Interoperability MATTERS
an initiative of The Sequoia Project

Understanding the Expanded Definition of Electronic Health Information in an Operational Context

Building from the Defining EHI and the Designated Record Set in an Electronic World Report

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This document provides guidance to Actors that must comply with the Information Blocking rules on operational steps needed to comply with the full definition of EHI that will be in effect in October 2022.

This document explores the expanded definition of Electronic Health Information (EHI) in the context of the operational information systems of Actors subject to the Information Blocking rules released by the Office of the National Coordinator for Health IT (ONC). It builds from the fall 2021 version of the report, "Defining EHI and the Designated Record Set in an Electronic World ("Defining EHI and the DRS"), completed by the American Health Information Management Association (AHIMA), American Medical Informatics Association (AMIA), Electronic Health Record Association (EHRA) EHI Task Force ("EHI Task Force"), by considering possible additions and/or refinements, identifying insights on the types of information technology (IT) systems where specific data types may be stored, and exploring considerations for how to share EHI for these data types with requestors electronically.

The report was created by the Information Blocking Compliance Workgroup of The Sequoia Project's Interoperability Matters Initiative, with the assistance of several additional subject matter experts. It reflects the operational experience of the individuals that volunteered their time and expertise to share operational experiences and approaches. We especially thank the following individuals who led the development of this resource:

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The findings in this report are intended primarily as a tool for informaticists, technologists, health information management (HIM) professionals, Chief Medical Officers, and Chief Medical Information Officers to operationalize access, exchange, and use of EHI consistent with the requirements of the information blocking regulations and to inform the creation of organizational policies by Actors under the information blocking regulations that facilitate compliance with these rules. The tool may also be used by policymakers, legal counsel for Actors and data requesters, and the larger policy community to better understand the responsibilities of an Actor as it relates to the full definition of EHI.

Actor organizations will likely need to follow their own internal change management processes to ensure that their operations, including the operationalization of the Designated Record Set (DRS) for their organization, are updated to accommodate the expanded definition of EHI. This tool should also be used in tandem with the other deliverables from the Information Blocking Workgroup released during September 2022 to develop a comprehensive understanding of and response to the complexity of EHI.

Note: The materials developed by the IBWG are intended to be educational and informational resources. These materials will be most helpful to those who have a strong understanding of the regulatory requirements but seek to understand real-world implications and approaches to implementation. They are not, and are not intended to, constitute legal advice or a treatise on the Information Blocking Rule. Regulated Actors are encouraged to seek appropriate counsel to advise on the Actor's legal compliance. No Actor should act or refrain from acting on the basis of the IBWG materials without first seeking legal advice from counsel. All liability with respect to actions taken or not taken based on the IBWG materials are hereby expressly disclaimed. The IBWG materials are provided "as is;" no representations are made that the content is error-free.

1. Process

The Workgroup undertook an extensive approach in developing this tool to assist Actors in prioritizing efforts to make EHI available consistent with ONC's rule definition based on the DRS. As a threshold matter, the full definition of EHI effective October 6, 2022 included electronic Protected Health Information (ePHI) that is part of the HIPAA-defined DRS. Operationalizing the regulatory definition of the DRS and its components will likely vary based with the Actor-category, health care setting and specific organization.

In summary, the DRS includes information meeting the above definition that is used by the applicable hospital, medical practice or facility or other type of health care provider to make decisions (clinical or billing) about individuals (but not necessarily the specific individual whose EHI is being requested). Note that this definition is applicable to Actors that do not provide care to patients but that may be Business Associates of provider organizations and either support the DRS of another Actor or maintain EHI per a Business Associate Agreement or other arrangements with a provider organization.

Some of the data classes identified in this tool are likely to be EHI in all or nearly all cases; but for other data classes, whether a certain data class, or data type within a data class, is included in an organization's DRS may also depend on the setting. For example, certain data in an ophthalmologist's practice may be included in their DRS, whereas it may not be either maintained or used to make patient decisions in a rehabilitation facility. Furthermore, information that is part of the US Core for Data Interoperability (USCDI), the basis for the pre-October 6 EHI definition, may not meet the definition of DRS (and therefore EHI) for a particular health care setting. Such non-EHI USCDI data might include data classes such as security label, facility data (name, address, contact information, organizational identifier, etc.) that are not used to make decisions about individuals.

