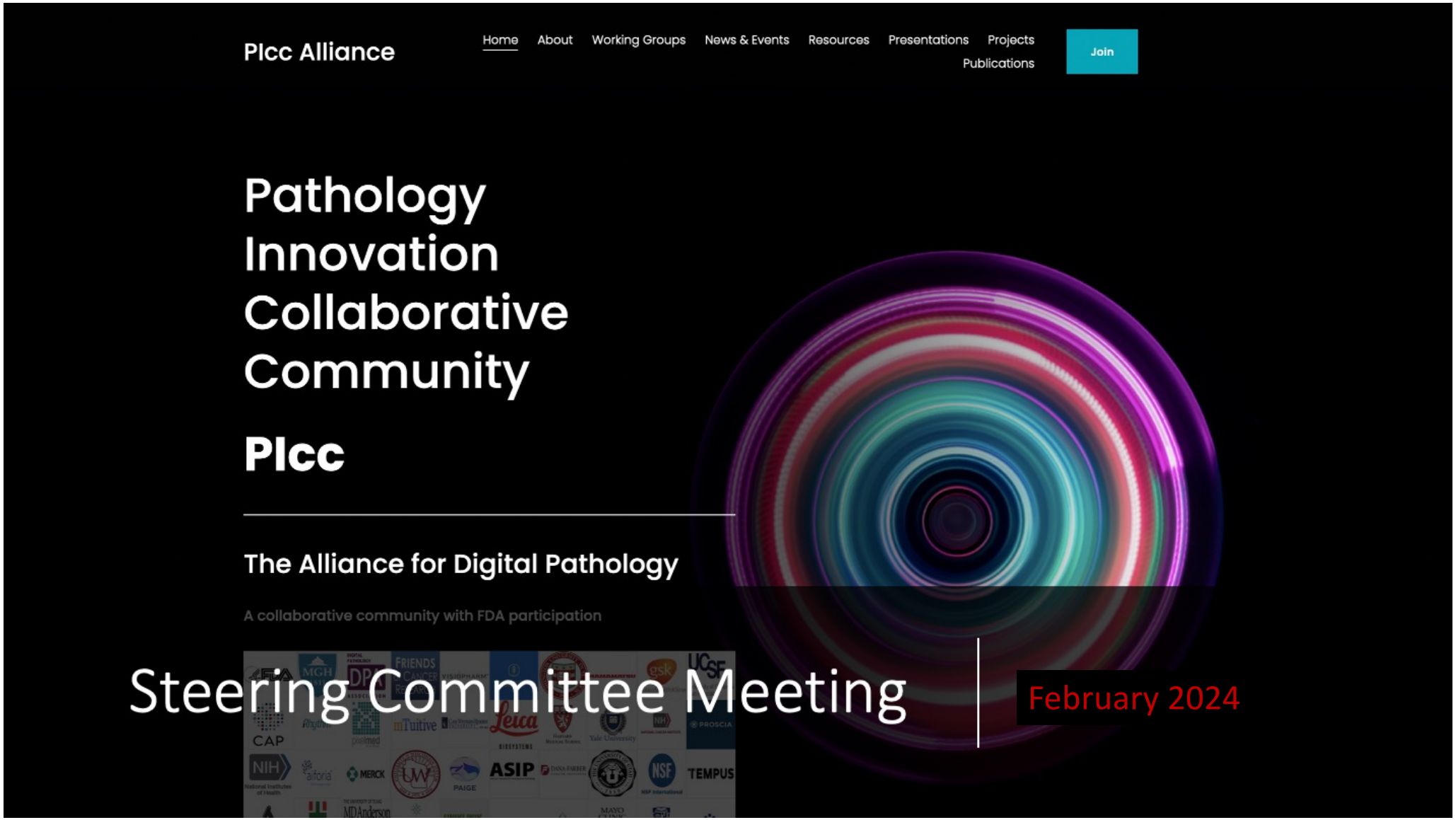
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The Alliance for Digital Pathology
A collaborative community with FDA participation
Steering Committee Meeting
February 2024

FDA

FDA and CMS: Americans Deserve Accurate and Reliable Diagnostic Tests, Wherever They Are Made

Medical Devices News and Events

CDRH Events

CDRH Statements

CDRH Newsletters

CDRHNew - News and Updates

FOR IMMEDIATE RELEASE
Jan. 18, 2024

The following is attributed to Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health (CDRH) and Dora Hughes, M.D., M.P.H., acting chief medical officer and acting director of the Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services (CMS)

Physicians heavily rely on laboratory tests to make critical decisions about their patients' care—roughly 70% of healthcare decisions depend on laboratory test results according to the Centers for Disease Control and Prevention (CDC). For example, results from laboratory tests can be the sole determinant of whether a patient with cancer gets a particular therapy, potentially risking the patient's life with an inaccurate test result. Because of the important role of laboratory tests in healthcare decisions, it is essential to ensure these tests work.

Content current as of:
01/18/2024

Regulated Product(s)
Medical Devices
Radiation-Emitting Products

* * * * *

Issued in Washington, DC, on September 28, 2023.

Karen L. Chiodini,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2023–21811 Filed 10–2–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 809

[Docket No. FDA–2023–N–2177]

RIN 0910–AI85

Medical Devices; Laboratory Developed Tests

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to amend its regulations to make explicit that in vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) including when the manufacturer of the IVD is a laboratory. In conjunction with this amendment, FDA is proposing a policy under which FDA intends to phase out its general enforcement discretion approach for laboratory developed tests

(LDTs) so that IVDs manufactured by a laboratory would generally fall under

• For written/paper comments submitted to the Dockets Management

FOR FURTHER INFORMATION CONTACT: Toby Lowe, Center for Devices and

U.S. FOOD & DRUG ADMINISTRATION

Welcome To Today's Webinar

Thanks for joining us!
We'll get started in a few minutes

Today's Topic:
FDA's Proposed Rule Regarding Laboratory Developed Tests

Date:
October 31, 2023

Proposed Rule: Medical Devices; Laboratory Developed Tests
October 31, 2023

Moderator: CDR Kim Piermatteo

CDR Kim Piermatteo: Hello and thanks for joining us for today's CDRH Webinar. This is Commander Kim Piermatteo of the United States Public Health Service and I serve as the Education Program Administrator in the Division of Industry and Consumer Education in CDRH's Office of Communication and Education. I'll be your moderator for today's webinar.

