ASTP Assistant Secretary for Technology Policy

USCDI+ Cancer Public Listening Session

Clinical Trials Matching

Immune-Related Adverse Events

November 7, 2024

1. Welcome and Opening Remarks (3mins)
2. USCDI+ Cancer Overview (10mins)
   - Introduction (5mins)
   - Bridging the Use Cases (5mins)
3. Clinical Trials Matching Use Case (5mins)
4. Immune-Related Adverse Events Use Case (5mins)
5. USCDI+ Platform Walkthrough (5mins)
6. Discussion (30mins)
7. Closing Remarks (3mins)

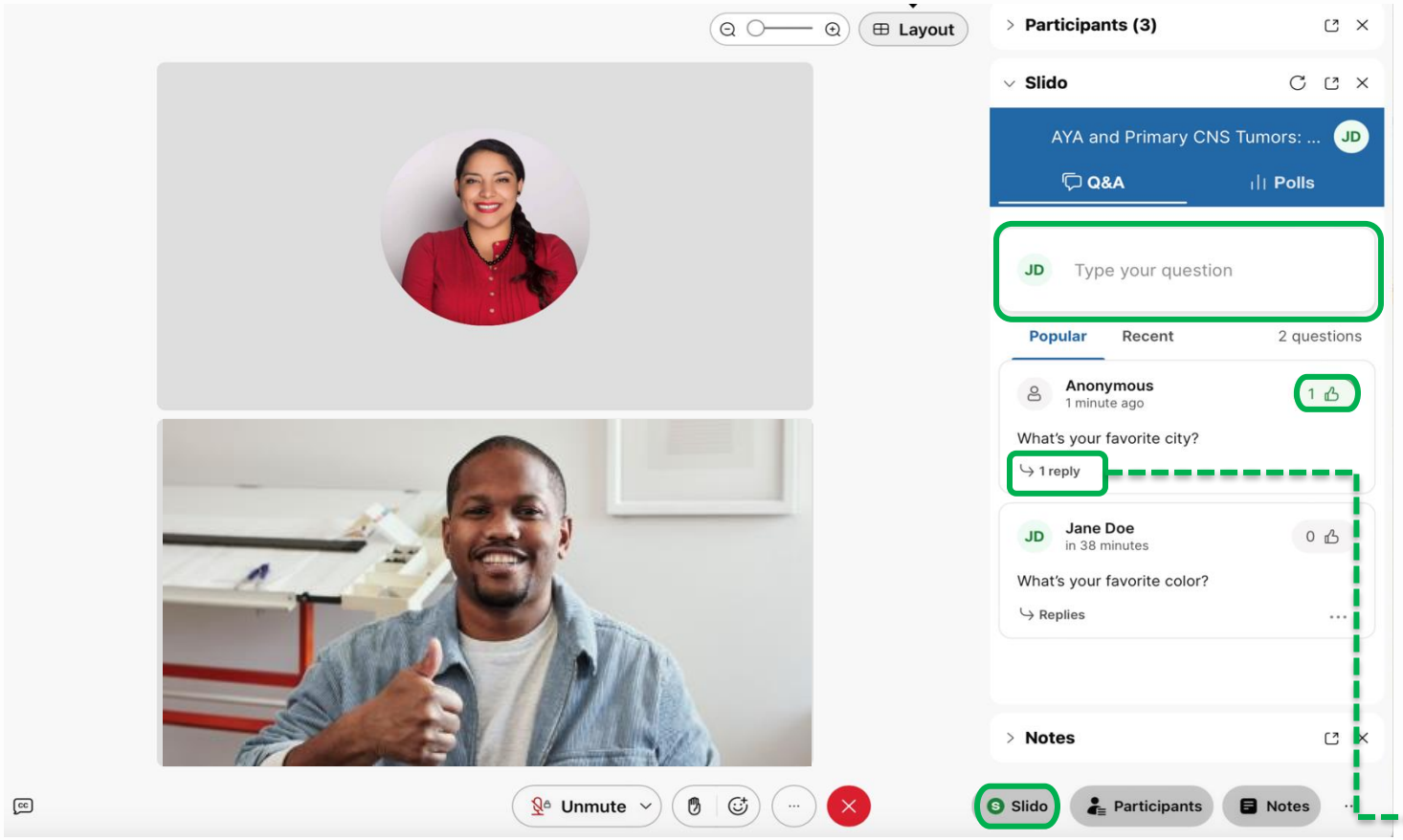
How to Interact during this Listening Session

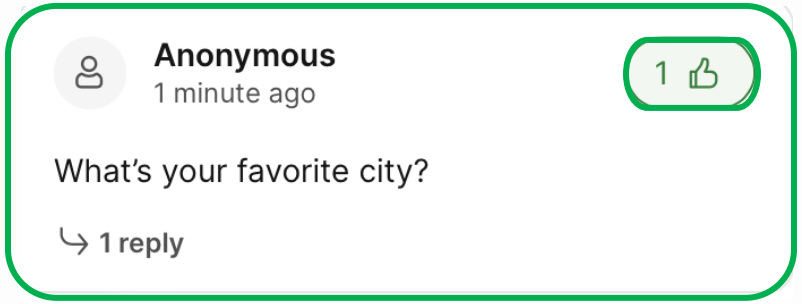
WELCOME

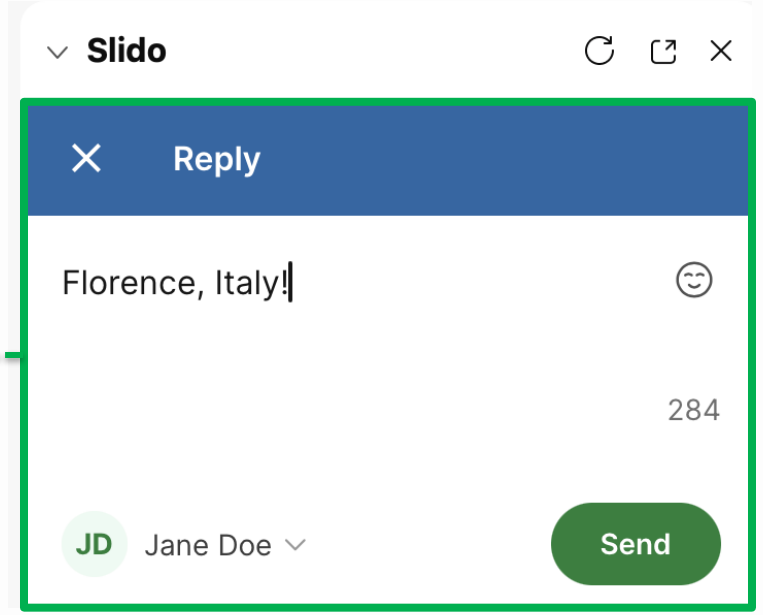
- This Webex Webinar is being recorded.
- The chat will be disabled.
- Join the conversation through the Slido Q&A (right-hand panel).

