



THE NATIONAL EVALUATION SYSTEM FOR HEALTH TECHNOLOGY

## NEST Mark™: Real-World Data Source

### Evaluation of a Real-World Data Source Independent of a Specific Research Question

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This questionnaire contains proprietary information much of which is protected by copyright. Please complete accurately and return within the requested timeline. All information will be treated as confidential and used solely for evaluation purposes.

Real-World Data Source Information	
Data source holder organization	
Name of data source	
Primary contact(s)	Name: _____ Title / Role: _____ Email: _____ Phone: _____
Version number & date of this questionnaire	

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## PURPOSE

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The purpose of this questionnaire is to assess the suitability of your organization's real-world data (RWD) source for research and regulatory use, including potential FDA submissions for medical devices (e.g., for label expansion), **independent of a specific research question**. *NOTE: This tool is not designed to assess whether a data source would be appropriate for a specific study.* Following NEST's assessment, a data source holder that demonstrates the presence of mature, well-governed systems and processes to ensure data accuracy, maintain data traceability, and evaluate data completeness may be granted the NEST Mark: Real-World Data Source designation.

The tool consists of eleven sections:

- Section 1: General Data Holder and Data Source Information
- Section 2: Governance and Quality Management System
- Section 3: Data Consistency & Stability and Quality Control Framework
- Section 4: Data Accrual, Traceability, and System and Data Source Versioning
- Section 5: ETL and Technical Controls
- Section 6: Data Integration and Linkage
- Section 7: Data Access & Sharing, Privacy & Security, and Regulatory Transparency
- Section 8: Data Source Representativeness, Continuity of Care, and Longitudinality
- Section 9: Quantitative Data Source Characteristics
- Section 10: Documentation Package
- Section 11: Signature

## HOW TO COMPLETE

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- Please complete one questionnaire for each distinct data source.
- Provide clear and comprehensive answers to each question. Unless otherwise noted for a particular question, text boxes can be expanded as necessary.
- Please answer all questions. This questionnaire is designed to be applicable to all types of data sources and data types. If a question is not applicable, mark N/A or "not applicable" and briefly explain.
- A list of recommended documents to be used to support your responses in the tool and your application for the NEST Mark recommendation is provided in **Appendix 1**.
- It is preferable to reference existing data source documentation in your responses (e.g., SOPs, flow diagrams, QA reports) by listing the relevant document name(s), section(s), and page number(s).
- For major processes with multiple extensive SOPs, please provide a brief summary of the overall process to help with clarity and review efficiency and reference the appropriate SOPs which govern the processes.

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- We anticipate that each organization may require multiple people, in different roles, to complete this form.
- Please ensure the accuracy and completeness of your responses, as this information will be used to determine the overall readiness of your data source for regulatory-grade studies and whether your data source is qualified for the NEST Mark: Real-World Data Source recommendation.
- NEST will follow-up with you for clarifications or additional information.
- Contact NEST at [nestcc@mdic.org](mailto:nestcc@mdic.org) with any questions.

### SECTION 1: GENERAL DATA HOLDER AND DATA SOURCE INFORMATION

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#### Data Source Holder Description

1.1 Please provide a **brief overview of the company** (or other entity) which owns / manages the RWD source including the following:

- ✓ General description
- ✓ Organizational structure (Organizational chart is encouraged)
- ✓ Primary area(s) of work, such as data provider and/or analytics
- ✓ Primary business function
- ✓ Year the business was established (If providing RWD for research or market analytic purposes was not an initial business function, indicate what year these functions were added)

Enter text. Reference document attachment and page number(s) as appropriate.

#### Data Source Description

1.2 Please provide an **overview of the RWD source** including the following:

- ✓ Original purpose of data collection for the data source (e.g., *research, patient care, payor*).
- ✓ Where the data originate
- ✓ How data are input into the data source
- ✓ Primary client base or intended users of data source (e.g., *commercial research, academic research, patient care*)
- ✓ Primary intended use(s) of RWD (e.g., a disease or device registry, a large-scale database of curated, research-ready healthcare data, special-purpose public or private data, insurance claims and payments)

Enter text. Reference document attachment and page number(s) as appropriate.

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1.3 Data source category(ies) (check all that apply). Indicate year(s) for which each category of data is available.

	Type	Start Year	End Year or Ongoing	Comments
<input type="checkbox"/>	Electronic Health Records (EHR)			
<input type="checkbox"/>	Administrative / Insurance / Billing Claims			
<input type="checkbox"/>	Disease Registry, specify disease(s):			
<input type="checkbox"/>	Device Registry, specify device(s):			
<input type="checkbox"/>	Digital Health Technologies (DHT)			
<input type="checkbox"/>	Device Generated Data			
<input type="checkbox"/>	Laboratory			
<input type="checkbox"/>	Imaging			
<input type="checkbox"/>	Biobank			
<input type="checkbox"/>	Public Health Surveillance Data			
<input type="checkbox"/>	Other (describe):			

Comments:

Enter text. Reference document attachment and page number(s) as appropriate.
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1.4 Which EHR system(s) is used for the data source (check all that apply)? Please note version if applicable.

<input type="checkbox"/>	Epic	Version: _____
<input type="checkbox"/>	Oracle/Cerner	Version: _____
<input type="checkbox"/>	Other (specify): _____	Version: _____
<input type="checkbox"/>	Not applicable (no EHR data)	
<input type="checkbox"/>	EHR data present, but not available for research	

Comments:

Enter text. Reference document attachment and page number(s) as appropriate.
--

1.5 How often is the data source updated and available for research purposes?

- Daily  
  Weekly  
  Monthly  
  Quarterly  
  Semi-annually  
  Annually  
 Other. (Specify, e.g., if the RWD source has different update frequency for various data types, care settings, etc., please provide a description):  
 Not applicable, no ongoing data capture

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Enter text. Reference document attachment and page number(s) as appropriate.

1.6 What is the time lag between data input and research readiness? \_\_\_\_\_

Not applicable, no ongoing data capture

1.7 What are the minimum and maximum ages (in years) of individuals represented in the data source? \_\_\_\_\_

1.8 Geographic regions covered by the RWD source? \_\_\_\_\_

### Prior Use of Data Source for RWD Research and Regulatory Submissions

1.9 Please describe how the data source has been **previously used for published RWD research** and/or regulatory submissions. Include the following in your response, as applicable:

- ✓ Whether it has been used for RWD research studies
- ✓ A bibliography of peer reviewed publications for RWD research studies using the data source
- ✓ Whether it has been used for regulatory submissions
- ✓ Examples of the use of the data source in regulatory decision-making (FDA, EMA, other) for devices, drugs, or biologics. Specify agency, submission type, and outcome for each example:
- ✓ Examples of how this data source could be used for other types of analytics (e.g., *policy, reimbursement, safety monitoring, etc.*)

Enter text. Reference document attachment and page number(s) as appropriate.

