



# Sparked



**Version 1.0 - 31 October 2024**

**Sparked AU FHIR Accelerator**

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**Document Control**

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## 1. Document Information

### 1.1. Document Information

<b>Name</b>	Australian eRequesting Data for Interoperability Release 1: Feedback from Community
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<b>Author</b>	Sparked AU FHIR Accelerator

### 1.2. Distribution

<b>Name</b>	<b>Title</b>	<b>Date</b>	<b>Version</b>
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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.*

## Table of Contents

<b>1. Document Information .....</b>	<b>3</b>
1.1. Document Information .....	3
1.2. Distribution .....	3
<b>2. Introduction .....</b>	<b>7</b>
2.1. Purpose of document .....	7
2.2. Intended audience of document .....	7
2.3. How to read this document .....	7
<b>3. Overall Feedback Themes and Actions .....</b>	<b>8</b>
<b>4. Summary of Changes .....</b>	<b>9</b>
<b>5. AUeReqDI Data Group: Service Request .....</b>	<b>13</b>
5.1. Overall Recommendations .....	13
5.2. Service Name .....	13
5.3. Clinical Indication .....	15
5.4. Clinical Context .....	16
5.5. Urgency .....	17
5.6. Service Due .....	18
5.7. Comment .....	19
5.8. Distribution List .....	21
5.9. Urgent Contact .....	21
5.10. Billing Guidance .....	22
5.11. General Feedback for Service Request .....	23
<b>6. AUeReqDI Data Group: Medical Imaging Request .....</b>	<b>29</b>
6.1. Overall Recommendations .....	29
6.2. ....	29
6.3. Test Name .....	29
6.4. Modality .....	31
6.5. Target Body Site .....	32
6.6. Contrast Use .....	34
6.7. General Feedback for Medical Imaging Request .....	35
<b>7. AUeReqDI Data Group: Pathology Test Request .....</b>	<b>38</b>
7.1. Overall Recommendations .....	38
7.2. Test Name .....	38

7.3.	Fasting Status .....	40
7.4.	General Feedback for Pathology Test Request .....	41
8.	<i>AUeReqDI Data Group: Implanted Medical Device Summary .....</i>	<i>47</i>
8.1.	Overall Recommendations.....	47
8.2.	Device Type Name .....	47
8.3.	Overall Status .....	48
8.4.	Overall Comment .....	49
8.5.	Last Updated .....	49
8.6.	General Feedback for Implanted Medical Device Summary.....	50
9.	<i>Problem/Diagnosis Summary and Sex and Gender .....</i>	<i>53</i>
9.1.	Problem/Diagnosis Summary and Sex and Gender .....	53
10.	<i>General Feedback .....</i>	<i>59</i>

## 2. Introduction

### 2.1. Purpose of document

The purpose of this document is to outline the feedback received during the Australian eRequesting Data for Interoperability (AUeReqDI) Release 1 Community Comment period and provide reflections, commentary, and summary of actions.

### 2.2. Intended audience of document

The intended audience of this document is stakeholders interested in improving health data 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.

### 2.3. How to read this document

This document is broken into two key sections:

- **Section 3:** high-level summary of the feedback received, and action taken
- **Section 4:** high-level summary of the changes to the AUeReqDI R1 document made following the community feedback period
- **Sections 5 – 10:** detailed feedback as received throughout the community comment period, with responses.

In addition to specific feedback, reviewers were also asked to provide an overall recommendation for each data group. The votes for each of the options were tallied for each data and included in this document. The options provided to reviewers were:

- **Accept** – if you have no suggestion for further improvement and consider the data group ready for publication without further review or if the suggested changes are trivial (e.g., spelling)
- **Minor revision** – if you consider that there are only small changes required to make the data group ready for publication
- **Major revision** – if you consider the data group needs large or significant modifications such as addition/removal of data elements
- **Reject** – if you consider the data group is not suitable for publication – for example that it is “unfit for purpose” or fundamentally flawed
- **Abstain** – if you feel you need to deliberately refrain from participating in the recommendation process. We encourage you to contribute from your unique point of view as the collaborative review process is intended to be inclusive of all points of view and not requiring specific skill sets or professional background.

### 3. Overall Feedback Themes and Actions

The following are the high-level feedback themes and actions taken as part of the AUeReqDI Release 1 community comment review.

Section	Feedback theme	Action
Overall Document	Request for clarification of scope e.g. participant, requester, billing guidance	Document updated for clarity
	Request for additional data elements/data groups	These have been added to a backlog
Service Request	Clarification requests for the use of clinical context and comment	Document updated for clarity
	The term 'Service due' did not reflect the meaning of the description	Data element name updated to "Service timing" to reflect its meaning more clearly
	Questions around the inclusion of the generic service request	Document updated for clarity
Medical Imaging Request	Target body site should allow multiple sites	Target body site data model updated
	Need for additional data elements	Identified data elements added to backlog
Pathology Test Request	Need for additional data elements	Identified data elements added to backlog
Implanted Medical Device Summary	Need for additional data elements	Identified data elements added to backlog
	"Overall status" name is unclear	"Overall status" name updated to "Current status"
AUCDI Data Elements	Request for clarification on the lack of inclusion of pregnancy and related information	Document updated for clarity
	Request for contextualisation of AUCDI data elements in the eRequest context and how they relate	Document updated



## 4. Summary of Changes

The following are the changes made to AUeReqDI Release 1 following the community comment review.

Original Section	Update (new) Section	Changes Made
Whole document		Minor editorial changes for clarity, changes to table colouring for readability and to indicate where data models have been copied across, addition of legends of diagrams, additional examples, additional alias(es), additional references, updated diagrams to reflect any changes in content
2 Definition of Terms		Updates to definitions
3 Introduction		No other major updates
4 About Sparked		No other major updates
5 About Australian eRequesting Data for Interoperability		Update to Figure 5 showing relationship between AUeReqDI and AUeReq FHIR IG Addition of section 5.5 Related programs of work (RANZCR's Radiology referral set project and RCPA's PITUS project) Update to section 5.6 (originally 5.5) Understanding the scope AUeReqDI updated for clarity
6 How to read the AUeReqDI		Addition of explanation of structure of data. Additional information about the Service data group and derivatives
7 AUeReqDI at a glance		Correction of diagram
8 AUeReqDI Library		No other major updates
8.1 Service Request		Addition of introductory context and clarification of scope
8.1.1		Update to considerations for use of implementation examples
8.1.2		No other major updates
8.1.3		Update of Service due data element to Service timing Additional clarification of Clinical context data element Updated description and examples of Urgency data element

		Update of considerations for Distribution list, Urgent contact and Billing guidance data elements
8.1.4		No other major updates
8.2 Medical Imaging Request		No other major updates
8.2.1		Update to considerations for use of implementation examples
8.2.2		No other major updates
8.2.3		Update of Service due data element to Service timing Additional clarification of Clinical context data element Target body site occurrence updated Contrast use examples updated Updated description and examples of Urgency data element Update of considerations for Distribution list, Urgent contact and Billing guidance data elements
8.2.4		No other major updates
8.3 Pathology test request		No other major updates
8.3.1		Update to considerations for use of implementation examples
8.3.2		No other major updates
8.3.3		Update of Service due data element to Service timing Additional clarification of Clinical context data element Updated description and examples of Urgency data element Update of considerations for Distribution list, Urgent contact and Billing guidance data elements
8.3.4		No other major updates

Sparked AUeReqDI R1 – Community Comment Feedback Responses

8.4 Implanted medical device summary		Addition of introductory context
8.4.1		Update to consideration for use
8.4.2		No other major updates
8.4.3		'Overall status' data element updated to 'Current status'
8.4.4		No other major updates
	8.5 Reuse of AUCDI data groups	New overarching section with an explanation of inclusion of AUCDI data groups
8.5 Adverse reaction risk summary	8.5.1 Adverse reaction risk summary	Overarching formatting updates to indicate copying of information from AUCDI
8.5.1	8.5.1.1	No other major updates
8.5.2	8.5.1.2	Addition of eRequest specific examples
8.5.3	8.5.1.3	No other major updates
8.6 Problem/Diagnosis summary	8.5.2 Problem/diagnosis summary	Overarching formatting updates to indicate copying of information from AUCDI
8.6.1	8.5.2.1	No other major updates
8.6.2	8.5.2.2	No other major updates
8.6.3	8.5.2.3	No other major updates
8.7 Sex and gender summary	8.5.3 Sex and gender summary	Overarching formatting updates to indicate copying of information from AUCDI
8.7.1	8.5.3.1	No other major updates
8.7.2	8.5.3.2	No other major updates

8.7.3	8.5.3.3	No other major updates
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## 5. AUeReqDI Data Group: Service Request

### 5.1. Overall Recommendations

Accept	Minor	Major	Reject	Abstain
6	7	3	2	3

### 5.2. Service Name

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI005	Is this a name or type? Names are not usually coded. None of the examples relate to eRequesting	<p>Wording updated and new content added to reflect comment.</p> <p>This is 'Service name', not type. 'Service type' is included in the model for future consideration.</p> <p>The data type is CodeableConcept which allows both coded and non-coded service names.</p> <p>Examples have been updated for clarity include a broader scope than pathology and imaging.</p>
AUeReqDI010	It is noted that 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 is also noted that the 'Medical imaging request' and 'Pathology test request' data groups are derived from the generic 'Service request' data group. The 'Medical imaging request' and 'Pathology test request' data groups are described as being consistent with the 'Service	<p>Comment noted, no change.</p> <p>The proposed value set in the generic 'Service request' is providing examples of service names in the broader AUeReqDI context.</p> <p>In contrast, the value set bound to the 'Test name' data element in the Pathology and Imaging requests is a highly constrained, purpose-specific subset of this broad value set.</p>

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	<p>request' data group, apart from specialisation of the 'Service name' data element and addition of data elements.</p> <p>Based on this information, it's not clear why a value set has been defined for the 'Service name' data element from the 'Service request' data group, considering this data element is being modified to a more specialised version for the purposes of pathology and medical imaging. It's difficult to comment on the appropriateness of the value set when it's not clear how this data element would be used in practice.</p>	
AUeReqDI014	<p>We suggest that 'service type' may be a more appropriate term than 'service name', and likewise for test type, as this may imply the name of the service (i.e. business name)</p>	<p>Wording updated to reflect comment.</p> <p>This is 'Service name', not type. 'Service type' is included in the model for future consideration.</p> <p>Examples have been updated for clarity.</p> <p>This data element does not refer to the service provider or service provider organisation.</p>

### 5.3. Clinical Indication

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI010	<p>The ‘Clinical indication’ value set seems too broad for to be used for multiple eRequesting use cases.</p> <p>For example:</p> <ul style="list-style-type: none"> <li>• The value ‘Abnormal movement in bone’ makes sense as a clinical indication for a medical imaging request but not as a clinical indication for a pathology test request.</li> <li>• The value ‘Measurement of cystathionine in urine specimen’ makes sense as a clinical indication for a pathology test request but not as a clinical indication for a medical imaging request.</li> <li>• The value ‘Able to budget’ does not make sense as a clinical indication for a pathology test request or medical imaging request.</li> </ul> <p>It is recommended that distinct clinical indication value sets are defined for each eRequesting use case e.g. pathology, medical imaging. Not constraining the value sets could impact the data quality by allowing for selection of inappropriate values. Constraining the value sets will support clinicians at the point of care by reducing the clinician burden and time to select the appropriate value.</p>	<p>Comment noted, no change.</p> <p>This data element references an existing NCTS value set. This value set is maximal in nature to support reuse across multiple use cases and support the breadth of the ecosystem to enable interoperability. This data set may be used in EMRs, patient or clinician apps, etc. Where the clinical context or use case requires it, specific IG specification or vendor implementations may specify constrained subsets of the AUCDI and eRequesting value sets.</p> <p>The examples provided make sense in the context, however for this generic Service request data group, we are unable to make assumptions of the scope of possible service requests.</p>
AUeReqDI017	<p>There are existing coding sets for clinical descriptions for Australia ICPC2+ (from BEACH).</p>	<p>Comment noted, no change.</p> <p>As SNOMED CT-AU is the preferred Australian clinical terminology, this has been reflected in the AUCDI. The scope of ICPC2+ should be</p>

		included in SNOMED CT-AU and where gaps are identified, please submit a request to the National Clinical Terminology Service (NCTS).
AUeReqDI018	Guidance on the usage of clinical indication and/or context is critical to avoid everything being pushed into free text instead of codable concepts	<p>Comment noted, no change.</p> <p>Agree. Guidance has been provided in the Considerations section of clinical indication - "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."</p> <p>Advice around training and user interface implementation to support data quality is out of scope of AUeReqDI.</p>

#### 5.4. Clinical Context

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI005	Why is there only one clinical context?	<p>Wording updated to reflect comment.</p> <p>This data element was specifically requested by service providers so that they can understand the context of the request and to support them when making decisions about whether the test request is appropriate for the clinical situation or if they need to consider alternative services or tests. It is intentionally a string to capture unlimited free text and is not intended to be adapted for other purposes, so only one occurrence is appropriate.</p> <p>The description of Clinical context has been updated for clarity to: "Narrative information providing an overview of the individual's current clinical situation."</p>
AUeReqDI024	Clinical context is often used interchangeable with comments when writing requests. To avoid confusion, we	Comment noted, no change.



