Tufts Center for the Study of Drug Development

TUFTS CSDD *INSIDER*

OCTOBER 2021

From the Director

Dear CSDD Friends:

Last month, the editors of the New England Journal of Medicine (NEJM) signaled the extent to which we can expect to see new requirements and incentives designed to raise transparency and ensure proportional representation of patients in clinical trials by gender, race and ethnicity.

Noting the difficulty that clinicians face in translating clinical research findings for the diverse group of patients under their care, beginning in January 2022, the NEJM editors will require all clinical research study authors to prepare a supplementary table containing detailed information on the representativeness of the study participants enrolled. As a requirement of accepting a manuscript for publication, the editors plan to assess the diversity of the study population enrolled in relation to disease prevalence and demographic disparities by country.

New tips, frameworks and guidelines to improve diversity, equity and inclusion (DEI) in drug development have been front and center during the past 18 months. Numerous white papers, articles and blog posts have focused on opportunities to address social determinants of health, improve clinical trial access and communication, and provide more effective and culturally-sensitive public and patient education and outreach.

Recent Tufts CSDD studies help inform new DEI strategies, practices and policies for sponsors, contract research organizations and investigative sites. One study, discussed in the *Insider* earlier this year, quantified the magnitude of gender, race and ethnic disparities in pivotal trials of approved drugs and biologics by disease condition. The Tufts CSDD team has just completed a study demonstrating a high, statistically significant relationship

between investigative site personnel diversity (race and ethnicity) and the diversity of patients enrolled in clinical trials. The results of this ground breaking study of nearly 3,200 global investigative sites offers valuable new insights into site selection and site management practices to improve proportional demographic representation of study volunteers. We are currently working on a manuscript for peer-review publication and will be featuring highlights from the study in our upcoming *Impact Report*.

Tufts CSDD will soon be launching a new study assessing DEI dynamics that women in drug development — scientists, senior and operating executives — face. We plan to examine the inequities, disparities and barriers that women encounter and their impact on drug development innovation and organizational performance. Please let us know if you'd like to learn more about supporting and participating in this study.

It has been a very busy and rewarding post-Labor Day period for Tufts CSDD with new study launches; an active pipeline of research activity; manuscript and article development; company meetings and conference presentations; and professional development programs. This *Insider* and the CSDD web site provide comprehensive updates as well as information on opportunities for you and your organization to participate and collaborate.

Kenneth Getz
Director and Professor

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

Congratulations

Tufts CSDD congratulates Dr. Ken Kaitin, professor and senior fellow, on receiving the 2021 SAPA Distinguished Achievement Award from the Sino-American Pharmaceutical Professionals Association.

Development and Advancement

Tufts CSDD has been actively welcoming its FY 2021 - 2022 Circle of Supporter members. Financial support from our community of sponsors is crucial to our mission and enables us to cover our operating costs, conduct longitudinal studies, inform our research priorities, prepare manuscripts, attend meetings and presentations,

train summer interns and mentor international university students. Twenty organizations have joined our Circle of Supporters and we encourage additional members. **Contact Michela Davola**, Associate Director, Development and Fundraising for more information.

Working Group Studies

Working Group Quantifying the Value Proposition of Organization-Specific Patient Engagement Initiatives

Tufts CSDD — in collaboration with the Drug Information Association (DIA) — is kicking-off a new working group quantifying the value proposition of organization-specific patient engagement initiatives. Participating companies will meet to define relevant outcome measures; shape a global survey instrument and secondary data gathering activity; review and discuss study results and their implications. **Contact us if you would like to participate.**

Professional Development Courses

Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation (Live in-person event)

Tufts CSDD's five-day Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation will resume in 2022 as a live in-person event. This highly acclaimed program provides 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**.

Robert Franco, PhD
Course Facilitator President, Coe Point Associates LLC

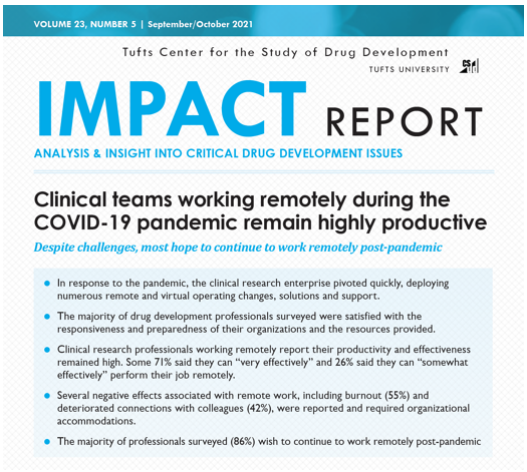
Kenneth Kaitin, PhD
Professor of Medicine and Senior Fellow, Tufts CSDD

Fall Leadership for Drug Development Teams (Online)

This is a highly interactive online case-based course bringing 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 in large and small groups over the course of four weeks. Tufts CSDD holds the Leadership for Drug Development Teams course several times each year. Custom programs are also available for professionals within a single organization. For more information, **contact Sundé Daniels**.