- For technical support please contact our NCI AV Team Line at 240-276-5880 or NCICRHelp@mail.nih.gov

Submit, reply to or vote for a question on Slido





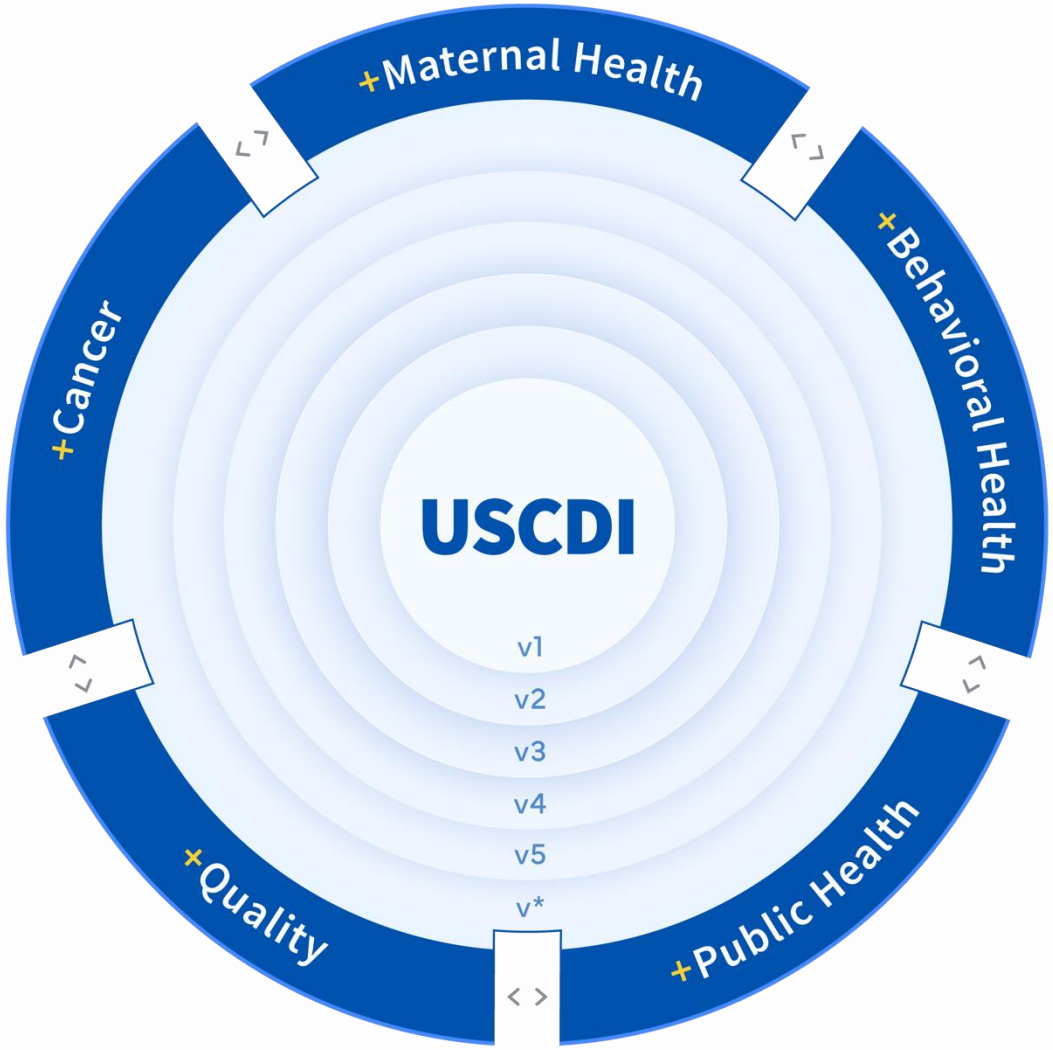


- Join the Q&A by typing your question.
- Select **Reply** in the Q&A panel, type your reply, and then select Send.
- Select 👍 to upvote the best questions.