	<p>recommend clinical notes be encapsulated in a separate structure referenced from the request, or a clear definition of relevant information to include in the clinical context.</p>	<p>The 'Clinical context' data element was specifically requested by service providers so that they can understand the context of the request and to support them when making decisions about whether the test request is appropriate for the clinical situation or if they need to consider alternative services or tests.</p> <p>The description of Clinical context has been updated for clarity to: "Narrative information providing an overview of the individual's current clinical situation."</p> <p>This data element describes the broader clinical background or circumstances related to the request, supporting the service provider in making informed decisions about service delivery.</p> <p>Historically, many paper forms featured a section labelled 'Clinical notes' to document relevant background content for each service request. This data element has been purposefully named 'Clinical context' to semantically differentiate it from the more generic 'Comment' which allows clinicians to record any additional information not captured in semantically-specific data elements.</p>
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### 5.5. Urgency

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI005	Where do these values come from? Is there not a valueset we can reuse?	<p>Comment noted.</p> <p>The proposed value set has been updated to SNOMED CT codes and is currently in development.</p>

## 5.6. Service Due

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI005	What about period, frequency, duration? Are you relating this to a FHIR datatype? If not why when others are?	Wording updated to reflect comment.  This data element has been changed to 'Service timing'. The datatype is the FHIR datatypes of Timing and String which allows for period, frequency and duration.
AUeReqDI007	The term “due” suggest the latest time it can be done or an expiry of the request. Service “service timing” or similar.	Wording updated to reflect comment.  Agree. Data element name has been changed to 'Service timing'.
AUeReqDI008	GPs need to be added to this in the consideration section as they are usually the long term Primary Care Provider who needs to be aware of the outcome or results of the request.	Wording updated to reflect comment.  Agree. Considerations in the Distribution list data elements have been updated to "healthcare providers" as any healthcare provider could be included here.

### 5.7. Comment

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI005	<p>Comment to whom? Why is this different from clinical context?</p>	<p>Comment noted, no change.</p> <p>The 'Clinical context' data element was specifically requested by service providers so that they can understand the context of the request and to support them when making decisions about whether the test request is appropriate for the clinical situation or if they need to consider alternative services or tests.</p> <p>The description of Clinical context has been updated for clarity to: "Narrative information providing an overview of the individual's current clinical situation."</p> <p>'Clinical context' describes the broader clinical background or circumstances related to the request, supporting the service provider in making informed decisions about service delivery.</p> <p>Historically, many paper forms featured a section labelled 'Clinical notes' to document relevant background content for each service request. This data element has been purposefully named 'Clinical context' to semantically differentiate it from the more generic 'Comment' which allows clinicians to record any additional information not captured in semantically-specific data elements.</p>
AUeReqDI007	<p>How is this different to Clinical context?</p> <p>As a user, if I was present with the two fields, how would I determine which one I would use for my "clinical notes". Given the definition of clinical context is same as "clinical notes", then what do I use comment for?</p>	<p>Comment noted, no change.</p> <p>The 'Clinical context' data element was specifically requested by service providers so that they can understand the context of the request and to support them when making decisions about whether the test request is appropriate for the clinical situation or if they need to consider alternative services or tests.</p>

	<p>Is this comment actually part of the original request or for ongoing commentary throughout the provision of the requested service?</p> <p>Do existing systems have a second field for comment?</p> <p>If so, is this at the individual service level, or for the request group?</p> <p>If additional element is necessary, please consider moving comment to the group level.</p> <p>Note that this will be difficult to map to FHIR (but not impossible) since there is only one note element, although repeating, there is no means to distinguish between type of notes.</p>	<p>The description of Clinical context has been updated for clarity to: "Narrative information providing an overview of the individual's current clinical situation."</p> <p>'Clinical context' describes the broader clinical background or circumstances related to the request, supporting the service provider in making informed decisions about service delivery.</p> <p>Historically, many paper forms featured a section labelled 'Clinical notes' to document relevant background content for each service request. This data element has been purposefully named 'Clinical context' to semantically differentiate it from the more generic 'Comment' which allows clinicians to record any additional information not captured in semantically-specific data elements.</p> <p>Existing systems represent narrative information in a variety of ways. This information model is intended to improve standardisation across all clinical systems, as a road map providing clarity and consistency in future requesting. Each vendor will need to resolve this in an appropriate way for their system.</p> <p>Each Service request can contain one or more activities, and the 'Comment' is related to each activity. Therefore, it is possible to make 'Comment's that are specific for each activity, but not to the group of activities or Service request as a whole. Any data fields intended to be applied to the group of activities or Service request as a whole are captured within the Protocol.</p>
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## 5.8. Distribution List

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI005	Why are government organisations called out separately from organisations? Why is this a reference? Is that not an implementation detail?	<p>Comment noted, no change.</p> <p>Clinicians, organisation, or agencies have been included. Government organisations have not been called out separately.</p> <p>The reference datatype was used to allow the Sparked Technical Design Group to define this.</p>
AUeReqDI024	When distributing results, it is important to know the role of each recipient. We recommend clearly differentiating the roles of each recipient in the distribution list, including but not limited to, the ordering and authorising providers.	<p>Comment noted, no change.</p> <p>The AUeReqDI is not describing the representation of the 'Distribution list'. The datatype proposed is a reference which would allow the Technical Design Group to define the recipients and their roles.</p>

## 5.9. Urgent Contact

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI005	Why isn't this out of scope as administrative information?	<p>Wording updated to reflect comment.</p> <p>Document updated for clarity.</p>
AUeReqDI024	We recommend removing this element from R1. This concept should instead be covered by a field such as ordering or authorizing provider.	<p>Wording updated and new content added to reflect comment.</p> <p>"Urgent contact" would not necessarily be the same as an ordering or authorising provider. It was a clinical requirement from the Sparked Clinical Design Group to identify someone who would be available to receive urgent notifications in an emergency or out of hours particularly if the ordering or authorizing provider was unavailable.</p>

		Considerations for "Urgent contact" have been updated to include "Use this data element if the outcome of the request requires an urgent or emergency response by the requester or requesting organisation, or if the requestor is not contactable at the time of testing and an alternative contact is nominated.
AUeReqDI017	Urgent contact must not be needed to be added each time for each request. This is a new (compared with current business model) and potentially onerous requirement for requestors (if they have to add it each time), and also implies that requestors will be available after-hours for urgent results. Many GPs would not tolerate this. There needs to be more conversation around this as pathology and DI centres are pushing this back onto requestors as GPs' responsibility.	Comment noted, no change.  The 'Urgent contact' data element is optional, however, was agreed as a requirement by the Clinical Design Group.

## 5.10. Billing Guidance

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI005	This has been previously described as out of scope.	Wording updated to reflect comment.  Document updated for clarity.
AUeReqDI007	Would expect that billing guidance will be coded or reference to existing data.	Wording updated to reflect comment.  Agree, the datatype has been updated to CodeableConcept.
AUeReqDI010	The [AUeReqDI010] suggest modifying the language to reflect the Australian context e.g. changing 'Government insurance scheme' to 'Medicare funded'.  The [AUeReqDI010] also suggest changing this to a Coded field rather than a String, given the examples provided under 'Considerations' indicate that it would be possible	Wording updated to reflect comment.  Agree, this has been updated. Considerations has been updated to include Medicare. The datatype has been updated to CodeableConcept.

	<p>to have an exhaustive list of options for a value set. This would make it easier for clinicians to record the information in a consistent manner.</p>	
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### 5.11. General Feedback for Service Request

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
<p>AUeReqDI003</p>	<p>Should this generic, abstract base model be included in the review process? I feel it only creates noise and complexity for the non-technically minded? I'm to assume any comment I make here applies to the later inherited models. Therefore my provided Accept/Reject status here is also inherited through the review. Which just highlights the point about it adding complexity.</p> <p>I expected a 'Requester' element to be covered in R1, is it not critical to provide information about who is requesting the services? 'Distribution List' was significant enough for inclusion, so I would have thought the requester was more so.</p>	<p>Wording and diagrams updated to reflect comment.</p> <p>The "Service request" is a foundational data group for AUeReqDI, comprising generic data elements that will support most simple requests for a service to be provide by another clinician, organisation or agency. It is anticipated that it will be used and reused in many future data collections related to both health and social care. It is included within the AUeReqDI scope because the specific "Pathology test request" and "Imaging request" are effectively extensions of the "Service request" – all data elements from the Service request are also included or adapted in these specific diagnostic data groups. In that context it is necessary for the "Service request" to be reviewed in parallel, to ensure that the common data elements are appropriate across both the generic and specific Pathology/Imaging use cases.</p> <p>The document and tables have been updated to represent the connection more clearly.</p> <p>The scope of AUeReqDI does not include representations of Participants (Patient, requester, receiving clinician, etc.) as they do not require clinical validation and defer to technical specifications for implementations. The concept of "Distribution list" was included as a clinical requirement but not explicitly defined and defers to the FHIR</p>

		<p>representation for detailed specifications. The document and tables have been updated for clarity.</p>
<p>AUeReqDI005</p>	<p>Why is our proposed roadmap based on OpenEHR and not FHIR?</p> <p>The introduction of a parallel OpenEHR universe against a FHIR implementation seems artificial and unnecessary.</p> <p>Why are we attempting to define a generic ServiceRequest as a requirement when these same elements are repeated in each of the imaging and pathology requests anyway? Given this is a logical model in theory, this will have no bearing on the FHIR implementation as generic service requests will not be exchanged and that is the focus of our Accelerator work.</p>	<p>Comment noted, no change.</p> <p>The AUeReqDI has been developed to align with the principles of AUCDI which has been deliberately designed with a focus on clinicians and stakeholders, ensuring that the conceptual data models represent common, well-defined requirements identified from agreed use cases. The structured representation of the AUCDI concepts, and therefore AUeReqDI has been informed by established clinical information model standards, particularly openEHR archetypes, which have been purposely developed by clinicians and informaticians focused on ensuring high-quality structured clinical data that is clinically safe and fit for purpose.</p> <p>All proposed roadmaps are based on openEHR archetypes as a starting point. Each roadmap is a candidate and can be updated based on requirements identified by other standards such as FHIR.</p> <p>The "Service request" is a foundational data group for AUCDI, comprising generic data elements that will support most simple requests for a service to be provide by another clinician, organisation or agency. It is anticipated that it will be used and reused in many future data collections related to both health and social care. It is included within the AUeReqDI scope because the specific "Pathology test request" and "Imaging request" are effectively extensions of the "Service request" – all data elements from the Service request are also included or adapted in these specific diagnostic data groups. In that context it is necessary for the "Service request" to be reviewed in parallel, to ensure that the common data elements are appropriate across both the generic and specific Pathology/Imaging use cases.</p> <p>The document and tables have been updated to represent the connection more clearly.</p>



		The AUeReqDI/AUeReqDI specifications represent clinical requirements, and it is expected that there will commonly be asynchronous development of FHIR IGs (and other technical specifications).
AUeReqDI007	<p>Rather than name of "Service request AUeReqDI", suggest "Request Group" or similar to ensure reflects the grouping of multiple service requests.</p> <p>Should there be a request date? This may be considered unnecessary administrative/implementation context, but I would expect to be fairly important clinically as well? It would certainly be important in a user interface for scheduling work etc.</p>	<p>Comment noted.</p> <p>Service request AUeReqDI has been renamed to Service request. This represents multiple components as part of a single service request (one request may have multiple tests).</p> <p>The service request model differs from the FHIR implementation, drawing from the openEHR approach. In the majority of service requests, there will be one activity per service, which reflects what clinicians expect when ordering. In situations where there is more than one activity per service (i.e. the same service provider and other protocol related parameters, the FHIR representation will require duplication of these repeating attributes and this can be managed at the IG level).</p> <p>Request date time stamp is out of scope, as it would be considered common across all requests and part of the system information about the technical aspects of recording the data. For scheduling, Service timing (updated from Service due) would be used.</p>
AUeReqDI008	as above, consideration for recurring services that may occur at fixed or variable timing	<p>Wording updated to reflect comment.</p> <p>Agree, for recurring services, Service timing (updated from Service due) would be used.</p>
AUeReqDI010	It is noted that 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 is also noted that the 'Medical imaging request' and 'Pathology test request' data groups are derived from	<p>Wording and diagrams updated to reflect comment. Comment noted, added to backlog.</p> <p>The 'Service request' is a core data group for AUeReqDI, consisting of data elements that will support most basic requests for services provided by clinicians, organisations or agencies. It is intended to be</p>

	<p>the generic ‘Service request’ data group. The ‘Medical imaging request’ and ‘Pathology test request’ data groups are described as being consistent with the ‘Service request’ data group, apart from specialisation of the ‘Service name’ data element and addition of data elements.</p> <p>It is suggested that the ‘Service request’ data group is removed from AUeReqDI and just used as a framework behind the scenes. The structure of AUeReqDI would be more intuitive if all relevant content was simply included under the ‘Medical imaging request’ and ‘Pathology test request’ data groups.</p> <p>It is noted that AUeReqDI R1 focuses on community-based pathology test and medical imaging but identifies eReferrals as another possible eRequesting use case. The [AUeReqDI010] would like to leverage referrals for a National Primary Health Care Data Collection (NPHCDC). Referrals-related data elements that the [AUeReqDI010] would like to collect for the NPHCDC are referral source, referral destination, reason for referral, date of referral and links to any relevant problems/diagnoses. These data elements would be useful for both primary and secondary use. It would be appreciated if these data elements could be added to the backlog.</p>	<p>adaptable and extendable to accommodate more complex eRequests. The ‘Pathology test request’ and ‘Medical imaging request’ are specific adaptations and extensions of the ‘Service request’ data group. All data elements from the Service request are either included directly or adapted for inclusion in these specialised diagnostic data groups. In this context, it is essential to review the ‘Service request’ in parallel to ensure that the common data elements are suitable across both the general and specific use cases for Pathology and Imaging.</p> <p>As AUeReqDI evolves, it is anticipated that additional data groups will be developed following this ‘Service request’ pattern to meet new eRequest requirements.</p> <p>The document and tables have been updated to represent the connection more clearly.</p> <p>The identified data elements have been added to the backlog.</p>
<p>AUeReqDI011</p>	<p>Some sort of Patient identifier is missing, both from the data group, and in the conceptual discussion.</p> <p>a service request such as a pathology request is non-transferrable and one of the main advantages for e-requesting over paper requesting is removing the need for data entry of patient demographic and administrative information. In addition, this type of personal information</p>	<p>Wording updated to reflect comment.</p> <p>Comment noted. Agree that these are requirements for the technical specification, however AUeReqDI is focused on the representation of the clinical content necessary for each of the data groups.</p> <p>Unless it is of clinical significance and requires clinical validation, they are deferred to technical standards for implementation.</p>

