USCDI+ Cancer
Post-Summit Summary Webinar

July 23, 2024

Agenda

- **Welcome and Opening Remarks**

  Matt Rahn, ONC; Jill Barnholtz-Sloan, PhD, NCI

- **Background**

  Liz Turi, ONC

- **Summary of Summit Findings**

  Shannon Silkensen, PhD, NCI

- **Current Use Case Development Activities**

  Liz Turi, ONC; Umit Topaloglu, PhD, FAMIA, NCI

- **Public Feedback for Cancer Registry Use Case Data Elements**

  Matt Elrod, PT, DPT, ONC

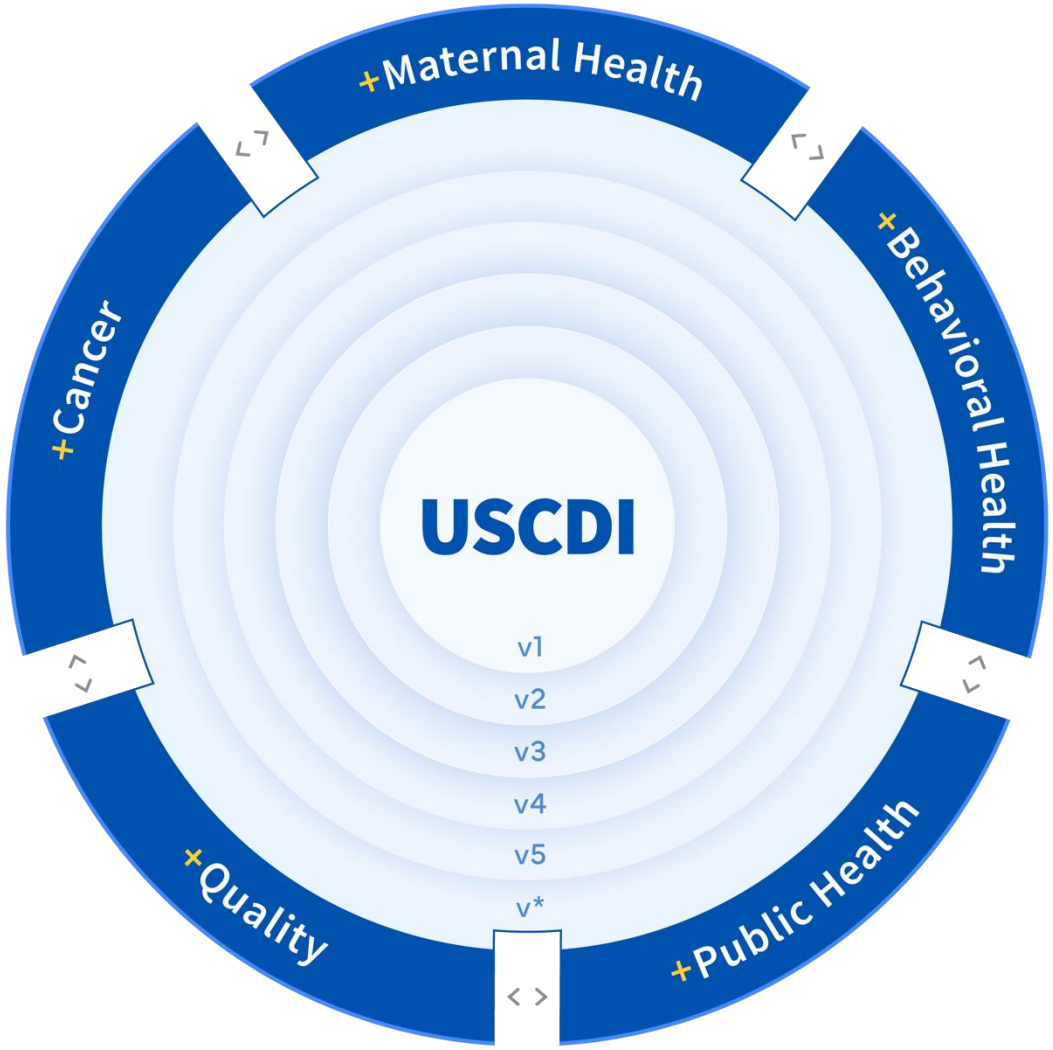
Welcome and Opening Remarks

Matt Rahn, ONC
Jill Barnholtz-Sloan, PhD, NCI

Background

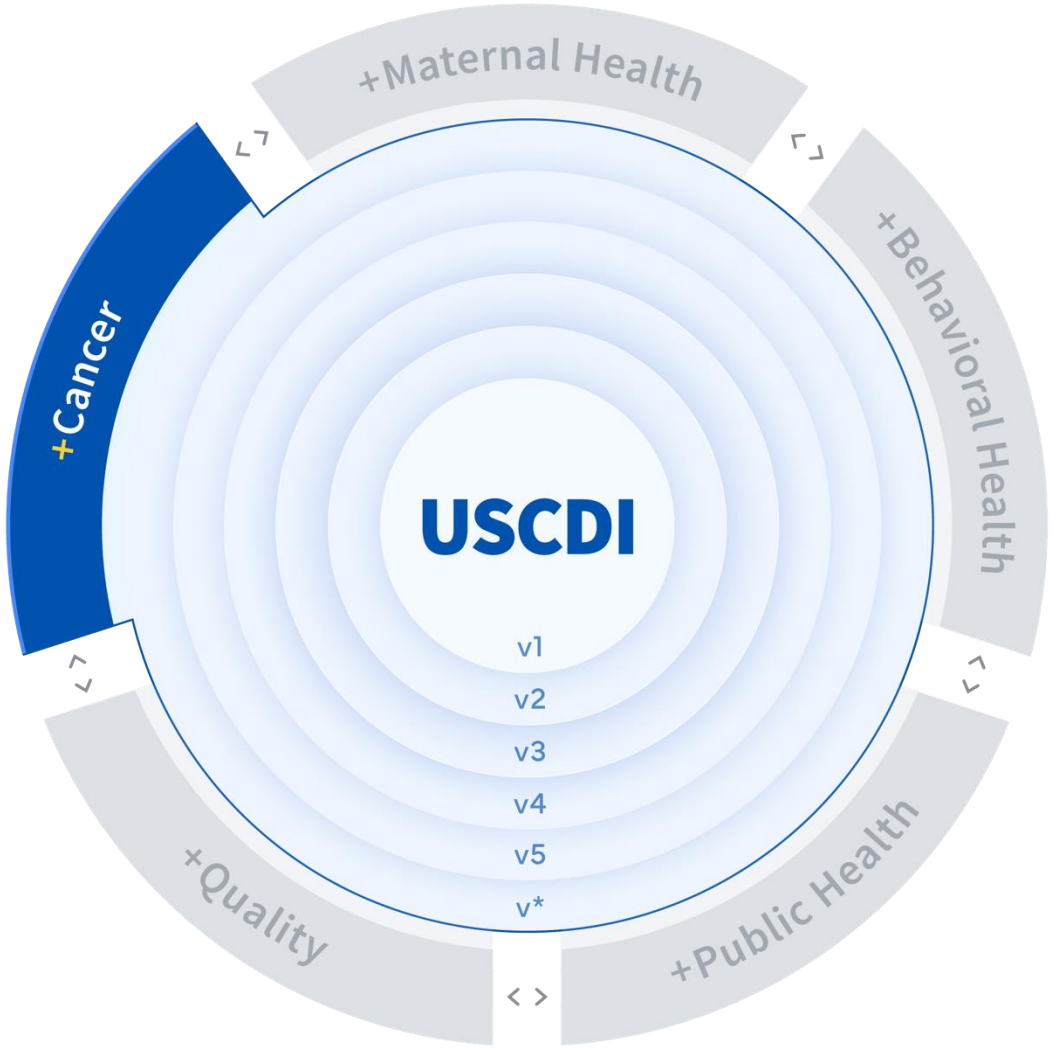
Liz Turi, ONC

USCDI+ Extending Beyond the USCDI



- Unique program and use case-specific data needs are sometimes not fully met by USCDI
