U.S. Core Data for Interoperability Task Force Preliminary Promotion Model Recommendations

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10/11/19

Agenda: 10/11/19

- List of Task Force Member

- List of Task Force Meetings and Presentations

- Overarching goals of USDCI Promotion Model

- Review: Revised Summary of the Data Element Advancement Process

- Review: Draft text to address TF/HITAC Comments

- Final consensus on 10/16/19 HITAC Presentation

USCDI Task Force Members

First Name	Last Name	Organization	Organization Type
CO-CHAIRS			
Christina	Caraballo	Audacious Inquiry	Consultant/Patient Advocacy
Terrence	O'Malley	Massachusetts General Hospital	Health & Hospital Organization
MEMBERS			
Tina	Esposito	Advocate Aurora Health	Health & Hospital Organization
Valerie	Grey	New York eHealth Collaborative	Health IT Organization
Kensaku	Kawamoto	University of Utah Health	Health & Hospital Organization
Steven	Lane	Sutter Health	Health & Hospital Organization
Leslie	Lenert	Medical University of South Carolina	Health & Hospital Organization
Clem	McDonald	National Library of Medicine (NLM)	Federal
Brett	Oliver	Baptist Health	Health & Hospital Organization
Steve	Ready	Norton Healthcare	Health & Hospital Organization
Mark	Roche	Centers for Medicare & Medicaid Services (CMS)	Federal
Sasha	TerMaat	Epic	EHR Vendor
Sheryl	Turney	Anthem Blue Cross Blue Shield	Health IT Technology
ONC STAFF			
Al	Taylor	ONC	Federal
Adam	Wong	ONC	Federal

Summary of USCDI Task Force Meeting and Presentations

Meeting Date	Potential Discussion Items
May 17, 2019	• Phase 2 Kickoff • Discuss Promotion Model Guidelines
May 31, 2019	• Discuss Promotion Model Lifecycle
June 14, 2019	• Discuss Data Element Submission Criteria
June 28, 2019	• Discuss Level 1 Classification
July 12, 2019	• Discuss Level 2 Classification
July 26, 2019	• Discuss USCDI Classification • Draft recommendations
August 9, 2019	• Update and refine recommendations
September 6, 2019	• Develop Data Element Submission Form
September 17 2019	• Present draft recommendations to HITAC
September 27, 2019	• Address HITAC and industry concerns/issues
October 11, 2019	• Finalize draft recommendations
October 16, 2019	• Present final recommendations to HITAC

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Overarching Goals of USCDI Promotion Model

- Open, public, and transparent submission and promotion processes that enables and encourages diverse stakeholders and communities of interest to propose and promote new data elements/classes

- Establish lowest possible barriers for data element submission

- Establish a high bar of technical specification and testing for promotion

- Establish clear requirements for promotion enabling submitters and/or communities of interest to plan appropriately

- Establish clear requirements for promotion enabling ONC to appropriately place elements/classes into the promotion process for inclusion in USCDI

- Provide opportunities for feedback

- Provide advance notice to industry

- Ensure that newly adopted data element(s) are ready for implementation, adoption and use

Key Components of Data Element Promotion Process

- Four Classifications: **Comment** ➡ **Level 1** ➡ **Level 2** ➡ **USCDI**

- Initial data element submission ~~process to be added~~ to the Comment section of a public-facing work space open to everyone

- Subsequent and ongoing submissions for specific data elements go to the same work space to enable and encourage the contribution of additional information as it becomes available to help advance data element(s)

- Promotion is based on meeting specific benchmarks
- Ongoing review by ONC to determine the appropriate classification
- Frequent notification of classification changes and opportunities for feedback
- Final evaluation by ONC with recommendations from HITAC to assess strategic priority and burden to implement

NEW DRAFT: ONC Role: Stalled Data Elements

The TF concluded that data elements that have neither advanced nor received additional submissions for an extended period of time should be removed from Level 1 and/or Level 2. The TF recommends that ONC institute the following process:

