Tufts CSDD’s multidisciplinary faculty conduct research, publish, and speak regularly on a wide variety of topics related to pharmaceutical and biopharmaceutical development.

<table>
<thead>
<tr>
<th>Contact</th>
<th>Expertise</th>
</tr>
</thead>
</table>
| **Kenneth I Kaitin, PhD**<br>Professor and Director<br>Tel 617-636-2181<br>Email kenneth.kaitin@tufts.edu | - Economic and regulatory environment  
- R&D and corporate strategy  
- Academic-industry partnerships  
- Emerging markets  
- New business models |
| **Christopher-Paul Milne, DVM, MPH, JD**<br>Research Associate Professor and Director of Research<br>Tel 617-636-2188<br>Email christopher.milne@tufts.edu | - Impact of regulatory policy  
- Orphan drug program  
- Pediatric initiative  
- Counter-bioterrorism initiatives  
- Global R&D and innovation |
| **Joseph A. DiMasi, PhD**<br>Research Associate Professor and Director of Economic Analysis<br>Tel 617-636-2116<br>Email joseph.dimasi@tufts.edu | - Cost of drug development  
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- Clinical approval success rates  
- Post-approval R&D  
- Therapeutic class development trends |
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- Formulary trends  
- Follow-on drug development trends  
- Prescription-to-over-the-counter switching |
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- Contract research organizations  
- Investigative site landscape  
- International clinical trials  
- E-technologies in drug development |
| **Ronald Evens, PharmD, FCCP**<br>Adjunct Research Professor<br>Tel 707-317-3046<br>Email medaff4biopharma@aol.com | - Biotechnology product development  
- Novel biotech research platforms  
- Biosimilar development  
- Biotech business models and financing |
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- Clinical pharmacology and therapeutics  
- Clinical research ethics |
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 a multidisciplinary, academic research group that develops strategic information to help all stakeholders in the life sciences enterprise—including drug developers, regulators, policy makers, payers, and investors—improve the quality and efficiency of biopharmaceutical discovery, development, and review.

Kenneth I Kaitin, PhD, director of Tufts CSDD since 1998, leads a team of six research professionals and 11 research and administrative 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.
- Analyze the development and review process for 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 Tufts CSDD’s views on near-term pharmaceutical and biopharmaceutical development trends. Data contained in Outlook 2015 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, academics, investors, service providers, and others involved in biomedical innovation.

Outlook 2015 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 programs, graduate level courses, workshops, and symposia. In addition, Tufts CSDD 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.
**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.

**Neglected diseases** — 13 diseases or disease categories defined by the G-FINDER (Global Funding of Innovation for Neglected Diseases Report), published in 2009 by the George Institute for International Health, which include malaria, kinetoplastids, diarrheal diseases, helminths, bacterial pneumonia and meningitis, and typhoid fever.

**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.

**Orphan drug** — Drugs developed for rare diseases and conditions, which, in the United States, 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.

**Phase IV** — Studies conducted after a drug is approved for marketing to provide expanded safety and efficacy data on the drug when used in the general patient population, and to generate information to improve the prescribing, use, quality, or manufacture of the product.

**Protocol** — A plan detailing the methodology of a clinical study.

**Recombinant protein** — Protein produced through the combination of DNA fragments from different sources.

**Specialty pharmaceuticals** — Drugs used to treat chronic, complex, or life threatening conditions, such as cancer and autoimmune diseases. They are typically priced higher than traditional medicines.
The essential challenge for drug sponsors, policy makers, and payers—today and for the foreseeable future—is to balance the need for new, innovative medicines with the equally pressing need to bring health care spending under control. New products that successfully treat complex diseases, while positive in and of themselves, are spurring demand for more—and usually more expensive—medicines for unmet medical needs. Success though, is not cheap—it now costs nearly $2.6 billion to develop and gain marketing approval for a new prescription drug. (See chart below.)

