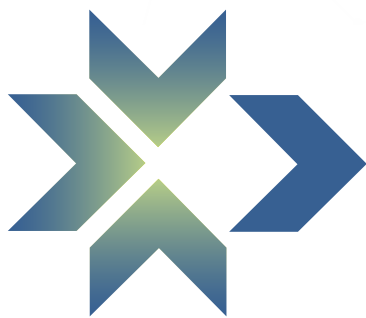


*The National  
Academies of*

SCIENCES  
ENGINEERING  
MEDICINE



Forum on  
**DRUG DISCOVERY,  
DEVELOPMENT,  
and TRANSLATION**

Activities, Products, Impact

# ABOUT THE FORUM

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 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 [www.nationalacademies.org/DrugForum](http://www.nationalacademies.org/DrugForum).





# FORUM THEMES AND PRIORITIES

## **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 can help 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



**Facilitate visibility and continuous discussion on important issues**



**Foster collaboration on topics where there is synergy among potential partners**



**Explore innovative and transformative approaches for resolving problem areas**



**Educate and elevate understanding of issues**



**Clarify and expand areas of agreement**

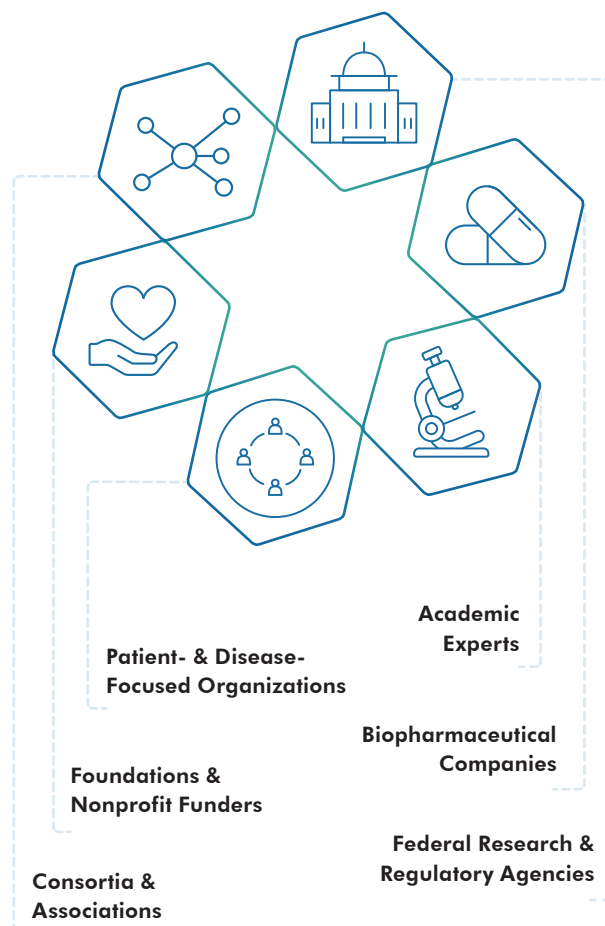


**Set the stage for future policy action**

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 above strategies.



## MEMBERS



The Forum has approximately 30-35 members, identified for their professional and expert perspective as well as their technical and/or public policy credentials. Expertise includes basic and clinical biomedical research, therapeutics development, health administration and policy, and patient/disease advocacy. Additional experts are invited to participate in particular Forum discussions and other activities on an ad hoc basis.



# ACTIVITIES

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. To supplement the perspectives and expertise of its members, the Forum holds public workshops to focus substantial public attention on critical areas of scientific and policy interest. The Forum also fosters action-oriented collaboratives that engage a wide range of experts, the policy community, and members of the public in an informal, neutral setting.

## Forum Meetings

Building on priorities identified by Forum members during the course of Forum meetings, the Forum membership envisions future workshops and collaborative activities.