USCDI+ Cancer Overview

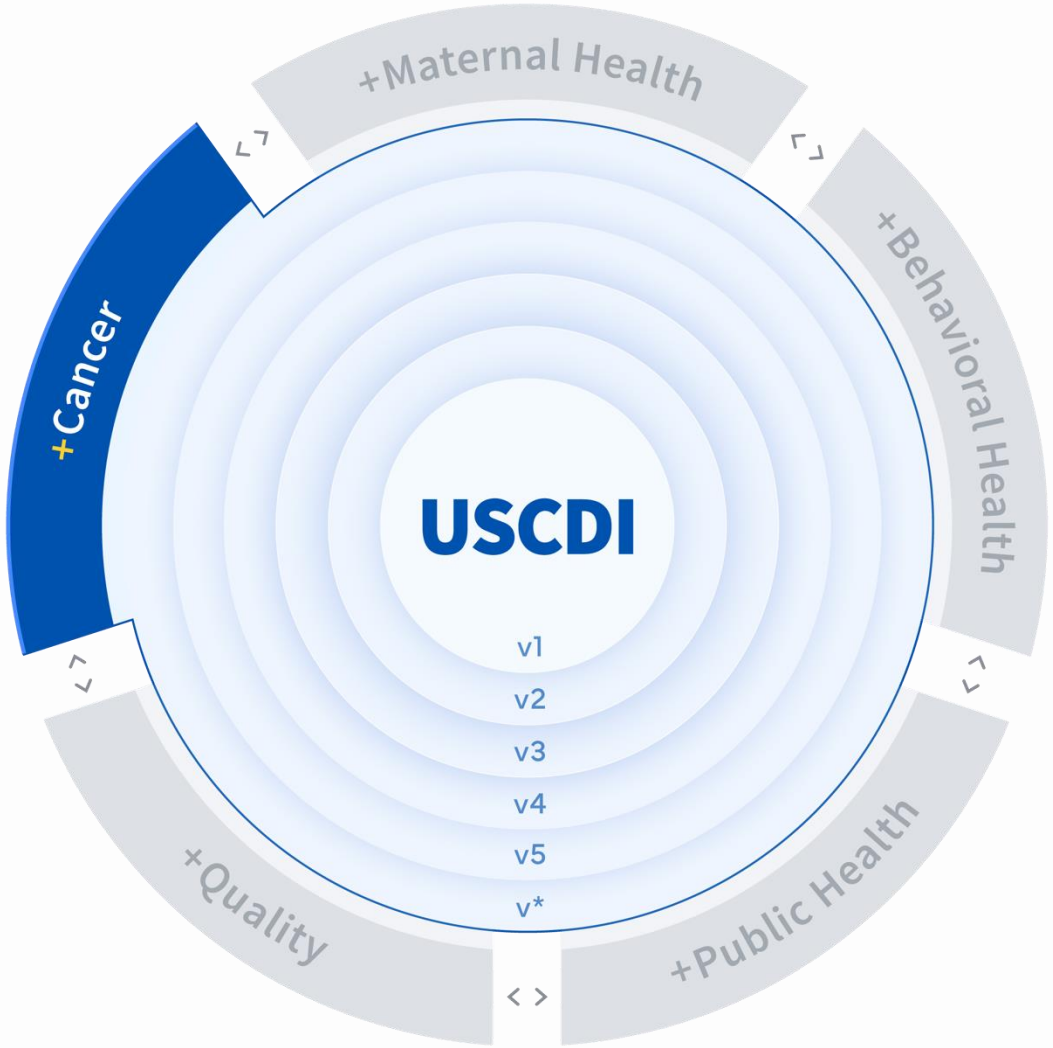
Liz Turi, ASTP

USCDI+: Extending Beyond the USCDI



- Unique program and use case-specific data needs are sometimes not fully met by USCDI.
- ASTP's USCDI+ initiative helps government and industry partners build on USCDI to support specific program needs.
- Applies USCDI processes for submission and harmonization while focusing on programmatic priorities.
- Seeks to leverage programs and authorities across HHS to drive adoption.

USCDI+ Cancer



- ASTP 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.

USCDI+ Cancer Timeline of Activities

Step 1: Develop Data Element Lists

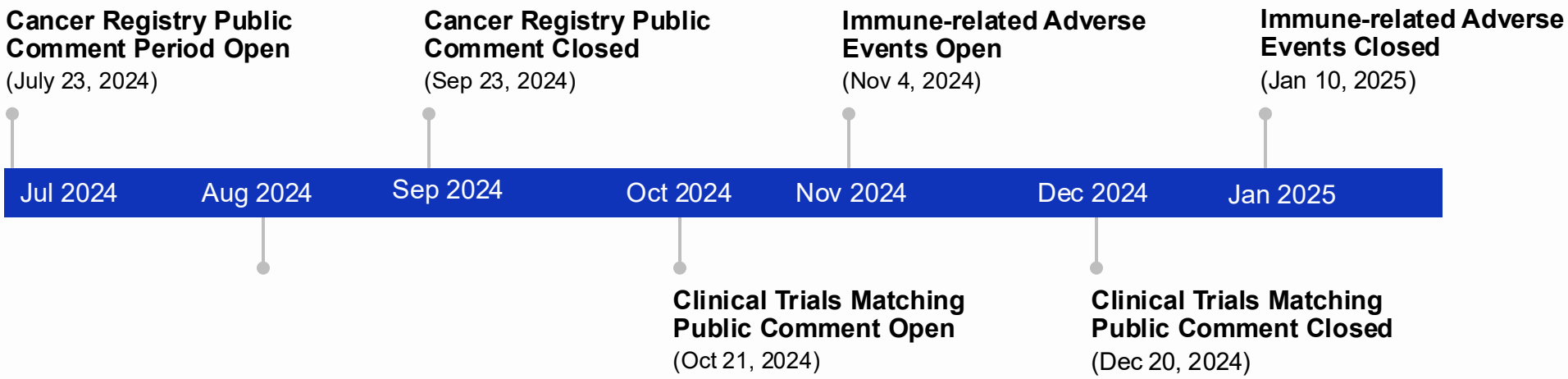
- Reviewed preliminary draft data element lists at Summit in May
- Prioritized and collected feedback
- Refined draft data element lists and publish on USCDI+ Cancer platform to solicit public comment

Step 2: Public Comment Period

- Solicit feedback through the USCDI+ Platform
- Review and disposition comments
- Update draft data elements based on public comments

Step 3: Beyond Public Comment

- Publish updated data element lists
- Develop implementation guidance
- Test
- Pilot



USCDI+ Cancer: Bridging the Use Cases

Umit Topaloglu, NCI

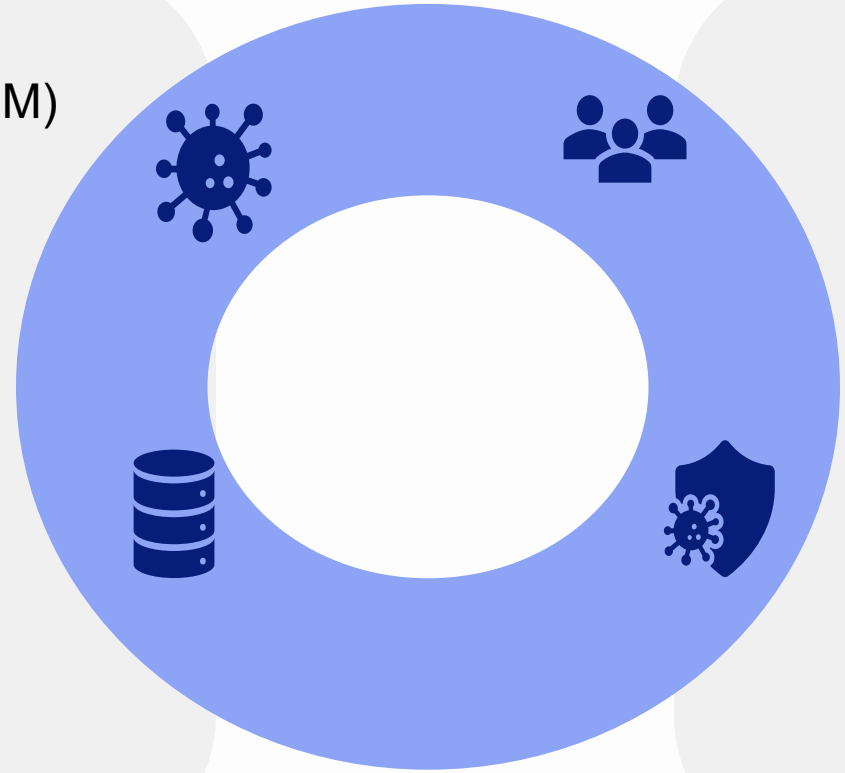
USCDI+ Cancer Use Cases: Data Exchange

Enhancing Oncology Model (EOM)

Align USCDI+ Cancer to EOM to standardize and harmonize data collection for CMMI model; establishes a minimum set of cancer-related data for exchange.