Sponsors looking for the most promising returns on investment have been transitioning from a high-volume, low-margin business model to a low-volume, high-margin model, directing a growing share of their resources toward development of precision medicines, specialty pharmaceuticals, and orphan drugs. However, in five years or so, when many of these narrowly targeted products now in development reach the market, they may encounter strong payer resistance. Recent payer reluctance to reimburse for Solvaldi, a hepatitis C cure that costs patients $1,000 a pill and $84,000 for a course of treatment, could be a harbinger of a reimbursement brick wall. Payers will need to make tough choices about what to cover and what not to cover. Ultimately, payers and sponsors will have to jointly determine what evidence is needed to demonstrate value, and what represents a fair price.

Government and regulators have significant roles to play in the unfolding health care cost drama. For example, in 2014, the Energy and Commerce Committee in the U.S. House of Representatives launched the 21st Century Cures Initiative, which aims to accelerate the pace of discovery, streamline drug and device development, and expand the use of digital medicine and social media in delivering treatment. European and Japanese authorities will likely explore similar programs, as they increasingly find that cost controls cannot rein in growing health care spending. A key challenge for all governments is to maintain strong incentives for sponsors to innovate, while finding new approaches to ensure that healthcare remains affordable.

Pressing ahead, all stakeholders—sponsors, payers, regulators, legislators, physicians, and patients—will need objective, unbiased data for effective decision making. Tufts CSDD, through its scholarly studies and analyses, will continue to fulfill its mission of informing this critical debate.

**NEW DRUGS NOW COST NEARLY $2.6 BILLION, SHAPING DIRECTION OF SPONSORS’ R&D EFFORTS**

*Average Cost to Develop and Win Marketing Approval for a New Drug*

Rising R&D costs, driven mainly by increased out-of-pocket costs and higher failure rates for drugs tested in human subjects, means the average cost to develop and gain marketing approval for a new prescription medicine, a process often lasting longer than a decade, is now $2.56 billion dollars. Drug developers continue to make efforts to rein in costs, but also have responded by focusing their R&D on products for markets with more attractive investment returns.

Source: Tufts Center for the Study of Drug Development
R&D Trends

Oncology development activity will expand, driven by advances in science, medical need, and regulatory and market incentives. Across all therapeutic areas, developers will increasingly rely on risk-sharing and collaborative relationships, from discovery through development, to spur innovation and reduce costs.

FIRMS WILL CONTINUE TO INVEST HEAVILY IN CANCER DRUG DEVELOPMENT

Trends in New Drug and Biologics Approvals by Therapeutic Class (four largest classes)

Drug and biologic developers will expand their investment in new cancer therapies as a consequence of advances in the scientific understanding of the molecular basis of human cancers, cancer immunotherapy and its role in dealing with drug resistance, and how cancer drug combinations can best be utilized.

U.S. policymakers will continue to spur innovation of drugs to treat resistant bacterial infections, following the recent approval of antimicrobials that were developed under the Generating Antibiotic Incentives Now (GAIN) program, authorized as part of the FDA Safety and Innovation Act of 2012.

Drug developers will continue to participate in risk-sharing relationships and other strategic partnerships with academic institutions, patient groups, contract research organizations, and other developers to improve R&D productivity. Pre-competitive consortia will grow as membership by developers expands.

Clinical trial costs will continue to increase as payers demand more information on how new drugs and biologics perform relative to products already on the market. Increases in trial costs due to comparator testing will be greater for new biologics than for small molecule drugs, because of the high cost of acquiring comparator biologics.

Pharmaceutical companies will increase their use of outsourcing providers during the development process, but will experiment with a number of outsourcing models to improve quality and reduce costs.

Firms will continue to invest heavily in cancer drug development

Cancer (antineoplastic) compounds now account for about 30% of all U.S. approvals. Interest in developing new cancer medicines has expanded, due in part to new approaches to development, including greater focus on new targets within validated and new pathways, novel drug formats, and improved clinical study design.

NOTE: Anti-infective excludes AIDS antivirals
Source: Tufts Center for the Study of Drug Development
Public demand for new and innovative medicines to treat a wide range of diseases, for broad as well as narrow populations, will spur regulatory authorities to increase engagement with stakeholders and encourage sponsors to explore novel development pathways.

