IHE Radiology Global Regulatory Monitoring Report

Volume 1 | Issue 4 | May 30, 2026

PREPARED BY IHE RADIOLOGY PLANNING COMMITTEE

Report date	May 30, 2026
Monitoring period	March 31, 2026 – May 30, 2026
Discovery window used	March 1, 2026 – May 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 31, 2026 – May 30, 2026, with discovery extended back to March 1, 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, the European Union, and Japan. In the United States, the CMS/ONC interoperability and prior authorization proposed rule remained active and was carried forward from the prior report, while an HHS health technology leadership alignment release was identified as a new policy signal. In Canada, Health Canada issued or updated medical device guidance relevant to machine learning-enabled devices and significant-change interpretation, and its May 2026 Ministerial Briefing Book provided a new digital health, interoperability, and AI policy signal. In the European Union, Commission and JRC activity continued to emphasize AI-enabled image screening, cardiovascular AI, and EHDS-linked digital health infrastructure. In Japan, MHLW published medical DX payment implementation materials that explicitly reference sharing clinical information including image information, and MHLW announced Program Medical Device Investigation Committee activity relevant to SaMD oversight.

Strategically, the current cycle reinforces five policy vectors important to IHE Radiology: standards-based clinical and image information exchange, API-centered payer-provider interoperability,

governance of AI-enabled clinical and imaging tools, medical device software lifecycle oversight, and payment or funding policies that reward digital health infrastructure. The most direct IHE Radiology opportunities involve articulating implementation patterns for image exchange and AI-enabled imaging workflows, aligning profile-based guidance with emerging health IT and payment requirements, and helping imaging organizations translate regulatory and pre-regulatory signals into procurement and implementation language.

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
HHS Aligns Health Technology Leadership to Deliver Data Liquidity, Affordability, and an AI-Enabled Health Care System for Americans	U.S. Department of Health and Human Services (HHS) / Office of the National Coordinator for Health Information Technology (ONC)	Official HHS/ONC policy release / organizational policy signal	March 31, 2026	Not applicable	3
*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
Guidance on how to interpret "significant change" of a medical device	Health Canada	Guidance Document	March 31, 2026	Not applicable	3
*Pre-market guidance for machine learning-enabled medical devices	Health Canada	Guidance Document	April 1, 2026	Not applicable	3
Health Canada Ministerial Briefing Book: Digital Health and Health Data, including Artificial Intelligence	Health Canada	Ministerial briefing book / strategic policy signal	May 15, 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
Info Day on digital health topics under the DIGITAL Europe Programme - Apply	European Commission, Directorate-General for Communications	Digital Europe Programme event / call	April 29, 2026	October 1, 2026	4

AI: Piloting AI-based image screening in medical centres	Networks, Content and Technology (DG CONNECT)	implementation guidance signal			
FY2026 Medical Fee Revision: Electronic Clinical Information Linkage System Readiness Add-on	Japan Ministry of Health, Labour and Welfare (MHLW)	Official medical fee revision guidance / payment policy implementation material	May 20, 2026	Not applicable	4
MHLW Program Medical Device Investigation Committee meeting notice	Japan Ministry of Health, Labour and Welfare (MHLW)	Committee meeting notice / pre-regulatory SaMD policy signal	May 13, 2026	Not applicable	3

3. North America Regulatory Scan

United States

***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: Official source

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, imaging operations are embedded in the same payer-provider data exchange environment and may be affected by the standards ecosystem created for electronic prior authorization and supporting documentation. Because this same policy item appeared in the immediately prior report, the title is marked with an asterisk.

Impact Assessment:

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

Relevance Score: 3

Canada

Guidance on how to interpret "significant change" of a medical device

Agency: Health Canada

Policy Type: Guidance Document

Publication Date: March 31, 2026

Official Source Link: Official source

Comment Deadline: Not applicable

Summary: Health Canada updated guidance explaining how to interpret significant changes for medical devices, including changes to device design, performance characteristics, software, accessories, and intended use. The guidance includes AI, ML, machine learning-enabled medical devices, and predetermined change control plan terminology and addresses software change categories such as infrastructure, architecture, algorithm, refactoring, and re-engineering changes. For imaging organizations, the guidance is relevant to vendor management and evaluation of medical device software changes, including changes to AI-enabled or machine learning-enabled imaging tools.