Cancer Registry

Develop approaches and tools to collect cancer registry data directly from EHR and other data sources, and support current data sharing & linkage via SEER and CDC



Clinical Trial Matching

Quickly and accurately extract USCDI+ Cancer RWD elements from EHR, targets the minimal data set needed for initial patient screening to identify potential trial matches.

Immune-related Adverse Events (irAE)

Focus on defining and refining standardized structured data elements that are crucial for identifying signals associated with common immune-related checkpoints for participants in clinical trials

USCDI+ Cancer: Data Class Representation

	EOM	Cancer Registry	CTM	irAE
Patient Demographics*	X	X	X	X
Problems*	X	X	X	X
Tumor	X	X	X	X
Laboratory*		X	X	X
Observations*		X	X	X
Comorbid Conditions			X	X
Radiation Therapy			X	X
Medications*			X	X
Diagnostic Imaging*		X		
Care Team Members*		X		
Facility Information*		X		
Cancer Stage	X			
Health Status Assessments*			X	
Personal Medical History			X	
Vital Signs*				X
Adverse Event				X

Legend

* USCDI Prime

- In all 4 use cases
- In 3 use cases
- In 2 use cases
- In 1 use case

USCDI+ Cancer CTM Use Case

Shannon Silkensen, NCI

Clinical Trials Matching

- Enrolling patients and conducting clinical trials involves extensive data exchange between clinical and research systems.
- This USCDI+ work specifically targets the **minimal data set** needed for **initial patient screening to identify potential trial matches**.
- Aim is to generate a potential list of trials for which a patient may be eligible.
- By narrowing down these options, patients and healthcare providers can engage more effectively in the decision-making process for cancer treatment and care.

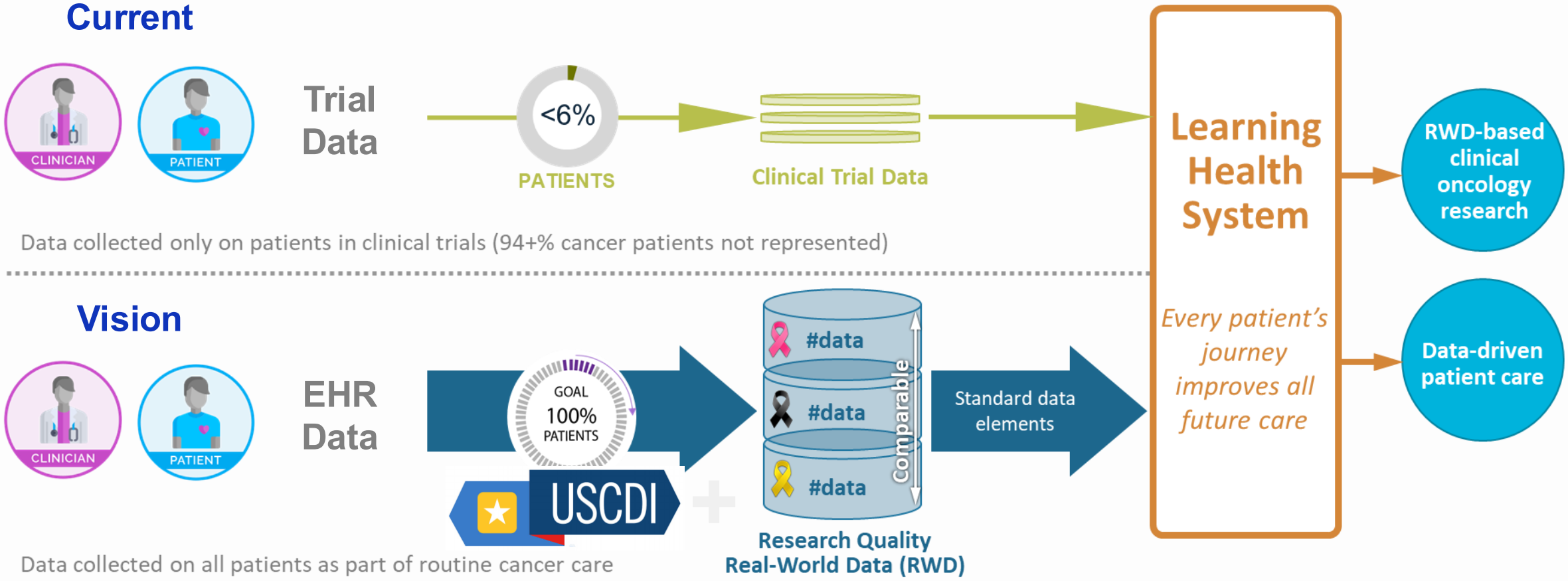
Clinical Trial Matching: Current Limitations and Future Solutions

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

USCDI+ Cancer irAE Use Case

Ali Abbasi, FDA

Real-World Data can help us learn from all patients



Adapted from ICAREdata® Project

Introduction to Immune-related adverse events

irAEs are associated with immune checkpoint blockade

FDA approved therapeutics:

