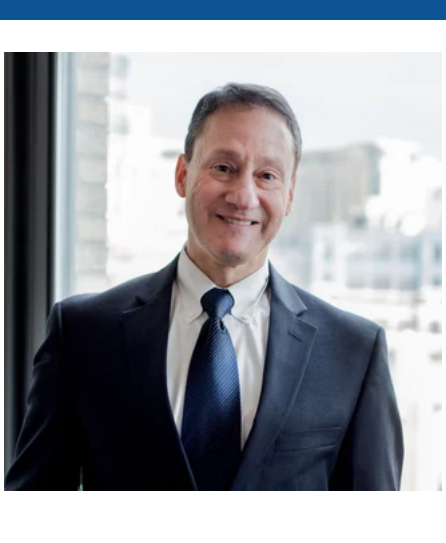
Tufts Center for the Study of Drug Development
TUFTS CSDD INSIDER
April 2023

From the Executive Director



Dear CSDD Friends:

It was a pleasure to see many of you at onsite meetings, roundtables and conferences in the US and Europe this past month. One particularly memorable visit: I was presented with a mock Q&A session where ChatGPT was instructed to impersonate me in its response to questions about Tufts CSDD study findings and their implications. The results were both interesting and very humbling!

The Center had one of its busiest months in recent memory with new and ongoing project activity and several new staff joining our team. We held one of two senior executive roundtables examining sponsor and CRO adoption experience with risk-based monitoring (RBM) and risk-based quality management (RBQM) components. The second roundtable will be conducted in Geneva, Switzerland in late April. Please let us know if you would like to participate.

This past month the Tufts CSDD team also met with more than a dozen pharmaceutical and biotechnology companies — in collaboration with ICON — to examine a more detailed taxonomy characterizing CRO sourcing models and their relationship with clinical trial performance, efficiency and cost outcomes. Later this year we will be applying this taxonomy to a large sample of clinical trials.

This month, Tufts CSDD will begin constituting a new working group study to gather detailed financials on the total direct and in-direct costs associated with planning and executing clinical trials. This study represents the most comprehensive financial assessment on clinical trials that we have ever performed and will include costs borne by each stakeholder group participating in clinical trials including patients. Please let me know if your organization would like to learn more about participating in this study.

In April Tufts CSDD will be offering a professional development course for middle- and senior executives looking to hone their skills in managing alliances and collaborations. And in May, we'll be offering a new course for senior executives to lead and direct high performance cross-functional teams.

This *Insider* contains more information about these upcoming professional development course and other new and ongoing Tufts CSDD research activities. Please refer to our **website** or reach out to me directly at **Ken Getz** with any questions or to share your thoughts.

