ASTP Assistant Secretary for Technology Policy

USCDI+ Cancer Update

Liz Turi, MEng, CPHIMS

Care Coordination and Collaboration Branch Chief

Office of Standards, Certification, and Analysis

ASTP

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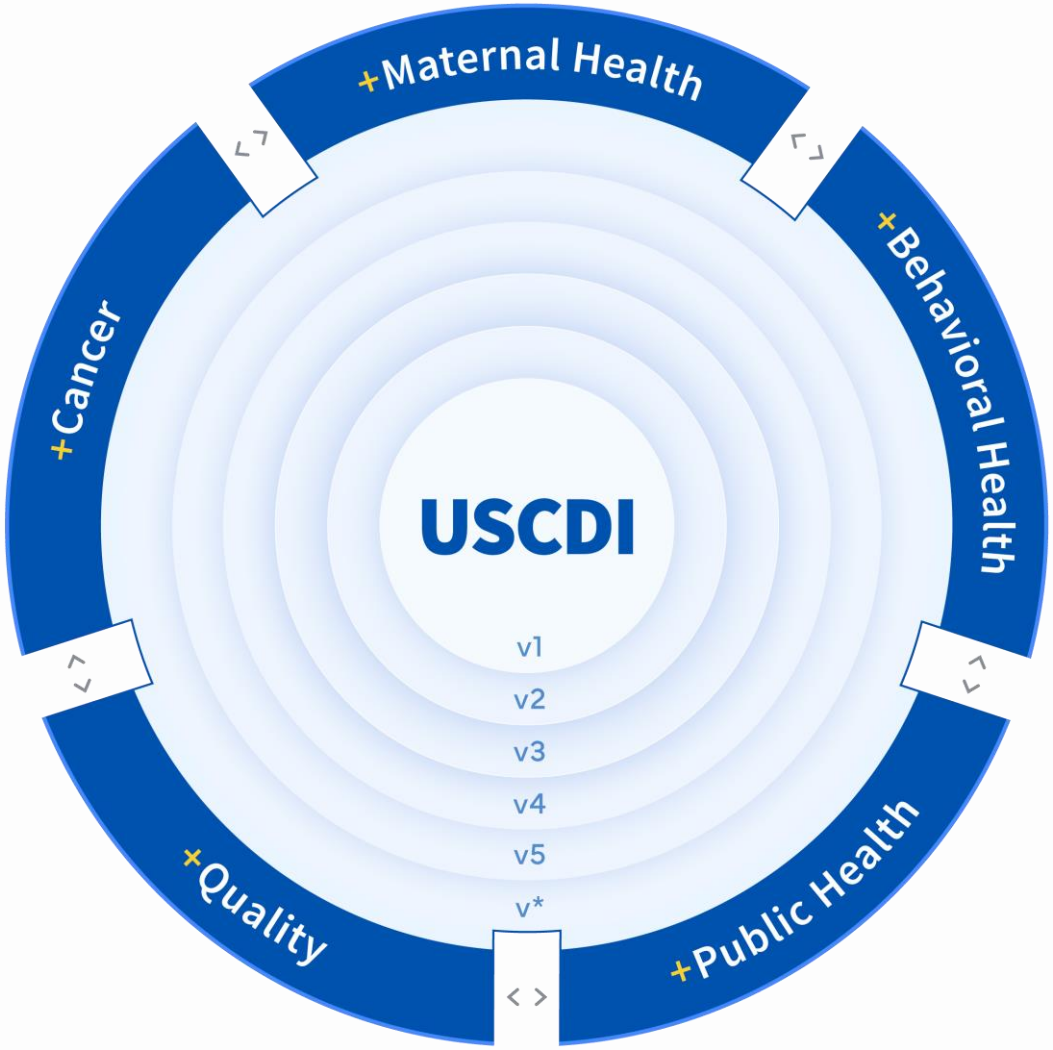
1. USCDI+ Cancer Background

2. Cancer Data Exchange Summit Recap

3. Use Case Update
   - Enhancing Oncology Model (EOM)
   - Cancer Registry (CR)
   - Clinical Trials Matching (CTM)
   - Immunotherapy Related Adverse Events (irAE)

