

IHE Radiology Global Regulatory Monitoring Report

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PREPARED BY IHE RADIOLOGY PLANNING COMMITTEE

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Monitoring period	March 1, 2026 – April 30, 2026
Discovery window used	January 30, 2026 – April 30, 2026
Source policy	All included items were verified against official government sources and include working official links.

Prepared for strategic monitoring of diagnostic imaging, interoperability, clinical AI governance, and digital health infrastructure.

1. Executive Summary

This report covers official government policy activity reviewed across North America (United States and Canada), the European Union, and Japan for the monitoring period of March 1, 2026 through April 30, 2026, with discovery extended back to January 30, 2026 to avoid missing relevant items whose action windows or continuing policy significance overlapped the monitoring cycle. Discovery was completed using the fixed protocol search terms and required source review process, followed by official-source verification, relevance scoring, and direct comparison against the immediately prior Volume/Issue before report construction.

The principal qualifying developments identified during this cycle were concentrated in the United States, Canada, and the European Union. In the United States, the diagnostic imaging interoperability RFI remained a carried-forward item because its comment deadline fell within the monitoring period, and CMS/ONC published a new proposed rule on interoperability standards and prior authorization for drugs. In Canada, Health Canada published pre-market guidance for machine learning-enabled medical devices, and its 2026–27 Departmental Plan remained a continuing pre-regulatory signal for interoperability and AI. In the European Union, official Commission and JRC publications identified current policy signals around AI in healthcare, AI-enabled image screening, digital health infrastructure, and imaging-adjacent cardiovascular AI use cases. No qualifying formal regulatory developments were identified for Japan during the monitoring window after completion of the required discovery pass.

Strategically, the current cycle reinforces four policy vectors that remain important for IHE Radiology: standards-based image access and exchange, API-centered payer-provider interoperability, governance of AI-enabled clinical and imaging tools, and digital health infrastructure capable of supporting structured data exchange. The most direct IHE Radiology opportunity remains the U.S. diagnostic imaging interoperability RFI, while the CMS/ONC prior authorization proposal and the EU and Canadian AI/digital health signals point to a broader environment in which implementation guidance, profile-aligned procurement language, and workflow-tested interoperability patterns remain valuable.

Asterisk Definition: Items marked with an asterisk (*) indicate that the policy, rule, or regulatory action was also identified in the immediately preceding Volume/Issue of the Monitoring Report. These items remain active, evolving, or unresolved and are carried forward for continued visibility.

2. Policy Signal Dashboard

Title	Agency	Policy Type	Publication Date	Comment Deadline	Relevance Score
*Request for Information: Diagnostic Imaging Interoperability Standards and Certification (RIN 0955-AA11)	U.S. Department of Health and Human Services (HHS), Office of the Secretary / ASTP-ONC	Federal Register – Request for Information	January 30, 2026	March 16, 2026	5
Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs (CMS-0062-P)	Centers for Medicare & Medicaid Services (CMS) and Office of the National Coordinator for Health Information Technology (ONC), HHS	Federal Register – Proposed Rule	April 14, 2026	June 15, 2026	3
Pre-market guidance for machine learning-enabled medical devices	Health Canada	Guidance Document	April 1, 2026	Not applicable	3
*Health Canada 2026–27 Departmental Plan: digital health, interoperability, and artificial intelligence priorities	Health Canada	Departmental Plan / strategic policy signal	March 13, 2026	Not applicable	3
Study on Artificial Intelligence in healthcare dissects digital health technologies in Europe	European Commission, Directorate-General for Communications Networks, Content and Technology (DG CONNECT)	Official European Commission report / study	March 17, 2026	Not applicable	3
Artificial intelligence in cardiovascular care: from promise to practice	European Commission Joint Research Centre (JRC)	Official JRC report / policy evidence signal	April 7, 2026	Not applicable	3
Commission makes €63.2 million available to support AI innovation in health and online safety	European Commission, Directorate-General for Communications Networks, Content and Technology (DG CONNECT)	Digital Europe Programme funding call / strategic policy signal	April 21, 2026	October 1, 2026	3

