ASTP Assistant Secretary for Technology Policy

Better Health Enabled by Data

Avinash Shanbhag, MS

Executive Director, Office of Standards, Certification and Analysis, Assistant Secretary for Technology Policy (ASTP)

June 4, 2025

Agenda

I. Introduction

II. Interoperability Today
- Data Standards
- API Standards
- Network Standards

III. How can ASTP/HHS help?

“Partner to Industry and Government”

Office of the National Coordinator for Health IT

- **Founded in 2004 by executive order, established in statute in 2009**
- **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 is now Assistant Secretary for Technology Policy (ASTP) to focus on data interoperability within HHS.**

Laying the foundation of EHRs across the industry

- $40B CMS investment to subsidize EHRs for hospitals and ambulatory providers
- ONC certification of EHR systems to support CMS and CDC programs

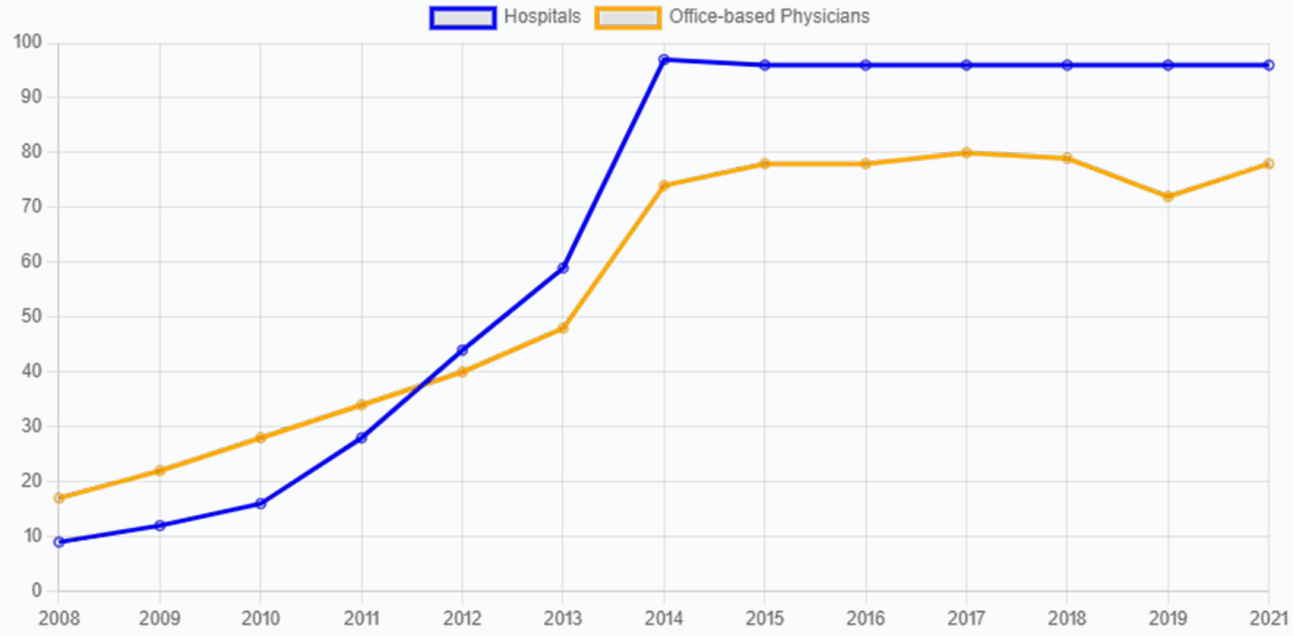
Leveraging EHRs to drive value

- **Information blocking**: Prohibits providers, technology developers, and health information networks from interfering with access, exchange, and use of electronic health information
- **Standards**: Requires access to information through APIs "without special effort"
- **TEFCA**: Requires nationwide governance for health information exchange networks – Trusted Exchange Framework and Common Agreement