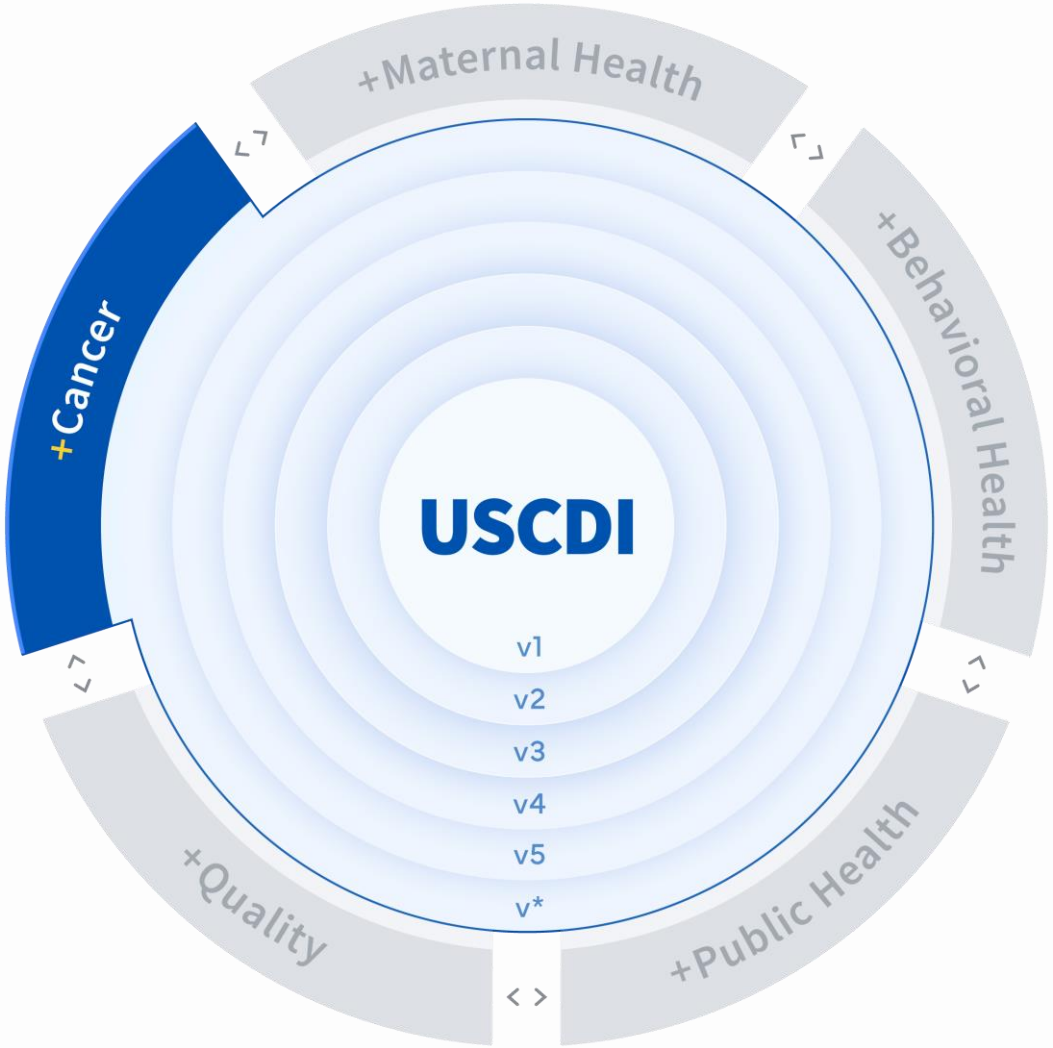
4. Next Steps

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



- 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.

Lifecycle of a USCDI+ Project

- This lifecycle assumes a USCDI+ Project that leverages use cases for refinement
- Not all projects have a specific production process as a goal

Special Considerations for USCDI+ Cancer

- White House Commitments by EHR Vendors
- Ties to Cancer Moonshot
- Need to Collect Information at an Accelerated Timeline

The World of USCDI+ Cancer

HealthIT.gov USCDI+

Use Cases

- Enhancing Oncology Model
- Cancer Registry
- Clinical Trial Matching
- Immune-related Adverse Events

Existing Standards

USCDI

mCODE™ NAACCR

Key Partners

ASTP Assistant Secretary for Technology Policy

CMS.gov

CDC Centers for Disease Control and Prevention

FDA

NIH National Cancer Institute

Accelerators

VULCAN HL7 FHIR

CodeX

FAST FHIR at Scale Taskforce HL7 FHIR

Community Initiatives

CancerX

The White House Washington

Research

Prospective Data Study

Real World Data

Retrospective Study Data

Additional Scope

Data Use Agreement

Research Authorization (Data Sharing)

Informed Consent (Study)

Cancer Data Exchange Summit Recap

Cancer Data Exchange Summit

Establish “The Why”

