Interoperability Standards Workgroup

Phase 1 – Recommendations on Draft USCDI Version 3

Steven Lane, Workgroup Co-chair

Arien Malec, Workgroup Co-chair

April 13, 2022

Workgroup Recommendations and Report

- Membership

- Background

- Charges

- Methods/Approach

- Phase 1 Recommendations

- Recommendations for Future ONC Focus

- Remaining WG Work

Interoperability Standards Workgroup Roster

Name	Organization	Name	Organization
Steven Lane (Co-Chair)	Sutter Health	Jim Jirjis	HCA Healthcare
Arien Malec (Co-Chair)	Change Healthcare	Kensaku Kawamoto	University of Utah Health
Kelly Aldrich	Vanderbilt University	Leslie Lenert	Medical University of South Carolina
Hans Buitendijk	Cerner	Hung S. Luu	Children's Health
Thomas Cantilina	DOD	David McCallie	Individual
Christina Caraballo	HIMSS	Clem McDonald	National Library of Medicine
Grace Cordovano	Enlightening Results	Mark Savage	Savage & Savage LLC
Steven Eichner	Texas Dept. of State Health Services	Michelle Schreiber	CMS
Adi Gundlapalli	CDC	Abby Sears	OCHIN
Rajesh Godavarthi	MCG Health	Ram Sriram	NIST

USCDI

Draft USCDI Version 3

Health Information Technology Advisory Committee
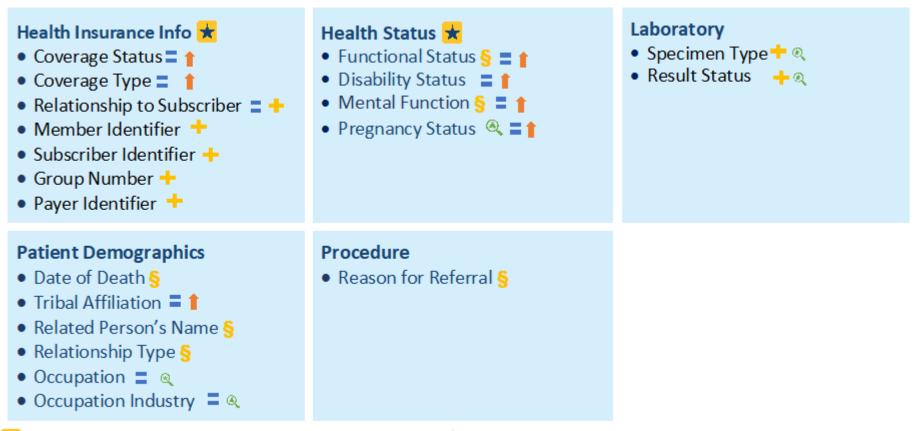The Office of the National Coordinator for Health Information Technology

Allergies and Intolerances
- Substance (Medication)
- Substance (Drug Class)
- Reaction

Assessment and Plan of Treatment
- Assessment and Plan of Treatment
- SDOH Assessment

Care Team Member(s)
- Care Team Member Name
- Care Team Member Identifier
- Care Team Member Role
- Care Team Member Location
- Care Team Member Telecom

Clinical Notes
- Consultation Note
- Discharge Summary Note
- History & Physical
- Procedure Note
- Progress Note

Clinical Tests
- Clinical Test
- Clinical Test Result/Report

Diagnostic Imaging
- Diagnostic Imaging Test
- Diagnostic Imaging Report

Encounter Information
- Encounter Type
- Encounter Diagnosis
- Encounter Time
- Encounter Location
- Encounter Disposition

Goals
- Patient Goals
- SDOH Goals

Health Insurance Information ⭐
- Coverage Status ⭐
- Coverage Type ⭐
- Relationship to Subscriber ⭐
- Member Identifier ⭐
- Subscriber Identifier ⭐
- Group Number ⭐
- Payer Identifier ⭐

Health Status
- Health Concerns ➡
- Functional Status ⭐
- Disability Status ⭐
- Mental Function ⭐
- Pregnancy Status ⭐
- Smoking Status ➡