### Device Information

1.10 Provide documentation or describe in detail how medical devices, in general, can be identified in the data source:

Enter text. Reference document attachment and page number(s) as appropriate.

1.11 For each medical device category available in the data source, please indicate which device identification elements are available. (*check all that apply.*) *If no device information is available for a given category, select "No device identification elements" Column.*

No medical device data are available in the data source overall **[STOP and contact NEST before proceeding]**

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Device Type	UDI	Product code	Brand name	Model number	Manufacturer	Other Specify	No device identification elements
Single use devices (e.g., syringes, catheters)							
Reusable devices (e.g., endoscopes, catheters, patient return electrode)							
Implantable (e.g., hip prosthesis, pacemakers, stents)							
Imaging (e.g., ultrasound and CT scanners)							
Medical equipment (e.g., anesthesia or hemodialysis machines, patient monitors)							
Software (e.g., computer aided diagnostics, Apps)							
In vitro diagnostics (e.g., glucometer, HIV tests)							
Surgical instruments (e.g., scalpels, forceps, trocars, lasers)							
Surgical robotic systems							
Laboratory instruments (e.g., centrifuges, PCR machines, mass spectrometers)							
Other (specify):							

Comments:

Enter text. Reference document attachment and page number(s) as appropriate.

1.12 How are device identification elements stored (check all that apply)?

Device Type	Structured fields	Curated free-text field(s) (e.g., variable extracted from data originally entered as	Clinical notes / other free text fields	Other, describe in text box

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		free text)		
Single use devices				
Reusable devices				
Implantable				
Imaging				
Medical equipment				
Software (Apps)				
In vitro diagnostics				
Surgical instruments				
Surgical robotic systems				
Laboratory instruments				
Other (specify):				

Comments:

Enter text. Reference document attachment and page number(s) as appropriate.

1.13 Please describe how *device-generated* or *technical data* are captured, including device identifiers and UDI (if applicable), and how these data are processed and made available to end users.

Not applicable

Enter text. Reference document attachment and page number(s) as appropriate.

1.14 At what level is the Device Identifier (DI) captured or linked?

Patient level

Patient encounter level

Not applicable

If applicable, describe differences across device type.

Enter text. Reference document attachment and page number(s) as appropriate.

**Data Domains**

1.15 Which data domains are available in the data source and available for research?

Check all that apply. If multiple ingestion sources exist, select all that apply and add brief notes as applicable.

	Domain / Data Type	EHR	Claims	Registry	Device / App Feed	Other, specify
<input type="checkbox"/>	Demographics					
<input type="checkbox"/>	Diagnoses					

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	Domain / Data Type	EHR	Claims	Registry	Device / App Feed	Other, specify
<input type="checkbox"/>	Medication prescriptions					
<input type="checkbox"/>	Medication administration					
<input type="checkbox"/>	Surgical procedures					
<input type="checkbox"/>	Elective					
<input type="checkbox"/>	Emergent					
<input type="checkbox"/>	Surgery Duration					
<input type="checkbox"/>	Surgeon Specialty					
<input type="checkbox"/>	Other procedures					
<input type="checkbox"/>	Vital signs					
<input type="checkbox"/>	Laboratory orders					
<input type="checkbox"/>	Laboratory results					
<input type="checkbox"/>	Imaging orders					
<input type="checkbox"/>	Imaging reports					
<input type="checkbox"/>	Pathology orders					
<input type="checkbox"/>	Pathology reports					
<input type="checkbox"/>	Diagnostic study orders					
<input type="checkbox"/>	Diagnostic study reports					
<input type="checkbox"/>	Other (specify)					

Comments:

Enter text. Reference document attachment and page number(s) as appropriate.
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1.16 For each type of data (e.g., *diagnoses, procedures, lab tests*), how are you able to identify the site of care (e.g., *physician office, hospital outpatient clinic, emergency room*), and how is this documented in the data source?

Enter text. Reference document attachment and page number(s) as appropriate.
--

1.17 Describe any data elements that are only available for a subset of the population (e.g., lab test results only available from hospital-based laboratories, outpatient care only available if provided at certain clinics, etc.).

Enter text. Reference document attachment and page number(s) as appropriate.
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1.18 Clinical Outcome Assessments (COAs) and Device-Generated Data

	Data Type	Primary source	Notes (optional)
<input type="checkbox"/>	Clinician-reported outcomes (ClinROs) (e.g., <i>clinical rating scales</i> )		
<input type="checkbox"/>	Patient-reported outcomes (PROs) (e.g., validated surveys, questionnaires, rating scales, quality of life measures)		
<input type="checkbox"/>	Patient-generated health data (PGHD) (e.g., <i>apps</i> )		
<input type="checkbox"/>	Device-generated data (e.g., <i>wearables</i> )		
<input type="checkbox"/>	Other (specify)		

Comments:

Enter text. Reference document attachment and page number(s) as appropriate.

1.19 Other Data Types

	Data Type	Primary source	Notes (required where applicable)
<input type="checkbox"/>	Mortality		Capture method; missingness; cause of death available (Y/N)
<input type="checkbox"/>	Biobank metadata		
<input type="checkbox"/>	Genomic data		
<input type="checkbox"/>	Other (specify)		

Comments:

Enter text. Reference document attachment and page number(s) as appropriate.

1.20 Claims and Cost Data

	Claims / Cost Type	Notes (optional)
<input type="checkbox"/>	Facility cost and/or charge data	
<input type="checkbox"/>	Open claims	
<input type="checkbox"/>	Closed claims	
<input type="checkbox"/>	Pharmacy claims	
<input type="checkbox"/>	Other domains (specify)	

Comments:

Enter text. Reference document attachment and page number(s) as appropriate.

### Services and Points of Care Captured

1.21 Which services / points of care are captured for patient encounters in the data source?  
 Check all that apply. Minimal notes requested only if capture is non-standard.

#### Inpatient-Based Care

	Service / Setting	Notes (optional)
<input type="checkbox"/>	Inpatient hospitalizations	
<input type="checkbox"/>	Hospital-based laboratories	
<input type="checkbox"/>	Hospital-based imaging	
<input type="checkbox"/>	Hospital-based diagnostic procedures	
<input type="checkbox"/>	Hospital-based medications	

#### Comments:

Enter text. Reference document attachment and page number(s) as appropriate.

