug Development and Quantifying ROI

This month, Tufts CSDD is launching a new multi-company study updating benchmarks on AI/ML 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 workspace practices, profiles of AI/ML use, and the impact of AI/ML investment on 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 year 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 Mary Gaze.

Updating Benchmarks on the Vendor Qualification Process

Later this fall, Tufts CSDD will be launching a new working group updating benchmarks on the vendor qualification process to identify and disseminate 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 Zoe Smith.

CHaDDT in drug development: How are you using CHaDDT for your pipe?

Research Highlights

Our Latest Impact Report

Impact Report Discussion Factors
Highly Successful and Impactful Trial Activities and Interest

The Sept/Oct 2021 issue of the Tufts CSDD Impact Report Series Vol. 26, No.5, is now available. This issue presents compelling results from a new study looking at the relationship between SES and attitudes, preferences, and participation in research among US participants and the public. The findings suggest new opportunities to inform and recruit prospective research.

Learn more | Purchase online

Recent Publications

Getz K. In Search of Attributes Predictive of Collaboration Effectiveness. *Applied Clinical Trials*. September 2021. Access article.

Kim JY, Mario Paula BA, Grieshy C, Getz KA. **Benchmarking Organizational Patient Engagement Capabilities in Clinical Research.** *Trial Vision Magazine Vol. Published online* July 2021. Access article.

Kim JY, Zinkhy A. **Is Your Organization's Remote Work Strategy "Working"? Exploring the Impact of Employees' Attitudes Toward Flexible Work Arrangements on Inclusion and Turnover Intention.** *Trial Vision Magazine*. Published online July 17, 2021. Access article.

Dabbiere L, Kim JY, Elkhart F, Chambers R, Getz K. **Applying Systems Thinking to Improve Recruitment Strategy Design and Deployment.** *Trial Vision Magazine* 2021; 2(4):38-42. Access article.

Getz K. **Optimizing the Process for Adopting DCT Solutions.** *Applied Clinical Trials*. June 2021. Access article.

Gilbert S, Getz K, Miller K, et al. **Introducing Patient.** *Applied Clinical Trials*. June 2021. Access article.

Kim J Y, & Bullock, E. (2021). **What is hindering the drug development industry from achieving diversity, equity and inclusion in its workforce?** *Value Exchange*, *1*(3), 2(3), 6(3). Access article.

Kim J, Paulsen Kristen MT, Grieshy C, Getz K. **Benchmarking patient engagement capabilities and preparedness of drug development sponsors.** *Therap Innov Regul Sci*. 2021 Jan 4. Epub ahead of print.

Dabbiere, JA, Smith Z, Gelsey-Crown J, Stevenson A, Costello M, Tenaerts P, Getz KA. **Assessing the Human Capital and Organizational clinical trial.** *Trial Vision Vol 2*. 2021:57-59.2 | Access article.

Smith Z, Getz K, Gaze M. **Patient and ethnic disparities in pivotal trials supporting FDA approved and European Commission-approved drugs.** *BioPharm Report*. Spring 2021. 50(1):8. Access article.

Getz K. **Assessing investigative site personnel diversity and its relationship with patient enrollment diversity.** *BioPharm Report*. Spring 2021 50(1):10. Access article.

Data Insights Digest

CRO Use and Protocol Deviations and Amendments

Global, Early-Stage Oncology Trials with Large Sample Size

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

Faculty and Staff Presentations

Upcoming Presentations

Speaker Series, SIR
Jennifer Kim, PhD
Strategies for Management of Revenue
Live | September 14

Quantifying the Impact of DEI: Making DEI Stick in Drug Development
Jennifer Kim, PhD
DIA Session
Live | September 13

Patient Preference for Virtual and Remote Clinical Trial Services
Ken Getz, MBA
DiPharm
Live | September 21

Increasing R&D Productivity to Sustain Biomedical Innovation
Ken Getz
IQVIA Institute Life Sciences Innovation Forum
Virtual | September 28

Examining the Vendor Qualification and Selection Process
Ken Getz
CORE Exec
Live | October 4-5

Clinical Trial Disruptions During Disasters and Public Health Emergencies
Ken Getz
CTTI and FDA public meeting
Virtual | October 19-20

Benchmarking Patient Enrollment and Use of Patient Recruitment Tactics
Mary-Jo Lamberti, PhD
Outsourcing in Clinical Trials New England
Boston, MA | November 11

Patient Recruitment and Site Burden in Clinical Trials
Ken Getz, MBA
DIA Annual Meeting Japan
Live | November 1, 3

Diversity and Representation in Oncology Trials
Zachary Smith, MA
Cancer Immunotherapy Summit
Boston, MA | Nov 8 - 9

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
Society for Clinical Operations Executives (SCOPE)
Orlando, FL | February 11-14

Recent Presentations

Myers-Lee A Clinician Can Impact Women in STEM
Jennifer Kim, PhD
Cornell School of Medicine
Live | August 31st

Ethics in Pre-Emptive Action: Impact of Leader Intervention Against COVID-19
Microaggressions
Jennifer Kim, PhD
Academy of Management
Boston, MA | August

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

A Site Perspective: The Impact of the Last 5 Years
Allanet Ortiz, MA
Clinical Operations in Oncology Trials East Coast
Boston, MA | June 9

Performance, Interrupted: Examining DEI Dynamics that can Impact Team Performance in Drug Development
Jennifer Kim, PhD
DIA Annual Meeting
Boston, MA | June 29 - 30

Measuring Impact of Patient Engagement Across Research and Development
Jennifer Kim, PhD
DIA Annual Meeting
Boston, MA | June 29 - 30

Sponsor-CRO Collaborations and the Impact of Decentralized Clinical Trials
Mary-Jo Lamberti, PhD
Outsourcing in Clinical Trials
Boston, MA | June 28

Benchmarking Diversity in Clinical Trials
Ken Getz, MBA
Pink Partners
Boston, MA | June 22

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
Allanet Ortiz, MA and **Ken Getz, MBA**
ACDP
Virtual | June 14

Clinical Trials for Small Biotechs
Ken Getz, MBA
ESC Nasa
Virtual | June 12

Innovation in Clinical Research: Why it Takes So Long to Adopt a New Solution
Ken Getz, MBA
NRG Cell Conference
Philadelphia | May 27 - 28

Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs
Ken Getz, MBA
Jefferies Healthcare Conference
Boston | May 10

Managing Patient Complexity to Optimize Clinical Trial Performance
Ken Getz, MBA
Cutting Lunches
Boston | May 10

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