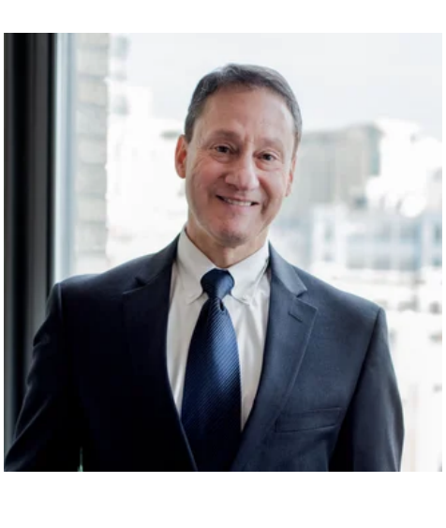
Tufts Center for the Study of Drug Development
TUFTS CSDD *INSIDER*
November 2023

From the Executive Director



Dear CSDD Friends:

Current global economic conditions are contributing to an already intense drug development operating environment. Reports of cost cutting measures, downsizings, reorganizations and delayed decisions and activities are common across the clinical research enterprise. We are also seeing high and rising demand for evidence to guide optimization strategies.

To that end, this past month Tufts CSDD launched several new studies assessing patient participation burden and investigative site participation burden based on protocol design characteristics. We have also initiated a new working group study gathering use cases of AI-enabled drug development activity with the aim of quantifying return on investment.

The CSDD team has been collecting and analyzing data for several studies underway. Our PALADIN consortium — a uniquely positioned pre-competitive group of 25 organizations dedicated to improving industry and patient advocacy group collaborative effectiveness — has been wrapping up Year One activities as it moves into Year Two. A second pre-competitive consortium managed by Tufts CSDD has initiated the collection of hard evidence characterizing the impact of decentralized clinical trial components on clinical trial performance and quality.

We have also been actively planning our 2024 Post-Graduate Course in Clinical Pharmacology, Drug Development and Regulation. Now celebrating its 51st anniversary, this internationally recognized program will be offered online throughout the month of February. The program is designed to provide mid- and senior level R&D professionals with a comprehensive understanding of the drug development process, from initial discovery through to regulatory approval and post-marketing activity. If you are new to the drug development industry; have limited understanding of the role that certain functional areas play in drug development; have little to no experience leading diverse collaborative teams and using new and potentially disruptive technologies and solutions - then this course is ideal for you.

This *Insider* provides additional information about the upcoming 2024 Post Graduate Course. You can also contact Sarah Wrobel or visit our website to learn more.

As always — I look forward to hearing from you, to seeing you at upcoming conferences and meetings, and to welcoming you to our working group studies, roundtables and professional development courses. Please contact me directly for information about any of our ongoing and upcoming activities.

