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National Evaluation System for health Technology Coordinating Center (NESTcc) Data Quality Framework

A Report of the Data Quality Subcommittee of the NEST Coordinating Center – An initiative of MDIC

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Notes:

* This publication reflects the views of the author and should not be construed to represent FDA's views or policies.

Conflict of Interest Disclosure Information for all Subcommittee members and additional contributors can be found here.

The Data Quality Subcommittee appreciates the thoughtful review and public comments regarding the Data Quality Framework. The Subcommittee's response to these comments can be found here.

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Preface

The National Evaluation System for health Technology Coordinating Center (NESTcc) seeks to support the sustainable generation and use of timely, reliable, and cost-effective Real-World Evidence (RWE) throughout the medical device total product lifecycle (TPLC), using high-quality Real-World Data (RWD) that is analyzed using robust methodological standards.

Stakeholders across the medical device ecosystem, including health systems, patient groups, industry, clinicians, payers, and regulators, stand to benefit from improved use of RWE and RWD generated in the course of clinical care and everyday life. Opportunities include increased patient awareness of device safety issues, efficient and low-cost evidence generation for regulatory review and reimbursement purposes, and improved patient and provider ability to make care decisions based on robust data.

NESTcc is growing its relationship with Data Network Collaborators to advance the use of RWE generation and foster collaboration with stakeholders across the medical device field. NESTcc has surveyed its Data Network to determine current capabilities, gaps, and priority areas for improving patient outcomes using high-quality RWD generated during the routine course of care. Our Data Network currently consists of 12 Network Collaborators. Together, they represent more than 195 hospitals and 3,942 outpatient clinics and have access to over 494 million patient records. Available data sources include electronic health records (EHRs), pharmacies, public and private claims, registries, and patient-generated data (PGD).

In conjunction with the development of the Data Network, NESTcc has established Data Quality and Methods Subcommittees to support its efforts to conduct RWE studies for medical devices. Each subcommittee has developed a Framework, the content of which follows this preface. These Frameworks build upon existing bodies of work and leverage subcommittee members' knowledge and experience from similar initiatives, including PCORnet, Sentinel, and MDEpiNet, and are intended to serve as guides for medical device ecosystem stakeholders wishing to collaborate with NESTcc to ensure the quality of data and research methodology.

The Subcommittees, established in 2018, are composed of representatives from health systems, including NESTcc Network Collaborators, medical device manufacturers, and the U.S. Food and Drug Administration (FDA). The 12-member Data Quality Subcommittee and 9-member Methods Subcommittee held monthly meetings to develop their respective Framework documents from June 2018 to November 2019.

Draft versions of NESTcc's Data Quality and Methods Frameworks were circulated to Network Collaborators for review and comment, followed by a public comment period. The public comment period took place over two months from May 2019 to July 2019, during which time the Frameworks received comments from seven organizations across the medical device ecosystem. The comments were then incorporated into these initial versions for publication through the continued efforts of subcommittee members and NESTcc leadership.

The Frameworks will be updated in the future based on key findings and lessons learned from NESTcc's RWE Test-Case projects, which address two primary objectives. First, they will explore the feasibility for medical device ecosystem stakeholders to work with RWD sources and NESTcc's initial set of Network Collaborators. Second, the Test-Cases will help identify areas where NESTcc could play a role in reducing transaction costs (e.g., contracting, IRB, data sharing agreements, publication policies etc.). Test-Case concepts were solicited from stakeholders across the ecosystem, including health systems, government organizations, non-profit patient organizations, and medical device manufacturers.

The Data Quality Framework is, in its current state, based mostly around EHR data in the clinical care setting while the Methods Frameworks is applicable to many different data sources. In future iterations, the Frameworks will be moving to a more complete version, incorporating other data sources for Data Quality assessment and further real-world evidence examples and best practices for methodology to provide a more complete resource for medical device ecosystem stakeholders.

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Introduction

In 2012, NEST was born to "quickly identify problematic devices, accurately and transparently characterize and disseminate information about device performance in clinical practice, and efficiently generate data to support premarket clearance or approval of new devices and new uses of currently marketed devices."[1]

In 2018, NESTcc's Data Quality Subcommittee was tasked with creating a Data Quality Framework that could be used by all stakeholders across the NESTcc medical device ecosystem. The initial version of that Framework, presented in this document, lays out the foundation for the capture and use of high-quality data for post-market evaluation of medical devices. Aligned with NESTcc's pragmatic approach to device evaluation, this Framework is grounded in the use of RWD gleaned from the clinical care setting instead of data collected specifically for research or evaluation purposes. This Framework focuses on RWD from the electronic health record rather than other clinically-based data sources such as health insurance claims or registries, which have been addressed elsewhere.[2,3]