#### Ambulatory Care

	Service / Setting	Notes (optional)
<input type="checkbox"/>	Primary care – hospital-affiliated	
<input type="checkbox"/>	Primary care – community (non-affiliated)	
<input type="checkbox"/>	Urgent care	
<input type="checkbox"/>	Specialty care – hospital-affiliated	
<input type="checkbox"/>	Specialty care – community (non-hospital affiliated)	
<input type="checkbox"/>	Ambulatory surgery centers	
<input type="checkbox"/>	Non-hospital-based laboratories	
<input type="checkbox"/>	Non-hospital-based imaging	
<input type="checkbox"/>	Non-hospital-based diagnostic procedures	
<input type="checkbox"/>	Other ambulatory settings (specify)	

#### Comments:

Enter text. Reference document attachment and page number(s) as appropriate.

#### Other Services

	Service / Setting	Notes (optional)
<input type="checkbox"/>	Emergency services	
<input type="checkbox"/>	Skilled nursing facilities	
<input type="checkbox"/>	Home care	
<input type="checkbox"/>	Hospice	

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<input type="checkbox"/>	Pharmacy services	
<input type="checkbox"/>	Dialysis centers	
<input type="checkbox"/>	Physical / occupational therapy, other rehabilitation	

Comments:

Enter text. Reference document attachment and page number(s) as appropriate.
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**Section Evidence References**

Please include a list of the supporting documents that are being submitted to support questions in this section.

Evidence item / question	Document name (or URL/path)	Section/page reference

**SECTION 2: GOVERNANCE AND QUALITY MANAGEMENT SYSTEM**

**Data Governance**

2.1 For each of the items below, please provide **documentation or a comprehensive description** of the following aspects of your data governance

- ✓ Governance structure (including department-level organizational chart, visualization recommended)
- ✓ Stakeholder involvement (e.g., roles of organizations such as hospitals that provide data to be aggregated, board of directors, clinicians, patients, outside consultants, etc.)
- ✓ Funding disclosure (describe how the data source is funded and how funding information is disclosed)
- ✓ Describe how conflicts of interest (of employees, stakeholders, etc.) are determined and disclosed

Enter text. Reference document attachment and page number(s) as appropriate.
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**Quality Management System**

2.2 Please provide an overview of your quality management system and provide reference documents. Include the following:

- ✓ QMS governance and accountability including the role(s) responsible for the overall QMS (provide an org chart of the QMS organization)

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- ✓ Quality Policy and Objectives
- ✓ QMS scope (core processes covered by the QMS)

Enter text. Reference document attachment and page number(s) as appropriate.

**SOP Processes**

2.3 Please provide the names and numbers (if applicable) of the SOP(s) that align with each topic in the table below. If there are additional SOPs that do not fit the following categories that help to describe the RWD business functions described in Section 1, please add a list of those below.

*NOTE: If you do not currently have an SOP or set of SOPs for any of the systems or processes below, you will be asked to provide a thorough description of your processes in the relevant section(s) of the tool.*

Topic	SOP Names & Numbers
SOP on SOPs (process for developing, approving, updating, and training on SOPs)	
Training & competency ( <i>beyond SOPs</i> )	
Roles, responsibilities & escalation	
Change control / versioning	
System and data Security	
Privacy	
Corrective and Preventive Actions (CAPA)	
Data accrual / capture	
Data provenance / traceability	
Audit trails	
Data quality control (QC) and accuracy (Please provide a listing of edit check or data verification steps used )	
Data quality assurance (QA) (Please provide with respect to the data dictionary)	
Regulatory compliance (audits and inspections)	
ETL and integrity/completeness checks (Extraction, loading, transformation. Include validation of transformations and methods to demonstrate completeness, with respect to the data dictionary)	
Data linkage (within the RWD source and/or with RWD sources)	
Access management (internal and external)	
De-identification methodologies and applicability	
Software validation (Software development life cycle (SDLC) and system validation)	
Research Integrity and research methodologies	
RWD use of data source by internal analytics team or external researchers	
Other (specify):	

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Comments:

Enter text. Reference document attachment and page number(s) as appropriate.

*If the information for the following questions is included in your SOP on SOPs, please note relevant pages.*

2.4 Describe the process for development, review, and approval of SOPs (authorship, stakeholder feedback, official review, approval):

Enter text. Reference document attachment and page number(s) as appropriate.

2.5 Describe the periodic review schedule for SOPs (who needs to review, how often does review take place, what processes are in place to ensure that SOPs are reviewed per the schedule):

Enter text. Reference document attachment and page number(s) as appropriate.

2.6 Please provide documentation of your company's standard process for **staying current** with the following and ensuring that SOPs are updated as needed:

- ✓ Changes in internal data source holder information (e.g., process changes, QA / QC findings, audits/inspections, etc.)
- ✓ Regulatory changes (e.g., FDA guidance updates, new privacy laws)
- ✓ Changes to industry standards (e.g., ISO standards, common data model structure, data and coding standards (that could affect your SOPs):

Enter text. Reference document attachment and page number(s) as appropriate.

2.7 What change control policies / change logs are in place for SOPs – who approves changes, how are changes tested, how are changes documented, how are changes communicated, how is training updated?

Enter text. Reference document attachment and page number(s) as appropriate.

2.8 What processes are in place to document exceptions and deviations from the SOPs – who approves exceptions, how are deviations identified, reviewed, and resolved?

Enter text. Reference document attachment and page number(s) as appropriate.

### Standards Alignment and Certification Status

2.9 Indicate which standards, if any, your processes align with and whether your organization is certified. (Check all that apply.)

Standard / Guidance	Processes Align With This Standard	Certified-Yes	Specify (if applicable)
21 CFR Part 11	<input type="checkbox"/>	<input type="checkbox"/>	
ISO 8000 series	<input type="checkbox"/>	<input type="checkbox"/>	
ISO 9000 series	<input type="checkbox"/>	<input type="checkbox"/>	
ISO 9001	<input type="checkbox"/>	<input type="checkbox"/>	
ISO 25012	<input type="checkbox"/>	<input type="checkbox"/>	
ISO 27001	<input type="checkbox"/>	<input type="checkbox"/>	
ISO/IEC 27701	<input type="checkbox"/>	<input type="checkbox"/>	
General Data Protection Regulation (GDPR)	<input type="checkbox"/>	Not applicable	
FDA Real-World Data (RWD) Guidances	<input type="checkbox"/>	Not applicable	
Other (specify)	<input type="checkbox"/>	<input type="checkbox"/>	
None of the above	<input type="checkbox"/>	Not applicable	

Comments:

Enter text. Reference document attachment and page number(s) as appropriate.
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### Audits and Inspections

2.10 Please indicate which of the following audits have been carried out within the **past 3 years** and provide sample reports. If no sample report is available, please explain.

