Tufts CSDD faculty experts are available to comment or discuss a wide variety of topics relating to drug development.

<table>
<thead>
<tr>
<th>CONTACT</th>
<th>EXPERTISE</th>
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<tbody>
<tr>
<td><strong>Kenneth I Kaitin, PhD</strong>&lt;br&gt;Director and Professor&lt;br&gt;Tel 617-636-2181&lt;br&gt;Email <a href="mailto:kenneth.kaitin@tufts.edu">kenneth.kaitin@tufts.edu</a></td>
<td>■ Economic and regulatory environment&lt;br&gt;■ R&amp;D and corporate strategy&lt;br&gt;■ Academic-industry partnerships&lt;br&gt;■ Emerging markets&lt;br&gt;■ New business models</td>
</tr>
<tr>
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<td>■ Impact of regulatory policy&lt;br&gt;■ Orphan drug program&lt;br&gt;■ Pediatric initiative&lt;br&gt;■ Counter-bioterrorism initiatives&lt;br&gt;■ Global R&amp;D and innovation</td>
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<tr>
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<td>■ Cost of drug development&lt;br&gt;■ R&amp;D efficiency&lt;br&gt;■ Post-approval R&amp;D&lt;br&gt;■ Therapeutic class development trends</td>
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<tr>
<td><strong>Joshua P. Cohen, PhD</strong>&lt;br&gt;Assistant Professor&lt;br&gt;Tel 617-636-3412&lt;br&gt;Email <a href="mailto:joshua.cohen@tufts.edu">joshua.cohen@tufts.edu</a></td>
<td>■ Prescription drug policy&lt;br&gt;■ Formulary trends&lt;br&gt;■ Follow-on drug development trends&lt;br&gt;■ Prescription-to-over-the-counter switching</td>
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<tr>
<td><strong>Ken Getz, MBA</strong>&lt;br&gt;Director of Sponsored Research Program and Associate Professor&lt;br&gt;Tel 617-636-3487&lt;br&gt;Email <a href="mailto:kenneth.getz@tufts.edu">kenneth.getz@tufts.edu</a></td>
<td>■ Drug development management trends&lt;br&gt;■ Contract research organizations&lt;br&gt;■ Investigative site landscape&lt;br&gt;■ International clinical trials&lt;br&gt;■ E-technologies in drug development</td>
</tr>
<tr>
<td><strong>Ronald Evens, PharmD, FCCP</strong>&lt;br&gt;Adjunct Faculty and Biotechnology Consultant with Tufts CSDD&lt;br&gt;Tel 707-317-3046&lt;br&gt;Email <a href="mailto:medaff4biopharma@aol.com">medaff4biopharma@aol.com</a></td>
<td>■ Biotechnology product development&lt;br&gt;■ Novel biotech research platforms&lt;br&gt;■ Biosimilar development&lt;br&gt;■ Biotech business models and financing</td>
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<tr>
<td><strong>Richard I. Shader, MD</strong>&lt;br&gt;Senior Research Fellow &amp; Medical Consultant; Professor Emeritus, Pharmacology &amp; Experimental Therapeutics&lt;br&gt;Tel 617-636-3856&lt;br&gt;Email <a href="mailto:richard.shader@tufts.edu">richard.shader@tufts.edu</a></td>
<td>■ Experimental design&lt;br&gt;■ Clinical pharmacology and therapeutics&lt;br&gt;■ Ethics</td>
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</table>
ABOUT TUFTS CSDD AND THIS REPORT

Founded in 1976, the Tufts Center for the Study of Drug Development at Tufts University School of Medicine is an independent, academic, nonprofit research group that develops strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical and biopharmaceutical development, review, and utilization.

Kenneth I Kaitin, PhD, director of Tufts CSDD since 1998, leads a team of 12 research professionals and four support staff who:

- Monitor and report on the development, regulation, and utilization of new drugs and biopharmaceuticals.
- Explore the economic, legal, scientific, and public policy issues affecting pharmaceutical and biopharmaceutical innovation worldwide.
- Provide analyses on the development and review of new therapeutic agents.
- Sponsor conferences, roundtables, and public forums that bring together the often diverse perspectives of government, industry, academia, and public health advocacy.
- Raise the level of national and international debate on issues related to new drug and biotechnology product development and regulation.