This Data Quality Framework serves as a guide to Network Collaborators and organizations that wish to collaborate with NESTcc, to ensure the quality of their data related to medical devices. The overarching goal of this Framework is to inform the retrospective and prospective capture and use of clinical information as high-quality data to support the generation of RWE, which will ultimately, and most importantly, provide better care to patients. The Framework provides guiding principles, rather than standards, that can be used for decision-making, and will be iteratively improved as experience grows. The next step of the Data Quality Subcommittee is to add the detail necessary to further operationalize this Framework.

This Framework is composed of five sections which cover the topics most salient to achieving the highest data quality around medical devices:

1. **Governance**: Involving and engaging stakeholders is critical to good governance for RWD and RWE. Governance ensures stakeholder representation, limits the potential for bias or unethical behaviors, and results in trustworthy findings and conclusions.

2. **Characteristics of Data**: Choosing and using data appropriately first necessitates understanding and specifying the data needed, along with the context and limitations of potential sources of that data. Shortcomings of the data that potentially limit their application must also be identified.

3. **Data Capture and Transformation**: The use of secondary data (e.g., data from an EHR) for analysis presents additional challenges in terms of data relevance and reliability. The processing and transformation of data into common data models (CDMs) provides a logical pathway for enabling analysis.

4. **Data Curation**: Curation turns raw data into information by organizing, assessing, and preparing the data for analysis. Data curation is an iterative process, with the goal to improve data quality over time.

5. **NESTcc Data Quality Maturity Model**: Maturity models are used by organizations to assess business capabilities, identify opportunities, and perform capacity planning. Maturity models also allow for benchmarking of relevant characteristics over time. The ability to capture data consistently and completely, to represent data via CDMs, to validate the accuracy of data, and to then use the data through automated queries are examples of key processes that drive data quality. The five proposed stages of maturity reflect increasingly advanced and integrated levels of performance for health care systems to partner within the NESTcc ecosystem. The NESTcc Data Quality Maturity Model, by itself, does not ensure improvement but is rather an indicator of progress. The model can help researchers identify weaknesses, thereby enabling research teams to address them.

1. Governance

RWD are defined by the FDA as "data related to patient health status and/or the delivery of health care routinely collected from electronic health records (EHRs), claims and billing data, data from product and disease registries, patient-generated data including home-use settings, and data gathered from other sources that can inform on health status, such as mobile devices."[4] To support the generation of RWE from RWD, core principles must be agreed on to establish:

- governance, including policies and processes for organizational transparency and integrity;
- data access, management, linkage and aggregation, and use;
- and submission, management, review, and acceptance of analytic requests.[5,6]

Stakeholder involvement and engagement is a critical component of good governance for RWD/RWE. The "Good Governance Standard for Public Services" has described stakeholder engagement as a core value of good governance.[7] As no individual party is free from bias or conflict of interest, governance provides a basis to balance stakeholder influences and provide equal representation, thereby limiting the potential for bias or unethical behaviors and allowing trustworthy research. The Patient-Centered Outcomes Research Institute (PCORI) has identified stakeholders to include patients, clinicians, researchers, purchasers, payors, industry, hospitals and health systems, policy makers, and training institutions,[8] and these same stakeholders, as well as governmental agencies such as regulators, remain relevant to the RWD and RWE domains. Additionally, engagement of stakeholders is necessary throughout the life cycle of evaluation, from study and analysis planning and conduct through dissemination of results.

NESTcc is fully committed to ensuring that the highest scientific and ethical standards are applied when using RWD to generate RWE. In doing so, evaluation activities (e.g., sharing patient data across various data sources) must incorporate patient protections such as ensuring patient privacy (e.g., HIPAA compliance) and complying with applicable local, state, federal, and foreign laws and regulations. Institutional review board review may be necessary. The best practices developed by the FDA Sentinel program offer a template for protecting patient privacy and institutional confidentiality when linking RWD across multiple health systems.[2,9]

The following principles can guide health systems and other clinical organizations in forming policies and procedures for RWD/RWE, along with the stakeholders engaged with NESTcc for the purpose of using RWD to generate RWE:

1.1 Organizational Transparency and Integrity

- **Leadership**: Organization establishes executive leadership group for RWD/RWE.
- **Data Stewardship**: Organization takes responsibility for the management, storage, and use of the organization's RWD.