- Provide a warning to submitter(s)/sponsor(s) indicating that data element(s) that have not advanced to the next level AND have not received additional submissions during the ~~average~~ expected advancement time are at risk for reassignment to a "stalled" category

- Place data elements that have neither advanced NOR received additional submissions in twice the average advancement time into the "Stalled Data Element" category

- Re-introduce the data element following submission of new information that indicates that the element is more likely to advance

Public/Submitter Feedback in Promotion Process

The TF was concerned that there was not an explicit process and timeline for obtaining public and data-element-submitter feedback on the readiness, applicability, or prioritization of a proposed data elements/classes. The TF recommends:

- Solicit public comment quarterly to coincide with updating the status of each data element in the process.

- Specifically seek comments on the maturity, adequacy, and adoption levels of a proposed data class/element.

- Specifically seek comments on the maturity and applicability of use cases, workflows, and value propositions which may be more broadly applicable ~~of~~ for a particular data class/element.

Proposal to Shorten the Promotion Process

HITAC members have indicated that the proposed Promotion Process is too long slow. In the ONC proposed model advancement from one level to the next level requires a minimum of one year. The TF believes that progress through Level 2 should be shortened as much as possible and recommends:

- Promotion occurs solely on the basis of meeting the required benchmarks without a minimum required promotion cycle time. (See Proposed New Promotion Model and Benchmarks slide)
- Decouple the promotion process from the Standards Advancement Process.
- Publish the status of all data elements in the Data Element Promotion process quarterly in conjunction with a public comment period (See Public/Submitter Feedback in Promotion Process Slide)

DRAFT: Introduction to Promotion Process Benchmarks

The TF recommends that ONC uses the following benchmarks to determine the promotion of data elements/classes. These benchmarks would also serve as guidance to data element sponsors. The benchmarks are discussed in four sections:

- Administrative requirements
- Promotion from Comment to Level 1
- Promotion from Level 1 to Level 2
- Promotion from Level 2 to USCDI

Promotion Model Benchmarks-Administrative

The TF recommends the following administrative expectations for data element sponsors:

- Complete submission form
- Adhere to guidance regarding acceptable standards, code sets and value sets
- Provide sufficient additional information to inform re-leveling
- Respond to ONC feedback regarding submissions required for further promotion

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Promotion Model Benchmarks-Comment to Level 1

The TF recommends the following criteria must be met to move from Comment to Level 1:

- Justification exists for data element capture and national exchange
- There are applicable use cases(s) involving this data element
- There are projects currently underway using this data element
- This data element is currently captured discreetly in one or more electronic systems with preliminary understanding of how often and how the data element is collected. (e.g., free text, coded data element)
- A content standard exists for this data element
- Standard is supported by an established SDO that uses a public balloting process
- An implementation guide exists that contains this data element
- There have been pilots, "Connect-a-thon"® testing, and/or production use of this data element
- There has been sufficient testing to satisfactorily meet the requirements of the proposed use case(s) in a "several" (more than 2?) applicable settings

Promotion Model Benchmarks-Level 1 to Level 2

The TF recommends the following criteria must be met to move from Level 1 to Level 2:

- The exchange of the data element(s) has been successfully tested at scale among several distinct/different EHR platforms/systems in a production environment using the previously cited content and transport standards
- Sufficient testing to satisfactorily meet the requirements of the proposed use case(s) in a~~a~~ "most" ("the majority of" ?) applicable settings

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The TF recommends the following criteria must be met to move from Level 2 to USCDI:

- Technical Maturity - The exchange of the data element(s) has been successfully tested at scale between most distinct/different EHR platforms/systems in a production environment sufficient to establish feasibility for the majority of anticipated users

