Garbage in, Garbage Out: Standardized data for Better Reuse

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Agenda

I.   ONC: Partner to Industry and Government

II.   USCDI and USCDI+: Standardizing Data for Healthcare Delivery System

III.   Our Powers Combined!

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# "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**

HITECH Act 2009 ⟶ **21st Century Cures Act 2016**

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
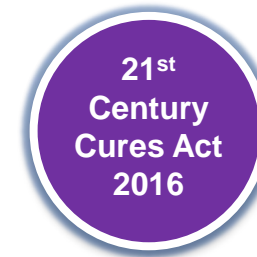
Leveraging EHRs to drive value

- Standards: Data and API standards for access "without special effort"
- Trusted Exchange Framework and Common Agreement: Nationwide governance for health information exchange networks
- Information blocking: Prohibits providers, technology developers, and health information networks from interfering with access, exchange, and use of electronic health information

EHR Certification And Adoption

- 900+ active certified EHR products

- 97% of hospitals and 90% of ambulatory providers now use EHRs

- Over 97% of hospital patients have electronic access to their medical records

Programs leveraging ONC EHR Certification

CMS
- Acute Myocardial Infarction (AMI)
- Bundled Payments for Care Improvement (BPCI)
- Chronic Care Management (CCM)
- Comprehensive ESRD
- Comprehensive Care for Joint Replacement (CJR)
- Comprehensive Primary Care Plus (CPC+)
- Coronary Artery Bypass Graft (CABG)
- Promoting Interoperability
- Inpatient Quality Reporting (IQR)
- Medicare Shared Savings Program (MSSP)
- Merit-based Incentive Payment System (MIPS)
- Million Hearts®: Cardiovascular Disease Risk Reduction Model
- Next Generation ACO
- Oncology Care Model (OCM)
- Outpatient Prospective Payment System
- Physician Self-Referral Law exception and Anti-kickback Statute safe harbor for certain EHR donations
- Qualified Health Plan (QHP), Affordable Care Act (ACA)

Other Federal
- Department of Defense Healthcare Management System Modernization Program
- The Joint Commission for Performance Measurement Initiative ("ORYX vendor" – eCQMs for hospitals)
- Substance Abuse and Mental Health Services Administration (SAMHSA) Section 223 Demonstration Program for Certified Community Behavioral Health Clinics (CCBHCs)
- Health Resources & Services Administration (HRSA) Health Center Controlled Networks
- CDC public health reporting requirements

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"the data"

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.
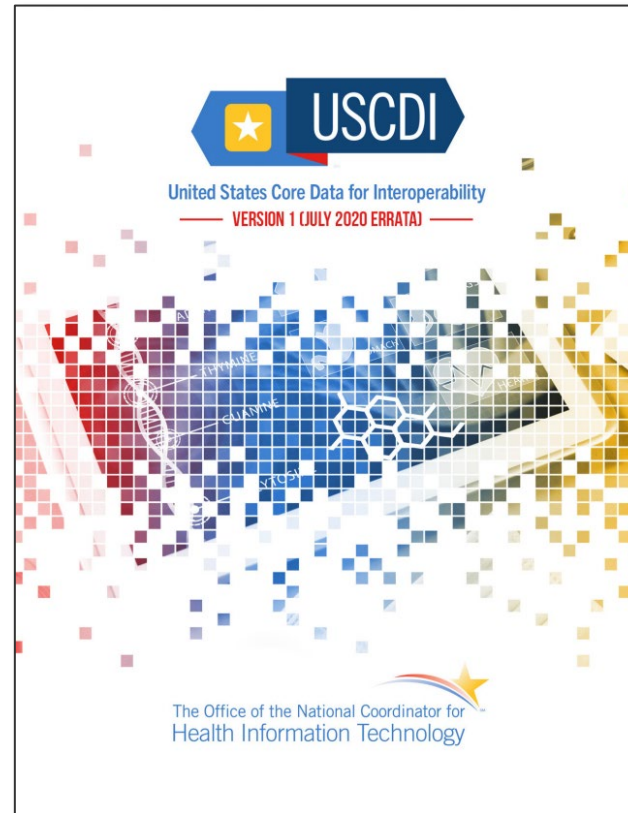
USCDI

