



# TUFTS CSDD QUARTERLY UPDATE

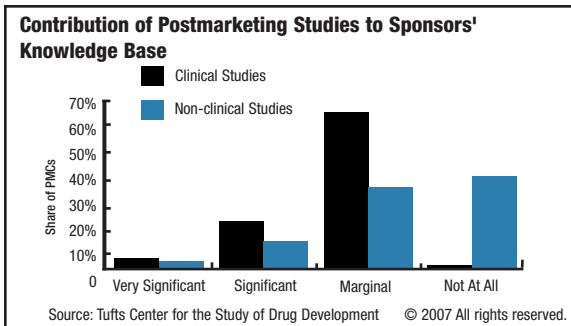
## Third Quarter 2007

It has been an exciting summer for Tufts CSDD. After 15 years at 192 South Street in Boston, on July 1st the Tufts Center moved several blocks to new offices at 75 Kneeland Street, 11th floor (see back page for more details). Our new location offers several distinct advantages: about 50% more office space than our previous location; the entire group is now on one floor; and we have greater proximity to Tufts Medical School. While we are settling into our new office space, we are working on several new initiatives, highlighted in this Quarterly Update. We are also developing the course agendas for the Professional Development programs starting in the Fall. Your sponsorship and support allow us to continue our research activities and pursue new opportunities that broaden Tufts CSDD's scope. We always welcome your feedback and encourage you to send us your ideas.

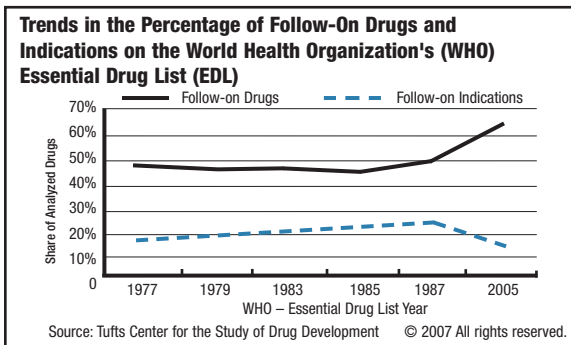
Sincerely,

Kenneth I Kaitin, Ph.D., Director

## Facts & Figures



- In a recent Tufts CSDD survey, 68% of clinical study sponsors and 79% of non-clinical study sponsors indicated that the results of required post-marketing studies contributed either marginally or not at all to their understanding of product safety, efficacy, or quality.



- The WHO's EDL is a listing of products and indications deemed essential to public health in developing countries.
- Since 1987, the share of follow-on drugs on the EDL grew 14 percent, highlighting the importance of incremental innovation to public health.

### Research Staff

- Kenneth Kaitin, PhD  
*Director*
- Christopher-Paul Milne, DVM, MPH, JD  
*Associate Director*
- Joseph DiMasi, PhD  
*Director, Economic Analysis*
- Joshua Cohen, PhD  
*Senior Research Fellow*
- Janice Reichert, PhD  
*Senior Research Fellow*
- Kenneth Getz, MBA  
*Senior Research Fellow*
- Laura Faden, BA  
*Senior Research Analyst*
- Stephanie Rochon, BA  
*Research Analyst*
- Julia Wenger, BA  
*Research Analyst*
- Julie DelPrato, BS  
*Database Administrator*
- Peg Hewitt, MS, L&IS  
*Research Librarian*

### Areas of Interest

- Time, Cost, and Risk of Drug Development
- Pharmaceutical Regulation
- Biotechnology Development
- International Comparisons
- Outsourcing Strategies
- Pediatric Initiative
- Reimbursement Programs
- Investigative Site Landscape
- E-Technology Adoption
- Patient Recruitment Challenges
- Phase IV Research Commitments
- Rx-to-OTC Switches

Tufts Center for the Study of Drug Development  
TUFTS UNIVERSITY  
Drug Development, Analysis, and Insight

## Tufts CSDD Research Agenda

For more information, call 617-636-2170 or visit <http://csdd.tufts.edu> and click on 'Research'

### R&D Innovation, Operations & Performance

- Cost of Biopharmaceutical R&D
- Capacity of Outsourcing to Meet R&D Needs
- Mapping the Investigative Site Landscape
- Sizing the Market and Adoption Rates for eClinical Technology Solutions
- Assessing Gender and Minority Disparity Among Clinical Research Investigators
- Assessing the Impact of Protocol Design Trends on Patient Recruitment Effectiveness
- Cancer Therapeutic and Vaccine Development Trends
- Efficiency in Innovation: Case Studies in OECD Countries
- Impact of Protocol Design Change on Development Performance
- Impact of Company Operating Structure on R&D Performance

### Regulatory Policy

- The Impact of Regulation on Innovation: FDA's Orphan and Fast Track Programs
- Progress of FDAMA's Pediatric Studies Incentive
- Assessing Impact and Implementation of the Critical Path Initiative
- FDA's Orphan Products Development Program: Results of a Survey of Grant Awardees
- Incentives for Innovation in Developing Countries to Address Unmet Medical Needs
- Survey of Sponsor Experience with FDA Postmarketing Commitments (PMCs)

### Drug Utilization

- Evaluating the Impact of Rx-to-OTC Switches Using a Decision-Analytical Model
- Impact of Disease Management and Reimbursement Practices on the Pharma and Managed Care Industries & Medicare
- Impact of Clinical Practice Guidelines and Formularies on Medicare Beneficiary Access to Pharmaceuticals
- Evaluating the Translational Process from Clinical Research to Clinical Practice
- Update of Trends for Late Phase Studies
- Trends in the Development of Line Extensions

## Did You Know?

- **Tufts CSDD Has Moved to New Office Space!**

Effective July 1, 2007, our new mailing address is 75 Kneeland Street, 11th floor, Boston, MA 02111. Please update your records. The office is located near the Tufts University School of Medicine campus in downtown Boston. If you're visiting Boston, please contact us and stop by.

