



From the Director



Dear CSDD Friends:

As many of you know, there is now considerable speculation about how the drug development enterprise will apply and embrace experiences and lessons learned during the pandemic. The results of recently completed CSDD studies help characterize major issues and challenges that will likely contribute to some retrenchment and more conservative adoption of decentralized clinical trial solutions.

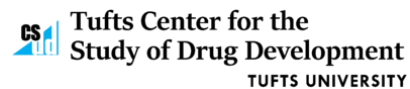
One such study entailed in-depth interviews conducted among 26 investigative sites between March and May 2021. Site personnel based globally indicated that remote and virtual clinical trial activity during the pandemic has increased their cycle times and inefficiencies. Investigators and study coordinators reported that operating virtually has increased time dedicated to learning new technology solutions; providing support to remote monitors and health professionals; training vendors unfamiliar with the clinical research process; and coordinating and integrating disparate and fragmented executional activities. Sites noted significant delays that they have encountered starting up studies, receiving clinical trial supplies and lab kits. Many conveyed concerns about the high level of uncertainty that may contribute to increased operating errors and mistakes. During the summer, the Tufts CSDD team will be publishing the results of this and other studies offering deeper insights into the full impact of pandemic response.

Later this month, we will be kicking-off a new working group study looking at how decentralized clinical trial models are impacting sponsor-CRO relationship structures, economics and the collaborative process. And toward the end of the summer we will be kicking off a study looking at the volume of protocol data collected and assessing the relevance of that data to protocol objectives and endpoints. As part of that assessment, the FDA has agreed to provide input that will be shared with participating companies.

More information about these upcoming studies is provided below. This Insider also contains updates on upcoming professional development course offerings, publications and presentations. As always, we welcome your ideas, feedback and collaboration.



Kenneth Getz
Director and Professor



Development and Advancement

Tufts CSDD has launched its new FY 2021-2022 development and fundraising drive. Your support is crucial to our mission. It enables us to prepare manuscripts and presentations; supports our ability to conduct longitudinal studies, to train summer interns and mentor an international community of university



students; and helps us cover our operating expenses. For more information and to join our Circle of Supporters, please contact **Michela Davola**, Associate Director, Development and Fundraising.

Working Group Studies



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

This month we are kicking 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 for more information.**

Professional Development Courses

2021 Fall Leadership for Drug Development Professionals

Online | October 6, 13, 20, 27 | 12 - 4pm ET



Robert Franco, PhD

Course Facilitator President,
Coe Point Associates LLC



Kenneth Kaitin, PhD

Professor of Medicine and Senior
Fellow, Tufts CSDD

October 6, 13, 20 & 27, 2021

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 Highlights

Our Latest Impact Report



Biotech R&D spending grew by more than 3x the rate of total industry spend in 2001-20

Our July/August 2021 Tufts CSDD Impact Report presents new research and analysis on the remarkable activity and growth of the global biotechnology industry.

[Learn more](#) | [Purchase online](#)

Recent Publications

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](#)

