# Forum on Drug Discovery, Development, and Translation

**Board on Health Sciences Policy**

**2018 Annual Report**

*The National Academies of*
SCIENCES • ENGINEERING • MEDICINE

**The Forum serves as a hub and a catalyst for nurturing new ideas and partnerships and offers a neutral space for stakeholders to advance critical policy discussions on biopharmaceutical innovation nationally and globally.**

Forum on
DRUG DISCOVERY,
DEVELOPMENT,
and TRANSLATION

## Message from the Co-Chairs

Russ Altman and Robert Califf

We have entered an exciting phase of biomedical research—a time when the biological, physical, and digital spheres are merging; clinical research and health care are at a critical juncture; and new technologies enable the collection of data in real-world settings. These opportunities hold great promise for advancing our understanding of health maintenance and prevention, disease progression, and developing new therapies for patients.

Clinical trials remain a cornerstone of medical product development by providing the scientific evidence that proves or disproves concepts developed during earlier stages of development about the safety and efficacy of medical products and by informing clinical care. At the same time, the clinical research enterprise faces continued and mounting pressures, strained from all sides by rising costs, an evolving regulatory and economic landscape, increasing clinical trial complexity, difficulties in the recruitment and retention of research participants, and a clinical research workforce that is under tremendous stress. These challenges cannot be overcome in isolation and will require collaboration among patients, providers, academia, industry, federal agencies, payers, nonprofit organizations, and funders.

The Forum on Drug Discovery, Development, and Translation (the Forum) of the National Academies of Sciences, Engineering, and Medicine (the National Academies) was created in 2005 by the National Academies' Board on Health Sciences Policy to foster communication, collaboration, and action in a neutral setting on issues of mutual interest across the drug research and development (R&D) lifecycle. The Forum membership includes leaders from the National Institutes of Health (NIH), the U.S. Food and Drug Administration (FDA), the biopharmaceutical industry, academia, consortia, foundations, journals, and patient-focused and disease advocacy organizations. Through the Forum's activities, participants have been better able to bring attention and visibility to important issues, explore new approaches for resolving problem areas, share information and find common ground, and work together to develop ideas into concrete actions and new collaborations.

In 2018, the Forum completed a three-part workshop series that explored a forward-looking agenda for generating and incorporating real-world evidence into medical product development and evaluation. The Forum also hosted the workshop Advancing the Science of Patient Input in Medical Product R&D: Towards a Research Agenda, which examined the barriers and opportunities for converting traditionally anecdotal patient input into rigorous, credible evidence to inform medical product decision making in a way that is meaningful for patients. To explore opportunities for a modern, patient-centric clinical trials enterprise in light of digital health tools, the Forum hosted the workshop Virtual Clinical Trials: Challenges and Opportunities. Among its membership, the Forum discussed emerging and pertinent science and policy issues relevant to drug discovery, development, and translation.

In 2019, more work is needed to spur biomedical innovation in a responsible manner and to ensure that research is adequately powered to answer real questions about the safety and effectiveness of medical products. The executive and legislative branches of the federal government have continued to show bipartisan support for biomedical research, including ongoing funding for programs such as the BRAIN Initiative, the Precision Medicine Initiative, and the 21st Century Cures Act. Government funders and regulators of biomedical research, such as FDA and NIH, stand to receive continued infusions of funding and support for relevant programmatic priorities.

The Forum serves as a hub and a catalyst for nurturing new ideas and partnerships and offers a neutral space for stakeholders to advance critical policy discussions on biopharmaceutical innovation nationally and globally. Looking ahead to 2019, the Forum plans to focus on important issues such as advancing the science of patient input in medical product R&D, enhancing the reproducibility of biomedical research through transparent reporting, spurring innovation for prevalent chronic diseases, and accelerating progress toward clinical trial data sharing.

We look forward to another groundbreaking and productive year for the Forum in 2019.

**Russ Altman**
*Co-Chair*

**Robert Califf**
*Co-Chair*


Forum members at the 41st Forum meeting held in October 2018.

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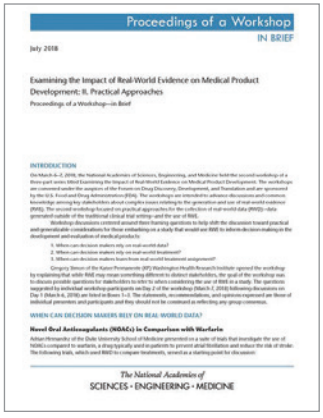
## Forum Activities in 2018

**Members of the Forum convene several times each year to identify, discuss, and act on key problems and strategies in the discovery, development, and translation of drugs.**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The National Academies of
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### Forum Membership Meetings

Members of the Forum convene several times each year to identify, discuss, and act on key problems and strategies in the discovery, development, and translation of drugs. In 2018, the Forum membership focused on diverse topics related to the Forum's priorities, including issues for emerging biotech companies; transforming clinical trials through digital health; improving the drug development process through examining late-stage failures; real-world evidence and medical product development; harmonizing clinical trial site standards; data-sharing principles for nonprofit clinical trial funders; the science of patient input in medical product R&D; innovative models to spur translational research and drug discovery; artificial intelligence applications for drug discovery and development; and other policy updates relevant to drug discovery, development, and translation. To supplement the perspectives and expertise of its members, the Forum holds public workshops to focus attention on critical areas of drug development. Summaries of these meetings are disseminated to the public through the Forum website and published proceedings.

