

Consortium Overview

The Biomarkers Consortium is a public-private biomedical research partnership managed by the Foundation for the National Institutes of Health (FNIH) that endeavors to discover, develop, and seek regulatory utilization (FDA Qualification) for drug development tools (e.g. biological markers or biomarkers) to support new drug development, preventive medicine, and medical diagnostics.

Vision

Improving health through meaningful measurements

Mission

To create and lead cross-sector efforts that validate and qualify biomarkers and other drug development tools to accelerate better decision making for the development of new therapeutics and health technologies.

The Biomarkers Consortium is helping facilitate, catalyze and support a new era of precision medicine, with more highly predictive drug development tools that have an impact during a patient's illness or lifespan. Its goal is to combine the forces of the public and private sectors to accelerate the development of biomarker-based technologies, medicines, and therapies for the prevention, early detection, diagnosis, and treatment of disease.

The Biomarkers Consortium is organized around several Steering Committees. The members of each represent a variety of sectors, including academia, government, industry and not-for-profit/advocacy organizations, and are led by two co-chairs representing two of the following three sectors: academia, government or industry.

Current Biomarkers Consortium Steering Committees:

- Cancer Steering Committee
- Inflammation & Immunity Steering Committee
- Metabolic Disorders Steering Committee
- Neuroscience Steering Committee

Executive Committee Charter

Description

The Biomarkers Consortium Executive Committee is its governing body, elected by the members and responsible for the Biomarkers Consortium mission, vision, strategy and oversight. Members' primary responsibility is to speak on behalf of public health by broadly representing the perspective of their stakeholder groups (i.e., National Institutes of Health (NIH), U.S. Food and Drug Administration (FDA), industry, Centers for Medicare and Medicaid Services (CMS), and the advocacy or academic communities) in shaping issues such as governance, policies, and procedures. The Executive Committee is responsible for selecting biomarkers projects for execution under the auspices of the Biomarkers Consortium that fit with strategy, mission and scope.

Members are selected based on recommendations or nominations from the executive leadership of the stakeholder constituency. There will be a fixed number of representatives from each major stakeholder group, as outlined below:

- NIH-3 members
- FDA-3 members
- CMS-1 member
- PhRMA- 1 member
- Pharmaceutical/Biotech Industries—3 members
- Public (academia, advocacy)—1 member
- FNIH-3 members (up to two at-large members and the chair, all non-voting)

Executive Committee members will seek and reach consensus regarding disease or scientific areas with particular promise for biomarkers development and convene Steering Committees in these areas when necessary. Voting members will decide on project concepts and/or Project Plans, brought by the Steering Committees, they feel are best executed through partnership under the Biomarkers Consortium.

The Executive Committee is led by a non-voting chair, who is responsible for convening the group periodically and serves as its primary spokesperson. The chair is appointed by the FNIH Board of Directors and serves as its liaison to the Biomarkers Consortium.

Terms of Service

Executive Committee members serve for terms of at least three years from the date of appointment (and whose terms are renewable by the other members of the Executive Committee). Appointments are staggered so that no more than approximately one-third of the members are appointed in a given year and those appointed in a given year do not constitute all of the representatives for a given stakeholder group. Each stakeholder group will appoint a central point of contact that will seek nominations for, and secure the commitment of, new representatives as existing representatives leave.

Roles and Responsibilities

Executive Committee members refine and maintain the overarching vision for the Biomarkers Consortium, establish and uphold necessary policies and procedures, and identify disease/scientific areas around which to convene Steering Committees and promising project concepts and plans. These activities are supported by FNIH staff.

Roles and responsibilities of the Executive Committee members fall into two main areas: **ongoing governance** and **concept and project selection**—as outlined below.

Ongoing Governance

- Support project concept approval and project implementation processes based on a two-step review and filling out the appropriate sections of the Project Development Form (provided by FNIH SC lead).
- Monitor business principles policies and procedures to ensure that they are upheld; mediate related discussions as required.
- Refine membership policies, requirements, and benefits as necessary.
- Obtain input from constituent group to ensure most effective representation.
- Oversee the Biomarkers Consortium policies and procedures and refine as necessary to ensure effective and productive collaboration.
- Conduct periodic scientific landscape review to help guide strategic priorities and inform annual Steering Committee priority setting.
- Recommend actions to the FNIH Board, as necessary.

