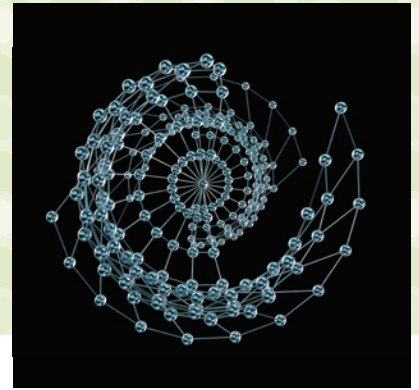


Forum on Drug Discovery, Development, and Translation

2011 Annual Report



INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Advising the nation • Improving health

Message from the Co-Chairs

Jeffrey Drazen and Steven Galson

The Institute of Medicine's (IOM's) Forum on Drug Discovery, Development, and Translation was created in 2005 by the IOM's Board on Health Sciences Policy to foster dialogue among stakeholders and provide ongoing opportunities to discuss issues of mutual interest in a neutral setting. The Forum provides a venue for dialogue and collaboration among its membership, which includes leaders from the pharmaceutical and biotech industries, academia, federal agencies, foundations, and patient groups. The Forum brings ongoing attention and visibility to important issues in drug development; explores new approaches for resolving problem areas; helps define the scope of the field and thus sets the stage for future policy action; provides a catalyst for collaboration on topics where there is synergy among potential partners; and elevates the general understanding of drug discovery, development, and translation among the research, public policy, and broader communities. The Forum is self-governing, with Forum membership convening several times each year to identify and prioritize the topics they wish to address.

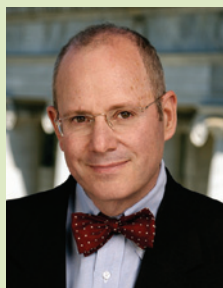
The need for venues such as the Forum to provide a neutral convening ground for stakeholders to address complex issues of health science policy has never been greater. The drug development science, regulatory, and economic landscape is fraught with uncertainty and risk. Despite significant recent scientific advances in areas such as nanotechnology, genomics, and synthetic biology, there remains large unmet medical need, particularly for patients experiencing rare or neglected diseases. Radically new approaches to the discovery and development of therapies may be necessary to break the bottlenecks and bridge the “valley of death” between preclinical and clinical efficacy.

The year 2011 saw the continued emergence throughout the biomedical science, policy, and business sectors of a focus on the need for *innovation*. The Forum contributed to this conversation in a variety of ways, includ-

ing envisioning a framework for a transformed clinical trials enterprise to facilitate the development of new therapies or indications, and advancement of regulatory science as a discipline to support the evaluation and regulation of therapies. The Forum membership dedicated activities to global health concerns and neglected diseases such as multidrug-resistant tuberculosis (MDR TB), and undertook concerted efforts to better engage the public in the drug discovery and development enterprise.

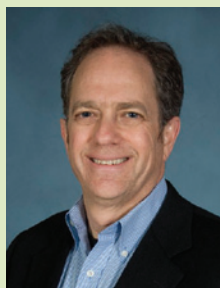
In 2012, the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) will continue to carry out key aspects of their expressed commitment to innovation in regulatory science and translational medicine, including the establishment of the new National Center for Advancing Translational Sciences (NCATS) at NIH. Collaboration and dialogue among the federal agencies, academia, and industry will be essential to ensuring the success of these efforts to promote innovation in drug discovery and development.

We look forward to another groundbreaking and productive year for the Forum in 2012.



A handwritten signature in black ink, appearing to read "Jeff M Drazen MD".

Jeffrey Drazen
Co-Chair



A handwritten signature in black ink, appearing to read "Steven Galson".

Steven Galson
Co-Chair

Reflecting Back

Forum Activities in 2011

Forum Meetings

The Forum membership met three times in 2011. Discussions at these meetings focused on diverse topics relating to the Forum's priorities, including observational drug safety monitoring; addressing quality in clinical trials and international efforts to harmonize regulation of medical research; drug development for rare and neglected diseases; and policy developments related to drug discovery, development, and translation. In addition, the Forum convened public workshops, described and grouped according to Forum priority topics below.