Additional considerations related to the DRS and EHI must be kept in mind by Actors when using this tool. First, when implementing policy around the DRS within an organization, it is important to ensure the definition of the DRS does not vary on an individual patient level. Rather, organizations need to look at the data sets within their setting and assess whether that data is used or reasonably likely to be used in decision making for any patient even if it was not used for the patient whose EHI is sought. Second, much like the definition of the DRS, the definition of EHI is not fixed as it is operationalized by organizations over time. Actors will need to evolve their policy over time as new or different data classes and data types are used for decision making and additional data types are available in electronic form.

With these threshold considerations in mind, this tool examines data classes previously identified by the EHI Task Force from various sources including the USCDI New Data Element & Class (ONDEC) Submission System[1], as well as data classes outside of ONDEC that could be part of the DRS. It is important to note that this tool applies the ONDEC definitions for the various data classes, which include specific date elements.

This tool additionally investigates which source system(s)[2] the data class and/or element may reside and whether the data class falls under the definition of EHI. The tool takes an HIT system-agnostic approach to assess settings across the care continuum where data may be found, including telehealth systems, the electronic health record (EHR), health information networks (HINs) and health information exchanges (HIE), patient portals, and other systems and technologies used across the ecosystem. In this regard, identifying where information originates should help Actors determine where information under their control is located to ensure completeness of access, exchange, and use of the EHI.

The tool also analyzes important factors that Actors might wish to consider in making EHI available to a data requestor. For example, a common factor identified in this tool is that certain data classes such as laboratory tests or social determinants of health (SDOH) data are not always documented in a standardized way. As a result, the information might exist in different places within the record or require additional segmentation before it may be disclosed.

Finally, this tool examines considerations for when an Actor might need to consider whether the EHI might not be available, appropriate, or permitted to be shared per an exception under the Cures Act Final Rule or other applicable federal or state law or

[1] The USCDI ONDEC supports the Office of the National Coordinator for Health IT's intent to develop new versions of the USCDI in a predictably, transparent and collaborative process and allows health IT stakeholders to submit new data elements and classes.

[2] More information on the diversity of source systems can be found in the Workstream #3 infographic.

regulation. The purpose of this analysis is not to identify reasons for Actors to not share but rather to identify instances where an exception or other applicable consideration might require additional analysis. Actors should make sure that, in instances where an exception might apply to a data class, they carefully review and ensure that the conditions that apply to the exception are fully met to avoid an assertion of information blocking and associated compliance risks.

Due to time constraints, the tool does not complete analysis of all data classes identified in the Defining EHI and the DRS report. As a result, it prioritizes the data classes that commonly generate questions within the stakeholder and policy community. This tool should be considered a "living document" and could evolve as the community continues to deepen its understanding of the full definition of EHI and the HIPAA Designated Record Set in the context of information blocking compliance.

2. Key Themes

Several key themes emerged throughout discussions that are captured in the table below. Such themes include:

2.1. The role of organizational policy

Organizational policy is a critical driver for adherence to regulatory requirements surrounding the definition of DRS and EHI. General agreement exists that organizational policy will and should guide decision making. However, Actors should consider the potential for non-adherence to organizational policy by clinicians and other staff and the need for processes to ensure consistent compliance.

2.2. Data from external systems

A key question identified in this analysis is whether data accessed from an external source is considered the EHI of the Actor accessing these data. After extensive discussion, including issues associated with reconciling data from external systems, this tool uses the following principles to guide its recommendations:

- ePHI viewed/referenced in an external system that is not controlled by the Actor that is not received/ingested/documented within the Actor's system is generally not likely to be considered EHI;
- ePHI created within or "pulled into" the Actor's medical record or Actor's other information system from an external system will generally be considered EHI if it otherwise meets the applicable definition;
- ePHI controlled by the Actor that is viewable and accessible outside the Actor's medical record or information system(s) but has not been ingested into or is no

longer available within what the Actor considers the active medical record (e.g., data in the Actor's data repository) will require each organization to make its own determination on a case-by-case basis.

Any time an external source system, such as an HIE/HIN, is noted in a data class in the table below, the above "external data source considerations" should be considered.

2.3. Non-standard or non-discrete data

This tool identifies a number of data classes that are generally captured in non-standard or non-discrete formats and the associated challenges that arise in sharing such information. Anytime a data class presents in a non-standard or non-discrete manner, considerations around the Infeasibility and Content and Manner exceptions arise, including whether the EHI can be made available in the format requested or an alternative agreed-upon format.

