ASTP Assistant Secretary for Technology Policy

NIH NATIONAL CANCER INSTITUTE

CMS FDA U.S. FOOD & DRUG ADMINISTRATION CDC

USCDI+ Cancer Registry

Public Listening Session

August 29, 2024

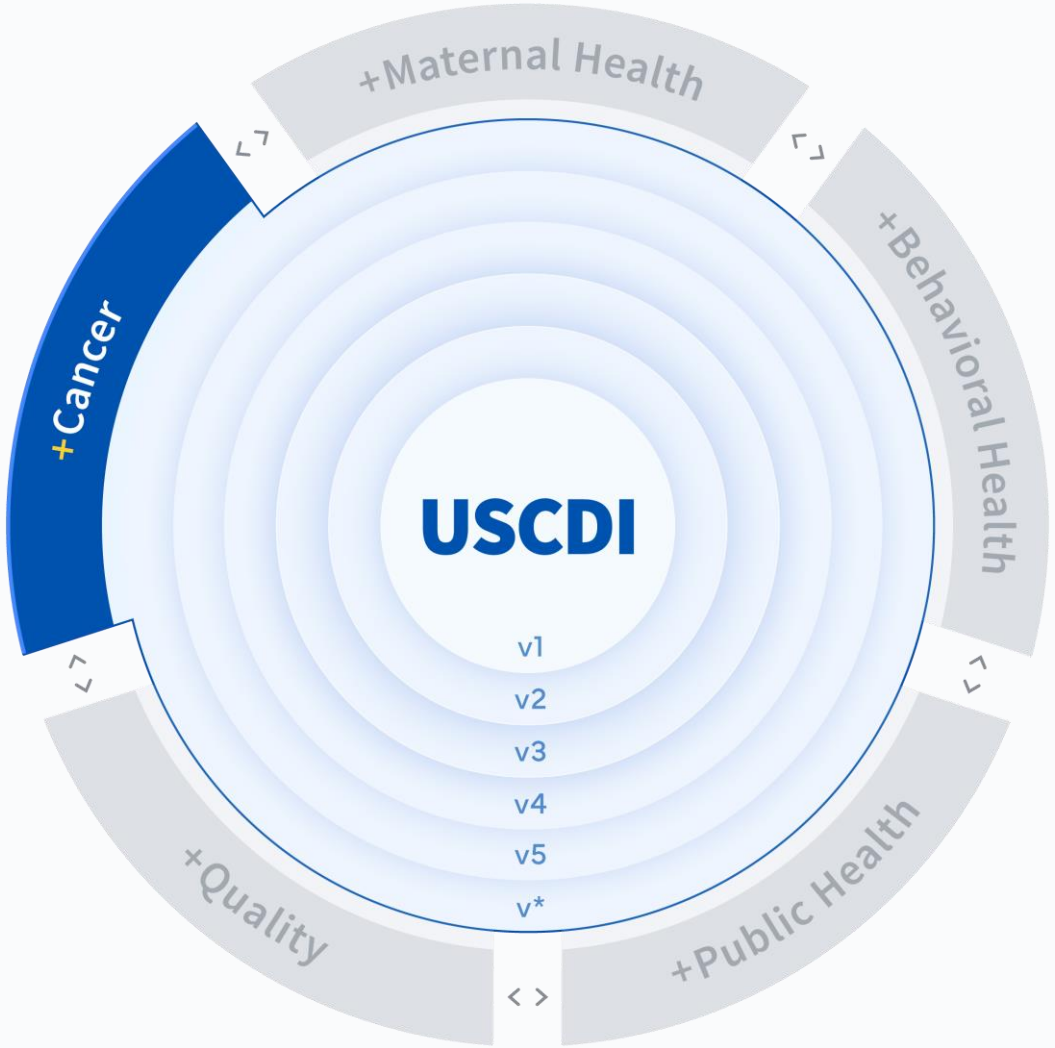
Agenda

- Welcome and Opening Remarks
- USCDI+ Cancer Overview and Use Case Scope
- Cancer Registry Data Flow and Additional Context
- Data Elements and Public Comment Submission Process
- Discussion
- Closing Remarks

USCDI+ Cancer Overview and Cancer Registry Scope

Liz Turi, ASTP

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.

