Integrating the Healthcare Enterprise

IHE Radiology
Technical Framework Supplement

Imaging Diagnostic Report
(IDR)

Phase II
Revision 1.2 – Draft for Public Comment

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Please verify you have the most recent version of this document. See here for Trial Implementation and Final Text versions and here for Public Comment versions.

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REVIEWER NOTES:

For the Public Comment process, this document is a hybrid; it contains all the new and revised content from Phase II of the IDR Profile work while interlacing hyperlinks to the IDR (Phase I) IG pages to easily refer to the existing information and places the new text will go.

This is intended to permit the use of line numbers for submitting comments and Word change tracking to facilitate tracking and reviewing the comment resolutions in the text. It also keeps the primary focus of this review on the new content rather than the existing text. (Comments on significant issues in the existing text are still welcome.)

During resolution of Public Comments, revisions will migrate into the IDR IG.
https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/index.html

Several "tags" remain in the document text during Public Comment:

- LATER indicates TODO items that will be completed during TI Preparation
- UP indicates facets of the profile evaluated as representing Uncertainty Points
- EUH indicates details related to harmonization with the EU specification

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Open Issues (Clinical):

Q. What kind of IPL queries would be useful? What would you "ask the catalog"?

How would you browse the findings in the Imaging Problem List?

Imagine your reporting workstation has retrieved and cataloged the contents of, say, five relevant prior reports for the current study you are about to read. How would you want to consume that information? Would you like a summary presented? If so, how? Would you like to "ask questions"? What kind of questions? E.g. "Show me all liver-related observations" Would you like to browse it? How? See also 56.4.2.5.1

Q. When do you describe change quantitatively vs qualitatively or is that just "style"?

When is a percentage change or absolute volume difference preferable to statements like slight growth, significant decrease, etc?

How common/recommended is the pattern of stating the current size and prior size (of a tumor or organ) while leaving the derivation of the change to the reader? ("Currently it measures 6, previously it measured 4", "So it grew?", "You said it, I didn't")

From a technical view, a quantitative change observation can use .derivedFrom to reference the two measurement observations. For a qualitative comparison the compared points may be implicit, not explicit unless you had a prior observation of "normal size" and a current one of "enlarged".

Open Issues (Technical):

Q: (UP) Include Store, Query, Retrieve, (Display?) Transactions or just do Basic content first?

Might limit to one transaction this pass? There are different drivers for the different transactions.

Having a Display Transaction would allow specification of baseline presentation requirements (to "ensure" clinically "accurate" presentation).

Q. Do we want to profile the use of FHIR ObservationDefinition Resources?

"When an Observation instantiates an ObservationDefinition, the elements of the Observation resource are expected to inherit their content from the corresponding definitional elements declared in the ObservationDefinition resource listed here."

Is there potential to improve consistency or reduce duplication of data elements?

Q. What use cases would call for more profiling of the Provenance Resource?

6.7.3.10 "Signature" profiles use of a Provenance Resource to attest and sign the DiagnosticReport and the content it contains. Hypothetically there could be additional Provenance resources to describe details such as radiologist approval of a set of, say, lumbar spine measurements while indicating that one was replaced by the radiologists own assessment. The question would be whether this is part of the Diagnostic Report or instead part of the workflow/dataflow and associated QA.

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Q. Have we overlooked any report content/details needed for billing and administration?

Are there examples where billing/reimbursement is contingent on a specific statement that needs to appear in the report narrative but might not otherwise appear?

Q. Do we need multi-procedure report mechanisms beyond basedOn 1-n ServiceRequest?

Scenarios exist in which one report is dictated that covers multiple orders/service requests (TIPS and paracentesis in same encounter). For billing reasons, historically the report is sometimes replicated so there is one copy per order. Given that DiagnosticReport.basedOn can reference 1-n ServiceRequests, is there still a need to consider/profile the creation of duplicate report instances? Are there query implications?

Q. Do patient transfer scenarios need DiagnosticReport copy sync handling discussion?

E.g. trauma patient is transferred to an advanced center. Ideally, imaging report is pushed ahead or with the patient, but might be preliminary report and local copy is finalized and/or amended later. Important to avoid duplicate imaging.

Q: (EUHO) Are changes to DiagnosticReport.composition required?

IDR proposes permitting 1-n presentation compositions. Bas noted FHIR (oddly) restricts the cardinality to 0..1. He has submitted a JIRA to get clarification on the usage, cardinality, and location of the .composition references, suggesting it might be clearer if .presentedForm could reference Compositions as well as Attachments. FHIR OO WIP.

Notes:

Composition “is only for purpose of readability, not to record critical relationships”; i.e. Composition is designed to support presentation, not encode semantics.

(EU) Composition->Report is an extension that creates a circular reference. The base reference is DiagnosticReport->composition

Q: Are any changes to ImagingSelection required?

ImagingSelection is becoming normative in R6. Last chance for foundational changes (basically closed). Do we have any?

Q: Should coding patterns be constrained for Observation.code and BodyStructure?

Proposed text encourages full anatomical pre-coordination (except for laterality) for the .structure code and minimal pre-coordination of the property in .code. See Table B.3-1 for examples of this in practice.

Variability in coding patterns can make searching and consuming such data a nightmare.

Q: Are there constraints/guidance on code sets that would be productive/”universal”?

See existing text in 56.4.1.3

Q: Would modelling new .morphology codes such as blood be appropriate and useful?

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FHIR says morphology can encompass both normal and abnormal morphologies. BodyStructure is slightly ambiguous as to whether it identifies a location, or anatomical object. When used with .morphology, it is a location. If we introduced a parenchyma .morphology code, it could always be location. Might also serve to distinguish a doppler velocity measurement of the blood at the mitral valve, from the velocity measurement of the mitral valve tissue. Any such modelling would, of course, involve relevant experts.

Q. Are there any issues with the recommended post-coordination patterns in Table B.3-1?

Post-coordination is intended to allow the flexibility of logical extension by implementations without having to obtain new pre-coordinated codes, and allows consumers of the data (for queries, or trigger logic) to handle similar situations using elemental or Boolean constructs rather than not understanding new codes or having to include very long lists of related pre-coordinated codes.

Q. Would an additional fully pre-coordinated value in Observation.code help or hurt?

As a CodeableConcept, Observation.code can contain multiple .coding items. These are intended to be alternate codes with the "same semantics". Given the presence of the post-coordinated property code (as shown in Table B.3-1), the profile could describe an additional coding item that partially or fully pre-coordinates the property with the semantics in .bodyStructure.structure, .laterality, .morphology, as well as Observation.method.

Is it likely this could be populated in a consistent manner and would it be helpful to consuming systems? DICOM Simplified Echo SR permitted such an optional post-coordinated code but there is no field experience on whether it is functional or dysfunctional. SNOMED does model post-coordinated queries in patient records.

If used this might be flagged (with a new value) in CodeSystem.concept.property (https://build.fhir.org/codesystem-concept-properties.html) although we are dealing with an information model for observations that is not dependent on the use of a particular CodeSystem.

Q. Should we provide an Example code set for PractionerRole.code?

Just considering PractionerRole.code, .specialty, .healthcareService.category, and .healthcareService.type, FHIR permits many coding pattern variations. E.g. at least a dozen patterns to code neuroradiologist, even without using multiple coding systems. FHIR guidance is for this to be managed by Implementation Guides substituting specific valuesets appropriate to their specific domain usage. IDR could define an Example set for .code to include Radiologist, Resident Radiologist, Attending Radiologist.