Ipilimumab

Nivolumab

Pembrolizumab

Atezolizumab

Avelumab

Durvalumab

Encephalitis, Aseptic Meningitis

Uveitis

Mucositis

Thyroiditis

Pneumonitis

Hepatitis

Adrenal Insufficiency

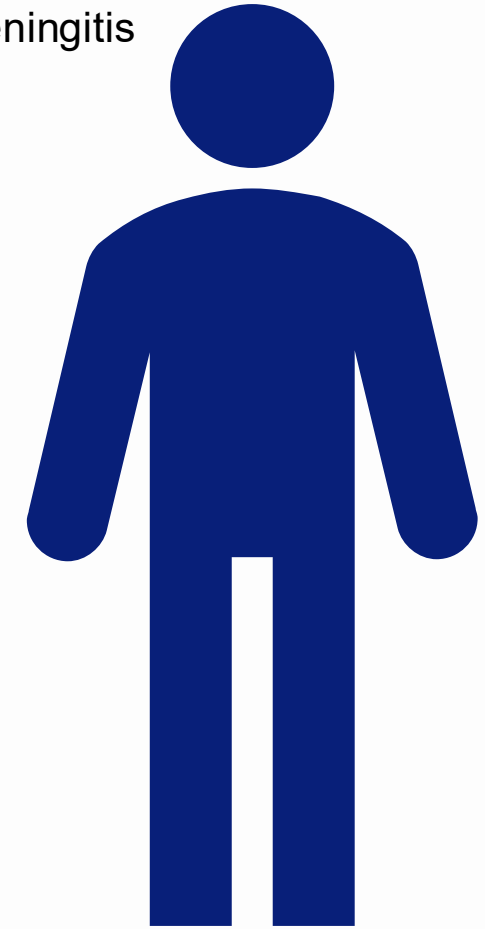
Pancreatitis, Diabetes

Colitis, Enteritis

Vasculitis

Arthralgia

Neuropathy



Immune-related Adverse Events Use Case Goals

- Significantly enhance the accuracy and reliability of detecting signals for immune-related adverse events using real-world data.
- Focus on defining and refining standardized structured data elements that are crucial for identifying signals associated with common immune-related checkpoints for participants in clinical trials*.
- Leverage Electronic Health Records (EHRs) as the primary data source, ensuring that these data elements are both comprehensive and precise.
- FDA-compliant adverse event reports will serve as a baseline to maintain high data quality, reinforced by clear protocols and are standardized data structures.
- Play a pivotal role in validating the extraction of irAEs using large language models (LLMs), further enhancing the accuracy and reliability of irAE reporting, improved detection of adverse event signals, and ultimately improving patient safety and outcomes in cancer treatment.

* Implementations may differ depending on trial phase

Immune-Related Adverse Events: Current Limitations and Future Solutions

- 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.
- 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.

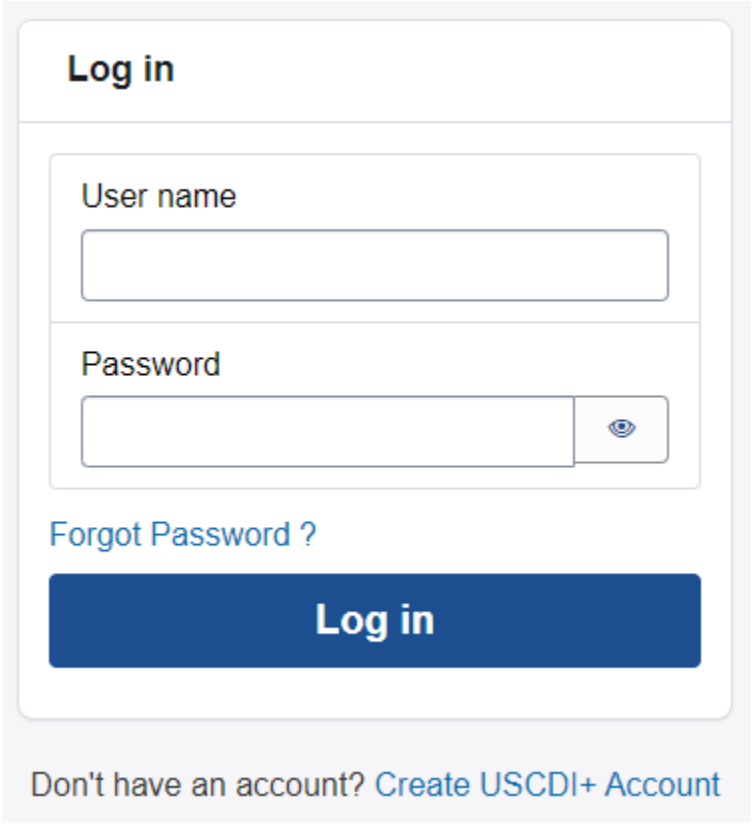
USCDI+ Platform Walkthrough

Matt Elrod, ASTP

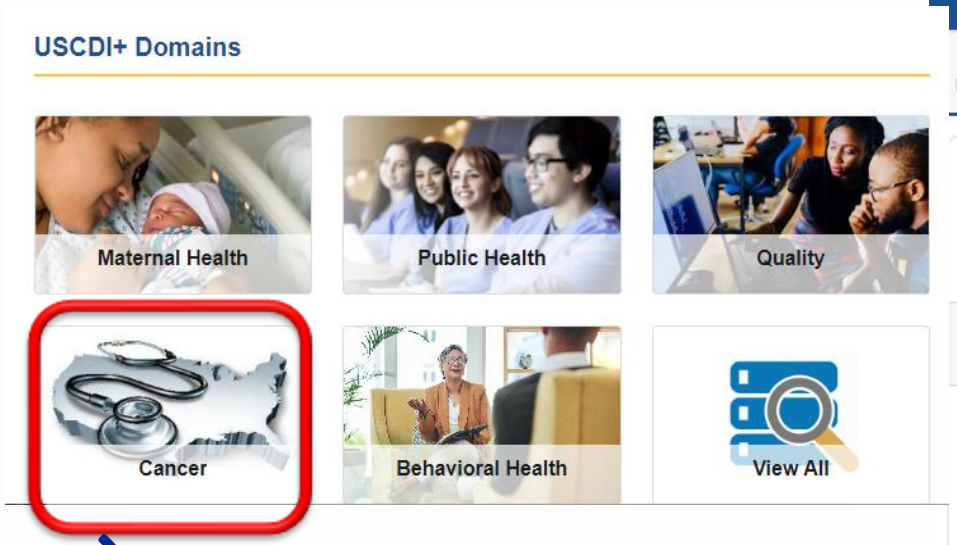
- Navigating USCDI+
- CTM and irAE Data Elements
- CTM and irAE Data Relationships
- Submitting Comments

Navigating USCDI+

https://uscdiplus.healthit.gov/



USCDI+ Domains: Cancer



CTM: 60-day Public Comment Period
Oct 21 – Dec 20, 2024

IrAE: 60-day Public Comment Period
Nov 4 – Jan 10, 2025

Cancer

The USCDI+ Cancer domain 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 Overarching	The superset of all data elements reflected across USCDI+ Cancer use cases currently available in USCDI+ Platform.
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). To maintain the highest quality and consistency in pathology reporting, ONC, NCI and CDC strongly recommend that implementers adhere to the CAP protocols when meeting pathology reporting requirements. CAP cancer protocols are available both as free downloadable templates, and in a licensed electronic format that can be incorporated in Laboratory Information Systems (LIS). Access the free CAP cancer protocols here: https://www.cap.org/protocols-and-guidelines/cancer-reporting-tools/cancer-protocol-templates
Clinical Trials Matching	This USCDI+ Cancer use case aims to optimize personalized treatment and clinical trial matching by developing a minimum core dataset that improves the accuracy and efficiency of matching patient data with open clinical trial protocols.
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.
Immune-related Adverse Events	This USCDI+ Cancer use case focuses on standardizing structured data elements for identifying signals associated with common immune-related adverse events, particularly in patients participating in cancer clinical trials.