Strengthening the Scientific Basis of Drug Regulation

Advancing Regulatory Science for Medical Countermeasure Development—Workshop (March 2011)

During public health emergencies such as pandemic influenza outbreaks or terrorism attacks, effective vaccines, drugs, diagnostics, and other medical countermeasures (MCMs) are essential to protecting national security and the well-being of the public. The August 2010 Department of Health and Human Services (HHS) Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Review made numerous recommendations to transform the PHEMCE to increase its speed, agility, capacity, and success rate, including the promotion of regulatory innovation and investment in regulatory science at FDA. To promote regulatory innovation and investment in regulatory science, FDA has established an MCM initiative. In March 2011, the Forum collaborated with the IOM's Forum on Medical and Public Health Preparedness for Catastrophic Events to conduct, at the request of FDA, a workshop that examined ways to advance regulatory science for MCM development and regulatory evaluation; identified scientific opportunities to improve, simplify, or speed MCM development; and identified tools and methods to improve the predictability and success rate of candidate MCMs.

FORUM ACTIVITIES TIMELINE

2000–2004

2005

Clinical Research Roundtable,
predecessor to the Drug Forum



Regulatory Science Workforce Workshop co-chairs Elaine Gallin and Barry Collier



Regulatory Science Workforce Workshop panel from left to right: Carl Peck, Alastair Wood, Steven Galson, Elaine Gallin, and Barry Collier

Strengthening a Workforce for Innovative Regulatory Science in Therapeutics Development—Workshop (September 2011)

A number of gaps in the regulatory science discipline and infrastructure have been identified. They include workforce and resource constraints; cultural differences and systematic barriers to collaboration and exchange; and deficiencies in the network and infrastructure necessary to forge the collaboration and communication needed to advance regulatory science. In September 2011, the Forum held a workshop that considered opportunities and needs for advancing innovation in the discipline of regulatory science for therapeutics development through an interdisciplinary regulatory science workforce. The workshop focused closely on the core components of a robust discipline of regulatory science; deliberated on the key competencies for a regulatory science workforce; and examined needs and opportunities to promote training, career development, and collaborative approaches to sustain and nurture a workforce in innovative regulatory science. The workshop was held at the request of Forum sponsor Burroughs Wellcome Fund (BWF) and was a follow-up to the regulatory science workshop held in February 2010.

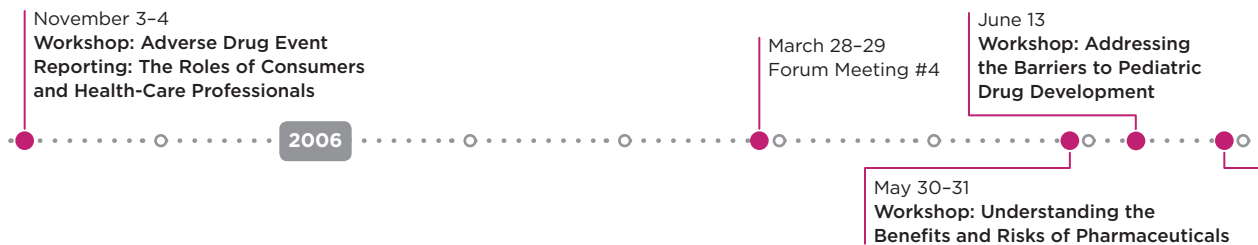
Transforming Research and Fostering Collaborative Research and Promoting Public Understanding of Drug Development

Public Engagement and Clinical Trials: New Models and Disruptive Technologies—Workshop (June 2011)

In June 2011, the Forum collaborated with the Mount Sinai School of Medicine Department of Health Evidence and Policy and Conduits, the Institutes for Translational Sciences at Mount Sinai, to convene a public workshop that explored systemic, cultural, and methodological issues underlying the problem of insufficient public engagement in the clinical trials enterprise, and considered models, methods, and messages for enhancing and supporting clinical research in the United States. Discussions at the workshop included consideration of the structures and culture of health care systems and delivery organizations that fail to support or engage with the clinical trials enterprise; how academic medical centers can create successful community partnerships to improve public engagement in clinical trials; models, methods, and messages for communication and engagement with the public; and novel clinical trial designs (such as adaptive clinical trial designs) that minimize enrollment needs and address treatment assignment concerns of physicians and their patients. This workshop was conducted as part of the Forum's clinical trials initiative to improve the clinical trials enterprise in the United States, including promotion of public understanding of and support for clinical trials and the drug development enterprise.