- **Patient-centeredness**: Patients are engaged in the RWD/RWE process and provide consent when applicable; organization adheres to ethical standards for responsible conduct of research.
- **Stakeholder Engagement**: Key stakeholders, including patients, clinicians, and other health system and organization staff, are engaged in RWD/RWE project development and execution.
- **Transparency**: Key individuals from the organization are made clear to the public, potential conflicts of interest are publicly disclosed/reported, and the organization's funding is publicly disclosed.
- **Oversight**: Organization assembles independent advisory board with responsibility for the organization's local data warehouse and research portfolio, which may include legal counsel to manage liability risk.

1.2 Data Access, Management, Linkage and Aggregation, and Use

- **Data Quality Assurance**: Data are accurate and complete; routine, documented, traceable, and repeatable measures are taken to assure data quality with attributes of validity, reliability, precision, integrity, and timeliness.
- **Data Storage**: Data are securely stored, minimizing risk of further distribution and use without the appropriate permissions/agreements; data retention is described.
- **Data Permission**: Appropriate agreements are in place for all data used for RWD/RWE, data are de-identified to the greatest extent possible, and patient protections are in place, while still allowing necessary analyses to be pursued; if identified data are used, analyses are conducted within secure network areas from which only aggregated or de-identified data can be removed.
- **Data Linkage**: Linkage of RWD within and across sources is performed with appropriate oversight and processes in place, particularly patient privacy protection.

1.3 Submission, Management, Review, and Acceptance of RWD/RWE Requests

- **Clear Criteria**: Criteria by which requests for RWD for RWE are considered are fair and publicly disclosed, including preclusion of access for non-scientific purposes, such as in pursuit of litigation, as well as qualifications for data security and storage.
- **Transparent Submission and Review Process**: Requests for RWD for RWE are publicly disclosed and considered by an independent approval panel (and ethics review as needed), whose determinations are also publicly disclosed.
- **Commitment to Responsible Analysis**: Requests for RWD for RWE include a description of collaborators (including affiliations and conflicts of interest) and proposed use of the RWD/RWE, including the pre-specified research or evaluation question, data elements of interest, main

outcome measures, and statistical analysis plan, which is publicly disclosed; considerations may be made for cases of commercial confidentiality.

- **Efficiency**: Approved requests for RWD/RWE are managed expeditiously, from initiation to analysis to dissemination.
- **Data Use Agreements**: Contractual requirements for data protection and privacy are established for any approved RWD/RWE request in compliance with applicable laws and regulations.
- **Commitment to Results Reporting**: All analyses pursued as part of RWD/RWE projects are publicly reported (which could potentially include the project data dictionary and analytic code, as well as all results) as appropriate, including both lay and scientific summaries, regardless of plans to publish in peer-reviewed literature, and are directly communicated to the FDA when issues with medical product safety are identified; considerations may be made for cases of commercial confidentiality.

Leveraging the use of RWD for RWE holds great promise for medical device evaluation. The principles described above should optimize the success of these efforts among health systems and other clinical organizations, protect patient privacy, and guide the governance of policies and procedures for RWD/RWE.

2. Characteristics of Data

Generating evidence to inform and guide clinical and regulatory decisions requires data. Useful data must be both reliable (high quality) and relevant (fit to purpose) across a broad and representative population based on the experimental, approved, or real-world use of a medical device. A full understanding of the evaluation question(s) is a prerequisite for determining the assessments, outcomes, and endpoints needed for analysis, as well as the sources, settings, and methodologies needed for data accumulation or acquisition. Choice and use of data require understanding the limitations of the data source(s) and acknowledging that the shortcomings of the data may limit the questions that can be addressed. For example, retrospective observational data acquired from real-world sources such as EHRs, although typically more pragmatic and accurate for addressing real-world practice and outcomes of device use (i.e., questions of generalizability), may lack the precision of data acquired in randomized clinical trials (i.e., questions of causality). However, rigorously designed prospective clinical trials that include assignment of therapy, randomization, and/or blinding can be embedded in existing RWD sources, permitting randomized experiments in more representative populations than those enrolled in traditional trials .[10] Many of these concepts are also considered in NESTcc's Methods Framework.

The characteristics of satisfactory data are predicated upon a detailed understanding of the question that allows the investigator to prospectively define:

- The appropriate study population;
- The specific data elements required to measure device or medical product utilization;
- The specific data elements required to assess performance and outcomes (including adverse events and their timing) in the course of the disease or treatment;
- The appropriate settings and sources for data acquisition including assessments of potential sources of bias and confounding;
- The development or revision of standardized datasets (i.e., development of a common data dictionary for common data elements [CDEs] and key outcomes and endpoints);
- The experimental methods to be used (e.g., causal inference from a prospective randomized controlled trial vs. informed decision making from available or collected observational data).