(FHIR Core noted that .code and .specialty cover different dimensions. Based on their definitions, one "describes the functional role they are practicing" while the other describes the "role [they] are authorized to perform". Implementers may find the distinction unclear without further guidance here. *https://jira.hl7.org/browse/FHIR-54942*)

Q. What extensibility should be permitted when encoding Radelement CDE Sets?

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Most importantly, can additional sub-observations be included?

And what is the Coding System identifier for Radelement codes?

Q. Is it helpful to have a "Presence" value in the parent of a grouped Observation Set?

Computed Properties and Summary/Derived Observations have a value in the parent observation, and the children are referenced with .derivedFrom. Measurement Groups have no value in the parent (.organizer=true), and the children are referenced from .hasMember. Hierarchical Targets have a value (often Presence) in the parent, and the children are referenced from .hasMember. Finding Sets (CDES) could go either way. In Radelement, they have no value in the parent and Presence is the first child, but they could be encoded with Presence being the value of the Set.

Q. Are there any issues with using the Flag resource to highlight and track actionable findings?

It seems to fit the intended use of the resource. Observation.note could describe whether the observation is significant or unexpected, but the data type is Annotation (text) not coded values. Condition.note is intended to describe the Condition, its diagnosis and prognosis (and is still text). Condition.severity is single valued and severity is distinct from actionability. Condition.category is open ended but also does not seem intended for this.

How should a radiologist locate specific followup actions? Should a subsequent ServiceRequest.reason reference the finding or DiagnosticReport? Should the ServiceRequest.supportingInfo reference the Flag? Should Flag.supportingInfo be updated to reference the followup action (when or after setting Flag.status to inactive)?

Q. Are requirements or guidance needed to support "fuzzy matching" for anatomy?

By default, matching is literal. A search for prior observations on "liver" might return a previous liver volume estimate and an observation it was "enlarged"; but it would not return observations on the left hepatic duct, the capsule, the portal vein, the hilum, or a cyst in the caudate lobe, because none of those equal "liver", let alone potentially related findings on the gall bladder or spleen. Sometimes the narrow focus is fine. But when the user would like to invoke "fuzzy matching" to cast a wider net, the question is whether the client, the server, or both should have more advanced functions. In theory, fuzzy matching could match against anatomy that is more granular than the query key (finding the children) and/or less granular than the query key (finding parents and siblings).

One possible contributing mechanism could be for the server to support a "fuzzy matching" flag which triggers it to leverage an anatomical tree to match against more things. This might be pre-indexed in it's query database.

Another possible mechanism could be for the client to similarly leverage an anatomical tree and submit a query for, say 29 terms, instead of just liver.

A third possibility would be for the body structure codes to include "more general codes" to facilitate such fuzzy matching.

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The FHIR search parameters for :below and :in=<ValueSet> were intended to facilitate some of this kind of thing.

In terms of tradeoffs, the Server is more aware of the entirety and structure of the database being searched, able to manage its content uniformity, and would allow centralized hosting/implementation of the anatomic modelling. On the other hand, the client is more aware of the user task and context. In practical terms the client can provide client-side filtering to manage browse the results if the server-side filtering is able to constrain the results to a "manageable" number of properly annotated results.

Also need to confirm that BodyStructure search patterns that allow for Boolean (AND/OR) combinations of things like structure, laterality, morphology.

From the user perspective, they don't want to miss getting relevant hits, but don't want to be swamped by "irrelevant" hits either. Will likely need to request additional standard search parameters or define extension parameters in this profile.

In the worst case, the client presumes server-side filtering, the server presumes client-side filtering, and the user gets no useful filtering.

Q. Are codes like "stent" OK in .morphology for physical objects as described in 6.7.3.6.2.3

An alternative would create a Device resource, reference that in Observation.focus and then explain that BodyStructure.included.structure describes the part of the .subject (patient) the stent is located in (e.g. descending coronary artery). That would break the pattern that BodyStructure describes the .subject unless there is .focus in which case it describes the .focus (e.g. when we do an observation on femur where .focus = fetus)

Q. Should we profile a standard Observation.code for the radiation dose summary text block?

See details in 6.7.3.4 Procedure.

Q. How should we profile generation of a diagnostic report resource Bundle?

FHIR has defined a $document operation that references a root resource and has the server marshal all the resources that the root resource references and collect them into a Bundle Resource for exchange with Bundle.type=document. This is a very helpful operation and exactly what we would like to have.

Currently, FHIR has defined this operation on the Composition Resource, but not the DiagnosticReport resource. (https://build.fhir.org/composition-operation-document.html)

Options to consider include:

- Request/profile the $document operation on Diagnostic Report too.
- Create a dummy composition that references the DiagnosticReport, use that as the root for the bundle, can leave it behind when unbundling.
- Use Bundle.type=transaction and define the bundle contents ourselves, like was done in IMR RAD-141

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It has not defined it for DiagnosticReport.

Q. How should we approach consolidating the IMR and IDR Profiles?

If done from scratch we might have done IDR first and then added an IMR option for including image/measurement hyperlinks in the body, perhaps as a Named Option.

Could do a Rev2 of IMR as a separate profile that aligns with IDR mechanics.

Consider if we merge RAD-141/RAD-Y1 (Store) and RAD-143/RAD-Y2 (Query). Probably keep RAD-142 (Display) and RAD-144 (Get Rendered Report).

Consider if we want to cut back on the level of specification granularity in RAD-141, perhaps update wording, consider dropping xml baseline requirements…

Closed Issues:

Q: How should we package the PC Draft for Phase II?

A: Use Word

Easier document for change tracking and to focus on new content. Include links to IG. Can do some updates in a revised IG when simpler.

Q: Should Observation.code contain the observed property or also pre-coordinate the anatomy?

A: Property.

Duplicating .bodyStructure information into .code via pre-coordination could get messy.

Q: Can Observation.derivedFrom be used for semantic derivation, not just mathematical?

A: Yes.

Q: Should Composition be used to encode semantics and relationships between Observations?

A: No.

FHIR says "Composition may also be used to organize observations and diagnostic reports, but that is only for purpose of readability, not to record critical relationships for interpretations."

Q: (EUHO) Are changes to DiagnosticReport.status required?

A: No.

IHE IDR .status comment: “Values of **preliminary** and **final** shall be used when their conventional meaning for imaging reports applies. A value of **registered** ~~**state**~~**may** be used while the report is being composed during the interpretation process. For addenda, a value of **amended** shall be used. . Note: Other FHIR status values such as **modified**, **corrected**, or **appended** are not profiled here. They may be addressed in a reporting workflow profile.”

Removed normative restrictions on the valueset.

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EU only shares Final. Preliminary may exist but not part of the use case. EU might stay silent or not prohibit Preliminary.

Note (per Ignacio comment) this is the status of the Report resource, which is influenced by, but is not the primary record of, the business status of the reporting workflow.

Q: (EUHC-OK) Are changes for radiation dose text required?

A: No.

Agree that in the report, dose is an optional text block, recommended in the text describing the procedure/technique. Its presence and content is driven by local reporting requirements. Diagnostic Reports are not a good dose database. Actual dose management should be based on detailed data in DICOM.

Q: (EUHC-OK) Are changes to DiagnosticReport.media required?

A: No.

Agree that media is for graphical elements like bullseye charts, vein diagrams, etc. Agree that acquired diagnostic data (which includes patient-taken photos) do not belong here. Also, the interpreted images are referenced from .study, not here. Comparison images are referenced from .comparison, not here.

Q: (EUHC) Is it a problem if the EU IG refers to the Report Consumer actor as Report Processor?