Tufts CSDD Outlook, published each January, showcases the Tufts Center's view on near-term pharmaceutical and biopharmaceutical development trends. Data contained in Outlook 2014 are based on proprietary research conducted by Tufts CSDD. Analyses are from the ongoing work of Tufts CSDD’s research staff, who confer regularly with a broad range of pharmaceutical and biopharmaceutical industry leaders, as well as with regulators, policy makers, investors, service providers, and others involved in biomedical innovation.

Outlook 2014 constitutes one element in a full range of information and related services focused on the research-based drug and biotechnology industry and other stakeholders in pharmaceutical innovation. Other Tufts CSDD offerings include professional development courses, workshops, and symposia. In addition, the Tufts Center publishes the Tufts CSDD Impact Report, a bi-monthly newsletter providing analysis and insight into critical drug development issues, and the Tufts CSDD R&D Management Report, a quarterly review of strategic issues in pharmaceutical R&D.

Research findings developed by Tufts CSDD are regularly published in peer-reviewed, trade, and business publications, and Tufts CSDD faculty are quoted frequently in the business, industry, scientific, and general interest press worldwide.

For more information, call 617-636-2170 or click on http://csdd.tufts.edu.
Glossary

Biomarker — Also called biological marker. A substance, measurement, or indicator of a biological state. Biomarkers may exist before clinical symptoms arise.

Biosimilar — A follow-on, approved biopharmaceutical that is biologically similar to an existing medicine.

Clinical trial — A specific type of clinical study in which a medical intervention is tested against a placebo or an active control in human subjects. Clinical study is a broader term that includes other forms of human participatory research, such as pharmacokinetic, epidemiologic, and behavioral studies.

Companion diagnostic — A diagnostic test linked to a therapeutic drug, which serves to stratify populations into responders and non-responders, as well as indicate likelihood of adverse events in particular patients.

CRO — Contract research organization. A business entity that manages one or more steps in the drug development process, including conduct of preclinical studies, clinical study design and execution, data management, analysis, medical writing, and regulatory submission.

Form 1572 — Contractual obligations signed by principal investigators that drug sponsors submit to the FDA prior to initiating clinical trials.

Monoclonal antibody (mAb) types — Murine mAbs are derived from mouse genes; human mAbs are derived from human genes; chimeric and humanized mAbs are each derived from varying amounts of mouse and human genes, with the humanized products containing more human protein sequence than the chimeric versions.

NICE — The National Institute for Health and Care Excellence, an independent organization in the United Kingdom that provides national guidance and standards on the promotion of good health and the prevention and treatment of ill health.

Orphan drug — Drugs developed for rare diseases and conditions, which, in the U.S., affect fewer than 200,000 people, or, in the European Union, affect 5 per 10,000 people or fewer. Because sales of orphan drugs are likely to be small compared to their development costs, pharmaceutical companies are awarded exclusive rights to market these medicines for a period of time as an incentive to develop them.

Personalized medicine — The tailoring of medical treatment and delivery of health care based on the individual characteristics of each patient, including genetic, molecular, imaging, and other personal determinants.

Phase I — Studies typically conducted in healthy volunteers to determine the pharmacokinetic and pharmacologic actions of a drug in humans, the side effects associated with increasing doses, and, in some cases, early evidence of effectiveness.

Phase II — Studies designed to obtain data on the efficacy of a drug for a particular indication or indications in patients with the disease or condition.

Phase III — Expanded controlled and uncontrolled trials to gain additional data about efficacy and safety needed to evaluate the benefits and risks of a drug.

Protocol — A plan detailing the methodology of a clinical study.
Over the last dozen years, drug sponsors have made important strides in improving R&D performance, largely by focusing on drug development efficiency or by implementing new strategic partnerships and alliances. Going forward, however, R&D success—measured by the number and pace of new product approvals—will require sponsors to pursue both avenues simultaneously.

Company efforts to speed development, boost success rates, and control runaway R&D costs, all of which are critical to improving R&D efficiency, require objective, robust metrics. However, it won’t make a difference in the long run if it simply feeds into an old and inefficient development paradigm. That’s why many companies are embracing newer and more efficient R&D models and utilizing enhanced and adaptive clinical trial designs.