3. North America Regulatory Scan

United States

***Request for Information: Diagnostic Imaging Interoperability Standards and Certification (RIN 0955-AA11)**

Agency: U.S. Department of Health and Human Services (HHS), Office of the Secretary / ASTP-ONC

Policy Type: Federal Register – Request for Information

Publication Date: January 30, 2026

Official Source Link: <https://www.federalregister.gov/documents/2026/01/30/2026-01866/request-for-information-diagnostic-imaging-interoperability-standards-and-certification>

Comment Deadline: March 16, 2026

Summary: HHS issued a request for information seeking public input on whether diagnostic imaging technical standards and certification criteria should be adopted under the ONC Health IT Certification Program. The item was published before the formal 60-day monitoring period but its comment deadline fell within the monitoring period, and it therefore remained a qualifying policy action during this run. The RFI is directly relevant to image access, exchange, patient access, and certification expectations for health IT that supports diagnostic imaging workflows. Because the same item appeared in the immediately prior report, the title is marked with an asterisk.

Impact Assessment:

- **Imaging Operations:** Potential future certification criteria could influence how imaging organizations exchange images with patients, referring clinicians, outside providers, and other care settings.
- **AI Governance:** Broader standards-based access to diagnostic images can become an enabling condition for AI-supported workflow, longitudinal imaging review, and governance of AI outputs tied to imaging data.
- **Interoperability:** Direct and high. The item is expressly focused on diagnostic imaging interoperability standards and certification criteria.

Relevance Score: 5

Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs (CMS-0062-P)

Agency: Centers for Medicare & Medicaid Services (CMS) and Office of the National Coordinator for Health Information Technology (ONC), HHS

Policy Type: Federal Register – Proposed Rule

Publication Date: April 14, 2026

Official Source Link: <https://www.federalregister.gov/documents/2026/04/14/2026-07205/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-standards>

Comment Deadline: June 15, 2026

Summary: CMS and ONC published a proposed rule intended to improve electronic exchange of health care data and streamline prior authorization by increasing interoperability across health care systems. The proposal would extend electronic prior authorization requirements to drugs, update health IT standards, require reporting of interoperability API endpoints and usage metrics, and modernize HIPAA prior authorization transaction standards using HL7 FHIR implementation specifications. Although the core proposal is not imaging-specific, it is relevant to IHE Radiology because imaging operations are embedded in the same standards-based payer-provider exchange ecosystem and because prior authorization workflows affect imaging-adjacent care coordination. The open comment deadline also makes this an active early-warning item for IHE monitoring.

Impact Assessment:

- **Imaging Operations:** Indirect but material. The proposed standards and API expectations could influence payer-provider workflow patterns, authorization documentation practices, and the surrounding infrastructure used by imaging providers.
- **AI Governance:** Indirect. Standardized APIs and documentation exchange can affect the infrastructure through which AI-enabled clinical and administrative workflows are deployed and monitored.
- **Interoperability:** Direct. The proposal focuses on FHIR-based interoperability standards, updated implementation specifications, and API endpoint reporting.

Relevance Score: 3

Canada

Pre-market guidance for machine learning-enabled medical devices

Agency: Health Canada

Policy Type: Guidance Document

Publication Date: April 1, 2026

Official Source Link: <https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/pre-market-guidance-machine-learning-enabled-medical-devices.html>

Comment Deadline: Not applicable

Summary: Health Canada published guidance for manufacturers submitting new or amended applications for Class II, III, and IV machine learning-enabled medical devices. The guidance addresses information relating to the machine learning system within the device, including expectations for

applications and amendments under the medical device licensing framework. Although the document is not limited to imaging, imaging AI products commonly fall within the broader class of machine learning-enabled medical devices. It is therefore relevant to IHE Radiology as part of the governance environment for AI-enabled diagnostic and workflow tools.