- Set context
  - Leadership
  - Federal
  - Industry
  - Patient

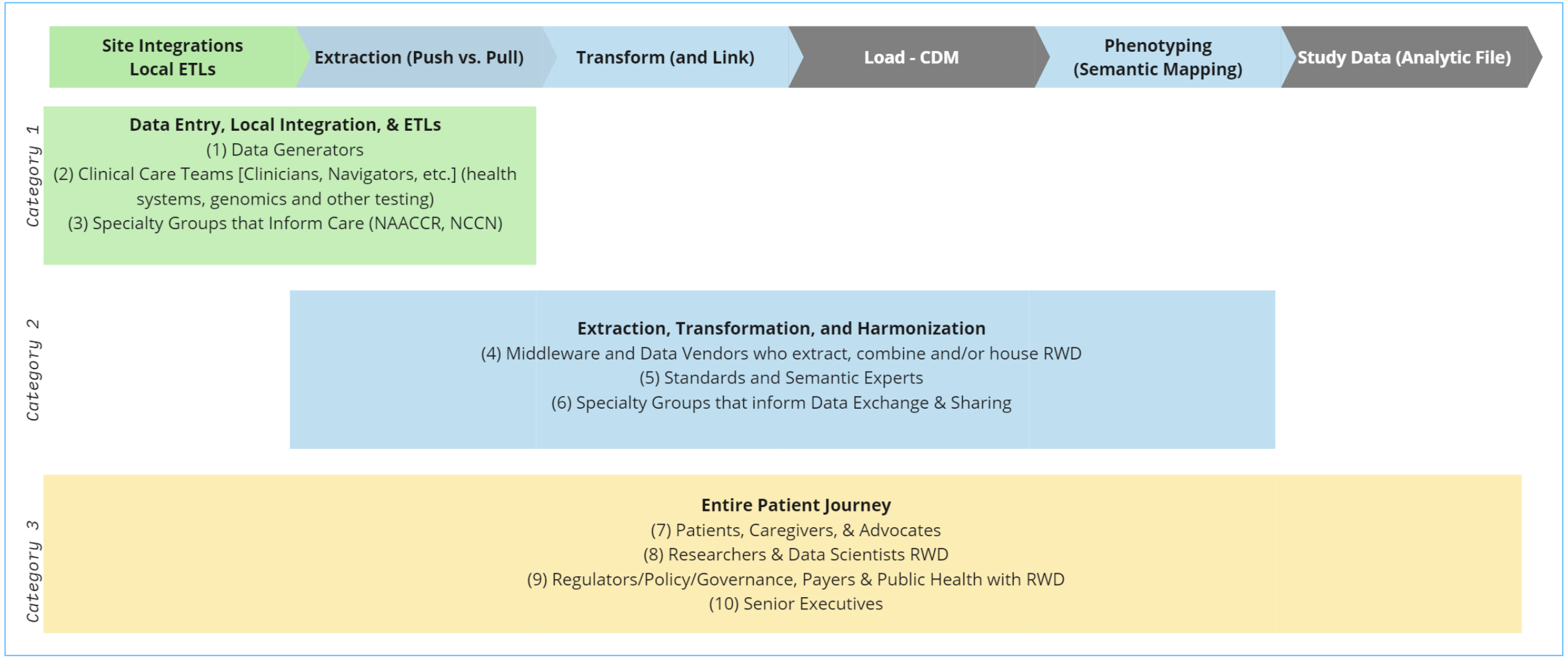
Breakout Across User Perspectives

- Ten User Perspectives
  - Data Generators
  - Clinical Care Teams
  - Specialty Groups that Inform Care
  - Middleware and Data Vendors
  - Standards and Semantics Experts
  - Specialty Groups that Inform Data Exchange and Sharing
  - Patients, Caregivers, & Advocates
  - Researchers & Data Scientist RWD
  - Regulatory/Policy/Governance, Payers & Public Health with RWD
  - Senior Executives

