



From the Executive Director



Dear CSDD Friends:

Throughout the summer we've received more inquiries than any other for data and insights into workforce shortages that organizations are facing and strategies they are implementing to address them. Sponsor and CRO companies in particular have been most vocal about study monitor and study coordinator shortages that are causing start-up and study conduct delays, data management and recruitment challenges.

A number of studies underway and several set to begin this fall at Tufts CSDD will contribute to our growing understanding of work force shortages in drug development. These studies aim to quantify the magnitude of these shortages by function and to explore the adoption and use of potential solutions including novel compensation packages; automation and remote and virtual technologies to augment capacity; risk-based monitoring and risk-based quality management; temporary staffing models; and new training programs. Please check our web site or this *Insider* 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 discuss areas most in need of evidence based, robust academic study in 2023. Please contact me at Kenneth.getz@tufts.edu if you would like to learn more about participating in the Council.

We look forward to seeing many of you at upcoming conferences between September and November. The CSDD team will be presenting the results of a number of recently completed studies including quantifying the ROI of decentralized clinical trial solutions; racial and ethnic disparities in pivotal trials of drugs approved by the EU and the FDA; and the role that site personnel diversity plays in facilitating patient enrollment diversity.

In late September we will be offering our Leadership for Drug Development Teams program. This virtual interactive program uses discussion and case studies to teach executives how to manage complex pharmaceutical R&D challenges and how to inspire and lead multi-disciplinary teams to collaborate effectively. And later this fall we will be offering a course on leadership in medical affairs in partnership with the IFAPP Academy.

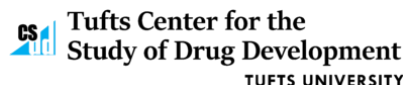
Please visit our website or contact Luna Rodriguez (Luna.rodriguez@tufts.edu) for more information.

Lastly, we will soon be accepting registrations for our award-winning Postgraduate Course in Clinical Pharmacology, Drug Development and Regulation. Now celebrating its 50th anniversary, this highly acclaimed program will be offered virtually during the month of February. More information is available on our website (csdd.tufts.edu).

As always, we welcome your ideas, input and collaboration. Wishing you the very best,



Kenneth Getz
Executive Director and Professor
Kenneth.Getz@tufts.edu



Working Group Studies



Working Group Study Assessing Drug Development Workforce Diversity and its Relationship with Innovation Effectiveness and Team Dynamics

Tufts CSDD has launched its DEI

Dynamics working group to examine the impact of DEI dynamics on team cohesion and productivity. We will develop a survey tool during the summer, and will launch the survey in the Fall. Interested companies should reach out to [Jennifer Kim](#) for more information.

Professional Development Courses

2022 Fall Leadership for Drug Development Teams

Online | September 21, 28 & October 5,12 | 12 - 4pm ET



Robert Franco, PhD

Course Facilitator; President, Coe Point Associates LLC

Sharpen your leadership skills and unleash your drug development team's potential!

This highly interactive online course, brings together team leaders, program managers, functional directors, and other drug development professionals from across the industry to build leadership skills, improve cross-functional performance, and enhance R&D productivity. Delegates meet online in large and small groups over the course of four weeks. Created specifically for pharmaceutical professionals, the program uses case studies to teach you how to lead multi-disciplinary teams and to collaborate effectively in managing complex challenges in pharmaceutical R&D. New program material has been incorporated to focus on how remote teams can operate effectively and productively. We will examine solutions and strategies for getting the most out of remote teams including creating and maintaining high levels of engagement, improving communications, sustaining motivation, establishing and measuring performance, and conducting more productive team meetings in a distributed environment. For more information, contact [Sundé Daniels](#).



CERTIFICATION PROGRAMS

Leadership in Medical Affairs

In Partnership with Tufts University's
Center for the Study of Drug
Development

For Medical Affairs professionals with aspirations in raising the profile of their role, we developed our Leadership in Medical Affairs course.