Impact Assessment:

- **Imaging Operations:** Potentially relevant to how imaging organizations evaluate vendor claims, regulatory status, model-change controls, and evidence for AI-enabled imaging tools.
- **AI Governance:** Direct. The guidance concerns machine learning-enabled medical devices and the information needed to support regulatory review and lifecycle oversight.
- **Interoperability:** Indirect. The guidance does not define exchange standards, but AI-enabled imaging tools often require integration with imaging, reporting, and clinical workflow systems.

Relevance Score: 3

***Health Canada 2026–27 Departmental Plan: digital health, interoperability, and artificial intelligence priorities**

Agency: Health Canada

Policy Type: Departmental Plan / strategic policy signal

Publication Date: March 13, 2026

Official Source Link: <https://www.canada.ca/en/health-canada/corporate/transparency/corporate-management-reporting/report-plans-priorities/2026-2027-departmental-plan.html>

Comment Deadline: Not applicable

Summary: Health Canada’s 2026–27 Departmental Plan remained a qualifying pre-regulatory signal during the current monitoring period. The plan identifies modern, risk-based regulatory processes as a key priority and, in associated transfer-payment information, describes federal support for pan-Canadian interoperability, health information access, common standards, AI-related trends, and digital health tools. The item is not a formal imaging regulation, but it remains relevant because it shows continued governmental attention to digital health infrastructure, interoperability, and AI-enabled care. Because the same policy signal appeared in the immediately prior report, the title is marked with an asterisk.

Impact Assessment:

- **Imaging Operations:** No immediate operational requirement, but continued Canadian investment in connected digital health systems could later influence imaging exchange and access expectations.
- **AI Governance:** Meaningful as an early policy signal, particularly because the associated interoperability roadmap refresh references emerging trends such as artificial intelligence.

- **Interoperability:** Direct as a strategic signal. The plan and supporting materials reference pan-Canadian interoperability, common standards, and secure health information movement across settings.

Relevance Score: 3

4. European Union Regulatory Scan

No qualifying formal European Union regulatory developments were identified during the monitoring window after completion of the required discovery and verification steps. Qualifying European Union policy signals that did not rise to the level of formal regulatory developments are included in Section 8.

5. Japan Regulatory Scan

No qualifying regulatory developments were identified for Japan during the monitoring window after completion of the required discovery and verification steps.

6. IHE Opportunity Scan

Policy signal	Potential IHE-aligned opportunity	Notes (non-policy)
*Diagnostic Imaging Interoperability Standards and Certification RFI (US)	Continue to refine implementation-ready interoperability patterns for access, exchange, and use of diagnostic images, including patient-facing and cross-enterprise workflows.	This remains the clearest direct opportunity for IHE Radiology to translate imaging exchange needs into standards-grounded implementation guidance.
CMS/ONC Interoperability Standards and Prior Authorization for Drugs Proposed Rule	Monitor FHIR-based prior authorization and payer-provider data exchange requirements for possible alignment with imaging-adjacent workflow and clinical documentation use cases.	The rule is not imaging-specific, but it shapes the broader API and standards environment in which imaging orders, supporting documentation, and results access operate.
Health Canada ML-enabled medical device guidance	Consider how IHE Radiology procurement and implementation guidance can help imaging organizations ask AI vendors for regulatory status, lifecycle controls, evidence, and integration documentation.	The guidance is not an interoperability specification, but it is relevant to governance of AI-enabled imaging tools.
*Health Canada 2026–27 Departmental Plan	Monitor whether Canadian digital health and interoperability priorities mature into more formal implementation requirements where IHE-style implementation guidance could be useful.	This is a carried-forward strategic signal rather than a formal regulation.
European Commission AI in healthcare and Digital Europe signals	Monitor AI-powered image screening, cardiovascular AI, and EHDS-linked digital health funding for future technical specifications, guidance, or procurement expectations.	These signals may create opportunities for practical deployment guidance, interoperability checklists, and profile-aligned procurement language.

