Tufts Center for the Study of Drug Development
TUFTS CSDD INSIDER
February 2024

From the Executive Director

Dear CSDD Friends:

Collaborations and conferences are in full swing as the new year gets underway. In them we see optimism and excitement in the promise of AI/Machine Learning, real-world data and evidence, digital technologies, protocol optimization and more agile and effective operating activity. But there is also a rising undercurrent of frustration and concern that has entered the mix as budgets tighten, organizations downsize, demand for select products and services softens, and commitments to long-term investments yield to shorter-term ROI expectations.

As always, Tufts CSDD is assessing these critical operating conditions and informing drug development strategy and practice. In January, we kicked off two new working group studies: one gathering case examples of AI-enabled activity in drug development. The other assessing inefficiencies and opportunities to improve the vendor qualification and partnering process.

I'm so pleased to report that the PALADIN consortium, a pre-competitive patient advocacy group-industry collaboration facilitated by Tufts CSDD, entered its second year of activity. PALADIN has developed invaluable resources to support more effective collaborations. The consortium is now encouraging broad use of these resources and soliciting feedback on ways to make them more effective. Please contact **Trish Davidson** for more information. The Reagan-Udall Foundation-funded PACT consortium (another pre-competitive collaboration facilitated by Tufts CSDD)

is now actively collecting data and evidence on DCT deployment experience. Please contact **Zak Smith** to learn more and to participate.

We recently received grant awards to study pre-approval community-engagement practices and their impact on post-approval uptake of new medical therapies, and intentional and unintentional negative attitudes and practices toward marginalized groups and their impact on clinical team performance. And Tufts CSDD will soon be kicking-off a study validating a new tool to forecast investigative site burden and applying the results to protocol planning and design. We are looking for 6-12 sponsor or CRO companies to participate. Please **contact me** if you are interested in learning more.

February marks the beginning of our 51st Postgraduate Course. We will be welcoming a large group of registrants from academia, government agencies and the private sector. This year's program offers a newly designed virtual format and an outstanding faculty.

This *Insider* and the **CSDD website** are always excellent ways to monitor and learn about our activities. We welcome hearing from you at any time with your observations, inquiries and requests for more data and insights.

Kenneth Getz
Executive Director and Professor

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

Professional Development Courses

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. Interested in more information? Visit our website for a list of sample topics or email **Sarah Wrobel**.

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.**

Investigative Site Participation Burden Tool Validation

Tufts CSDD is launching a new study to validate a tool designed to assess investigative site participation burden in clinical trials. Up to a dozen sponsors and CROs will receive the tool and training on its use. If your organization would like to participate, contact **Ken Getz.**

Research Highlights

Introducing Our New January/February Impact Report

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

Florez M, Smith Z, Olah Z, Martin M, Getz K. **Quantifying Site Burden to Optimize Protocol Performance**. TIRS. 2024. **Access article**.

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.

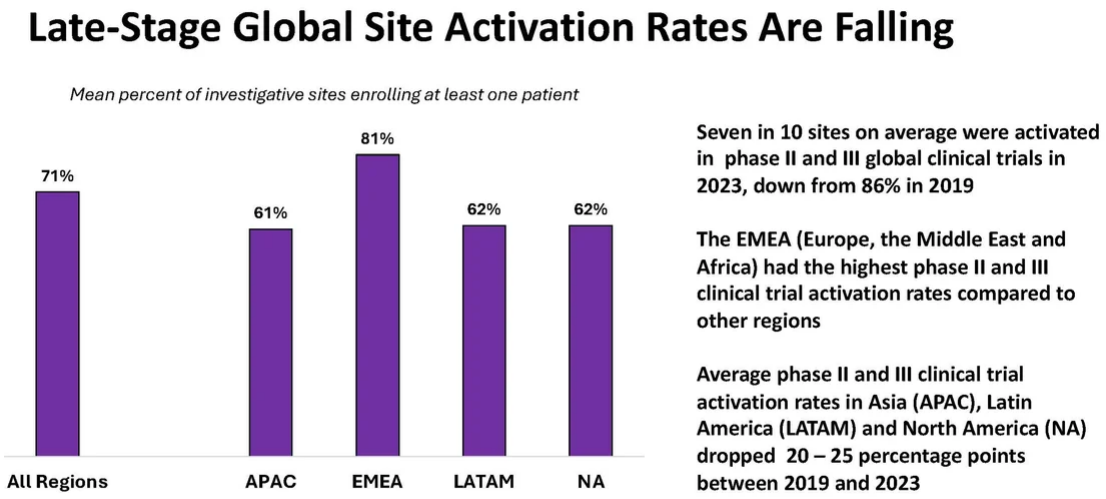
Outsourcing Model Usage and Its Relationship to Clinical Trial Performance, *Applied Clinical Trials.* Published October 12, 2023. **Access article.**

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



Source: Tufts CSDD; n= 11,000 global investigative sites

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

Site Activation and Patients Enrollment Benchmarks Among Sponsors and CROs

Mary Jo Lamberti

Summit for Clinical Operations Executives (SCOPE)

Orlando, FL| February 14

Assessing Current Levels and Identifying Barriers to RBQM Adoption

Ken Getz

Summit for Clinical Operations Executives (SCOPE)

Orlando, FL | February 14

Protocol Design Trends and Their Impact on Performance

Ken Getz

Summit for Clinical Operations Executives (SCOPE)

Orlando, FL | February 14

Optimization in the Age of Hyper-Customization

Ken Getz

Harvard – MIT Center for Regulatory Science

Virtual | March 5

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

Anticipating New Directions in Response to a Changing Drug Development Landscape

Ken Getz

EQuaTR – NorthWestern University Feinberg School of Medicine

Chicago IL | April 10

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

Panel Discussion on Innovation Adoption

Ken Getz

InformaConnect

Philadelphia, PA | April 16

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

Protocol Simplification or Optimization?

Ken Getz

CMO Summit

Boston MA | April 17

Benchmarking Patient Enrollment and Use of Patient Recruitment Tactics in Global Trials

Mary Jo Lamberti

World BI

Boston, MA | May 2

Retail Pharmacies and Clinical Trials: Perspectives from Industry, Sites & Patients

Emily Botto

Association of Clinical Research Professionals 2024

Anaheim, CA | May 4

Recent Presentations

Optimizing Study Design and Setting the Stage for Efficient Study Conduct Through Quality by Design

Ken Getz

Robert J. Margolis Center for Health Policy at Duke University and the Food and Drug Administration
Washington DC | January 31

Measuring RBQM Adoption: Insights & Opportunities
Maria Florez & Abigail Dirks
Dynamic Global Events RBQM Summit
Philadelphia, PA | January 25

The Promise and Perils of Decentralized Clinical Trials (DCT)
Ken Getz
Tufts CSDD – Cambridge University Joint Webinar
Virtual | January 22

Advancing Diversity in Clinical Trials: Insights from Recent Research
Ken Getz
LinkedIn Live
Virtual | January 18

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

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About Tufts CSDD

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