Tufts Center for the Study of Drug Development

TUFTS CSDD *INSIDER*

OCTOBER 2022

From the Executive Director

Dear CSDD Friends:

This month we will begin constituting our newest working group study aimed at gathering benchmarks on site activation, patient enrollment and retention experience since the beginning of the global pandemic. This is a particularly timely study. Sponsors and CROs have observed notable lengthening of study start-up and study conduct durations and declining recruitment and retention rates during the past 24 months. This important study will
gather hard data to compare against pre-pandemic benchmarks, to identify subgroups that have been the most impacted, and to provide valuable insights into opportunities to optimize study initiation, recruitment and retention effectiveness. Please let me know if your organization would like to participate in this important study.

Tufts CSDD's working group studies provide a unique and invaluable opportunity for organizations to collaborate on gathering useful and practical empirical evidence. In addition to helping to shape a robust methodology and establish consensus metrics; participating companies share experiences, ideas and insights; provide real data; discuss the results and their implications; co-author and co-present key takeaways.

Coming up in early 2023, we will be kicking off several new working groups:

- Updating benchmarks on the cost to develop a successful drug or biologic;
- Characterizing the impact of decentralized clinical trial solutions on patient enrollment diversity;
- Measuring between phase transition durations and the factors and strategies that expand and reduce this white space.

September was a particularly busy period for the CSDD team: launching new studies; collecting and analyzing data for studies underway; attending and presenting study results at meetings and conferences; publishing manuscripts and articles; preparing and producing professional development course offerings; and responding to requests for proposals.

This *Insider* and our website highlight our many ongoing and newly launched initiatives and professional development courses. We will also be distributing more detailed announcements about specific upcoming initiatives. As always, send me your feedback, questions and suggestions. We welcome your collaboration.

Kenneth Getz
Executive Director and Professor
Kenneth.Getz@tufts.edu

Tufts Center for the Study of Drug Development
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Working Group Studies

Working Group Study Examining Site Activation, Patient Enrollment and Retention Performance During the Pandemic

Tufts CSDD is launching a new working group study aimed at gathering benchmark metrics on site activation, patient enrollment and retention experience since the beginning of the global pandemic. We will gather recent clinical trial performance metrics to compare with pre-pandemic benchmarks to identify impact areas and opportunities to optimize start-up, recruitment and retention effectiveness. Contact **Ken Getz** for more information.

Professional Development Courses

Invest in the most impactful 24 hours of your pharmaceutical career!

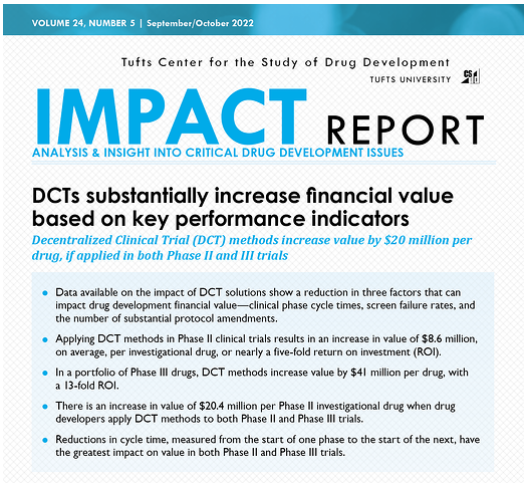
Tufts CSDD's Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation will resume in 2023 as an interactive and convenient online program, held on six separate days, throughout the month of February. Whether you are new to the industry or need a refresher, this highly acclaimed program will provide you with advanced instruction in practical and technical problem-solving in the areas of clinical pharmacology, drug development & clinical trial strategies, biopharmaceutical development, drug safety, and new drug regulation. During an exclusive Q&A session with a senior FDA official, participants will receive first-hand insights into FDA priorities and operations and will emerge with a better understanding of the regulatory process. For more information, **contact Luna Rodriguez**.

Identify, resolve and mitigate conflicts that might arise with team members, functions, or senior management using practical and productive approaches

All drug development teams must be able to resolve disputes in an efficient and constructive manner. TCSDD's Conflict Resolution for High Performance Drug Development Teams is an interactive course that will teach participants how to identify, resolve and mitigate conflicts that might arise with team members, functions, or senior management using practical and productive approaches. We will examine the latest frameworks, models and strategies for reducing and resolving conflicts, at both the individual and team levels, while sustaining motivation, enhancing productivity and building high performance teams. We will also study ways to enhance communication and curb potential disputes before they escalate into conflict. Through case studies and breakout sessions participants will gain hands on experience with multiple conflict resolution strategies. For more information, **contact Luna Rodriguez**.