The ONC Health IT Certification Program

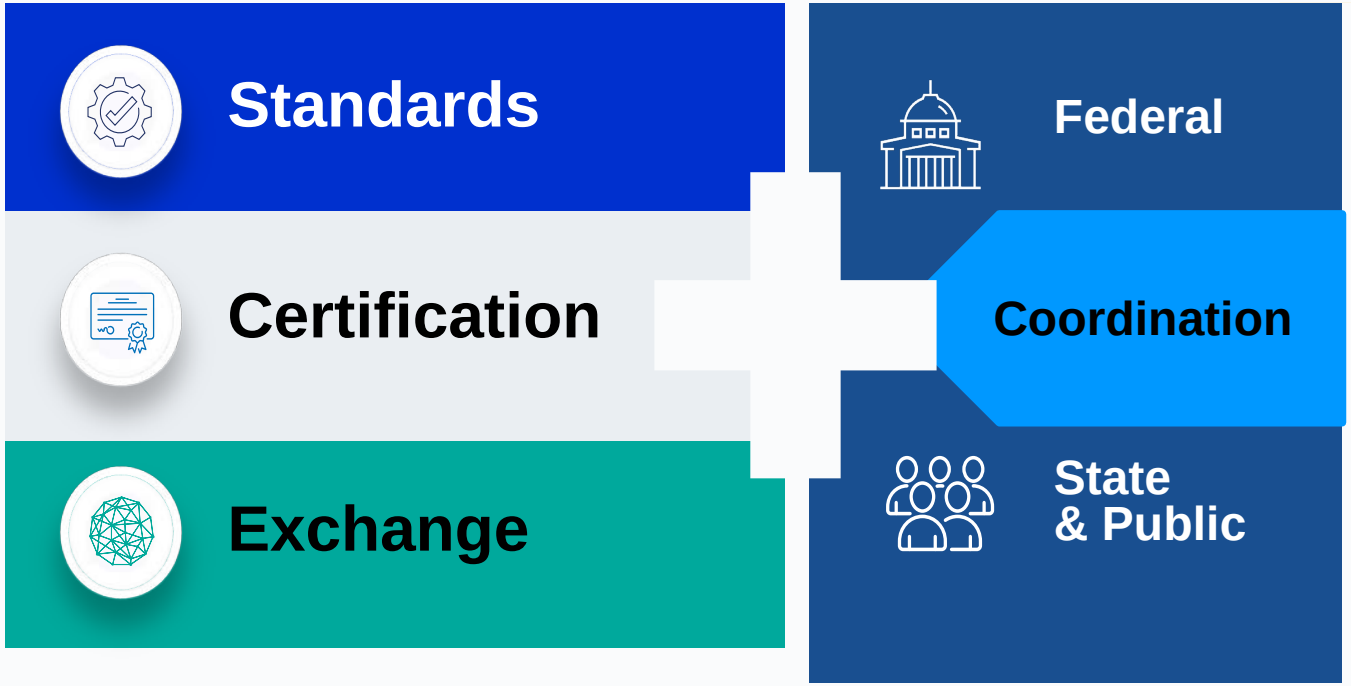
- Supports a dynamic market of 400+ health IT products
- Certifies EHRs used by >96% of hospitals and 80% of office-based physicians
- Relies on private sector expertise and market-driven innovation to establish requirements

- Represents the foundation of our national digital health infrastructure
  - Sets industry-baseline for data, standards, and interoperability
  - Certifies capabilities like electronic prescribing and patient portals used millions of times daily
  - Applies to both software functions and health IT developers' business practices



ASTP/ONC: Activities and Objectives

ASTP/ONC Activities



ASTP/ONC Objectives

- Advance the development and use of health IT capabilities
- Establish expectations for data sharing

“Interoperability Today”

“the data”

Advancing Health Data Standards

Why are health data standards important?

Health data standards form the fundamental building blocks for product development by establishing consistent protocols that can be universally understood and adopted. This helps simplify product development and speeds up time-to-market.

- Work closely with Standards Development Organizations to advance data standards used in healthcare, including Health Level Seven (HL7), National Council for Prescription Drug Programs (NCPDP), Integrating the Healthcare Enterprise (IHE), and Regenstrief Institute.
- Coordinate with federal agency partners and industry to establish data standards that meet agency programmatic goals while ensuring that they are harmonized across agencies for similar data needs.

USCDI: Core Principles

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.