CTM and irAE Use Cases: Data Elements

Clinical Trials Matching

This USCDI+ Cancer use case aims to optimize personalized treatment and clinical trial matching by developing a minimum core dataset that improves the accuracy and efficiency of matching patient data with open clinical trial protocols.

Details | Comments

Details

Data Element	Description
Behavior Code	Code for the behavior of the tumor being reported using ICD-O-3.
Clinical Performance Status	A physician's assessment of the clinical performance of the patient, as measured b rating or scale, considering disease and potential responses to therapy.
Clinical Performance Status Assessment Date	Clinically relevant time/time-period for the assessment.
Comorbid Condition Name	Medical or health condition that is concomitant or concurrent with the primary condition or disease under study.
Current Address	Place where a person is located or may be contacted.
Current Clinical Status Date	Clinically relevant time/time-period for observation.
Current Clinical Status Trend	How patient's given disease, condition, or ability is trending. EOM allowed values are: - Patient's condition improved - Patient's condition stable

Immune-related Adverse Events

This USCDI+ Cancer use case focuses on standardizing structured data elements for identifying signals associated with common immune-related adverse events, particularly in patients participating in cancer clinical trials.

Details | Comments

Details

Keyword Search

Data Element	Description	Data Class	Domain
Adverse Event Onset Date	The date on which the adverse event was first evident.	Adverse Events	Cancer
Adverse Event Resolution Date	The date on which the adverse event was resolved.	Adverse Events	Cancer
Behavior Code	Code for the behavior of the tumor being reported using ICD-O-3.	Tumor	Cancer
Body Height	The vertical measurement of an individual's stature from the feet to the top of the head when standing upright.	Vital Signs	Cancer
Body Weight	The measurement of weight without heavy items located on the person.	Vital Signs	Cancer
Comorbid Condition Name	Medical or health condition that is concomitant or concurrent with the primary condition or disease under study.	Comorbid Conditions	Cancer
CTCAE Grade	Grade refers to the severity of the AE. The CTCAE displays Grades 1 through 5 with unique clinical descriptions of severity for each AE based on a general guideline	Adverse Events	Cancer

Data Element - Details

Histology

Details | Relationships | Comments

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

Histology

Data Element Name:
Histology

Submission Status:
Published

USCDI+ Leve

Description:
The morphologic and behavioral characteristics of the cancer reported using ICD-O-3.

Additional Information:
USCDI+ Cancer: This data element aligns with but is not defined by NAACCR Item #522

USCDI Information

In USCDI:
No

Current USCDI Level:

USCDI URL:

Standards and Projects

Applicable Vocabulary Standard(s):
ICD-O

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

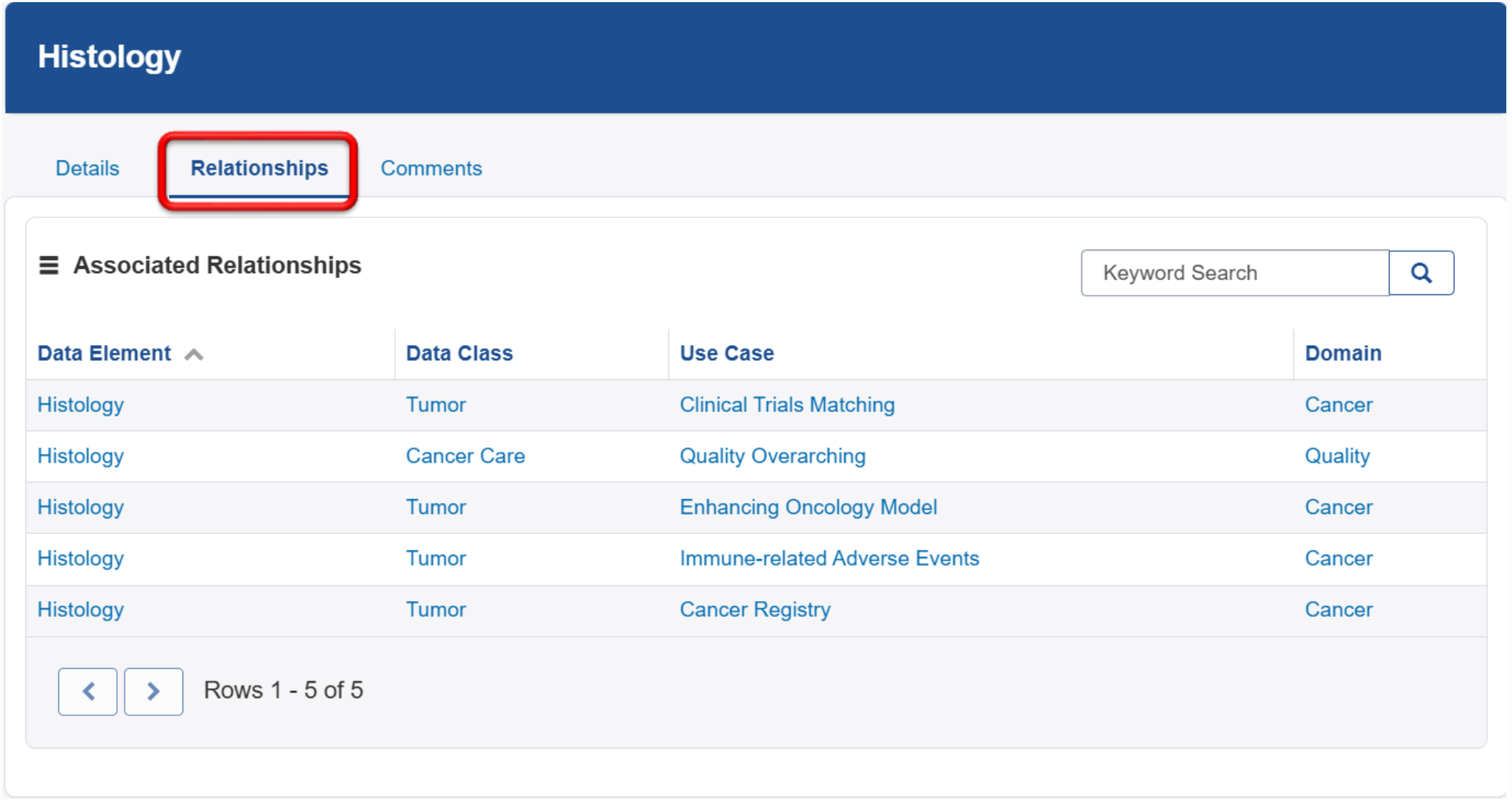
Associated US Core Profile(s):

