Tufts Center for the Study of Drug Development

OUTLOOK 2016

Tufts University

BENCHMARKING THE DRUG DEVELOPMENT PROCESS

IMPROVING BIOPHARMACEUTICAL R&D EFFICIENCY

REGULATORY INITIATIVES TO FOSTER BIOMEDICAL INNOVATION

PHARMACEUTICAL VALUE AND PATIENT ACCESS
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>
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ABOUT TUFTS CSDD AND THIS REPORT

Founded in 1976, the Tufts Center for the Study of Drug Development at Tufts University School of Medicine celebrates its 40th anniversary in 2016 and continues to fulfill its original mission: To help advance biomedical innovation through scholarly analyses of pharmaceutical economics, policy, law, science, and regulation.

As a multidisciplinary, academic research group, Tufts CSDD develops strategic information to help all stakeholders in the life sciences enterprise—drug developers, regulators, policy makers, payers, patients, care providers, health networks, 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 regularly:

- Monitor and report on the development, regulation, and utilization of new drugs and biopharmaceuticals.
- 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, finance, and patient advocacy.
- Raise the level of national and international debate on issues related to new drug and biotechnology product development and regulation.

Tufts CSDD’s Outlook, published each January, showcases Tufts CSDD’s views on near-term pharmaceutical and biopharmaceutical development trends. Data contained in Outlook 2016 are based on proprietary research conducted by Tufts CSDD. Analyses are from the ongoing work of Tufts CSDD’s research faculty and 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 2016 is one element of a full range of information and related activities focused on the research-based drug and biotechnology industry and other stakeholders in pharmaceutical innovation. Other Tufts CSDD activities 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 periodic reviews 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 visit csdd.tufts.edu.
The research-based drug development enterprise is at a crossroads. As demand for new therapies to address unmet medical needs remains high, the time required to bring new medicines to market remains stubbornly long, while the effort to develop them has become more complex than ever. It takes an average of $2.6 billion and 15 years to develop and win approval for a new drug. A typical Phase III protocol now entails an average of 167 procedures, 60% more than at the start of the millennium.

The pharmaceutical industry along with major regulatory authorities worldwide are committed to improving R&D efficiency, most notably by transforming the clinical trial process. To that end drug developers are making greater use of information technology, Big Data, adaptive clinical trial designs, strategic alliances, and integrated partnerships involving patients, payers, contract service organizations, government research agencies, and health care providers. But more is required to achieve the scale of improvements needed.

Supported by the drug industry, advocacy organizations, and independent analysts, the U.S. Congress authorized the Breakthrough Therapy Designation, a development pathway that would shorten clinical development time in cases where a large effect in a serious disease is observed early in development. A similar coalescing of interests, supported by federal funding for related basic research, could lead to new drugs to address unmet needs.

Regulation has an important role to play, as well. In the U.S., the Food and Drug Administration (FDA) could, for example, create incentive programs to extend marketing exclusivity periods for certain classes of drugs deemed critical to national health and encourage development of generic drugs to increase competition and lower costs of therapies to treat specific diseases.

**Regulators Can Have a Decisive Impact on Speeding New Drug Development**

*Comparison of FDA Programs to Expedite Drug Development and Review*

- Pre-IND
- IND
- End of Phase I
- End of Phase II
- End of Phase III Submission
- NDA/BLA Approval
- NDA/BLA Marketing
- Priority
- Accelerated Approval
- Fast Track Designation
- Breakthrough Designation

= FDA willing to discuss issues
= Issues still needing resolution
= Post-approval requirements

Source: Tufts Center for the Study of Drug Development
Despite rising costs and increasingly cost-conscious payers, sponsors will move aggressively on new drug development, building on scientific advances, risk-sharing Re/D relationships, and new regulatory programs.

With competition in drug discovery and development intensifying, and a growing number of independent drug sponsors pursuing similar targets, patients will benefit, as important therapeutic advances are likely to be marketed at a growing pace.