Moreover, many pharmaceutical and biotech companies are forging new strategic alliances, partnerships, and consortia—for example, with patient groups, academic medical centers, contract research organizations, investors, and even competitors. By sharing knowledge and leveraging resources, sponsors hope to make significant strides in finding new drugs to treat many of today’s most challenging and complex indications. Early results suggest great potential—and payoff.

The industry’s focus on operational efficiency and the willingness of diverse stakeholders to collaborate emphasizes a long overdue critical examination of the R&D process. It is worth noting that the drug industry’s development model fundamentally has not changed in over 50 years—since the Kefauver-Harris Amendments of 1962 established the current standard for the clinical testing of investigational drugs. This stands in stark contrast to many other research-intensive industries that regularly revamp their development processes.

Perhaps the greatest gain from clinical design improvements and new partnership models will be the development of industry best practices, which will enable companies to maximize their formidable R&D investment and help ensure future commercial success.

**Outlook 2014**

**Drug Sponsor Success Will Be Tied to an Ability to Coordinate Complex Processes**

**Use of Strategic Sourcing Models**

<table>
<thead>
<tr>
<th>Functional Area</th>
<th>Activities/Tasks</th>
<th>Share Kept In-house</th>
<th>Share Outsourced</th>
<th>Primary Relationship Model</th>
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</thead>
<tbody>
<tr>
<td>Design + Planning</td>
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<td></td>
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<tr>
<td></td>
<td>Selection</td>
<td>30%</td>
<td>70%</td>
<td>Full, FSP*, Alliance</td>
</tr>
<tr>
<td></td>
<td>Contracts &amp; Budgets</td>
<td>40%</td>
<td>60%</td>
<td>Full, FSP, Alliance</td>
</tr>
<tr>
<td></td>
<td>Start-Up</td>
<td>20%</td>
<td>80%</td>
<td>Full, FSP Alliance</td>
</tr>
<tr>
<td></td>
<td>Enrollment</td>
<td>25%</td>
<td>75%</td>
<td>All</td>
</tr>
<tr>
<td>Data Management</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Enrollment</td>
<td>25%</td>
<td>75%</td>
<td>FSP, Alliance</td>
</tr>
<tr>
<td>Statistical Analysis</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Enrollment</td>
<td>25%</td>
<td>75%</td>
<td>FSP, Alliance</td>
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<tr>
<td>Medical Writing</td>
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<tr>
<td></td>
<td>Enrollment</td>
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<td>60%</td>
<td>All</td>
</tr>
<tr>
<td>Regulatory</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Strategy</td>
<td>85%</td>
<td>15%</td>
<td>Niche</td>
</tr>
<tr>
<td></td>
<td>Support</td>
<td>45%</td>
<td>55%</td>
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</tr>
</tbody>
</table>

* Source: Tufts Center for the Study of Drug Development

* FSP = Functional service provider
While drug sponsors have taken numerous steps during the last decade to increase R&D productivity, investors, payers, and other stakeholders are pushing for further improvements, which will boost bioinnovation.

Advances in understanding the pathophysiology of a growing number of diseases, resulting from genetics research and the identification and validation of new biomarkers, will spur development in therapeutic areas, such as neurological and psychiatric disorders and cancer, where there is significant medical need.

In an effort to improve success rates, speed development times, expand pipelines, and diversify risk, pharmaceutical companies will engage in an increasing number of novel collaborations and strategic alliances involving other pharma and biotech firms, academic research centers, patient groups, contract research organizations, and venture investors.

Drug companies will increase their focus on personalized and targeted medicines, as well as development of companion diagnostics, as payers in the United States increase their coverage of diagnostic products.

Growing concern over expensive, late-stage clinical development failures will lead firms to reassess their use of meta-analyses and subgroup analysis—which have been used to justify pushing compounds forward in development, despite poor Phase II results—and make more realistic assessments about the likelihood of candidate success.

Continued growth in emerging markets will account for an expanding share of global pharmaceutical sales and profits, providing R&D incentives that favor development of drugs to meet demand in these markets.