USCDI

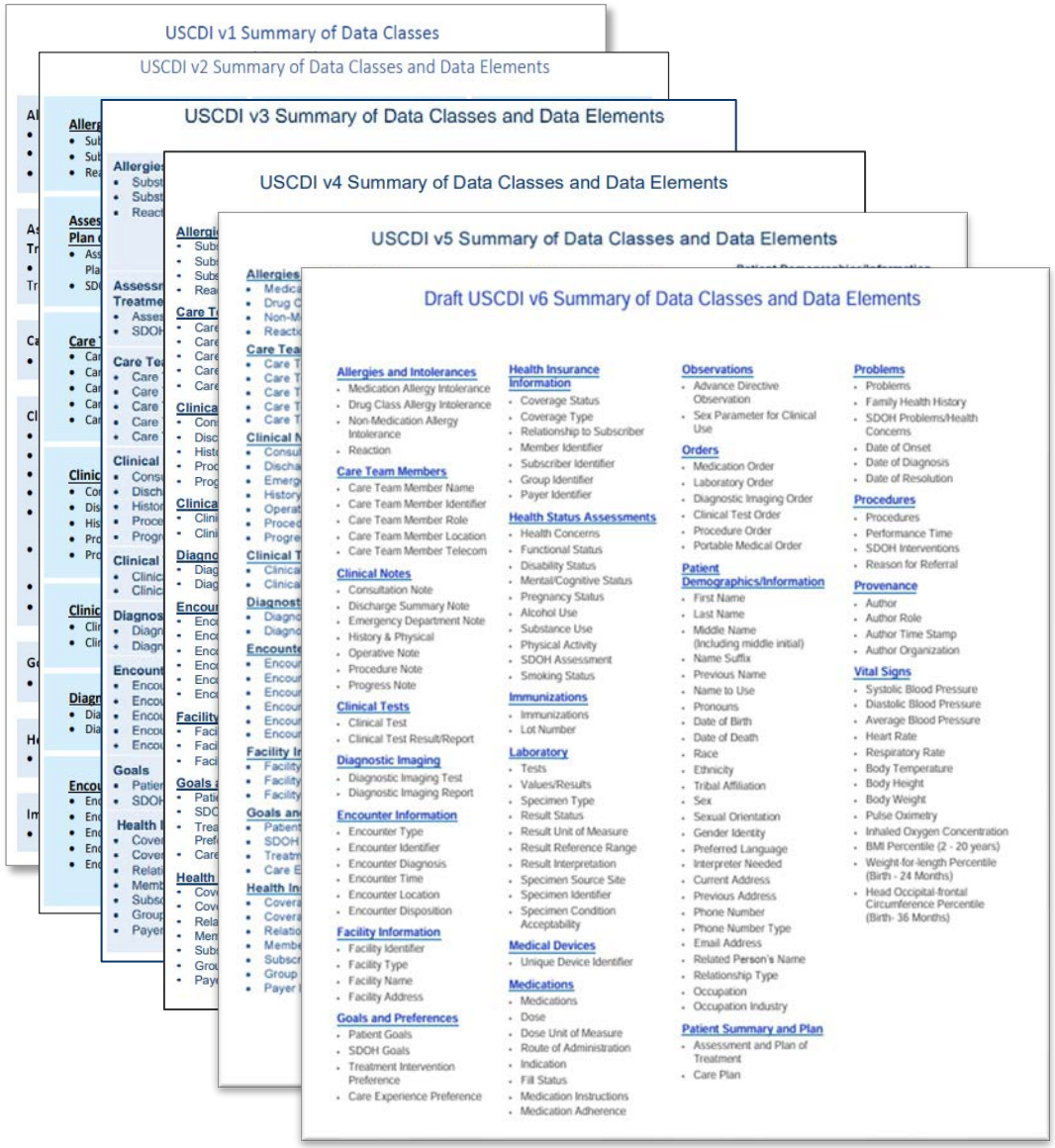
- Comprises a core set of data needed to support patient care and facilitate patient access using health IT
- Establishes a consistent baseline of data for other use cases
- Expands over time via a predictable, transparent, and collaborative **public** process

USCDI: The Minimum Dataset of the Healthcare Delivery System

- USCDI is the core dataset needed to be shared if available to support patient care and facilitate patient access in certified EHRs.
- USCDI has become the **de facto minimum dataset** of the healthcare delivery system.

USCDI Version	Number of Data Elements	Year Finalized
1.0	52	2020
2.0	74	2021
3.0	94	2022
4.0	114	2023
5.0	130	2024
6.0 (draft)	*135*	*2025 planned*

https://www.healthit.gov/uscdi



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))	
Transitions of care (§170.315(b)(1))	Update to USCDI by December 31, 2022 (replacing Common Clinical Data Set)
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

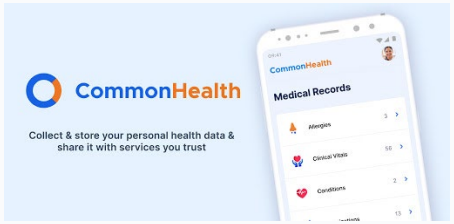
TEFCA
The Office of the National Coordinator for Health Information Technology