Spurred on by growing antimicrobial resistance and a notable decline in the development of new antibacterials over several decades, incentives included in the FDA Safety and Innovation Act of 2012 will bear fruit and new antibacterials will begin to reach the market over the next several years.

Continued scientific achievements that increase understanding of the pathophysiology of oncological diseases will result in approvals of new cancer therapies, which will outpace new drug approvals in other therapeutic areas, as has been the case over the last 15 years.

Major developments in immune-oncology (I/O) are expected in several areas in which research has been focused, including concomitant PDL-1 blockade with other I/O treatments; new I/O product approvals; greater use of oncologic vaccines with I/O treatments; and growing use of enhanced cell therapies such as CART and TCR for T-lymphocytes and enhanced NK cells.

New biotechnology therapeutics, which during the last 15 years have been approved for marketing in the U.S. at a rate of 10 to 13 new products annually, will continue to be approved at a substantial rate in 2016, especially in the oncology area.
Recognition by drug developers of the need to improve R&D efficiency will stimulate increased use of integrated data (“Big Data”), new strategic partnerships, and patient and health care community engagement.

- Sponsors and CROs will make greater use of electronic medical information and drug development management metrics to perform more robust, predictive analytics to drive operating efficiency, improve feasibility, inform portfolio strategy, and support more effective patient recruitment.

- The U.S. investigative site market, which is more fragmented than in Europe, will consolidate. Site networks, often supported by private equity, will acquire more sites and form stronger partnerships with large health systems.

- The patient-centered drug development movement will drive drug developers, regulatory agencies, research professionals, health care providers, and payers to explore and implement initiatives to more proactively and effectively define endpoints, modify clinical trial execution practices and solutions, and establish more formal benefit-risk assessment approaches.

**Drug Developers Will Increase Their Reliance on CRO Partners to Perform Essential Functions**

*Outsourcing Models for Selected Development Functions*

A Tufts CSDD study, which found that CROs are playing a prominent and growing role in managing investigative site relationships, suggests that top CROs will get more involved in conducting clinical trials. This trend will build, in part, on recent mergers and acquisitions with central labs that offer CROs unprecedented access to remote study locations.
U.S. and international regulatory authorities will seek to align review requirements with evolving drug development practices to help speed development and approval of urgently needed medicines.

Reauthorization of the Prescription Drug User Fee Act (PDUFA), which would take effect in late 2017, is expected to include regulatory review enhancements to better account for advances in technology and patient-focused drug development, e.g., next generation sequencing and adaptive clinical trials designs.

The FDA will expand and improve its Sentinel Program, which enables querying of diverse health care data sources to evaluate possible medical product safety issues quickly and securely.

The FDA and NIH will look to spur the Precision Medicine Initiative by identifying new disease biomarkers via the NIH’s million-person research cohort, and integrate existing ones into the regulatory process through the FDA’s biomarker qualification program, while also initiating an expanded regulatory scheme for laboratory-developed tests, among other efforts.

The U.S. will reach out to emerging markets, especially India and China, to foster and support industry best practices in globalized clinical trials, pharmacovigilance, and manufacturing.

Major regulatory agencies will emphasize harmonization of global activities to coordinate and facilitate pediatric studies, prompted by recent changes in policy that will increase the demand for pediatric patients to participate in clinical trials.

REGULATORY ADVANCES ARE EXPECTED TO SPUR THE GLOBAL REGENERATIVE MEDICINE MARKET

Regenerative Medicine Market Outlook

Aided by rapid advances in science and supported by regulators in Europe, Japan, and the U.S., the global market for regenerative medicine products is expected to more than quadruple – from $16 billion in 2014 to $68 billion in 2020.

Sources: Tufts Center for the Study of Drug Development, Alliance for Regenerative Medicine, Allied Market Research

2020 market in U.S.$ billions (est.)

