

## From the Director



Dear CSDD Friends:

Operational ‘agility’ has been one of the most discussed topics coming out of the pandemic. How can organizations build new infrastructure, change corporate cultures, adjust standard practices, and train personnel to be more nimble, flexible and adaptive to accommodate a wider range of

patient-centered operating models? A number of CSDD studies offer insights and areas to target including new research assessing the impact of decentralized clinical trials on development performance, and research looking at modified management practices associated with contract clinical services and technology solutions.

Our studies not only point to targeted improvement opportunities but also suggest that organizational agility is a mindset and skillset that can be taught and acquired over time. Beyond the infrastructure needed, senior leaders play a key role in setting, investing in and communicating — clearly and consistently — their vision for being an agile organization. And functional areas reinforce agile behaviors, identify and address barriers and inefficiencies, and routinely measure progress and improvements.

In July we kicked-off a new working group study looking at how remote and virtual clinical trials are impacting sponsor-CRO relationship structure, process and economics. In August we will be kicking-off a study in collaboration with the FDA looking at the rationale and relevance of clinical research data collected to support protocol endpoints and objectives.

We have been very busy preparing for our upcoming September professional development Grab ‘n Go program: Accelerating Product Development. This February, we will also be offering our internationally recognized five-day Postgraduate Course in Clinical

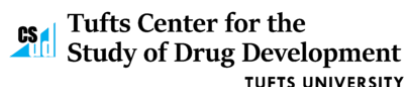
Pharmacology, Drug Development and Regulation. Please check our web site to learn about and to register for our upcoming programs.

As always, thank you for your support, collaboration, feedback and ideas.



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

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 for more information.**

## Professional Development Courses

**Grab 'n Go**

**Accelerating Product Development:  
Advanced Project Planning Strategies**

Online | September 15 | 12 - 3pm ET

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

### 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.**

# 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

## 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](#)

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### Recent Publications

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](#)

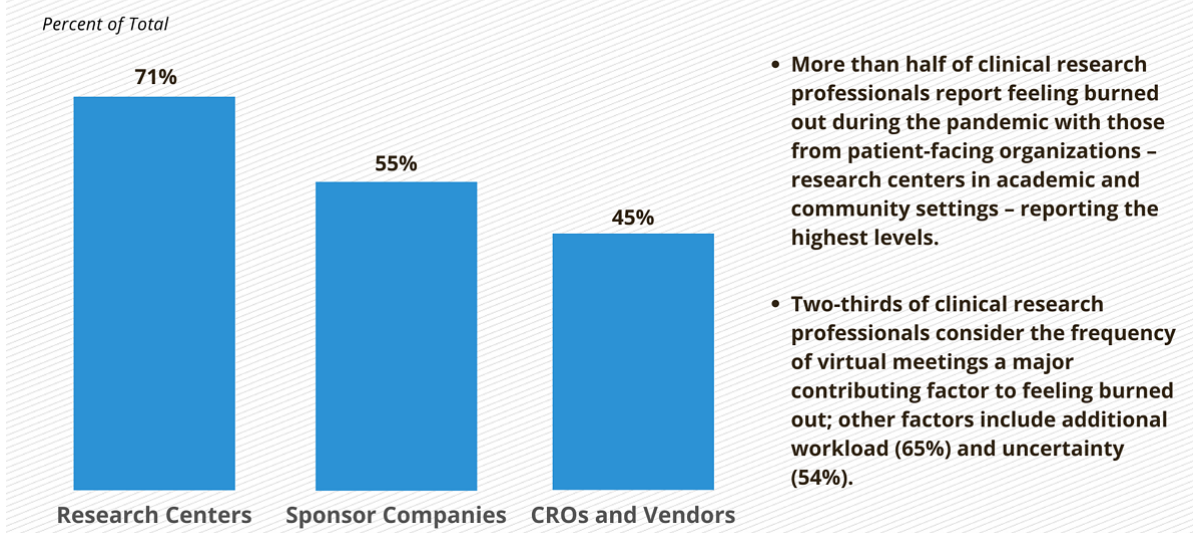
Florez M, and Getz K. **Anticipating digital transformation of the drug development workforce.** Pharmaceutical Executive, March 26. [Access article](#)

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

Milne C-P and Kaitin KI (2019) **Are Regulation and Innovation Priorities Serving Public Health Needs?** Front. Pharmacol. 10:144. [Access article](#)

### Data Insights Digest

## High Levels of Burn-Out Reported by Clinical Research Personnel During Pandemic



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

## Faculty and Staff Presentations

### Upcoming Presentations

#### 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



#### 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



Academy of Physicians  
in Clinical Research

## **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



## **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**

## **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

### Impact of COVID-19 on Clinical Trial Execution

**Mary Jo Lamberti, PhD**

DIA Annual Meeting

Online | June 27 - July 1



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

**Ken Getz, MBA**

CenterWatch webinar

Online | June 17



### Global Trends in R&D

**Ken Getz, MBA**

IQVIA Institute

Online | June 11

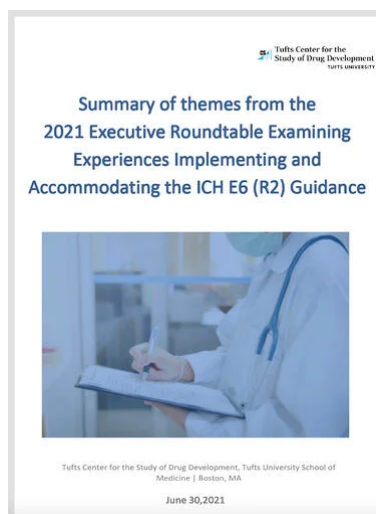


## Subscriptions Papers and Books





## Purchase Impact Reports



## 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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