Wishing you the very best,

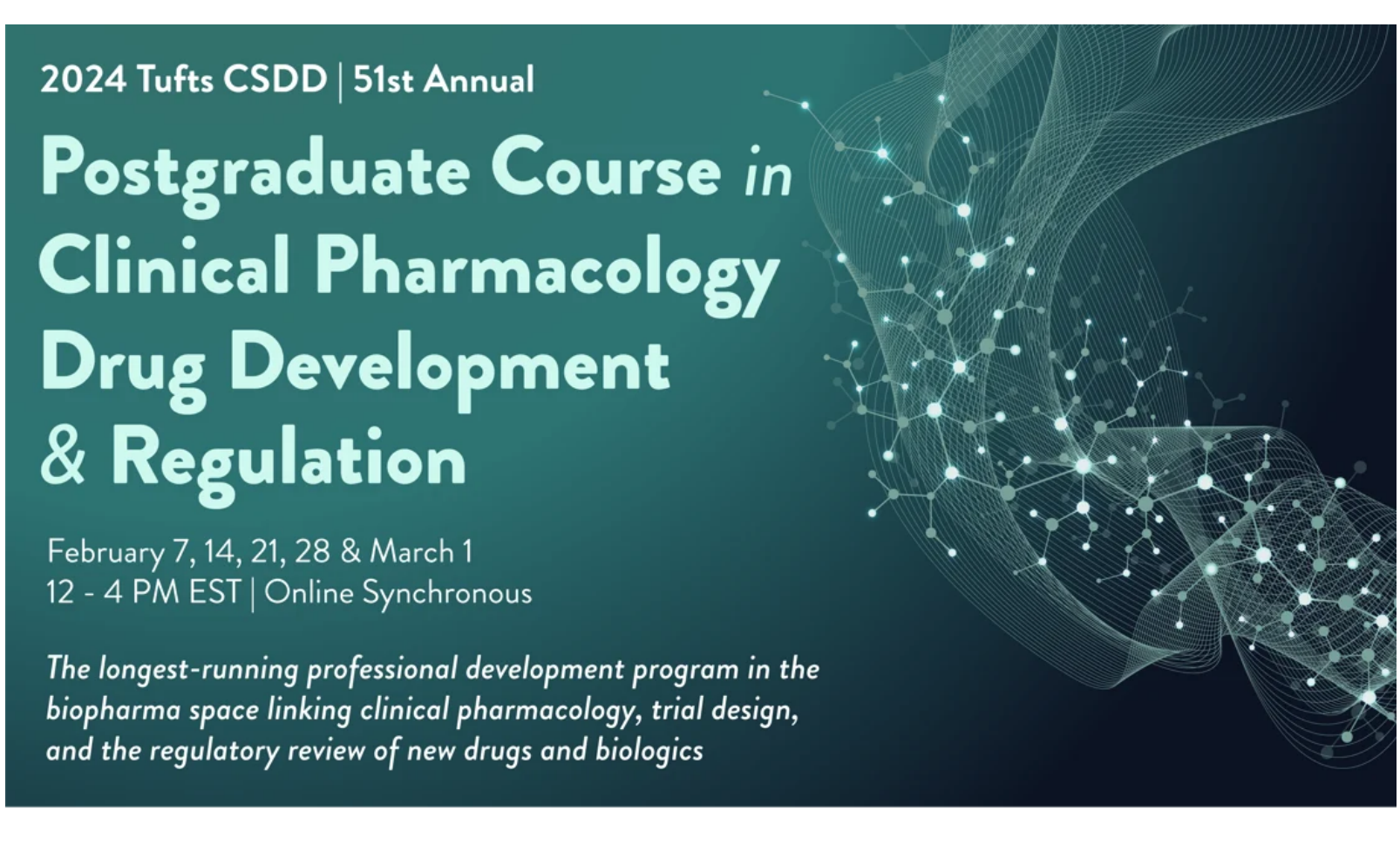
Ken

Ken

Kenneth Getz
Executive Director and Professor

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

Professional Development Courses



2024 Tufts CSDD | 51st Annual

Postgraduate Course *in* Clinical Pharmacology Drug Development & Regulation

February 7, 14, 21, 28 & March 1
12 - 4 PM EST | Online Synchronous

The longest-running professional development program in the biopharma space linking clinical pharmacology, trial design, and the regulatory review of new drugs and biologics

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This winter, Tufts CSDD will host the 51st annual **Postgraduate Course in Clinical Pharmacology, Drug Development, & Regulation.** This course is designed to provide participants with a comprehensive understanding of the drug development process, from initial discovery through to regulatory approval and post-marketing surveillance. Whether you are new to the industry or need a refresher, the program will provide you with 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.

To review the program agenda and register for the program, contact **Sarah Wrobel** or visit the **Tufts CSDD website**

Tufts CSDD offers a variety of **Custom On-Site and Virtual Drug Development Training Courses** covering fundamental areas of drug development and regulatory science, and hot topics on issues, challenges, new practices, and solutions. Programs are customized to the specific needs of individual organizations. **This brochure** contains a list of topics from which to choose and design your program. Tufts CSDD can also work with you to add topics not listed below. Once you have selected topics of interest, Tufts CSDD will prepare a proposal and budget and will identify and engage faculty.

