



Office of the National Coordinator  
for Health Information Technology

# Supporting Innovation in Health IT

Detroit MedHealth Summit – April 16<sup>th</sup>, 2024

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HHS Office of the Secretary



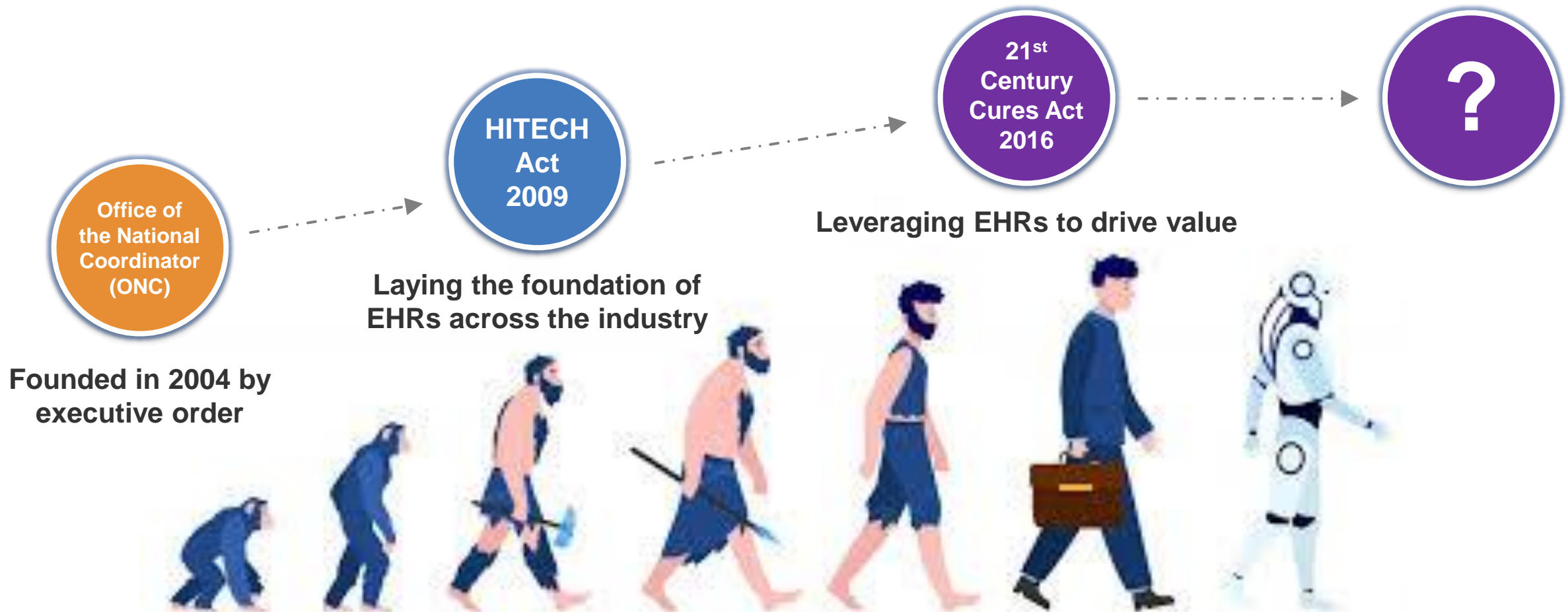


# **History of Health IT Coordination**

**(in the United States)**

# The Evolution of Health IT & Digital Health (in the US)

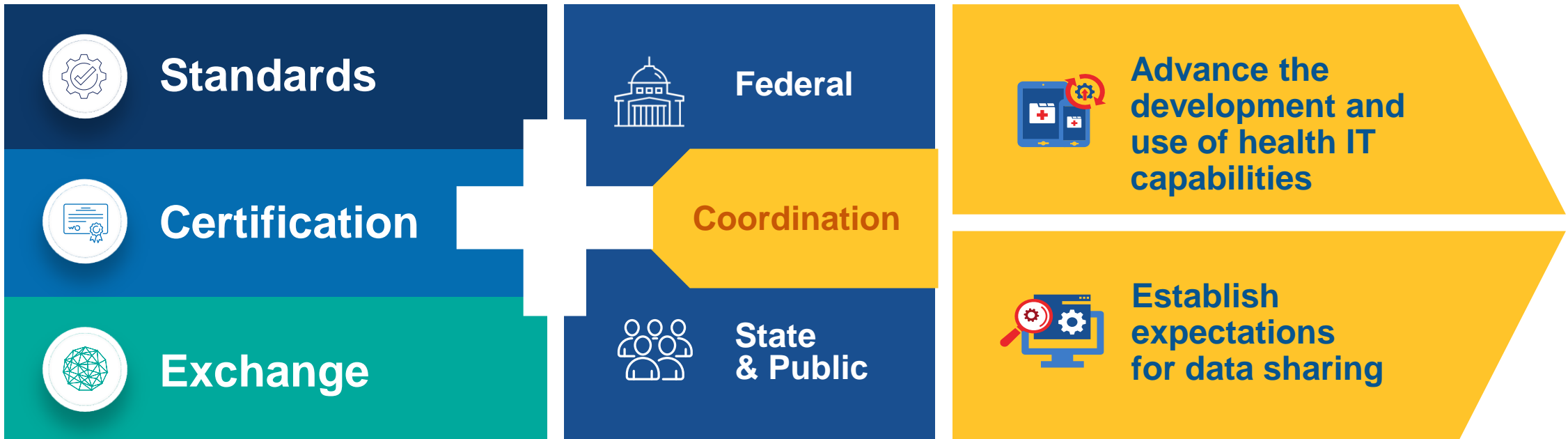
ONC is charged with formulating the **federal government's health IT strategy** to advance national goals for better and safer health care through **an interoperable nationwide health IT infrastructure**