A: Probably not.

Just explain that the EU Report Processor is called Report Consumer in IHE Rad Profiles. EU is considering to go with Report Consumer… Check later.

Q: Are targeted codes for List.emptyreason and List.status needed for .comparison usage?

A: Not now.

Once usage is more clear in the future, might identify some helpful distinctions/codes to request, but for now the existing ones seem adequate. https://build.fhir.org/valueset-list-empty-reason.html

Q: Where should the radiologist assessment of the quality and limitations of the study go?

A: For study level assessments use ImagingStudy.note to reference an Annotation; for caveats on specific observations put text in Observation.note.

Ultimately, it is an assessment by the radiologist of the quality of the study data in the context of the reason for the exam. Limitations may arise from how the data was handled, how the acquisition was performed, or even the (in)appropriateness of the ordered exam given the indications.

Chose not to get into the logistics of cross-mapping between KOS-encoded quality issue flags in this profile.

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If there is a need to get general text into the Findings or Conclusion section, could consider profiling an Observation with .focus=ImagingStudy and .code=study limitations.

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56 Imaging Diagnostic Report (IDR)

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-1.html

The Imaging Diagnostic Report Profile describes a machine-readable format for reports on diagnostic procedures of common radiology specialties using common modalities. It defines a FHIR-based encoding of the report, specifically addressing standard imaging report sections, including order, history, procedure/technique, comparison, findings/observations, impression/conclusion, recommendations, and signatures.

Specific attention is given to the impression and recommendation content as being of primary interest to the main consumers of diagnostic reports. Machine-readable coding of this content facilitates machine support such as placing orders for recommended followups or clinical decision support driven by report impression content.

Specific attention has also been given to machine-readable coding of the Findings section. Findings are of particular interest to the subsequent radiologist using the report as a prior.

Driven by European Health Data Space (EHDS) activities, HL7 Europe has also developed an Imaging Report IG. It was created with the intention of being compatible with the existing Phase I work of this IHE IDR Profile and with this Phase II update. A standardized, uniform, encoding/format for imaging reports is, of course, highly desirable for systems that receive, display, process, database, and implement automations based on those reports. Creating and distributing reports with encoding variations increases implementation effort and reduces interoperability. To that end, this Phase II work specifically engaged HL7 EU Imaging Report Working Group participants to collaborate on further harmonization of the specifications with the goal of a core global specification with (hopefully minimal) national/regional extensions to simplify implementations and promote interoperability.

Out of Scope:

This Profile does not address all imaging specialties; specifically, cardiology, pathology, dentistry, and ophthalmology are not specifically considered. Much of the specification here might be useful in those specialties, but that would need to be confirmed, and it is highly likely each would require additional capabilities not considered here.

This Profile does not address the reporting workflow used to compose the content that is ultimately encoded as described in this Profile, nor does it address integration of tools during that workflow. See X.6 for some discussion of other Profiles which may be relevant.

56.1 IDR Actors, Transactions, and Content Modules

…

56.1.1.3 Report Reader

A Report Reader accesses reports from the Report Repository for presentation to a user.

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…

56.1.1.4 Report Consumer

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-1.html#56114-report-consumer

<added paragraph breaks>

A Report Consumer accesses reports from the Report Repository for processing.

The capabilities to process those reports is not otherwise constrained here. **Some Report Consumers will likely take advantage of the coded content in the FHIR resources, others might be limited to processing just the text or HTML renderings.**

Systems that might implement this actor include clinical decision support (CDS) systems, workflow automation tools, and clinical registries. A reporting workstation might also implement this actor to access and incorporate content from prior reports into the current report **(see 56.4.2.5 Use Case #5)**.

56.2 IDR Actor Options

…

56.4.1 Concepts

This section presents concepts and considerations that may be helpful to better understand, implement, and deploy this profile. This material is informative; there are no conformance requirements in this section.

For brevity, this section will sometimes refer to imaging diagnostic reports simply as “reports”.

56.4.1.1 Report Formats: ORU, PDF, SR, CDA, FHIR

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-1.html#56411-report-formats-oru-pdf-sr-cda-fhir

The proposed FHIR DiagnosticReport format would take its place among a number of existing report formats in use, to varying degrees, in existing hospital systems. This profile does not mandate specific transcoding capabilities, but since that will likely be part of successful product implementations, some guidance is provided here.

HL7 V2 ORU messages containing formatted or unformatted text are, as of the early 2020's, still a very common format for distributing reports. The primary advantage of **continuing to use** this **format**~~**approach**~~ is its compatibility with the large install base of V2 systems, in particular when including the report in HL7 V2-driven electronic medical record systems. While the inclusion of OBX segments in the ORU message can provide some coded information, this is still poorly adopted and not well standardized. As a result, the machine-readability is quite low and the underlying mechanisms are not well suited to significant improvement of that.

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See Annex C.0 for a discussion of t~~T~~ranscoding between ORU messages and **FHIR** DiagnosticReport **~~will likely make use of the DiagnosticReport.text, and potentially DiagnosticReport.presentedForm.~~**

PDF renderings …

DICOM Structured Report (SR) introduced …

HL7 Clinical Document Architecture (CDA) defines …

HL7 FHIR DiagnosticReport Resources have the potential to permit sophisticated levels of machine-readable data while also providing human-friendly presentations of the report, all within a FHIR-based HIT environment. Those are some of the key motivations for this profile. Details on encoding imaging diagnostic reports based on the FHIR DiagnosticReport resource are provided in RAD TF-3:6.7 Imaging Diagnostic Report Content.

56.4.1.2 Purpose and Structure

…

56.4.1.2.1 Sections

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-1.html#564121-sections

…

Findings: This section provides a detailed description of the findings on the imaging examination. The findings should be described in a clear and concise manner, using standardized anatomic, pathologic, and radiologic terminology whenever possible.

When there are significant numbers of findings, the imaging clinician will typically organize them into groups, typically by anatomy. Reporting templates for particular procedure types (such as those at radreport.org) **~~will also~~** often **demonstrate such** organiz**ation of~~e the~~** findings.

An important distinction between Findings and Impressions is that Findings capture what the imaging clinician saw in the image, while Impressions capture what they inferred/concluded. **For example, t~~T~~**he findings might record a radiolucency, while the impression records a fracture. There are some cases where the two overlap, but generally imaging clinicians try to capture in the Findings what the significant image features are and strive in the Impressions to communicate to the referring physician what they think those represent in clinical terms. **All conclusions and actionable findings, i.e. the clinical information that is most important for the referring physician, will appear in the Impression section.**

Impression, sometimes also called Conclusion or Diagnosis, …

…

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56.4.1.3 Codes and Codesets

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-1.html#56413-codes-and-codesets

While this profile does not mandate the use of particular codesets for many of the details that are coded, agreeing within the local site or organization on common codesets will be a key prerequisite of effective deployment of this profile. This is necessary to facilitate automated functions such as those described in Section 56.4.2.4.1. Further, since reports are typically circulated to other organizations, the use of codes from widely adopted standards will be particularly important to realize the full potential of coded reports. Many of the examples in this profile demonstrate the use of SNOMED codes (indicated by an SCT coding system value). SNOMED has agreements with DICOM and FHIR that identify a very large set of codes which can be used free of charge in DICOM and FHIR implementations anywhere in the world, independent of national licensing. This profile permits implementations to use alternate coding systems, for example if they need to use codes outside of the aforementioned sets in countries that do not have SNOMED licensing agreements.