Envisioning a Transformed Clinical Trials Enterprise in the United States: Establishing an Agenda for 2020—Workshop (November 2011)

Since 2009, the Forum has been engaged in a focused effort to address challenges facing the U.S. clinical trials enterprise and to engage stakeholders in an open





Forum member Janet Woodcock



Forum co-chair Jeffrey Drazen

discussion of potentially transformative strategies to improve the efficiency and effectiveness of clinical trials. Key themes considered throughout the initiative included (1) regulation and infrastructure of clinical trials in the United States and (2) public engagement in the clinical trials enterprise. In November 2011, the Forum convened a major workshop to serve as a “capstone” to this clinical trials workshop series, which established a vision and a framework for a transformed national clinical trials enterprise. The workshop was supported by and organized around a series of four discussion papers authored by collaborative, cross-sector working groups of Forum members and outside experts. The workshop focused on core themes, including vision for a clinical trials enterprise in the health care system of 2020; clinical trials workforce development; alignment of cultural and financial incentives; and infrastructure to support a transformed clinical trials enterprise.

Developing Drugs for Rare and Neglected Diseases and Addressing Urgent Global Health Problems

Facing the Reality of Multidrug-Resistant Tuberculosis: Challenges and Potential Solutions in India—Workshop (April 2011)

The Forum’s initiative on MDR TB includes a series of workshops that have gained international attention. The first workshops—held in the United



Workshop delegation: MDR TB in India

States in 2008 and 2009—highlighted new data in conducting a realistic assessment of the magnitude of the problem and the gaps needed to address the rapid spread of drug-resistant (DR) TB. These meetings led to the development of workshops taking place in the four highest-burden countries—South Africa, Russia, India, and China. The Forum collaborated with the National Institute of Allergy and Infectious Diseases (NIAID) of NIH to develop coordinated MDR TB–related research meetings in South Africa, Russia, and India, and that collaboration is continuing in 2012 as the Forum plans its next workshop in Beijing, China. In April 2011, the Forum hosted the third workshop in its workshop series on MDR TB in New Delhi, India. The workshop was held in partnership with the Indian National Science Academy and the Indian Council of Medical Research, and took place at the Indian National Science Academy conference facility. The workshop addressed the current status of



DR TB in India and across the globe; highlighted key challenges to controlling the spread of DR strains; and discussed innovative strategies to advance and harmonize local and international efforts to prevent and treat DR TB. In India, the NIH portion of the meeting focused on basic science and opportunities for scientific collaboration in the discovery and development of TB drugs, while the IOM portion addressed health care delivery, drug procurement, public health, and policy issues.

Also in 2011, the Forum extended dissemination of and engagement with its initiative on DR TB by convening two workshop summary report release events.

In July 2011, in Durban, South Africa, the Forum partnered with the Academy of Science of South Africa to hold an official release event, which took place at the Nelson Mandela School of Medicine of the University of KwaZulu-Natal, in conjunction with the Groundbreaking Symposium of the new KwaZulu-Natal Research Institute for Tuberculosis and HIV (K-RITH), a collaboration between the Howard Hughes Medical Institute and the University of KwaZulu-Natal.

In November 2011, in Moscow, Russia, the Forum partnered with the Russian Academy of Medical Sciences to hold an official release event, which was held in conjunction with a meeting hosted by the International Science and Technology Center addressing pediatric DR TB. The event immediately preceded the convening of a major biomedical conference held as a collaborative forum among the Fogarty International Center, the Foundation for the NIH, the Russian Academy of Sciences, the Russian Academy of Medical Sciences, the National Academy of Sciences, and the IOM.

November 30
Discussion Series: A Conversation
with Tony Fauci

2008

February 20–21
Discussion Series: Comparative
Effectiveness (Forum Meeting #9)

April 21
Discussion Series:
Science at FDA: Challenges
and Opportunities

June 23
Workshop: Breakthrough
Business Models: Drug
Development for Rare
and Neglected Diseases

June 23–24
Symposium: Diseases and Individualized
Therapies (Forum Meeting #10)

