

THE NATIONAL EVALUATION CENTER FOR HEALTH TECHNOLOGY

Governing Committee Charter

Article I: Name, Preamble, Mission, and Vision

SECTION 1: NAME

The National Evaluation System for health Technology Coordinating Center (hereinafter called “NESTcc”) is an initiative of the Medical Device Innovation Consortium (hereinafter called “MDIC”), a nonprofit organization incorporated in the state of Minnesota.

SECTION 2: PREAMBLE

Several categories of documents will govern NESTcc activities, duties, and responsibilities. NESTcc-specific documents may include but may not be limited to: (1) NESTcc Governance Policies and (2) Standard Operating Procedures. If there is any perceived inconsistency between (1) and (2), this document governs. In addition, NESTcc is at all times subject to applicable provisions in the Articles of Incorporation, Bylaws, and Charter of the MDIC.

SECTION 3: MISSION AND VISION

The Mission and Vision of NESTcc are:

Mission: The NEST community is passionately committed to transforming the way medical device technologies are tested, approved, and monitored.

Vision: We envision a world in which people are empowered to make informed medical choices that enable patients to live their lives to the fullest extent possible.

Article II: Governing Committee

SECTION 1: RESPONSIBILITIES OF MEMBERSHIP

The Governing Committee supports the President of NEST in the successful establishment and maintenance of NESTcc, and recommends strategic and operational goals and NESTcc policies, consistent with, but not limited to, Medical Device User Fee Amendments (MDUFA) requirements. Members of the Governing Committee will be responsible for representing and securing buy-in from their

larger communities on the direction of NESTcc. The Governing Committee is also responsible for establishing new Subcommittees, and approving Subcommittee members – with the intent to ensure diverse and distributed leadership of NESTcc. Governing Committee members must attend 75% of the regular Governing Committee meetings.

SECTION 2: TERMS OF MEMBERS

Governing Committee members serve for up to a three-year term and may be reappointed for one additional three-year term by the MDIC Board of Directors (hereinafter called “MDIC Board”). Representatives from the U.S. Food and Drug Administration (FDA), Centers for Medicare & Medicaid Services (CMS) and MDIC are exempt from term limits so long as they remain employed by and have the approval of their respective organizations.

SECTION 3: COMPOSITION OF MEMBERSHIP

The Governing Committee is composed of up to 20 members representing a diverse range of stakeholders including, but not limited to, patients, clinicians, device manufacturers, regulators, health systems and payers. Four seats must be filled by trade associations, with one each, from the following: AdvaMed, AdvaMed Imaging, the Medical Device Manufacturers Association (MDMA), and American Clinical Laboratory Association (ACLA). Additionally, three seats are reserved one each for the FDA, CMS, and MDIC. Each of these organizations will appoint a representative to be on the Governing Committee. The representative from each trade association may be part of the staff of the association or appointed from a member company. If any of the trade associations elects not to participate on the governing board or for any additional seats allocated to industry, the participating trade associations will determine how to fill any vacant Industry positions. The remaining seats must be filled through an open nomination process. Of the remaining seats, two seats are reserved for patient organizations and one seat will be reserved for a current member of NESTcc Research Network. Industry representation on the NESTcc Governing Committee must make up at least 25% of Governing Committee membership and shall be selected by the trade associations.

SECTION 4: SELECTION PROCESS OF MEMBERS

The remaining seats on the Governing Committee will be filled through an open nomination process and review. The Executive Committee puts forward recommendations for Governing Committee members for approval to the MDIC Executive Committee and makes recommendations for filling additional seats and renewing terms. Approval of the recommended members by the MDIC Executive Committee shall only be withheld for good reason and such reason(s) shall be discussed with the Governing Committee before a final decision is made.

SECTION 5: REGULAR MEETINGS

Regular meetings of the Governing Committee shall be held at least three times per calendar year, in-person or remotely. Governing Committee members must attend 75% of the regular Governing Committee meetings.

SECTION 6: SPECIAL MEETINGS AND REMOTE VOTING

Special meetings of the Governing Committee may be called at any time by the Governing Committee Chair. Notice of the time and place of each special meeting will be provided to each Governing Committee member at least three days in advance of the meeting. Remote voting may also occur via e-mail ballots as long as a quorum votes.