LOINC has a significant collection of codes for measurements that could be of significant value in coding Findings. LOINC is also the source of the sections codes in RAD TF-3: 6.7.3.0.1, which were drawn from the two panels defined in (81220-6, LN, Diagnostic imaging report – recommended C-CDA R2.0 and R2.1 sections) and (87416-4, LN, Diagnostic imaging report - recommended DICOM PS3.20 sections).

Implementers are encouraged to consider the Playbook set of procedure codes. The codes may be found by searching for "playbook" within LOINC and were originally developed by the RadLex initiative.

When cataloging findings from prior reports (see RAD TF-1:56.4.2.4.1.x), it is likely they will span multiple institutions which may have chosen different coding conventions, resulting in significant challenges. This profile encourages post-coordination of anatomy, morphology, and observed characteristics and properties (see RAD TF-3.6.7.3.6) which may make it more likely that different sites are at least partially aligned, and may make it easier to maintain mapping tables and perform transcoding.

Many FHIR elements use a datatype of CodeableConcept (or CodeableReference which has a .concept element of type CodeableConcept). Two specific mechanisms provided by those datatypes may be useful to implementors of Report Creators and/or Report Consumers.

- **<element>.text allows a simple text string to be provided instead of a code.**
- **<element>.coding may contain multiple entries which represent equivalent codes. E.g. (80891009, SCT, "Heart"), (LP191607-3, LN, "Heart"), and (RID1385, RadLex, "Heart").**

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56.4.1.4 Relevant FHIR Resources

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-1.html#56414-relevant-fhir-resources

This section briefly introduces FHIR resources relevant to imaging diagnostic reports, and outlines their intended purpose, usage, and main details. The **maturity level <u>at the time this specification was published</u>** is shown in (parentheses).

LATER Update to R6 maturity levels (N)

Guidance on using these for encoding reports is provided in RAD TF-3: 6.7 (Imaging Diagnostic Report Content)

…

The **Observation** Resource (N) encodes individual observed details such as those that appear in the findings and impressions of imaging diagnostic reports. Observation supports nesting and other relationship mechanisms to capture groups of associated observations.

…

56.4.1.5 Preliminary Reports, Final Reports, and Addendums

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-1.html#56415-preliminary-reports-final-reports-and-addendums

56.4.1.6 Narrative vs Encoded Content and Structure

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-1.html#56416-narrative-vs-encoded-content-and-structure

Historically, reports have been entirely narrative with a small amount of coded metadata for management. For example, when communicated in an HL7 V2 ORU message, the narrative may be prefixed by just the encoded patient name, MRN, Accession #, and date/time of the exam.

Providing report details as coded content makes that information machine-readable which opens the door to automated and semi-automated functions in systems that receive and process the diagnostic reports. **<u>Coded content is also typically more uniform, making it easier to database than narrative content, which varies with individual preferences.</u>**

~~The focus then shifts to considering what automated functions are of interest, and what report details they need in coded form to be able to operate effectively.~~ Given that coding the entire content of the diagnostic report will be an enormous piece of work, identifying the functions that would provide the most value and utility also helps prioritize which parts of the report **<u>product implementations and site deployments</u>~~we~~** should consider coding first. For additional discussion, see Section 56.4.2.4.1 Report Processing Use Case.

The target of this profile is to capture today's narrative text reports in a FHIR encoding that includes metadata for intelligent handling and starts coding key pieces of content**~~, such as the impressions and recommendations,~~** to facilitate automated workflows. This is intended to start

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the transition to FHIR-based reports. ~~**Subsequent profiles will tackle coding increasing amounts of the semantic content of the reports, especially findings, to support additional use cases.**~~ Some principles the committee has discussed include:

- All **significant clinical details**~~**elements**~~ present in the report in coded form are also visible in the rendered .text (and typically in .presentedForms, if present).
    - **Some coded metadata details do not normally appear in the conventional narrative and would clutter the text. Those might not be rendered in text.**
- Some data generated for/during the reporting process goes into the study, not into the report. i.e., Report is not the transport for additional data that isn't "in the report"
    - E.g., AI analysis data underlying the summary conclusion that was included
- Some elements in the report are there to support billing and administrative processes, not clinical processes.
- Someday, all (or at least more) semantics visible in the .text (one or more of the .presentedForm, if present) will be present in the report in coded form.
- It will help, when adding more coding specs, to be use case driven

As documented in RAD TF-3: 6.7.3 Imaging Diagnostic Report Encodings, the referenced resources are the primary containers for the coded report information, the DiagnosticReport.text is the primary container for the report narrative and is readily rendered for human consumption and readily parsed for machine consumption. The DiagnosticReport.presentedForm may optionally provide additional renderings for various use cases, such as fixed PDF presentations of the content, or HTML presentations that leverage features not available in the .text XHTML. The DiagnosticReport.composition may also optionally provide additional arrangements of the content to suit particular use cases or user preferences.

ADD the following sections (no change tracking shown)

56.4.1.7 Terminology for Findings and Observations

Terms like “finding” and “observation” may be understood differently by different readers. Within the scope of this imaging-oriented profile, the following information model is used (heavily influenced by modelling in SNOMED and DICOM).

Body Structure encompasses both anatomical structures (like the brain or the apex of the heart) and morphologic abnormalities (like a lesion, cyst, inflammation, aneurysm, fracture or abscess). Anatomy that is paired has **laterality** (left, right, both); unpaired anatomy does not.

(Imaging) Observation refers to a feature or characteristic that is visible in an image. An observation may serve as the basis for determination that a finding is present and/or it may further characterize a finding (e.g. describing size or texture details). Imaging observations may be encoded in FHIR Observation Resources.

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(Clinical) Finding refers to the determination that a clinical entity is present or absent, or the assessment that a clinical entity is normal or abnormal. Clinical Findings may be observed directly or inferred from other observations. The determinations and assessments may be made with varying degrees of certainty. Clinical findings appear in the Findings section of the report. Some findings, typically the most significant, also appear in the Impression/Conclusion section of the report. Positive findings may be encoded in FHIR Condition Resources. Per the policy of the FHIR Working Groups, negative findings are encoded in FHIR Observation Resources unless they represent a remission, resolution, or refutation of a prior positive finding, in which case they are encoded in Condition Resources.

In a report, the section titled Findings generally contains both clinical findings and imaging observations. E.g. the presence of a tumor is a finding, a recorded diameter of the tumor is an observation, the rate of growth of the tumor is an observation, a determination that the tumor is benign is a finding, the presence of gallstones is a finding, signs such as the Mercedes Benz sign and the shadow sign (which may be caused by said gallstones) are observations.

Observations are often grouped or related in some way. See Section 56.4.1.8.2 for further discussion of the types of relationships and groupings.

56.4.1.8 Findings Encoding Framework

Some metadata in the Observation and Condition resources included in the DiagnosticReport applies similarly to most findings. That encoding is described in IHE RAD TF-3: 6.7.3.6.1. Other metadata will vary based on the finding concepts described here. That encoding is described in other subsections of IHE RAD TF-3: 6.7.3.6.

56.4.1.8.1 Observation Types

Types of observations are proposed here to bring some structure to the significant breadth across the many pathologies and other details that may be observed in various specialties and imaging modalities.

Note: These are image-based observations. “Liver is normal” means the appearance of the liver in this image is normal; due to limitations of the modality, there may be aspects of the liver that cannot be visualized in this image which are not normal. This is one reason observations are categorized as imaging results.