2.4. Exceptions

Several exceptions are potentially applicable to a majority of the identified data classes. The applicability of these exceptions will be situational, depending on the specific circumstances relevant to the data class, the Actor, and the patient(s) whose data is being requested, as well as on the relationship between the Actor and requestor. For example, the Preventing Harm exception may apply when sharing with the patient but not when sharing the same data with another covered entity under treatment, payment, and healthcare operations purposes of use as defined by HIPAA.

Below is a descriptive list of the exceptions and other criterion identified in this tool that should be considered by Actors when determining whether a data class and/or element should be shared. This list is not intended to be a comprehensive review of the exceptions but rather is intended to highlight exception considerations that are likely to apply to specific data classes and/or elements:

- **Content and Manner** if the data cannot be released in the manner in which it was requested (e.g., if the data is in a non-discrete form and discrete data is needed for the requested manner of access or the data cannot be sent using a requested standard).
- **Infeasibility** if the data is technically or otherwise (e.g., due to licensing restrictions) unable to be produced or if the requested data is tied to sensitive information and cannot be unambiguously segmented from that sensitive information.

- **Privacy** if one of the conditions of this exception applies to the EHI requested (e.g., the patient does not want to share the information, or the data is subject to privacy laws that limit or prohibit its release).
- **Preventing Harm** on a case-by-case basis if the data is misidentified/mismatched or corrupted or when considering the risk to the patient or another person other than the patient (e.g., the care team members or family member) who could be harmed consistent with the harm standard.
- **Security** if the Actor has reason to believe that there is a security risk associated with the requested access to the EHI, whether for that EHI or other EHI held by the Actor (e.g., concerns with the validity of the credentials used to access the EHI). Note that certain scenarios could involve both Security and Privacy exceptions.
- **Applicable Law** (e.g., HIPAA, 42 CFR Part 2, state, tribal, or local law) that limits access to requested data in specified circumstances (e.g., data relating to substance abuse or test results associated with certain conditions).
- **Business Associate Agreement (BAA)** that limits the ability of an Actor to provide the requested data (e.g., that require the Actor to direct the data requestor back to the originating entity).

3. Additional Considerations

As a result of its analysis, the tool identifies several areas for further consideration. In collaboration with the Information Blocking Workgroup's Good Practices Task Group and all three EHI workstreams, the Sequoia Project will develop a list of potential FAQs to submit to ONC for consideration. Below are some examples of remaining uncertainty. We urge Actors to review these issues as applicable with legal counsel and regulatory experts and to monitor for further regulatory guidance:

- This tool assumes that Actors are generally not required to invest in or build technology that has not been acquired or implemented. While there is nothing in the rule that requires Actors to acquire new technology to facilitate the production of EHI when requested, in considering whether there is an obligation to deploy existing infrastructure, features, or interfaces within existing resources to facilitate access, exchange, and use, Actors should consider ONC guidance.

- Preliminary results are likely to be considered part of the DRS if used in decision making for the patient[3]. However, Actors should consider in what circumstances they would need to be segmented from final results.

[3] 2067-Is a clinical laboratory required to provide an individual with access to a test report that is not yet complete? | HHS.gov and ONC's Cures Act Final Rule (healthit.gov)

- An Actor's organizational policy might instruct clinicians to not use certain data in decision making (e.g., provider to provider messages and draft data/preliminary results). Can such an organizational policy be relied upon when a provider fails to adhere to the policy and there is an allegation of information blocking when that information is not shared pursuant to a request?

- Because the definition of care team is quite broad under USCDI and can vary across institutions, Actors should ensure they have sufficiently defined and documented the scope of care team members.

- This tool assumes that chart corrections are generally going to be considered EHI but an open question remains as to whether the data to be considered EHI includes the entire documented flow of the decision-making process, including the request from the patient, the amendment decision by the provider, a potential written disagreement by the patient, and the rebuttal from the provider if there is a disagreement regarding the chart correction between the patient and provider. This question should be considered in organizational policy.

- Licensing issues may arise with respect to certain code sets and other copyrighted data elements and organizations should consult with legal counsel with respect to this issue.