Concept and Project Selection

- Monitor disease/scientific areas of particular interest for biomarker development (i.e., cancer, metabolic disorders, neuroscience, immunity and inflammation).
 - support disease- or scientific-area Steering Committees to generate project concepts for these broad areas
 - seek public/expert input to flesh out project plans as needed.
- Ensure public awareness of Consortium activities by publicizing opportunities through appropriate mechanisms.
- Review detailed project plans generated by Steering Committees for approval.
 - project concept and plan review is limited to assessing strategic fit and expected impact. The Executive Committee is not expected to address all scientific details of a project (which is the responsibility of the Steering Committees).
- Evaluate funding feasibility of projects at the concept level and assist Steering Committees with fundraising prioritization.
- Nominate and appoint co-chairs to head each Steering Committee, identify and recruit Steering Committee participants or allow the Steering Committee co-chairs to do so.

- Form additional Steering Committees or ad hoc advisory groups for areas where there is potential to fund a project, but no Steering Committee currently exists.

Time Commitment

The time commitment for executive committee members is in two areas, outlined below:

Governance and review duties:

- The Executive Committee will meet periodically to carry out its ongoing responsibilities.
- Executive Committee members may be requested to participate in additional ad hoc sub-team meetings that address areas of needs within the Biomarkers Consortium to maintain governance and relevance (e.g. Communications, Governance and Funding, etc.).

Meetings:

- In person for a half-day in the DC Metro/Bethesda, Maryland area twice a year
- Up to four 2-3-hour teleconferences.

Staffing

The FNIH staff, under the leadership of the director of the Biomarkers Consortium, provides staff support to the Executive Committee. FNIH staff assists the members of the Executive Committee in carrying out their responsibilities, arranging meetings, preparing agendas and minutes, keeping official records, and following up on action items to implement agreed upon plans.

Steering Committee Charter

Description

The Biomarkers Consortium's Steering Committees are currently organized to generate drug development tools and are responsible for identifying and moving forward promising pre-competitive projects for implementation by the Biomarkers Consortium. After project launch (i.e. initial contractual agreements have been executed), the Steering Committee is responsible for overseeing each individual project under its purview. Each Steering Committee will be focused on a particular disease or scientific area and will operate in accordance with the principles and policies of the Biomarkers Consortium [<https://fnih.org/what-we-do/biomarkers-consortium/about/policies>].

Functions

The primary tasks of Steering Committees are:

- Identifying, prioritizing, and/or refining high-impact biomarker opportunities/project concepts within their focus areas through interactive, cross-sector dialogue among Steering Committee members and throughout the broader scientific community.
- Prioritizing high-impact biomarker opportunities proposed by members of the Executive Committee, the public, and the Steering Committee itself that fall within the committee's mandated scientific and/or disease area.
- Encouraging the development of new ideas and projects through working groups or other mechanisms.
- Evaluating project concepts and upon approval of a concept, facilitating the assembly of a project development team for each concept.
 - Each project development team will develop a project plan with guidance from the Steering Committee to achieve the project's stated objectives effectively and efficiently.
- Ensure scientific quality of project concepts and plans to be submitted to the Executive Committee.
- Submitting project concepts and plans to the Executive Committee for approval.
- Overseeing and facilitating the evolution of the project development team into the project execution team.

Membership

Each Steering Committee is led by two co-chairs who are appointed by the Executive Committee. The co-chairs each represent different sectors from among academia, industry, and the federal government. The co-chairs are responsible for convening their Steering Committee as needed and communicating its recommendations to the Executive Committee, with support from FNIH staff.

The membership of each Steering Committee includes broad representation from all sectors, especially, relevant experts from key Consortium partners (NIH, FDA, CMS, industry, academia, and the advocacy community).

Steering committee membership is limited to:

- Private members in good standing of the Biomarkers Consortium.
- Federal government agency representatives from organizations related to the steering committee goals.
- Steering Committee members may suggest qualified academic investigators to work on specific areas of interest.

The size and composition of each Steering Committee is under the discretion of its co-chairs and depends on the type of expertise needed.

Steering Committee members are encouraged to attend all meetings. The substitution of Steering Committee members by proxies is discouraged, as this hampers continuity and familiarity of participants. If substitution is necessary, designated proxies should be introduced to the Steering Committee FNIH staff lead prior to the meeting. The participation of any person on a Steering Committee requires prior notice of the co-chairs, followed by the signing of compliance statements by the participant for review of a specific project concept or plan. While the participation of proxies is discouraged, members are strongly encouraged to solicit input from colleagues with appropriate expertise from within their organization.

Terms of Service

Terms for Steering Committee members will be two years and are renewable; terms of those representing member private partners are left to the discretion of the member organization, provided dues are paid and they are in good standing. The terms of the co-chairs will be three years, renewable only by the Executive Committee. Whenever possible, terms of all Steering Committee members should be staggered so that no more than one-third of the members will rotate annually. Every year the FNIH and Steering Committee will perform a review of membership participation to ensure all members are engaged and in good standing.

