Tufts Center for the Study of Drug Development

TUFTS CSDD *INSIDER*

January 2021

From the Director

Dear CSDD Friends,

This January Insider marks the beginning of my tenure as the Center's new director. It is a responsibility that comes at a critical point in time. Although last year was filled with uncertainty and significant challenge, we can all agree that it was also remarkable for its unprecedented collaboration, resiliency and innovation. In responding to the pandemic, all aspects of drug development science, operations and regulation received greater visibility and attention, and offered compelling new insight into the possibilities for accelerating timelines and improving efficiencies and quality.

The CSDD team and I are very excited about the opportunities ahead. During the first half of 2021, we will publish the results of just-completed studies including new benchmarks on protocol design practices and their impact on clinical trial performance; operating team experience adapting to rapid growth in data volume and the increasing frequency of interim assessments; and another validating a comprehensive patient burden algorithm to optimize protocol design.

In collaboration with the Bill & Melinda Gates Medical Research Institute, we will launch a global survey in late January assessing remote team effectiveness and efficiency managing drug development activity. We'll send out invitations to participate in this important survey shortly.

Several CSDD studies are underway looking at diversity and inclusion: One quantifying participant demographic diversity in drug and biologic approvals by the European Medicines Agency and another study looking at the diversity of global investigative site personnel and ways to better enable their involvement and success in clinical research.

This Insider is a good place to find highlights and updates on Center activity. I also encourage you to visit our **website** periodically for more information and to get involved in our programs and studies. As always, we welcome your ideas, input and feedback.

Given growing demand for robust, evidence-based inquiry to improve drug development performance, efficiency and economics, the work of the Tufts Center could not be more important or relevant.

Wishing all of you a healthy, prosperous and meaningful new year.

Ken

Kenneth Getz
Director and Professor

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

Working Group Studies

Working Group Study to Benchmark Global Investigative Site Diversity

In December, Tufts CSDD kicked off a new study benchmarking diversity and disparities among the global community of investigative sites involved with industry-funded clinical trials. Twenty companies—sponsors and CROs— have already joined the working group, and there is room for more. **Contact us for more information.**

New Working Group Study to Identify Best Practices in the Adoption of Innovations Supporting Clinical Operations

In late January and early February, Tufts CSDD is launching a new working group study looking at how sponsors and CROs adopt new and transformational practices and solutions to support clinical research operations. The study will identify best practices and opportunities to accelerate innovation adoption. **Contact us for more information.**

Global Surveys

New Global Survey Assessing Remote Team Effectiveness in Managing Clinical Research Activity

This month, Tufts CSDD— in collaboration with the Bill & Melinda Gates Medical Research Institute—will launch a global survey to assess how the remote management of clinical research activity impacts study team interactions, productivity, overall performance and continuity. We encourage the clinical research community to take part in this important survey. If you are interested in receiving a link to the online survey when it is launched, **please provide your contact information.**

Professional Development Courses

Health Economics and Outcomes Research (HEOR) Certificate Program

The Tufts University **Graduate School of Biomedical Sciences (GSBS)** Clinical and Translational Science (CTS) Graduate Program offers an accredited **Certificate Program in Health Economics and Outcomes Research (HEOR)**.

Individuals seeking an introduction to HEOR, including professionals in the pharmaceutical and biotechnology industry, clinicians and other health care professionals, graduate degree holders, and graduate degree students, are encouraged to apply.

The Program is designed to accommodate the schedules of learners who are already immersed in professional careers or other training programs. There are three courses:

- Introduction to Health Economics and Outcomes Research (2 credits)
- Health Technology Assessment (HTA) (2 credits)
- Real World Evidence (1 Credit)

Learn more and apply for January 2021 semester

Tufts CSDD Partnership with The American College of Greece (ACG)

