ASTP Assistant Secretary for Technology Policy

# ASTP Update for National Advisory Council on Nurse Education and Practice

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# About ASTP/ONC

## Our Vision

Better health enabled by data.

## Our Mission

To create systemic improvements in health and care through the access, exchange, and use of data.

## PRIORITIES

### Build the digital foundation

- Data standards
- Health IT gaps
- HHS Health IT Alignment Policy

### Make interoperability easy

- TEFCA
- APIs
- Expand education and outreach

### Promote information sharing

- Information blocking rules
- HHS Health IT Alignment Policy

### Ensure proper use of digital information and tools

- Health equity by design (data capture and use)
- Transparency in areas such as algorithm use and safety

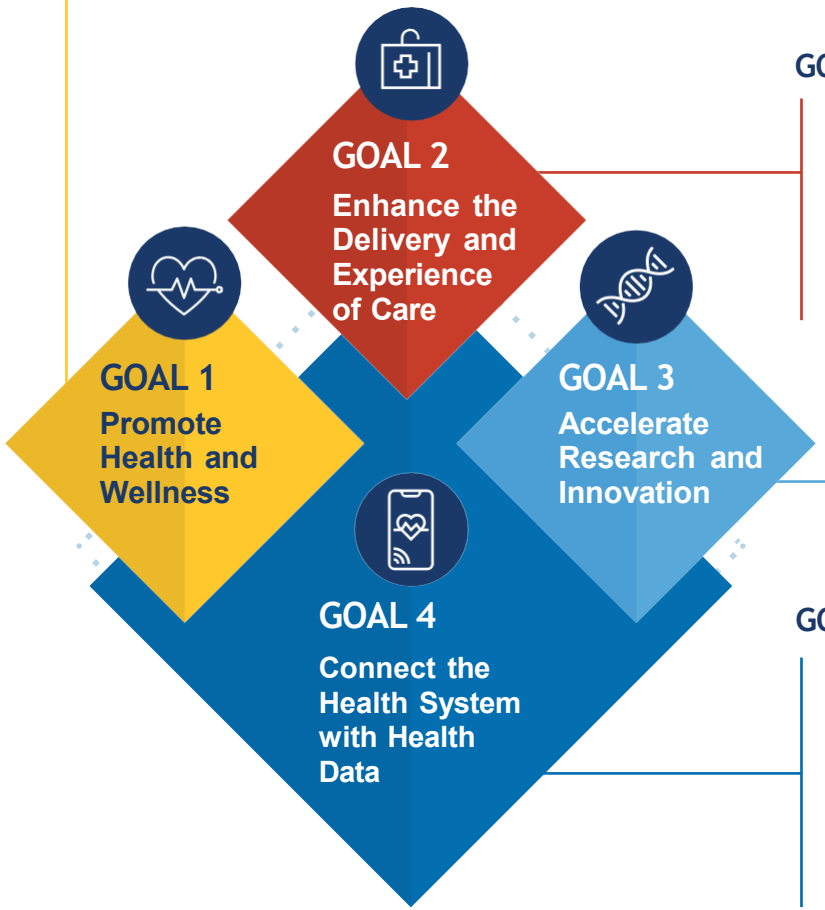
# “What we do”


ONC Activities
ONC Objectives
Standards
Certification
Exchange
Federal
Coordination
State & Public
Advance the development and use of health IT capabilities
Establish expectations for data sharing

# Federal Health IT Strategic Plan Framework

2024-2030
**Federal Health IT**
Strategic Plan

## GOALS AND OBJECTIVES




### GOAL 1 : OBJECTIVES

- A Individuals are empowered to manage their health
- B Individuals and populations experience modern and equitable health care
- C Communities are healthier and safer

### GOAL 2 : OBJECTIVES

- A Providers deliver safe, equitable, high-quality, and improved care
- B Patients experience expanded access to quality care and reduced or eliminated health disparities
- C Health care is improved through greater competition and transparency
- D Providers experience reduced regulatory and administrative burden
- E The health care workforce uses health IT with confidence

### GOAL 3 : OBJECTIVES

- A Researchers and other health IT users have appropriate access to health data to drive individual and population health improvement
- B Individual and population-level research and analysis are enhanced by health IT
- C Researchers advance health equity by using health data that includes underrepresented groups

### GOAL 4 : OBJECTIVES

- A Development and use of health IT capabilities continues to advance
- B Health IT users have clear and shared expectations for data sharing
- C Underserved communities and populations have access to infrastructure that supports health IT use
- D Individuals' electronic health information is protected, private, and secure
- E Communities are supported by modern and integrated U.S. public health data systems and infrastructure

# 21st Century Cures Act

# 21st Century Cures Act - Section 4003(b)

*"[T]he National Coordinator shall convene appropriate public and private stakeholders to **develop or support** a **trusted exchange framework** for trust policies and practices and for a **common agreement** for exchange between health information networks."*

*[emphasis added]*

# ONC FHIR API Requirements: Access "without special effort"


- **Open "application programming interfaces" (APIs) and apps are what make it easy to check your bank account or buy stocks or order meal delivery on your smartphone**
  - We want providers and patients to have that same experience the health care system
- **21st Century Cures Act requires availability of APIs that can be accessed "without special effort"**
  - ONC rule takes steps to prevent business and technical barriers to information-sharing
- **By December 31, 2022, all certified technology developers were required to deploy a standard FHIR API (individual and bulk) across their entire customer base**
  - Created a climate for innovation as apps can now be developed that will work across all EHR systems
- **Looking ahead to interactive functions: questionnaires, scheduling, FHIR links, subscriptions, FHIR hooks**

# 2024 Draft FHIR Action Plan

- Comments accepted until Monday, November 25, 2024.