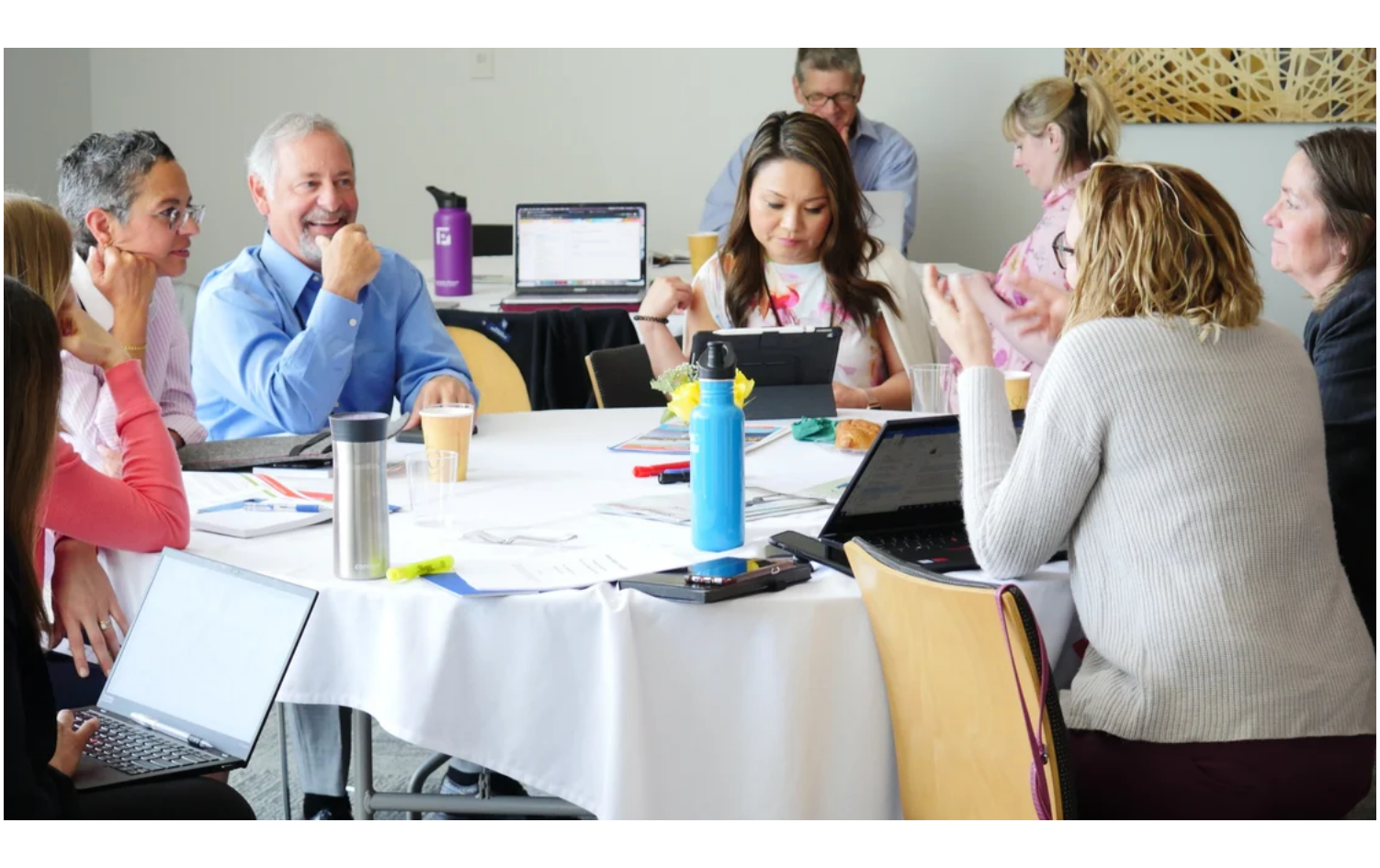
As always, thank you for your support and collaboration,

Ken

Kenneth Getz
Executive Director and Professor

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

Professional Development Courses



For spring 2023, Tufts CSDD is pleased to offer the following two programs for research executives:

An interactive half-day leadership workshop on April 20th, 2023 — **Better Together: Creating a Value Driven Partnership Network.** This program is led and moderated by Christine Carberry (MS Certified Strategic Alliance, Professional (CSAP), Carberry Consulting) and Robert Franco (Senior Fellow Tufts CSDD and President, Coe Point Associates LLC.) and teaches participants how to conceive and apply alliance management strategies to optimize drug development planning and execution. For more information and to register — **Sarah Wrobel** or visit the Tufts CSDD **website**.

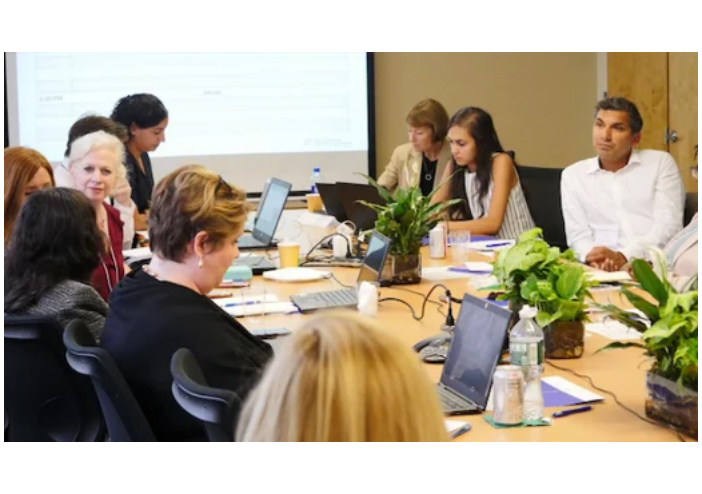
An intensive four-day virtual course on May 23,2023 — **Leadership for Drug Development Teams.** Intended for research executives looking to build and sharpen their leadership skills and improve cross-functional team performance and productivity, this internationally-recognized program is facilitated by Dr. Robert Franco with an outstanding faculty. Course enrollees will have ample opportunity to interact with faculty and colleagues. To learn more about the course, receive the course agenda, or to register — contact **Sarah Wrobel** or visit the Tufts CSDD **website**.