We are holding this webinar to provide information on the Proposed Rule Regarding Laboratory Developed Tests, or LDTs. Today, we will provide an overview of the rulemaking proposal to amend the FDA's regulations to make explicit that in vitro diagnostic products or IVDs, are devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the IVD is a laboratory. And we will describe the proposed phaseout of FDA's general enforcement discretion approach to LDTs.

Resources

Cited Resource	URL
Proposed Rule Regarding LDTs	https://www.federalregister.gov/documents/2023/10/03/2023-21662/medical-devices-laboratory-developed-tests
Preliminary Regulatory Impact Analysis (PRIA)	https://www.regulations.gov/document/FDA-2023-N-2177-0077
Redacted Memo of Examples of IVDs Offered as LDTs that Raise Public Health Concerns	https://www.regulations.gov/document/FDA-2023-N-2177-0076
Memo Summarizing Findings from Analysis of First 125 EUA Requests from Labs for Molecular Diagnostic COVID Tests	https://www.regulations.gov/document/FDA-2023-N-2177-0121
e-Comment Portal	https://www.federalregister.gov/documents/2023/10/03/2023-21662/medical-devices-laboratory-developed-tests#open-comment

QMS

This document is scheduled to be published in the Federal Register on 02/02/2024 and available online at **https://federalregister.gov/d/2024-01709**, and on **https://govinfo.gov**

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 4 and 820

[Docket No. FDA-2021-N-0507]

RIN 0910-AH99

Medical Devices; Quality System Regulation Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to amend the device current good manufacturing practice (CGMP) requirements of the Quality System (QS) regulation to harmonize and modernize the regulation. We are harmonizing to align more closely with the international consensus standard for devices by converging with the quality management system (QMS) requirements used by other regulatory authorities from other jurisdictions (i.e., other countries). We are doing so by incorporating by reference an international standard specific for device quality management systems. Through this rulemaking we also establish additional requirements and make conforming edits to clarify the device CGMP requirements for such products. This action will continue our efforts to align our regulatory framework with that used by regulatory authorities in other jurisdictions to promote consistency in the regulation of devices and provide timelier introduction of safe, effective, high-quality devices for patients.

DATES: This rule is effective February 2, 2026. The incorporation by reference of certain

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/Acronym	What It Means
ANPRM	Advance Notice of Proposed Rulemaking
CFR	Code of Federal Regulations
CGMP	Current Good Manufacturing Practice
CPG	Compliance Policy Guide
EO	Executive Order
EIR	Establishment Inspection Report
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDA	U.S. Food and Drug Administration
GHTF	Global Harmonization Task Force
GMP	Good Manufacturing Practice
IMDFR	International Medical Device Regulators Forum
ISO	International Organization for Standardization
ISO 13485	Medical devices--Quality management systems--Requirements for regulatory purposes--ISO 13485:2016
ISO 9000	Quality Management Systems--Fundamentals and Vocabulary --ISO 9000:2015
ISO 14971	Medical Devices--Application of Risk Management to Medical Devices
MDR	Medical Device Reporting
MDSAP	
OMB	
QMS	
QMSR	
QS	
QSIT	
UDI	

FDA and Life Sciences

FDA Aligns U.S. Medical Device Quality System Regulation with International Standards

On February 2, 2024, the U.S. Food and Drug Administration (FDA) published a final rule[1] amending the device good manufacturing practice (GMP) requirements of the Quality System Regulation (QSR)[2] and harmonizing them with internationally accepted standards set forth in ISO 13485:2016.[3] In the final rule, FDA reframes FDA's QSR under the new monicker, "Quality Management System Regulation" (or "QMSR") and aligns U.S. medical device regulatory requirements with ISO 13485, as

ACLA
AMERICAN CLINICAL LABORATORY ASSOCIATION

December 4, 2023

U.S. Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: ACLA Comments on Proposed Rule, "Medical Devices; Laboratory Developed Tests" (Docket No. FDA-2023-N-2177)

The American Clinical Laboratory Association (ACLA) submits the attached comments on FDA's Proposed Rule, "Medical Devices; Laboratory Developed Tests" (Docket No. FDA-2023-N-2177) ("Proposed Rule") which, if finalized, would subject laboratory developed tests (LDTs) to regulation as medical devices.

ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers by advocating for policies that expand access to the highest quality clinical laboratory services, improve patient outcomes, and advance the next generation of personalized care. ACLA member laboratories are at the forefront of developing tests to respond to emerging health issues, and they frequently innovate new areas of science. LDTs offered by ACLA members play an indispensable role in delivering healthcare to patients.

As detailed in the attached, ACLA has grave concerns with FDA's Proposed Rule, both as a matter of public policy and as a matter of law, and urges FDA to withdraw it. If implemented, the imposition of the ill-suited and rigid medical device authorities on LDTs would reduce patient access to widely used tests and dampen diagnostic innovations that improve and save lives. Over the past several years, ACLA worked collaboratively with FDA, Congress, and patient, provider, and diagnostic manufacturer stakeholders on legislation that could have established a role for FDA in an appropriate regulatory system for all diagnostics, complimentary to the already robust oversight of LDTs. ACLA's goal throughout that process was to develop a regulatory approach that would account for the unique attributes of laboratory diagnostics and which would strike the right balance between encouraging diagnostic innovation, maintaining access to important tests, and regulatory oversight. ACLA steadfastly maintains that legislation is the right – and only – approach for FDA to have a role in the regulation of LDTs. FDA's unilateral imposition of device law is misguided.