Data Class/Element (from EHI Definition TF document)	Is it EHI?	Source System(s) (descriptive, not vendor-based)[4]	Factors to consider in making data available (interfaces, software to access, archives, draft data)	Additional Considerations
USCDI v1 Data Classes (as defined by ONC)				
Allergies and Intolerances	Yes	Electronic Health Record (EHR), Pharmacy, Health Information Exchange/Health Information Network (HIN), Patient Generated Health Data (PGHD), Patient Portal, Radiology Information System (RIS), Picture Archiving and Communication System (PACS), Specialty EHR/IT	External data source considerations. Data could be generated by the patient, and then viewed and/or reconciled by the provider.	https://www.healthit.gov/isa/uscdi-data-class/allergies-and-intolerances
Assessment and plan of treatment	Yes	EHR, non-traditional HIT, HIE/HIN, Specialty EHR/IT	Because the data class is not well defined, Actor may not be aware of the full scope of where the data resides within their health IT/organization. Multiple clinicians may do the assessment and plan of treatment. External data source considerations.	Not well defined in the USCDI https://www.healthit.gov/isa/uscdi-data-class/assessment-and-plan-treatment

[4] More information on source systems can be found in the Workstream #3 infographic.

Data Class/Element (from EHI Definition TF document)	Is it EHI?	Source System(s) (descriptive, not vendor-based)[4]	Factors to consider in making data available (interfaces, software to access, archives, draft data)	Additional Considerations
Care team members	Yes	EHR, Billing/RCM, HIE/HIN, Patient Portal, Scheduling	Definition of Care Team is very broad and how care team is defined varies between institutions, for example some institutions may include the entire nursing staff as part of the care team where others may not. Data is often not kept up to date. External data source considerations. Care Team members may vary episodically vs. longitudinally. Depending on encounter, Care Team may include members that are no longer involved.	EHI only when linked to an identified patient as a relationship. https://www.healthit.gov/isa/uscdi-data-class/care-team-members
Clinical notes	Yes	EHR, RIS, PACS, External Messaging, Laboratory Information System (LIS), Billing/RCM, Pharmacy, Specialty EHR/IT	Audit trails could have more information about how the data was created. External data source considerations.	https://www.healthit.gov/isa/uscdi-data-class/clinical-notes
Goals	Yes	EHR, HIE/HIN, PGHD, Patient Portal	Data is not always documented in a standardized way or can be embedded into non-discrete or unstructured formats, for example screening tools. Many clinicians set goals so Actor may not be aware of the full scope of where the data resides.	https://www.healthit.gov/isa/uscdi-data-class/goals

Data Class/Element (from EHI Definition TF document)	Is it EHI?	Source System(s) (descriptive, not vendor-based)[4]	Factors to consider in making data available (interfaces, software to access, archives, draft data)	Additional Considerations
			External data source considerations.	
Health concerns	Yes	EHR, PGHD, Patient Portal, HIE/HIN	Data is not always documented in a standardized way or can be embedded into non-discrete or unstructured formats (e.g., SDOH). This data class is not well defined and is therefore subject to organizational definitions. External data source considerations.	https://www.healthit.gov/isa/uscdi-data-class/health-concerns
Immunizations	Yes	EHR, Immunization Registry, Patient Portal, PGHD, HIE/HIN	External data source considerations. There could be a discrepancy between data originating in the Actor's system versus data brought in from an external system that needs to be reconciled.	https://www.healthit.gov/isa/uscdi-data-class/immunizations
Laboratory tests, values/results	Yes	EHR, LIS, HIE/HIN, RIS, PACS, PGHD, Patient Portal	External data source considerations. Data is not always documented in a standardized way, for example a lab test can be both discrete and in PDF form (e.g., reference labs).	https://www.healthit.gov/isa/uscdi-data-class/laboratory
Patient Demographics	Yes	EHR, HIE/HIN, Patient Portal, PGHD, Scheduling, Registration, LIS, PACS, Billing/RCM	External data source considerations. Data is not always documented in a standardized way. Need for good data segmentation if certain demographic attributes are sensitive (e.g.--privacy on addresses of foster parent).	https://www.healthit.gov/isa/uscdi-data-class/patient-demographics