Research Higlights

Our latest Impact Report:



DCTs Substantially Increase Financial Value Based on Key Performance Indicators

The September/October 2022 issue of the Tufts CSDD Impact Report Series (Vol. 24, No.5) is now available.This issue provides highlights from a recent Tufts CSDD study quantifying the net financial return on investment (ROI) on deployments of decentralized clinical trial solutions.

Learn more | Purchase

Recent Publications

Getz K, Shah S, Luithle J, Travers M. **Redefining CRO Sourcing Model Terminology to Optimize Outsourcing Strategies.** Applied Clinical Trials. September 20, 2022. **Access article**

Getz K. **Contemplating a Pressing Drug Development Paradox**. Applied Clinical Trials. September 7, 2022. **Access article**

Botto E, Florez M, Allen A, Bhagat R, Getz E, Getz K. **Racial and Ethnic Disparities Among the Clinical Research Workforce: Insights and Opportunities.** *ACRP.* August 16, 2022. **Access article**

Getz K, Smith Z, Kravet M. **Protocol design and performance benchmarks by phase and by oncology and rare disease subgroups.** TIRS. 2022; doi.org/10.1007/s43441-022-00438-5. **Access article**

Moore E, Edwards K, Getz K. **Examining the current value of ClinicalTrials.Gov listings for patients and the public.** *Applied Clinical Trials*. August 12, 2022. **Access article**

Kim, J. Y. , & Meister, A. **Microaggressions, Interrupted : The Experience and Effects of Gender Microaggressions for Women in STEM.** *Journal of Business Ethics*. **Access article**

Lamberti MJ, Smith Z, Dirks A, Caruana T, Mitchell T, Getz K. The Impact of Decentralized and Hybrid Trials on Sponsor and CRO Collaborations. *Applied Clinical Trials.* 2022. **Access article**

Getz K. **Quantifying Protocol Deviation Experience by Clinical Phase.** *Applied Clinical Trials.* 2022; volume 32, issue 6. **Access article**

Florez M, Botto E, Foster Z, Seltzer W, Valastro B, Ashmore L, Getz K. **Improving Diversity in Clinical Trial Volunteer Participation by Addressing Racial and Ethnic Representation Among the Clinical Research Workforce.** *Applied Clinical Trials.* **Access article**

Getz K, Florez M, Botto E, Ribeiro K, Goller G, Robinson L, Abdullah O. **Global Investigative Site Personnel Diversity and Its Relationship with Study Participant Diversity.** TIRS. 2022. Doi.org/10.1007/243441-022-00418-9. **Access article**

Smith Z, Botto E, Getz K. **Quantifying Diversity and Representation in Pivotal Trials Leading to Marketing Authorization in Europe.** TIRS. 2022. Doi.org/10.1007/s43441-022-00421-0. **Access article**

Kim, J. Y. & Botto, E. (2022). **The Impact of Gender Microaggressions on Team Performance in Drug Development.** *Applied Clinical Trials*. **Access article**

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

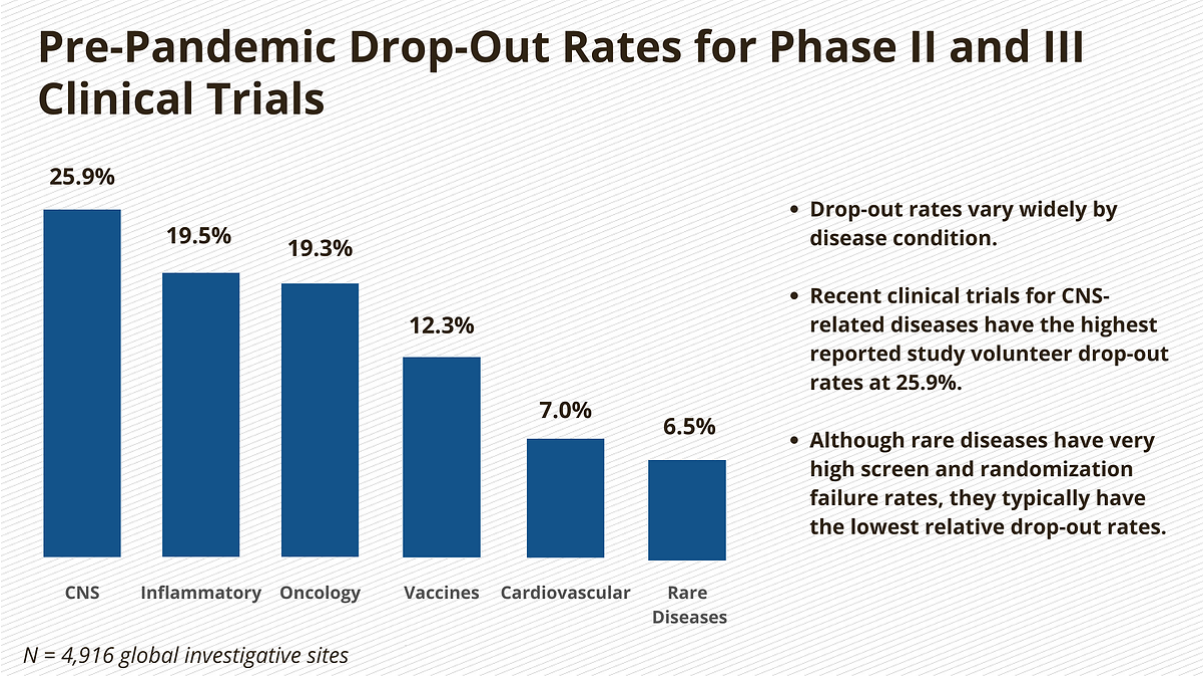
Burt T, Roffel AD, Langer O, Anderson K, DiMasi JA. **Strategic, feasibility, economic, and cultural aspects of Phase 0 approaches.** Clinical and Translational Science 2022. **Access article**