- USCDI+ initiative:
  - Builds on USCDI and supports the programmatic needs of government, academic, and industry partners.
  - Establishes USCDI processes for submitting feedback.
  - Leverages programs and authorities across HHS to drive adoption.

USCDI+ Cancer



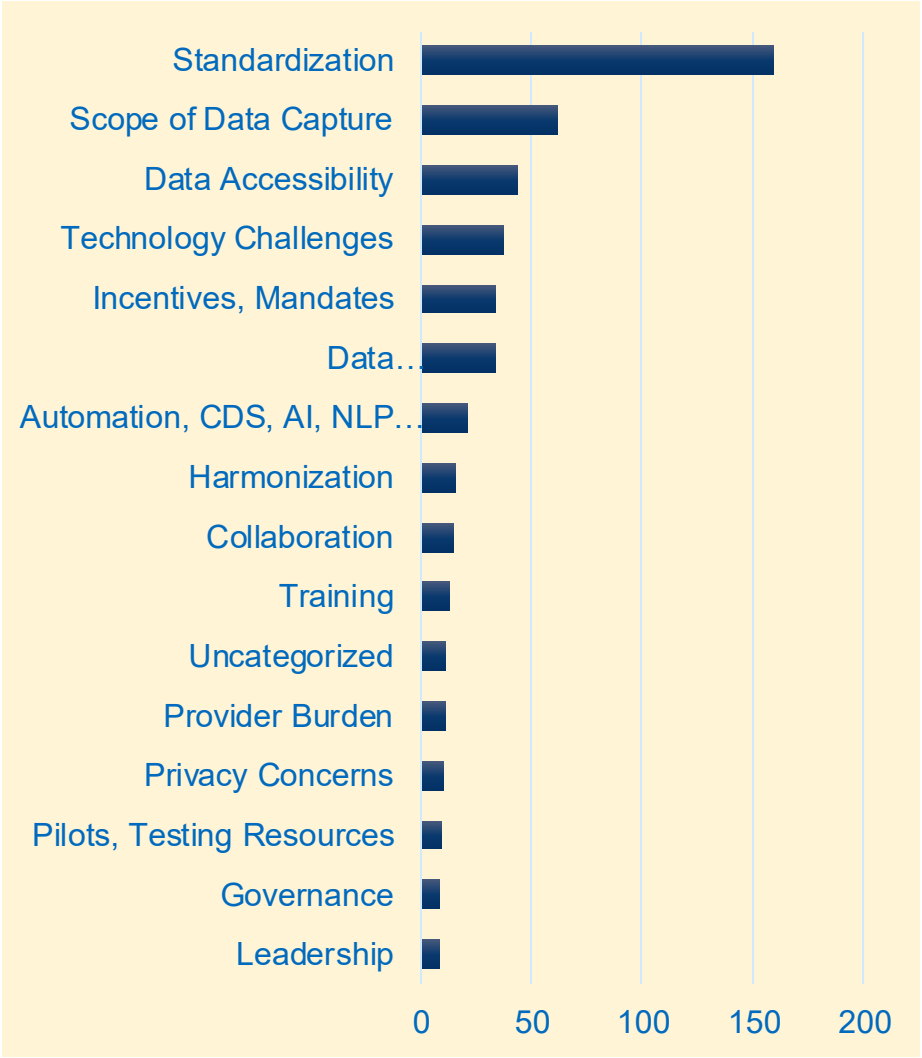
- ONC partnership with NCI, CMS, CDC, and FDA.
- Supports the White House Cancer Moonshot Initiative.
- USCDI+ Cancer aims to:
  - Capture the data needs for cancer reporting that fall outside the scope of USCDI.
  - Create a list of cancer data elements that addresses multiple partner needs and use cases.
  - Support data integration.
  - Align HHS policies for cancer reporting programs.