### Workshops

#### Examining the Impact of Real-World Evidence on Medical Product Development: A Workshop Series

The Forum convened a three-part workshop series, sponsored by FDA, examining how real-world evidence development and uptake could enhance medical product development and evaluation. The workshops advanced the discussions and common knowledge about complex issues relating to the generation and use of

Forum member Ellen Sigal shares her thoughts at the March 2018 Forum meeting.

real-world evidence, including fostering the development and implementation of the science and technology of real-world evidence generation and utilization. Workshop One: Incentives (**September 19–20, 2017**) focused on how to align incentives to support the collection and use of real-world evidence in medical product review, payment, and delivery, including the incentives needed to address barriers impeding the uptake of real-world evidence, such as transparency. Workshop Two: Practical Approaches (**March 6–7, 2018**) was a "Town Hall" style meeting with in-depth audience discussion and active participation to illuminate which types of data may be appropriate for specific purposes and to discuss practical approaches for data collection and evidence use. Workshop Three: Application (**July 17–18, 2018**) examined approaches for operationalizing the collection and use of real-world evidence.

**To supplement the perspectives and expertise of its members, the Forum holds public workshops to focus attention on critical areas of drug development. Summaries of these meetings are disseminated to the public through the Forum website and published proceedings.**

### Advancing the Science of Patient Input in Medical Product R&D: Towards a Research Agenda: A Workshop

The Forum convened a 1-day workshop on **May 9, 2018,** focused on the science of patient input for pre-market medical product R&D (including pre-discovery, discovery, pre-clinical development, and clinical development), with consideration of downstream regulatory and post-market decision making. At this workshop, subject-matter experts representing a range of disciplines engaged in presentations and discussions to:

- Examine the current state of the science, including successes and limitations of current efforts, for soliciting and incorporating patient input in pre-market R&D.
- Explore gaps in the knowledge base and other barriers that impede progress, including but not limited to:
  - parameters for soliciting and incorporating different types of patient input along the spectrum of medical product R&D;
  - availability, accessibility, and applicability of data sources for patient input;
  - tools and methodologies for collecting and analyzing patient input to produce scientifically rigorous, credible evidence; and
  - understanding of the ethical and value considerations for soliciting and incorporating patient input into medical product R&D decision making.
- Review a potential framework for and components of a research agenda for addressing the gaps or barriers to realizing a science of patient input.

### Virtual Clinical Trials: Challenges and Opportunities: A Workshop

The Forum convened a 2-day workshop on **November 28–29, 2018,** which provided a venue to explore opportunities for a modern clinical trials enterprise capable of more efficiently answering questions about medical products by bringing participants closer to the clinical trial through the use of digital health tools. Clinical trials are a cornerstone of medical product development—supporting the evaluation of efficacy and the identification of safety issues of new drugs and devices—and a necessary regulatory requirement for bringing novel therapies to market. Since 2009, the


Forum member Tanisha Carino participates in a small group discussion during the plenary session of the Advancing the Science of Patient Input workshop in May 2018.

Forum has been engaged in a focused effort, anchored by a multi-workshop series, to address the challenges facing the U.S. clinical trials enterprise and to engage stakeholders in an ongoing discussion of potentially transformative strategies to improve the efficiency and effectiveness of clinical trials. This workshop built on this work and examined opportunities for a modern clinical trials enterprise in light of digital health tools. Participants highlighted opportunities for systemic improvements in the clinical trials enterprise, considered novel platform designs and digital health tools to increase efficiency and enhance the interface between clinicians and participants in a clinical trial, and discussed digital platforms to facilitate recruitment and maintain diverse participation in clinical trials.


Robert Califf

# **Looking Forward:** Forum Activities in 2019

### Forum Membership Meetings

The Forum membership will meet in March, July, and October 2019 to continue its discussions of key problems and strategies in the discovery, development, and translation of drugs. Forum workshop planning committees, working groups, and Action Collaboratives will convene to discuss and act on identified priority areas, including the following activities.

### Workshops and Meetings

#### Updating Labels for Generic Oncology Drugs: A Meeting

The Forum, in collaboration with the National Academies' National Cancer Policy Forum, will host a public meeting, sponsored by FDA, on **March 26, 2019.** Participants at this meeting will examine the challenges and opportunities for updating labels for generic oncology drugs. The meeting may include discussions on current FDA guidelines regarding the quality and quantity of evidence required to support claims of safety and effectiveness in new drug applications. Additionally, meeting participants may discuss potential criteria and sources of data to guide decision making for generic label updates on indications, dosing, and adverse events, and approaches for addressing specific gaps in labeling, such as for certain patient populations (e.g., pediatric) and for cross-labeling combination therapies.