Looking Forward

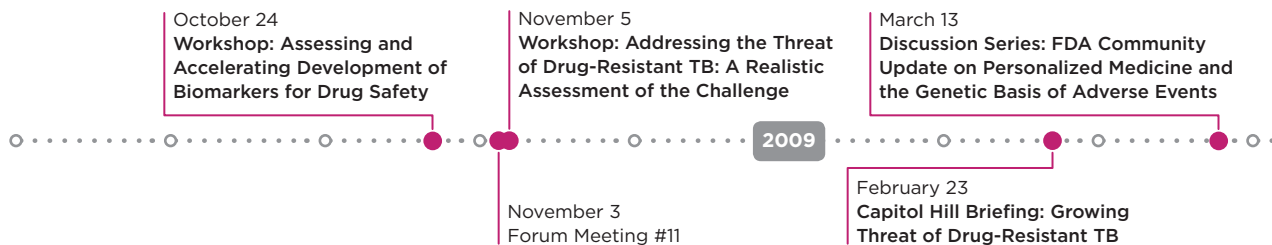
Forum Activities in 2012

Forum Meetings

The Forum membership will meet in March, June, and October 2012 to continue its discussions of key problems and strategies in the discovery, development, and translation of drugs. The March meeting will include a discussion organized by the Forum's innovation working group, which is exploring potentially breakthrough ideas to advance "disruptive innovation" to break out of the current crisis in R&D productivity, as well as a discussion with the leadership of the new FDA-supported academic Centers of Excellence in Regulatory Science. Forum working groups are convening to discuss and explore potential workshop topics in the areas of clinical research data sharing, benefit-risk assessment, international drug regulatory harmonization, and clinical trials informatics. In addition, the Forum is convening a number of public meetings, described below.

Maximizing the Goals of the Cures Acceleration Network (CAN) to Accelerate the Development of New Drugs and Diagnostics—Workshop (June 2012)

Recent years have seen both extraordinary opportunity and complex challenges in pharmaceutical innovation. New biomedical technology platforms are creating novel avenues for research and new opportunities for the discovery and clinical development of innovative diagnostics and therapies. Yet despite these advances, the pathway from basic science to new therapeutics faces challenges on many fronts. Bringing a new diagnostic, drug, or biologic product to market has become increasingly expensive and risky; the scientific challenges in finding novel drug



targets are profound; the pharmaceutical business model and acquisition of capital are challenged; and the nurturing and collaborative research environment necessary for a robust biomedical research enterprise has eroded. New collaborative approaches within the federal agencies, academia, and industry are directing focused attention on the advancement of the drug development enterprise. The leadership at both NIH and FDA have established dedicated efforts to promote innovation in regulatory science and translational medicine, including establishment of a FDA-NIH Joint Leadership Council that is charged with identifying critical areas where cross-agency collaborative action can be taken, and the establishment of NCATS at NIH. In response to a request from NCATS, the Forum will convene a public workshop that will explore ways to maximize the usefulness and impact of CAN in order to advance translational sciences. The workshop will include consideration of the effective use of CAN authorities for the development of new tools and methods to enhance the development and testing of therapies and diagnostics to patients. In addition to providing suggestions to NCATS, the workshop is, in part, in response to congressional interest in CAN expressed in the FY 2012 appropriations act conference report. The workshop will inform NIH/NCATS in its efforts to implement CAN and advance translational sciences, and will also inform the public, policy community, and other stakeholders as all of these parties continue to work to enhance the development and testing of therapies and diagnostics to patients. The summary will be provided to NCATS and the newly established CAN Board to help it identify ways to accelerate and expand the number of cures. A summary of this workshop will be prepared and made available on the Forum website.

April 27
**Workshop: Streamlining
Clinical Trial and Material
Transfer Negotiations**

April 27-28
Forum Meeting #12

September 2
**Discussion Series: FDA
Community Update on
Post-Market Drug Safety**

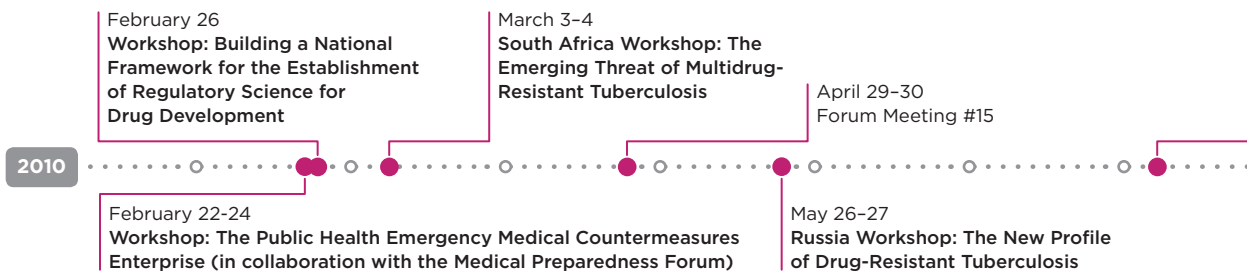
July 10
**Symposium: Drug Regulation with
FDA Commissioner, Peggy Hamburg
(Forum Meeting #13)**