Roles and Responsibilities

Steering Committee members are encouraged to attend monthly telephone conference calls and occasional face-to-face meetings. Those who are unable to attend four meetings/teleconferences in a row may be asked to step down from their committee membership, unless unusual circumstances contributed to this absence. If a member is unable to attend a meeting, it is their responsibility to assign a proxy to take their place. Please see the Membership section regarding the assignment of proxy.

Steering Committee members will generate and evaluate project concepts within their therapeutic area and evaluate all relevant project concepts proposed by others. Upon

approval of project concepts, Steering Committees will facilitate the assembly of project teams to develop project plans and will oversee the project teams as they carry out each approved project.

Roles and responsibilities of each Steering Committee fall into three areas—[concept identification and review](#), [project plan development](#), and [project implementation](#)—as outlined below.

Concept Identification and Review

- Identify subject areas and project concepts of high priority to all stakeholders through interactive conversation, gap analyses, etc., and engage experts from the public to advise and refine project concepts.
- Consider project concepts submitted by the Executive Committee and the public.
- Evaluate all project concepts under consideration.
- Assess fundability of all project concepts.

Project Plan Development

- For each project concept approved, create a project development team to develop a project plan, according to the “Biomarkers Consortium Project Development Form.”
- Work with the FNIH to convene advisory groups, host workshops, release requests for information, engage consultants (i.e., clinical research organizations), etc., to complete the project planning process.
- Facilitate the formation of subgroups needed to carry out project development activities.
- Aid in assessing feasibility of funding and ensuring projects are fully funded, as appropriate.
- Recommend completed project plans to the Executive Committee.

Project Implementation

- Once a project is approved by the Executive Committee, oversee the transformation from Project Development Team into the Project Execution Team. Please see the Project Team charters for further information.
- Oversee Project Execution Team as they implement each Project Plan approved by the Executive Committee, to ensure the goals and objectives of the project are met.
- Work with the FNIH to convene advisory groups, workshops, or engage consultants, clinical research organizations, or other collaborating centers to help develop and execute project plans.
- Assist the FNIH in identifying potential funding partners and in securing funding for approved Projects.
- Assist the FNIH in promoting all approved projects, including launch and key milestones met throughout the duration of the project.

Project Development Team Charter

Description

A project development team will be created when a proposal for a project obtains approval from the relevant Steering Committee. If there is no appropriate Steering Committee, the Executive Committee may convene a project development team and assign to a particular Steering Committee. All project development teams will operate in accordance with the principles and policies of the Biomarkers Consortium and follow the guidelines below.

Functions

Project development teams have the following responsibilities:

- Develop a detailed project plan for the approved project concept.
- Submit completed project plans to the Executive Committee, through the relevant Steering Committee, for confirmation of feasibility.
- Develop project team governance based on individual resource contribution to the project.
- Develop a strategy for obtaining funding commitments with sufficient confidence that the project will be successful.
- Upon approval of the project plan by the Executive Committee each project will operate under an appropriate contractual agreement between the FNIH and the institution executing or managing a project.

Membership

The chair(s) and members of the project development team will be appointed by the Steering Committee, in consultation with FNIH staff. The Executive Committee will be informed of the final project team composition before the project plan is approved. It is preferred that members of Steering Committees serve as project development team members, should they have the appropriate expertise and available time for the meetings. Steering Committee members may also invite appropriate individuals from outside the Biomarkers Consortium to join project development teams. Steering Committee co-chairs are discouraged from serving as project development team chairs but may participate as project team members.

Members should include as broad a representation as possible from the following as appropriate for the project:

- Lead or managed by FNIH staff
- Key consortium partners (NIH, FDA, industry) who are expert in the specific disease or scientific area of a project.
- Biomarkers Consortium member partners who plan to contribute funding to support a particular project can nominate participants to that project development team in keeping with The Biomarkers Consortium governance

principles and any guidelines developed by the Steering Committee for the particular project.

- Members of the advocacy and non-profit communities, Centers for Medicare & Medicaid Services, or other Federal partners, academia, or other relevant partner representatives.
- All project development team members must be approved by the project development team chair(s) prior to Steering Committee consent
- If there are no potential funders from among the Biomarkers Consortium membership, the project cannot be brought forward to the Executive Committee.

Terms of Service

Project development team members will serve for the duration of the development phase. Members of the project development team may join the project execution team if their organization contributes financially or in/kind support to the project.

- Should any member(s) of the project development team need to be replaced or added for any reason, the project development team will make recommendations to the appropriate Steering Committee to identify potential new members.

