

Profile

The Tufts Center for the Study of Drug Development

Researching the Science, Regulation, and Economics of Drug Development

1. Aims of the Tufts Center

The Tufts Center for the Study of Drug Development is an independent, academic, non-profit research group affiliated with Tufts University in Boston, Massachusetts. Founded in 1976 by Dr Louis Lasagna, an internationally renowned pioneer in clinical and basic pharmacology, Tufts CSDD is the foremost authority on drug development policy. For over twenty years, Tufts CSDD has played an active role in formulating public policy and contributing to improvements in the drug development process. Its unique cumulative databases on investigational and approved new drugs and biopharmaceuticals allow Tufts CSDD to monitor the rate of pharmaceutical innovation and to track trends in the time, cost, and risks associated with new product development.

2. Objectives

To monitor and report on the development, regulation, and utilization of new drugs and biopharmaceuticals.

To explore the economic, legal, scientific, and public policy issues affecting pharmaceutical and biopharmaceutical innovation worldwide.

To serve as a resource for information on the development and review of new therapeutic agents.

To sponsor public forums and conferences that bring together the perspectives of government, industry, academia, and public health advocates.

To raise the level of national and international debate on issues related to new drug and biotechnology product development and regulation.

3. Research activities

Tufts CSDD's research over the past twenty years has helped shape and inform policy debates on drug development, approval, and regulation. In addition, results from center studies have provided valuable benchmarking information for industry in its efforts to improve the efficiency and speed of the development process. Tufts CSDD has pioneered work on innovation in the pharmaceutical industry, the drug lag, the cost of new drug development, the decline of effective patent life, and innovation in the

biotechnology industry. Recently, Tufts CSDD was an important contributor to the public debates on the FDA Modernization Act of 1997, re-authorization of the Prescription Drug User Fee Act of 1992, and pharmaceutical patent extension.

Tufts CSDD's current research agenda includes the following high priority projects:

- calculating a new estimate of the cost of new drug R&D;
- evaluating the impact of recent regulatory initiatives on new drug development;
- examining the integration of pharmacoeconomic studies in drug development programs;
- estimating success rates in biopharmaceutical development;
- exploring the impact of FDA's recent pediatric initiative on development strategies.

4. Data resources

Tufts CSDD maintains several unique databases that constitute the most detailed source of historical information available on pharmaceutical and biopharmaceutical innovation in the US. Through annual surveys of companies marketing new therapeutic agents and triennial surveys to US companies doing investigational work, Tufts CSDD obtains data on drugs and biologics that have entered human testing for the first time worldwide as well as those that have received approval for marketing in the US. Center databases contain data on products approved from 1963 to the present.

5. Corporate support

Tufts CSDD is a non-profit organization funded primarily by contributions from pharmaceutical and biopharmaceutical companies, trade associations, contract research organizations, and consulting firms. This funding is unrestricted, allowing the center's researchers to maintain academic freedom and ensuring objective and unbiased studies. Although Tufts CSDD is an integral part of Tufts University, it does not receive any direct funding from the university.

Tufts CSDD relies on the generous contributions of its nearly fifty corporate sponsors. Benefits of corporate sponsorship include access to more than twenty years of aggregate data on new and investigational drugs and biologics, confidential benchmarking reports, and reduced registration fees to conferences and workshops sponsored by Tufts CSDD. In addition, corporate sponsors are invited to attend Tufts CSDD's annual corporate sponsors meeting, to review progress on on-going studies, and to suggest areas for future research. In funding Tufts CSDD, corporate sponsors are directly supporting independent and objective research vital to the industry. For more information on sponsorship of Tufts CSDD, please contact Dr Kenneth Kaitin, director.

6. Other activities

- The *Tufts CSDD Newsletter* is sent to more than 2,500 individuals three times a year. Included with the newsletter are reprints of articles published by Tufts CSDD staff members and other articles of interest.
- Tufts CSDD sponsors symposia on a range of issues. Recent meetings include the Center's 1998 annual spring forum, entitled, "Improving the Process of Biopharmaceutical Development: Impact

of Recent Initiatives”; the annual workshop on R&D management, focusing on project management initiatives in the pharmaceutical and biotechnology industries; and the biennial symposium at the Tufts European Center in Talloires, France, entitled, “Dynamics of the International Pharmaceutical Marketplace: Major Forces in the Late 1990”.

- Tufts CSDD regularly responds to requests for information from industry, government, national organizations, the media, and other interested individuals. Our research librarian provides knowledgeable, authoritative, and informed responses to reference questions. Tufts CSDD’s library on drug development and regulation contains more than 18,000 items. Books, journal articles, government publications, and trade and popular articles are included.
- Tufts CSDD’s Annual Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation is a unique four-day program designed as an introduction to and overview of such topics as pharmacokinetics, clinical pharmacology, the design and analysis of clinical drug studies, crisis management, and drug development and regulation.

For more information, contact the center’s administrative manager or access the center’s site on the World Wide Web at <http://www.tufts.edu/med/research/csdd>

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