



**HL7 AUSTRALIA
FHIR IG VARIANCE REQUIREMENTS
V1.0**



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Version Control

Version	Date	Descriptor	Contributors	Distributed to
1.0	17/10	Released	B Esler	HL7 AU Confluence

AU FHIR IG Variance Requirements

The AU Base FHIR Implementation Guide and AU Core FHIR Implementation Guide define primary conformance recommendations and requirements for HL7 Australia published FHIR implementation guides under the governance of the HL7 Australia FHIR Work Group.

These specifications also provide FHIR implementation detail as guidance for systems implementing and exchanging information that address concepts defined in the AU CDI and associated CDI Sparked Accelerator publications.

All HL7 Australia FHIR Implementation Guide projects are obliged to assess content and publish a Variance Statement with respect to AU Base and AU Core Implementation Guides.

The FHIR Work Group (FHIRWG) will assess and govern Variance Statement acceptance as part of the FHIR IG balloting process.

Definition of Variance

For assessment of variance in FHIR implementation guides the primary objectives are to:

- Explicitly identify profiles in a FHIR IG that have an AU Base and/or AU Core profile with overlapping scope of use.
- Determine if FHIR instances conforming to FHIR IG defined profiles will:
 - Remain at all times conformant with AU Base / AU Core profiles.
 - Explicitly how conformance may not be guaranteed.
 - A rationale for the variance.
- Explicitly identify profiles in a FHIR IG that do not have any overlapping scope of usage with AU Base and/or AU Core profiles.

This variance can then be considered for impact on implementers in terms of variability in implementation required for different scenarios of use.

Variance Requirements

All HL7 Australia published FHIR implementation guides under the governance of the HL7 Australia FHIR Work Group projects agree to the following publishing requirements:

- 1) These FHIR implementation guides **SHOULD** use AU Core profiles.
 - a) If this FHIR implementation guide is unable to *comply with** an AU Core profile we will document the variances and notify the FHIR WG.
- 2) These FHIR implementation guides **SHOULD** use AU Base profiles and extensions.
 - a) If this FHIR implementation guide is unable to reuse an AU Base extension or is unable to *comply with** an AU Base profile we will document the variances and notify the FHIRWG.

**comply with: the downstream profile satisfies the expectations established by the AU Base/AU Core profile. Instances that are valid against the downstream IG profile are also automatically valid the AU Base/AU Core profile.*

Variance Process

HL7 AU Variance Review Process

- 1) FHIRWG Project Approval
 - i) Variance known on proposal of project
- 2) HL7 AU Project AU Realm FHIR IG Responsibilities:
 - i) **SHALL** Document Variance in FHIR IG content.
 - ii) **SHALL** Notify FHIRWG co-chairs with a link to the page via email to fhirwg@hl7.com.au
- 3) FHIRWG Variance Review
 - i) Accept variance notification via return email.
 - ii) FHIRWG co-chair will provide a week to review the variance and then will discuss the issue at the next scheduled FHIRWG meeting after that week of review.
 - iii) Provide a response to the HL7 AU Project with acceptance/rejection and advice.
- 4) FHIRWG Ballot Review
 - i) Before each ballot FHIRWG will confirm that all downstream IG profiles comply with AU Core & AU Base profiles and reuse AU Base extensions or that there is documented variance. (Notice of Intent to Ballot approval)
 - ii) At working standard/standard (trial-use/normative) publication FHIR WG will confirm that all downstream IG profiles comply with AU Core & AU Base profiles and reuse AU Base extensions or that there is documented variance. (Publishing for ballot approval)

Note: No variance is required when new or changed content is only found in the CI build version of AU Base or AU Core.

Note: Multiple variance requests for the same type of profile will be considered for inclusion into AU Core and/or AU Base.

Documenting Variance

Documenting Variance In an Implementation Guide

To document a variance in an implementation guide:

- 1) Each FHIR IG **SHALL** include an AU Variance Statement page.
- 2) State the version of the applicable AU FHIR IG Variance Requirements.
- 3) State the versions of AU Base and/or AU Core to which the Variance Statement page is related.
- 4) List all FHIR artefacts (such as profiles, extensions, and terminology) defined in the downstream implementation guide. The artefacts are listed by their title hyperlinked to its definition
- 5) Document each variance:
 - i) For every artefact listed, detail the variance. This should include the specific reasons why the AU Core profile, AU Base extension or AU Base data type profile cannot be used as is.
 - ii) If an artifact is fully compliant with the existing AU Base profiles, clearly state this compliance as a confirmation of alignment.
 - iii) When choosing not to use an AU Base extension, document the reasons why this extension does not meet the needs of your IG, including any limitations or mismatches with the supported use cases.

If a variance involves data type profiles from AU Base, outline why these profiles are not suitable, detailing the specific requirements of your use case that caused the variance.

