Tufts Center for the Study of Drug Development

TUFTS CSDD *INSIDER*

DECEMBER 2021

From the Director

Dear CSDD Friends:

The conclusion of this month will mark my first full year as the Center's director. These past 12-months have been filled with learnings and inspiration – for me personally and for Tufts CSDD as a whole. I have been deeply impressed and moved by the level of resilience, collaboration, enthusiasm
and resourcefulness from internal colleagues and from our supporters and partners throughout the industry.

Our research focus has expanded significantly in parallel with the ways that drug development science, operations and regulation have pivoted and adjusted during the pandemic. The relevance and value of the results of our research to inform strategies and tactics that accelerate timelines, improve quality and optimize efficiency have continued to grow. Faculty and staff have joined our team this year bringing new skills and perspectives to meet the needs of this evolving landscape.

This month and continuing through the first half of 2022, Tufts CSDD will be publishing the results of recently completed studies including the role that site selection and management plays in increasing patient enrollment diversity; the impact of decentralized clinical trials solutions on the expected net present value of drug development programs; new benchmarks on the process of adopting innovations supporting drug development planning and operations; and measuring diversity and disparities among patients participating in pivotal trials of newly approved drugs and biologics. Publication dates and links to the manuscripts and articles can be found on our web site and in the *Insider*.

Our working group quantifying the value proposition of patient engagement is now underway, and in early 2022, Tufts's CSDD will be kicking off a new working group study benchmarking protocol deviations and substantial amendments and identifying improvement opportunities. Last month CSDD launched the Research Priority Council with the participation of senior drug development executives from 15 sponsor and CRO companies. The purpose of the council is to identify and discuss areas most in need of evidence-based, robust academic research in 2022. Please contact me if you would like to learn more about joining our working groups and the Research Priority Council.

Two other notable items: this month we are launching our new E-Sourcebook on the global biotechnology industry. This online, searchable resource provides the most comprehensive data and analysis on this rapidly growing and highly productive sector. Our internationally recognized Postgraduate Course — celebrating its 49th year — in clinical pharmacology, drug development and regulation is now open for registration. More information about the new E-Sourcebook, Postgraduate Course and other CSDD updates can be found in this *Insider*.

Thank you for your collaboration, encouragement and support in 2021. Warm wishes for a healthy, productive and meaningful 2022!

Kenneth Getz
Director and Professor

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

Development and Advancement

This month Tufts CSDD is receiving donations as part of its annual end-of-year campaign. Please consider making a donation individually or as a company. Financial support from our community is crucial to our mission and enables us to cover

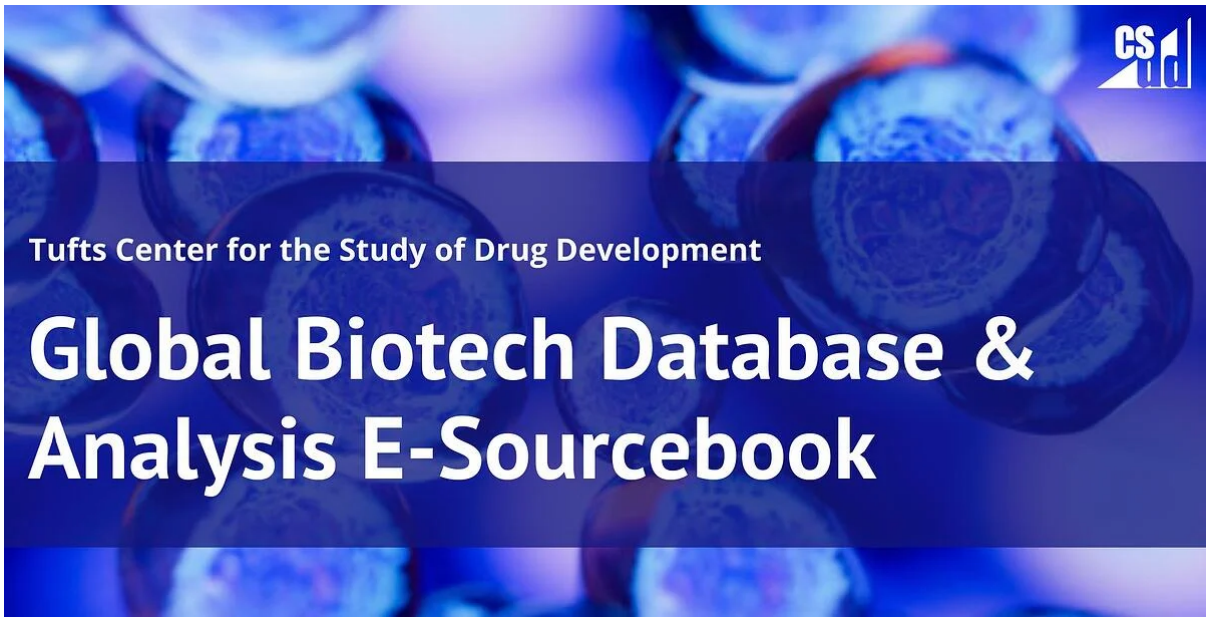
our operating costs, conduct longitudinal studies, prepare manuscripts, attend meetings, and mentor and train young professionals and university students. Please visit our **website** for more information or to make a donation.

