



**AdvaMed**

Advanced Medical Technology Association

# **AdvaMed Principles Regarding The Use of Real World Evidence (“RWE”) in the National Evaluation System for Health Technology (“NEST”) and Similar Systems**

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The Food and Drug Administration (“FDA”), in collaboration with other organizations including the Medical Device Innovation Consortium (“MDIC”) as the Coordinating Center, is developing the NEST, which when operational will have the potential to aggregate or facilitate aggregation of medical device-related data from multiple data sources. We believe that certain foundational principles should guide the use, governance and operation of the NEST or any similar regulatory or quasi-regulatory system that may be established in the future.

## **I. BACKGROUND**

FDA has defined real world evidence (“RWE”) as evidence derived from the aggregation and analysis of real-world data (“RWD”). RWD, in turn, is defined as data collected from sources outside of traditional clinical trials. RWE may consist of information from many data sources, including but not limited to:

1. Registries;
2. Patient Communities;
3. Public and Private Health Plans, including Medicare, Medicaid and private payer claims information;
4. Manufacturers;
5. Delivery Systems, including electronic health records (EHR);
6. FDA;
7. Safety surveillance systems, such as The Medical Device Epidemiological Network (MDEpiNet) and the Sentinel system;

8. The National Patient-Centered Clinical Research Network (PCORnet); and
9. Observational studies and scientific literature.

AdvaMed and its members are committed to the principles of appropriate analysis of medical technologies. Stakeholders, such as patients, their caregivers, providers, payers, regulators, and manufacturers share in the commitment to improve the quality and increase the efficiency of healthcare. As medical device manufacturers, we recognize the

need to ensure adequate and accurate information concerning the safety, effectiveness, and impact of medical interventions to guide healthcare decision-making. We further recognize there may be a number of benefits with respect to the use of RWE, including the following:

1. Improve patient care and outcomes;
2. Improve patient access to new therapies and diagnostics by efficiently collecting data to support regulatory submissions for expanded use and indications or expanded coverage;
3. Support device modifications;
4. Support patient access through expanded coverage, reimbursement, and value analysis based on RWD evaluation and collection;
5. Evaluate the “real-world” safety and/or effectiveness of products outside of randomized controlled clinical trials or other clinical study designs;
6. Meet regulatory requirements for post-market data collection;
7. Provide regulators with alternative methods to monitor the performance of technologies to reduce existing pre- and post-market data collection burdens;
8. Develop hypotheses for further clinical and economic evaluation; and
9. Aid in the development or assessment of care guidelines.

Although we recognize these potential benefits as possible outcomes of the NEST or a similar system, by definition RWD is not data collected from a clinical investigation. Therefore, it is important that this information be appropriately analyzed and validated prior to dissemination and use.

In addition, we believe protections must be in place to prevent the spread of incorrect, incomplete, biased or misleading information. The public health relies on the communication and dissemination of accurate and reliable information from public health agencies. In this regard, we provide below key principles to guide the use, governance and operation of the NEST or any similar system that may be established in the future.

## II. PRINCIPLES

1. The NEST or similar system design must include clear purpose, objective, and participation requirements for promoting the use of RWE to facilitate understanding of medical technology and innovation.
  - a. Criteria for NEST partners and sources of data must be established to ensure partners providing information are committed to the system goals and that data are relevant and useful for RWE purposes.
  - b. NEST partners must establish sufficient safeguards to ensure that RWE data are of appropriate quality for the intended use of the data.
  - c. The NEST or similar system must be validated for each purpose before its intended use.
  - d. Data integrity and security must be maintained across the system by NEST partners.
  - e. NEST partners must agree to follow data governance standards.
2. Before the launch of the NEST or a similar system, a data governance committee (that includes medical device manufacturers) must be formed and written procedures for data ownership, data access, data use, and NEST participation must be established.
  - a. The NEST or similar system must collect sufficient data to identify, consider and allow risk adjustment for modifiable risk factors such as social, demographic and disease-related factors, including changes in applicable evidence based practice guidelines over time.
  - b. The NEST data governance committee must establish procedures for reviewing proposed research protocols that would use RWE or RWD obtained through the NEST.
  - c. Findings derived from RWE or RWD obtained through the NEST must be reviewed by the NEST data governance committee or through an appropriate peer review committee prior to release. Manufacturers of the technologies studied must be part of the review process as the manufacturer may have relevant information to any conclusion. Manufacturers, however, do not need to approve the conclusion.
  - d. The NEST data governance committee must establish a process to ensure transparency of the process for proposing, conducting, and releasing reports based on RWE.
3. The FDA or other regulatory agency must have clear policies regarding the use of data from the NEST or a similar system. Use of data in the system to make a regulatory determination of device safety or effectiveness must only be conducted by FDA in accordance with its statutory authorities.
  - a. FDA should seek input from and share relevant information with manufacturers prior to taking any regulatory action based upon data derived from the NEST or a similar system.

- b. FDA should actively work with sponsors and manufacturers to identify possible uses of RWE derived from the NEST and similar systems to address pre-market requirements in a least burdensome manner.
  - c. In the interest of reducing healthcare costs, device surveillance systems derived from the NEST or similar systems should be developed to replace, rather than supplement, existing passive surveillance systems.
  - d. The NEST and similar systems must make clear that RWD and RWE analysis plans are not clinical investigations.
  - e. Manufacturers should be able to communicate truthful and non-misleading information about analyses of RWD, provided research methods are sound and well-described.
4. Access to data through the NEST or similar system should be granted only upon request by qualified scientific, medical and economic researchers for purposes benefiting public health or patient care. Procedures should be developed and employed by the data governance committee to receive and review data access and dissemination requests prior to approving the release of any data.
- a. Requests for data access must be based on clear criteria established by the data governance committee, including the validity of the hypothesis, whether the data requested and analysis plan will address the hypothesis, and the qualifications of the requestor.
  - b. The data governance committee must establish a process for adequate data protection, including a process to ensure agreement from individuals granted system access not to transfer the data or information to parties not identified in the research proposal.
  - c. An approved analysis plan must address how data on patient characteristics, patient medical conditions and co-morbidities, facility characteristics, physician experience, interventional technique and associated parameters, and device characteristics (including unique device identifiers, if applicable) will be used to identify potential factors that affect study conclusions.
  - d. NEST research partners must define a prospective process for considering changes in the analysis plan after initiation, including items such as data collection and protocol revisions.
  - e. Device manufacturers must be allowed full and timely access to data on their products.
  - f. Data requesters may be charged reasonable fees.
5. The NEST and similar systems must comply with all applicable laws and regulatory requirements.
- a. Patient privacy must be protected, and any required consent must be obtained.
  - b. All confidential manufacturer, physician, and hospital data must be identified as confidential and protected from release.
  - c. Data provided to the NEST or a similar system does not absolve facility, physician or manufacturer obligations to file reports required under applicable laws or regulations.

- d. In choosing the best care for their patients, health care professionals exercise their medical judgment and may use legally marketed products for off-label uses. The collection or analysis of off-label use data in a system funded in whole or in part by commercial entities does not represent off-label promotion by those commercial entities.