Tufts Center for the Study of Drug Development

TUFTS CSDD *INSIDER*

AUGUST 2022

From the Executive Director

Dear CSDD Friends:

Today's drug development operating environment is rich – some might say 'overloaded' – with unprecedented opportunities for customization. To support and enable planning and design, execution, analysis and reporting, numerous collaborations, approaches and solutions are being leveraged and deployed, each offering the promise of compressing clinical trial timelines, improving quality, driving efficiency, and reducing costs. Yet actual program
and clinical trial outcomes have consistently shown the opposite: Customization is associated with longer cycle items, inefficiency, higher cost and risk.

In discussions with drug development thought leaders and executives, there is clearly growing interest in exploring novel initiatives to transform the traditional drug development paradigm and counter the negative effects of customization. To name a few: Parallel vs. sequential development stages and processes; agile multi-functional coordination; integrated vs. siloed systems and data elements; comprehensive and embedded machine learning vs. Localized functional learning.

Many of Tufts CSDD's current and planned empirical studies are adding to our understanding of combinations of customization solutions including hybrid approaches that drive better development performance. One study underway is looking at multiple scientific and executional protocol design variables that are associated with faster clinical and regulatory durations; another study is assessing the spectrum of full service and functional service outsourcing models in use today and their relationship with clinical trial performance outcomes. In September we will be launching studies looking at pandemic/post-pandemic site activation, enrollment and retention rates and at the impact of DCT approaches on patient enrollment diversity and access.

July was a very busy period for the CSDD team. We have been preparing our fall and winter professional development course offerings; responding to requests for proposals; actively collecting study data; kicking off and completing projects; and preparing manuscripts, articles and presentations.

Please check our web site (CSDD.tufts.edu) or send me an email to learn more about our current and planned studies.This *Insider* is also a good source for updates on Tufts CSDD research projects, course offerings, publications and presentations.

As always, we welcome your inquiries, input and collaboration. Enjoy the rest of your summer!

Kenneth Getz
Executive Director and Professor
Kenneth.Getz@tufts.edu

Tufts Center for the Study of Drug Development
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Working Group Studies

Working Group Study Assessing Drug Development Workforce Diversity and its Relationship with Innovation Effectiveness and Team Dynamics

Tufts CSDD has launched its DEI
Dynamics working group to examine the impact of DEI dynamics on team cohesion and productivity. We will develop a survey tool during the summer, and will launch the survey in the Fall. Interested companies should reach out to **Jennifer Kim** for more information.

Professional Development Courses

Robert Franco, PhD

Course Facilitator; President, Coe Point Associates LLC

Sharpen your leadership skills and unleash your drug development team's potential!

This highly interactive online course, brings together team leaders, program managers, functional directors, and other drug development professionals from across the industry to build leadership skills, improve cross-functional performance, and enhance R&D productivity. Delegates meet online in large and small groups over the course of four weeks. Created specifically for pharmaceutical professionals, the program uses case studies to teach you how to lead multi-disciplinary teams and to collaborate effectively in managing complex challenges in pharmaceutical R&D. New program material has been incorporated to focus on how remote teams can operate effectively and productively. We will examine solutions and strategies for getting the most out of remote teams including creating and maintaining high levels of engagement, improving communications, sustaining motivation, establishing and measuring performance, and conducting more productive team meetings in a distributed environment. For more information, contact **Sundé Daniels**.

Research Higlights

Our latest Impact Report:

Innovations Supporting Clinical Trial Execution Take Nearly Six Years to Adopt

The July/August 2022 issue of the Tufts CSDD Impact Report Series (Vol. 24, No.4) is now available. This issue provides new baseline duration measures for a standard four-step adoption cycle and identifies factors that can accelerate the deployment and use of new innovations supporting clinical trials.