Summary of Summit Findings

Shannon Silkensen, PhD, NCI

Summit Findings - Key Themes and Challenges

- Standardization and Process
  - Need for uniform standards for data elements, including genetic tests
  - Need a clear and concise process for common data element development
  - Heterogeneity of EHR integrations make data collection, sharing, and reuse challenging
- Clear Data Definitions
  - Existing terminologies need to be more responsive to the complexity and evolution in oncology researches
  - Address the tension between the detailed data collection needed research and clinical care with minimizing clinical documentation burdens
- Data Access
  - Unsystematic integration of EHRs makes essential data elements difficult and unevenly collected
  - Need improvements in scaling, transparency, and customization of APIs for better data access for everyone



Barriers and Enablers of Success

Barriers

1. Missing data standards for many of the required data elements (i.e. biomarkers).
2. Unsystematic capture of key data elements in EMRs (i.e, a single concept may be located in different parts of a patient's record).
3. Protocol / trial data submissions are
   - Disparate between federal agencies
   - Not aligned with FHIR data standards.
4. Lack of data portability from 3rd party vendors.
5. Limited adoption and scaling and of existing technologies.
   - Due to limited financial, operational, leadership, and technical expertise

Enablers

1. Technology adoption is often incentivized by regulatory action
   - USCDI+ has inter-agency collaboration and support.
   - Scientific, academic, and industry community feedback impacts regulations.
2. Many robust private-public engagements (e.g., Vulcan, CodeX/mCODE, CancerX, ARPA-H, etc.) to test data elements and implementation guides.
3. FHIR adoption and innovation is increasing; more provider and payer systems are using FHIR to exchange data.

The scalability problem: Certified FHIR servers exist Why are they not widely used by academia or pharma?

Scaling issues that confound the adoption of digital portability

1. 3rd party vendors – middleware problem (EDCs, assay platforms, etc.) e.g., today, EDC vendors do not have standardized data structure
2. Move beyond the small # of structured common data elements to disease-specific terminologies and the vast body of unstructured data
3. Internal clinical & research group-specific terminology
4. Inconsistent use of downstream data, e.g. CT Matching, CT reporting to NCI/FDA, registries, CMS

Blockers and challenges to scaling

1. Manual data entry is costly
2. Variability
3. Currently, NCI, FDA, CMS, CDC, others have different requirements for data submission. Not all are aligned with the FHIR data standards
4. There are multiple data streams with multiple mappings
5. Adoption of new standards is spotty and uncoordinated

What are the enablers?
How can we begin to solve this?

1. Encourage providers to take advantage of the existing standards

2. Demonstrate success (What sites have made the commitment.) e.g., Texas Oncology: Certified FHIR server w/ mCODE elements

3. Create a value chain roadmap – make clear to all parties how the data can be used to for multiple purposes

4. Identify communities that will use of data - outside of original purpose

Possible Solutions to increase adoption rate of USCDI+

1. Establish use cases for research data ecosystem and data delivery mechanism, e.g., to the NCI
2. Collaborate to create a common data submission standard and adoption strategy
3. Work with NCI-designated Cancer Centers and their software developers to implement USCDI+ Cancer
4. Professional and standards organizations could support adoption
5. Consider levers around grants that incorporate USCDI+ Cancer