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

United States Core Data for Interoperability (USCDI)

- **Data standard established by ONC in the 2020 21st Century Cures Act Final Rule**

- **Minimum dataset required for interoperability**
  - Defines required data elements and vocabulary standards
  - Agnostic to format
  - Focuses on patient access/care coordination use cases

- **Updated on annual cycle with federal agency and industry input**
  - Updates based on multiple criteria including standards maturity and public/industry priority
  - Process is transparent and open for widespread participation

USCDI

United States Core Data for Interoperability
VERSION 1 (JULY 2020 ERRATA)

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USCDI v1 Summary of Data Classes and Data Elements

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

Assessment and Plan of Treatment
- Assessment and Plan of Treatment

Care Team Members
- Care Team Members

Clinical Notes
- Consultation Note
- Discharge Summary Note
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

Goals
- Patient Goals

Health Concerns
- Health Concerns

Immunizations
- Immunizations

Laboratory
- Tests
- Values/Results

Medications
- Medications

Patient Demographics
- First Name
- Last Name
- Previous Name
- Middle Name (incl Middle Initial)
- Suffix
- Birth Sex
- Date of Birth
- Race
- Ethnicity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address

Problems
- Problems

Procedures
- Procedures

Provenance
- Author Time Stamp
- Author Organization

Smoking Status
- Smoking Status

Unique Device Identifier(s) for a Patient's Implantable Device(s)
- Unique Device Identifier(s) for a Patient's Implantable Device(s)

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

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.

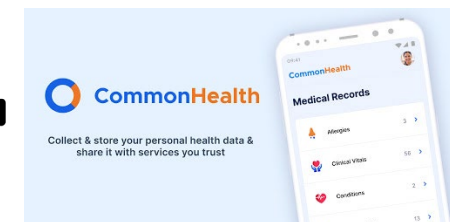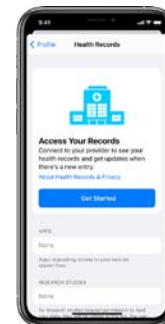**ACTION:** Final rule.

Interoperability networks requiring USCDI

Mobile apps based on USCDI

USCDI and Relationship to Implementation Specifications

USCDI: The 21st Century Cures Act and Beyond

- USCDI v1 includes four new data elements: clinical notes, provenance, pediatric vital signs and address

- USCDI v2 added three data classes and 22 data elements in support of advancing health equity (SOGI and SDOH)

- USCDI v3 focused on factors promoting equity, reducing disparities and supporting public health data interoperability