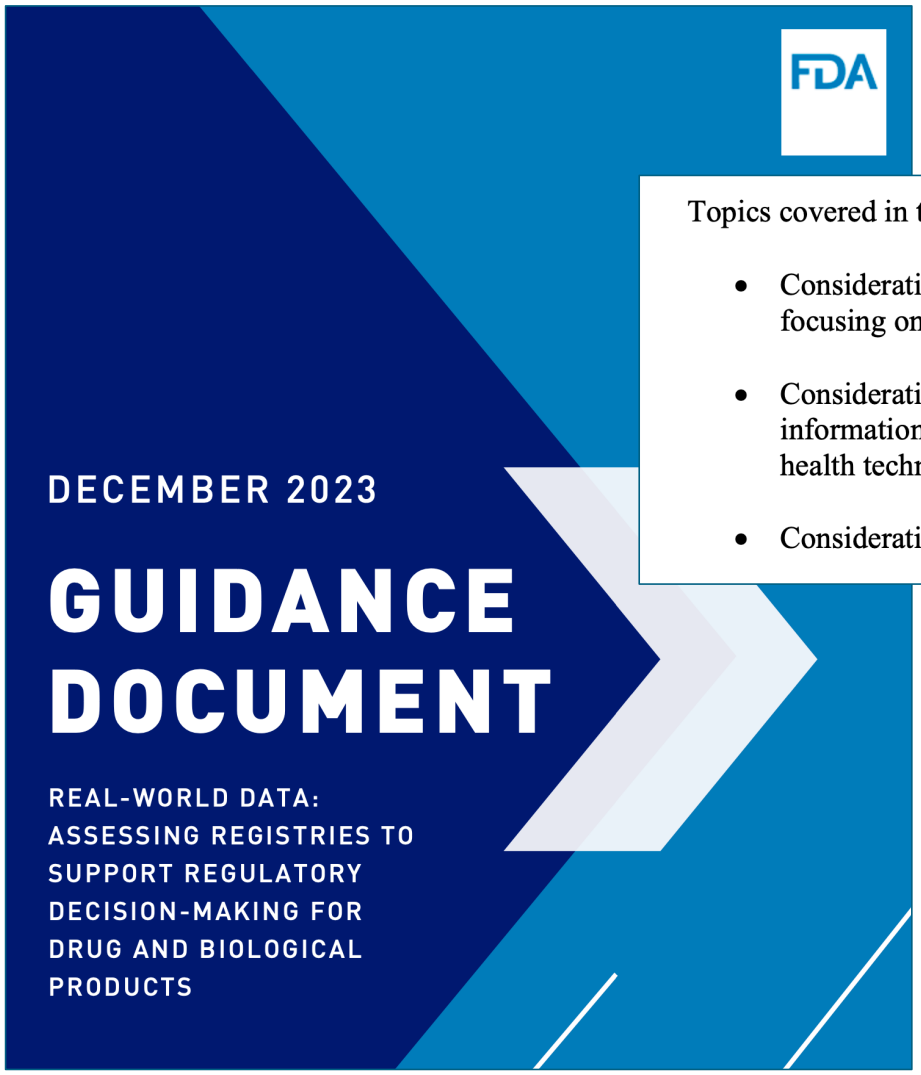
We would be pleased to further engage with FDA on any of the topics discussed in the attached comments.

Sincerely,

Susan Van Meter
President

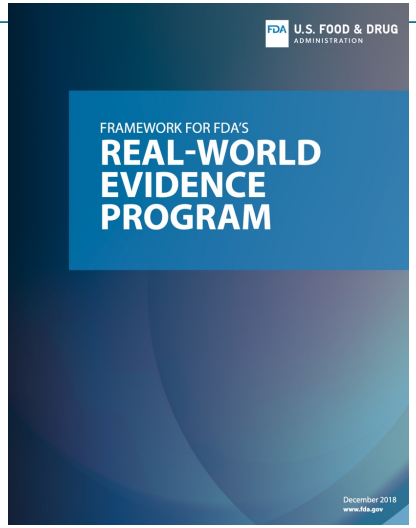
COMMENTS OF THE
AMERICAN CLINICAL LABORATORY ASSOCIATION

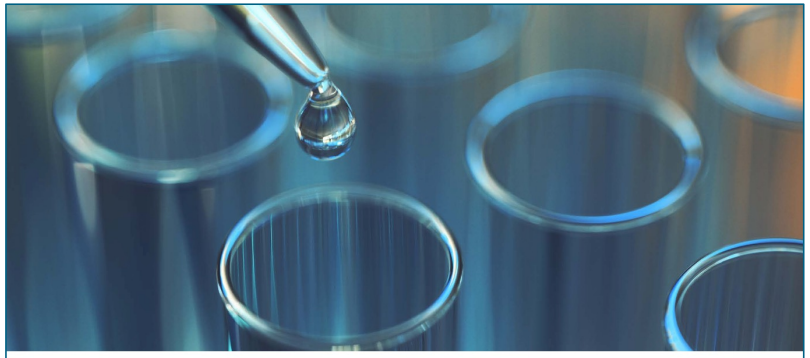
Contents



Topics covered in this guidance include:

- Considerations regarding a registry's fitness-for-use in regulatory decision-making, focusing on attributes of a registry that support the collection of relevant and reliable data
- Considerations when linking a registry to another data source for supplemental information, such as data from medical claims, electronic health records (EHRs),[6] digital health technologies,[7] or other registries
- Considerations for supporting FDA review of submissions that include registry data





Innovation: Use of Expedited Development and Review Pathways

CDER used diverse regulatory approaches to enhance and expedite drug review in 2023. These approaches enable increased flexibility, efficiency, and interactions between CDER staff and drug developers. They often also allow shorter review times to speed the availability of new therapies to patients with serious conditions, especially in cases where there are no satisfactory alternatives, while preserving FDA's rigorous standards for safety and effectiveness.

LEGISLATIVE UPDATES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 170, 171

RIN 0955–AA03

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule implements the Electronic Health Record (EHR) Reporting Program provision of the 21st Century Cures Act by establishing new Conditions and Maintenance of Certification requirements for health information technology (health IT) developers under the ONC Health IT

Table of Contents

Events…

EO

October 30th 2023

Biden Executive Order Calls for HHS to Establish Health Care-Specific Artificial Intelligence Programs and Policies

By **Pat G. Ouellette, Lara D. Compton, Madison M. Castle**

On October 30, 2023, the Biden Administration released and signed an **Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence** (Executive Order) that articulates White House priorities and policies related to the use and development of artificial intelligence (AI) across different sectors, including health care.