- **GOALS**
  - This draft action plan's primary goal is to align federal agencies' adoption and use of FHIR around a set of essential components and capabilities that agencies have implemented or are planning to implement in the next two years. Many of these components are mature and already being used in production.
  - By publishing the draft action plan, we also seek to identify those areas in which additional development and investment is needed and to spur federal partners and the standards community to identify new components for their uses.

- **PURPOSE**
  - The heart of the draft action plan lies in the component tables in the FHIR Ecosystem section. These tables group FHIR components into six categories:
  - **Core Components**
    Core FHIR specifications and components are the most foundational and have the broadest applicability across healthcare services. They are used for fundamental operations and serve as reusable building blocks to support many use cases.
  - **Network Components**
    Network specifications apply to FHIR capabilities for accessing and exchanging data between health information networks for securely sharing data on a nationwide scale.
  - **Payment and Health Quality Components**
    FHIR-based Payment and Health Quality specifications have been developed to reduce reporting burden for clinicians and caregivers.
  - **Care Delivery and Engagement Components**
    Care Delivery and Engagement specifications based on FHIR seek to ease patients' access to their health data and to the healthcare system. They also seek to reduce provider burden and assist providers in areas such as decision support.
  - **Public Health and Emergency Response Components**
    Public Health and Emergency Response FHIR specifications seek to modernize public health data and infrastructure.
  - **Research Components**
    Research specifications are intended to drive toward a fully digital health system that uses FHIR for research activities.

# HTI-1 Rule

# Purpose of HTI-1 Final Rule

## Implementing the 21st Century Cures Act

- EHR Reporting Program
- APIs that allow EHI to be accessed, exchanged, and used without special effort
- Reasonable and necessary activities that do not constitute information blocking

## Achieving the Goals of the Biden-Harris Administration Executive Orders

- E.O. 13994 “Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats”
- E.O. 13985 “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government” and E.O 14091 “Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government”
- E.O. 14110 “Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence”

## Leveraging Health IT and Advancing Interoperability

- HITECH Act
- Interoperability Advancement
- ONC Health IT Certification Program

# Resources Available on HealthIT.gov!

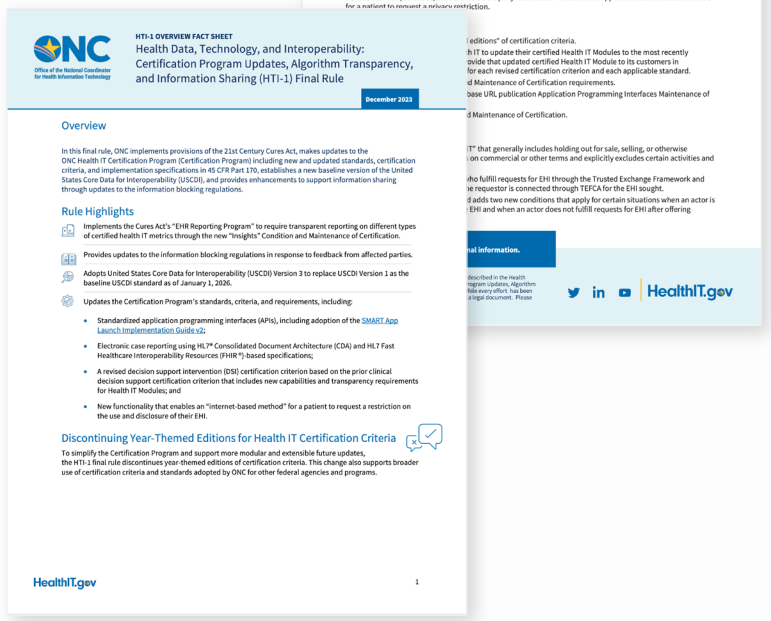
Visit https://healthIT.gov/HTI-1 for additional information.

