

**Second Quarter 2008**

It's a busy time of year for us at the Tufts Center. Here are some Second Quarter highlights.

I'm pleased to announce that our new *Tufts CSDD Executive Forum* has received a very positive response from pharma companies and CROs, some of whom have already signed on as members. Our first two roundtables of 2008 featured insightful presentations and stimulating discussion. Also, on April 25th, we hosted a group from the Spanish pharmaceutical trade association, *Farmaindustria*. And, on the research front, we completed several major projects, published two *Tufts CSDD Impact Reports* (on reimbursement under Medicare, and development metrics for monoclonal antibodies), and prepared an *R&D Management Report*, on pharma outsourcing strategies. Several members of our research staff are participating in the Drug Information Association's annual meeting, June 21-26 in Boston. Check the DIA program for dates and times. We are also preparing for our annual Leadership for Drug Development Teams course, to be held October 27-29 in Boston.

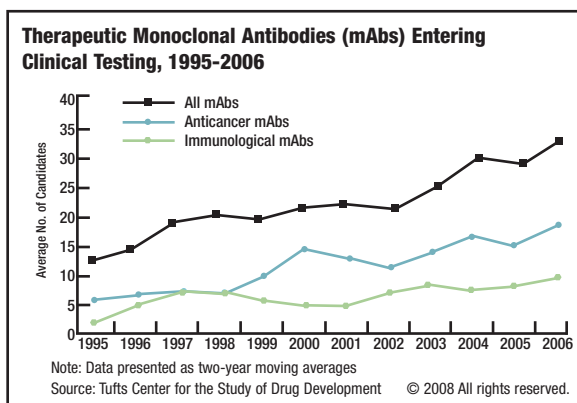
As always, we appreciate your support. It is that support that allows us to continue our research activities and pursue new opportunities that broaden the scope of the Tufts Center's work.

Sincerely,

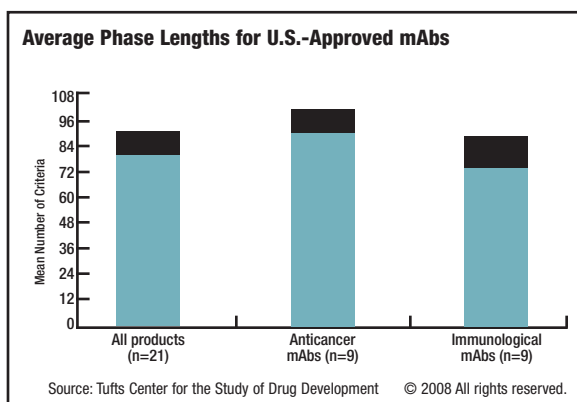


Kenneth I Kaitin, Ph.D., Director

**Facts & Figures**



- Since the mid-1990s, the number of mAbs entering the clinic nearly tripled.
- This growth is due primarily to an increase in anti-cancer candidates.



- Mean clinical and approval phases for all mAbs were 80.8 and 115.5 mos., respectively.
- The clinical phase for anti-cancer mAbs was 12% longer than for all mAbs.

**Research Staff**

- Kenneth I Kaitin, PhD  
*Director*
- Christopher-Paul Milne, DVM, MPH, JD  
*Associate Director*
- Joseph A. DiMasi, PhD  
*Director, Economic Analysis*
- Joshua P. Cohen, PhD  
*Senior Research Fellow*
- Kenneth A. Getz, MBA  
*Senior Research Fellow*
- Janice M. Reichert, PhD  
*Senior Research Fellow*
- Richard I. Shader, MD  
*Senior Research Fellow & Medical Consultant*
- Laura B. Faden, BA  
*Senior Research Analyst*
- Stephanie L. Rochon, BA  
*Research Analyst*
- Abraham G. Seckler, BS  
*Research Analyst*
- Andrew W. Wilson, BS  
*Research Analyst*
- Rachael B. Zuckerman, BA  
*Research Analyst*
- Julie T. 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

**DID YOU KNOW...**

Tufts CSDD senior research staff is available to conduct one-day, on-site programs, at your site, on pharmaceutical and biotech drug development issues.