Audit type	No audit in past 3 years	Yes, Report attached	Yes, Report not available (explain)
Data quality audit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____
Internal QMS audit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____
Internal data source audit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____
External vendor audit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____
Health Authority inspection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____

Comments:

Enter text. Reference document attachment and page number(s) as appropriate.
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2.11 Please describe how your data source tracks all findings and any CAPAs that result from internal and external audits and inspections with respect to any of the applicable workstreams (i.e. those listed in Question 2.3).

Enter text. Reference document attachment and page number(s) as appropriate.

2.12 Describe how your data source maintains documentation of all health authority communications.

Enter text. Reference document attachment and page number(s) as appropriate.

2.13 Describe your data source preparedness for unannounced regulatory inspections

Enter text. Reference document attachment and page number(s) as appropriate.

### Section Evidence References

Please include a list of the supporting documents that are being submitted to support questions in this section.

Evidence item / question	Document name (or URL/path)	Section/page reference

## SECTION 3: DATA CONSISTENCY & STABILITY AND QUALITY CONTROL FRAMEWORK

### Data Consistency and Stability

3.1 Please describe any **known sources of variability** that could affect comparability across sites (hospital systems, hospitals, clinics), systems, or time in terms of the following: Describe how variability is monitored, documented, and mitigated. Please also note any differences that might significantly limit the ability to conduct medical device studies, in general.

- ✓ Site-level workflow / processes
- ✓ Coding practices
- ✓ Different EHR systems/versions
- ✓ Care patterns
- ✓ Temporal changes (coding/EHR/workflows)
- ✓ Geographic differences
- ✓ Other (specify)

Enter text. Reference document attachment and page number(s) as appropriate.

### Quality Control and Quality Assurance

3.2 For **each** of the **key data types** provided (e.g., diagnoses, medications, procedures, labs) and **points of care** listed (e.g., inpatient care, ambulatory care), please provide documentation (including processes and sample reports) or a description regarding the following types of routine data monitoring and cleaning procedures including frequency, metrics / key performance indicators (KPIs), how reports are generated and reviewed, and how day-to-day issues are resolved:

- ✓ Site and data monitoring
- ✓ Data validation rules / checks for implausible values at time of entry
- ✓ Procedures for minimization of missingness
- ✓ Data review procedures (for missingness, plausibility, duplicates)
- ✓ Automatic and manual data queries
- ✓ Review of code mappings (conformance checks)
- ✓ Outlier detection
- ✓ Other methods of data monitoring / cleaning
- ✓ Error correction workstreams
- ✓ Issue logging and tracking

Enter text. Reference document attachment and page number(s) as appropriate.

3.3 Please provide documentation or describe the **quality assurance processes** your data source uses to evaluate process compliance, error detection / prevention, first time quality (records entered correctly without rework), errors caught at point of entry vs. downstream, adherence to standards, quality improvement methods to enhance your processes to prevent errors and improve data quality. Include information on the review processes, frequency, approvals, and escalation.

- ✓ Validation rule effectiveness
- ✓ How issues noted through your QC processes are tracked, resolved, and prevented (including CAPA / quality improvement processes)
  - ✓ How you evaluate and report organizational / data source adherence to the healthcare data standards
  - ✓ How you evaluate trends in error rates over time
  - ✓ Any comparisons of KPIs against reference standards (e.g., *amount of missing data, data accuracy, etc.*)

Enter text. Reference document attachment and page number(s) as appropriate.

### Tracking of All Extracts and Data Queries for Research Purposes

3.4 Please describe your process for tracking and logging all data extractions **provided to**

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**external researchers** (or the data partner's research group)?

Not applicable

Enter text. Reference document attachment and page number(s) as appropriate.

3.5 Please describe your processes for **tracking and logging all data queries and analyses done for a given research study**. Include both scenarios when the data source holder conducts the analyses and when external researchers conduct the analyses.

Not applicable

Enter text. Reference document attachment and page number(s) as appropriate.

### Section Evidence References

Please include a list of the supporting documents that are being submitted to support questions in this section.

Evidence item / question	Document name (or URL/path)	Section/page reference

## SECTION 4: DATA ACCRUAL, TRACEABILITY AND SYSTEM AND DATA SOURCE VERSIONING

### Data Accrual and Provenance

4.1 For **each** of the **key data types** (e.g., diagnoses, medications, procedures, labs) and **points of care** (e.g., inpatient care, ambulatory care) in your data source, please provide documentation or a description of the following aspects of your data accrual processes which are applicable to your data source.

- ✓ How data are obtained at point of capture (e.g., who, how (point of care entry into EHR, generation by device, entry of codes for billing purposes), where, when)
- ✓ High-level data flow diagram from source → ingestion → transformation → storage → release
- ✓ Definitions of patient encounters / visits
- ✓ Data dictionary(ies)
- ✓ Data collection manuals
- ✓ Code books
- ✓ Data entry guidelines (for various data types and care settings)
- ✓ Common data capture form(s)
- ✓ Required data elements

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✓ Reference to applicable SOPs

Enter text. Reference document attachment and page number(s) as appropriate.

4.2 Please indicate which **common definitional frameworks and coding terminologies** are used and describe how they are applied. (*Check all that apply.*)

Framework / Coding Terminology	Used	Version	Description of how used (e.g., data capture, standardization, mapping, analysis, reporting)
ALCOA+ (Attributable, Legible, Contemporaneous, Original, Accurate, Consistent, Enduring, Available, Traceable)	<input type="checkbox"/>		
CDISC (e.g., CDASH, SDTM, ADaM)	<input type="checkbox"/>		
HL7 (Health Level 7)	<input type="checkbox"/>		
HL7 FHIR	<input type="checkbox"/>		
openEHR	<input type="checkbox"/>		
OMOP CDM (Observational Medical Outcomes Partnership)	<input type="checkbox"/>		
OHDSI (Observational Health Data Sciences and Informatics)	<input type="checkbox"/>		
PCORnet CDM (Patient-Centered Clinical Research Network)	<input type="checkbox"/>		
Sentinel CDM	<input type="checkbox"/>		
PHIN (Public Health Information Network)	<input type="checkbox"/>		
NDC (National Drug Codes)	<input type="checkbox"/>		
ICD-10-CM (Diagnosis codes)	<input type="checkbox"/>		
SNOMED CT	<input type="checkbox"/>		
ICD-9-PCS	<input type="checkbox"/>		
ICD-10-PCS	<input type="checkbox"/>		
CPT (Current Procedural Terminology)	<input type="checkbox"/>		
HCPCS (Healthcare Common Procedure Coding System)	<input type="checkbox"/>		
LOINC	<input type="checkbox"/>		
UCUM (Units of Measure)	<input type="checkbox"/>		
RxNorm	<input type="checkbox"/>		
WHO Drug Dictionary	<input type="checkbox"/>		
MedDRA	<input type="checkbox"/>		
DICOM	<input type="checkbox"/>		
RadLex	<input type="checkbox"/>		
BI-RADS	<input type="checkbox"/>		