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Cancer Registry Use Case Scope

Scope

- Surveillance, Epidemiology, and End Results (SEER) program.
- Centers for Disease Control and Prevention / National Program of Cancer Registries (CDC/NPCR) state cancer registries.
- North American Association of Central Cancer Registries (NAACCR).
- Understand the cancer burden in the US related to incidence, treatment patterns, mortality, and survival
- Data is spread across multiple sources, including EHRs and pathology labs, making it challenging to compile comprehensive datasets
- Address the current delays in data collection, which result in available data being up to 3 years behind

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 incidence reporting using **minimum** dataset

Integration of College of American Pathologists (CAP) Protocols for Pathology Reporting

- Provides comprehensive electronic Cancer Protocols (eCP) for collecting essential data elements for the accurate reporting of malignant tumors.
- Ensures pathologists stay current with advancements in cancer reporting.
- Supports standardized and precise pathology reporting, crucial for improving patient care and advancing medical research.

- **Recommendation for Implementers**
  - ASTP/ONC, NCI, and CDC strongly recommend adherence to CAP protocols for pathology reporting requirements.
  - CAP eCP are accessible here: Cancer Protocol Templates | College of American Pathologists (cap.org)
- **Benefits of Adhering to CAP protocols**
  - Promotes a unified and efficient healthcare data ecosystem.
  - Enhances interoperability and data exchange across different platforms and systems.

USCDI+ Cancer: Cancer Registry Activities

Activities

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

Next Steps (now through September)

- Public comment for draft data element list from July 23 – Sept 23
- Public Listening Session today

Beyond September

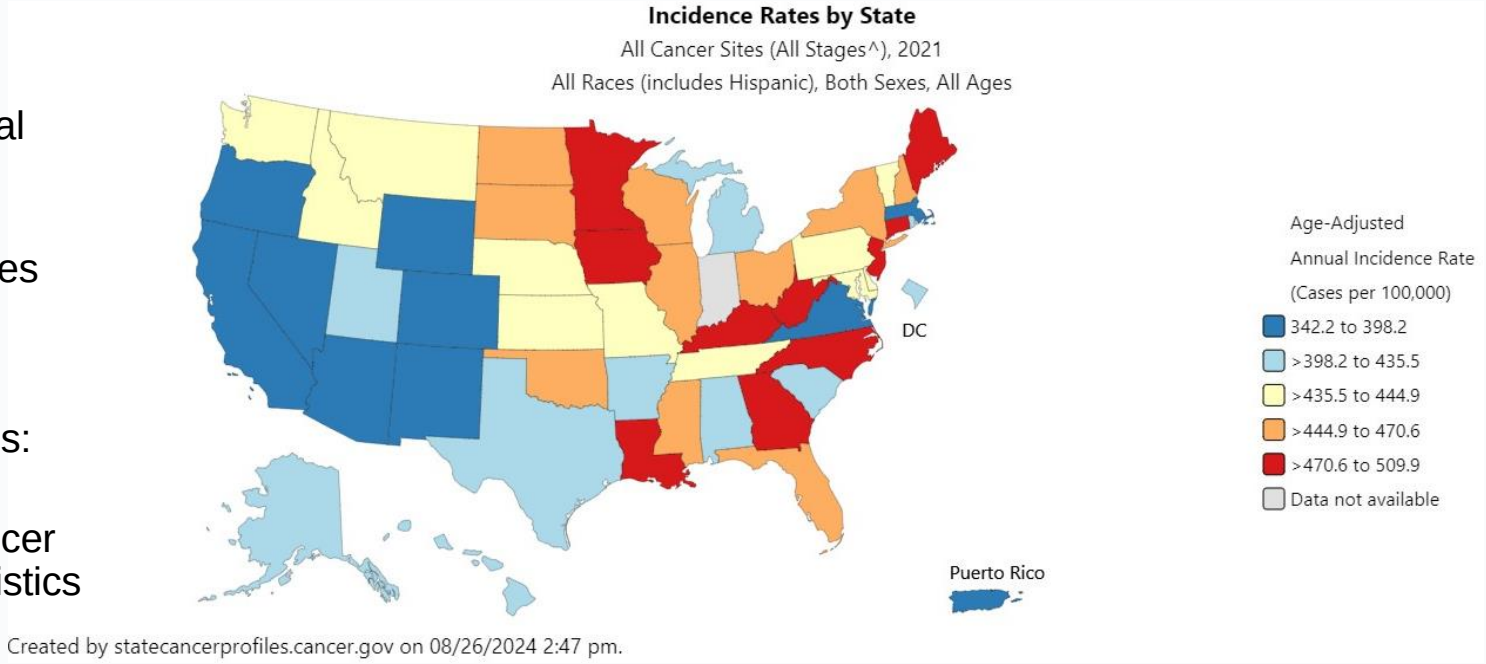
- Publish Implementation Guide
- Test, Pilot