Forum staff Amanda Wagner Gee listening to co-chairs (left to right) Russ Altman and Robert Califf at the March 2018 Forum meeting.

### Enhancing Scientific Reproducibility Through Transparent Reporting: A Workshop

The Forum will convene a workshop on **September 25–26, 2019,** exploring issues related to transparent reporting (e.g., the disclosure of the availability and location of data, materials, analysis, and methodology) to improve rigor and reproducibility in biomedical research. Workshop attendees will discuss the challenges and opportunities for the harmonization of guidelines for transparent reporting throughout the biomedical research lifecycle. The agenda will include a panel discussion on facilitating the development of consistent guidelines (e.g., a common set of minimal reporting standards) that could be applied across journals and funders to increase transparency in proposing and reporting biomedical research.

### Sharing Clinical Trial Data: Reflecting Back and Looking Ahead: A Workshop

This workshop will examine the progress and remaining gaps in clinical trial data sharing following the publication of the 2015 Institute of Medicine (IOM) report *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk*. The public workshop will examine the recent advances, remaining challenges, and new opportunities in clinical trial data sharing. Workshop presentations and discussions may include case studies and trends in clinical trial data sharing and reuse as well as the consideration of best practices and lessons learned.


Forum members (from left to right) Jeff Hurd, Gregory Keenan, and Joseph Menetski sharing their thoughts at the March 2018 Forum meeting.

# Action Collaboratives[1]

**Action collaboratives are ad hoc, participant-driven activities associated with the Forum that foster collaboration and information sharing among Forum members and external thought leaders and stakeholders.**

Action collaboratives are ad hoc, participant-driven activities associated with the Forum that foster collaboration and information sharing among Forum members and external thought leaders and stakeholders. Action collaboratives engage experts with similar interests and responsibilities to analyze in-depth, high-priority issues and to advance the identified goals of the Forum and recommendations highlighted in National Academies' Consensus Study Reports.

### Advancing the Science of Patient Input in Medical Product R&D

There is growing momentum to incorporate patient input into medical product R&D and regulatory decision-making processes. Converting traditionally anecdotal patient input to rigorous, credible evidence for use by a broad range of stakeholders—including academic and clinical researchers, medical product developers, patient/disease advocacy groups, and regulatory decision makers—could better align medical product development and regulation with patient perspectives on disease experience, burden, management, and treatment. Many efforts have been launched to advance a science of patient input. However, there is a need to identify key gaps in the knowledge base and other barriers that impede progress and to develop an approach for addressing them. This action collaborative launched in 2017 to foster the development of a strategic research framework to advance the science of

[1]Each action collaborative is an ad hoc activity associated with the Forum at the National Academies. The work each produces does not necessarily represent the views of any one organization, the Forum, or the National Academies and is not subjected to the review procedures of, nor is it a publication or product of, the National Academies.

patient input. During the first phase of work, collaborative participants catalogued current efforts and progress in the science of patient input and identified gaps in the knowledge base and other barriers that impede progress. In the second phase, collaborative participants laid the groundwork for a public workshop hosted by the Forum on **May 9, 2018,** titled Advancing the Science of Patient Input in Medical Product R&D: Towards a Research Agenda. Topics raised during this discussion-based workshop will help inform the third phase, which will focus on the development of a research framework for advancing the science of patient input.

### Clinical Trial Site Standards Harmonization

Mobilized in 2012, this action collaborative set out to explore opportunities to improve clinical trial site functioning with the goal of increasing productivity in medical product development. To date, the collaborative has drawn together a group of diverse stakeholders for four in-person meetings (December 2012, August 2013, March 2014, and September 2018). Collaborative participants published a National Academy of Medicine Discussion Paper in October 2017, which summarizes their perspectives on a proposed launching point for harmonizing the requirements applied to clinical trial sites and the development of standards. In 2018, the


A working group reviews and discusses potential baseline clinical trial site standards during an action collaborative meeting in September 2018.

collaborative collected, analyzed, and assessed a set of baseline site standards necessary for launching the majority of phase II, III, and IV clinical trials, and which could be considered for broad application across clinical trial sites by research sponsors.