	<p>is likely much easier codify in standards than clinical information.</p> <p>We are aware that the “patient” concept is part of the AU Core, rather than e-requesting per se, but the patient personal data is still an essential part of all service requests.</p> <p>In addition, “Date of request” is a key concept within the Medicare benefits claiming framework and is also relevant for the request receiver interpreting the clinical information provided. While this might be implicit in the “Service due” field, Date of request (and likely time of request as well) should be included as a mandatory field in all Service Requests.</p> <p>these comments also apply to the derived "Pathology test request" data group.</p>	<p>The scope of AUeReqDI does not include representations of Participants (Patient, requester, receiving clinician, etc.) as they do not require clinical validation. Request date time stamp is out of scope, as it would be considered common across all requests and part of the system information about the technical aspects of recording the data. The document has been updated for clarity.</p>
<p>AUeReqDI024</p>	<p>"We recommend reviewing the overall structure of the service request model in R1. The grouping of multiple activities under a single service request deviates from international standards such as FHIR, where the relation between service request and activity is one to one. We recommend using a service request to represent a requested activity, and not grouping activities by the protocol concept.</p> <p>We also recommend including additional fields for ordering and authorizing providers in R1."</p>	<p>Wording updated and new content added to reflect comment.</p> <p>The service request model differs from the FHIR implementation, drawing from the openEHR approach. In the majority of service requests, there will be one activity per service, which reflects what clinicians expect when ordering. In situations where there is more than one activity per service (i.e. the same service provider and other protocol related parameters, the FHIR representation will require duplication of these repeating attributes and this can be managed at the IG level).</p> <p>The ordering and authorising providers are out of scope and intentionally not specified in the clinical model. It is assumed this will be managed in a consistent manner in the IG specification along with all other system and demographic related attributes.</p>

		<p>Section 5.5.1 has been updated to reflect the items that are considered out of scope for AUeReqDI, keeping it focused on the data required to represent the clinical data for exchange.</p>
<p>AUeReqDI018</p>	<p>This does not provide for identification of the requester, nor for a unique identifier for the specific request; it does provide a “distribution list” and an “urgent contact”.</p> <p>Presumably the requester and request ID are to be addressed in the Implementation Guide</p> <p>Can this be confirmed? If yes then our recommendation changes from major revision to accept</p>	<p>Comment noted, no change.</p> <p>As AUeReqDI is focused on the representation of the clinical content necessary for each of the data groups, unless it is of clinical significance and requires clinical validation, they are deferred to technical standards for implementation. Identification of requestor and unique identifiers for specific requests are out of scope for AUeReqDI. These should be raised in the AU eRequesting Technical Design Group.</p>

## 6. AUeReqDI Data Group: Medical Imaging Request

### 6.1. Overall Recommendations

Accept	Minor	Major	Reject	Abstain
9	6	3	0	3

### 6.2.

### 6.3. Test Name

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI008	Consideration for procedural items including therapeutic procedures requiring imaging as a modality eg CT-guided corticosteroid injection, USS guided FNA, USS guided pleural tap	Comment noted, added to backlog. Agree. This is currently out of scope for R1, however, is in the backlog for future consideration.
AUeReqDI010	It is noted that 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. Will there be an opportunity to review and provide feedback on the proposed value set for medical imaging request test name?	Comment noted, no change. The Radiology Referral Value Set (RRV) which supports the AU eRequesting FHIR IG will be available for review as part of the ballot review process. It will be available on the National Clinical Terminology Service (NCTS) website at that time.

AUeReqDI025	During the HL7 v2 O&O working group, we made the decision to avoid the use of the word "test" because it was too ambiguous - "Test" could refer to an orderable concept that may describe one test or a battery of tests, or an observation (where an observation is a child of the order). Consider calling this "Imaging exam name" to be unambiguous.	New content added to reflect comment.  "Study name", "Examination name" and "Procedure name" have been added to the Aliases.
AUeReqDI018	<p>(i) Recommended code system/value set should specifically mention the RRS, including its current work in progress status (cf ref to SPIA in 8.3.3)</p> <p>(ii) Could we include some examples from the RRS of "Test name" ?</p> <p>(iii) "Aliases" could include things like "Examination", "Imaging study" "Study requested" etc</p> <p>(iv) Considerations – should again mention the RRS</p>	<p>Wording updated and new content added to reflect comment.</p> <p>(i) A section at the beginning of the document has been added to share the work done by RANZCR and RCPA.</p> <p>(ii) Examples from the RRV has been included for "Test name".</p> <p>(iii) Agree, have updated Aliases with "Study name", "Examination name" and "Procedure name".</p> <p>(iv) A section at the beginning of the document has been added to share the work done by RANZCR and RCPA.</p>

#### 6.4. Modality

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI005	Given this is a logical model, why is it necessary to define a separate code for modality?	<p>Comment noted, no change.</p> <p>This data element is optional and may be used when modality has not been included in the precoordinated test name, or when a precoordinated term is not available.</p>
AUeReqDI010	It is noted that 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. Will there be an opportunity to review and provide feedback on the proposed value set for medical imaging request modality?	<p>Comment noted, no change.</p> <p>The RRS project is a work in progress and is referenced by AUeReqDI. The development and publication are auspiced by RANZCR.</p>
AUeReqDI018	<p>(i) Occurrence – should be mandatory (or please explain justification for optional)</p> <p>(ii) Recommended – should quote the modality codes accepted for the RRS (XR, MG, RF, US, CT, BMD, NM, PT, IR, INR, MR – these were derived from (and an improvement on) the modalities specified in DICOM part 3.3 C7.3.1.1.1, which lists 79 items, only 12 of which are commonly used in diagnostic &amp; interventional radiology. [another, PX, for OPG, may be worth inclusion in the RRS later].</p>	<p>Comment noted, no change.</p> <p>(i) This has been marked as optional for instances where the modality is assumed (e.g. Barium swallow) or has been included in the "Test name" (X-ray of left foot).</p> <p>(ii) SNOMED CT-AU is the national clinical terminology for requests, and it is appropriate that the RRS includes SNOMED CT-AU for modality as part of its expressions.</p> <p>(iii) SNOMED CT-AU is the national clinical terminology for requests. These abbreviations can be requested to be included in SNOMED CT-</p>

	<p>(iii) some examples (from the list of 11) could be listed here</p> <p>(iv) Aliases could include something like “scan” or “scan type”</p> <p>(v) considerations – DSA is not recognised as a distinct modality (DICOM has retired it with terms assigned to XA, we would include under RF, IR or INR depending on type of angio)</p>	<p>AU as part of a description (SNOMED International editorial rules would define how these would be represented).</p> <p>(iv) Scan and Scan type is more specific than Modality (a subtype) so would not be considered an equivalent term.</p> <p>(v) DSA has not been included in the examples for Modality.</p>
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## 6.5. Target Body Site

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI005	Given this is a logical model, why is it necessary to define a separate code for bodysite?	<p>Comment noted, no change.</p> <p>This data element is optional and may be used when body site has not been included in the precoordinated test name, or when a precoordinated term is not available.</p>
AUeReqDI008	Laterality not to be mandatory as many organs not bilateral eg liver, brain, uterus	<p>Wording updated to reflect comment.</p> <p>Agree. This has not been made mandatory.</p>
AUeReqDI010	It is noted that 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. Will there be an opportunity to review and provide feedback on the proposed value set for medical imaging request target body site?	<p>Comment noted, no change.</p> <p>The RRS project is a work in progress and is referenced by AUeReqDI. The development and publication are auspiced by RANZCR.</p>
AUeReqDI024	We recommend updating the cardinality to multiple occurrence. The description of "Target body site -	Wording updated to reflect comment.



	considerations" describes the data element as allowing multiple occurrences.	Agree, this has been updated.
AUeReqDI018	<p>(i) Occurrence - again, not sure that this can be optional – most things that can be done as whole body scans (eg nuclear medicine bone scan) may also be applied to smaller regions</p> <p>(ii) Recommended code system - Body site ontology will need to be created consistent with RRS, Codeable concepts will need to have options for fallback code systems should the primary code system be unable to encapsulate the information</p> <p>(iii) Aliases could include “region” body part”, etc</p>	<p>Comment noted, no change.</p> <p>(i) This has been marked as optional for instances where the body site is assumed (e.g. Barium swallow) or has been included in the "Test name" (X-ray of left foot).</p> <p>(ii) A SNOMED CT-AU value set is to be developed that aligns with this work.</p> <p>(iii) Comment noted. Target body site is an overarching term that includes regions and body parts, and so these specific terms would be considered to be a finer level of granularity and not synonymous.</p>

## 6.6. Contrast Use

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI005	Where do these proposals come from? This is not the common representation used.	<p>Comment noted, no change.</p> <p>AUeReqDI is intentionally designed to record the most accurate and precise data. The data structure can be mapped to a different user interface based on requirements.</p> <p>The proposed value set leverages an existing SNOMED CT code, and an additional code was created to match.</p>
AUeReqDI009	<p>Contrast option – think there should be an option “with/without contrast” where the radiologist is best to determine the need for contrast based on the clinical indications.</p> <ul style="list-style-type: none"> <li>• Most recent creatinine/eGFR for imaging where contrast or with/without contrast has been selected.</li> </ul>	<p>Comment noted, added to backlog.</p> <p>Contrast use is an optional data element, so a null value is acceptable. A null value would reflect no recommendation from the requester. This has been added to the backlog for further consideration as potential future extensions.</p>
AUeReqDI024	<p>"We recommend adding a value of ""with and without"" for scenarios in which a requesting provider may want imaging performed both with and without contrast.</p> <p>We also recommend clearly defining the usage of ""without contrast"" as either an administrative concept, or if it is a clinically relevant field due to risk of adverse reaction."</p>	<p>Comment noted, added to backlog.</p> <p>Comment noted. This has been added to the backlog for further consideration as potential future extensions.</p> <p>Clinical relevance is not limited to 'adverse reaction risk' but also conditions and pregnancy, all of which can be included as supplementary data attached to the request using those specific data groups.</p>
AUeReqDI018	<p>Considerations – should highlight that this element is in very early development, and currently only refers to whether (any sort of) contrast agent is requested, administered via any route – IV, oral, rectal, etc – details of the requested agent and its route of administration (or of any contra-indicated agent) to be spelt out in the</p>	<p>Comment noted, no change. Added to the backlog.</p> <p>Comment noted. This data element is intended only to indicate the broad recommendation by the requester for the use of contrast.</p> <p>Other suggested data elements have been added to the backlog.</p>

	<p>“considerations” section (perhaps by link to other elements) - should be expanded in later releases</p>	
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### 6.7. General Feedback for Medical Imaging Request

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
<p>AUeReqDI005</p>	<p>It is unclear what the role or purpose is of the generic service request given all attributes are repeated here. The same issues of scope and logical vs platform information modelling approaches are relevant here. Also unclear why our future design is being pegged against OpenEHR rather than FHIR. There seems to be some confusion of whether these requests represent one, or one or more requests as the description in Representation and Considerations for Use don't match.</p>	<p>Wording and diagrams updated to reflect comment.</p> <p>The AUeReqDI has been developed to align with the principles of AUCDI which has been deliberately designed with a focus on clinicians and stakeholders, ensuring that the conceptual data models represent common, well-defined requirements identified from agreed use cases. The structured representation of the AUCDI concepts, and therefore AUeReqDI has been informed by established clinical information model standards, particularly openEHR archetypes, which have been purposely developed by clinicians and informaticians focused on ensuring high-quality structured clinical data that is clinically safe and fit for purpose.</p> <p>All proposed roadmaps are based on openEHR archetypes as a starting point. Each roadmap is a candidate and can be updated based on requirements identified by other standards such as FHIR.</p> <p>The "Service request" is a foundational data group for AUCDI, comprising generic data elements that will support most simple requests for a service to be provide by another clinician, organisation or agency. It is anticipated that it will be used and reused in many future data collections related to both health and social care. It is included within the AUeReqDI scope because the specific "Pathology test request" and "Imaging request" are effectively extensions of the "Service request" – all data elements from the Service request are also</p>

		<p>included or adapted in these specific diagnostic data groups. In that context it is necessary for the "Service request" to be reviewed in parallel, to ensure that the common data elements are appropriate across both the generic and specific Pathology/Imaging use cases.</p> <p>The document and tables have been updated to represent the connection more clearly.</p> <p>This data group can be used to represent a request for one or more services. Document has been updated for clarity.</p> <p>The AUeReqDI/AUeReqDI specifications represent clinical requirements, and it is expected that there will commonly be asynchronous development of FHIR IGs (and other technical specifications).</p>
AUeReqDI008	<p>Should "Pregnancy status" be added as a fixed variable eg Yes/No/Unknown/ NA</p> <p>Major risk for potential foetal malformations or foetal death if inadvertent exposure to radiation or teratogens.</p>	<p>Comment noted, no change.</p> <p>The Sparked Clinical Design Group agreed that Pregnancy status would not be included in the AUeReqDI and should be included in AUeReqDI, and discussed as a high priority for R2 and to determine the best way to represent pregnancy related data.</p>
AUeReqDI010	<p>The data element 'Test name' aligns to a data element within the [AUeReqDI010] data model for a National Primary Health Care Data Collection (NPHCDC) and could be leveraged for this purpose. Other imaging-related data elements that the [AUeReqDI010] would like to collect for the NPHCDC are the date the imaging test was requested, the date the imaging test was performed, the imaging test results, and links to any relevant problems/diagnoses. These data elements would be useful for both primary and secondary use. It would be appreciated if these data elements could be added to the backlog.</p>	<p>Comment noted, no change.</p> <p>Request date time stamp is out of scope, as it would be considered common across all requests and part of the system information about the technical aspects of recording the data.</p> <p>The other data elements listed correspond to results and are out of scope.</p>
AUeReqDI025	<p>"An order and a referral are two different concepts, where an order is a child of a referral. I don't agree that</p>	<p>Comment noted, no change.</p>

	<p>they are synonyms, and they should sit on different levels of the eRequesting hierarchy.</p> <p>Consider changing the concept description to ""A request for a medical or diagnostic imaging services"".</p> <p>The purpose would then be: ""To record a request for one or more medical imaging services"".</p> <p>The term ""request"" aligns with the ""Medical imaging request AUeReqDI"" concept title."</p>	<p>In some contexts, request, order and referral may not always be considered synonymous, however, in the context of medical or diagnostic imaging services they are often considered the same and used interchangeably.</p> <p>The concept description is intended to define or describe the data group concept without being self-describing.</p>
AUeReqDI017	<p>See comments above under 'Service request: Urgent contact'.</p>	<p>Comment noted, no change.</p> <p>The 'Urgent contact' data element is optional, however, was agreed for inclusion by the Clinical Design Group.</p>

## 7. AUeReqDI Data Group: Pathology Test Request

### 7.1. Overall Recommendations

Accept	Minor	Major	Reject	Abstain
9	5	4	0	3

### 7.2. Test Name

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI009	<ul style="list-style-type: none"> <li>Limiting the test names, test names should be flexible with synonyms and alternative names to meet the different reporting formats of all labs.</li> <li>Panels ordering or test grouping would be problematic to standardise and its discussions around it should include representative from each sector to cover the different labs (public and private).</li> <li>Test names – it will be impossible to have one to one matching of test names – labs will presumably have the map the ordering to the most logical test in their system and potentially have some rules to alert to any specific requirements.</li> </ul>	<p>Comment noted, no change.</p> <p>The lack of standardisation around panels is recognised and is an implementation issue that needs to be considered.</p> <p>Noted. Mapping process is an implementation issue that will need to be considered.</p>
AUeReqDI024	We recommend including additional codesets such as LOINC.	<p>Comment noted, no change.</p> <p>RCPA recommends the use of SNOMED CT-AU for requesting in Australia, which is reflected in AUeReqDI.</p>
AUeReqDI025	"During the HL7 v2 O&O working group, we made the decision to avoid the use of the word ""test"" because it	New content added to reflect comment.