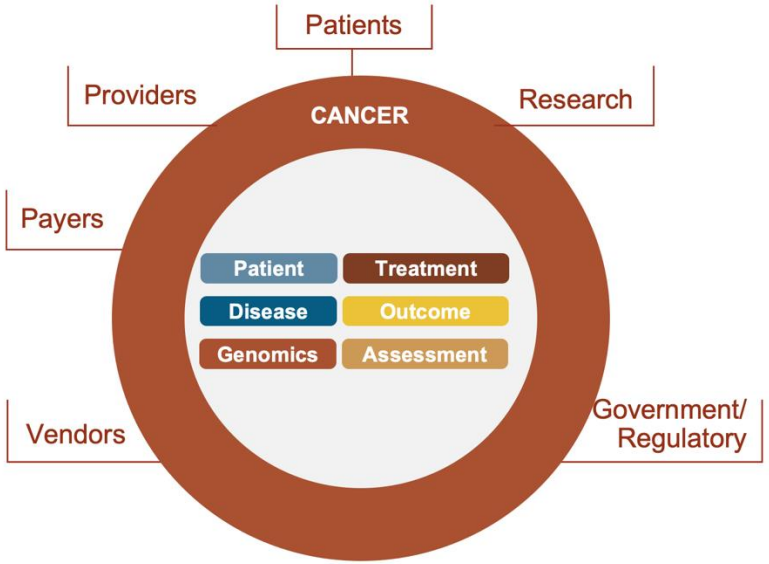
Current Activities

Liz Turi, ONC
Umit Topaloglu, PhD, FAMIA, NCI

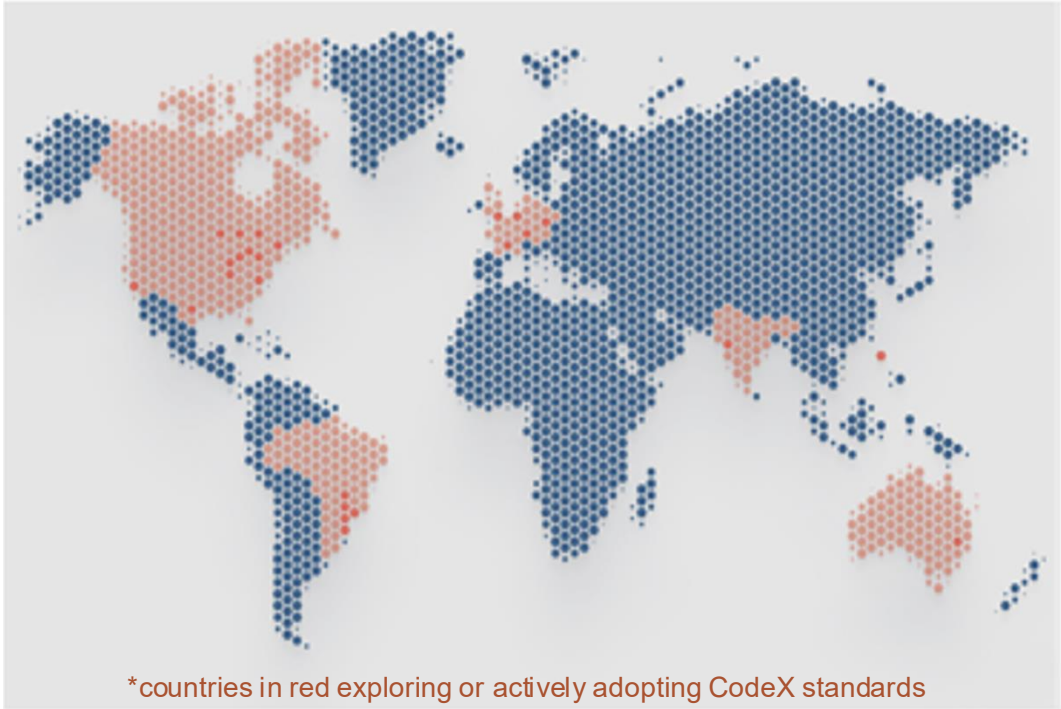
mCODE™

minimal Common Oncology Data Elements

- **FHIR-based core set of common data elements for cancer**
- **Standardized, computable, clinically applicable and available in electronic health records for cancer patients**



*mCODE STU3: http://hl7.org/fhir/us/mcode/



*countries in red exploring or actively adopting CodeX standards

50%
U.S. patient health records covered by mCODE consistent vendor systems
(in active development or already available)

80%
of North American radiation therapy sites have vendors adopting mCODE

140+
Publications referencing mCODE and/or CodeX

*mCODE was co-founded by ASCO AMERICAN SOCIETY OF CLINICAL ONCOLOGY KNOWLEDGE CONQUERS CANCER MITRE

CodeX™

An HL7® FHIR® Accelerator

CodeX Use Cases

7 In Execution

- EHR Endpoints for Cancer Clinical Trials (ICAREdata)
- Integrated Trial Matching for Cancer Patients and Providers
- Cancer Registry Reporting
- Radiation Treatment Therapy Data for Cancer
- Prior Authorization in Oncology
- Genomics Data Exchange
- CardX Hypertension Management

3 In Planning

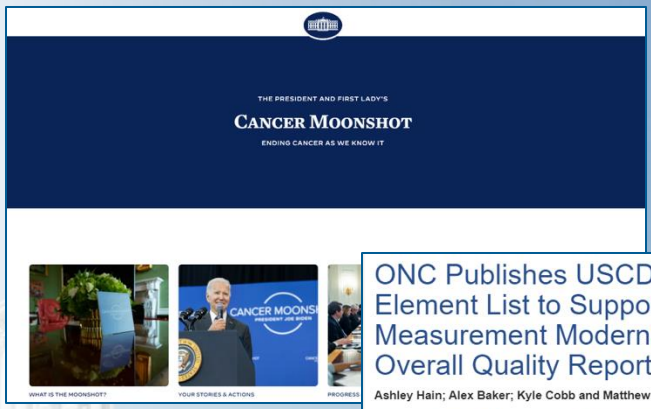
- Genomics Operations
- Risk Evaluation and Mitigation Strategies
- Quality Measures for Cancer

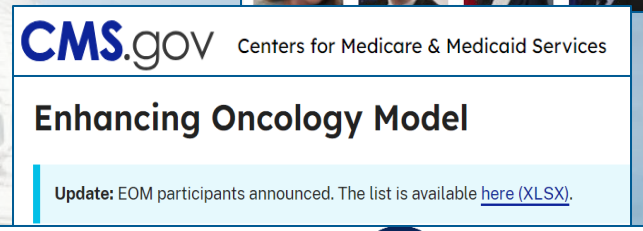
CODEX DOMAINS:

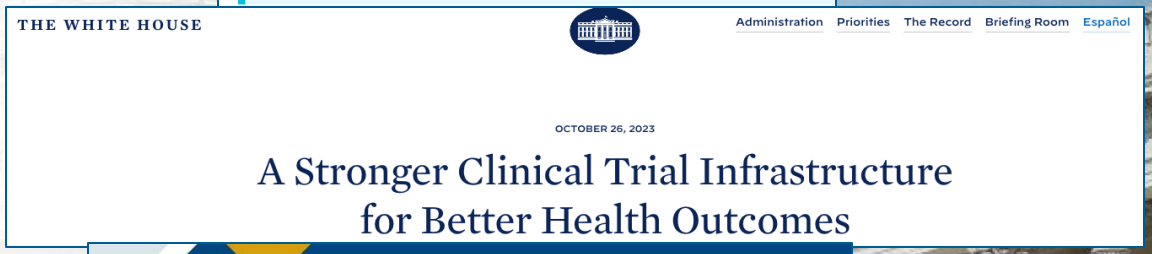
Oncology | Radiation Oncology | Genomics | Cardiovascular Health

Scale with Aligned Federal Initiatives

- **White House Cancer Moonshot** initiatives leveraging mCODE:
  - **ONC's** US Core Data For Interoperability **(USCDI) + Cancer**
  - **CMS Enhancing Oncology Model**
- **OSTP** and **ARPA-H** noted CodeX and Vulcan as important partners in strengthening the nation's clinical trial infrastructure
- **President's Cancer Panel** noted the importance of mCODE in recommendations for **NCI's National Cancer Plan**
- **FDA** championing CodeX **REMS Integration** Use Case
- **CDC**'s use of mCODE for **Central Cancer Registry Reporting IG**
- **ONC** included select mCODE data elements in their **USCDI+ proposed Quality Data Element List**







Vulcan Interoperability Bridge

- The White House Office of Science and Technology Policy (OSTP) seeks to improve the ability to respond to emergencies such as pandemics, with rapid and coordinate clinical trials
- Interoperability Bridge
  - Collaboration between Vulcan, ONC, FDA, and with NCI involvement
  - Connectathon-like event to highlight possibilities in evolving the current ecosystem
- Identify possibilities of interoperability in clinical care and research
- Use cases include Cancer Clinical Trial Matching
  - Align with USCDI+ Cancer

