Tufts Center for the Study of Drug Development

TUFTS CSDD *INSIDER*

May 2024

From the Executive Director

Dear CSDD Friends:

We enter the month of May with a very active pipeline of projects. The team kicked off a record number of new studies including one assessing study volunteer and investigative site perceptions and experience with direct-to-patient investigational drug delivery, one evaluating opportunities to optimize clinical research data collection and use, another quantifying the net financial value of a novel end-to-end portfolio of drug development services, and one examining the relationship between pre-approval clinical trial practices and new medical therapy post-approval adoption.

We're fielding questionnaire responses and collecting data for several studies. Results are being analyzed and will be reported soon from our working group study looking at decentralized clinical trial solutions usage and their impact on clinical trial performance. Surveys are underway looking at use cases for Generative AI in drug development and at the vendor qualification process. We encourage you to share your experience and participate in these surveys. Information is provided below.

I'm very excited to announce that on June 3rd Tufts CSDD will be hosting a very special research symposium in Boston entitled New Medicines Development at a Crossroads: Trends & Transformation in Drug Development. A valuable and informative program is planned and we will be honoring the legacy of Ken Kaitin, CSDD's former director. A reception will follow the program. We invite you and your colleagues to join us. See below for more information and please contact **Sarah Wrobel** to register for this special event. We hope to see you there.

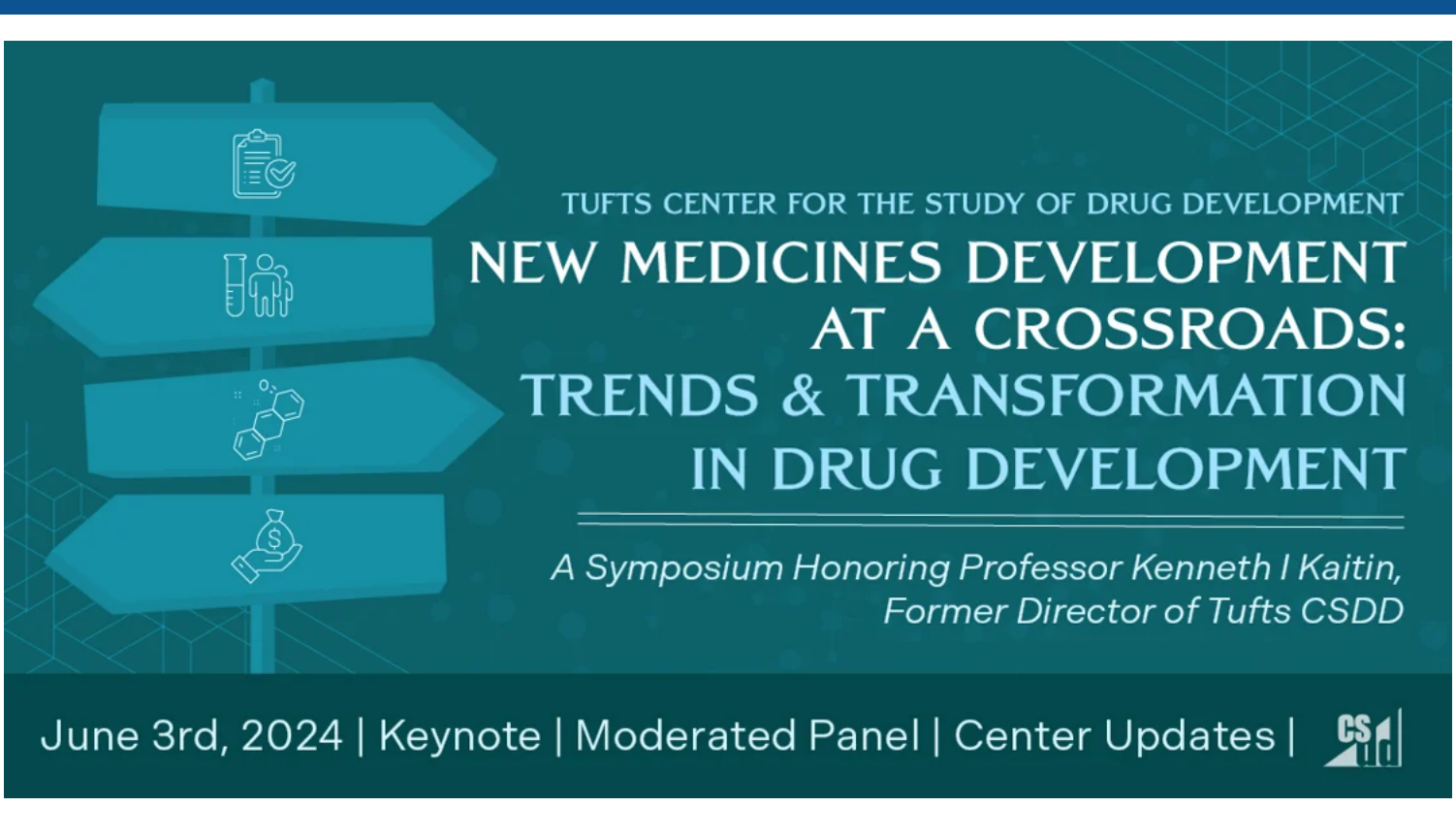
As always, we welcome your input and collaboration.