Current market in U.S.$ billions

U.S. companies with product approvals

Product approvals (Q2 2015)

Products in late-stage development (Q2 2015)
U.S. pricing and reimbursement policies will increasingly align price and value, similar to current practices of international health authorities.

Recent increases in cancer and orphan drug approvals and the rise in cancer and orphan drug prices are leading to a reconsideration of U.S. pricing and reimbursement policies.

U.S. payers and providers will quantify clinical benefits of new cancer and orphan products to align price with value by measuring safety, effectiveness, convenience of use, and other attributes in relation to cost, e.g., Memorial Sloan Kettering Cancer Center’s use of a cancer drug “abacus” to measure safety, effectiveness, toxicity, convenience of use, and other attributes.

Payers will impose increasingly higher patient cost-sharing, particularly for outpatient cancer and orphan drugs.

Certain classes of therapeutically interchangeable drugs will see more use of value-based insurance design: lower patient cost sharing for higher value products and higher patient cost sharing for lower value products.

The number of personalized cancer and orphan drugs, along with companion diagnostics, will continue to increase to meet expanding demand.

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**HIGH COST OF CANCER DRUGS IS FORCING PAYERS TO RETHINK WAYS OF CLASSIFYING PATIENTS**

**Cost of selected cancer drugs**

<table>
<thead>
<tr>
<th>GENERIC DRUG NAME (TRADE NAME)</th>
<th>ORIGINAL FDA-APPROVED INDICATION</th>
<th>DRUG COST PER YEAR (U.S. $)</th>
<th>PERSONALIZED</th>
<th>INJECTABLE OR ORAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bevacizumab (Avastin)</td>
<td>Colorectal cancer</td>
<td>95,000</td>
<td>No</td>
<td>Injectable</td>
</tr>
<tr>
<td>Cetuximab (Erbitux)</td>
<td>Colorectal cancer</td>
<td>120,000</td>
<td>Yes</td>
<td>Injectable</td>
</tr>
<tr>
<td>Crizotinib (Xalkori)</td>
<td>Non-small cell lung cancer</td>
<td>125,000</td>
<td>Yes</td>
<td>Oral</td>
</tr>
<tr>
<td>Dasatinib (Sprycel)</td>
<td>Chronic myeloid leukemia</td>
<td>115,000</td>
<td>Yes</td>
<td>Oral</td>
</tr>
<tr>
<td>Imatinib (Gleevec)</td>
<td>Chronic myeloid leukemia</td>
<td>80,000</td>
<td>Yes</td>
<td>Oral</td>
</tr>
<tr>
<td>Lenalidomide (Revlimid)</td>
<td>Multiple myeloma</td>
<td>90,000</td>
<td>No</td>
<td>Oral</td>
</tr>
<tr>
<td>Ofatumumab (Arzerra)</td>
<td>Chronic lymphoid leukemia</td>
<td>120,000</td>
<td>No</td>
<td>Injectable</td>
</tr>
<tr>
<td>Panitumumab (Vectibix)</td>
<td>Colorectal cancer</td>
<td>100,000</td>
<td>Yes</td>
<td>Injectable</td>
</tr>
<tr>
<td>Sipuleucel-T (Provenge)</td>
<td>Prostate cancer</td>
<td>90,000</td>
<td>No</td>
<td>Injectable</td>
</tr>
<tr>
<td>Trastuzumab (Herceptin)</td>
<td>Breast cancer</td>
<td>55,000</td>
<td>Yes</td>
<td>Injectable</td>
</tr>
<tr>
<td>Vemurafenib (Zelboraf)</td>
<td>Melanoma</td>
<td>136,000</td>
<td>Yes</td>
<td>Oral</td>
</tr>
</tbody>
</table>

*Given the high costs of many cancer drugs, U.S. payers are looking to stratify subgroups of patients into likely responders vs. non-responders, which can help health care providers prescribe the most appropriate drug in a timely fashion while saving costs.*

Source: Tufts Center for the Study of Drug Development
SELECTED CSDD PUBLICATIONS

Listed below are selected articles published in 2015 by Tufts CSDD research staff.