# ONC Activities & Objectives

## ONC Activities

## ONC Objectives



# ONC Active Health IT Engagements with Federal Partners

## Non-HHS Federal Agencies



## HHS Operational Divisions



## HHS Staff Divisions





# 21st Century Cures Act

# ONC's 21st Century Cures Act Final Rule

## Putting the patient first in health technology enables the health care system to deliver:

- Transparency into the cost and outcomes of their care
- Competitive options in getting medical care
- Modern smartphone apps to provide them convenient access to their records
- An app economy that provides patients, physicians, hospitals, payers, and employers with innovation and choice

## Direct Links;

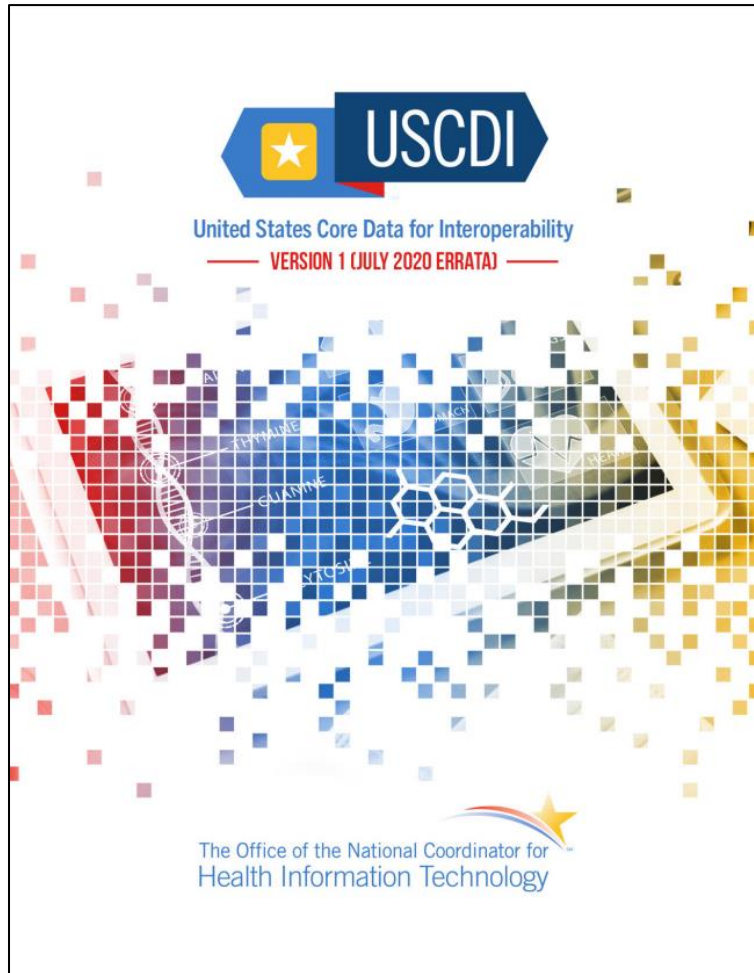
- [Fact Sheets](#)
- [Webinars](#)
- [Media/Press](#)
- [Blog Post](#)
- [Download Final Rule](#)

## Main Landing Page;

<https://www.healthit.gov/curesrule/>

# US Core Data for Interoperability (USCDI):

## *The Minimum Dataset of the Health Care Delivery System*



- **ONC standard for minimum dataset required for interoperability**
  - Defines required data elements and vocabulary standards
  - Agnostic to format
- **Updated on annual cycle with federal agency and industry input**
  - Updates based on multiple criteria including standards maturity and public/industry priority



# USCDI is the minimum data set for key EHR functions, interoperability, and patient access

## *EHR functions requiring USCDI*

USCDI is a required component for following 2015 Edition Cures Update Certification Criteria	
Standardized API for patient and population services (§170.315(g)(10))	Update to USCDI by December 31, 2022 (replacing Common Clinical Data Set)
Transitions of care (§170.315(b)(1))	
Clinical information reconciliation and incorporation (§170.315(b)(2))	
View, download, and transmit to 3rd party (§170.315(e)(1))	
Transmission to public health agencies –electronic case reporting (§170.315(f)(5))	
Consolidated CDA creation performance (§170.315(g)(6))	
Application access –all data request (§170.315(g)(9))	

## *CMS patient access rule requires USCDI*

**Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers**

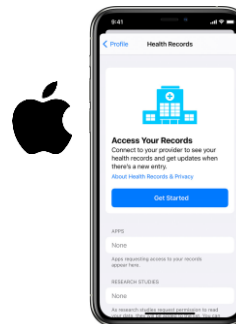
**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule.

