Tufts Center for the Study of Drug Development

TUFTS CSDD *INSIDER*

MARCH 2022

From the Executive Director

Dear CSDD Friends:

The range of Tufts CSDD activity this past month is indicative of the depth and breadth of global stakeholder demand for more data and new insights to inform drug development strategy, practice and policy.

A Tufts CSDD delegation, for example, met with health and life sciences officials and professionals in Abu Dhabi to analyze and assess the infrastructure and capabilities needed to support a new center of biopharma innovation excellence. CSDD faculty fielded inquiries in response to the release of initial results quantifying the impact of decentralized clinical trial (DCT) solutions on the expected net present value of a typical drug development program. Faculty and staff gave presentations and facilitated virtual and onsite meetings on the results of recently completed studies informing new strategies and tactics to optimize clinical trial performance and improve the racial and ethnic diversity of enrolled study volunteers.

Numerous projects are underway or will soon be initiated. Tufts CSDD has been working with sponsor companies to apply a validated, systematic diagnostic approach to measure subjective patient participation burden. We're working with the Food and Drug Administration to assess the relevance and value of protocol data collected. The CSDD team is working with sponsors to assess the impact of patient-centric practices and we are assessing the evolution of sponsor-CRO relationships facilitated by the transition to virtual and remotely-executed clinical trials. At this time we are also responding to an unprecedented number of requests for proposals.

There is clearly no shortage of important, timely and relevant drug development topics to study empirically. As always, please contact me if you would like to learn about and discuss any of our completed and ongoing studies or to discuss new study opportunities.

I also want to mention that this month we are launching a new working group study looking at trends in the incidence, causes, cost and impact of implementing substantial and country-specific protocol amendments. We hope to have 20 companies participating; 15 have already committed. We encourage your organization to join this important and timely study to not only receive valuable and practical insights but also to share experiences and ideas with peer companies.

Lastly, we continue to receive a very strong response to our Postgraduate Course. This internationally recognized program, now in its 49th year, will be offered as a virtual, interactive program throughout the month of April. We encourage you to register. More information is available in this *Insider* and on the CSDD web site (CSDD.tufts.edu).

As always, we welcome your ideas, feedback and participation.

Kenneth Getz
Executive Director and Professor

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

Working Group Studies

New Study on Benchmarking and Optimizing Protocol Amendments Begins March 24, 2022

Tufts CSDD is forming a working group study updating benchmarks on trends in

the incidence, causes, cost and impact of protocol amendments. The study will gather more granular data on direct and in-direct implementation costs and on both substantial and country-specific amendments. Participating companies help shape the methodology,

gather data, and discuss the results and their implications. **Contact CSDD** if you would like to learn more.

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

Tufts CSDD will also be launching a new
working group study in early May looking at diversity dynamics in the drug development workforce and their relationship to innovation and organizational performance. This study will be informed, in part, by a project funded by PhRMA now underway. Participating companies will be involved in all aspects of the research. **Contact CSDD** to learn more about this important and ground-breaking study.

Survey on the Impact of Decentralized Clinical Trials (DCTs) on Sponsor-CRO Collaborations

Tufts CSDD is conducting a global survey to understand the impact of decentralized clinical trials (DCTs) on sponsor-CRO collaborations. This survey is focused on gaining insights and perceptions across a wide range of organizations. All responses will be reported in the aggregate and no individuals or companies will be disclosed. In appreciation for your efforts, we will provide you with a topline summary of the survey results. Thank you for your time on this research! If you have any questions, please reach out to **Zak Smith** or **Mary Jo Lamberti**.

Click here to fill out the survey

NEW Global Biotech E-Sourcebook

The New Tufts CSDD Global Biotech Database & E-Sourcebook!

Introducing the NEW Global Biotech E-Sourcebook — a fully searchable, comprehensive database on the biotechnology industry capturing its rapid growth and change during the period 2001-2020. The E-Sourcebook captures more than 440 products and 325 biotech and pharmaceutical companies and provides detailed financial, economic and trend data. Ideal for strategic and R&D planning, financial and economic analyses, market intelligence, M&A and investment analysis, regulatory and pipeline tracking. **For more information and to order your copy.**