Impact Assessment:

- **Imaging Operations:** Potentially relevant to change control expectations for imaging devices, device software, workstations, and AI-enabled tools used in imaging workflows.
- **AI Governance:** Direct. The guidance addresses MLMDs, PCCPs, model drift, and software changes that can affect safety or effectiveness.
- **Interoperability:** Indirect. Software, infrastructure, and compatibility changes can affect integration with imaging, reporting, and clinical information systems.

Relevance Score: 3

***Pre-market guidance for machine learning-enabled medical devices**

Agency: Health Canada

Policy Type: Guidance Document

Publication Date: April 1, 2026

Official Source Link: Official source

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 good machine learning practice, design, risk management, data selection and management, testing, clinical validation, transparency, post-market monitoring, and predetermined change control plans. Although not limited

to imaging, imaging AI products commonly fall within the broader class of machine learning-enabled medical devices. Because this same policy item appeared in the immediately prior report, the title is marked with an asterisk.

Impact Assessment:

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

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

FY2026 Medical Fee Revision: Electronic Clinical Information Linkage System Readiness Add-on

Agency: Japan Ministry of Health, Labour and Welfare (MHLW)

Policy Type: Official medical fee revision guidance / payment policy implementation material

Publication Date: May 20, 2026

Official Source Link: Official source

Comment Deadline: Not applicable

Summary: MHLW published FY2026 medical fee revision materials describing medical DX and ICT linkage evaluations, including a new electronic clinical information linkage system readiness add-on. The materials describe requirements involving electronic prescription systems, electronic medical record information sharing services, cybersecurity measures, and networks that allow multiple medical institutions to share or view clinical information including laboratory results and image information. This is relevant to IHE Radiology because it connects payment policy implementation to clinical information sharing infrastructure that explicitly includes image information.

Impact Assessment:

- **Imaging Operations:** Direct-to-moderate. The item connects payment policy and facility readiness to the ability to share or view clinical information, including image information, across multiple medical institutions.
- **AI Governance:** Indirect. The item does not govern AI directly, but it strengthens digital clinical data infrastructure that may later support AI-enabled care and analytics.
- **Interoperability:** Direct. The item addresses electronic clinical information linkage, electronic record sharing interfaces, and networks for shared access to clinical and image information.

Relevance Score: 4

6. IHE Opportunity Scan

Policy signal	Potential IHE-aligned opportunity	Notes (non-policy)
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 ordering, documentation, and results-access workflows.	The rule is not imaging-specific, but it shapes the broader API and standards environment in which imaging orders, documentation, and results access operate.
Health Canada ML-enabled medical device guidance and significant-change guidance	Develop procurement and implementation questions that help imaging organizations ask AI vendors for regulatory status, lifecycle controls, model-change handling, clinical validation evidence, and integration documentation.	Both guidance documents are relevant to medical device software and AI-enabled imaging tools, even though they do not define interoperability profiles.
EU AI-powered image screening calls and JRC cardiovascular AI evidence signal	Map IHE Radiology profiles and implementation guidance to AI-enabled image screening workflows, image access, result integration, evidence capture, and monitoring needs.	These signals explicitly reference medical image screening, CT-related cardiovascular AI use cases, and pressure on radiology services.
Japan MHLW electronic clinical information linkage payment materials	Assess whether IHE Radiology profile guidance can support networked sharing or viewing of clinical information, including image information, across multiple medical institutions.	This is a direct opportunity to align standards-based imaging exchange with payment-linked digital health readiness criteria.
HHS and Health Canada digital health infrastructure signals	Continue positioning IHE Radiology as practical implementation guidance for health data exchange, imaging data liquidity, and AI-ready clinical data infrastructure.	These are broad policy signals, but they reinforce an environment in which interoperability implementation guidance remains valuable.

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
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

Apply AI: Piloting AI-based image screening in medical centres	European Union	October 1, 2026 submission deadline; May 21, 2026 Info Day	Official source
MHLW Program Medical Device Investigation Committee	Japan	May 27, 2026 meeting date	Official source

8. Emerging Policy Signals (Pre-Regulatory)

HHS Aligns Health Technology Leadership to Deliver Data Liquidity, Affordability, and an AI-Enabled Health Care System for Americans

Agency: U.S. Department of Health and Human Services (HHS) / Office of the National Coordinator for Health Information Technology (ONC)

Policy Type: Official HHS/ONC policy release / organizational policy signal

Publication Date: March 31, 2026

Official Source Link: Official source

Comment Deadline: Not applicable

Summary: HHS announced a revised health technology leadership alignment that returns enterprise technology roles, including the Chief Technology Officer, Chief Artificial Intelligence Officer, and Chief Data Officer, under the HHS Chief Information Officer while preserving ONC's mission focus on nationwide health IT interoperability and data liquidity. The announcement frames the operational model around technology leadership, responsible and trustworthy artificial intelligence, and enterprise data governance and analytics. Although this is not an imaging-specific rule, it is relevant to IHE Radiology because HHS health IT standards, certification, data liquidity, and AI governance shape the environment in which imaging interoperability and AI implementation expectations develop.