Learn more | Purchase

Recent Publications

Lamberti MJ, Smith Z, Dirks A, Caruana T, Mitchell T, Getz K. The Impact of Decentralized and Hybrid Trials on Sponsor and CRO Collaborations. *Applied Clinical Trials.* 2022. **Access article**

Getz K. **Quantifying Protocol Deviation Experience by Clinical Phase.** *Applied Clinical Trials.* 2022; volume 32, issue 6. **Access article**

Florez M, Botto E, Foster Z, Seltzer W, Valastro B, Ashmore L, Getz K. **Improving Diversity in Clinical Trial Volunteer Participation by Addressing Racial and Ethnic Representation Among the Clinical Research Workforce.** *Applied Clinical Trials.* **Access article**

Getz K, Florez M, Botto E, Ribeiro K, Goller G, Robinson L, Abdullah O. **Global Investigative Site Personnel Diversity and Its Relationship with Study Participant Diversity.** TIRS. 2022. Doi.org/10.1007/243441-022-00418-9. **Access article**

Smith Z, Botto E, Getz K. **Quantifying Diversity and Representation in Pivotal Trials Leading to Marketing Authorization in Europe.** TIRS. 2022. Doi.org/10.1007/s43441-022-00421-0. **Access article**

Kim, J. Y. & Botto, E. (2022). **The Impact of Gender Microaggressions on Team Performance in Drug Development.** *Applied Clinical Trials*. **Access article**

Getz K, Smith Z, Jain A, Krauss R. **Benchmarking Protocol Deviations and their Variation by Major Disease Category.** *TIRS* 2022. **Access article**

Burt T, Roffel AD, Langer O, Anderson K, DiMasi JA. **Strategic, feasibility, economic, and cultural aspects of Phase 0 approaches.** Clinical and Translational Science 2022. **Access article**

Kim, J. Y. & Getz, K. (2022). **Measuring patient satisfaction as a primary outcome for patient-centric initiatives.** *Applied Clinical Trials*. **Access article**

Kim, J. Y., Brockner, J., & Block, C. J. (2022). **Tailoring the intervention to the self: Congruence between self-affirmation and self- construal eliminates the MBA gender performance gap.** *Organizational Behavior and Human Decision Processes*, *169* (March). **Access article**

Smith Z, Bilke R, Pretorius S, Getz K. **Protocol Design Variables Highly Correlated with, and Predictive of, Clinical Trial Performance.** Ther Innov Regul Sci. 2022 Jan 30. doi: 10.1007/s43441-021-00370-0. Epub ahead of print. PMID: 35094369. **Access article**

Data Insights Digest

Oncology and Non-Oncology Clinical Trials Durations

(from Protocol Ready to Database Lock -- 2014-2019)

Mean Days and (Coefficient of Variation)	Non-Oncology Drugs and Biologics	Oncology Drugs and Biologics
Phase I	573.1 (.57)	1,018.3 (.35)
Phase II	991.4 (.66)	1,481.7 (.62)
Phase III	1,214.3 (.46)	1,769.3 (.49)

- **The duration of clinical trials for oncology drugs and biologics in each phase are considerably longer – by 12 to 18 months on average.**
- **The coefficients of variation around mean clinical trial durations for oncology and non-oncology drugs and biologics are comparable.**
- **Despite longer trial durations by phase, the average overall clinical duration for oncology development programs is only five months longer than non-oncology due to more parallel and phase II-III combination activity.**

Source: Tufts CSDD

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Faculty and Staff Presentations

Upcoming Presentations

Hot Topics in Drug Development
Ken Getz, MBA
ZS Biostatistics Leadership Council
Online | August 4

The Changing Environment for RBQM
Ken Getz, MBA
RBQM Live
Online | September 8

RBQMLIVE

Evolving the Biomedical Innovation System
Ken Getz, MBA

IQVIA Life Sciences Innovation Forum
Online | September 13

Accelerating Innovation Adoptions Supporting Clinical Trial Execution
Ken Getz, MBA
CTTI Fall Steering Committee Meeting
Washington DC | September 20

Characterizing the Innovation Adoption Cycle for Innovations Supporting Virtual Clinical Trials
Maria Florez
Scope Europe
Barcelona | October 3-4

