Australian Government
Australian Digital Health Agency

FHIR Framework Operations and Governance

Connecting Australian Healthcare

Version 26.1



Australian Digital Health Agency

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Acknowledgement of Country

All partners acknowledge and respect Aboriginal and Torres Strait Islander peoples as the Traditional Custodians of Country throughout Australia and their continuing connection to land, seas and community. We pay our respects to their cultures and to Elders past and present.

Thank you to partners and contributors

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Role of the Australian Digital Health Agency

The Australian Digital Health Agency (the Agency) is a corporate Commonwealth entity supported by all Australian governments to accelerate adoption and use of digital services and technologies across the Australian health ecosystem, as set out under the Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016 (Agency Rule). The Agency Rule was created under the *Public Governance, Performance and Accountability Act 2013*. Under the Agency Rule, the Agency is charged with developing a digital health strategy at the national level for Australia.

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Section 1

Introduction

About the FHIR Framework

The FHIR Framework (the Framework) supports delivery of the National Digital Health Strategy (2023–2028), specifically Outcome 1 (Digitally Enabled Health System) by providing the national approach for standards adoption and implementation.

The Framework supports the following priority area and associated initiatives:

- **Priority area 1.3:** Enhance and maintain modern and integrated digital solutions, which reflects the expectations of the Strategy and supports the Strategy Delivery Roadmap initiatives:
  - **Initiative 1.3.2:** Develop accurate terminology, interoperability standards and conformance for sustained and widespread use
  - **Initiative 1.3.3:** Develop Fast Healthcare Interoperability Resources® (FHIR®) core standards to support consistent capture and sharing of health information
  - **Initiative 1.3.4:** Continue implementing standards and resilience measures to protect personal health information and digital infrastructure from cyber threats and environmental events

The Framework is a set of policies and processes that govern the adoption and use of the Health Level Seven International (HL7®) FHIR® standard in the Australian Digital Health Agency (the Agency).

The Framework underpins the production of all the Agency's FHIR-based technical specifications (FHIR Specifications).

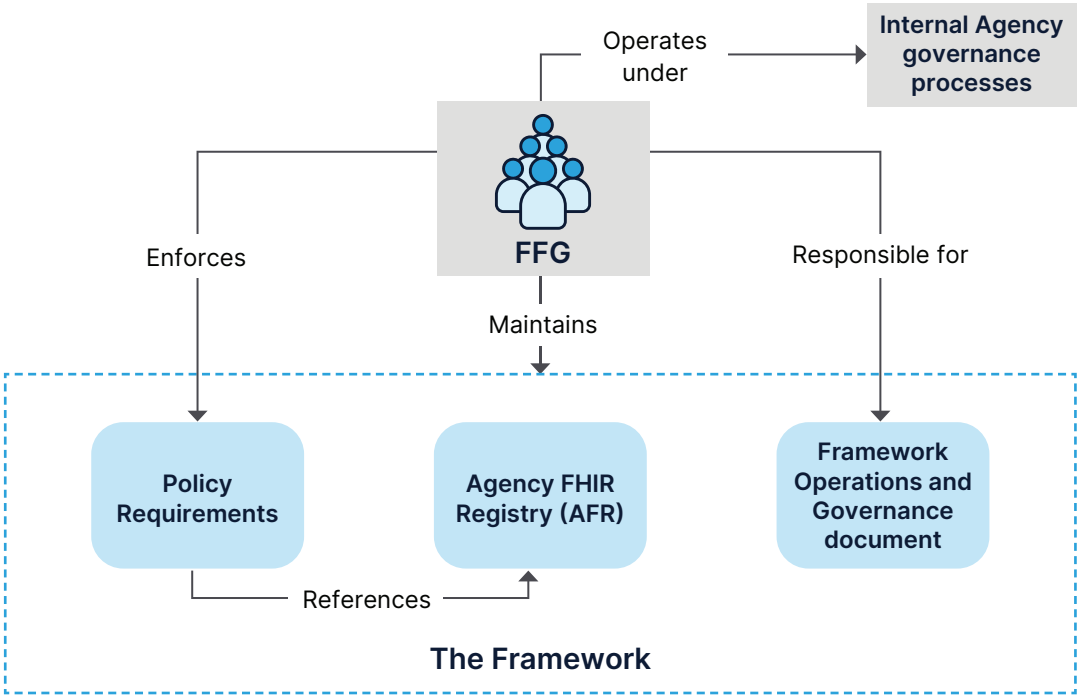
The Framework is published on the Agency's Implementer Hub and is comprised of 3 key components:

1. Framework Operation & Governance (this document)
2. Policy Requirements for the Agency's FHIR Specifications
3. The Agency FHIR Registry (AFR): a published list of approved FHIR specifications and artefact's (both internally and externally developed) for use by the Agency.

The Agency's FHIR Framework Group (FFG) is responsible for the operation of the Framework, including enforcement and maintenance activities, and is governed by their own Terms of Reference.

The following diagram describes the relationships between the FFG and the components that make up the Framework.

Figure 1: Composition of the Framework and relationship to FFG



Vision

The vision for the Framework is that:

- The Agency's adoption and use of the HL7 FHIR standard is:
  - transparent and understood by all stakeholders; and
  - supported by effective, well-maintained policies and robust governance processes that ensure continual evolution and compliance.
- Framework-aligned FHIR Specifications (and, by extension, solutions based on these specifications) represent a benchmark for excellence, fostering broad recognition, acceptance, and adoption across the Australian and global FHIR communities.
- The Agency's use of the HL7 FHIR standard is acknowledged globally as world-leading.

Objectives

- Provide a set of documented and well governed policy requirements[1] for the Agency's FHIR Specifications to comply with.
- Ensure that FHIR Specifications effectively leverage HL7 FHIR and related standards to address interoperability problems.
- Minimise or eliminate:
  - Unnecessary diversity and variation in technical approaches employed in the content of FHIR Specifications
  - Technical and policy uncertainty experienced by FHIR Specification developers
  - Avoidable duplication of effort in the development of FHIR Specifications
- Increase:
  - Adoption of best and leading practices in FHIR Specification development
  - Uniformity and standardisation of approaches and content in FHIR Specifications e.g., for naming conventions, URI patterns, and versioning schemes
  - Reusability of approaches and technical artefacts in FHIR Specifications
  - Visibility and accessibility of FHIR Specifications along with their technical artefacts
  - Quality of FHIR Specifications

Guiding Principles

The Framework is informed by the following guiding principles:

- **Primacy of interoperability** - The Framework's policy requirements are designed with interoperability in mind, ensuring they can be adopted across different systems, organisations, and jurisdictions, with strong alignment to Australian and international standards wherever possible.
- **Effective governance** - Oversight and operation of the Framework is structured with:
  - clear roles for the Agency's established governance groups and committees; and
  - processes for assessment, change management, and dispute resolution.
- **FHIR community alignment** - The Agency adopts and adapts the HL7 FHIR standard in ways that are consistent with the broader international and Australian FHIR communities, requiring clear and justified arguments for any divergence. Key examples of this alignment include preferable adoption of openly developed and balloted FHIR specifications through

1 These are Agency maintained policy requirements. Compliance with external engagement requirements e.g. HL7 Australia's Australian FHIR Community Process (AFCP) will be addressed in a different Agency policy instrument.

standards development organisations.

- **Clarity and consistency** - The Framework uses and promotes clear, unambiguous naming, identifiers, terminology, and structure.
- **Sustainability and maintainability** - Framework-aligned specifications must minimise duplication, reduce maintenance burden, and ensure long-term viability.
- **Reduced burden -** The Framework's policy requirements must not place unnecessary burdens on FHIR Specification authors nor on the adopters of Framework-aligned FHIR Specifications.
- **Achievable interoperability** - The Framework's policy requirements ensure FHIR Specifications strike an acceptable balance between what can realistically be achieved by implementers and an unrealistically high level of interoperability.
- **Stewardship** - The Framework ensures that technical artefacts and other dependencies of FHIR Specifications (e.g., copyright and IP obligations) are well-managed and made accessible through a governed registry.
- **Evidence-based improvement** - The Framework evolves based on lessons learned from implementations, feedback from internal and external stakeholders, and operational data (e.g., analytics from Agency-operated national services).