The Biden Administration acknowledged the various competing interests related to AI, including weighing significant technological innovation against unintended societal consequences. Our Mintz and ML Strategies colleagues broadly covered the Executive Order in **this week's issue of *AI: The Washington Report***. Some sections of the Executive Order are sector-agnostic but will be especially relevant in health care, such as the requirement that agencies use available policy and technical tools, including privacy-enhancing technologies (PETs) where appropriate, to protect privacy and to combat the improper collection and use of individuals' data.

// PUBLISHED

November 02, 2023

// VIEWPOINT TOPICS

Health Care

Artificial Intelligence

Technology

// PROFESSIONALS

Rule

916 pages

HHS & ONC published

https://www.healthit.gov/sites/default/files/page/2023-12/hti-1-final-rule.pdf

Rule

February 8th, 2024

HOME › INSIGHTS CENTER

HHS, ONC HTI-1 Final Rule Introduces New Transparency Requirements for Artificial Intelligence in Certified Health IT

By **Pat G. Ouellette**

The Department of Health and Human Services (HHS) was tasked with coordinating efforts to regulate artificial intelligence (AI) in health care under the November 2023 **Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence (AI EO)**, but has already begun its formal regulation of AI within certain certified health IT.

// PUBLISHED

January 08, 2024

Top-level Summary

- **Decision Support Interventions (DSI) Replace Clinical Decision Support Criterion**
- **Predictive DSIs and Evidence-Based DSIs**
  - Evidence-Based DSIs are currently defined under existing CDS criterion in 45 C.F.R § 170.315(a)(9) as interventions that "enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions
- **DSI Source Attributes**
- **Intervention Risk Management Practices**
- **ONC Alignment with FDA Oversight of AI/ML**

Definitions

“safe, secure, and trustworthy use and purchase and use” of AI in health care, including alignment with FAVES,

- **Fair:** Outcomes of model do not exhibit prejudice or favoritism toward an individual or group based on their inherent or acquired characteristics.
- **Appropriate:** Model and process outputs are well matched to produce results appropriate for specific contexts and populations to which they are applied
- **Valid:** Model and process outputs have been shown to estimate targeted values accurately and as expected in both internal and external data.
- **Effective:** Outcomes of model have demonstrated benefit in real-world conditions.
- **Safe:** Outcomes of model are free from any known unacceptable risks and for which the probable benefits outweigh any probable risk.

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Case for Quality program critical resource for improving CAPA processes at Elixir Medical

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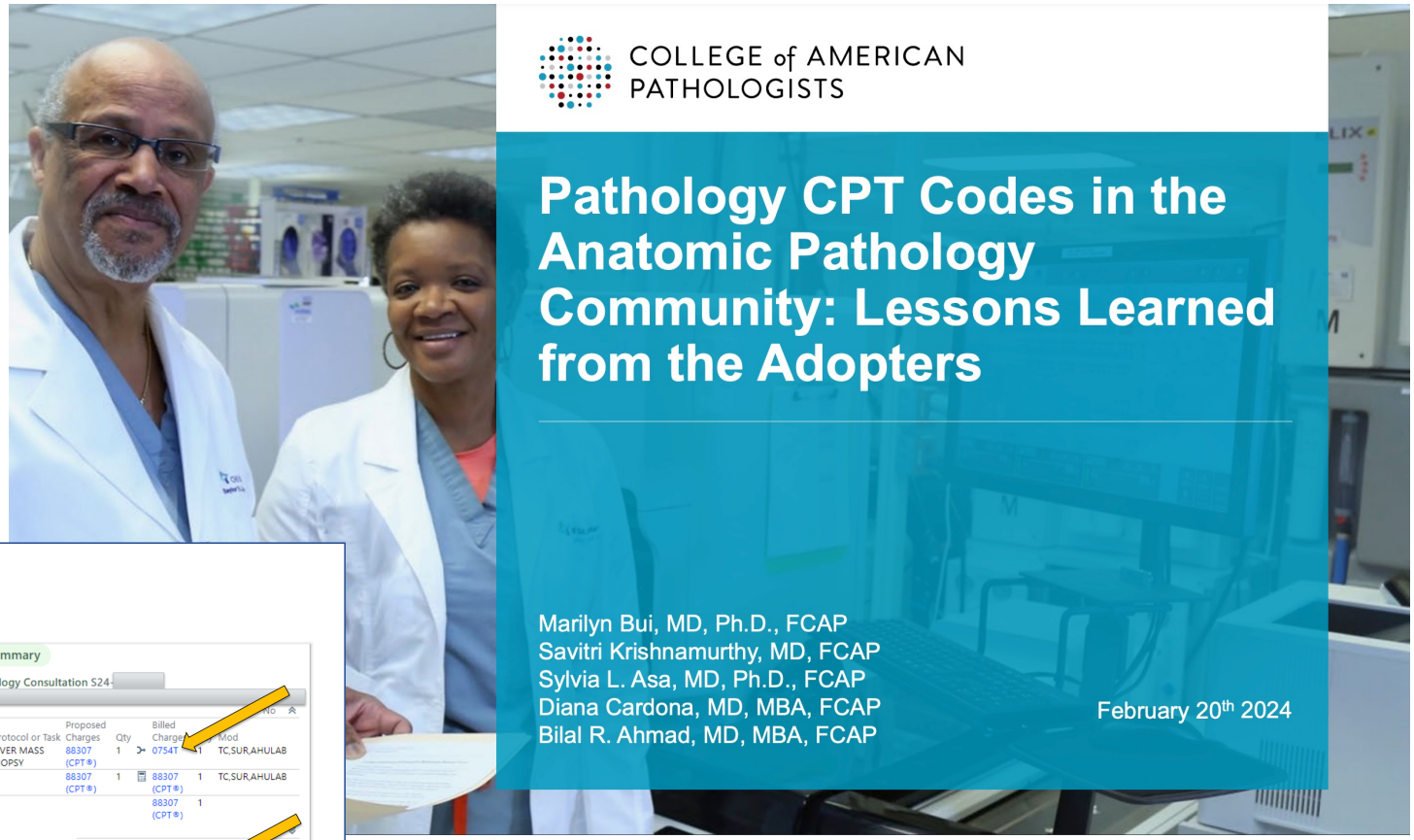
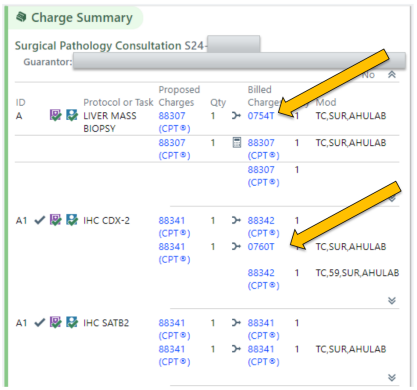
Professional Societies