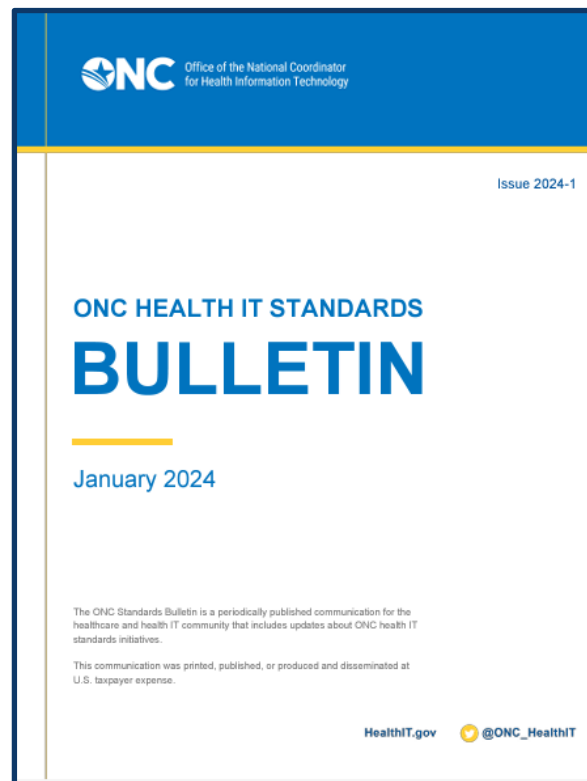
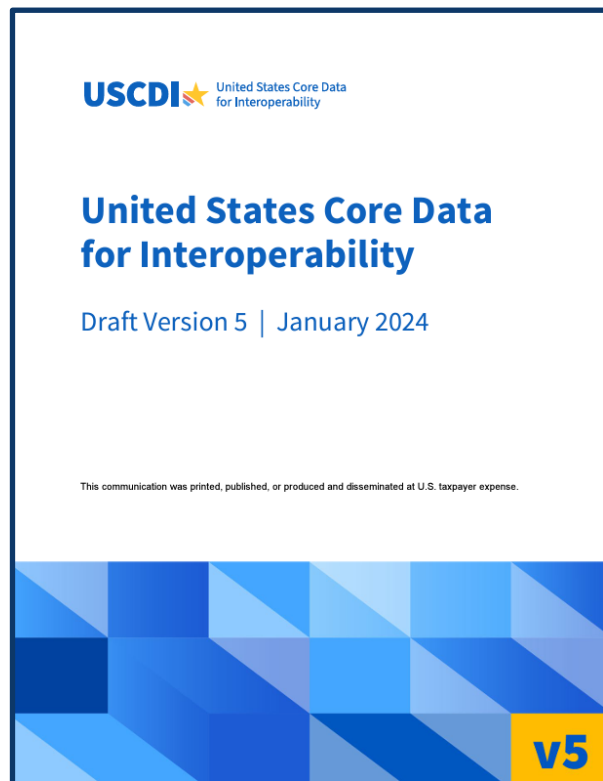
## *Interoperability networks requiring USCDI*



## *Mobile apps based on USCDI*



# Draft Version 5



**As part of the annual update process, ONC identifies key policy priorities that include:**

- Health data needs for providing equitable care to underserved communities, public health reporting, and behavioral health integration with primary care.
- Important additions over previous USCDI versions that will broadly benefit health IT users.
- Implementation burden for: standards development organizations; developers of certified health IT products; and health care entities who will integrate these changes into clinical and other workflows.
- Outside factors such as new regulatory requirements (e.g., those included in the recently published HTI-1 final rule) are also considered.

***ONC is accepts submissions for new data elements through the ONDEC system and feedback on existing data elements.***

# USCDI Draft v5 Summary of Data Classes and Data Elements

Draft USCDI v5 includes 13 new data elements and two new data classes.

Please reference the [Draft USCDI v5 standard document](#) and the [Standards Bulletin 2024-1](#) for details.

ONC is accepting feedback on the proposed new data elements on the Draft USCDI v5 website until Monday, April 15, 2024 at 11:59 p.m. ET.

Feedback will be considered as ONC develops the final version of USCDI v5, which we anticipate publishing in July 2024.

## Allergies and Intolerances

- Substance (Medication)
- Substance (Drug Class)
- Substance (Non-Medication)
- Reaction

## Care Team Members

- Care Team Member Name
- Care Team Member Identifier
- Care Team Member Role
- Care Team Member Location
- Care Team Member Telecom

## Clinical Notes

- Consultation Note
- Discharge Summary Note
- Emergency Department Note
- History & Physical
- Operative Note
- Procedure Note
- Progress Note

## Clinical Tests

- Clinical Test
- Clinical Test Result/Report

## Diagnostic Imaging

- Diagnostic Imaging Test
- Diagnostic Imaging Report

## Encounter Information

- Encounter Type
- Encounter Identifier
- Encounter Diagnosis
- Encounter Time
- Encounter Location
- Encounter Disposition

## Facility Information

- Facility Identifier
- Facility Type
- Facility Name

## Goals and Preferences

- Patient Goals
- SDOH Goals
- Treatment Intervention Preference
- Care Experience Preference

## Health Insurance Information

- Coverage Status
- Coverage Type
- Relationship to Subscriber
- Member Identifier
- Subscriber Identifier
- Group Identifier
- Payer Identifier

## Health Status Assessments

- Health Concerns
- Functional Status
- Disability Status
- Mental/Cognitive Status
- Pregnancy Status
- Alcohol Use
- Substance Use
- Physical Activity
- SDOH Assessment
- Smoking Status

## Immunizations

- Immunizations
- Lot Number

## Laboratory

- Tests
- Values/Results
- Specimen Type
- Result Status
- Result Unit of Measure
- Result Reference Range
- Test Kit Unique Device Identifier
- Result Interpretation
- Specimen Source Site
- Specimen Identifier
- Specimen Condition Acceptability

## Medical Devices

- Unique Device Identifier - Implantable

## Medications

- Medications
- Dose
- Dose Unit of Measure
- Route
- Indication
- Fill Status
- Medication Instructions
- Medication Adherence

## Observations

- Advance Directive Observation
- Sex Parameter for Clinical Use

## Orders

- Orders

## Patient Demographics/ Information

- First Name
- Last Name
- Middle Name (including middle initial)
- Name Suffix
- Previous Name
- Name to Use
- Pronoun
- Date of Birth
- Date of Death

## Patient Demographics /Information (cont)

- Race
- Ethnicity
- Tribal Affiliation
- Sex
- Sexual Orientation
- Gender Identity
- Preferred Language
- Interpreter Needed
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address
- Related Person's Name
- Relationship Type
- Occupation
- Occupation Industry