Purpose

The purpose of this document is to describe the Framework as well as its ongoing operation and governance.

Intended audience

- Agency staff developing the Agency's FHIR Specifications
- Agency staff responsible for the ongoing maintenance and enforcement of the Framework.
- Agency staff and external stakeholders who seek to understand how the HL7 FHIR standard is adopted and used by the Agency in the Agency's FHIR Specifications.

In scope

The scope of the Agency's FHIR Framework is limited to:

- The operation and governance of the Framework
- The FHIR Framework Group (FFG) that is responsible for the operation of the Framework
- Policy requirements for the Agency's FHIR Specifications (that is, FHIR Specifications which may be developed by the Agency or external suppliers, and which may be publicly available or only available to a closed/limited group)
- The Agency FHIR Registry: a published list of approved FHIR specifications and artefacts (both internally and externally developed) for use by the Agency

Out of scope

The following are not within the scope of the Agency's FHIR Framework:

- Project and program management activities
- Mapping and transformation between FHIR and other standards
- The Agency's policies for participation in external SDO ballots for FHIR Implementation Guides or other FHIR standards
- Australian FHIR Community Process (AFCP) related consultations
- Conformance profile development and testing of external applications that have implemented the Agency's FHIR Specifications – noting that the Framework indirectly supports conformance processes as the Framework's policy requirements can inform FHIR Specifications which are the subject of such conformance testing
- Policies for the Agency's FHIR solutions (that is, ICT solutions, services or applications that use FHIR specifications and are owned by the Agency or which the Agency is responsible for and may be operated by the Agency or external suppliers)
- An external engagement policy describing approaches to external engagement when developing FHIR specifications that are either owned by the Agency (referred to as 'FHIR Specifications' in the Framework) or are required by the Agency



Section 2

FHIR overview

The Health Level Seven International organisation

Health Level Seven (HL7) International is a not-for-profit, ANSI-accredited standards development organisation dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. Some well-known standards from HL7 International include

- Version 2 (V2)
- Version 3 (V3)
- Clinical Document Architecture (CDA)
- Fast Healthcare Interoperability Resources (FHIR)

The HL7 FHIR interoperability standard

HL7 FHIR is a free and open interoperability standard from HL7 International for exchanging healthcare information electronically. FHIR is designed to provide greater support for implementers through adoption of modern, web-based technologies while harnessing the long-standing clinical foundation of existing HL7 standards. At a high level, FHIR provides an open API specification and a data model for representing health and health-related information. The standard also defines patterns for resources used in workflow processes.

The FHIR community

In addition to being standard, FHIR is also a global community of individuals and organisations involved in the development and adoption of the HL7 FHIR standard.

FHIR in Australia

In Australia, the HL7 FHIR standard has seen significant but not yet widespread adoption.

The official HL7 Affiliate for Australia – HL7 Australia – has supported the FHIR standard since 2017 with the introduction of the first version of the foundational AU Base FHIR Implementation Guide which provides support for adoption of FHIR in the Australian context through provision of FHIR extensions, profiles and terminology artefacts to represent key Australian concepts like national healthcare identifiers for consumers and practitioners.

Through its Australian e-Health Research Centre (AEHRC) the CSIRO, a federal government scientific and industrial research organisation, has also contributed significantly to the adoption of FHIR through the development of FHIR Implementation Guides, terminology-related software applications like the Ontoserver terminology server and, as a supplier to the Agency, the National Clinical Terminology Service (NCTS).

In 2023, the Agency (in partnership with the Australian Government Department of Health, Disability and Ageing, the CSIRO and HL7 Australia) launched Sparked, Australia's first FHIR Accelerator. Sparked was established to develop FHIR Implementation Guide specifications including AU Core, AU eRequesting and the International Patient Summary (IPS)-aligned Australian Patient Summary.

Additionally, a growing number of significant solutions healthcare solutions from commercial and private organisations are known to have adopted FHIR including:

- Pathology and radiology eRequesting solutions; and
- APIs for clinical information systems to share healthcare information.

