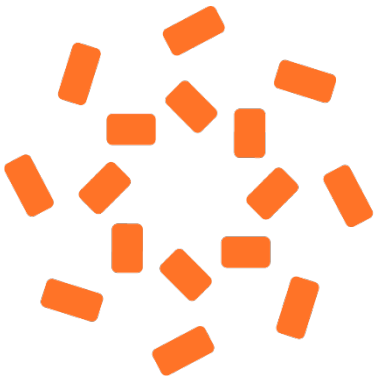

Sparked

Australian eRequesting Data for Interoperability Release 1

Version 1.0 – May 2024

Draft for Community Comment

Sparked AU FHIR Accelerator

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1. Document Information

1.1. Document Information

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Community Acknowledgement

We thank all community members, in particular, the Sparked Clinical and Technical Design Groups, the Clinical Leads and our founding members who contributed their time, expertise, passion, resources and energy to deliver the first release of the Australian eRequesting Data for Interoperability.

We look forward to the community continuing to grow and working with you all to share resources and specifications to enable the meaningful use, exchange, and reuse of clinical information.

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2. Definition of Terms

Table 1. Definition of terms.

Term / Acronym	Definition
Archetype	A reusable, computable information model based on the openEHR specification, that describes the structure of data for a specific clinical or other health-related concept.
AU Core	FHIR Implementation Guide supporting the technical
AUCDI	Australian Core Data for Interoperability
AUCDI R1	Australian Core Data for Interoperability Release 1
AUeReqDI	Australian eRequesting Data for Interoperability
AUeReqDI R1	Australian eRequesting Data for Interoperability Release 1
Clinician	Any health and care professional involved in the management/treatment/planning of care for an individual.
Data element	An individual data component within a data group
Data group	A standalone content specification about a single clinical concept which focuses on the structure of data and the relationships between data elements. It incorporates codes or value sets from a terminology system, as appropriate.
FHIR	Fast Healthcare Interoperability Resources[1] – An international standard for healthcare data exchange, published by HL7 International.
GMDN	Global Medical Device Nomenclature
HL7	Heath Level Seven[2] – a standards development organisation responsible for a range of health information exchange standards, including FHIR
IG	Implementation Guide – it is the mechanism that describes how FHIR is used to meet a specific Use Case or cases. provides detailed instructions on how to consistently implement a FHIR specification for a given use case within software applications.
LOINC	LOINC[3] is a terminology for identifying health measurements, observations, and documents.
openEHR	A specification for an electronic health record architecture, including development and governance of standardised clinical information models, known as archetypes.[4]
RANZCR	The Royal Australian and New Zealand College of Radiologists
RCPA	The Royal College of Pathologists of Australasia
RRS	Radiology Referral Set – a set of SNOMED CT-AU terminologies that can be used in the background of referrers' software systems, providing greatly enhanced interoperability and data accuracy between referrers and radiology providers.[5]
SNOMED CT-AU/SCT-AU	Systematised Nomenclature of Medicine[6] – Clinical Terms (Australian Extension). SNOMED CT-AU is Australia's national terminology[7] for clinical terms.

1 https://fhir.org/

2 https://www.hl7.org/

3 https://loinc.org/

4 https://openehr.org/

5 https://www.ranzcr.com/whats-on/news-media/ranzcr-and-adia-release-radiology-referral-set-to-enhance-interoperability-of-digital-imaging-services-for-australian-patients

6 https://www.snomed.org/

7 https://www.healthterminologies.gov.au/

Sparked	Australia's first FHIR accelerator, delivering national core clinical data for interoperability to support health information sharing.
Sparked AU Core TDG	Sparked AU Core Technical Design Group – the technical community responsible for the development of the FHIR AU Core implementation guide for Sparked.
Sparked AU eRequesting TDG	Sparked AU eRequesting Technical Design Group – the technical community responsible for the development of the FHIR eRequesting implementation guide for Sparked.
Sparked CDG	Sparked Clinical Design Group – the clinical community responsible for the clinical definition of data requirements to inform the Sparked technical design groups.
SPIA	Standardised Pathology Informatics in Australia (SPIA) Guidelines - a set of best practice recommendations for pathology requesting, reporting, and report rendering developed by the RCPA
UDI	Unique Device Identification
TGA	Therapeutic Goods Administration
Value set	An agreed, defined list of coded terms to support standardised data capture and use (often using a standardised terminology system, e.g., SNOMED CT).

3. Introduction

3.1. Purpose of the document

The purpose of this document is to outline the contents of the Australian eRequesting Data for Interoperability (AUeReqDI) Release 1 and to provide insights into its development context.

3.2. Intended audience of the document

The intended audience of this document are stakeholders interested in improving health data quality and interoperability in Australia. This includes consumers, clinical and technical subject matter experts, healthcare organisations, peak bodies, technology and software industry partner organisations, jurisdictions, and government organisations.

3.3. How to read the document

This document is organised into two main sections: Sections 4 and 5 offer background information on Sparked and the AUeReqDI, respectively, while Section 6 onwards details the specifics of the AUeReqDI.

4. About Sparked

4.1. Sparked overview

As part of 2023-24 Federal Budget funding to implement new initiatives to improve digital health information sharing, the Australian Government provided $15.7 million over two years to progress national health information sharing priorities. This funding included $9.3 million over two years for Australia's Commonwealth Scientific and Industrial Research Organisation (CSIRO) as the community coordinator in partnership with Department of Health and Aged Care (DOHAC), the Australian Digital Health Agency (Agency), HL7 Australia (HL7 AU)and the health technology industry to develop and adopt national data standards, including clinical information models, terminology value sets and Fast Healthcare Interoperability Resources (FHIR) standards.

Australia's first FHIR accelerator, '*Sparked*', was launched in August 2023 to deliver national core clinical data for interoperability to support health information sharing, the AUCDI. Over the next two years, the technical community will develop aligned FHIR standards to support the implementation of AUCDI in Australian settings.

Sparked is a community-driven collaboration comprising government, technology and software industry partners, provider organisations, clinical and industry peak bodies, healthcare practitioners, and domain experts with a common goal – to accelerate the creation and use of national FHIR standards in healthcare information exchange.

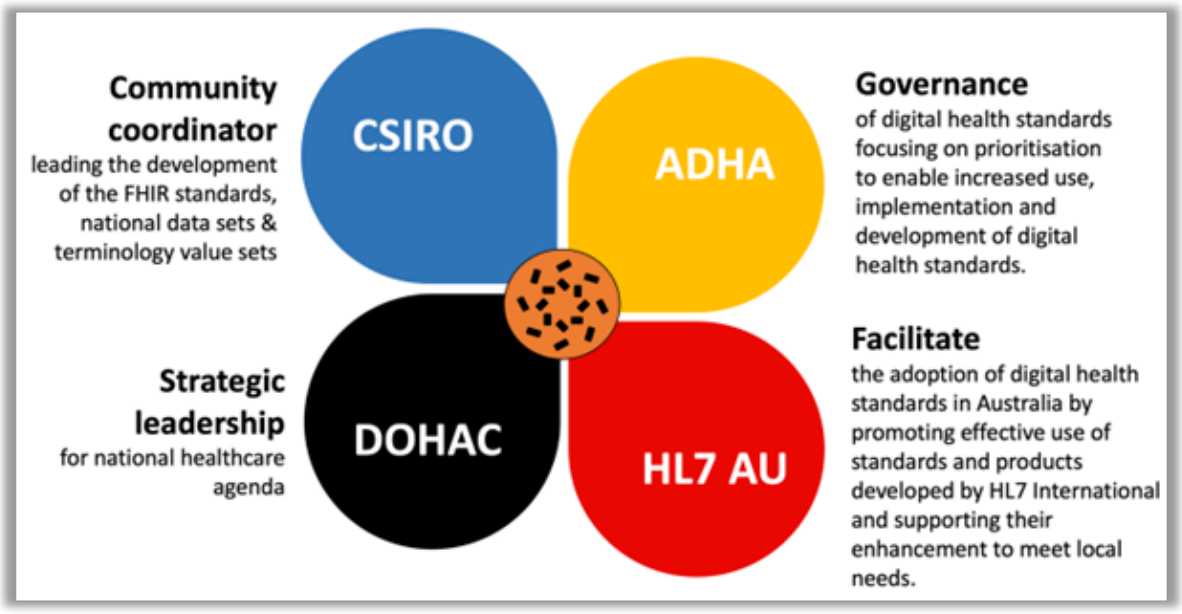

Figure 1. Sparked partnership.

4.2. Sparked deliverables

CSIRO is leading the clinical and technical community collaboration and consensus for developing the first release of AUCDI and AU Core FHIR implementation guides, which are expected to be published by mid-2025.

Sparked will create the following products during the two-year program:

- Australian Core Data for Interoperability (AUCDI),

- AU eRequesting Data for Interoperability (AUeReqDI),
- AU Core FHIR Implementation Guide,
- AU eRequesting FHIR Implementation Guide,
- Pathology request value sets in partnership with Royal College of Pathologists Australasia (RCPA),
- Radiology referral value sets in partnership with Royal Australian and New Zealand College of Radiologists (RANZCR),
- Target Operating Model for FHIR Standards development, and
- Standards development roadmap to highlight priorities and sequence going forward.

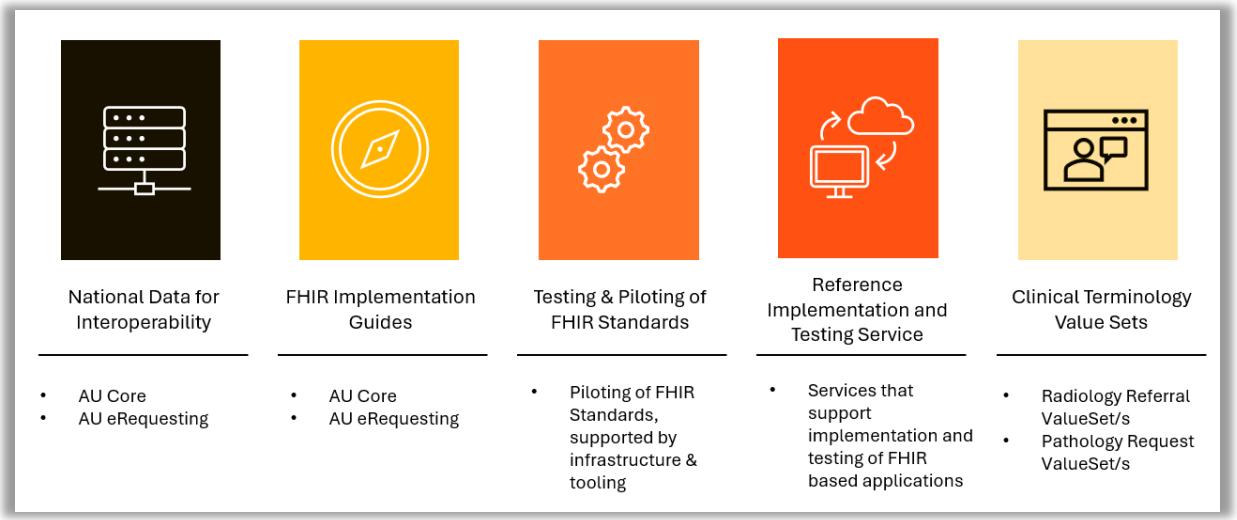

Figure 2. Sparked deliverables.

This document describes the first release (R1) of the Australian eRequesting Data for Interoperability (AUeReqDI).

4.3. Sparked community approach

Using an open and transparent standards development approach, Sparked is developing an active community of clinicians, software industry vendors, private and public healthcare organisations, and government agencies to co-design and validate nationally agreed health data standards. The Clinical Design Group (CDG) is made up of community members who are interested in defining the clinical requirements that should be in systems as a foundation for interoperability. The Technical Design Groups (TDG) are made up of community members who are interested in developing the technical artefacts to be used in implementation and exchange.

This community-centric and consensus-driven approach will ensure standards are driven by community needs and are more readily understood, adopted, and implemented. This builds on the successful approach adopted globally through US-based HL7 FHIR Accelerators such as the Argonaut project.

To participate in our Sparked community – visit our registration page at sparked.csiro.au.

5. About Australian eRequesting Data for Interoperability

5.1. Background

The Australian health IT landscape has isolated and disjointed health information systems, often confined within single clinics or organisations. This fragmentation occurs across primary, acute, and tertiary care sectors. Any consistency in health data structure is generally limited to systems provided by the same technology industry partner, leading to a lack of alignment between different clinical systems.

This situation poses significant challenges in sharing and exchanging information across systems, impacting the development and implementation of value-added services like clinical decision support. The local and often proprietary development of these systems has necessitated the mapping or transformation of health data between systems, increasing the risk of errors from transcribing and mapping, and potential loss of critical clinical data.

Pathology and medical imaging services play a large role in clinical diagnosis. While there are siloed examples of electronic requests (eRequests) in the Australian health ecosystem, a large proportion of requests, particularly for pathology and medical imaging services, are managed through paper forms.

This manual process leads to a fractured approach, hindering service requesters and providers from efficiently tracking workflow and fulfillment status, and preventing consumers from having awareness of their care pathways. Additionally, the software systems used by pathology and medical imaging providers vary in data structure and functionality, resulting in a variety of ways for requesters to receive test results.

This lack of standardisation further contributes to the fragmentation within the sector. Consequently, the overall landscape is disjointed and does not readily support the principle of consumer choice. Starting with medical imaging and pathology test requesting when developing an electronic requesting (eRequesting) FHIR standard enables the community to focus on what it means to support a person-centred view of requesting. The following scenarios will be supported by a national eRequesting approach:

1. Healthcare provider discusses and agrees with consumer the recommended provider with a request generated to that provider
2. Request generated, and consumer can choose a suitable provider
3. Healthcare provider discusses and agrees with consumer a recommended provider, request generated and later the consumer chooses an alternative to the recommended provider

The Australian Government's share-by-default agenda is seeking to support the mandated upload of test results. However, standardised data foundations are required to support a future end-to-end 'request to result' workflow for test requesting based on atomic data moving throughout the Australian healthcare ecosystem.