Data Class/Element (from EHI Definition TF document)	Is it EHI?	Source System(s) (descriptive, not vendor-based)[4]	Factors to consider in making data available (interfaces, software to access, archives, draft data)	Additional Considerations
Problems	Yes	EHR, HIE/HIN, Patient Portal, PGHD	External data source considerations.	https://www.healthit.gov/isa/uscdi-data-class/problems
Procedures	Yes	EHR, HIE/HIN, Patient Portal, PACS, LIS, RIS	External data source considerations. Data not always documented in a standardized way.	https://www.healthit.gov/isa/uscdi-data-class/procedures
Provenance	By virtue of being part of USCDI v1, provenance is EHI until 10/6/2022. That said, provenance, as metadata may not necessarily be used for decision-making and therefore is generally not part of the DRS.	Provenance is not exclusive to any single source system.	If the documentation tied to the provenance is sensitive, then provenance will be sensitive and subject to privacy and harm exceptions (e.g., behavioral health and psychosocial data). The provenance itself could also be sensitive if the data is coming from a certain healthcare team member with protections (behavioral health, etc.).	https://www.healthit.gov/isa/uscdi-data-class/provenance
Smoking status	Yes	EHR, HIE/HIN, PGHD, Patient Portal	Data is often patient contributed, which is important to have documented in the Provenance. External data source considerations.	https://www.healthit.gov/isa/uscdi-data-class/smoking-status

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Unique Device Identifier(s) for a Patient's Implantable Device(s)	Yes	EHR, including notes, Registry, HIE/HIN, PGHD, Patient Portal, Third-party app, Personal Health Record (PHR)	External data source considerations. Data might be non-discrete or in a non-standard form.	Data in Implant Registry or the invoice from the vendor on the implant will not be applicable but data documented in the medical record recording the implant is DRS. https://www.healthit.gov/isa/uscdi-data-class/medical-device-or-equipment https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system
Vital Signs	Yes	EHR, HIE/HIN, third party monitoring systems, PGHD, Patient portal, PHR, Third party app	Challenges with integrating data from home monitoring devices into source systems. External data source considerations. Data not exclusive to vitals collected by providers. For additional discussion regarding vitals collected via wearables, please see the Wearables data class.	https://www.healthit.gov/isa/uscdi-data-class/vital-signs

Data Class/Element (from EHI Definition TF document)	Is it EHI?	Source System(s) (descriptive, not vendor-based)[4]	Factors to consider in making data available (interfaces, software to access, archives, draft data)	Additional Considerations
USCDI v2 Data Classes				
Encounters	Yes	EHR, HIE/HIN, PGHD, Patient Portal, Telehealth, Care Management	Definition of Encounter is very broad (varies by organization, organizations do not always use the same definition as USCDI). Organizations need a policy that states how the organization defines Encounter. There could be a difference between the technical definition (what documentation is called an encounter within a given health IT system) and the clinically relevant definition. The way the EHR system defines encounters is probably broader than the subset of encounters that meet the definition of DRS (e.g., billing question, chart correction, CRM inquiries.) Patient portal messages from the patient can also create an encounter. External data source considerations. Data not always captured in a standardized or discrete manner.	Encounters include past encounters as well as scheduled appointments. Encounters should be defined by organization (face to face, telemedicine, telephone only, documentation only). https://www.healthit.gov/isa/uscdi-data-class/encounter-information
Diagnostic imaging	Yes	EHR, RIS, PACS, other diagnostic imaging solutions, external imaging	Organizations should inventory what meets this definition. (For purposes of this tool, the data class includes	

Data Class/Element (from EHI Definition TF document)	Is it EHI?	Source System(s) (descriptive, not vendor-based)[4]	Factors to consider in making data available (interfaces, software to access, archives, draft data)	Additional Considerations
		devices, vendor neutral archive (VNA)	not only radiology, but images related to cardiology, neurology, audiology, etc.). Actors should consider systems used in certain medical specialties that are used to capture a diagnostic image that is used for medical interpretation. Making the DICOM image available, versus providing the report, may be difficult given size and potential number of images (e.g., for an MRI or CT vs. an X-ray) and/or lack of interfaces to send to the portal or ability to send via an ONC certified FHIR API. Questions arise whether additional information (e.g., metadata) is needed to make use of the image. If yes, when possible, organizations should release and share metadata and interpretation along with the image. Organizations need to define how to handle preliminary reads and discrepancies. External data source considerations.	https://www.healthit.gov/isa/uscdi-data-class/diagnostic-imaging

