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

From the Director

Dear CSDD Friends:

At a global conference I was recently asked — given CSDD's rich and growing knowledge about protocol design and clinical trial performance — if Lasagna's Law still applies. The question gave me pause. Our research suggests that the Law – which holds that the incidence of patient availability decreases when a clinical trial begins and returns when a clinical trial ends – remains universally true, but its explanation is deeper.

Dr. Louis Lasagna – founder of Tufts CSDD and a recognized thought leader and pioneer in clinical pharmacology and the science of drug regulation — originally attributed the 'Law' to the observed over-optimism of investigative site patient accrual forecasting. Narrow eligibility criteria was considered the primary cause of the mis-estimation.

Tufts CSDD study findings indicate that research professionals under-estimate several factors: (1) the role that the burden of disease plays; (2) patient perceptions of the demands of protocol adherence; and (3) the commitment of treating nurses and physicians to facilitate and enable participation in clinical trials. And these three essential factors each vary widely by demographic and disease subgroups.

Current and upcoming Tufts CSDD grant-funded research studies are helping to further quantify the impact of factors that ultimately drive recruitment and retention challenges. Also this month we are fielding a global survey assessing the diversity of the investigative site landscape and variation in familiarity and experience participating in clinical trials. We are currently conducting a detailed evaluation of the diversity of participants in pivotal trials supporting recent drugs and biologics approved by the European Medicines Agency.

Last month Tufts CSDD received strong interest in our new algorithm assigning participant burden scores based on protocol design characteristics. In response, during April we are launching a workshop for sponsor companies to apply the algorithm to prospective protocol design activity.

This Insider highlights a number of exciting and important ongoing and newly launched initiatives including not only grant-funded studies but also new professional development courses offered this spring and fall. Please reach out if you are interested in learning more. And as always, we welcome your feedback.

Ken

Kenneth Getz
Director and Professor

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

Roundtables

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

Drug development executives and regulatory agency representations will come together to discuss ICH E6 R2 implementation challenges and solutions and to 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

Join Our Working Group Study Characterizing and Improving 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

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**.

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*

Planned and Unplanned Mid-study Updates Challenge Clinical Trial Timelines

Our March/April 2021 *Tufts CSDD Impact Report* presents results of recent research examining how the clinical data management function is managing unprecedented challenges as clinical trial data volume and data diversity continue to grow.

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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**

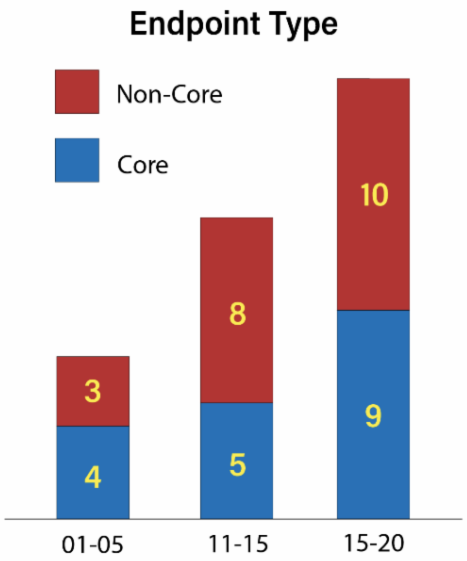
Smartly. *Nature Reviews Drug Discovery* 2020; September 23. Published online: **Access article**

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

Trends in Phase III Protocol Endpoints



- During the past 15 years, the number of core endpoints – those supporting primary and key secondary outcomes, baseline assessments and those supporting regulatory compliance – has more than doubled.
- During that same period, the number of non-core endpoints has more than tripled as sponsor company demand for data supporting exploratory, miscellaneous and tertiary end-points has intensified.

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

Faculty and Staff Presentations

Recent Presentations

Phase 0/Microdosing Approaches: Time for Mainstream Application in Drug Development?
Joseph A. DiMasi, PhD
American Association of Pharmaceutical Scientists
Online | February 4

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

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

Upcoming Presentations

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

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

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