carequality

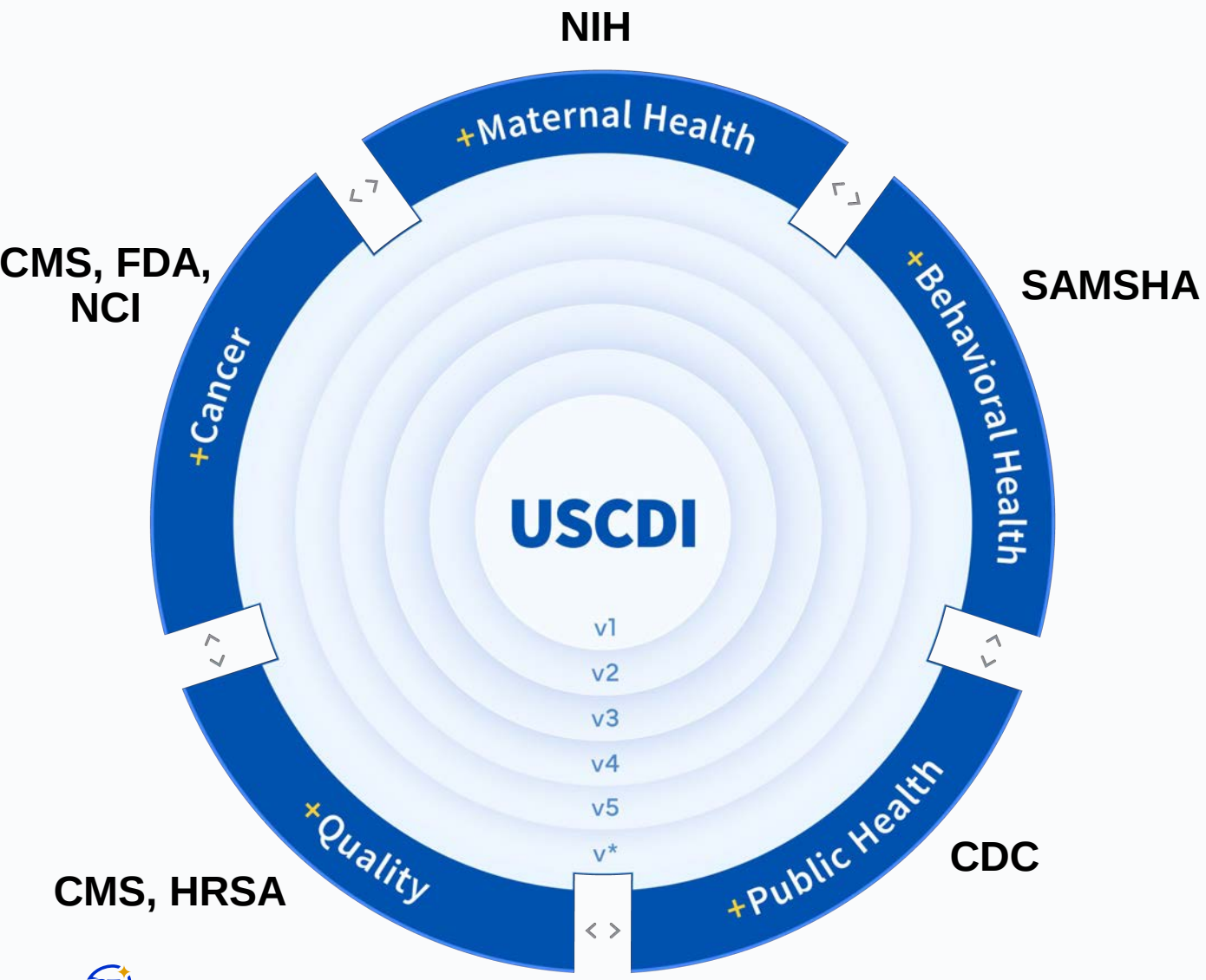
eHealth Exchange

commonwell® HEALTH ALLIANCE

Mobile apps based on USCDI



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.

https://uscdiplus.healthit.gov

“the Application Programming Interface (API)”