Associated Project(s):
NAACCR Incidence

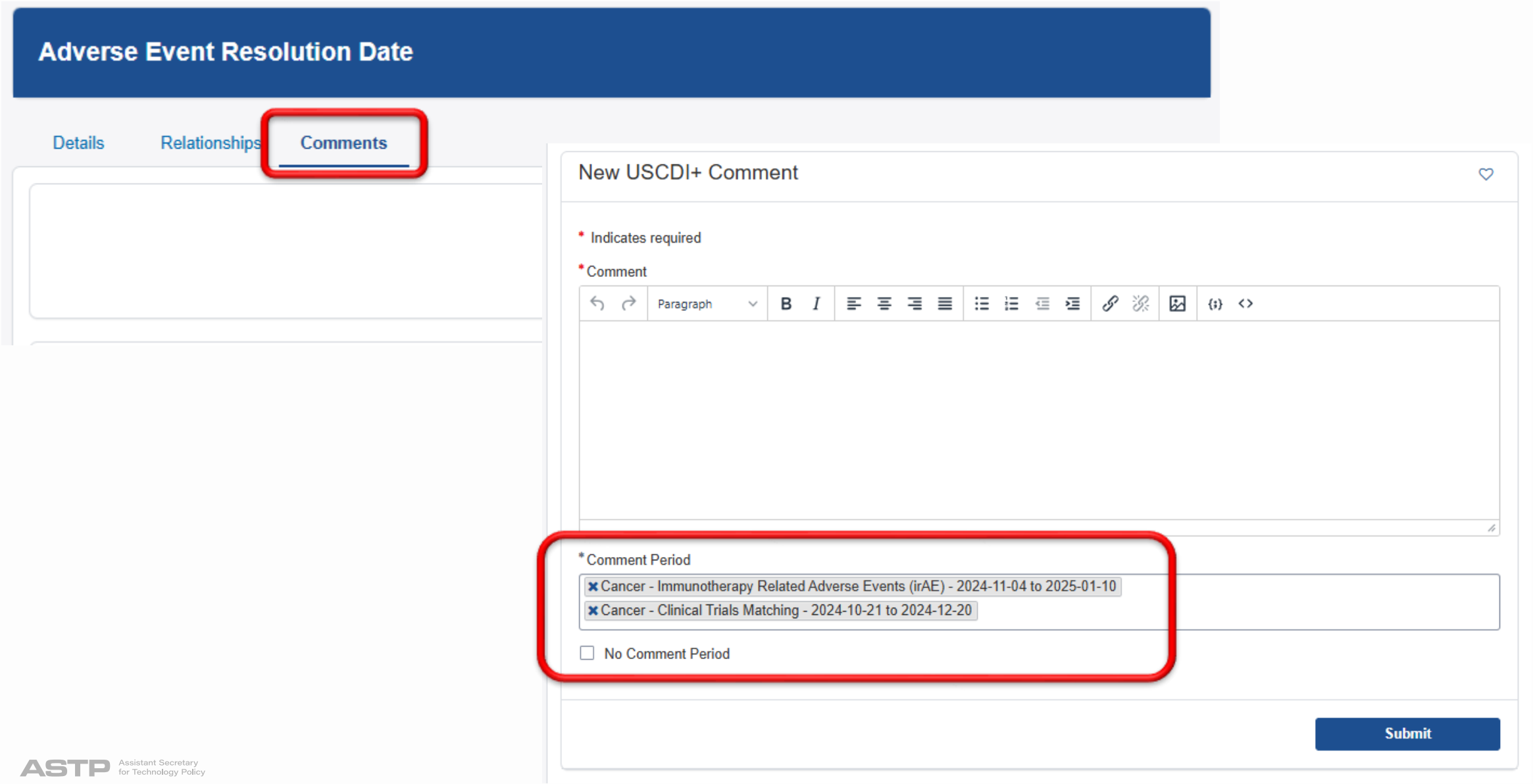
Associated IG or Profile(s):
Primary Cancer Condition

EOM Primary Cancer Condition

Data Element - Relationships



USCDI+ Cancer: Comments



Discussion

Elad Sharon, Dana Farber Institute

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Join the conversation through the Slido Q&A (right-hand panel).