Cancer Registry - Additional Context

Serban Negoita, NCI – SEER

Federal Cancer Surveillance Programs, Central Cancer Registries, Hospital Reporters: Roles in Cancer Statistics

- Central Cancer Registries
  - Role of cancer registries in the cancer surveillance system
    - Collect and integrate cancer abstracts and clinical documents (i.e., path reports) from healthcare facilities in their jurisdiction
    - Conduct linkages with up to 32 external databases
    - Create consolidated, deduplicated records
    - From all states and territories of the US
    - Submit deidentified case files to federal programs: NCI-SEER and CDC-NPCR
    - Support the publication of the United States Cancer Statistics (USCS), the official federal cancer statistics
  - Data collection process
    - Relies on state law-mandated cancer reporting from hospitals (cancer abstracts, NAACCR layout)
    - Pathology reporting, not mandated in all jurisdictions, not all electronic, some synoptic reports
    - Increasingly, linkages with external databases



Cancer Statistics limited by the timeliness and completeness of hospital abstracts!

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Cancer Surveillance System: Current Limitations and Future Solutions

- For most reportable cancers, it takes an Oncology Data Specialist between 6-18 mos. to complete and transmit a full abstract
  - Non-funded mandate, financial supported by healthcare systems/facilities
- Abstracts are curated at central cancer registry level within 6-12 mos.
  - Requires matching and deduplication, external linkages (i.e., vital statistics), data integration (AKA consolidation), quality control
- Federal programs receive de-identified curated case records twice a year
  - Federal cancer statistics are released approximately 6 months after data are submitted from states and territories
  - Completeness is a key quality metric; reporting time of full abstracts cannot be compressed below 6 mos. or expanded beyond 18 mos. without exponential cost increases
- Solution cannot rely on manual abstracting, coding and consolidation of an ever-increasing number of clinical documents
- Standardization/Interoperability, the Use of Alternative Data Sources/Streams, Automation and the Collaboration of Healthcare facilities/vendors, Central Registries and Federal Programs could all part of the solution

The Case for Interoperability Standards in Support of Expanding the Acquisition of Data Sources in Cancer Surveillance

- Standardization/Interoperability will benefit from USCDI + Cancer
  - Currently, registries operate using NAACCR Standards
  - NAACCR Standards could be adapted to fit one national standard (USCDI + Cancer)
  - NAACCR Standards cannot be retrofitted to thousands of heavily customized LISs and EHRs
- Use of Additional Data Sources/Streams
  - A full abstract cannot be completed before treatment is completed, does not cover outcomes and disease management beyond that first course of treatment
  - Pathology reports, medical imaging, clinical notes available in EHR could speed up the initial reporting and extend longitudinal coverage of outcomes and subsequent treatment