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- Nationwide Applicability
  - » Provide evidence, if applicable, for the impact of the data element(s) on healthcare costs (add "quaity" ?) for individuals or populations
  - » There is an estimate of the number of stakeholders who would use this data element/class
  - » All known restrictions potentially limiting the standardization of this data element (e.g. proprietary codes, value sets) have been (noted) addressed
  - » All known restrictions potentially limiting the use of this data element (e.g. licensing and fees) have been (noted) addressed
  - » There is an estimate of the overall burden to implement (e.g., clinician data capture, patient data submission, health IT upgrade costs)

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Size of Data Class vs. Complexity of Use Cases

The TF discussed the potential burden on industry of having to implement large data classes as part of USCDI (e.g., lab results, imaging results, medications). Size alone was felt to be less of a concern as long as the data class was clearly structured and used exchanged using widely accepted standards. However, data that support multiple, complex use cases may present more significant challenges to implementers.

The TF recommends that ONC adds data use in multiple complex use cases in its final review as a criterion to assess the burden to of implementation.

DRAFT: Harmonization of Data Elements

The TF discussed the issue of harmonization of data elements that express similar concepts or that require nuanced definitions to work satisfactorily in different use cases. There is a balance between parsimony and subtle but important variation. Harmonization at the earliest possible step in the promotion process is ~~ideal~~ desirable.

The TF makes the following recommendations:

- Develop a process for reviewing submitted data elements to identify those that express similar concepts
- Develop a process to determine whether the elements should be merged or remain separate

DRAFT: ONC Role: Establish Process for Data Element Harmonization

The TF discussed the risks and benefits of data harmonization as part of the Data Element Promotion Model and recognized the potential advantage of harmonization to reduce semantic variability and create larger communities of interest to advance ~~the~~ proposed data elements. On the other hand, there may be semantic nuances that are needed for different use cases ~~with~~ as defined by different communities of interest.

The TF recommends:

As part of its annual review of the Promotion Process, ONC should assess whether guidance is necessary regarding the grouping or un-grouping of data elements, and whether ONC should direct a process to re-configure data classes.

Replace with slide 18

Final Review Data Elements Proposed for USCDI

The TF discussed the process for the final review of data elements that have met all of the benchmarks for advancement into USCDI.

TF recommendations:

- Review data elements for:
    - Technical maturity
    - Industry readiness and alignment with identified national priorities
    - Barriers to implementation, adoption and use
- Process:
    - ONC provides the HITAC ~~and RCE~~ with a proposed draft of data elements that meet the criteria for promotion into USCDI based upon
    - HITAC ~~& RCE each~~ provides ONC with recommendations regarding the proposed draft
    - ONC publishes final decisions taking into consideration public comment and HITAC recommendations ~~and RCE recommendations~~

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Proposal for Annual Review of Promotion Model

The TF raised concerns that there is still a lot of uncertainty and this process should be re-evaluated to make necessary adjustments.

TF Recommendation:

- ONC conducts an annual review of the Data Element Promotion Model, reports the results and requests public comments
- Specific issues to include (but not limited to)
    - Volume of submissions, advancements by level, and failures to advance
    - Time for advancement to next level
    - Aggregate time from submission to USCDI
    - Harmonization of data elements
    - High priority data elements found to be missing
    - High priority data elements submitted, volume of all submissions, advancements by level, and failures to advance
    - Need to prioritize promotion of qualified data elements to USCDI vs. excessive volume

Draft: Annual Review: Who will do the upfront work

TF has raised concerns about the sustainability of the different business models that underpin creation, testing, and maintenance of standards and value sets which underlie the USCDI Data Element Promotion Process.

The TF recommends:

- As part of the Annual Review of the Promotion Process, ONC assesses the adequacy of financial support for entities that create, support, test, and maintain important interoperability standards, code sets and value sets.

- If ONC finds gaps that may delay or imperil activities that are essential for nationwide interoperability, it will address these gaps using available remedies.