USCDI+ Cancer: Enhancing Oncology Model (EOM)

Goals

- Initial use case for USCDI+ Cancer
- Aligned with CMS EOM goal to drive transformation and improvements in care coordination in oncology
- Standardize and harmonize data collection for CMMI model
- Establish a minimum set of cancer-related data for exchange

Activities

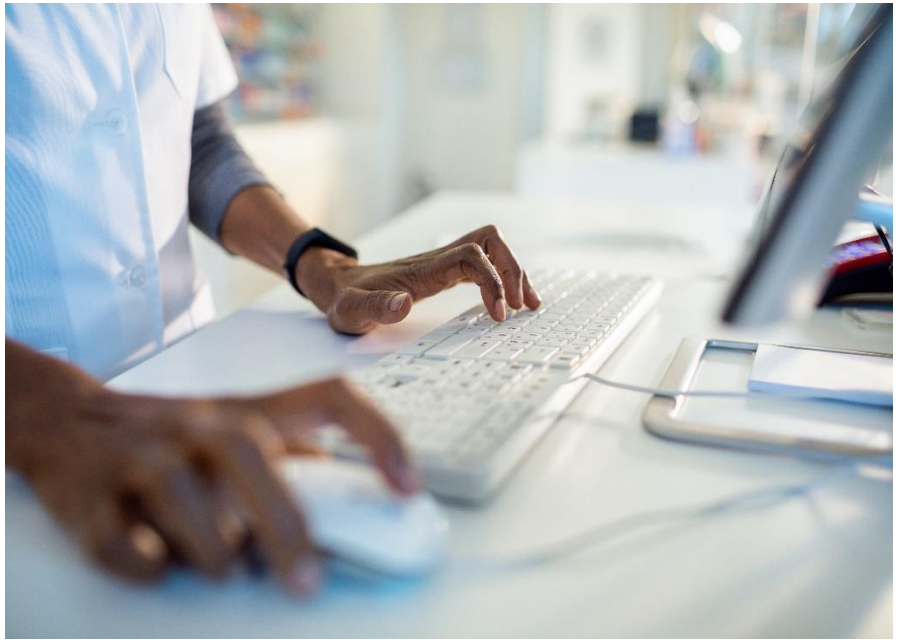
- Published on USCDI+ Cancer platform in May
- Developed EOM IG providing guidance on details, terminologies, and definitions necessary for collection and reporting of clinical data for specific cancer types
- Tested at May HL7, and July CMS FHIR Connectathon

Next Steps (now through October)

- Publish updates from testing
- EOM Participants leverage EOM IG to report clinical data elements

Need

USCDI+ Cancer EOM use case supports President's Cancer Moonshot initiative priorities of supporting patients, caregivers, and survivors, and targeting the right treatments for the right patients.



USCDI+ Cancer: Clinical Trials Matching (CTM)

Goals

- Quickly and accurately extract key eligibility criteria needed to match patients to a trial from the EHR.
- Semantically map eligibility criteria to existing data standards (eg, mCODE).
- Support clinical trial matching from both provider and patient perspectives.

Considerations

- Leveraging NCIt, FHIR/mCODE-based profiles for eligibility criteria. Having criterion-specific matching algorithms and data interoperability along with standardized markup languages.
- Facilitating patient access to their health data through APIs and optimizing data use by operators improves the efficiency, accuracy, and personalization of the trial matching process.
- Implementation inconsistencies, inadequate inclusion/exclusion criteria data, reliance on manual processes,

Need

- Clinical trials are vital to improve patient treatment options and outcomes.
- Limited tools are available for rapidly comparing patient data to open protocols.
- Aligning protocols and key eligibility criteria using a common format (e.g., FHIR, mCODE) helps support comparisons to patient EMR data.
- Support tools that extract key data from EHRs and trial protocols, enable care teams and researchers to match patients to eligible trials.

USCDI+ Cancer: Clinical Trials Matching (CTM) Cont.

Activities

- Developed preliminary data element list
- Reviewed preliminary data elements at Summit in May
- Prioritized and collected feedback on data elements

Next Steps (now through September 2024)

- Update current and future state diagram
- Refine use case scope
- Publish draft data element list for public comment

Beyond September

- Publish Implementation Guide
- Test, Pilot

Why

- Effective clinical trial matching ensures that patients receive access to the most suitable experimental therapies based on their specific cancer profile, improving the likelihood of positive outcomes
- By efficiently matching patients to trials, research can progress more rapidly, leading to faster development of new treatments and a broader understanding of therapies, ultimately benefiting the wider patient community.

USCDI+ Cancer: Immune-related Adverse Events

Goals

- Capture Adverse Events (AEs) from participants in Phase I, II, and III clinical trials using EHR, imaging, molecular, and pathological data to obtain the needed irAE data
- Improve assessment of interventions by providing higher-quality and more timely information
- Identify and develop data standards necessary to appropriately capture irAEs

Considerations

- Limited number of EHR systems facilitates standardization and consistency in data collection.
- EHRs making it difficult to accurately capture and manage irAE data. Additionally, the absence of a universal patient identifier complicates data integration across different healthcare systems.
- Operational challenges, such as using manual processes to track trial slots and patient statuses, hinder efficient and accurate irAE monitoring and trial matching.

Need

- Early detection and accurate documentation of irAEs allow for prompt management, reducing the severity and duration of adverse effects, thereby improving overall patient outcomes.
- AE data scattered across multiple systems leading to inconsistent and incomplete information.
- Understanding the frequency and nature of irAEs aids clinicians in tailoring immunotherapy regimens to individual patient needs, balancing efficacy and safety.