The Case for Automation and Collaboration to Improve the Efficiency of Registry Operations

- Automation:
  - Increasing number of data sources will exponentially increase the need for curation procedures at central registries
    - *2 abstracts per case require **1** consolidation procedure*
    - *2 abstracts + 2 path reports + 2 EHR messages requires **5** consolidation procedures*
  - In the absence of automated processing tools, access to EHR systems can overwhelm and ultimately slow the registry operations
  - Efficiency in registry operations = increased access to data sources + algorithmic processing of the new data!
- Healthcare facility/vendor + Central Registry + Federal Surveillance Programs Collaboration
  - NCI & CDC have been collaborating with CoC, AJCC, CAP, NCRA, with support from NAACCR
  - Cancer Registry Use Case requires and will receive the support of the cancer surveillance community at all levels!

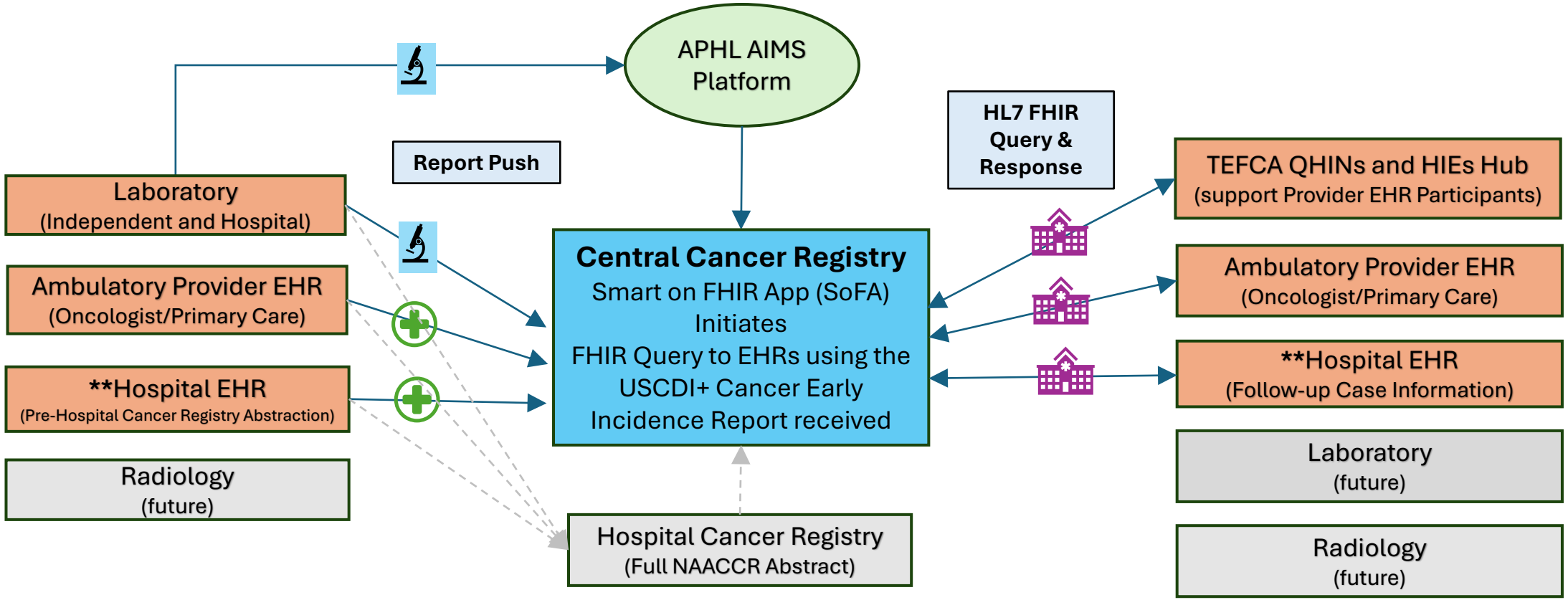
Conclusion

- Cancer surveillance needs a new paradigm to release more timely data for cancer control and more comprehensive treatment and outcome data for cancer research
- A new strategy based on Early Incidence Reports and Query & Response systems facilitated by USCDI + Cancer can help the cancer control and research community achieve these goals

