Tufts Center for the Study of Drug Development

TUFTS CSDD *INSIDER*

JANUARY 2022

From the Executive Director

Dear CSDD Friends:

We begin 2022 with momentum fueled by promising, transformational changes underway including heightened focus and investment on improving diversity, equity and inclusion in clinical trials; regulatory agency encouragement and rising adoption of virtual and remote solutions
supporting patient engagement; and the increasing leverage of clinical, real world and operating data to optimize drug development outcomes and performance.

We also enter 2022 with criticisms and concerns that have been raised. To name but a few: COVID vaccines were developed and approved too quickly; R&D associated with the pandemic has diverted resources and activity away from critical unmet disease conditions; most COVID-19 related Emergency Use Authorizations (EUAs) have relied on insufficient data —comparative data to previously authorized assays or on nonclinical data — requiring more dynamic standards of evidence based on experience from the earliest market entrants; and sponsors are retrenching from decentralized clinical trial technology adoption in the absence of clear return on investment.

Transformational change, internal and external forces impacting the drug development enterprise drive our work at Tufts CSDD. We strive to conduct objective, robust, data-driven assessments and analyses to derive impactful, strategic insights and actionable, practical solutions. We're very excited about our working list of research priorities — informed by input from our community of supporters and stakeholders — in 2022:

- Updating drug development cost, success rate and speed benchmarks;

- Assessing the impact of regulatory modernization initiatives;
- Studying the impact of protocol designs on clinical trial performance and quality;
- Measuring workforce and patient recruitment diversity and addressing disparities;
- Evaluating new practices, solutions and models improving patient engagement and optimizing clinical trial outcomes and execution.

Please reach out to me directly to share your thoughts on these and other research priority areas of interest.

Two other items to call out: (1) we have launched our new E-Sourcebook on the global biotechnology industry. This searchable database and reference resource is ideal for strategic and R&D planning, market intelligence and investment analyses; and (2) We are now receiving registrations for our Postgraduate Course in clinical pharmacology, drug development and regulation. The program — now in its 49th year — will be held virtually during the month of April. We're seeing strong interest from organizations looking to send multiple staff to attend this internationally recognized, refresher program. More information about these items and other CSDD updates are provided below.

Happy New Year. We look forward to collaborating with you in 2022!

Kenneth Getz
Executive Director and Professor

Tufts Center for the Study of Drug Development
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Working Group Studies

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

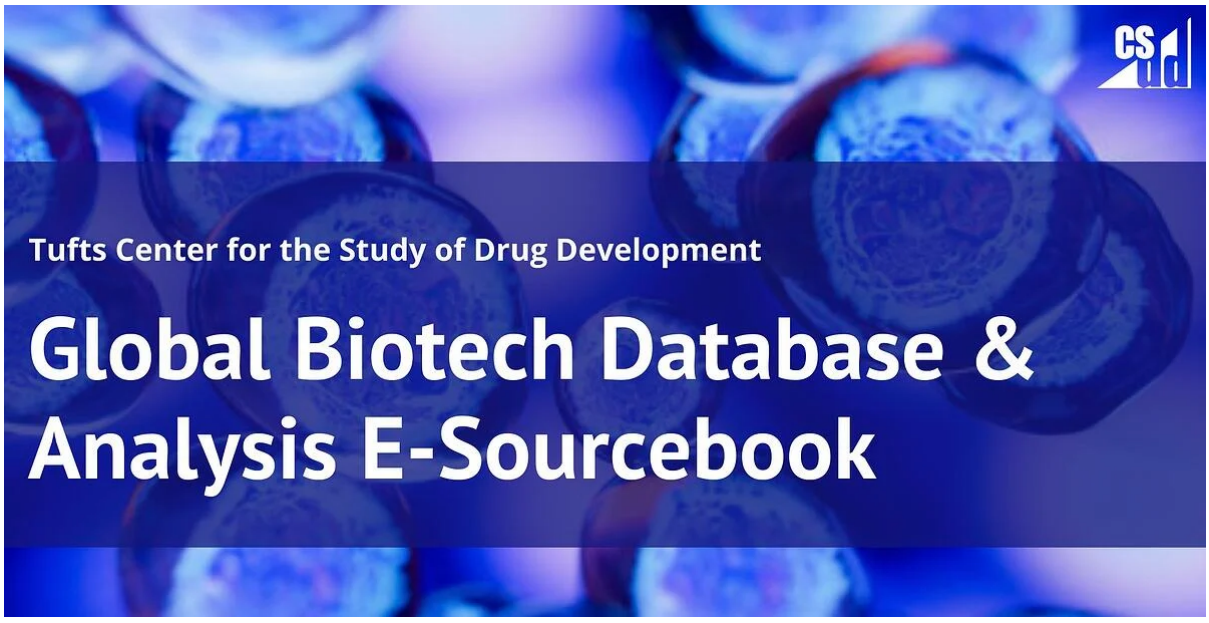
Tuft CSDD is kicking-off a new study

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.