	<p>was too ambiguous and introduced confusion during implementation, especially in the pathology domain. "Test" can refer to an orderable concept that may describe one test or a battery of tests, or an observation (where an observation is a child of the order).</p> <p>The way it is used in this document can mean one test (e.g. Haemoglobin) or a battery of tests (e.g. Full blood count). The order is the Haemoglobin or the Full blood count.</p> <p>Suggest we include both of these in the Test name examples to demonstrate:</p> <p>271026005   Haemoglobin level estimation   26604007   Full blood count  </p> <p>Consider calling this "Pathology order name" to be unambiguous (this is equivalent to the preferred requesting term specified in the RCPA SPIA reference set and the service identifiers in HL7 v2 OBR-4). The pathology order name must then map to an orderable concept in the lab system's order catalogue, which could be a "test" or a "battery of tests".</p>	<p>Noted. The following have been added as examples – 767002   White blood cell count  , 26604007   Full blood count  , 167995008  Sputum microscopy , 302792004  Sperm count  and 171149006  Screening for malignant neoplasm of cervix .</p> <p>Pathology order name could be synonymous with the entire request, rather than an individual analyte or panel so has not been added as an alias.</p>
<p>AUeReqDI011</p>	<p>As mentioned in our general feedback, we would note that, in spite of the SPIA existing for a number of years, and the RCPA promoting its universal adoption, there are still significant variations in test nomenclature both from requestors and even within laboratory operations groups. Significant provider education, and time, will be required if the standard is going to enforce strict compliance with any single naming convention.</p>	<p>Comment noted, no change.</p> <p>Agree, discussions are ongoing in this area.</p>

### 7.3. Fasting Status

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI005	Why is the logical model setting requirements on the representation in the implementation?	<p>Comment noted, no change.</p> <p>Fasting status has been represented the same way as all coded data elements in AUeReqDI and AUeReqDI and does not impose any additional requirements on implementations. The data structure can be mapped to a different user interface based on requirements.</p>
AUeReqDI024	Fasting status is just one specific condition that may need to be included in a pathology request. Given the range of other conditions that matter in pathology testing and how those would be represented in different systems, we recommend a generic data model to allow for additional test parameters to be specified.	<p>Comment noted, no change.</p> <p>No other data elements that are unique for a pathology request have been identified. Other parameters that are commonly found on forms, such as Pregnancy status and Menopausal status will be represented using specific data groups identified in AUeReqDI R2+.</p>
AUeReqDI009	<ul style="list-style-type: none"> <li>• Can the fasting status only come across when relevant? It gets annoying otherwise as not applicable for most tests. Also – what is the purpose of fasting question? Is it for when the clinician is collecting the blood at the time the request is written? Is it to alert the patient of the requirements of the test if they attend a collection centre instead? I don't think the laboratory can believe a request written often days before the patient has the test. The person requesting the test will have no idea the fasting status at the time the patient has the test. That is why the collecting staff will always the patient if they are fasting – they will need the ability to change this in the request.</li> </ul>	<p>Comment noted, no change.</p> <p>Fasting status is optional and is a recommendation related to the fasting state of the patient at the time of specimen collection. Implementation is out of scope for AUeReqDI.</p>



**7.4. General Feedback for Pathology Test Request**

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI005	<p>It is unclear what the role or purpose is of the generic service request given all attributes are repeated here. The same issues of scope and logical vs platform information modelling approaches are relevant here. Also unclear why our future design is being pegged against OpenEHR rather than FHIR and OpenEHR is always appearing as the primary reference even though FHIR is our implementation target. There seems to be some confusion of whether these requests represent one, or one or more requests as the description in Representation and Considerations for Use don't match.</p>	<p>Wording and diagrams updated to reflect comment.</p> <p>The AUeReqDI has been developed to align with the principles of AUCDI which has been deliberately designed with a focus on clinicians and stakeholders, ensuring that the conceptual data models represent common, well-defined requirements identified from agreed use cases. The structured representation of the AUCDI concepts, and therefore AUeReqDI has been informed by established clinical information model standards, particularly openEHR archetypes, which have been purposely developed by clinicians and informaticians focused on ensuring high-quality structured clinical data that is clinically safe and fit for purpose.</p> <p>All proposed roadmaps are based on openEHR archetypes as a starting point. Each roadmap is a candidate and can be updated based on requirements identified by other standards such as FHIR.</p> <p>The "Service request" is a foundational data group for AUCDI, comprising generic data elements that will support most simple requests for a service to be provide by another clinician, organisation or agency. It is anticipated that it will be used and reused in many future data collections related to both health and social care. It is included within the AUeReqDI scope because the specific "Pathology test request" and "Imaging request" are effectively extensions of the "Service request" – all data elements from the Service request are also included or adapted in these specific diagnostic data groups. In that context it is necessary for the "Service request" to be reviewed in</p>

		<p>parallel, to ensure that the common data elements are appropriate across both the generic and specific Pathology/Imaging use cases.</p> <p>The document and tables have been updated to represent the connection more clearly.</p> <p>This data group can be used to represent a request for one or more services. Document has been updated for clarity.</p> <p>The AUeReqDI/AUCDI specifications represent clinical requirements, and it is expected that there will commonly be asynchronous development of FHIR IGs (and other technical specifications).</p>
<p>AUeReqDI009</p>	<p>Missing elements from AU eReq DI R1:</p> <ul style="list-style-type: none"> <li>• Information about stage of menstrual cycle and gestation age is important as testing might be warranted at a specific time of the menstrual cycle and this should be followed to get an informed report guiding the screening / diagnosis / management. Gestational age is also needed for certain tests as FTS and OGTT and Trimester specific TFT reference intervals.....etc.</li> <li>• Medication information, including date and time of the last dose, is needed to therapeutic drug monitoring to decide the therapeutic range used whether trough/ peak levels. It's a missed opportunity not to have included Medications. We presume that AU eReq DI R1 could draw this from the clinical medical record systems of GPs, specialists and hospital systems as this would be helpful in the interpretation a substantial number of Pathology test results.</li> <li>• Non-blood specimens – there doesn't seem to be any data fields to collect the specimen type and specimen</li> </ul>	<p>Comment noted, added to backlog.</p> <p>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 Clinical Design Group 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).</p> <p>Last administration date/time for Medication use statement has been placed in the AUCDI backlog for future consideration.</p> <p>The specimen source/site has been placed in the AUeReqDI backlog for future consideration.</p> <p>Patient specimen collection details is currently out of scope for AUeReqDI R1 and has been placed in the backlog for future consideration.</p> <p>AUeReqDI was developed to be agnostic of pathology specialties and can be used for histopathology and cytology requests pending</p>

	<p>source/site. There also needs to the free text fields for at least the specimen source/site.</p> <ul style="list-style-type: none"> <li>• How will any patient specimen collected outside the laboratory and requisitioned to the laboratory - what details will be provided (such as time/date/collection method' etc)</li> <li>• How will the AU eReq DI R1 - support Pathology Service Requests for Histopathology, Cytology requests, as the current information model seems to be blood/urine pathology test/collection specific.</li> <li>• For Anatomical Pathology and Microbiology - will the 'Clinical Context' data element in the pathology service request information model - support the feature for 'free-text' and ability for clinicians to upload or digitally attach diagrams - about patient specimen location etc.</li> <li>• Aboriginal and Torres Strait Islander status – this is meant to be a requirement for pathology; is it going to be collected in some other manner.</li> <li>• MyHealth record opt out – will patients still be given the option of opting out?</li> <li>• Certain tests would need customised questions eg HPV/cervical screening - can these be built into the Pathology Service Request.</li> </ul>	<p>specimen collection details which is currently out of scope for AUeReqDI R1 and has been placed in the backlog for future consideration.</p> <p>The Clinical context data element is a string so is intended for free-text/narrative. The requirement for a multimedia representation has been added to the backlog for future consideration.</p> <p>Indigenous status has been placed on the backlog for future consideration.</p> <p>MyHR Opt-out is considered part of implementation and workflow. The AUeReqDI specification is not a technical implementation guide and intentionally kept neutral of implementation strategies and functional workflow and so this is currently out of scope of the data model.</p> <p>Yes, HPV/cervical screening data requirements has been placed on the backlog for future consideration.</p>
AUeReqDI010	<p>The data element 'Test name' aligns to a data element within the [AUeReqDI010] data model for a National Primary Health Care Data Collection (NPHCDC) and could be leveraged for this purpose. Other pathology-related data elements that the [AUeReqDI010] would like to</p>	<p>Comment noted, no change.</p> <p>Request date time stamp is out of scope, as it would be considered common across all requests and part of the system information about the technical aspects of recording the data.</p>

	<p>collect for the NPHCDC are the date the pathology test was requested, the date the pathology test was performed, the pathology test result value, the pathology test result units, a flag to indicate abnormal pathology test results, and links to any relevant problems/diagnoses. These data elements would be useful for both primary and secondary use. It would be appreciated if these data elements could be added to the backlog.</p>	<p>The other data elements listed correspond to results and are out of scope.</p>
AUeReqDI011	<p>Patient data and date/time of request are key information. The biggest advantage of electronic requesting over paper form requests is removing the need to re-enter patient data (name, DoB, Medicare number etc) into the laboratory's information management system.</p>	<p>Wording updated to reflect comment.</p> <p>Comment noted. Agree that these are requirements for the technical specification, however, AUeReqDI is focused on the representation of the clinical content necessary for each of the data groups.</p> <p>Unless it is of clinical significance and requires clinical validation, they are deferred to technical standards for implementation.</p> <p>The scope of AUeReqDI does not include representations of Participants (Patient, requester, receiving clinician, etc.) as they do not require clinical validation. Request date time stamp is out of scope, as it would be considered common across all requests and part of the system information about the technical aspects of recording the data. The document has been updated for clarity.</p>
AUeReqDI024	<p>We recommend adding a data concept for specimen and collection information. When requesting specific tests, providers may specify the specimen source and collection method based on relevant clinical context at the point of ordering.</p>	<p>Comment noted, added to backlog.</p> <p>Agree. Patient specimen collection details is currently out of scope for AUeReqDI R1 and has been placed in the backlog for future consideration.</p>
AUeReqDI017	<p>General approach to requesting is outlined on page 13. The first step is for the GP to agree with the consumer a recommended provider for the test. This is fundamentally different from usual workflows where paper forms are</p>	<p>Comment noted, no change.</p> <p>Comment noted. The AUeReqDI is focused on the representation of the clinical content necessary for each of the data groups.</p>

	<p>valid at any provider and the provider is chosen by the patient for convenience, continuity, cost reasons. Any eRequest will need to be accessible from the cloud by any provider chosen by the patient, much like e-prescriptions.</p> <p>Page 16/17 describes the purpose of AUeReqDI R1 to facilitate end-to-end requesting and receipt of pathology and imaging. There is scant attention to the purpose of sharing clinical information from requesting GP to the provider. Essentially the clinical information needs to:</p> <ol style="list-style-type: none"> <li>1. Ensure safe care, so pregnancy status, latest eGFR, allergies need to be included in requests for imaging.</li> <li>2. Allow provider to add or subtract or recommend changes to the request. For example if iron overload is being checked, full iron studies are needed, if iron deficiency is being checked, only ferritin is needed.</li> <li>3. Enable the provider to give clinically relevant results with some level of interpretation. HbA1c test to case find for diabetes will be different from monitoring glycaemic control for established diabetes.</li> </ol> <p>Consider the potential advantages of eRequests rather than just replacing paper with eRequest. There request should allow for better communication between referrer and provider as a clinical exchange - not just an isolated technical procedure. If treated just as a technical procedure, there is no need to have radiologists and pathologists involved - just lab techs and radiographers.</p> <p>eRequests might be designed to facilitate advances in reporting results. Evidence shows that 'structured</p>	<p>Unless it is of clinical significance and requires clinical validation, they are deferred to technical standards for implementation.</p> <p>Many of the points raised are important implementation requirements which are the responsibility of the Sparked Technical Design Group. It is recommended to provide input to the Sparked Technical Design Group to ensure these requirements are addressed.</p> <p>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 Clinical Design Group 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 AUeReqDI and will be modelled for persistence. These data elements that have been placed in the AUeReqDI backlog are: Current pregnancy status, Estimated Date of Delivery, Last menstrual period (LMP), and Post-menopausal status (Menstruation summary).</p> <p>Comment noted. Diagnostic test results are not in scope for AUeReqDI but is in the backlog for AUeReqDI.</p>
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	<p>reports' contain better information and are preferred by requesting clinicians. Ideally, structured reports that are atomised and machine readable should be the aim so that computer decision support and population health management and health service research are all facilitated.</p>	
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## 8. AUeReqDI Data Group: Implanted Medical Device Summary

### 8.1. Overall Recommendations

Accept	Minor	Major	Reject	Abstain
8	2	5	0	6

### 8.2. Device Type Name

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI004	There seems to be only a loose definition of what constitutes as medical device. Might benefit from strengthening.	Wording updated to reflect comment.  Document has been updated for clarity, including 'In this data group, the definition of an 'implanted medical device' is deliberately broad to be inclusive of any medical device intentionally implanted in the body, including devices that are considered short-term, long-term or permanent.'
AUeReqDI008	Needs to have option to include implanted medication delivery devices eg Implanon, GNRH inhibitors, Mirena etc	Comment noted, no change. These have not been excluded from this data group; however, consideration is required on how it crosses over with medication data groups and its implementation consequences.
AUeReqDI010	It is noted that a value set to support implanted device type requirements will be developed to support imaging requests. Will there be an opportunity to review and provide feedback on the proposed value set for implanted medical device type name?	Comment noted, no change.  The value set to support implanted device type will require input from interested stakeholders and is currently on the backlog.
AUeReqDI016	In the listed "considerations for use" (page 45 of 61) it would be beneficial to include spinal cord stimulators.	Wording updated and new content added to reflect comment.