CPT Digital Pathology



After Signout



World Health Organization

World Health Organization

Health Topics | Countries | Newsroom | Emergencies | Data | About WHO

Home / Publications / Overview / Health for All: Transforming economies to deliver what matters

Health for All: Transforming economies to deliver what matters

Final report

23 May 2023 | Publication

Overview

The Council was established in late 2020 by Dr Tedros Adhanom Ghebreyesus (Director-General, WH economic thinking – reassessing how health and wellbeing are valued, produced and distributed ac

The Council chaired by Professor Mariana Mazzucato, is composed of an all-female group of 10 distin economists and area experts. The Council has focused on reimagining how to put Health for All at th government decision-making and private sector collaboration at regional, national and international

The Council – in this report and in its previous work – has recommended policy approaches underpin economic narrative. The choices made about how to channel and shape public and private investme whether the world continues to struggle with the consequences of major health challenges, or succe new political economy based on Health for All.

The report can be accessed here

Diversity Equity & Inclusion

1 February 2024

Global cancer burden growing, amidst mounting need for services

Cancer Topics

Ahead of World Cancer Day, the World Health Organization (WHO)'s cancer

Brief Report

ONLINE FIRST

January 4, 2024

Review of Racial and Ethnic Representation of Participants Enrolled in Pediatric Clinical Trials of Oncology Drugs Conducted Through FDA Written Requests

Lola A. Fashoyin-Aje, MD, MPH[1]; Alemayehu Y. Akalu, PharmD[1]; Jessica Boehmer, MBA[1]; et al

» Author Affiliations

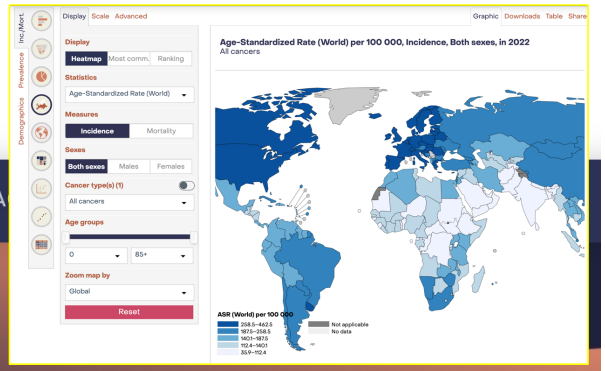
JAMA Oncol. Published online January 4, 2024. doi:10.1001/jamaoncol.2023.5781

Meaning The study results suggest that representation of participants of racial and ethnic minority groups in studies supporting pediatric exclusivity requests appears comparable with the racial distribution of childhood cancers in the US based on data from the National Childhood Cancer Registry, although Hispanic participants appear to be underrepresented.

International Agency for Research on Cancer

World Health Organization

CANCER TODAY



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Data visualization tools for exploring the global cancer burden in 2022

Bars Pie chart Heatmap Scatter plot Table

Patient advocacy

FRIENDS of CANCER RESEARCH

About ▾ Projects ▾ Events ▾ News ▾ Publications ▾ Donate ProgressforPatients.org

Advancing Cancer Research Through Collaboration

Friends of Cancer Research (*Friends*) is working to accelerate policy change, support groundbreaking science, and deliver new therapies to patients quickly and safely.

About *Friends*

Upcoming Event: Register Today!

Tuesday, Feb. 20th, Friends of Cancer Research is co-hosting a public meeting with Aetion, Duke-Margolis Center for Health Policy, and Regan-Udall Foundation for the FDA

Advancing Real-World Data to Generate Regulatory Grade Real-World Evidence in Oncology

February 20, 2024 | Conference, Meeting, Workshop

Advancing Real-World Data to Generate Regulatory Grade Real-World Evi… Oncology

Read More

February 15, 2024 | Conference, Meeting

Enhancing Diversity in Clinical Tri… Implementation of Diversity Plan…

Read More

February 1, 2024 | Conference, Meeting

The Future of Diagnostic Tests: New Data & Modern Policy

Read More

Friends of Cancer Research Virtual Meeting

Enhancing Diversity in Clinical Trials: Implementation of Diversity Plans

Thursday, February 15, 2024
12:00PM – 1:30PM ET

Thank you to all that attended!
Click HERE to Watch the Meeting.
Click HERE to read the meeting discussion document.

Friends of Cancer Research (*Friends*) is proud to announce a new virtual meeting, **Diversity in Clinical Trials: Implementation of Diversity Plans.**

Resources

Blog
Events
Honors and Awards
Department Publications
Media Kit

Announcement • March 31, 2014

End of an Era: The Demise of Film in Radiology

The following was written by David Avrin, MD, PhD, clinical member of the Interventional Radiology and Abdominal Imaging Sections at UCSF, Vice-Chair of Informatics, & Thomas Urbania, MD, Assistant Professor of Clinical Radiology at UCSF.

The days of comparing **film screen radiology** to computed or **digital radiology** are coming to an end. When originally introduced, computed and digital radiography suffered from deficient modulation transfer function compared with film-screen technology for small detail. Over the past two decades, that deficiency has essentially disappeared, and digital technologies have the added advantage of "window/level" contrast adjustments, magnification, and other more sophisticated image-processing tools at the workstation and preprocessor. Early digital radiology also suffered from the lack of **high-resolution** displays. Financial barriers such as the cost of detectors and displays were (and remain) relative obstacles to adoption. The cost of storage is no longer a significant financial issue. (Our department spends more annually on picture archiving and communication system [PACS] support employee salaries than on the capital acquisition of short- and long-term storage systems.)

Setting the agenda in research

Comment

ANNE-CHRISTINE POUJOULAT/AFP/GETTY

Getting access to samples will become increasingly important as approaches for the molecular profiling of tumours improve.