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Framework / Coding Terminology	Used	Version	Description of how used (e.g., data capture, standardization, mapping, analysis, reporting)
Other (specify):	<input type="checkbox"/>		
None of the above	<input type="checkbox"/>	Not applicable	Not applicable

4.3 Comments on data standards / coding systems including whether / how data are updated to new versions of standards (e.g., crosswalks):

Enter text. Reference document attachment and page number(s) as appropriate.

**Traceability**

4.4 Audit trails

Please describe audit trails / logs available documenting all changes to data fields (e.g., *who made the changes, what changes were made, when the changes were made*). Please provide sample audit trails / logs documenting changes to data fields.

*If no data trails are available, describe how your data source documents the traceability of your data from the original source through the ETL process.*

Enter text. Reference document attachment and page number(s) as appropriate.

**System and Data Source Versioning**

4.5 Please describe how you **maintain and document version control** for the following. Refer to documents that describe your change control procedures and system life cycle processes. Include a description of your release cadence (time frame/data latency), version identifiers, data refreshes, retention of prior version, etc.)

- ✓ System components
- ✓ Database instances
- ✓ “Research-ready data sets” (if applicable)

Enter text. Reference document attachment and page number(s) as appropriate.

**Section Evidence References**

Please include a list of the supporting documents that are being submitted to support questions in this section.

THE NATIONAL EVALUATION SYSTEM FOR HEALTH TECHNOLOGY

Evidence item / question	Document name (or URL/path)	Section/page reference

**SECTION 5: ETL AND TECHNICAL CONTROLS**

---

**Overall ETL Process**

5.1 Please provide an **overview of your entire ETL process** using diagrams as appropriate. Describe how data are collected and aggregated, transformed, and loaded in a data warehouse or server environment where they are represented in a format that supports downstream analytics and use cases.

Enter text. Reference document attachment and page number(s) as appropriate.

*In subsequent ETL sections, please provide comprehensive documentation for each step of your ETL processes. Where the set of process documents is extensive, please provide an overview of the process and diagrams to orient reviewers to the process.*

**Extraction**

5.2 Please provide documentation or a thorough description of your **data extraction processes**, including information on the following:

- ✓ Overall data extraction processes (include a visual description)
- ✓ Processes for extracting (a) incremental new data; (b) updated data when corrections have been made in the original data source
- ✓ How data content is assessed (*e.g., counts, values*) before and after extraction into the data staging area (temporary storage prior to transformation and loading) to ensure fidelity
- ✓ Validation checks and error mitigation strategies that are used to ensure accurate and complete data pull (*e.g., counts, values, etc.*)
- ✓ Known limitations in the data extraction process and what approaches are in place to mitigate the limitations, if possible
- ✓ Procedures for:
  - Ensuring data completeness
  - Minimizing missing data extraction
  - Assessing data redundancy
  - De-duplication

Enter text. Reference document attachment and page number(s) as appropriate.

## Transformation

5.3 Please provide documentation or a thorough description of your **transformation processes**, including information on the following:

- ✓ Description of the data model that is being used to represent the data, if applicable
- ✓ Characterization of controlled vocabularies
- ✓ Mapping of raw data to controlled vocabularies
- ✓ Standardization / Normalization of data (e.g., standardization of labs to specific units, crosswalks between different coding systems)
- ✓ Mappings necessary for the CDM or other target data model
- ✓ How out-of-range values are handled during the transformation step (e.g., physiologically impossible values, values that cannot be mapped to the controlled vocabulary)
- ✓ How data content is assessed before and after transformation to ensure accuracy and completeness
- ✓ What type of accounting is available for all data elements that are transformed (changed, removed, expanded, etc.)
- ✓ How original data are maintained
- ✓ Processes in place to identify, document, and resolve any transformations that result in lost information
- ✓ Processes in place to validate the transformations and assess their potential impact
- ✓ Known limitations in the data transformation process and what approaches are in place to mitigate the limitations, if possible

Enter text. Reference document attachment and page number(s) as appropriate.

## Algorithmically Derived Fields, Unstructured Data, and AI/ML Methods

5.4 If your data source includes **algorithmically derived fields** (e.g., BMI from height / weight, age from birthdate) or **unstructured data** captured or fields derived / modified via artificial intelligence, machine learning, or large language models, please provide documentation or a description of the following:

- ✓ Technologies used to abstract unstructured data
- ✓ Technologies used to ensure accuracy (e.g., *acronyms, spelling*)
- ✓ Details on algorithmically derived fields
- ✓ Details on structured data fields extracted from clinical notes
- ✓ Details on data fields modified using AI / ML / LLM

Not applicable

Enter text. Reference document attachment and page number(s) as appropriate.

5.5 If not currently used, does your organization have the **capabilities** (e.g., *trained personnel*) to use AI / ML methods?  Yes  No

If no, explain:

Enter text. Reference document attachment and page number(s) as appropriate.

### Privacy-Preserving Data Transformations

5.6 Please provide **documentation or describe privacy-preserving data transformations** for the data source including aggregation, removal of rare values, data shifting, filtering, sampling, restrictions to exclude records, or other processes.

Enter text. Reference document attachment and page number(s) as appropriate.

5.7 What **proportion of patients** in the data source are affected by these transformations?

- <10%     
  >10-25%     
  >25-50%     
  >50%

5.8 What **proportion of encounters** (healthcare visits) in the data source are affected by these transformations?

- <10%     
  >10-25%     
  >25-50%     
  >50%

5.9 Describe any **known limitations / mitigations** (e.g., based on previous studies) in use of the data source for medical device studies due to the effect of privacy-preserving data transformations on sample composition, representativeness, and/or bias.

Enter text. Reference document attachment and page number(s) as appropriate.