7. Regulatory Early Warning Dashboard

Upcoming or recently closed action dates associated with qualifying items are summarized below.

Item	Agency/Region	Comment deadline / action date	Link
Request for Information: Diagnostic Imaging Interoperability Standards and Certification (RIN 0955-AA11)	United States	March 16, 2026	Official source
CMS/ONC Interoperability Standards and Prior Authorization for Drugs Proposed Rule (CMS-0062-P)	United States	June 15, 2026	Official source
Digital Europe Programme calls supporting AI-powered image screening and EHDS-linked digital health systems	European Union	October 1, 2026	Official source

8. Emerging Policy Signals (Pre-Regulatory)

Study on Artificial Intelligence in healthcare dissects digital health technologies in Europe

Agency: European Commission, Directorate-General for Communications Networks, Content and Technology (DG CONNECT)

Policy Type: Official European Commission report / study

Publication Date: March 17, 2026

Official Source Link: <https://digital-strategy.ec.europa.eu/en/library/study-artificial-intelligence-healthcare-dissects-digital-health-technologies-europe>

Comment Deadline: Not applicable

Summary: The European Commission published a study analyzing the EU digital health market and the economic impact of digital health technologies, including AI-enabled solutions. The study identifies growing AI adoption in healthcare, notes that AI-powered diagnostic tools are among the more mature emerging technologies, and frames AI in health as a priority workstream. This is not a binding regulatory action, but it is a policy-relevant evidence base for future EU digital health and AI policy work. Its relevance to IHE Radiology comes from the connection between diagnostic AI, digital health infrastructure, and cross-border scale-up barriers.

Impact Assessment:

- **Imaging Operations:** Potential indirect relevance through future EU initiatives encouraging adoption of AI-supported diagnostic and operational tools.
- **AI Governance:** Direct as a policy evidence signal because it addresses AI in healthcare, market maturity, adoption barriers, and the need for trustworthy deployment.

- **Interoperability:** Indirect. Fragmented markets and cross-border expansion barriers can increase the importance of interoperable implementation patterns for digital health and AI tools.

Relevance Score: 3

Artificial intelligence in cardiovascular care: from promise to practice

Agency: European Commission Joint Research Centre (JRC)

Policy Type: Official JRC report / policy evidence signal

Publication Date: April 7, 2026

Official Source Link: https://joint-research-centre.ec.europa.eu/jrc-news-and-updates/artificial-intelligence-cardiovascular-care-promise-practice-2026-04-07_en

Comment Deadline: Not applicable

Summary: The European Commission Joint Research Centre published a report and policy-facing summary on the use of AI in cardiovascular care. The summary identifies current and potential AI uses involving CT imaging, including coronary artery calcium scoring, CT-derived fractional flow reserve, and acute stroke CT workflows, and it emphasizes evidence, infrastructure, and regulatory simplification needs. The item is not a regulation, but it is a highly relevant EU policy evidence signal for imaging-adjacent clinical AI deployment. It also supports monitoring of future technical specifications and guidance under Europe's cardiovascular and digital health policy work.

Impact Assessment:

- **Imaging Operations:** Relevant because several examples involve CT-based imaging workflows and operational deployment barriers in hospitals.
- **AI Governance:** Direct. The item addresses clinical evidence, validation, infrastructure, and regulatory issues for AI-supported care.
- **Interoperability:** Indirect-to-moderate. Hospital IT infrastructure and clinical integration needs are central barriers to AI deployment in imaging-adjacent cardiovascular workflows.