Working Group Study Assessing Gender Based Inequities in the Drug Development Workforce

In early 2022, we are launching a new study looking at equity and inclusion dynamics that female scientists and female executives face in drug development. The study will examine the impact of inequities, disparities and barriers that women encounter on innovation and organizational performance. **Contact CSDD** to learn more about participating in this important, ground-breaking 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 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

Available January 5, 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

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**

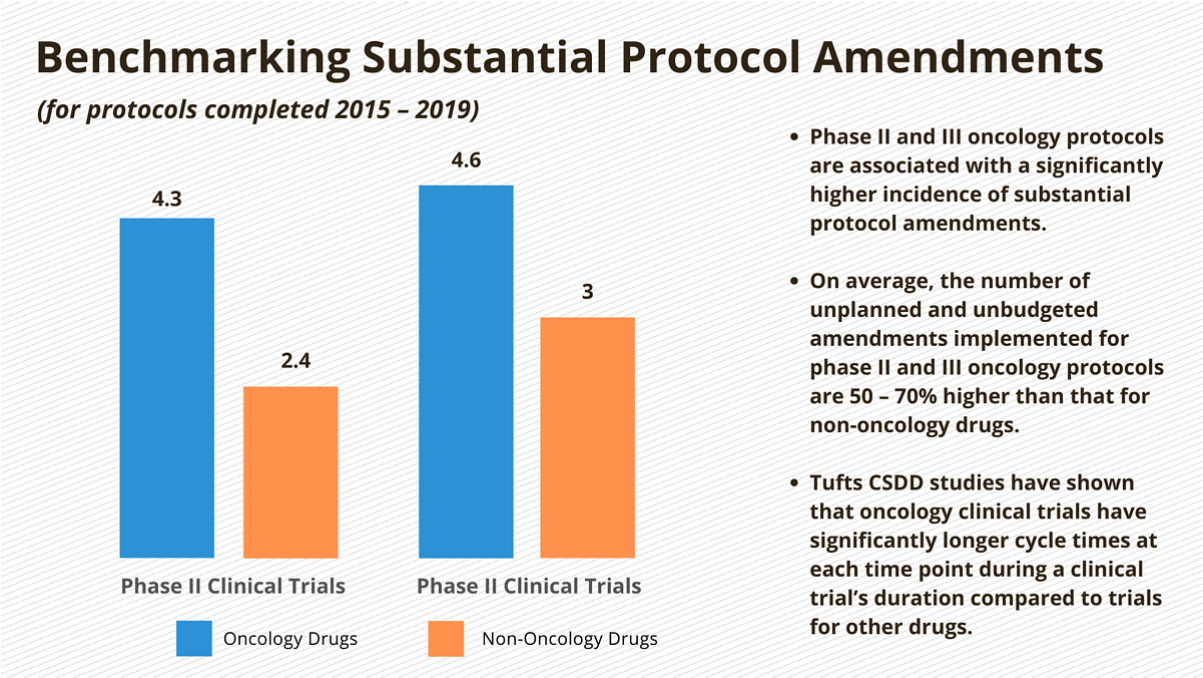
Michaels, D.L., Peña, Y., Kunz, B.L., Getz K. **Evaluating the Feasibility and Validity of a New Tool to Assess Organizational Preparedness and Capabilities to Support Patient Engagement in Drug Development.** TIRS (2021). **Access article**

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**

Data Insights Digest



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Faculty and Staff Presentations

Upcoming Presentations

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

New Models for Clinical Trial Execution
Ken Getz, MBA
Tempus Grand Rounds
Online| January 26

TEMPUS

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

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

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

VIRTUAL EVENT
Clinical Trials Europe

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

VIRTUAL EVENT
Clinical Trials Europe

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

Speid & Associates, Inc
SPEEDING NEW DRUGS TO MARKET
BROWN
Alpert Medical School

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

Subscriptions Papers and Books

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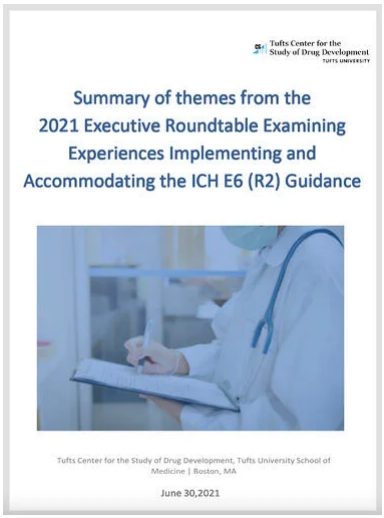

Download White Paper

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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