SECTION 7: QUORUM

The Governing Committees will seek to reach decisions collaboratively and through consensus. When a vote is taken, except in those instances when a higher threshold to meet a quorum is required, a simple majority of Governing Committee members at a meeting at which a quorum is present is required to approve an action. A quorum is achieved if greater than 50% of members are present. If the Governing Committee is voting to change the Charter, elect a new Chair, Vice Chair, or Secretary, or approve the addition of a new Governing Committee member, two-thirds of Governing Committee members must be present to meet the quorum threshold for such votes.

SECTION 8: ACTIONS OF THE GOVERNING COMMITTEE

Until such time, if at all, that NESTcc becomes a separate legal entity, the Governing Committee serves in an advisory capacity to the President of NEST except to the extent that the Governing Committee is authorized by the MDIC Executive Committee to take action on specific or general matters. The Governing Committee's actions will be consistent with the mission and vision of NESTcc and MDIC.

The Governing Committee will review the Governing Committee Charter and the NESTcc Strategic and Operational Plan on an annual basis. Both will then be submitted to the MDIC Executive Committee for consideration and approval (simple majority). In addition, the Governing Committee will advise the President of NEST in the development of the selection process for a NESTcc sustainability plan. These will be submitted to the MDIC Executive Committee for consideration and approval (simple majority).

SECTION 9: RESIGNATIONS

Governing Committee members may resign at any time by providing written notice to the Governing Committee Chair.

SECTION 10: VACANCIES

Vacancies will be filled using the same selection process noted above. Governing Committee members who fill a vacant seat will serve out the remainder of that term and will then be eligible to serve one additional three-year term, provided it is approved by the MDIC Executive Committee.

SECTION 11: CONFLICT OF INTEREST

All Governing Committee members will comply with the MDIC Conflict of Interest Policy. Disclosure statements are to be completed by all Governing Committee members on an annual basis and are to be made available on the NESTcc public website. If a new conflict of interest, as defined by the MDIC Conflict of Interest Policy, arises during the time between annual disclosures, it is the obligation of the Governing Committee members to provide an update to their disclosure statement.

Article III: Committees, Subcommittees, Task Forces, and Working Groups

SECTION 1: EXECUTIVE COMMITTEE

Section 1.1: Composition

The Executive Committee is composed of the President of NEST, Governing Committee Chair, Vice Chair, Secretary, and may include a number (to be agreed upon by the existing Executive Committee) of Executive Committee members at large. The Executive Committee will be comprised of representatives from at least two different stakeholder groups and will meet on an ad hoc basis.

Section 1.2: Responsibilities

The responsibilities of the Executive Committee are to:

- Review nominations for Chair, Vice Chair, and Secretary and present a slate to the Governing Committee
- Assess the composition of the Governing Committee and put forward recommendations for Governing Committee members who add diverse perspectives, knowledge, and skills for approval to the MDIC Executive Committee and make recommendations for filling additional seats and renewing terms
- Provide input to the President of NEST on an ad hoc basis
- Annually review MDIC policies to ensure that the NESTcc staff can perform their programmatic duties without conflict of interest, or the appearance of conflict of interest, that could arise as NESTcc evaluates medical devices from companies that are members of MDIC and/or serve on the MDIC Board or NESTcc Governing Committee. In the event that such policies are not in place,

the President will make recommendations to the MDIC President and CEO, MDIC Board, or a committee of the MDIC Board for the establishment of such policies

- If requested by the President and CEO of MDIC, MDIC Board, or a committee of the MDIC Board, provide input into the annual performance review of the President of NEST

SECTION 2: SUBCOMMITTEES, TASK FORCES, AND WORKING GROUPS

Subcommittees, Task Forces, and Working Groups can be established by the Governing Committee on an ad hoc basis in furtherance of NESTcc’s approved plans. The purpose and composition of these groups is subject to approval by the Governing Committee.

- Term lengths for internal Subcommittees will align to the Subcommittee member’s terms on the Governing Committee
- Term lengths for external Subcommittees, Workgroups, and Task Forces will be determined by the Governing Committee
- In general, Working Groups and Task Forces will have a time-limited engagement. The Governing Committee has the authority to dissolve and end the work of these groups

Article IV: Officers

SECTION 1: GOVERNING COMMITTEE OFFICERS

The officers of the Governing Committee shall be the Chair, Vice Chair, and Secretary.

SECTION 2: ELECTIONS AND TERMS

The Chair, Vice Chair, and Secretary are selected through a nomination process that may include self-nominations. Nominations made by others will only be accepted if the individual nominated agrees in advance to serve if selected. Nominations are reviewed by the Executive Committee, which discusses and provides a slate for the Governing Committee to approve. The Chair position serves one four-year term, The Vice Chair and Secretary serve one three-year term. The term is not renewable.