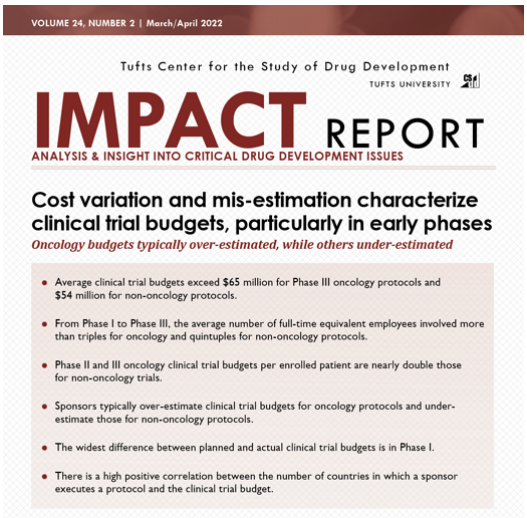
Professional Development Courses

Invest in the most impactful 24 hours of your pharmaceutical career

Tufts CSDD's Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation will resume in 2022 as an interactive and convenient online program, held on six separate days, throughout the month of April. Whether you are new to the industry or need a refresher, this highly acclaimed program will provide you with advanced instruction in practical and technical problem-solving in the areas of clinical pharmacology, drug development & clinical trial strategies, biopharmaceutical development, drug safety, and new drug regulation. During an exclusive Q&A session with a senior FDA official, participants will receive first-hand insights into FDA priorities and operations and will emerge with a better understanding of the regulatory process. For more information, **contact Sundé Daniels**.

Research Higlights

Our latest Impact Report:



Cost Variation and Mis-Estimation Characterize Clinical Trial Budgets, Particularly in Early Phases

The March/April 2022 issue of the Tufts CSDD Impact Report (Vol 24; No 2) is now available. Cost variation and mis-estimation characterize clinical trial budgets, particularly in early phases, According to Tufts Center for the Study of Drug Development.

Learn more | Purchase

Recent Publications

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**

Kim, J. Y., & Roberson, L. **I'm biased and so are you. What should organizations do? A review of organizational implicit-bias training programs.** Consulting Psychology Journal: Practice and Research (2021). **Access article**

Getz K. **Tracking Change in the Global Investigative Site Landscape: New benchmarks uncover a maturing and globally-shifting market.** Applied Clinical Trials. December 2021. **Access article**

Kim, J. Y., Block, C. J., & Yu, H. **Debunking the 'model minority' myth: How positive attitudes towards Asian Americans influence perceptions of racial microaggressions.** Journal of Vocational Behavior, 131(December 2021) **Access article**

Shang, Z., Kim, J. Y., & Cheng, S. O. **Discrimination experienced by Asian Canadian and Asian American healthcare workers during the COVID-19 pandemic: A qualitative study.** Canadian Medical Association Journal Open (November 2021) **Access article**

Botto E, Lamberti M.J., Shah M, Getz K. **Assessing Sponsor and CRO Awareness of Receptivity and Response to the Evolving Nature of Clinical Trial Patient Oversight.** Applied Clinical Trials. November 2021. **Access article**

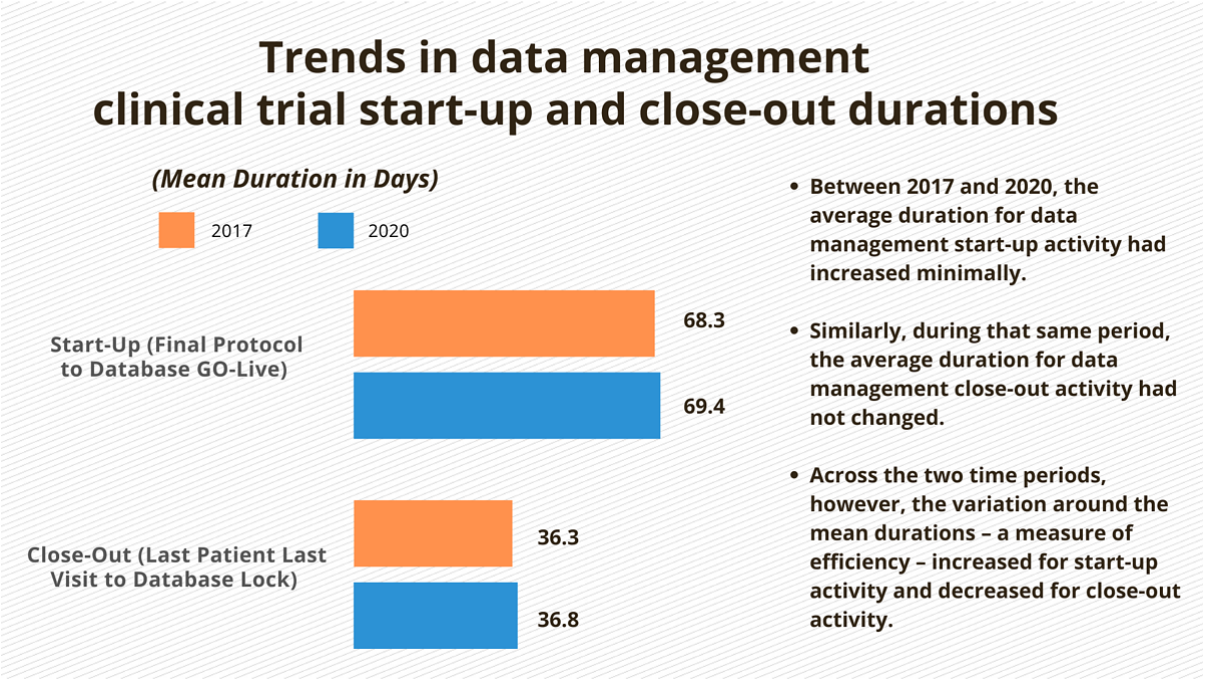
Getz K. **Amplifying Patient Voices in Protocol Design**. Applied Clinical Trials. Sept 2021; 30:9 **Access article**