## Patient Summary and Plan

- Assessment and Plan of Treatment

## Problems

- Problems
- SDOH Problems/Health Concerns
- Date of Diagnosis
- Date of Resolution

## Procedures

- Procedures
- Performance Time
- SDOH Interventions
- Reason for Referral

## Provenance

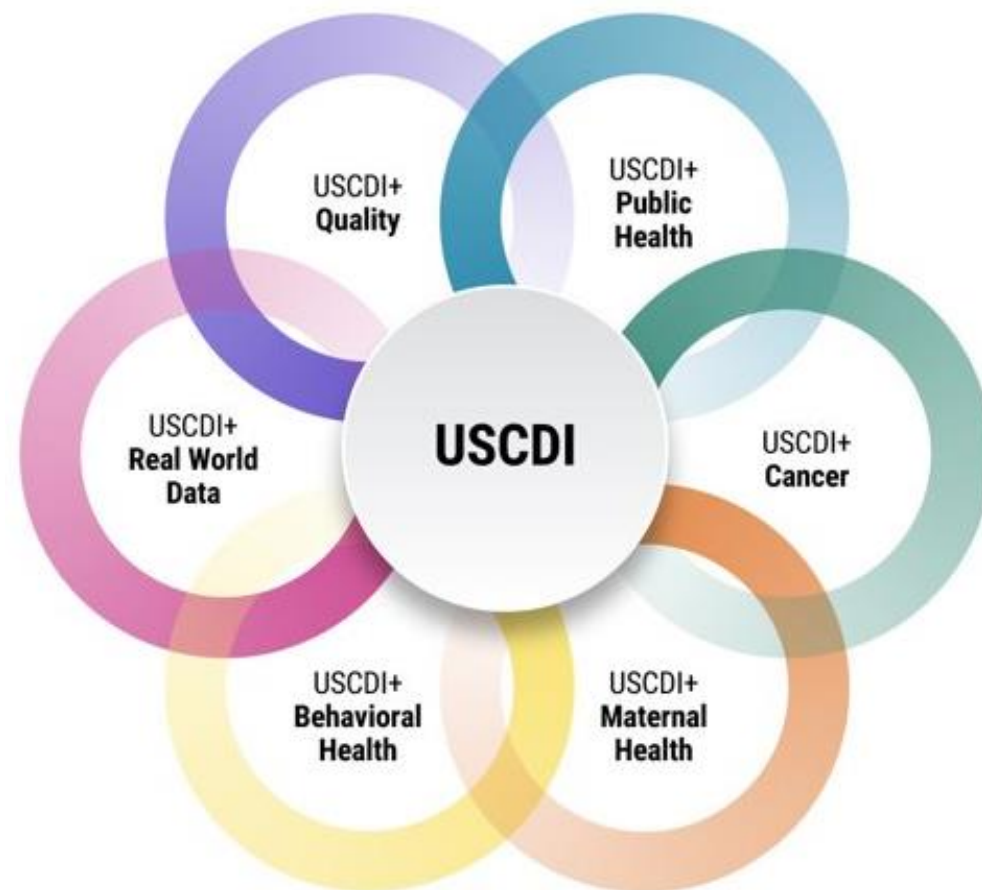
- Author
- Author Role
- Author Time Stamp
- Author Organization

## Vital Signs

- Systolic Blood Pressure
- Diastolic Blood Pressure
- Average Blood Pressure
- Heart Rate
- Respiratory Rate
- Body Temperature
- Body Height
- Body Weight
- Pulse Oximetry
- Inhaled Oxygen Concentration
- BMI Percentile (2 - 20 years)
- Weight-for-length Percentile (Birth - 24 Months)
- Head Occipital-frontal Circumference Percentile (Birth- 36 Months)

# USCDI+: Extending Beyond the USCDI

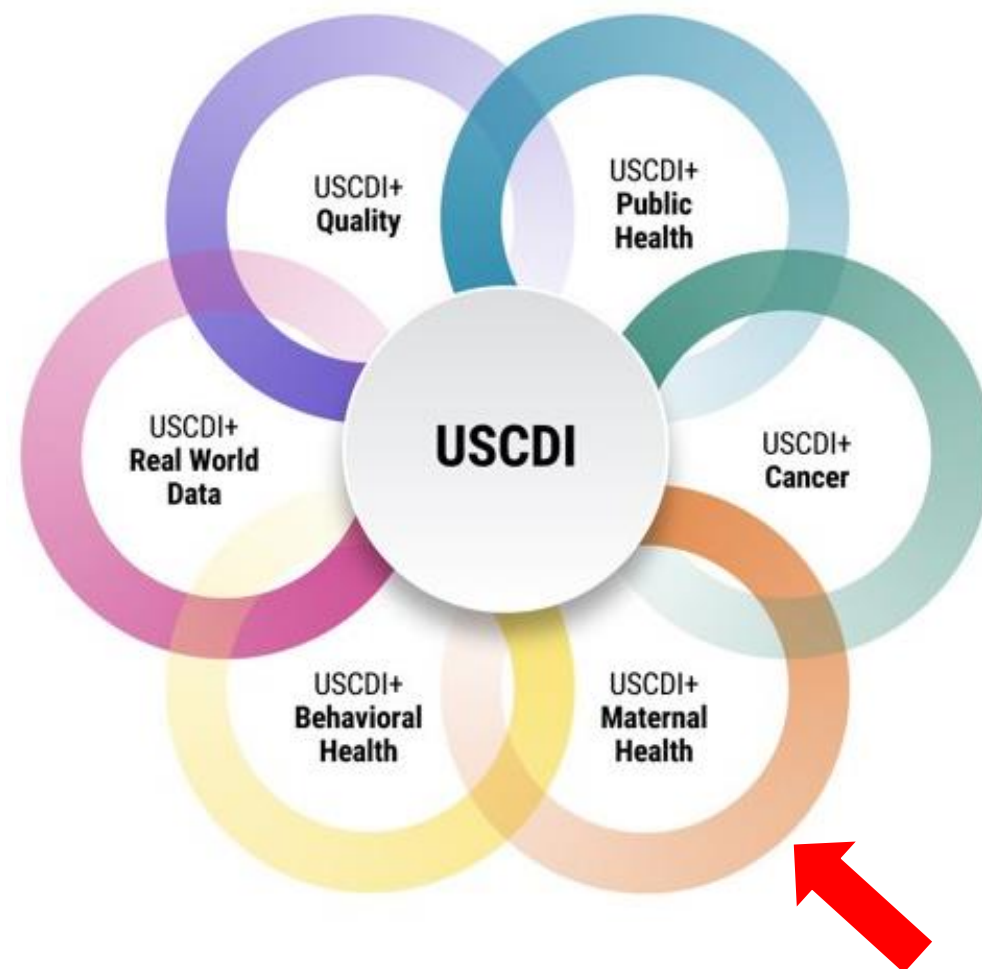
- Unique program and use case-specific data needs are sometimes not fully met by USCDI.
- ONC's USCDI+ initiative helps government and industry partners build on USCDI to support specific program needs.
- Applies USCDI processes for submission and harmonization while focusing on programmatic priorities.
- Seeks to leverage programs and authorities across HHS to drive adoption.
- USCDI+ for Quality Measurement and Public Health kicked off with CDC, CMS and HRSA.
- USCDI+ for Cancer underway with NCI, CMMI, and VA