Development of personalized medicines is prompting changes in the way drug sponsors do R&D, leading to new partnerships and alliances. Co-development of drugs and diagnostics requires careful life cycle planning and management, as teaming with external partners raises questions regarding project stewardship and intellectual property rights. Factors developers need to manage include assay and platform improvements, regional differences in technologies, testing requirements, barriers to diagnostic testing, and how to demonstrate clinical utility.
**REGULATORY ENVIRONMENT**

*Regulatory authorities in the U.S. and Europe will become more proactive, working in a quasi-partnership manner with drug sponsors to increase the pace of new product development while stepping up vigilance over patient safety.*

**THE FDA’S REGULATORY FRAMEWORK WILL BE EMPLOYED TO ADVANCE MORE RAPID DRUG DEVELOPMENT**

*FDA Expedited Programs*

- The U.S. Food and Drug Administration (FDA) in 2014 will push to complete by 2015 the 140 actions required by the FDA Safety & Innovation Act, including developing or enhancing databases on active pharmaceutical ingredient (API), dosage form manufacturing, and bioequivalence for use by generics-related firms.

- Re-organization of the European Medicines Agency (EMA), first announced in December 2012, will continue to absorb the agency’s attention and resources as, among other actions, it establishes five new divisions for R&D support, medicines evaluation, inspections and pharmacovigilance, procedure management and business support, and stakeholders and communication.

- The FDA will push sponsors to comply with new requirements of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act to enhance harmonization with the EMA program of early submission of pediatric assessments.

- With 40% of finished drugs and nearly 80% of active ingredients of drugs consumed in the U.S. imported, the FDA will assign higher priority to protecting the drug supply chain.

- The FDA will foster greater use of patient-reported outcomes to support labeling claims in drug applications and make greater use of social media and the Internet to communicate with patients, caregivers, and patient advocates.

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*The FDA’s new Breakthrough Therapy Designation (BTD), assigned to drug or biological drug development programs as early as Phase I clinical trials, not only aims to speed development but also seeks to encourage use of advances such as adaptive clinical trial designs and companion diagnostics. Sponsors have responded favorably, filing nearly 100 BTD requests in the program’s first year (FY 2013). Concern that oncology compounds would dominate BTD requests proved unwarranted based on a comparison with recent FDA special program approvals (2008-2012).*

Source: Tufts Center for the Study of Drug Development
Continued development of new technology platforms will foster a growing cornucopia of biotech products, which, in turn, will reinforce Big Pharma interest and investment in large molecule product development.

Sustaining the recent pace of investments in new biotech companies—more than 40 initial public offerings in 2013 valued at more than $3 billion—will be a major challenge in 2014, which will spur further development of alternative financing approaches, e.g., industry based venture capital groups and patient support foundations.

Big Pharma acquisitions of biotech companies will continue in 2014 as major company pipelines continue to thin out and blockbuster drugs go off patent; acquisition targets will include companies with novel pipeline assets and innovative platforms.

Although Europe outpaces the U.S. in biosimilar approvals, going forward, such approvals will be more common in the U.S. as a variety of marketed drugs, including many blockbuster products, lose patent protection.

Novel mechanisms of action and marginally improved outcomes may not be enough to convince payers to cover the high cost of biotech products, posing a growing barrier to their broader utilization; annual per-patient costs for therapies for chronic diseases commonly surpass $50,000, and patient co-pays can be 10%-25% or more of the total drug cost.

Monoclonal antibodies, especially those that use antibody-drug conjugates and antibody fragments, will dominate biotech product development for the next few years. However, the full scope of molecules, including vaccines, cell and tissue therapies, RNA interference, gene therapy, proteins, and peptides, will be developed as well. At the end of 2013, more than 200 biotech molecules were in Phase III trials or filed with the FDA.
Rising prescription drug costs and growing use of drug therapies by an expanding patient population worldwide will lead payers to impose stricter reimbursement regimes.

**Cancer drugs** – Payers increasingly will be reluctant to provide reimbursement for newly approved cancer drugs that offer relatively small, incremental benefit in terms of survival and quality of life.

**Personalized medicine** – More approvals of co-developed companion diagnostics and therapeutics are likely. However, diagnostics without evidence of positive impact on health outcomes will continue to face reimbursement challenges.