Ken

Kenneth Getz
Executive Director and Professor

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

News of Note



Join us on June 3rd for a special Tufts CSDD event at the Dubois Auditorium, the Medical Education Building at the Tufts University School of Medicine. Our keynote will focus on today's most pressing issues impacting global drug development and patient access to novel medical therapies. A guest speaker from the Food and Drug Administration will be discussing the newly created Office of Clinical Trial Innovation. And a distinguished panel of experts will be discussing promising and concerning drug development trends. To learn more and to attend the program and afternoon reception, please contact Sarah Wrobel.

Professional Development Courses

Join our interactive online session tailored for emerging leaders in the pharma & biotech sectors moderated by Dr. Robert Franco. Ideal for those stepping into a supervisory role, this workshop offers valuable insights and strategies for success in your leadership position.

This course will be held via Zoom on June 11, 13, 20, & 21st, 2024 from 11-3 pm EST. Course information coming soon! Sign up to be the first to know more at: **https://csdd.tufts.edu/leadership** or email Course Facilitator **Sarah Wrobel**.

Upcoming Studies

Vendor Qualification Assessment (VQA) Survey

Tufts CSDD is conducting a new and innovative benchmarking study on the Vendor Qualification Assessment (VQA) process. We will be exploring perceptions and perspectives from multiple stakeholders including Sponsors/CROs who conduct vendor and site qualifications as well as CROs or service providers who respond to requests/proposals (RFIs/RFPs) and investigative sites who complete study feasibility assessments and site qualification activities.

Click this link if your organization conducts qualifications of clinical trial service Providers or third-party vendors: https://bit.ly/3vUxRUe

Click this link if your organization hosts qualification requests from other Providers or Sponsors: https://bit.ly/3U6KC65

Click this link if you are a site that hosts qualification requests: https://bit.ly/3W4j4Rr

For questions regarding the survey, please contact **Zak Smith**.

Research Highlights

Introducing Our May/June Impact Report


VOLUME 26, NUMBER 3 | May/June 2024

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

IMPACT REPORT
ANALYSIS & INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Use of digital endpoints to collect clinical trial data is rapidly increasing
Digital endpoint use has doubled every three years since 2015

- Over the last eight years, drug sponsors rapidly increased the use of digital endpoints to collect data in clinical trials, employing wearables, sensors, and other technologies.
- The two technologies deployed most often to create digital endpoints in clinical trials, making up almost 80% of use, are internet connected sensors and continuous glucose monitors.
- Clinical trials on treatments for central nervous system diseases and diabetes are the most common therapeutic areas in which drug developers are using digital endpoints.
- More than half of digital endpoints are used to support secondary clinical trial outcomes.
- Use of digital endpoints in clinical trials in North America far surpasses use in other geographic regions of the world.
- Developer costs to create a digital endpoint measure—reported at a median of $3.8 million—far exceed the median costs to sponsors to implement and validate those endpoints.

Use of Digital Endpoints to Collect Clinical Trial Data is Rapidly Increasing

The May/June 2024 Impact Report(Volume 26, Number 3) is now available. The issue presents new research on the increased usage of digital endpoints as a data collection method in clinical trials.

