Tufts Center for the Study of Drug Development

TUFTS CSDD *INSIDER*

FEBRUARY 2022

From the Executive Director

Dear CSDD Friends:

Collaborations and conferences are in full swing as the new year gets underway. In them we see much optimism and buzz around high and rising levels of non-COVID global drug development activity, an exceptionally bullish venture capital and private equity environment, and the unprecedented promise of novel technologies, data management solutions and clinical trial execution models.

But there is also an undercurrent of uncertainty that has recently entered the mix: A large and growing number of organizations are encountering workforce challenges: Workloads are increasing, demand for new skill sets (e.g., digitally transformed and more agile functions) has intensified, and workforce retention and replacement have become much more difficult. The 'Great Resignation' concurrent with wage increases are compounding these pressures.

Tufts CSDD is measuring and monitoring these critical trends. This month, we are also forming a consortium comprised of senior R&D and Human Resources leadership to examine these challenges and map out new workforce strategies that de-risk and leverage opportunities presented by the current operating environment. The consortium will share pre-competitive experiences and insights culminating in a practical framework and training model for organizations to apply in building a stronger leadership team and a more sustainable and effective workforce. Please contact my colleague, **Sunde Daniels** to learn more about and to join the consortium.

Two working group studies are also now recruiting participating companies: One is looking at trends in the incidence, causes and impact of substantial and country-specific protocol

amendments. The other is exploring the relationship between R&D workforce diversity and innovation effectiveness. Later in the year we plan to initiate a large working group to begin our next Drug Development Cost study. More information about the two working groups that have already been launched is provided in this *Insider*.

We've received 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 for the course. More information and a link to the full program agenda are provided in this *Insider.*

The Tufts CSDD team has been very busy with studies underway, with presentations at conferences and company meetings, and with manuscript preparation. The *Insider* and the CSDD web site (CSDD.tufts.edu) are always excellent ways to monitor and learn about our activities. We also welcome hearing from you at any time with observations, inquiries and requests for more data and insights.

Kenneth Getz
Executive Director and Professor

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

Working Group Studies

New Working Group Study on Optimizing the Implementation of Protocol Amendments

Tufts CSDD is now forming a working group study updating benchmarks on trends in the causes and impact of protocol amendments. The study will also 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 about the study.

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

We are launching a new working group
study 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 participating in this important, 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:

The Incidence of Protocol Deviations and Amendments is High and Rising

Our new January/February 2022 Impact Report provides updated benchmarks on substantial amendments and deviations per protocol and new insights into optimizing protocol design.

Learn more | Purchase

Recent Publications

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**

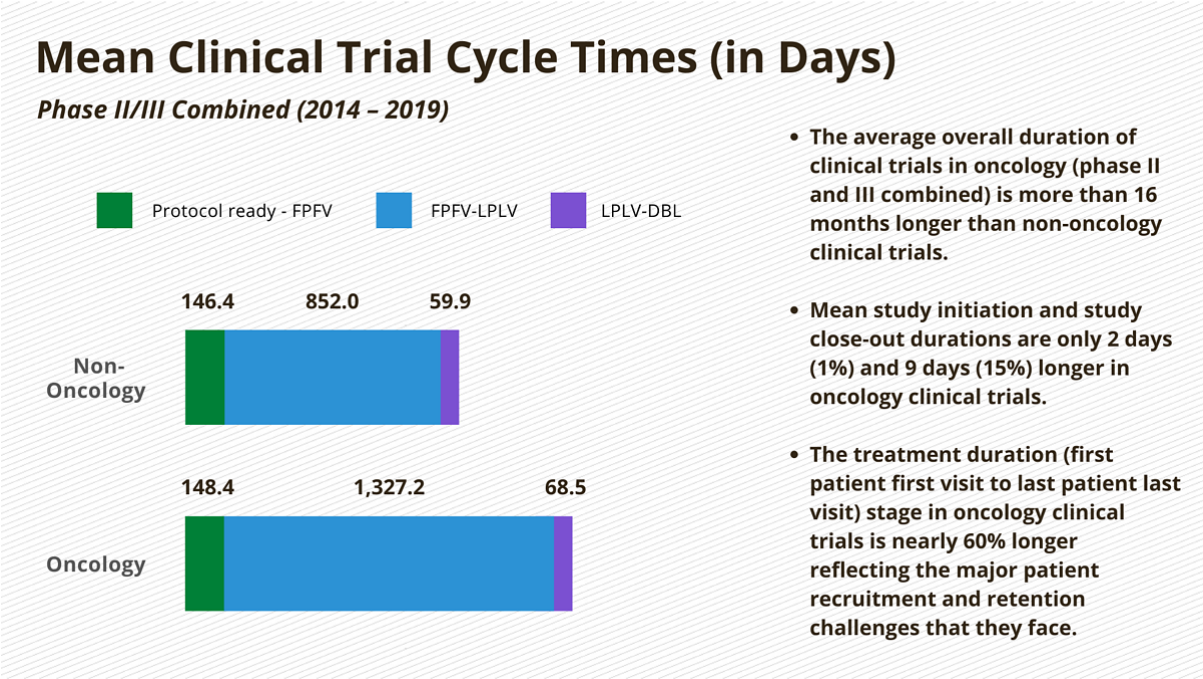
Getz K. **Amplifying Patient Voices in Protocol Design**. Applied Clinical Trials. Sept 2021; 30:9 **Access article**

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

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

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

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

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

Leadership in Medical Affairs
Kenneth Kaitin, PhD
IFAPP Academy
Online | October 18

Recent Presentations

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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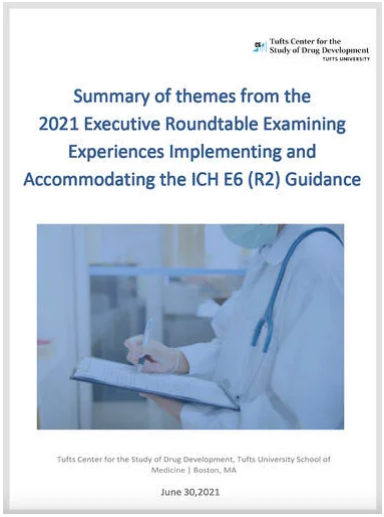

Download White Paper

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About Tufts CSDD

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