Impact Assessment:

- **Imaging Operations:** Indirect. The item does not impose imaging operational requirements, but it may influence the federal infrastructure supporting standards implementation, health IT certification, data exchange, and AI-enabled care delivery.
- **AI Governance:** Direct as a governance signal. HHS identifies responsible and trustworthy AI as an enterprise leadership function under the HHS CIO structure.
- **Interoperability:** Direct as a health IT policy signal. ONC's sharpened mission focus is described in terms of nationwide health IT interoperability and data liquidity.

Relevance Score: 3

Health Canada Ministerial Briefing Book: Digital Health and Health Data, including Artificial Intelligence

Agency: Health Canada

Policy Type: Ministerial briefing book / strategic policy signal

Publication Date: May 15, 2026

Official Source Link: Official source

Comment Deadline: Not applicable

Summary: Health Canada's May 2026 Ministerial Briefing Book includes a digital health and health data section identifying connected, quality health data as essential for clinical decisions, public health response, accountability, and health system performance. The briefing states that access, exchange, and use of health data require digital systems to connect through interoperability and that connected systems provide a foundation for standardized health data, including the data needed by artificial intelligence. The item is a pre-regulatory signal rather than a formal rule, but it reinforces Canada's continuing federal emphasis on interoperability, health data access, and AI-ready digital health infrastructure.

Impact Assessment:

- **Imaging Operations:** Indirect. The signal does not create imaging obligations, but imaging exchange and reporting are part of the broader connected health data environment.
- **AI Governance:** Meaningful as a policy signal. The briefing explicitly links AI value to comprehensive, standardized health data.
- **Interoperability:** Direct as a strategic signal. The briefing identifies interoperability as necessary for access, exchange, and use of health data.

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: Official source

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 item identifies current and potential AI uses involving CT imaging and imaging-adjacent clinical workflows, including coronary artery calcium scoring, CT-derived fractional flow reserve, and acute stroke CT workflows. The report emphasizes evidence, infrastructure, and regulatory simplification needs for AI deployment in cardiovascular care. Because this same policy item appeared in the immediately prior report, the title is marked with an asterisk.

Impact Assessment:

- **Imaging Operations:** Relevant because several examples involve CT-based imaging workflows and 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: Official source

  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 €24.4 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. Because this same policy item appeared in the immediately prior report, the title is marked with an asterisk.

  Impact Assessment:

- **Imaging Operations:** Potential relevance to deployment of AI-powered image screening in medical centres and related implementation expectations.
- **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

  Info Day on digital health topics under the DIGITAL Europe Programme - Apply AI: Piloting AI-based image screening in medical centres

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

  Policy Type: Digital Europe Programme event / call implementation guidance signal

  Publication Date: April 29, 2026

  Official Source Link: Official source

  Comment Deadline: October 1, 2026

Summary: The European Commission published an Info Day notice for the Digital Europe Programme call DIGITAL-2026-AI-PILOTING-10-SCREENING, focused on piloting AI-based image screening in medical centres. The notice states that the topic aims to accelerate adoption and deployment of cloud-based AI systems running European AI algorithms for medical image screening, with a focus on early detection and diagnosis of cancer and cardiovascular diseases. It identifies expected outcomes including improving detection and diagnostic workflows, supporting prioritization of critical cases, reducing pressure on radiology services, and contributing to more equitable screening access.

Impact Assessment:

- **Imaging Operations:** Direct. The call explicitly targets medical image screening, detection and diagnostic workflows, case prioritization, and pressure on radiology services.
- **AI Governance:** Direct. The signal concerns cloud-based AI systems for clinical image screening under an EU implementation and funding framework.
- **Interoperability:** Moderate. Cloud-based AI screening deployment will depend on integration with imaging, screening, reporting, and health data infrastructure.