## Fact Sheets

- General Overview
- Final Rule At-a-Glance
- Decision Support Interventions and Predictive Models
- Insights Condition
- HTI-1 Information Blocking
- HTI-1 Key Dates

## Measurement Spec Sheets

- For each of the Insights Condition measures

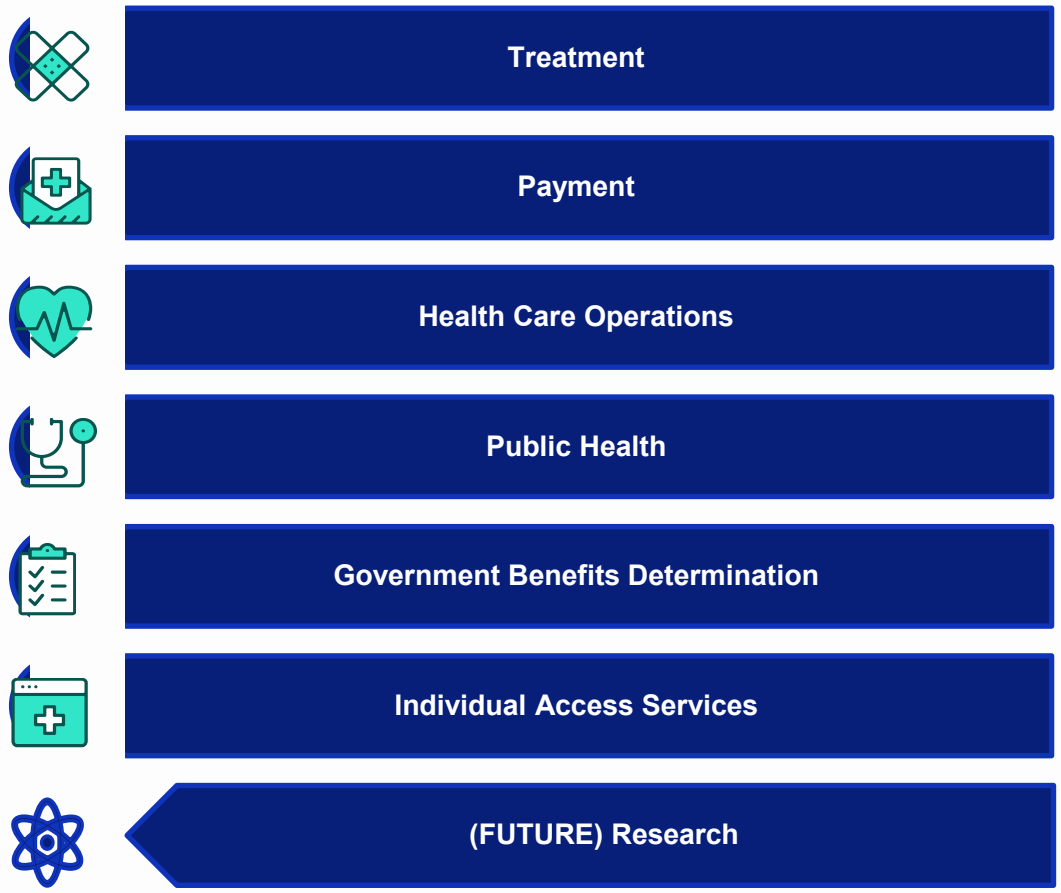


# Trusted Exchange Framework & Common Agreement (TEFCA)

# TEFCA℠

- **The Exchange Purpose identifies the reason for which information could be requested or shared through QHIN-to-QHIN exchange**
- **Only these six Exchange Purposes are currently authorized under the Common Agreement.**
- **“Exchange Purpose #7”: Research**
  - Standardized consent
  - Data de-identification
  - Data requirements and standards

**Permitted Exchange Purposes**



# Benefits of TEFCA

## Relevant, trusted information from nationwide sources for:

### Individuals

Use an app to access their own records from TEFCA-connected sources located across the nation.

### Providers and Health Systems

Improve care, coordination and population health by obtaining a more informed picture of care across settings through fewer connection points.

### Public Health

Improve quality, reduce costs, and expand public health interoperability.

### Payers

Get and share data needed for care management, value-based care, payer-to-payer exchange, etc.

### Health Information Networks

Enhance the value of network participation and lower the cost of connecting with other networks.

### Technology Developers

Provide a scalable policy and technical ecosystem for innovation.

### Researchers (Future)

Improve quality, reduce costs, and expand participation in clinical research.

For more detail on the benefits of TEFCA for stakeholders, see factsheets at: https://rce.sequoiaproject.org/tefca-and-rce-resources/

# USCDI

# United States Core Data for Interoperability (USCDI) v3

- Adopted USCDI v3 as the new baseline for certification.
- Expanding the data elements and data classes included in USCDI increases the amount of data available to be used and exchanged for patient care.
    - ONC is expanding the USCDI by moving from USCDI v1 to the adoption of USCDI v3 in 45 CFR 170.213(b) by **January 1, 2026**. Until that time, both versions will be accepted as in compliance with the USCDI standard in § 170.213.
- Health IT Modules certified to criteria that reference USCDI would need to update to USCDI v3 by the January 1, 2026, using the applicable US Core IG and C-CDA Companion Guide:

- § 170.315(b)(1): Transitions of Care
- § 170.315(b)(2): Clinical Information Reconciliation and Incorporation
- § 170.315(b)(9): Care Plan*
- § 170.315(e)(1): View, Download, and Transmit 3rd Party
- § 170.315(g)(6): Consolidated CDA Creation Performance
- § 170.315(g)(9): Application Access-All Data Request
- § 170.315(g)(10): Standardized API for Patient and Population Service