Learn more | Purchase online

Recent Publications

Lamberti MJ, Dirks A, Kikuchi N et al. **Benchmarking Site Activation and Patient Enrollment**. *TIRS*. April 3, 2024. **Access Article**

Botto, E., Smith, Z. & Getz, K. **New Benchmarks on Protocol Amendment Experience in Oncology Clinical Trials**. *TIRS*. March 26, 2024. **Access article.**

Lamberti M, Dirks A, Nicholas K, Cervantes N, Getz K. **An Examination of the Use of Patient Recruitment and Retention Tactics for Global Studies**. *Applied Clinical Trials*. March 18, 2024. **Access article.**

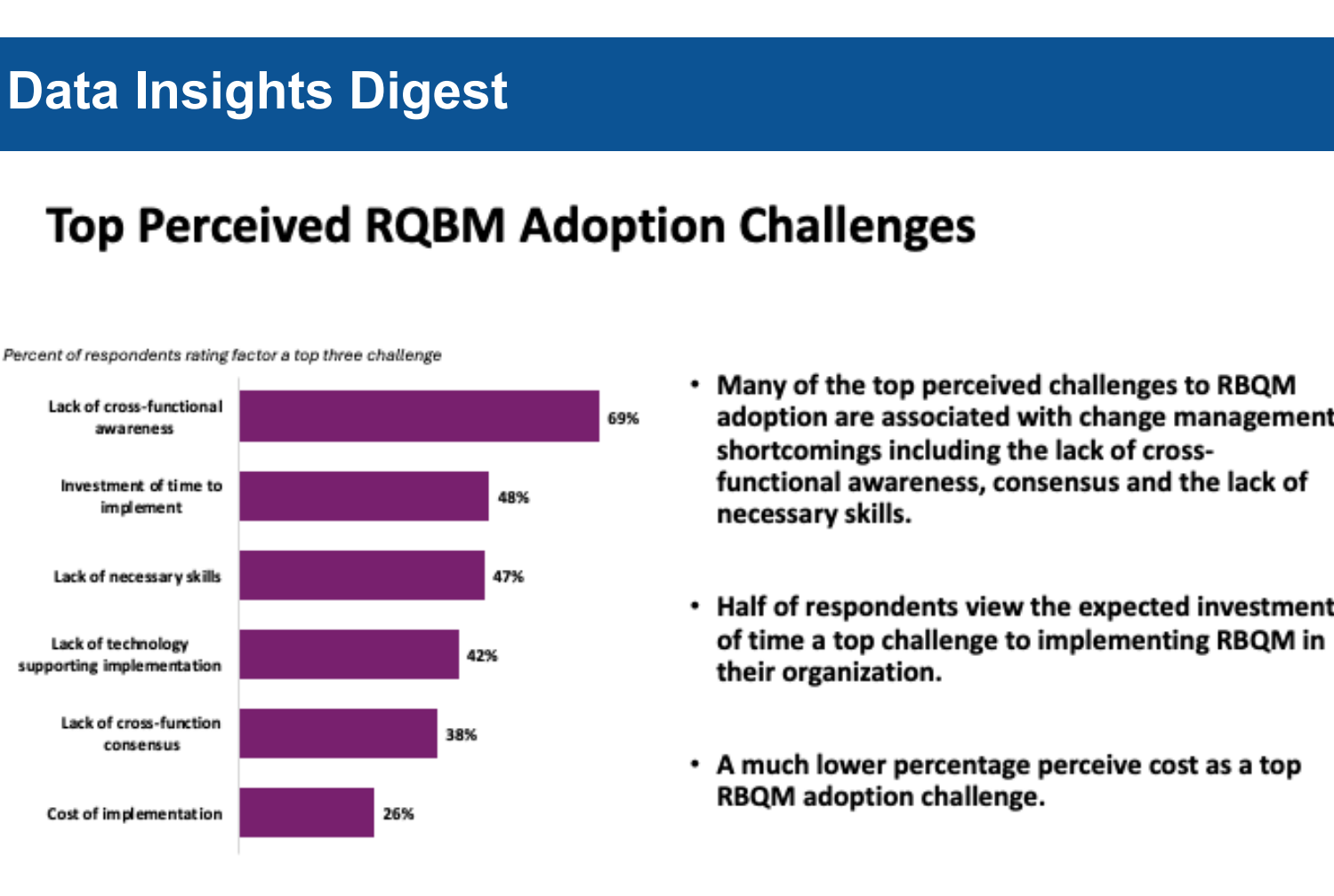
Botto E, Ford MR, Do H, Getz K. **Patient and Site Personnel Perceptions of Retail Pharmacy Involvement in Clinical Research.** *Applied Clinical Trials*. March 7, 2024. **Access article.**

Botto E, Smith Z, Getz K. **New Benchmarks of Protocol Amendment Experience in Oncology Clinical Trials.** *TIRS*. March 2024. **Access article.**

Getz K. **Calling Out Check-the-Box Patient Engagement**. *Applied Clinical Trials*. March 2024.