# USCDI+: Extending Beyond the USCDI

## Maternal Health

- USCDI+ Maternal Health was developed to establish a core set of data necessary for high quality care, equitable outcomes, and maternal health research. Data elements are focused on helping to understand how maternal health may impact outcomes in both mother and child.
- USCDI+ Maternal Health goals are to:
  - Assess maternal health patients' experience in accessing electronic health records
  - Identify consistent set of data elements and lab tests required for prenatal screening for prevention of mortalities / co-morbidities for the mother and child
  - Provide patients with information to empower them to request better care and help them identify any preventable risks
  - Determine approaches and mechanisms to pilot recommended minimum datasets across provider types no matter the circumstance or level of technical proficiency of the patient and/or provider





# New Resource for MATERNITY Health Care Records!



## Interoperability of Maternity Health Care Records: Best Practices Informational Resource

March 2024

**Purpose:** This document focuses on the functionalities and standards that maternal healthcare providers may leverage in health IT to support the safe and effective healthcare of pregnant persons as part of peri- and post-natal care and to advance the interoperability (capture, exchange, and use) of this health data.



## **Health Equity by Design (HEBD)**



## HEBD – Primary Goals

- Equity considerations identified and incorporated as early as possible in design, build, implementation process.
- Health IT products, capabilities, and services are designed to be foundationally equity enforcing – making the implicit explicit.
- Strategies, tactics, and policies keep equity in mind from end to end.



# Health Equity by Design Concept Paper



## Advancing Health Equity by Design and Health Information Technology: Proposed Approach, Invitation for Public Input, and Call to Action

Prepared by:

The Office of the National Coordinator for Health Information Technology

APRIL 2024



Office of the National Coordinator  
for Health Information Technology

FACT SHEET | HEALTH EQUITY BY DESIGN

## Advancing Health Equity

**[Fact Sheet \[PDF - 279 KB\]](#)**

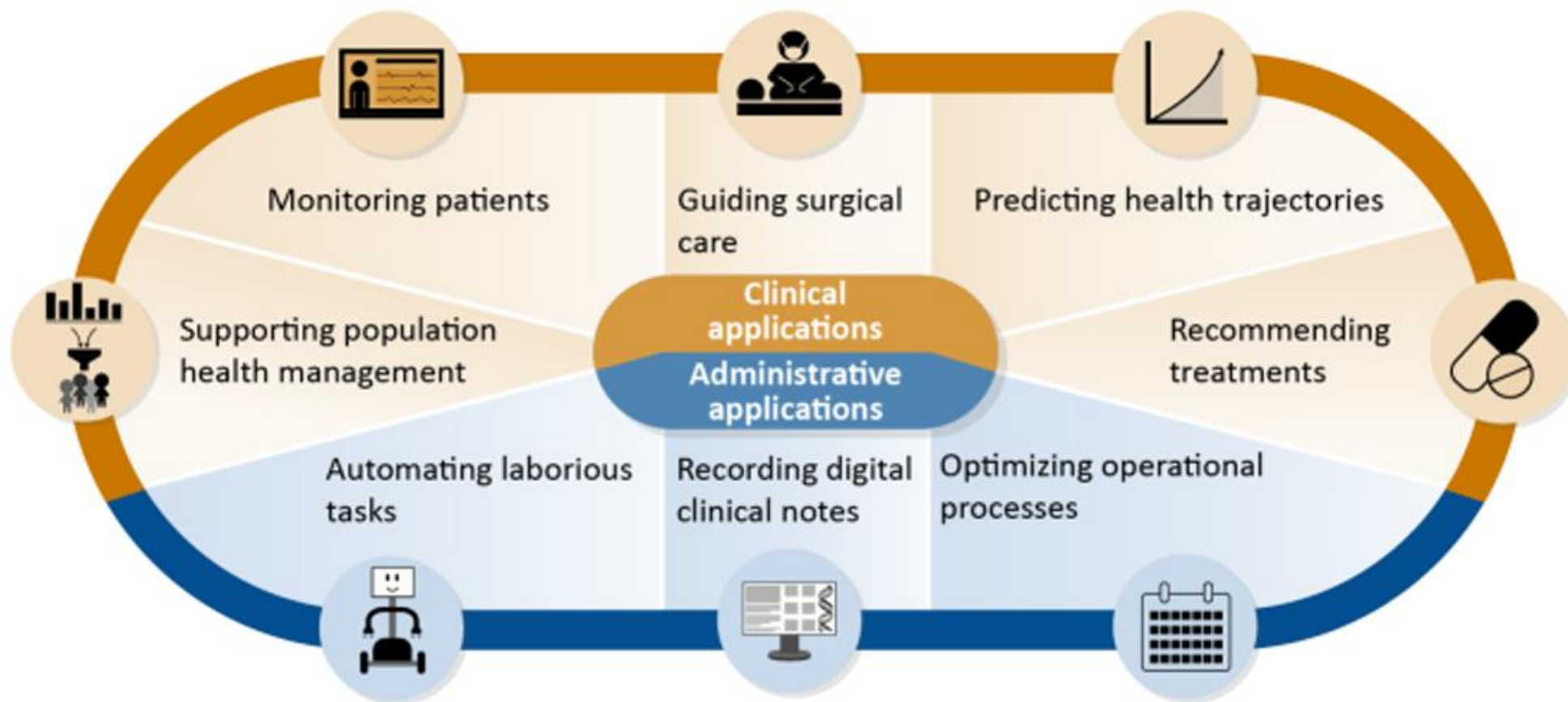
**[Read the White Paper \[PDF - 743 KB\] →](#)**