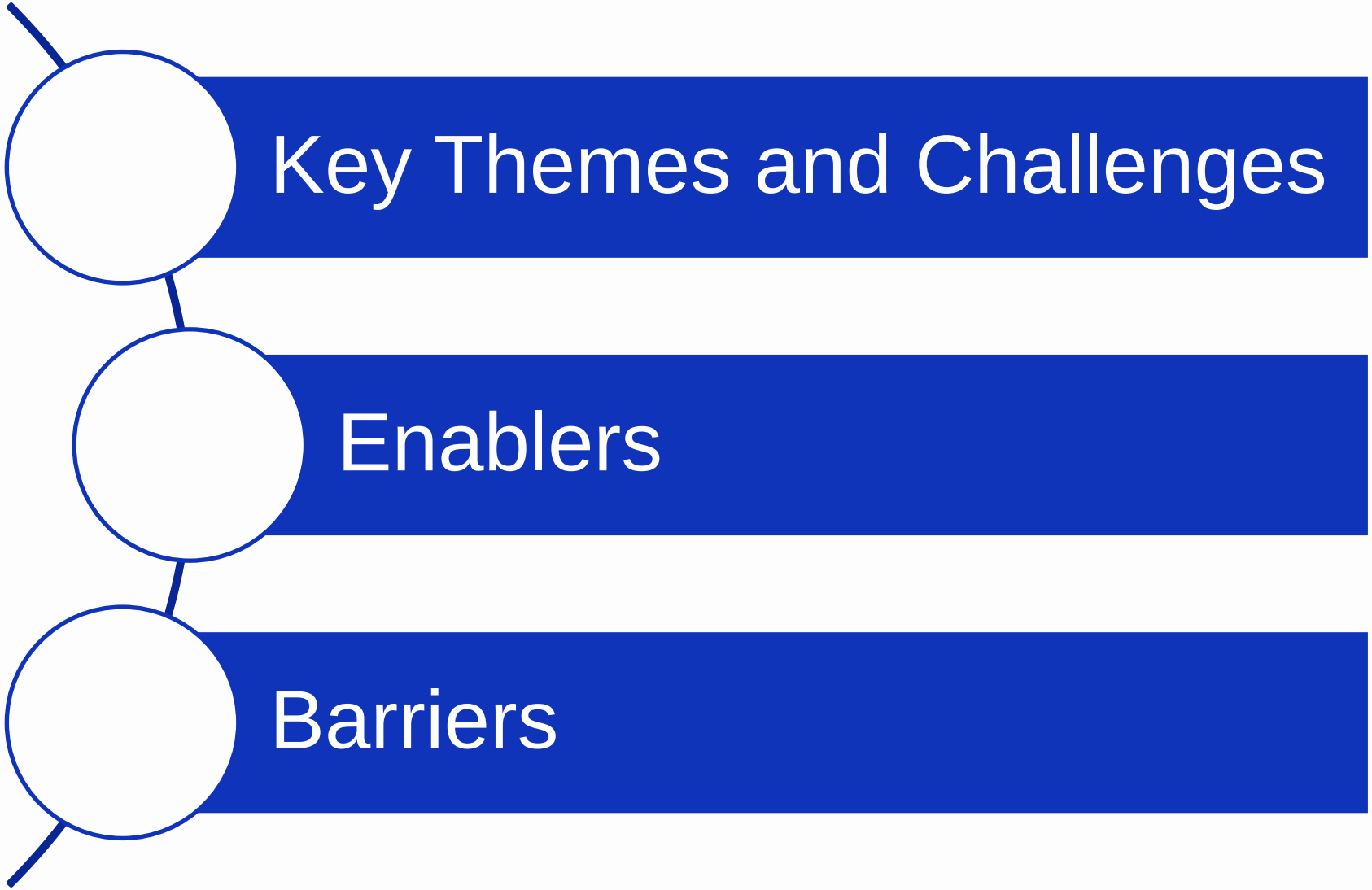
Breakout Across Use Cases

- Enhancing Oncology Model (EOM)
- Cancer Registry (CR)
- Clinical Trials Matching (CTM)
- Immunotherapy-related Adverse Events (irAE)