* § 170.315(b)(9) is only updated to the C-CDA Companion Guide

# USCDI v3


**Allergies and Intolerances**
- ☐ Substance (Medication)
- ☐ Substance (Drug Class)
- ☐ Reaction

**Assessment and Plan of Treatment**
- ☐ Assessment and Plan of Treatment
- ☐ SDOH Assessment

**Care Team Member(s)**
- ☐ 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
- ☐ History & Physical
- ☐ 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 Diagnosis
- ☐ Encounter Time
- ☐ Encounter Location
- ☐ Encounter Disposition

**Goals**
- ☐ Patient Goals
- ☐ SDOH Goals

**Health Insurance Information** ★
- ☐ Coverage Status ★
- ☐ Coverage Type ★
- ☐ Relationship to Subscriber ★
- ☐ Member Identifier
- ☐ Subscriber Identifier ★
- ☐ Group Number ★
- ☐ Payer Identifier ★

**Health Status/ Assessments** ★★
- ☐ Health Concerns →
- ☐ Functional Status ★
- ☐ Disability Status ★
- ☐ Mental Function ★
- ☐ Pregnancy Status ★
- ☐ Smoking Status →

**Immunizations**
- ☐ Immunizations

**Laboratory**
- ☐ Test
- ☐ Values/Results
- ☐ Specimen Type ★
- ☐ Result Status ★

**Medications**
- ☐ Medications
- ☐ Dose ★
- ☐ Dose Units of ★Measure
- ☐ Indication ★
- ☐ Fill Status ★

**Patient Demographics/ Information** ★★
- ☐ First Name
- ☐ Last Name
- ☐ Middle Name (Including middle initial)
- ☐ Name Suffix ★★
- ☐ Previous Name
- ☐ Date of Birth
- ☐ Date of Death ★
- ☐ Race
- ☐ Ethnicity
- ☐ Tribal Affiliation ★
- ☐ Sex ★★
- ☐ Sexual Orientation
- ☐ Gender Identity
- ☐ Preferred Language
- ☐ Current Address
- ☐ Previous Address
- ☐ Phone Number
- ☐ Phone Number Type
- ☐ Email Address
- ☐ Related Person's Name
- ☐ Related Person's Relationship ★
- ☐ Occupation
- ☐ Occupation Industry ★

**Problems**
- ☐ Problems
- ☐ SDOH Problems/Health Concerns ★
- ☐ Date of Diagnosis
- ☐ Date of Resolution

**Procedures**
- ☐ Procedures
- ☐ SDOH Interventions
- ☐ Reason for Referral ★

**Provenance**
- ☐ Author Organization
- ☐ Author Time Stamp

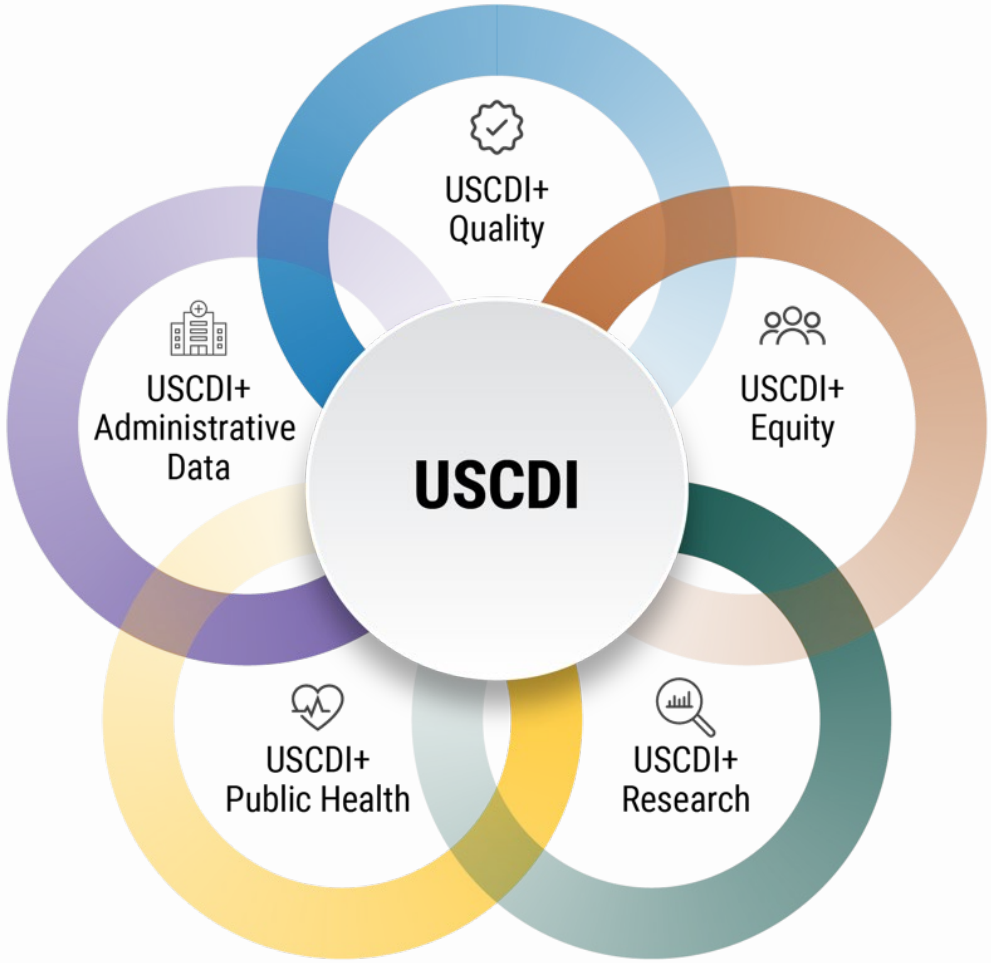
**Unique Device Identifier(s) for a Patient's Implantable Device(s)**
- ☐ Unique Device Identifier(s) for a patient's implantable device(s)