Research Higlights

Our Latest Impact Report



Clinical teams working remotely during the COVID-19 pandemic remain highly productive

Our September/October 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

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**

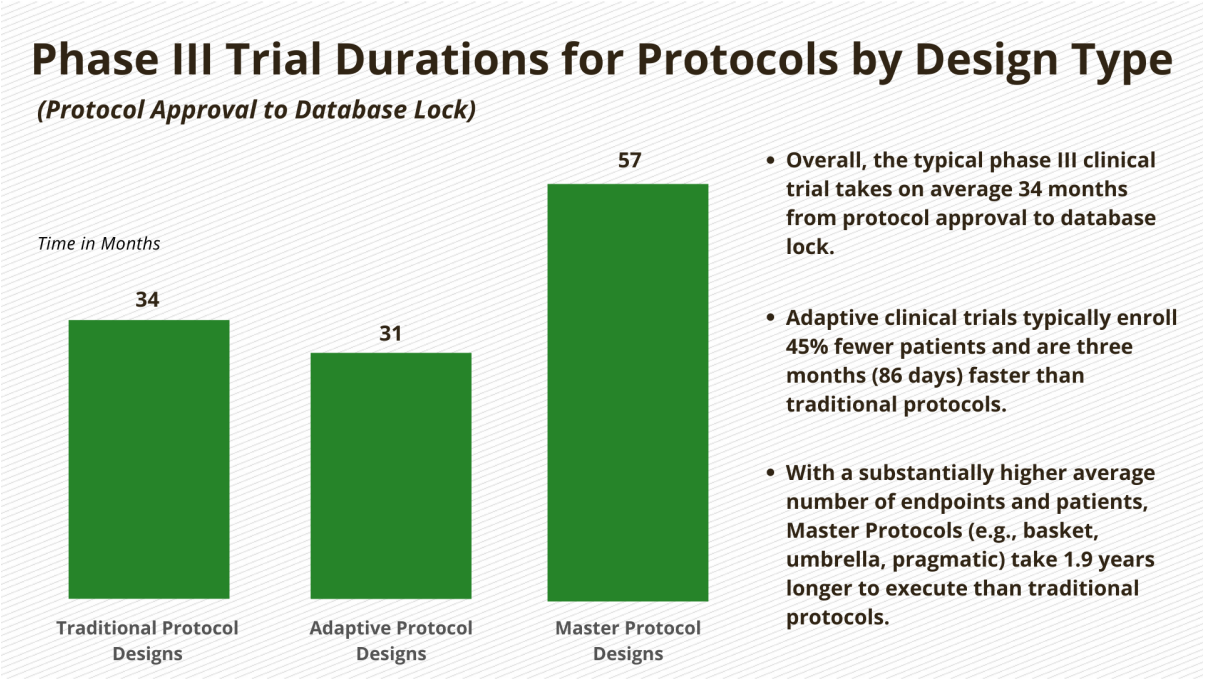
DiMasi, JA, Wilkinson M. **The financial benefits of faster development times: integrated formulation development, real-time manufacturing, and clinical testing.** TIRS 2020;54(6):1453-1460. **Access article**

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

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

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

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

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

Digital Transformation and Clinical Research Team Effectiveness
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

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

CTO Clinical Operations in Oncology Trials
VIRTUAL EXPERIENCE

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

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

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

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

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

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

Managing Complexity and Customization in Clinical Trials
Ken Getz, MBA

Jackson Laboratories, OneJax Seminar Series
Online | August 30

Trends in Diversity and Inclusion in Clinical Research
Ken Getz, MBA
Veeva Systems Webinar
Online | August 24

Subscriptions Papers and Books

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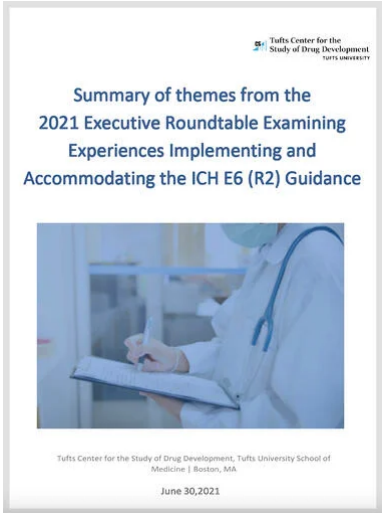

Download White Paper

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About Tufts CSDD

Support Tufts CSDD

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