

## NEST Coordinating Center (NESTcc) Charter

### 1.0 Preamble

Several categories of documents will govern NESTcc activities, duties, and responsibilities. NESTcc specific documents include but may not be limited to: (1) NESTcc Governance Policies; (2) Standard Operating Procedures; and, (3) Working Group charters. If there is any perceived inconsistency among (1), (2), and (3), 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”).

### 2.0 Vision and Mission of the NESTcc

#### 2.1 [Draft] Vision

NESTcc is a real-world data powered national evaluation system to generate evidence more efficiently for use throughout the medical device total product lifecycle.

#### 2.2 [Draft] Mission

NESTcc’s mission is to support the sustainable generation and use of timely, reliable and cost-effective real world evidence throughout the medical device lifecycle, using real world data that meets robust methodological standards and is generated in the course of clinical care and everyday life by patients, providers, or payers, and for the purpose of enhancing regulatory and clinical decision-making.

### 3.0 Leadership and Decision-Making

#### 3.1 Organizational Structure

NESTcc’s organizational structure consists of a Governing Committee, which is a Committee established by the MDIC Board of Directors, 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.

##### 3.1.1 Medical Device Innovation Consortium Board

The MDIC Board:

- Is responsible for financial and general oversight of the NESTcc
- Oversees 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

##### 3.1.2 Governing Committee

###### 3.1.2.1 Governing Committee Composition

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, MDMA, MITA, ACLA. Two seats will be reserved for patient organizations. The Food and Drug Administration (FDA), Centers for Medicare & Medicaid Services (CMS), and the Medical Device Innovation Consortium (MDIC) each may recommend a member. The remaining seats will be filled through an open nomination process and review. The Executive Director puts forward recommendations for Governing Committee members for approval to the MDIC Board and makes recommendations for filling additional seats and for renewing terms. Governing Committee members serve for up to a three-year term, and may be reappointed by the MDIC Board.

### **3.1.2.2 Governing Committee Responsibilities**

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, [MDUFA IV requirements](#). Governing Committee members must attend 75% of the Governing Committee meetings.

The Governing Committee's actions will be consistent with the mission and vision of the MDIC to advance regulatory science.

### **3.1.2.3 Governing Committee Decision-Making**

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 Executive Director will chair the Governing Committee for the inaugural year.

The Governing Committee and Working Groups will seek to reach decisions collaboratively and through consensus. When a vote is taken, a simple majority of the Governing Committee or Working Group members present at a meeting at which a quorum is present will be required to approve an action. The Executive Director shall have no vote except a deciding vote in case of an equal division.

The Governing Committee will develop a proposed Governing Committee charter and strategic plan for consideration and approval by the MDIC Board of Directors. In addition, the Governing Committee will advise the Executive Director in the development of a proposed operational plan, process to select NESTcc demonstration projects, and a sustainability plan for consideration and approval by the MDIC Board of Directors.

### **3.1.2.4 Conflict of Interest**

Governing Committee members will comply with the [MDIC Conflict of Interest Policy](#), which has as its purpose protecting the interests of the MDIC, as a tax-exempt organization, when a personal, private or other interest of an officer, director or committee member could cause such person to not act in the best interests of MDIC and the public. Various duties that arise under the Policy include disclosing actual or possible conflicts of interest and following applicable procedures for addressing conflicts of interest. Disclosures will be made available on the NESTcc public website.

## **3.1.3 NESTcc Executive Director**

The Executive Director:

- Has overall responsibility for establishing and maintaining the NESTcc, engaging with stakeholders and transforming the NESTcc into a successful enterprise with the support of the Governing Committee.
- Chairs the Governing Committee for the inaugural year, makes recommendations to the Governing Committee on matters to be considered, and implements the strategic and operational plan of the NESTcc with program staff or consultants.
- Works to incorporate all perspectives to the extent feasible and appropriate, of the Governing Committee in final work products
- Is an employee of MDIC and is therefore accountable to MDIC Board and President, who establish performance goals consistent with the priorities developed by the Governing Committee and the MDUFA IV requirements

## **3.1.4 Methods Consultation Mechanism**

A number of methodological experts will be invited to consult to 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.

## **3.1.5 Data Quality Consultation Mechanism**

A number of recognized leaders in the evaluation of data quality will be invited to consult to the NESTcc Governing Committee and staff on data quality related issues.

### 3.1.6 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 will be at the discretion of the Governing Committee. Similarly, the Governing Committee will have the authority to dissolve and end the work of a Working Group. Formal approval and dissolution of Working Groups will take place through a recommendation by the Executive Director to the Governing Committee.

### 3.1.7 The Food and Drug Administration (FDA)

The FDA provides initial funding for the NESTcc through a cooperative agreement to the MDIC through 2021 and following the requirements of the [MDUFA IV commitment letter](#).

### 3.1.8 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 an issue, the MDIC Executive Committee and the Governing Committee will hold a joint meeting to discuss the issue. The MDIC Board of Directors will retain the authority to make final decisions.

## 4.0 Charter Revisions

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