To learn more, contact **Sarah Wrobel** or visit the **Tufts CSDD website**

Upcoming Studies

Benchmarking AI use in Drug Development and Quantifying ROI

Tufts CSDD has launched a new multi-company study updating benchmarks on AI/Machine Learning use in clinical development planning, design, execution, reporting and oversight. Conducted in collaboration with the Drug Information Association, the study will look at drug development landscape practices, profile specific use cases, and quantify the return on AI investment in drug development. For more information, contact **Mary Jo Lamberti.**

New Consortium Launched to Gather Empirical Data on DCT Deployment Experience and the Impact of DCT

A new multi-company, pre-competitive consortium was formed this past June to gather and analyze empirical data on company experience with the deployment of virtual and remote solutions supporting clinical trial planning, design, and execution. Tufts CSDD has received grant funding from the Reagan-Udall Foundation to support the consortium. Thirty sponsors and CROs are currently participating. Data collection is under way. For more information and if you would like to participate, please contact **Ken Getz.**

Updating Benchmarks on the Vendor Qualification Process

Next month, Tufts CSDD will be launching a new working group study updating benchmarks on the vendor qualification assessment process and identifying improvement opportunities. Sponsors, CROs and other service providers dedicate substantial resources and time annually to support this process and to accommodate increasingly complex operating activity. For more information, contact **Zak Smith**

Research Highlights

Our Latest Impact Report

VOLUME 25, NUMBER 6 | November/December 2023

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

IMPACT REPORT
ANALYSIS & INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Number of biotech products in late-stage clinical trials has quadrupled during the past decade

Biotech products currently comprise 60% of all FDA new drug approvals

- The biotechnology industry has seen explosive growth over the past decade, with a quadrupling of the number of biotech products in Phase III clinical trials.
- The number of novel biotech products, marketed products, and biosimilars in late-stage clinical trials grew to 594, 146, and 192 respectively in 2023.
- While spending on biotech mergers and acquisitions (M&A) dipped in 2021, the number rebounded in 2023, to $85 billion in total spending.
- Since 2021, 50%-60% of novel therapies approved by the U.S. Food and Drug Administration (FDA) are biotech products.
- Total worldwide sales of biotech products have undergone steady growth since 2018, reaching over $466 billion in 2022.
- Biotech product sales have captured a growing percent of the total global market for pharmaceutical products, reaching 30% in 2023.

Number of Biotech Products in Late-Stage Clinical Trials has Quadrupled During the Past Decade

The November/December 2023 issue of the Tufts CSDD Impact Report Series (volume 25, number 6) is now available. This issue presents data characterizing dramatic growth and change in the biotech industry: with more than 430 companies now sponsoring clinical trial activity, 200+ recent mergers and acquisitions and global product sales reaching nearly $500 billion in 2022.

Learn more | Purchase online

Recent Publications

Botto E, Ford RM, Do H, Getz K. **Assessing Sponsor Attitudes Toward Retail Pharmacy Involvement in Clinical Trial Recruitment and Execution.** *Applied Clinical Trials.* Published October 30, 2023. **Access article.**

Lamberti MJ, Smith Z, DiPietro M, Barry J, Getz K. **Outsourcing Model Usage and Its Relationship to Clinical Trial Performance.** *Applied Clinical Trials.* Published October 12, 2023. **Access article.**

Smith Z, Botto E, Johnson O, Rudo T, Getz K. **New Benchmarks on Demographic Disparities in Pivotal Trials Supporting FDA-Approved Drugs and Biologics.** *Ther Innov Regul Sci.* Published September 29, 2023. **Access article.**

