



Office of the National Coordinator
for Health Information Technology

CancerX and USCDI+ Cancer

Presenters:

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Kyle Cobb, Acting Deputy Director, Standards Division, Office of Technology



CANCERX™

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The reignited Cancer Moonshot has ambitious goals...



Reduce the #
of deaths from
cancer by 50%

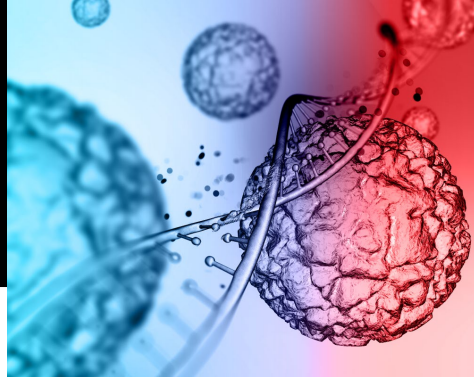


Improve the experience of
people and their families
living with & surviving cancer

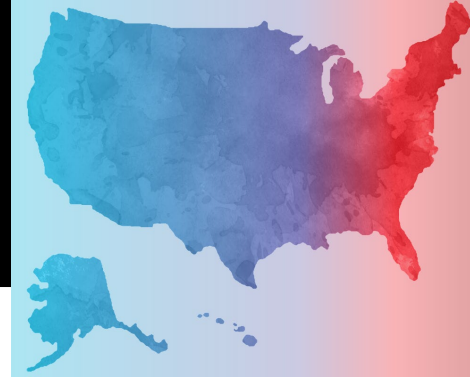
..and we must harness the power of innovation to achieve these goals



1,958,310
new cancer cases
predicted for 2023



609,820
cancer deaths
predicted for 2023



2nd
leading cause of
deaths in the U.S.



Cancer survivors are
2.5x more likely to
declare bankruptcy

CancerX is responding to the call of the White House ...

- [Announced by the White House](#) on February 3, 2023.
- A public-private partnership to boost innovation in the fight against cancer.
- Co-hosted by the [Moffitt Cancer Center](#) and [Digital Medicine Society \(DiMe\)](#), alongside ONC and OASH.
- Convenes the many diverse stakeholders needed to unleash the power of innovation to create a future free of the burden of cancer.

2022
White House Reignites Cancer Moonshot

Feb 2023
White House Announces CancerX

March 2023
CancerX Announces
1st Pre-Competitive Evidence
Generation Project: *Financial
Toxicity and Health Equity*

Aug - Sept 2023
CancerX Announces
Steering Committee, Strategic
Priorities, Briefs White House

Oct 2023
CancerX Announces
1st Demonstration Project:
Oncology Data Sprint

November 2024
CancerX to Announce Startup
Accelerator Open for Applications

CancerX Members



Members also include the National Cancer Institute

CancerX Steering Committee



Andrea Downing
Co-Founder and
Chief Executive
Officer
**The Light
Collective**



Ben Moscovitch
Healthcare and Life
Sciences, Americas,
AWS Public Policy
**Amazon Web
Services**



Cait Reimers Brumme
Chief Executive Officer
MassChallenge



David Fredrickson
Executive Vice
President,
Oncology Business
AstraZeneca



Kate Wallis
Vice President of
Clinical Innovation
Point32Health



Mary Tolikas
Senior Vice
President & Chief
Innovation Officer
**Dana-Farber
Cancer Institute**



Matt Bettonville
Healthcare Investor
Yosemite



Najat Khan
Najat Khan, Ph.D., Chief
Data Science Officer
and Global Head,
Strategy, Portfolio &
Operations, R&D,
**Janssen
Pharmaceutical
Companies of Johnson
& Johnson**



Omid Toloui
Vice President
Innovation
Elevance



Rasu Shrestha
Executive Vice
President, Chief
Innovation &
Commercialization
Officer
Atrium Health



Sally Werner
Chief Experience Officer
**Cancer Support
Community**



Ted Gaubert
Chief Technology Officer
Graphite Health

Inaugural Member Summit and The White House Meet



CancerX's 2023-2024 strategic priorities



Demonstrate CancerX as the global leader in advancing digital innovation in oncology in alignment with the goals of the reignited Cancer Moonshot.