To generate information and evidence contextually suitable for generating actionable insights and informing clinical or regulatory decisions, the investigator must consider the question at hand including a prospective determination of the sources, settings, and methods needed for collected data to provide an appropriate answer. Data must be accessible, which includes procuring any necessary permissions to collect, analyze, and/or distribute the data and related findings.

To be useful, accessible data must possess four characteristics:[3]

1. High quality;
2. Relevant to purpose and context;
3. Amendable to the application of appropriate analytic methods (i.e., convertible to evidence);
4. Interpretable using clinical and scientific judgment.

High-quality data are (to the greatest extent possible) complete, accurate, and timely. The quality of the raw data increases when common definitional and temporal frameworks can be applied across disparate data sources. Adjudication, use of modular datasets with defined data elements, outcome verification from multiple sources, source traceability, and other mechanisms might be needed to provide additional assurances of the overall reliability of available data.

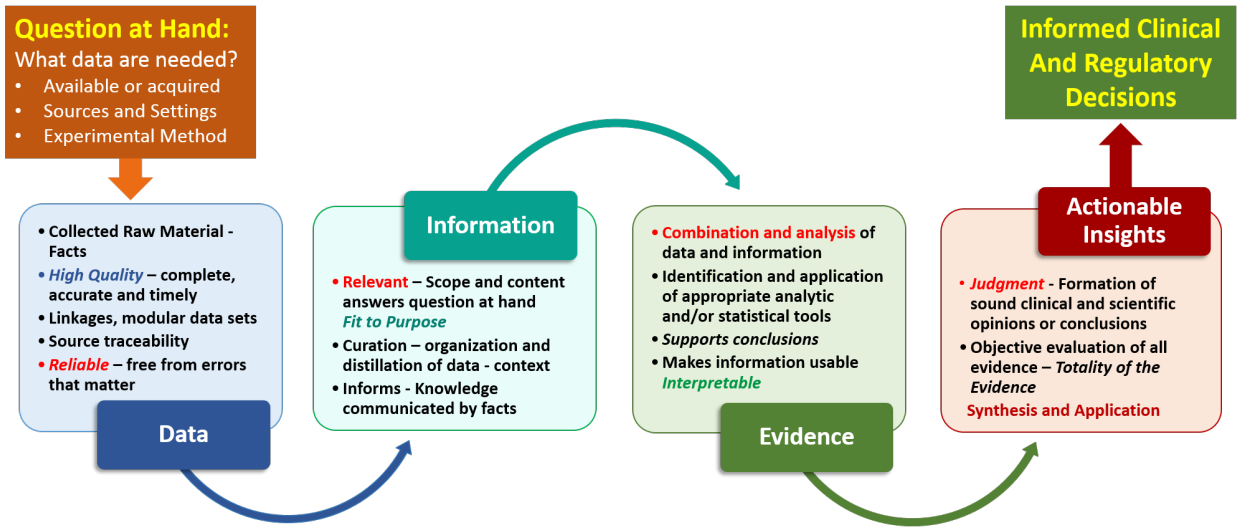
Data must be relevant or fit to purpose. This means the data are reliable and have the scope and content needed to answer the question(s) at hand. Pre-study planning and assessment of the various available data sources must be sufficient to determine whether existing data are contextually appropriate, whether critical data are acceptably complete and accurate, and whether additional data are necessary. Detailed documentation of the characteristics of the EHR system and of available data elements are fundamental to this assessment. Linkages of multiple high-quality datasets for either retrospective or prospective data generation may be used as needed to ensure all needed data are

available. Accurate assessments of the totality of the data that will be available for the pre-specified analyses are essential.

The combination and analysis of data and information is the final step in the production of evidence. Effective analysis requires the application of appropriate analytic and statistical tools. Pre-specified statistical analysis plans are essential to minimize bias. Rigorous analysis makes information interpretable, transforming it into evidence. Objective evaluation of the totality of the evidence coupled with clinical and/or regulatory judgment leads to insights that can be used to inform clinical and regulatory decisions based on the question (see figure below).