October 15-16
Forum Meeting #14

October 7-8
**Workshop: Transforming Clinical
Research in the United States**

Addressing the Global Supply Chain for Second-Line Anti-TB Drugs— Workshop (Summer 2012)

To effectively treat patients diagnosed with DR TB, and protect the population from further transmission of this disease, an uninterrupted supply of quality-assured second-line anti-TB drugs (SLDs) is necessary. When SLDs are unavailable to the National Tuberculosis Control Program (NTP) and medical providers, patients miss critical doses of medicine or never start treatment—risking the escalation of disease/amplification of drug-resistance, enhanced infectivity and transmission of disease to others, and death. Ensuring a reliable and affordable supply of high-quality SLDs is a complex public health intervention that, thus far, has not been organized or implemented in a way that allows all providers and patients access to SLDs when they are needed. Although some MDR TB patients without access to SLDs through a Green Light Committee–approved program may receive appropriate treatment through a government-run or other quality assurance program, it is estimated that approximately 90 percent of patients with DR TB are not receiving treatment through a government-run or quality-assured program. In other words, these patients are likely receiving treatment from sources of unknown quality or no treatment at all. The global supply chain for SLDs faces a number of challenges: (1) the overall market for SLDs is relatively small due to limited diagnostic capacity at the country level; (2) demand-forecasting mechanisms do not fully capture patient needs for SLDs; (3) markets are opaque, with high barriers to entry that may deter



manufacturers; (4) drugs carry high prices; and (5) there are lengthy timelines for countries to receive drugs. The workshop will be convened by the Forum to provide a format for establishing a specific agenda to address the needs and opportunities for a global supply chain for TB SLDs. An international supply chain expert was commissioned to prepare a paper examining gaps in the global TB SLD supply chain and identifying potential solutions to those gaps. A summary of this workshop will be prepared and made available on the Forum website.

Drug-Resistant Tuberculosis in China—Workshop (January 2013)

The final workshop in the Forum's international workshop series on MDR TB will be held in China in January 2013 in collaboration with the Chinese Academy of Sciences. This workshop will address the current status of DR TB in China and across the globe; highlight key challenges to controlling the spread of DR strains; and discuss innovative strategies to advance and harmonize local and international efforts to prevent and treat DR TB. The meeting will focus on various aspects of DR TB, including epidemiology, diagnostics and preventive therapies, treatment, transmission and infection control, pediatric TB, innovative approaches to TB control, and drug procurement and supply issues. A summary of this workshop will be prepared and made available on the Forum website.



Forum Initiatives

Addressing the Approach to Drug Development

Despite exciting scientific advances, the pathway from basic science to new therapeutics faces challenges on many fronts. New paradigms for discovering and developing drugs are being sought to bridge the ever-widening gap between scientific discoveries and translation of those discoveries into life-changing medications. The Forum has explored these issues from many perspectives—emerging technology platforms, regulatory efficiency, intellectual property concerns, the potential for precompetitive collaboration, and innovative business models that address the “valley of death.”

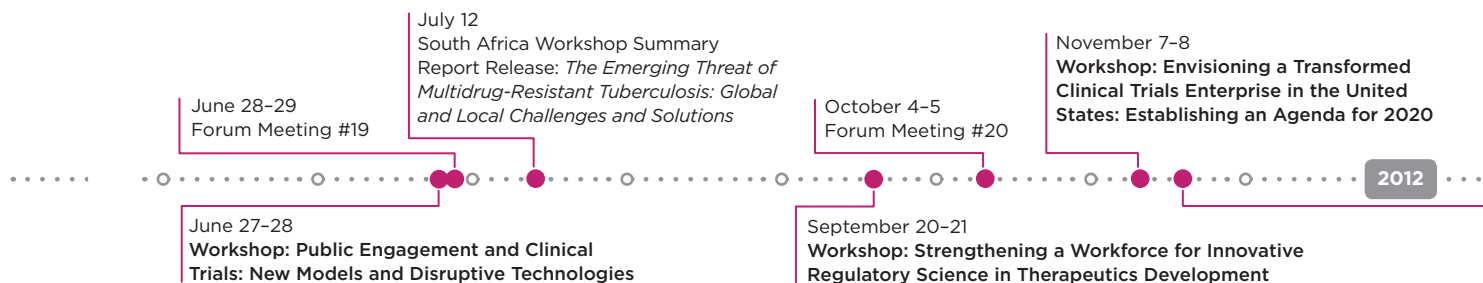
Strengthening the Scientific Basis of Drug Regulation

