

[It is noted that any language in this charter will be aligned to the operating agreements between MDIC and FDA and any appropriate changes made to insure consistency]

THE NATIONAL EVALUATION CENTER FOR HEALTH TECHNOLOGY

## Governing Committee Charter

### ARTICLE I: NAME, PREAMBLE, AND MISSION

#### SECTION 1: NAME

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

#### SECTION 2: PREAMBLE

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

#### SECTION 3: MISSION

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

### ARTICLE II: EXECUTIVE GOVERNING COMMITTEES

#### SECTION 1: RESPONSIBILITIES OF MEMBERSHIP

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The Executive Governing Committee (hereinafter called “Executive Committee”) is responsible for review, approval, and oversight of the following- annual and long-term strategic and operational goals, annual budget, and charter updates, consistent with, but not limited to, Medical Device User Fee Amendments (MDUFA) provisions regarding trade participation and that MDUFDA-funded NEST activities comply with fee requirements. Members of the Executive Committee are responsible for representing and securing buy-in from their larger communities on the direction of NEST. The Executive Committee is

also responsible for oversight of the Governance Committee and establishing and participating in Executive Committee Subcommittees, as needed, and approving new Executive Committee members. Executive Committee members must attend at least two-thirds (2/3) of the regular Executive Committee meetings to remain in good standing for continued participation.

## **SECTION 2: TERMS OF MEMBERS**

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Executive Committee members serve for up to a three-year term and may be reappointed for one (1) additional three-year term. Representatives from governmental agencies (e.g., the U.S. Food and Drug Administration (FDA), Centers for Medicare & Medicaid Services (CMS), etc.) and MDIC are exempt from term limits so long as they remain employed by, have the approval of their respective organizations, and remain in good standing for continued participation.

## **SECTION 3: COMPOSITION OF MEMBERSHIP**

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The Executive Committee is composed of up to fourteen (14) members representing a diverse range of stakeholders including, but not limited to, patient groups, clinicians, trade organizations, regulators, health systems, and academic institutions.

The Executive Committee seats will break down as follows:

As required by the MDUFA V commitment, four (4) seats must be filled by trade associations, with one (1) each, from the following: Advanced Medical Technology Association (AdvaMed), Medical Imaging and Technology Alliance (MITA), the Medical Device Manufacturers Association (MDMA), and American Clinical Laboratory Association (ACLA). The representative from each trade association may be part of the association staff or appointed from a member company and industry must make up at least 25% of the governing board at all times.

Four (4) seats are reserved for governmental agency associates (e.g., from FDA, CMS, regulators, etc.) with at least one (1) representative from FDA and at least one (1) representative from CMS. A minimum of three (3) seats must be filled by governmental agency associates. Regardless of how many of the four (4) seats that the governmental agency associates choose to occupy they will receive the equivalent of four (4) votes to ensure balance with the trade associations.

MDIC is represented by three (3) seats- President of NEST, MDIC CEO, and one MDIC Board of Directors' Executive Committee (MDIC Executive Committee) member.

The remaining three (3) seats are reserved for independent committee members. One of these seats is reserved for an independent industry member (i.e., not appointed by a trade association, however, the individual or individual's company may be a trade association member). The final two (2) seats are reserved members who represent important constituencies, such as the patient groups, clinicians, health systems or academic institutions.

#### **SECTION 4: SELECTION PROCESS OF NEW MEMBERS**

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Trade associations, governmental agencies, and MDIC will appoint representatives for their respective organizations to be on the Executive Committee. The remaining seats on the Executive Committee will be filled through an open nomination process and review. Current members of the Executive Committee may put forward recommendations to the Executive Committee for voting (See ARTICLE II, SECTION 7: QUORUM). Approval of the recommended members shall only be withheld for good reason and such reason(s) shall be discussed with the Executive Committee before a final decision is made.

#### **SECTION 5: REGULAR MEETINGS**

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Regular meetings of the Executive Committee shall be held at least six (6) times per calendar year, in-person or remotely. Executive Committee members must attend at least two-thirds (2/3) of the regular Executive Committee meetings to remain in good standing.

Executive Committee members are permitted to attend regular Governance Committee meetings; however, their attendance is not required or obligatory.

#### **SECTION 6: SPECIAL MEETINGS**

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Special meetings of the Executive Committee may be called at any time by the Executive Committee Chair or President of NEST. Notice of the time and place of each special meeting will be provided to each Executive Committee member at least three (3) business days in advance of the meeting.

#### **SECTION 7: QUORUM**

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The Executive Committee seeks to reach decisions collaboratively and through consensus. Trade association, MDIC/NEST, and independent industry/patient/institutional organization Executive Committee representatives each have one (1) vote. Governmental agency representatives are counted as a voting bloc of up to four (4) votes to ensure equity between trades and regulators. The governmental agencies voting bloc size may be adjusted to match trade representation (e.g., three (3) trade representatives are present, then governmental agencies voting bloc equals three (3) votes).