BENCHMARKING THE DRUG DEVELOPMENT PROCESS


IMPROVING BIOPHARMACEUTICAL R&D EFFICIENCY


REGULATORY INITIATIVES TO FOSTER BIOMEDICAL INNOVATION


PHARMACEUTICAL VALUE AND PATIENT ACCESS


AGENDA 2016

CSDD RESEARCH PROJECTS AND PRESENTATIONS

Following are selected Tufts CSDD projects and presentations scheduled for delivery in 2016.

SELECTED PROJECTS:

BENCHMARKING THE DRUG DEVELOPMENT PROCESS
- Biopharmaceutical Industry R&D Costs by Therapeutic Category
- Competitive Dynamics in Biopharmaceutical Industry New Drug Development
- Validating and Benchmarking Drug Development Cost Modeling
- Trends in Cardiovascular Drug Development

IMPROVING BIOPHARMACEUTICAL R&D EFFICIENCY
- Quantifying the Value Proposition of Comparative Oncology
- Measuring Return on Patient Engagement Initiatives
- Assessing Gaps in the Global Patient Recruitment Process

REGULATORY INITIATIVES TO FOSTER BIOMEDICAL INNOVATION
- Impact of Regulatory Science on Regenerative Medicine in Europe, Japan, and the U.S.
- Evaluating the U.S. Food and Drug Administration’s 505(b)(2) Regulatory Pathway

PHARMACEUTICAL VALUE AND PATIENT ACCESS
- Patient Access to Orphan Drugs
- Role of Clinical and Cost-Effectiveness in Determining PBM Exclusion Lists
- Precision Medicine Trends: Interviews with Leading Pharmaceutical and Diagnostic Companies

SELECTED PRESENTATIONS:

The Development of New Medicines, Alpert Medical School, Brown University, Providence, RI, Jan 20: Kenneth Kaitin

Landscape for Biomedical Innovation, Tuck Business School, Dartmouth University, Hanover, NH, Jan 25: Kenneth Kaitin

Uptake of Biosimilars, 11th Summit on Biosimilars, CBI, Alexandria, VA, Jan 28-29: Joshua Cohen

Precision Medicine: A New Paradigm for R&D Investment, International Conference on Drug Development, Austin, TX, Feb 22: Kenneth Kaitin

Evidence Generation for Post Approval Research, SCOPE Conference, Miami, FL, Feb 23-24: Christopher Milne

ROI Expectations for Optimized Patient Awareness and Engagement, SCOPE Conference, Miami, FL, Feb 23-24: Kenneth Getz

Today’s Drug Development Operating Environment, R&D Leaders Summit, Manalapan, FL, Mar 7-8: Kenneth Getz

Incorporating the Patient’s Voice in Clinical Trial Design, Patients as Partners Conference, Philadelphia, PA, Mar 14-15: Kenneth Getz

Disruptive New Partnerships in Drug Development, Collaborations Conference, Boston, MA, Mar 22: Kenneth Getz

Cost-Effectiveness in Determining PBM Formulary Exclusions, PBM Formulary Exclusions Summit, CBI, Atlanta, GA, Mar 28-29: Joshua Cohen

Sticker Shock! Decoding the Drug Development Process and the Vagaries of Drug Pricing, Suffolk District Medical Society Annual Meeting, Boston, Mar 30: Kenneth Kaitin

Outsourcing Practices among Pharmaceutical Companies, Procurement and Outsourcing Congress, Philadelphia, PA, Mar 22-23: Mary Jo Lamberti

Best Practices in Protocol Design, DIA 28th Annual EuroMeeting, Hamburg, Germany, Apr 6-8: Stella Stergiopoulos

Challenges in Global Drug Development, Annual National Congress, Associação Nacional das Farmácias, Lisbon, Portugal, Apr 16: Kenneth Kaitin

The Economics of Pharmaceutical Innovation, Boston University School of Medicine, Boston, Apr 27: Joseph DiMasi
AGENDA 2016
TUFTS CSDDD RESEARCH INITIATIVES

The following issues will be the focus of Tufts CSDDD research initiatives in 2016.