**[Provide Feedback →](#)**



# **Responsible Use of AI in Health IT**

# How can AI be used in healthcare?



# How ONC fits into the broader Health AI HHS Regulatory Picture



## Health AI Areas of HHS Activity



### Applicable Federal Policies

**Nondiscrimination in Health Programs and Activities Proposed Rule (Section 1557 of the Affordable Care Act)**

**CDS and Device Software Function-related Guidance Documents**

**ONC Health IT Certification Program (HTI-1 rulemaking)**

### Who Must Comply?

*Health care provider, health plan, or recipients of financial assistance from HHS using AI to support decision-making in covered health programs and activities*

*Manufacturer of device software functions (e.g., AI-enabled software that meets the definition of medical device)*

*Developers of certified health IT that supply a predictive DSI as part of its Health IT Module*

### What Must Be Done?

Not use clinical algorithms in discriminatory ways (proposed rule)

Receive FDA-approval for demonstrating the device software function's safety and effectiveness

Enable user access to predictive DSI performance information, apply risk management practices, keep information and practices up-to-date

# Coalition for Health AI (CHAI)

## Founding Coalition Members

- Berkeley
- Duke Health
- Johns Hopkins University
- MITRE
- Mayo Clinic
- Stanford Medicine
- University of California San Francisco

## Industry Members

- Change Healthcare
- Google
- Microsoft
- SAS

## U.S. Federal Observers

- U.S. Food and Drug Administration (FDA)
- Office of the National Coordinator for Health Information Technology (ONC)
- National Institutes of Health (NIH)
- White House Office of Science and Technology Policy



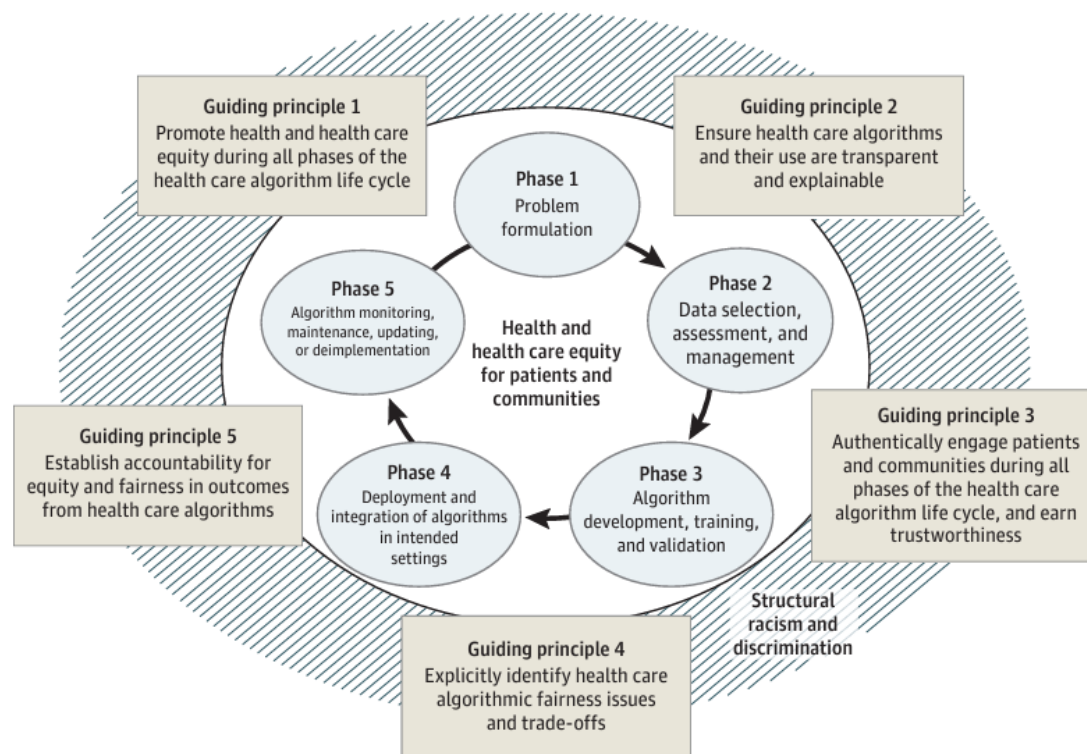
**CHAI**  
Coalition for Health AI

Providing guidelines  
for the responsible  
use of AI in healthcare

# Guiding Principles to Address the Impact of Algorithm Bias on Racial and Ethnic Disparities in Health and HealthCare

JAMA Network Open, December 13<sup>th</sup>, 2023 ([link](#))

Figure. Conceptual Framework for Applying Guiding Principles to Mitigate and Prevent Bias Across an Algorithm's Life Cycle



Guiding principles apply at each phase to mitigate and prevent bias in an algorithm.  
Operationalization of the principles takes place at 3 levels: individual, institutional, and societal.

