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

From the Executive Director

Dear CSDD Friends:

Tufts CSDD studies conducted during the past several years have quantified significant racial and ethnic disparities, that vary by disease prevalence, among patients enrolled in pivotal trials supporting FDA approvals and EU authorizations. A recent study — and the focus of this month's *Impact Report* — documents the incidence of discriminatory and demeaning behavior in part toward individuals by race and ethnicity among drug development professionals.

The study found that 60% of professionals report experiencing 'microaggressions' including encountering unprofessional behavior, being perceived as incompetent, and receiving unsolicited negative comments. This important study expands our understanding of the extent to which diversity, equity, and inclusion challenges exist within the drug development enterprise and highlights another critical area requiring attention and improvement. For more information about this new *Impact Report*, please visit our webpage.

Our portfolio of research projects underway includes another study looking at examining conscious and unconscious bias among healthcare professionals when referring minority patients into clinical trials. And two working group studies — one profiling case examples of AI-enabled approaches supporting drug development planning and operations; another assessing inefficiencies in the vendor qualification and collaboration process — will soon begin fielding data.

This month, Tufts CSDD will be kicking-off a study validating a new tool that forecasts investigative site participation burden when executing protocols. We also anticipate initiating a study looking at optimizing the management of clinical data volume in clinical trials. Please contact me if you're interested in learning more, and participating in, any of our upcoming studies.

I also want to take a moment to thank those who reached out to me last month to discuss major operating challenges and concerns, and to suggest new areas of empirical research. Your feedback, suggestions and ideas are always welcome. Our web site (csdd.tufts.edu) and the *Insider* are always good places to periodically monitor Tufts CSDD news, projects, workshops, course offerings, publications and presentations.

Wishing you the very best,

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.

News of Note

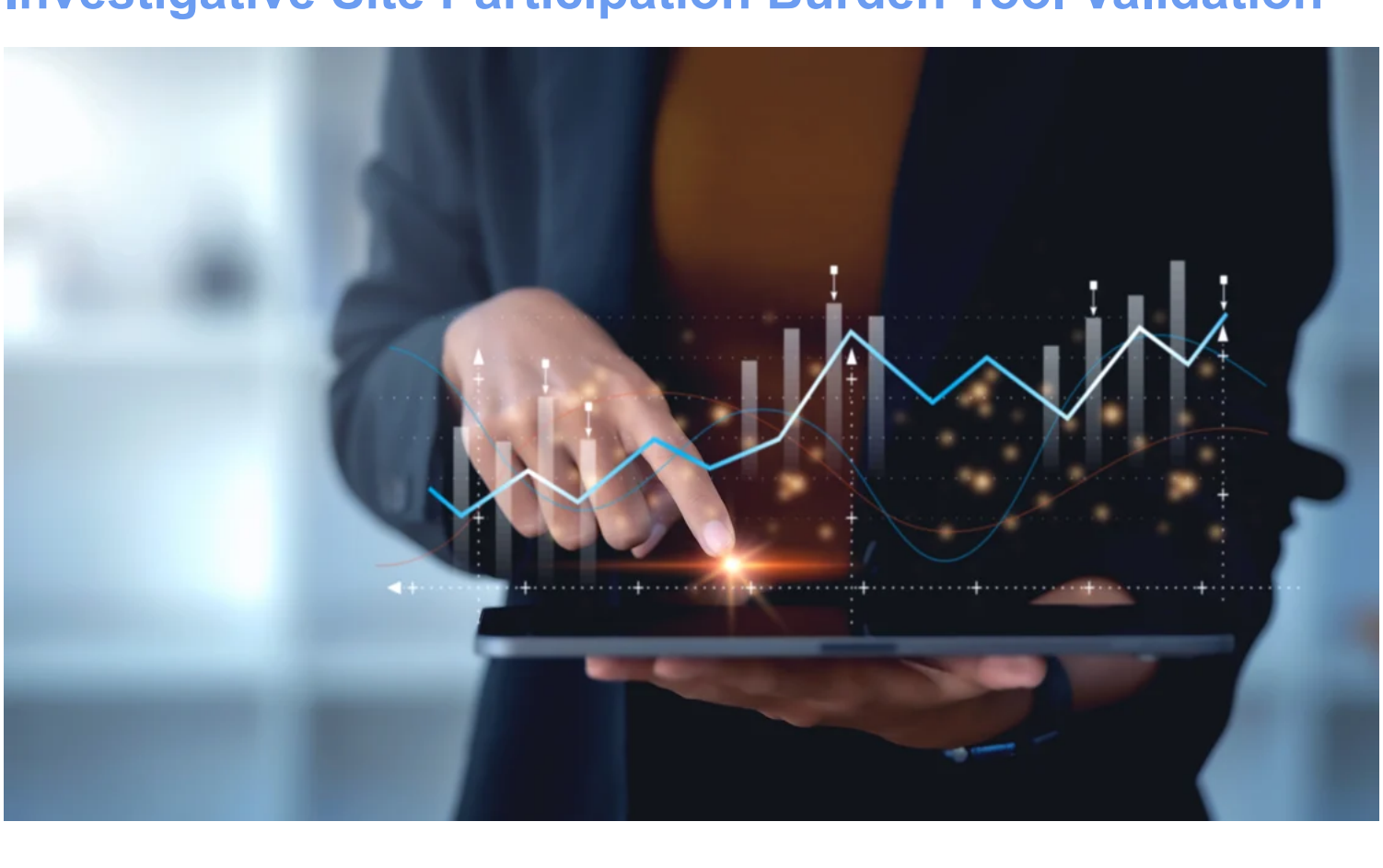
On March 1, Tufts CSDD's PALADIN Consortium launched a Playbook and a Repository of Resources for patient advocacy groups (PAG) and biopharmaceutical companies to use in optimizing their collaborations. The Playbook provides process maps and forms to initiate and guide collaborations as well as template service and confidentiality agreements to expedite PAG-industry engagements. The Resource Repository contains over 100 identified and assessed best-in-class operational resources with links to the organizations that developed them. Both the Playbook and the Resource Repository are accessible on Paladinconsortium.org and they are available free of charge.