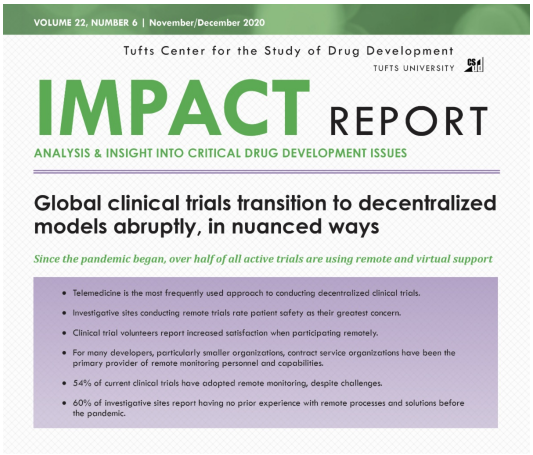
ACG Professional Certificate in Clinical Pharmacology, Drug Development and Regulation

Tufts Center for the Study of Drug Development is excited to collaborate with The American College of Greece to offer an online version of its highly acclaimed Postgraduate Course in Clinical Pharmacology, Drug Development and Regulation. This new two-week, intensive, live-interactive program offers a Professional Certificate in Clinical Pharmacology, Drug Development and Regulation from the Deree – School of Graduate and Professional Education.

Learn more and register online

Research Highlights

Our Latest *Impact Report*



Transition to Decentralized Clinical Trials during the Coronavirus Pandemic is Far More Nuanced than Expected

Our November/December 2020 *Tufts CSDD Impact Report* presents results of our analysis of global surveys of investigative sites and interviews with representatives of the largest pharmaceutical companies.

Learn more | Purchase online

***Coming in Early January:**
Rising Protocol Design Complexity Driving Rapid Growth in Clinical Data Volume

Individual subscription | Corporate subscription

Recent Publications

Getz K. **Public Trust and the 'Last Mile' for COVID-19 Vaccines.** *Applied Clinical Trials*. 2020; 29 (12): 11 – 12. **Access article**

Gottlieb, N, Byrne, J, Getz, K. **Investigative Site Placement Practices to Support Operation Warp Speed**. 2020; 29 (12): 26-28. **Access article**

Raj Indupuri, Sheila Rocchio, Kenneth A. Getz, Beth Harper, Michael Wilkinson. **Enabling Digital Transformation: Managing External Clinical Data Sources to Advance Drug Development.** *Applied Clinical Trials* 2020; November 13. **Access article**

Stephen LeBreton, Mary Jo Lamberti, Adam Dion, Kenneth A. Getz. **COVID-19 and Its Impact on the Future of Clinical Trial Execution.** *Applied Clinical Trials* 2020; October 22. **Access article**

Galson S, Austin C, Khandekar E, Hudson L, DiMasi J, Califf R, Wagner J. **The Failure to Fail Smartly.** *Nature Reviews Drug Discovery* 2020; Sep 23. Published online: **Access article**

Harper B, Wilkinson M, Indupuri R, Rocchio S, Getz, K. **Evolving Clinical Data Strategies and Tactics in Response to Digital Transformation**. *Ther Innov Regul Sci* 2020; Sep 14.

Access article

DiMasi, J.A. **Research and Development Costs of New Drugs [Letter to the Editor].** *JAMA* 2020; 324(5):517. Access article

Cameron D, Willoughby C, Messer D, Lux M, Aitken M, Getz K. **Assessing Participation Burden in Clinical Trials: Introducing the Patient Friction Coefficient.** *Clinical Therapeutics* 2020; 42(8):e150-e159. Access article

Faculty and Staff Presentations

Recent Presentations

Town Hall: Where R&D Meets WFH
Ken Getz, MBA
Copyright Clearance Center
Online | December 15

Trials and Tribulations of Antimicrobial Drug Development: Assessing the Economic and Political Landscape
Kenneth I Kaitin, PhD
Stuart B. Levy Center for Integrated Management of Antimicrobial Resistance Seminar
Online | December 17

Leveraging Patient and Participant Input to Optimize Protocol Design
Ken Getz, MBA
Trial Innovation Network
Online | January 4

Upcoming Presentations

Predictive Dosing to Reduce Clinical Trial Risk
Ken Getz, MBA
xTalks
Online | February 10

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About Tufts CSDD

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