



From the Executive Director



Dear CSDD Friends:

This *Insider* coincides with the 20th anniversary of *TIME Magazine*'s issue dedicated to exposing the sinister and dangerous world of clinical research. Many of us can recall its shocking cover image with a woman in a hospital gown, cold, alone and vulnerable in an animal crate. The magazine heading — **'How Medical Testing has Turned Millions of Us into Human Guinea Pigs'** —

and its feature stories—"At Your Own Risk"; "Poisoning for Dollars"; "They're Dying to Get In" — were clearly sensationalistic. But they also conveyed truth that surprised and stung stakeholders throughout the clinical research enterprise. Ultimately, that *TIME* magazine issue served as a rallying cry and an inflection point for many individuals and organizations who recognized that we can and must do better to partner and engage with patients and the public.

For the past two decades we have seen clinical research professionals in both public and private sectors develop and implement a wide variety of initiatives and solutions designed to amplify patient voices and needs; educate the public; improve transparency and disclosure; enrich the clinical trial participation experience; and promote collaboration between patients, clinical care, and clinical research communities.

Reflecting on recently completed and active projects in Tufts CSDD's portfolio, I'm struck by the large number that inform industry-wide patient engagement efforts. A partial list: Our widely referenced study quantifying the financial return on patient engagement investments; a study underway tying specific patient engagement practices to drug development performance outcomes; a new study predicting patient participation burden based on draft protocol designs; studies on the distribution of patients by race and ethnicity in pivotal trials supporting FDA and EU commission approvals; and a study looking at the relationship between demographic representation of investigative site personnel and the diversity of patients enrolled.

As we move through the spring months, the Tufts CSDD team is very active with ongoing and newly launched studies, preparing and submitting manuscripts, and presenting at conferences and company meetings. This *Insider* and the [CSDD website](#) are good places

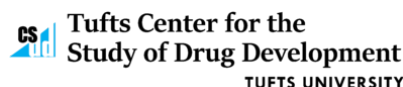
to learn about our many activities. And twice a year, companies in our Circle of Supporter community meet to discuss CSDD's ongoing and future research priorities. Please let me know if you would like to learn more about joining and participating in this community forum.

As always, we welcome your collaboration and look forward to receiving your inquiries, observations and insights.



Kenneth Getz

Executive Director and Professor



Working Group Studies



Working Group Study Assessing Drug Development Workforce Diversity and its Relationship with Innovation Effectiveness and Team Dynamics

On June 7, Tufts CSDD will be launching a new working group study examining diversity, equity and inclusion dynamics and their impact on clinical team effectiveness. This study builds on the results of a just-completed project funded by PhRMA. Participating companies will be involved in all aspects of the research. **Contact CSDD** to learn more about this timely and ground-breaking study.

New survey examining how sponsors and CROs are supporting patient engagement practices

Tufts CSDD is conducting an important new survey to examine patient engagement practices in sponsor and CRO organizations and operations. The brief survey should take only 20 - 25 minutes to complete. The results of this study will characterize how

companies are structured to support patient engagement and where they are directing their resources and investment. All responses are confidential and will only be reported in the aggregate. For more information, contact [Dr. Jennifer Kim](#), Assistant Professor, Tufts CSDD.

[Click here to fill out the survey](#)

Professional Development Courses

<p>Summer Leadership for Drug Development Professionals</p> <p>Online June 8, 15, 22, 29 12 - 4pm ET</p>	<p>Fall Leadership for Drug Development Teams</p> <p>Online Sept 21, 28 Oct 5, 12 12 - 4pm ET</p>
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Robert Franco, PhD
Course Facilitator; President,
Coe Point Associates LLC



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

Become a more strategic leader and unleash your drug development team's potential!

This highly interactive online course, offered twice each year, brings 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 online in large and small groups over the course of four weeks. Created specifically for pharmaceutical professionals, the program uses case studies to teach you how to lead multi-disciplinary teams and to collaborate effectively in managing complex challenges in pharmaceutical R&D. New program material has been incorporated to focus on how remote teams can operate effectively and productively. We will examine solutions and strategies for getting the most out of remote teams including creating and maintaining high levels of engagement, improving communications, sustaining motivation, establishing and measuring performance, and conducting more productive team meetings in a distributed environment. For more information, contact [Sundé Daniels](#).