Commencing with a key focus on the development of pathology and medical imaging requesting data sets, provides an opportunity to explore what these foundations can mean for exchanging relevant patient summaries, optimising test requesting practices, and providing consumer-focused views of health information that can support patient choice.

5.2. Role and purpose of AUeReqDI

The AUeReqDI builds upon and complements the foundational Australian Core Data for Interoperability (AUCDI) and focuses on the specific use case of eRequesting. The AUCDI Release 1 document can be found on the Sparked website.
Just like the AUCDI, the AUeReqDI is intentionally agnostic of:

- Any single clinical system vendor, while still being informed by functionality and data available in current clinical systems;
- Any single current referrer-consumer-provider workflow, while still being informed by the requirements to support directed and undirected workflows, and
- Any single technical implementation or exchange approach, while providing the clinical data requirements for developing the FHIR AU eRequesting Implementation Guide (IG).

The AUeReqDI:

- Supports a broad approach to eRequesting within the Australian health context;
- Describes and defines a set of data groups, each comprising of one or more data elements, as a common language foundation that allows systems to exchange semantically accurate data for eRequests;
- Incorporates and builds upon existing standards and prior work from national and international programs and initiatives including the AUCDI, the Royal College of Pathologists of Australasia (RCPA)'s Pathology Information, Terminology and Units Standardisation (PITUS) framework and the Royal Australian New Zealand College of Radiology (RANZCR's) Radiology Referral Set; and
- Is a living artefact that will evolve in future iterations to support additional request use cases – adding breadth by including new clinical data groups and depth by expanding with further detail. Additional request use cases to be considered include eReferrals and Service Requests.

AUeReqDI R1 is focused on electronic pathology and medical imaging requests in primary and community-based care provision.

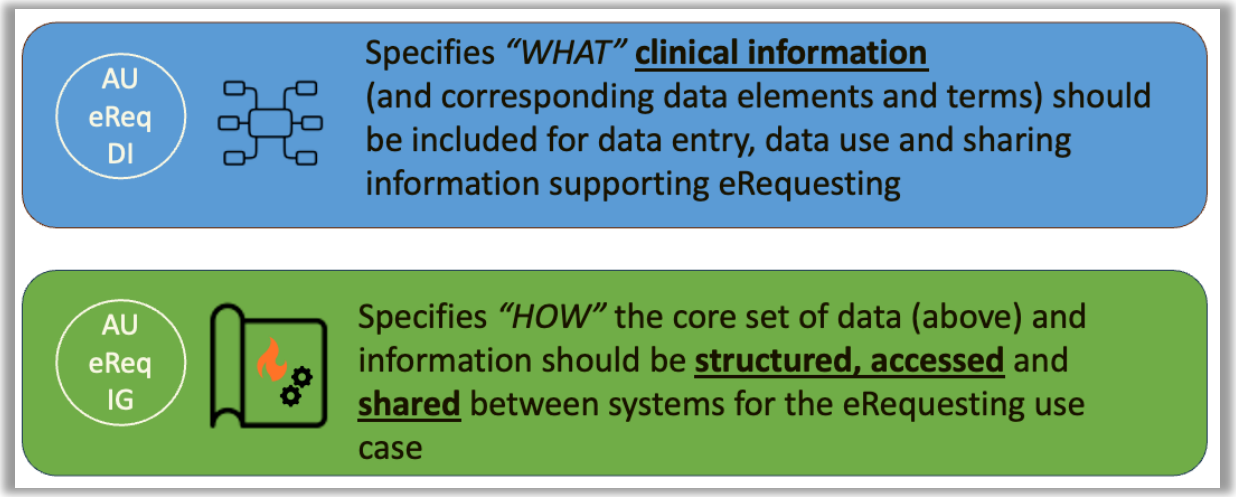

Figure 3. Focus points of AU eRequesting DI for the Sparked Clinical Design Group and the Technical Design Group.

5.3. AUeReqDI data groups

The AUeReqDI data groups consist of two components – clinical information models and terminologies. For more explanation on these components, see the Sparked website and the HL7 AU Sparked FHIR Accelerator Confluence site.

5.4. Relationship between the AUCDI, AUeReqDI and their FHIR implementation guides

The AUCDI established the foundation for an evolving ecosystem of agreed data groups, purpose-built to reflect clinical requirements to support the provision of care, exchange, aggregation of data for analysis, and clinical decision support. AUCDI R1 focuses on “the core of the core” common data elements, meaning the absolute minimum data required to support standardised clinical information capture at the point of care as well as enable the safe and meaningful exchange of information to other care providers. Future releases will build upon this foundation adding breadth and depth to the data groups developed in R1.

It is intended that the AUCDI inform and be reused within use case specific data models, where appropriate, for example, this AUeReqDI specification. In turn, during the process of clinical requirements gathering for the use case specific examples, the CDG may identify data groups which have significant potential for reuse in other contexts. For the AUeReqDI, the CDG has identified items around pregnancy status, menstrual status, and gestational information as future data groups for inclusion in AUCDI. These items have been placed as high priority proposals for the next release of AUCDI.

The developing AU Core FHIR IG has been based on the AUCDI, transforming the logical models defined as AUCDI data groups into equivalent FHIR technical artefacts. The Sparked HL7 AU Core Technical Design Group (AU Core TDG) has been tasked to co-design the AU Core FHIR IG under the governance framework of the HL7 AU Australian FHIR Management Framework.

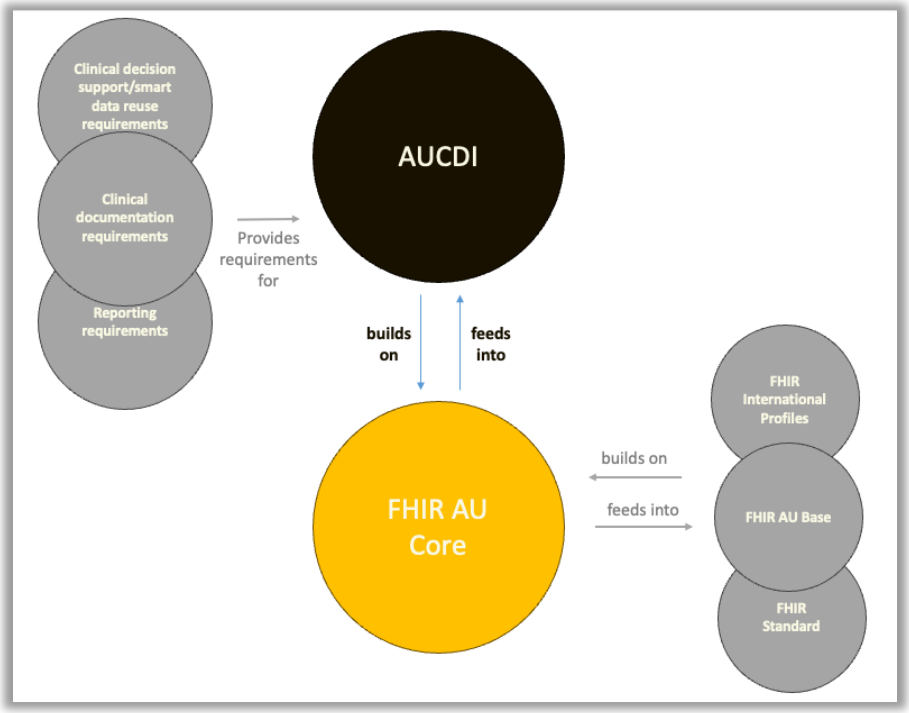

Figure 4. Relationship between AUCDI and FHIR AU Core.

AUeReqDI defines the data requirements for eRequesting, incorporating relevant data groups from AUCDI and contains additional data groups that are required to facilitate the exchange of a pathology test and medical imaging request.
Like AU Core FHIR IG referencing the AUCDI, the AU eRequesting FHIR IG is being developed to reference the AUeReqDI, representing each of the AUeReqDI data groups as FHIR artefacts.

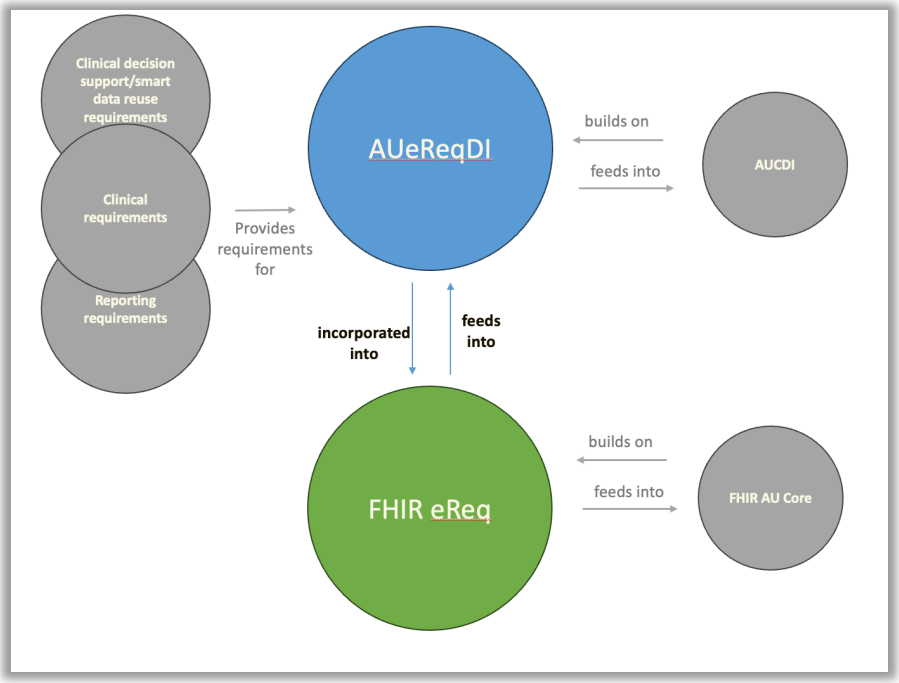

Figure 5. Relationship between AueReqDI and FHIR eReq.

5.5. Understanding the scope of AUeReqDI

The AUeReqDI focuses on data required to support eRequesting. It incorporates data elements from the AUCDI. The AUeReqDI R1 focuses on community-based pathology test and medical imaging requests, as the initial foundation from which we can build additional eRequesting use cases, including eReferral.

The initial scope drivers for AUeReqDI R1 are restricted to pathology test and medical imaging requesting by the community, including primary care, specialist care, and allied health, and hospital outpatient departments. These requests will be available to all public and private providers, both local or interstate.

5.5.1. Scope of AUeReqDI R1

The R1 scope of AUeReqDI includes:

- Service request;
- Medical imaging request;
- Pathology test request;
- Implanted medical device summary;
- Adverse reaction risk summary (from AUCDI);
- Problem/diagnosis summary (from AUCDI); and
- Sex and gender (from AUCDI).

The focus of the AUeReqDI is the representation of the clinical content required for each of the data groups. System information, or system-derived information, is deliberately excluded from the scope of AUeReqDI unless it is also of clinically significant and requires clinical validation. Information

related to technical aspects of recording data (such as author and record date/timestamp) will be managed in the technical implementation specifications (e.g., FHIR IG).

The scope of AUeReqDI R1 does not include:

- Administrative, workflow and billing information;
- Higher-level technical concepts such as security, access, privacy, and consent;
- Non-clinical recording context such as author, location, patient (including date of birth); or
- MBS workflow items like self-determined and rule 3 exemptions.

While these topics are not addressed in AUeReqDI, it is recognised that these aspects need to be considered for implementation including legislation and policy.

AUeReqDI R1 also does not address user interface or form implementation requirements. These have been left to the responsibility of other specifications such as the AU eRequesting FHIR IG.

During the development of the AUeReqDI R1, several elements were identified as variably collected in electronic and paper pathology and imaging request forms. These were discussed by the Sparked CDG which decided to exclude them from AUeReqDI R1 for both pathology test and medical imaging requests. However, these elements are to be prioritised for inclusion in future releases of AUCDI and will be modelled for persistence. These data elements that have been placed in the AUCDI backlog are:

- Current pregnancy status;
- Estimated Date of Delivery;
- Last menstrual period (LMP); and
- Post-menopausal status (Menstruation summary).

It is anticipated that once these are agreed in AUCDI, they can be revisited and potentially included in future eRequesting enhancements.

5.6. Design of AUeReqDI

The AUeReqDI has been developed in collaboration with the community and is focused on data required for pathology test requests and medical imaging requests. There was also interest in building a generic service request data group (see section 1.11) which underpins both these request types and can be expanded on in the future as the data model matures.

In order to support maximum reuse and leveraging previous investment, the data model has been informed by other key local and international initiatives and programs such as previous Australian specifications and international standards. This includes HL7 FHIR and openEHR.

The core design principles initially developed to assist the development of AUCDI and to allow prioritisation by the Sparked team and the community, were used for AUeReqDI. Table 2 sets out the design principles used and how the clinical information model has been aligned.

Table 2. Core design principles.