When a vote is taken, except in those instances when a higher threshold to meet a quorum is required as outlined below, a simple majority is required to approve an action. A quorum is achieved if greater than 50% of Executive Committee members are either (1) present or (2) remotely vote via an e-mail ballot. If the Executive Committee is voting to change the Charter, elect a new Chair, approve the annual or long-term strategic goals, approve the annual budget, or approve the addition of a new Executive Committee member, two-thirds (2/3) of existing Executive Committee members must be either (1) present or (2) remotely vote via an e-mail ballot to meet the quorum threshold for such votes. In the event of a deadlock resulting from an evenly split vote, the Executive Committee Chair is vested with the exclusive

authority to exercise a tie-breaking vote, thereby determining the approval or rejection of the proposed action or decision.

## **SECTION 8: ACTIONS OF THE EXECUTIVE COMMITTEE**

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

The Executive Committee will review and approve NEST's budget and goals annually, the Executive Committee Charter biannually (every two (2) years), and new Executive Committee member nominations, as needed. In accordance with the MDIC Bylaws, the MDIC Executive Committee members vote and otherwise act on behalf of the MDIC Board, however, reserve the option to refer approval to the full MDIC Board for consideration (See ARTICLE VI, SECTION 3: DISPUTE RESOLUTION). In addition, the Executive Committee will approve new Subcommittees and appoint at least one (1) member of the Executive Committee to participate in each Subcommittee. Finally, the Executive Committee will advise the President of NEST in the development of a NEST long-term strategic plan.

## **SECTION 9: RESIGNATIONS**

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Executive Committee members may resign at any time by providing written notice to the Executive Committee Chair. The Executive Committee requests at least one (1) month notice prior to the effective resignation date to allow the Executive Committee sufficient time to backfill the vacancy.

## **SECTION 10: VACANCIES**

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Vacancies will be filled using the same selection process noted above (See ARTICLE II, SECTION 4: SELECTION PROCESS OF NEW MEMBERS). Executive Committee members who fill a vacant seat will serve out the remainder of that term and will then be eligible to serve one (1) additional three-year term.

## **SECTION 11: CONFLICT OF INTEREST**

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All Executive Committee members will comply with the MDIC Conflict of Interest and Ethics Policy. Disclosure statements are to be completed by all Executive Committee members on an annual basis and are to be made available upon request. If a new conflict of interest, as defined by the MDIC Conflict of Interest and Ethics Policy, arises during the time between annual disclosures, it is the obligation of the Executive Committee members to provide an update to their disclosure statement. Additionally, all Executive Committee Members must review and sign the NEST Governance Committee NDA prior to

onboarding.

## **ARTICLE III: GOVERNANCE COMMITTEE, SUBCOMMITTEES, TASK FORCES, AND WORKING GROUPS**

### **SECTION 1: GOVERNANCE COMMITTEE**

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The Governance Committee is composed of members representing a diverse range of stakeholders including, but not limited to, patients, clinicians, device manufacturers, health systems and payers, and is responsible for the identification, prioritization, and recommendation of key initiatives that advance real-world evidence (RWE) generation for medical devices and support NEST's objectives and plans. The Governance Committee is granted authority to set goals and operationalize as seen fit. The Governance Committee must report on progress to goals to the Executive Committee in the second (2<sup>nd</sup>) and fourth (4<sup>th</sup>) quarters of each calendar year.

The Governance Committee is chaired by the Governance Committee Chairperson, who will serve a term of up to four (4) years, with accountability to the Executive Committee. Future Governance Committee Chairpersons may be self- or peer-nominated and elected by a simple majority amongst Governance Committee members.

There are no limits on stakeholder participation nor term limits, however, industry representatives must make up at least 25% of the governing board at all times to comply with the MDUFA V commitment. The Governance Committee members may resign at any time by providing written notice to the Governance Committee Chair. Additional seats may be filled through an open nomination process and review. Current members of the Governance Committee may put forward recommendations to the Governance Committee for voting by simple majority amongst Governance Committee members. Approval of the recommended members shall only be withheld for good reason and such reason(s) shall be discussed with the Governance Committee before a final decision is made.

### **SECTION 2: SUBCOMMITTEES, TASK FORCES, AND WORKING GROUPS**

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

- Subcommittees: there are no limits on stakeholder participation nor term limits, however, each Subcommittee must include at least one (1) member of the Executive Committee. It is expected that Subcommittee participants will remain engaged and participate in Subcommittees to ensure progress is being made by the Subcommittee. Subcommittees will appoint a Subcommittee chair for a term of up two (2) years as selected by simple majority amongst

Subcommittee members, with oversight by the Executive Committee. Subcommittees are granted authority to set goals and operationalize and administer Subcommittee as seen fit. The Subcommittee must report on progress to goals to the Executive Committee in the fourth (4<sup>th</sup>) quarter of each calendar year.