**Vital Signs**
- ☐ Systolic blood pressure
- ★ Diastolic 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)

★ New Data Classes and Elements → Data Element Reclassified ★ ★ Name and Other Changes to Existing Data Classes/Elements

# USCDI+: Extending Beyond the USCDI

- Unique program and use case-specific data needs are sometimes not fully met by USCDI.
- 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 & HRSA.



# Artificial Intelligence

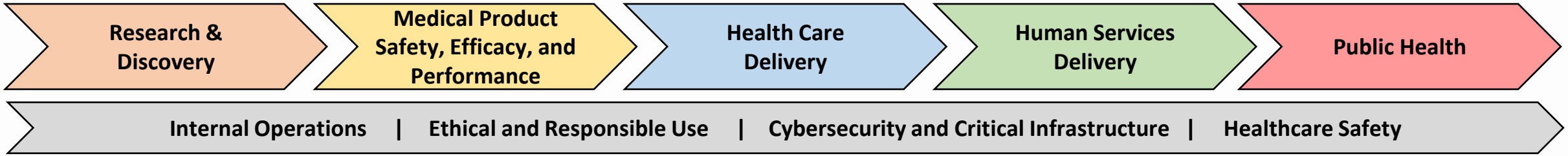
# AI spotlight

- History – HITECH Act in 2009 required Clinical Decision Support (CDS) as part of "Qualified EHR"

- In 14+ years a lot has changed – adoption and CDS technologies
  - From: react to my data based on a prior defined rule set/algorithm
  - To: Give me insights – "tell me something I don't know" and help me be faster/better/smarter

- Predictive models are increasingly being used and relied upon to inform an array of decision-makers, including clinicians, payers, researchers, and individuals
  - ONC-certified health IT plays a central role (data source and/or executing and/or enabling)

# HHS AI Strategy Development




**Main Policy Objectives**

1. Encourage health AI innovation and adoption
2. Promote trustworthy AI development and use
3. Democratize AI technologies and resources
4. Cultivate AI-empowered workforces and organization cultures

**Key Levers for HHS**

1. Regulations, policies, and guidance
2. Grants and funding programs and procurement
3. Public education and outreach
4. Internal infrastructure and operations

# Executive Order on the Safe, Secure, and Trustworthy Development and Use of AI

- HHS AI Task Force that shall develop a strategic plan on responsible deployment and use of AI and AI-enabled technologies in the health and human services sector, including:
  - Long-term safety and real-world performance monitoring
  - Development, maintenance, and availability of documentation to help users determine appropriate and safe uses of AI in local settings
  - Development of AI assurance policy – to evaluate important aspects of the performance of AI-enabled healthcare tools


- Establish an AI safety program that, in partnership with voluntary federally listed Patient Safety Organizations that:
  - Establishes a common framework for approaches to identifying and capturing clinical errors resulting from AI deployed in healthcare settings
  - Specifications for a central tracking repository for associated incidents that cause harm, including through bias or discrimination, to patients, caregivers, or other parties