Data Class/Element (from EHI Definition TF document)	Is it EHI?	Source System(s) (descriptive, not vendor-based)[4]	Factors to consider in making data available (interfaces, software to access, archives, draft data)	Additional Considerations
ONC ONDEC Data Classes				
Facility-level data (name, address, contact information, organizational identifier, etc.)	Uncertain	Facility-level data is not exclusive to any single source system.	This data class is usually publicly available when not linked to an identified patient. However, when linked to the patient, it could be considered EHI. If linked to identifiable information or embedded, the Actor should not redact it.	https://www.healthit.gov/isa/uscdi-data-class/facility-level-data
Family health history	Yes	EHR, HIE/HIN, PGHD, Patient Portal, Third-party app, PHR, Specialty EHR/IT	There is increasing functionality to link records between family members, therefore good data segmentation will be important for this data class. Information may not be discrete and exist in different places of the record. External data source considerations.	https://www.healthit.gov/isa/uscdi-data-class/family-health-history https://www.healthit.gov/curesrule/faq/which-patient-access-cases-does-preventing-harm-exception-recognize-substantial-harm https://www.healthit.gov/curesrule/faq/non-final-clinical-information-such-draft-clinical-notes-or-incomplete-test-results-are-pending
Health insurance	Yes	EHR, third party payor eligibility system,	Information may change from episode to episode.	https://www.healthit.gov/isa/uscdi-data-class/health-insurance-information

Data Class/Element (from EHI Definition TF document)	Is it EHI?	Source System(s) (descriptive, not vendor-based)[4]	Factors to consider in making data available (interfaces, software to access, archives, draft data)	Additional Considerations
		Billing/RCM, PGHD, Patient Portal	Organizations will need good data segmentation to segment self-pay data per the applicable HIPAA requirement for a covered entity to honor an individual's request not to share PHI for self-pay service. External data source considerations.	
Orders	Yes	EHR, HIE/HIN, billing/RCM, in-house pharmacy systems, Specialty EHR/IT, LIS, RIS	Orders have direct correlation to results so there is a need for good data segmentation. Consider other regulations (e.g., CLIA) that have documentation requirements. Organizations need to consider how to handle incomplete orders.	https://www.healthit.gov/isa/uscdi-data-class/orders
Observations	Yes	EHR, HIE/HIN, non-traditional HIT, Patient Portal	Many clinicians record observations, therefore Actor may not know where all such data resides within its health IT systems. Definition of observation in USCDI is unclear. Source systems across various disciplines might reference/tag observations differently. External data source considerations.	Subgroup questioned how this data class was different from Assessment and vitals. https://www.healthit.gov/isa/uscdi-data-class/observations

Data Class/Element (from EHI Definition TF document)	Is it EHI?	Source System(s) (descriptive, not vendor-based)[4]	Factors to consider in making data available (interfaces, software to access, archives, draft data)	Additional Considerations
			Observations may include images in addition to text component (e.g.--wound pictures embedded in text itself).	
Medical devices or equipment	Yes to implanted devices, No to others	EHR, Registries, third party systems, Patient Portal, PGHD, Pharmacy systems, third-party apps	Information may exist in different places (e.g.--discharge instructions) Certain DME equipment and devices (e.g.--wheelchair, compression socks) may be documented discretely as provided but not invoiced. If device supplier invoices, information may exist in financial documents and therefore EHI (e.g.--cochlear implants). Definition of medical devices in USCDI is very broad so organizations need to define what they consider a medical device. External data source considerations.	Medical devices may be EHI only when linked to an identified patient due to usage, implantation, etc. https://www.healthit.gov/isa/uscdi-data-class/medical-device-or-equipment
Social determinants of health (SDOH)	Yes	EHR, PGHD, HIE/HIN, Patient portal, referral systems, external systems, payer systems, Billing/RCM	Information may be part of patient's social history or other data classes. Information may live in different places and is not always discretely captured (e.g., can live in an H&P). Organizations may have their own specific SDOH data elements	SDOH is considered EHI if documented in the course of care or if accepted, received or stored by an actor and used for decision making. https://www.healthit.gov/isa/taxonomy/term/1801/uscdi-v2

Data Class/Element (from EHI Definition TF document)	Is it EHI?	Source System(s) (descriptive, not vendor-based)[4]	Factors to consider in making data available (interfaces, software to access, archives, draft data)	Additional Considerations
			beyond what is defined in USCDI or ICD-10. External data source considerations.	https://www.healthit.gov/isa/taxonomy/term/1836/uscdi-v2 https://www.healthit.gov/isa/taxonomy/term/1806/uscdi-v2 https://www.healthit.gov/isa/taxonomy/term/1841/uscdi-v2 https://www.healthit.gov/isa/taxonomy/term/1846/level-2
Social history	Yes	EHR, PGHD, HIE/HIN, external systems, billing/RCM, third-party apps, Patient Portal	Information is typically discrete but not always. Organizations will need the ability to segment data. SDOH can be seen as a subset of social history. External data source considerations.	https://www.healthit.gov/isa/uscdi-data-class/social-history
Specimen type	Yes	EHR, LIS, RIS, Pathology systems, Pathology equipment (data from advanced microscope taking digital picture)	Regarding specimen type and biologically-derived products, the HHS Office for Civil Rights (OCR) has made clear that while information about the specimen is considered protected health	https://www.healthit.gov/isa/taxonomy/term/2491/draft-uscdi-v3

