Tufts Center for the Study of Drug Development

TUFTS CSDD *INSIDER*

JUNE 2022

From the Executive Director

Dear CSDD Friends:

Escalating geopolitical risk; supply and talent shortages; intensifying competition; increasing complexity and inefficiencies; longer delays; higher failure rates; polarizing domestic political agendas; rising levels of public distrust and confusion — these are only a partial list of the many factors challenging today's drug development operating environment. Tufts CSDD's
pipeline of active and soon-to-be-initiated projects reflect a rich collection of areas where research sponsors and their collaborators are seeking data and evidence to inform strategies and practices to address these challenges.

Tufts CSDD studies funded by grants from individual sponsors, for example, are looking at the evolving use and impact of risk-based quality management practices; coordinated use of integrated evidence to supplement and replace clinical research data and drive more rapid commercialization; actual experience and performance outcomes associated with decentralized clinical trial solutions; and factors contributing to being a partner-of-choice among select investigative sites.

The Tufts CSDD faculty and staff recently kicked-off two new, multi-sponsor working group studies — one looking at the prevalence, causes and cost of protocol amendments. The other looking at the impact of diversity, equity and inclusion on clinical team dynamics and effectiveness. There is still time to join these studies if you are interested.

Working group studies provide a unique and invaluable opportunity for organizations of all sizes to collaborate on gathering important and strategic empirical evidence. Participants help shape the study methodology; establish consensus metrics; share experiences and insights; gather comparative data; and discuss the results and their implications. Several new working group studies are scheduled to begin in the fall including:

- New benchmarks on pandemic/post-pandemic site activation, enrollment and retention rates
- The evolving investigative site landscape — including clinical care and pharmacy-chain settings — and implications for optimizing site management practices

- Identifying factors contributing to long 'white space' durations between clinical phases

Please let me know if you are interested in learning about, and participating in, any of these new working group studies.

This *Insider* presents updates on our ongoing and planned initiatives, upcoming professional development courses, recent publications and presentations. You can also visit our website — at CSDD.tufts.edu — for more details, to reach us and to subscribe to our widely circulated and valued Impact Reports. As always, we welcome your inquiries, 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

On June 7, Tufts CSDD will be launching a new working group study examining diversity, equity and inclusion dynamics and their impact on clinical team effectiveness. This study builds on the results of a just-completed project funded by PhRMA. Participating companies will be involved in all aspects of the research. **Contact CSDD** to learn more about this timely and ground-breaking study.

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

Kenneth Kaitin, PhD

Professor of Medicine and Senior Fellow, Tufts CSDD

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

Our latest Impact Report:


VOLUME 24, NUMBER 3 | May/June 2022

Tufts Center for the Study of Drug Development
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IMPACT REPORT

ANALYSIS & INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

In Europe, demographic under-representation in clinical trials persists

Wide disparities among non-white races, and Hispanic and Latino ethnicities

- Participant demographics—particularly race and ethnicity—are under-reported in pivotal trials supporting the approval of new medicines in the European Union (EU), though reporting completeness has improved over time.
- During 2007-19, only 64% of pivotal trials supporting the EU Commission approval process reported any data on study participants' race, and only 29% provided data on ethnicity.
- The percentage of Black participants decreased significantly, while the percentage of Asian participants increased between 2007 and 2019. No significant changes were observed among other demographics.
- More than half of pivotal trials supporting EU Commission approval under-represented non-white racial identities by greater than 20%.
- Compared to pivotal trials supporting Food and Drug Administration (FDA) approvals, those supporting EU Commission approvals of new medicines under the Centralized Procedure provide less demographic data.
- Racial disparities are most frequently observed in pivotal trials supporting the approval of new respiratory, cardiovascular, and oncology therapeutics in the EU.

In Europe, demographic under-representation in clinical trials persists

The May/June 2022 issue of the Tufts CSDD Impact Report (Vol 24; No 3) is now available. The results of this new Tufts CSDD study show high levels of under-reporting and under-representation of non-white racial identities and Hispanic/Latino ethnicities in pivotal trials supporting the approval of new medicines in the EU.

Learn more | Purchase

Recent Publications

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

Oncology and Other Drug Clinical Trial Scope Changes

(Means)	Oncology Drugs		Other Drugs	
	Number of Sites	Number of Countries	Number of Sites	Number of Countries
Phase I	6.7	2.0	1.6	1.1
Phase II	32.1	5.7	28.4	3.6
Phase III	135.2	17.1	90.5	9.2

- Across all phases, oncology drug clinical trials involve more sites and countries compared to all other drugs
- Although oncology and other drug clinical trials increase scope significantly in each successive clinical phase, the former do so more extensively
- The large relative number of sites and countries to recruit comparably lower mean numbers of evaluable patients underscores recruitment and retention difficulties in oncology

Source: Tufts Center for the Study of Drug Development; 2015-2020 Drug Pipeline Data

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

Faculty and Staff Presentations

Upcoming Presentations

COVID-19 Clinical Development Lessons Learned
Ken Getz, MBA
IQVIA Institute
Webinar | June 7

State of the Drug Development Industry
Ken Getz, MBA
WCG
Webinar | June 15

Keynote Diamond Panel Discussion: The Future of Healthcare
Ken Getz, MBA
DIA Annual Meeting
Chicago, IL | June 20

DIAmond SESSIONS

Quantifying Return on DCT Investment
Ken Getz, MBA
DIA Annual Meeting - Innovation Theater
Chicago, IL | June 21

DIA 2022 JUNE 19-23, 2022 IN-PERSON & ON DEMAND

Approaching the Assessment of Clinical Protocol Complexity
Zak Smith, MA; Denise Messer
DIA Annual Meeting
Chicago, IL | June 21

DIA 2022 JUNE 19-23, 2022 IN-PERSON & ON DEMAND

Where Are We? Assessing Organizational Preparedness and Capabilities to Support Patient Engagement
Ken Getz, MBA
DIA Annual Meeting
Chicago, IL | June 21

DIA 2022 JUNE 19-23, 2022 IN-PERSON & ON DEMAND

Ensuring Diversity in Clinical Trials
Maria Florez, MA
DIA Annual Meeting
Chicago, IL | June 23

DIA 2022 JUNE 19-23, 2022 IN-PERSON & ON DEMAND

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

DIA 2022 JUNE 19-23, 2022 IN-PERSON & ON DEMAND

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

CTO Clinical Operations in Oncology Trials East Coast

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

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

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

DIA EUROPE 2022
ADVANCING HEALTH PRIORITIES
29-31 March 2022

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

NIH National Center for Advancing Translational Sciences

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

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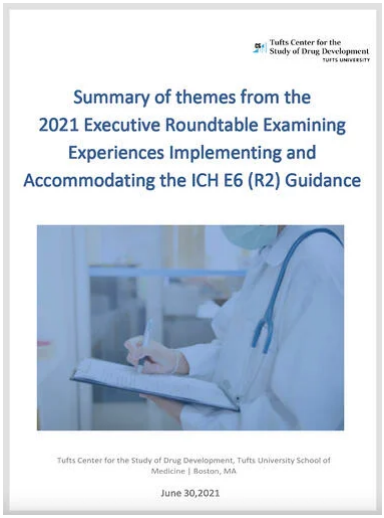

Download White Paper

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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