Tufts Center for the Study of Drug Development
TUFTS CSDD *INSIDER*
MAY 2021

From the Director

Dear CSDD Friends:

The incredible speed in which COVID-19 vaccines and treatments moved through clinical trials has elevated an already high interest among sponsor companies in compressing cycle times.

Until recently, cycle time acceleration strategies primarily focused on tasks and timelines *within* clinical phases. Lately, more attention has focused on addressing the inefficiencies that occur *between* phases when clinical data and operations transition from one research phase to the next. These transitions - also referred to as 'White Space'— appear to be ideal targets for information technology, open collaboration, augmented analytics and machine learning.

A recent Tufts CSDD analysis found that these white space transitions are not only common, they are also time-intensive and growing. For all non-expedited development programs approved between 2008 and 2018, 82% had between-phase transitions that lasted 17 months on average. One-out-of-six (18%) programs had no white space as phase II completion and phase III pivotal trial timelines overlapped. Between 2008 to 2013, the mean white space duration was 12 months. In the more recent period between 2014 and 2018, phase transition durations have nearly doubled to 21.6 months on average.

Data for our white space analysis was drawn from databases that Tufts CSDD routinely maintains and updates. We frequently leverage our proprietary data for benchmarking and trend analyses. Our data is also being used in studies modeling the financial return-on-investment (ROI) of new practices and solutions impacting clinical trial operations and drug development performance. Please contact us to learn more about our expected net present value (eNPV) modeling and ROI assessment expertise.

This past month, we have been very active preparing manuscripts and presenting our study findings at conferences and meetings Tufts CSDD also kicked-off a study looking at how sponsor companies adopt innovations supporting clinical development planning, design, execution, data management and logistics. We've had an excellent response from companies wishing to participate. Please let me know if you would like to join this important and timely study.

In addition to our monthly *Insider*, please check our newly upgraded website for Center announcements, activity updates, and listings of professional development courses. And, as always we welcome your ideas, feedback and collaboration.

Ken

Kenneth Getz

Roundtables

Join us on May 17 for a virtual roundtable on ICH E6 R2.

Drug development professionals and regulators will come together to discuss evolving ICH E6 R2 implementation challenges and explore ways to accommodate changing clinical research operating models - some facilitated by the pandemic. Space is limited to promote highly active and engaged roundtable discussion. For more information, **contact Sundé Daniels.**

Working Group Studies

New Working Group Study Assessing Impact of DCTs on Sponsor-CRO Collaborations

In late May/early June 2021, we will be launching a new study characterizing and benchmarking the impact of decentralized clinical trial (DCT) and data management models on sponsor-CRO relationship structure, economics and effectiveness. Sponsor companies and CROs will participate in systematically assessing how collaborations have changed in response to the pandemic and will continue to evolve long-term. **Contact us for more information.**

Working Group Study Launched to Characterize and Improve the Innovation Adoption Process

Tufts CSDD has initiated a new working group study looking at how sponsor companies adopt innovations supporting drug development planning, design, execution, data management and logistics. The study will characterize best practices including those associated with pandemic response; apply lessons learned from other heavily regulated industries; and identify opportunities to accelerate innovation adoption. **Contact us for more information.**

Global Surveys

Participate in the Tufts CSDD Global Study on Investigative Site Diversity

Tufts CSDD is conducting an ambitious, first-of-its-kind global study mapping and examining the demographic diversity of the global investigative site landscape. The goal of the study is to inform new strategies and practices that will enable sponsors and CROs to more successfully partner with investigative sites. We encourage site professionals to participate. **Complete the CSDD Survey.**

Professional Development Courses

Robert Franco, PhD
Course Facilitator President,
Coe Point Associates LLC

Chandresh Harjivan, PharmD
Lead, Public Health Sector Practice,
Boston Consulting Group

May 12, 2021

Grab n' Go course: Enhancing Productivity and Performance of Remote or Distributed Teams (Online)

Designed for professionals with very tight schedules, this half-day program focuses on critical leadership skills and management practice development. All Grab n' Go courses combine lecture and small group discussion to generate actionable ideas and insights that can be put into practice immediately. Class sizes are limited. For more information, **contact Sundé Daniels**.

Robert Franco, PhD
Course Facilitator President, Coe Point Associates LLC

Kenneth Kaitin, PhD
Professor of Medicine and Senior Fellow, Tufts CSDD

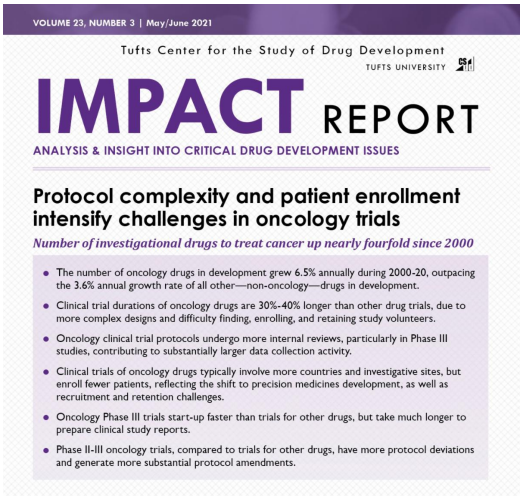
June 9, 16, 23 & 30, 2021

Summer Leadership for Drug Development Teams (Online)

This more in-depth course is designed 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 beginning in early June. For more information, **contact Sundé Daniels**.