The U.S. Food and Drug Administration (FDA) will respond to Congressional calls for improved clinical trial efficiency by supporting initiatives, such as the Lung Cancer Master Protocol, that create a single clinical trial infrastructure for testing several drugs simultaneously, and evaluating the Special Medical Use or Limited Population Pathway, that encourages novel development programs for limited, well-defined subpopulations with unmet medical needs.

The FDA will expand stakeholder engagement under the auspices of 22 public-private-partnerships, and will push forward on patient-focused drug development, informed by public meetings with advocacy groups and others.

European and U.S. regulators will continue to encourage use of expedited development programs aimed at bringing new drugs to market more quickly: the European Medicines Agency (EMA) has launched an adaptive licensing pilot program, while the FDA’s Breakthrough Therapy Designation program is booming – with more than 200 requests.

Regulatory agencies will expand use of new tools, standards, and approaches to evaluate new technologies and novel products. For example, the FDA is focusing its efforts on nanotechnology and nanomaterials; the EMA is relying on new methods and tools to study the impact of juvenile diabetes and age-related macular degeneration; Japan’s Pharmaceutical and Medical Devices Agency is looking to become the world leader for conditional approval of, and accelerated reimbursement for, regenerative medicines.

The Medical Countermeasures Initiative—launched in 2002 to coordinate development, preparedness, and response against threats to U.S. and global public health, including from emerging infectious diseases and pandemics—has spawned a growing number of compounds now in development. The chart above demonstrates the increase in the pipeline over time for just one such threat – Ebola. In addition to biopharmaceutical sponsors, a fledgling R&D sector comprised of small firms and public sector research institutes is working to counter rapidly developing threats to public health, but there remains an open question whether it can proceed fast enough.
Biotechnology Sector Trends

The pace of biotech development and product approvals will build on recent activity—25 biological approvals in the U.S. in the first 10 months of 2014—as the sector gains a growing share of total pharmaceutical sales.

A resurgence of genetic therapies, now underway for near-term product opportunities, will continue, evidenced by the number of biotech companies focused on RNA inhibition products (20+) and gene therapies (25+). Development agreements between pharma companies and bio-genetic companies will increase.

Cell therapies (CT) and stem cell therapies (SCT) have become a significant focus of product development, with 30+ CT companies and 20+ SCT companies engaged in all stages of clinical research.

Immunotherapy is evolving rapidly, especially in oncology, with a broader variety of novel molecules and mechanisms of action and higher expected efficacy levels, e.g., chimeric antigen receptor t-cells, newly targeted monoclonal antibodies, bispecific antibodies, and improved vaccines.

Alliances between pharma and biotech companies will continue to be a mainstay of venture capital and other investment, building on the recent past, e.g., 392 antibody drug conjugate deals from 2009 through August 2014 (about 50 to 70 per year) generated sales reported at more than $31 billion.

Biosimilars are poised to have a significant impact on the U.S. and EU markets, with monoclonal antibodies constituting the biggest target for developers. In the fourth quarter of 2014, 13 U.S. and EU companies had 30 to 40 molecules in late stage clinical trials, while an estimated 100 to 200 emerging market companies were engaged in trials at different stages.

VARIETY AND NUMBER OF PRODUCTS IN DEVELOPMENT BODE WELL FOR BIOTECH INDUSTRY GROWTH

Biotechnology Product Phase III Clinical Trials in 2014

<table>
<thead>
<tr>
<th>Product Categories</th>
<th>Number of Products*</th>
<th>Therapeutic Areas</th>
<th>Number of Indications*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monoclonal antibodies</td>
<td>74 (14)</td>
<td>Oncology</td>
<td>71 (23)</td>
</tr>
<tr>
<td>Recombinant proteins</td>
<td>46 (4)</td>
<td>Rheumatology</td>
<td>25 (6)</td>
</tr>
<tr>
<td>Biotech vaccines</td>
<td>23</td>
<td>Hematology</td>
<td>14</td>
</tr>
<tr>
<td>Cell therapy</td>
<td>14</td>
<td>Cardio-vascular</td>
<td>12 (3)</td>
</tr>
<tr>
<td>Genetic therapies</td>
<td>14</td>
<td>Neurology</td>
<td>11 (1)</td>
</tr>
<tr>
<td>Peptides</td>
<td>5</td>
<td>Diabetes mellitus</td>
<td>11</td>
</tr>
<tr>
<td>Other</td>
<td>7 (1)</td>
<td>Other areas (7 in total)</td>
<td>46 (14)</td>
</tr>
<tr>
<td>TOTALS</td>
<td>183 (19)</td>
<td>TOTALS</td>
<td>190 (47)</td>
</tr>
</tbody>
</table>