FHIR in the Agency

FHIR Specifications

Most FHIR technical specifications in the Agency are developed as FHIR Implementation Guides by the Informatics and Standards branch of the Digital Solutions Division. The following are some of the Agency's FHIR Specifications:

- NCTS Content Types and NCTS Conformant Server Applications technical specifications
- Comprehensive Health Assessment Program FHIR Implementation Guide

- Clinical Document Architecture with Australian Schema FHIR Implementation Guide
- My Health Record FHIR Implementation Guide
- Provider Connect Australia FHIR Implementation Guide
- Medicare Records FHIR Implementation Guide

The Namespaces website also supports several Agency FHIR Specifications.

FHIR solutions

The Architecture branch of the Digital Solutions Division in the Agency is responsible for the development of solution architectures for FHIR-based solutions. Implementation and deployment of these solutions may be undertaken by external suppliers, or internally by software development teams in the Agency.

The following Agency solutions currently use, or are being developed to use, the HL7 FHIR standard:

- The National Clinical Terminology Service (NCTS)
- The My Health Record FHIR Gateway API for Mobile Application integration
- Provider Connect Australia (PCA)
- Comprehensive Health Assessment Program (CHAP): National Forms App, Forms Service and App Hosting Service
- Health Connect Australia Provider Directory (the Provider Directory)

FHIR governance

Governance of the adoption of FHIR for Agency owned and operated products and services, both in FHIR solutions and FHIR Specifications, is the responsibility of the Agency's Architecture and Standards Committee (ASC) Tier 3 committee.

The ASC provide expert advice to the CEO's delegate(s) on decisions relating to technology architecture, design and standards associated with the Agency's national products and services and internal ICT systems that support the function of the Agency.

The Committee is the primary technical governance body for the Agency for internal and external products and infrastructure having regard to architectural alignment and standards. This includes governance over the use and implementation of FHIR and FHIR standards across the Agency's products and services, including review and endorsement of FHIR Specifications and FHIR solutions.

The ASC's decision making for endorsement will consider various factors including alignment with the Framework and other policies such as ones for external engagement.



Section 3

Framework operation and governance

Framework operation

The Framework operates through its policy requirements being published, maintained, and enforced within the Agency. The value of the Framework is realised through compliance with these policy requirements in the development of the Agency's FHIR specifications ultimately leading to the implementation of improved and more consistent FHIR-based technical solutions. Compliance with the Framework is mandatory for all teams and individuals in the Agency with allowed deviations from the Framework at the discretion of the ASC.

The **FHIR Framework Group (FFG)** is responsible for the operation of the Framework which includes enforcement and maintenance activities.

The FFG **enforces the Framework** by:

- assessing Agency-produced FHIR Specifications against relevant policies
- providing required decisions, expert advice and guidance to the ASC to assist them in making FHIR Specification related endorsement decisions.

The FFG **maintains the Framework** by:

- reviewing change requests for the Framework operation & governance (this document), Framework policy requirements, and the AFR
- conducting regular reviews of the Framework over time
- obtaining ASC endorsement for each version of the Framework
- publishing the Framework.

The FFG has no formal relationships with external FHIR-related organisations such as HL7 International, HL7 Australia and CSIRO, or with FHIR-related initiatives, such as the Sparked FHIR Accelerator. However, it is likely that the members of the FFG will engage with these organisations and initiatives. Additionally, the outputs of these organisations and initiatives are likely to be considered by the FFG for inclusion in the Framework's policy requirements and/or the AFR.

Framework endorsement

The ASC is responsible for endorsing all versions of the Framework.

The latest ASC-endorsed version of the Framework (that is, the 'in-force' version) is used in the operation of the Framework including by the FFG during the Framework assessment process.

Framework governance

The Framework operates under existing Agency internal governance processes.

The **Architecture and Standards Committee** (ASC) is one of several (tier 3) committees that report to the Agency's Senior Executive Committee (SEC). It is the primary technical governance body for the Agency for internal and external products and infrastructure having regard to architectural alignment and standards.