# Workshops

## Activity Goals

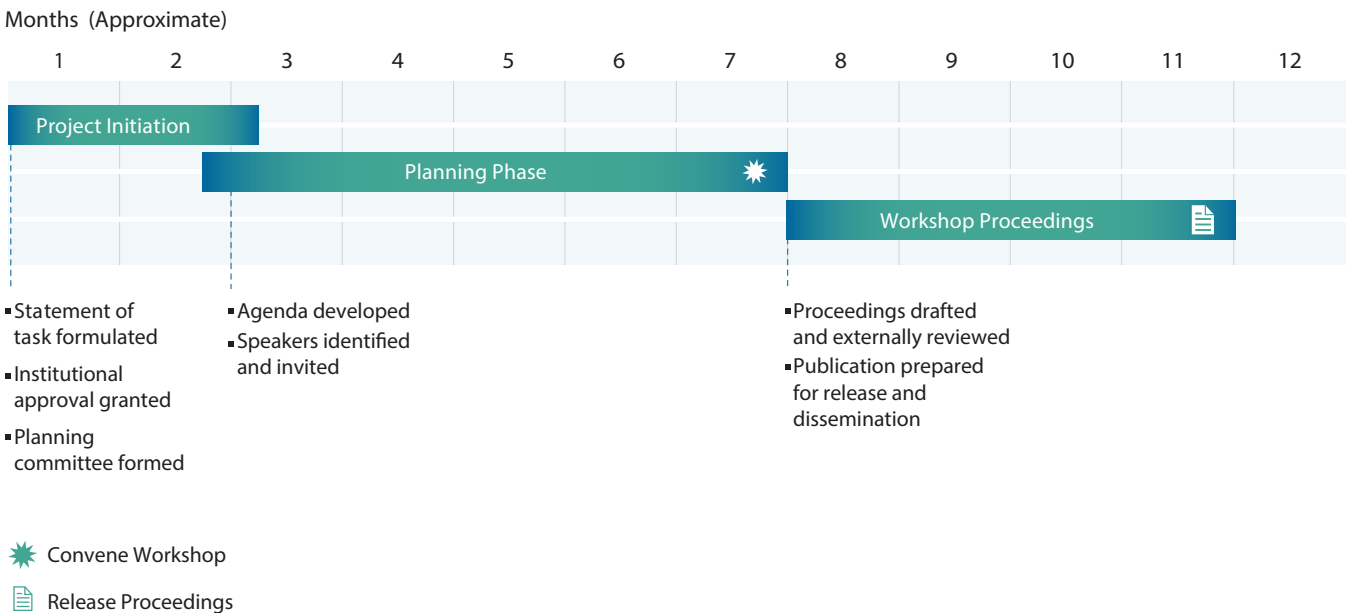
Public workshops convene experts, thought leaders, stakeholders, and members of the public from across the drug R&D and regulatory ecosystem to report on the current knowledge in an area, highlight and elucidate problems, focus substantial public attention on critical areas of scientific and policy interest, or discuss the progress of policy change following the release of a National Academies consensus study report.

## Process

Workshops are organized by planning committees, which may include Forum members. Over the course of five to six months, the planning committee convenes to scope and plan the workshop (see the figure below). Forum staff facilitate convening the planning committee and promoting the workshop to relevant stakeholders and the public. Workshops typically result in the publication of a workshop proceedings (find out more under “Products”).

## Outcomes

Workshop proceedings are published to communicate the information and dialogue presented at the workshop to a wider audience. Workshops may result in the formation of action collaboratives, follow-on discussion papers or commentaries, a workshop series, or spin-off consensus studies.



## Action Collaboratives

### Activity Goals

The Forum fosters action collaboratives to engage participants with similar interests and responsibilities in cooperative activities that analyze in-depth high-priority issues and advance identified goals of the Forum and progress on recommendations highlighted in previous National Academies consensus reports. Collaboratives are participant-driven, action-oriented activities that foster collaboration and information sharing among Forum members and external thought leaders and stakeholders. Collaboratives may:

- identify issues of common interest and marshal needed leadership, expertise, and resources;
- highlight potential paths forward through, e.g., individually authored (or small group) literature summaries or discussion papers or through the convening of technical discussions;
- engage in cooperative development of tools needed for progress;
- incubate and pilot-test novel approaches; and
- develop proposals for formal workshops and studies for consideration by the National Academies.