Data and information should be viewed as a continuum, capable of developing evidence over the total product life cycle of a device or procedure.[1] Accessibility of the evidence as it evolves requires continuous data access coupled with seamless curation, analysis, and interpretation. Integrated data solutions that allow permanent linkages between previously isolated sources of data and development of open standards will foster a cooperative environment where duplication and costs are minimized and the value of evidence and the underlying infrastructure is maximized.[11,12]

Figure 1. Evidence generation and evaluation: Actionable insights for informed clinical and regulatory decisions (adapted from Califf RM, Sherman R. What we mean when we talk about data. MassDevice. December 11, 2015. https://www.massdevice.com/44947-2/)



3. Data Capture and Transformation

The use of EHR data for research purposes poses additional challenges to data relevance and reliability. Standardizing definitions for identifying patient cohorts and study endpoints or outcomes, increasing health care systems' interoperability to capture longitudinal patient data, and universally implementing the unique device identifier (UDI) capture will improve the relevance of EHR-based medical device research. Considerations for use of EHR data to conduct research also include understanding provenance, completeness, accuracy, and consistency of the data, as well as awareness of what internal and external validation checks have been performed to evaluate the quality of data entry.[13]

Regardless of improvements in data collection systems to accommodate EHR-based research, researchers have little control over data recording and collection processes in clinical care facilities. Individuals using EHR data to derive RWE should understand how and why the data of interest were originally obtained as well as data provenance including subsequent data processing and other nuances that might affect reliability of the data. This information will help the researcher determine whether the EHR data are of suitable quality for a particular evaluation.

Improving data quality at the point of care and at data entry should be the ultimate goal. Wherever possible, the key stakeholder communities should agree regarding the clinical concepts that need to be captured as data for use within the medical device evaluation ecosystem. This might be accomplished at

data entry (e.g., when tied to reimbursement or as required in clinical decision support). In these contexts, clinical concepts must be specified and defined as domain specific CDEs, which ideally use standardized definitions and are harmonized with CDMs for optimal utility. Currently, most clinical information in an EHR is conveyed as free text rather than in the ideal form of discrete, structured data fields. Clinical workflows and documentation systems will likely require modifications to ensure capture of structured data at the point of care.

Once data are captured as discrete elements, extraction, transformation, and loading (ETL) are more amenable to standardization. Discrete data elements, semantic interoperability, compatibility of data capture, and appropriate specification of CDM conventions allow for application of a CDM that subsequently permits execution of standardized analyses or queries by data partners.

Current capabilities may only allow a hybrid approach that combines auto-populating certain discrete structured data elements (e.g., demographics, numerical values, ICD codes) complemented by manual abstraction of other data into a CDM. Alternatively, or in combination, a process such as natural language processing (NLP) could be used to obtain the data of interest from unstructured text. Processes that use NLP or artificial intelligence/machine learning for data capture and transformation should be appropriately tested and validated. Of note, NLP cannot synthesize data elements or derive inferential conclusions. Moving toward greater agreement and use of computable phenotypes to assist with population identification and perhaps endpoint or outcome identification might address this issue.[14] Such an approach would need to be as comprehensive as possible and include input from all members of the health care ecosystem.

The capture of quality data is one component that determines the quality of the ETL process, which describes how data are extracted and transformed to conform to data standards and CDM specifications, and then loaded into a defined location and available for queries (e.g., via a distributed research network).[15] Additional consideration must also be given to applicable patient privacy requirements and agreements or contracts.

Designing the ETL process should follow established best practices, such as seeking input from CDM and data experts as well as clinical experts to create coding maps for the process, technical experts to implement the process, and all stakeholders to design and implement quality control procedures.[16]

Data assurance and quality control are essential to the reliability of the RWD for RWE generation. Quality control processes should be integrated throughout, including a review of the ETL design documentation and verification and validation of each step of the ETL process.[16]

Consistency in data element definitions on the data capture side, along with the use of standards to support consistency in the ETL process, will allow researchers to have confidence in the quality of the data extracted from the EHR. Data aggregation is relatively straightforward when data are captured and transformed consistently and reproducibly.

4. Data Curation

Data curation is one of the steps used to turn raw data into information. Through the curation process, data are organized, assessed, and prepared for analysis. Many frameworks exist to guide this translation of RWD into fit-to-purpose data, but one approach described recently is to consider a two-stage process.[17] The first, foundational stage takes the raw data and applies a series of transformations and quality checks to make the dataset "research ready." It examines the data repository or datamart in the context of broad research concepts (e.g., are laboratory results mapped to an appropriate coding scheme?). The second, study-specific stage applies another series of transformations and quality checks to ensure that the dataset is "fit-to-purpose" for the specific question and patient population (e.g., are critical variables available and complete for the study population?). As an example, loading EHR data into a CDM and then satisfying a series of baseline quality checks might make a dataset "research ready," but additional investigation would be needed to assess the specific variables/outcomes for the population in question. Note that networks or projects that assemble datasets for a specific purpose (e.g., registries) may end up combining both of these stages into a single process.