### Loading

5.10 Please provide documentation or a thorough description of your **loading processes**, including information on the following:

- ✓ Overall data loading processes to create the fully integrated data source
- ✓ Quality evaluations on the transformed and loaded data

Enter text. Reference document attachment and page number(s) as appropriate.

5.11 Do you have procedures for recording the following load quality checks? Please indicate Yes or No for each item and provide documentation as appropriate.

Load Quality Check	Yes	No	Comments / Notes (optional)
Reporting the proportion of data mapped to controlled vocabularies	<input type="checkbox"/>	<input type="checkbox"/>	
Documenting implausible values	<input type="checkbox"/>	<input type="checkbox"/>	
Documenting missing, out-of-range, invalid, or non-normalizable values	<input type="checkbox"/>	<input type="checkbox"/>	

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Load Quality Check	Yes	No	Comments / Notes (optional)
Documenting and characterizing missing data	<input type="checkbox"/>	<input type="checkbox"/>	
Documenting and characterizing imputation of missing data	<input type="checkbox"/>	<input type="checkbox"/>	
Summarizing evaluation and resolution of data element duplication or redundancy	<input type="checkbox"/>	<input type="checkbox"/>	
Evaluation of measurement bias across the full ETL data source	<input type="checkbox"/>	<input type="checkbox"/>	
Data cross-reference validations	<input type="checkbox"/>	<input type="checkbox"/>	

Comments:

Enter text. Reference document attachment and page number(s) as appropriate.
--

**Section Evidence References**

Please include a list of the supporting documents that are being submitted to support questions in this section.

Evidence item / question	Document name (or URL/path)	Section/page reference

**SECTION 6: DATA INTEGRATION AND LINKAGE**

6.1 Please describe any internal (within the data source) or external (with other data sources) linkage that you perform for your data source.

Not applicable

Enter text. Reference document attachment and page number(s) as appropriate.
--

6.2 Provide documentation (including technical information, linkage logs, diagrams, etc.) or describe the following:

- ✓ Reasons for linkages
- ✓ Whether linkages are internal or external
- ✓ What data sources are linked
- ✓ How data are linked. Please include the following
  - How patient identifying information is used for direct linkage (with patient consent or IRB waiver of consent)?
  - Privacy preserving linkage technology such as tokenization
  - Linkage algorithms used (deterministic matching, probabilistic matching)
  - De-duplication methods to avoid multiple records for the same patient based on

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different original data sources (e.g., when merging claims from more than one insurance plan)

- ✓ Any known limitations with linkages with your data source

Enter text. Reference document attachment and page number(s) as appropriate.

6.3 Please describe how you **assess linkage accuracy** and the types of post-linkage characterization (e.g., completeness of linked datasets, population overlap, overlap of time periods, potential biases, etc.) done by your data source. Describe how different sources of data are cross-referenced and integrated (e.g., methods to compare and validate data across multiple data sources). Provide sample reports of linkage accuracy, post-linkage characterization, and cross-source data validation.

- ✓ Match rates (proportion of matches linked [true positive links divided by total matches conducted])
- ✓ Link accuracy (proportion of correct links [true positive links divided by total links conducted])
- ✓ False linkage rates (proportion of different individuals that are erroneously linked among all linked individuals)
- ✓ Missed linkage rates (proportion of records belonging to the same individual that fail to be linked among linkable individuals)

Not applicable

Enter text. Reference document attachment and page number(s) as appropriate.

6.4 Describe any significant changes in your linkage process over time:

Not applicable

Enter text. Reference document attachment and page number(s) as appropriate.

### Section Evidence References

Please include a list of the supporting documents that are being submitted to support questions in this section.

Evidence item / question	Document name (or URL/path)	Section/page reference

## SECTION 7: DATA ACCESS & SHARING, PRIVACY & SECURITY AND REGULATORY TRANSPARENCY

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### Data Access and Sharing

#### Internal Data Access

7.1 Please provide documentation or describe established procedures and defined permission levels for **internal personnel accessing the data source**. Include information on the following:

- ✓ Overall **data access procedures and permission levels** for all data source partner personnel and others that may be involved in data collection, quality control, ETL, governance, security, reporting, research, etc. for the data source
- ✓ **Roles** of those having access and their specific levels (e.g., access to enter data for an individual site, read-only access to the entire integrated data source to run reports, full database access for ETL purposes, access to de-identified data for research purposes)
- ✓ Established **governance body** that oversees and grants these access permissions
- ✓ **Privacy-preserving** data access and data sharing procedures by role
- ✓ **Stages during the ETL process** for which access is granted by role
- ✓ Protective measures against **unauthorized access** or use, how security is tested, and how branches are managed
- ✓ Training for:
- ✓ Data access / use, and how training is tracked
- ✓ QMS
- ✓ RWD processes: Data Access, Data Sharing, and Informed Consent/IRB Requirements for Internal Researchers

Enter text. Reference document attachment and page number(s) as appropriate.

#### External Researcher Data Access

7.2 Describe the overall procedures for **data sharing for research purposes**. Please provide documentation and/or complete below.

- ✓ **Established governance** to oversee data access and procedures for granting and tracking access to data for research purposes (e.g., *data use committees*)
- ✓ **Privacy-preserving** data access and data sharing procedures by role
- ✓ **Data security requirements** that are mandatory for the external researchers to protect against unauthorized access or use
- ✓ **Training** for external researchers about use of the data source for RWD research
- ✓ Requirements for **secure destruction** of data files

Enter text. Reference document attachment and page number(s) as appropriate.

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7.3 Provide documentation or describe the established legal and ethical frameworks (e.g., *Agreements, IRBs*) required before a study begins.

- ✓ Type of **data sharing agreement** required for use of the data (e.g., Business Associate Agreement, Data Use Agreement, Third Party Identifier [TPI]):
- ✓ **How long** it usually takes to get an agreement in place (average & range)
- ✓ **Restrictions** regarding use of specific types of data from the data source
- ✓ Whether each separate **research question** requires approval from the data source
- ✓ Whether there are any **restrictions on publications** by researchers who have a data sharing agreement in place
- ✓ Whether there are any **data suppression policies** in place (e.g., *minimum cell size*) for publications
- ✓ Whether independent Ethics Committee (IEC) / **IRB approvals are required** before a study is undertaken in this data source (including specific IRBs if necessary and the expected time for approval (mean, range).

Enter text. Reference document attachment and page number(s) as appropriate.

7.4 Is **informed consent or a waiver already in place** or is one required before a study is undertaken using this data source? *If informed consent is only required under specific circumstances, please explain*

- Informed consent required before a study is undertaken
- Informed consent is in place
- Informed consent waiver is in place
- Not applicable (Please explain)

Enter text. Reference document attachment and page number(s) as appropriate.