NEW Global Biotech E-Sourcebook

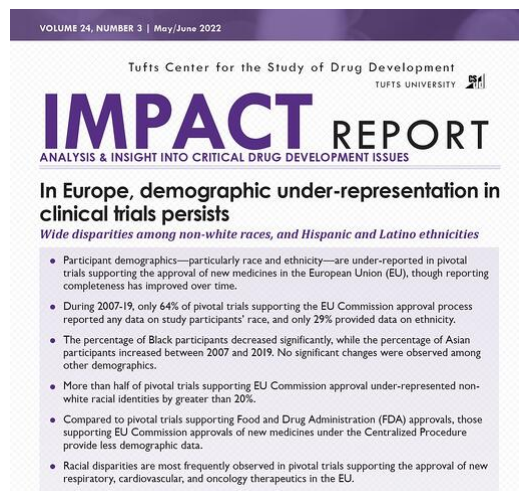


The New Tufts CSDD Global Biotech Database & E-Sourcebook!

Introducing the NEW Global Biotech E-Sourcebook — a fully searchable, comprehensive database on the biotechnology industry capturing its rapid growth and change during the period 2001-2020. The E-Sourcebook captures more than 440 products and 325 biotech and pharmaceutical companies and provides detailed financial, economic and trend data. Ideal for strategic and R&D planning, financial and economic analyses, market intelligence, M&A and investment analysis, regulatory and pipeline tracking. **For more information and to order your copy.**

Research Highlights

Our latest Impact Report:



In Europe, demographic under-representation in clinical trials persists

The May/June 2022 issue of the Tufts CSDD Impact Report (Vol 24; No 3) is now available. The results of this new Tufts CSDD study show high levels of under-reporting and under-representation of non-white racial identities and Hispanic/Latino ethnicities in pivotal trials supporting the approval of new medicines in the EU.

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

Recent Publications

Getz K, Smith Z, Jain A, Krauss R. **Benchmarking Protocol Deviations and their Variation by Major Disease Category.** *TIRS 2022.* [Access article](#)

Burt T, Roffel AD, Langer O, Anderson K, DiMasi JA. **Strategic, feasibility, economic, and cultural aspects of Phase 0 approaches.** *Clinical and Translational Science 2022.* [Access article](#)

Kim, J. Y. & Getz, K. (2022). **Measuring patient satisfaction as a primary outcome for patient-centric initiatives.** *Applied Clinical Trials.* [Access article](#)

Kim, J. Y., Brockner, J., & Block, C. J. (2022). **Tailoring the intervention to the self: Congruence between self-affirmation and self- construal eliminates the MBA gender performance gap.** *Organizational Behavior and Human Decision Processes*, 169 (March). [Access article](#)

Smith Z, Bilke R, Pretorius S, Getz K. **Protocol Design Variables Highly Correlated with, and Predictive of, Clinical Trial Performance.** *Ther Innov Regul Sci.* 2022 Jan 30. doi: 10.1007/s43441-021-00370-0. Epub ahead of print. PMID: 35094369. [Access article](#)

Kim, J. Y., & Roberson, L. **I'm biased and so are you. What should organizations do? A review of organizational implicit-bias training programs.** *Consulting Psychology Journal: Practice and Research* (2021). [Access article](#)

Getz K. **Tracking Change in the Global Investigative Site Landscape: New benchmarks uncover a maturing and globally-shifting market.** *Applied Clinical Trials.* December 2021. [Access article](#)

Kim, J. Y., Block, C. J., & Yu, H. **Debunking the 'model minority' myth: How positive attitudes towards Asian Americans influence perceptions of racial microaggressions.** *Journal of Vocational Behavior*, 131(December 2021) [Access article](#)

Shang, Z., Kim, J. Y., & Cheng, S. O. **Discrimination experienced by Asian Canadian and Asian American healthcare workers during the COVID-19 pandemic: A qualitative study.** *Canadian Medical Association Journal Open* (November 2021) [Access article](#)

Botto E, Lamberti M.J., Shah M, Getz K. **Assessing Sponsor and CRO Awareness of Receptivity and Response to the Evolving Nature of Clinical Trial Patient Oversight.** *Applied Clinical Trials.* November 2021. [Access article](#)

Getz K. **Amplifying Patient Voices in Protocol Design.** *Applied Clinical Trials.* Sept 2021; 30:9 [Access article](#)

Data Insights Digest

Proportion of US investigators conducting one clinical trial per year by site type

	Academic/ Affiliated Sites	Community- based part-time investigators	Dedicated sites and For-Profit Site Networks
2016	63%	57%	37%
2018	55%	57%	36%
2020	55%	48%	34%