From now until May 31st, with your referral, your colleague can save 10% on their *Tufts CSDD Impact Report* subscription.

Tufts CSDD Director Ken Kaitin and Associate Director Chris Milne have been named to the Program Committee for the 44th Annual Meeting of the Drug Information Association.

Save the Dates! February 8-13, 2009  
*Tufts CSDD 36th Annual Postgraduate Course in Clinical Pharmacology, Drug Development and Regulation*

Two *Tufts CSDD Impact Reports* have been cited frequently by the media: "Growing protocol design complexity stresses investigators, volunteers," and "Number of mAbs entering clinical study nearly tripled in last decade."

## Our Mission

The Tufts Center for the Study of Drug Development at Tufts University is an independent, academic research organization. Our mission is to develop strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization.

## Research Agenda

### 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
- Efficiency in Innovation: Case Studies in OECD Countries
- Impact of Protocol Design Change & Development Performance
- Impact of Company Operating Structure on R&D Performance
- Effect of Fast Track Designation on Drug Development
- Innovation in China's Biotechnology Industry

### Regulatory Policy

- The Impact of Regulation on Innovation: FDA's Orphan and Fast Track Programs
- Progress of FDAMAs 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 Postmarketing Commitments (PMCs)
- Recent FDA Drug Approvals: Trends in Drug Development and Regulation

### 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
- Market Access for Targeted Therapeutics

## TUFTS CSDD EXECUTIVE FORUM

Continuing to meet the needs of the industry, we've created the *Tufts CSDD Executive Forum*, a new membership subscription offering, designed to provide its members the opportunity to share ideas and hear colleagues discuss their experiences with R&D practices and strategies. Quarterly Roundtables focus on topical R&D issues, in a neutral venue, for members to freely and candidly discuss R&D issues of mutual concern.



*Tufts CSDD Executive Forum* member companies receive the following benefits:

- Opportunity for two attendees to participate in the Quarterly Roundtables.
- *Tufts CSDD R&D Management Reports* summarizing the main discussion points of each roundtable.
- Presentations by Tufts CSDD Senior Research Staff on cutting-edge research.
- Opportunity to network with industry colleagues.

Roundtable Topics for 2008:

- Strategic Outsourcing & Global Drug Development
- Leveraging Metrics & Market Factors for Portfolio Decision Making
- Optimizing Protocol Design
- Assessing Change and Opportunity in the Phase I Landscape

## Tufts CSDD Institute for Professional Development

### Leadership for Drug Development Teams

Date Change—October 27-29, 2008.

This three-day course will prepare participants to:

- Lead teams more effectively
- Build collaboration among dispersed organizations
- Engage senior management support
- Motivate team members to deliver on milestones
- Resolve conflicts over the most critical factors impacting development success

## Published Academic Research Papers

- Faden LB Kaitin KI. Assessing the performance of the EMEA's centralized procedure: a comparative analysis with the US FDA. *Drug Information Journal* 2008; 42(1):45-56 [RS 2806]
- Reichert JM Wenger JB. Development trends for new cancer therapeutics and vaccines. *Drug Discovery Today* 2008 Jan;13(1-2):30-7 [RS 2805]
- Cohen JP Kaitin KI. Follow-on drugs and indications: the importance of incremental innovation to medical practice. *American Journal of Therapeutics* 2008 Jan/Feb;15(1):89-91 [RS 2804]

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 2008

- Dr. Christopher Milne—IIR Post-Approval Conf. (moderator & keynote)—Baltimore, MD, May 21-23
- Dr. Kenneth Kaitin—Achieving Health Competitiveness Roundtable (co-chair & speaker)—Sao Paulo, Brazil, May 27-28

### June 2008

- Dr. Joshua Cohen—DIA annual meeting—Boston, MA
- Dr. Joseph DiMasi—DIA annual meeting—Boston, MA
- Dr. Kenneth Kaitin—DIA annual meeting—Boston, MA
- Dr. Christopher Milne—DIA annual meeting—Boston, MA
- Ms. Laura Faden—DIA annual meeting—Boston, MA

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>.

We value your support as a Tufts CSDD Sponsor, and we welcome your feedback regarding our activities, our 2008 initiatives, and this Quarterly Update.

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