Data Journey Framework



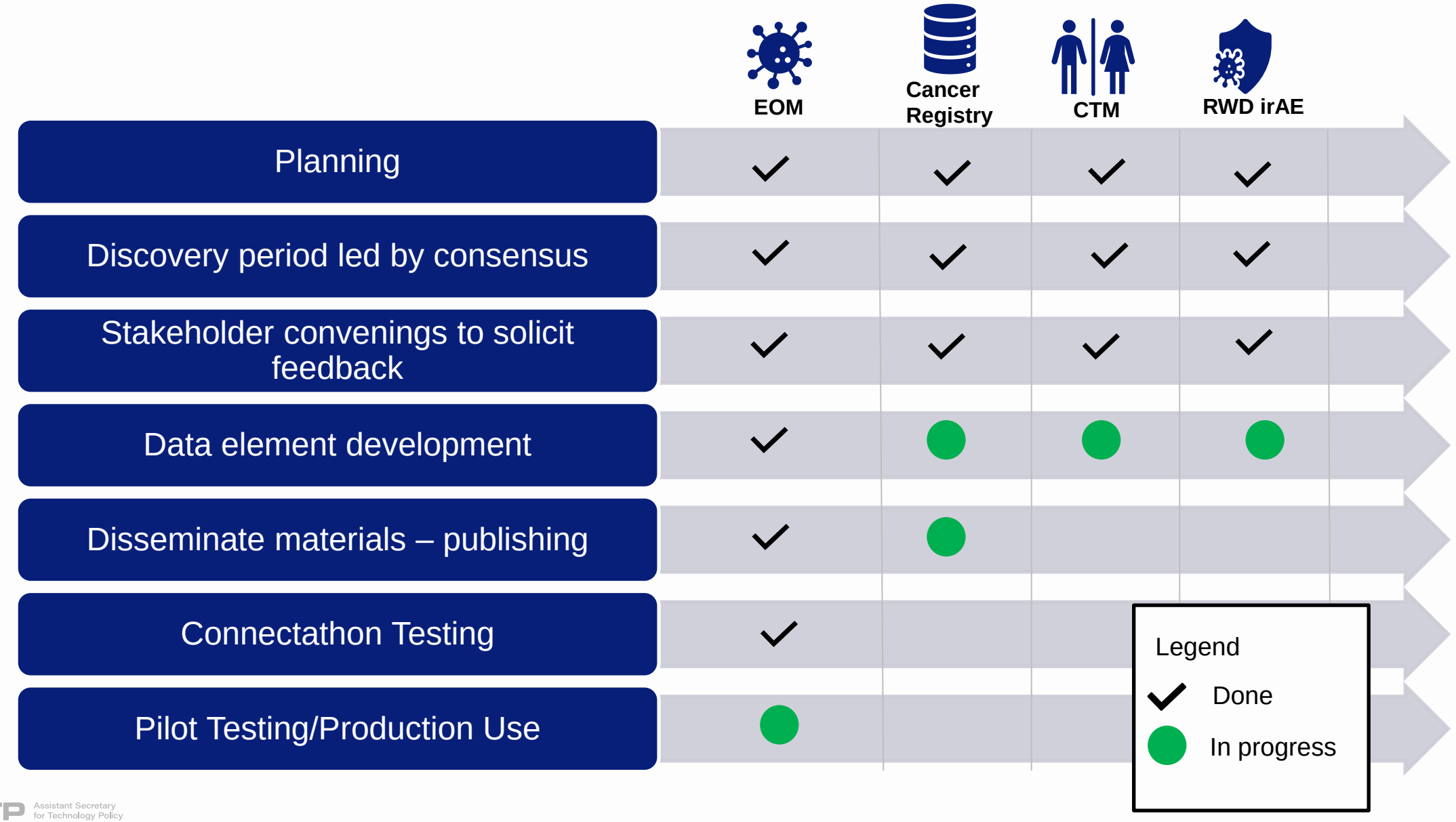
Summit Focus Areas



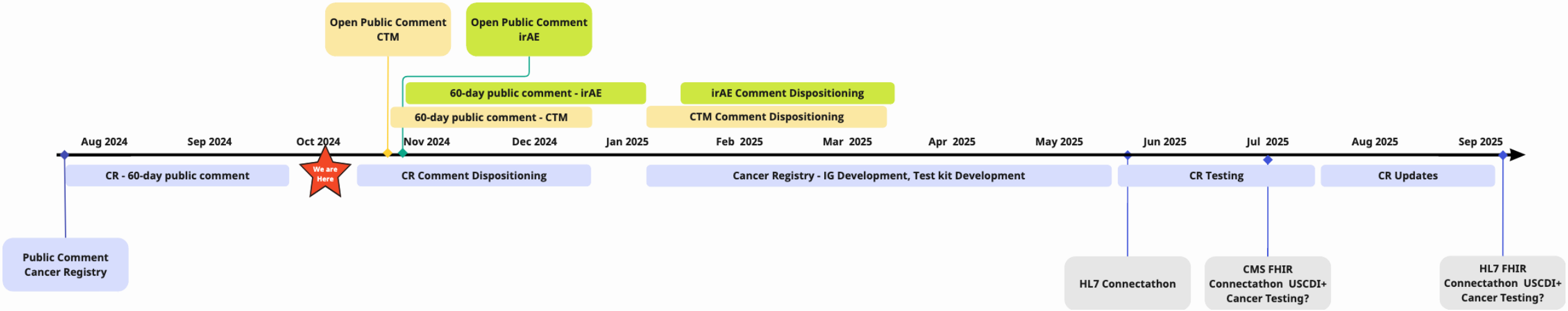
Use Cases


Clinical Trials Matching (CTM)
Immunotherapy related Adverse Events (irAE)
Cancer Registry: Early Incidence Reporting (CR)
Enhancing Oncology Model (EOM)