### Improving the Drug Development Process Through Examining Late-Stage Failures

The development of new drugs is inherently complex and costly, with sources documenting up to $2.6 billion and more than 9 years in investment to bring a new treatment to market. The high cost is driven, at least in part, by the failure rate for new compounds entering late-stage development, but also encompasses opportunity costs due to time and resources not spent on developing an alternate treatment candidate, as well as investment in clinical trial infrastructure. Most importantly, these failures have an impact on patients—those who participate in the clinical trials associated with the testing of a failed drug candidate and those who will not benefit from having access to treatments that could have been developed instead. The goal of this action collaborative is to examine the contributing factors to late-stage failures and develop a set of key considerations for stakeholders to improve the probability of success in late-stage product development. In 2018, collaborative participants conducted structured, qualitative interviews with subject-matter experts; analyzed and synthesized responses from these interviews; considered information compiled from a literature survey; and held a meeting on **October 3, 2018,** to discuss and inform the key considerations. In 2019, collaborative participants will continue to prepare and publish a written summary of the key considerations and points identified by this activity.

## Sharing Clinical Trial Data

Sharing clinical trial data can help facilitate more efficient and effective development of better medicines, diagnostics, and procedures for the ultimate benefit of patients. At the same time, sharing data presents risks, burdens, and challenges that need to be addressed by a broad set of stakeholders. These opportunities and challenges were laid out in the IOM report *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk,* which calls on stakeholders to foster a culture of sharing and offers a blueprint for action within and across sectors. Four National Academies forums and roundtables, including the Forum, provided momentum and a framework for initiating the consensus study that produced the report and continue to work together to support coordination and collaboration among stakeholders engaged in data-sharing initiatives through convening and other activities.

This action collaborative, in collaboration with Brigham and Women's Hospital and Harvard University's Multi-Regional Clinical Trials Center, helped inform the establishment of Vivli—a global data repository, Cloud-based analytics platform, and in-depth search engine. The public launch of Vivli took place at the National Academies on **July 19, 2018.** The action collaborative also worked to establish data-sharing goals for nonprofit funders of clinical trials. On **November 30, 2017,** the collaborative convened a meeting of leaders of nonprofit disease advocacy organizations, philanthropic organizations and foundations, federal government, academia, industry, and others to review a draft of the Statement of Data-Sharing Goals for Nonprofit Funders of Clinical Trials, discuss the associated risks and challenges with implementing the goals, and explore the next steps for operationalizing them. In 2019, collaborative participants will continue to work toward publication of this statement of data-sharing goals.

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**Action collaboratives engage experts with similar interests and responsibilities to analyze in-depth, high-priority issues and to advance the identified goals of the Forum and recommendations highlighted in National Academies' Consensus Study Reports.**

# Forum Themes and Priorities

**The Forum fosters innovative efforts to identify and highlight potentially breakthrough ideas and visionary approaches to the drug development and translational science enterprise of the future.**

*The Forum seeks to address the key challenges and opportunities in the discovery, development, and translation of new therapeutics for patients, covering the full continuum from basic discovery to the approval and adoption of new therapies into clinical practice. As an overarching and cross-cutting theme, the Forum fosters innovative efforts to identify and highlight potentially breakthrough ideas and visionary approaches to the drug development and translational science enterprise of the future. The Forum identified four core components across the R&D lifecycle, which serve as thematic pillars to frame the Forum's focus areas and activities: (1) Innovation and the Drug Research and Development Enterprise; (2) Science Across the Biomedical Research Lifecycle (Basic, Translational, and Regulatory Sciences); (3) Clinical Trials and Medical Product Development; and (4) Infrastructure and Workforce for Advancing Drug Discovery, Development, and Translation.*

### Innovation and the Drug Research and Development Enterprise

Despite exciting scientific advances, the path from basic science to new therapeutics faces challenges on many fronts. Innovative paradigms are needed to bridge the ever-widening gap between scientific discoveries and the translation of those discoveries into life-changing medications. There is increasing recognition of the need for new models and methodologies to advance drug discovery, development, and translational science. The Forum serves as a hub and a catalyst for nurturing new ideas, collaborations, and partnerships and offers a neutral space for stakeholders to help chart a course through the turbulent forces of disruptive innovation and advance critical policy discussions on biopharmaceutical R&D nationally and globally.

### Science Across the Biomedical Research Lifecycle

Revolutionary advances in biomedical research and technology applications present new and exciting opportunities for the discovery and development of new therapies for patients. At the same time, key gaps remain in our knowledge about the science, technology, and methodologies needed to support the research that underpins drug discovery and development. The Forum provides a neutral venue to focus attention on key scientific issues across the biomedical research lifecycle and facilitate the exploration of new and more patient-centric approaches to spur innovation. The Forum continues to support activities that contribute toward the defining, establishment, and refinement of biomedical and regulatory science and other critical aspects of drug discovery and medical product development.