The way we name cancers needs to change

Fabrice André, Elie Rassy, Aurélien Marabelle, Stefan Michiels & Benjamin Besse

2005 Studies show that cells with *BRCA1/2* mutations can be killed by PARP inhibitors.

2009 Clinical trials begin for a drug called olaparib (a type of PARP inhibitor) involving participants with ovarian cancer.

2014 FDA* approves use of olaparib for ovarian cancer

Between 2014 and 2018, about 100,000 patients with breast cancer, who might have benefited from treatment with olaparib, died.

2018 Use of olaparib for breast cancer is approved

2019 Use of olaparib for pancreatic cancer is approved

2020 Use of olaparib for prostate cancer is approved

Between 2014 and 2020, about 200,000 patients with prostate or pancreatic cancer, who might have benefited from olaparib treatment, died.

*FDA, US Food and Drug Administration.

Case Study

Innovative Reimbursement Strategy for Digital Therapeutics

January 29, 2024

Liesl M. Oldstone, PhD
VP, Health Economics & Market Access
AppliedVR, Inc

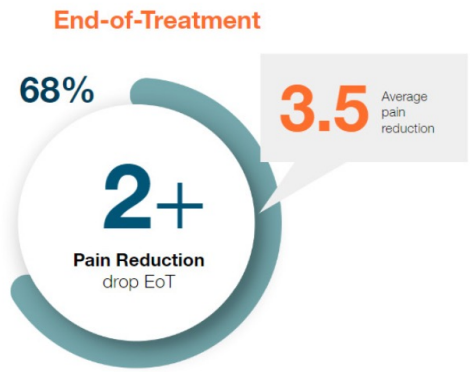
Emily Judge
VP, Strategic Partnerships
AppliedVR, Inc

MDIC Medical Device Innovation Consortium | AppliedVR

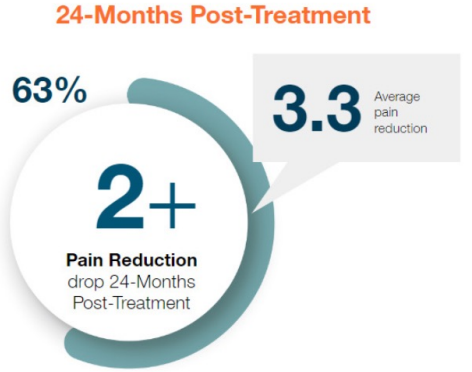
Individual Participant Performance and Treatment Durability

RelieVRx® led to clinically meaningful pain reductions at the group level, but it is important to determine whether they are also reflected at the individual participant level. To address this question, a responder analysis was performed to assess the percentage of RelieVRx® participants who met or exceeded a 2-point pain intensity or interference reduction. The results were clear at the end of treatment, with nearly 7 in 10 participants achieving a 2-point reduction in pain intensity, pain interference or both, with an average pain reduction of nearly 3.5 in this group. This result was quite robust with just over 6 in 10 participants achieving a 2-point reduction in pain intensity, pain interference or both, at 24-months post-treatment [11], with an average pain reduction of 3.3 in this group.

A key takeaway here is that home-based VR therapies like RelieVRx® hold the potential to broaden access to effective and on-demand nonpharmacologic treatments for chronic lower back pain that are durable well beyond the end of treatment.



68% of participants achieved a 2+ point reduction in pain intensity, pain interference, or both with an average pain reduction of 3.5 points.



63% of participants achieved a 2+ point reduction in pain intensity, pain interference, or both with an average pain reduction of 3.3 points

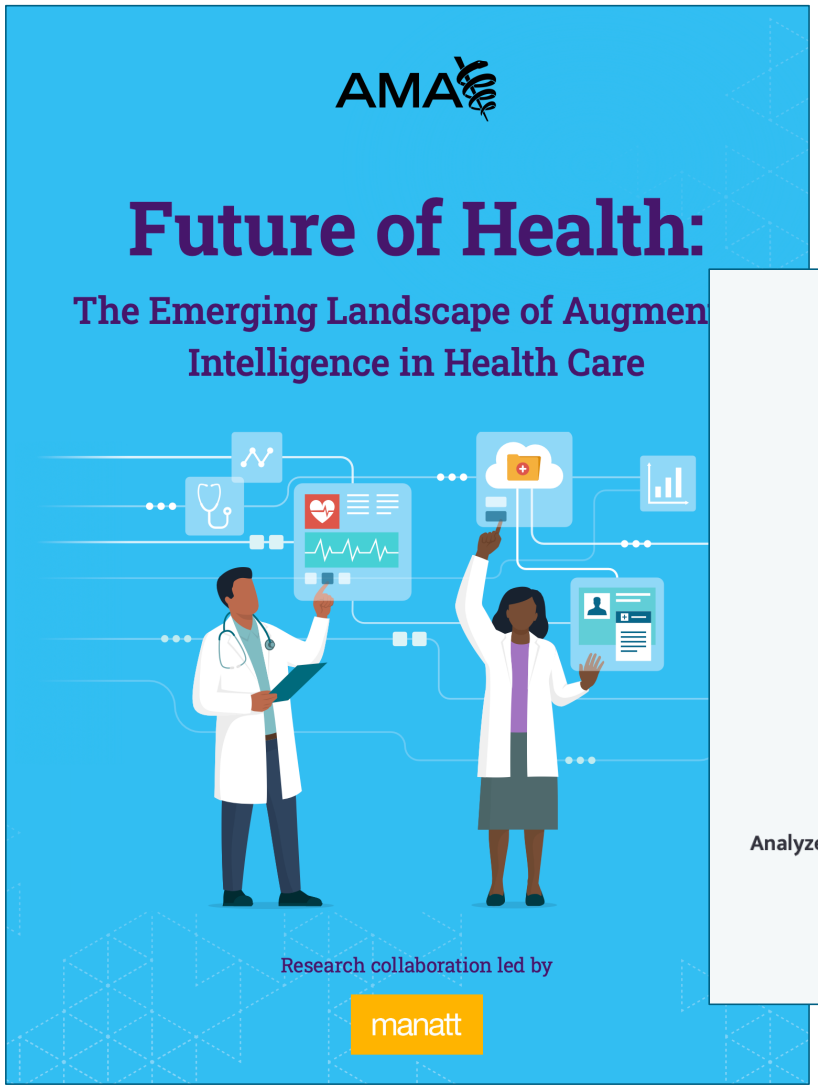
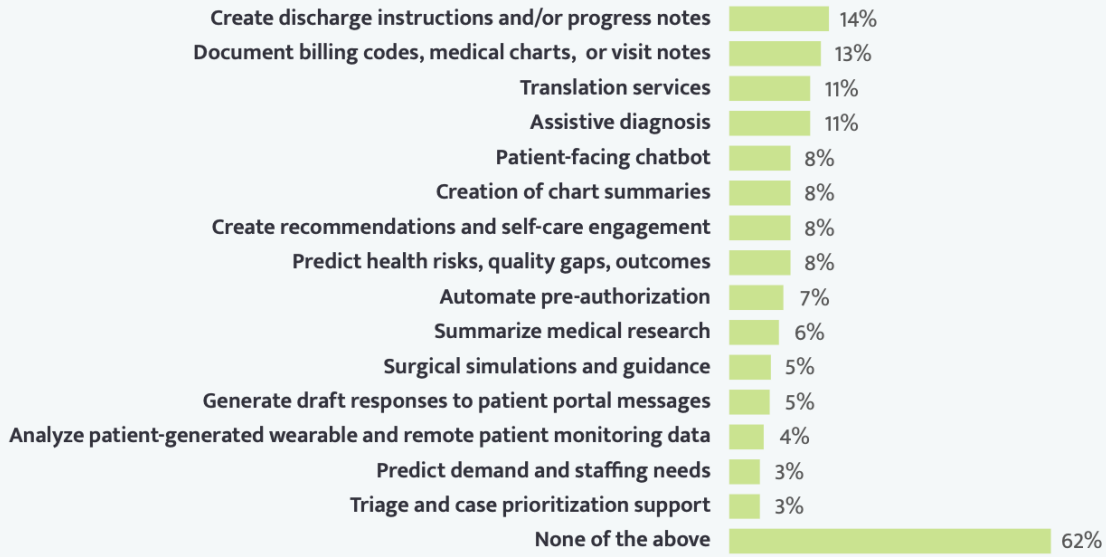