USCDI+ Cancer Status: Development Progress



USCDI+ Cancer Draft Timeline – through September 2025



USCDI+ Cancer Comment Disposition Process

Coordination across use cases, domains, and with USCDI

Organization

- Gather comments from Platform
- Clean up, consolidate, and categorize comments
- Sorting themes, types of updates/changes

Harmonization

- Identify data elements that have comments impacting other use cases, prioritize these to ensure harmonization
- Identify data element comments that are impacted by USCDI
- Identify data element comments that impact or are impacted by other USCDI+ domains

Partner Agency Input

- Initial review by small group of federal partners leading use case
- Weekly updates with small group in advance of larger federal partner group
- Final review and decision making through wider group of federal partners engaged in USCDI+ Cancer

Disposition

- Consensus driven within context of the needs of the use case
  - Remove
  - Replace
  - Update
    - Change definition
    - Harmonize definition

Enhancing Oncology Model (EOM)

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

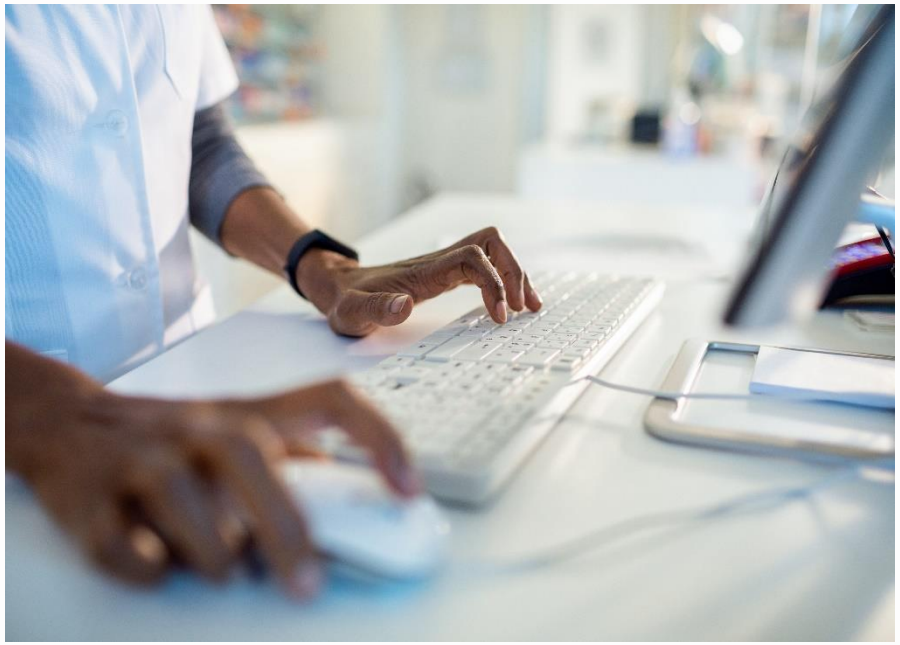
- Published on USCDI+ Cancer platform in May
- Developed EOM IG providing guidance on details, terminologies, and definitions necessary for collection and reporting of clinical data for specific cancer types
- Tested at May HL7, and July CMS FHIR Connectathon
- Publish updates from testing

Next Steps (now through October)

- EOM Participants leverage EOM IG to report clinical data elements for Production “high tech” submissions.

Need

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



Cancer Registry (CR)