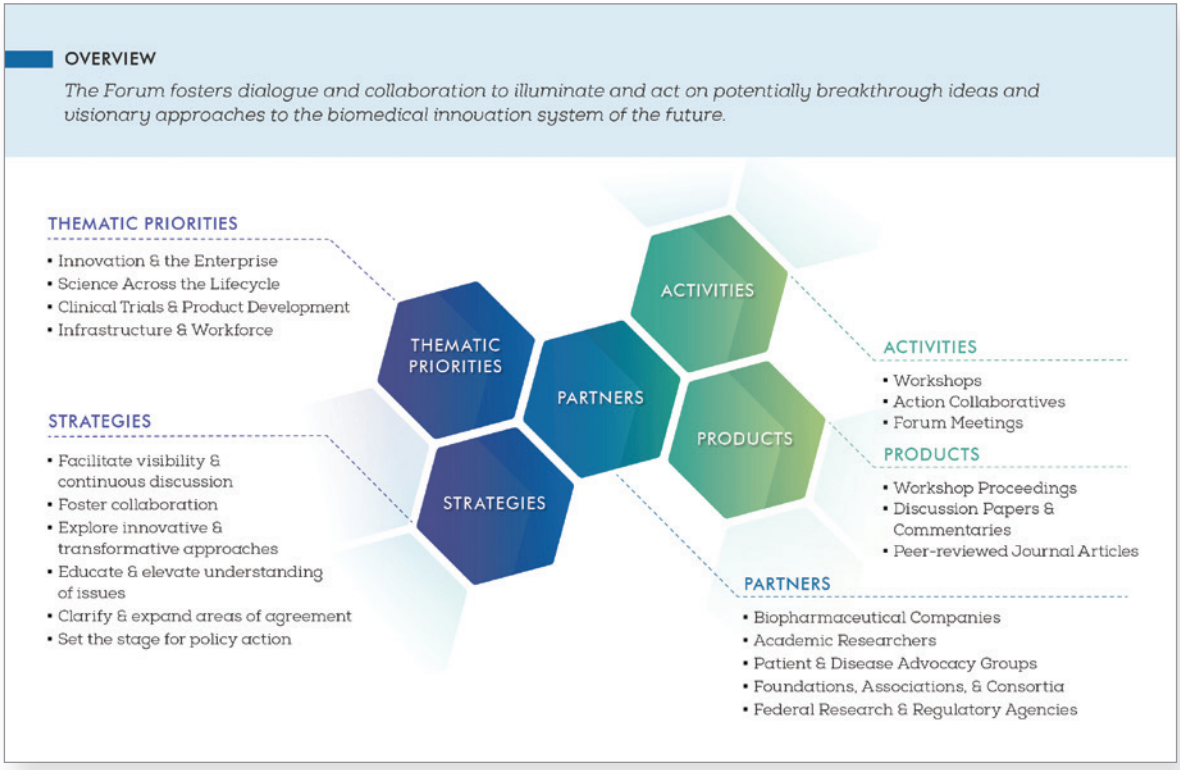
### Clinical Trials and Medical Product Development

Clinical research provides a critical link between the laboratory bench and patients' bedside when it comes to developing new therapeutics and advancing understanding of health maintenance and prevention and disease progression. However, the clinical research enterprise faces continued and mounting pressures, strained from all sides by rising costs, an evolving regulatory and economic landscape, increasing clinical trial complexity, difficulties in the recruitment and retention of research participants, and a clinical research workforce that is under tremendous stress. Collaborative, cross-sector approaches that engage patients, providers, academia, industry, federal agencies, payers, nonprofit organizations, and funders are needed to effectively address the key challenges and to develop systems-based solutions.

### Infrastructure and Workforce for Advancing Drug Discovery, Development, and Translation

Considerable opportunities remain for the improvement and enhancement of the infrastructure—the organizational framework, systems, workforce, and other resources—that supports the drug discovery and development enterprise. The fields of drug discovery and development, clinical research, and clinical practice are intersecting, cross-cutting, and multidisciplinary. However, career paths in

these fields are difficult to pursue, training may be lacking, and career opportunities may be limited. The Forum has considered workforce needs as foundational for the advancement of drug discovery, development, and translation and has focused substantial attention on these issues and fostered the development of strategies to improve the discipline of innovative regulatory science through the development of a robust workforce.



## Strategies

Topics addressed by the Forum span a broad range of issues in drug discovery, development, policy, and practice. In providing a venue for independent, systematic discussions of these issues, the Forum employs the following strategies.