* Number of investigational biotech products in Phase III clinical trials; figure in parentheses is the number of already marketed products undergoing Phase III trials for new indications (as of October 2014)

Source: Tufts Center for the Study of Drug Development

New biotech development—driven largely by monoclonal antibody products based on novel platforms and recombinant protein compounds—will highlight biotech advances in 2015 and beyond. Novel monoclonal antibodies include blockbuster potential treatments for hypercholesterolemia and further antibody drug conjugates in oncology.

Novel second-generation proteins will be a major development area, e.g., pegylation of molecules may extend the duration of action, allowing for reduced dosing frequency.
The continued rise in prices charged for specialty pharmaceuticals will be tempered by competition in several key therapeutic classes, as well as the introduction of biosimilars.

**Neglected diseases** – The Ebola outbreak will renew focus on policies to stimulate R&D spending for neglected disease drug development. Drug companies will enhance their drug donation programs targeting neglected disease patients in the developing world.

**Orphan drugs** – Currently, more than one-third of U.S. marketing approvals for new medicines are for orphan drugs. This trend will likely continue, with nearly 40% of new orphan approvals during the next five years expected to be related to cancer treatment.

**Pricing** – High-priced drugs to treat a number of diseases for which inadequate or no therapies currently exist—for example, a typical 12-week course of treatment with Sovaldi for a patient with Hepatitis C costs $84,000—will face growing resistance from payers, who increasingly will seek lower-priced alternatives.

**Biosimilars** – U.S. approval of a relatively large number of biosimilars is likely within one to three years, now that a regulatory pathway is 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 are initially likely to occur in the U.S., but then biosimilar uptake will expand rapidly as payers look to biosimilars to reduce costs.

### BIOSIMILARS ARE COMING IN THE UNITED STATES

<table>
<thead>
<tr>
<th>Originator biologic</th>
<th>Selected indication(s)</th>
<th>Introduced in U.S.</th>
<th>Biosimilar</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotropin (somatropin)</td>
<td>Growth failure</td>
<td>2006</td>
<td>Omnitrope</td>
</tr>
<tr>
<td>Xaparin (enoxaparin)</td>
<td>Blood thinner</td>
<td>2010</td>
<td>Lovenox</td>
</tr>
<tr>
<td>Neupogen (filgrastim)</td>
<td>Bone marrow stimulant</td>
<td>2015</td>
<td>NA</td>
</tr>
<tr>
<td>Epogen (epoetin alfa)</td>
<td>Renal anemia</td>
<td>2015</td>
<td>NA</td>
</tr>
<tr>
<td>Humalog (insulin lispro)</td>
<td>Diabetes</td>
<td>2015</td>
<td>NA</td>
</tr>
<tr>
<td>Enbrel (etanercept)</td>
<td>Psoriasis, Rheumatoid arthritis</td>
<td>2016</td>
<td>NA</td>
</tr>
<tr>
<td>Humira (adalimumab)</td>
<td>Rheumatoid arthritis, Crohn’s disease, Ulcerative colitis, Psoriasis</td>
<td>2017</td>
<td>NA</td>
</tr>
<tr>
<td>Rituxan (rituximab)</td>
<td>Rheumatoid arthritis, Non-Hodgkin’s lymphoma, Chronic lymphocytic leukemia</td>
<td>2017</td>
<td>NA</td>
</tr>
<tr>
<td>Remicade (infliximab)</td>
<td>Rheumatoid arthritis, Ulcerative colitis, Crohn’s disease</td>
<td>2018</td>
<td>NA</td>
</tr>
<tr>
<td>Herceptin (trastuzumab)</td>
<td>Breast cancer</td>
<td>2019</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Source: Tufts Center for the Study of Drug Development*