Activate the ecosystem by fostering a dynamic innovator community for collaborative knowledge sharing, leveraging national platforms and US government partnerships to enhance outcomes through combined public and private sector strengths.

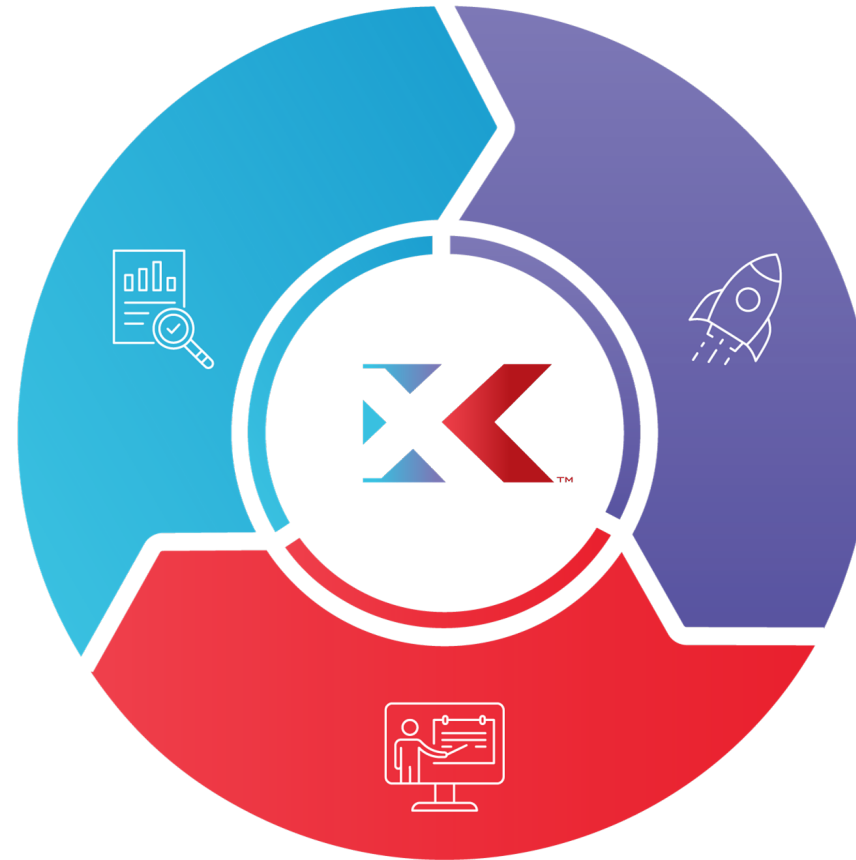


Identify, support, grow, and implement world-class digital solutions in the market dedicated to reducing the burden of cancer for all people.

The Approach

1) Pre-competitive Evidence Generation

A rolling series of multi-stakeholder initiatives will develop evidence, best practices, toolkits and value models to drive the success of the mission.



2) Accelerator

This program will provide mentorship, education, and exposure to funding and clinical partnership opportunities to a start-up cohort aligned with the mission.

3) Demonstration Projects

These implementation projects will pilot novel, mission aligned approaches to demonstrate their value and sustainability for scale to drive broad adoption.

1) Pre-competitive Evidence Generation Projects

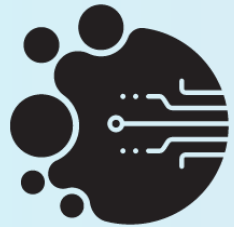


- Appropriate to initiate when forward progress in the field is inhibited by:
 - Absence of scientific, technical, or operational best practices
 - Needs of stakeholders are poorly understood
 - Incentives are not clearly aligned
- Led by CancerX staff with SME input from a multi-stakeholder working group
- Characterized by rigorous evidence generation and the development of open-access, action-oriented resources such as:
 - Best practices and scientific frameworks
 - Templates, implementation guides, decision tools, and checklists
 - Core competencies, maturity models, case studies
 - Value models and ROI calculators
- Drives change by equipping the field with a shared vision of ‘what good looks like’ and tools and incentives to implement these practices

Work is already underway



Leaders in the field are showing the way



Advancing Cancer
Treatment Through
DIGITAL INNOVATION

CANCERX™

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MOFFITT
CANCER CENTER



DIME
DIGITAL
MEDICINE
SOCIETY

Project Partners



U.S. Department
of Veterans Affairs

Project Approach: CancerX Project on Equity In Access to Care and Financial Toxicity



Workstream Approach

- **WS1** develop best practices for digital innovation that improve access and reduce financial toxicity
- **WS2** implement practices effectively and at scale based on end-user characteristics
- **WS3** quantify value of digital solutions for decision makers



Priority Researchable Questions

- How can drivers of financial toxicity in cancer treatment be addressed using digital solutions?
- How can barriers in access to cancer treatment be addressed using digital solutions?



