National Evaluation System for health Technology (NESTcc)

Improving evidence generation for medical devices

MDEpiNet RAPID Phase II/III
Working Group Meeting
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Mission and Vision of the National Evaluation System for health Technology (NESTcc)

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

Mission
NESTcc's mission is to establish and operate the decentralized, federated NESTcc based on the foundational principles of trust, transparency, scalability, sustainability and accountability serving device manufacturers, payers, regulatory agencies, patient groups, physicians, providers and other relevant stakeholders

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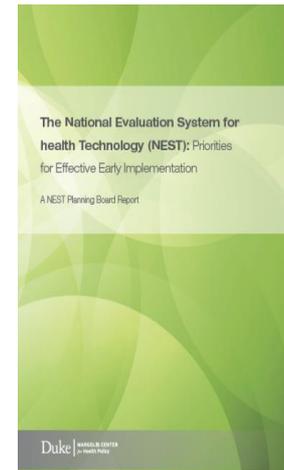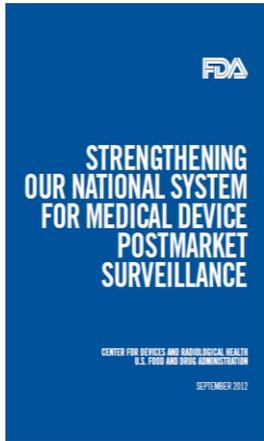MEDICAL DEVICE INNOVATION CONSORTIUM

NESTcc's vision is to support a paradigm shift to resolve challenges in our current system

- Moving from **passive** surveillance to **active** real time surveillance

- Leveraging **RWE** to support regulatory decisions

- Making better use of data generated in the course of **clinical care** or by **patients** themselves

- Moving away from lengthy, one-off, cost-prohibitive studies to an ecosystem that supports more **routine evidence generation**
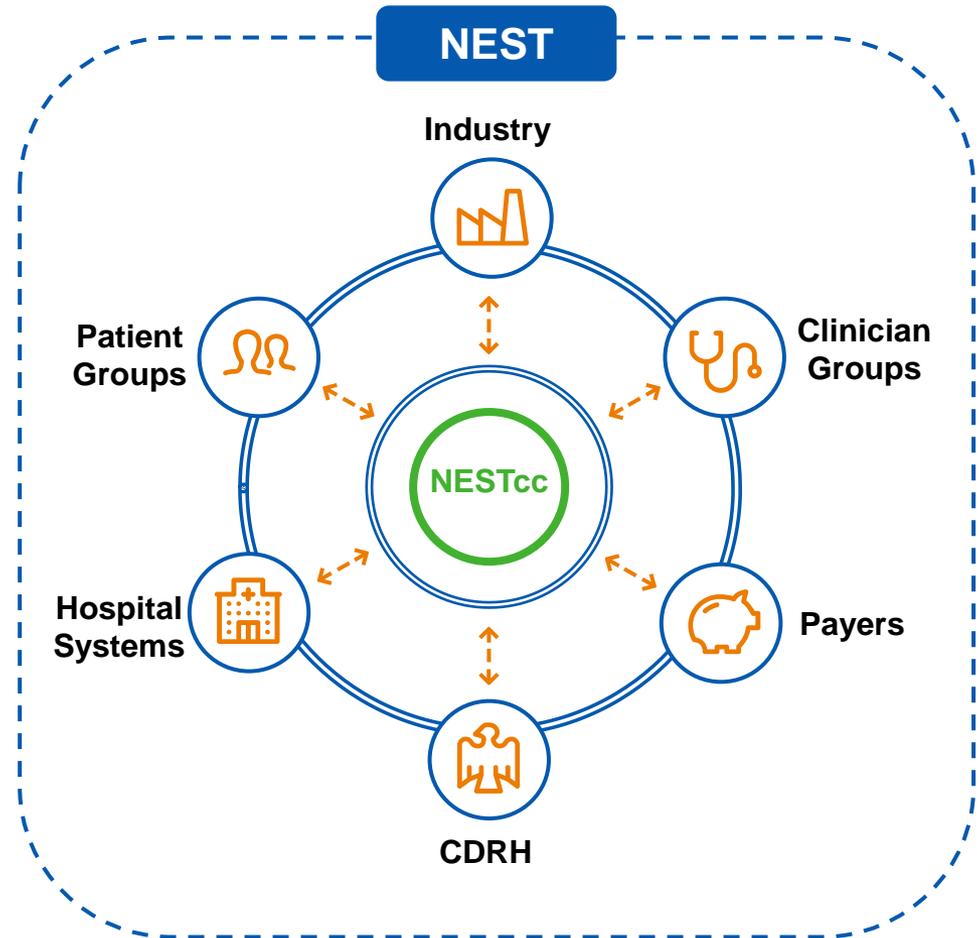
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Foundational Work Supporting NESTcc Strategy and Operational Plan