Working Group Studies

New Working Group Study Gathering Rich Data on the Impact of DCT Deployments on Clinical Trial Outcomes

Tufts CSDD is launching a new working group to gather, aggregate, analyze and disseminate metrics on actual experience with virtual and remote solutions supporting clinical trial execution. Participating companies will share de-identified hard data on the use of DCT solutions and their impact on performance and other clinical trial outcomes. For more information and if you would like to participate, please contact. **Ken Getz.**

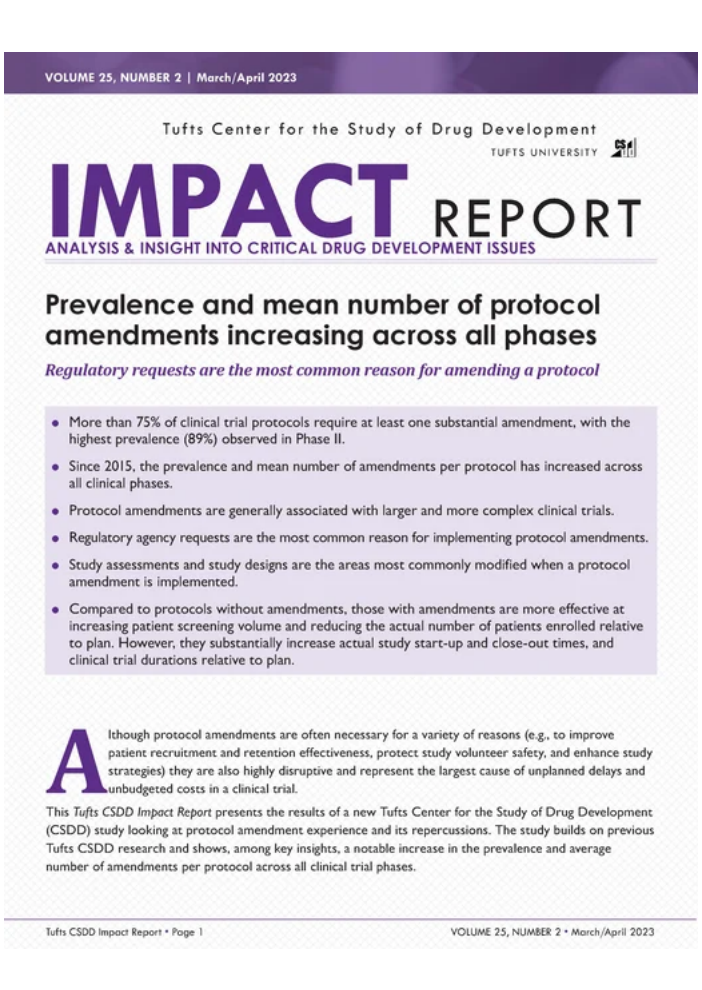
New Working Group Study Gathering Benchmark Metrics on Site Activation, Patient Enrollment, and Retention Experience Since The Beginning of the Pandemic



Tufts CSDD has launched a new working group study 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 **Mary Jo Lamberti** for more information.

Research Highlights

Our Latest Impact Report


VOLUME 25, NUMBER 2 | March/April 2023

Tufts Center for the Study of Drug Development
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IMPACT REPORT
ANALYSIS & INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Prevalence and mean number of protocol amendments increasing across all phases

Regulatory requests are the most common reason for amending a protocol

- More than 75% of clinical trial protocols require at least one substantial amendment, with the highest prevalence (89%) observed in Phase II.
- Since 2015, the prevalence and mean number of amendments per protocol has increased across all clinical phases.
- Protocol amendments are generally associated with larger and more complex clinical trials.
- Regulatory agency requests are the most common reason for implementing protocol amendments.
- Study assessments and study designs are the areas most commonly modified when a protocol amendment is implemented.
- Compared to protocols without amendments, those with amendments are more effective at increasing patient screening volume and reducing the actual number of patients enrolled relative to plan. However, they substantially increase actual study start-up and close-out times, and clinical trial durations relative to plan.

Although protocol amendments are often necessary for a variety of reasons (e.g., to improve patient recruitment and retention effectiveness, protect study volunteer safety, and enhance study strategies) they are also highly disruptive and represent the largest cause of unplanned delays and unbudgeted costs in a clinical trial.

This *Tufts CSDD Impact Report* presents the results of a new Tufts Center for the Study of Drug Development (CSDD) study looking at protocol amendment experience and its repercussions. The study builds on previous Tufts CSDD research and shows, among key insights, a notable increase in the prevalence and average number of amendments per protocol across all clinical trial phases.

