



TUFTS CSDD QUARTERLY UPDATE

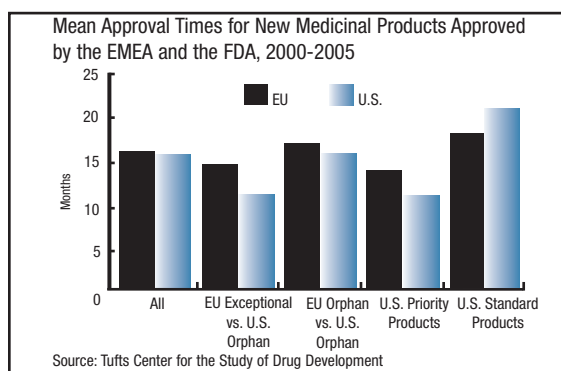
Second Quarter 2007

Difficult to believe 1st quarter 2007 has come and gone. We are focusing our energies on 2nd quarter activities, sponsored events, and new initiatives, which are highlighted in this quarterly update. Through your support, we are able to continue our research activities and pursue new opportunities that broaden Tufts CSDD's scope. As always, we welcome your feedback and encourage you to send us your ideas.

Sincerely,

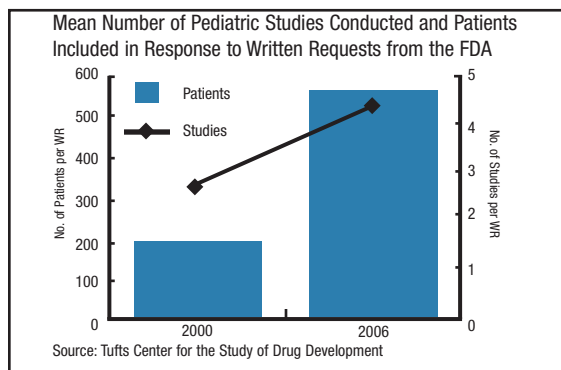
Kenneth I Kaitin, Ph.D., Director

Facts & Figures



- Mean approval times for 71 new products approved by both EMEA and FDA during 2000-2005 were similar: 15.8 and 15.7 months, respectively.

- Those products that were given a priority rating by the FDA were reviewed faster in the US than in the EU, while those with a standard rating were reviewed slower.



- Since 2000, the numbers of studies done and patients included per written request have increased substantially: by 60% and 178%, respectively.

- The *Best Pharmaceuticals for Children Act*, which is up for renewal, has resulted in studies on about 120 diseases and conditions, and has led to new labeling for 120 new or approved drugs for use in children.

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
- Julia Wenger, BA
Research Analyst
- Brian Young, BS
Research Analyst
- Julie DelPrato
Database Administrator
- Peg Hewitt, MS, L&S
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'

Premarket R&D

- Cost of Biopharmaceutical R&D
- Capacity of Outsourcing to Meet R&D Needs
- Trends in the Development of Line Extensions
- Sizing the Market and Adoption Rates for eClinical Technology Solutions
- Gender and Minority Disparities Among Clinical Research Investigators
- Impact of Protocol Design Trends on Patient Recruitment Effectiveness
- Cancer Therapeutic and Vaccine Development Trends
- Incentives for Innovation in Developing Countries to Address R&D for Unmet Medical Needs
- Impact of Protocol Design Change & Development Performance

Regulatory

- The Impact of Regulation on Innovation: FDA's Orphan and Fast Track Programs
- Progress of FDAMAs Pediatric Studies Incentive
- Assessing Implementation and Impact of the Critical Path Initiative
- FDA's Orphan Products Development Program: Results of a Survey of Grant Awardees
- Efficiency in Innovation: Case Studies in OECD Countries

Postapproval

- 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 FDA Postmarketing Commitments (PMCs)
- Impact of Company Operating Structure on R&D Performance

Did You Know?