Research Highlights

Our Latest *Impact Report*


VOLUME 23, NUMBER 3 | May/June 2021

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

IMPACT REPORT

ANALYSIS & INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Protocol complexity and patient enrollment intensify challenges in oncology trials

Number of investigational drugs to treat cancer up nearly fourfold since 2000

- The number of oncology drugs in development grew 6.5% annually during 2000-20, outpacing the 3.6% annual growth rate of all other—non-oncology—drugs in development.
- Clinical trial durations of oncology drugs are 30%-40% longer than other drug trials, due to more complex designs and difficulty finding, enrolling, and retaining study volunteers.
- Oncology clinical trial protocols undergo more internal reviews, particularly in Phase III studies, contributing to substantially larger data collection activity.
- Clinical trials of oncology drugs typically involve more countries and investigative sites, but enroll fewer patients, reflecting the shift to precision medicines development, as well as recruitment and retention challenges.
- Oncology Phase III trials start-up faster than trials for other drugs, but take much longer to prepare clinical study reports.
- Phase II-III oncology trials, compared to trials for other drugs, have more protocol deviations and generate more substantial protocol amendments.

Protocol Complexity and Patient Enrollment Intensify Challenges in Oncology Trials

Our May/June 2021 Tufts CSDD Impact Report presents new research examining and benchmarking the unique executional challenges associated with cancer clinical trials.

Learn more | Purchase online

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Recent Publications

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

Gottlieb, N, Byrne, J, Getz, K. **Investigative Site Placement Practices to Support Operation Warp Speed**. *Applied Clinical Trials* 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; September 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; September 14. Access article

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

Data Insights Digest

Quantifying Diversity in Clinical Trials

Participant race and ethnicity in pivotal trials for NDAs and BLAs approved between 2007 and 2017	Actual Proportion	Expected Proportion (based on disease prevalence)
Black and African Descent	5.4%	15.6%
Hispanic/Latinx	7.2%	8.2%
White	75.9%	67.1%
Asian	8.6%	3.5%
Other (e.g., indigenous communities)	3.0%	5.5%

- Based on the prevalence of diseases targeted by approved drugs and biologics, communities of several races and ethnicities were highly under-represented compared to the actual proportions enrolled
- Participants of Black/African Descent showed the highest disparity; nearly three times as many participants should have been enrolled in pivotal trials of approved drugs and biologics

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Faculty and Staff Presentations

Recent Presentations

Accelerating Drug Development During the Pandemic - Lessons Learned and Their Implications
Ken Getz, MBA
SCOPE Virtual Summit for Clinical Ops Executives
Online | March 2

Anticipating Changes in Clinical Trial Design and Execution Post Pandemic
Ken Getz, MBA
Clinical Development and Innovation Forum 2021
Online | March 9

New Benchmarks on Protocol Design Practices and Their Impact on Clinical Trial Performance and Efficiency
Michael Wilkinson, MPH, Zak Smith, MS, Ken Getz MBA
MCC Study Quality Trailblazer Group Meeting
Online | March 10

New Strategies to Balance Protocol Complexity, Customization and Executional Feasibility
Ken Getz, MBA
Reuters Pharma: Clinical 2021
Online | April 7

Taking Patient Centricity to the Next Level
Ken Getz, MBA
Patients as Partners
Online | April 9

Rapid Innovation in Clinical Research
Ken Getz, MBA
Avoca Quality Consortium
Online | April 20

Trends in the Development & Approval of New Anti-infectives: Cycle Times, Success Rates & Expedited Regulatory Pathways
Joseph A. DiMasi, PhD
Anti-Infectives Drug Development
Online | April 21

Examining Strategic Implications of Pandemic Response on the Global Investigative Site Landscape
Ken Getz, MBA
SCRS EU Summit
Online | April 22

Upcoming Presentations

Characterizing the Future of Clinical Trials
Ken Getz, MBA
Portland Clinical Research Professionals
Northwest Association for Biomedical Research
Online | May 5

Powered by the Pandemic: How Pharma has Succeeded and How it Will Continue to Embrace Operational Changes Facilitated by COVID-19
Ken Getz, MBA
RBQM Live
Online | May 20

The Evolving State of Clinical Trial Execution: Pilots or Permanent Change?
Ken Getz, MBA
ACRP Annual Meeting
Online | May 20

Drug Development Pain Points and Challenges
Ken Getz, MBA
BIO NJ Clinical Development Briefing
Online | May 27

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Tufts Center for the Study of Drug Development
75 Kneeland Street, Suite 1110
Boston, MA 02111
617-636-2170