Design Principles	Alignment
Reduce duplication - single entry, single development (multiple use and reuse)	Data collected in a structured and coded manner enables data to be reused for clinical decision support, population of summary information, forms, and letters, and for secondary uses like population health analytics.
Supports person-centred care - driven by a clinical quality and safety use case	Using standardised coded structured data for health information will support good clinical care, unambiguous transfer of clinical information and clinical decision support. This allows delivery of the right care to the right person at the right time.
No data for data's sake	Every proposed data element has a practical purpose.
Driven by clinical data use not secondary data use needs	Data models are intentionally minimal to start with, incorporating the minimum data elements to support safe and effective care, rather than collecting a comprehensive data set. In future releases, new data group concepts will be added and the level of detail of existing data groups will be increased to support clinical priorities and data requirements.
Supports best practice care, clinical guidelines, and clinician workflow	The use of standardised, coded, structured data for clinical information will support best practice clinical care, clinical decision support including guidelines, and streamlined clinician workflow.
Systems can support now or with minimal effort, supporting a strategic roadmap with an agile iterative process	Most systems can support the minimal model proposed in R1. In future releases, the R1 data groups may be enhanced or additional data groups added to evolve towards a strategic roadmap with an agile iterative process.
Alignment with national health data standards and initiatives	Reference national standards and initiatives, such as: • SNOMED CT-AU and the Australian Medicines Terminology (AMT) • My Health Record • Royal College of Pathologists Australasia (RCPA)'s Standards for Pathology Informatics in Australia (SPIA) • The Royal Australian New Zealand College of Radiology (RANZCR)'s Radiology Referral Set (RRS) • The Royal Australian College of General Practitioners "Minimum requirements for general practice clinical information systems to improve usability"

Alignment with international standards and initiatives	Reference international standards and initiatives, such as:
	• Information models:
	  ○ FHIR Resources
	  ○ openEHR archetypes

Involve and consider all healthcare domains and care modalities	The data groups are agnostic of any specific use case and needs to support usage in all healthcare domains and across healthcare modalities. Stakeholders engaged include primary, acute, and tertiary care and specialised domains and professions such as aged care and allied health.

6. How to read the AUeReqDI

Each data group represents one or more data elements about a single, discrete concept. The sections below (6.1.1 through to 6.1.1.3) provide examples of how the data groups and elements are represented in the AUeReqDI.

6.1.1. <Data group name> (for example Service request)

6.1.1.1. Data group context

Every data group contains a table that explains the general attributes, or metadata, of the data group as a whole, comprising:

Table 3. Example context.

Clinical description	A definition or description of the data group concept.
Purpose	An explanation of the reason and objective for the data group.
Representation	A description of how a clinician might anticipate the data might be recorded within a clinical information system.
Alias(es)	One or more synonyms for the name of the data group
Considerations for use	A description of factors that may impact the implementation or use of this data group within a clinical system.
Misuse	Guidance for implementers about possible scenarios or use cases in which this specific data group (as a whole) is not recommended, incorrect or inappropriate. Where applicable, a suitable alternative data group will be suggested.

In addition, every data group contains an introductory narrative framing the concept by highlighting design, use, and implementation considerations.

Note the two exceptions, ‘Measurements and Vital signs’ and ‘Biomarkers’ where a set of data groups have been grouped into a collection of similar concepts, framed by a shared context.

6.1.1.2. Concept representation

Each data group contains an image of a mind map showing all AUeReqDI R1 data elements.

In the mind maps, each data group is visually separated into distinct sections, with variations in representation depending on the specific type of information model required. This approach to information modelling is used by openEHR to support the different data structures required for various modelling requirements.

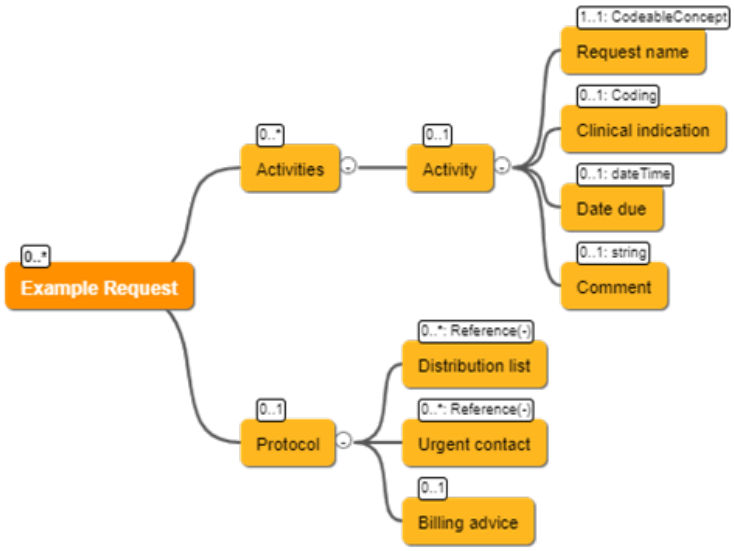

Figure 6. Example request concept representation mind map.

For the Service Request data group family, which includes Service Request, Medical Imaging Request, and Pathology Test Request, there is a standard structure that applies to any order or instruction. This structure consists of two main types of data:

- 'Activities' – This section consists of a repeatable set of one or more 'Activity' data groupings, each containing all the clinical data elements necessary for the request.
- 'Protocol' – Each order or instruction consists of a single Protocol that applies to all 'Activity' groupings, and contains the non-clinical information needed to execute the order. In the Service request context, each data group contains currently addressing details, urgent contact information, billing recommendations, and a distribution list for handling responses or results.

The Service Request family is specifically structured to support the ordering of more than one 'Activity' group as part of a single request, accompanied by a single Protocol. In this context of eRequesting, this structure allows a single request, comprising multiple fully specified pathology or imaging tests, to be sent to a single laboratory or imaging provider.

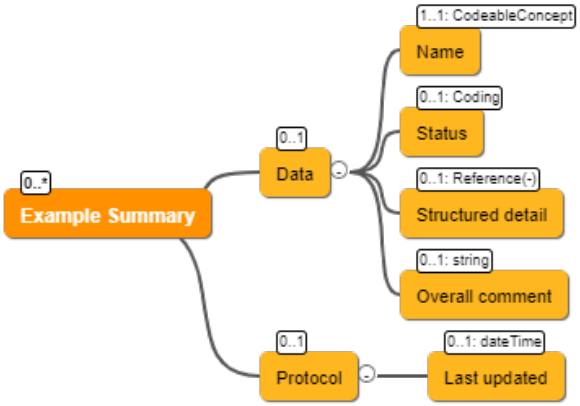

Figure 7. Example summary concept representation mind map.

For the Implanted Medical Device Summary data group and included AUCDI data groups, there is a slightly different structure that applies to information models that represent a summary or overview of a clinical concept. Each summary data group is intended to be recorded once within a health

record and updated, as necessary, over time. This structure also consists of two main types of data, with only one instance of each allowed:

- 'Data' – This section consists of all the clinical data elements relevant for the summary.
- 'Protocol' – This section consists of the non-clinical information. In most of the current data groups, this has been limited to a data element for 'Last updated', though future releases of AUeReqDI or AUCDI will likely require additional data.

6.1.1.3. Information model

Every data group also contains a table that explains the specific attributes for each data element comprising:

Table 4. Example information model.

Data element name	Description	A description or definition of the name of the data element
	Element occurrence	Optional or mandatory: single occurrence only or allows more than one occurrence, for example, to record more than one coded value
	Data type	An indication of the type of data allowed to be captured; a choice of data type is allowed if more than one data type is noted. Definitions of the data types can be found in **Error! Reference source not found.**.
	Proposed code system/value set	For CodeableConcept data types, a proposed value set will be recommended or proposed.
	Examples	Examples of acceptable data entries may be provided to clarify what information could be recorded in this data element.
	Alias(es)	A list of synonyms for the name of the data element.
	Considerations	A description of factors that may impact the implementation or use of this data element within a clinical system.

Table 5. Explanation of data types.

Data type[8]	Description
String	A sequence of Unicode characters, used to record free text as a narrative.
Coding	A direct reference to a code defined by a code system. The code may be part of a terminology value set.

8 Definition of data types used in this document, referenced from https://build.fhir.org/datatypes.html#2.1.28.0

CodeableConcept	A value that is usually supplied by providing a reference to one or more terminologies or ontologies but may also be defined by the provision of text.
Reference	A reference from one FHIR resource to another
DateTime	A date, date-time or partial date (e.g. just year or year + month) as used in human communication.
Timing	A timing schedule that specifies an event that may occur multiple times.

7. AUeReqDI at a glance

The scope of the AUeReqDI library of data groups (as clinical information models) is focused on pathology test and medical imaging request concepts, comprising the data elements confirmed by clinicians as 'core' for the eRequesting use case. The library is composed of the data groups and their component elements, including reusable data groups and component elements from AUCDI shown in Figure 8.

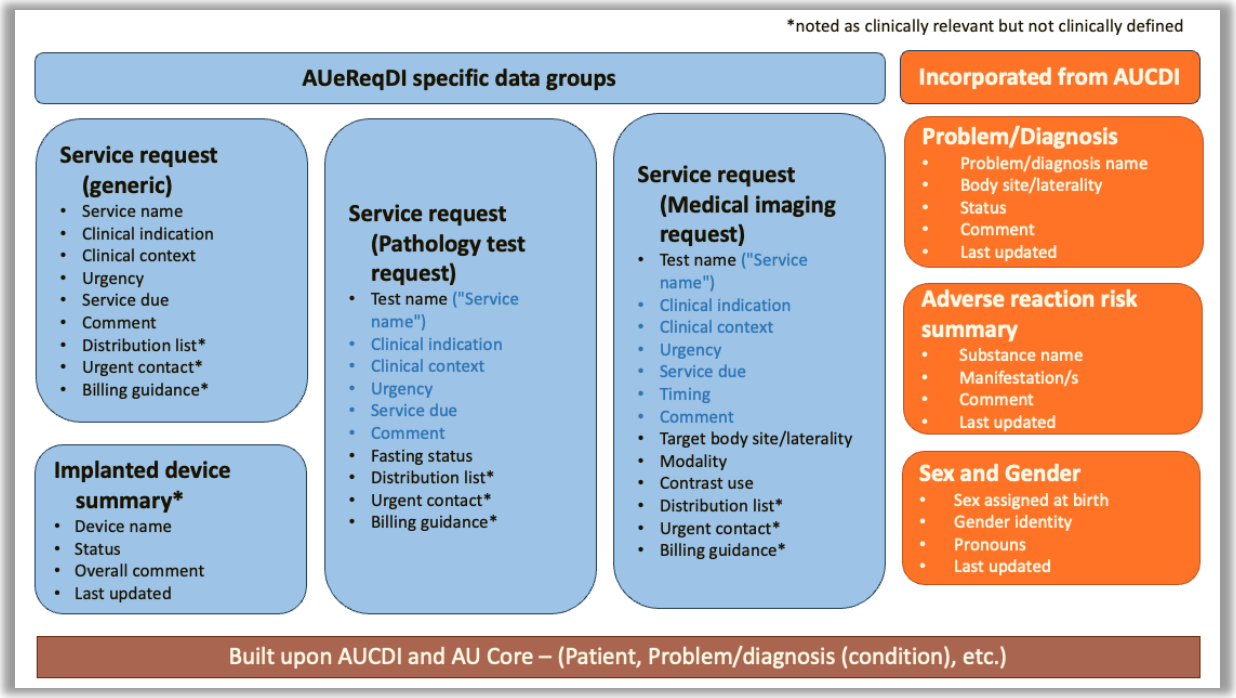

Figure 8. AUeReqDI R1 scope.

8. AUeReqDI R1 Draft for Comment Library

The clinical content scope and granularity in AUeReqDI R1 are primarily driven and approved by clinicians and informaticians to ensure utility and clinical safety, focusing on data groups necessary for medical imaging requests and pathology test requests. Additionally, the selection of most data elements has been guided by an underlying principle of ensuring alignment with existing data structures available in clinical systems. Any new data elements proposed have been carefully chosen for their clinical significance or safety purposes.

8.1. Service request AUeReqDI

8.1.1. Data group context

Table 6. Service Request - Data group context.

Concept description	Request for a health-related service or activity to be delivered by a clinician, organisation**,** or agency.
Purpose	A generic framework for a request for a health-related service or activity to be delivered by a clinician, organisation, or agency.
Representation	Record one instance of this data group for each request. Each request contains: • one or more 'Activity' groupings that describe the clinical data elements related to the request. Each 'Activity' grouping represents a separate test; and • a single Protocol grouping that describes the non-clinical data elements that relate to all 'Activity' groups in the request.
Alias(es)	Referral
Considerations for use	Use to record a request for a health-related service or activity to be delivered by a clinician, organisation, or agency. This generic data group has been designed as a framework that can be used as the basis for a wide range of requests: • a request from one clinician, organisation or agency to another clinician, organisation, or agency for a health-related service. For example: a referral to a specialist clinician for treatment or a second clinical opinion; transfer of care to an emergency department; four hourly vital signs monitoring; diagnostic investigations; and provision of home services from a municipal council; or • a request for a follow-up service to be scheduled for the same clinician, organisation, or agency. For example: an outpatient appointment for review in 6 weeks. It can be used to represent a request for one or more services, in one of two ways:

	• If multiple services need to be requested and the information recorded in the 'protocol' (for example 'Receiver') is the same - use a separate 'Activity' instance within this data group for each request. • If multiple services need to be requested and the information recorded in the 'Protocol' (for example 'Receiver') is different - use a separate instance of this data group for each request. Implementation examples: • Consider a clinician referring a patient to an Endocrinologist for diabetes treatment advice - the 'Service name will be 'Referral'; the 'Clinical indication' will be 'Type 1 Diabetes Mellitus'; and the 'Clinical context' may contain a narrative about the duration and previous management of their diabetes, current treatment, plus recent weight gain and information about the recent death of their spouse; current treatment. • Consider a clinician ordering diabetes education - the 'Service name' will be 'Diabetes education'; the 'Clinical indication' will be 'Type 1 Diabetes Mellitus'; and the 'Clinical context' may be 'Newly diagnosed diabetic for initial education and instruction in insulin administration'. • Consider a clinician ordering a meal home-delivery service from the municipal council - the 'Service name' may be 'Meals on wheels program'; the 'Clinical indication' may be 'Emphysema' and 'General frailty. • Consider a clinician ordering a follow-up appointment in 6 weeks - the 'Service name' will be 'Follow-up appointment'. If they enter '6 weeks' as the proposed timing for the appointment in the User Interface, the clinical system will record the date six weeks from today in the 'Service due' data element. • Consider a clinician ordering an ultrasound of the left leg to exclude a deep venous thrombosis – it would be more appropriate to use the specific 'Medical imaging request' data group. • Consider a clinician ordering a recurring blood test, such as an INR - – it would be more appropriate to use the specific 'Pathology test request' data group.
References	• Service request, Published archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 May 09]. Available from: https://ckm.openehr.org/ckm/archetypes/1013.1.614

	• ServiceRequest, HL7 FHIR Resource [Internet]. Health Level Seven International; [cited: 2024 May 09]. Available from: https://hl7.org/fhir/servicerequest.html

The 'Service request' data group is a generic, foundational framework intended for any service request or referral for a health-related service or activity which will be fulfilled by a clinician, organisation, or agency. It comprises the common data elements that form the basis of most of the common types of requests used in healthcare. As a result, it has a broad range of use, for both clinical and social care purposes.