Relevance Score: 3

Commission makes €63.2 million available to support AI innovation in health and online safety

Agency: European Commission, Directorate-General for Communications Networks, Content and Technology (DG CONNECT)

Policy Type: Digital Europe Programme funding call / strategic policy signal

Publication Date: April 21, 2026

Official Source Link: <https://digital-strategy.ec.europa.eu/en/news/commission-makes-eu632-million-available-support-ai-innovation-health-and-online-safety>

Comment Deadline: October 1, 2026

Summary: The European Commission opened Digital Europe Programme calls totaling €63.2 million for AI in health, digital health, digital skills, and online safety. The announcement states that €9 million is available for AI-powered image screening in medical centres and that €24 million will support digital health services and systems under the European Health Data Space. This is a funding and implementation signal rather than a formal regulation, but it is directly relevant to imaging AI and digital health infrastructure. It also creates a concrete future action date because the calls close on October 1, 2026.

Impact Assessment:

- **Imaging Operations:** Potential relevance to deployment of AI-powered image screening in medical centres and related implementation requirements.
- **AI Governance:** Direct as a policy implementation signal supporting AI in health under EU strategic priorities.
- **Interoperability:** Meaningful because part of the funding supports digital health services and systems under the European Health Data Space.

Relevance Score: 3

9. International Policy Developments IHE Radiology Should Monitor

No qualifying developments outside the primary monitored regions were identified from official government sources during this execution cycle.

10. Appendix A – Regulatory Sources Monitored

Discovery evidence log for required monitored sources. Date range and search execution were recorded to satisfy the protocol's minimum discovery completeness rule.

Source	Discovery method	Date range applied	Exact search terms / pages reviewed	Outcome
Federal Register (United States)	Site search and Federal Register listing/page review	January 30, 2026 – April 30, 2026	Fixed protocol term set: radiology; diagnostic imaging; medical imaging; CT; computed tomography; MRI; magnetic resonance imaging; PET; nuclear medicine; radiation dose; interoperability; FHIR; health information exchange; USCDI; health IT certification; information blocking; clinical decision support; artificial intelligence; AI; machine learning; clinical AI; Software as a Medical Device; SaMD; physician fee schedule; hospital outpatient; digital quality measure; healthcare interoperability.	Candidate items identified.
Regulations.gov (United States)	Docket search for federal rulemaking candidates associated with identified Federal Register items	January 30, 2026 – April 30, 2026	CMS-0062-P docket and fixed protocol term set applied where available.	Candidate item identified for CMS-0062-P; no additional qualifying candidate items found.
CMS policy announcements	Official CMS newsroom, policy, and rulemaking page review	January 30, 2026 – April 30, 2026	Fixed protocol term set: radiology; diagnostic imaging; medical imaging; CT; computed tomography; MRI; magnetic resonance	Candidate item identified.