> **INFO: Architecture and Standards Committee**
>
> **The Architecture and Standards Committee (ASC) has primary responsibility for oversight of the Agency's Corporate Plan Area of Focus: 'Deliver National Digital Health Infrastructure' however all Agency Areas of Focus will be considered in its deliberations.**
>
> **Through effective governance, the Committee supports the Agency to transform national infrastructure and move to a contemporary, structured data-rich ecosystem capable of connecting systems across settings and supporting real-time access to information for the patient and the broader care team, anywhere, anytime.**
>
> **The Committee enables the Agency to deliver products and services in line with the expectations of Australians and increase adoption of Agency's products and services based on their experiences and needs.**

The Agency also has an Architecture Advisory Review Group (AARG) Tier 4 committee that reviews and provides recommendations on architecture deliverables (which includes, but is not limited to, architecture for FHIR solutions).

INFO: Architecture Advisory Review Group

The Architecture Advisory and Review Group (AARG) provide a structured and formalised review mechanism for architectural designs, artefacts, blueprints and/or any related deliverables. It ensures that all architecture related activities align with the Agency's Architecture Framework, Principles, and Standards. The key responsibility of the AARG is to provide recommendations on architectural decisions to the Architecture and Standards Committee (ASC). The AARG is a sub committee of the ASC.

Key responsibilities of the AARG include:

- **Review and Recommendations: The AARG reviews concept, solution, and technical design deliverables, providing critical analysis and recommendations.**
- **Consensus Building: Acts as a central point for achieving consensus on proposals, architecture designs, patterns, and decisions as the AARG consists of cross functional team members of different functions/ divisions.**
- **Guidance and Support: Offers guidance on best practices, ensuring designs underpin the Agency's Strategy, Vision, Customer interactions, and Business operating model.**
- **Exemptions and Decisions: Provides recommendations to the Architecture and Standards Committee (ASC) regarding design decisions and exemptions.**

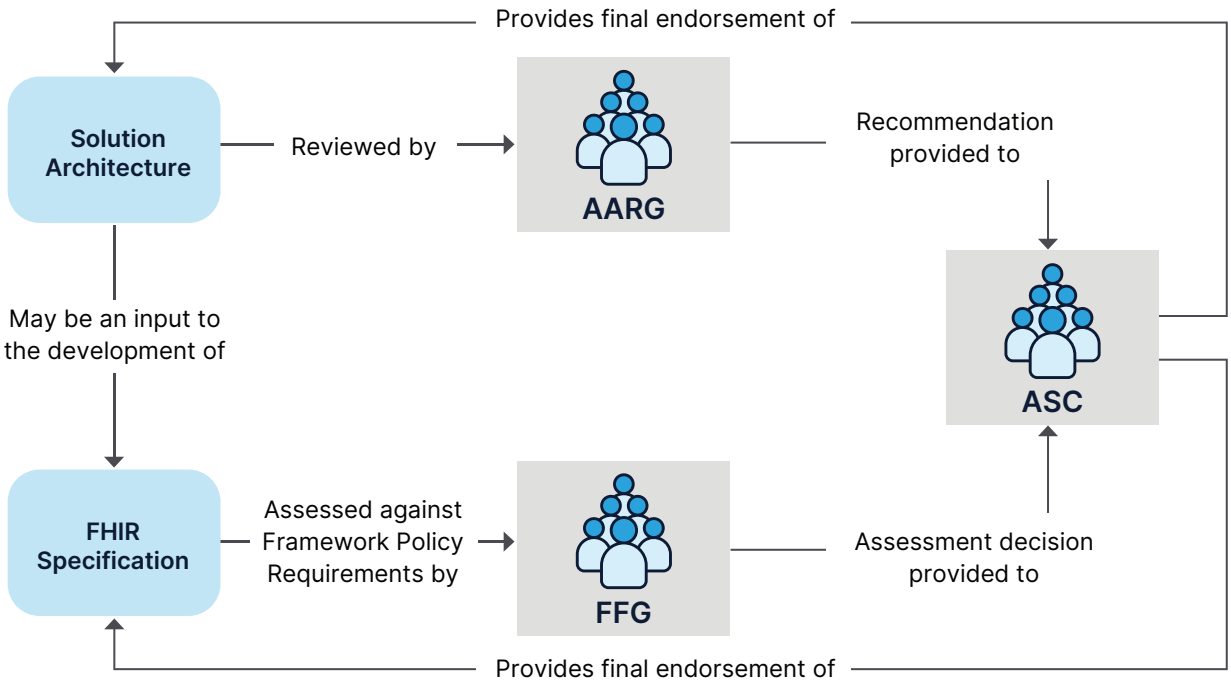
The FFG operates as a Tier 4 committee alongside the AARG, with both groups providing recommendations and input to the ASC to help inform their endorsement decisions:

- The **AARG** provides a broad architectural review process for all **architectural deliverables** (including those for FHIR solutions) and provides recommendations to the ASC.
- The **FFG** provides assurance to the ASC that **FHIR Specifications** (that may be developed based on architectural designs that have undergone AARG review, amongst other inputs such as information & business requirements) meet all the applicable Framework policy requirements.

The ASC is ultimately responsible for endorsing all FHIR Specifications (with FFG assessment as a prerequisite) and FHIR solution architectures (with AARG review as a prerequisite).

The following diagram describes the relationship between the AARG, the FFG and the ASC as they relate to the endorsement of FHIR Specifications:

Figure 2: Relationships between the AARG, the FFG, and the ASC



While it is likely that FHIR Specifications will be developed in parallel to (and before ASC endorsement of) the associated Solution Architecture that is being used as an input, it is expected that the Solution Architecture used to inform the development of the FHIR Specification has been reviewed by the AARG prior to the FHIR Specification being assessed by the FFG.

It is also expected that the team responsible for a FHIR Specification will seek ASC endorsement prior to publication. As part of its development the FHIR Specification may undergo other external review/engagement processes, such as the Australian FHIR Community Process (AFCP). The external engagement policy for FHIR Specifications is within the remit of the Agency's Informatics & Standards branch and not in the scope of the Framework or the FFG.

Section 4

Acronyms

Acronym	Description
AARG	Architecture Advisory Review Group
AFR	Agency FHIR Registry
ASC	Architecture and Standards Committee
CI	Clinical Informatics
FFG	FHIR Framework Group
FHIR IG	FHIR Implementation Guide
ToR	Terms of Reference

Section 5

Glossary

Term	Meaning
FHIR extension	Where implementations require support for data or functionality not natively provided by the FHIR, the FHIR standard supports extensibility through extensions. In FHIR, extensions allow FHIR data types and resources to support additional information components. To make FHIR extensions safe and manageable, the FHIR standard applies strict governance rules to the definition and use of extensions. Like profiles, extensions can be formally defined as machine processible technical artefacts using the FHIR StructureDefinition resource type.
FHIR Implementation Guide (IG)	The FHIR standard is a platform specification designed to be use case agnostic and to support multiple contexts. Accordingly, a need exists to provide specifications which adapt the FHIR standard to address specific use cases. FHIR IGs are technical specifications used to describe use of FHIR in a specific context or to address a particular use case or interoperability problem.
FHIR profile	A set of constraints on a FHIR resource type or data type thereby making it more specific to a particular use case e.g. profiling the Patient resource to mandate inclusion of at least one patient identifier. Profiles may be formally described as machine processible technical artefacts using the FHIR StructureDefinition resource type.
FHIR registry	The term 'FHIR registry' (not capitalised) defines a technical infrastructure service which allows sharing and discovery of FHIR resources. FHIR registries are typically operated on the internet with a web-based user interface which allows individuals and organisations to register and access the content held in the registry. FHIR registries may also implement an API to provide access to the content.
Agency FHIR Registry (AFR) (Framework defined term)	The Agency's FHIR registry - a published list of approved FHIR specifications and artefacts (both internally and externally developed) for use by the Agency.
FHIR specification	The term 'FHIR specification' (not capitalised) is used to refer more generally to any FHIR specification, including those not owned by the Agency.
FHIR Specification (Framework defined term)	Technical specifications based on FHIR standards and are owned by the Agency and may be developed by the Agency or external suppliers.
FHIR solution	ICT solutions, services or applications that use FHIR standards and are owned by the Agency or which the Agency is responsible for and may be operated by the Agency or external suppliers.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