This conceptual framework builds on a National Academy of Medicine<sup>13</sup> algorithm life cycle framework adapted by Roski et al.<sup>14</sup>



## HTI-1 Final Rule



## An inclusive framing of how to address challenges

**FAVES** is our quality framework describing the characteristics of “high-quality” algorithms and communicates how we may get the best out of predictive models in health care.

### Fair (unbiased, equitable)

Model does not exhibit biased performance, prejudice or favoritism toward an individual or group based on their inherent or acquired characteristics. The impact of using the model is similar across same or different populations or groups.

### Appropriate

Model is well matched to specific contexts and populations to which it is applied.

### Valid

Model has been shown to estimate targeted values accurately and as expected in both internal and external data.

### Effective

Model has demonstrated benefit and significant results in real-world conditions.

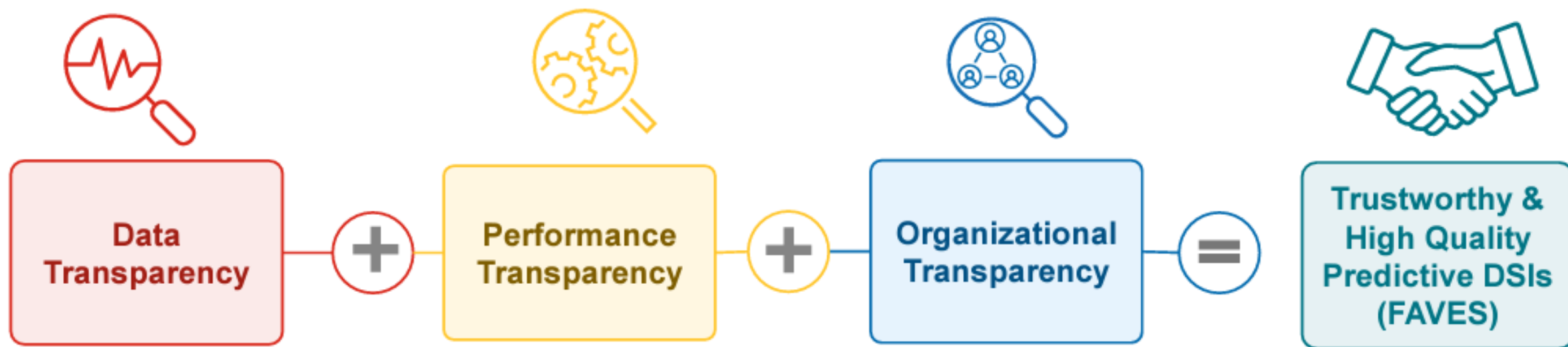
### Safe

Model use has probable benefits that outweigh any probable risk.





# Transparency Is a Prerequisite for Trustworthy AI



## Data Transparency

Requirements enable users to know when a DSI uses specific data elements relevant to health equity

## Performance Transparency

Enable users to have consistent and routine electronic access to technical, and performance information on Predictive DSIs

## Organizational Transparency

Requirement for Certified Health IT developers to apply intervention risk management for each Predictive DSI they supply as part of their Health IT Module



# HTI-1 Final Rule

Health Data, Technology, and Interoperability (HTI-1): Certification Program Updates, Algorithm Transparency, and Information Sharing

## Algorithm Transparency:

- Establishes first of its kind transparency requirements for the artificial [intelligence](#) (AI) and other predictive algorithms that are part of certified health IT.
- ONC-certified health IT supports the care delivered by more than 96% of hospitals and 78% of office-based physicians around the country.
- HHS' leading-edge regulatory approach will promote responsible AI and make it possible for clinical users to access a consistent, baseline set of information about the algorithms they use to support their decision making and to assess such algorithms for fairness, appropriateness, validity, effectiveness, and safety.

## Key Dates

- **December 31, 2024:** Health IT developers will need to update health IT currently certified to the CDS criterion (170.315(a)(9)) to meet the DSI criterion's requirements and provide the updated certified health IT to customers by December 31, 2024.
- **Starting January 1, 2025:**
  - Developers with health IT certified to the DSI criterion must comply with the associated maintenance of certification requirement adopted at 170.402(b)(4).
  - The DSI criterion will become the criterion required for health care providers to have health IT that continues to meet the Base EHR definition and thus be in a position to have "Certified EHR Technology" for the purposes of certain Centers for Medicare & Medicaid Services programs.