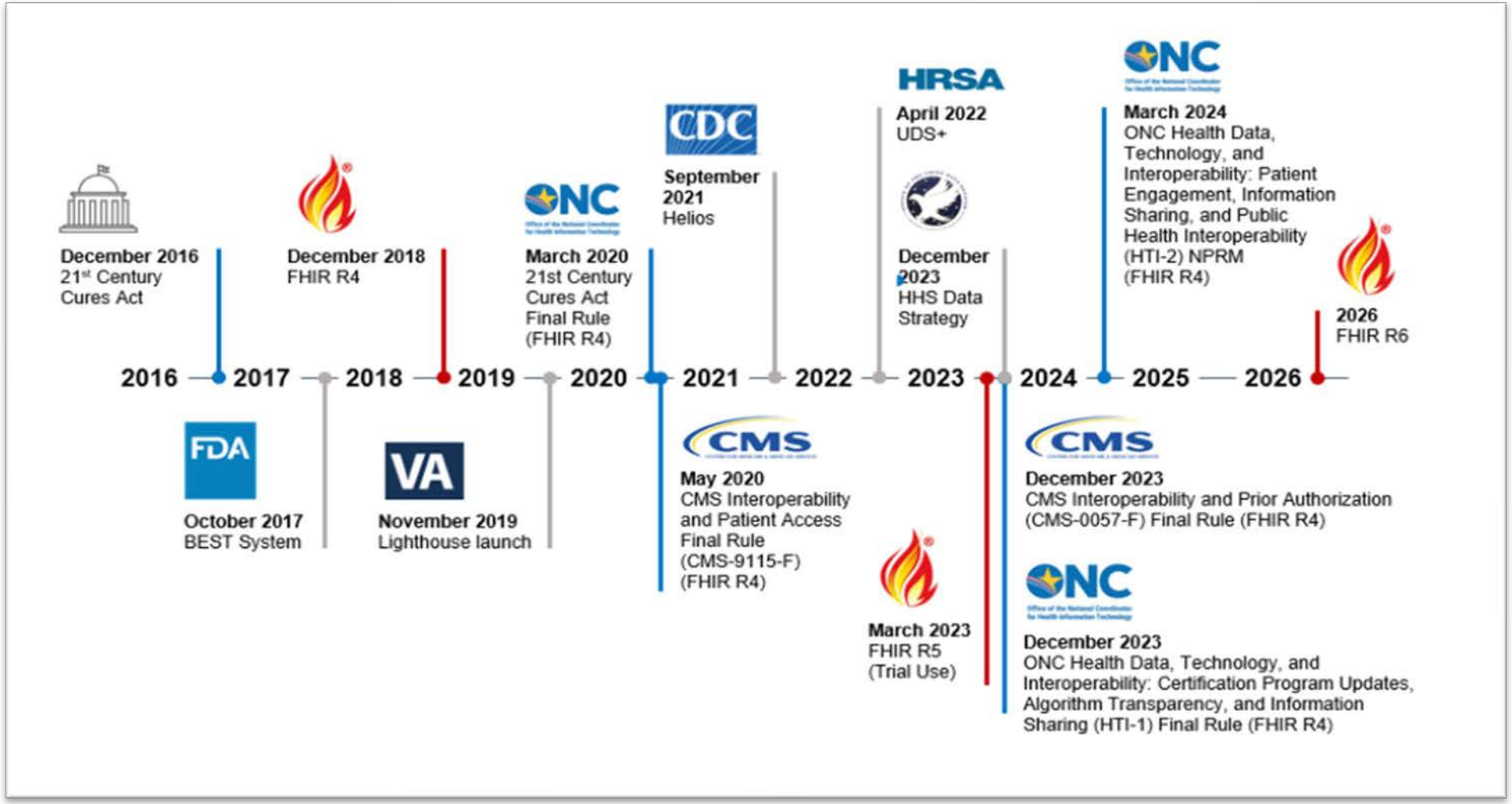
Advancing Modern Application Programming Interface (API) Standards in healthcare

Why are FHIR APIs important?

FHIR APIs are open, non-proprietary standards widely supported by the health IT industry that enable app developers to build innovative tools rapidly and efficiently.

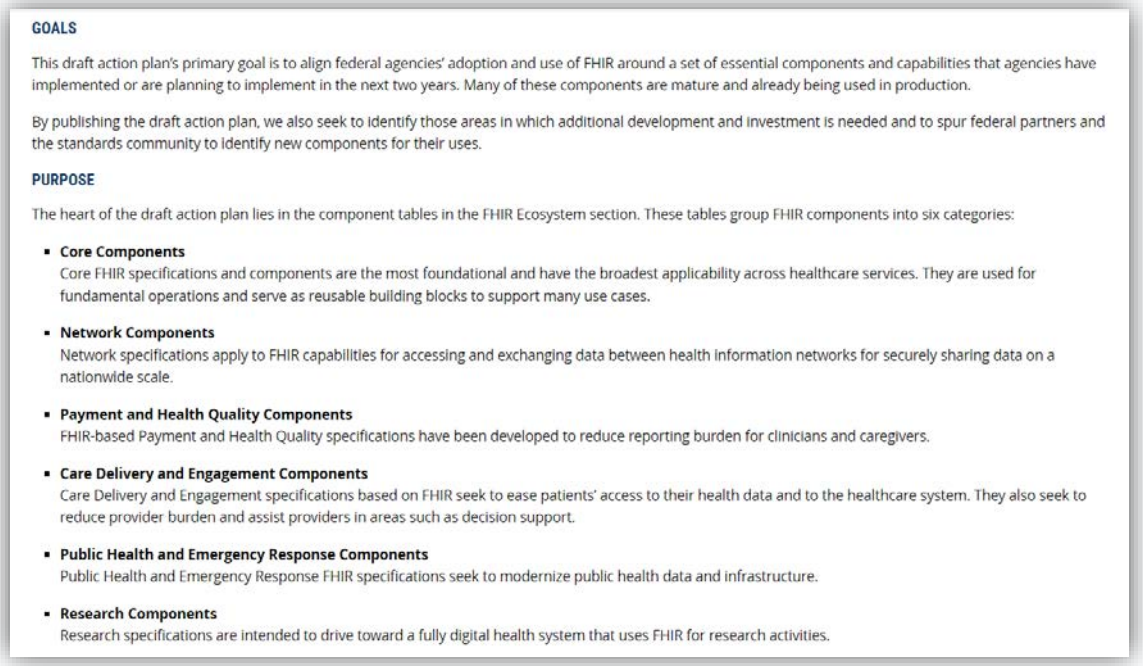
- ASTP established FHIR APIs as a foundational requirement in the ASTP/ONC Health IT Certification Program as part of the 21st Century Cures Act.
- ASTP supports the advancement of FHIR API standards by actively funding the HL7 standards development organization and encouraging industry adoption.
- ASTP coordinates with federal agencies to leverage FHIR APIs across federal health IT programs to deliver on the promise of a modern, digital healthcare system.