Deliverables | July 2024

- Standards and best practices for implementing digital health solutions to improve access and out-of-pocket cost for cancer patients
- Toolkits and technical assistance deliverables to support implementation of best practices at scale
- Impact models to quantify and articulate the impact of digital solutions on access and cost measures

Exploring Emerging Themes: CancerX Project on Equity in Access to Care and Financial Toxicity

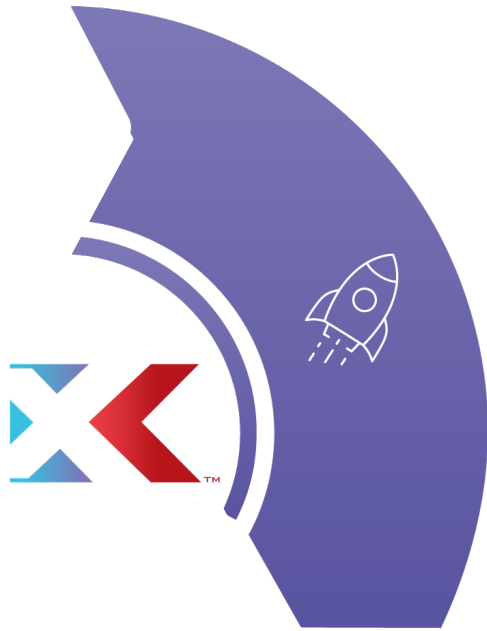
Systematic Review Objectives and Emerging Themes

- Designed to identify commentary in the literature about how digital health tools are currently being used, or can be used in the future, to address core drivers of financial toxicity as well as barriers in access to cancer care (clinical research as a care option included)
- Literature primarily discusses relationship between the following digital tools and our financial toxicity concept of interest
 - Electronic Health Record (EHR) systems
 - Patient-facing navigation tools
 - Telemedicine platforms
 - Artificial Intelligence/ Machine Learning (AI/ML) algorithms

Exploring Emerging Themes: The Use of Digital Health Tools (DHTs) to Impact Financial Toxicity

- EHR
 - Characterizing Social Determinants of Health (SDOHs)
 - Alerts for additional consults & services
- Patient-Facing Navigation
 - Psychosocial need measurement
 - Coaching & decision aid
 - PRO data collection
- Telemedicine
 - Access to care (reduced travel burden)
- AI/ML
 - Diagnosis aid
- Use Cases for Other DHTs
 - Care coordination
 - Reliance on non-physician HCPs
- Factors of Financial Toxicity
 - SDOHs
 - Interpersonal wealth
 - *Others to come*

2) Startup Accelerator (program launch on 11.08.23)



Each accelerator cohort will be slightly different, with the first launching this fall. Each will be modeled following the best practices and principles of [HSS InnovationX accelerators](#) and other [industry led accelerators](#). Regardless of the exact model, the goal is to foster innovation by supporting innovators in bringing their life saving ideas to fruition through the development of high-value, commercially viable solutions.

- Early-stage startup financing can come from different sources.
- Accelerators are mentor-based programs that provide guidance, support and resources for a set period of time, typically three months.
- There are 100s of programs globally and they differ in approach, focus, cost and effectiveness.



