



Tufts Center for the Study of Drug Development

TUFTS CSDD INSIDER

JUNE 2021

From the Director



Dear CSDD Friends:

I'm writing this letter as the Tufts Center celebrates its 45th anniversary. Dr. Margaret Mead gave the keynote address at the Center's inaugural event in May 1976. One of her best known quotes has long inspired me and it is particularly poignant given how successfully the drug development enterprise has responded to the pandemic:

'Never doubt that a small group of people can change the world. Indeed that is the one thing that ever has.'

We continue to gather new insights into ways that response to the pandemic has impacted drug development operations and performance. A study that we recently completed in collaboration with the Bill & Melinda Gates Medical Research Institute finds that the global community of clinical research professionals gives their employers high marks for their preparedness and responsiveness in supporting the shift to remote operating models. The majority of clinical research professionals report that they have been effective and at least as productive as they were before the pandemic. Nearly 90% want to continue to work remotely.

But more than half report feeling burned out in large part due to the frequency of virtual meetings and an increased workload. And 40% believe that their connections with colleagues have deteriorated. The full results of this important new study and their implications — overall and by meaningful subgroups (e.g., organization type; geographic area; and demographics) — will be available shortly in publications and presentations.

It has been a busy spring with numerous CSDD projects underway including an ambitious global study looking at the diversity of the global investigative site landscape; a study modeling the expected net present value of decentralized clinical trial activity; and another mapping and benchmarking how innovations supporting clinical research planning and execution are adopted.

In June, we will be kicking-off a new working group looking at how virtual and remote clinical trial and data management models are impacting sponsor-CRO relationships. Please let us know if you would like to participate in the study. Also this month, we will be holding our Summer Leadership in Drug Development program. Based in part on case studies, the program is highly interactive and brings together team leaders, program and functional directors and managers to build leadership skills, improve cross-functional performance and enhance R&D productivity. Refer to the information below, and on the CSDD web site, to register for this program.

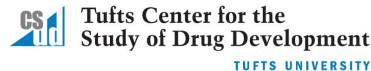
Lastly, we're delighted to be welcoming Michela Davola, Associate Director of Development and Fundraising to the Tufts CSDD team. Michela will be helping to re-energize our fundraising

and sponsorship activity. In the coming months we'll be sending out more information.

As always, we're grateful for your input, encouragement, support and participation in Tufts CSDD research and activities.



Kenneth Getz
Director and Professor



Working Group Studies

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

In June 2021, we will be kicking off a new study characterizing and benchmarking the impact of decentralized clinical trial (DCT) and data management models on sponsor-CRO relationship structure and the collaboration process. Sponsor companies and CROs will participate in systematically assessing how collaborations have changed in response to the pandemic and will continue to evolve long-term. [Contact us for more information.](#)

Working Group Study Launched to Characterize and Improve the Innovation Adoption Process

Tufts CSDD has initiated a new working group study looking at how sponsor companies adopt innovations supporting drug development planning, design, execution, data management and logistics. The study will characterize best practices including those associated with pandemic response; apply lessons learned from other heavily regulated industries; and identify opportunities to accelerate innovation adoption. [Contact us for more information.](#)

Development and Advancement

Tufts CSDD is excited to launch a new annual fund campaign to grow and expand our community of supporters. Tufts CSDD relies on grant funding to support its research studies, and relies on its annual circle of supporters to enable us to share our study findings and their implications in peer-review and trade journals, conferences and meetings. Our annual fund campaign allows us to conduct longitudinal studies, train summer interns, and mentor university students around the world. For more information about our annual fund campaign or to join our circle of supporters, please contact our Associate Director, Development and Fundraising, [Michela Davola](#).

Professional Development Courses

2021 Summer Leadership for Drug Development Professionals

Online | June 9, 16, 23, 30 | 12 - 4pm ET



Robert Franco, PhD

Course Facilitator President,
Coe Point Associates LLC



Kenneth Kaitin, PhD

Professor of Medicine and Senior
Fellow, Tufts CSDD

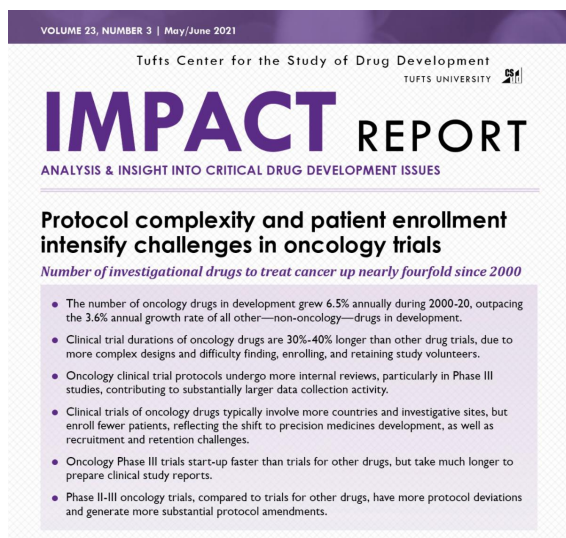
June 9, 16, 23 & 30, 2021

Summer Leadership for Drug Development Teams (Online)

It is not too late to register for this internationally recognized program. An in-depth course, it is designed to build leadership skills, improve cross-functional performance and enhance R&D productivity. Delegates meet online in large and small groups over the course of four weeks beginning in early June. For more information, [contact Sundé Daniels](#).

