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

From the Executive Director

Dear CSDD Friends:

This past month, we received an unprecedented number of invitations and requests to speak at global conferences, company meetings, and webinars. The most requested topics for us to cover include our studies on the value and impact of decentralized clinical trial technology solutions; the ROI of integrated evidence use in drug development programs; racial and ethnic disparities in clinical trials and in the clinical research professional workforce; and optimizing protocol design to drive performance. This *Insider* lists upcoming speaking engagements below.

The CSDD team is working on a number of multi-company studies: one assessing investigative site activation and enrollment achievement in the wake of the pandemic; another evaluating the role that socio-economic factors play in the recruitment and retention of a diverse community of patients; and a third quantifying the return-on-investment/value proposition of using digital endpoints in clinical trials.

During May we held a roundtable in Europe among sponsors and CROs to examine company experience with risk-based monitoring and risk-based quality management. We also held a workshop in Boston to discuss refining our methodology and initiate a new study quantifying the capitalized cost to develop a single successful medical therapy. And we launched our four-week professional development program 'Leadership for Drug Development Teams'.

Lastly, we will soon be initiating a new multi-company study mapping the current use of, and experience with, artificial intelligence (e.g., machine learning, natural language processing) supporting the continuum of drug development science and operations. This study is an update to one that we conducted in 2018. Please let me know if your organization is interested in learning more about participating.

Please contact me directly at Kenneth.getz@tufts.edu for information about any of our upcoming and ongoing activities. I also welcome hearing your thoughts on new areas of research inquiry.

My best regards,

Ken

Kenneth Getz
Executive Director and Professor

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

Professional Development Courses

To learn more about upcoming courses, — contact **Sarah Wrobel** or visit the Tufts CSDD **website**.

Upcoming Studies

New Working Group Study Gathering Rich Data on the Impact of DCT Deployments on Clinical Trial Outcomes

In June, Tufts CSDD is launching a new multi-company, pre-competitive consortium 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 a major foundation grant to establish this consortium. We anticipate that 18 – 20 sponsors and CROs will participate. For more information and if you would like to participate, please contact **Ken Getz.**

Research Highlights

Our Latest Impact Report


VOLUME 25, NUMBER 3 | May/June 2023
Tufts Center for the Study of Drug Development
IMPACT REPORT
ANALYSIS & INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES
Protocol design scope and execution burden continue to rise, most notably in Phase III
More countries and investigative sites contributing to operational complexity

Protocol Design Scope and Execution Burden Continue to Rise, Most Notably in Phase III

Tufts CSDD's new May/June Impact Report (Volume 25, Number 3) is now available. This issue presents insights into protocol scope variables impacting study execution burden, clinical trial timelines and performance.

Learn more | Purchase online

Recent Publications

Getz K. **Optimizing the Process for Adopting DCT Solutions**. Applied Clinical Trials. June 2023. Access article

Smith Z, Botto E, Getz K. **Racial and ethnic disparities in pivotal trials supporting FDA-approved and European Commission-approved drugs.** BioPharm Report. Spring 2023; 30(1): 6-8. Access article

Getz K. **Assessing investigative site personnel diversity and its relationship with patient enrollment diversity**. BioPharm Report. Spring 2023; 30(1): 9-12. Access article

Kim J. Y., Botto E. **Examining the Impact of Exclusionary Behaviors on Team Dynamics.** Applied Clinical Trials, March 24, 2023. Access article

Kim J. Y., Shang Z. **Research: How Anti-Asian Racism Has Manifested at Work in the Pandemic.** Applied Clinical Trials, March 13, 2023. Access article

Dirks A., Harper B., Getz K. **Assessing Investigative Site Outlook and Operating Experience Post-Pandemic.** Applied Clinical Trials, March 7, 2023. Access article

Getz K. **Rebooting the statistic that 5% of eligible patients participate in clinical trials.** Applied Clinical Trials, March 2, 2023. Access article

Lamberti M.J., Dirks A., Howie R., Getz K. **An examination of the role of the clinical research associate and factors impacting performance and experience**. Applied Clinical Trials, December 22, 2022. Access article