SECTION 3: RESIGNATIONS AN VACANCIES

Resignations and vacancies shall be handled with the same processes outlined for the Governing Committee resignations and vacancies.

SECTION 4: CHAIR

The Chair is responsible for:

- Working collaboratively with the President of NEST to set Governing Committee meeting agendas
- Engaging with key stakeholders to help ensure NESTcc's success in meeting key milestones
- Presiding over Governing Committee meetings
- Serving on and chairing the Executive Committee

SECTION 5: VICE CHAIR

The Vice Chair is responsible for:

- Engaging with key stakeholders to help ensure NESTcc's success in meeting key milestones
- Presiding over Governing Committee meetings in the absence of the Chair
- Becoming the Chair upon completion of a two-year term as Vice Chair or in the event of an unplanned vacancy of the Chair position
- Serving on the Executive Committee

SECTION 6: SECRETARY

The Secretary is responsible for:

- Engaging with key stakeholders to help ensure NESTcc's success in meeting key milestones
Presiding over the Governing Committee meetings in the absence of the Chair and Vice Chair
- Serving on the Executive Committee

Article V: President of NESTcc

The President of NESTcc is an employee of MDIC and is therefore accountable to the MDIC Board and President, who establish performance goals consistent with the priorities developed by the Governing Committee and the MDUFA requirements.

The President of NESTcc is responsible for:

- Leading MDIC's NESTcc program, engaging with external stakeholders, and establishing NESTcc as a successful program for MDIC with the support of the Governing Committee
- Making recommendations to the Governing Committee on matters to be considered and implementing the strategic and operational plan of NESTcc with program staff or consultants

Article VI: Structure

NESTcc is a program of MDIC and is under the responsibility of the President and CEO of MDIC and ultimately under the responsibility of the MDIC Board. NESTcc's organizational structure consists of a Governing Committee, which is an advisory Committee established by the MDIC Board of Directors; Subcommittees, which may be established by the NESTcc Governing Committee; and a President supported by program staff. Working Groups composed of experts representing diverse perspectives may be established by the Governing Committee on an ad hoc basis.

SECTION 1: FDA

The FDA provided initial funding for NESTcc through a cooperative agreement to MDIC through 2022, following the requirements of the MDUFA IV commitment letter. The cooperative agreement was granted a continuation thru April 30th, 2026, under which NESTcc will abide by the requirements of the MDUFA V commitment letter to use any funding provided to NESTcc to transparently:

- Support the development of RWD resources to facilitate appropriate access for research studies
- Convene experts to develop best practices and, advance innovative methodology approaches with respect to RWE development and analysis

SECTION 2: MDIC BOARD

The MDIC Board is responsible for:

- Providing financial and general oversight of NESTcc
- Overseeing compliance of NESTcc activities with MDIC's charitable mission, tax exempt status, governing documents, and, with the FDA cooperative agreement and MDUFA commitment, determining what authority to delegate to the Governing Committee to undertake NESTcc-related activities
- Administering MDIC's Conflict of Interest Policy and periodically reviewing and suggesting modifications, as needed, to the Policy to improve its effectiveness regarding NESTcc activities

SECTION 3: DISPUTE RESOLUTION

In the event that the Governing Committee or MDIC Board determines that communication between the two parties is necessary or appropriate with respect to a disputed issue over which the MDIC Board has authority, the MDIC Executive Committee and the NESTcc Executive Committee will hold a joint meeting to discuss the issue. The MDIC Board will retain the authority to make the final determination in such an event.

Article VII: Amendments

This Charter will be reviewed and approved by the Governing Committee on no less than an annual basis.

Charter Approvals:

Version	Approver	Date
V1	NESTcc Governing Committee	August 29, 2017
	MDIC Board	December 5, 2017
V2	NESTcc Governing Committee	August 22, 2018
	MDIC Board	September 6, 2018
V3	NESTcc Governing Committee	September 17, 2019
	MDIC Board	September 18, 2019
V4	NESTcc Governing Committee	April 21, 2020
	MDIC Board	May 29, 2020
V5	NESTcc Governing Committee	March 16, 2023
	MDIC Board	May 10, 2023
V6	NESTcc Governing Committee	June 12, 2024
	MDIC EC	July 24, 2024