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**

Data Insights Digest



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Faculty and Staff Presentations

Upcoming Presentations

Diversity and Representation Among the Clinical Research Workforce: A factor in patient engagement and recruitment?
Maria Florez, MA
Scope Europe
Barcelona | October 3-4

Characterizing the Innovation Adoption Cycle for Innovations Supporting Virtual Clinical Trials
Maria Florez, MA
Scope Europe
Barcelona | October 3-4

Examining ENPV of DCT Deployments
Ken Getz, MBA
Medable User Group Meeting
Live | October 11

The Impact of Decentralized Trials on Sponsor-CRO Collaborations
Mary Jo Lamberti, PhD
Outsourcing in Clinical Trials New England
Boston, MA | October 12-13

Exploring the Impact of Decentralized Clinical Trials
Ken Getz, MBA
Prometrika
Live and Online | October 13

The Economics of Decentralized Clinical Trials: Assessing the Net Financial Benefit
Joseph DiMasi, PhD
Decentralized Clinical Trials Summit
Philadelphia, PA | October 26

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

New Trends and Practices Impacting the Drug Development Landscape
Ken Getz, MBA
CT Europe
Live | November 7-9

"Where has the Industry Been and Where Should it Be Going: Using Industry Development Benchmarks (Time, Risk and Cost Metrics)"
Joseph DiMasi, PhD
Speid & Associates, Inc and Alpert Medical School, Brown University | Drug Development Boot Camp

Boston, MA | November 17

The Impact of Decentralized Clinical Trials Disruption on Sponsor-CRO Relationships
Mary Jo Lamberti, PhD
SCOPE
Orlando, FL | February 6-9

Recent Presentations

Innovation Adoption Cycles for Tools Supporting DCT Research
Maria Florez, MA
Precision in Clinical Trials Summit
Frankfurt | September 28

Racial and Ethnic Disparities in Access to Professional Opportunities in Drug Development
Emily Botto
Clinical Trials Global
Online | September 28

Accelerating Innovation Adoptions Supporting Clinical Trial Execution
Ken Getz, MBA
CTTI Fall Steering Committee Meeting
Washington DC | September 20

CRO Landscape Trends – Sponsor Demand, Sector Growth, and the Impact of COVID-19
Emily Botto
Contract Pharma
New Brunswick, NJ | September 20

Evolving the Biomedical Innovation System
Ken Getz, MBA
IQVIA Life Sciences Innovation Forum
Online | September 13

The Changing Environment for RBQM
Ken Getz, MBA
RBQM Live
Online | September 8

Hot Topics in Drug Development
Ken Getz, MBA
ZS Biostatistics Leadership Council
Online | August 4

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

Optimizing the Pharma Workforce for Trial Success in the Digital Era
Maria Florez, MA
DIA Annual Meeting
Chicago, IL | June 23

Ensuring Diversity in Clinical Trials
Maria Florez, MA
DIA Annual Meeting
Chicago, IL | June 23

Where Are We? Assessing Organizational Preparedness and Capabilities to Support Patient Engagement
Ken Getz, MBA

DIA Annual Meeting
Chicago, IL | June 21

Approaching the Assessment of Clinical Protocol Complexity
Zak Smith, MA; Denise Messer
DIA Annual Meeting
Chicago, IL | June 21

Quantifying Return on DCT Investment
Ken Getz, MBA
DIA Annual Meeting - Innovation Theater
Chicago, IL | June 21

Keynote Diamond Panel Discussion: The Future of Healthcare
Ken Getz, MBA
DIA Annual Meeting
Chicago, IL | June 20

State of the Drug Development Industry
Ken Getz, MBA
WCG
Webinar | June 15

COVID-19 Clinical Development Lessons Learned
Ken Getz, MBA
IQVIA Institute
Webinar | June 7

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