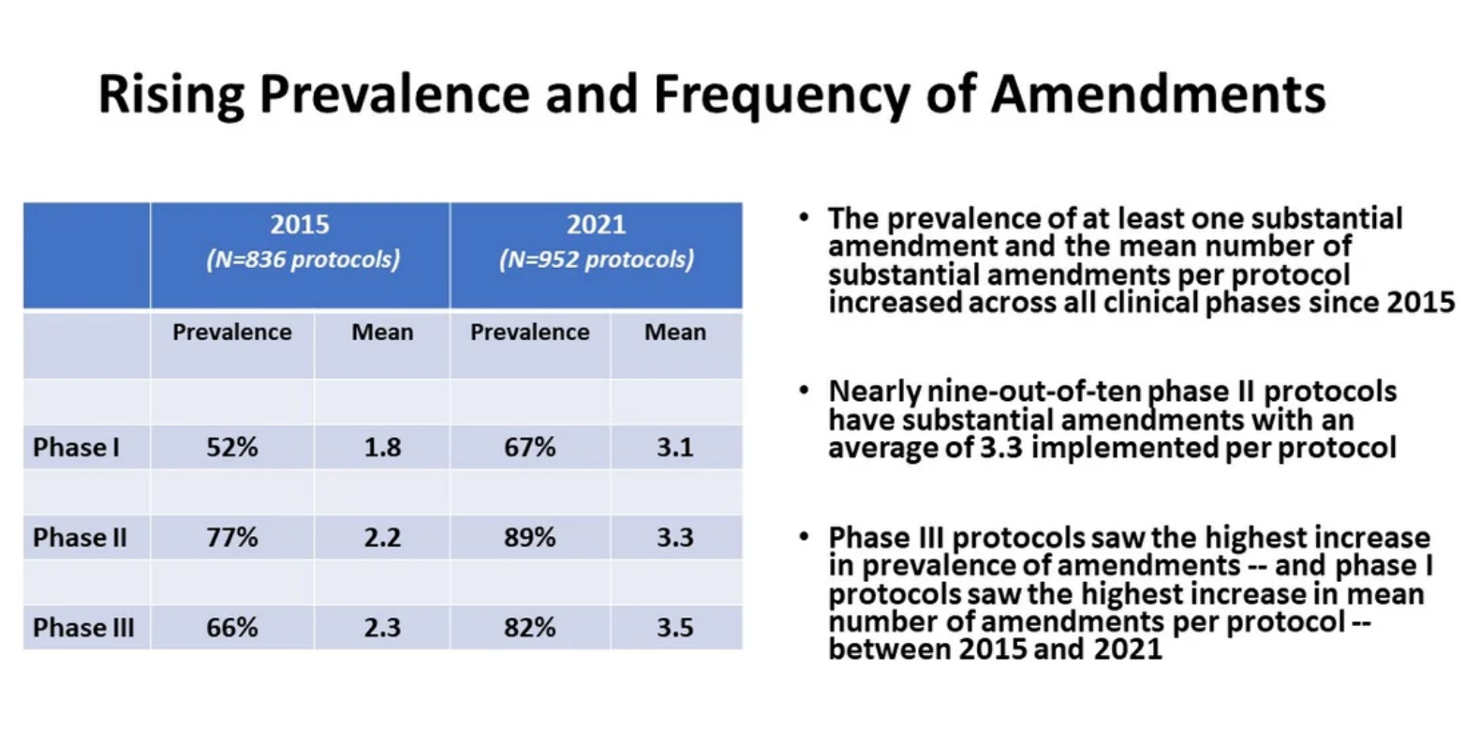
Zheng W, Kim JY, Kark R, Mascolo L. **What Makes an Inclusive Leader,** *Harvard Business Review.* Published September 27, 2023. **Access article.**

Getz K. **In Search of Attributes Predictive of Collaboration Effectiveness**. *Applied Clinical Trials.* September 2023. **Access article**

Kim JY, Maria Paula BA, Granville C, Getz KA. **Benchmarking Organizational Patient Engagement Capabilities in Clinical Research.** *Ther Innov Regul Sci.* Published online July 2023. **Access article**

Kim JY, Dirks A. **Is Your Organization's Remote Work Strategy "Working"? Exploring the Impact of Employees' Attitudes Toward Flexible Work Arrangements on Inclusion and Turnover Intention.** *Ther Innov Regul Sci.* Published online July 17, 2023. **Access article**

Data Insights Digest



Rising Prevalence and Frequency of Amendments

	2015 *(N=836 protocols)*		2021 *(N=952 protocols)*	
	Prevalence	Mean	Prevalence	Mean
Phase I	52%	1.8	67%	3.1
Phase II	77%	2.2	89%	3.3
Phase III	66%	2.3	82%	3.5

- **The prevalence of at least one substantial amendment and the mean number of substantial amendments per protocol increased across all clinical phases since 2015**
- **Nearly nine-out-of-ten phase II protocols have substantial amendments with an average of 3.3 implemented per protocol**
- **Phase III protocols saw the highest increase in prevalence of amendments -- and phase I protocols saw the highest increase in mean number of amendments per protocol -- between 2015 and 2021**

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

Faculty and Staff Presentations

Upcoming Presentations

Benchmarking Patient Enrollment and Use of Patient Recruitment Tactics
Mary Jo Lamberti, PhD
Outsourcing in Clinical Trials New England
Boston, MA | November 1