Anatomic Entities, Pathologic Entities, and Physical Object Entities (Image Entities)

The target of an observation (sometimes referred to as a finding site or a target entity) is typically either an anatomic image entity, a pathologic image entity, or a physical object image entity. An anatomic image entity is a specific piece of anatomy visible in the image, such as the left adrenal gland, or the caudate lobe of the liver. A pathologic image entity is a specific pathologic process or piece of tissue visible in the image, such as swelling or a lesion. Pathologic entities are almost always associated with an anatomic location (e.g., consolidation in the lower lobe of the right lung). A physical object image entity is an artificial object visible in the image, such as a piece of shrapnel, a stent, or a screw. Physical objects that are the target of an observation are almost always inside, and associated with, the patient anatomy. Physical objects that are outside the

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patient, like ECG leads or patient supports, are visible in the images, but less commonly the target of observations.

Measurements and Assessments (Image Features)

The content of an observation is typically either a measurement or an assessment of the target of the observation. A measurement records a numeric value for a measurable feature, such as diameter or a flow rate (e.g., pancreatic duct diameter is 2 mm). An assessment records a coded value for an assessed characteristic, such as shape or texture. (e.g., liver contour is smooth).

Sometimes, instead of a specific characteristic, an assessment may assess the overall normality of an anatomic entity (e.g., adrenal glands are normal) or the simple presence of a pathologic entity (e.g. no bladder wall thickening). Such overall present/absent or normal/abnormal observations are sometimes referred to as Clinical Findings.

Unstructured Observation

Despite the goal to structure and code as much report content as possible, as modeled above, some unstructured observations may be expected to occur in reports.

Structured, coded data reduces variabilities and removes ambiguities present in natural language and improves the machine readability, facilitating automation and other data-driven features. However, developing specifications, code sets and software that covers the breadth of information that can be expressed in an imaging report will be an ongoing process. In the meantime, capturing unstructured narrative observations in the DiagnosticReport resource is necessary.

56.4.1.8.2 Observation Relationships (i.e. Organization and Groupings)

Some findings are individual “standalone” observations. It is, however, quite common to have observations that are grouped together, potentially at multiple levels. And even individual findings/observations may have semantic relationships with other findings/ observations. This section describes such relationships and groupings.

Finding Set

Some groups of observations are anchored by a root finding, such as the presence of a lung nodule, with a set of associated observations that contain further measurements, assessments, and characterizations, such as the morphology, diameter, and composition of the nodule. Many such finding sets are listed as CDE Sets at https://radelement.org. The associated observations are semantically related to the root finding in that they provide further detail.

Summary/Derived Observation

Somewhat similar to a Finding Set, a number of reporting systems have been developed that involve a summary score or assessment that is derived from a collection of more detailed specific sub-observations. For example, the LungRads Score is derived from the grading of one or more lung nodules which in turn are derived from observed characteristics of each nodule.

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In contrast to the root finding of a Finding Set, which is typically observed first and is supplemented by the associated observations, the summary observation is created last as it is derived from the associated observations, usually via a specific algorithm.

Hierarchical Target Entity

The target entity may have hierarchical structure, for example a pulmonary nodule may have a solid component and a non-solid component. Observations on the different characteristics of the different components of the structure are semantically related by all being part of the larger target entity.

Compound Statement

Physicians may dictate compound statements, such as "the liver, gallbladder, pancreas, and spleen are unremarkable." These are encoded as individual observations about each of the anatomic entities that do not depend on having an inherent semantic relationship.

This is frequently used as a convenient shortcut to record a cluster of observations, particularly for a set of anatomic entities that are normal or unremarkable, or for a set of pathologic entities that are absent (pertinent negatives). E.g.,

- "No abnormalities in the chest"
- "Liver, gallbladder, pancreas, and spleen are unremarkable."
- "The C2-3 and C3-4 discs are degenerated."
- "Moderate amount of fluid in the radiocarpal and midcarpal wrist compartments."
- "Ventricles and cisterns are normal in size and configuration."
- "Bones and joints are intact without fracture or dislocation."

The cluster of observations is typically based on anatomic proximity, symmetric paired structures, related biological function, or shared imaging characteristics (e.g. lungs and pleural spaces). In these cases, the semantic relationship is more about standard anatomical relationships than inherent relationships between the observations.

The viewer of the report, such as the referring physician, may have preferences about how all the observations are grouped for presentation, e.g. by anatomy or anatomical region. Addressing such rendering preferences in the report viewer will typically be more effective than getting all the report creators to create presented forms for all the different viewer preference patterns.

SR Measurement Group

Some observations are related because they have been transcoded from a DICOM SR instance and were encoded together in a Measurement Group container.

Derived Observation

Some observations are directly derived, usually mathematically, from one or more other observations. Examples include ratios, calculated areas or volumes, normalized indices like BMI, mean values derived from multiple sample measurements, etc. It can be useful for provenance

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and validation purposes to maintain the semantic relationship between the derived observation and its sources. For example, a prostate volume observation of 30 cc might be estimated from dimension observations of 4.2 × 3.8 × 3.6 cm along three axes.

Temporal Comparison

Change over time, or lack thereof, can both provide significant diagnostic information. It is very common for a given anatomic or pathologic entity to be observed in a current study and that observation compared to other observations of the same entity at one or more time points in the past. This can result in derived observations about the entity, such as it being unchanged, or having a measured rate of growth or size doubling time. This may also be referred to as a trend observation.

Temporal comparisons can differ from simple derived observations by typically spanning multiple exams and duplicating a copy of the prior observation(s) into the current report, while more typical derived observations involve the source observations all originating in the current exam.

If the entity appears in a prior exam but the specific observation was not reported in the prior exam, the current physician may perform and include a new observation on the prior exam in the current exam report (appropriately labeled, of course). Even if the observation existed in the prior report, the current physician may sometimes still create a new observation on the prior exam for improved consistency.

It is useful to be able to determine in which prior exams/reports the entity in question appeared. This is facilitated by the use of longitudinal tracking IDs for such entities, but that also requires matching and mapping to be performed to be effective.

Conclusion Support

Observations may be associated with a report conclusion, for example when the observation is suggestive of, or definitively proves, a particular diagnosis. This includes the case of suggesting, or definitively proving, the absence of a particular condition.

Causal relationship

Observations may have a semantic relationship because one is causing the other. For example, an observed cerebral hemorrhage may also be the (likely) cause of an observed herniation or displacement of anatomical structures, such as a midline shift or compression of a ventricle.

One causation pattern involves a process, such as a pneumonia infection, which manifests entities such as pleural effusion or consolidation in the lungs. Another causation pattern involves a procedure or treatment, such as surgery or a course of drugs, which can result in both intended effects and/or unintended complications.

In some cases, both the cause and the effect are visibly observable in the images. Alternatively, one may be recorded as inferred from the presence of the other. Report language such as “X is consistent with Y” may be used to record the observed presence of X and the inference that Y may be present.

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Common Cause

An expansion of the causal relationship involves multiple "independent" observables that share a common cause. A pathologic entity might manifest in multiple ways. A known traumatic impact might cause multiple observable conditions.

Conversely, the observables may contribute evidence for a conclusion that a causal pathology is present. An infection might manifest in inflammation and swelling in multiple locations. Diverticulitis might be expected to present a focal area of inflammation at a location in the bowel wall (perhaps a specific diverticula), perforations at one or more locations, abscesses or fluid collection at one or more locations, and/or a vessiculocolonic fistula (communication between bladder and colon). A report might rule out diverticulitis in the presence of some of these due to the absence of others, or might include a conclusion of diverticulitis despite the lack of one of these observables. The nature of these related findings might support a severity assessment of mild/moderate/severe.