- USCDI v4 added Alcohol and Substance Use Assessments, Physical Activity, Treatment Intervention and Care Experience Preferences, and Medication Adherence data elements
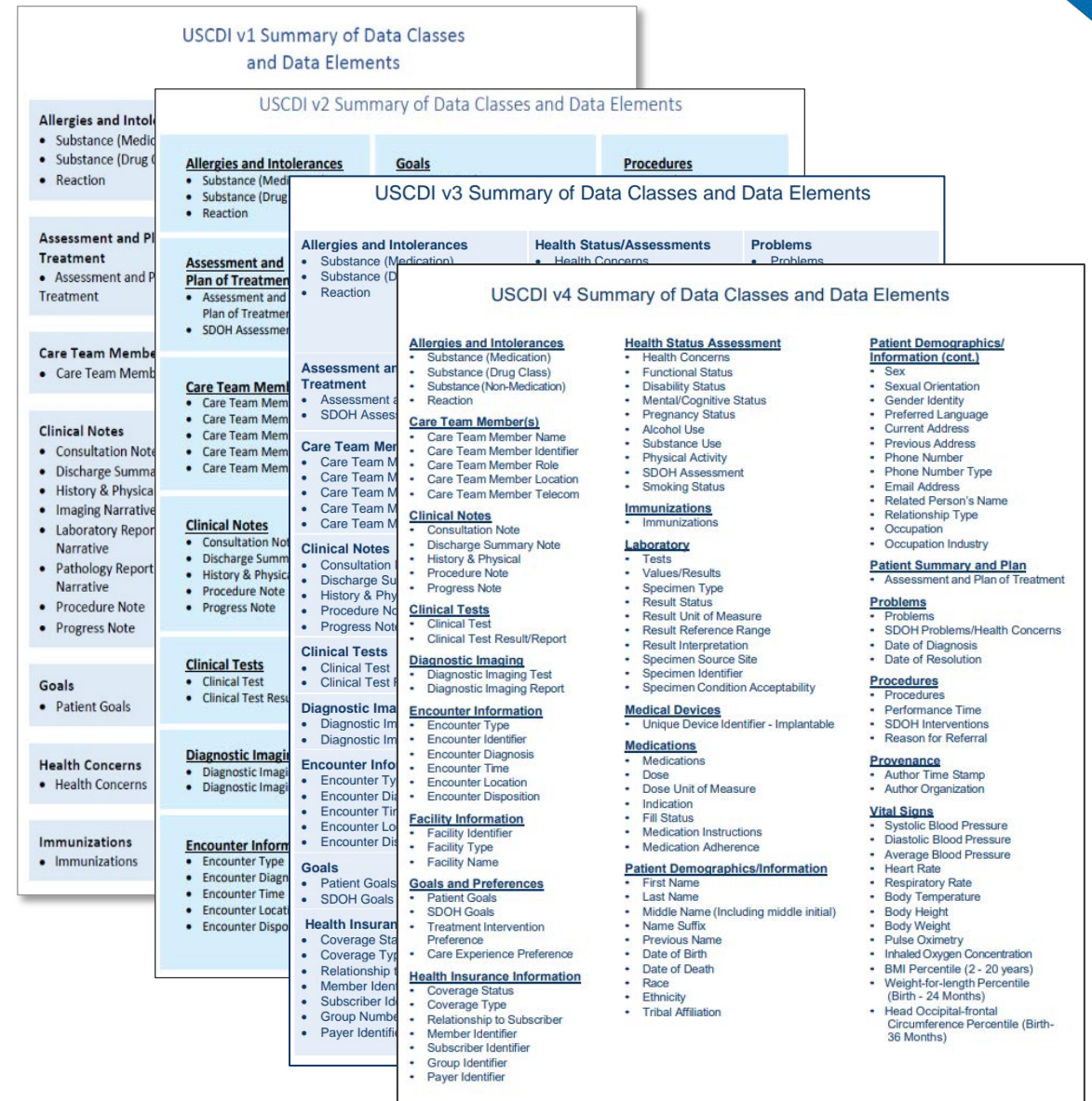
What is USCDI+

USCDI+ is **a service** that ONC provides to **federal agencies,** in collaboration with their key stakeholders, who need to establish, harmonize, and advance the use of **interoperable datasets** that extend **beyond** the core data in the **USCDI** to meet agency or use-case specific programmatic requirements

USCDI+ Program Overview & Goals

- **Collaborate** across USCDI+ partners, healthcare providers, and the health IT community to inform and support health IT advancement for priority use cases.

- **Adopt** standards across relevant partners, including federal agencies, clinical stakeholders, the health IT community, public health agencies and users of health IT.

