Tufts Center for the Study of Drug Development

TUFTS CSDD *INSIDER*

SEPTEMBER 2021

From the Director

Dear CSDD Friends:

Late last month the FDA gave full approval for use of the Pfizer-BioNTech COVID-19 vaccine. The decision marks a critical step in encouraging organizations to mandate vaccinations. Within hours after the approval, employers in both the public and private sectors began announcing vaccination requirements for their employees.

Health and research professionals are also hoping that the FDA's approval of Comirnaty (the vaccine's branded name) will meet a necessary condition to finally convince reluctant individuals to be vaccinated. But it is unclear whether there will be a measurable impact. Public and patient hesitancy remains an intractable issue in both clinical care and clinical research and demands new insights and ideas.

Sponsor and CRO companies, organizations and associations are devoting considerable resources and attention at this time to understand the fundamental factors effecting diverse community willingness to participate in, enroll and complete their clinical trials. Several Tufts CSDD studies underway inform these efforts including one looking at the diversity of global investigative site personnel and its relationship with study volunteer diversity and another assessing demographic subgroup differences in managing the burden of diseases and its impact on clinical trial participation burden.

Tufts CSDD is launching a new working group study, in collaboration with the Drug Information Association (DIA) — to evaluate how patient engagement is evolving and to quantify its value proposition. The study will link organization-specific engagement initiatives to clinical trial and program-level performance and quality outcomes. We also have a full line-up of upcoming professional development courses. This issue of the

Insider and our website (csdd.tufts.edu) provide information on all of our activities and we encourage your collaboration and participation.

Lastly, in August we welcomed a new faculty member. Dr. Jennifer Kim has an extensive background in organizational behavior and her research focuses on identifying systemic barriers faced by marginalized and underrepresented groups and drawing insights on ways that organizations can improve engagement and productivity. Years ago I had the privilege of working with Jenny when she was an analyst at Tufts CSDD prior to her graduate studies. Please join me in welcoming Dr. Kim to the Tufts CSDD team!

Kenneth Getz
Director and Professor

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Working Group Studies

New 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.**

Working Group Study Assessing Impact of DCTs on Sponsor-CRO Collaborations

Tufts CSDD has kicked off a new study characterizing and benchmarking the impact of decentralized clinical trial
(DCT) models on sponsor-CRO relationship structure, economics and the collaboration process. Fifteen sponsor and CRO companies have already joined this working group study. **Contact us if you would like to participate.**

Professional Development Courses

Accelerating Product Development: Advanced Project Planning Strategies (Online)

Project development efforts constantly struggle to meet ever increasing time to market, quality and cost objectives. Many projects must also solve new and unexpected problems throughout their development. Tufts Center for Study of Drug Development's Accelerating product development: Advanced Project Planning Strategies is an interactive course that will teach participants how to apply advanced planning strategies to optimize their development plans and meet unique challenges. For more information, **contact Sundé Daniels**.

Robert Franco, PhD

Course Facilitator President, Coe Point Associates LLC

Kenneth Kaitin, PhD

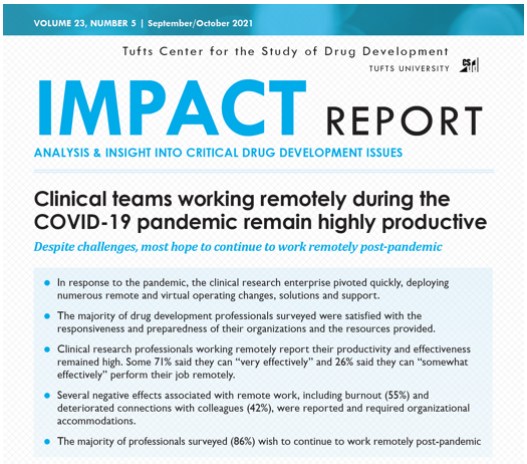
Professor of Medicine and Senior Fellow, Tufts CSDD

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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Tufts Center for the Study of Drug Development
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IMPACT REPORT

ANALYSIS & INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

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

Despite challenges, most hope to continue to work remotely post-pandemic

- In response to the pandemic, the clinical research enterprise pivoted quickly, deploying numerous remote and virtual operating changes, solutions and support.
- The majority of drug development professionals surveyed were satisfied with the responsiveness and preparedness of their organizations and the resources provided.
- Clinical research professionals working remotely report their productivity and effectiveness remained high. Some 71% said they can "very effectively" and 26% said they can "somewhat effectively" perform their job remotely.
- Several negative effects associated with remote work, including burnout (55%) and deteriorated connections with colleagues (42%), were reported and required organizational accommodations.
- The majority of professionals surveyed (86%) wish to continue to work remotely post-pandemic