	This is an emerging issue of concern and the inclusion of this device would greatly assist the department of Health in assessing the usage of these devices.	Document has been updated to include this example.
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### 8.3. Overall Status

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI005	Why would you record a device, for the purpose of eRequesting, that isn't current in the body?	<p>Wording updated to reflect comment.</p> <p>Overall status has been updated to 'Current status' in the model and has been included to ensure that the receiver has the most up to date information and is aware of any changes to the device status, for example if there have been previous tests with previous devices in situ, but have since been removed, the receiver will be notified.</p> <p>This data could be extracted from an electronic health record and could be filtered as required for an eRequest.</p>
AUeReqDI007	What does "overall" add to this element name. Can this better reflect the intent of indicating that the patient has this device inserted in the body or not.	<p>Wording updated to reflect comment.</p> <p>Agree, this has been updated to 'Current status' in the model.</p>
AUeReqDI016	Very good.	Thank you for your support.



#### 8.4. Overall Comment

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI007	What does "overall" add to this element name. Suggest comment is sufficient.	Comment noted, no change.  This data element represents a comment about all insertions of this device type.
AUeReqDI016	Acceptable	Thank you for your support.

#### 8.5. Last Updated

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI005	Why is this not out of scope? It is administrative in nature.	Comment noted, no change.  Last updated has been included as a clinically requested requirement in all summary like data in AUcDI and AUeReqDI.
AUeReqDI016	In the listed "considerations for use" (page 45 of 61) it would be beneficial to include spinal cord stimulators. This is an emerging issue of concern and the inclusion of this device would greatly assist the department of Health in assessing the usage of these devices.	New content added to reflect comment.  Agree. Document has been updated.

## 8.6. General Feedback for Implanted Medical Device Summary

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI005	<p>There is no clinical context described for how and why it is relevant to an eRequest. The description is for a data element within a clinical record not an eRequesting transaction. Why is there no reference to a FHIR Device? Same comments apply about positioning relative to a future use within FHIR vs OpenEHR.</p>	<p>Wording updated to reflect comment.</p> <p>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.</p> <p>Document has been updated for clarity.</p> <p>The AUeReqDI has been developed to align with the principles of AUCDI which has been deliberately designed with a focus on clinicians and stakeholders, ensuring that the conceptual data models represent common, well-defined requirements identified from agreed use cases. The structured representation of the AUCDI concepts, and therefore AUeReqDI has been informed by established clinical information model standards, particularly openEHR archetypes, which have been purposely developed by clinicians and informaticians focused on ensuring high-quality structured clinical data that is clinically safe and fit for purpose.</p> <p>All proposed roadmaps are based on openEHR archetypes as a starting point. Each roadmap is a candidate and can be updated based on requirements identified by other standards such as FHIR. The FHIR Device family of resources are administrative and have been included in the future considerations section for this data group. Document has been updated to reflect this.</p>
AUeReqDI007	<p>The description suggests the record is to represent a device that can be inserted, while the considerations for use, and the data elements suggest it is recording that the device has been implanted into the patient. The latter</p>	<p>Comment noted, no change.</p> <p>Noted. The document has been extensively updated for clarification about this model being about the presence of an implanted device in a</p>

	<p>suggests this is more like recording an observation or condition related to the state of the patient with an implanted device rather than the device itself.</p> <p>This should be made more clear and consistently defined.</p> <p>The misuse indicates not recording as a procedure, but this might actually be a good way to represent this if not as an observation or condition.</p> <p>Given the base model is an openEHR evaluation, it tends towards being a condition of sorts.</p> <p>Furthermore, it is unclear in the context of the Service Request data group, where this fits given that there is no concept of supporting information or similar to relate to this data group.</p>	<p>patient to support clinical management. Details about the actual device will likely be added in future releases as an extension to this first iteration.</p> <p>Information captured in clinical systems using this data group are intended to be sent alongside each request as part of a message, if clinically relevant, for example as components of a patient summary.</p> <p>This is one of a range of clinical concepts that are required to support safe clinical requesting.</p>
<p>AUeReqDI008</p>	<p>Need to have field for ‘Insertion Date”</p> <p>Initially optional but should be mandatory for all new devices inserted eventually. As a single instance of data insertion that should reside in the clinicians EMR this should not be overly onerous for clinicians. This data is important as the clinical considerations for example a new hip replacement or valve replacement are significantly different to that of a device that has been ‘in situ” for 20 years.</p>	<p>Comment noted, added to backlog.</p> <p>Agree, date of insertion has been added to the backlog for future consideration.</p>
<p>AUeReqDI010</p>	<p>Implanted medical devices are not currently included in the [AUeReqDI010] data model for a National Primary Health Care Data Collection (NPHCDC), however they will now be considered for inclusion. If implanted medical devices were included in the NPHCDC, other data elements that the [AUeReqDI010] would want to collect</p>	<p>Comment noted, added to backlog.</p> <p>Date of insertion, date of expiry, date of removal and clinical indication has been added to the backlog for future consideration.</p>

	are the date the medical device was implanted, the date the medical device expires (e.g. for a contraceptive implant), the date the medical device was removed, the reason for implanting the medical device, and links to any relevant problems/diagnoses. These data elements would be useful for both primary and secondary use. It would be appreciated if these data elements could be added to the backlog.	
AUeReqDI016	In the listed "considerations for use" (page 45 of 61) it would be beneficial to include spinal cord stimulators. This is an emerging issue of concern and the inclusion of this device would greatly assist the department of Health in assessing the usage of these devices.	Wording updated and new content added to reflect comment. The document has been updated to include this example.
AUeReqDI018	recommend checking what is used for the National Product Catalogue – it may be that the pending TGA “UDI” code set, or even the GMDN, has significant advantages.  In collaboration with the [AUeReqDI018] MRI reference group we could develop a much shorter list of items commonly encountered, and/or potentially problematic, in MRI, for mapping to whichever general list is chosen.  (ii) p48 – mindmap - another future subgroup of the “specific implanted device details” could be MRI conditional requirements (likely with some sub-elements)	Comment noted, added to backlog.  Medical Device regulations for 'Unique Device Identification' (UDI) are currently under development at the Therapeutic Goods Administration (TGA) and these include specific mandatory requirements regarding the identification of the specific device (UDI) and categorisation using the Global Medical Device Nomenclature (GMDN) has been noted in our future considerations.  An MRI specific list of devices would be beneficial for MRI requests as an implementation subset.  Procedure specific attributes (For example attributes of a device that would contraindicate an MRI or similar) has been added to the backlog.
AUeReqDI024	We recommend more closely adhering to accepted international standards and models such as the FHIR Device resource. This resource already has defined value and code sets, and includes important details about devices such as the device name.	Comment noted, added to backlog.  Agree, the FHIR Device resource will be added to future consideration extension and backlog.

AUeReqDI019	There is a reference in the paper regarding UDI so it's good to see that acknowledged. The TGA should be engaged as early as possible to start informing requirements so that future rework can be minimised - even if the GMDN is only for future consideration.	Agree, thank you for your support.
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## 9. Problem/Diagnosis Summary and Sex and Gender

### 9.1. Problem/Diagnosis Summary and Sex and Gender

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI002	Gender being included is very important my concern is what standard of gender items will be expected to be used. There are varying models out there and the model must be consistent and endorsed to be used nationally for Australia	Agree, thank you for your support.
AUeReqDI003	There is nothing regarding pregnancy status. As stated it was pushed to R2 as it was deemed complex. I'm not sure how (Pregnant: Yes/No ) became so difficult and yet it's a pretty fundamental aspect of diagnostic requests today. I'd argue it's fundamental that we remind the requester to convey the information. Conversely, we have structured 'Problem/Diagnosis summary' and 'adverse reaction risk summary' information which we don't receive today. I struggle with how these two can be prioritised ahead of pregnancy status.	<p>Comment noted, no change.</p> <p>The Sparked Clinical Design Group agreed that Pregnancy status would not be included in the AUeReqDI and should be included in AUCDI and discussed as a high priority for R2 and to determine the best way to represent pregnancy related data.</p> <p>Problem/diagnosis summary and Adverse reaction risk have been included as they were identified by the clinicians as being clinically relevant for the eRequesting context and demonstrates ready reuse of AUCDI.</p>
AUeReqDI005	These data elements are not contextualised for their use in eRequesting but rather directly refer to their inclusion	Wording updated.

	<p>in medical records. That is not our focus. The same issues about scope and the role of OpenEHR vs FHIR as a source of design guidance into the future.</p>	<p>The document has been updated to provide examples for use in the eRequesting context where relevant. These specific data groups were included as they were identified by the clinicians as being clinically relevant for the eRequesting context.</p> <p>AUCDI and AUeReqDI is focused on capture and reuse of data, including and not limited to medical records. The FHIR IG is focused on exchange specification for a specific use case.</p> <p>Both openEHR and FHIR are informing the clinical content in AUCDI and AUeReqDI, even though one of the primary outputs of the Sparked program is a FHIR IG. Where there are artifacts present in both FHIR and openEHR, they are both referenced and inform the clinical specification. Where only openEHR artifacts exist, they are the primary source of modelling, especially where there has been extensive international clinical validation and review.</p> <p>In addition, an introduction to the reused AUCDI section has been added, as well as a contextual introduction for each model. The examples for Adverse reaction have been updated to support the imaging request context. The examples in Problem/diagnosis and Sex and Gender are universally applicable.</p>
<p>AUeReqDI007</p>	<p>How are these are related to the Service Request data group, given that there is no concept of supporting information or similar to relate to this data group.</p>	<p>Comment noted, no change.</p> <p>Information captured in clinical systems using these data groups are intended to be sent alongside each request as part of a message, if clinically relevant, for example as components of a patient summary.</p> <p>This is one of a range of clinical concepts that are required to support safe clinical requesting.</p>
<p>AUeReqDI010</p>	<p>The feedback provided about Adverse reaction risk summary, Problem/Diagnosis summary and Sex and gender in [AUeReqDI010] response to AUCDI R1 also applies to their inclusion in AUeReqDI R1. This feedback</p>	<p>Comment noted, added to backlog.</p> <p>The scope of AUeReqDI does not include representations of Participants (Patient, requester, receiving clinician, etc.) as they do not</p>

	<p>has not been restated in this document but should be also be considered for the feedback on the AUeReqDI.</p> <p>There is a lack of clarity about why these were deemed to be the highest priority components of AUcDI that needed to be pulled across to AUeReqDI. It seems unusual that patient date of birth and patient address have not been defined as part of AUcDI and pulled across to AUeReqDI, given these are fundamental data elements for eRequesting.</p> <p>Some additional feedback about problem/diagnosis that wasn't captured in the original response to AUcDI R1 is interest in capturing external cause codes for injury. This was flagged by the [AUeReqDI010] Unit who report on injuries using ICD-10-AM data from hospitals. It is acknowledged that external cause codes are a feature of ICD-10-AM and that SNOMED CT-AU is structured quite differently, so it would be difficult to define comparable rules about when the use of external cause codes is appropriate. Consideration of how to capture external cause codes within primary care is recommended, as this will be an important part of creating alignment with hospitals data.</p>	<p>require clinical validation and defer to technical specifications for implementations. Date of birth, address, etc., are a part of Patient.</p> <p>External cause of injury in Problem/Diagnosis summary has been added to the backlog for future consideration.</p>
AUeReqDI015	<p>8.5.1. Data group context</p> <p>Alias(es) - Add idiosyncrasy– this covers side effects and drug toxicities as listed in the “Considerations for use” section</p>	<p>Comment noted, added to backlog.</p> <p>Thank you for your feedback.</p> <p>For AUeReqDI, these sections reproduce the AUcDI data groups such as ‘Adverse reaction risk summary’ data group as published in AUcDI Release 1. The only changes that have been made are ‘Substance</p>