# 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.

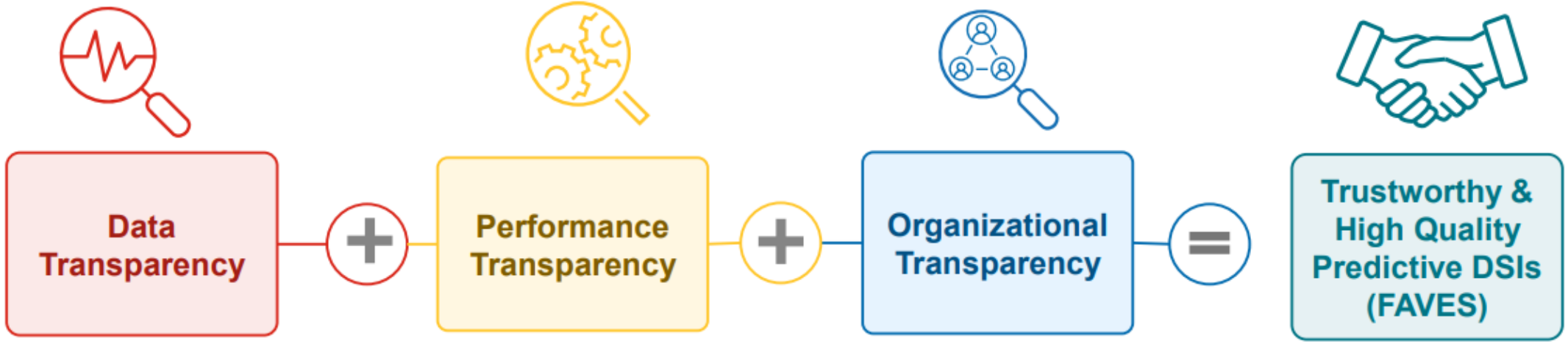
## Effective

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

# Predictive Decision Support Intervention:

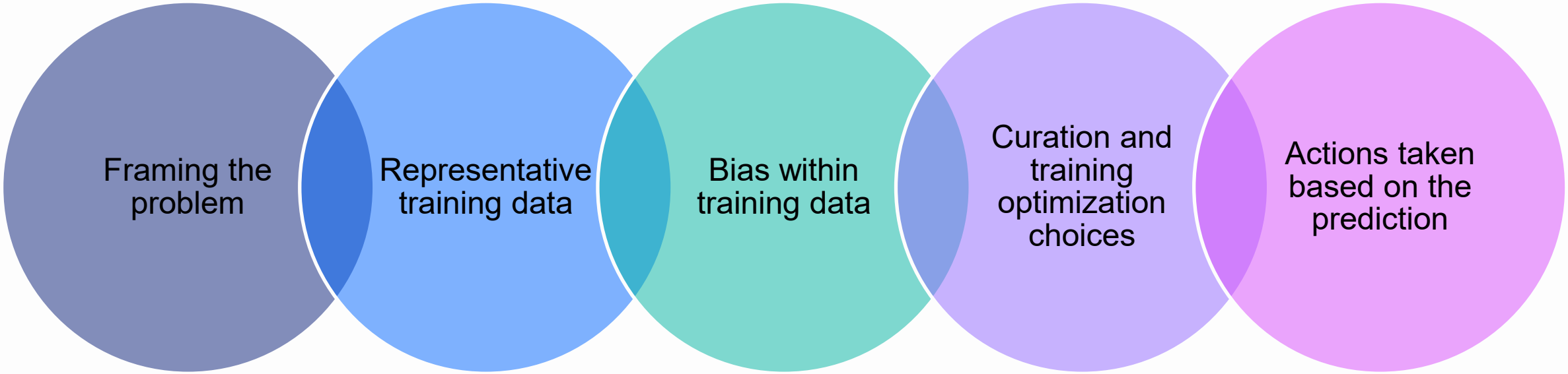
> ***"Technology intended to support decision-making based on algorithms or models that derive relationships from training or example data and then are used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation, or analysis."***

Examples include:

- Simple statistics and regression models used in a risk calculator (e.g., such as the widely used ASCVD model, which predicts heart events, and APACHE IV model, which predicts in-hospital death for ICU patients)
- Machine learning models of various complexity, including neural networks and gradient boosted machines (used, for example, to predict hospital readmission, sepsis onset, and patient no-shows) and large language models including generative pre-trained transformers (e.g., ChatGPT)

Outputs of predictive model may be presented in a broad array of forms that DSIs can take (e.g., alerts, order sets, flowsheets, etc.).

# How does AI become biased or unfair?




**Source:** Duke Margolis Center for Health Policy

**Social & institutional bias**

Unequal access to quality healthcare (e.g., under-representation in health care data)

**Data bias**

There is incomplete data on factors affecting health (e.g., SDOH)