Working Group Studies

Working Group Study Updating Benchmarks and identifying Opportunities to Reduce Protocol Deviations and Substantial Protocol Amendments

In early 2022, Tuft CSDD is kicking-off a new study to gather benchmarks and identify the root causes, cost and impact of protocol deviations and substantial protocol amendments. Participating companies will 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.

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 pre-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

New Study Finds Site Personnel Race and Ethnicity Highly Correlated with Diversity of Patients Enrolled

Our November/December Tufts CSDD Impact Report presents compelling results characterizing how organizations have adapted during the pandemic, what steps were taken and resources provided, and the impact on clinical team attitudes and experience.

Learn more | Purchase online

Recent Publications

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**

Qian H, Qui L, Fanzhen L, Kaitin KI, Shao L. **A survey of survival outcomes for targeted cancer drugs approved by the US Food and Drug Administration.** TIRS 2021;55(4):676-684. **Access article**

Orkin A. et al. **Guidelines for Reporting Trial Protocols and Completed Trials Modified Due to the COVID-19 Pandemic and Other Extenuating Circumstances.** JAMA. Published online June 21, 2021. doi:10.1001/jama.2021.9941. **Access article**

Harper B, Smith Z, Snowdon J, DiCicco R, Hekmat R, Willis V, Weeraratne D, Getz K. **Characterizing Pain Points in Clinical Data Management and Assessing the Impact of Mid-Study Updates.** Ther Innov Regul Sci. 2021 May 17. **Access article**

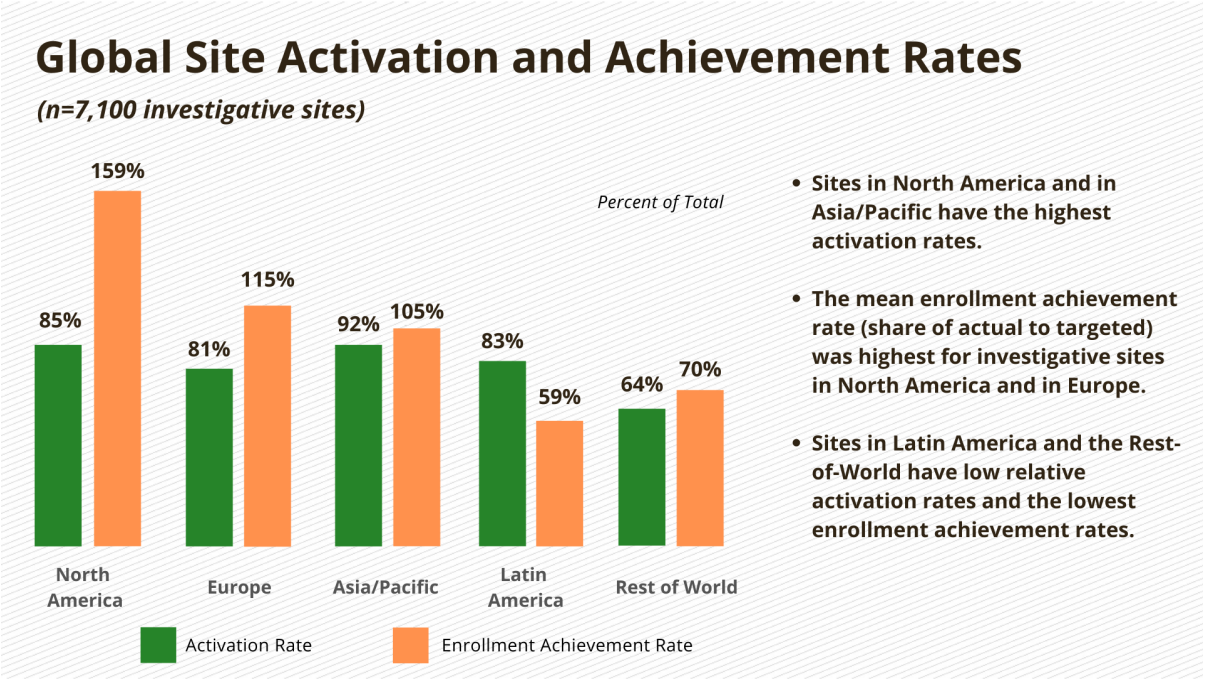
DiMasi, JA, Wilkinson M. **The financial benefits of faster development times: integrated formulation development, real-time manufacturing, and clinical testing.** TIRS 2020;54(6):1453-1460. **Access article**

