Tufts Center for the Study of Drug Development

# TUFTS CSDD *INSIDER*

NOVEMBER 2021

## From the Director

Dear CSDD Friends:

Demand for data and insights to inform drug development strategy and execution has peaked as we confront a new and uncertain operating environment post pandemic. Improvement in diversity, equity and inclusion (DEI); adoption of decentralized clinical trial support to facilitate patient engagement; establishment of new collaboration models; implementation of new clinical trial designs; collection and analysis of more structured and unstructured data; and the optimization of manufacturing and delivery of investigational product and clinical trial supplies are but a partial list of high demand areas.

Tufts CSDD research projects and educational offerings are addressing this demand in a variety of ways. Several CSDD studies underway, for example, are using benchmark data to model the return-on-investment of new solutions and practices (e.g., DEI programs, DCT initiatives, real world evidence) and to identify predictors of development performance, economics and clinical phase and overall success. The CSDD team continues its assessment of clinical trial designs and their relationship to patient and investigative site participation burden. This month we will be completing a study characterizing and identifying ways to optimize the adoption of innovations supporting clinical trial planning and execution and another examining the compelling relationship between investigative site personnel diversity and the demographic representation of patients enrolled in clinical trials.

Rising demand for data and insights is also reflected in our growing Circle of Supporter membership. This community of supporters not only participates in our working group studies and receives our publications, but also leverages Tufts CSDD expertise, data and insights in one-on-one and company meetings and offsite programs. Please contact Michela Davola (Michela.davola@tufts.edu) to learn more about joining our Circle of Supporters.

This monthly *Insider* highlights studies that will soon begin and are underway. It also lists places where the results of completed research are being shared and discussed in peer-reviewed journals, trade publications and conference presentations. In addition to the *Insider,* I encourage you to periodically check our web site for updates on all Center activity including our virtual and in-person professional development and leadership courses. As always, we welcome your ideas, feedback and participation.

Kenneth Getz
Director and Professor

Tufts Center for the Study of Drug Development
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## Development and Advancement

Tufts CSDD has been actively welcoming its FY 2021 - 2022 Circle of Supporter members. Financial support from our community of sponsors is crucial to our mission and enables us to cover our operating costs, conduct longitudinal studies, inform our research priorities, prepare manuscripts, attend meetings and presentations,

train summer interns and mentor international university students. Twenty organizations have joined our Circle of Supporters and we encourage additional members. **Contact Michela Davola**, Associate Director, Development and Fundraising for more information.

## Working Group Studies

### Working Group Quantifying the Value Proposition of Organization-Specific Patient Engagement Initiatives

Tufts CSDD — in collaboration with the Drug Information Association (DIA) — is kicking-off a new working group quantifying the value proposition of organization-specific patient engagement initiatives. Participating companies will meet to define relevant outcome measures; shape a global survey instrument and secondary data gathering activity; review and discuss study results and their implications. **Contact us if you would like to participate.**

## Professional Development Courses


### Invest in the most impactful 24 hours of your pharmaceutical career

Tufts CSDD's Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation will resume in 2022 as an interactive and convenient online program, held on six separate days, throughout the month of April. Whether you are new to the industry or need a refresher, this highly acclaimed program will provide you with advanced instruction in practical and technical problem-solving in the areas of clinical pharmacology, drug

development & clinical trial strategies, biopharmaceutical development, drug safety, and new drug regulation. During an exclusive Q&A session with a senior FDA official, participants will receive first-hand insights into FDA priorities and operations and will emerge with a better understanding of the regulatory process. For more information, contact Sundé Daniels.

## Research Higlights

### Our Latest Impact Report


VOLUME 23, NUMBER 6 | November/December 2021

Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

IMPACT REPORT

ANALYSIS & INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

New study finds site personnel race and ethnicity highly correlated with diversity of patients enrolled

*Staff in private sector sites more reflective of diverse patient communities*

- In the U.S., one-third of site personnel based in academic medical centers (AMCs) and community hospitals and nearly half of personnel in dedicated sites and private practices are representative of minority populations.
- Less than 10% of investigative site personnel in Europe are representative of minority populations.
- Among the most active therapeutic areas in drug development, infectious diseases, vaccines, and endocrinology have the most diverse clinical trial personnel.
- AMCs and community hospitals worldwide enroll a disproportionately high percentage of white patients into industry-funded clinical trials, whereas dedicated sites and private practices enroll much more diverse patient populations.
- Worldwide, regardless of geographic location, as the mix of site personnel by race and ethnicity increases, the diversity of patients enrolled—with the exception of Asian patients—also increases.
- The proportion of a given race or ethnicity among site personnel closely aligns with the corresponding race or ethnicity of patients enrolled in clinical trials at that site.
- Sites with more diverse personnel are more likely to view diversity as a critical success factor and to have developed standard operating procedures to encourage and support diversity.

### New Study Finds Site Personnel Race and Ethnicity Highly Correlated with Diversity of Patients Enrolled

Our November/December Tufts CSDD Impact Report presents compelling results characterizing how organizations have adapted during the pandemic, what steps were taken and resources provided, and the impact on clinical team attitudes and experience.