There has been considerable and increasing attention to the need for robust science to underlay and serve as the basis for regulatory decision making. “Regulatory science” involves the development and application of scientific tools and methodologies to improve



Regulatory Science Workforce Workshop panelists Steven Galson and Clifford Lane

the development, review, and oversight of new therapeutics. Recent rapid advances in innovative drug development science present an opportunity for revolutionary developments of new scientific techniques, therapeutic products, and applications. For example, advances in genomic science, systems biology, and cell-based technologies have led to exciting new avenues of biomedical research and drug discovery and have given us glimpses of the “personalized” future of medicine. As FDA



has recognized, both science and infrastructure are key components in ensuring that the highest-quality regulatory decisions are made to ensure the safety and public health of the U.S. population while fostering, not inhibiting, innovation in an increasingly challenging and globalized business environment. The Forum has focused considerable attention on the need to develop, support, and enhance a discipline of regulatory science as an essential component of the drug discovery enterprise and translational sciences. Activities undertaken by the Forum, including symposia and workshops, have contributed to the defining and establishment of regulatory science, and have considered in-depth issues such as cutting-edge drug safety science, development of biomarkers for safety, personalized medicine, adverse event reporting and post-marketing safety surveillance, infrastructure and workforce needs, and collaborative approaches to support and sustain regulatory science and drug development.

Transforming Clinical Research and Fostering Collaborative Research

Clinical research is the critical link between bench and bedside in developing new therapeutics. Significant infrastructural, cultural, and regulatory impediments challenge efforts to integrate clinical trials into the health care delivery system. Collaborative, cross-sector approaches can help articulate and address these key challenges and foster systemic responses, such as a comprehensive clinical trials infrastructure and harmonization of regulatory standards and institutional



Forum member James Doroshow



processes. The Forum has established an initiative to examine the state of clinical trials in the United States, identify areas of strength and weakness in our current clinical trials enterprise, and consider transformative strategies for enhancing the ways in which clinical trials are organized and conducted. Ongoing efforts will examine issues with the clinical and translational research workforce, including academic career paths.

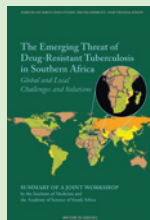
Developing Drugs for Rare and Neglected Diseases and Addressing Urgent Global Health Problems

There are a number of diseases for which there is extensive unmet medical need and a lack of therapeutics, where the population affected by the disease is very small (rare/orphan diseases) or the market for the therapeutic product is underdeveloped or inaccessible (neglected diseases). For these diseases, economic markets alone are insufficient to incentivize product development, and financial and regulatory incentives have been sought to stimulate therapeutics development and access to products. The Forum has recognized that the emergence of DR TB is a global threat and warrants focused attention to address the multitude of complex problems in drug development and access to therapeutics for patients affected by this neglected disease. The Forum is sponsoring a series of international collaborative workshops on DR TB, with a focus on drug delivery issues in the four countries with the highest burden of DR TB. The Forum has also held focused meetings and public workshops considering particular issues impeding the development of orphan drug products and other areas of unmet medical need, such as MCMs.

Promoting Public Understanding of Drug Development

In these increasingly resource-constrained times, it is essential that the public understand both the complexity of and the need for the drug development process. Collaborative efforts to de-risk drug development are reported to be limited in some cases by a lack of public understanding of the need to support innovation and collaboration among the federal government, academia, industry, and other entities such as voluntary health organizations. In addition, successful introduction of new therapeutic entities requires testing in an informed and motivated public. The Forum has spent concerted effort to understand what limits public engagement and how to enhance more widespread acceptance of the importance of advancing therapeutic development through public participation in and support for the drug development process.

Reports Released in 2011

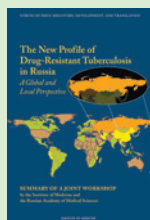


The Emerging Threat of Drug-Resistant Tuberculosis in Southern Africa: Global and Local Challenges and Solutions: Summary of a Joint Workshop

Released: March 24, 2011

TB kills approximately 4,500 people worldwide every day. While most cases of TB can be treated with antibiotics, some strains have developed drug resistance that

makes their treatment more expensive, more toxic, and less effective for the patient. The IOM Forum on Drug Discovery, Development, and Translation and the Academy of Science of South Africa held a workshop to discuss ways to fight the growing threat of DR TB.