Relevance Score: 4

MHLW Program Medical Device Investigation Committee meeting notice

Agency: Japan Ministry of Health, Labour and Welfare (MHLW)

Policy Type: Committee meeting notice / pre-regulatory SaMD policy signal

Publication Date: May 13, 2026

Official Source Link: Official source

Comment Deadline: Not applicable

Summary: MHLW announced a May 27, 2026 meeting of the Program Medical Device Investigation Committee. The notice identifies the responsible MHLW medical device review management office and states that the meeting would be partly closed because company intellectual property and related information may be disclosed. The notice does not itself establish a new rule, but it is a pre-regulatory signal relevant to SaMD oversight and therefore to imaging AI and diagnostic software governance.

Impact Assessment:

- **Imaging Operations:** Indirect. The notice does not impose operational requirements, but SaMD policy activity may affect imaging software and AI products used in clinical workflows.
- **AI Governance:** Direct as a pre-regulatory signal. Program medical devices include software-based medical devices, a category that commonly overlaps with AI-enabled clinical and imaging tools.
- **Interoperability:** Indirect. Future SaMD policy could influence integration expectations for software connected to clinical systems.

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 HHS index/listing page review	March 1, 2026 – May 30, 2026	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. Pages reviewed included Federal Register search results and HHS Department index for 2026.	Candidate item identified: CMS-0062-P. No additional qualifying diagnostic imaging-specific Federal Register item identified in the monitoring window.
Regulations.gov (United States)	Docket search for federal rulemaking candidates associated with identified Federal Register items	March 1, 2026 – May 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	March 1, 2026 – May 30, 2026	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: CMS-0062-P CMS policy materials; no additional qualifying imaging-specific candidate item found.
ONC / ASTP publications	Official HealthIT.gov / ONC news, standards,	March 1, 2026 – May 30, 2026	radiology; diagnostic imaging; medical imaging; CT; computed tomography; MRI; magnetic	Candidate items identified: CMS-0062-P connection

	and certification page review		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.	and HHS/ONC health technology leadership policy signal.
FDA policy announcements	Official FDA medical device, AI-enabled device, SaMD, radiology, and CDRH news page review	March 1, 2026 – May 30, 2026	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/ONC health technology policy page and release review	March 1, 2026 – May 30, 2026	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: HHS health technology leadership alignment policy signal.
Canada Gazette	Chronological listings and site search reviewed	March 1, 2026 – May 30, 2026	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, medical device, what-new, policy, and planning pages reviewed	March 1, 2026 – May 30, 2026	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: significant change guidance, ML-enabled medical device pre-market guidance, and May 2026 Ministerial Briefing Book digital health/AI signal.
Government of Canada health interoperability publications	Official Canada.ca digital health, health data, and interoperability pages reviewed	March 1, 2026 – May 30, 2026	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 Ministerial Briefing Book; no additional qualifying candidate item found.
European Commission Health Directorate	Official European Commission health policy pages reviewed	March 1, 2026 – May 30, 2026	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; no qualifying formal regulatory item found.
EUR-Lex regulatory publications	Official EUR-Lex / Official Journal listing and search review	March 1, 2026 – May 30, 2026	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	Discovery completed — no new qualifying formal regulatory item found for this source in the monitoring window.

			schedule; hospital outpatient; digital quality measure; healthcare interoperability.	
EU Digital Strategy portal	Official Digital Strategy portal review and site search	March 1, 2026 – May 30, 2026	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: Digital Europe AI health funding call and AI-based image screening info day.
EMA publications	Official EMA publication/news search reviewed	March 1, 2026 – May 30, 2026	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 new information listing, notices, committee pages, and policy materials reviewed	March 1, 2026 – May 30, 2026	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. Japanese search terms included 医療, AI, 医療機器, プログラム医療機器, 画像情報, 医療 DX, 情報連携.	Candidate items identified: FY2026 medical fee revision medical DX/electronic clinical information linkage materials and Program Medical Device Investigation Committee meeting notice.
Pharmaceuticals and Medical Devices Agency (PMDA)	Official PMDA announcement, guidance, and SaMD pages reviewed	March 1, 2026 – May 30, 2026	radiology; diagnostic imaging; medical imaging; CT; computed tomography; MRI; magnetic resonance imaging; PET; nuclear medicine; radiation dose;	Discovery completed — no qualifying candidate item with verified publication date inside the

			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. Japanese search terms included 医療機器, プログラム医療機器, AI, 画像診断, SaMD.	monitoring window found for this source.
Digital Agency (Japan)	Official Digital Agency page review and search	March 1, 2026 – May 30, 2026	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	March 1, 2026 – May 30, 2026	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.