USCDI+ Cancer: Immune-related Adverse Events Cont

Activities

- Current and future state diagrams are being updated
- Developed preliminary data element list
  - Reviewed preliminary data element list at Summit in May
- Prioritized and collected feedback on data elements

Next Steps (now through Jan 2025)

- Refine use case scope and update the future state
- Publish draft data element list for public comment

Beyond Jan 2025

- Publish Implementation Guide
- Test, Pilot

Why

- Immunotherapy has demonstrated significant improvements in survival and response rates in various cancers, including melanoma, lung, and hematologic malignancies.
- Ongoing trials are expanding its potential through combination therapies and novel agents, driving transformative advances in oncology

USCDI+ Cancer: Cancer Registry

Goals

- Enhance efficiency and timeliness of collection of cancer registry data by identifying standards (e.g., FHIR, mCODE, etc.) to efficiently extract and/or collect cancer registry data directly from EHRs and pathology labs
- Data should be collected at a level of granularity that serves the clinical, public health, and research communities
- Enable early real-time incidence reporting using minimum dataset

Activities

- Developed and reviewed preliminary data element list at Summit in May.
- Prioritized and collected feedback on draft data elements
- Refined draft data elements

Next Steps (now through September)

- Public comment for draft data element list from July 23 – Sept 23
- Upcoming Public Listening Session on August 29

Beyond September

- Publish Implementation Guide
- Test, Pilot

Need

- Current methods of collecting cancer registry data are time-consuming and labor-intensive, leading to delays in data availability.
- Cancer registry data is spread across multiple sources, including EHRs and pathology labs, making it challenging to compile comprehensive datasets.

Public Feedback for Cancer Registry Use Case Data Elements

Matt Elrod, PT, DPT, ONC

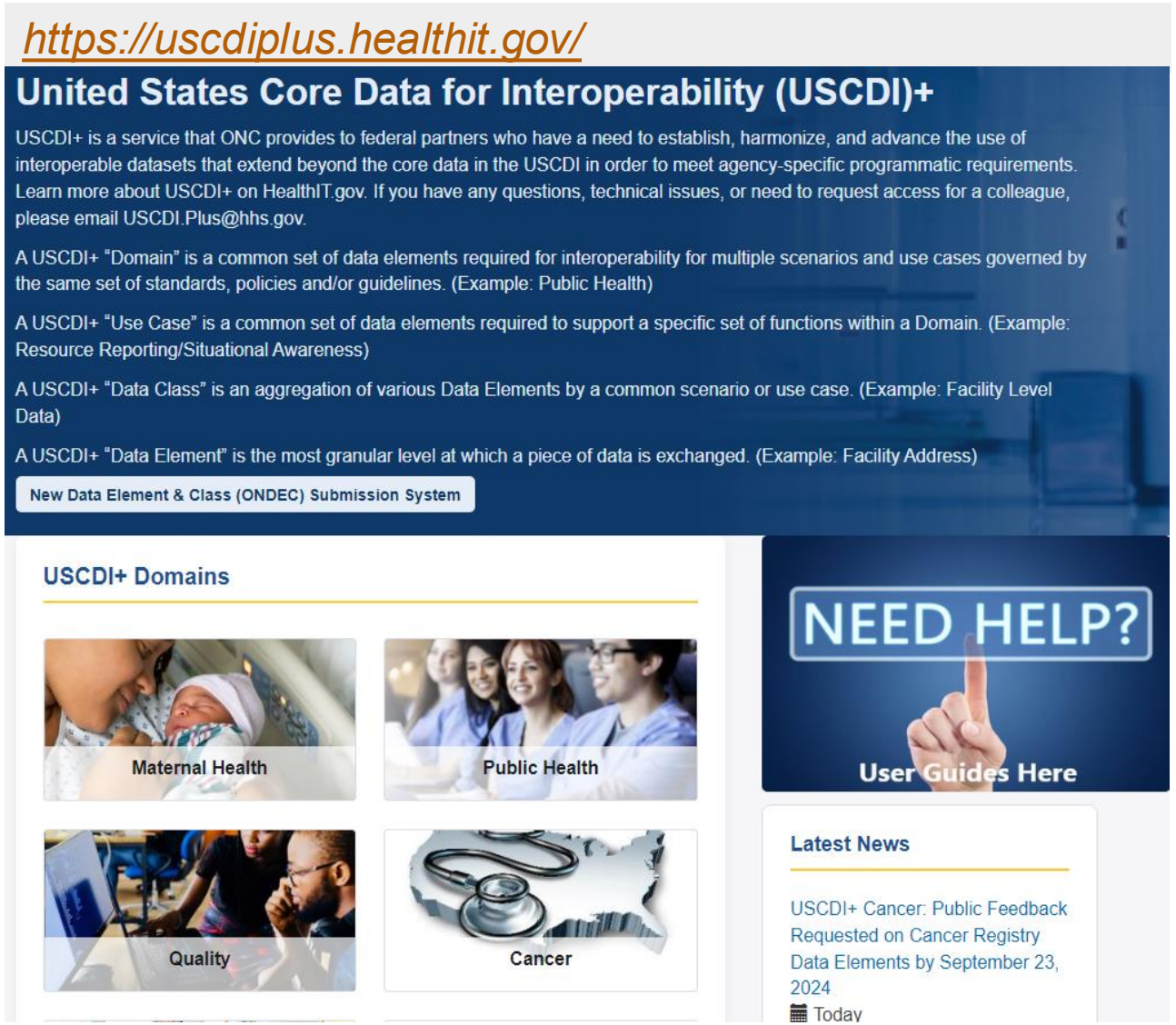
Community Engagement - Cancer Registry Data Elements