Optimizing Clinical Trial Performance
Ken Getz, MBA
OCT New England
Live | November 2

Assessing the Net Financial Benefits of Employing Digital Endpoints in Clinical Trials
Joseph DiMasi, PhD
4th Annual Digital Biomarkers & Digital Measurements East Summit
Boston, MA | November 2

Measuring Patient and Site Burden in Clinical Trials
Ken Getz, MBA
DIA Annual Meeting Japan
Live | November 5 - 8

Diversity and Representation in Oncology Trials
Zachary Smith, MA
Cancer Immunotherapy Summit
Boston, MA | Nov 6 - 8

Adoption Cycle for Technologies that Support DCTs
Maria Florez
Webcast Series: Effectively Adopt a Decentralized Approach, DCT Week
Virtual | November 7

Understanding and Overcoming Barriers to Technology Adoption in Clinical Trials
Maria Florez
Clinical Trials Innovation Programme US
Brooklyn, NY | November 17

Leveraging Patient Engagement Strategies to Optimize Protocol Performance
Ken Getz
Evolution Summit
Live | December 4

Site Activation and Patients Enrollment Benchmarks Among Sponsors and CROs
Mary Jo Lamberti
Summit for Clinical Operations Executives (SCOPE)
Orlando, FL| February 11-14

Protocol Design Trends and Their Impact on Performance
Ken Getz
Summit for Clinical Operations Executives (SCOPE)
Orlando, FL | February 14

Workshop: Upskilling for Successful Digital Transformations in Europe
Maria Florez
DIA Europe
Brussels, BE | March 12-13

Frequency and Impact of Protocol Amendments on Clinical Trial Performance
Emily Botto
Festival of Biologics
San Diego, CA | April 15

Retail Pharmacies and Clinical Trials: Perspectives from Industry, Sites & Patients
Emily Botto
Association of Clinical Research Professionals 2024
Anaheim, CA | May 4

Recent Presentations

Examining the Vendor Qualification and Selection Process
Ken Getz
CORE East
Live | October 4-6

Overcoming Barriers Slowing the Adoption of Disruptive Technologies
Maria Florez
Disruptive Technologies in Clinical Trials
Boston, MA | October 10

Adopting Technologies that Enable Digital Transformations
Maria Florez
Precision in Clinical Trials Summit
San Diego, CA | October 16

Envisioning the Future Landscape: Preparing the Future Workforce for Drug Research & Development - A Workshop
National Academies
Mary Jo Lamberti, PhD
Washington D.C. | October 16-17

Clinical Trial Disruptions During Disasters and Public Health Emergencies
Ken Getz
CTTI and FDA public meeting
Virtual | October 18 - 19

Increasing R&D Productivity to Sustain Biomedical Innovation
Ken Getz
IQVIA Institute Life Sciences Innovation Forum
Virtual | September 26

Patient Preferences for Virtual and Remote Clinical Trial Services
Ken Getz, MBA
DPharm
Live | September 22

Quantifying the Impact of DEI: Making DEI Stick in Drug Development
Jennifer Kim, PhD
EMD Serono
Live | September 13

Speaker Series: DEI
Jennifer Kim, PhD
Massachusetts Department of Revenue
Live | September 11

How Lack of Inclusion Can Impact Women In STEM
Jennifer Kim, PhD
Cornell School of Medicine
Live | August 31st

Silence is Not Always Golden: Impact of Leader Intervention Against COVID-19 Microaggressions
Jennifer Kim, PhD
Academy of Management
Boston, MA | August 8

Methods in Organizational Change Research: Dialogue on the Past, Present, and Future of Organization
Jennifer Kim, PhD
Academy of Management
Boston, MA | August 7

Subscriptions Papers and Books

IMPACT REPORT

IMPACT REPORT

IMPACT REPORT

Biotech R&D spending grew by more than 3X the rate of total industry spend in 2001-20

Purchase Impact Reports

Tufts Center for the Study of Drug Development
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BENCHMARKING AND OPTIMIZING THE PROCESS FOR ADOPTING INNOVATIONS SUPPORTING CLINICAL TRIAL EXECUTION

Tufts CSDD White Paper
Fall 2022

Kenneth Getz, Maria Florez and Beth Harper

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