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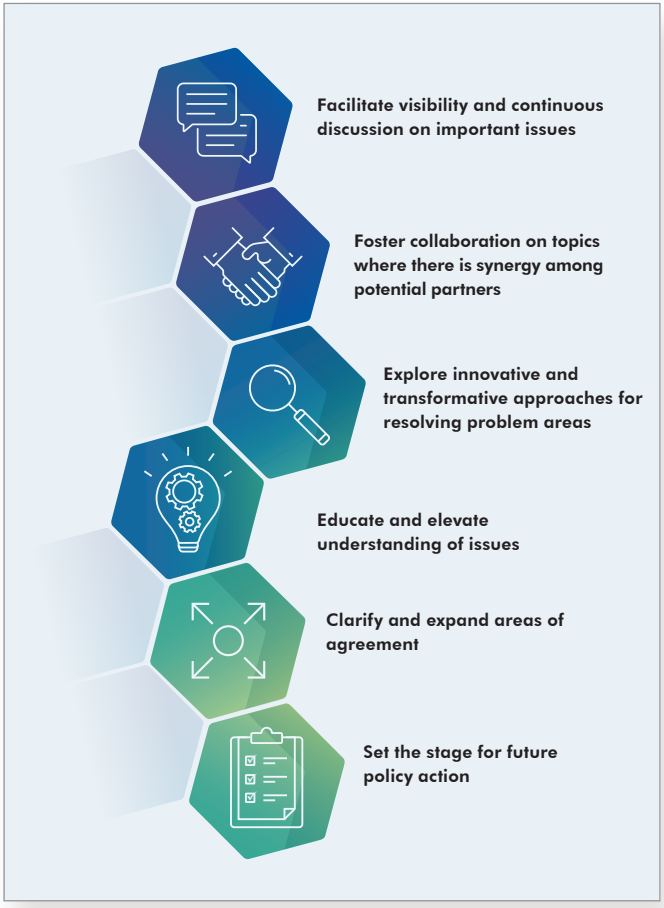

## SPONSORS
(as of December 31, 2018)

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

### Government
Center for Drug Evaluation and Research (FDA)
National Cancer Institute (NIH)
National Center for Advancing Translational Sciences (NIH)
National Institute of Allergy and Infectious Diseases (NIH)
National Institute of Mental Health (NIH)
National Institute of Neurological Disorders and Stroke (NIH)
Office of Science Policy (NIH)

### Industry
AbbVie Inc.
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GlaxoSmithKline
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### Private Foundation
Burroughs Wellcome Fund

### Nonprofit Organizations
American Diabetes Association
Association of American Medical Colleges
Critical Path Institute
FasterCures
Foundation for the National Institutes of Health
Friends of Cancer Research
*New England Journal of Medicine*

## MEMBERS
(as of December 31, 2018)

**Forum membership includes a diverse range of stakeholders from multiple sectors, including government, biopharmaceutical industry, biomedical research funders and sponsors, academia, foundations, consortia, disease advocacy, and patient-focused groups.**

**Russ Altman** (*Co-Chair*)
Stanford University

**Robert Califf** (*Co-Chair*)
Duke University and Verily Life Sciences

**Christopher Austin**
National Center for Advancing Translational Sciences, NIH

**Linda Brady**
National Institute of Mental Health, NIH

**Tanisha Carino**
FasterCures

**Tamara Darsow**
American Diabetes Association
*(until May 2018)*

**Richard Davey**
National Institute of Allergy and Infectious Diseases, NIH
*(as of June 2018)*

**Lori Dodd**
National Institute of Allergy and Infectious Diseases, NIH
*(until June 2018)*

**James Doroshow**
National Cancer Institute, NIH

**Jeffrey Drazen**
*New England Journal of Medicine*

**Steven Galson**
Amgen Inc.

**Carlos Garner**
Eli Lilly and Company

**Julie Gerberding**
Merck & Co., Inc.

**Lynn Hudson**
Critical Path Institute

**Jeff Hurd**
AstraZeneca
*(as of September 2018)*

**S. Claiborne Johnston**
Dell Medical School, The University of Texas at Austin

**Gregory Keenan**
AstraZeneca
*(until September 2018)*

**Rusty Kelley**
Burroughs Wellcome Fund

**Katharine Knobil**
GlaxoSmithKline

**Freda Lewis-Hall**
Pfizer Inc.

**Allison McElvaine**
American Diabetes Association
*(as of May 2018)*

**Ross McKinney**
Association of American Medical Colleges

**Joseph Menetski**
Foundation for the National Institutes of Health

**Bernard Munos**
InnoThink Center for Research in Biomedical Innovation

**Michael Severino**
AbbVie Inc.

**Rachel Sherman**
Office of the Commissioner, FDA

**Ellen Sigal**
Friends of Cancer Research

**Lana Skirboll**
Sanofi

**Brian Strom**
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**Pamela Tenaerts**
Clinical Trials Transformation Initiative

**John Wagner**
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**Joanne Waldstreicher**
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**Carrie Wolinetz**
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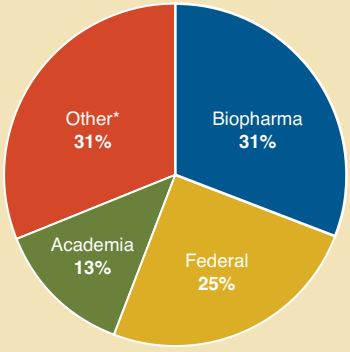
**Janet Woodcock**
Center for Drug Evaluation and Research, FDA

## Membership




*Consortia, Foundations, Journals, Patient-Focused/ Disease Advocacy Organizations