The New Profile of Drug-Resistant Tuberculosis in Russia: A Global And Local Perspective: Summary of a Joint Workshop

Released: April 8, 2011

DR TB presents a number of significant challenges in terms of controlling its spread, diagnosing patients quickly and accurately, and using drugs to treat patients effectively. In Russia in recent decades, the rise of these strains of TB, resistant to standard antibiotic treatment, has been exacerbated by the occurrence of social, political, and economic upheavals. The IOM Forum on Drug Discovery, Development, and Translation, in conjunction with the Russian Academy of Medical Sciences, held a workshop to discuss ways to fight the growing threat of DR TB.

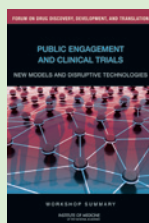


Advancing Regulatory Science for Medical Countermeasure Development: Workshop Summary

Released: June 15, 2011

Whether or not the United States has safe and effective MCMs—such as vaccines, drugs, and diagnostic tools—available for use during a disaster can mean the difference between life and death for many Americans. FDA and the scientific community at large could benefit from improved scientific tools and analytic techniques to undertake the complex scientific evaluation and decision making needed to make essential MCMs available. At the request of FDA, the IOM

Forum on Drug Discovery, Development, and Translation and the Forum on Medical and Public Health Preparedness for Catastrophic Events held a workshop to examine methods to improve the development, evaluation, approval, and regulation of MCMs.



Public Engagement and Clinical Trials: New Models and Disruptive Technologies: Workshop Summary

Released: October 14, 2011

Clinical trials provide essential information needed to turn basic medical research findings into patient treatments. New treatments must be studied in large numbers of humans to find out whether

they are effective and to assess any harm that may arise from treatment. There is growing recognition among many stakeholders that the U.S. clinical trials enterprise is unable to keep pace with the national demand for research results. The IOM Forum on Drug Discovery, Development, and Translation, along with the Mount Sinai School of Medicine, held a workshop to engage stakeholders and experts in a discussion about possible solutions to improve public engagement in clinical trials.



Strengthening a Workforce for Innovative Regulatory Science in Therapeutics Development: Workshop Summary

Released: December 21, 2011

The development and application of regulatory science—which FDA has defined as the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products—calls for a well-trained, scientifically engaged, and motivated workforce. FDA faces challenges in retaining regulatory scientists and providing them with opportunities for professional development. In the private sector, advancement of innovative regulatory science in drug development has not always been clearly defined, well-coordinated, or connected to the needs of the agency. As a follow-up to a 2010 workshop, the IOM Forum on Drug Discovery, Development, and Translation held a workshop to provide a format for establishing a specific agenda to implement the vision and principles relating to a regulatory science workforce and disciplinary infrastructure as discussed in the 2010 workshop.

Forum Members

(as of December 31, 2011)

Membership in the Forum includes a diverse range of stakeholders from multiple sectors, including government, the pharmaceutical and biotechnology industries, academic health centers, and patient groups.

Jeffrey Drazen (Co-Chair)

New England Journal of Medicine

Steven Galson (Co-Chair)

Amgen Inc.

Margaret Anderson

FasterCures

Hugh Auchincloss

National Institute of Allergy and Infectious Diseases

Leslie Benet

University of California, San Francisco

Ann Bonham

Association of American Medical Colleges

Linda Brady

National Institute of Mental Health

Robert Califf

Duke University Medical Center

Scott Campbell

Foundation for the NIH

C. Thomas Caskey

Baylor College of Medicine

Gail Cassell

Harvard Medical School Department of Social and Global Medicine (visiting)

Peter Corr

Celtic Therapeutics, LLLP

Andrew Dahlem

Eli Lilly & Co.

James Doroshow

National Cancer Institute

Gary Filerman

Atlas Health Foundation

Garret FitzGerald

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Elaine Gallin

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Stanford University School of Medicine

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NIH Office of Rare Disease Research

Anthony Hayward

National Center for Research Resources

Lynn Hudson

Critical Path Institute

Annalisa Jenkins

Merck Serono S.A.

Michael Katz

March of Dimes Foundation

Petra Kaufmann

National Institute of Neurological Disorders and Stroke

Jack Keene

Duke University Medical Center

Ronald Krall

University of Pennsylvania

Freda Lewis-Hall

Pfizer Inc.