Diversity and Representation Among the Clinical Research Workforce: A factor in patient engagement and recruitment?
Maria Florez
Scope Europe
Barcelona | October 3-4

The Impact of Decentralized Trials on Sponsor-CRO Collaborations
Mary Jo Lamberti, PhD
Outsourcing in Clinical Trials New England
Boston, MA | October 12-13

Digitizing Clinical Trials
Maria Florez, MA
18th Clinical Trials Innovation Programme
Boston, MA | October 26-27

The Impact of Decentralized Clinical Trials Disruption on Sponsor-CRO Relationships
Mary Jo Lamberti, PhD
SCOPE
Orlando, FL | February 6-9

Recent Presentations

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 East Coast
Boston, MA | July 12-13

Optimizing the Pharma Workforce for Trial Success in the Digital Era
Maria Florez, MA
DIA Annual Meeting
Chicago, IL | June 23

Ensuring Diversity in Clinical Trials
Maria Florez, MA
DIA Annual Meeting
Chicago, IL | June 23

Where Are We? Assessing Organizational Preparedness and Capabilities to Support Patient Engagement
Ken Getz, MBA
DIA Annual Meeting
Chicago, IL | June 21

Approaching the Assessment of Clinical Protocol Complexity
Zak Smith, MA; Denise Messer

DIA Annual Meeting
Chicago, IL | June 21

Quantifying Return on DCT Investment
Ken Getz, MBA
DIA Annual Meeting - Innovation Theater
Chicago, IL | June 21

Keynote Diamond Panel Discussion: The Future of Healthcare
Ken Getz, MBA
DIA Annual Meeting
Chicago, IL | June 20

State of the Drug Development Industry
Ken Getz, MBA
WCG
Webinar | June 15

COVID-19 Clinical Development Lessons Learned
Ken Getz, MBA
IQVIA Institute
Webinar | June 7

Protocol Simplification and Optimization
Ken Getz, MBA
French AMMIS
Online | May 24

Characterizing the Innovation Adoption Process for Technologies Supporting Virtual Clinical Trials
Maria Florez, MA
Virtual Clinical Trials Summit
Philadelphia | May 18 - 19

VIRTUAL CLINICAL TRIALS Summit

Signature Series: Fostering Diversity and Inclusion in Clinical Research
Maria Florez, MA
ACRP 2022
Orlando, FL | April 24

The Economics of Phase-0 Approaches, Safer, Accelerated, Targeted, and Human-Specific Translation in Drug Development
Joseph DiMasi, PhD
3rd International Phase-0/Microdosing Stakeholder Meeting
The Netherlands | April 22

Phase-0 Microdosing Network

Patient Engagement and the Deployment of DTC
Ken Getz, MBA
DTC National
Live | April 20

Assessing the Adoption of Innovations Supporting Drug Development Operations
Ken Getz MBA
R&D Leadership Summit, The Conference Forum
Aventura, FL | April 11

State of the Drug Development Industry
Ken Getz, MBA
Chief Medical Officers Summit, The Conference Forum
Boston, MA | April 4

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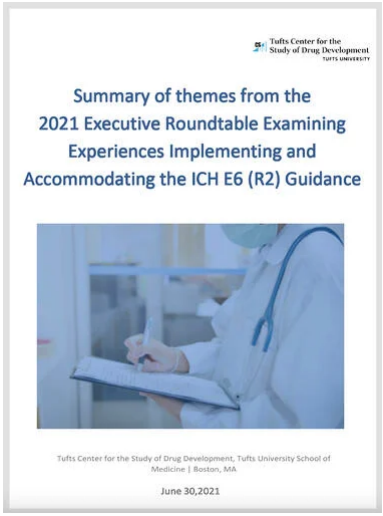

Download White Paper

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About Tufts CSDD

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Tufts CSDD, 145 Harrison Ave, Boston, Massachusetts 02111, United States, (617) 636-2170