**Biosimilars** – U.S. approval of a growing number of biosimilars, beyond the two now being marketed, are likely within three to five years with a regulatory pathway in place. In Europe, where a pathway was enacted in 2006, uptake has been slow due to safety concerns and lack of familiarity among physicians. Similar challenges will likely confront biosimilar manufacturers in the U.S.

**Orphan drugs** – New approvals that carry costs exceeding $100,000 per year per patient are likely to encounter more pushback from payers.

**Payers are likely to continue to challenge orphan drug reimbursement requests**

<table>
<thead>
<tr>
<th></th>
<th>U.S.</th>
<th>England and Wales</th>
<th>The Netherlands</th>
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</thead>
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<tr>
<td><strong>Drug regulatory agency</strong></td>
<td>FDA</td>
<td>EMA/MHRA</td>
<td>CBG</td>
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<td>No single health authority</td>
<td>National Institute for Health and Clinical Excellence (NICE)</td>
<td>Health Insurance Board</td>
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<td><strong>Number of drugs approved by drug regulatory agency</strong></td>
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<td>85</td>
<td>85</td>
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<td><strong>Number of drugs reviewed by health authority</strong></td>
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<td>31</td>
<td>79</td>
</tr>
<tr>
<td><strong>Number of drugs covered</strong></td>
<td>84</td>
<td>19**</td>
<td>72</td>
</tr>
<tr>
<td><strong>Number of drugs rejected by health authority or plan(s)</strong></td>
<td>15</td>
<td>12</td>
<td>7</td>
</tr>
<tr>
<td><strong>Number of drugs conditionally covered</strong></td>
<td>79</td>
<td>9</td>
<td>20</td>
</tr>
</tbody>
</table>

Source: Tufts Center for the Study of Drug Development

* Either covered by the Dutch health authority or given a “positive recommendation” by NICE. Of the 85 approvals, NICE only reviewed 31, and the Dutch Health Insurance Board 79.

** NICE reviewed 31 drugs, and recommended 19 for reimbursement. Note: Drugs that NICE has not reviewed are not necessarily not covered.

In the U.S., 15% of the 99 outpatient orphan drugs approved by the FDA between 1983 and 2008 were rejected by at least one major health plan. In England and Wales, 39% of the 31 drugs reviewed by NICE were given negative recommendations, while only 9% of 79 similarly reviewed drugs by the Health Insurance Board in The Netherlands were denied reimbursement.
Drug developers will deploy strategies to optimize study design, collaborative relationships, and patient engagement in clinical research to drive higher levels of operating performance at lower cost.

As development spending decelerates and programs target smaller market opportunities, cost and time pressures will prompt sponsors to collect more robust, real-time management metrics to guide their relationships with contract research organizations (CROs) and investigative sites.

The ongoing transfer of operating risk to integrated alliance partners will drive leading CROs to invest in big data systems, project management technology solutions, and stronger relationships with preferred investigative sites.

Adoption of adaptive clinical trial designs will accelerate, particularly in earlier clinical phases, as cross-functional teams within sponsor companies look to increase program success rates while lowering costs and disruptions from protocol amendments.

Facing limited government spending on clinical research, academic institutions will turn in earnest to industry-funded clinical trials, where health systems are gaining a competitive advantage by offering access to large patient populations and their centralized and integrated electronic medical and claims records.

Consolidation is likely among the global investigative site community to drive scale efficiencies and improve patient recruitment success as demand from sponsors and CROs for more effective and predictable study conduct performance intensifies.

**A FRAGMENTED INVESTIGATIVE SITE LANDSCAPE WILL CONTINUE TO CHALLENGE SPONSORS**

*Active Unique Investigators Worldwide Filing Form 1572*

Source: Tufts Center for the Study of Drug Development analysis of the FDA’s Bioresearch Monitoring Information System

The number of principal investigators participating in FDA-regulated studies worldwide reached an all-time high in 2012, with the vast majority operating as part-time research centers in community settings. The global site landscape has remained highly fragmented with widely variable performance, underscoring the critical need for this sector to consolidate and build infrastructure and scale efficiencies.
Listed below are selected articles published in 2013 by Tufts CSDD research staff.

