



## NEST Coordinating Center (NESTcc) 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 among (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 Medical Device Innovation Consortium (“MDIC”).

#### Section 3: Mission and Vision

The Mission and Vision of NESTcc are:

**Mission:** To accelerate the development and translation of new and safe health technologies, leveraging real-world evidence, and innovative research.

**Vision:** To be the leading organization within the health technology and medical device ecosystem for conducting efficient and timely high-quality real-world evidence (RWE) studies throughout the total product life cycle (TPLC).

### Article II: Governing Committee

#### Section 1: Responsibilities of Membership

The Governing Committee supports the Executive Director 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 IV) requirements. The Governing Committee is also responsible for establishing new subcommittees, approving subcommittee members, and approving new NESTcc opportunities for public or targeted announcements. Governing Committee members must attend 75% of the 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 term by the MDIC Board. Initial Governing Committee members who decide to serve for a second term shall have staggered terms of one, two, or three years as determined by drawing of lots. Subsequent Governing Committee members will serve standard three-year terms. 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 nominees from each of the following trade associations: AdvaMed, the Medical Device Manufacturers Association (MDMA), Medical Imaging & Technology Alliance (MITA), and American Clinical Laboratory Association (ACLA). Two seats are reserved for patient organizations. FDA, CMS, and MDIC will each recommend a member. Industry representation on the NESTcc Governing Committee must make up at least 25% of Governing Committee Membership.

### 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 Board and makes recommendations for filling additional seats and renewing terms. Approval of the recommended members by the MDIC Board 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 four times per calendar year, in-person or remotely.

### Section 6: Special Meetings

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.

### Section 7: Quorum

The Governing Committee, Subcommittees, and Working Groups 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 the Governing Committee, Subcommittee, or Working Group members present at a meeting at which a quorum is present is required to approve an action. A quorum is achieved if greater than 50 percent of members are present. If the Governing Committee is voting to change the charter or elect a new Chair, Vice Chair, or Treasurer, 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 NESTcc Executive Director, except to the extent that the Governing Committee is authorized by the MDIC Board to take action on specific or general matters. The Governing Committee's actions will be consistent with the mission and vision of MDIC to advance regulatory science.

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 Board of Directors for consideration and approval. In addition, the Governing Committee will advise the Executive Director in the development of the selection process for NESTcc demonstration projects and a sustainability plan. These will be submitted to the MDIC Board of Directors for consideration and approval.

### 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 term, provided it is approved by the MDIC Board.

## 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 once a year 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 member to provide an update to their disclosure statement.

# Article III: Committees, Subcommittees, and Working Groups

## Section 1: Executive Committee

### Section 1.1: Composition

The Executive Committee is composed of the Governing Committee Chair, Vice Chair, and Treasurer. The Executive Committee will be comprised of representatives of 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 Treasurer and present a slate to the Governing Committee
- Assess the composition of the Governing Committee and put forward recommendations for Governing Committee members for approval to the MDIC Board and make recommendations for filling additional seats and renewing terms
- Provide input to the Executive Director on an ad hoc basis

## Section 2: Subcommittees

The Governing Committee may establish subcommittees. The purpose and composition of each subcommittee are subject to approval by the Governing Committee.

### Section 2.1: Charter Subcommittee

#### *Section 2.1.1: Composition*

The Charter Subcommittee will be composed of Governing Committee Members. Term lengths will align to the subcommittee members' terms on the Governing Committee.

#### *Section 2.1.2: Responsibilities*

Responsibilities of the NESTcc Charter Subcommittee include:

- Reviewing the NESTcc Charter and recommending any necessary changes on an annual basis.

### Section 2.2: Sustainability Subcommittee

#### *Section 2.2.1: Composition*

The Sustainability Subcommittee will be composed of Governing Committee Members. Term lengths will align to the subcommittee members' terms on the Governing Committee.

### *Section 2.2.2: Responsibilities*

Responsibilities of the Sustainability Subcommittee include:

- Providing insight on NESTcc sustainability work
- Overseeing the development of a market analysis and business plan for NESTcc

## Section 2.3 Methods Subcommittee

### *Section 2.3.1: Composition*

Upon the establishment of a Methods Subcommittee, methodological experts will advise the NESTcc Governing Committee and staff on statistical and analytical methods to ensure that NESTcc's activities are using the most appropriate and rigorous methods of analysis.