60-day Public Comment Period

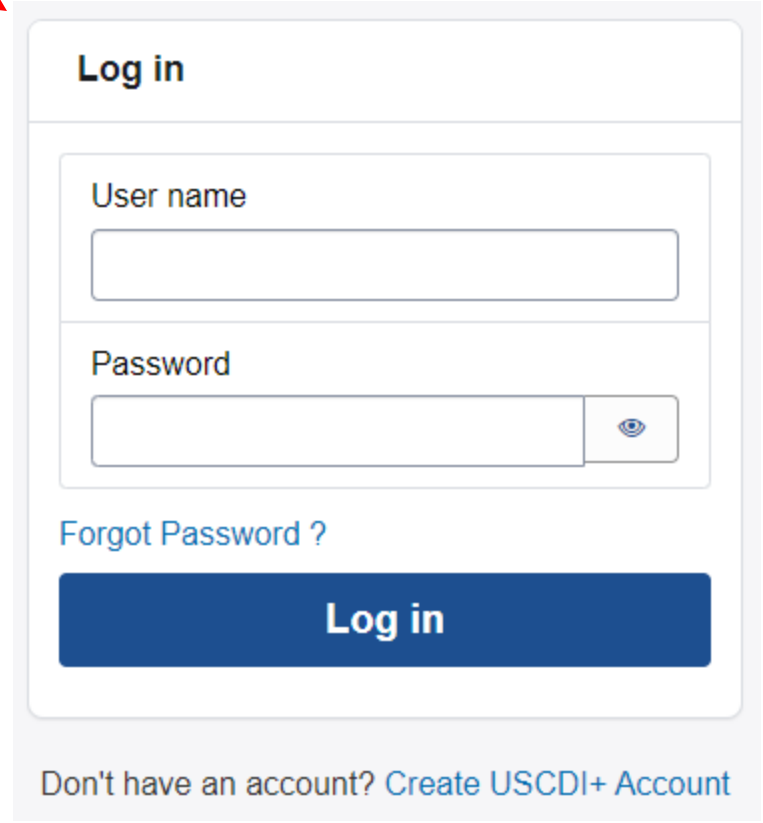
July 23 – September 23, 2024

Public Listening Session on August 29, 2024 2 - 3pm ET

https://uscdiplus.healthit.gov/



Navigating USCDI+



USCDI+ Domains: Cancer

60-day Public Comment Period

July 23 – September 23, 2024

Public Listening Session on August 29, 2024
2 - 3pm ET

Cancer

The USCDI+ cancer category contains data elements to advance the development and adoption of a data model for use by the cancer community, and promote access to standardized data for research from real-world implementations

Use Cases | Details | Comments

Use Cases in Domain

Keyword Search

Name	Description
Cancer Registry	Minimum dataset needed to efficiently identify and extract required data and support the current data sharing and linkage approaches for cancer registry data via Surveillance, Epidemiology, and End Results (SEER) program and the Centers for Disease Control and Prevention / National Program of Cancer Registries (CDC/NPCR) .
Enhancing Oncology Model	USCDI+Cancer has aligned with the Centers for Medicare & Medicaid (CMS) Enhancing Oncology Model (EOM). The EOM aims to drive transformation and improve care coordination in oncology care by preserving and enhancing the quality of care furnished to beneficiaries undergoing treatment for cancer while reducing program spending under Medicare fee-for-service. EOM supports President Biden's Unity Agenda and Cancer Moonshot initiative to improve the experience of people and their families living with and surviving cancer. EOM aligns with the Cancer Moonshot pillars and priorities of supporting patients, caregivers, and survivors, learning from all patients, targeting the right treatments for the right patients, and addressing inequities.

Rows 1 - 2 of 2

Cancer Registry Use Case: Data Classes

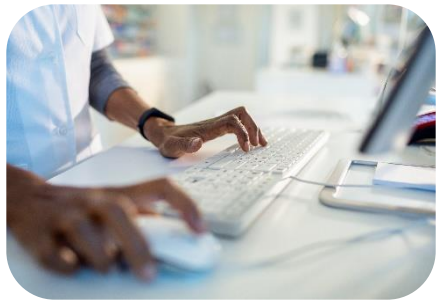
Patient Demographics

Facility Information

Diagnostic Imaging

Laboratory

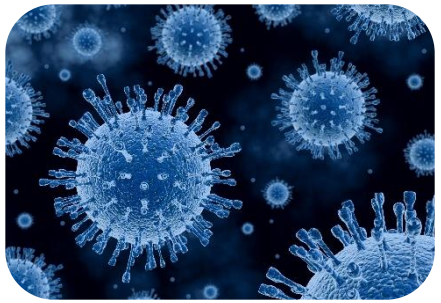
Care Team Member



Observations

Problems

Procedures



Cancer Stage

Tumor

Cancer Registry Use Case: Data Elements

Cancer Registry

Minimum dataset needed to efficiently identify and extract required data and support the current data sharing and linkage approaches for cancer registry data via Surveillance, Epidemiology, and End Results (SEER) program and the Centers for Disease Control and Prevention / National Program of Cancer Registries (CDC/NPCR) .

Details | Comments

Details

Keyword Search

Data Element	Description	Data Class	Domain
Behavior Code ICD-O-3	Code for the behavior of the tumor being reported using ICD-O-3.	Tumor	Cancer
Cancer Diagnosis	The cancer-related condition, diagnosis, or reason for seeking medical attention. Usage note: The initial cancer diagnosis is required while the final cancer diagnosis is optional.	Problems	Cancer
Current Address	Place where a person is located or may be contacted. Includes street name, number, city/town, state, and zip code.	Patient Demographics	Cancer
Date of Birth	Known or estimated year, month, and day of the patient's birth.	Patient Demographics	Cancer

Cancer Registry Use Case: Data Element- Details

Histology

Details | Relationsh… | Comments

Click on the Relationships tab for the Domain, Use Case, and Data Class values.

Histology

Data Element Name:
Histology

Submission Status:
Published

USCDI+ Level:

Description:
The morphologic and behavioral characteristics of the cancer.