**R&D TRENDS**


**PRESCRIPTION DRUG POLICY**


**R&D MANAGEMENT AND OPERATIONS**


Getz KA, Stergiopoulos S, Marlborough M, Whitehill J, Curran M, Kaitin KI. Quantifying the magnitude and cost of collecting extraneous protocol data. *American Journal of Therapeutics* [Published online April 9, 2013]. http://dx.doi.org/10.1097/MJT.0b013e31826fc4aa


## R&D TRENDS: STRATEGY, OPERATIONS, AND MANAGEMENT

- Measuring the cost of drug development: Tufts CSDD’s newest estimate
- Identifying predictors of success for compounds entering late-stage clinical trials
- Analyzing the prevalence of companion/complementary diagnostics development in late-stage pipelines
- Quantifying the adoption and impact of adaptive clinical trial designs
- Assessing outsourcing strategies and operations [CSDD Multi-Company Project Series]
- Benchmarking risk-based monitoring practices [CSDD Multi-Company Project Series]
- Assessing the magnitude and cost of collecting unused and excessive protocol data [CSDD Multi-Company Project Series]
- Evaluating best practices in improving minority patient participation [CSDD Multi-Company Project Series]
- Assessing sponsor-site relationship quality and effectiveness
- Measuring the adoption and use of electronic health records in clinical trials [CSDD Multi-Company Project Series]

## REGULATORY TRENDS

- Assessing the relative performance of FDA reviewing divisions
- Evaluating the FDA’s expedited review and development programs and the impact of the new Breakthrough Therapy Designation
- Measuring the cost of regulatory harmonization [CSDD Multi-Company Project Series]

## BIOTECHNOLOGY SECTOR TRENDS

- Analyzing the landscape for biopharmaceutical products and sponsors
- Evaluating biosimilar diffusion barriers in the U.S. market
- Reviewing the evolution of biotechnology innovation

## PHARMACEUTICAL POLICY AND MARKET TRENDS

- Analyzing the market for prescription to over-the-counter switches in the U.S. and E.U.
- Examining trends in orphan drug reimbursement
- Evaluating the alignment of state and federal regulations on essential drug benefits in the U.S.
- Assessing the impact of drug and device reimbursement policies on innovation
- Examining pharmaceutical industry donation programs targeting neglected diseases
- Evaluating the personalized medicine reimbursement landscape
- Examining the company and product landscape for medical countermeasures
- Quantifying the impact of generic drug manufacturers on U.S. state economies [CSDD Multi-Company Project Series]
- Examining the challenges of post-approval evidence generation for regulatory and reimbursement authorities [CSDD Multi-Company Project Series]
- Developing standard practices and policies for optimizing social and digital media communities in clinical research [CSDD Multi-Company Project Series]
- Mapping and identifying gaps in the adverse events reporting system in the U.S. [CSDD Multi-Company Project Series]
February 3-7, 2014  Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation
Now in its 41st year, the Tufts CSDD Postgraduate Course provides advanced instruction in clinical pharmacology, drug development, clinical trial strategies, biopharmaceutical development, drug safety, and the regulatory process. The 2014 course features lectures, breakout groups, and an interactive panel discussion. Over five days, expert faculty will examine clinical trial ethics, outcomes research, epidemiology, and vaccine development. The program includes an interactive, mock presentation to regulators, providing participants with a unique opportunity to identify and analyze the impact of drug design protocols on the regulatory process.

February 20, 2014  Tufts CSDD Executive Forum Roundtable: Predictors of Clinical Success: New Approaches to Boosting Success Rates
The Tufts CSDD Executive Forum Roundtable Series brings together R&D leaders from industry, academia, and contract services organizations to discuss strategic R&D issues and new approaches that will guide the research-based industry to future success. More on Inside Back Cover.

May 15, 2014  Tufts CSDD Executive Forum Roundtable: Risk-Sharing Partnerships and Alliances: Strategic and Operational Challenges
See Inside Back Cover.

Designed in collaboration with industry R&D leaders, the curriculum is based on challenges experienced by hundreds of development teams, program managers, and functional directors. Two-thirds of the course is devoted to hands-on casework, with the rest focused on interactive discussion with faculty. Attendance is limited to 35.