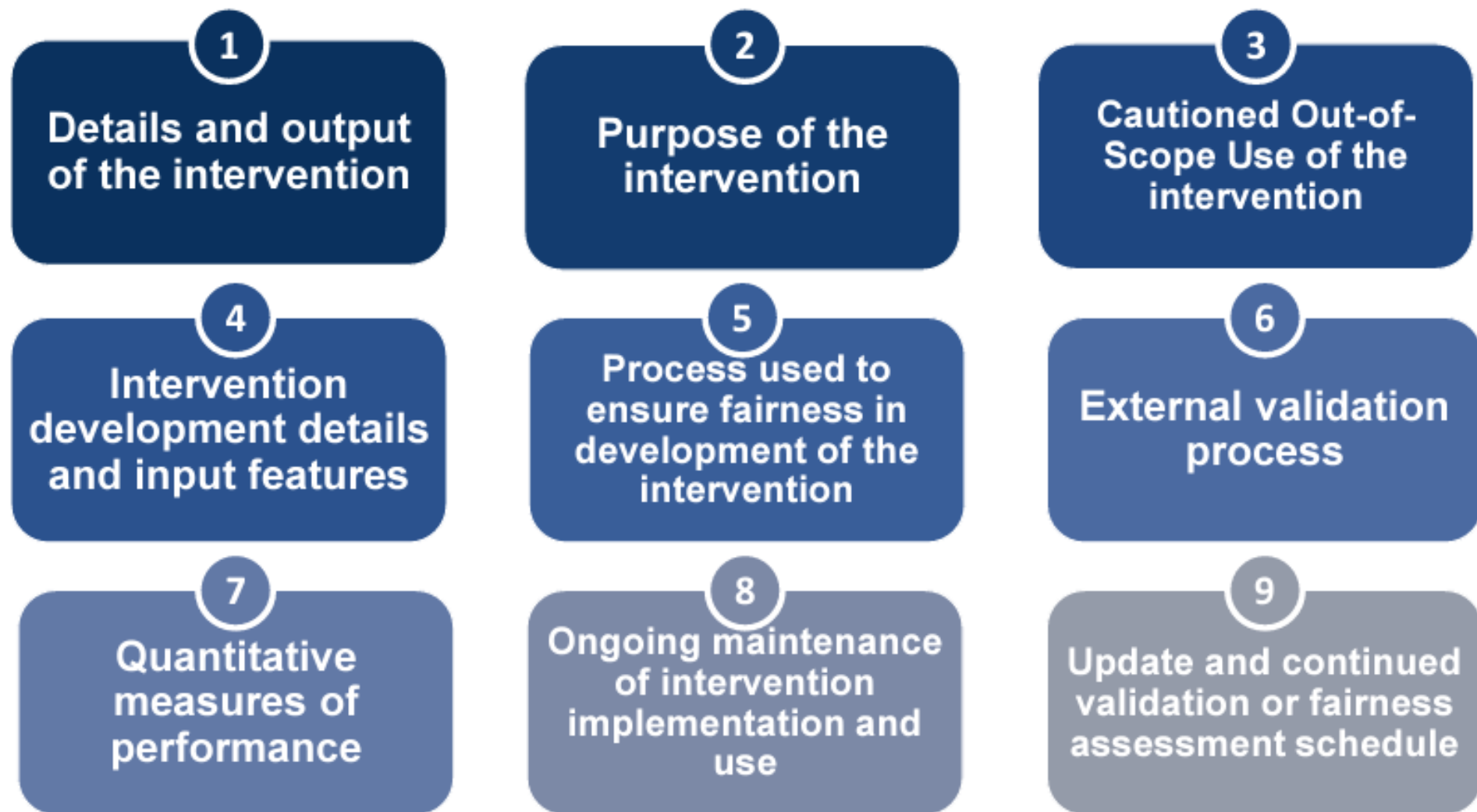
## HTI-1 Final Rule Decision Support Interventions Information Session

- [Presentation Slides \[PDF- 883 KB\]](#)
- [View Recording](#)

## Fact Sheets on the Final Rule

- [Decision Support Interventions and Predictive Models Fact Sheet \[PDF - 281 KB\]](#)

## Final Source Attribute Categories for Predictive DSIs





## **ONC's Innovation Portfolio**

# HITECH Act (3001(b)(10))

***“Among many duties, the National Coordinator is tasked with promoting:***

- *...a more effective marketplace*
- *greater competition*
- *greater systems analysis*
- *increased consumer choice, and*
- *improved outcomes in health care service”*

## The Health IT “Horizon”

To be prepared for the future, we need to keep an eye on;

- Emerging technology and trends
- Areas with a need for greater focus and coordination
- Potential risks or threats in the Health IT marketplace

***“An ounce of action is worth a ton of theory.”***

— Ralph Waldo Emerson

***“The future depends on what you do today.”***

— Mahatma Gandhi

# Defining the Health IT Innovation Community

1. **Early adopters** who implement and test emerging technology and novel approaches
2. **Entrepreneurs** and **developers** who build new technology and bring it to market
3. **Investors** who financially support the builders and implementers of new technology and novel approaches
4. **Incubators, accelerators, bootcamps, associations and membership networks** that support any of the above 3 types of innovation stakeholder categories

# Innovation Spectrum Support Stages

## • Ideation Support (stage 1)

### Purposes:

- Exploration / discovery research
- Calls to action / raise awareness
- Signal priorities
- Address pain points / areas of need

### Examples:

- Research grants
- White paper solicitations
- Workshops / meetups
- Challenge competitions
- Hackathons / code-a-thons
- Think tanks

## • Development Support (stage 2)

### Purposes:

- Build
- Test
- Evaluate
- Iterate
- Validate

### Examples:

- Bootcamps
- Accelerator programs
- Pilots
- Mentorship
- Resources / toolkits
- Challenge competitions

## • Deployment Support (stage 3)

### Purposes:

- Commercialization
- Market penetration
- Implementation / utilization

### Examples:

- Public / private partnerships
- Connections to capital / investment
- Matchmaking / surfacing promising solutions
- Alignment with contracting opportunities
- Policy levers / incentives

Open Data



# Public Private Partnerships



A National Public Private Partnership Initiative to Accelerator the Pace of Innovation for Cancer

## 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.

## Accelerator

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

## Demonstration Projects

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

[www.CancerX.health](http://www.CancerX.health)

# CancerX Membership



170+ members strong and growing!



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for Health Information Technology

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**Health IT Feedback Form:**

<https://www.healthit.gov/form/healthit-feedback-form>



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