Tufts Center for the Study of Drug Development

# TUFTS CSDD *INSIDER*

APRIL 2022

## From the Executive Director

Dear CSDD Friends:

In late March we launched our newest working group study looking at updating benchmark data on the prevalence, incidence, causes and impact of substantial protocol protocol amendments. This study has attracted a large and engaged group of 25 participating companies, a testament to the study's relevance and timeliness. There is still time to join this study if your organization is interested.

Tufts CSDD's working group studies provide a unique and invaluable opportunity for organizations to collaborate on gathering important empirical evidence. In addition to helping to shape a robust methodology and establish consensus metrics; participating companies share experiences and insights; provide hard global data; discuss the results and their implications; co-author and co-present key takeaways. Later this year, we will be kicking off several new working groups to evaluate:

- The impact of diversity, equity and inclusion on clinical team dynamics and effectiveness
- New benchmarks on recruitment and retention practices
- The evolving investigative site landscape and implications for optimizing site management practices

And in the fall, we will be launching our next CSDD Cost Study to update and inform the widely cited and referenced metrics on the capitalized cost to develop a new drug or biologic. Please let me know if you would like to learn more about any of these upcoming studies.

Lastly, I'm delighted to mention that we will be holding our 2022 Postgraduate Course this month! Nearly 90 registrants will be attending this internationally recognized program offered this year in a virtual format. Registrants represent a wide variety of organizations in

the private and public sectors including mid-sized and large pharmaceutical companies, emerging biotechnology companies, academia, teaching hospitals and government agencies.

This *Insider* and our website highlight our many ongoing and newly launched initiatives and professional development courses. As always, we welcome your feedback and collaboration.

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 Launched

Tufts CSDD has launched a working group study updating benchmarks and

trends on the incidence, frequency, causes, costs 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.

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

Tufts CSDD will 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.**

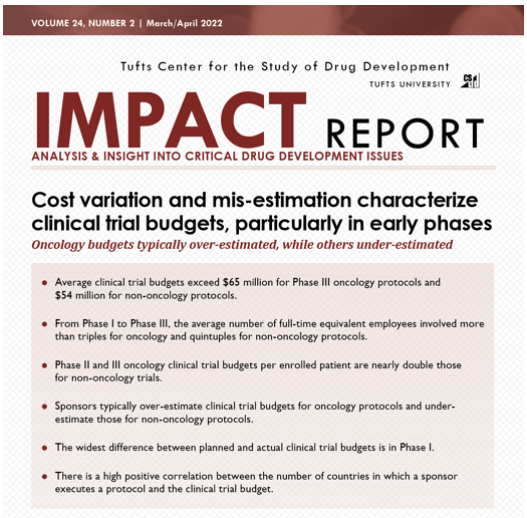
## Professional Development Courses

### Invest in the most impactful 24 hours of your pharmaceutical career

Tufts CSDD's 2022 Postgraduate Course in Clinical Pharmacology, Drug Development and Regulation will be offered this month. The interactive and convenient online program will be 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

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### Recent Publications

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 (in press). **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**

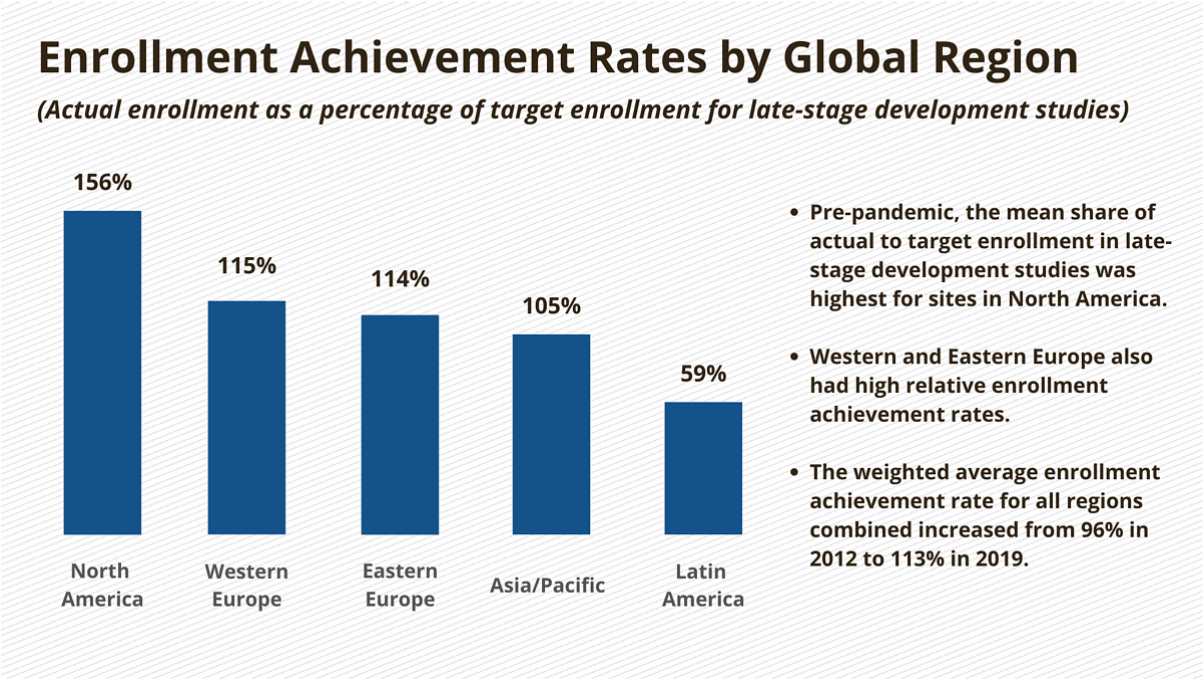
Getz K. **Amplifying Patient Voices in Protocol Design**. Applied Clinical Trials. Sept 2021; 30:9 **Access article**

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

**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

**Patient Engagement and the Deployment of DTC**
**Ken Getz, MBA**
DTC National
Live | April 20

**"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

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

ACRP

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

WorldBI
Conference | Summits | Webinars

**Protocol Simplification and Optimization**
Ken Getz
French AMMIS
Online | May 24

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

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

**Ensuring Diversity in Clinical Trials**
**Maria Florez, MA**
DIA Global 2022
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 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

**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

**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

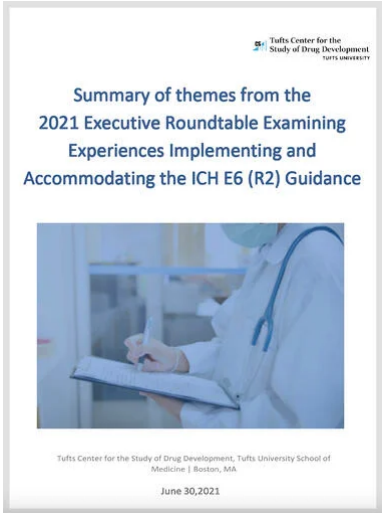
TEMPUS

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

parexel

## Subscriptions Papers and Books


**Purchase Impact Reports**

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**About Tufts CSDD**

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