	<p>Substances include but are not limited to: - Add radiocontrast media, Change to insect sting or bite, Add: "Non-therapeutic substance e.g. chlorhexidine, latex)"</p> <p>[AUeReqDI015] are in the process of developing penicillin allergy de-labelling guidelines. Although these will initially be restricted to penicillin, protocols around labelling requirements can be updated here once developed.</p> <p>Active has a connotation that this is adverse reaction is actively occurring. Current may be better in this context.</p> <p>[AUeReqDI015] recommends that health professionals specifically and accurately state the substance or agent. Use the name of the drug the patient is specifically allergic to, instead of the group of drugs. For example, add amoxicillin or phenoxymethylpenicillin instead of penicillin.</p> <p>Introduce 'suspected allergic' and 'confirmed allergic' terminology here.</p> <p>Misuse - Add: Not to be used for recording expected effect of medication.</p> <p>"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." (Excluding exercise-induced anaphylaxis and cold induced urticaria)</p> <p>8.5.3. Information model: Substance name</p> <p>[AUeReqDI015] are in the process of updating drug allergy terminology. The updated terms need to be incorporated into this standard.</p>	<p>name' examples that are relevant to the medical imaging domain have been added to the existing list.</p> <p>These suggestions and comments have been added to the AUeReqDI backlog for future consideration.</p>
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	<p>Alias(es): Medication, Media</p> <p>Considerations: as above, change to insect sting or bite, add “Non-therapeutic substance e.g. chlorhexidine, latex)”</p> <p>8.5.3. Information model: Manifestation</p> <p>[AUeReqDI015] are in the process of updating drug allergy terminology. The updated terms need to be incorporated into this standard.</p> <p>8.6.3. Information model: Problem/ Diagnosis name</p> <p>Examples: Include allergy example. Does severity of problem fit here? i.e. if it is a mild or moderate allergic reaction, or a severe allergic reaction (anaphylaxis)</p> <p>Recommended code system/value set: As above, we should avoid using the word active, unless it is well understood that active does not mean it is actively a problem, but needs management (e.g. active avoidance in the case of drug or food allergy)</p> <p>The following terms should be used instead:</p> <ul style="list-style-type: none"> <li>• Suspected allergic</li> <li>• Confirmed not allergic</li> <li>• Confirmed allergic</li> <li>• Patient must avoid statement</li> </ul>	
AUeReqDI025	<p>Only to say well done for including sex and gender here. This is a problem area in diagnostics services. Thank you.</p>	<p>Thank you for your support.</p>

<p>AUeReqDI018</p>	<p>Adverse reaction risk summary</p> <p>(i) Data group context, 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”</p> <p>- This could be read as excluding contrast reactions occurring during/immediately after a radiology procedure. It would be highly desirable to INCLUDE such reactions in this model _ may need a specific exception to the guidance above.</p> <p>p51 – information model, recommended code system – its our understanding that contrast agents are included in SNOMED-CT (AU)- they are required to have TGA approval - but it would be good if a SNOMED expert could check a few examples (e.g. trade names Gastrografin, Ultravist, Dotarem/generic amidotrizoate, iopromide, gadoterate)</p> <p>5. P60, Sex and Gender s8.7.3, information model</p> <p>(i) Sex assigned at birth “considerations” could include comment about any anatomical structures or physiological parameters that may be at variance with either, or both, the sex assigned at birth and the gender identity – such anomalies may be important in interpretation of both imaging and pathology results, and specific detail, rather than a generic “intersex” label would be helpful</p>	<p>Comment noted, added to backlog.</p> <p>The misuse statement in the Adverse reaction data group is deliberately excluding entry of any formal <b>diagnosis</b> within this data group, even if it is the diagnosis of an allergy, as all diagnoses should be recorded using the Problem/Diagnosis group.</p> <p>If an individual has a true allergic reaction to a Ultravist-150 during an imaging procedure, in the Adverse reaction data group the index data element identifies the Substance causing the reaction, using codes from the SNOMED Substance hierarchy or AMT Trade Product hierarchy (e.g. AMT 916171000168108 Ultravist-150 ) and the Manifestation will identify the allergic reaction. In contrast, within the Problem/diagnosis data group, the index data element is the Problem/Diagnosis name, using codes from the Finding hierarchy (e.g. SCT-AU 294913003   Allergy to iodine compound (finding)  ).</p> <p>Gastrografin (77154011000036100 Gastrografin solution, 100 mL, bottle  , Ultravist (916171000168108 Ultravist-150 312 mg (iodine 150 mg)/mL injection, 100 mL bottle  , Dotarem (86180011000036103 Dotarem 1.4 g/5 mL injection, 5 mL ampoule ), amidotrizoate (696051000168103 amidotrizoate meglumine 660 mg/mL + sodium amidotrizoate 100 mg/mL solution) and others are available in SNOMED CT-AU.</p> <p>Sexual variance has been added to the backlog for future consideration as part of physical examination findings. 'Intersex' is clinically recognised as individuals born with any of several sex characteristics that do not fit typical binary notions of male or female bodies.</p>
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## 10. General Feedback

Responder	Community Comment Feedback	Sparked Reflection/Action Taken
AUeReqDI001	A small extension to the glossary or other front-matter section to describe the conventions (especially colour) used in the mindmap diagrams would be useful.	Diagrams updated added to reflect comment. Agree. A legend has been added to each mind map displaying the roadmap containing future candidates for data elements.
AUeReqDI003	It's difficult to grasp AUeReqDI's scope, what it's to include and what it's not. What its boundaries are. For instance, there is no patient info, no date of birth (DOB), and no requester.	Wording updated to reflect comment. Noted. The scope of AUeReqDI does not include representations of Participants (Patient, requester, receiving clinician, etc.) as they do not require clinical validation and defer to technical specifications for implementations. The document has been updated for clarity.
AUeReqDI005	This review form limits the amount of text you can include in entry boxes so all of my comments have been included. There needs to be some clarity around eReqDI scope and the context of medical record content representations vs the specific data required for eRequesting interoperability.	Wording updated to reflect comment. The document has been updated to provide clarity around eReqDI scope as suggested.
AUeReqDI008	Overall excellent piece of work.	Thank you for your support.
AUeReqDI001	There is no convention described here for colouring of the "mindmap" diagrams, such as Figure 10, which contains some yellow boxes, and some grey boxes. It would be useful to know what the semantics of the colour scheme is. I have already checked for obvious possibilities, such as mandatory/optional, or datatype/reference, which are given as text, but these do not correlate.	Diagrams updated added to reflect comment. Agree. A legend has been added to each mind map displaying the roadmap containing future candidates for data elements.

<p>AUeReqDI003</p>	<p>It seems contradictory to say in the scoping section '5.5.1 Scope of AUeReqDI R1' that “The scope of AUeReqDI R1 does not include: Administrative, workflow and billing information” when all three request models have a 'Billing Guidance' property.</p> <p>In section '5.6. Design of AUeReqDI' is reads: "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. "</p> <p>It feels disingenuous to not call out by name the incumbent Australian standards for eRequesting used today. Standards deployed at scale by the three largest private Australian pathology providers and many other public providers and numerous Diagnostic Imaging providers. Those being AS 4700.2 Pathology and Diagnostic Imaging Order &amp; Results, and its most recent incarnation HL7AUSD-STD-OO-ADRM-2021.1. HL7 V2 may be old, informaticians may scoff, but it's the incumbent elephant in the room; so best we believe it's been considered. Because you did consider it right?</p> <p>Section '6.1.1.3 Information Model' First table, row two second cell has a missing reference: Error! Reference source not found..</p>	<p>Wording updated to reflect comment.</p> <p>Noted. This has been extensively updated in the document for clarity.</p> <p>In the scope section, this has been updated to specify payment information rather than billing information i.e. "Administrative, addressing, workflow and <u>payment information</u>" as billing guidance is not the payment information, but is a recommendation for how a clinician would like a payment to be billed, for example when a patient is in financial distress. This has been updated in the document to the following:</p> <p>"It is recognised that in Section 5.6.1 payment information is out of scope because it does not require clinical validation, however 'Billing guidance' has been included in scope because it has clinical significance by enabling clinicians to make a recommendation to the receiver regarding the payment method for the service, for example when the clinician is aware a patient is in financial distress. "</p> <p>The HL7AUSD standard has been added as a reference in the document. There already exists a body of work establishing the relationship between the commonly implemented HL7v2 diagnostic standards and the newer FHIR diagnostic standards. The information model that forms the basis of the AUeReqDI specifications was initially proposed by the Sparked Technical Design Group Co-Chairs, reflecting a technical view of current practice, and informed by HL7AUSD-STD-OO-ADRM-2021.1 and the established mappings. It subsequently falls under the responsibility of the Sparked Technical Design Group to ensure that HL7v2 standards are appropriately considered during the development of the AUeReq FHIR Implementation Guide.</p>
<p>AUeReqDI005</p>	<p>From what I can see, references to FHIR are to R5 and not R4 which will be the basis for the eReq IG.</p> <p>In 2. Definition of Terms</p>	<p>Wording and diagrams updated to reflect comment.</p> <p>Thank you, these have been updated to reflect R4.</p> <p>Thank you, these have been updated.</p>

	<ul style="list-style-type: none"> <li>- the AU Core definition seems to have been truncated.</li> <li>- the IG definition needs fixed as it seems to have included part of an additional sentence.</li> <li>- RRS, why is this limited to "background" use?</li> <li>- Sparked, this seems to suggest that CDI is the soul purpose of Sparked rather than the created of FHIR implementation guides.</li> </ul> <p>4.1, para 2</p> <ul style="list-style-type: none"> <li>- this again suggests that sparked was created to build AU CDI. This is not accurate.</li> </ul> <p>4.1, para 3</p> <ul style="list-style-type: none"> <li>- the previous para says that Sparked was created to build AU CDI but this one says the goal is the creation and use of FHIR standards. This is confusing.</li> </ul> <p>4.3, para 1</p> <ul style="list-style-type: none"> <li>- requirements are not in systems. This also contradicts statements made that the CDG is building an information model rather than defining requirements. Need to be clear which it is and how they are distinguished.</li> </ul> <p>5.1, para 5</p> <ul style="list-style-type: none"> <li>- the scenario descriptions seem repetitive</li> </ul> <p>5.1, para 7</p> <ul style="list-style-type: none"> <li>- this does not describe the needs of the filler</li> </ul>	<p>Thank you, 4.1 and 4.3 have been updated.</p> <p>5.1 para 5 – This is intended to be explicit.</p> <p>5.1 para 7 – These are intended to support a common national eRequesting approach, not including the filling.</p> <p>5.2 para 2 – The AUReqDI's intention is to support a broad approach to eRequesting with an initial focus of pathology and imaging. The current scope of the Sparked Technical Design Group's IG is narrow and specific to the pathology and imaging use cases.</p> <p>5.4 para 3 – Thank you this has been updated.</p> <p>5.4, para 4 – AUReqDI is defining the logical data requirements that informs the FHIR IG. This paragraph has been updated to</p> <p>"AUReqDI documents the logical data requirements identified by the Sparked Clinical Design Group for eRequesting, containing data groups that are required to facilitate the exchange of a pathology test and medical imaging request and reusing data groups from AU CDI where relevant.</p> <p>Like AU Core FHIR IG referencing the AU CDI, the AU eRequesting FHIR IG is being developed to reference the AUReqDI."</p> <p>5.5.1, para 1 – These were identified by the Sparked Clinical Design Group.</p> <p>5.5.1, para 2 – AUReqDI is defining the logical data requirements that informs the FHIR IG and is independent of any specific technical implementation.</p> <p>5.5.1, para 5 – User interface and implementation are out of scope for AUReqDI. Understanding current data collection practices have informed the clinical requirements.</p>
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	<p>5.2, para 2</p> <ul style="list-style-type: none"> <li>- the eRequesting approach should be a specific not broad approach. we are after a very specific FHIR approach to digital requesting.</li> </ul> <p>5.4, para 3</p> <ul style="list-style-type: none"> <li>- who is the TDG co-designing with? itself? is that co-design?</li> </ul> <p>5.4, para 4</p> <ul style="list-style-type: none"> <li>- Is AUeReqDI defining data requirements or defining a logical model or is the model the requirement? This is not clear as it was stated that AUeReqDI were not defining requirements in our meetings.</li> <li>- AUeReqDI is input into, not a definition of, and thus not all data groups may become FHIR artefacts. This needs to be reworded or rethought.</li> </ul> <p>5.5.1, para 1</p> <ul style="list-style-type: none"> <li>- how do adverse reaction and problem/diagnosis summary relate to erequesting? We were previously told that no structured clinical history was going to be provided. Why were these chosen, and say, current medications were not?</li> </ul> <p>5.5.1, para 2</p> <ul style="list-style-type: none"> <li>- This is now talking about representation of clinical content which is neither a requirement or a logical model specification. A logical model is independent of technical implementation. Why is AUeReqDI making decisions about how something is technically represented?</li> </ul> <p>5.5.1, para 5</p>	<p>5.5.1, para 6 – These were identified and confirmed by the Sparked Clinical Design Group as the highest priority.</p> <p>'Modelled for persistence' means modelled to be stored in as part of an electronic record and can then be used or derived for exchange purposes.</p> <p>The Sparked Clinical Design Group decided that the current representation of pregnancy on forms was not clinically appropriate and so was not included as a requirement for AUeReqDI R1.</p> <p>5.6, para 3 – Updated.</p> <p>5.6, principle 4 – Noted, thank you for feedback.</p> <p>5.6, principle 5 – Noted, thank you for feedback.</p> <p>5.6, principle 9 – This has been updated.</p> <p>6.1.1.2, para 3 – The document has been extensively updated for clarity around activities and protocol, to explain these data groups in more detail and to provide examples of relevant use cases and a clarification around the scope.</p> <p>6.1.1.3 Table 4, row 2 – Thank you, this has been updated.</p> <p>6.1.1.3 Table 4, row 3 – Data types were required to accurately represent the data by Sparked Clinical Design Group. FHIR data types were used as there is a FHIR output.</p>
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	<p>- It is previously stated that data input is in scope but this user interface is out of scope. Which is it? Why have we been talking about the issues with checkboxes if the user interface is out of scope?</p> <p>5.5.1, para 6</p> <p>- what criteria was chosen to support some clinical request data and not others. For instance, not medications but allergies and problems? These are not within existing form structures.</p> <p>- what does "modelled for persistence" mean? The scope of eRequesting is the interoperability of digital requests between organisations, not the persistence of data with clinical records.</p> <p>- pregnancy within a request is common across all forms. this is needed.</p> <p>5.6, para 3</p> <p>- missing reference</p> <p>5.6, principle 4</p> <p>- secondary data use may be clinical</p> <p>5.6, principle 5</p> <p>- this is not written as a principle. to make it clearer each principle should have an rationale and implication.</p> <p>5.6, principle 9</p> <p>- eReq is a set of specific use cases so saying that data groups are agnostic to use cases is not very useful.</p>	
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	<p>6.1.1.2, para 3</p> <p>- What is the purpose of introducing activities and protocols given the focus of this work is to influence the build of a FHIR IG and the majority of protocol components are out of scope, e.g. billing, distribution lists, or what has previously been referred to as admin data. Later you describe Last Updated as being included where as clearly this is technical/admin data that has nothing to do with clinical data for interoperability.</p> <p>6.1.1.3 Table 4, row 2</p> <p>- missing reference</p> <p>6.1.1.3 Table 4, row 3</p> <p>- why is this logical model using FHIR impementation concepts? Why is the CDG dealing with FHIR constructs? Are these requirements, reqpresentations, or is this a logical model? Same thing in Table 5 with discussion of a FHIR reference. cont'd</p>	
<p>AUeReqDI007</p>	<p>On page 21, it is stated that "in this context of eRequesting, this structure allows a single request, comprising multiple fully specified ...". This is a little hard to understand compared with the proceeding sentence, but if I understand correctly it is saying "Example Request" and multiple "Activities".</p> <p>However, the "Example Request" has a cardinality label of 0..* in the Figure 7. This label should be removed or changed to 0..1 or 1..1, not sure which makes sense, hence removal being the preferred option. Renaming the Activities/Activity nodes to "request" or similar would make it easier to comprehend the model and not require significant narrative to define what these mean and how</p>	<p>Wording updated to reflect comment.</p> <p>Noted. The semantics of a request is often interpreted slightly differently. In this case data group as a whole represents a single request or order, incorporating one or more 'activities' and only one protocol.</p> <p>The document has been extensively updated for clarity, to explain these data groups in more detail and to provide examples of relevant use cases.</p> <p>The 0..* on the index node 'Example request' is indicative that there may be more than one request recorded i.e. one instance per request, in comparison with the 'Sex and gender summary' which is set to 0..1</p>