Surveys or metadata about data elements, the workflows that give rise to them, and source system provenance further inform the process of data curation and, when combined with information about data latency and extraction and transformation processes, help ensure that fitness-for-use can be assessed as needed. Examples of data curation processes developed by distributed research networks are shown in Table 1 below. Depending on the data sources/collaborators involved, some frameworks may be more appropriate for specific research questions or study designs. The development of a new framework is outside the scope of this initial document.

Table 1. Data Curation Processes for Specific Distributed Research Networks

Network	Collaborators		Approach to Data Characterization
	Health systems	Payors	
HCSRN	X	X	Detailed checks look at ranges, cross-field agreement, implausible data patterns, and cross-site comparisons. Partners execute data characterization package each time data are refreshed. Results are returned to the HCSRN Coordinating Center. Potential quality issues are flagged and mitigated at the partner level.[18]
Sentinel	X	X	Detailed checks look at ranges, cross-field agreement, implausible data patterns, and cross-site comparisons. Partners execute data characterization package each time data are refreshed. Results are returned to the Sentinel Coordinating Center. Potential quality issues are flagged and mitigated at the partner level.[19]
PCORnet	X	X	Includes *foundational data curation* process, which establishes a baseline level of research readiness for all network partners to support prep-to-research queries, and *study-specific data curation*, which includes assessments of outcomes/variables or other derived concepts for the cohort under study.[20]
OHDSI	X	X	Optional – each datamart can generate a standardized data profile that is viewable through a web-based tool (Achilles). Institutions can choose whether to share these profiles or retain them locally.[21]
ACT	X		Under development.

ACT = Accrual for Clinical Trials; HCSRN = Health Care Systems Research Network; OHDSI = Observational Health Data Sciences and Informatics; PCORnet = National Patient-Centered Clinical Research Network.

Key to the curation process are *data characterization routines*, which run against a collaborator's data repository or CDM and describe their performance against a series of *data quality checks* through descriptive statistics such as summaries of missing values, outliers, and frequency distributions. Many data checks rely on concepts analogous to conformance ("does the format of the data adhere to the underlying model?"), completeness ("are there values where we expect to see data populated?"), and plausibility ("do the values that appear make sense?"), as well as comparisons across collaborators.[22] As an example, the most recent PCORnet data characterization process consists of a set of SAS procedures that execute against the tables of the PCORnet CDM.[23] There are 31 unique types of data checks,[24] many of which apply to multiple fields or tables within the CDM (e.g., required fields are present, tables do not have orphan patient identifiers), for a total of 1,144 individual quality checks. These routines also generate additional tables of descriptive statistics, including the frequencies of specific data elements,

crosstabs of data (e.g., procedure and procedure type), and counts of missing, non-missing, and distinct records. FDA Sentinel follows a similar process[25] and, as described below, NESTcc expects collaborators to utilize an approach that is suitable for the dataset and the question(s) being asked. While the data characterization routines are necessarily designed to assess quality within a collaborator's data repository, the summary results are aggregated and analyzed across a network to establish baseline trends and identify outliers or other anomalies.

4.1 Metadata about Data Provenance

The results of data characterization alone are not always enough to determine whether a given dataset is fit to purpose. Information on provenance also plays a role, as there is widespread variability in how data are entered into EHRs or processed as claims, as well as how health systems and health plans extract those data to populate a given table within their repository or CDM. Knowledge about data collection practices and the decisions made to translate the source material into the target CDM can help provide additional context.[26]

Many networks ask their collaborators to complete surveys or data flow diagrams that describe the provenance of their data sources, providing additional insight into the characteristics of their clinical workflows and/or source systems, and ideally including information that is excluded from any transformations (e.g., mental health visits, patients above or below a certain age).[27,28] Data curation can help uncover these issues as well, but having it documented can reinforce that they were deliberate decisions. In some cases, provenance can also be derived automatically as part of the data capture or data transformation process (e.g., did the record originate from a billing system, or was it entered by a clinician?). This is important, because in studies on inpatient medication usage, for instance, one must know whether a datamart has included records only for medications that were administered to patients or all medications that were ordered, including prescriptions written prophylactically (or both), as they will generate markedly different characterization profiles.

4.2 Documentation of the Iterative Process of Data Curation

Data curation is an iterative process, with the expectation that characterization activities will help quality improve over time. Therefore, the operational definition of a given data check should stay consistent to allow comparisons over time. Networks may have data checks that are required or investigative. Given the variability in health system data, networks often limit required checks to those related to conformance. Investigative data checks may be remediable by a health system (e.g., >80% of laboratory results have a Logical Observation Identifiers Names and Codes [LOINC] code), or not be remediable due to source system limitations (e.g., <10% of medication orders include an end date).