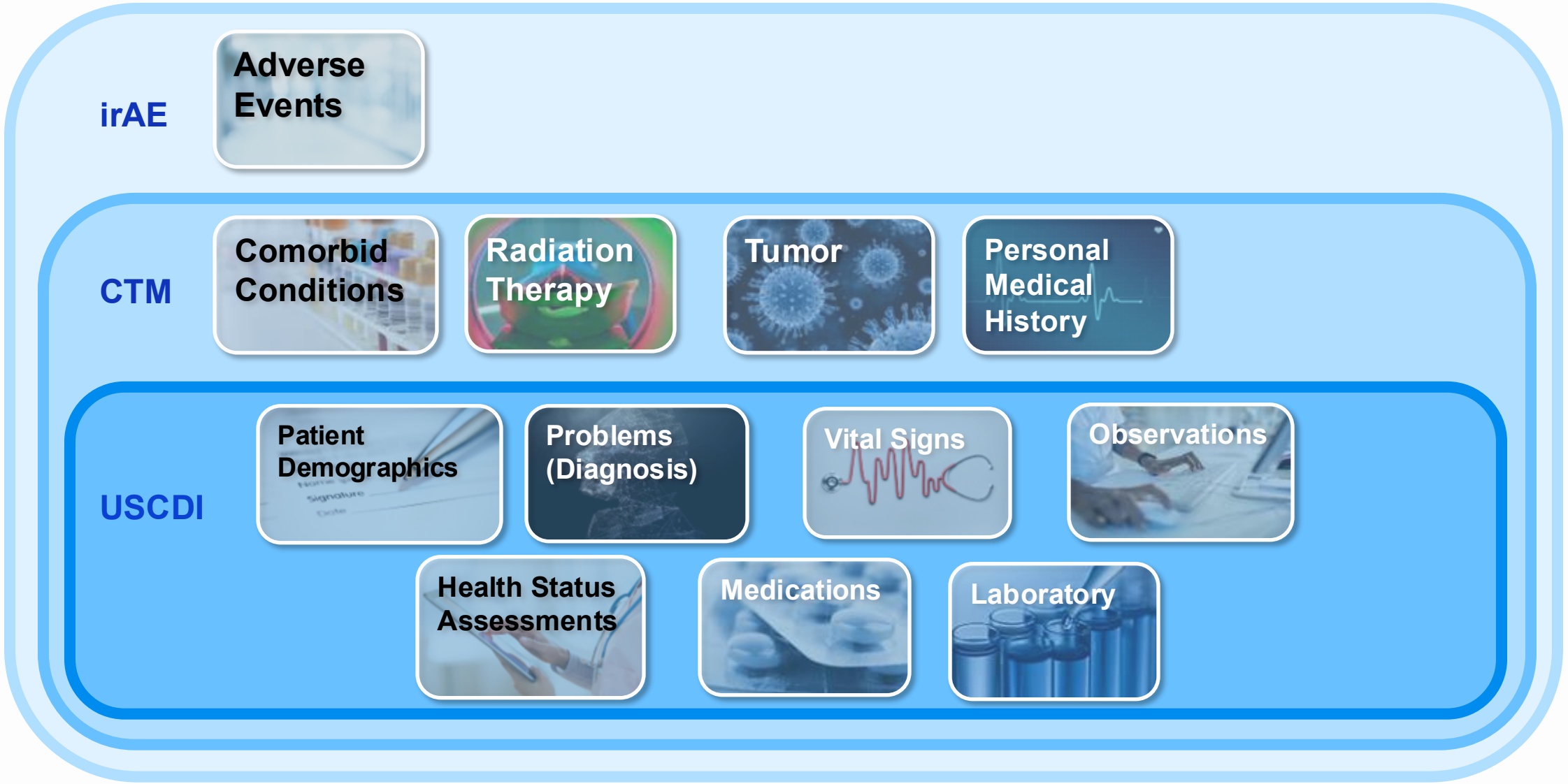
- **Join the Q&A by typing your question.**
- **Select Reply in the Q&A panel, type your reply, and then select Send.**
- **Select**  **to upvote the best questions.**

For technical support please contact our NCI AV Team Line at 240-276-5880 or NCICRHelp@mail.nih.gov

Key Considerations for Feedback

- Level of Specificity
- Data Quality, e.g. Completeness
- Integration of Elements Related to Cancer Treatment and Outcomes
- Implementation Considerations

USCDI+ Cancer – CTM and irAE Data Classes



Community Engagement

Liz Turi, ASTP

Learn More and Stay Engaged!

1

View summit recordings here

2

View the Post-Summit Webinar and other Listening Session recordings here

3

Share feedback on USCDI+ CTM and irAE data elements here

4

Reach out to the USCDI+ Cancer Team

USCDI.Plus@hhs.gov

Reach out via phone or web

202-690-7151

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

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CTM Use Case Data Elements

Data Class	Data Element
Comorbid Conditions	Comorbid Condition Name
Health Status Assessment	Clinical Performance Status
Health Status Assessment	Clinical Performance Status Assessment Date
Health Status Assessment	Pregnancy Status +
Health Status Assessment	Smoking Status +
Laboratory	Laboratory Results: Date and Timestamps
Laboratory	Result Reference Range ^
Laboratory	Result Unit of Measure ^
Laboratory	Tests +
Laboratory	Values/Results +
Medications	Date Medication Administered
Medications	Medication Class
Medications	Medications +
Observations	Sex Assigned at Birth +

Legend

USCDI v3 +

USCDI v4 ^

USCDI v5 **O**

Data Class	Data Element
Patient Demographics	Current Address +
Patient Demographics	Date of Birth +
Patient Demographics	Ethnicity +
Patient Demographics	Race +
Personal Medical History	Personal Medical History Procedure Name
Personal Medical History	Personal Medical History Procedure Performance Date
Problems	Current Clinical Status Date
Problems	Current Clinical Status Trend
Problems	Date of Diagnosis +
Problems	Recurrence or Relapse Clinical Status
Radiation Therapy	Radiation Therapy Indicator
Tumor	Behavior Code
Tumor	Histology
Tumor	Metastasis Anatomic Site
Tumor	Primary Site

irAE Use Case Data Elements

Data Class	Data Element
Adverse Events	Adverse Event Onset Date
Adverse Events	Adverse Event Resolution Date
Adverse Events	CTCAE Grade
Adverse Events	CTCAE Term
Comorbid Conditions	Comorbid Condition Name
Laboratory	Laboratory Results: Date and Timestamps
Laboratory	Result Reference Range ^
Laboratory	Result Unit of Measure ^
Laboratory	Specimen Type +
Laboratory	Tests +
Laboratory	Values/Results +
Medications	Date Medication Administered
Medications	Medications +
Observations	Sex Assigned at Birth +
Patient Demographics	Date of Birth +
Patient Demographics	Ethnicity +

Legend

USCDI v3 **+**

USCDI v4 ^

USCDI v5 **O**

ES

Data Class	Data Element
Patient Demographics	Patient Identifier
Patient Demographics	Patient Identifier Type
Patient Demographics	Race +
Problems	Current Clinical Status Date
Problems	Current Clinical Status Trend
Problems	Date of Diagnosis +
Problems	Recurrence or Relapse Clinical Status
Radiation Therapy	Radiation Cumulative Dose
Radiation Therapy	Radiation Cumulative Dose Unit of Measure
Radiation Therapy	Radiation Therapy Anatomic Site
Radiation Therapy	Radiation Therapy End Date
Radiation Therapy	Radiation Therapy Indicator
Radiation Therapy	Radiation Therapy Start Date
Tumor	Behavior Code
Tumor	Histology
Tumor	Laterality
Tumor	Metastasis Anatomic Site
Tumor	Primary Site
Vital Signs	Body Height +
Vital Signs	Body Weight +