	<p>they related to a group of request group or individual requests, which I indicated was difficult to grasp in my first comment above.</p> <p>Although I understand the need for the Activities node to reflect the multiplicity of the individual requests, I don't see the value of Activity and Protocol nodes. At least the Protocol node is described, but the Activity node is not.</p> <p>Similar in Figure 7, I don't see the value of data and protocol in these logical models. They are not separated out in the tabular structure.</p>	<p>to indicate a maximum of one instance of the sex and gender data group is permitted per health record.</p> <p>The data and protocol are included as they are required to reflect the cardinality of the different data components of the information model. They have not been included in the tabular structure as they unnecessarily complicate the table which is intended to focus on the data components.</p>
<p>AUeReqDI010</p>	<p>The general comments supplied by [AUeReqDI010] on the AUcDI also apply to the AUeReqDI and should be considered as part of [AUeReqDI010] AUeReqDI feedback.</p> <p>Suggestions for additional data elements relating to pathology, imaging and referrals have been included later in the feedback. Aside from these data groups, there are several other additional data elements that the [AUeReqDI010] would like considered for inclusion which were not flagged in the [AUeReqDI010] AUcDI R1 feedback. These data elements would be useful for both primary and secondary use. From a primary use perspective, these data elements would support the delivery of patient-centred care by capturing the full patient story which can inform and improve patient care. It would be appreciated if these data elements could be added to the backlog (noting that many of these would be in the backlog for AUcDI, rather than AUeReqDI):</p>	<p>Comment noted, no change.</p> <p>Following the same approach used for the development of AUcDI Release 1, unless it is of clinical significance and requires clinical validation, the Release 1 scope of AUeReqDI does NOT include:</p> <ul style="list-style-type: none"> <li>• Representation of Participants <ul style="list-style-type: none"> <li>o Patient (including date of birth, Aboriginal and Torres Strait Islander status),</li> <li>o Requester and authoriser,</li> <li>o Receiving clinician or organisation who will perform the service, and</li> <li>o Healthcare providers identified for inclusion in the Distribution list or as the nominated Urgent contact.</li> </ul> </li> <li>• System information, or system-derived information – includes information related to technical aspects of recording data (such as author and date of request timestamp) and will be managed in the technical implementation specifications (for example in a FHIR IG),</li> </ul>

	<ul style="list-style-type: none"> <li>• Patient: Individual Healthcare Identifier, given name, family name, name title, date of birth, date of death, postcode, SA2, state/territory, Indigenous status, country of birth, ethnicity, main language other than English spoken at home, proficiency in spoken English</li> <li>• Organisation: Healthcare Provider Identifier – Organisation, postcode, SA2, state/territory</li> <li>• Practitioner: Healthcare Provider Identifier – Individual, profession</li> <li>• Encounter: Date of encounter, encounter duration, encounter type, encounter attendees, MBS item number, encounter funding source</li> <li>• Social context: Aged care status, disability status, carer status, domestic and family violence status, Australian defence force status, Department of Veterans’ Affairs status, refugee status, marital status, living arrangement type, employment status, education status, date of social context assessment</li> <li>• Lifestyle risk factors: Alcohol consumption frequency, alcohol consumption amount, consumption of 6 or more drinks on one occasion, AUDIT-C result, smoking type, smoking start date, smoking quit date, substance use status, substance use type, substance use start date, substance use quit date, physical activity, absolute cardiovascular risk assessment score, date of lifestyle risk factor assessment</li> <li>• Diagnosis: Diagnosis source, date of diagnosis onset</li> <li>• Medication: PBS item number, medication status, date medication prescribed</li> </ul>	<ul style="list-style-type: none"> <li>• Administrative, addressing, workflow and payment information</li> <li>• Request identifier</li> <li>• User interface or form implementation requirements</li> <li>• MBS workflow items like self-determined and rule 3 exemptions,</li> <li>• Higher-level technical concepts such as security, access, privacy, and consent, and</li> <li>• Non-clinical recording context such as author, location of service.</li> </ul> <p>For the suggested items, the following items are currently on the backlog as they require clinical validation and are in scope of AUeReqDI.</p> <p>Date of death, Indigenous status, Ethnicity, Country of birth, Languages spoken, Location of encounter, Type of encounter, Encounter outcome, Social context (Aged care status, disability status, carer status, domestic and family violence status, Australian defence force status, Department of Veterans’ Affairs status, refugee status, marital status, living arrangement type, employment status, education status, date of social context assessment), Alcohol consumption summary, Smoking summary, Substance use summary, Physical activity, Absolute cardiovascular risk assessment score, Problem/diagnosis source, Problem/diagnosis onset date, Medication date first prescribed, Medication status, Prescription date, Procedure request, Vaccination batch number, Reason for vaccination/Target disease, Adverse event summary, Adverse reaction risk summary items, Pregnancy status.</p>
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	<ul style="list-style-type: none"> <li>• Procedure: Date procedure requested</li> <li>• Vaccination: Batch number, reason for vaccination</li> <li>• Adverse event: Adverse event category, adverse event severity, adverse event contributing factor, adverse event outcome, date of adverse event</li> <li>• Allergy: Allergy status, allergy exposure route, allergy criticality, date of allergy onset</li> <li>• Pregnancy: Pregnancy statue</li> </ul> <p>The AUeReqDI R1 document has the same issue as AUcDI R1 did with respect to searchability:</p> <ul style="list-style-type: none"> <li>• All instances of ‘tt’ are showing up as ‘d’ e.g. ‘attribute’ is showing up as ‘adribute’ in the search and after copying and pasting the content.</li> <li>• All instances of ‘ti’ are showing up as ‘C’ e.g. ‘prioritised’ is showing up as ‘prioriCsed’ in the search and after copying and pasting the content.</li> <li>• All instances of ‘ft’ are showing up as ‘G’ e.g. ‘left’ is showing up as ‘leG’ in the search and after copying and pasting the content.</li> </ul>	
AUeReqDI011	<p>[AUeReqDI011] agrees that data standardisation has value and is worth pursuing. However, we note that this kind of standardisation is something that the pathology sector has been pursuing for decades without success.</p> <p>Neither referrers nor pathology service providers have a standardised nomenclature for tests, results or other clinical information, in spite of the existence of</p>	<p>Noted, no change. Thank you for your feedback.</p> <p>Following the same approach used for the development of AUcDI Release 1, unless it is of clinical significance and requires clinical validation, the Release 1 scope of AUeReqDI does NOT include:</p> <ul style="list-style-type: none"> <li>• Representation of Participants</li> </ul>

	<p>professional guidance and other standards. E.g. in spite of the existence of SPIA and associated best practice guidelines, there is still significant variation in the way pathology results are reported (particularly with order of reporting, and test units). It would be folly to try and enforce a single reporting standard across the sector – which the sector has already been trying to do themselves. Instead, the key issue from a clinical perspective is that the differences that exist between providers need to be manageable. From an AUeReqDI e-requesting perspective, the key issue then is to avoid attempting to force compliance, but instead to establish a flexible enough framework that encompasses the variety of practice that exists in medicine in Australia today and into the future.</p> <p>Pathology providers and clinicians are already using electronic requests. These are bilateral communications (section 5.1 describes these as "siloeed" examples of eRequests) partly because of the fact that every laboratory does things differently. No provider wants to be the one who has to change, because this sort of change requires considerable effort, incurs significant clinical risks, and also the commercial risk of upsetting existing users of the service. The AUeReqDI seems to be trying to make communications of pathology requests and results multilateral. However it is not clear what purpose this would serve. Patients already know that requests can be taken to any provider (and do). Patients are already making choices about which pathology provider is best for them – whether this is based on ease of access, or quality, or cost, and all this already occurs across the existing "siloeed" systems.</p>	<ul style="list-style-type: none"> <li>o Patient (including date of birth, Aboriginal and Torres Strait Islander status),</li> <li>o Requester and authoriser,</li> <li>o Receiving clinician or organisation who will perform the service, and</li> <li>o Healthcare providers identified for inclusion in the Distribution list or as the nominated Urgent contact.</li> </ul> <ul style="list-style-type: none"> <li>• System information, or system-derived information – includes information related to technical aspects of recording data (such as author and date of request timestamp) and will be managed in the technical implementation specifications (for example in a FHIR IG),</li> <li>• Administrative, addressing, workflow and payment information</li> <li>• Request identifier</li> <li>• User interface or form implementation requirements</li> <li>• MBS workflow items like self-determined and rule 3 exemptions,</li> <li>• Higher-level technical concepts such as security, access, privacy, and consent, and</li> <li>• Non-clinical recording context such as author, location of service</li> </ul>
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	<p>There already exist many working bilateral eRequest-result systems for pathology. Ideally, the AUcDI eRequesting standard will simply be a framework into which the existing systems either already comply, or can be made compliant with a low investment of developer time. The time and effort taken to develop the AUcDI standards will be wasted if medical service providers either do not want, or cannot afford, to implement the changes in their existing information systems, which are already successfully working to support going concerns. This is especially true given that there already exist products that allow electronic communication of pathology requests and results between a requestor and a laboratory.</p> <p>The concept of "the patient" is conspicuously absent from this draft. While it does not make sense for e-requesting to be "patient-centric" (as it's fundamentally about a treating clinician communicating with a specialist service), at the same time, service requests of all sorts are specific to a particular patient. Unlike pharmaceutical prescriptions (where it is useful to allow them to be filled on behalf of the patient by a relative or carer), it does not make sense for pathology or imaging requests to be transferable.</p> <p>e.g in table 6, under 8.1.1: the concept description for Service request AUeReqDI, reads, "Request for a health-related service or activity to be delivered by a clinician, organisation, or agency" should have the phrase "for the patient" appended. While it is implied, it would be better to make explicit that requests are specific to an individual</p>	
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	<p>patient, and for this to be supported by the data structure. We understand that the concept of "patient" is within AUCDI Core rather than eRequesting, but nevertheless we consider this to be a significant omission from the current draft.</p>	
AUeReqDI012	<p>Acknowledging that [AUeReqDI012] has had input to the wording of this document, we have some further suggested amendments upon feedback review. These are in line with representing patient choice:</p> <p>Page 13 - 5. About Australian eRequesting Data for Interoperability   5.1 Background</p> <ol style="list-style-type: none"> <li>1. "Healthcare provider discusses and agrees with consumer the recommended provider with a request generated to that provider</li> <li>2. Request generated, and consumer can choose a suitable provider</li> <li>3. Healthcare provider discusses and agrees with consumer a recommended provider, request generated and later the consumer chooses an alternative to the recommended provider"</li> </ol> <p>Noted: As the consumer's ability to choose a suitable provider is equally applicable to dot points 1 and 3, we may need to change the language to articulate that dot point 2 encompasses not only the selection of a provider but also the consumer's role in directing the request for services. Also, regarding reassignment of the request in dot point 3, this is not solely dependent on the consumer changing to an alternative recommended provider. Other factors may also necessitate reassignment including actions by the referring provider.</p>	<p>Wording updated and new content added to reflect comment.</p> <p>Document has been updated to include reassigned.</p>

	<p>Suggestion:</p> <p>2. Request generated and not directed to any specific provider, remaining open for the consumer to assign.</p> <p>3. Healthcare provider discusses and agrees with consumer a recommended provider, request generated to that provider but is subsequently redirected to another provider based on the consumer's preference or other factors.</p> <p>Page 14 - 5.2 Role and purpose of AUeReqDI</p> <ul style="list-style-type: none"> <li>• “Any single current referrer-consumer-provider workflow, while still being informed by the requirements to support directed and undirected workflows”</li> </ul> <p>Noting reassigned’ was omitted. Suggestion: “... to support directed, undirected and reassigned workflows; and....”.</p> <p>Page 18 – 5.6 Design of AUeReqDI</p> <p>“The core design principles initially developed to assist the development of AUeReqDI and to allow prioritisation by the Sparked team and the community, were used for AUeReqDI. Error! Reference source not found. sets out the design principles used and how the clinical information model has been aligned.”</p> <p>Error! Reference source not found - maybe a glitch?</p> <p>Really appreciate all the hard work, please reach out if further clarification is required.</p>	
AUeReqDI013	We have 2 high level comments at the moment:	Comment noted, added to backlog.