Coordinated, Multi-Agency Support for FHIR Ecosystem



Draft Federal FHIR Action Plan: Aligning Federal Agencies Use of FHIR

- FHIR Action Plan serves as a public resource for federal agencies and developers looking for FHIR-based capabilities being used by the federal government
- Plan focuses on a limited number of areas that are broadly applicable, and lists the most mature technical standards supported by federal agencies
- Identifies early-stage capabilities where federal engagement is underway
- Public comments are being processed and aiming to finalize version 1 in 2025.



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.

https://www.healthit.gov/isp/about-fhir-action-plan

ASTP

“the network”

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]

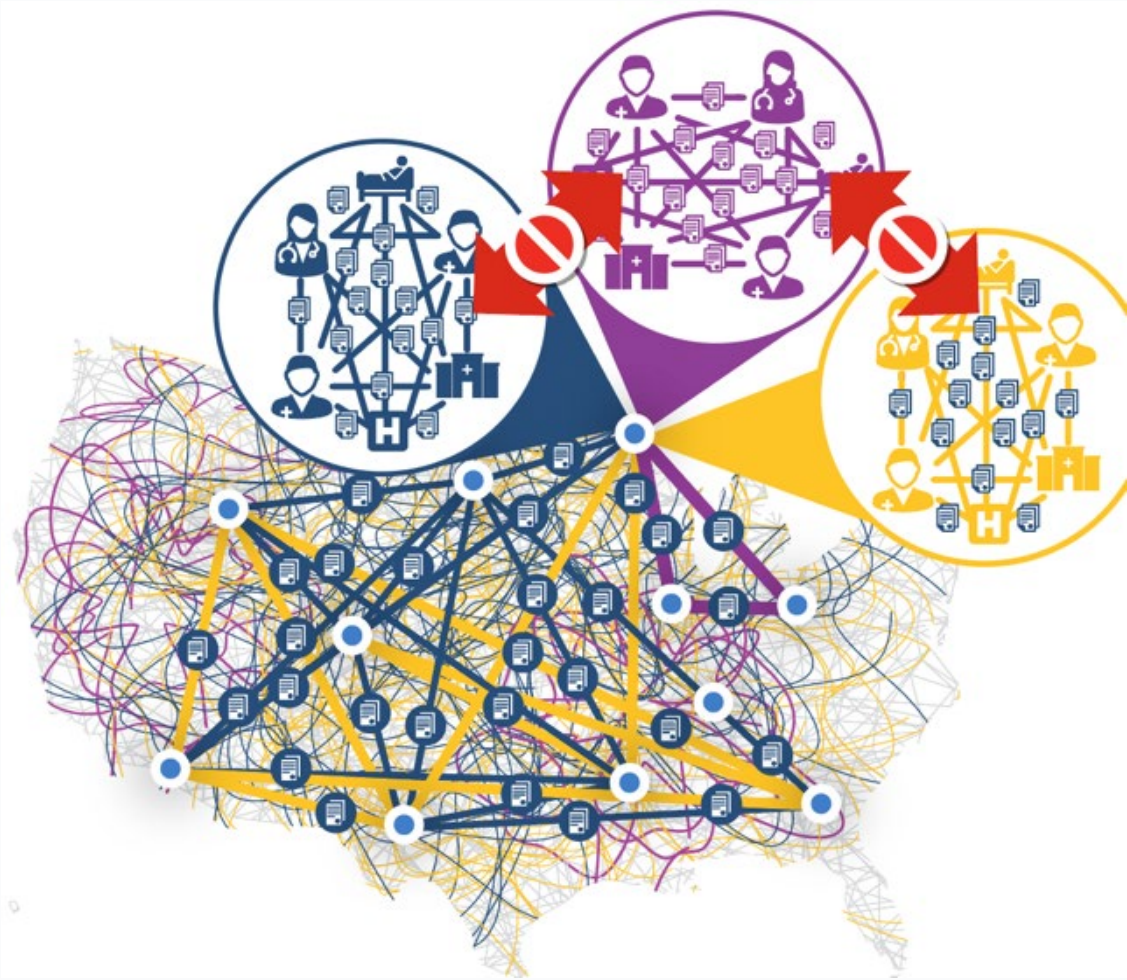
TEFCA Will Simplify Health Data Exchange