Immunizations
- Immunizations

Laboratory
- Test
- Values/Results
- Specimen Type ⭐
- Result Status ⭐

Medications
- Medications

Patient Demographics
- First Name
- Last Name
- Middle Name (Including middle initial)
- Suffix
- Previous Name
- Date of Birth
- Date of Death ⭐
- Race
- Ethnicity
- Tribal Affiliation ⭐
- Sex (Assigned at Birth)
- Sexual Orientation
- Gender Identity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address
- Related Person's Name ⭐
- Related Person's Relationship ⭐
- Occupation ⭐
- Occupation Industry ⭐

Problems
- Problems
- SDOH Problems/Health Concerns
- Date of Diagnosis
- Date of Resolution

Procedures
- Procedures
- SDOH Interventions
- Reason for Referral ⭐

Provenance
- Author Organization
- Author Time Stamp

Unique Device Identifier(s) for a Patient's Implantable Device(s)
- Unique Device Identifier(s) for a patient's implantable device(s)

Vital Signs
- Systolic blood pressure
- Diastolic blood pressure
- Heart Rate
- Respiratory rate
- Body temperature
- Body height
- Body weight
- Pulse oximetry
- Inhaled oxygen concentration
- BMI Percentile (2 - 20 years)
- Weight-for-length Percentile (Birth - 36 Months)
- Head Occipital-frontal Circumference Percentile (Birth - 36 Months)

⭐ New Data Classes and Elements ➡ Data Element Reclassified

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New Data Classes and Elements in Draft USCDI v3

Health Insurance Info ⭐
- Coverage Status
- Coverage Type
- Relationship to Subscriber
- Member Identifier
- Subscriber Identifier
- Group Number
- Payer Identifier

Health Status ⭐
- Functional Status
- Disability Status
- Mental Function
- Pregnancy Status

Laboratory
- Specimen Type
- Result Status

Patient Demographics
- Date of Death
- Tribal Affiliation
- Related Person's Name
- Relationship Type
- Occupation
- Occupation Industry

Procedure
- Reason for Referral

⭐ New Data Classes   ＝ Equity Based   ⬆ Underserved   🔍 Public Health   ✚ Add'l USCDI Needs   § ONC Cert

Draft USCDI v3 Public Feedback Period

General Feedback on Draft USCDI v3

1. Data class and element improvements:
   - Data class and element names and definitions?
   - Examples or value sets to better define scope of data elements?
2. Other data elements that should be added to USCDI v3?
3. Barriers to development, implementation, or use of any data elements that would warrant not including them in USCDI v3?

Specific Feedback on several data elements:

1. Sex assigned at birth
   - Alignment with Gender Harmony "Recorded Sex or Gender"?
2. Gender Identity
   - Alignment of ONC value set with that of Gender Harmony project?
3. Current and Previous Address (Patient Address)
   - Use of Unified Specification for Address in Health Care (Project US@)?

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Interoperability Standards Workgroup Charge

Overarching charge: Review and provide recommendations on the Draft USCDI Version 3 and other interoperability standards

Specific charges: <u>**Due**</u>

    1   **Evaluate Draft USCDI v3 and provide HITAC with recommendations for:**   **April 13, 2022**
         1a - New data classes and elements from Draft USCDI v3
         1b - Level 2 data classes and elements not included in Draft USCDI v3

    2   **Identify opportunities to update the ONC Interoperability**   **June 16, 2022**
       Standards Advisory (ISA) to address the HITAC priority uses of health IT,
       including related standards and implementation specifications.

Additional Areas of Focus

Gender Harmony Overview (Sex and Gender data elements)

- Carol Macumber, MS, Clinical Architecture
- Rob McClure, MD, MD Partners

Patient Address/Project US@ (Current and Previous Address)

- Carmen Smiley, IT Specialist ONC

Disability Rights Education and Defense Fund

- Silvia Yee, BM, MA, LLB, Disability Rights Education and Defense Fund
- Bonnielin Swenor, PhD, MPH, Johns Hopkins Disability Health Research Center
- Megan A. Morris, PhD, MPH, CCC-SLP, Disability Equity Collaborative

MaxMD (Disability and Functioning)