### *Section 2.3.2: Responsibilities*

Responsibilities of the Methods Subcommittee include:

- Developing a research agenda which identifies critical issues in methods in device, imaging, and diagnostic technologies studies across the TPLC
- Developing a "living" methods playbook for NESTcc including device-specific considerations in benefit/risk studies (both observational and interventional) and safety signal detection
- Providing advice on an ad hoc basis to NESTcc staff and the Governing Committee to ensure that NESTcc activities are using the most appropriate and rigorous methods of analysis

## Section 2.4: Data Quality Subcommittee

### *Section 2.4.1: Composition*

Upon the establishment of a Data Quality Subcommittee, recognized leaders in the evaluation of data quality will be invited to advise the NESTcc Governing Committee and staff on data quality related issues through the establishment of a Data Quality Subcommittee.

### *Section 2.4.2: Responsibilities*

Responsibilities of the Data Quality Subcommittee include:

- Developing NESTcc Data Quality Standards for NESTcc Network Collaborators
- Designing a collaborative process by which NESTcc Network Collaborators can demonstrate their conformance with the NESTcc Data Quality Standards and providing recommendations on the implementation of this process
- Providing advice on an ad hoc basis to NESTcc staff and the NESTcc Governing Committee to support NESTcc Network Collaborators abiding by robust standards of data quality

## Section 3: Working Groups

Working Groups may be established by the Governing Committee on an ad hoc basis in furtherance of NESTcc's approved plans and demonstration projects. In general, Working Groups will have a time-limited engagement. The composition of each Working Group is at the discretion of the Governing Committee. Similarly, the Governing Committee has the authority to dissolve and end the work of a Working Group. Formal approval and dissolution of Working Groups takes place through a recommendation by the Executive Director to the Governing Committee.

## Article IV: Officers

### Section 1: Governing Committee Officers

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

## Section 2: Elections and Terms

The Chair, Vice Chair, and Treasurer are selected through a nomination process which 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. Individuals must have served on the Governing Committee for at least one year prior to being nominated for Chair, Vice Chair, or Treasurer. All three positions serve one two-year term. The term is not renewable.

## Section 3: Resignations and 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 NESTcc Executive Director 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: Treasurer

The Treasurer is responsible for:

- Providing in-depth feedback on the NESTcc budget
- Serving as the Chair of the Sustainability Subcommittee
- Serving on the Executive Committee

## Article V: Executive Director

The Executive Director 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 IV requirements.

The Executive Director is responsible for:

- Establishing and maintaining NESTcc, engaging with stakeholders, and transforming NESTcc into a successful enterprise 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
- Working to incorporate the perspectives of the Governing Committee in final work products to the extent feasible and appropriate

## Article VI: Structure

NESTcc’s organizational structure consists of a Governing Committee, which is a Committee established by the MDIC Board of Directors, Subcommittees, which may be established by the NESTcc Governing Committee, and an Executive Director 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 provides initial funding for NESTcc through a cooperative agreement to MDIC through 2022, following the requirements of the [MDUFA IV commitment letter](#).

### 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 IV commitment, determines what authority to delegate to the Governing Committee to undertake NESTcc-related activities

### Section 3: Dispute Resolution

In the event that the Governing Committee or MDIC Board of Directors determines that communication between the two parties is necessary or appropriate with respect to a disputed issue over which the MDIC Board of Directors has authority, the MDIC Executive Committee and the Governing Committee Executive Committee will hold a joint meeting to discuss the issue. The MDIC Board of Directors will retain the authority to make the final determination in such 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
Version 1	National Evaluation System for health Technology Coordinating Center (NESTcc) Governing Committee	August 29, 2017
	Medical Device Innovation Consortium (MDIC) Board	December 5, 2017
Version 2	National Evaluation System for health Technology Coordinating Center (NESTcc) Governing Committee	August 22, 2018
	Medical Device Innovation Consortium (MDIC) Board	September 6, 2018