Draft: Ambiguous Prioritization of Data Elements

The TF was concerned about the potential need for a "data element prioritization" step before promotion to USCDI. The TF makes the following recommendations:

- If in its annual review of the Data Element Promotion Model ONC finds that there are a large number of data elements eligible for simultaneous promotion to USCDI, ONC should establish a prioritization process to reduce the likelihood of overwhelming both providers and the vendor community with new requirements
- The prioritization process should consider, among other issues,
  - the extent of applicability,
  - the presence of clearly defined use cases and workflows associated with the data class/element.
  - clear value propositions for adopting the data class/element

DRAFT: Potential ONC Role: Promote Submission and Advancement of High Priority Data Elements

- The TF raised a concern that a promotion process that relies heavily on the private sector to identify and advance data elements of value may not necessarily identify and advance data elements that address national priorities

- As part of its annual review of the Promotion Process, if ONC identifies that one or more high priority data elements are missing from the Promotion Process then it will use the tools at its disposal to facilitate the submission and advancement of missing priority data elements.

To make a comment please call:

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*(once connected, press "*1" to speak)*

All public comments will be limited to three minutes.

You may enter a comment in the
"Public Comment" field below this presentation.

Or, email your public comment to onc-hitac@accelsolutionsllc.com.

Written comments will not be read at this time, but they will be delivered to members of the Workgroup and made part of the Public Record.

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Health IT Advisory Committee

Thank you
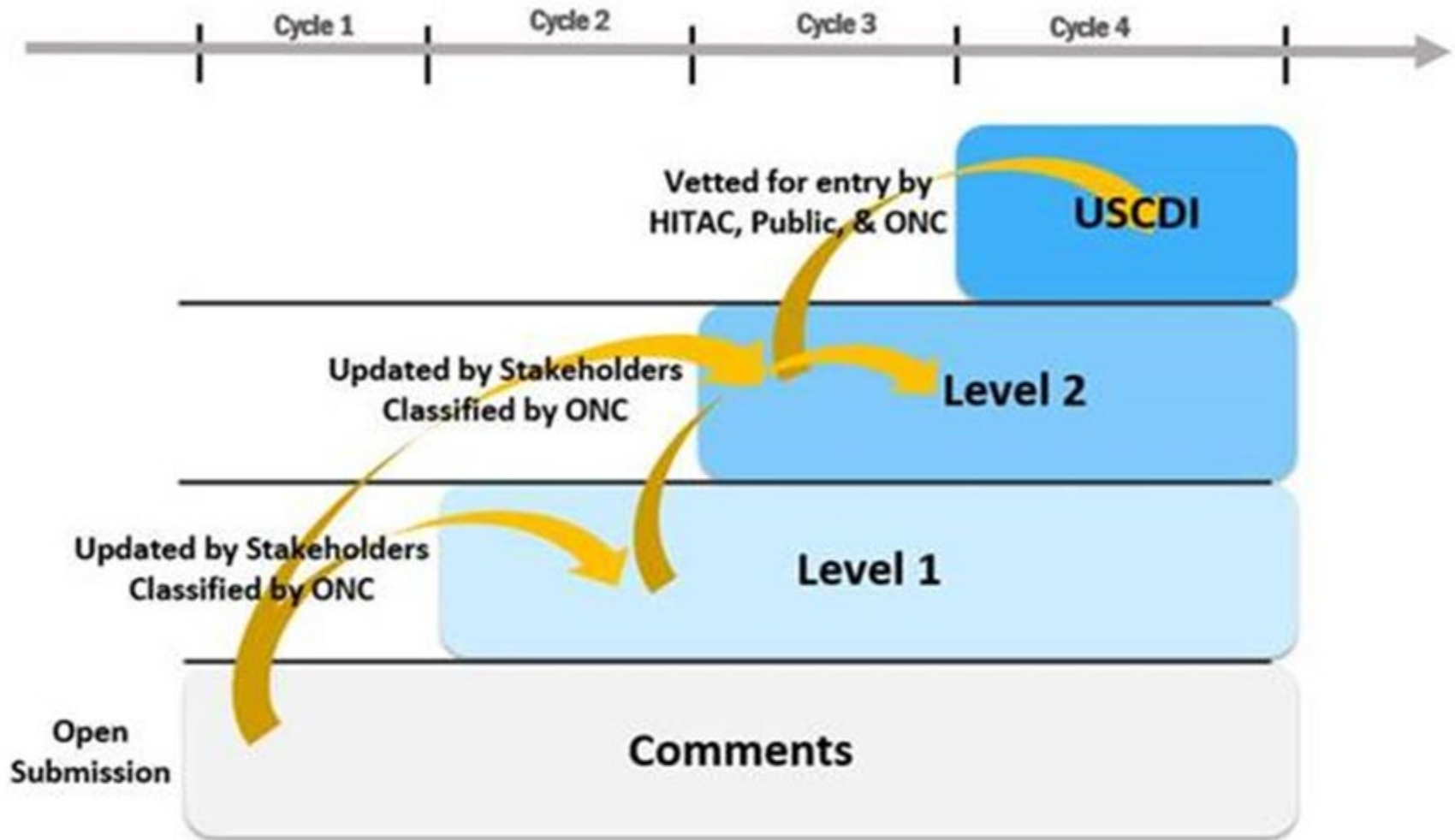
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USCDI Task Force Charge