Nguyen DV, Block CJ, Kim JY, Yu H. **General and Stereotype-Based Microaggresions Experienced by Asians and Asian Americans in the Workplace: A Qualitative Study.** *American Behavioral Scientist.* March 1, 2024. **Access article.**

Data Insights Digest



To access hard-hitting Tufts CSDD charts and tables, visit https://csdd.tufts.edu/impact-reports.

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

Faculty and Staff Presentations

Upcoming Presentations

Benchmarking Patient Enrollment and Use of Patient Recruitment Tactics in Global Trials
Mary Jo Lamberti
World BI | Boston, MA | May 2

Retail Pharmacies and Clinical Trials: Perspectives from Industry, Sites & Patients
Emily Botto
Association of Clinical Research Professionals 2024 | Anaheim, CA | May 4

The Impact of Technology in Today's Clinical Trial Ecosystem
Ken Getz
Egnyte Summit | Boston, MA | May 8

Clinical Trials Landscape: Trends and Insights
Abigail Dirks
CiteLine Elevate Meeting | Boston, MA |. May 8

Fireside Chat
Maria Florez
8th Decentralized and Hybrid Clinical Trials | Philadelphia, PA | May 16

Assessing the Financial Value of Patient Engagement: A Quantitative Approach From CTTI's Patient Groups and Clinical Trials Project
Jennifer Kim
DIA China 2024 | Suzhou, China | May 18

DCT/Technique Empowered High-Efficiency Clinical Trial
Jennifer Kim
DIA China 2024 | Suzhou, China | May 18

Having the End in Mind: Building Quality into Clinical Trials
Ken Getz
DIA Annual Meeting | San Diego, CA | June 17

An Update on the PALADIN Consortium
Ken Getz
DIA Annual Meeting | San Diego, CA | June 18

Improving Communication Across Differences in Drug Development Teams
Jennifer Kim & Emily Botto & Madison Ford
DIA 2024 | San Diego, CA | June 19

Regulatory Affairs of the Future: Is Now
Maria Florez
DIA 2024 | San Diego, CA | June 20

Measuring RBQM Adoption: Insights and Opportunities
Maria Florez & Abigail Dirks
13th Clinical Trials in Oncology East Coast | Boston, MA | July 9

Recent Presentations

Protocol Simplification or Optimization?
Ken Getz
CMO Summit | Boston MA | April 17

Quantifying the Financial Value of Digital Endpoints in Clinical Trials | *Data Driven, Hybrid & Full Decentralized Trials*
Joseph DiMasi
Informa Connect | Philadelphia, PA | April 16-17

Amplifying the Patient Voice in Drug Development
Ken Getz
Reuter's Pharma 2024 | Barcelona | April 16

Panel Discussion on Innovation Adoption
Zak Smith
InformaConnect | Philadelphia, PA | April 16

Frequency and Impact of Protocol Amendments on Clinical Trial Performance
Emily Botto
Festival of Biologics | San Diego, CA | April 15

Where has the Industry Been and Where Should it be Going?: Using Industry Development Benchmarks (Time, Risk, and Cost Metrics) to Improve Performance
Joseph DiMasi
Drug Development Boot Camp, Speid & Associates, Inc & Brown | University Alpert Medical School | Virtual | April 11

Navigating Academia. Colloquium.
Jennifer Kim
Teachers College, Columbia University | New York, NY | April 9

DEI from Within: Keynote
Jennifer Kim
SCRS Site Solutions Summit | Atlanta, GA | April 8

DEI from Within: The Impact of Diverse Clinical Research Teams on Patient Inclusion
Jennifer Kim
SCRS Site Solutions Summit | Atlanta, GA | April 8

Get Involved

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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