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**

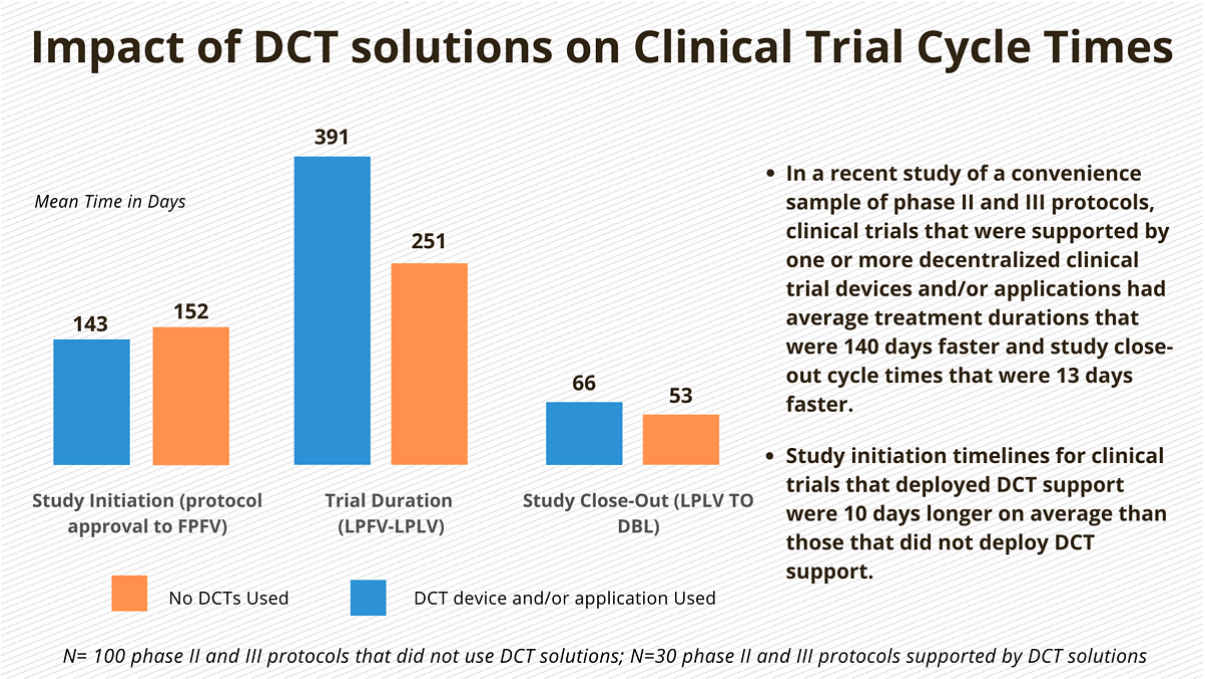
DiMasi, JA, Wilkinson M. **The financial benefits of faster development times: integrated formulation development, real-time manufacturing, and clinical testing.** TIRS 2020;54(6):1453-1460. **Access article**

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

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

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

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

24TH NORTH AMERICAN ISSX MEETING

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

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

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

BROWN
Alpert Medical School

Recent Presentations

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

Managing Complexity and Customization in Clinical Trials
Ken Getz, MBA
Jackson Laboratories, OneJax Seminar Series
Online | August 30

The Jackson Laboratory

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

Veeva

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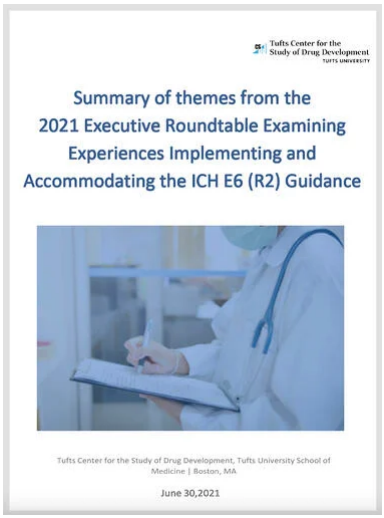

Download White Paper

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

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