- **Overarching Charge:** Review and provide feedback on the U.S. Core Data for Interoperability (USCDI) Data Element Promotion Model.

- **Specific Charge:** Provide recommendations on the following:
  - » Promotion Model Lifecycle for Submitted Data Elements
  - » Data Element Submission Information
  - » Data Element Promotion Criteria

- **Supplemental Charge:** Discuss additional defining criteria as needed

- **Informal Charge:** "Put meat on the bones"
  - » Add details
  - » Think through the process from the "User's" perspective

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Detailed Presentation

- Level advancement

  » Criteria to move from Comment to Level 1

  » Criteria to move from Level 1 to Level 2

  » Criteria to move from Level 2 to USCDI

- Criteria to move to USCDI

  » Role of HITAC

  » Role of ONC

- Submission process / Submission form

- User's Guide

Item	Use of Criterion	Criterion Required for Advancement	Level if Criterion is Missing	Comments/Concerns for ONC's Consideration
Justification exists for data element capture and national exchange	Estimate of potential significance	n/a	n/a	Helps determine potential significance of data element
There are applicable Use Cases(s) involving this data element	Clarification	Required for Level 1	Comment	Helps determine potential significance of data element
There are projects currently underway using this data element	Clarification	Required for Level 1	Comment	Helps determine potential significance of data element and potential for promotion

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Item	Use of Criterion	Criterion Required for Advancement	Level if Criterion is Missing	Comments/Concerns for ONC's Consideration
This data element is currently captured electronically in one or more electronic systems	Feasibility of capture	Required for Level 1	Comment	- Any format is acceptable - This demonstrates that someone wants the data electronically
Regarding the systems cited above, how often is the data element colleted and how is the data element collected? (free text, coded data element)	Clarification of feasibility	Required for level 1	Comment	- Important if these data elements are being collected and in what format

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Item	Use of Criterion	Criterion Required for Advancement	Level if Criterion is Missing	Comments/Concerns for ONC's Consideration
A content standard exists for this data element	Technical maturity, feasibility	required for Level 1	Comment	- NOTE: this requires only a content standard OR the existence of data element in an implementation guide. Not both. - Indicate if the data element is "captured" in discrete field(s), is encoded, or if it is typically in free text.
An implementation guide exists that contains this data element	Technical maturity, feasibility	required for Level 1	Comment	- NOTE: As above, only a content standard OR the existence of the data element in an implementation guide is required. Not both.
There have been pilots, "Connect-a-thon" ® testing, or production use of this data element	Technical maturity, feasibility	required for Level 1	Comment	- Demonstrates that an SDO has initiated work and interest. At an early stage..