7.5 Please describe the **types of data that external research parties** (NEST, NEST Partner, Sponsor) **are able to access** from the data source (e.g., data source partner must conduct all analyses, researchers may be granted access to / provided with a copy of a de-identified version of the full data source for analysis, researchers may have access to / be provided with de-identified data for a limited research cohort for analysis, etc.)

Enter text. Reference document attachment and page number(s) as appropriate.

7.6 Please describe how data can be **accessed by external research parties** (NEST, NEST Partner, Sponsor) (e.g., remote access via cloud or data source holder interface, secure / encrypted data transfer to research partner via FTP, or other method)

Enter text. Reference document attachment and page number(s) as appropriate.

### Regulatory Access

7.7 Please describe the **types of data that FDA** would be able to access from the data source (e.g., data source partner must conduct all analyses, researchers may be granted access to / provided with a copy of a de-identified version of the full data source for analysis, researchers may have access to / be provided with de-identified data for a limited research cohort for analysis. If access cannot be provided to the FDA, please explain.

Enter text. Reference document attachment and page number(s) as appropriate.

7.8 Please describe **how data can be accessed by FDA** (e.g., remote access via cloud or data source holder interface, secure / encrypted data transfer to research partner via FTP or other method)

Enter text. Reference document attachment and page number(s) as appropriate.

### Data Storage, Retention, and Correction Processes

7.9 Describe the location and environment of **data storage for the data source**:

- Microsoft Azure
- Amazon Web Services (AWS)
- Google Cloud Platform
- On premises
- Other, specify:

Enter text. Reference document attachment and page number(s) as appropriate.

7.10 Please **provide documentation or describe the security controls** in place for the data source (technical, administrative and physical safeguards that protect data from unauthorized access, alteration, or loss). Include information regarding the following:

- ✓ Access management (e.g., multi-factor authentication and least privilege)
- ✓ Encryption for data confidentiality
- ✓ Regular backups and recovery plans
- ✓ Intrusion detection systems to spot threats
- ✓ Breach notifications
- ✓ Robust data security policies and procedures for employees

Enter text. Reference document attachment and page number(s) as appropriate.

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7.11 Describe the location and environment (*e.g., cloud system*) of **data storage for the research-ready data source** (if there is a separate instance of or extraction from the data source that is used for research studies):

- No separate research-ready data source
- Microsoft Azure
- Amazon Web Services (AWS)
- Google Cloud Platform
- On premises
- Other, specify

Enter text. Reference document attachment and page number(s) as appropriate.

7.12 Describe the **security controls in place for the research-ready data source** (technical, administrative and physical safeguards that protect data from unauthorized access, alteration, or loss). Include information regarding:

- ✓ Access management (*e.g., multi-factor authentication and least privilege*)
- ✓ Encryption for data confidentiality
- ✓ Regular backups and recovery plans
- ✓ Intrusion detection systems to spot threats
- ✓ Breach notifications
- ✓ Robust data security policies and procedures for employees

- No separate research-ready data source

Enter text. Reference document attachment and page number(s) as appropriate.

7.13 Please describe your **data retention policies**:

Enter text. Reference document attachment and page number(s) as appropriate.

7.14 Please describe how you deal with **patient requests** to correct data or remove access to data

Enter text. Reference document attachment and page number(s) as appropriate.

## Data Privacy

7.15 Please describe your data source **compliance with HIPAA and other privacy laws** (*e.g., General Data Protection Regulation [GDPR], California Consumer Privacy Act [CCPA]*). Indicate which of these standards your data source is compliant with.

- GDPR
- CCPA

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- HIPAA
- HITECH Act breach reporting
- AES-256 encryption
- Multi-factor authentication
- Role-based access control (RBAC)
- Other, specify:

Enter text. Reference document attachment and page number(s) as appropriate.

### Data De-identification

7.16 Please provide documentation or describe the overall **data de-identification processes** for the data source. Please include information on the following aspects of your processes:

- ✓ For which types of data and healthcare settings you receive data that has **patient identifiers** (PPI) (*e.g., name, medical record number*) that are used to link data in your data source
- ✓ For which types of data and healthcare settings you receive data that is **already de-identified** (with or without tokenization)
- ✓ At **what stage of the ETL process** any data received with patient identifiers, are de-identified
- ✓ **Methods used for de-identification** of data during ETL (*e.g. risk-based, HIPAA safe harbor*)
- ✓ Procedures for de-identifying Protected Health Information (PHI) in **unstructured data**
- ✓ Privacy-preserving **linkages**
- ✓ De-identification and re-identification **risk assessment** procedures

Enter text. Reference document attachment and page number(s) as appropriate.

7.17 Describe any **identifiers remaining in the released data set** (*e.g., device serial numbers, tokens*) that are permissible to use for further linkage to additional datasets by analytic teams. Describe whether the remaining identifiers provide adequate information to avoid / remove duplicate records.

- Not applicable

Enter text. Reference document attachment and page number(s) as appropriate.

### Section Evidence References

Please include a list of the supporting documents that are being submitted to support questions in this section.

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Evidence item / question	Document name (or URL/path)	Section/page reference

**SECTION 8: DATA SOURCE REPRESENTATIVENESS, CONTINUITY OF CARE, AND LONGITUDINALITY**

**Target Population and Representativeness of Data Source**

8.1 Describe the **target population** covered by the data source (e.g., U.S. population, population of a particular state / region, population with a given disease or device, population with a particular insurance plan, Medicaid, Medicare [FFS, Advantage]). Please also include the following:

- ✓ Metrics on your data source coverage profile (e.g., number of hospitals, sites, other care settings, geography, etc.)
- ✓ Information comparing the characteristics of the population in the data source to the target population.
- ✓ Any known population differences or limitations (if any)

Enter text. Reference document attachment and page number(s) as appropriate.

**Continuity of Care and Observability**

8.2 Describe how **the data source captures patient encounters and episodes of care** across settings, including hospitals, medical specialties, labs, etc. to provide a comprehensive view of the patients' medical care. Please include information on the following:

- ✓ Whether all information supporting the continuity of care originates in one system (e.g., *EHR or registry*) or whether multiple databases are linked to form the data source
- ✓ Whether the data source includes data from more than one insurance plan, how patients are tracked across insurance plans, and what happens if patients change plans
- ✓ Whether there are specific types of **settings, patient care, devices, medications, or other data** for which significant amounts of **data may not be captured** in the data source (e.g., because patients receive care outside of the settings covered by the data source, because care is out of network or not covered by included insurance plans). Include any known limitations and strategies that could be used to mitigate them (e.g., linkage to other data sources)

Enter text. Reference document attachment and page number(s) as appropriate.