Bootstrapping



Incubators

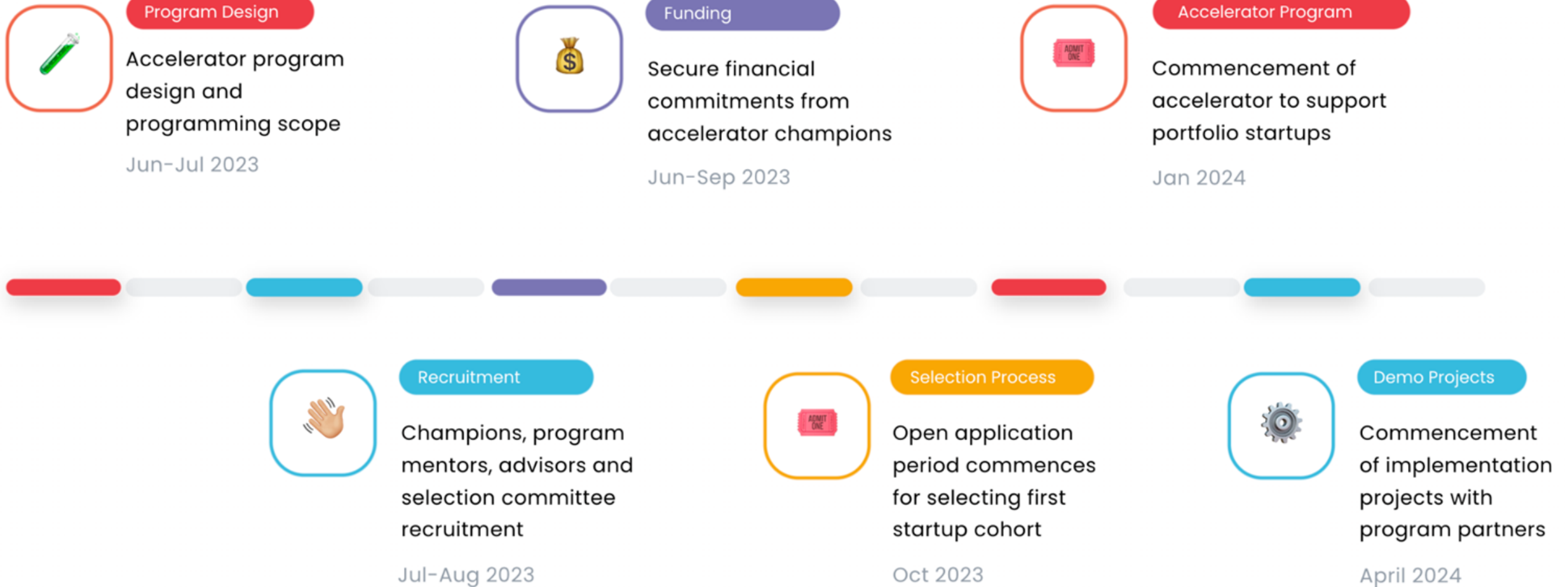


Angel Investment



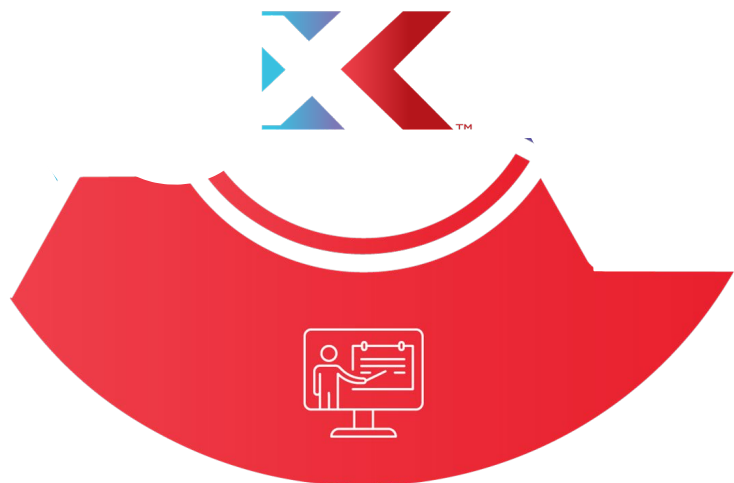
Accelerators

Accelerator Timeline



3) Demonstration Projects

CancerX Demonstration projects fall into two broad categories:



1. Community initiated that CancerX supports
 - Examples include the current data sprint and potential data challenge
2. CancerX initiated seeking implementation and evaluation of novel, digital enabled solutions that advance our goal
 - The scale and scope of our first proposed CancerX initiated demonstration project illustrates the ambition of this work