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.

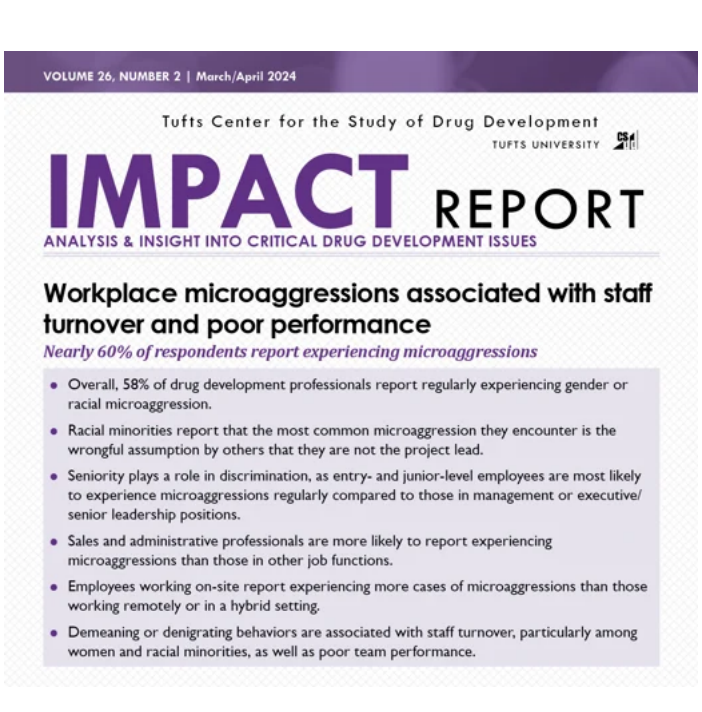
Investigative Site Participation Burden Tool Validation



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 March/April Impact Report


VOLUME 26, NUMBER 2 | March/April 2024
Tufts Center for the Study of Drug Development
IMPACT REPORT
ANALYSIS & INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES
Workplace microaggressions associated with staff turnover and poor performance
Nearly 60% of respondents report experiencing microaggressions

Workplace Microaggressions Associated with Staff Turnover and Poor Performance

The March/April Impact Report (Volume 26, Number 2) is now available. The issue presents the results of a groundbreaking new study quantifying the incidence and impact of gender and racial microaggressions among drug development professionals. The report also documents the association between microaggressions and employee turnover and poor clinical team performance.

Learn more | Purchase online

Recent Publications

Getz K. **Calling Out Check-the-Box Patient Engagement**. *Applied Clinical Trials*. March 2024.

Getz K, Smith Z, Botto E, Murphy E, Dauchy A. **New Benchmarks on Protocol Amendment Practices, Trends and their Impact on Clinical Trial Performance.** *TIRS*. 2024. Access article.

Dirks A, Florez M, Torche F, Young S, Slizgi B, Getz K. **Comprehensive Assessment of Risk-Based Quality Management Adoption in Clinical Trials**. *TIRS*. February 2024. Access article.

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.