- Working Groups or Task Forces: there are no limits on stakeholder participation, however, there is time-limited engagement given distinct and discrete initiatives and objectives of the Working Group or Task Force. Working Groups or Task Forces will appoint a Working Group or Task Force chair for the duration of the Working Group or Task Force as selected by simple majority amongst Working Group or Task Force members. Working Groups or Task Forces execute on goals and objectives set forth by the Executive Committee, however, may operationalize and administer to a plan as seen fit. The Working Groups or Task Forces must report on progress to goals to the Executive Committee in the second (2<sup>nd</sup>) and fourth (4<sup>th</sup>) quarters of each calendar year.
- The Executive Committee has the authority to dissolve and end the work of any Subcommittee, Working Group, or Task Force.

## **ARTICLE IV: OFFICERS**

### **SECTION 1: EXECUTIVE COMMITTEE OFFICERS**

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The officer of the Executive Committee shall be the Chair, and others as needed, all of which may be elected in accordance with the provisions of this Article.

### **SECTION 2: ELECTIONS AND TERMS**

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The Chair is elected 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 Executive Committee to approve. The Chair position serves one four-year term and may be reappointed for one (1) additional four-year term.

### **SECTION 3: RESIGNATIONS AND VACANCIES**

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Resignations and vacancies shall be handled with the same processes outlined for the Executive Committee resignations and vacancies (See ARTICLE II: EXECUTIVE GOVERNING COMMITTEE, SECTION 9: RESIGNATIONS).

### **SECTION 4: CHAIR**

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The Chair is responsible for:

- Working collaboratively with the President of NEST to set Executive Committee meeting agendas.
- Engaging with key stakeholders to help ensure NEST's success in meeting key milestones.
- Serving on and presiding over Executive Committee meetings.
- Exercising the tie-breaking vote in the event of a deadlock resulting from an evenly split vote.

## **ARTICLE V: PRESIDENT OF NEST**

The President of NEST 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 Executive Committee and the MDUFA requirements.

The President of NEST is responsible for:

- Leading MDIC's NEST program, engaging with external stakeholders, and establishing NEST as a successful program for MDIC with the support of the Executive Committee.
- Leading development of and execution to annual goals.
- Administering NEST program within annual budget.
- Making recommendations to the Executive Committee on matters to be considered and implementing the strategic and operational plan of NEST with program staff or consultants.

## **ARTICLE VI: STRUCTURE**

NEST 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. NEST's organizational structure consists of an Executive Committee, which is an advisory Committee overseen by the MDIC Board of Directors' Executive Committee; Subcommittees, which may be established by the NEST Executive Committee; and a President supported by program staff. Working Groups and Task Forces composed of experts representing diverse perspectives may be established by the Executive Committee on an ad hoc basis (See ARTICLE III, SECTION 1: SUBCOMMITTEES, TASK FORCES, AND WORKING GROUPS).

### **SECTION 1: FDA**

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The FDA provided initial funding for NEST 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 NEST will abide by the requirements of the MDUFA V commitment letter to use any funding provided to NEST to transparently:

- Support the development of real-world data (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 EXECUTIVE COMMITTEE**

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The MDIC Executive Committee, on behalf of the MDIC Board, is responsible for:

- Providing financial and general oversight of NEST.
- Overseeing compliance of NEST 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 Executive Committee to undertake NEST-related activities.
- Administering MDIC’s Conflict of Interest and Ethics Policy and periodically reviewing and suggesting modifications, as needed, to the Policy to improve its effectiveness regarding NEST activities.

## **SECTION 3: DISPUTE RESOLUTION**

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All matters are intended to be resolved at the NEST Executive Committee level through reasonable efforts to reach consensus. The MDIC CEO may refer an unresolved matter to the MDIC Executive Committee for review and consideration by a written communication to the Chair of the MDIC Executive Committee with a copy to the Chair of the NEST Executive Committee. Upon such notice, the MDIC Executive Committee shall convene a joint meeting with the NEST Executive Committee for discussion and potential resolution. Should resolution not be reached, then the MDIC Executive Committee is granted dispositive power to vote on the matter.

## **ARTICLE VII: AMENDMENTS**

This Charter will be reviewed and approved by the Executive Committee on no less than a biannual (every two (2) years) basis. Charter amendments do not impact the term durations or positions of existing Executive Committee Chair and members.



**Charter Approvals:**

<b>Version</b>	<b>Approver</b>	<b>Date</b>
V1	NEST Governing Committee	August 29, 2017
	MDIC Board	December 5, 2017
V2	NEST Governing Committee	August 22, 2018
	MDIC Board	September 6, 2018
V3	NEST Governing Committee	September 17, 2019
	MDIC Board	September 18, 2019
V4	NEST Governing Committee	April 21, 2020
	MDIC Board	May 29, 2020
V5	NEST Governing Committee	March 16, 2023
	MDIC Board	May 10, 2023
V6	NEST Governing Committee	June 12, 2024
	MDIC Executive Committee	July 24, 2024
V7	NEST Governing Committee	March 14, 2025
	MDIC Executive Committee	January 21, 2025