Tufts CSDD Impact Report • Page 1 VOLUME 25, NUMBER 2 • March/April 2023

Prevalence and mean number of protocol amendments increasing across all phases

Tufts CSDD's March/April 2023 Impact Report (Volume 25, Number 2) is now available. This issue presents compelling new benchmarks on sponsor experience with protocol amendments, their causes and impact on clinical trial performance.

Learn more | Purchase online

Recent Publications

Kim J. Y., Botto E. **Examining the Impact of Exclusionary Behaviors on Team Dynamics.** Applied Clinical Trials, March 24, 2023. Access article

Dirks A., Harper B., Getz K. **Assessing Investigative Site Outlook and Operating Experience Post-Pandemic.** Applied Clinical Trials, March 7, 2023. Access article

Getz K. **Rebooting the statistic that 5% of eligible patients participate in clinical trials.** Applied Clinical Trials, March 2, 2023. Access article

Lamberti M.J., Dirks A., Howie R., Getz K. **An examination of the role of the clinical research associate and factors impacting performance and experience**. Applied Clinical Trials, December 22, 2022. Access article

Kim, J. Y., & Shang, Z. (2022). **No, I do belong: Agentic identity work by Asian Americans to combat COVID-19 related racial microaggressions. *Journal of Management Studies*.** December 7, 2022. Access article

Kim J. Y., Botto E. **Methods to recruit healthcare providers for virtual advisory boards in drug development.** November 17, 2022. **Access article**

Getz K, Smith Z, Peachey J, Li G. **Leveraging Data Insights to Address the Perils of Linear Practices in Site Identification and Activation.** Applied Clinical Trials, October 18, 2022. Access article

Smith Z, Botto E, Carney C, Bagga A, Qutab B, Getz K. **Insights from a Multi-company Workshop to Apply a Patient Participation Burden Algorithm to Protocol Data.** Ther Innov Regul Sci. October 16, 2022. Access article

Kim, J. Y. & Meister, A. **How to Intervene When You Witness a Microaggression.** Harvard Business Review, September 30, 2022. Access article

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

DiMasi, J.A., Smith, Z., Oakley-Girvan, I. *et al.* **Assessing the Financial Value of Decentralized Clinical Trials.** Ther Innov Regul Sci. September 14, 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 M.J., 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

Data Insights Digest

Oncology and Non-Oncology Clinical Trials Durations

(from Protocol Ready to Database Lock -- 2014-2019)

Mean Days and (Coefficient of Variation)	Non-Oncology Drugs and Biologics	Oncology Drugs and Biologics
Phase I	573.1 (.57)	1,018.3 (.35)
Phase II	991.4 (.66)	1,481.7 (.62)
Phase III	1,214.3 (.46)	1,769.3 (.49)

Source: Tufts CSDD

- The duration of clinical trials for oncology drugs and biologics in each phase are considerably longer – by 12 to 18 months on average.
- The coefficients of variation around mean clinical trial durations for oncology and non-oncology drugs and biologics are comparable.
- Despite longer trial durations by phase, the average overall clinical duration for oncology development programs is only five months longer than non-oncology due to more parallel and phase II-III combination activity.

Subscribe today to get your copy of the Tufts CSDD Impact Report.

Faculty and Staff Presentations

Upcoming Presentations

State of the Drug Development Industry
Ken Getz, MBA
Chief Medical Officers Summit
Boston, MA | April 3 - 4

Quantifying the Value Proposition of DCT Deployment
Ken Getz, MBA
Informa Decentralized Clinical Trials
Boston, MA | April 18 - 20

The Impact of DCT Use on Sponsor-CRO Relationships
Mary Jo Lamberti, PhD
Informa Decentralized Clinical Trials
Boston, MA | April 19

The Economics of Implementing Phase 0 Techniques – Methods for measuring Financial Value
Joseph DiMasi, PhD
4th International Phase-0/Microdosing Stakeholder Meeting: Intra-Target Microdosing (ITM): Revolutionizing Clinical Pharmacology and Drug Development
Boston, MA | April 24

Innovation in Clinical Research: Why it Takes So Long to Adopt a New Solution
Ken Getz, MBA
MAGI East Conference
Philadelphia | May 21 - 24

Sponsor-CRO Collaborations and the Impact of Decentralized Clinical Trials
Mary Jo Lamberti, PhD
DIA Annual Meeting
Boston, MA | June 26

Recent Presentations

Assessing Patient Engagement Capabilities and their Impact
Ken Getz, MBA
DIA Europe
Basel, Switzerland | March 23

Examining Current Patient Engagement Activities and Investments within Sponsor and CRO Companies
Ken Getz, MBA
DIA Europe
Basel, Switzerland | March 22