Modify the following section (renumber)

56.4.1.9~~7~~ Environmental Assumptions

Hybrid environments (mixing FHIR and HL7 V2 messaging) are inevitable. If FHIR is the primary stored representation of the report, it will inevitably need to be sent to a text/V2 based environment. This will be an important part of making deployment practical in existing hospitals.

HL7 is working on general guidance for conversion of content that is encoded in HL7 v2 Messages into roughly equivalent FHIR resources (https://build.fhir.org/ig/HL7/v2-to-fhir/)

Future revisions of this document might provide guidance specific to imaging diagnostic reports and related resources.

ADD the following sections (no change tracking shown)

56.4.1.10 Imaging Workflow, Reporting Workflow, and Reports

The scope of this profile is focused on imaging diagnostic reports which makes it predominantly a Content Profile. The reports are the output of Reporting Workflow, which in turn is a component of Imaging Workflow.

Reporting Workflow is centered on the diagnostic interpretation process during which an imaging clinician reviews the current imaging study along with relevant data from the patient's medical record, including prior imaging studies. Other components of the Reporting Workflow may include reporting worklists, clinical analysis and other reporting tools (AI-based or conventional), assembly of the semantic content of the report, and reporting QA.

Imaging Workflow begins with initial placement of the order, and encompasses scheduling, protocoling, acquisition, quality assurance, post-processing, data routing, the Reporting Workflow, and delivery and handling of the resulting report.

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The Imaging Workflow and the Reporting Workflow are outside the scope of this profile. Some parts are addressed in other IHE Profiles. See 56.6 Cross-profile Considerations.

That said, there are overlaps. Some FHIR Resources that might be created in those workflows, such as the ServiceRequest that represents the initial order, or the ImagingStudy that represents the acquired and processed data, might later be referenced in the imaging report. Implementations in those workflows might find it useful to consider the Resource specifications here.

Conversely, there will be data created (in DICOM and FHIR formats) that are not referenced in the imaging report but are still persisted in the DICOM Study or elsewhere in the patient's medical record. For example, there may be AI results created in the course of the reporting process that might be stored in the Imaging Study, but not explicitly included or referenced in the resulting DiagnosticReport. The DiagnosticReport is not a container for intermediate data produced over the course of the Imaging or Reporting Workflow. The Imaging Study is the primary container for all persisted data from the imaging procedure.

Similarly, a given imaging study might trigger the execution of a large number of opportunistic screening AI algorithms, many of which are unrelated to the indicated reason for the exam. Typically, most or all of them will return negative results. The discretion of the radiologist will determine which are sufficiently relevant and/or significant to be present in the report. The rest of the result data might or might not be retained as imaging study data based on local policies and/or radiologist determination.

Another common example is ultrasound measurements made during obstetric studies. The sonographer routinely makes many measurements which are stored in DICOM Structured Report (SR) instances in the DICOM Study. Some, but typically not all, of those are mirrored in the report while the rest are commonly retained as study data.

For another example, a radiologist might note that the image quality of the study was not optimal. The radiologist could create a DICOM KOS containing a quality assessment of the images that would drive subsequent imaging department quality improvement processes. The radiologist could dictate an assessment of the image quality into the diagnostic report content to communicate potential limitations of the interpretation. Or they could do both or neither.

MODIFY the following sections as shown

56.4.2 Use Cases

56.4.2.1 Use Case #1: Report Creation

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-1.html#56421-use-case-1-report-creation

The focus here is on encoding the collection of information at the end of the interpretation process into a DiagnosticReport-based format.

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Marshalling the constellation of input data and interacting with that data during the interpretation process and assembling the report content is briefly discussed and shown here for context**~~, but is not addressed by this specification~~**.

Note**s**: **1.** Other profiles that touch on **report creation and data handling~~that area~~** (See Section 56.6 Cross Profile Considerations) include:
- Integrated Reporting Applications (IRA)
- AI Results (AIR)
- Remote Radiology Reporting Workflow (RRR-WF)
- Management of Radiology Reporting Templates (MRRT)

2. Collating and using finding data from prior reports is discussed in Use Case 5 (See Section 56.4.2.5.1)

…

LATER Put the UML text blocks into the IG for all use case flows.

56.4.2.2 Use Case #2: Report Storage & Distribution

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-1.html#56422-use-case-2-report-storage--distribution

…

The EMR (Electronic Medical Record), in the role of either Report Reader or Report Repository, will likely index reports for browsing, in addition to using the query/retrieve model. The imaging study would appear as an entry in the medical record with an associated datetime, body part, and modality or exam type. The report may appear in a list of patient documents, also with an associated datetime, body part, and modality or exam type. The originating order will appear in the medical record, but references go from the DiagnosticReport and ImagingStudy resources to the ServiceRequest resource, not the other way around. So going from the ServiceRequest to the report involves a query for the matching Accession Number, or ServiceRequest reference, rather than navigating the reference from the ServiceRequest.

The European eHealth Network (eHN) has published "Guidelines on Medical imaging studies and reports" that is intended to support making them available in a cross-border context to a requesting health professional to support clinical decision making, consultation and continuity of care.

The intended distribution pattern involves a clinician in country A asking its National Contact Point (NCP) for clinical content about the patient. The NCP of Country A contacts the NCP of Country B, which retrieves clinical information from its national infrastructure (e.g. IHE-MHD based systems) and returns it. The NCP of Country A provides the records to the Clinician, potentially having translated it into the local language.

A significant requirement is the ability to identify relevant studies and reports in a manner similar to local access based on key metadata such as time period, modality, body part, or procedure type.

Query patterns will vary by practice and no specific query capabilities are required beyond that described in the Query Imaging Diagnostic Report [RAD-Y2] transaction . That said, the following are query scenarios and capabilities that would likely be useful to some sites.

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…

56.4.2.3 Use Case #3: Report Presentation

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-1.html#56423-use-case-3-report-presentation

56.4.2.4 Use Case #4: Report Processing

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-1.html#56424-use-case-4-report-processing

56.4.2.4.1 Report Processing Use Case Description

…

The following subsections describe some specific examples of report processing.

56.4.2.4.1.1 Ordering Support for Recommendations

…

56.4.2.4.1.2 Clinical Decision Support for the Referring Physician

…

56.4.2.4.1.3 Actionable Finding and Recommendation Follow-up

…

56.4.2.4.1.4 Clinical Registry Submissions

…

56.4.2.4.1.5 Smart Notifications & Routing of Reports

…

56.4.2.4.1.6 QA and Safety Processes

…

56.4.2.4.1.7 Other Workflow Automation

The software used by the referring physician could also facilitate interacting with other EMR structures such as the Problem List and Allergies (contrast) based on information provided in and extracted from the DiagnosticReport. This will likely involve some selection by the referring physician and some intelligence and sophistication from the software to judiciously suggest updates to the master lists. It is also important to consider removal of entries from those lists when appropriate to help combat “note bloat”.

Similarly, intelligent extraction of key details from the DiagnosticReport for inclusion in discharge notes, referral letters, and patient instructions could save time and energy.

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Technique and finding information from prior reports could be used to intelligently protocol the current exam. Technique and reconstruction could be selected to closely match the prior images, and scan range could be selected to facilitate effective follow-up of pertinent "problem list" items (see also 56.4.2.5 Use Case #5: Prior Finding Catalog).

Another useful workflow function that could be enabled is the often-discussed radiology-pathology correlation feedback. Many radiologists would appreciate a dashboard that collects certain impression entries, like nodules or masses that are suspicious for cancer, and tracks subsequent anatomical histopathology reports to extract information on which were malignant and which benign.