# TIMELINE

**2002–2004** | Clinical Research Roundtable, predecessor to the Forum

**2005** | Forum on Drug Discovery, Development, and Translation founded | **March 23–24** Forum Meeting #1 | **June 29–30** Forum Meeting #2 | **September 8–9** Forum Meeting #3 | **November 3–4** Workshop: Adverse Drug Event Reporting: The Roles of Consumers and Health-Care Professionals

**2006** | **March 28–29** Forum Meeting #4 | **May 30–31** Workshop: Understanding the Benefits and Risks of Pharmaceuticals | **June 13** Workshop: Addressing the Barriers to Pediatric Drug Development | **June 27–28** Forum Meeting #5 | **October 24–25** Forum Meeting #6

**2007** | **March 12** Symposium: The Future of Drug Safety: Challenges for the FDA | **April 23–24** Workshop: Emerging Safety Science | **April 24** Forum Meeting #7 | **September 14** Discussion Series: From Patient Needs to New Drug Therapies: Can We Improve the Pathway? | **October 15–16** Forum Meeting #8 | **November 30** Discussion Series: A Conversation with Tony Fauci

**2008** | **February 20–21** Forum Meeting #9 | **February 20** Discussion Series: Comparative Effectiveness | **April 21** Discussion Series: Science at FDA: Challenges and Opportunities | **June 23** Workshop: Breakthrough Business Models: Drug Development for Rare and Neglected Diseases and Individualized Therapies | **June 24** Forum Meeting #10 | **October 24** Workshop: Assessing and Accelerating Development of Biomarkers for Drug Safety | **November 2–3** Forum Meeting #11 | **November 5** Workshop: Addressing the Threat of Drug-Resistant Tuberculosis: A Realistic Assessment of the Challenge

**2009** | **February 23** Capitol Hill Briefing: Growing Threat of Drug-Resistant Tuberculosis | **March 13** Discussion Series: FDA Community Update on Personalized Medicine and the Genetic Basis of Adverse Events | **April 27** Workshop: Streamlining Clinical Trial and Material Transfer Negotiations | **April 27–28** Forum Meeting #12 | **July 10** Symposium: Drug Regulation with FDA Commissioner Peggy Hamburg and Forum Meeting #13 | **September 2** Discussion Series: FDA Community Update: Improving the Science of Drug Safety | **October 7–8** Workshop: Transforming Clinical Research in the United States | **October 15–16** Forum Meeting #14

**2010** | **February 23–24** Workshop: The Public Health Emergency Medical Countermeasures Enterprise *(in collaboration with the Medical Preparedness Forum)* | **February 26** Workshop: Building a National Framework for the Establishment of Regulatory Science for Drug Development | **March 3–4** Workshop: The Emerging Threat of Multidrug-Resistant Tuberculosis (Pretoria, South

Africa) | **April 29–30** Forum Meeting #15 | **May 26–27** Workshop: The New Profile of Drug-Resistant Tuberculosis (Moscow, Russia) | **August 5** Forum Meeting #16 | **October 29** Forum Meeting #17

**2011** I **March 28** Forum Meeting #18 | **March 29–30** Workshop: Advancing Regulatory Science for Medical Countermeasure Development *(in collaboration with the Medical Preparedness Forum)* | **April 18–19 and 21** Workshop: Facing the Reality of Multidrug-Resistant Tuberculosis: Challenges and Potential Solutions (New Delhi, India) | **June 27–28** Workshop: Public Engagement and Clinical Trials: New Models and Disruptive Technologies *(in collaboration with the Mount Sinai School of Medicine)* | **June 28–29** Forum Meeting #19 | **July 12** Workshop Summary Report Release: The Emerging Threat of Multidrug-Resistant Tuberculosis: Global and Local Challenges and Solutions (Durban, South Africa) | **September 20–21** Workshop: Strengthening a Workforce for Innovative Regulatory Science in Therapeutics Development | **October 4–5** Forum Meeting #20 | **November 7–8** Workshop: Envisioning a Transformed Clinical Trials Enterprise in the United States: Establishing an Agenda for 2020 | **November 15** Workshop Summary Report Release: The New Profile of Drug-Resistant Tuberculosis: A Global and Local Perspective (Moscow, Russia)

**2012** I **March 13–14** Forum Meeting #21 | **June 4–5** Workshop: Maximizing the Goals of the Cures Acceleration Network to Accelerate the Development of New Drugs and Diagnostics | **June 5** Forum Meeting #22 | **July 31–August 1** Workshop: Developing and Strengthening the Global Supply Chain for Second-Line Drugs for Multidrug-Resistant Tuberculosis | **October 4–5** Workshop: Sharing Clinical Research Data *(in collaboration with the Neuroscience Forum, National Cancer Policy Forum, and Genomics Roundtable)* | **October 23–24** Forum Meeting #23 | **November 26–27** Workshop: Large Simple Trials and Knowledge Generation in a Learning Health System *(in collaboration with the Leadership Consortium for a Value & Science-Driven Health System)*