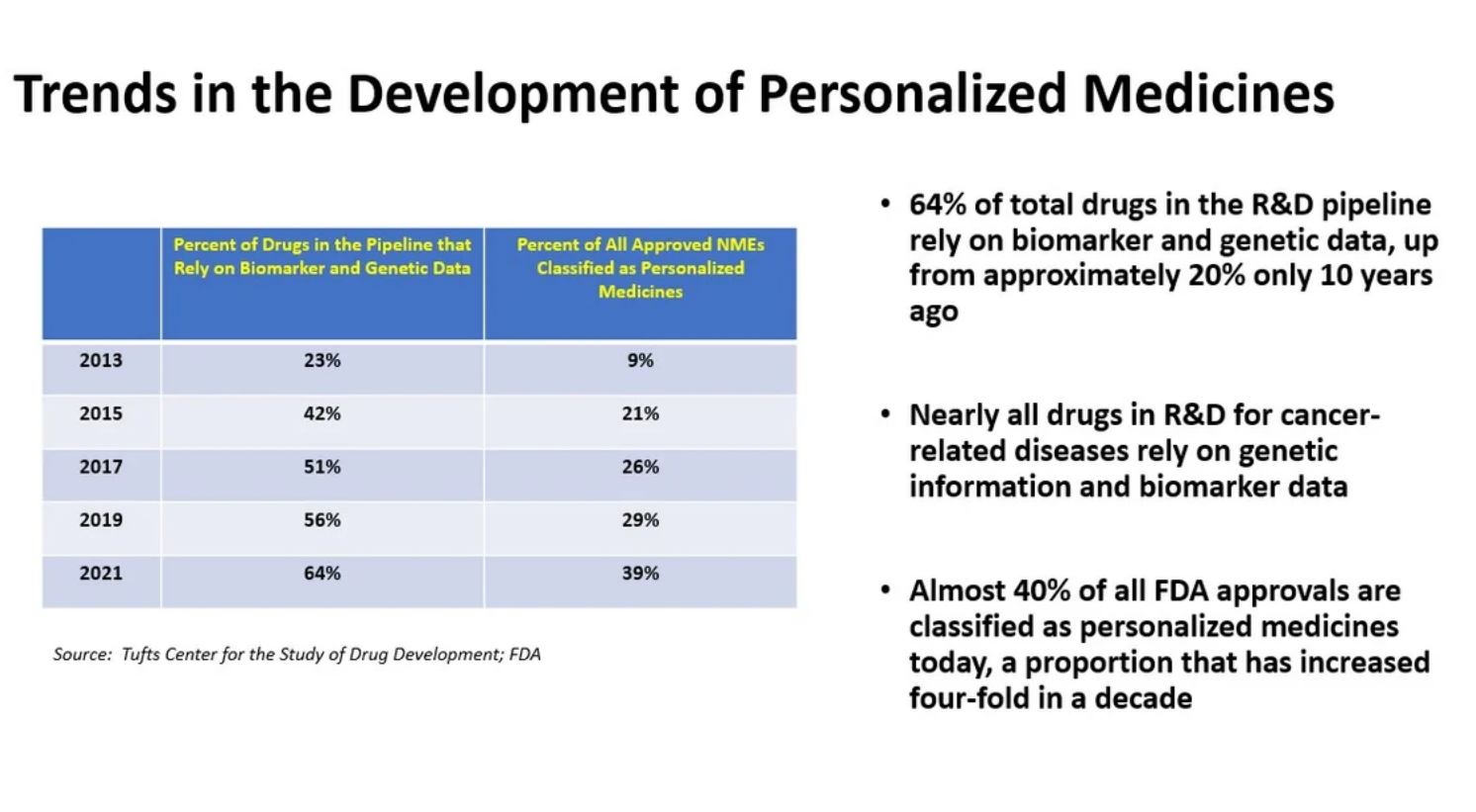
Kim, J. Y., & Shang, Z. (2022). **No, I do belong: Agentic identity work by Asian Americans to combat COVID-19 related racial microaggressions.** ***Journal of Management Studies*.** December 7, 2022. Access article

Kim J. Y., Botto E. **Methods to recruit healthcare providers for virtual advisory boards in drug development.** November 17, 2022. **Access article**

Getz K, Smith Z, Peachey J, Li G. **Leveraging Data Insights to Address the Perils of Linear Practices in Site Identification and Activation.** Applied Clinical Trials, October 18, 2022. Access article

Smith Z, Botto E, Carney C, Bagga A, Qutab B, Getz K. **Insights from a Multi-company Workshop to Apply a Patient Participation Burden Algorithm to Protocol Data.** Ther Innov Regul Sci. October 16, 2022. Access article

Data Insights Digest



Trends in the Development of Personalized Medicines

	Percent of Drugs in the Pipeline that Rely on Biomarker and Genetic Data	Percent of All Approved NMEs Classified as Personalized Medicines
2013	23%	9%
2015	42%	21%
2017	51%	26%
2019	56%	29%
2021	64%	39%

Source: Tufts Center for the Study of Drug Development; FDA

- 64% of total drugs in the R&D pipeline rely on biomarker and genetic data, up from approximately 20% only 10 years ago
- Nearly all drugs in R&D for cancer-related diseases rely on genetic information and biomarker data
- Almost 40% of all FDA approvals are classified as personalized medicines today, a proportion that has increased four-fold in a decade

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Faculty and Staff Presentations