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USCDI Promotion Criteria: Level 1 to Level 2

Item	Use of Criterion	Criterion Required for Advancement	Level if Criterion is Missing	Comments/Concerns for ONC's Consideration
The exchange of this data element has been successfully tested at scale between two or more distinct/different EHR platform systems in a production environment	Technical maturity, feasibility	Required for Level 2	Level 1	- "unrelated", "different platform", "technically unrelated systems", "distinct EHR platform systems", "commercially separate"; what about registries?

USCDI Promotion Criteria: Level 2 to USCDI

Item	Use of Criterion	Criterion Required for Advancement	Level if Criterion is Missing	Comments/Concerns for ONC's Consideration
The exchange of this data element been successfully tested at scale between four or more distinct/different EHR platform systems in a production environment	Technical maturity	Required for USCDI level	Level 2	We recomment that this item is both about how much the data element has been adopted/scaled and its technical maturity and readiness. (e.g., largest vendors sharing the data vs. smaller specialty systems.)

USCDI Promotion Criteria: HITAC and ONC Review

Item	Use of Criterion	Criterion Required for Advancement	Level if Criterion is Missing	Comments/Concerns for ONC's Consideration
Evidence exists for the impact of this data element on healthcare costs for individuals or populations	significance, strategic value	Facilitates advancement to USCDI level	Level 2	Submitter to present best argument regarding impact
There is an estimate of the number of providers who would use this data element/class	significance, strategic value	Facilitates advancement to USCDI level	Level 2	Submitter to present best argument regarding impact

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Item	Use of Criterion	Criterion Required for Advancement	Level if Criterion is Missing	Comments/Concerns for ONC's Consideration
The following restrictions potentially limit the standardization of this data element	barriers to deployment	Presence might impede advancement to USCDI level		
The following restrictions potentially limit the use of this data element.	barriers to deployment	Presence might impede advancement to USCDI level		
There is an estimate of the overall burden to implement	barriers to deployment	Presence might impede advancement to USCDI level		Submitter to provide estimates from a variety of viewpoints such as patient, provider, vendors, society, other stakeholders. Give consideration to public comments prior to clearance for USCDI

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USCDI Promotion Criteria: Review by HITAC

- HITAC will recommend for or against promotion based on a data element achieving technical maturity and weighing the balance between its value to advance the quadruple aim versus the costs and barriers to deployment.

- To fulfill this responsibility, the HITAC will:

  » Review the evidence for technical maturity

  » Review the evidence for the impact of this data element on healthcare costs for individuals or populations

  » Review the estimate of the number of stakeholders (providers, patients, researchers, public health, etc.) who would use this data element/class

  » Assess the significance of restrictions that might potentially limit the use of this data element.

  » Assess the overall burden to implement

USCDI Promotion Criteria: Review by ONC

- Review HITAC recommendations
- Duplicate HITAC review as needed
- Review public comments
- Make final determination on advancement (benefit vs burden)
- Make determination for inclusion in Requirements for Certification and Maintenance of Certification
- Set timeline for industry compliance

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Estimated Process Time: Each Cycle = 1 Year

- Shortest
  - Level 2 to USCDI: 1 cycle
  - Level 1 to USCDI: 2 cycles
  - Comment to USCDI: 3 cycles

- Longest before required resubmission
  - Level 2 to USCDI: 3 cycle
  - Level 1 to USCDI: 4 cycles
  - Comment to USCDI: 5 cycles

Submission Process

- Process open to anyone

- Submit single elements or entire data classes

- Submissions made electronically to an open, searchable, public resource maintained by ONC

- Require sufficient information in the application form to enable ONC to easily and accurately place the submission in the proper level

- Require the submitter to review the public resource to identify if similar or related elements have been previously submitted

