Tufts Center for the Study of Drug Development

TUFTS CSDD *INSIDER*

JANUARY 2024

From the Executive Director

Dear CSDD Friends:

Happy New Year! We begin 2024 with many transformational trends unfolding as operating pressures to lower costs and increase efficiency intensify.

Key trends that promise to optimize aspects of drug development performance and economics: Growing but cautious use of generative AI; rising integration of real-world evidence; increasing customization and patient-centric use of automation, virtual and remote solutions to support clinical trial execution models; and new and agile approaches to engage personnel, collaborative service providers and patient advocacy groups. External pressures include volatile global economic conditions, industry consolidation and the potential fall out of the inflation reduction act.

Transformational trends and pressures drive Tufts CSDD's 2024 agenda as we conduct objective, relevant, empirical research & analysis to inform strategic and actionable insights. We're very excited about our current portfolio of activity — here's a partial list:

- Assessing patient participation burden in clinical trials including those involving decentralized (DCT) elements and clinical outcomes assessments
- Mapping AI/machine-learning use cases across clinical and clinical operating functions
- Quantifying the short- and long-term financial and operating impact of DCT

deployments
- Anticipating regulatory modernization initiatives including the inflation reduction act
- Evaluating strategies and practices to optimize protocol design and clinical data management
- Measuring the return-on-investment of generative AI applications
- Updating benchmarks on the vendor qualification assessment process and identifying opportunities to improve speed and efficiency
- Assessing trends and issues associated with workforce and patient recruitment diversity

Please reach out to me directly **(Kenneth.getz@tufts.edu)** for more information about any of these current projects.

With the beginning of the new year, **Tufts CSDD's 2024 Postgraduate Course in Clinical Pharmacology, Drug Development and Regulation** is just around the corner. Now celebrating its 51st anniversary, the program welcomes academics interested in transitioning to industry, regulatory professionals, clinical investigators, government agency employees, and research professionals with a wide range of backgrounds including MDs, PhDs, JDs and MBAs. The program is offered virtually each week in February and the first week in March and provides participants with a well-rounded understanding of the drug development landscape (economic, scientific, regulatory, operating, political) and what it takes to bring a new drug or biologic to market.

Thousands of drug development professionals are alumni of this prestigious one-of-a-kind program. Top speakers from industry, academia, and the FDA share their expertise to create a highly stimulating and rewarding learning environment. Many organizations take advantage of our group registration discounts and send multiple staff each year. Please contact **Sarah Wrobel** or **Ava Feuer** or visit **our website** to register and for more information.

As always, we welcome your suggestions and ideas. And again – a happy New Year. We look forward to collaborating with you in 2024!

Kenneth Getz
Executive Director and Professor

Tufts Center for the Study of Drug Development
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Professional Development Courses

Beginning next month Tufts CSDD is hosting the 2024 **Postgraduate Course in Clinical Pharmacology, Drug Development and Regulation**. Held virtually one afternoon each week in February and early March, this course is the longest-running professional development program offered annually. Ideal for new and experienced drug developers, regulators, policy makers, clinical investigators, and academic researchers seeking a holistic understanding of the drug development process. Special rates are offered for group registrations.

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

Join our upcoming interactive webinar **"The Promise and Perils of Decentralized Clinical Trials (DCT): A Candid Conversation on the Strategic Adoption of DCTs"** – a collaboration between Tufts CSDD and Cambridge University Judge Business School.

Decentralized Clinical Trials (DCTs) have the potential to revolutionize drug development by making clinical trials more accessible. However, DCTs also bring new challenges, particularly around data quality, patient safety, and patient burden. Join us for a thought-provoking, interactive conversation on the ups and downs of DCTs in clinical research. The panel will feature: **Mary Costello (Medable**), **James Donohue (Genentech), Cristina Duran (AstraZeneca), and Ken Getz (Tufts CSDD),** and will be moderated by **Lidia Betcheva (Genentech)** and **Jennifer Kim (Tufts CSDD).** Audience members will have an opportunity to participate in both small and large group discussions.

January 22, 2024, 12:00-1:15PM EST | Register Here

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.**

Research Highlights

Introducing Our New January/February Impact Report


VOLUME 26, NUMBER 1 | January/February 2024

Tufts Center for the Study of Drug Development
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IMPACT REPORT

ANALYSIS & INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Global site activation and patient enrollment strategies produce mixed results

Activation and completion rates worsen; enrollment achievement improves

- On average, seven in 10 investigative sites (71%) were activated in late development clinical trials across all global regions—a drop from 2019 when 85.7% of sites were activated.
- The highest proportion of global investigative sites was activated in Europe, the Middle East, and Africa (EMEA), at 81%, while all other regions, including North America, Latin America, and Asia Pacific, had just over 60% of sites activated.
- Latin American investigative sites saw improvement in mean enrollment achievement (actual enrollment as a proportion of targeted enrollment) from 2019 to 2023.
- Oncology and central nervous system/neuroscience clinical trials had a significantly higher mean number of eligibility criteria than vaccine and inflammatory disease clinical trials.
- From 2019 to 2023, there was a substantial increase in mean total patients screened, but the mean numbers of patients completing trials were similar.

Global Site Activation and Patient Enrollment Strategies Produce Mixed Results

The January/February 2024 Impact Report (Volume 26, Number 1) is now available. The issue presents new benchmark data on site activation and patient recruitment and retention performance in recent global clinical trials. The report also provides data on the impact of COVID-19 on investigative site performance.