- The CancerX co-hosts will act as the Operations Center for demonstration projects
- All members of the CancerX community will be offered the exclusive opportunity to contribute to all aspects of the scientific planning, operational implementation, and evaluation process
 - These members will be recognized for their efforts in the media and in scientific publications, where appropriate
- Where applicable, CancerX community members will be eligible for sub-awards

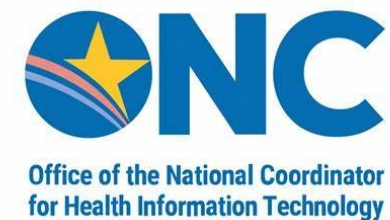
An Overview of CancerX Data Sprint

(Launched October 2023)

The CancerX community is committed to support the collective efforts by the Center for Medicare and Medicaid Innovation (CMMI), the National Cancer Institute (NCI), US Food and Drug Administration (FDA), the Office of the National Coordinator for Health Information Technology (ONC) to advance cancer related data standards.

Specifically at the intersection of work on the CMMI's [Enhancing Oncology Model \(EOM\)](#) and the development of ONC's [USCDI+ Oncology extension](#), CancerX aims to supercharge the quality and availability of comprehensive real-world datasets in the field of oncology.

A report will be produced sometime in late November / early December 2023.



CancerX Data Sprint Approach



Step 1

Identify the high-value research questions that may be asked of the standardized RWD/E generated by participants through the EOM



Step 2

Supplement the existing data elements planned for collection through the EOM, with the additional data elements necessary to optimize the RWD/E to support these scientific inquiries



Step 3

Support piloting the implementation of these data elements in coordination with work being led by CMML, NCI, FDA and ONC

Website and Follow-up Info

<https://cancerx.health/>

For additional questions, please contact:

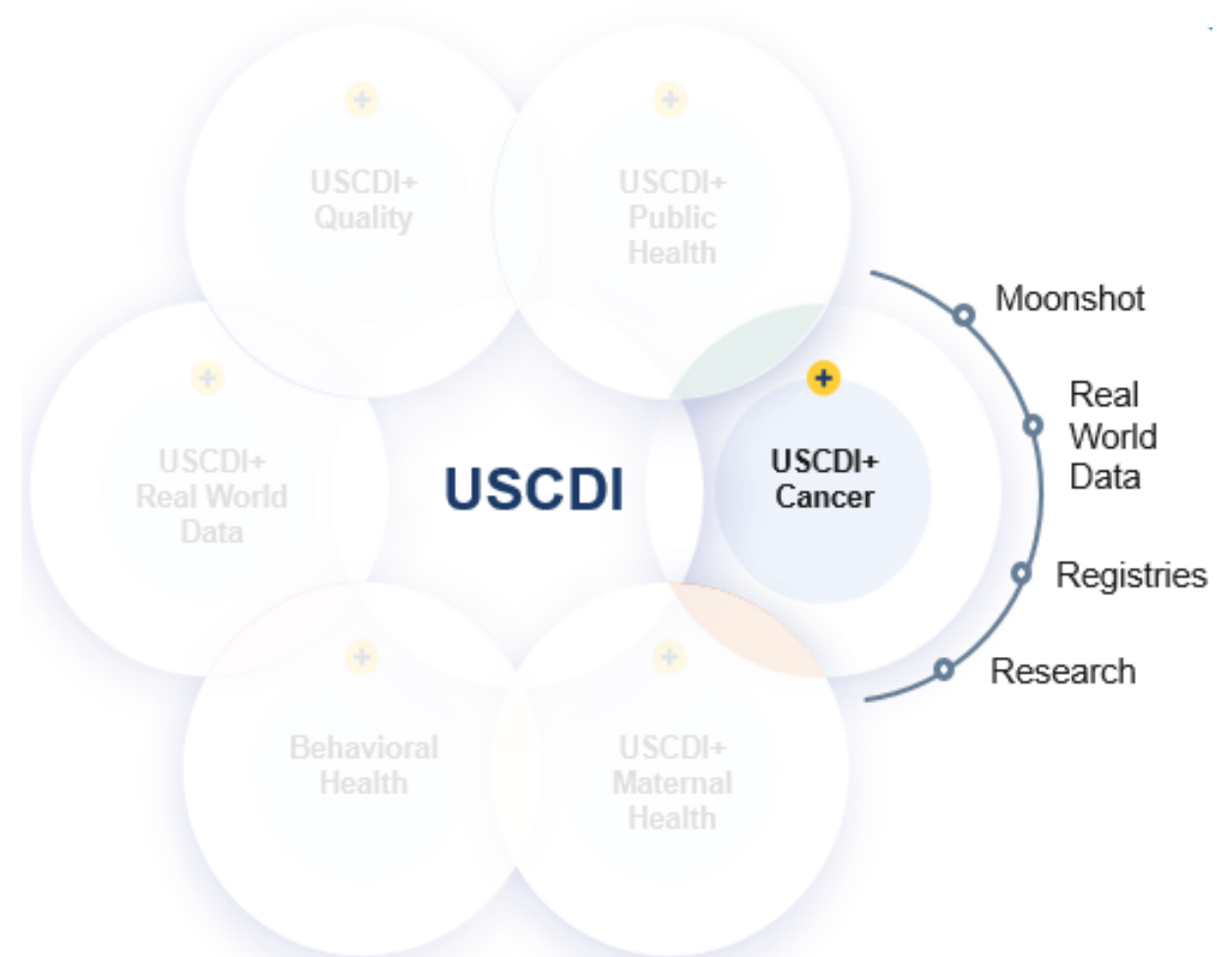
Stephen@Konya@hhs.gov



USCDI+ for Cancer

USCDI+: Cancer

- GOAL: Capture the data needs for Cancer reporting that fall outside the scope of USCDI to support research, quality reporting, and patient care.
- Harmonize Cancer data elements into a common data element list that addresses multiple federal partner needs and use cases.
- Support NCI and Cancer Moonshot real world data use cases.
- Identify opportunities for policy alignment around Cancer reporting programs under existing authorities across HHS agencies.





USCDI+ Cancer RWD Inputs and Key Sources

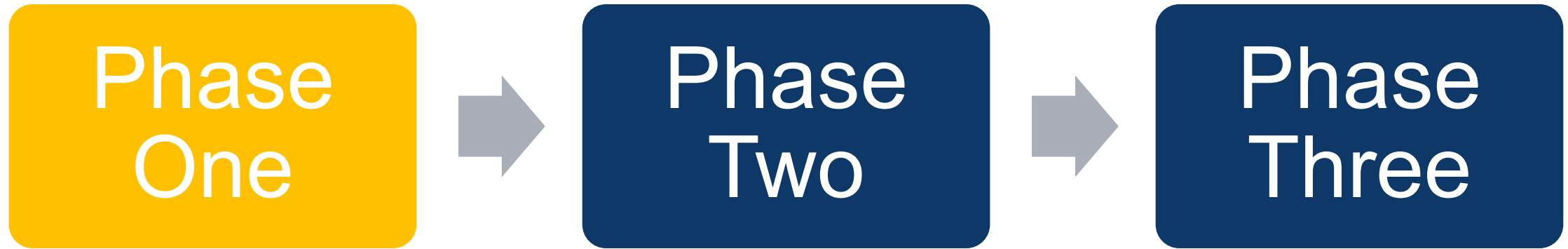
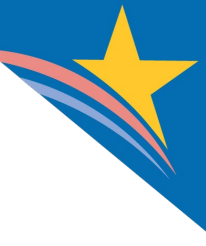
- Cancer Moonshot
 - CC Direct
 - Data & Innovation Task Force
- The Center for Medicare and Medicaid Innovation (CMMI) - Enhancing Oncology Model
- Minimal Common Oncology Data Elements (mCODE)
 - Data Dictionary
 - FHIR Implementation Guide (IG)
- Central Cancer Registry Reporting Content FHIR IG
- HL7 CDA R2 IG: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers Vol. II
- Cancer Pathology Data Sharing FHIR IG



Overview of Current Cancer Data Set

- 112 data elements
 - 86 data elements in USCDI
 - 64 data elements shared with Quality Domain
 - 41 data elements shared with Public Health Domain
 - 37 data elements shared with Maternal Health Domain
- 24 Unique Cancer data elements (not in other domains or USCDI)
 - Body Site – Problem Laterality, Location; Procedure Laterality, Location
 - Cancer Disease Status
 - Radiation – Administered Start Date, Reason Reference; Radiation Therapy – Body Site, Intent, Modality Code, Technique, Termination Reason Code
 - Specimen – Collection Method, Collector, Laterality
 - Tumor – Morphology; Tumor Size – Longest Dimension