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Engagement with all stakeholders in the ecosystem

- In September 2016, FDA awarded a $3M grant for the NESTcc to MDIC
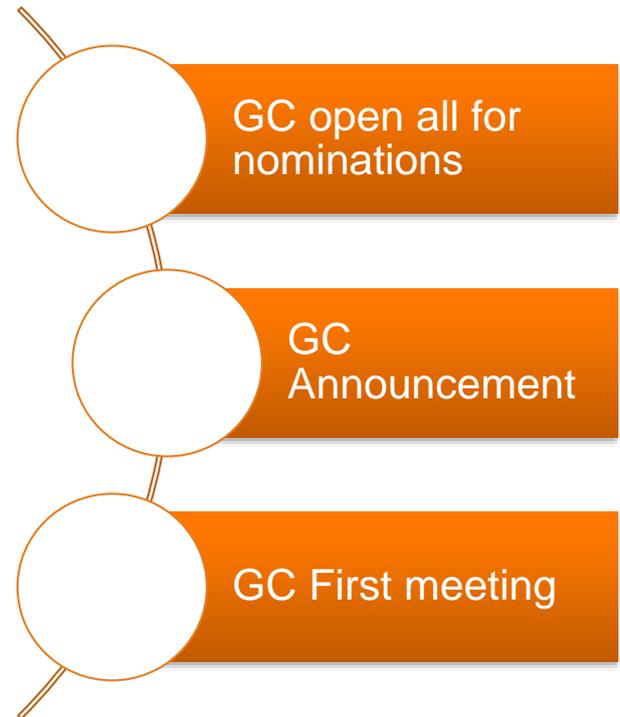
- $6M per year for five years from MUDFA IV

NEST

Industry

Patient Groups

Clinician Groups

NESTcc

Hospital Systems

Payers

CDRH

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NESTcc 2017 Key Areas of Focus

- Governance
- Sustainability
- Demonstration Projects
- Engagement and Communication

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NESTcc Governance

- **Governing Committee** to be announced **June 2017**

- **Role**: set strategic and operational plans for NESTcc and be responsible for their implementation under the leadership of the ED

- **Process**: open nomination process, stakeholder review, diversity of representation (patients, clinicians, industry, HealthIT, health systems, payers, FDA, CMS, MDIC)

- **Guiding principles:** Independence, transparency including conflict of interest disclosures

GC open all for nominations

GC Announcement

GC First meeting

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NESTcc Sustainability Planning

- NESTcc must be sustainable beyond the initial FDA and MDUFA IV funding

- **Guiding principle: functions and activities must be developed within a coherent business model, provide value to the ecosystem and meet NESTcc goals of developing a "seamless" and integrated evidence generation system.**

- Possible NESTcc functions:
  - Accreditation of NESTcc data partners based on specific criteria (Health systems, registries etc.)
  - Provision of NESTcc Study Designation based on criteria around data quality, methods, reporting, dissemination etc.
  - Establishment of a NESTcc Commons for tools, methods, resources
  - Provision of up to date information on devices to patients and clinicians to inform care decisions
  - Leadership through convening of expert Work Groups in critical areas: UDI, methods, cybersecurity etc.
  - *Qualifier: All strategic directions for NESTcc will be approved by the Governing Committee*

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NESTcc Demonstration Projects

- Goals of the demonstration projects:
  - Provide proof of concept for approaches supporting future state of "seamless" evidence generation
  - Accelerate building of sustainable infrastructure through focused projects
  - Must provide value to the ecosystem and lead to improved patient health outcomes

- Prior initiatives have identified criteria, areas for focus and high-priority device areas
  - Impact, feasibility, sustainability (Duke-Margolis report, April 2016)
  - Active surveillance, pre-post-market shift, patient mediated data, evaluation of class II devices (Duke-Margolis report, April 2016)
  - Coordinated Registry Networks and high priority device areas (Medical Device Registry Task Force Report, August 2015)

  - Possible path forward:
    - Development of criteria for selection
    - Review of possible studies
    - Approval of "Demonstration Project" status by the GC
    - Number of projects and funding implications TBD

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NESTcc Engagement and Communication