In the context of eRequesting, this generic data group has been specialised for two very specific purposes - to request a pathology test and a medical imaging test. The underlying data elements for all three data groups, Service request and the two specialisations is in common. It is anticipated that additional specialisations may be added to AUCDI in the same way as part of future releases.

8.1.2. Concept representation

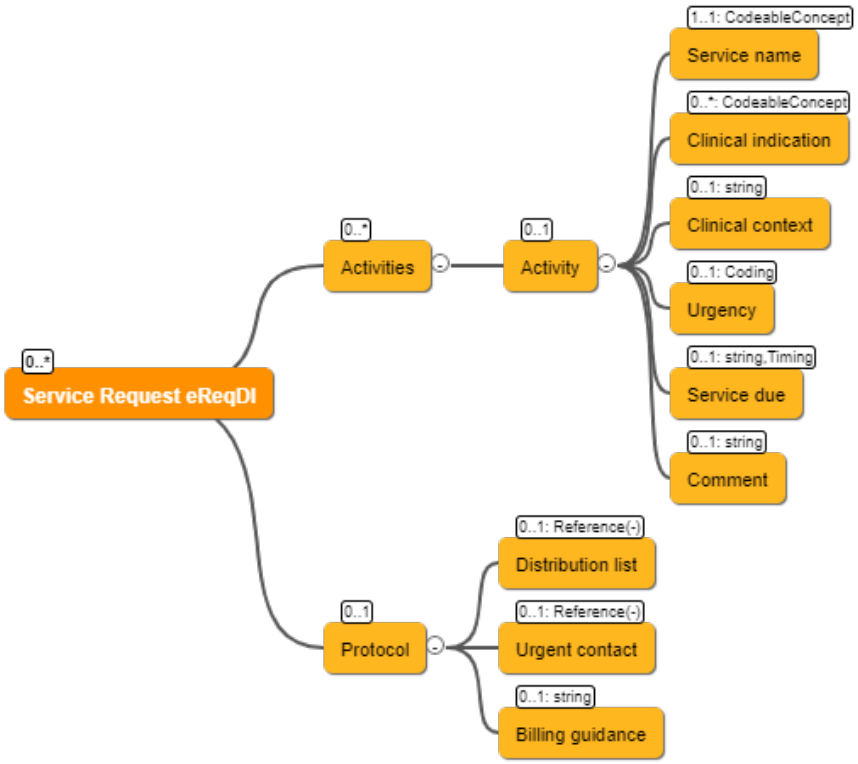

Figure 9. Service request - Concept representation.

8.1.3. Information model

Table 7. Service Request - Information model.

Data elements		
Service name	Description	The name of the service requested.
	Occurrence	Mandatory, single occurrence
	Data type	CodeableConcept
	Proposed code system / value set	The Procedure value set published by the NCTS is a value set containing a broad range of procedures and clinical interventions that can be associated with a person.
	Examples	SNOMED CT-AU: • 183681001 |Arrange Meals on Wheels | • 390906007 | Follow up encounter| • 3457005 | Patient referral |
	Alias(es)	N/A
	Considerations	Coding of the 'Service name' with a terminology is strongly recommended, if available. Free text entry should only be permitted if no appropriate coded value is available.
Clinical indication	Description	The symptom, sign or diagnosis that prompts the need for the requested test.
	Occurrence	Optional, multiple occurrences
	Data type	CodeableConcept
	Proposed code system / value set	The Reason for Request value set published by the NCTS is a broad reference set including clinical findings, procedures, situation with explicit context, and event concepts.
	Examples	SNOMED CT-AU: • 46635009 | Type 1 diabetes mellitus | • 87433001 | Pulmonary emphysema | • 418399005 | Motor vehicle accident | • 275109007 | FH: Bowel cancer |
	Alias(es)	Reason for service
	Considerations	Coding of the 'Clinical indication' with a terminology is recommended, if available. This data element allows multiple occurrences to enable the user to record more than one response if required. Free text entry should only be permitted if no appropriate coded value is available.
Clinical context	Description	Narrative information about the individual and their situation, providing relevant background for the request.
	Occurrence	Optional, single occurrence
	Data type	String
	Alias(es)	N/A
	Considerations	Also known as 'Clinical notes', although this name has intentionally been avoided to clearly differentiate from the 'Notes' attribute in many FHIR resources.
Urgency	Description	The urgency of the request for service.

	Occurrence	Optional, single occurrence
	Data type	Coding
	Proposed code system / value set	A value set is to be developed. Proposed values: • Emergency [The request requires immediate attention.] • Urgent [The request requires prioritised attention.] • Routine [The request does not require prioritised scheduling.]
	Alias(es)	N/A
	Considerations	Specific definitions of emergency and urgent will vary between clinical contexts, clinical systems, and the nature of the request itself, so have not been defined in this data group. If more precise timing is required, use the 'Service due' data element.
Service due	Description	The timing for provision of the requested service.
	Occurrence	Optional, single occurrence
	Data type	Timing or String
	Alias(es)	N/A
	Considerations	This data element enables the recording of the intended timing for the service in various formats, including precise timing details such as specific dates and times, or through textual descriptors like 'Next available'. Additionally, the Timing data type is designed to accommodate more complex timing scenarios if needed.
Comment	Description	Additional narrative about the service request not captured in other fields.
	Occurrence	Optional, single occurrence
	Data type	String
	Alias(es)	N/A
Distribution list	Description	Contact details of one or more clinicians, organisations or agencies that need to be informed of the outcome of this service request.
	Occurrence	Optional, single occurrence
	Data type	Reference
	Alias(es)	Cc list
	Considerations	For example: specialists or allied health providers who need to be notified of test results or available reports.
Urgent contact	Description	Contact details about one or more designated contact people or organisations and their preferred method of communication for urgent or emergency notifications concerning this request.
	Occurrence	Optional, single occurrence
	Data type	Reference
	Alias(es)	N/A

	Considerations	For example: if the outcome of the request requires an urgent or emergency response by the requester or requesting organisation.
Billing guidance	Description	A recommendation from the requester to the receiver regarding the payment method for the service.
	Occurrence	Optional, single occurrence
	Data type	String
	Alias(es)	N/A
	Considerations	For example: 'Private'; 'Government insurance scheme'; or 'Private insurance'.

8.1.1. For future consideration

The FHIR 'ServiceRequest' resource and the published openEHR 'Service request' archetype are mature information models that have been used globally in a broad range of implementations over many years. They form the basis for this initial AUeReqDI R1 data group and provide guidance for potential future augmentation.

The mind map below demonstrates a proposed roadmap for the 'Service request' data group, based on the openEHR archetype. The nodes in yellow represent data elements already included in AUeReqDI R1; while the nodes in grey represent potential future data elements.

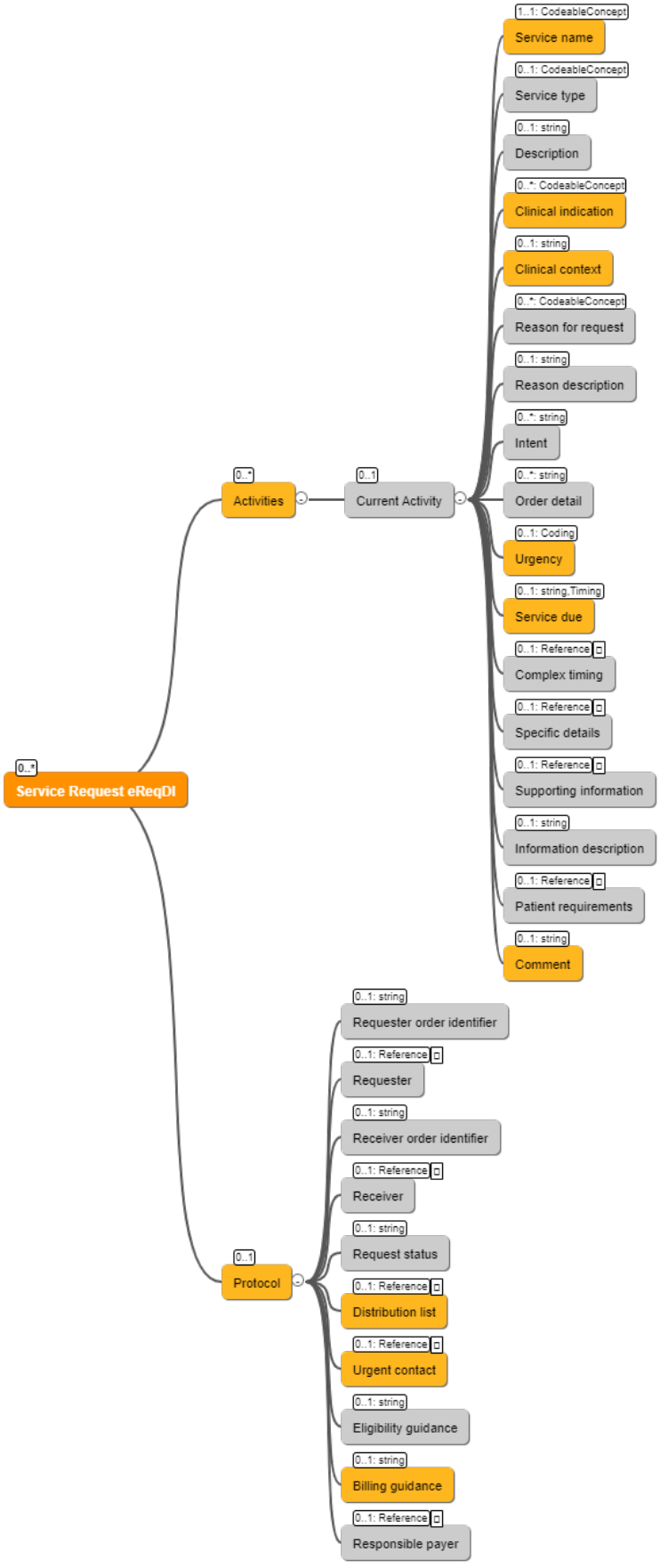

Figure 10. Service request - proposed roadmap.

8.2. Medical imaging request AUeReqDI

8.2.1. Data group context

Table 8. Medical imaging request - Data group context.

Concept description	An order or referral for a medical or diagnostic imaging service.
Purpose	To record an order or referral for a medical imaging test.
Representation	Record one instance of this data group for each request. Each request contains: • one or more 'Activity' groupings that describe the clinical data elements related to the request. Each 'Activity' grouping represents a separate test; and • a single 'Protocol' grouping that describes the non-clinical data elements that relate to all 'Activity' groups in the request.
Alias(es)	Imaging request, Diagnostic imaging request, Radiology request, Imaging examination request
Considerations for use	Use to record an order or referral for a medical imaging test. This data group can be used to represent a request for one or more services, in one of two ways: • If multiple services need to be requested and the information recorded in the 'Protocol' (for example 'Receiver') is the same – use a separate 'Activity' instance within this data group for each request. • If multiple services need to be requested and the information recorded in the 'Protocol' (for example 'Receiver') is different – use a separate instance of this data group for each request. Implementation examples: • Consider a clinician ordering an ultrasound of the left leg to exclude a deep venous thrombosis – the 'Service name' will be 'Ultrasound left lower leg'; the 'Clinical indication' may be 'swollen left ankle'; and the 'Clinical context' may be 'gradually increasing pitting oedema to mid-calf in the left leg over the past 3 days'. The 'Service name' may be a precoordinated term, which can be deconstructed and stored in its' component data elements – 'Modality' as 'Ultrasound'; 'Target body site' as 'Left lower leg'. • Consider a clinician ordering a barium enema – the 'Service name' will be 'Barium enema'; and the 'Clinical indication' may be 'Ulcerative colitis'.

	• A clinical system user interface may provide the clinician with separate data elements for 'Modality' and 'Target body site', each with searchable specific value sets, and concatenate them into the 'Test name' field.
References	• Imaging examination request, Draft archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 May 09]. Available from: https://ckm.openehr.org/ckm/archetypes/1013.1.7240 • Diagnostic Request, HL7 AU Base FHIR Profile [Internet]. Health Level Seven Australia; [cited: 2024 May 09]. Available from: https://hl7.org.au/fhir/4.1.1-preview/StructureDefinition-au-diagnosticrequest.html

This data group is derived from the generic Service request data group, following modelling specialisation principles. It is consistent with the 'Service request' apart from two types of changes:

- Specialisation of 'Service name' to the more specific and relevant 'Test name'; and
- Addition of 'Modality', 'Target body site' and 'Contrast use' data elements.