- Matt Elrod PT, DPT, Med, MaxMD

Med Allies (Functional Status Assessments)

- Holly Miller, MD, MBA, FHIMSS
- Terry O'Malley, MD

Phase 1 Recommendations

- New data classes and elements included in Draft USCDI v3
  - Recommendations 1-12

- Level 2 data elements not included in Draft USCDI v3
  - Recommendations 13-16

- Data elements from prior versions of USCDI
  - Recommendations 17-23

- Recommendations for future ONC focus
  - Recommendations A-E

Phase 1 Recommendations -

Data Elements Included in Draft USCDI v3

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Phase 1 Recommendations - Data Elements Included in Draft USCDI v3

The ISWG supports the addition of all the new data elements and data classes included in Draft USCDI v3

The ISWG makes the following recommendations on specific data elements and classes

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Phase 1 Recommendations - Data Elements Included in Draft USCDI v3

IS-WG-2022-Phase 1_Recommendation 01

Rename the Health Status data class as Health Status/Assessments and specify LOINC as the applicable vocabulary standard

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Phase 1 Recommendations - Data Elements Included in Draft USCDI v3

IS-WG-2022-Phase 1_Recommendation 02

Leave the Health Concerns data element in the current (USCDI v2) Health Concerns data class as opposed to moving into the new Health Status data class

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Phase 1 Recommendations - Data Elements Included in Draft USCDI v3

IS-WG-2022-Phase 1_Recommendation 03

Establish a robust set of LOINC coded terms representing Health Status/Assessment data elements Functional Status, Disability Status and Mental/Cognitive Status

- These data elements should represent, at a minimum, structured, standardized assessments with associated LOINC codes
- Appendix B contains seven recommended questions for Disability Status, self-reported by the individual, and suggested example terms and codes for Mental/Cognitive Status and Functional Status
- The data element labeled "Mental Function" in Draft USCDI v3 should be labeled "Mental/Cognitive Status".
- Work with stakeholders to identify additional terms for these data elements (learning disability, mental disability, autism/social disability, and caregivers' disability status)

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Phase 1 Recommendations - Data Elements Included in Draft USCDI v3

IS-WG-2022-Phase 1_Recommendation 03 (continued)

Suggested Questions/LOINC terms for Disability Status

American Community Survey (U.S. Census)

- Deaf or serious difficulty hearing?
- Blind or difficulty seeing, even with glasses?
- Serious difficulty walking or climbing stairs?
- Difficulty concentrating, remembering, or making decisions?
- Difficulty dressing or bathing?
- Difficulty doing errands alone such as visiting a doctor's office or shopping?

Washington Group on Disability Statistics

- Difficulty communicating using your usual language?

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Phase 1 Recommendations -
Data Elements Included in Draft USCDI v3

IS-WG-2022-Phase 1_Recommendation 03 (continued)

Suggested terms for Mental/Cognitive Status

- AUDIT-C - LOINC 72109-2
- DAST-10 - LOINC 82666-9
- GAD-7 – LOINC 69737-5
- GDS – LOINC 48542-5
- GCS – LOINC 35088-4
- HARK - LOINC 76499-3
- MACE – SNOMED CT 273249006
- MMSE - LOINC 72107-6

- MOCA – LOINC 72133-2
- Neuropsych batteries – SNOMED CT (e.g., LURIA 273581001)
- PHQ 2 – LOINC 55757-9
- PHQ 9 – LOINC 44249-1
- SLUMS – LOINC 71492-6
- TAPS - LOINC 96845-3

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Phase 1 Recommendations - Data Elements Included in Draft USCDI v3

IS-WG-2022-Phase 1_Recommendation 03 (continued)

Suggested terms for Functional Status:

- ADLs/IADLs – LOINC 57048-1
- Barthel index – LOINC 96762-0
- Morse Fall Scale – LOINC 59460-6
- Braden Pressure Ulcer Risk scale – LOINC 81636-3
- Self-care activities- functional ability panel – LOINC 83180-0
- Timed Up and Go Test – LOINC 89422-0
- Functional assessment of Incontinence Therapy-Fecal – LOINC 70831-3
- Functional Assessment of Incontinence Therapy-Urinary – LOINC 70837-0
- Norton scale – LOINC 75248-5
- Karnofsky Performance Scale – LOINC 89243-0
- Functional Assessment of Chronic Illness Therapy (FACIT) – LOINC 70504-6
- Visual Analog Scale – LOINC 38214-3
- Brief Pain Inventory – LOINC 77564
- Functional Capacity Evaluation LOINC 47420-5