ADD the following sections (no change tracking shown)

56.4.2.5 Use Case #5: Prior Finding Catalog (UP)

A Report Consumer processes the content of multiple prior reports to create a catalog of prior findings for use by the imaging clinician during the interpretation of the current study.

56.4.2.5.1 Prior Finding Catalog Use Case Description

During the creation of a radiology report for a current study, the content of relevant prior reports can be very useful to the reading radiologist. This is sometimes conceptualized as an "imaging problem list" which are the findings (and conclusions) of a collection of prior reports collated into a construct that facilitates navigation, comprehension, and analysis by the radiologist, typically in the context of preparing a new Current Report.

The software used by the radiologist could support the current reading activity by performing functions such as the following (likely subject to configurability):

Note: This is more detailed than a typical Use Case Description in the hope of exercising the Finding encoding specifications.

- Retrieve multiple relevant prior reports (both local and remote)
- Extract (all) findings and conclusions from each report
- Correlate/index the findings into a catalog
- Support browsing through the (organized) content, E.g.
    - Prepare a concise summary of the patients imaging history
    - Create a finding summary with each noted condition listed as present or absent
    - Create a single composite report with timestamps on details (as an IPL representation not a storage artifact)?
- Support queries for particular details or types of content, E.g.
    - Present prior observations (positive/negative) about given anatomy or pathology
        - E.g. unexpected lytic lesion in a chest study might trigger a query to present any cancer or hematologic malignancy findings of which the

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lesion might be a metastasis. If many results are available, grouping observations by occurrence, then summarizing its history/trajectory could help. Note: studies well outside the current "field of view" become relevant in this scenario.

- Identify any prior observations "related to" this current observation

- Provide reporting support and automation features, E.g.,
  - Highlight details present in the history/catalog that the radiologist has not (yet) commented on (to facilitate completeness)
  - Identify, and/or automatically perform, current measurements to mirror prior ones
    - Support selection of measurements in the "workspace" to go into the report, or selection of auto-populated measurements in the report to be removed (or revised)
  - Plot/present trends over time for given measurements or observations
  - Identify proposed matches between entities (e.g., nodules) in prior studies and the current study. Support tracking UIDs and/or references to registration objects.
  - Display side-by-side frames from two or more studies for correlated findings/ entities (and label them).
  - Generate a markdown file for feeding into an LLM as context.
- Provide Clinical Decision Support for the Radiologist, e.g.,
  - Suggest follow-up recommendations based on changes between prior and current and corresponding from input guidelines.
  - Based on selected/key findings, provide differential diagnosis and/or possible etiology for consideration by the radiologist and/or inclusion in the Impression.

Notes: 1. Whether the software generates such a catalog on the fly from currently available priors, or whether it maintains catalog data and updates that content as needed is left to implementers.

2. This profile specifies an encoding (with the implied information model) for a single report. The information model for a multi-report catalog is out of scope and is left to implementers.

3. This profile is intended to facilitate interoperable encoding of content and index fields. Prescribing the business logic or algorithms for the above features, such as how to determine relevancy or perform spatial matching, is out of scope.

4. Selected details from this catalog might be incorporated into the history section and/or the finding section of the current imaging report at the discretion of the reading physician, but it is not expected that the entire catalog, or even large parts of it, would be so incorporated.

5. Although this use case focuses on prior imaging findings, many clinical scenarios will depend on information from the patients broader medical record, including labs, medications, social history, etc., which is not described here.

A distinction of this Use Case is that while the preceding four focus on the content of a single study, and a single report, this Use Case considers organizing data from multiple studies into a larger information model.

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56.4.2.1.2 Prior Finding Catalog Process Flow

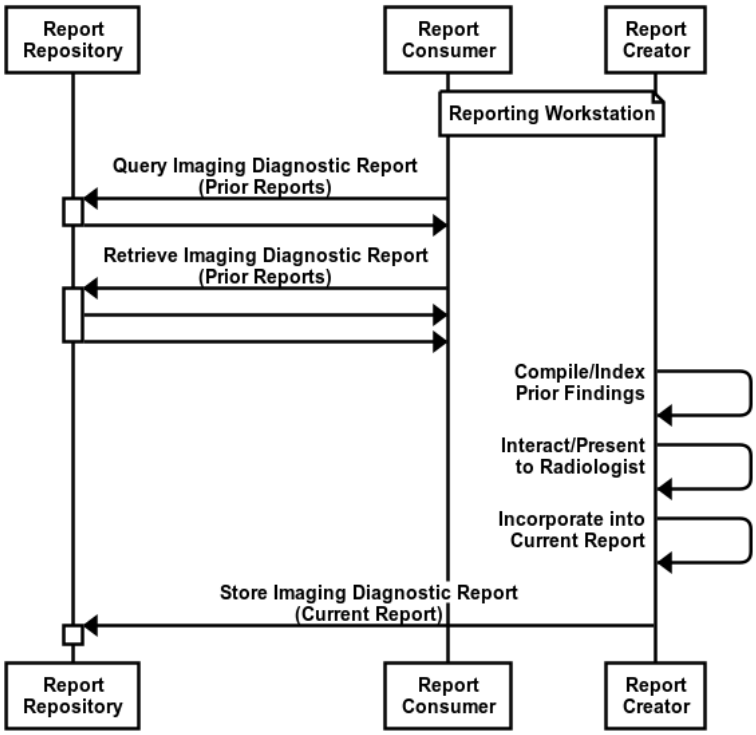

Figure 56.4.2.1.2-1: Prior Finding Catalog Process Flow

```
participant "Report\nRepository" as Repository
participant "Report\nConsumer" as Consumer
participant "Report\nCreator" as Creator
note over Consumer, Creator: Reporting Workstation
Consumer->+Repository : Query Imaging Diagnostic Report\n(Prior Reports)
Repository->-Consumer :
Consumer->+Repository : Retrieve Imaging Diagnostic Report\n(Prior Reports)
Repository->Consumer :
Repository->-Consumer :
Creator->Creator : Compile/Index\nPrior Findings
Creator->Creator : Interact/Present\nto Radiologist
Creator->Creator : Incorporate into\nCurrent Report
Creator->+Repository : Store Imaging Diagnostic Report\n(Current Report)
```

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IHE Radiology Technical Framework Vol 2 (Transactions)

4.Y1 Store Imaging Diagnostic Report

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/rad-Y1.html#4-y1-store-imaging-diagnostic-report

4.Y1.1 Scope

This transaction is used to send imaging diagnostic reports.

The report is encoded as a bundle of FHIR Resources, anchored by the Diagnostic Report Resource.

4.Y1.2 Actor Roles

The roles in this transaction are defined in the following table and may be played by the actors shown here:

Table 4.Y1.2-1: Actor Roles

Role:	Sender: Sends an imaging diagnostic report instance.
Actor(s):	The following actors may play the role of Sender: Report Creator
Role:	Receiver: Receives and stores imaging diagnostic report instances.
Actor(s):	The following actors may play the role of Receiver: Report Repository

Transaction text specifies behavior for each role. The behavior of specific actors may also be specified when it goes beyond that of the general role.

4.Y1.3 Referenced Standards

- FHIR R6

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4.Y1.4 Messages

Figure 4.Y1.4-1: Interaction Diagram

4.Y1.4.1 Store Request Message

The Sender sends an imaging diagnostic report to the Receiver.

The Receiver shall support handling such messages from more than one Sender. The Sender shall support making requests to more than one Receiver.