Upcoming Presentations

Clinical Trials for Small Biotechs
Ken Getz, MBA
STAT News
Online | June 12

The Impact of the last 5 years on investigative sites
Abigail Dirks, MS, and **Ken Getz, MBA**
ACRP
Online | June 14

The Impact of Patient Engagement on Drug Development Performance
Ken Getz, MBA
DIA China
Online | June 17

Maximizing Diversity in Clinical Trials
Ken Getz, MBA
Finn Partners
Boston | June 20

Performance, interrupted: Examining DEI dynamics that can impact team performance in drug development.
Jennifer Kim, PhD
DIA Annual Meeting
Boston | June 26 - 29

Measuring Impact of Patient Engagement Across Research and Development
Jennifer Kim, PhD
DIA Annual Meeting
Boston | June 26 – 29

Sponsor-CRO Collaborations and the Impact of Decentralized Clinical Trials
Mary Jo Lamberti, PhD
DIA Annual Meeting
Boston, MA | June 26

Recent Presentations

Managing Protocol Complexity to Optimize Clinical Trial Performance
Ken Getz, MBA
Linking Leaders
Boston | May 10

Innovation in the pharmaceutical industry: New estimates of R&D costs
Joe Dimasi, PHD
PhRMA R&D Roundtable
Boston | May 11

Innovation in Clinical Research: Why it Takes So Long to Adopt a New Solution
Ken Getz, MBA
MAGI East Conference
Philadelphia | May 21 - 24

Sponsor-CRO Collaborations and the Impact of Decentralized Clinical Trials
Mary Jo Lamberti, PhD
DIA Annual Meeting
Boston, MA | June 26

State of the Drug Development Industry
Ken Getz, MBA
Chief Medical Officers Summit
Boston, MA | April 3 - 4

Quantifying the Value Proposition of DCT Deployment
Ken Getz, MBA
Informa Decentralized Clinical Trials
Boston, MA | April 18 - 20

The Impact of DCT Use on Sponsor-CRO Relationships
Mary Jo Lamberti, PhD
Informa Decentralized Clinical Trials
Boston, MA | April 19

The Economics of Implementing Phase 0 Techniques – Methods for measuring Financial Value
Joseph DiMasi, PhD
4th International Phase-0/Microdosing Stakeholder Meeting: Intra-Target Microdosing (ITM): Revolutionizing Clinical Pharmacology and Drug Development
Boston, MA | April 24

Assessing Patient Engagement Capabilities and their Impact
Ken Getz, MBA
DIA Europe
Basel, Switzerland | March 23

Examining Current Patient Engagement Activities and Investments within Sponsor and CRO Companies
Ken Getz, MBA
DIA Europe
Basel, Switzerland | March 22

The Impact of Decentralized and Hybrid Trials on Sponsor-CRO Collaborations
Mary Jo Lamberti, PhD
SCOPE Summit
Orlando, FL | February 8

Panel Discussion - Navigating Global Crises: Pandemic War, Hyperinflation and Supply Chain
Ken Getz, MBA
SCOPE Summit
Orlando, FL | February 7

Remote Teams in Clinical Research During the COVID-19 Pandemic
Maria Florez, MA and Mary Jo Lamberti, PhD
Clinical Research Webinar
Online | January 26-27

Clinical Operations and Clinical Outsourcing Roundtables
Ken Getz, MBA
Linking Leaders
New York, NY| January 17 - 18

New Insights into Managing Investigative Sites to Optimize Patient Enrollment Diversity
Ken Getz, MBA
Evolution Summit
Orlando, FL | December 8

Clinical Research Professionals and the Shift to Remote Work During the COVID-19 Pandemic
Maria Florez, MA and Mary Jo Lamberti, PhD
Clinical Operations in Oncology, Virtual Conference
Online | December 1

Measuring the Impact of the Pandemic on Drug Development Productivity and Performance
Ken Getz, MBA
Outsourcing Clinical Trials New England
Boston, MA | November 10

Digital Transformation and Clinical Research Team Effectiveness
Maria Florez, MA
Clinical Trials Europe
Online | November 2-4

Impact of Running Clinical Trials During the Pandemic and Lessons Learnt
Ken Getz, MBA and Maria Florez, MA
Clinical Trials Europe
Online | November 2-4

Where Has the Industry Been, and Where Should it be Going?
Joseph DiMasi, PhD
Speid Associates, Inc and Brown University Medical School
Online | November 2-4

Increasing Efficiency and Reducing Cycle-Times in Drug Development: Multi-Stakeholder Views on the Topic
Zak Smith, MA
Clinical Trials Europe
Online | November 3

Optimizing protocol design to improve performance and efficiency
Ken Getz, MBA
Clinical Trials Europe
Online | November 2

Subscriptions Papers and Books

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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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