USCDI+ Cancer RWD Phased Approach



Use Cases

- Patient matching for clinical trials (part of recruitment)
 - Patient Consent (Research Authorization)
 - Data Provenance (Source Organization)
- Immune related AE (irAE) tracking in immunotherapy trials
- Cancer registry model for identifying and extracting required data

Use Cases

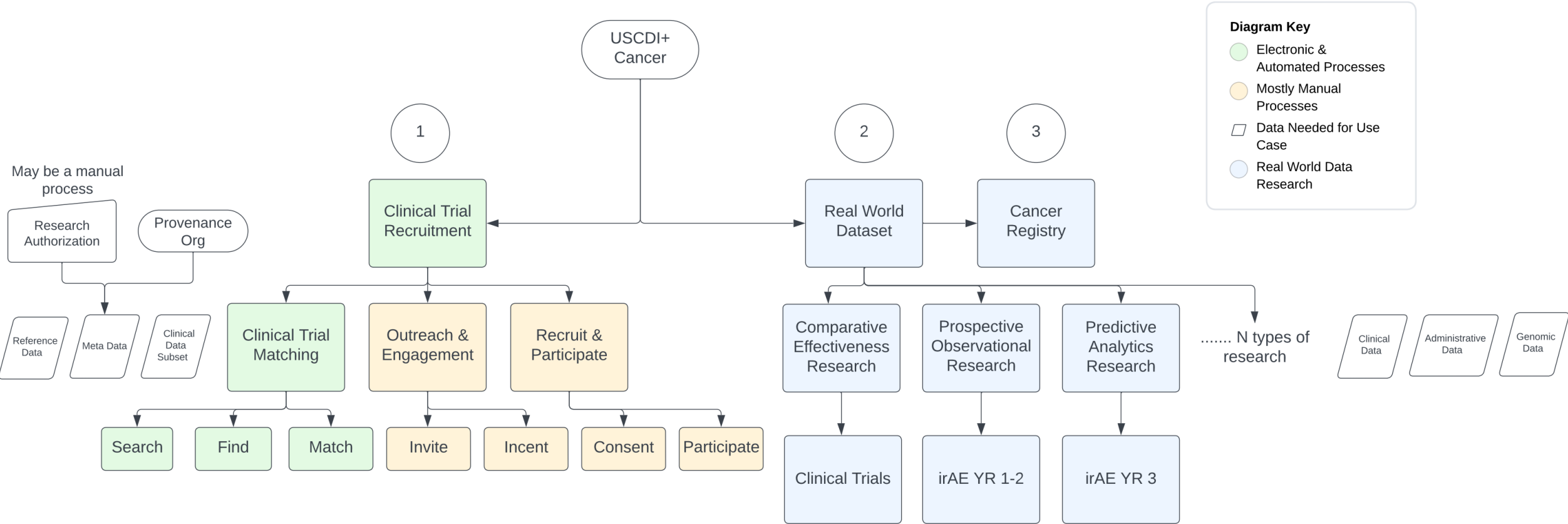
CC DIRECT Pediatric

Use Cases

TBD



USCDI+ Cancer Use Case Wireframe





Upcoming Activities

- ONC and NCI are establishing scope of work for Moonshot to encompass standards for clinical research and evidence (USCDI+ Cancer **Real World Data**).
 - CMMI Enhancing Oncology Model (EOM) data elements will be included in this use case
 - CancerX data sprint (fall 2023) will identify a small set of additional data elements to extend EOM data elements for RWD
- USCDI+ Cancer will align to mCODE and will follow relevant FHIR Accelerators projects:
 - CodeX: Integrated Trial Matching for Cancer Patients and Providers; Cancer Registry Reporting
 - FAST: Digital Consent
 - Vulcan: Real World Data (RWD); Adverse Events (AE)
- ONC and NCI are engaging FDA and CDC in this work in a more official capacity outside of Moonshot to support Clinical Trial and Registry Use Cases.



Discussion