Research Highlights

Our Latest Impact Report



Protocol Complexity and Patient Enrollment Intensify Challenges in Oncology Trials

Our May/June 2021 Tufts CSDD Impact Report presents new research examining and benchmarking the unique executional challenges associated with cancer clinical trials.

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

Coming in July:

**New Trends Characterizing the Global Biotechnology
Landscape**



Recent Publications

Getz K. **Contemplating the Full Measure of Pandemic Response.** Applied Clinical Trials, 2021. June 7. [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](#)

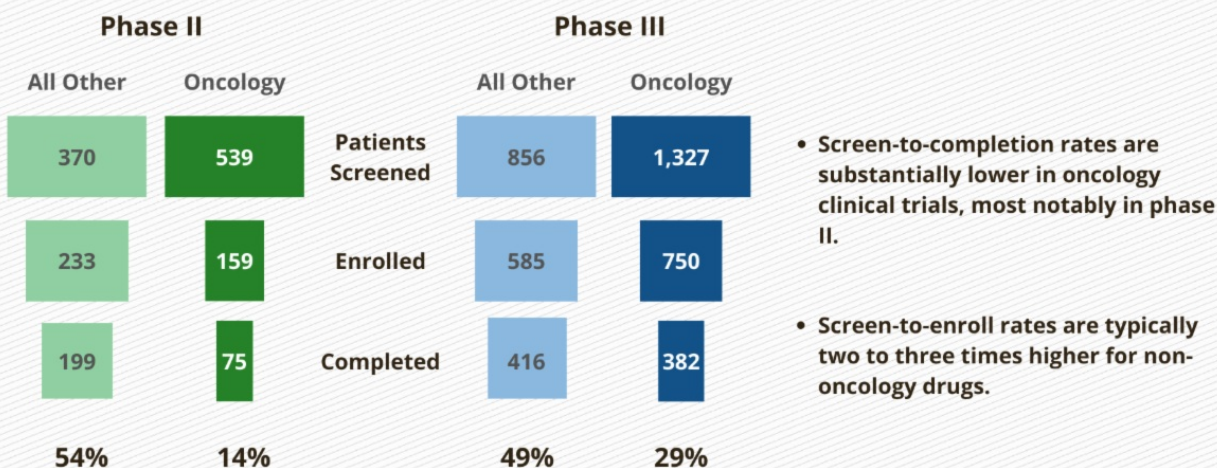
Stephen LeBreton, Mary Jo Lamberti, Adam Dion, Kenneth A. Getz. **COVID-19 and Its Impact on the Future of Clinical Trial Execution.** Applied Clinical Trials 2020; October 22. [Access article](#)

Galson S, Austin C, Khandekar E, Hudson L, DiMasi J, Califf R, Wagner J. **The Failure to Fail Smartly.** Nature Reviews Drug Discovery 2020; September 23. Published online: [Access article](#)

Harper B, Wilkinson M, Indupuri R, Rocchio S, Getz, K. **Evolving Clinical Data Strategies and Tactics in Response to Digital Transformation.** Ther Innov Regul Sci 2020; September 14. [Access article](#)

DiMasi, J.A. **Research and Development Costs of New Drugs [Letter to the Editor].** JAMA 2020; 324(5):517. [Access article](#)

Protocol Enrollment Benchmarks (2014-2019)



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

Faculty and Staff Presentations

Recent Presentations

New Strategies to Balance Protocol Complexity, Customization and Executional Feasibility

Ken Getz, MBA

Reuters Pharma: Clinical 2021

Online | April 7



Taking Patient Centricity to the Next Level

Ken Getz, MBA

Patients as Partners

Online | April 9



Rapid Innovation in Clinical Research

Ken Getz, MBA

Avoca Quality Consortium

Online | April 20



Trends in the Development & Approval of New Anti-infectives: Cycle Times, Success Rates & Expedited Regulatory Pathways

Joseph A. DiMasi, PhD

Anti-Infectives Drug Development

Online | April 21



Examining Strategic Implications of Pandemic Response on the Global Investigative Site Landscape

Ken Getz, MBA



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



Upcoming Presentations

Measuring eClinical Data Challenges and Performance

Zachary Smith, MA

Arena International
Online | June 2



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



Enhancing Patient Participation Burden Assessment

Ken Getz, MBA

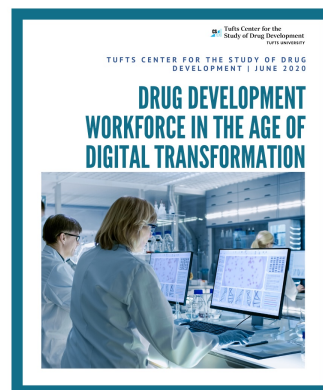
ZS Impact Webinar
Online | June 23



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](#)

[Support Tufts CSDD](#)

Tufts Center for the Study of Drug Development
75 Kneeland Street, Suite 1110
Boston, MA 02111
617-636-2170



[Unsubscribe {recipient's email}](#)