- Engaging with key stakeholders
- Reporting on NESTcc activities and progress
  - Meeting transparency requirements
- Establishing a communication strategy
- Establishing NESTcc's brand

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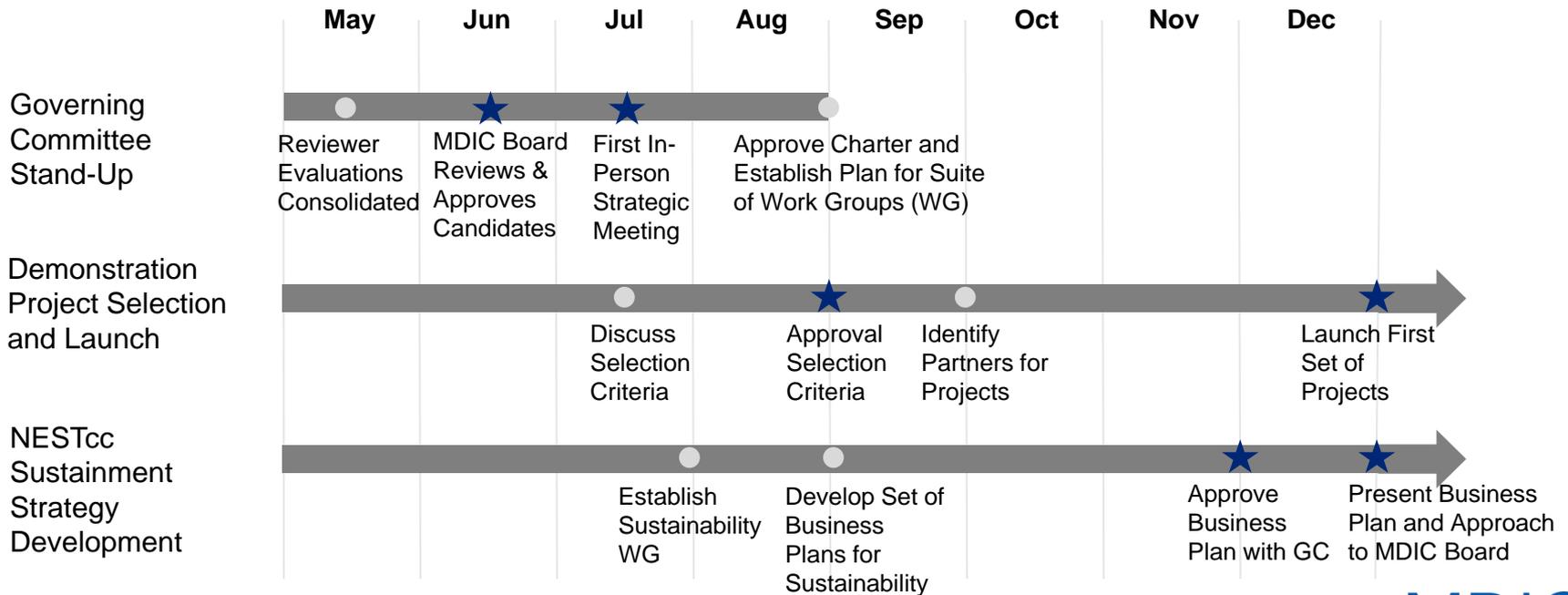# NESTcc 2017 Priorities

Stand up the NEST Coordinating Center (NESTcc) Governing Committee (GC)

Select near-term demonstration projects within the context of the portfolio of projects

Work with GC to develop sustainability strategy for NEST that identifies NEST customers and offerings

Timeline

	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Governing Committee Stand-Up	Reviewer Evaluations Consolidated	MDIC Board Reviews & Approves Candidates	First In-Person Strategic Meeting	Approve Charter and Establish Plan for Suite of Work Groups (WG)				
Demonstration Project Selection and Launch			Discuss Selection Criteria	Approval Selection Criteria	Identify Partners for Projects			Launch First Set of Projects
NESTcc Sustainment Strategy Development			Establish Sustainability WG	Develop Set of Business Plans for Sustainability			Approve Business Plan with GC	Present Business Plan and Approach to MDIC Board

★ = Milestone ● = Event

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Learn More about the Coordinating Center

Visit our webpage at: **http://mdic.org/cc**

Background and mission of NESTcc

NESTcc One-Pager summary document

Governing Committee announced early Summer 2017

Voices will Include:

- Patients
- Clinicians
- Industry
- Federal Regulators
- Hospitals
- Health Plans

And others…

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