### Longitudinal Depth and Follow-up

8.3 Describe how your data source **captures medical records over time** for a given patient. Include the following information:

- ✓ How longitudinal data capture is defined and implemented in the data source, including any mechanisms used to support continuous capture of patient data over time (*e.g., routine data refreshes, updates based on corrected data*)
- ✓ Any known limitations in the data source in terms of longitudinality and methods that may be used to mitigate them (*including variability impacting data elements and/or across care settings over time, in general*)
- ✓ Provide a report or describe quantitative data on patient follow-up, encounter density, and censoring.
- ✓ Whether you are able to determine if a patient is readmitted for the same diagnosis

Enter text. Reference document attachment and page number(s) as appropriate.

8.4 Does your organization have the **capabilities to collect additional data** if needed for enhancement of variables already collected (*e.g., additional device information*) or for the collection of variables not captured thus far (*e.g., contacting participating physicians, extracting data from unstructured fields*)?

Yes, please describe:       No

Enter text. Reference document attachment and page number(s) as appropriate.

### Section Evidence References

Please include a list of the supporting documents that are being submitted to support questions in this section.

Evidence item / question	Document name (or URL/path)	Section/page reference

## SECTION 9: QUANTITATIVE DATA SOURCE CHARACTERISTICS

---

9.1 Please provide metrics for the characteristics listed.

- For continuous variables, report: N, N missing, mean (SD), median, lower and upper quartiles, min and max.

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- For categorical variables, report: N, N missing, frequency distribution

9.2 Continuous Demographic Characteristics

Variable	N	N Missing	Mean (SD)	Minimum	Q1	Median	Q3	Maximum
Age								
Height								
Weight								

Comments:

Enter text. Reference document attachment and page number(s) as appropriate.
--

9.3 Categorical Demographic Characteristics

Characteristic	N (%)
<b>Gender</b>	
Male	
Female	
Add other categories based on categorization in your data source	
Missing	
<b>Race</b> (use categories as defined in your data source)	
White	
Black/African American	
Asian	
American Indian or Alaska Native	
Native Hawaiian or Other Pacific Islander	
Some other race	
Two or more races	
Missing	
<b>Ethnicity</b>	
Hispanic or Latino	
Not Hispanic or Latino	
<b>Insurance Type</b> (use categories as defined in your data source)	
Commercial	
Medicare FFS	
Medicare Advantage	
Medicaid	
DoD / VA	

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Comments:

Enter text. Reference document attachment and page number(s) as appropriate.

9.4 Patients/Encounters by Care Setting

Please complete the following table or provide a report which includes the following data regarding the numbers of individuals in your data source with various types of data and the number of encounters (visits) with that type of data in your data source.

For example, the number with an inpatient hospital admission; the number with visits (as defined in your data source) with laboratory test results (not the number of separate lab tests).

Measure	Entire Database Period		3 Most Recent Calendar or Fiscal Years					
			Year: ____		Year: ____		Year: ____	
	# of Patients	# of Encounters	# of Patients	# of Encounters	# of Patients	# of Encounters	# of Patients	# of Encounters
Any healthcare encounter								
Inpatient hospitalizations								
Hospital-based surgery (with inpatient stay)								
Ambulatory surgery								
ED visit								
Primary care physician visits								
Specialist clinic visits								
Lab data available (for encounters, provide # of visits (dates with labs), not # of individual lab tests)								
Imaging data available (IMAGES)								
Imaging data available								

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Measure	Entire Database Period		3 Most Recent Calendar or Fiscal Years					
			Year: ____		Year: ____		Year: ____	
	# of Patients	# of Encounters	# of Patients	# of Encounters	# of Patients	# of Encounters	# of Patients	# of Encounters
(Imaging REPORTS)								
Medication data available for encounters, provide # of visits (dates with medications), not # of individual medications)								
Encounters in ≥ 2 care settings (e.g., hospital/inpatient, ED, ambulatory surgery, clinic/outpatient)								

Comments:

Enter text. Reference document attachment and page number(s) as appropriate.

**Follow-up**

9.5 Maximum timeframe for follow-up in RWE studies during which outcomes are likely to be captured in this data source:

- Index encounter only (initial procedure/surgery hospitalization only)
- ≥30 days
- ≥90 days
- ≥1 year
- ≥2 years
- ≥5 years
- Other: \_\_\_\_\_

9.6 Please complete the following tables describing the longitudinality of the data:

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Number (%) of patients with at least one encounter in data source during the given time interval after the patient's first encounter in the data source						
Within 3 months	Within 6 months	>3 to < 6 months	>6 to <12 months	>12 to <24 months	>24 to <36 months	>36 months

Comments:

Enter text. Reference document attachment and page number(s) as appropriate.

9.7 Length of follow-up (post first instance) for patients in the data source

Metric	Length of Follow-up
Minimum	
Q1	
Median	
Q3	
Maximum	

Comments:

Enter text. Reference document attachment and page number(s) as appropriate.

**Section Evidence References**

Please include a list of the supporting documents that are being submitted to support questions in this section.

Evidence item / question	Document name (or URL/path)	Section/page reference

**SECTION 10: DOCUMENTATION PACKAGE**

10.1 Provide a comprehensive list of documents that you are providing. If there are any other relevant documents for your data source that have not been previously mentioned, please include them on this list and include with your submission, For example certifications (ISO, etc.), whitepapers / publications, organizational charts, redacted Establishment Inspection Report (EIR).

Enter text. Reference document attachment and page number(s) as appropriate.

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10.2 Is there any additional information about your data source that you think is important for us to know?

Enter text. Reference document attachment and page number(s) as appropriate.
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### SECTION 11: SIGNATURE

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11.1 By signing below, the data source holder confirms that the information provided is accurate and complete to the best of their knowledge.

Data Source Holder Representative Name: \_\_\_\_\_

Title: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Thank you for completing this Information

Please send the completed Data Source Evaluation to [nestcc@mdic.org](mailto:nestcc@mdic.org).

We will review the document and be in touch regarding any follow up questions in advance of our next meeting.

### APPENDIX 1: LIST OF DOCUMENTS NEEDED TO SUPPORT APPLICATION

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See supplementary link

### APPENDIX 2: LIST OF ACRONYMS

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See supplementary link

### APPENDIX 3: GLOSSARY OF TERMS

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See supplementary link