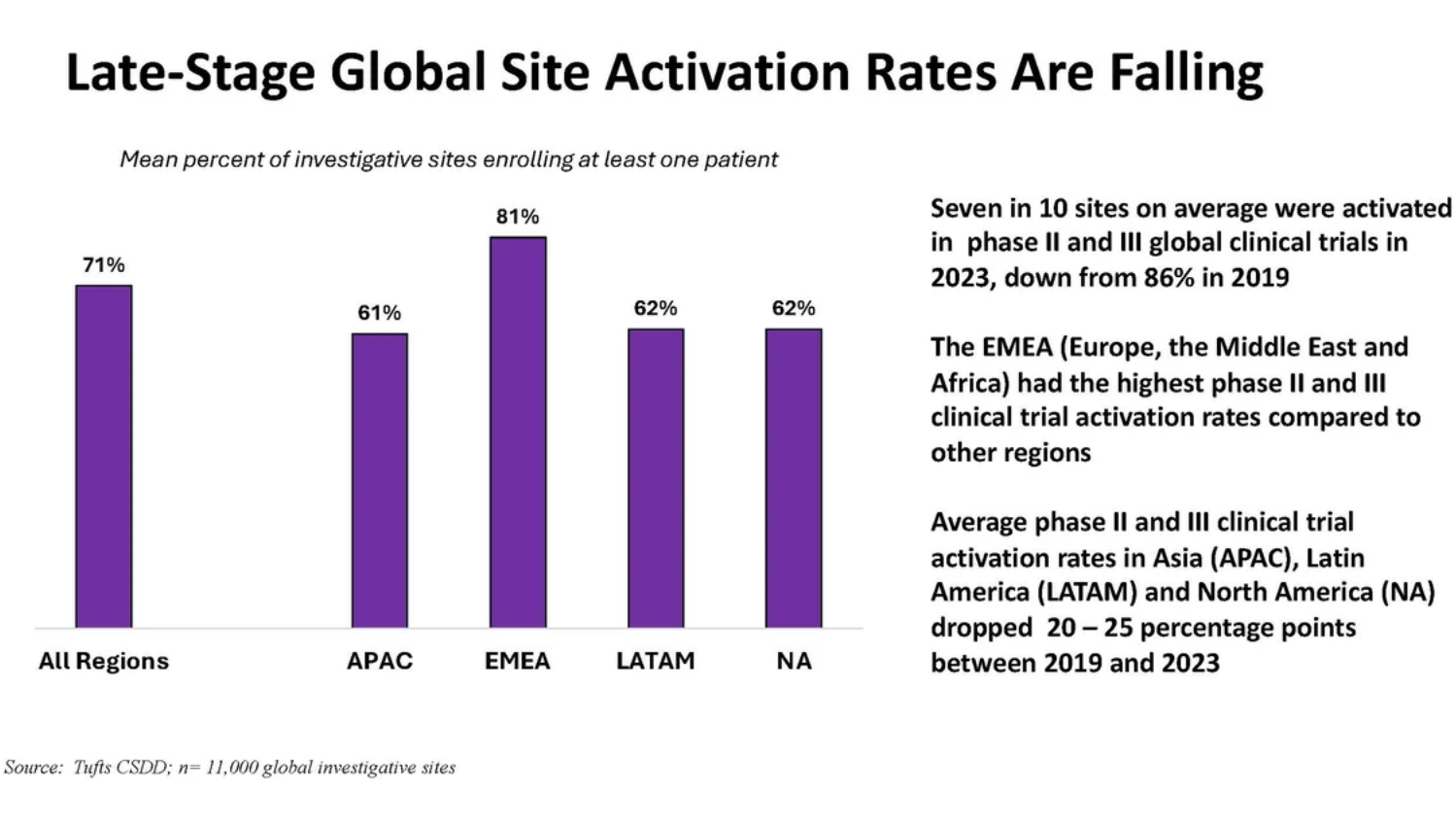
Lamberti MJ, Smith Z, DiPietro M, Barry J, Getz K. **Outsourcing Model Usage and Its Relationship to Clinical Trial Performance**, *Applied Clinical Trials.* Published October 12, 2023. Access article.

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
Mean percent of investigative sites enrolling at least one patient
71%
61%
81%
62%
62%
All Regions
APAC
EMEA
LATAM
NA
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

Interactive Workshop: Upskilling for Successful Digital Transformations in Regulatory Affairs and Clinical Operations
Maria Florez
DIA Europe
Brussels, BE | March 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
Zak Smith
InformaConnect
Philadelphia, PA | April 16

Amplifying the Patient Voice in Drug Development
Ken Getz
Reuter's Pharma 2024
Barcelona | 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

Subscriptions Papers and Books

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

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