Data Class/Element (from EHI Definition TF document)	Is it EHI?	Source System(s) (descriptive, not vendor-based)[4]	Factors to consider in making data available (interfaces, software to access, archives, draft data)	Additional Considerations
			information (PHI), the specimen itself is not considered PHI.	
Travel information	Yes	EHR, PGHD, Patient Portal, HIE/HIN, third-party app, public health systems	Could be considered social history. Information can be both episodic and longitudinal. Information can be discrete or non-discrete. External data source considerations.	Assumed EHI when linked to an individually identifiable patient. https://www.healthit.gov/isa/uscdi-data-class/travel-information
Advance directives	Yes	EHR, external systems (e.g., State Attorney General or EMS system), HIE/HIN, PGHD, Patient Portal, third-party apps	Certain components may vary depending on episode of care (e.g., Durable Power of Attorney for Health Care Decisions (DPAHC), Living Will, Do Not Resuscitate, Physician Orders for Life-Sustaining Treatment (POLST)) External data source considerations.	https://www.healthit.gov/isa/uscdi-data-class/advance-directives
Biologically derived product	Yes	Registry or external system data, HIE/HIN, EHR, organ donor network, transplant teams, PGHD, patient portal (e.g., if you are the transplant center), blood bank systems	Regarding specimen type and biologically-derived products, the HHS Office for Civil Rights (OCR) has made clear that while information about the specimen is considered protected health information (PHI), the specimen itself is not considered PHI. Certain data elements related to biologically derived product may be	https://www.healthit.gov/isa/uscdi-data-class/biologically-derived-product

Data Class/Element (from EHI Definition TF document)	Is it EHI?	Source System(s) (descriptive, not vendor-based)[4]	Factors to consider in making data available (interfaces, software to access, archives, draft data)	Additional Considerations
			captured in other data classes (e.g., vaccinations, medications, implantables). External data source considerations.	
Ophthalmic data	Yes	EHR, specialty ophthalmology information systems, PACS, RIS, HIE/HIN, Patient Portal	Consider both the discrete data from documented evaluations and the data stored externally in digital images from camera (e.g., RetCams, etc.). Digital images could be considered part of the diagnostic imaging data class. External data source considerations.	https://www.healthit.gov/isa/uscdi-data-class/ophthalmic-data
Security label	Yes, if tied to individually identifiable information	Security labels are not exclusive to any single source system.	Definition of security label is broad under USCDI and could be covered by other data classes (e.g., unique device identifiers for a patient's implantable device and biologically derived product). Facts and circumstances (e.g., who is the requestor) may play heavily into threshold question of whether security labels are considered DRS and therefore EHI.	https://www.healthit.gov/isa/uscdi-data-class/security-label https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html
Substance use	Yes	EHR, HIE/HIN, PGHD, patient portal, third-party app, pharmacy systems, Specialty EHR/IT	Information is typically discrete but could also be in narratives (e.g., social history, clinical note, and SDOH).	https://www.healthit.gov/isa/uscdi-data-class/substance-use

Data Class/Element (from EHI Definition TF document)	Is it EHI?	Source System(s) (descriptive, not vendor-based)[4]	Factors to consider in making data available (interfaces, software to access, archives, draft data)	Additional Considerations
			Organizations will need the ability to segment data. External data source considerations.	
Work information	Yes	EHR, HIE/HIN, Payer systems, PGHD, Patient Portal	Information is typically discrete but could also be in narratives (e.g., social history, clinical note). Organizations will need the ability to segment data. Certain data elements (e.g., employer, occupation) are often collected but not every data element in the data class is typically collected. Data is often changing and may vary from episode to episode. External data source considerations.	https://www.healthit.gov/isa/uscdi-data-class/work-information Employment records are not PHI
Functioning	Yes	EHR, HIE/HIN, third party tools/apps, Patient Portals, PGHD	Functioning is both episodic and longitudinal. Data may be collected and documented by both physicians and non-physicians (e.g., RN, PT/OT) Data may be summarized in reports as well as collected and documented in standardized instruments.	https://www.healthit.gov/isa/uscdi-data-class/functioning