Cancer Registry - Data Flow

Sandy Jones, CDC – NPCR

Cancer Registry Reporting Use Case
USCDI+ Cancer Early Incidence Reporting and Query-Response



****Includes CoC Accredited and Non-CoC Hospitals**

Legend:
- In Scope
- Out of Scope

Report Push: USCDI+ Cancer Early Incidence Reporting

NAACCR Laboratory HL7 v2.5.1 **CAP eCP** and Narrative Reports
(future) HL7 FHIR Cancer Pathology Data Sharing IG

HL7 FHIR USCDI+ Cancer Early Incidence Report Profile/IG (To Be Developed)

HL7 FHIR Query & Response:

- HL7 FHIR Central Cancer Registry Reporting IG
- HL7 CDA Ambulatory Provider Report to Cancer Registry IG
- HL7 FHIR mCODE Profiles

Data Elements and Public Comment Submission Process

Matt Elrod, PT, DPT, ASTP

Cancer Registry Data Elements (minimum dataset)

Data Class	Data Element
Care Team Member	Ordering Physician
Care Team Member	Provider NPI
Diagnostic Imaging	Diagnostic Imaging Report*
Facility Information	Facility Identifier▲
Laboratory	Pathology Report Number
Observations	Sex Parameter for Clinical Use ■
Patient Demographics	Date of Birth*
Patient Demographics	Patient Identifier
Patient Demographics	Race*
Patient Demographics	Previous Address*
Patient Demographics	Medical Record Number
Patient Demographics	Middle Name (Including middle initial)*

Legend

- USCDI v3*
- USCDI v4▲
- USCDI v5■

Data Class	Data Element
Patient Demographics	Current Address*
Patient Demographics	Ethnicity*
Patient Demographics	First Name*
Patient Demographics	Last Name*
Problems	Cancer Diagnosis
Problems	Date of Diagnosis*
Problems	Diagnostic Confirmation
Tumor	Behavior Code ICD-O-3
Tumor	Histology
Tumor	Laterality
Tumor	Primary Site

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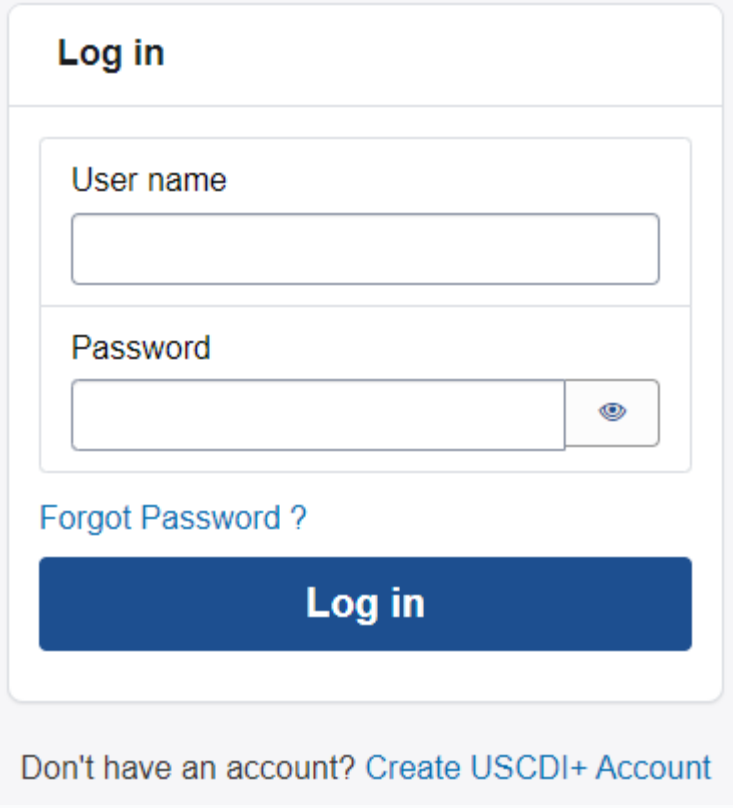
Navigating USCDI+