8.2.2. Concept representation

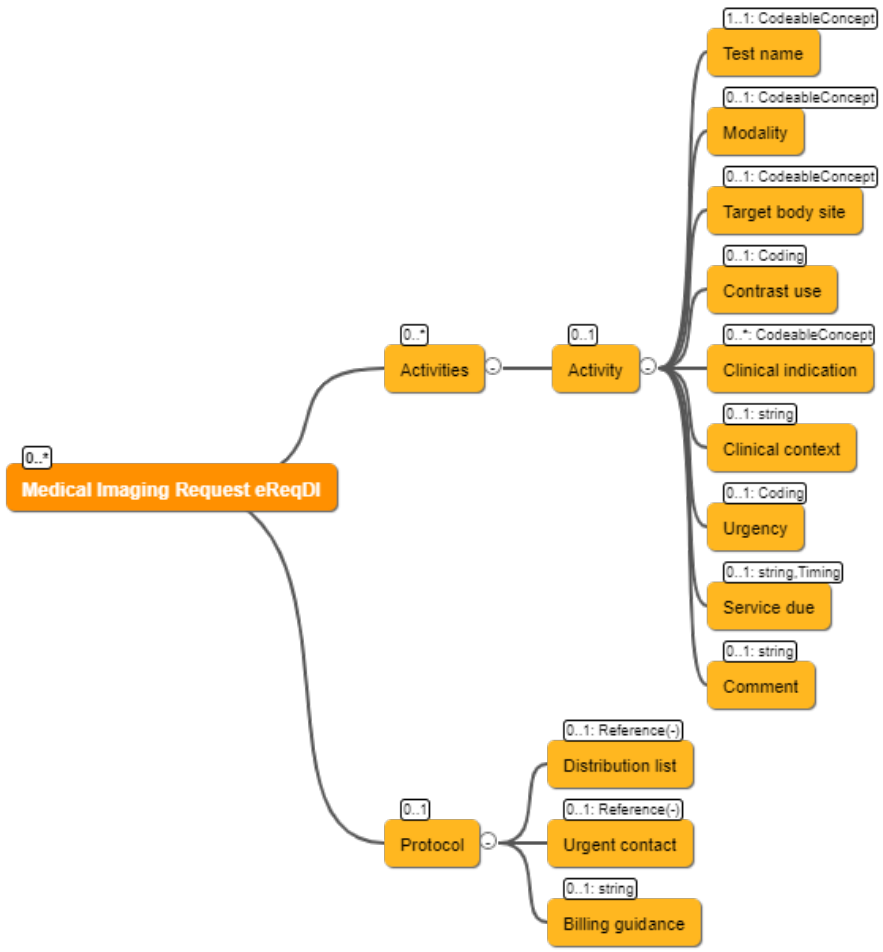

Figure 11. Medical imaging request - Concept representation.

8.2.3. Information model

Table 9. Medical imaging request - Information model.

Data elements		
Test name	Description	The name of the test requested.
	Occurrence	Mandatory, single occurrence
	Data type	CodeableConcept
	Recommended code system/value set	Value sets are currently in development to support the implementation of the Radiology Referral Sets (RRS) developed by the Royal Australian and New Zealand College of Radiologists (RANZCR) and additional content in line with the national clinical terminology approach
	Examples	TBC
	Alias(es)	N/A
	Considerations	Coding of the 'Test name' with a terminology is strongly recommended, if available. Free text entry should only be permitted if no appropriate coded value is available.
Modality	Description	The type of device, process or method used to acquire or produce the image or data.
	Occurrence	Optional, single occurrence
	Data type	CodeableConcept
	Recommended code system/value set	Value sets are currently in development to support the implementation of the Radiology Referral Sets (RRS) developed by the Royal Australian and New Zealand College of Radiologists (RANZCR) and additional content in line with the national clinical terminology approach
	Examples	TBC
	Alias(es)	N/A
	Considerations	Coding of the 'Modality' with a terminology is recommended, if available. For example: 'X-Ray'; 'Ultrasound'; 'Medical Resonance Imaging (MRI)'; 'Positron Emission Tomography (PET)'; 'Mammography'; 'Fluoroscopy'; or 'Digital Subtraction Angiography (DSA)'. Free text entry should only be permitted if no appropriate coded value is available.
Target body site	Description	Identification of the area of the body targeted for the imaging test, including laterality.
	Occurrence	Optional, single occurrence
	Data type	CodeableConcept
	Recommended code system/value set	Value sets are currently in development to support the implementation of the Radiology Referral Sets (RRS) developed by the Royal Australian and New Zealand College of Radiologists (RANZCR) and additional content in line with the national clinical terminology approach
	Examples	TBC
	Alias(es)	N/A
	Considerations	Coding of the 'Target body site' with a terminology is desirable, including precoordinated terms, if available. This data element allows multiple occurrences to enable the user to record more than one body site for the selected modality, if required. For example: 'heart'; 'both lungs';

		'right breast'; and 'left upper limb'; both 'right ankle' and 'right knee'. Free text entry should only be permitted if no appropriate coded value is available.
Contrast use	Description	Recommendation related to use of contrast as a component of the imaging test.
	Occurrence	Optional, single occurrence
	Data type	Coding
	Recommended code system/value set	A value set is to be developed. Proposed values: • With contrast [The test should be carried out using contrast.] • Without contrast [The test should be carried out with NO contrast.]
	Alias(es)	N/A
	Considerations	For example: a clinician may need to specify whether contrast is required in this specific clinical scenario, especially in situations where contrast use is optional and not typically administered; or a clinician may need to clearly state that contrast should be avoided, to highlight a known risk of adverse reaction to the contrast, which will be fully detailed elsewhere in the health record or in supplementary information accompanying the request.
Clinical indication	Description	The symptom, sign or diagnosis that prompts the need for the requested test.
	Occurrence	Optional, multiple occurrences
	Data type	CodeableConcept
	Recommended code system/value set	The Reason For Request value set published by the NCTS is a broad reference set including clinical findings, procedures, situation with explicit context, and event concepts.
	Examples	SNOMED CT-AU: • 267039000 |Swollen ankle| • 316761000119109 |Pain of left forearm| • 64766004 |Ulcerative colitis|
	Alias(es)	N/A
	Considerations	Coding of the 'Clinical indication' with a terminology is recommended, if available. Free text entry should only be permitted if no appropriate coded value is available. This data element allows multiple occurrences to enable the user to record more than one response if required.
Clinical context	Description	Narrative information about the individual and their situation, providing relevant background for the request.
	Occurrence	Optional, single occurrence
	Data type	String
	Alias(es)	N/A
	Considerations	Also known as 'Clinical notes', although this name has intentionally been avoided to clearly differentiate from the 'Notes' attribute in many FHIR resources.

Urgency	Description	The urgency of the request for service.
	Occurrence	Optional, single occurrence
	Data type	Coding
	Recommended code system/value set	A value set is to be developed. Proposed values: • Emergency [The request requires immediate attention.] • Urgent [The request requires prioritised attention.] • Routine [The request does not require prioritised scheduling.]
	Alias(es)	N/A
	Considerations	Specific definitions of emergency and urgent will vary between clinical contexts, clinical systems and the nature of the request itself, so have not been defined in this data group. If more precise timing is required, use the 'Service due' data element.
Service due	Description	The date/time or description about timing for provision of the requested service.
	Occurrence	Optional, single occurrence
	Data type	Timing or String
	Alias(es)	N/A
	Considerations	This data element enables the recording of the intended timing for the service in various formats, including precise timing details such as specific dates and times, or through textual descriptors like 'Next available'. Additionally, the Timing data type is designed to accommodate more complex timing scenarios if needed.
Comment	Description	Additional narrative about the service request not captured in other fields.
	Occurrence	Optional, single occurrence
	Data type	String
	Alias(es)	N/A
Distribution list	Description	Contact details of one or more clinicians, organisations or agencies that need to be informed of the outcome of this service request.
	Occurrence	Optional, single occurrence
	Data type	Reference
	Alias(es)	Cc list
	Considerations	For example: specialists or allied health providers who need to be notified of test results or available reports.
Urgent contact	Description	Contact details about one or more designated contact people or organisations and their preferred method of communication for urgent or emergency notifications concerning this request.
	Occurrence	Optional, single occurrence
	Data type	Reference
	Alias(es)	N/A

	Considerations	For example: if the outcome of the request requires an urgent or emergency response by the requester or requesting organisation.
Billing guidance	Description	A recommendation from the requester to the receiver regarding the payment method for the service.
	Occurrence	Optional, single occurrence
	Data type	String
	Alias(es)	N/A
	Considerations	For example: 'Private'; 'Government insurance scheme'; or 'Private insurance'.

8.2.4. For future consideration

The FHIR 'ServiceRequest' resource and the published openEHR 'Service request' archetype are mature information models that have been used globally in a broad range of implementations over many years. The openEHR Imaging examination request' archetype is a draft specialisation of the 'Service request' archetype. Together they form the basis for this initial AUeReqDI R1 data group and provide guidance for potential future augmentation.

The mind map below demonstrates a proposed roadmap for the 'Medical Imaging request' data group, based on the openEHR archetype. The nodes in yellow represent data elements already included in AUeReqDI R1; while the nodes in grey represent potential future data elements.

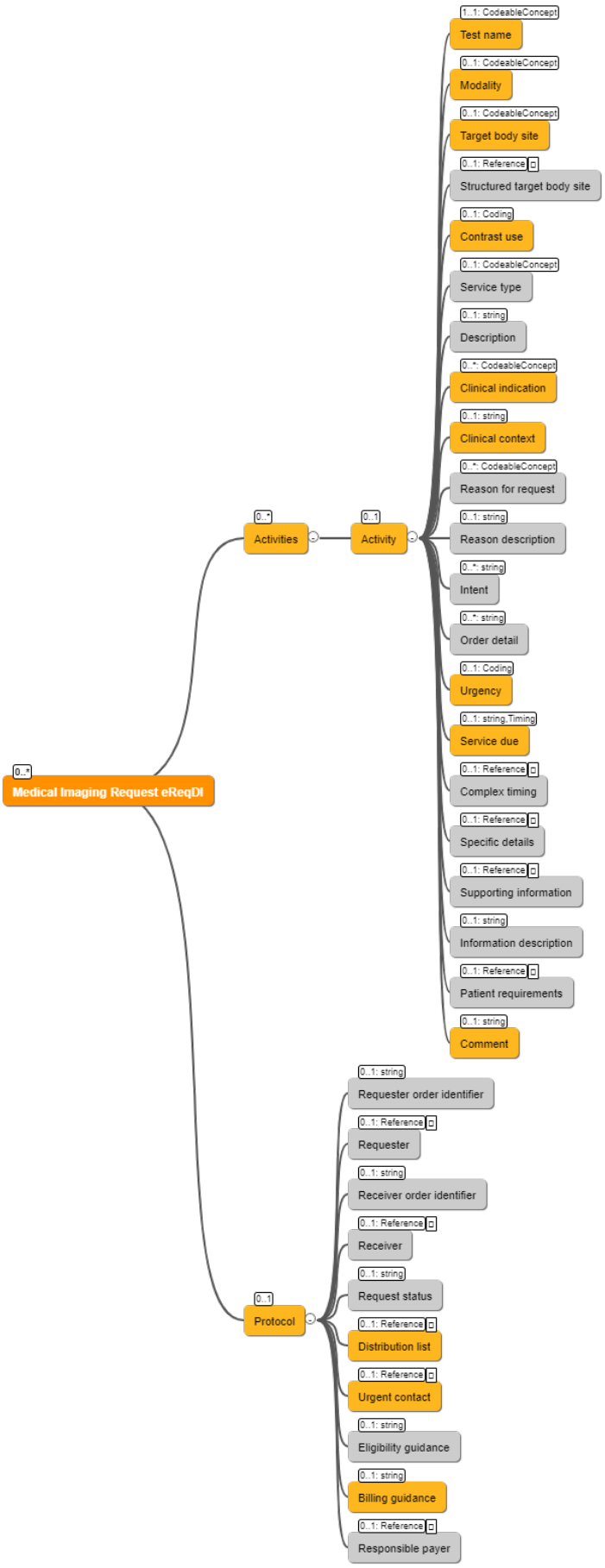

Figure 12. Medical imaging Request - proposed roadmap.

8.3. Pathology test request AUeReqDI

8.3.1. Data group context

Table 10. Pathology test request - Data group context.

Concept description	An order or referral for a pathology or laboratory service.
Purpose	To record an order or referral for a pathology or laboratory test.
Representation	Record one instance of this data group for each request. Each request contains: • one or more 'Activity' groupings that describe the clinical data elements related to the request. Each 'Activity' grouping represents a separate test; and • a single 'Protocol' grouping that describes the non-clinical data elements that relate to all 'Activity' groups in the request.
Alias(es)	Laboratory test request
Considerations for use	Use to record an order or referral for a pathology or laboratory test. This data group can be used to represent a request for one or more services, in one of two ways: • If multiple services need to be requested and the information recorded in the 'protocol' (for example 'Receiver') is the same – use a separate 'Activity' instance within this data group for each request. • If multiple services need to be requested and the information recorded in the 'protocol' (for example 'Receiver') is different – use a separate instance of this data group for each request. • Consider a clinician managing an elderly patient with Type 2 Diabetes ordering 'HbA1c' and a fasting 'Glucose' – the 'Service name' will carry both 'Haemoglobin A1C' and 'Glucose'; the 'Clinical indication' may be 'Type 2 Diabetes'; and 'Fasting status' will be 'Fasting'. • Consider a clinician managing a patient with chest pain – the 'Service name' will carry 'Urea', 'Electrolytes', 'Creatinine', 'GFR estimated (eGFR)', 'Glucose', 'Liver function tests', 'Troponin I', 'Troponin T', and 'Full blood count'; 'Clinical indication' will be 'Chest pain'; ; and the 'Clinical context' may be '4 hours of atypical left-sided chest pain and associated nausea'.
References	• Laboratory test request, Draft archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited:

	2024 May 09]. Available from: https://ckm.openehr.org/ckm/archetypes/1013.1.7230 • Diagnostic Request, HL7 AU Base FHIR Profile [Internet]. Health Level Seven Australia; [cited: 2024 May 09]. Available from: https://hl7.org.au/fhir/4.1.1-preview/StructureDefinition-au-diagnosticrequest.html

This data group is derived from the generic Service request data group, following modelling specialisation principles. It is consistent with the 'Service request' apart from two changes:

- Specialisation of 'Service name' to the more specific and relevant 'Test name'; and
- Addition of the 'Fasting status' data element.