Patent expirations on several high-profile biologics in 2013 and 2014 paved the way for the introduction of biosimilars. With biosimilars expected to be priced 25% – 30% below the price of originator biologics, payers in the U.S. are likely to save tens of millions of dollars over the next five years.
**R&D Management and Operations**

**Drug sponsors will implement new strategies to improve clinical study design feasibility, data transparency and disclosure, and collaborative effectiveness with CROs and investigative sites to achieve higher levels of study volunteer engagement and satisfaction.**

- Simultaneous and inconsistent use of contract research organization (CRO) partners to support project- and program-specific responsibilities is causing operating friction and inefficiency, which will lead some sponsors to rethink their outsourcing strategies.

- Private equity will consolidate the global investigative site landscape to drive up scale efficiencies as sponsors and CROs demand higher levels of performance in recruiting and retaining volunteers at contained costs.

- Adoption of simple (e.g., early futility, sample size re-estimation) and more sophisticated (e.g., dose response, randomization ratios) adaptive clinical trial designs will accelerate as functions within sponsor companies vie to increase data quality and program success rates.

- Sponsors and CROs will make greater use of large structured and unstructured datasets to perform predictive analytics, refine research agendas and protocol designs, identify and engage study volunteers, gather real-time management metrics, and improve regulatory submissions.

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**NUMEROUS FACTORS ARE ESSENTIAL TO LEVERAGING THE VALUE OF STRATEGIC RELATIONSHIPS**

**Change Orders by Outsourcing Relationship Model**

- Although it is widely anticipated that strategic alliances will result in fewer change orders (defined as formal, written changes to the original scope of work agreement), due to greater shared upfront planning between sponsors and CROs and more operating autonomy transferred to contract service providers, a recent Tufts CSDD study found no difference in the frequency of change orders between traditional transactional relationships and strategic alliances. This suggests that the latter have a limited impact on development efficiency.
Selected CSDD Publications

Listed below are selected articles published in 2014 by Tufts CSDD research staff.

**R&D TRENDS**


**PRESCRIPTION DRUG REGULATION AND POLICY**


Milne C-P, Davis J. The Pediatric Studies Initiative: After 15 years have we reached the limits of the law? *Clinical Therapeutics* 2014;36(2):156-162.


**R&D MANAGEMENT AND OPERATIONS**


R&D TRENDS: STRATEGY, OPERATIONS, AND MANAGEMENT

- Cost of pharmaceutical R&D
- Measuring R&D costs by therapeutic class
- Predictors of success rates for compounds entering late-stage clinical trials
- Current state of personalized medicine and companion diagnostic development: update of 2010 Tufts CSDD assessment
- Drug-diagnostic co-development in late-stage personalized medicine pipeline
- Adaptive clinical trial designs: adoption and impact
- Outsourcing strategies and operations
- Use and impact of new investigative site start-up practices and solutions
- Protocol amendments: direct and indirect costs [CSDD Multi-Company Project Series]
- Big Data adoption and use in clinical research [CSDD Multi-Company Project Series]
- Benchmarking risk-based monitoring practices [CSDD Multi-Company Project Series]
- New investigative site management strategies [CSDD Multi-Company Project Series]
- Clinical supply logistics strategies and their impact [CSDD Multi-Company Project Series]

REGULATORY TRENDS

- FDA’s Breakthrough Therapy Designation program: a progress report
- Medical countermeasures for bioterrorism: impact of new regulatory policies and procedures on product landscape
- Cost of regulatory harmonization [CSDD Multi-Company Project Series]

BIOTECHNOLOGY SECTOR TRENDS

- Rates of return for new biologics and biosimilars compared to new small molecules
- Landscape for biopharmaceutical products and sponsors
- Trends in vaccine development and regulation