https://uscdiplus.healthit.gov/



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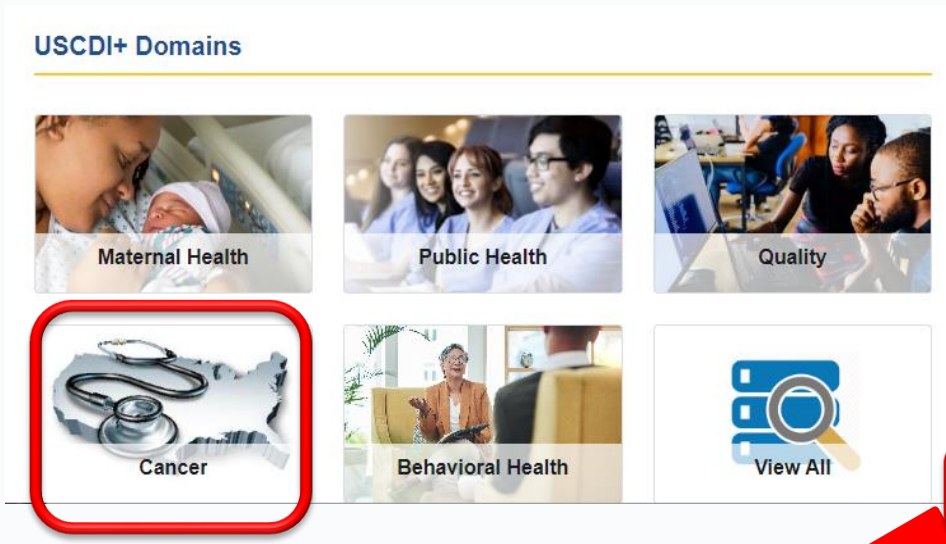
USCDI+ Domains: Cancer



60-day Public Comment Period

July 23 – September 23, 2024

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

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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

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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

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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

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Cancer Registry Use Case: Comments

Cancer Registry

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Details **Comments**

Cancer Diagnosis

Details Relationships **Comments**

*Comment Period

Cancer - Cancer Registry - 2024-07-23 to 2024-09-23

Quality - Quality Draft V1 - 2024-08-15 to 2024-10-15

Submit

*Comment Period

Cancer - Cancer Registry - 2024-07-23 to 2024-09-23

No Comment Period

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Discussion

Eric Durbin, DrPH, MS, Kentucky Cancer Registry

Key Considerations for Feedback

- Level of Specificity
- Data Quality and Completeness
- Integration of Elements Related to Cancer Treatment and Outcomes
- Early Incidence Reporting
- Implementation Considerations

Cancer Registry Use Case: Data Classes

Patient Demographics

Problems (Diagnosis)

Facility Information

Cancer Team Member

Diagnostic Imaging

Laboratory

Observations

Tumor

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Tumor	Behavior Code ICD-O-3
Tumor	Histology
Tumor	Laterality
Tumor	Primary Site

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Community Engagement

Liz Turi, ASTP

Learn More and Stay Engaged!

1

View summit recordings here

2

View the Post-Summit Webinar here

3

Share feedback on USCDI+ Cancer Registry data elements here

4

Reach out to the USCDI+ Cancer Team

USCDI.Plus@hhs.gov

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Reach out via phone or web

202-690-7252

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

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