Roles and Responsibilities

Project Planning

- With the input of the Steering Committee and appropriate experts, prepare the project plan for the approved project concept, using “The Biomarkers Consortium Project Development Form.”
- Conduct project-specific gap analyses as required.
- Develop project-specific guidelines and infrastructure to support the project execution.
- Recommend additional experts to serve on the project team when needed.
- Convene advisory groups, host workshops, release requests for information, engage consultants (i.e., clinical research organizations), etc., to improve and refine the project planning process.
- Present project concept to the Executive Committee first for an assessment of fundability and feasibility.
- Upon concept approval from Executive Committee, finalize the details of the project including; governance, risks and benefits, communications plan, deliverables timeline, funding strategy and the data security and legal compliance.
- Project plan cannot be submitted to the Executive Committee for final approval before funding partners have been identified to the FNIH sufficient to ensure necessary financial support for the Project budget.
- During the transition from the project development team to the project execution team, members of the latter must complete all appropriate contractual agreements. Members of the project development team may only be considered

for the project execution team if they are providing unique scientific (for non-industry), financial or material support to the project.

Note: The project development team chair(s), with help from FNIH staff, will have the main responsibility of running the team meetings, participating actively in writing the project plan and ensuring that other team members stay actively involved throughout the development and execution of the project.

Staffing

The FNIH staff, under the leadership of the director of The Biomarkers Consortium, will provide staff support to each project team. The FNIH staff will assist each project development team chair(s) in carrying out their responsibilities, arranging meetings, preparing agendas and minutes, keeping official records, and completing action items for the plans. FNIH staff will also advise each project team chair(s) on The Biomarkers Consortium policies and procedures and will assure uniformity across project teams.

Project Execution Team Charter

Description

A project execution team will be convened by the relevant Steering Committee for each project that it approves. If there is no appropriate Steering Committee, the Executive Committee may convene a project execution team. All project execution teams will operate in accordance with the principles and policies of The Biomarkers Consortium.

Functions

Project execution teams have the following responsibilities:

- Overseeing and executing the project plan created by the project development team.
- Supervise the day to day progress and tracking of the project until project completion and close out.

Membership

The chair(s) and members of the project execution team will be suggested by the project development team in consultation with FNIH staff; membership must be approved by the Steering Committee. The Executive Committee will be informed about the final project execution team composition before the project plan is approved. Members of the project development team are preferred to serve as members of project execution teams should they have the appropriate expertise and available time for the meetings. Project development team members are not automatically selected for the project execution team and must have contractual connection to the project. Steering Committee co-chairs are discouraged from serving as project execution team chairs.

Members should include the same broad representation as found in the project development team.

Terms of Service

Project execution team members will serve for the duration of the project. Should member(s) need to be replaced or added for any reason, the project execution team will make recommendations to the appropriate Steering Committee to identify potential new members.

Roles and Responsibilities

Project Implementation

- Upon approval of the project plan by the Executive Committee, execute and oversee the conduct of the project as described in the project plan and the contractual obligations with the FNIH.

- As appropriate to the project, assist FNIH staff with the development of requests for proposals to seek grantees or contractors capable of performing the required work.
- Provide project progress reports to the Steering Committee.

Note: The project team chair(s) will have the main responsibility of running the team meetings, participating actively in writing the project plan and ensuring that other team members stay actively involved throughout the development and execution of the project.

Staffing

The FNIH staff, under the leadership of the director of The Biomarkers Consortium, will provide staff support to each project team. The FNIH staff will assist each project team chair(s) in carrying out their responsibilities, arranging meetings, preparing agendas and minutes, keeping official records, and completing action items for the plans. FNIH staff will also advise each project team chair(s) on The Biomarkers Consortium policies and procedures and will assure uniformity across project teams.

Appendices

Click on the links below to access the additional reference materials

Appendix A _____ **Business Principles and Policies**
_____ Found on BC Website

Appendix B _____ **Strategic Priorities and Governance**

Appendix B: Strategic Priorities and Governance

Strategic Priorities Agreed upon by the Executive Committee (March 29, 2018)

- Clarify Biomarker Consortium’s scope/differentiation: a collaboration infrastructure that aims to validate and qualify biomarkers/DDTs in areas of greatest need
- Become more “strategic” and able to adapt to evolving needs in identifying and defining BC projects and activities
- Revamp funding model to support a more strategic approach – e.g., earlier funding commitments, flexible (or pilot) funding, broader membership base
 - Enhance governance, and shorten/optimize process to become more nimble
- Improve communications with all stakeholder groups: clarify mission, disseminate findings and tout success

Project plan development pathway and governance review points.