Investigative data checks that are broadly remediable across the network are good candidates for having thresholds that are raised or lowered to reflect improvements in data quality (e.g., requiring that >50% of laboratory results be mapped to LOINC initially, gradually raising the minimum threshold to >80% as collaborators develop their mappings). Collaborators should track their efforts to address failed

investigative data checks, and networks should ensure that they perform purpose-specific curation for the population/question in these areas to determine whether the data support the study of interest. All of these steps should be documented and included as part of any analysis plan.

As the base of RWE studies grows and the FDA releases more guidance, we expect to see best practices and standards emerge as to how to convey this information. We also expect to see greater sharing and harmonization of data check definitions, especially as collaborators look to link datasets from multiple sources or run data quality checks from one network/model against another.

4.3 Data Curation Should Be Fit-to-Purpose

The minimum requirements for data curation will vary depending on the dataset and the study, and over time, we expect to see more recommendations on how to make that determination. In the meantime, the curation process must at least indicate whether the data can answer the question of interest within the context of the intended use. For example, studies of overall utilization patterns for exploratory analyses will require a different level of certainty than a comparative study intended for policy or regulatory decision-making. Studies that use data from emerging domains (e.g., patient-generated data, information derived from NLP) may require a higher level of interrogation than a prep-to-research query using a well-known data source. Collaborators who participate in distributed research networks with formalized curation processes may be "pre-cleared" to support a range of activities if their data pass all relevant checks. Collaborators who are not part of any existing network will need to decide how much to invest in data curation. Ensuring that the resulting dataset can be used to answer operational questions that are of value to the health system/health plan is one way to justify the potential expense. Collaborators with data that have been subjected to only a cursory level of curation may still be able to participate but may find themselves restricted to lower-level or preliminary exercises.

5. NESTcc Data Quality Maturity Model

Organizational maturity can be described as an expression of the capabilities of an organization in a specific domain, with the intent to foster continuous improvement across those capabilities. Maturity models organize levels of maturity into a framework, typically assessing culture, process, and/or technology.[29] Maturity models are typically self-administered by organizations to assess current state, model business capabilities, identify opportunities, and perform capacity planning. A key benefit is the benchmarking of relevant characteristics over time. In health care, the Healthcare Information and Management Systems Society (HIMSS) has published several maturity models, including the Health Usability Maturity Model (www.himss.org/himss-usability-maturity-model), the Electronic Medical Record Adoption Model (www.himssanalytics.org/emram), and the Adoption Model for Analytics Maturity (www.himssanalytics.org/amam). Specific to models developed for enterprise data governance, a detailed descriptive model from Stanford University addresses the axes of people,

policies, and capabilities across the dimensions of awareness, formalization, metadata, stewardship, data quality, and master data.[30]

To describe expected capabilities at different levels of organizational maturity with respect to RWD quality, we have developed the NESTcc Data Quality Maturity Model. The model targets the governance, processes, and technologies of health care organizations used in RWD capture and management, principally via EHR and other clinical documentation systems.

We propose five stages of maturity reflecting increasingly advanced and integrated levels of performance for health care organizations to partner within the NESTcc ecosystem. Of note, the model is use-case specific (i.e., evaluation of the maturity of the organization is relevant to an intended purpose of the data). As shown in Table 2 below, the stages are at least partially aligned with previous maturity models, of which the HIMSS Usability Model is most informative:

Table 2. Comparability of Stages of NESTcc and Other Maturity Models

NESTcc Stage	**HIMSS Usability Model**	**Capability Maturity Model Integration (CMMI) Model**	**Stanford Model**
1. Conceptual	Unrecognized	Initial	Awareness
2. Reactive	Preliminary	Managed	Formalization
3. Structured	Implemented	Defined	Stewardship
4. Complete	Integrated	Quantitatively managed	Data quality
5. Advanced	Strategic	Optimizing	Master data

Stage 1: Conceptual – Clinical processes capture information primarily in verbose, unstructured documents, not as discrete data; lack of organizational awareness of data utility, no effort to systematically manage health care data; lack of consistent or centralized governance, policies, and/or resources; data not organized centrally; data not available for organizational use and analysis; individual data units are project-oriented or focused on immediate profits.