8.3.2. Concept representation

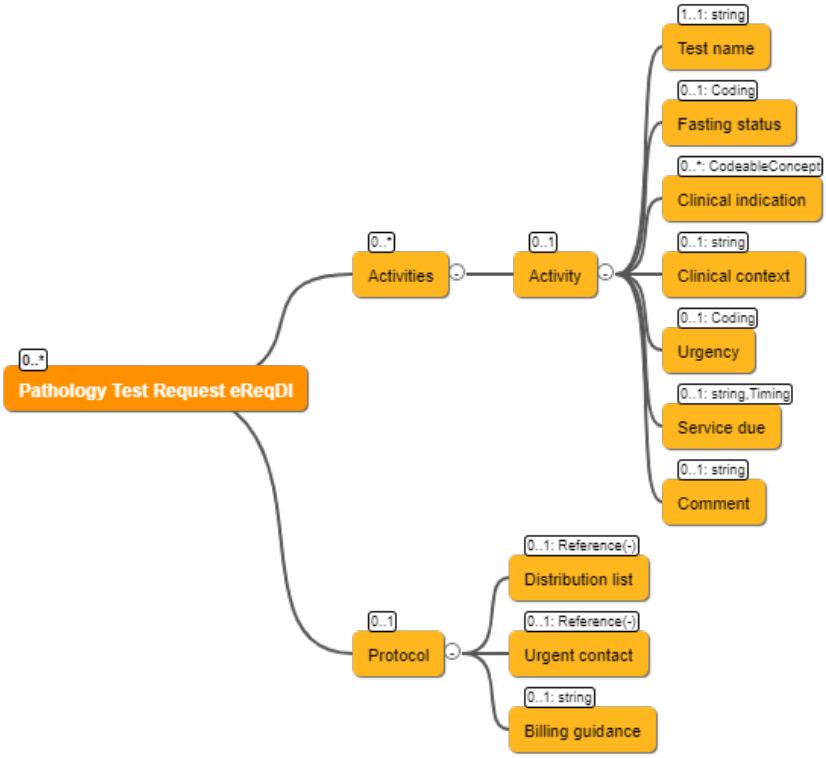

Figure 13. Pathology test request - Concept representation.

8.3.3. Information model

Table 11. Pathology test request - Information model.

Data elements		
Test name	Description	The name of the test requested.
	Occurrence	Mandatory, single occurrence
	Data type	CodeableConcept
	Recommended code system/value set	The RCPA - SPIA Requesting Pathology Terminology Reference Set published by the NCTS includes standard codes for use in requesting pathology tests in Australia, based on the SPIA Requesting Pathology Reference Set (v3.1).
	Examples	SNOMED CT-AU: • 121302000 |3-Methyl,4-hydroxymandelate measurement| • 413450008 |Adenovirus nucleic acid assay|
	Alias(es)	N/A
	Considerations	Coding of the 'Test name' with a terminology is strongly recommended, if available. Free text entry should only be permitted if no appropriate coded value is available.
Fasting status	Description	Recommendation related to the fasting state of the patient at the time of specimen collection.
	Occurrence	Optional, single occurrence
	Data type	Coding
	Recommended code system/value set	A value set is to be developed. Proposed values: • Fasting [The test should be carried out on a fasted individual.] • Non-fasting [The test should be carried out on a non-fasted individual.]
	Alias(es)	N/A
Clinical indication	Description	The symptom, sign or diagnosis that prompts the need for the requested test.
	Occurrence	Optional, multiple occurrences
	Data type	CodeableConcept
	Recommended code system/value set	The Reason For Request value set published by the NCTS is a broad reference set including clinical findings, procedures, situation with explicit context, and event concepts.
	Examples	SNOMED CT-AU: • 29857009|Chest pain| • 44054006 |Type 2 diabetes mellitus|
	Alias(es)	Reason for request
	Considerations	Coding of the 'Clinical indication' with a terminology is recommended, if available. Free text entry should only be permitted if no appropriate coded value is available. This

		data element allows multiple occurrences to enable the user to record more than one response if required.
Clinical context	Description	Narrative information about the individual and their situation, providing relevant background for the request.
	Occurrence	Optional, single occurrence
	Data type	String
	Alias(es)	N/A
	Considerations	Also known as 'Clinical notes', although this name has intentionally been avoided to clearly differentiate from the 'Notes' attribute in many FHIR resources.
Urgency	Description	The urgency of the request for service.
	Occurrence	Optional, single occurrence
	Data type	Coding
	Recommended code system/value set	A value set is to be developed. Proposed values: • Emergency [The request requires immediate attention.] • Urgent [The request requires prioritised attention.] • Routine [The request does not require prioritised scheduling.]
	Alias(es)	N/A
	Considerations	Specific definitions of emergency and urgent will vary between clinical contexts, clinical systems, and the nature of the request itself, so have not been defined in this data group. If more precise timing is required, use the 'Service due' data element.
Service due	Description	The date/time or description about timing for provision of the requested service.
	Occurrence	Optional, single occurrence
	Data type	Timing or String
	Alias(es)	N/A
	Considerations	This data element enables the recording of the intended timing for the service in various formats, including precise timing details such as specific dates and times, or through textual descriptors like ‘Next available’. Additionally, the Timing data type is designed to accommodate more complex timing scenarios if needed.
Comment	Description	Additional narrative about the service request not captured in other fields.
	Occurrence	Optional, single occurrence
	Data type	String
	Alias(es)	N/A
Distribution list	Description	Contact details of one or more clinicians, organisations or agencies that need to be informed of the outcome of this service request.
	Occurrence	Optional, single occurrence
	Data type	Reference

	Alias(es)	Cc list
	Considerations	For example: specialists or allied health providers who need to be notified of test results or available reports.
Urgent contact	Description	Contact details about one or more designated contact people or organisations and their preferred method of communication for urgent or emergency notifications concerning this request.
	Occurrence	Optional, single occurrence
	Data type	Reference
	Alias(es)	N/A
	Considerations	• Use this data element to nominate a contact point in case urgent communication is required about the process or outcome of the request requires an urgent or emergency response by the requester or requesting organisation. • While the occurrence of the data element is singular, the 'Reference' data type will permit more than one contact to be recorded.
Billing guidance	Description	A recommendation from the requester to the receiver regarding the payment method for the service.
	Occurrence	Optional, single occurrence
	Data type	String
	Alias(es)	N/A
	Considerations	For example: 'Private'; 'Government insurance scheme'; or 'Private insurance'.

8.3.4. For future consideration

The FHIR 'ServiceRequest' resource and the published openEHR 'Service request' archetype are mature information models that have been used globally in a broad range of implementations over many years. The openEHR 'Laboratory test request' archetype is a draft specialisation of the 'Service request' archetype. Together they form the basis for this initial AUeReqDI R1 data group and provide guidance for potential future augmentation.

The mind map below demonstrates a proposed roadmap for the 'Pathology test request' data group, based on the openEHR archetype. The nodes in yellow represent data elements already included in AUeReqDI R1; while the nodes in grey represent potential future data elements.

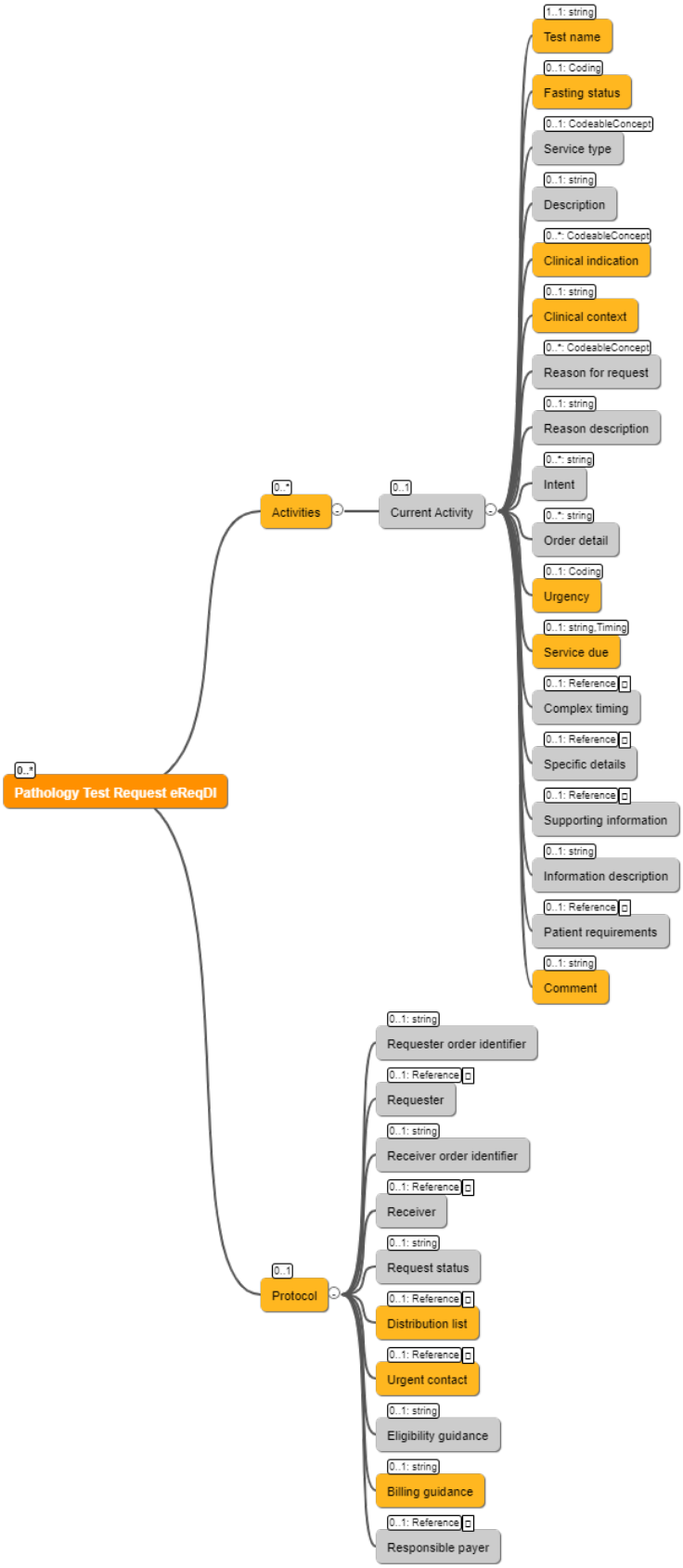

Figure 14. Pathology test request - Proposed roadmap.

8.4. Implanted medical device summary AUeReqDI

8.4.1. Data group context

Table 12. Implanted medical device summary - Data group context.

Concept description	A summary or overview of a single medical device, or category of device, that can be implanted in the body through surgery.
Purpose	To record a summary or overview of a single implanted medical device, or category of device.
Representation	Record one summary instance per medical device or device category within a health record.
Alias(es)	N/A
Considerations for use	Use to record a summary or overview of a single implanted medical device, or category of device. The intended scope of implanted medical devices includes, but is not limited to: • a cochlear implant; • an intracardiac pacemaker; • one or more aneurysm clips; • a femoral head prosthesis; • a coronary stent; • bone fixation devices such as screws or plates; • deep brain electrical stimulation system lead; or • deep brain electrical stimulation system pulse generator. This data group has been specifically designed to support the identification of implanted medical devices in situ that may carry health risks for imaging and other health-related activities, and to carry critical information such as device identification that will support product recalls. The repeating 'Specific implant details' group of data elements supports documentation about each insertion of each specific medical device, including more precise identification and summary details about the medical device insertion and/or removal. This group can be further extended to document medical device details such as the manufacturer, batch numbers and device identifiers by nesting the proposed 'Device details' data group within a future iteration of this data group. If specific devices have been used in the past, as much detail as is available can be added in this data group to create a context that may influence decisions about current or future devices of the same type.

Misuse	Not to be used to record details about a surgical procedure - use the 'Procedure completed' data group for this purpose.
References	Implanted medical device summary, Draft archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 May 09]. Available from: https://ckm.openehr.org/ckm/archetypes/1013.1.7294

8.4.2. Concept representation

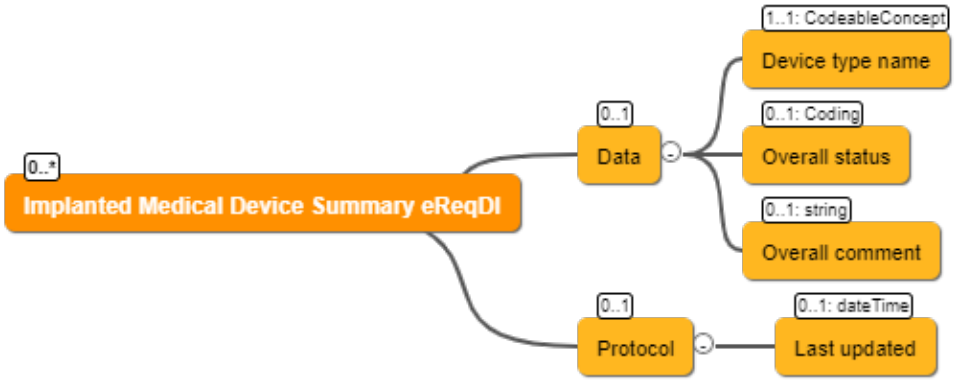

Figure 15. Implanted medical device summary - Concept representation.

8.4.3. Information model

Table 13. Implanted medical device summary - Information model.

Data elements		
Device type name	Description	Name of the implanted medical device category.
	Occurrence	Mandatory, single occurrence
	Data type	CodeableConcept
	Recommended code system/value set	An initial value set to support implanted device type requirements will be developed to support imaging requests. The value set will be further extended for broader use cases in future releases, if required.
	Examples	TBC
	Considerations	Coding of the 'Device type name' with an external terminology is strongly recommended, if available. Free text entry should only be permitted if no appropriate coded value is available.
Overall status	Description	Assertion about the whether the device type is currently in situ.
	Occurrence	Optional, single occurrence
	Data type	Coding

	Recommended code system/value set	Value set to be developed. Proposed value set: • In situ [The device type is currently inserted or implanted in the body.] • Removed [The device type has been removed from the body.]
	Alias(es)	N/A
Overall comment	Description	Additional narrative about the implanted medical device type, not captured in other fields.
	Occurrence	Optional, single occurrence
	Data type	String
Last updated	Description	The date when this Implanted medical device summary was last updated.
	Occurrence	Optional, single occurrence
	Data type	DateTime

8.4.4. For future consideration

Medical Device regulations for 'Unique Device Identification' (UDI) are currently under development at the Therapeutic Goods Administration (TGA) and these include specific mandatory requirements with regard to the identification of the specific device (UDI) and categorisation using the Global Medical Device Nomenclature (GMDN).