Mark McClellan

The Brookings Institution

Carol Mimura

University of California, Berkeley

Elizabeth (Betsy) Myers

Doris Duke Charitable Foundation

John Orloff

Novartis Pharmaceuticals Corporation

Amy Patterson

NIH Office of the Director

Michael Rosenblatt

Merck & Co., Inc.

Janet Shoemaker

American Society for Microbiology

Ellen Sigal

Friends of Cancer Research

Elliott Sigal

Bristol-Myers Squibb

Nancy Sung

Burroughs Wellcome Fund

Janet Tobias

Ikana Media and Mount Sinai School of Medicine

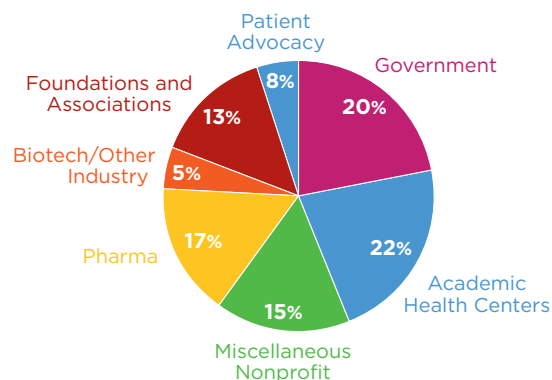
Joanne Waldstreicher

Johnson & Johnson

Janet Woodcock

FDA Center for Drug Evaluation and Research

Membership



Forum Sponsorship

(as of December 31, 2011)

Financial support for the Forum is derived from private foundations, government agencies, industry sponsors, and nonprofit associations.

Private Foundations

Burroughs Wellcome Fund
Doris Duke Charitable Foundation

Other Nonprofit Organizations

American Society for Microbiology
Association of American Medical Colleges
Critical Path Institute
Faster Cures
Foundation for the National Institutes of Health
Friends of Cancer Research

Government Sponsors

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National Center for Research Resources (National Institutes of Health)
National Institute of Allergy and Infectious Diseases (National Institutes of Health)
National Institute of Mental Health (National Institutes of Health)
National Institute of Neurological Disorders and Stroke (National Institutes of Health)
Office of Rare Diseases Research (National Institutes of Health)

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Johnson & Johnson
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Novartis Pharmaceuticals Corporation
Pfizer Inc.

About the Forum on Drug Discovery, Development, and Translation

The IOM's Forum on Drug Discovery, Development, and Translation was created in 2005 by the IOM's Board on Health Sciences Policy to provide a unique platform for dialogue and collaboration among thought leaders and stakeholders in government, academia, industry, foundations, and patient advocacy. The Forum brings together leaders from private-sector sponsors of biomedical and clinical research, federal agencies sponsoring and regulating biomedical and clinical research, the academic community, and consumers, and in doing so serves to educate the policy community about issues where science and policy intersect.

The Forum convenes several times each year to identify and discuss key problems and strategies in the discovery, development, and translation of drugs. To supplement the perspectives and expertise of its members, the Forum also holds public workshops to engage a wide range of experts, members of the public, and the policy community in discussing areas of concern in the science and policy of drug development. The Forum's public meetings focus substantial public attention on critical areas of drug development. Proceedings and speaker presentations are disseminated to the public through published summaries and the Forum website. For more information about the Forum on Drug Discovery, Development, and Translation, please visit our website at: www.iom.edu/drug.

About the Institute of Medicine

The Institute of Medicine was established in 1970 by the National Academy of Sciences to secure the services of eminent members of appropriate professions in the examination of policy matters pertaining to the health of the public. The Institute acts under the responsibility assigned to the National Academy of Sciences by its congressional charter to serve as an adviser to the federal government and, upon its own initiative, to identify issues needing attention in the areas of medical care, research, and education.

Forum Staff

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Associate Program Officer

Elizabeth F. C. Tyson

Research Associate

Robin Guyse

Senior Program Assistant

Board on Health Sciences Policy

Andrew M. Pope, Ph.D.

Director



INSTITUTE OF MEDICINE

OF THE NATIONAL ACADEMIES

Advising the nation • Improving health

The Institute of Medicine serves as adviser to the nation to improve health.

Established in 1970 under the charter of the National Academy of Sciences, the Institute of Medicine provides independent, objective, evidence-based advice to policymakers, health professionals, the private sector, and the public.

The mission of the Institute of Medicine embraces the health of people everywhere.