Smith, Z; Wilkinson, M; Carney, C; Grove, N; Qutab, B; and Getz, K. **Enhancing the Measure of Participation Burden in Protocol Design to Incorporate Logistics, Lifestyle, and Demographic Characteristics.** TIRS (2021). **Access article**

Michaels, D.L., Peña, Y., Kunz, B.L., Getz K. **Evaluating the Feasibility and Validity of a New Tool to Assess Organizational Preparedness and Capabilities to Support Patient Engagement in Drug Development.** TIRS (2021). **Access article**

Florez M., Lamberti M.J., Getz K. **Remote Clinical Research Team Experience and Effectiveness During the COVID-19 Pandemic.** Applied Clinical Trials. Published Online. July 13, 2021. **Access article**

Data Insights Digest



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Faculty and Staff Presentations

Upcoming Presentations

Translational Science Education Roundtable
Ken Getz, MBA
National Center for Advancing Translational Science (NCATS), NIH, DHHS
Online | March 10

Patient Engagement
Jennifer Kim, PhD
DIA Patient Advisory Council
Online | March 28

Anticipating the Impact of Digital Transformation and Remote Operating Models on the Workforce of Tomorrow
Maria Florez, MA
DIA Europe 2022
Brussels, Belgium | March 31

Enhancing Patient Engagement: Emerging Research and Recommendations
Maria Florez, MA
DIA Europe 2022
Brussels, Belgium | March 31

State of the Drug Development Industry
Ken Getz, MBA
Chief Medical Officers Summit, The Conference Forum
Boston, MA | April 4

Assessing the Adoption of Innovations Supporting Drug Development Operations
Ken Getz MBA
R&D Leadership Summit, The Conference Forum
Aventura, FL | April 11

Signature Series: Fostering Diversity and Inclusion in Clinical Research
Maria Florez, MA
ACRP 2022
Orlando, FL | April 24

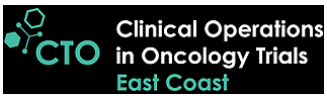
Digitizing Clinical Trials
Maria Florez, MA
18th Clinical Trials Innovation Programme
Boston, MA | May 17

Where Are We? Assessing Organizational Preparedness and Capabilities to Support Patient Engagement
Jennifer Kim, PhD
DIA Global 2022
Chicago, IL | June 21

Ensuring Diversity in Clinical Trials
Maria Florez, MA
DIA Global 2022
Chicago, IL | June 23

Optimizing the Pharma Workforce for Trial Success in the Digital Era
Maria Florez, MA
DIA Global 2022
Chicago, IL | June 23

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



Recent Presentations

Characterizing the Environment for Global Clinical Trials
Ken Getz, MBA
Brandeis University Business of Biotech Program
Online | March 1

Measuring and Anticipating Patient Participation Burden in Clinical Trials
Ken Getz, MBA
SCOPE Summit
Online | February 9

Assessing Patient Enrollment Diversity in Clinical Trials
Zak Smith, MA; Emily Botto, BA; Ken Getz MBA
Finch Therapeutics Virtual Lunch & Learn
Online | February 4

Protocol Complexity in Oncology
Ken Getz, MBA
Seagen Development Knowledge Exchange
Online | February 2

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

New Models for Clinical Trial Execution
Ken Getz, MBA
Tempus Grand Rounds
Online| January 26

Patient-First Trends in Drug Development
Ken Getz, MBA
Parexel Leadership Summit
Online| January 25 - 27

New Insights into Managing Investigative Sites to Optimize Patient Enrollment Diversity
Ken Getz, MBA
Evolution Summit
Orlando, FL | December 8

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, Virtual Conference
Online | December 1

Subscriptions Papers and Books

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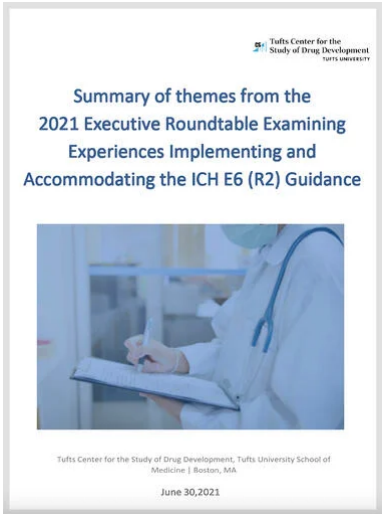

Download White Paper

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About Tufts CSDD

Support Tufts CSDD

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