- **TUFTS CSDD IS RELOCATING IN JUNE.** We will keep you posted as our moving date gets closer.
- The Tufts CSDD *R&D Management Report*, entitled "Structuring the Clinical Organization to Improve R&D Productivity," provides a summary of Tufts CSDD's 10th annual *Senior Executive R&D Roundtable* held last November. A copy of the report was mailed to you in March. I hope you found the report interesting, useful, and insightful. If you did not receive your copy, please email csdd@tufts.edu. We hope to see you at our 11th annual meeting, scheduled for November 8, 2007 in Boston.
- Corporate subscriptions are available for the *Tufts CSDD Impact Reports*. For more information, contact us at 617-636-2170 or email csdd@tufts.edu. As a Tufts CSDD Corporate Sponsor, you'll receive a discount on corporate subscription rates.
- The Tufts CSDD *Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation* held in February 2007 was a huge success and well attended: 118 registrants—the largest group ever. A special 'thank you' to our Tufts CSDD sponsors who sent their employees to participate in the course.

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

Mark Your Calendars

The Institute for Professional Development Programs are scheduled for Fall 2007 and February 2008 in Boston, MA.

Please mark your calendars for these upcoming events.

- **Leadership for Drug Development Teams: October 15-17, 2007**
- **Senior Executive R&D Roundtable: November 8, 2007**
- **Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation: February 4-8, 2008**

As a Tufts CSDD Sponsor, you receive significant discounts on single tuition or group registrations to our professional development courses. For program details, please visit <http://csdd.tufts.edu/Institute/>.



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 several of our published research papers:

- Milne C-P. Pediatric assessment: an essential part of standard drug development. *International Journal of Pharmaceutical Medicine* 2006;20(5):297-301
- Getz KA. Drowning in the sea of regulatory compliance. *Applied Clinical Trials* 2007 Feb; 16(2):32, 34
- Reichert JM. Trends in the development and approval of monoclonal antibodies for viral infections. *Biodrugs* 2007;21(1):1-7
- DiMasi JA Grabowski HG. Economics of new oncology drug development. *Journal of Clinical Oncology* 2007 10 Jan;25(2):209-16
- Getz KA Wenger J. High times for CRO heavyweights. *Scrip* 2007 March;5-6

To request an article reprint, email peg.hewitt@tufts.edu or visit the Bibliography section under 'Information Services' on our web site, <http://csdd.tufts.edu>.



Tufts CSDD Selected Staff Presentations

Please note: conference presentations are available to attendees only.

February 2007

- Dr. Kenneth Kaitin—U.S. House of Representatives, Congressional Briefing—Washington, DC, February 21
- Dr. Christopher-Paul Milne—Marcus Evans Annual Phase IV Clinical Trials Conference—Halladale Beach, FL, February 26-28
- Mr. Kenneth Getz—CHI on Globalization—San Francisco, CA, February 28-March 1

March 2007

- Dr. Kenneth Kaitin—HBM Partners Mountain Retreat—St. Moritz, Switzerland, March 12-14
- Dr. Joseph DiMasi—Special Librarian's Association Annual Meeting (keynote)—Boston, MA, March 18
- Dr. Christopher Milne—ViB Pharmacovigilance & Risk Management—Philadelphia, PA, March 20-21
- Mr. Kenneth Getz—DIA Euro Annual Meeting—Vienna Austria, March 27
- Dr. Kenneth Kaitin—Patient Advocacy Associations Briefing—Washington, DC, March 28

April 2007

- Dr. Kenneth Kaitin—Tuck School of Business, Dartmouth University—Hanover, NH, April 10
- Dr. Kenneth Kaitin—Cornell University Government & Public Policy Seminar—Ithaca, NY, April 18
- Ms. Joan Chambers—ACRP Annual Meeting—Seattle, WA, April 21-24
- Dr. Kenneth Kaitin—DIA Conference on Clinical Research & Product Registration in India & China—San Diego, CA, April 26-27
- Mr. Kenneth Getz—Marcus Evans, Virginia, April 30-May 1

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