- Require the submitter to provide updated information as available to inform ONC's leveling decision

- Submission Form includes all items required by ONC for leveling

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Submission Form

Five Sections

I. Identification of Data Element
II. Justification for Data Element promotion
III. Extent of use and technical specification
IV. Potential impact
V. Potential barriers

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Submission Form Detail

Section I: Identification of Data Element

- Name of Proposer
- Contact Information of Proposer
- Data Element Name
- Data Element Description
- Related data elements
- Proposed Data Class (Optional)
- Do similar data elements currently reside in the UDA? Y/N/Ukn
  - » If yes, please explain why this data element should be considered separately

Submission Form Detail continued

Section II: Justification for Data Element Promotion

- Explain why this data element should be captured and available for national exchange
- Briefly describe a representative use case

Section III: Extent of Use and Technical Specification

- Is this data element currently captured electronically in any electronic system?
  - » If yes, please cite known systems that capture this data element and briefly describe the format and frequency of capture
- Does a content standard exist for citing this data element?
  - » If yes, please provide a link to the applicable standard

Submission Form Detail continued

Section III: Extent of Use and Technical Specification continued

- Does an implementation guide exist that contains this data element?
  - » If yes, please provide a link to the IG
- Has there been any "Connect-a-thon"® testing, pilots, or production use of the data element?
  - » If yes, please provide links to artifacts describing its use
- Has the exchange of this data element been successfully tested between two or more different platforms in a production environment?
  - » If yes, please provide links to supporting artifacts
- Has the exchange of this data element been successfully tested at scale between four or more different platforms in a production environment?

Submission Form Detail continued

Section IV: Potential Impact

- Is there evidence for the impact of this data element on healthcare costs for individuals or populations?
  - » If yes, please provide supporting data
- Please provide an estimate of the potential number of users of this data element and the basis of the estimate.

Section V: Potential Barriers

- Are there any restrictions on the standardization of this data element (e.g. proprietary code)?
- Are there any restrictions on the use of this data element (e.g. licensing, user fees)?
- Please provide an overall estimate of burden to implement

Leveling and Promotion

- ONC assumes the following responsibilities:

  - Assess accuracy of submission

  - Identify the need for and request supplemental information

  - Display submissions in ways that enable other interested parties to form "communities of interest" and contribute to the promotion of a data element/class. (ISA and "Proving Ground" as potential models)

- ONC provides oversight of the Promotion Process by:

  - Monitoring the progress (or lack thereof) of data elements/classes

  - Identifying high priority data elements/classes that might need additional resources to advance

  - Regularly announcing leveling decisions

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Summary of Proposed Responsibilities: Submitter and ONC

- Submitter: initiate process

  » Complete Data Element Submission/Application process

  » Review data base for similar or related data elements

  » Provide updated information to inform levelling decisions

- ONC: create, revise and maintain data element promotion process

  » Provide examples of successful applications and review submissions

  » Publish data element in searchable, public platform

  » Adjudicate leveling/advancement decisions in a timely manner

  » Assist/provide guidance to submitters and communities of interest to submit additional submission information as needed

  » Provide oversight of data element progress

  » Identify data elements with national strategic importance (quadruple aim), identify gaps, develop strategies to add/advance data elements

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Flagged Issues for Further/Future Discussion

- Should there be a process to identify high priority data elements that are either missing or not advancing?

  » Does ONC have a role to identify high priority data elements?

  » Does ONC have a role to propose specific data elements? Or is this best left to the Submission Process?

  » Does ONC have a role to facilitate the advancement of specific data elements? Or is this best left to the "market"?

- Should there be a process for harmonizing similar or related data elements?

- Would additional tools facilitate this process (e.g. a "sandbox", "proving ground", frequent summary updates of data element progress)?

- How does this process apply to "bulk" data classes (e.g.: lab tests, results, medications)? Is there a limit to the number of data elements that can advance at one time?