			imaging; PET; nuclear medicine; radiation dose; interoperability; FHIR; health information exchange; USCDI; health IT certification; information blocking; clinical decision support; artificial intelligence; AI; machine learning; clinical AI; Software as a Medical Device; SaMD; physician fee schedule; hospital outpatient; digital quality measure; healthcare interoperability.	
ONC / ASTP publications	Official HealthIT.gov / ONC publications and resources reviewed	January 30, 2026 – April 30, 2026	Fixed protocol term set: radiology; diagnostic imaging; medical imaging; CT; computed tomography; MRI; magnetic resonance imaging; PET; nuclear medicine; radiation dose; interoperability; FHIR; health information exchange; USCDI; health IT certification; information blocking; clinical decision support; artificial intelligence; AI; machine learning; clinical AI; Software as a Medical Device; SaMD; physician fee schedule; hospital outpatient; digital quality measure; healthcare interoperability.	Candidate item identified in connection with CMS-0062-P.
FDA policy announcements	Official FDA AI/device/SaMD and radiology-related policy pages reviewed	January 30, 2026 – April 30, 2026	Fixed protocol term set: radiology; diagnostic imaging; medical imaging; CT; computed tomography; MRI; magnetic resonance imaging; PET; nuclear medicine; radiation dose; interoperability; FHIR; health information exchange; USCDI; health IT certification; information blocking; clinical decision support; artificial intelligence; AI; machine learning; clinical AI; Software as a Medical Device; SaMD; physician fee schedule; hospital outpatient; digital quality measure; healthcare interoperability.	Discovery completed — no candidate items found for this source in the monitoring window.
HHS policy releases	Official HHS/Federal Register health policy search and page review	January 30, 2026 – April 30, 2026	Fixed protocol term set: radiology; diagnostic imaging; medical imaging; CT; computed tomography; MRI; magnetic resonance imaging; PET; nuclear medicine; radiation dose; interoperability; FHIR; health information exchange; USCDI; health IT certification; information blocking; clinical decision support; artificial intelligence; AI; machine learning; clinical AI; Software as a Medical Device; SaMD; physician fee schedule; hospital outpatient; digital quality measure; healthcare interoperability.	Candidate items identified through Federal Register/CMS/ONC sources; no additional separate HHS candidate item found.
Canada Gazette	Chronological listings and site search reviewed	January 30, 2026 – April 30, 2026	Fixed protocol term set: radiology; diagnostic imaging; medical imaging; CT; computed tomography; MRI; magnetic resonance imaging; PET; nuclear medicine; radiation dose; interoperability; FHIR; health information exchange; USCDI; health IT certification; information blocking; clinical decision support; artificial intelligence; AI; machine learning; clinical AI; Software as a Medical Device; SaMD; physician fee schedule; hospital outpatient; digital quality measure; healthcare interoperability.	Discovery completed — no candidate items found for this source in the monitoring window.
Health Canada policy announcements	Official Health Canada guidance, policy, and planning pages reviewed	January 30, 2026 – April 30, 2026	Fixed protocol term set: radiology; diagnostic imaging; medical imaging; CT; computed tomography; MRI; magnetic resonance imaging; PET; nuclear medicine; radiation dose; interoperability; FHIR; health information exchange; USCDI; health IT certification; information blocking; clinical decision support; artificial intelligence; AI; machine learning; clinical AI; Software as a Medical Device; SaMD; physician fee	Candidate items identified.

			schedule; hospital outpatient; digital quality measure; healthcare interoperability.	
Government of Canada health interoperability publications	Official Canada.ca digital health, health data, and interoperability pages reviewed	January 30, 2026 – April 30, 2026	Fixed protocol term set: radiology; diagnostic imaging; medical imaging; CT; computed tomography; MRI; magnetic resonance imaging; PET; nuclear medicine; radiation dose; interoperability; FHIR; health information exchange; USCDI; health IT certification; information blocking; clinical decision support; artificial intelligence; AI; machine learning; clinical AI; Software as a Medical Device; SaMD; physician fee schedule; hospital outpatient; digital quality measure; healthcare interoperability.	Candidate item identified through Health Canada Departmental Plan and transfer-payment materials; no additional qualifying candidate item found.
European Commission Health Directorate	Official European Commission health policy pages reviewed	January 30, 2026 – April 30, 2026	Fixed protocol term set: radiology; diagnostic imaging; medical imaging; CT; computed tomography; MRI; magnetic resonance imaging; PET; nuclear medicine; radiation dose; interoperability; FHIR; health information exchange; USCDI; health IT certification; information blocking; clinical decision support; artificial intelligence; AI; machine learning; clinical AI; Software as a Medical Device; SaMD; physician fee schedule; hospital outpatient; digital quality measure; healthcare interoperability.	Candidate pre-regulatory/policy signal items identified.
EUR-Lex regulatory publications	Official EUR-Lex / Official Journal listing and search review	January 30, 2026 – April 30, 2026	Fixed protocol term set: radiology; diagnostic imaging; medical imaging; CT; computed tomography; MRI; magnetic resonance imaging; PET; nuclear medicine; radiation dose; interoperability; FHIR; health information exchange; USCDI; health IT certification; information blocking; clinical decision support; artificial intelligence; AI; machine learning; clinical AI; Software as a Medical Device; SaMD; physician fee schedule; hospital outpatient; digital quality measure; healthcare interoperability.	Discovery completed — no new qualifying formal regulatory item found for this source in the monitoring window.
EU Digital Strategy portal	Official Digital Strategy portal review and site search	January 30, 2026 – April 30, 2026	Fixed protocol term set: radiology; diagnostic imaging; medical imaging; CT; computed tomography; MRI; magnetic resonance imaging; PET; nuclear medicine; radiation dose; interoperability; FHIR; health information exchange; USCDI; health IT certification; information blocking; clinical decision support; artificial intelligence; AI; machine learning; clinical AI; Software as a Medical Device; SaMD; physician fee schedule; hospital outpatient; digital quality measure; healthcare interoperability.	Candidate policy signal items identified.
EMA publications	Official EMA publication/news search reviewed	January 30, 2026 – April 30, 2026	Fixed protocol term set: radiology; diagnostic imaging; medical imaging; CT; computed tomography; MRI; magnetic resonance imaging; PET; nuclear medicine; radiation dose; interoperability; FHIR; health information exchange; USCDI; health IT certification; information blocking; clinical decision support; artificial intelligence; AI; machine learning; clinical AI; Software as a Medical Device; SaMD; physician fee schedule; hospital outpatient; digital quality measure; healthcare interoperability.	Discovery completed — no candidate items found for this source in the monitoring window.
Ministry of Health, Labour and Welfare (MHLW)	Official MHLW site search and notice review	January 30, 2026 – April 30, 2026	Fixed protocol term set: radiology; diagnostic imaging; medical imaging; CT; computed tomography; MRI; magnetic resonance imaging; PET; nuclear medicine; radiation dose; interoperability; FHIR; health	Discovery completed — no candidate items found for this source in the monitoring window.