Figure 4: AMA 2023 AI Physician Survey: Current use cases across specialties



editorials

The National Clinical Trials Network: A Valuable and Undervalued Resource

Howard A. Burris III, MD[1]

In the 50 years since the signing of the National Cancer Act in 1971, the National Cancer Institute's (NCI) National Clinical Trials Network (NCTN) has been conducting studies resulting in important discoveries for improving the care of patients with cancer. The current

sponsored by pharmaceuti
leading to rapid regulato
standard and expectation
cancer subtypes. Efficient a
ment is an appropriate and

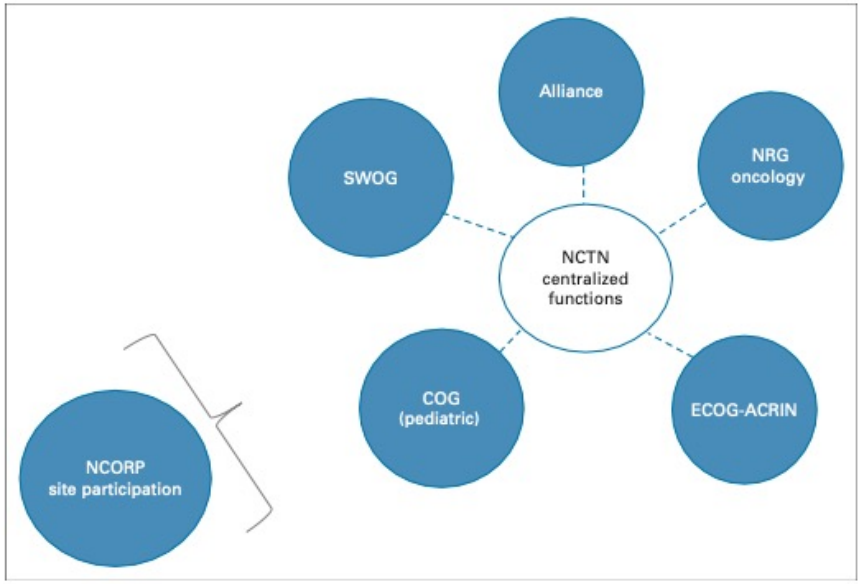


FIG 1. NCI's NCTN is a group of sites and physicians that conduct cancer clinical trials at more than 2,200 sites across the United States, Canada, and internationally. NCTN provides the infrastructure for NCI-funded treatment studies designed to improve the lives of people with cancer. ACRIN, American College of Radiology Imaging Network; COG, Children's Oncology Group; ECOG, Eastern Cooperative Oncology Group; NCI, National Cancer Institute; NCORP, NCI Community Oncology Research Program; NCTN, National Clinical Trials Network; NRG, National Surgical Adjuvant Breast and Bowel Project, Radiation Therapy Oncology Group, and Gynecologic Oncology Group.

The future of the global clinical trial ecosystem: a vision from the first WHO Global Clinical Trials Forum

Published Online
December 18, 2023
https://doi.org/10.1016/
S0140-6736(23)02798-8

The first WHO Global Clinical Trials Forum[1] held at WHO, Geneva, Switzerland, on Nov 20–21, 2023, brought together a diverse community to advance sustainable global clinical trial infrastructure. To secure the improvements needed to "strengthen clinical trials", as mandated by the World Health Assembly in May, 2022,[2] the Forum agreed a unified vision of "always on, always busy", whereby sustained national and global clinical trial capacity during and between crises ensures clinical

communities, and organisations in the Global South should share an equal leadership role for prioritisation, trial design, and analyses and increasingly invest domestic resources as feasible and appropriate to support sustained national clinical research infrastructure as part of routine health services. Given the global rise in non-communicable diseases,[4] including cancer, cardiovascular diseases, neurological disorders, and mental illness, in many low-income and middle-income countries, future