Stating No Variance

Where you have no variance from AU Base, insert this statement:

This implementation guide has no variance (i.e. fully compliant) from AU Base FHIR Implementation Guide version [insert version].

Where you have no variance from AU Core, insert this statement:

This implementation guide has no variance (i.e. fully compliant) from AU Core FHIR Implementation Guide version [insert version].

Adding Profiles Not Related to AU Base or AU Core

For FHIR implementation guides that introduce profiles that are not represented in AU Base or AU Core Implementation Guides, the HL7 FHIRWG recommends listing all of these profiles. This will assist in identifying potential profiles for the FHIRWG to develop further.

Under the heading **Additional Profiled Resources** state

This implementation guide profiles the following resources that are not profiled in AU Base:

and/or

This implementation guide profiles the following resources that are not profiled in AU Core:

Then a list of resource types (e.g. Observation) as the parent bullet point with a list of profiles (with links) that have been added to the FHIR IG as 2nd level.

Examples of an AU Variance Statement is visible in the [HL7 AU Draft FHIR IG](#).

Defined Types of Variance

Examples of the expected types of variances on are included below:

- **Relaxed cardinality** changes where a downstream profile relaxes cardinality rules set in AU Base or AU Core profile.
 - For example, a Patient profile in a downstream IG allows multiple Medicare numbers by setting the Patient.identifier:medicare slice cardinality to 0..* where the cardinality in [AU Core Patient](#) profile is 0..1.
- **Expanding terminology** changes such as including additional codes in a predefined required binding value set or intersecting extensibly bound value sets.
 - For example, defining use, through value set binding containing the LOINC Answer code [LA18978-9](#) Never smoker for [AU Core Smoking Status](#) Observation.value binding. This expands terminology in conflict with [extensible](#) binding defined in the profile as the code SNOMED-CT [266919005](#) Lifetime non-smoker is already contained in the value set.
- **Removal of Must Support** from elements that are flagged as Must Support in AU Core profile.
 - For example, a Patient resource profile removes *Must Support* obligations from identifier , name , gender and birthDate .
- **Relaxed invariants** constraint invariant expressions are removed or relaxed.
 - For example, AU Core Patient invariant au-core-pat-01 least one patient identifier shall be valid is removed, relaxing allowed Identifier content.
- **Altered Missing and Suppressed data rules** removal or addition of missing/suppressed data requirements of AU Core.
 - For example, Missing Data requirements are modified or not specified as appropriate for missing mandatory data.
- **Adding alternative extensions** adding extensions that overlap with scope of use with AU Base/AU Core defined or referenced extensions.
 - For example, an IG specific added extension is created to represent patient gender identity overlapping with content defined in the referenced patient-genderIdentity extension.

This includes resource profiles, datatype profiles, extension and terminology artefact variance.

What is Not Considered a Variance?

Not all differences from a base specification or profile qualify as a variance. Specifically, an HL7 AU profile that meets the expectations set by its base definition in AU Base or AU Core and adds additional rules on top of these expectations to meet a specific use case.

Some examples of differences that would not be classified as a variance:

- **Constrained cardinality.**
 - For example, AllergyIntolerance.code cardinality in [AU Base AllergyIntolerance](#) profile has been changed from 0..1 in [AU Base AllergyIntolerance](#) to 1..1.
- **Increased terminology binding strength.**
 - For example, terminology binding strength on Condition.code element in [AU Core Condition](#) has been changed from [preferred](#) in [AU Base Condition](#) to [extensible](#).
- **Adding terms to extensible ValueSets** where extensibly bound terms may be added that do not duplicate existing concepts.
 - For example, through introduction of a value set binding containing the term SNOMED-CT 160616005 Trying to give up smoking for [AU Core Smoking Status](#) Observation.value binding. This expands terminology acceptable with [extensible](#) binding defined in the profile as the code SNOMED-CT [266919005](#) Lifetime non-smoker is already contained in the value set.
- **Constraining bound ValueSet** constraining out the use of terms to a restricted value set.
 - For example, through introduction of a value set binding restricting terms for the [AU Core Smoking Status](#) Observation.value binding to only two terms SNOMED-CT 77176002 Current Smoker and 8517006 Ex-smoker . This restricts the use of terms but remains conformant to AU Base/AU Core.
- **Added use of FHIR standard extensions** that are officially defined within the FHIR standard.
 - For example, introducing the use of the [mother's maiden name extension](#) with a Patient profile; this is a standard FHIR extension and does not overlap with any AU Core/AU Base defined or referenced extensions.
- **Added Must Support** to elements that are not in scope for AU Core.
 - For example, a profile on patient adds a Must Support or obligation on Patient.generalPractitioner which is not constrained in AU Base/AU Core profiles.