Getz K. **Characterizing White Space in the Quest to Drive Development Speed.** Applied Clinical Trials, 2021; April 7. **Access article**

Florez M, and Getz K. **Anticipating digital transformation of the drug development workforce.** Pharmaceutical Executive, March 26. **Access article**

Getz K. **Public Trust and the 'Last Mile' for COVID-19 Vaccines.** Applied Clinical Trials 2020; 29 (12): 11 – 12. **Access article**

Data Insights Digest



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Faculty and Staff Presentations

Upcoming Presentations

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

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

Recent Presentations

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

Measuring the Impact of the Pandemic on Drug Development Productivity and Performance
Ken Getz, MBA
Outsourcing Clinical Trials New England
Boston, MA | November 10

Digital Transformation and Clinical Research Team Effectiveness
Maria Florez, MA
Clinical Trials Europe
Online | November 2-4

Impact of Running Clinical Trials During the Pandemic and Lessons Learnt
Ken Getz, MBA and Maria Florez, MA
Clinical Trials Europe
Online | November 2-4

Where Has the Industry Been, and Where Should it be Going?
Joseph DiMasi, PhD
Speid Associates, Inc and Brown University Medical School
Online | November 2-4

Increasing Efficiency and Reducing Cycle-Times in Drug Development: Multi-Stakeholder Views on the Topic
Zak Smith, MA
Clinical Trials Europe
Online | November 3

VIRTUAL EVENT
Clinical Trials Europe

Optimizing protocol design to improve performance and efficiency
Ken Getz, MBA
Clinical Trials Europe
Online | November 2

VIRTUAL EVENT
Clinical Trials Europe

Accommodating and managing agile drug development execution
Ken Getz, MBA
Chief Medical Officers Summit
Online | October 14

CMOSUMMIT360

Impact of COVID-19 on Clinical Operations
Ken Getz, MBA
Dutch Federation of Pharmaceutical Medicine
Online | October 7

NVFG

How We Become Agile to Remain Viable in a Post-COVID World
Ken Getz, MBA
DPharm
Online | September 29

Dpharm

The Economics of the Pharmaceutical Industry
Joseph DiMasi, PhD
24th North American ISSX Annual Meeting
Online | September 13-17

24TH NORTH AMERICAN ISSX MEETING

Insights into Rare Disease Development
Ken Getz, MBA
Ultragenyx
Online | September 13

ultragenyx pharmaceutical

Remote Clinical Research Team Experience and Effectiveness During the COVID-19 Pandemic
Maria Florez, MA and Mary Jo Lamberti, PhD
Association of Medical Research Charities
Online | September 9

amrc ASSOCIATION OF MEDICAL RESEARCH CHARITIES

Remote Clinical Research Team Experience and Effectiveness During the COVID-19 Pandemic
Maria Florez, MA and Mary Jo Lamberti, PhD
Academy of Physicians in Clinical Research
Online | September 1

APCR Academy of Physicians in Clinical Research

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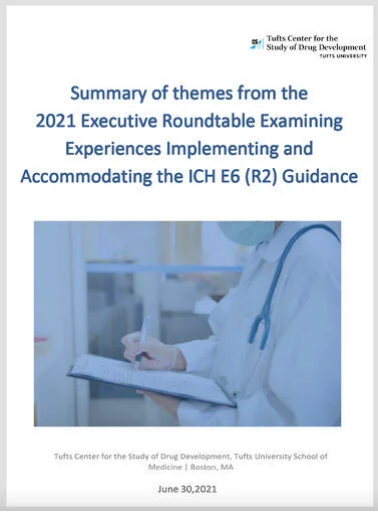

Download White Paper

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

Support Tufts CSDD

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