ONC Office of the National Coordinator for Health Information Technology

ONC TEFCA RECOGNIZED COORDINATING ENTITY

Common Agreement for Nationwide Health Information Interoperability

Version 1.1

November 2023

TEFCA Trusted Exchange Framework and Common Agreement

ONC

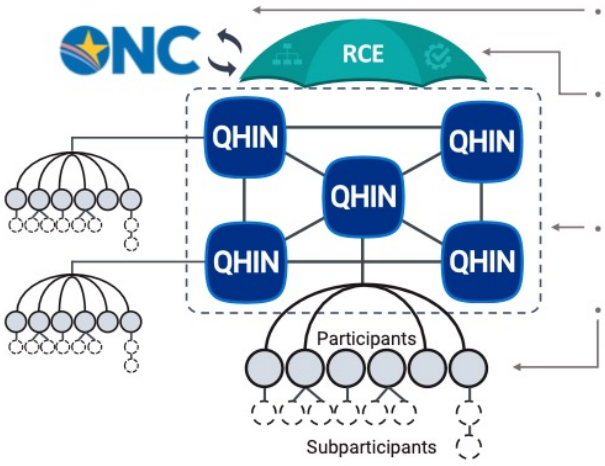
Trusted Exchange Framework and Common Agreement[SM] (TEFCA[SM])

TEFCA

- Establishes a universal floor for interoperability across the country.
- Creates baseline governance, legal, and technical requirements that will enable secure information sharing across different networks nationwide.
- Enables an expanded set of exchange purposes beyond Treatment including Individual Access Services, Public Health, Payment, Health Care

nd organizations with
secure access to more

How will exchange work under TEFCA?



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DATA FOR HEALTH
WORKSHOP
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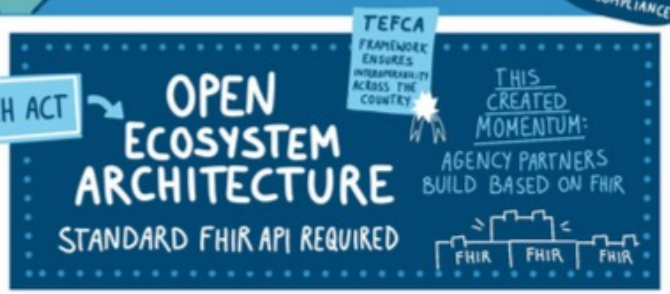
BOSTON, MA, USA

Keynote

Micky Tripathi, National Coordinator for Health Information Technology at the U.S. Department of Health and Human Service



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Issue Brief 16

Current State of Diagnostic Safety: Implications for Research, Practice, and Policy

Agency for Healthcare Research and Quality

PATIENT SAFETY

Issue Brief 16

Current State of Diagnostic Safety: Implications for Research, Practice, and Policy

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Hiroshima Process International Code of Conduct for Organizations Developing Advanced AI Systems

On the basis of the International Guiding Principl
AI systems, the International Code of Conduct f
Systems aims to promote safe, secure, and t
voluntary guidance for actions by organizations
including the most advanced foundation model
"advanced AI systems").

Organizations should follow these actions in line

Organizations that may endorse this Code of Co
from academia, civil society, the private sector, a

Hiroshima Process International Guiding Principles for Organizations Developing Advanced AI system

The International Guiding Principles for Organizations Developing Advanced AI Systems aims to promote safe, secure, and trustworthy AI worldwide and will provide guidance for organizations developing and using the most advanced AI systems, including the most advanced foundation models and generative AI systems (henceforth "advanced AI systems"). Organizations may include, among others, entities from academia, civil society, the private sector, and the public sector.

This non-exhaustive list of guiding principles is discussed and elaborated as a living document to build on the existing OECD AI Principles in response to recent developments in advanced AI systems and are meant to help seize the benefits and address the risks and challenges brought by these technologies. These principles should apply to all AI actors, when and as applicable to cover the design, development, deployment and use of advanced AI systems.

We look forward to developing these principles further as part of the comprehensive policy framework, with input from other nations and wider stakeholders in academia, business and civil

IQCP INDIVIDUALIZED QUALITY CONTROL PLAN

DEVELOPING AN IQCP

A STEP-BY-STEP GUIDE

CDC CENTERS FOR DISEASE CONTROL AND PREVENTION

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

U.S. Department of Health and Human Services

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Laboratory QA

IQCP: Guideline and Helpful Tools for Implementation

*Linda C. Bruno, MA, MT(ASCP)**

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ABSTRACT

This article will help laboratories understand what changed with external quality control testing, why it changed, who changed it, when the changes became effective, and how these changes affect clinical laboratories. The new Individualized Quality Control Plan (IQCP) option that became effective January 1, 2016, will be explained. Three other quality control changes that took effect January 1, 2016, and dramatically affect quality control requirements for antimicrobial susceptibility testing, identification test systems, and exempt culture media will also be explained. Guidelines and tools are provided that can assist laboratories in determining what is eligible for IQCP and how to design an IQCP program.

Keywords: individualized quality control plan, IQCP, quality control requirements

For a brief historical review, the Centers for Medicare and Medicaid Services (CMS) in 1967 created the Clinical Laboratory Improvement Act of 1967 (CLIA '67) to regulate laboratories that performed Medicare billing and/or engaged

still following the manufacturers' QC frequency recommendations, EQC allowed laboratories to decrease external QC while saving dollars in laboratory supplies and labor.[1] Although EQC was adopted by many laboratories, over

Health Sector Coordinating Council
Cybersecurity Working Group

Monitor Threats | Manage Risks | Respond & Recover | Measure Effectiveness

Health Industry Cybersecurity – Strategic Plan (2024–2029)

FEBRUARY 2024

Ref ID	Cybersecurity Goals What does this cybersecurity-enabled end state look like?	Industry Trends						
		Shifts in care delivery	Accelerated use of emerging technologies	Pace of Change	Acute Financial Distress	Managing Talent / Workforce	Evolving Regulatory Requirements	Global Instability and Climate Change
		T1	T2	T3	T4	T5	T6	T7
	TARGET FUTURE STATES • **Healthcare cybersecurity - both practiced and regulated - is reflexive, evolving, accessible, documented and implemented for practitioners and patients** • **Workforce cybersecurity learning and application is an infrastructure wellness continuum**							
G1	Healthcare and wellness delivery services are user-friendly, accessible, safe, secure, and compliant	✓	✓	✓	✓	✓	✓	