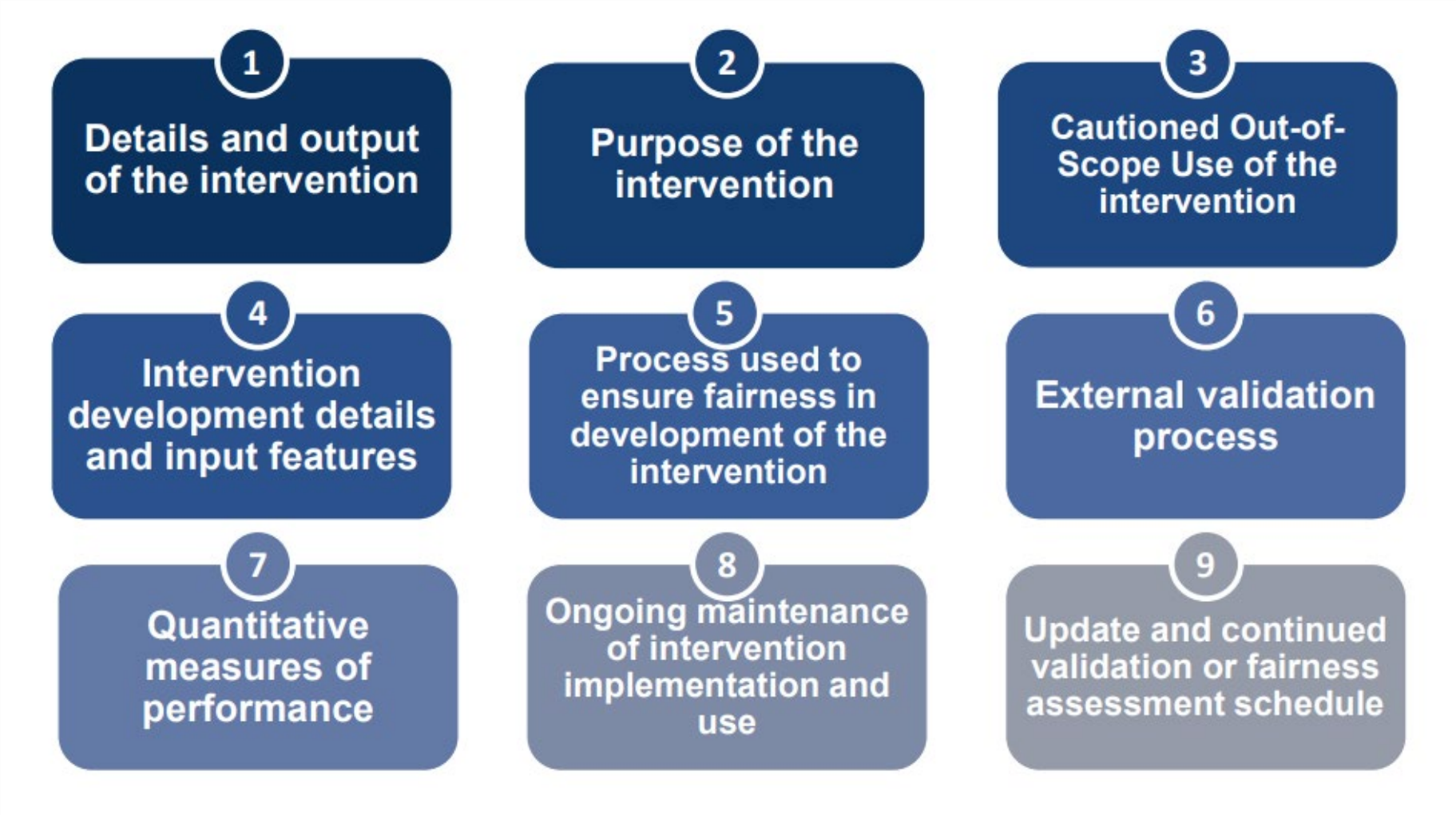
**Programming bias**

Computer programs may make create spurious results (e.g., correlation is not causation)

**Use bias**

Health care providers may inappropriately use results (e.g., deciding resource allocations)

# Source Attributes: A “Nutrition Label” for AI Products



**1. Details and output of the intervention,** including:

- Name and contact information for the intervention developer;
- Funding source of the technical implementation for the intervention(s) development;
- Description of value that the intervention produces as an output; and
- Whether the intervention output is a prediction, classification, recommendation, evaluation, analysis, or other type of output.

**2. Purpose of the intervention,** including:

- Intended use of the intervention;
- Intended patient population(s) for the intervention's use;
- Intended user(s); and
- Intended decision-making role for which the intervention was designed to be used/for (e.g., informs, augments, replaces clinical management).

**3. Cautioned out-of-scope use** of the intervention, including:

- Description of tasks, situations, or populations where a user is cautioned against applying the intervention; and
- Known risks, inappropriate settings, inappropriate uses, or known limitations.

**4. Intervention development details and input features,** including at a minimum:

- Exclusion and inclusion criteria that influenced the training data set;
- Use of variables in paragraph (b)(11)(iv)(A)(5)-(13) as input features;
- Description of demographic representativeness according to variables in paragraph (b)(11)(iv)(A)(5)-(13) including, at a minimum, those used as input features in the intervention;
- Description of relevance of training data to intended deployed setting.

**5. Process used to ensure fairness in development of the intervention,** including:

- Description of the approach the intervention developer has taken to ensure that the intervention's output is fair; and
- Description of approaches to manage, reduce, or eliminate bias.

**6. External validation process,** including:

- Description of the data source, clinical setting, or environment where an intervention's validity and fairness has been assessed, other than the source of training and testing data;
- Party that conducted the external testing;
- Description of demographic representativeness of external data according to variables in paragraph (b)(11)(iv)(A)(5)-(13) including, at a minimum, those used as input features in the intervention; and
- Description of external validation process.

**7. Quantitative measures of performance,** including:

- Validity of intervention in test data derived from the same source as the initial training data;
- Fairness of intervention in test data derived from the same source as the initial training data;
- Validity of intervention in data external to or from a different source than the initial training data;
- Fairness of intervention in data external to or from a different source than the initial training data;
- References to evaluation of use of the intervention on outcomes, including, bibliographic citations or hyperlinks to evaluations of how well the intervention reduced morbidity, mortality, length of stay, or other outcomes.