- The *Tufts CSDD Leadership for Drug Development Teams* course, to be held October 15-17, 2007 at the Taj Boston hotel, is quickly filling up. There are very few open spots available. As a Tufts CSDD Sponsor, you're eligible to send a colleague at a discount tuition rate. For program details, please visit <http://csdd.tufts.edu/Institute>

- Tufts CSDD brings broad expertise, creativity, and 30 years of research experience to special commissioned projects. In addition to Tufts CSDD's regular research agenda, we conduct commissioned and custom projects on a wide variety of topics identified by individual or multiple project sponsors. Here is a sampling of recent projects conducted:

- Market sizing for a biotechnology company
- Long-range projections on the adoption of e-clinical technology
- Quantitative assessment of the impact of clinical outsourcing on development performance, quality, and cost
- Assessing gender & minority disparity among clinical investigators
- Impact of protocol design trends on patient recruitment effectiveness

For more information about Tufts CSDD Commissioned Projects, please contact Ken Getz, Senior Research Fellow, at 617-636 3487 or [kenneth.getz@tufts.edu](mailto:kenneth.getz@tufts.edu)

We value your support as a Tufts CSDD Sponsor, and we welcome your feedback regarding our activities, our 2007 initiatives, and this Quarterly Update.

## Tufts CSDD Institute for Professional Development

### "Tufts CSDD's 11th Annual Senior Executive R&D Roundtable"

Tufts CSDD's 2007 **Senior Executive R&D Roundtable** will focus on *'Operating Models and the Pursuit of R&D Excellence: The Large Pharma and the Small/Mid-Tier Pharma Experience.'* Kenneth Kaitin, Ph.D., Director of Tufts CSDD and Robert Franco, Ph.D., Director of Life Sciences Consulting of PRTM will co-chair the one-day meeting, to be held Thursday, November 8, 2007 at the Taj Boston Hotel.

As a Tufts CSDD Sponsor, you receive a significant discount on tuition. For program details and to reserve your seat, please visit <http://csdd.tufts.edu/Institute/>, call 617-636-2170, or email [csdd@tufts.edu](mailto:csdd@tufts.edu)



## Published Academic Research Papers

Tufts CSDD regularly publishes its research reports in peer-reviewed, trade, and business publications. Reprints are available upon request. Here are a few new published research papers:

- Milne C-P Kaitin KI DiMasi DA. Mandatory comparator trials for therapeutically similar drugs: an assessment of the facts. *American Journal of Therapeutics* 2007 May/Jun;14(3):231-4 [RS 2715]
- Reichert JM Valge-Archer VE. Development trends for monoclonal antibody cancer therapeutics. *Nature Reviews Drug Discovery* 2007 May;6(5):349-56 [RS 2713]
- Getz KA. Industry trials poised to win back academia. *Applied Clinical Trials* 2007; Apr:16(4):40-2,4 [RS 2711]

To request an article reprint, email [peg.hewitt@tufts.edu](mailto:peg.hewitt@tufts.edu) or visit the Bibliography section under 'Information Services' on our website, <http://csdd.tufts.edu>



## Tufts CSDD Selected Staff Presentations

### May 2007

- Dr. Kenneth Kaitin, Dr. Christopher-Paul Milne—BIO Annual Meeting—Boston, MA, May 7-8
- Dr. Kenneth Kaitin—PhRMA Law Section Annual Meeting—Boston, MA, May 10
- Dr. Joshua Cohen—EU/Dutch Academy of Science Meeting—The Hague, May 11
- Mr. Kenneth Getz—IIR Globalization Conference—Philadelphia, May 15-16
- Dr. Kenneth Kaitin—Accenture COO Leaders Forum—Philadelphia, May 23
- Dr. Kenneth Kaitin—Millennium R&D Presentation—Cambridge, MA, May 30

### June 2007

- Mr. Kenneth Getz—FOCUS Presentation—Ottawa, Canada, June 1
- Mr. Kenneth Getz—Endocrine Society—Toronto, Canada, June 2
- Dr. Kenneth Kaitin—Patheon R&D Forum—Toronto, Canada, June 12
- Dr. Christopher-Paul Milne—IIR Post-Approval Research—Philadelphia, PA, June 12-14
- Dr. Janice Reichert—Crossroads in Biotech—Montreal, Canada, June 13-14
- Dr. Christopher-Paul Milne—CMR Institute for Regulatory Sciences Workshop—Washington, DC, June 14-15
- Dr. Joseph DiMasi, Dr. Christopher-Paul Milne, Mr. Kenneth Getz—DIA Annual Meeting—Atlanta, GA, June 21-23
- Dr. Kenneth Kaitin—Convergence R&D Leaders Retreat—Martha's Vineyard, MA, June 21-23

### July 2007

- Dr. Joseph DiMasi—International Health Economics Association World Congress—Copenhagen, July 8-11
- Dr. Christopher-Paul Milne—PABORD—London, July 10-11
- Dr. Christopher-Paul Milne—iiBIG Pharmaceutical & Biotech Outsourcing—Atlantic City, NJ, July 11-12
- Dr. Kenneth Kaitin—Massachusetts Biotech Caucus—MA Statehouse, Boston, MA, July 24

For more information on these presentations and upcoming presentations, please call 617-636-2170 or email [csdd@tufts.edu](mailto:csdd@tufts.edu), or visit <http://csdd.tufts.edu/About/StaffPresentations.asp>.

