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. The Forum provides a unique platform for dialogue and collaboration among thought leaders and stakeholders in government, academia, industry, foundations, and disease and patient advocacy with an interest in improving the system of drug discovery, development, and translation, educating the policy community about issues where biomedical science and policy intersect.

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 drug discovery and development. Proceedings of these meetings are disseminated to the public. In addition, the Forum commissions or fosters the development of papers to explore scientific and policy issues on selected topics. The Forum also fosters collaborations among its members and constituencies.

The overarching theme underpinning all of the Forum’s activities, workshops, publications, and working groups is to understand and improve the system of drug discovery, development, and translation in a rapidly changing scientific and regulatory environment, in order to improve the public’s health.
Despite exciting scientific advances, the pathway from basic science to new therapeutics faces challenges on many fronts. Innovative 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. There is also increasing recognition of the need for new models and methods for drug discovery, development, and translational science. To address this need, “precompetitive collaborations” and other partnerships, including public–private partnerships, are proliferating. The Forum offers a venue to discuss effective collaboration in the drug discovery and development enterprise and hosts discussions that could help chart a course through the turbulent forces of disruptive innovation in the drug discovery and development “enterprise.”

Key gaps remain in our knowledge about the science, technology, and methods needed to support drug discovery and development. Recent rapid advances in the science of drug discovery and development present opportunity for revolutionary developments of new scientific techniques, as well as therapeutic products and applications. The Forum provides a venue to focus ongoing attention and visibility on these important needs and facilitates exploration of new approaches across the lifecycle of drug discovery and development. The Forum has held workshops that have contributed to the defining, establishment, and refinement of regulatory science and have helped inform aspects of drug regulatory evaluation.

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. In addition to sponsoring multiple symposia and workshops to examine the state of clinical trials in the United States, the Forum fosters innovative, collaborative efforts to facilitate needed change in areas such as improvement of clinical trial site performance and sharing of clinical trial data.

Considerable opportunities remain for enhancement and improvement of the infrastructure that supports the drug discovery and development enterprise. That infrastructure, which includes the organizational structure, framework, systems, and resources that facilitate the conduct of biomedical science for drug development, faces significant challenges. The science of drug discovery and development, and its translation into clinical practice, is cross-cutting and multidisciplinary. Career paths can be opaque or lack incentives such as recognition, career advancement, or financial security. The Forum has considered workforce needs as foundational to the advancement of drug discovery, development, and translation. It has convened workshops examining these issues, including consideration of strategies for developing a discipline of innovative regulatory science through the development of a robust workforce.
Topics addressed by the Forum are likely to 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 these strategies.

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.
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 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 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.

### Months (Approximate)

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<th>Months</th>
<th>Project Initiation</th>
<th>Planning Phase</th>
<th>Workshop Proceedings</th>
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<tbody>
<tr>
<td>1</td>
<td>Statement of task formulated</td>
<td>Agenda developed</td>
<td>Proceedings drafted and externally reviewed</td>
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<tr>
<td>2</td>
<td>Institutional approval granted</td>
<td>Speakers identified and invited</td>
<td>Publication prepared for release and dissemination</td>
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<td>3-6</td>
<td>Planning committee formed</td>
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- **Project Initiation**: Statement of task formulated, Institutional approval granted, Planning committee formed
- **Planning Phase**: Agenda developed, Speakers identified and invited
- **Workshop Proceedings**: Proceedings drafted and externally reviewed, Publication prepared for release and dissemination

- ![Convene Workshop](image)
- ![Release Proceedings](image)
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 on Drug Discovery, Development, and Translation (the Forum) at the National Academies of Sciences, Engineering, and Medicine (the National Academies). The work it produces does not necessarily represent the views of any one organization, the Collaborative, the Forum, or the National Academies and is not 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.
**IMPACT**

By bringing together a diverse group of stakeholders several times a year, the Forum fosters new professional relationships, facilitates cross-sector collaborations, and enables professional development and networking.

The Forum encourages the open sharing of diverse perspectives and the interchange of ideas among multidisciplinary stakeholders. Through these interactions and connections, participants in Forum activities often generate novel ideas and approaches to overcome existing challenges, spurring progress and inspiring action.

The discussions and products arising from Forum activities can inform policy and legislation, programmatic planning, direction, and budgets, educational initiatives, such as curricula and training programs, and activities such as demonstration projects.

The dialogue and ideas generated during the convening activities of the Forum and captured in related products reach varied, multidisciplinary audiences interested in health and medicine. The Forum helps to advance and shape the field by framing issues, shining a light on important topics, and fostering the cultivation of new leaders.

**WORKSHOP PROCEEDINGS**

Workshops often result in a Proceedings of a Workshop (or Proceedings of a Workshop—in Brief), published by the National Academies Press. A workshop proceedings is written as a direct account of the workshop discussion and dialogue by National Academies staff and/or hired consultants, serving as rapporteurs. Members of the Forum and of the planning committee may not serve as rapporteurs. A workshop proceedings is reviewed by an independent panel. Forum members may serve as reviewers, along with other experts in the field.

**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. Though distributed by the National Academy of Medicine (NAM), the views in discussion papers and commentaries represent only those of the authors, not necessarily of the authors’ organizations, the NAM, or the National Academies. These papers are not subject to the review procedures of the National Academies. All discussion papers and commentaries are designed to be shared publicly.

In addition to Perspectives, 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.

**INDEPENDENT JOURNAL ARTICLES AND OTHER PUBLICATIONS**

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