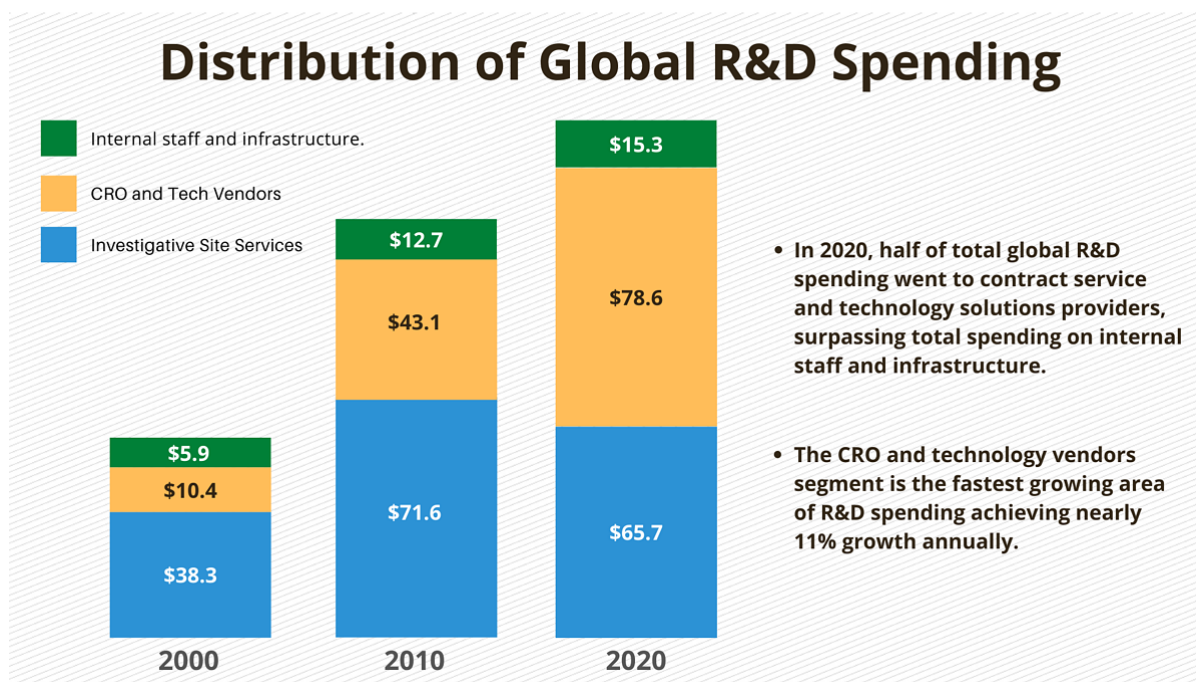
Getz K. **Public Trust and the 'Last Mile' for COVID-19 Vaccines.** Applied Clinical Trials 2020; 29 (12): 11 – 12. [Access article](#)

Gottlieb, N, Byrne, J, Getz, K. **Investigative Site Placement Practices to Support Operation Warp Speed.** Applied Clinical Trials 2020; 29 (12): 26-28. [Access article](#)

Raj Indupuri, Sheila Rocchio, Kenneth A. Getz, Beth Harper, Michael Wilkinson. **Enabling Digital Transformation: Managing External Clinical Data Sources to Advance Drug Development.** Applied Clinical Trials 2020; November 13. [Access article](#)

Stephen LeBreton, Mary Jo Lamberti, Adam Dion, Kenneth A. Getz. **COVID-19 and Its Impact on the Future of Clinical Trial Execution.** Applied Clinical Trials 2020; October 22. [Access article](#)

Data Insights Digest



Subscribe today to get your copy of the [Tufts CSDD Impact Report](#).

Faculty and Staff Presentations

Characterizing the Future of Clinical Trials

Ken Getz, MBA

Portland Clinical Research Professionals

Northwest Association for Biomedical Research

Online | May 5



Powered by the Pandemic: How Pharma has Succeeded and How it Will Continue to Embrace Operational Changes Facilitated by COVID-19

Ken Getz, MBA

RBQM Live

Online | May 20



The Evolving State of Clinical Trial Execution: Pilots or Permanent Change?

Ken Getz, MBA

ACRP Annual Meeting

Online | May 20



Drug Development Pain Points and Challenges

Ken Getz, MBA

BIO NJ Clinical Development Briefing

Online | May 27



Global Trends in R&D

Ken Getz, MBA

IQVIA Institute

Online | June 11



Common Pitfalls that Cause Clinical Trial Delays and How to Avoid Them

Ken Getz, MBA

CenterWatch webinar

Online | June 17



Impact of COVID-19 on Clinical Trial Execution

Mary Jo Lamberti, PhD

DIA Annual Meeting

Online | June 27 - July 1



Remote Clinical Team Effectiveness and Experience During the Pandemic

Maria Florez, MA

Association of Medical Research Charities

Online | July 21



Remote Clinical Team Effectiveness and Experience During the Pandemic

Maria Florez, MA

Academy of Physicians in Clinical Research

Online | August 4



Trends in Diversity and Inclusion in Clinical Research

Ken Getz, MBA

Veeva Systems Webinar

Online | August 24



Managing Complexity and Customization in Clinical Trials

Ken Getz, MBA

Jackson Laboratories, OneJax Seminar Series

Online | August 30



The Economics of the Pharmaceutical Industry

Joseph DiMasi, PhD

24th North American ISSX Annual Meeting

Online | September 13-17



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



BROWN
Alpert Medical School

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About Tufts CSDD

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Tufts CSDD, 75 Kneeland Street, Suite 1100, Boston, Massachusetts 02111, United States, (617) 636-2170

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