We partnered with Tufts University's Center for the Study of Drug Development (CSDD) to create a course that encompasses both the theory and the application of leadership principles in Medical Affairs. You will gain leadership insights from industry leaders while interacting with other global biomedical professionals over business case reviews. You can also build networks with faculty and peers across the industry via discussion panels, lectures, webinars, and forums in an interactive online setting. Add this course to your portfolio of formal training and develop professional leadership skills so you can leverage the strategic decision-making within your organization. For more information, click [here](#).

Research Highlights

Our latest Impact Report:



DCTs Substantially Increase Financial Value Based on Key Performance Indicators

The September/October 2022 issue of the Tufts CSDD Impact Report Series (Vol. 24, No.5) is now available. This issue provides highlights from a recent Tufts CSDD study quantifying the net financial return on investment (ROI) on deployments of decentralized clinical trial solutions.

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

Recent Publications

Botto E, Florez M, Allen A, Bhagat R, Getz E, Getz K. **Racial and Ethnic Disparities Among the Clinical Research Workforce: Insights and Opportunities.** *ACRP*. August 16, 2022. [Access article](#)

Getz K, Smith Z, Kravet M. **Protocol design and performance benchmarks by phase and by oncology and rare disease subgroups.** *TIRS*. 2022; doi.org/10.1007/s43441-022-00438-5. [Access article](#)

Moore E, Edwards K, Getz K. **Examining the current value of ClinicalTrials.gov listings for patients and the public.** *Applied Clinical Trials*. August 12, 2022. [Access article](#)

Kim, J. Y. , & Meister, A. **Microaggressions, Interrupted : The Experience and Effects of Gender Microaggressions for Women in STEM.** *Journal of Business Ethics*. [Access article](#)

Lamberti MJ, Smith Z, Dirks A, Caruana T, Mitchell T, Getz K. **The Impact of Decentralized and Hybrid Trials on Sponsor and CRO Collaborations.** *Applied Clinical Trials*. 2022. [Access article](#)

Getz K. **Quantifying Protocol Deviation Experience by Clinical Phase.** *Applied Clinical Trials*. 2022; volume 32, issue 6. [Access article](#)

Florez M, Botto E, Foster Z, Seltzer W, Valastro B, Ashmore L, Getz K. **Improving Diversity in Clinical Trial Volunteer Participation by Addressing Racial and Ethnic Representation Among the Clinical Research Workforce.** *Applied Clinical Trials*. [Access article](#)

Getz K, Florez M, Botto E, Ribeiro K, Goller G, Robinson L, Abdullah O. **Global Investigative Site Personnel Diversity and Its Relationship with Study Participant Diversity.** *TIRS*. 2022. Doi.org/10.1007/243441-022-00418-9. [Access article](#)

Smith Z, Botto E, Getz K. **Quantifying Diversity and Representation in Pivotal Trials Leading to Marketing Authorization in Europe.** *TIRS*. 2022. Doi.org/10.1007/s43441-022-00421-0. [Access article](#)

Kim, J. Y. & Botto, E. (2022). **The Impact of Gender Microaggressions on Team Performance in Drug Development.** *Applied Clinical Trials*. [Access article](#)

Getz K, Smith Z, Jain A, Krauss R. **Benchmarking Protocol Deviations and their Variation by Major Disease Category.** *TIRS* 2022. [Access article](#)