- **Implement** specifications to ensure that the use of standards is aligned across federal programs and with key partners, including state, local, tribal, and territorial governments, across specialties and sites of service, improving interoperability on a national scale.
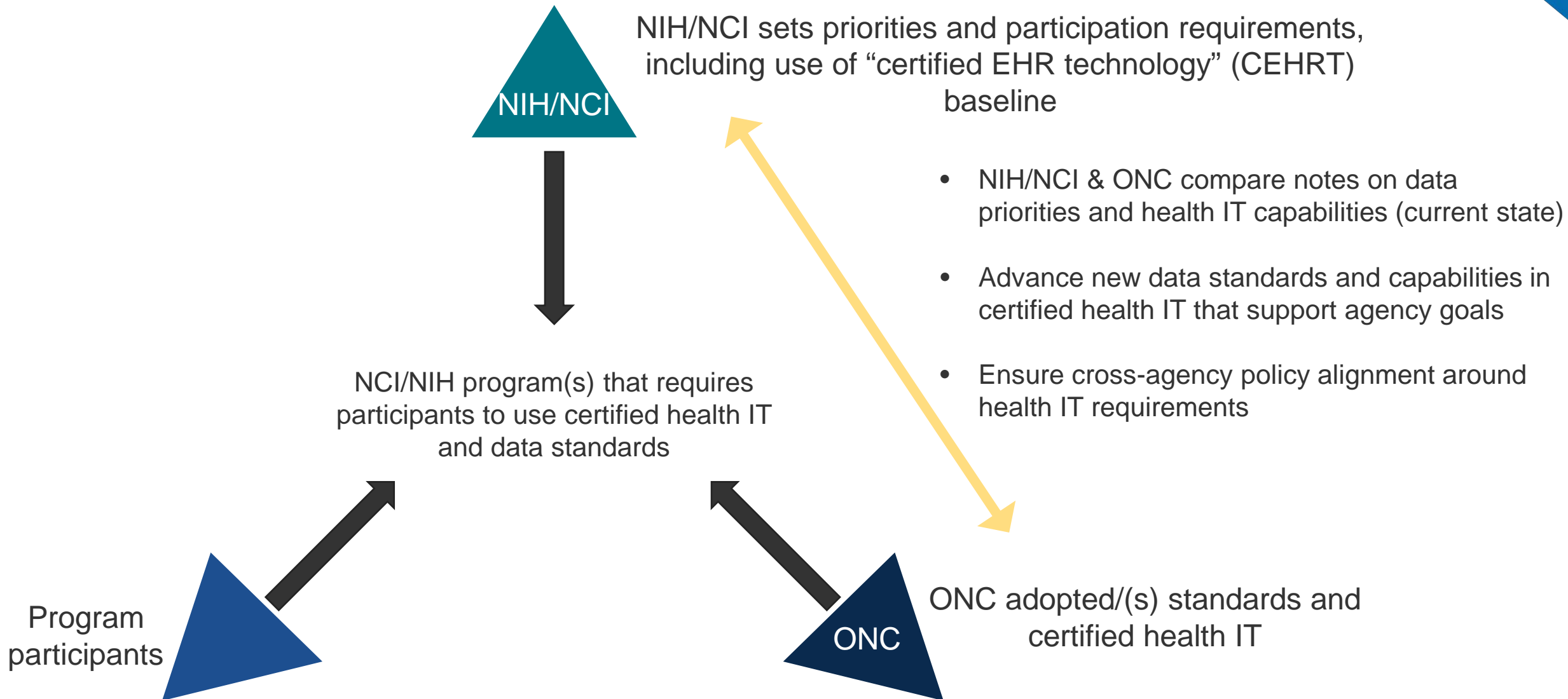
USCDI+ Cancer

- ONC has partnered with the National Cancer Institute (NCI), Centers for Medicare and Medicaid Innovation (CMMI), the Centers for Disease Control and Prevention (CDC), and the US Food and Drug Administration (FDA) to support Cancer Moonshot by establishing USCDI+ Cancer.

- USCDI+ Cancer aims:

  - Capture the data needs for Cancer reporting that fall outside the scope of USCDI.

  - Harmonize Cancer data elements into a common data element list for that addresses multiple partner needs and use cases.

  - Support the integration of federal data systems.

  - Identify opportunities for policy alignment around Cancer reporting programs under existing authorities across HHS agencies.

"Our powers combined"

Triangulating Policy, Authorities, and Interests

NIH/NCI

NIH/NCI sets priorities and participation requirements, including use of "certified EHR technology" (CEHRT) baseline

- NIH/NCI & ONC compare notes on data priorities and health IT capabilities (current state)

- Advance new data standards and capabilities in certified health IT that support agency goals

- Ensure cross-agency policy alignment around health IT requirements

NCI/NIH program(s) that requires participants to use certified health IT and data standards

Program participants

ONC

ONC adopted/(s) standards and certified health IT

Contact ONC

ONC
Office of the National Coordinator for Health Information Technology

📞 **Phone:** 202-690-7151

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

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