Tufts Center for the Study of Drug Development

TUFTS CSDD *INSIDER*

JULY 2022

From the Executive Director

Dear CSDD Friends:

It was a pleasure to see many of you at the recent ASCO and DIA annual meetings. Top themes at these two meetings relevant to drug development operating conditions included: workforce shortages; diversity, equity & inclusion; virtual and remote solutions adoption; augmented data analytics; and insights that can be applied from our collective response to the COVID-19
health crisis. With regards to this last theme, many organizations are critically asking if an accelerated, highly effective coordinated, global, multi-stakeholder response to the pandemic can be replicated in other unmet disease conditions.

My colleagues and I at Tufts CSDD are optimistic. Based on our recent interactions with private- and public-sector stakeholders, we are already seeing research sponsors forming larger, more open and agile collaborative teams; conducting more pragmatic clinical trials and collecting evidence through parallel activity instead of the usual sequential approaches; leveraging more real-world data and coordinating and integrating decentralized and clinical care infrastructure.

We have seen an unprecedented number of requests for proposals during May and June. And several new studies have been recently launched including a study updating the adoption and impact of Risk-Based Quality Management (RBQM) approaches; another empirically characterizing the impact of decentralized clinical trial solutions on patient enrollment diversity and clinical trial performance.

There is a strong need and demand for empirical data on many critical drug development issues at this time. Please contact me if you would like to discuss new study ideas or the results of our recently completed studies. We typically receive 3- 5 requests every month to give virtual and live presentations at company meetings and professional society, association and industry conferences. Our Circle of Supporter group also meets twice a year to discuss burning issues and research priorities for CSDD to focus on. Please let me know if your organization is interested in joining our Circle.

This *Insider* and the CSDD website (CSDD.tufts.edu) are always good places to learn about Tufts CSDD projects, publications and presentations. As always, we welcome your

input and collaboration.

Kenneth Getz
Executive Director and Professor
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Tufts Center for the Study of Drug Development
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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.

New survey examining how sponsors and CROs are supporting patient engagement practices

Tufts CSDD is conducting an important new survey to examine patient engagement practices in sponsor and CRO organizations and operations. The brief survey should take only 20 - 25 minutes to complete. The results of this study will characterize how companies are structured to support patient engagement and where they are directing their resources and investment. All responses are confidential and will only be reported in the aggregate. For more information, contact **Dr. Jennifer Kim**, Assistant Professor, Tufts CSDD.

Click here to fill out the survey

Professional Development Courses

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**.

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.**

Research Higlights

Available July 6th, our latest Impact Report:

Innovations Supporting Clinical Trial Execution Take Nearly Six Years to

Adopt The July/August 2022 issue of the Tufts CSDD Impact Report Series (Vol. 24, No.4) is now available. This issue provides new baseline duration measures for a standard four-step adoption cycle and identifies factors that can accelerate the deployment and use of new innovations supporting clinical trials.

Learn more | Purchase

Recent Publications

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**

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**

Data Insights Digest

Trends in the Development of Personalized Medicines

	Percent of Drugs in the Pipeline that Rely on Biomarker and Genetic Data	Percent of All Approved NMEs Classified as Personalized Medicines
2013	23%	9%
2015	42%	21%
2017	51%	26%
2019	56%	29%
2021	64%	39%

- 64% of total drugs in the R&D pipeline rely on biomarker and genetic data, up from approximately 20% only 10 years ago
- Nearly all drugs in R&D for cancer-related diseases rely on genetic information and biomarker data
- Almost 40% of all FDA approvals are classified as personalized medicines today, a proportion that has increased four-fold in a decade

Source: Tufts CSDD; based on FDA 1572 filings

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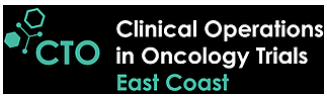
Faculty and Staff Presentations

Upcoming Presentations

Characterizing the Innovation Adoption Cycle for Innovations Supporting Virtual Clinical Trials
Maria Florez
Scope Europe
Barcelona | October 3-4

Diversity and Representation Among the Clinical Research Workforce: A factor in patient engagement and recruitment?
Maria Florez
Scope Europe
Barcelona | October 3-4

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



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

Recent Presentations

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

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

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

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

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

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

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

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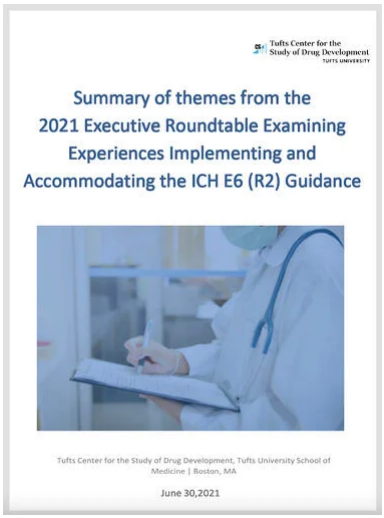

Download White Paper

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

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