September 18, 2014  Tufts CSDD Executive Forum Roundtable: New Directions in Outsourcing
See Inside Back Cover.

November 6, 2014  Tufts CSDD Executive Forum Roundtable: Managing the Changing Investigative Site Landscape
See Inside Back Cover.

Looking ahead... February 2015  Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation
See description above.

For more information about these programs, call the Tufts Center for the Study of Drug Development at 617-636-2170, email to csdd@tufts.edu, or visit http://csdd.tufts.edu and click on the “COURSES” section.
STAY ON TOP OF THE RAPIDLY CHANGING DRUG DEVELOPMENT LANDSCAPE WITH THE TUFTS CSDD IMPACT REPORT

A bi-monthly, authoritative analysis of critical drug development issues, highlighting current research of the Tufts Center for the Study of Drug Development.

Tufts CSDD Impact Reports have become must reading for professionals worldwide who are looking to understand the current state of drug development and regulation. Presented in a concise, four-page format, each issue delivers original research, analysis, and insight on mission-critical topics relating to the nature and pace of drug development and regulation that can’t be found anywhere else.

It’s why readers, year after year, describe Tufts CSDD Impact Reports as “thoughtful and timely,” “excellent,” and “a real asset.”

Available electronically or in hard copy format.

2014 EDITORIAL CALENDAR:
January/February — Breakthrough Therapy Designation: Building on Existing FDA Special Programs
March/April — Social Media in Clinical Research: Standard Practices and Policies
June/July — Interrupted and Uninterrupted Drug Development Performance Assessment
July/August — Orphan Drug Reimbursement Landscape
September/October — Study Design Optimization Strategies: Governance Mechanisms and Adaptive Designs
November/December — Development Trends for Central Nervous System Medicines

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Tufts CSDD corporate subscriptions are available at volume discounts. Contact Jonathan Hsieh at 617-636-0840 or email Jonathan.Hsieh@tufts.edu for details.
TUFTS CSDD EXECUTIVE FORUM ROUNDTABLE SERIES

An ongoing program of highly interactive, one-day roundtable discussions for senior R&D leaders, hosted by the Tufts Center for the Study of Drug Development.

February 20, 2014  
PREDICTORS OF CLINICAL SUCCESS: NEW APPROACHES TO BOOSTING SUCCESS RATES
Improving clinical success rates remains one of the pharmaceutical industry’s greatest—and most vexing—challenges. High attrition rates are associated with extended development times, increased costs, and diminished investor and public confidence. Tufts CSDD recently analyzed a set of clinical and operating attributes of successful and terminated drug candidates in an effort to create a tool to better predict clinical success or failure. This roundtable will open with a presentation of CSDD’s findings, and will follow with a discussion of new approaches by companies to improve overall success rates.

May 15, 2014  
RISK-SHARING PARTNERSHIPS AND ALLIANCES: STRATEGIC AND OPERATIONAL CHALLENGES
Over the past several years, numerous partnerships, alliances, and consortia have been formed to share risk, lower cost, and drive efficiency and speed in pharmaceutical R&D. This roundtable will look at recently created and established collaborations and explore their strategic and operational challenges. We also will look at their actual and anticipated impact on performance, cost, and quality.

September 18, 2014  
NEW DIRECTIONS IN OUTSOURCING
Sponsor-CRO relationships continue to evolve to drive higher levels of efficiency, performance, and cost advantage. This roundtable will examine ways that sponsors are modifying their strategic and integrated alliance models to meet current demands. We will review innovative synergies and assets that CROs are bringing to their relationships with sponsors, and we will assess new management mechanisms to better leverage collaborative partnerships.

November 6, 2014  
MANAGING THE CHANGING INVESTIGATIVE SITE LANDSCAPE
The global investigative site landscape remains fragmented and undeveloped with highly variable and unpredictable clinical trials performance. This roundtable will open with a review of recent Tufts CSDD studies characterizing the current investigative site landscape and benchmarking site management practices and their impact. Subsequent presentations will examine opportunities to consolidate the global investigative site landscape and drive higher levels of operating sophistication, maturity, and efficiency.

Roundtables are held 10 a.m. – 4 p.m. at the Tufts Center for the Study of Drug Development in Boston.

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