			information exchange; USCDI; health IT certification; information blocking; clinical decision support; artificial intelligence; AI; machine learning; clinical AI; Software as a Medical Device; SaMD; physician fee schedule; hospital outpatient; digital quality measure; healthcare interoperability.	
Pharmaceuticals and Medical Devices Agency (PMDA)	Official PMDA announcement and guidance search reviewed	January 30, 2026 – April 30, 2026	Fixed protocol term set: radiology; diagnostic imaging; medical imaging; CT; computed tomography; MRI; magnetic resonance imaging; PET; nuclear medicine; radiation dose; interoperability; FHIR; health information exchange; USCDI; health IT certification; information blocking; clinical decision support; artificial intelligence; AI; machine learning; clinical AI; Software as a Medical Device; SaMD; physician fee schedule; hospital outpatient; digital quality measure; healthcare interoperability.	Discovery completed — no candidate items found for this source in the monitoring window.
Digital Agency (Japan)	Official Digital Agency page review and search	January 30, 2026 – April 30, 2026	Fixed protocol term set: radiology; diagnostic imaging; medical imaging; CT; computed tomography; MRI; magnetic resonance imaging; PET; nuclear medicine; radiation dose; interoperability; FHIR; health information exchange; USCDI; health IT certification; information blocking; clinical decision support; artificial intelligence; AI; machine learning; clinical AI; Software as a Medical Device; SaMD; physician fee schedule; hospital outpatient; digital quality measure; healthcare interoperability.	Discovery completed — no candidate items found for this source in the monitoring window.
Ministry of Internal Affairs and Communications (MIC / Soumu)	Official MIC page review and search	January 30, 2026 – April 30, 2026	Fixed protocol term set: radiology; diagnostic imaging; medical imaging; CT; computed tomography; MRI; magnetic resonance imaging; PET; nuclear medicine; radiation dose; interoperability; FHIR; health information exchange; USCDI; health IT certification; information blocking; clinical decision support; artificial intelligence; AI; machine learning; clinical AI; Software as a Medical Device; SaMD; physician fee schedule; hospital outpatient; digital quality measure; healthcare interoperability.	Discovery completed — no candidate items found for this source in the monitoring window.