The openEHR 'Implanted medical device summary' archetype is a draft information model that has been developed to support management of implanted medical devices. It forms the basis for this initial AUeReqDI R1 data group and provides guidance for potential future augmentation.

The mind map below demonstrates a proposed roadmap for the 'Implanted medical device summary' data group, based on the openEHR archetype. The nodes in yellow represent data elements already included in AUeReqDI R1; while the nodes in grey represent potential future data elements, including a group that describes details about specific implanted device. This model can potentially be further extended to incorporate more detailed data elements based on:

- the published openEHR 'Medical device' archetype which include unique identifiers, manufacturer, model number, software version and date of expiry; and
- the draft 'Medical device details' archetype which includes details about asset management, such as device calibration and servicing.

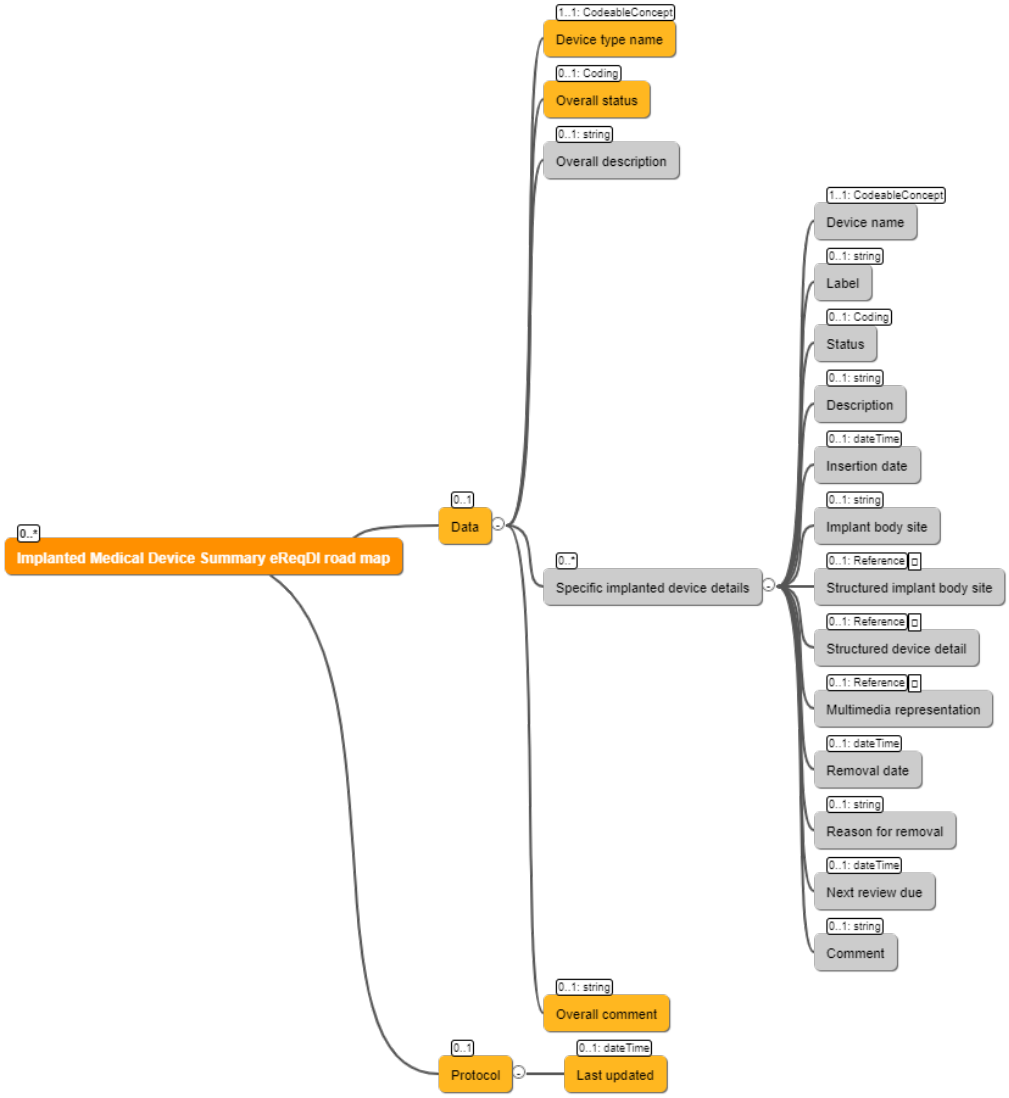

Figure 16. Implanted medical device summary - Proposed roadmap.

8.5. Adverse reaction risk summary AUCDI

8.5.1. Data group context

Table 14. Adverse reaction risk summary (AUCDI) - Data group context.

Concept description	A summary or overview of a clinical assessment that identifies the potential for a harmful or undesirable physiological reaction unique to an individual and associated with exposure to a specific substance.
Purpose	To record: • An assessment of the risk or propensity of a future adverse reaction if exposed, or re-exposed, to an identified substance. • Evidence supporting the risk assessment, such as a summary of each exposure event or genomics test results.
Representation	Record one summary instance per substance within a health record.
Alias(es)	Adverse reaction, Allergy, Intolerance, Hypersensitivity

Considerations for use	• Substances include but are not limited to:
	  ○ A therapeutic substance administered correctly at an appropriate dosage for the individual, including medications or vaccinations,
	  ○ Food,
	  ○ Material derived from plants or animals, or
	  ○ Venom from insect stings.
	• Manifestations include any symptom, sign, or diagnosis.
	• It is also possible to record the absence of a reaction on re-exposure to a substance where an existing adverse reaction summary exists. This may trigger further investigation to confirm whether the previously assumed causal relationship to the substance is correct or mistaken.
	• This data group is intended to provide a single place within the health record to document the propensity for the full range of adverse reactions, from trivial to life-threatening, irrespective of the underlying physical mechanism. This includes but is not limited to:
	  ○ Immune-mediated: Types I-IV (including allergic reactions and hypersensitivities); or
	  ○ Non-immune-mediated: such as pseudo-allergic reactions, side effects, intolerances, and drug toxicities in individuals with impaired excretion.
	• In R1, all adverse reactions are assumed active in the context of a summary for exchange.
	• The clinical finding of an allergy to a specific substance, for example, “Allergy to penicillin”, may also be recorded in the Problem/Diagnosis data group, if required, in addition to recording ‘Penicillin’ as the substance in this Adverse reaction risk summary data group.

	• In future updates, it is anticipated this data group will be extended to incorporate additional detail.
Misuse	• Not to be used to record a diagnosis of an adverse reaction as the conclusion of a clinical consultation or investigation – use the Problem/Diagnosis data type for this purpose. • Not to be used for recording predictable physiological reactions on exposure to physical agents or activities, such as heat, cold, sunlight, vibration, exercise, by infectious agents, or food contaminants. • Not to be used to record adverse events, including failures of clinical processes, interventions, or products. For example, abnormal use, incorrect dosage or maladministration of an agent or substance, mislabelling, overdose, or poisoning.
References	• Adverse reaction risk, Published archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: https://ckm.openehr.org/ckm/archetypes/1013.1.7022 • Adverse reaction event, Published archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: https://ckm.openehr.org/ckm/archetypes/1013.1.5795 • AllergyIntolerance, HL7 FHIR Resource [Internet]. Health Level Seven International; [cited: 2024 Feb 05]. Available from: https://hl7.org/fhir/R5/allergyintolerance.html. • AllergyIntolerance profile, International Patient Summary Implementation Guide, [Internet]. Patient Care Working Group, Health Level Seven International; [cited: 2024 Feb 05]. Available from: https://build.fhir.org/ig/HL7/fhir-ips/StructureDefinition-AllergyIntolerance-uv-ips.html

This data group documents a clinician's recommendation to avoid future exposure to a particular substance, emphasising the assessment of exposure risk and its substantiating evidence. In R1 the 'Clinical evidence' supporting the risk assessment is limited to the 'Manifestation' - symptoms or signs observed as part of an adverse reaction occurring on exposure to a substance. In future releases, it is anticipated that the details about the reaction event will be expanded and additional types of clinical evidence, such as immunogenetic test results can be included.

While highlighting the clinical safety driver for accurately documenting adverse reactions, it is also important to recognise that such documentation within a clinical system will not always be limited to reactions categorised as true allergies, hypersensitivities, or intolerances. In practice, clinicians may encounter situations where the underlying pathophysiology of a reaction may not be known. Despite this, they still need to document that, in their judgment, the patient should avoid a specific substance. Such an entry is vital to prompt clinical safety alerts that prevent re-exposure, with previous manifestations offering insights into the risk of potential future harm, regardless of the unknown physiological mechanisms involved.

Use cases include, but are not limited to:

- 'Adverse Reaction List', or similar document, containing one or more 'Adverse reaction summary' data groups,

- Triggering clinical decision alerts when prescribing, dispensing, and administering a medication, and
- To exchange safety-critical adverse reaction information with other healthcare providers.

8.5.2. Concept representation

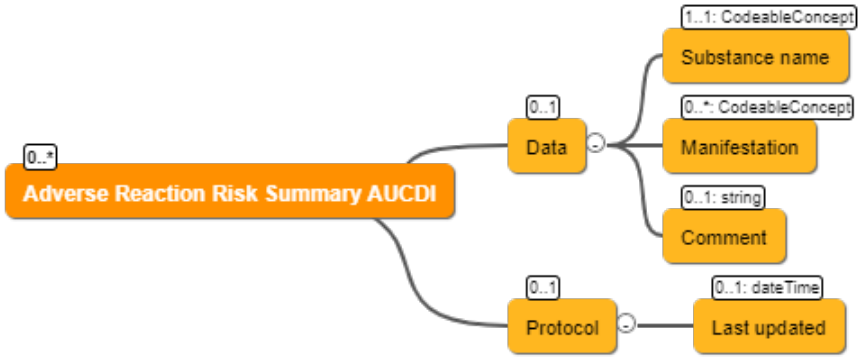

Figure 17. Adverse reaction risk summary (AUCDI) - Concept representation.

In this mind map, 'Manifestation' is represented as 0..*, indicating that more than one reaction manifestation per substance can be recorded, if necessary.

8.5.3. Information model

Table 15. Adverse reaction risk summary (AUCDI) - Information model.

Data elements		
Substance name	Description	Identification of a specific substance, compounded product, combination therapy product, or class of substances that is considered to have a causal link to the adverse reaction.
	Occurrence	Mandatory, single occurrence
	Data type	CodeableConcept
	Recommended code system/value set	The Adverse Reaction Agent value set published by the NCTS currently includes all Substances (and classes) within SNOMED CT-AU and all AMT Product (notable) concepts.
	Examples	AMT provides concepts at various granularities from brand to specific substance: • TP: 3738011000036101|Amoxil| • TPUU: 4542011000036104|Amoxil Forte Sugar Free oral liquid| • MP: 27658006| Product containing amoxicillin| • MP: 831021000168104 |measles + mumps + rubella live vaccine|

		Note: The above examples reflect the future state of AMT, v4. Specific substances and non-medicinal substances from SCT-AU: • 372687004| Amoxicillin| • 764147003 |Cephalosporin| • 111088007 | Latex | • 256259004 | Pollen | • 762952008| Peanut | • 1222501000168103 | Vegemite | • 348608005 | Surgical adhesive tape | • 'Band-Aid'
	Alias(es)	Agent, Class, Product, Drug, Allergen, Medicine
	Considerations	In this context, appropriate values for 'Substance name' include, but are not limited to: • A therapeutic substance administered correctly at an appropriate dosage for the individual, • Food, • Material derived from plants or animals, • Venom from insect stings, and Physical objects commonly recorded as the proxy for a substance, such as Band-Aids or surgical tape. It is strongly recommended that 'Substance name' be coded with a terminology capable of triggering decision support, where possible. Free text entry should only be permitted if no appropriate coded value is available.
Manifestation	Description	Symptom or sign observed or associated with the reaction.
	Occurrence	Optional, multiple occurrences
	Data type	CodeableConcept
	Recommended code system/value set	The Clinical Finding value set published by the NCTS currently includes all Clinical findings within SNOMED CT-AU that could manifest as the result of an adverse reaction. Additionally, the Clinical manifestation reference set is a subset of Clinical Findings that is published as part of SNOMED CT-AU that was developed collaboratively with a number of different health jurisdictions to identify the most commonly encountered reactions.

	Examples	SNOMED CT-AU: • 247472004 | Hives | • 267038008 | Oedema | • 62315008 | Diarrhoea | • 422587007 | Nausea | • 39579001 | Anaphylaxis |
	Alias(es)	Reaction, Nature of reaction, Clinical manifestation, Sign, Symptom
	Considerations	It is strongly recommended that 'Manifestation' be coded with a terminology capable of triggering decision support, where possible. Free text entry should only be permitted if no appropriate coded value is available. This data element has multiple occurrences to allow the recording of more than one manifestation per substance.
Comment	Description	Additional narrative about the propensity for the adverse reaction, not captured in other fields.
	Occurrence	Optional, single occurrence
	Data type	String
	Alias(es)	Note
	Considerations	For example: instructions related to future exposure or administration of the Substance, such as administration within an Intensive Care Unit or under corticosteroid cover.
Last updated	Description	The date when the Adverse reaction risk summary data group was last updated.
	Occurrence	Optional, single occurrence
	Data type	DateTime
	Alias(es)	N/A
	Considerations	Partial dates are not permitted for contemporaneous recording. Date examples: • March 15, 2024 • 2015-02-07T13:28:17-05:00

8.6. Problem/Diagnosis summary AUCDI

8.6.1. Data group context

Table 16. Problem/Diagnosis summary (AUCDI) - Data group context.