Additional Information:
USCDI+ Cancer: NAACCR Item #522

USCDI Information

In USCDI:
No

Current USCDI Level:

USCDI URL:

Standards and Projects

Applicable Vocabulary Standard(s):
ICD-O-3

Associated Reporting Program(s):
Center for Medicare and Medicaid Innovation - Enhancing Oncology Model

Associated US Core Profile(s):

Associated Project(s):
NAACCR Incidence

Associated IG or Profile(s):
Primary Cancer Condition

EOM Primary Cancer Condition

Cancer Registry Use Case: Data Element- Relationships

Histology

Details | **Relations…** | Comments

Associated Relationships

Keyword Search

Data Element	Data Class	Use Case	Domain
Histology	Tumor	Cancer Registry	Cancer
Histology	Tumor	Enhancing Oncology Model	Cancer

Rows 1 - 2 of 2

Date of Birth

Details | **Relationships** | Comments

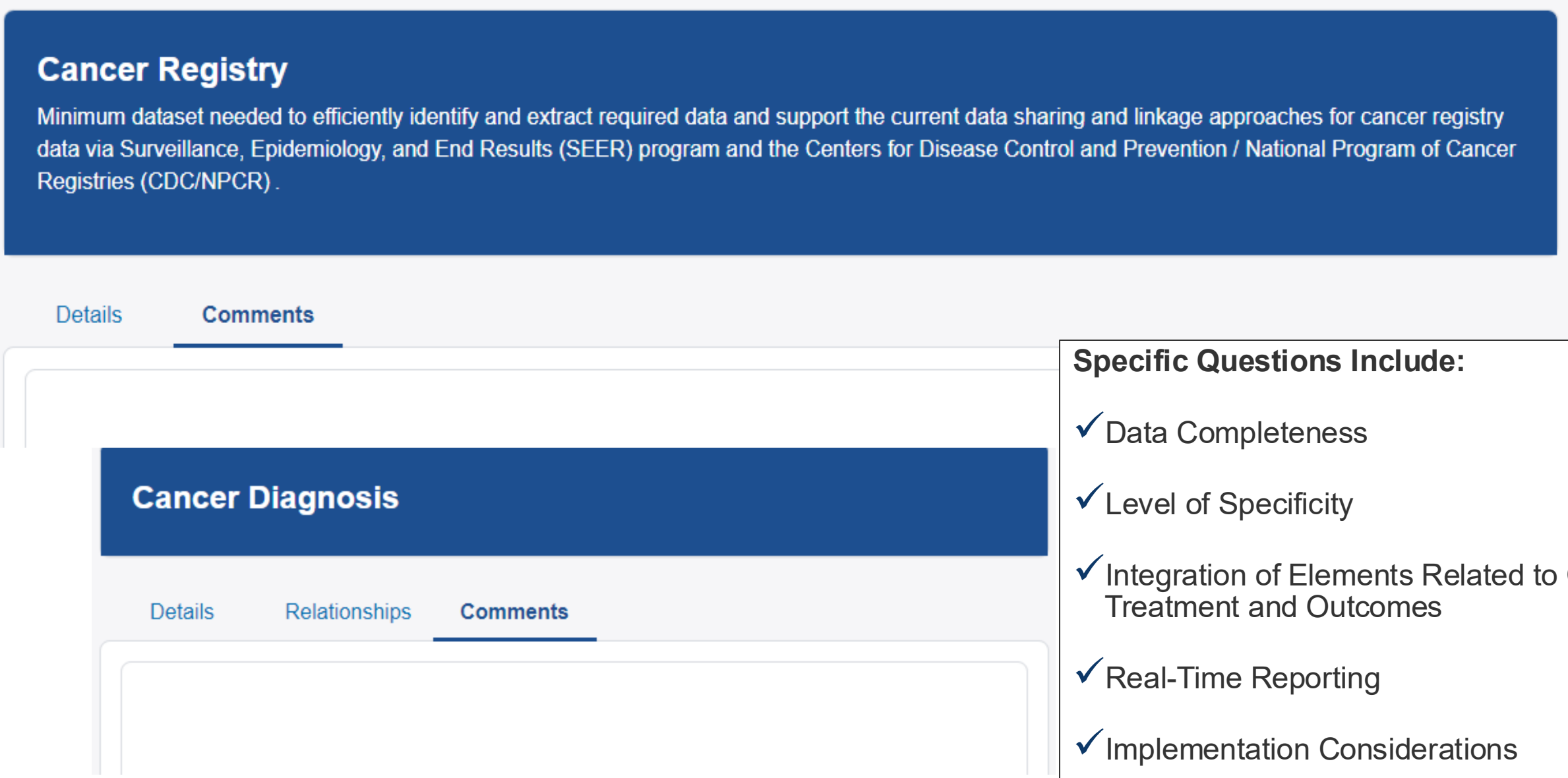
Associated Relationships

Keyword Search

Data Element	Data Class	Use Case	Domain
Date of Birth	Patient Demographics	Comprehensive Care	Behavioral Health
Date of Birth	Patient Demographics	Enhancing Oncology Model	Cancer
Date of Birth	Patient Demographics	Case Reporting	Public Health
Date of Birth	Patient Demographics	Maternal Health Overarching	Maternal Health
Date of Birth	Patient Demographics	Cancer Registry	Cancer

Rows 1 - 5 of 5

Cancer Registry Use Case: Comments



Specific Questions Include:

- ✓ Data Completeness
- ✓ Level of Specificity
- ✓ Integration of Elements Related to Cancer Treatment and Outcomes
- ✓ Real-Time Reporting
- ✓ Implementation Considerations

Community Engagement

Liz Turi, ONC

Learn More and Stay Engaged!

1

View summit recordings https://events.cancer.gov/nci/cancer-data-exchange-summit/agenda

2

Share feedback on USCDI+ Cancer Registry data elements

https://uscdiplus.healthit.gov/uscdi

3

Join the Public Listening Session for USCDI+ Cancer Registry on August 29th (more information to come)

4

Reach out to the USCDI+ Cancer Team

USCDI.Plus@hhs.gov

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uscdi.plus@hhs.gov

Phone: 202-690-7151

Health IT Feedback Form:
https://www.healthit.gov/form/healthit-feedback-form

Twitter: @onc_healthIT

LinkedIn: Office of the National Coordinator for Health Information Technology

Youtube:
https://www.youtube.com/user/HHSONC

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