BENCHMARKING THE DRUG DEVELOPMENT PROCESS

- Time, cost, and risk of bringing new drugs and biologics to market
- Assessments by therapeutic class and molecule type
- Discovery and non-clinical development metrics
- Regulatory review metrics
- Development of first-in-class and later-in-class drugs
- Return on investment
- Vaccines development
- Biosimilar and Biobetter development
- Precision/personalized medicine, specialty pharma development
- Operating function performance
- Personnel workload and capacity

IMPROVING BIOPHARMACEUTICAL R&D EFFICIENCY

- Clinical trial operations
- Protocol design complexity
- Investigator site landscape
- Contract service providers
- Adaptive trial designs
- Social media
- Strategic partnerships and integrated alliances
- Industry best practices
- Patient-centricity and use of Big Data
- Clinical supply sourcing and logistics
- eClinical technology usage and standards adoption
- Site selection and site management practices
- Public and private sector contributions to biopharmaceutical R&D
- Pediatric studies of oncology drugs in development for adults

REGULATORY INITIATIVES TO FOSTER BIOMEDICAL INNOVATION

- Breakthrough therapy designation
- Fast track process/accelerated approval
- Orphan product designation
- Addressing problems and solutions in pediatric study compliance
- Regulatory and policy strategies for complementary versus companion diagnostics
- Regulatory science for new technologies (e.g., regenerative medicine, nanotechnology)
- Medical countermeasures and the emerging sponsor landscape
- Harmonization priorities for FDA, EMA, and PMDA

PHARMACEUTICAL VALUE AND PATIENT ACCESS

- Utilization and economic impact of comparative effectiveness research, cost-effectiveness, health technology assessment, and budget impact studies
- International comparisons of pricing and reimbursement strategies and practices
- Formulary management of cancer and orphan drugs
- Patient access to neglected disease medicines
- Measuring innovation and value, and impact of reimbursement on innovation
- Use of labeling and other prescribing information in the health care system
- Shows that clinical approval success rates have fallen to 16%
- Documents lack of clinically useful diagnostics in personalized medicine development
Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation

Now in its 43rd 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 2016 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.


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.

TUFTS CSDD EXECUTIVE FORUM ROUNDTABLE: Integrating Pediatric Studies into Adult Oncology Drug Development: Maximizing Efficiency and Economics While Meeting FDA and EMA Requirements

See description above.

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.

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.


- First to document dramatic rise in protocol complexity
- Updates cost study: it now takes $2.6B to develop a new drug
- First comprehensive analysis of vaccine development trends

2012 | FDA Safety & Innovation Act enacted
2013 | The White House BRAIN Initiative introduced
2014 | 2015
GLOSSARY

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.

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.

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.

REGENERATIVE MEDICINE — Treatments and techniques, including pharmaceuticals, biologics, devices, cell therapies, tissue engineering, gene therapy, and biomedical engineering, to replace or regenerate human cells, tissues, or organs aimed at restoring or establishing normal function.
Emerging Regions

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.

2016 EDITORIAL CALENDAR:

- January/February – Protocol amendments update
- March/April – Immune-oncology trends and challenges
- May/June – Pharmacy benefits manager exclusion lists
- July/August – The next wave of advanced therapies in regenerative medicine
- September/ October – Success rates and development trends by therapeutic class
- November/December – Health care provider perceptions and experiences with clinical trials

To preview Tufts CSDD Impact Reports, visit http://csdd.tufts.edu/reports for a complimentary PDF download. To subscribe, visit http://csdd.tufts.edu/reports to order online.

Tufts CSDD corporate subscriptions are available at volume discounts. Contact Jonathan Hsieh at 617-636-0840 or email jonathan.hsieh@tufts.edu for details.