Concept description	A summary or overview of a single health condition, injury, disability, or any other issue that impacts the physical, mental and/or social well-being of an individual.
Purpose	To record summary information about a single problem or diagnosis.
Representation	Record one instance per problem or diagnosis within a health record; changes or updates over time are captured as a revision rather than a new entry.
Alias(es)	Condition
Considerations for use	Both problems or diagnoses can be recorded using this same data model without distinguishing and labelling them as one or the other. The recording pattern is closely aligned, and what may initially be considered a 'soft' problem may evolve towards a formal diagnosis as more clinical evidence is discovered. In future updates, it is anticipated this data group will be extended to incorporate additional detail.
Misuse	Not to be used to record summary information about a single pregnancy. The clinical requirements for recording summary details about a pregnancy are quite different to typical problems and diagnoses and therefore out of scope for this data group. It is anticipated that a separate 'Pregnancy summary' data group will be proposed for future releases of AUCDI. Note: Problems or Diagnoses identified during the pregnancy or as direct complications of the pregnancy may be added using this data group – for example, 'Gestational diabetes', 'Pre-eclampsia' or 'Urinary tract infection'.
References	• Problem/Diagnosis, Published archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: https://ckm.openehr.org/ckm/archetypes/1013.1.169 • Condition, HL7 FHIR Resource [Internet]. Health Level Seven International; [cited: 2024 Feb 05]. Available from: https://hl7.org/fhir/R5/condition.html. • Condition profile, International Patient Summary Implementation Guide, [Internet]. HL7 International / Patient care Patient Care Working Group, Health Level Seven International; [cited: 2024 Feb 05]. Available from: https://build.fhir.org/ig/HL7/fhir-ips/StructureDefinition-Condition-uv-ips.html.

This data group documents a summary or overview of a single active, inactive, or resolved problem or diagnosis, gathered and integrated from various information sources, including multiple consultations and other activities, accumulated, and updated over time. An exception is summary information about a specific pregnancy; a condition that requires a very different data structure.

Traditionally, differentiating between problems and diagnoses has been difficult because they often exist on a continuum, both conceptually and in practice. As clinical evidence accumulates, what begins as a 'problem' may develop into a definitive 'diagnosis.' Adopting a unified data group for both facilitates the collection of clinical evidence and recognises the dynamic and interconnected nature of their relationship.

Use cases include, but are not limited to:

- Recording a diagnosis as the conclusion of a Consultation note,
- A 'Problem List', ‘Medical history’ or similar document, containing one or more ‘Problem/Diagnosis summary’ data groups,
- Triggering clinical decision support related to preventive health and chronic disease management, or

To exchange critical information about problems or diagnoses with other healthcare providers.

8.6.2. Concept representation

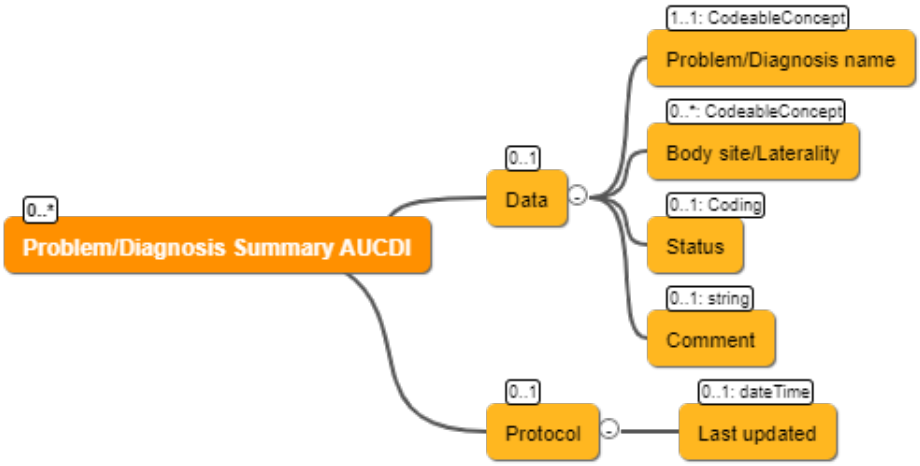

Figure 18. Problem/Diagnosis summary (AUCDI) - Concept representation.

8.6.3. Information model

Table 17. Problem/Diagnosis summary (AUCDI) - Information model.

Data elements		
Problem / Diagnosis name	Description	Identification of the problem or diagnosis, by name.
	Occurrence	Mandatory, single occurrence
	Data type	CodeableConcept
	Recommended code system/value set	The Clinical Condition value set value set published by the NCTS currently includes all members of the *Problem/Diagnosis reference set* in SNOMED CT-AU. This includes (most) subtypes of • 272379006|Event| • 243796009| Situation with explicit context| • 404684003|Clinical Finding|
	Examples	SNOMED CT-AU: • 195967001 |Asthma | • 46635009 | Diabetes Mellitus Type 1 | • 13746004 | Bipolar disorder| • 307608006 | Ewing's sarcoma of bone | • 254837009 | Malignant neoplasm of breast | • 44465007 | Sprain of ankle | • 112981000119107| Bilateral osteoarthritis of knees| • 20902002|Fall from bed| • 315604002| Missed contraceptive pill|
	Alias(es)	Condition name
	Considerations	It is strongly recommended that the 'Problem/Diagnosis name' be coded with a terminology capable of triggering decision support, where possible. Free text entry should only be permitted if no appropriate coded value is available.
Body site	Description	The anatomical location or body structure where the 'Problem or diagnosis' is manifested, including laterality.
	Occurrence	Optional, multiple occurrences
	Data type	CodeableConcept
	Recommended code system/value set	The Body Site value set published by the NCTS is a subset of the SNOMED CT-AU Body structure hierarchy. It includes anatomical structures (including acquired structures) with

		laterality but excludes morphologic abnormalities and cellular/intercellular structures.
	Examples	SNOMED CT-AU: • 761920005 | Bone structure of shaft of right humerus | • 51636004 | Left ankle | • 38033009 | Amputation stump| • 110501003 | Upper outer quadrant of left breast |
	Alias(es)	Anatomical location
	Considerations	Specification of 'Body site' is recommended when it is required to provide additional clarity about the Problem/Diagnosis and the 'Problem/Diagnosis name' does not include or imply a specific body site. This data element has multiple occurrences to allow the recording of more than one body site for each problem or diagnosis – for example, to record multiple skin sites affected by a rash. It is strongly recommended that the 'Body site' be coded with a terminology, where possible. Free text entry should only be permitted if no appropriate coded value is available.
Status	Description	A clinical assertion whether a problem or diagnosis is currently active or inactive.
	Occurrence	Optional, single occurrence
	Data type	Coding
	Recommended code system/value set	Coded terms for 'Status' will be selected from a value set, yet to be developed, and limited to the following two values: • Active – a current, ongoing health condition that requires active treatment or management; or • Inactive – a health condition that has resolved, is in remission, or no longer requires active treatment or management.
	Alias(es)	Clinical status
	Considerations	None
Comment	Description	Additional narrative about the problem or diagnosis not captured in other fields.
	Occurrence	Optional, single occurrence
	Data type	String
	Alias(es)	Note

	Considerations	None
Last updated	Description	The date when the Problem/Diagnosis summary data group was last updated.
	Occurrence	Optional, single occurrence
	Data type	DateTime

	Considerations	• Partial dates are not permitted for contemporaneous recording.
		• Date examples:
		  ○ March 15, 2024
		  ○ 2015-02-07T13:28:17-05:00

8.7. Sex and gender AUCDI

8.7.1. Data group context

Table 18. Sex and gender (AUCDI) - Data group context.

Concept description	A collection of clinically significant concepts related to the sex and gender of an individual.
Purpose	To record information related to sex and gender to ensure safe and appropriate clinical care and support respectful communication.
Representation	Record one instance per data group within a health record; changes or updates over time are captured as a revision rather than a new entry.
Alias(es)	Sex, Gender
Considerations for use	This data group may be expanded in future updates to include more concepts as related data elements. In future updates, this data group may be extended to incorporate additional related concepts.
References	• Gender, Published archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: https://ckm.openehr.org/ckm/archetypes/1013.1.3715 • McClure RC, Macumber CL, Kronk C, Grasso C, Horn RJ, Queen R, Posnack S, Davison K. Gender harmony: improved standards to support affirmative care of gender-marginalized people through inclusive gender and sex representation. J Am Med Inform Assoc. 2022 Jan 12;29(2):354-363. doi: 10.1093/jamia/ocab196. Erratum in: J Am Med Inform Assoc. 2021 Nov 25;: PMID: 34613410; PMCID: PMC8757317. • HL7 Cross Paradigm Implementation Guide: Gender Harmony - Sex and Gender Representation, Edition 1

	[Internet]. HL7 International; [cited: 2024 Feb 05]. Available from: https://hl7.org/xprod/ig/uv/gender-harmony/

This data group records information regarding an individual's sex assigned at birth and their self-identified gender preferences.

The current approach to recording sex and gender information varies significantly across clinical systems, with some not yet capturing self-identified gender preferences. Historically, data has often been collected within a generic 'Sex' or 'Administrative sex' field without clear definitions and guidance for collection. This has resulted in the accumulation of ambiguous data. It is not possible to tell if the data reflects biological sex, gender identity, legal sex, or other representations and is not suitable for use in either administrative or clinical contexts.

Use cases for this data group include, but are not limited to:

- As a foundation for personalised medical treatment, supporting both biological- and gender-specific health needs, and improving assessment of disease risk and outcomes,
- Facilitate healthcare accessibility, delivery and communication that acknowledges and incorporates the differences in health needs, experiences, and outcomes across different genders, and
- Facilitate research and public health monitoring.

8.7.2. Concept representation

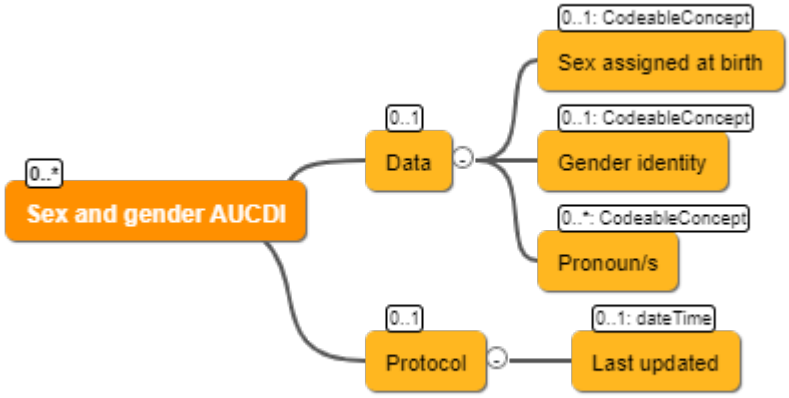

Figure 19. Sex and gender (AUCDI) - Concept representation.

8.7.3. Information model

Table 19. Sex and gender (AUCDI) - Information model.

Data elements		
Sex assigned at birth	Description	The sex of an individual, as determined by inspection of external genitalia or diagnostic testing at birth or early infancy.
	Occurrence	Optional, single occurrence
	Data type	Coding
	Recommended code system/value set	The Biological Sex value set published by NCTS includes SNOMED CT-AU concepts that represent the biological sex of an individual.

	Examples	SNOMED CT-AU: • 248152002|Female • 32570681000036106|Indeterminate • 32570691000036108|Intersex
	Alias(es)	Birth sex, Natal sex
	Considerations	• It is strongly recommended that 'Sex assigned at birth' be coded with a terminology. • The term 'Sex assigned at birth' usually reflects the clinical observation of the infant's external genitalia made at birth by the clinician, as recorded in the infant's birth record. • 'Sex assigned at birth' is assumed to be reliable in the majority of births and will not change unless an error is determined by subsequent testing. Any error in 'Sex assigned at birth' should be updated. • The 'Sex assigned at birth' in a birth record is usually the source of information for the 'Sex' or 'Birth sex' on the infant's original Birth Certificate document. However, as the 'Sex' can be legally changed on birth certificates and other official documents, Birth Certificates should not be considered to be an equivalent of 'Sex assigned at birth'. • Other designations related to sex, such as types of 'Legal sex', can change throughout the individual's lifetime and can differ from 'Sex assigned at birth'.
Gender identity	Description	The individual's perception of their gender.
	Occurrence	Optional, single occurrence
	Data type	CodeableConcept
	Recommended code system/value set	The Gender Identity Response value set published by NCTS includes SNOMED CT-AU concepts that may be used to represent a response for an individual's gender.
	Examples	SNOMED CT-AU: • 446151000124109| Identifies as male gender • 33791000087105|Identifies as nonbinary gender|
	Alias(es)	Gender, Gender identification
	Considerations	It is strongly recommended that 'Gender identity' be coded, where possible. Free text entry should be permitted if no appropriate coded value is available.

Pronoun/s	Description	Pronouns specified by the individual.
	Occurrence	Optional, multiple occurrences
	Data type	CodeableConcept
	Recommended code system/value set	The Personal Pronouns value set published by HL7 included codes from LOINC (LOINC Parts) that be used when communicating with or about an individual. This is still under discussion, see: https://confluence.hl7.org/pages/viewpage.action?pageId=212730453
	Examples	• she/her/her/hers/herself; • they/them/their/theirs/themselves; or • xe/xem/xyr, ze/hir/hirs, and ey/em/eir
	Alias(es)	Neopronouns
	Considerations	• It is desirable that 'Pronouns' be coded with a terminology, if available. Free text entry is permitted if no appropriate coded value is available. • To be used when speaking directly to the individual or referring to the individual in written documentation. • This data element has multiple occurrences to allow the recording of more than one group of pronouns to be used.
Last updated	Description	The date when the 'Sex and gender' data group was last updated.
	Occurrence	Optional, single occurrence
	Data type	DateTime

	Alias(es)	• Partial dates are not permitted for contemporaneous recording.
		• Date examples:
		  ○ March 15, 2024
		  ○ 2015-02-07T13:28:17-05:00