Source: Tufts CSDD; based on FDA 1572 filings

- Across all site segments, the proportion of investigators conducting only one industry-funded clinical trial per year has declined since 2016
- As expected, the dedicated sites/site networks segment has matured and scaled with only one-third of investigators conducting a single clinical trial in 2020
- The proportion of investigators conducting a single trial per year within academic and affiliated site settings has declined the most between 2016 and 2020

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

Faculty and Staff Presentations

Upcoming Presentations

Protocol Simplification and Optimization

Ken Getz, MBA
French AMMIS
Online | May 24

Characterizing the Innovation Adoption Process for Technologies Supporting Virtual Clinical Trials

Maria Florez, MA
Virtual Clinical Trials Summit
Philadelphia | May 18 - 19



DIAMOND Panel Discussion: Patient Centered Healthcare in the Future

Ken Getz, MBA
DIA Annual Meeting
Chicago, IL | June 20



Where Are We? Assessing Organizational Preparedness and Capabilities to Support Patient Engagement

Ken Getz, MBA
DIA Global 2022
Chicago, IL | June 21



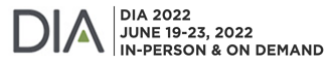
Ensuring Diversity in Clinical Trials

Maria Florez, MA
DIA Global 2022
Chicago, IL | June 23



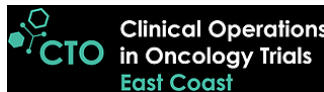
Optimizing the Pharma Workforce for Trial Success in the Digital Era

Maria Florez, MA
DIA Global 2022
Chicago, IL | June 23



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 East Coast
Boston, MA | July 12-13



Digitizing Clinical Trials

Maria Florez, MA
18th Clinical Trials Innovation Programme
Boston, MA | October 26-27



Recent Presentations

Signature Series: Fostering Diversity and Inclusion in Clinical Research

Maria Florez, MA
ACRP 2022
Orlando, FL | April 24



The Economics of Phase-0 Approaches, Safer, Accelerated, Targeted, and Human-Specific Translation in Drug Development

Joseph DiMasi, PhD

3rd International Phase-0/Microdosing Stakeholder Meeting

The Netherlands | April 22

Phase-0 Microdosing Network

Patient Engagement and the Deployment of DTC

Ken Getz, MBA

DTC National

Live | April 20



Assessing the Adoption of Innovations Supporting Drug Development Operations

Ken Getz MBA

R&D Leadership Summit, The Conference Forum

Aventura, FL | April 11



State of the Drug Development Industry

Ken Getz, MBA

Chief Medical Officers Summit, The Conference Forum

Boston, MA | April 4



Enhancing Patient Engagement: Emerging Research and Recommendations

Maria Florez, MA

DIA Europe 2022

Brussels, Belgium | March 31



Anticipating the Impact of Digital Transformation and Remote Operating Models on the Workforce of Tomorrow

Maria Florez, MA

DIA Europe 2022

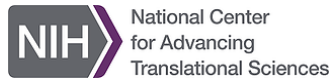
Brussels, Belgium | March 31



Patient Engagement
Jennifer Kim, PhD
DIA Patient Advisory Council
Online | March 28



Translational Science Education Roundtable
Ken Getz, MBA
National Center for Advancing Translational Science (NCATS), NIH, DHHS
Online | March 10



Characterizing the Environment for Global Clinical Trials
Ken Getz, MBA
Brandeis University Business of Biotech Program
Online | March 1



Measuring and Anticipating Patient Participation Burden in Clinical Trials
Ken Getz, MBA
SCOPE Summit
Online | February 9



Assessing Patient Enrollment Diversity in Clinical Trials
Zak Smith, MA; Emily Botto, BA; Ken Getz MBA
Finch Therapeutics Virtual Lunch & Learn
Online | February 4



Protocol Complexity in Oncology

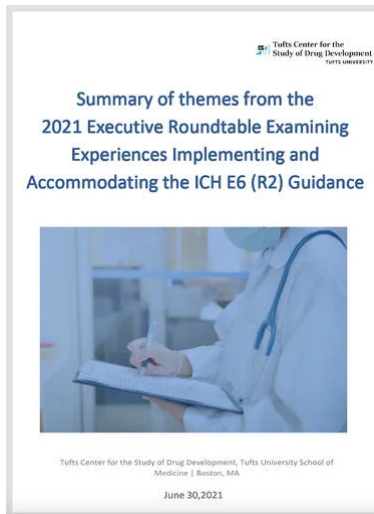
Ken Getz, MBA
Seagen Development Knowledge Exchange
Online | February 2



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