Data Class/Element (from EHI Definition TF document)	Is it EHI?	Source System(s) (descriptive, not vendor-based)[4]	Factors to consider in making data available (interfaces, software to access, archives, draft data)	Additional Considerations
			Functioning may be covered by assessment data class. External data source considerations.	
Organization data	Yes if linked to an identifiable patient.	EHR, third party tools/apps, HIE/HIN, Scheduling system, Billing/RCM, Payor systems, referral systems	Organization data may be covered by other data classes (e.g., provenance, care team member) External data source considerations.	https://www.healthit.gov/isa/uscdi-data-class/organization
Referrals	Yes	EHR, HIE/HIN, Billing/RCM, Payor systems, third party referral systems (e.g., unite us, findhelp)	Referrals may be covered by other data classes (e.g., assessments, orders). Organizations will need the ability to segment data. External data source considerations.	https://www.healthit.gov/isa/uscdi-data-class/referral
Research data	Yes if part of DRS	EHR, clinical trial databases, HIE/HIN, FDA, registry systems (e.g., implants, devices, etc.)	Organizations will need the ability to segment data. There may be sensitive information implied even in a study name. External data source considerations.	https://www.healthit.gov/isa/uscdi-data-class/research-data
Genomics	Yes	EHR, HIE/HIN, third party apps, PHR, LIS, PACS	External data source considerations. Data may include information related to other family members (e.g., pedigree data).	https://www.healthit.gov/isa/uscdi-data-class/genomics

Data Class/Element (from EHI Definition TF document)	Is it EHI?	Source System(s) (descriptive, not vendor-based)[4]	Factors to consider in making data available (interfaces, software to access, archives, draft data)	Additional Considerations
			Information is not commonly released through the patient portal but may be released through release of information processes.	
Additional data classes discussed				
Provider-provider messages with patient-identifiable information† (e.g., chat/email inbox, sticky notes, secure messages)	Yes if part of DRS	EHR; workflow tools for providers within the EHR (e.g., chat/email inbox, sticky notes, secure messages)	Communications from provider to provider may or may not meet the definition of "designated record set," depending on the context, even if those conversations are about a patient. For example, a communication where clinicians are engaged in digital dialogue (such as by e-mail or text) but where the content of that communication is not of a type that clinicians would rely on for delivery of care, would not meet the definition of designated record set. On the other hand, a clinician-to-clinician conversation that communicates clinical information to be used in care would meet the designated record set definition and be EHI. A helpful practice to distinguish the non-designated record set digital conversations from those that are EHI could be to have a policy of purging such communications after a	

Data Class/Element (from EHI Definition TF document)	Is it EHI?	Source System(s) (descriptive, not vendor-based)[4]	Factors to consider in making data available (interfaces, software to access, archives, draft data)	Additional Considerations
			designated period of time, with an obligation on clinicians to store clinically-relevant communications somewhere in the medical record.	
Patient-provider messages†	Yes	EHR, Patient portal	Messages may be captured as encounters within EHR. Much like provider-provider messages, the content of the message itself determines whether it is considered DRS and therefore EHI versus the mode of communication itself. Important to determine whether message is from a proxy or the patient itself (e.g., parent versus adolescent).	This category is specific to messages that go directly to providers and does not include administrative messages
Patient messaging for chart corrections (even if they don't go to a provider)	Yes	EHR, PGHD, Patient Portal, HIE/HIN	Much like provider-provider messages, the content of the message itself determines whether it is considered DRS and therefore EHI versus the mode of communication itself External data source considerations.	
Wearables	Yes if using for patient care and was brought into the	EHR, PGHD, Patient Portal, third-party apps	Data comes in from external wearable devices for proactive monitoring and is not always in the Actor's control.	Doesn't need to be considered as its own data class

Data Class/Element (from EHI Definition TF document)	Is it EHI?	Source System(s) (descriptive, not vendor-based)[4]	Factors to consider in making data available (interfaces, software to access, archives, draft data)	Additional Considerations
	EHR or other health IT		Organizations may need to work with wearable vendors to understand data ownership (stewardship). If a provider is able to ingest data, they must document where the data came from or if it was observed and obtained from the patient. External data source considerations.	There may be other wearables collecting information that may be EHI that is not already identified or addressed in other data classes defined.