Trusted Exchange Framework and Common Agreement (TEFCA) went live in December 2023

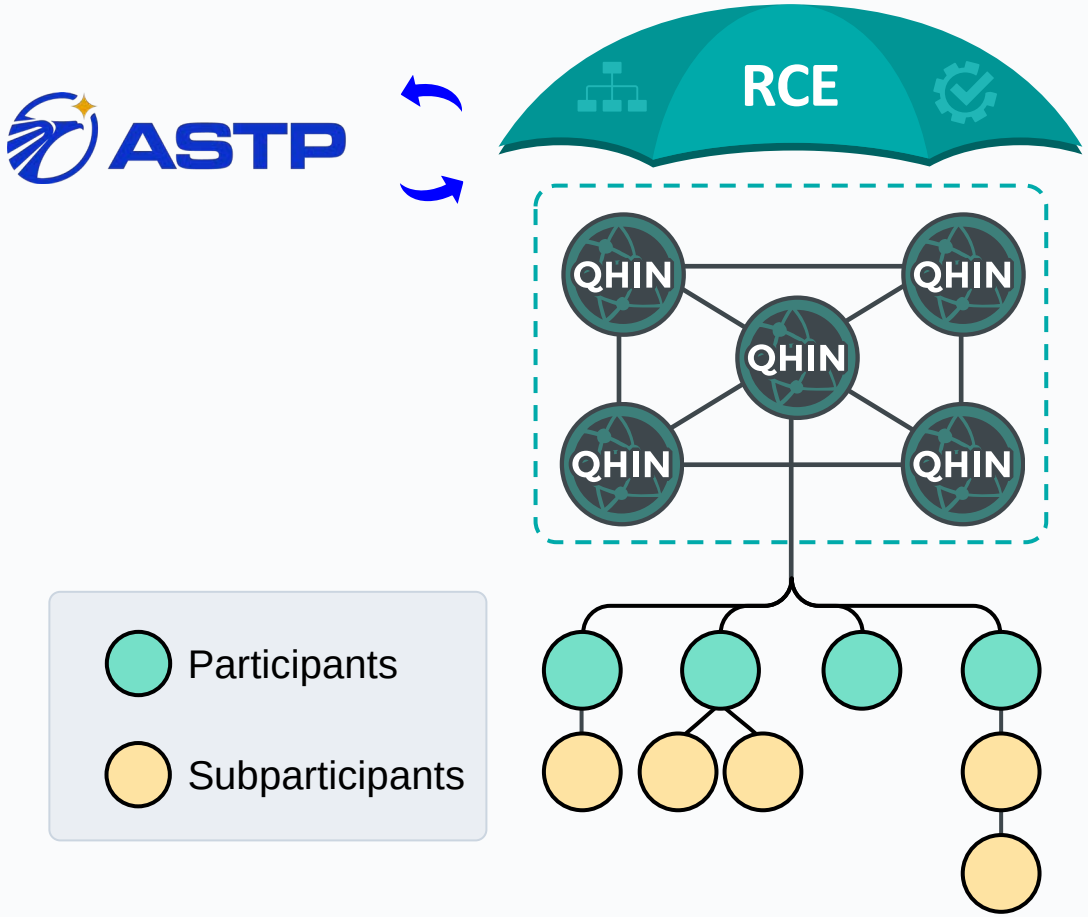
While there has been growth in health information networks, there is much unfinished business

- Different business models
- Different participants
- Different exchange modes
- Different technical architecture
- Different maturity levels

Federal government involvement required to spur the further evolution of nationwide network interoperability



TEFCA Framework



ASTP defines overall policy and certain governance requirements

RCE provides oversight and governing approach for QHINs

QHINs connect directly to each other to facilitate nationwide interoperability

Each QHIN connects Participants, which connect Subparticipants

Participants and Subparticipants connect to each other through TEFCA Exchange

- Participants contract directly with a QHIN and may choose to also provide connectivity to others (Subparticipants), creating an expanded network of networks
- Participants and Subparticipants agree to the same Terms of Participation and can generally participate in TEFCA Exchange in the same manner

TEFCA Establishes Policy and Technical Requirements for Sharing Electronic Health Information

The Common Agreement, including the Terms of Participation, establishes clear policy and technical requirements for the exchange of information by organizations participating in TEFCA.