Stage 2: Reactive – Able to react to requests for analysis and respond to research requests – but mostly accomplished by manual chart review and abstraction; data management inefficient and expensive, with only sporadic recognition of data utility beyond immediate use; tacit support from leadership regarding need for centralized data governance and management, but only limited allocation of resources; data not available for organizational use and analysis beyond individual requests; individual data units are project-oriented or focused on immediate profits.

Stage 3: Structured – Clinical systems manage transactional data types (e.g., orders, transactions, laboratory results, medication prescriptions) as discrete data; clinical information (i.e., clinical documentation) largely analog text requiring abstraction into data for clinically focused analytics such as

quality, performance measurements, or outcomes assessment. Support from leadership (with resources provided) for centralized data governance and management of transactional data types and limited clinical data types at the enterprise level (e.g., support for ETL among internal systems); commitment to centralized enterprise data governance, management, and curation via managed processes, people, and technologies (e.g., enterprise data warehouse [EDW]); non-administrative queries (clinical questions, research) conducted mostly as one-offs via individual queries, still moderate-to-high cost to extract data for analysis; able to support a CDM but not done routinely and automatically; data transmission to registries still largely accomplished by manual chart review and abstraction.

Stage 4: Complete – Granular clinical data based on standardized, semantically interoperable clinical CDEs captured in the processes of care, integrated into those care processes; less than one-quarter of clinical data submitted to registries requires chart abstraction or manual processing; UDI captured in the processes of care and available in supply chain, clinical documentation, EHR, and EDW systems; EDW routinely and systematically represents data externally via various CDMs, including efficient queries, support for large number of research projects; leadership provides centralized data governance, management, and curation at the enterprise level, ensuring performance and data quality of local units and achieving financial sustainability.

Stage 5: Advanced – Data linkage and aggregation across systems enabled and open to external queries; semantic interoperability of the vast majority of clinical data accomplished; multiple sources of sustainable funding support for research; engagement of regulatory and industry enterprises with enterprise data; leadership responsible for centralized data governance, management, and curation at the enterprise level; business benefit well understood, with financial sustainability and recognition and participation in initiatives external to the organization.

5.1 Key Data Process Domains that Drive Data Quality

Optimally, use of RWD of health care organizations requires competency across several data process domains, including data consistency, completeness, and automation.[13] Building on these data process domains, Table 3 below describes expectations at each NESTcc maturity stage. A foundational requirement is **consistent** clinical data based on standardized data dictionaries and/or applicable data standards. While data consistency can be most easily understood within the confines of an individual health care organization, ideally the data are semantically interoperable (i.e., have the same clinical and computational meaning) across organizations. Once standards have been implemented, the ability to capture complete datasets (including interpretation and accounting of the absence of data) characterizes the data **completeness** domain. The ability to represent the data via **CDMs**, to validate the **accuracy** of the data, and to then use the data through **automation** of queries are additional domains that describe business capabilities related to data quality.

Table 3. Organizational Operational Characteristics Typical of NESTcc Maturity Model Stages

	NESTcc Data Quality Domain				
	Consistency[a]	**Completeness[b]**	**CDM[c]**	**Accuracy[d]**	**Automation[e]**
1. Conceptual					
2. Reactive	+	+	+/-		
3. Structured	+	+	+	+/-	
4. Complete	+	+	+	+	+
5. Advanced	+	+	+	+	+

[a]Data Consistency: Relevant uniformity of the meaning of the data across contexts (hospitals, clinicians, outpatient environment) in population/cohort identification, clinical documentation practices/policies, workflow descriptions, and analytics
[b]Data Completeness: Presence of the necessary data elements, with data being electronically available and either complete or with minimal missingness for the intended purpose
[c]Data Models: CDMs include all data needed for the intended purpose (e.g., clinical data elements, UDI)
[d]Data Accuracy: EHR data are validated systematically, with comparison to the source, independent measurement, upstream data source, and known standard or valid values (e.g., audits from charts)
[e]Data Automation: Queries are able to be run automatically against CDMs

Conclusion

High-quality data are essential to support the post-market evaluation of medical devices and to inform regulatory decision-making. In this initial version of the NESTcc Data Quality Framework, we discuss the most salient topics associated with achieving high-quality data, including data governance, characteristics of data, approaches to data capture and transformation, and best practices in data curation. We synthesize these topics in the NESTcc Data Quality Maturity Model, which enables collaborators to indicate their progress toward achieving the highest quality data. The next iteration of this Framework will include the NESTcc Data Quality Self-Evaluation, a checklist which charts the specific actions that organizations can take to move between stages of the maturity model. We welcome further discussion about how the Framework can be operationalized by health systems, given the variability in maturity among individual clinics that compose a health system.

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