**Learn more | Purchase online**

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### Recent Publications

Getz K. **Amplifying Patient Voices in Protocol Design**. Applied Clinical Trials. Sept 2021; 30:9 **Access article**

Smith, Z; Wilkinson, M; Carney, C; Grove, N; Qutab, B; and Getz, K. **Enhancing the Measure of Participation Burden in Protocol Design to Incorporate Logistics, Lifestyle, and Demographic Characteristics.** TIRS (2021). **Access article**

Michaels, D.L., Peña, Y., Kunz, B.L., Getz K. **Evaluating the Feasibility and Validity of a New Tool to Assess Organizational Preparedness and Capabilities to Support**

**Patient Engagement in Drug Development.** TIRS (2021). **Access article**

Florez M., Lamberti M.J., Getz K. **Remote Clinical Research Team Experience and Effectiveness During the COVID-19 Pandemic.** Applied Clinical Trials. Published Online. July 13, 2021. **Access article**

Qian H, Qui L, Fanzhen L, Kaitin KI, Shao L. **A survey of survival outcomes for targeted cancer drugs approved by the US Food and Drug Administration.** TIRS 2021;55(4):676-684. **Access article**

Orkin A. et al. **Guidelines for Reporting Trial Protocols and Completed Trials Modified Due to the COVID-19 Pandemic and Other Extenuating Circumstances.** JAMA. Published online June 21, 2021. doi:10.1001/jama.2021.9941. **Access article**

Harper B, Smith Z, Snowdon J, DiCicco R, Hekmat R, Willis V, Weeraratne D, Getz K. **Characterizing Pain Points in Clinical Data Management and Assessing the Impact of Mid-Study Updates.** Ther Innov Regul Sci. 2021 May 17. **Access article**

DiMasi, JA, Wilkinson M. **The financial benefits of faster development times: integrated formulation development, real-time manufacturing, and clinical testing.** TIRS 2020;54(6):1453-1460. **Access article**

Getz K. **Characterizing White Space in the Quest to Drive Development Speed.** Applied Clinical Trials, 2021; April 7. **Access article**

Florez M, and Getz K. **Anticipating digital transformation of the drug development workforce.** Pharmaceutical Executive, March 26. **Access article**

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

## Data Insights Digest

### Average Number of Enrolled Patients by Phase

***(All FDA-Approved Drugs and Biologics)***

| Means | 2008-2013 | 2014-2018 | Change |
|---|---|---|---|
| Phase I | 42 | 45 | +7.1% |
| Phase II | 152 | 166 | +9.2% |
| Phase III | 778 | 817 | +5.0% |
| Phase IV | 310 | 229 | -26.1% |

- **The mean number of participants per clinical trial has increased in all pre-approval phases with the highest growth observed in phase II.**
- **Very high variation is observed around the mean number of participants in each phase, and this variation has increased between the two time periods.**
- **The mean number of participants in phase IV clinical trials has declined sharply in part due to the growth in orphan drugs as a share of all approvals.**

**Subscribe today to get your copy of the Tufts CSDD Impact Report.**

## Faculty and Staff Presentations

### Upcoming Presentations

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

VIRTUAL EVENT
Clinical Trials Europe

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

VIRTUAL EVENT
Clinical Trials Europe

**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

VIRTUAL EVENT
Clinical Trials Europe

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

VIRTUAL EVENT
Clinical Trials Europe

**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

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

**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

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

**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

## Recent Presentations

**Accommodating and managing agile drug development execution**
**Ken Getz, MBA**
Chief Medical Officers Summit
Online | October 14

**Impact of COVID-19 on Clinical Operations**
**Ken Getz, MBA**
Dutch Federation of Pharmaceutical Medicine
Online | October 7

**How We Become Agile to Remain Viable in a Post-COVID World**
**Ken Getz, MBA**
DPharm
Online | September 29

**The Economics of the Pharmaceutical Industry**
**Joseph DiMasi, PhD**
24th North American ISSX Annual Meeting
Online | September 13-17

**Insights into Rare Disease Development**
**Ken Getz, MBA**
Ultragenyx
Online | September 13

**Remote Clinical Research Team Experience and Effectiveness During the COVID-19 Pandemic**
**Maria Florez, MA and Mary Jo Lamberti, PhD**
Association of Medical Research Charities
Online | September 9

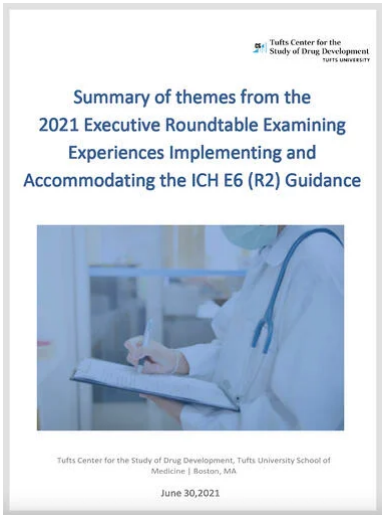
**Remote Clinical Research Team Experience and Effectiveness During the COVID-19 Pandemic**
**Maria Florez, MA and Mary Jo Lamberti, PhD**
Academy of Physicians in Clinical Research
Online | September 1

**Managing Complexity and Customization in Clinical Trials**
**Ken Getz, MBA**
Jackson Laboratories, OneJax Seminar Series
Online | August 30

**Trends in Diversity and Inclusion in Clinical Research**
**Ken Getz, MBA**
Veeva Systems Webinar
Online | August 24

## Subscriptions Papers and Books


**Purchase Impact Reports**




**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**

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