Learn more | Purchase online

Recent Publications

Getz K. **Shining a Light on Inefficiencies in Protocol Amendment Implementation**. *Applied Clinical Trials.* Published December 6, 2023. **Access article**.

Smith Z, Getz K. **A Case Study Assessment on the Rationale for, and Relevance of, Non-Core Protocol Data.** *Ther Innov Regul Sci*. Published December 1, 2023. **Access article.**

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.**

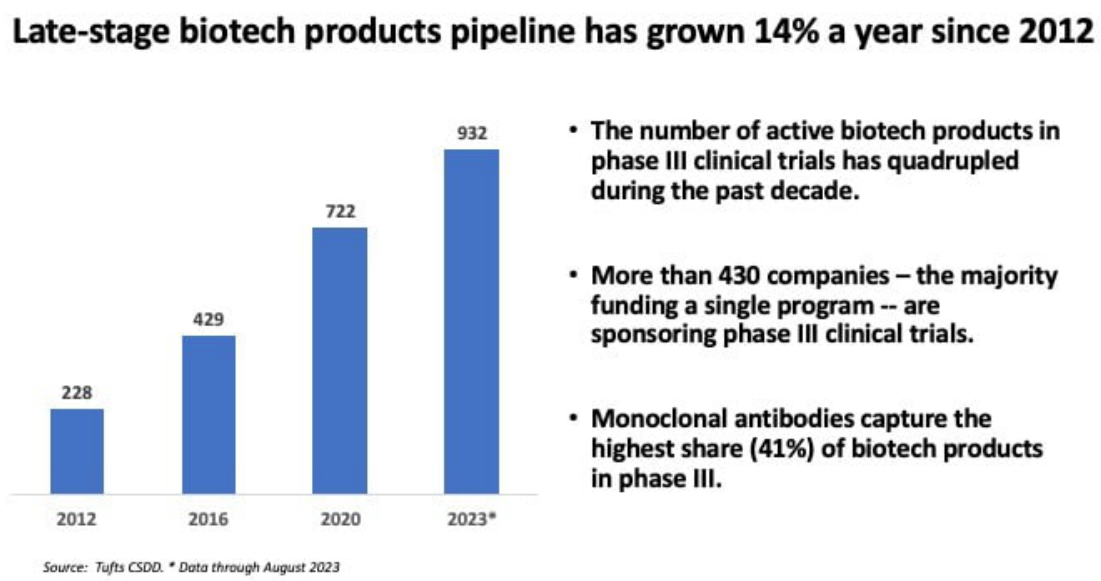
Zheng W, Kim JY, Kark R, Mascolo L. **What Makes an Inclusive Leader.** *Harvard Business Review*. Published September 27, 2023. **Access article**.

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

Data Insights Digest

2013-2015 *(N=836)*		2018-2021 *(N=952)*	
ntage of ols with ast 1 tantial dment	Mean number of substantial amendments	Percentage of protocols with at least 1 substantial amendment	Mean number of substantial amendments
2%	1.8	67%	3.1

- For all phases combine least one amendment by 20 percentage poin 2022, from 57% to 77%
- Since 2015, the preval number of amendmen increased in all clinical



To access hard-hitting Tufts CSDD charts and tables, visit https://csdd.tufts.edu/impact-reports.

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

Faculty and Staff Presentations

Upcoming Presentations

Advancing Diversity in Clinical Trials: Insights from Recent Research

Ken Getz

LinkedIn Live

Virtual | January 18

The Promise and Perils of Decentralized Clinical Trials (DCT)

Ken Getz

Tufts CSDD – Cambridge University Joint Webinar

Virtual | January 22

Trailblazers Webinar Series Discussion

Ken Getz

Greenphire

Virtual | January 30

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

Amplifying and Applying Patient Voices in Protocol Planning and Design
Ken Getz
Patients as Partners
Philadelphia, PA | March 22

Where has the Industry Been and Where Should it be Going?: Using Industry Development Benchmarks (Time, Risk, and Cost Metrics) to Improve Performance
Joseph DiMasi
Drug Development Boot Camp, Speid & Associates, Inc & Brown University Alpert Medical School
Virtual | April 11

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

Quantifying the Financial Value of Digital Endpoints in Clinical Trials | *Data Driven, Hybrid & Full Decentralized Trials*
Joseph DiMasi
Informa Connect
Philadelphia, PA | April 16-17

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

Recent Presentations

Leveraging Patient Engagement Strategies to Optimize Protocol Performance

Ken Getz

Evolution Summit

Live | December 4

Understanding and Overcoming Barriers to Technology Adoption in Clinical Trials

Maria Florez

Clinical Trials Innovation Programme US

Brooklyn, NY | November 17

Adoption Cycle for Technologies that Support DCTs

Maria Florez

Webcast Series: Effectively Adopt a Decentralized Approach, DCT Week

Virtual | November 7

Diversity and Representation in Oncology Trials

Zachary Smith, MA

Cancer Immunotherapy Summit

Boston, MA | Nov 6 - 8

Measuring Patient and Site Burden in Clinical Trials

Ken Getz, MBA

DIA Annual Meeting Japan

Live | November 5 - 8

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

Optimizing Clinical Trial Performance

Ken Getz, MBA

OCT New England

Live | November 2

Benchmarking Patient Enrollment and Use of Patient Recruitment Tactics

Mary Jo Lamberti, PhD

Outsourcing in Clinical Trials New England
Boston, MA | November 1

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

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About Tufts CSDD **Support Tufts CSDD**

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