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

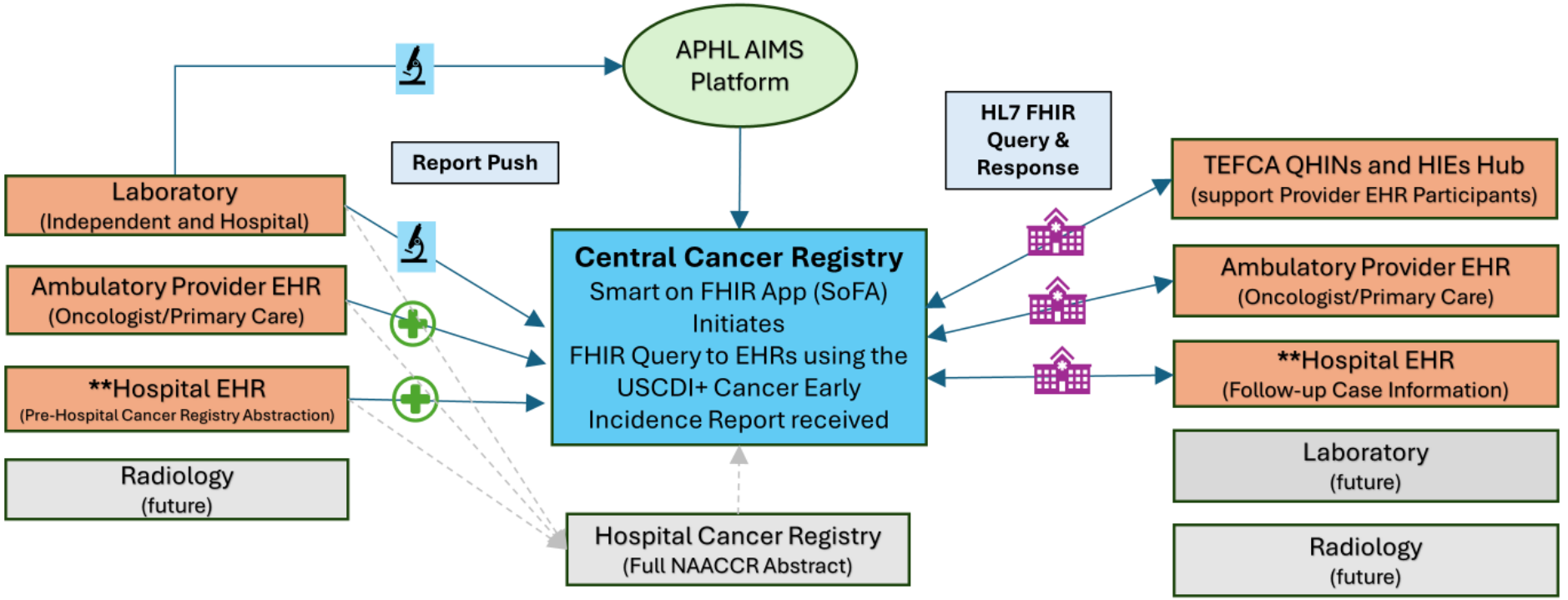
Beyond September

- 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.

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

Feedback Summary

Total Number of Comments	**84**
Total Number of Commenters	26
Total Consolidated Comments	60

CR Published Data Elements	**23**
CR Data Elements requiring no action	4
CR Data Elements with proposed changes	19
CR Data Elements proposed to be added	57

EOM Published Data Elements	**18**
EOM Data Elements with proposed changes	3
EOM Data Elements proposed to be added	24

Clinical Trials Matching (CTM)

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 (e.g., 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
- Refined use case scope

Next Steps (now through October 2024)

- Publish draft data element list for public comment

Beyond October

- Publish final data element list
- Develop and 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.

Immunotherapy Related Adverse Events (irAE)

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 Continued

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
- Refined use case scope

Next Steps (now through November 2024)