PHARMACEUTICAL POLICY AND MARKET TRENDS

- Relative contribution of the private and public sectors to the R&D of the most transformational drugs of the last quarter century
- Market for prescription to over-the-counter switches in the U.S. and EU
- Drug and device reimbursement policies: impact on innovation
- Pharmaceutical industry donation programs targeting neglected diseases
- Drug shortages: causes and impact
- Assessing the personalized medicine landscape
February 2-6, 2015  
**Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation**  
Now in its 42nd 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 2015 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 26, 2015  
**Tufts CSDD Executive Forum Roundtable: FDA’s Breakthrough Therapy Designation – A Three-Year Assessment**  
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 14, 2015  
**Tufts CSDD Executive Forum Roundtable: Diagnostic-Therapeutic Co-development Strategies and Best Practices**  
See Inside Back Cover.

July 7-8, 2015  
**Leadership for Drug Development Teams: Improving Cross-Functional R&D Performance**  
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 17, 2015  
**Tufts CSDD Executive Forum Roundtable: Novel Approaches to Overhauling the Clinical Development Process**  
See Inside Back Cover.

November 12, 2015  
**Tufts CSDD Executive Forum Roundtable: Patient Recruitment and Retention 2.0**  
See Inside Back Cover.

LOOKING AHEAD:

February 2016  
**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 & FORUMS” section.
Professionals worldwide who need to understand the current state of drug development and regulation read the Tufts CSDD Impact Report

Shouldn’t you?

Tufts CSDD Impact Reports provide a bi-monthly, authoritative analysis of critical drug development issues, highlighting current research from the Tufts Center for the Study of Drug Development – clearly, concisely.

Each issue, presented in an easily accessible four-page format, delivers original research, analysis, and insight on mission-critical topics relating to the nature and pace of drug development and regulation, which can’t be found anywhere else.

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

Available electronically or in hard copy.

2015 EDITORIAL CALENDAR:
- January/February — The Current Investigative Site Landscape
- March/April — Personalized Medicines: Development and Market Trends
- May/June — Trends in Vaccine Development
- July/August — The Biosimilars Market
- September/October — Clinical Success Rates in New Drug Development
- November/December — New Outsourcing Strategies and Operations

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

**February 26, 2015**  
**FDA’s Breakthrough Therapy Designation – A Three-Year Assessment**  
Breakthrough Therapy Designation (BTD), part of the reauthorization of the Prescription Drug User Fee Act in 2012, allows the FDA to expedite the development and review of drugs intended to treat a serious condition where preliminary clinical evidence suggests substantial improvement over available therapy on a clinically significant endpoint or on symptoms that represent serious consequences of the disease. The roundtable will open with a review of recent CSDD data on the BTD program in its first three years. This will be followed by individual company experiences and lessons learned.

**May 14, 2015**  
**Diagnostic-Therapeutic Co-development Strategies and Best Practices**  
The R&D portfolio of many pharmaceutical companies currently includes personalized and targeted medicines. However, having an effective strategy for the co-development of a complementary or companion diagnostic often represents a significant bottleneck in the R&D process. In this roundtable, we will explore different diagnostic-therapeutic co-development strategies and discuss insights and best practices.

**September 17, 2015**  
**Novel Approaches to Overhauling the Clinical Development Process**  
The time, cost, and risk of drug development remain formidable obstacles for drug sponsors and CROs. This roundtable will explore novel approaches that are being piloted and widely adopted by leading pharma companies to speed development time, lower cost, improve efficiency, and increase the probability of success for clinical candidates. As we review these novel and innovative approaches, the goal will be to assess what works and what doesn’t work.

**November 12, 2015**  
**Patient Recruitment and Retention 2.0**  
The convergence of clinical care data, clinical research data, and engaged patient communities has introduced promising new approaches to identifying, attracting, and retaining study volunteers for pre- and post-approval clinical trials. This roundtable will begin with a CSDD assessment of a variety of novel approaches and their impact to date. We will then discuss specific case examples in detail to shed light on strategic insights and opportunities.

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

*For more information, call Robert Chung at 617-636-2187, or email robert.chung@tufts.edu.*