The Impact of Decentralized and Hybrid Trials on Sponsor-CRO Collaborations
Mary Jo Lamberti, PhD
SCOPE Summit
Orlando, FL | February 8

Panel Discussion - Navigating Global Crises: Pandemic War, Hyperinflation and Supply Chain
Ken Getz, MBA
SCOPE Summit
Orlando, FL | February 7

Remote Teams in Clinical Research During the COVID-19 Pandemic
Maria Florez, MA and Mary Jo Lamberti, PhD
Clinical Research Webinar
Online | January 26-27

Clinical Operations and Clinical Outsourcing Roundtables
Ken Getz, MBA
Linking Leaders
New York, NY| January 17 - 18

New Insights into Managing Investigative Sites to Optimize Patient Enrollment Diversity
Ken Getz, MBA
Evolution Summit
Orlando, FL | December 8

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, Virtual Conference
Online | December 1

Measuring the Impact of the Pandemic on Drug Development Productivity and Performance
Ken Getz, MBA
Outsourcing Clinical Trials New England
Boston, MA | November 10

Digital Transformation and Clinical Research Team Effectiveness
Maria Florez, MA
Clinical Trials Europe
Online | November 2-4

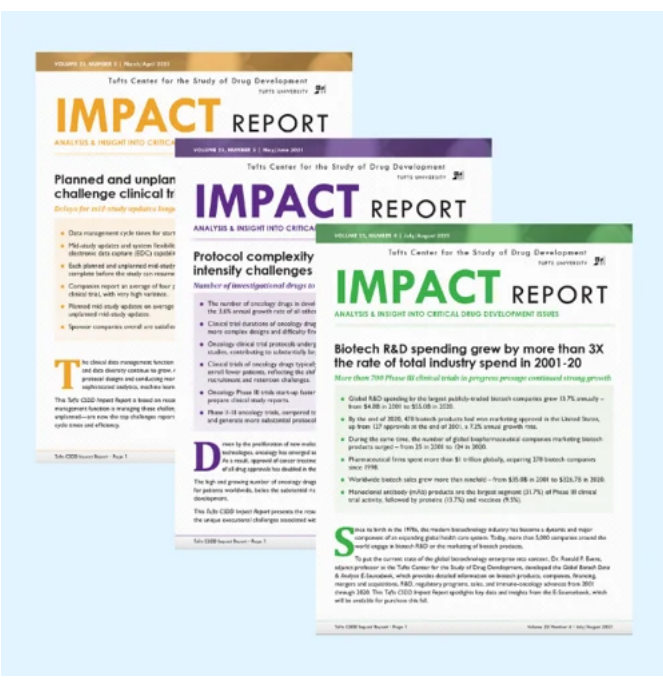
Impact of Running Clinical Trials During the Pandemic and Lessons Learnt
Ken Getz, MBA and Maria Florez, MA
Clinical Trials Europe
Online | November 2-4

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

Increasing Efficiency and Reducing Cycle-Times in Drug Development: Multi-Stakeholder Views on the Topic
Zak Smith, MA
Clinical Trials Europe
Online | November 3

Optimizing protocol design to improve performance and efficiency
Ken Getz, MBA
Clinical Trials Europe
Online | November 2

Subscriptions Papers and Books



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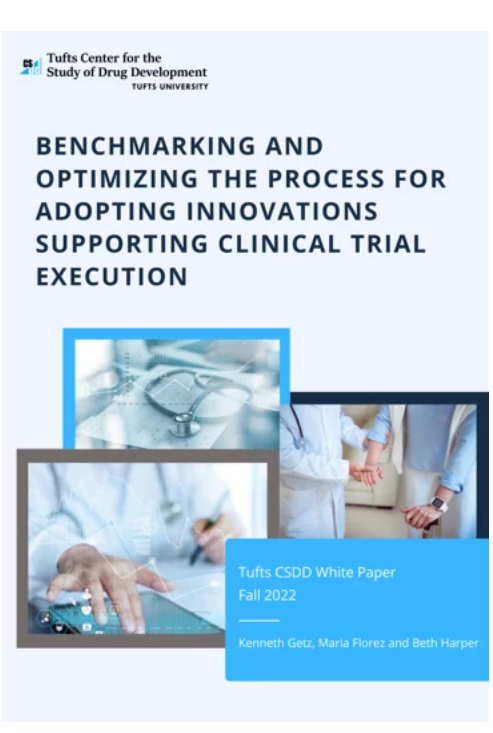

Download White Paper

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About Tufts CSDD | **Support Tufts CSDD**

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