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Phase 1 Recommendations - Data Elements Included in Draft USCDI v3

IS-WG-2022-Phase 1_Recommendation 04

Consider referencing the International Classification of Functioning, Disability, and Health (ICF) model as a value set applicable to the Health Status/Assessments data class

- ICF uses a hierarchy of 4 categories
  - Body Function
  - Body Structure
  - Activities and Participation
  - Environmental Factors
    - ICF supported by CMS/LTPAC, PROMIS, AM-PAC

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Phase 1 Recommendations - Data Elements Included in Draft USCDI v3

IS-WG-2022-Phase 1_Recommendation 05

Specify that the data elements in the Health Status/Assessments data class may be populated with patient generated health data by either or both:

- Accommodating self-assessments with appropriate LOINC codes, or
- Adding the Author data element to the Provenance data class to indicate that the source of assessment data is the individual

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Phase 1 Recommendations -
Data Elements Included in Draft USCDI v3

IS-WG-2022-Phase 1_Recommendation 06

Clarify that the intent of the Related Person and Related Person's Relationship data elements is to identify relationships for medical record linkage, patient matching, and similar demographic purposes

- Distinguish this from the roles of care team members

Phase 1 Recommendations -
Data Elements Included in Draft USCDI v3

IS-WG-2022-Phase 1_Recommendation 07

Add a value capturing "intent to become pregnant" to the Pregnancy Status data element within the Health Status data class

- This is in addition to pregnant, not pregnant, and unknown terms in Draft USCDI v3

Phase 1 Recommendations - Data Elements Included in Draft USCDI v3

IS-WG-2022-Phase 1_Recommendation 08

Provide clarification of the intent for the Reason for Referral data element within the Procedures data class with appropriate examples

- Recommend clarity regarding whether the collection of this data element would be required by all certified HIT
- *This clarification is needed across all USCDI*

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Phase 1 Recommendations -
Data Elements Included in Draft USCDI v3

IS-WG-2022-Phase 1_Recommendation 09

Change the name of the Reason for Referral data element within the Procedures data class to Reason/Indication for Referral or Procedure

- This alternative name would better describe the appropriate purpose and scope of the data element

Phase 1 Recommendations -
Data Elements Included in Draft USCDI v3

IS-WG-2022-Phase 1_Recommendation 10

Specify SNOMED-CT as an applicable vocabulary standard for the Specimen Type data element in the Laboratory data class

- ONC should also consider specifying the following value sets defined by HL7®
  - HL7VS-specimenType
  - FHIR v2 Specimen Types

Phase 1 Recommendations - Data Elements Included in Draft USCDI v3

IS-WG-2022-Phase 1_Recommendation 11

Specify the applicable vocabulary standard for the Laboratory Values/Results data element as SNOMED CT for qualitative lab result, and UCUM for numerical results

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Phase 1 Recommendations -
Data Elements Included in Draft USCDI v3

IS-WG-2022-Phase 1_Recommendation 12

Define the initial scope of the Health Insurance Information data class and its component data elements as the overall primary and secondary coverage for the individual

- In some cases, health insurance information and benefit for a particular encounter or claim may be different from the individual's overall insurance coverage (e.g., in the case of worker's comp encounters)
- ONC should work with stakeholders, (X12, NCPDP, HL7) to align the minimum initial vocabulary and value set for Coverage Type and to extend this over time

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Phase 1 Recommendations -

Level 2 Data Elements Not Included in Draft USCDI v3

Phase 1 Recommendations - Level 2 Data Elements Not Included in Draft USCDI v3

IS-WG-2022-Phase 1_Recommendation 13

Add the data element Author to the Provenance data class

- This data element is especially relevant in conjunction with patient-generated health data (PGHD) and patient-reported outcomes (PROs)
- We recommend, at the very least, that Author is used for the following data elements that typically represent self-reported data and thus warrant identifying the individual as the author when applicable:
  - Race/Ethnicity
  - Gender Identity
  - Sexual Orientation
  - Disability Status
  - Pregnancy Status