	<p>We think that the specimen(s) object should be included in these groups from the get-go, even if there is often no specimen collected at the point of the original request - it is a key part of the process and it's characteristics are strongly linked to the requested test.</p> <p>We feel that for Labgnostic as an implementer this stage in the process is a little early for us to be providing detailed responses, but we look forward to reviewing and commenting on the more specific workflows you are looking to implement.</p>	<p>The specimen source/site has been placed in the backlog for future consideration.</p> <p>Thank you for your support. We would recommend participating in the Sparked AU eRequesting Technical Design Group who are developing the AU eRequesting FHIR IG as they are developing the technical implementation specification.</p>
<p>AUeReqDI014</p>	<p>[AUeReqDI014] appreciate the opportunity to review the draft Australian eRequesting Data for Interoperability (AUeReqDI).</p> <p>As a standalone agency, the [AUeReqDI014] will be a potential secondary end user of data from the AUeReqDI. AUeReqDI could enhance the [AUeReqDI014] capabilities in disease monitoring, outbreak managements, and public health planning, leading to better health outcomes for all Australians. This includes:</p> <ul style="list-style-type: none"> <li>• Enhanced data integration: AUeReqDI facilitates seamless data sharing and integration across various healthcare systems. This could enable the [AUeReqDI014] to aggregate and analyse data from multiple sources, improving the accuracy and completeness of disease surveillance and response.</li> <li>• Timely access to information: with standardised electronic data requests, the [AUeReqDI014] could obtain real-time information on disease outbreaks, laboratory test results and other critical health metrics.</li> </ul>	<p>Thank you for your support.</p>



	<p>This timeliness is crucial for early detection and rapid response to emerging public health issues.</p> <ul style="list-style-type: none"> <li>• Efficient resource allocation: By having a unified and accessible data system, the [AUeReqDI014] could better allocate resources, such as vaccines and medical supplies, based on current and predictive data trends, optimising public health interventions.</li> <li>• Support for public health research: AUeReqDI provides robust data infrastructure that could support epidemiological and public health research. The [AUeReqDI014] could leverage this data to identify patterns, assess the effectiveness of interventions, and develop evidence-based policies.</li> </ul> <p>Specifically, we make the following observations</p> <ul style="list-style-type: none"> <li>• The distinction between 'data for interoperability' and FHIR implementation guidance is important. That is, acknowledging FHIR is the shell, but it is also important to specify what goes in that shell.</li> <li>• Regarding the design principle on being driven by clinical data use, and not secondary data use. This is an important point for the team to make from a burden of clinical admin perspective. However, as a public health entity with interest in secondary use of data, we emphasise that standardising data for clinical use increases capacity for secondary use, so it supports both.</li> </ul>	
AUeReqDI019	Document background and context sufficient to inform reader. Model appears comprehensive enough to	Thank you for your suggestions and support.

	<p>consider initial use cases, noting that the model will evolve.</p> <p>This comment is not specifically related to AUeReqDI R1. Engagement approach across digital health community has been stellar. Keen to see it reach beyond the 'converted', i.e. beyond the community of 'evangelists'. Might be worth targeting specific clinical colleges and engaging via conferences and/or other forums to increase opportunities for awareness and understanding (perhaps this is already being done). Be great to see better representation from jurisdictions too (e.g. eHealth Qld and NSW ).</p>	
<p>AUeReqDIO20</p>	<p>[AUeReqDIO20] is supportive of the AueReqDI and e-Requesting providing that it does not limit choice of provider and does not impact equity of access to pathology services.</p> <p>Barriers to adoption are:</p> <p>Laboratory Information Systems (LIS) vendor and development timelines/capability.</p> <p>Cybersecurity.</p> <p>State e-Health agencies ability to build a solution to accept the messages for consumption to the LIS.</p> <p>Resourcing to support the introduction and changes workflow.</p> <p>The concern in the public sector is that due to resource limitations, some public pathology providers will not be in a position to accept e-requests and this will impact on patient access to services. From a practical point of view, when the system is rolled out there may be a need to</p>	<p>Thank you for your support.</p>

	mandate paper request forms be issued for a period until all pathology providers have the capability of accepting e-requests.	
AUeReqDI020	<p>Further to my email on 14 June, please note that [AUeReqDI014] members have also expressed the need for request time and date and collection time and date to be included as both are important for the purpose of claiming Medicare benefits for pathology services.</p> <p>The request and collection date should be included with the other elements in the pathology service request (p24).</p> <p>The time and date of request and collection are more apt for a pathology service than “service due” (p42).</p> <p>There is also an omitted reference source error on p22.</p>	<p>Comment noted, added to backlog. Wording updated to reflect comment. Typographical error corrected.</p> <p>Noted. The scope of AUeReqDI does not include representations of Participants (Patient, requester, receiving clinician, etc.) as they do not require clinical validation. Request date time stamp is out of scope, as it would be considered common across all requests and part of the system information about the technical aspects of recording the data. The document has been updated for clarity.</p> <p>Specimen details have been added to the backlog for future consideration.</p> <p>"Service due" has been updated to "Service timing" to better reflect its meaning.</p> <p>Thank you, the document has been updated.</p>
AUeReqDI021	<p>Overall is reflective of discussions at Clinical Design Group</p> <p>Noting this a Minimum Viable Product for release, it will be important to follow this with a second release, to maximise value/ benefits</p> <p>to cover items noted in the DI as excluded</p> <p>These include the inclusion of Pregnancy information</p> <p>A lack of information on MBS Claiming rules etc is an issue for all parties including requestors, consumers and providers. I think this is different from Billing Guidance</p>	<p>Wording updated to reflect comment.</p> <p>Thank you for your support.</p> <p>Agree, Billing guidance is a recommendation by the clinician to the receiver regarding the payment method for the service and not MBS Claiming rules.</p> <p>Consent is not in scope of AUeReqDI and needs to be addressed by other national standards.</p> <p>We have updated the document to Standardised Pathology Informatics in Australia (SPIA) Guidelines.</p>

	<p>Query – is there any information to flag consent to share with MHR? Is that part of core, so not here, or admin so not here.</p> <p>P18 – change Standards for Pathology Informatics in Australia to Standardised Pathology Informatics in Australia (SPIA) Guidelines</p> <p>Query – how are duplicate requests identified – assume that is for the Implementation Guide rather than here</p>	
<p>AUeReqDI022</p>	<p>Thank you for the opportunity to provide feedback on the Australian eRequesting Data for Interoperability (AUeReqDI) Release 1 Draft. As the peak body in the field of audiology and hearing health, we would like to highlight a few critical points regarding the variety of implants and the appropriate confirmation of clinical content.</p> <p>It is important to recognise that there are several types of implants beyond just cochlear implants. These include:</p> <ul style="list-style-type: none"> <li>Hybrid implants</li> <li>Middle ear implants</li> <li>Bone conduction implants</li> <li>Brainstem implants</li> <li>Vestibular implants</li> <li>Monitoring electrodes</li> </ul> <p>Each of these implants serves different purposes and addresses various hearing and balance disorders. Given this diversity, it is crucial that the clinical data system is comprehensive and able to accurately capture information related to all these implant types.</p>	<p>Thank you for your support.</p> <p>Comment noted, no change.</p> <p>Agree. The examples provided were not intended to be exhaustive, but rather indicative of a range of implants that might be considered. Medical Device regulations for 'Unique Device Identification' (UDI) are currently under development at the Therapeutic Goods Administration (TGA) and these include specific mandatory requirements regarding the identification of the specific device (UDI) and categorisation using the Global Medical Device Nomenclature (GMDN). The examples provided should be considered for inclusion.</p>

	<p>These implant procedures are performed by Ear, Nose, and Throat specialists (ENTs). Given their expertise and direct involvement in these surgical procedures, ENTs are best positioned to confirm the clinical content related to these implants. Their responsibility in verifying the accuracy and completeness of clinical data ensures that the information is reliable and can be used effectively for patient care, research, and quality improvement initiatives.</p> <p>We recommend that the eRequesting system be designed to accommodate the full range of implants. We hope that ENTs and other associated surgical teams have been able to provide input to the clinical content but please contact us if you require further information regarding the clinical information of the mapping stage of the devices.</p> <p>Thank you for considering our feedback. We look forward to any further opportunities to contribute to the development of this important system</p>	
<p>AUeReqDI023</p>	<p>There is no data group for patient rights.</p> <p>They are entitled to go where they chose.</p> <p>There should be a data group that places software the need to email the form with the email address of the patient gathered at the front desk.</p> <p>Current models cut out the patient right to do this.</p> <p>Many times they don't want to go where the doctor sends them via the script but the script forces them electronically and it takes away their choice to choose.</p>	<p>Comment noted, no change.</p> <p>We agree that patients have a right to choose. However, AUeReqDI is agnostic of workflow and is focused on the content of the request only. The concerns that you have raised are very valid and relate to the implementation side of eRequesting, rather than the data standards. The AU eRequesting standard, of which AUeReqDI is a component, will support directed, undirected and re-direct requests. This is to ensure that patients will be supported to have a choice of provider in future eRequesting implementations, including changing their mind.</p> <p>The Department of Health and Aged Care is undertaking a project to explore the workflow requirements and future design of a patient</p>

	<p>Only sending to one company takes away the ability to compete, and the price for partnership just to have your email as an option on the doctors software is about \$10000. This should be reduced.</p> <p>All the changes keep advantaging the bigger companies preventing competition especially when the big players join forces and collaborate.</p> <p>If these data groups get missed and community referring becomes totally digital, then smaller radiology businesses will go missing too.</p> <p>I request feed back if you can please</p>	<p>centred national eRequesting capability – this will have patient choice as a key principle. It is recognised that a future national eRequesting capability will need to consider patient interactions and how they will be supported to make informed decisions about service providers and locations.</p> <p>We do appreciate your concerns and thank you again for taking the time to provide us your feedback.</p>
<p>AUeReqDI024</p>	<p>As a data model for enabling interoperability, AU eRequesting DI should focus on the data models necessary for information exchange without dictating the collection or use of health data. As written, it is unclear if the goal of AU eRequesting DI is for interoperability of health data or enforcing data collection and modeling on clinical systems and practices. While interoperability specifications can define a technology’s capability of exchanging a data element, interoperability technology itself is incapable of (and unrelated to) ensuring data use or collection in clinical workflow. We recommend AU eRequesting DI focus on the data modeling necessary for interoperability, and that data entry and use for clinical practices be addressed separately through other policies with appropriate clinical and vendor engagement.</p> <p>We recommend that AU eRequesting DI be included in AU CDI, and AU CDI be maintained as the single formal information model for healthcare interoperability in Australia. To avoid fragmentation of processes, owners, and models, separate data sets should not be created for</p>	<p>Comment noted, no change.</p> <p>AUCDI and AUeReqDI is focused on collection and reuse of data, including but not limited to medical records. The FHIR IG is focused on exchange specification for a specific use case. AUeReqDI (and AUCDI) are not intending to enforce data collection and modelling on clinical systems and practices, but rather to encourage collection of standardised data to support meaningful exchange.</p> <p>Thank you for your feedback, we will take this suggestion on and feed this into future discussions.</p>

	<p>individual use cases. The combined AUcDI model should form the basis for all interoperability use cases in Australia, and FHIR implementation guides should be used to detail use case solutions, such as the AU Core FHIR IG, the AU eRequesting IG, and future use cases.</p>	
AUeReqDI025	<p>Thank you for the opportunity to respond!</p>	<p>Thank you for your support</p>
AUeReqDI025	<p>"I am familiar with HL7 Australia v2.4 for diagnostic messaging so I'm looking for alignment with those existing concepts and structures that support current business processes and reporting requirements. From the document I found it difficult to get a clear understanding... If we are to win the hearts and minds of the diagnostics community, then these models need to be clearly relatable to real world concepts. (Note that I haven't participated in the eRequesting working groups to date, so I apologise if my feedback is ill-informed).</p> <p>For example, to see clearly what represents a pathology request and a pathology order (where one pathology service request can have one or more orders, and one order can represent one or more tests). These concepts are not explained in the definition of terms, and I find them unclear in the models too.</p> <p>I think it would be helpful to include a conceptual data model that demonstrates the relationships of the eRequesting data groups to other related data groups and resources, such as Patient, Provider, Specimen, Observation, Diagnostic report. This would reduce the abstract nature of the document as eRequesting can't</p>	<p>Comment noted, no change.</p> <p>The HL7AUSD standard has been added as a reference in the document. There already exists a body of work establishing the relationship between the commonly implemented HL7v2 diagnostic standards and the newer FHIR diagnostic standards. The information model that forms the basis of the AUeReqDI specifications was initially proposed by the Technical Design Group Co-Chairs, reflecting a technical view of current practice, and informed by HL7AUSD-STD-OO-ADRM-2021.1 and the established mappings. It subsequently falls under the responsibility of the Technical Design Group to ensure that HL7v2 standards are appropriately considered during the development of the AUeReq FHIR Implementation Guide.</p>

	<p>exist alone without these other groups to give context to its meaning.</p> <p>I assume multiple pathology activities (orders) arising from one request will remain children of the original request throughout the request-analyse-report lifecycle, or will they become orphaned and that grouping is lost for the order placer and the order filler? This grouping is an important feature in Australia that I believe is not necessarily a requirement in the USA so I hope we don't lose it.</p> <p>I may be old-fashioned... but I think there is value in mapping these concepts to the equivalent HL7 v2 concept, to ensure continuity during transition, the ability migrate data and business processes, and retain important business keys over time.</p> <p>The Background problem statement expresses the viewpoint of the government, requesting doctor and patient but does not mention the role of the pathology and radiology providers, or the requirement for diagnostic providers to have the ability to govern their own master data to support these specifications, for example to manage their own order catalogue to align with this model and map to the value sets, and the relationship of an order to a set of observations."</p>	
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