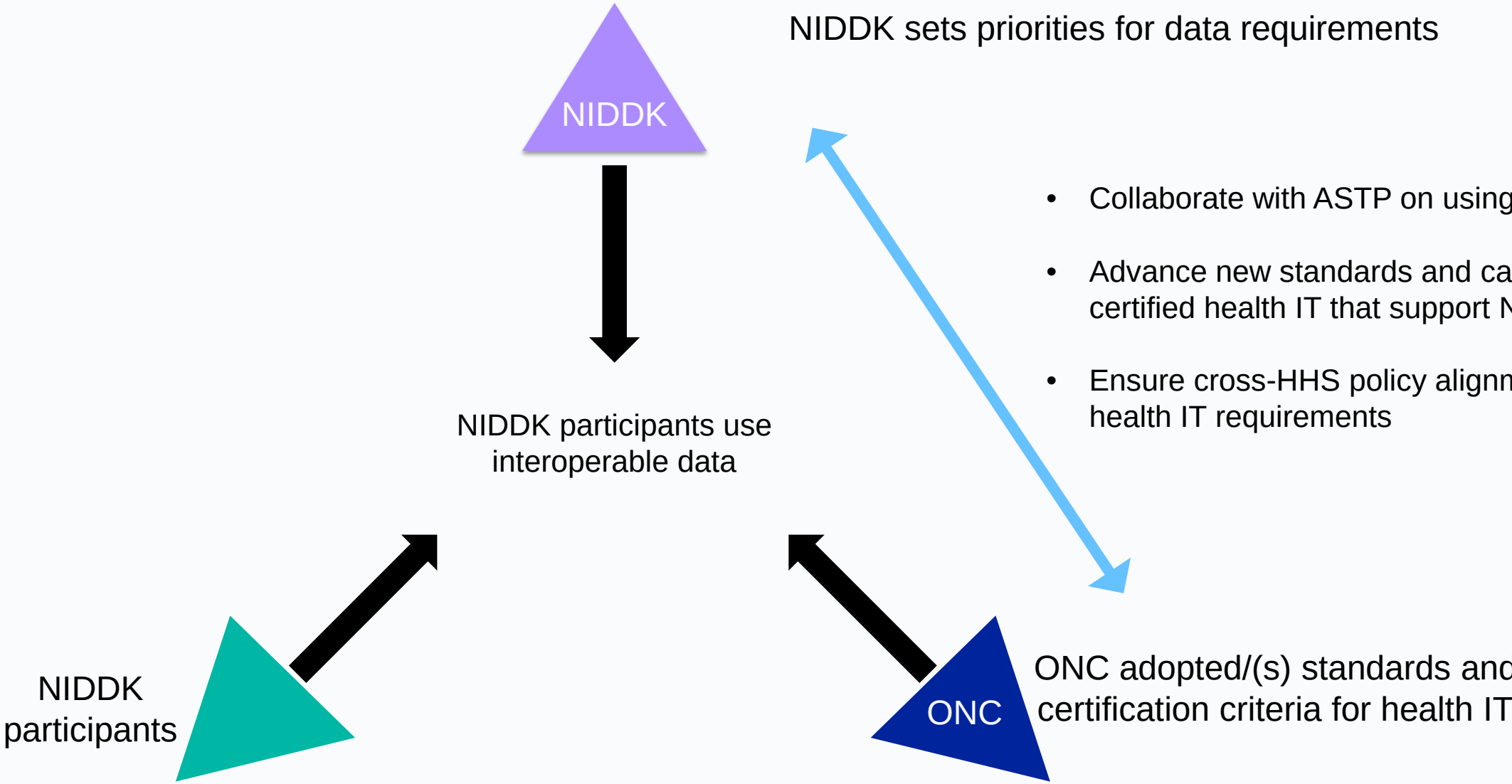
This means that TEFCA QHINs, Participants, and Subparticipants know what business practices are expected of their organization and what to expect from all the other participating organizations.

The TEFCA framework, including the QHIN Technical Framework, provides:

- A shared governance structure for all QHINs
- A structured onboarding process to ensure QHINs can adhere to the Common Agreement requirements
- Common protocols for authenticating and authorizing users
- A shared directory service to support exchange of electronic health information
- Provisions on how QHINs respond to all data requests as may be required under the Common Agreement
- Provisions on compliance with relevant privacy and security rules
- A security incident notification process

“our powers combined”

Triangulating Policy, Authorities, and Interests



- Collaborate with ASTP on using data from EHRs
- Advance new standards and capabilities in certified health IT that support NIDDK goals
- Ensure cross-HHS policy alignment around health IT requirements

Contact Information

Reach out via phone or web

- 202-690-7151
- Feedback Form: https://www.healthit.gov/form/healthit-feedback-form

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- https://www.youtube.com/user/HHSONC

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