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.

Ken

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

VOLUME 26, NUMBER 1 | January/February 2024

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

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

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.

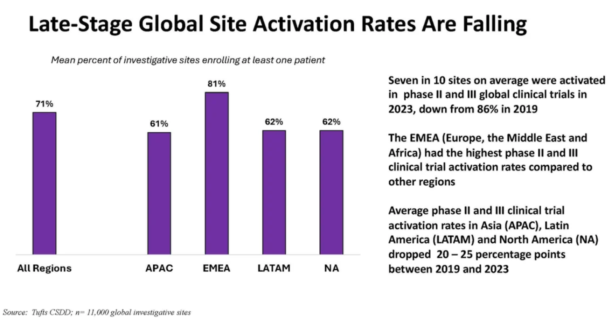
Lamberti MJ, Smith Z, DiPietro M, Barry J, Getz K. **Outsourcing Model Usage and Its Relationship to Clinical Trial Performance**. *Applied Clinical Trials*. Published October 12, 2023. Access article.

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



Late-Stage Global Site Activation Rates Are Falling

Seven in 10 sites on average were activated in phase II and III global clinical trials in 2023, down from 86% in 2019

The EMEA (Europe, the Middle East and Africa) had the highest phase II and III clinical trial activation rates compared to other regions

Average phase II and III clinical trial activation rates in Asia (APAC), Latin America (LATAM) and North America (NA) dropped 20 – 25 percentage points between 2019 and 2023

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

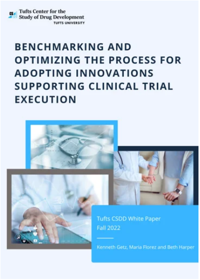
Optimizing Clinical Trial Performance
Ken Getz, MBA
OCT New England
Live | November 2

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

Subscriptions Papers and Books

Tufts Center for the Study of Drug Development
IMPACT REPORT
Planned and unplan… challenge clinical tr…
IMPACT REPORT
Protocol complexity… intensify challenges
IMPACT REPORT
ANALYSIS & INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES
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
TUFTS UNIVERSITY
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**