**2013** I **January 15** Workshop Summary Report Release: Developing and Strengthening the Global Supply Chain for Second-Line Drugs for Multidrug-Resistant Tuberculosis | **January 16–18** Workshop: The Global Crisis of Drug-Resistant Tuberculosis and Leadership of the BRICS Countries (Beijing, China) | **February 12** Forum Meeting #24 | **February 13–14** Workshop: International Regulatory Harmonization Amid Globalization of Biomedical Research and Medical Product Development | **June 3** Forum Meeting #25 | **October 28–29** Forum Meeting #26

# TIMELINE

**2014 | February 12** Workshop: Characterizing and Communicating Uncertainty in the Assessment of Benefits and Risks of Pharmaceutical Products (Day 1) | **March 3–4** Forum Meeting #27 | **May 12** Workshop: Characterizing and Communicating Uncertainty in the Assessment of Benefits and Risks of Pharmaceutical Products (Day 2) | **June 10–11** Forum Meeting #28 | **October 7–8** Forum Meeting #29

**2015 | January 20–21** Workshop: Financial Incentives to Support Unmet Medical Needs for Nervous System Disorders *(in collaboration with the Neuroscience Forum)* | **March 17–18** Forum Meeting #30 | **March 26–27** Workshop: Rapid Medical Countermeasure Response to Infectious Diseases: Enabling Sustainable Capabilities Through Ongoing Public- and Private-Sector Partnerships *(in collaboration with the Medical Preparedness Forum)* | **June 23–24** Forum Meeting #31 | **October 20** Workshop: Advancing the Discipline of Regulatory Science for Medical Product Development: An Update on Progress and a Forward-Looking Agenda | **October 21** Forum Meeting #32

**2016 | March 22** Workshop: Deriving Drug Discovery Value from Large-Scale Genetic Bioresources *(in collaboration with the Genomics Roundtable)* | **March 23** Forum Meeting #33 | **July 19–20** Forum Meeting #34 | **October 18** Forum Meeting #35 | **October 19** Workshop: Real-World Evidence Generation and Evaluation of Therapeutics | **December 12–13** Workshop: The Drug Development Paradigm in Oncology *(in collaboration with the National Cancer Policy Forum)*

**2017 | March 8** Workshop: Enabling Precision Medicine: The Role of Genetics in Clinical Drug Development *(in collaboration with the Genomics Roundtable)* | **March 9** Forum Meeting #36 | **July 10–11** Forum Meeting #37 | **September 19–20** Workshop Series: Examining the Impact of Real-World Evidence on Medical Product Development—Workshop 1: Incentives | **October 24–25** Forum Meeting #38

**2018 | March 6–7** Workshop Series: Examining the Impact of Real-World Evidence on Medical Product Development—Workshop 2: Practical Approaches | **March 19–20** Forum Meeting #39 | **May 9** Workshop: Advancing the Science of Patient Input in Medical Product R&D—Towards a Research Agenda | **July 17–18** Workshop Series: Examining the Impact of Real-World Evidence on Medical Product Development—Workshop 3: Application | **July 18** Forum Meeting #40 | **October 3–4** Forum Meeting #41 | **November 28–29** Workshop: Virtual Clinical Trials—Challenges and Opportunities

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## ABOUT THE FORUM

The Forum on Drug Discovery, Development, and Translation of the National Academies of Sciences, Engineering, and Medicine was created in 2005 by the National Academies' 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 with an interest in improving the system of drug discovery, development, and translation. 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 patients, and in doing so serves to educate the policy community about issues where science and policy intersect.

The Forum convenes a few 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. The Forum also fosters collaborations among its members and constituencies. For more information about the Forum on Drug Discovery, Development, and Translation, please visit our website at http://www.nationalacademies.org/DrugForum.

## ABOUT THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE

The **National Academy of Sciences** was established in 1863 by an Act of Congress, signed by President Lincoln, as a private, nongovernmental institution to advise the nation on issues related to science and technology. Members are elected by their peers for outstanding contributions to research. Dr. Marcia McNutt is president.

The **National Academy of Engineering** was established in 1964 under the charter of the National Academy of Sciences to bring the practices of engineering to advising the nation. Members are elected by their peers for extraordinary contributions to engineering. Dr. C. D. Mote, Jr., is president.

The **National Academy of Medicine** (formerly the Institute of Medicine) was established in 1970 under the charter of the National Academy of Sciences to advise the nation on medical and health issues. Members are elected by their peers for distinguished contributions to medicine and health. Dr. Victor J. Dzau is president.

The three Academies work together as the **National Academies of Sciences, Engineering, and Medicine** to provide independent, objective analysis and advice to the nation and conduct other activities to solve complex problems and inform public policy decisions. The National Academies also encourage education and research, recognize outstanding contributions to knowledge, and increase public understanding in matters of science, engineering, and medicine.

Learn more about the National Academies of Sciences, Engineering, and Medicine at **www.nationalacademies.org.**

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