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

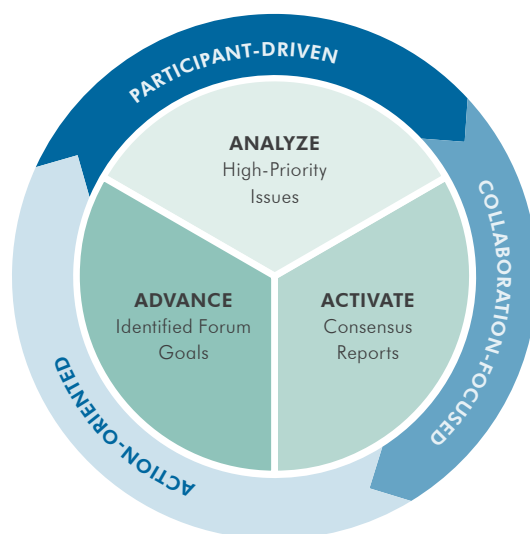
### Process

Collaboratives meet under the auspices of the Forum. They vary in structure and content to meet the specified needs and challenges identified by their participants. Collaborative participants and their colleagues often provide in-kind support (such as human resources) to further the Collaborative's goals, with support and facilitation by Forum staff. The timeline and frequency with which Collaboratives meet is determined by its participants; however, many Collaboratives meet for an average of 1.5–2 years, hold regular teleconferences, and meet in person several times.

### Impact/Reach

Collaboratives offer considerable flexibility for their participants to pursue a wide range of activities and products and the opportunity to have an impact on the field. Products are ascribed to the Collaborative participants and are not products of the National Academies, and endorsement and use of the Collaborative's work is at the discretion of its participants' individual organizations. Examples of impact/reach might include:

- advancing progress on recommendations highlighted in previous National Academies reports;
- developing papers authored by individual participants in the Collaborative;
- submitting journal articles to independent publications;
- spurring formation of public–private partnerships; and
- envisioning a charge for a planning committee to convene a workshop or a consensus study.





# PRODUCTS

## **Workshop Proceedings**

Workshops often result in a Proceedings of a Workshop (or Proceedings of a Workshop-in Brief). A workshop proceedings is written by National Academies staff and/or hired consultants, serving as rapporteurs, as a direct account of the workshop discussions and dialogue by workshop participants and members of the Forum. Members of the Forum and of the planning committee may not serve as rapporteurs. A workshop proceedings is reviewed by a diverse range of experts, which may include Forum members.

## **Perspectives: Discussion Papers and Commentaries**

Authored discussion papers and commentaries (collectively termed Perspectives) can disseminate information or further elucidate topics covered in Forum discussions, workshops, or action collaboratives. Perspectives, published by the National Academy of Medicine (NAM), are individually authored by Roundtable and Forum members and outside experts in health and health care. The views expressed in these papers are those of the authors and not necessarily of the authors' organizations, the NAM, or the National Academies of Sciences, Engineering, and Medicine (the National Academies). Perspectives are intended to help inform and stimulate discussion. They are not reports of the NAM or the National Academies.

## **Independent Journal Articles and Other Publications**

The Forum may commission or foster the development of papers to undertake new research, as well as synthesize existing literature and explore scientific and policy issues on selected topics, through the publication of journal articles in independent publications or consultant-developed documents.



# IMPACT

## **Influence Policies and Programs**

Forum activities can inform policy and legislation; programmatic planning, direction, and budgets; educational initiatives, such as curricula and training programs; and other activities.

## **Foster Relationships and Collaborations**

By bringing together a diverse group of stakeholders around particular topics, the Forum fosters new professional relationships, facilitates cross-sector collaborations, and enables professional development and networking, including the cultivation of new leaders.

## **Inspire New Ideas and Shape the Field**

The dialogue and ideas generated through Forum activities and captured in related products encourages the open sharing of diverse perspectives and the interchange of ideas among multidisciplinary stakeholders. The Forum can advance and shape the field by framing issues and shining a light on important topics, and by generating novel approaches to overcome existing challenges, spurring progress and inspiring action.