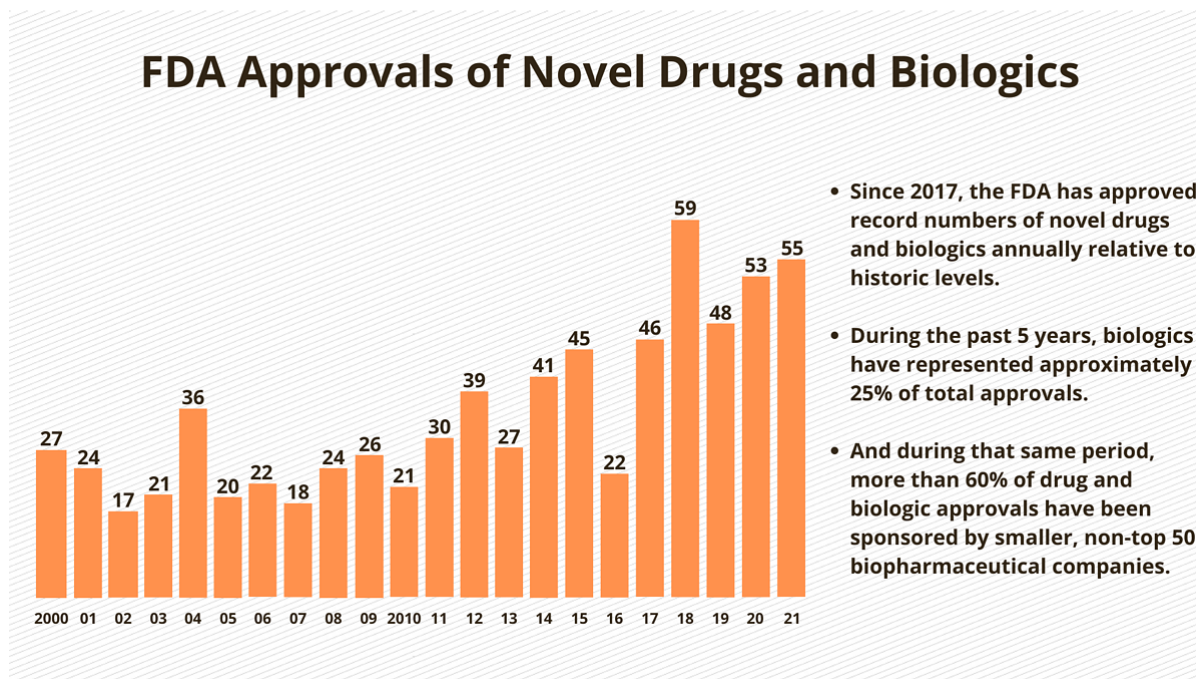
Burt T, Roffel AD, Langer O, Anderson K, DiMasi JA. **Strategic, feasibility, economic, and cultural aspects of Phase 0 approaches.** *Clinical and Translational Science* 2022. [Access article](#)

Kim, J. Y. & Getz, K. (2022). **Measuring patient satisfaction as a primary outcome for patient-centric initiatives.** *Applied Clinical Trials*. [Access article](#)

Kim, J. Y., Brockner, J., & Block, C. J. (2022). **Tailoring the intervention to the self: Congruence between self-affirmation and self- construal eliminates the MBA gender performance gap.** *Organizational Behavior and Human Decision Processes*, 169 (March). [Access article](#)

Smith Z, Bilke R, Pretorius S, Getz K. **Protocol Design Variables Highly Correlated with, and Predictive of, Clinical Trial Performance.** *Ther Innov Regul Sci*. 2022 Jan 30. doi: 10.1007/s43441-021-00370-0. Epub ahead of print. PMID: 35094369. [Access article](#)

Data Insights Digest



Subscribe today to get your copy of the [Tufts CSDD Impact Report](#).

Faculty and Staff Presentations

Upcoming Presentations

The Changing Environment for RBQM
Ken Getz, MBA
 RBQM Live
 Online | September 8



Evolving the Biomedical Innovation System
Ken Getz, MBA
 IQVIA Life Sciences Innovation Forum
 Online | September 13



Racial and Ethnic Disparities in Access to Professional Opportunities in Drug Development

Emily Botto

Clinical Trials Global

Online | September 28

CRO Landscape Trends – Sponsor Demand, Sector Growth, and the Impact of COVID-19

Emily Botto

Contract Pharma

New Brunswick, NJ | September 20



Accelerating Innovation Adoptions Supporting Clinical Trial Execution

Ken Getz, MBA

CTTI Fall Steering Committee Meeting

Washington DC | September 20



Innovation Adoption Cycles for Tools Supporting DCT Research

Maria Florez, MA

Precision in Clinical Trials Summit

Frankfurt | September 28



Characterizing the Innovation Adoption Cycle for Innovations Supporting Virtual Clinical Trials

Maria Florez, MA

Scope Europe

Barcelona | October 3-4



Diversity and Representation Among the Clinical Research Workforce: A factor in patient engagement and recruitment?