- Publish draft data element list for public comment

Beyond November 2024

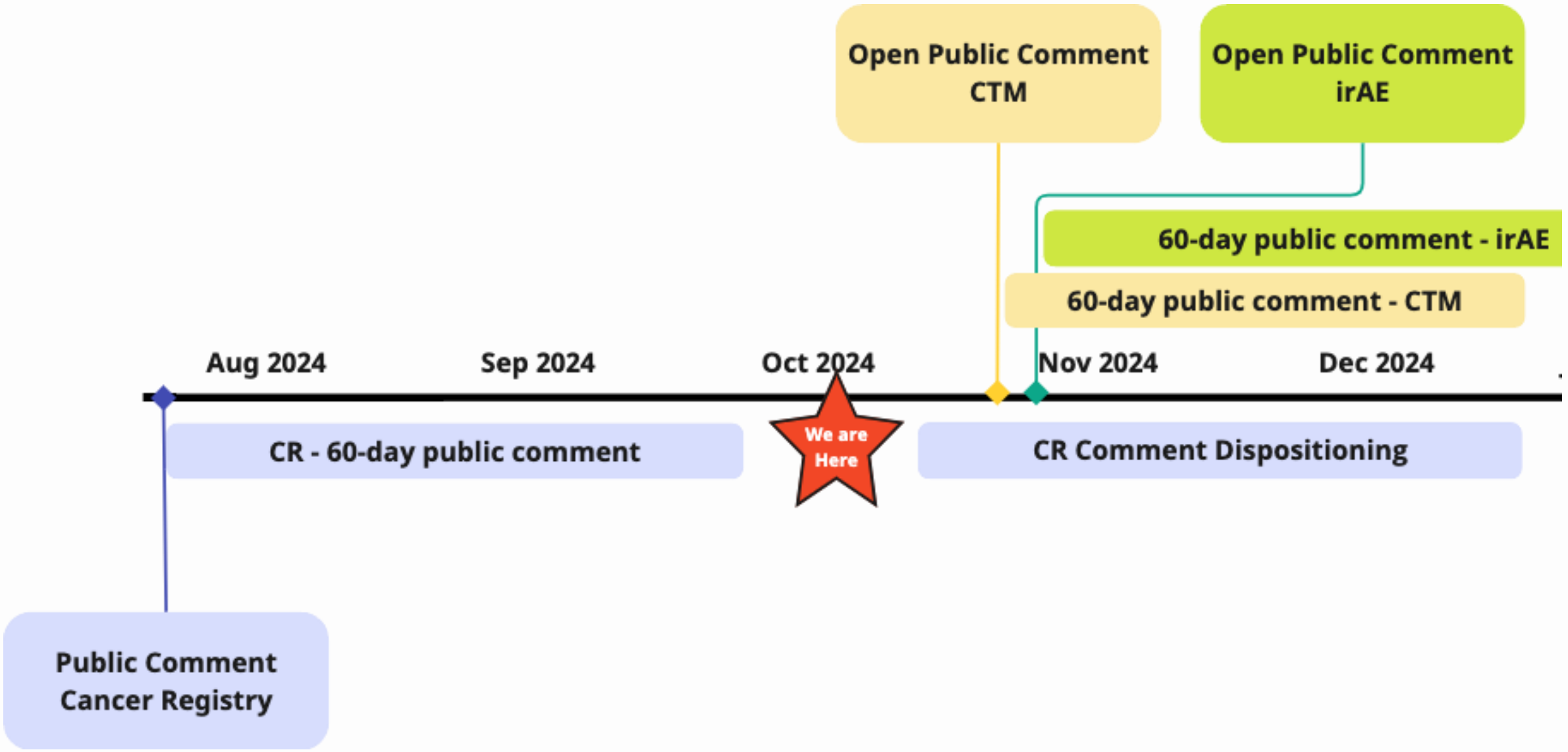
- Finalize data element list
- Develop and Publish Implementation Guide
- Test, Pilot

Why

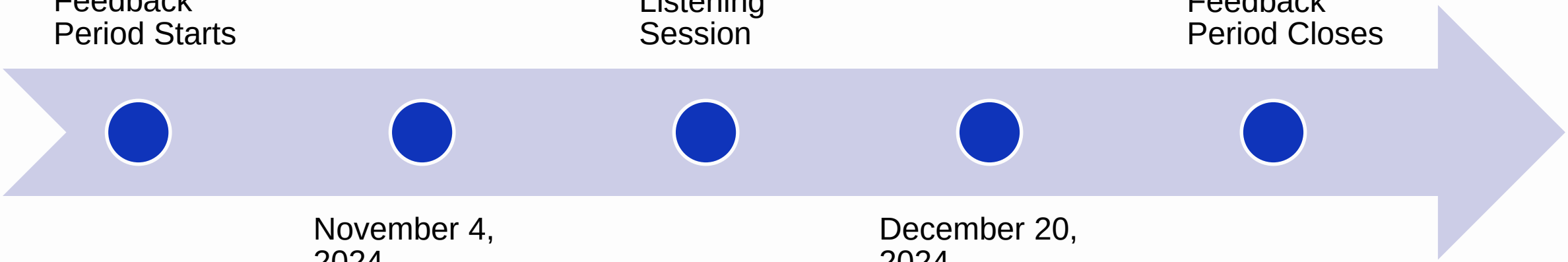
- Immunotherapy has demonstrated significant improvements in survival and response rates in various cancers, including melanoma, lung, and hematologic malignancies.
- Ongoing trials are expanding its potential through combination therapies and novel agents, driving transformative advances in oncology.

Next Steps

USCDI+ Cancer Draft Timeline – Aug through Dec 2024



Key Upcoming Dates



October 21, 2024

- CTM Draft Data Element List published
- CTM Public Feedback Period Starts

November 4, 2024

- irAE Draft Data Element List published
- irAE Public Feedback Period Starts

November 7, 2024

- Public Listening Session

December 20, 2024

- CTM Public Feedback Period Closes

January 10, 2025

- irAE Public Feedback Period Closes

Learn More and Stay Engaged!

1

View Summit and all listening session recordings here

2

Share feedback on USCDI+ Platform in upcoming public feedback periods for data elements here

3

Reach out to the USCDI+ Cancer Team

USCDI.Plus@hhs.gov

Questions and Discussion