Phase 1 Recommendations - Level 2 Data Elements Not Included in Draft USCDI v3

IS-WG-2022-Phase 1_Recommendation 14

Add the following Level 2 data elements to USCDI v3

- Family Health History
- Problems: Date of Onset
- Allergies: Substance (non-medication)
- Allergies: Substance (food)
- Travel Information
- The scope and definition for these data elements should include both clinical observations and patient reported data (PGHD)

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Phase 1 Recommendations - Level 2 Data Elements Not Included in Draft USCDI v3

IS-WG-2022-Phase 1_Recommendation 15

Add support for Averaged values of multiple observations of the Systolic and Diastolic Blood Pressure data elements

- Average blood pressure is recommended by the American Medical Association and the American Hospital Association's M.A.P. program
- Recommend that ONC work with stakeholders to determine how to best accommodate this utilizing LOINC codes or other means

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Phase 1 Recommendations -
Level 2 Data Elements Not Included in Draft USCDI v3

IS-WG-2022-Phase 1_Recommendation 16

USCDI V3 include an Organizational Identifier, with combination of Identifier and Assigning Authority

- Recommend that the defined set of Assigning Authorities include national organization identifiers in common use, which would need to accommodate NPI, CCN and PTAN
- Recommend that multiple identifiers be included. We recommend that USCDI v3 identify the Organization Identifier with the encounter. This data should be required if known.

Phase 1 Recommendations -

Data Elements in Prior Versions of USCDI

Phase 1 Recommendations -
Data Elements from Prior Versions of USCDI

IS-WG-2022-Phase 1_Recommendation 17

Clarify that the Discharge Summary data element within the Clinical Notes data class refers to the unstructured narrative clinical note portion of a Discharge Summary and does not imply the specification of or requirement for discrete data elements

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Phase 1 Recommendations - Data Elements from Prior Versions of USCDI

IS-WG-2022-Phase 1_Recommendation 18

Clinical Notes data class should include all note types coded in the LOINC Document Ontology

- At a minimum, Surgical Operation Note (LOINC 11504-8) and Tumor Board Notes (LOINC 85231-9) should be added to current Clinical Note data elements in USCDI
- ONC should clarify that Clinical Notes data elements include narrative or free text data and do not require CDA® formatted structured documents

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Phase 1 Recommendations - Data Elements from Prior Versions of USCDI

IS-WG-2022-Phase 1_Recommendation 18 (continued)

Clinical Notes data class should include all note types coded in the LOINC Document Ontology

- This recommendation is not intended to suggest that all certified health IT need to generate all possible note types, but that when notes are documented/captured, they should be indexed with the appropriate associated LOINC code, and that when notes are received, they are received with the context provided by the associated LOINC code to support queries based on note type
- For purposes of conformance testing, ONC should consider working with stakeholders on creation of a core value set of note types to be tested
- ONC should consider encouraging LOINC to develop a new code to designate legacy notes not coded more specifically at the time of their creation or subsequently

Phase 1 Recommendations - Data Elements from Prior Versions of USCDI

IS-WG-2022-Phase 1_Recommendation 19

Clarify that the Smoking Status data element may be represented using any of several specific assessment instruments and include a set of examples

Phase 1 Recommendations - Data Elements from Prior Versions of USCDI

IS-WG-2022-Phase 1_Recommendation 20

Include in USCDI v3 a fully scoped Medication data class with data elements that are included in current Health IT Certification criteria using NCPDP SCRIPT, FHIR and C-CDA, including:

- Dose
- Strength
- Formulation
- Sig/Dosing Instructions
- Route
- Status

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Phase 1 Recommendations -
Data Elements from Prior Versions of USCDI

IS-WG-2022-Phase 1_Recommendation 21

Adopt the Project US@ specification as the applicable vocabulary standard for Current Address and Previous Address. This recommendation includes:

- Current and Previous Address should also contain a value or values from the Patient Address Metadata Schema, which is able to represent homelessness or temporary addresses
- ONC should consider encouraging and supporting the use of an additional metadata element indicating the content model used (i.e., Non-normalized / pre-Project US@ vs. Project US@ compliant, including the applicable AHIMA Companion Guide)

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Phase 1 Recommendations -
Data Elements from Prior Versions of USCDI

IS-WG-2022-Phase 1_Recommendation 22

Include in USCDI v3 the Gender Harmony Project's five data elements and their specified minimum value sets

- Gender Identity
- Sex for Clinical Use
- Recorded Sex or Gender
- Name to Use
- Pronouns
- We recommend the following Gender Identity value set which combines values from both Gender Harmony and ONC
  - Female
  - Male
  - Nonbinary
  - Unknown
  - Additional gender category or other, please specify
  - Choose not to disclose

Phase 1 Recommendations -
Data Elements from Prior Versions of USCDI

IS-WG-2022-Phase 1_Recommendation 22 (Continued)

- Recommend changing label and definition of Sex Assigned at Birth to become one part of Recorded Sex or Gender, i.e., recorded at birth
- Recommend that Gender Identity remain in the Patient Demographics data class, and that Name to Use and Pronouns be included in that class as well
- Gender Identity, Name to Use, and Pronouns should be specified as typically being self-reported by the individual
- Recorded Sex or Gender may be clinical values derived through clinical assessment or legal documentary sources

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Phase 1 Recommendations -
Data Elements from Prior Versions of USCDI

IS-WG-2022-Phase 1_Recommendation 22 (Continued)

- Sex for Clinical Use should be specified as context dependent and should not be interpreted as a singular assessment. For some patient populations, Sex for Clinical Use may be different at the same point in time for different assessments or procedures (e.g., imaging studies vs. laboratory assessments).
- Recommend including associated metadata identifying the source (e.g., individual self-report, clinical observation) and method of collecting values for each data element

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Phase 1 Recommendations -
Data Elements from Prior Versions of USCDI

IS-WG-2022-Phase 1_Recommendation 23

Include in USCDI v3 these Level 2 Laboratory data elements that are already included in CLIA and mapped to existing certification requirements using FHIR, C-CDA and ELR specifications

- Unit of Measure
- Laboratory results: Date and time stamps
- Laboratory Test Performed Date
- Specimen Source Site
- Test Kit Unique Identifier
- It should be specified that these data elements are required to be sent if present/available and that their inclusion in USCDI does not imply a requirement of collection

Phase 1 Recommendations -

Recommendations for Future ONC Focus

Phase 1 Recommendations - Recommendations for Future ONC Focus

Recommendation A

The WG requests that ONC charge the Workgroup with development of recommendations for data elements that would support Current Medication List and Discharge Medications

- In this effort it would be useful to point USCDI at the content models implied by IGs used in Health IT certification in addition to vocabulary standards and to assess the need for additions to these content models
- While ONC has removed the certification requirements to maintain these lists, it is important to represent these lists when clinically maintained for interoperability

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Phase 1 Recommendations - Recommendations for Future ONC Focus

Recommendation B

The WG requests that ONC charge the Workgroup with development of recommendations for data models necessary to support the interoperability of discrete laboratory test results and include additional applicable data elements in the future

Phase 1 Recommendations - Recommendations for Future ONC Focus

Recommendation C

The WG encourages ONC to explore how to support the exchange of qualifiers regarding collection and measurement of vital signs (e.g., supine vs. seated BP) in future versions of USCDI and point to existing LOINC support for such qualifiers

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Phase 1 Recommendations - Recommendations for Future ONC Focus

Recommendation D

The WG encourages ONC to work with stakeholders to develop a new data element, Accommodations, within the appropriate data class to support care for a person with disabilities

Phase 1 Recommendations - Recommendations for Future ONC Focus

Recommendation E

The WG encourages ONC to work with stakeholders to advance the Laboratory Reference Range and Interpretation (Level 1) data elements, which are required by CLIA and already referenced by existing Health IT certification criteria so that they can be included in a future version of USCDI

Interoperability Standards Workgroup

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Questions/Voting

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Thank you!