**8. Ongoing maintenance of intervention implementation and use,** including:

- Description of process and frequency by which the intervention's validity is monitored over time;
- Validity of intervention in local data;
- Description of the process and frequency by which the intervention's fairness is monitored over time;
- Fairness of intervention in local data.

**9. Update and continued validation or fairness assessment schedule,** including:

- Description of process and frequency by which the intervention is updated; and
- Description of frequency by which the intervention's performance is corrected when risks related to validity and fairness are identified.

# Transparency in AI Governance

**Intervention risk management practices must be applied for each Predictive DSI supplied by the health IT developer as part of its Health IT Module**

1. Validity
2. Reliability
3. Robustness
4. Fairness
5. Intelligibility
6. Safety
7. Security
8. Privacy

- Predictive DSI(s) must be subject to
  - Analysis of potential risks and adverse impacts
  - Practices to mitigate identified risks
  - Policies and implemented controls for governance, including how data are acquired, managed, and used
- Final Rule preamble describes each characteristic and associated approaches that can be taken to assess and mitigate risks
  - Note: many of the terms and concepts in the IRM requirements rely on the National Institute of Standards and Technology (NIST) AI Risk Management Framework

Specifically, we have not finalized that developers review risk management information from *other parties* nor that developers include risk management information from *other parties* as part of documentation requirements

# Involvement in Policy

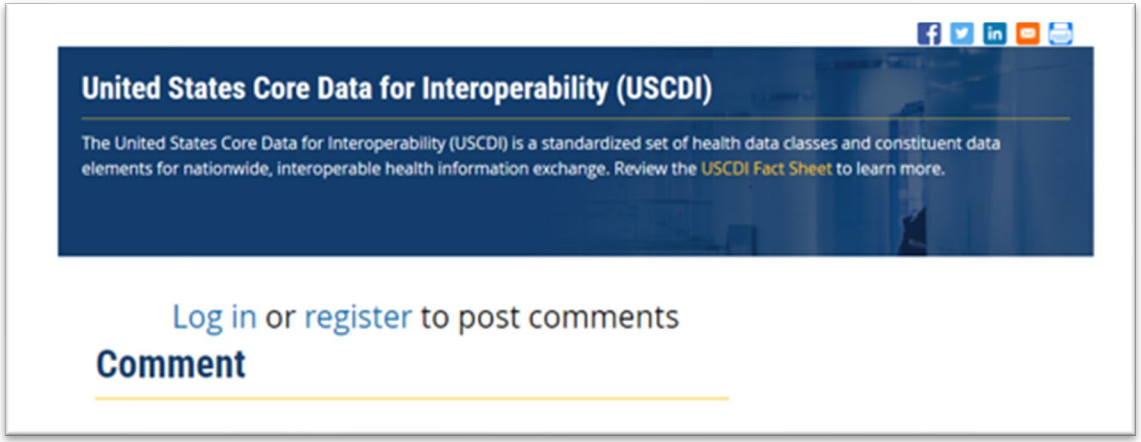
# Commenting on Current Work

## About the Draft Federal FHIR® Action Plan

The Draft Federal FHIR® Action Plan ("draft action plan") is intended to help guic
of the National Coordinator for Health IT (formerly ONC and hereafter ASTP) cor
This draft action plan builds off the work of that group and provides additional c
engagement. (HL7® and FHIR® are the registered trademarks of Health Level S

In addition, recent regulations published by ASTP and CMS – ASTP's Health, Tech
Interoperability and Prior Authorization Final Rule; and ASTP's Health, Technolog
capabilities.

Federal agencies and implementation partners are encouraged to use this draft



## United States Core Data for Interoperability (USCDI)

The United States Core Data for Interoperability (USCDI) is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. Review the USCDI Fact Sheet to learn more.

Log in or register to post comments

**Comment**

## USCDI+ Cancer: Public Feedback Requested on Clinical Trials Matching Draft Dataset by December 20th

17d ago • 16059 Views

The Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) seeks public feedback on the USCDI+ Cancer - Clinical Trials Matching draft dataset

### Clinical Trials Matching (CTM) Use Case Overview

Clinical trials are essential for advancing patient cancer prevention, improving diagnoses, developing new

# Sign Up for Email Updates

Health IT

## Navigating Healthcare Transformation: A Nurse's Perspective on ONC's HTI-1 Final Rule

Melinda (Mindy) Kidder | MAY 6, 2024

Post Share Share Email

In the ever-evolving landscape of health care, nurses are at the forefront of patient care, witnessing firsthand the impact of transformative initiatives and regulatory updates. ONC's HTI-1 final rule is a catalyst for change, ushering in a new era for health IT. In this blog post, we take a look from a nursing perspective at the promises, challenges, and potential HTI-1 implementation holds for patient care.

HTI-1 was published as part of ONC's broader effort to advance interoperability, improve patient access to health information, and reduce information blocking. For nurses, this rule represents a significant shift in how we engage with technology to deliver care efficiently and collaboratively.

**NAME**

**TITLE**

**EMAIL**

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

**Twitter:** @HHS_TechPolicy

**LinkedIn:** Assistant Secretary for Technology Policy

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