Maria Florez, MA

Scope Europe

Barcelona | October 3-4



The Impact of Decentralized Trials on Sponsor-CRO Collaborations

Mary Jo Lamberti, PhD

Outsourcing in Clinical Trials New England
Boston, MA | October 12-13



Digitizing Clinical Trials

Maria Florez, MA

18th Clinical Trials Innovation Programme
Boston, MA | October 26-27

The Economics of Decentralized Clinical Trials: Assessing the Net Financial Benefit

Joseph DiMasi, PhD

Decentralized Clinical Trials Summit
Philadelphia, PA | October 26



“Where has the Industry Been and Where Should it Be Going: Using Industry Development Benchmarks (Time, Risk and Cost Metrics)”

Joseph DiMasi, PhD

Speid & Associates, Inc and Alpert Medical School, Brown University | Drug Development Boot Camp
Boston, MA | November 17



The Impact of Decentralized Clinical Trials Disruption on Sponsor-CRO Relationships

Mary Jo Lamberti, PhD

SCOPE
Orlando, FL | February 6-9



Recent Presentations

Hot Topics in Drug Development

Ken Getz, MBA

ZS Biostatistics Leadership Council

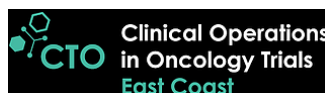
Online | August 4

Clinical Research Professionals and the Shift to Remote Work During the COVID-19 Pandemic

Maria Florez, MA and Mary Jo Lamberti, PhD

Clinical Operations in Oncology East Coast

Boston, MA | July 12-13

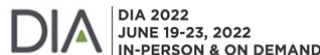


Optimizing the Pharma Workforce for Trial Success in the Digital Era

Maria Florez, MA

DIA Annual Meeting

Chicago, IL | June 23

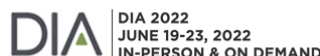


Ensuring Diversity in Clinical Trials

Maria Florez, MA

DIA Annual Meeting

Chicago, IL | June 23

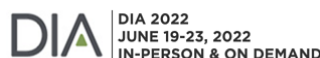


Where Are We? Assessing Organizational Preparedness and Capabilities to Support Patient Engagement

Ken Getz, MBA

DIA Annual Meeting

Chicago, IL | June 21

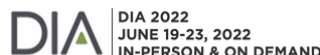


Approaching the Assessment of Clinical Protocol Complexity

Zak Smith, MA; Denise Messer

DIA Annual Meeting

Chicago, IL | June 21



Quantifying Return on DCT Investment**Ken Getz, MBA**

DIA Annual Meeting - Innovation Theater

Chicago, IL | June 21

**Keynote Diamond Panel Discussion: The Future of Healthcare****Ken Getz, MBA**

DIA Annual Meeting

Chicago, IL | June 20

**State of the Drug Development Industry****Ken Getz, MBA**

WCG

Webinar | June 15

**COVID-19 Clinical Development Lessons Learned****Ken Getz, MBA**

IQVIA Institute

Webinar | June 7

**Protocol Simplification and Optimization****Ken Getz, MBA**

French AMMIS

Online | May 24

Characterizing the Innovation Adoption Process for Technologies Supporting Virtual Clinical Trials**Maria Florez, MA**

Virtual Clinical Trials Summit

Philadelphia | May 18 - 19

**Signature Series: Fostering Diversity and Inclusion in Clinical Research****Maria Florez, MA**

ACRP 2022

Orlando, FL | April 24



The Economics of Phase-0 Approaches, Safer, Accelerated, Targeted, and Human-Specific Translation in Drug Development

Joseph DiMasi, PhD

3rd International Phase-0/Microdosing Stakeholder Meeting

The Netherlands | April 22

**Phase-0 Microdosing
Network**

Patient Engagement and the Deployment of DTC

Ken Getz, MBA

DTC National

Live | April 20



Assessing the Adoption of Innovations Supporting Drug Development Operations

Ken Getz MBA

R&D Leadership Summit, The Conference Forum

Aventura, FL | April 11



State of the Drug Development Industry

Ken Getz, MBA

Chief Medical Officers Summit, The Conference Forum

Boston, MA | April 4



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