4.Y1.4.1.1 Trigger Events

A user or an automated function on the Sender determines that an imaging diagnostic report should be sent to the Receiver.

This might occur when the report is initially created or during subsequent distribution steps.

4.Y1.4.1.2 Message Semantics

The message is an HTTP POST that initiates a FHIR "transaction" using a "create" action. The Sender is the User Agent. The Receiver is the Original Server.

The payload is an IDR Bundle Resource that shall conform to the specifications and guidance in 4.Y1.4.1.2.1.

The media type of the HTTP body SHALL be either application/fhir+json or application/fhir+xml.

See http://hl7.org/fhir/http.html#transaction for complete requirements of a FHIR transaction. See http://hl7.org/fhir/bundle-transaction.html for an example of a transaction bundle.

The Sender SHALL send the message to the base URL as defined in FHIR. See http://hl7.org/fhir/R4/http.html for the definition of "HTTP" access methods and "base".

4.Y1.4.1.2.1 Imaging Diagnostic Report Bundle Specifications and Guidance

See Open Issue on generation of a diagnostic report resource Bundle. (UP)

- *(EUHO) Check with FHIR do we need to profile a "root composition" that references DiagnosticReport in order to obtain a document bundle generation Action and signature operation?*

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Note: The DiagnosticReport resource depends on resources such as Patient, Organization, Practitioner or PractitionerRole that are critical but are not necessarily part of the bundle when exchanging the report within the enterprise because they are expected to already exist; hence, they are referenced by the resources in the bundle, rather than created by the Sender. See Section 1:52.4.1.6 DiagnosticReport Referenced Resources for more details.

When exchanging between enterprises, these other resources would need to be present in the bundle, at least in summary form. The receiving enterprise might choose to instantiate those resources locally, or might use the summary information to match them to the equivalent local resource, e.g. the local Patient Resource for that patient, and update the references in the Diagnostic Report.

Additional discussion on bundling diagnostic report-related Resources is found in RAD TF-3:6.7.3.13.

4.Y1.4.1.3 Expected Actions

The Receiver SHALL accept both media types application/fhir+json and application/fhir+xml.

On receipt of the request message, the Receiver SHALL validate the resources and respond with one of the HTTP codes defined in the response Message Semantics.

The Receiver SHALL process the transaction bundle atomically as specified in http://hl7.org/fhir/http.html#transaction.

Note: Local policy might reject bundles containing resources such as Patient, Organization, Practitioner, etc. referenced that are unknown to the Receiver. Therefore, the actual behavior is at the discretion of the Receiver Actor policy.

The Receiver SHALL retrieve any Resources referenced by absolute URLs in the FHIR Bundle Resource.

The Receiver SHALL validate the bundle first against the FHIR specification. Guidance on what FHIR considers a valid Resource can be found at http://hl7.org/fhir/validation.html.

Once the bundle is validated, the Receiver SHALL store the report and all associated resources.

The Receiver SHALL NOT send a success response until the multimedia report is completely processed and persisted as appropriate to the Receiver configuration.

If the Receiver encounters any errors or if any validation fails, the Receiver SHALL return an appropriate error.

LATER – Profile the response like in IMR? https://profiles.ihe.net/RAD/IMR/RAD-141.html#2414142-store-multimedia-report-bundle-response-message

4.Y1.5 Security Considerations

The FHIR Resources conveyed typically constitute personal health information.

The Sender MAY use external URLs in presentedForm.url. In this case, the Receiver SHOULD consider validating the URL to ensure that it is a valid URL referencing a known legitimate host to avoid phishing attack.

4.Y1.5.1 Security Audit Considerations

This transaction is associated with a 'Patient-record-event' ATNA Trigger Event on both the Sender and the Receiver. See ITI TF-2: 3.20.4.1.1.1.

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4.Y2 Query Imaging Diagnostic Report

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/rad-Y2.html#4-y2-query-imaging-diagnostic-report

LATER If the Query transaction is to be included in the TI draft, Map out FHIR Query with focus on query fields driven by our use case/scenarios and consider mandatory query tags

4.Y2.x Report Query Scenarios (UP)

- Find the Report corresponding to an order (ServiceRequest or Accession #).
  - Match for .basedOn reference to ServiceRequest
  - Match for .identifier of Accession #
- Find a "known" report without the order/accession number (e.g. patient or referring finding the report for a (recent) study based on recalled details)
  - **Constrain** Patient; **Filter** on date range, modality, body part.
  - Highlight FHIR "last 5" function (return 5 most recent matching reports)
    - https://build.fhir.org/observation-operation-lastn.html
- Find prior reports that are relevant to a current study
  - **Constrain** Patient, body region; **Filter** on modality, date range
    - Consider search expansion to adjacent regions; e.g. an Abdomen search might also return Chest since the scan extent sometimes overlaps, such as in the case of an adrenal mass that might have been partly visible but overlooked in a chest CT.
  - Set matching criteria based on Reason for Study? (Levels of relevance?)
- Find (many) reports with a particular reason for study or specific findings/conditions
  - Filter on reason for study, conclusion codes, observation codes, maybe body part
  - Consider patient demographics, modality

Note: See discussion of anatomical search expansion in IHE RAD TF-3:6.7.3.6.y.

4.Y3 Retrieve Imaging Diagnostic Report

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/rad-Y3.html#4-y3-retrieve-imaging-diagnostic-report

4.Y3.1 Scope

This transaction is used to retrieve imaging diagnostic reports.

The report is encoded as a bundle of FHIR Resources, anchored by the Diagnostic Report Resource.

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4.Y3.2 Actor Roles

The roles in this transaction are defined in the following table and may be played by the actors shown here:

Table 4.Y3.2-1: Actor Roles

Role:	Requester: Requests retrieval of an imaging diagnostic report instance.
Actor(s):	The following actors may play the role of Sender: Report Consumer Report Reader
Role:	Responder: Returns requested imaging diagnostic report instances.
Actor(s):	The following actors may play the role of Receiver: Report Repository

Transaction text specifies behavior for each role. The behavior of specific actors may also be specified when it goes beyond that of the general role.

4.Y3.3 Referenced Standards

- FHIR R6

4.Y3.4 Messages

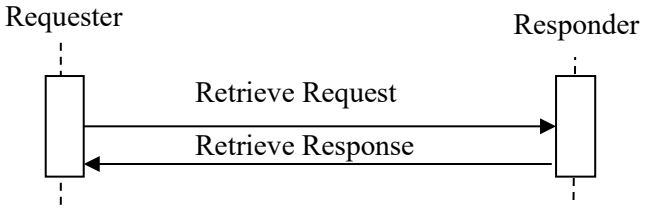

Figure 4.Y3.4-1: Interaction Diagram

4.Y3.4.1 Retrieve Request Message

The Requester requests an imaging diagnostic report from the Responder.

The Responder shall support handling such messages from more than one Requester. The Requester shall support making requests to more than one Responder.

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4.Y3.4.1.1 Trigger Events

A user or an automated function on the Requester determines that an imaging diagnostic report is desired from the Receiver. This might be subsequent to identifying the desired report based on the response to a Query.

4.Y3.4.1.2 Message Semantics

The message is an HTTP GET request. The Requester is the User Agent. The Responder is the Original Server.

The Requester MAY provide HTTP Accept header, according to the semantics of the HTTP protocols (see RFC2616, Section 14.1). This enables the Requester to indicate preferred mime-types.

4.Y3.4.1.3 Expected Actions

The Responder SHALL provide a Retrieve Response to the Requester.

The Responder SHALL attempt to compose an IDR Bundle Resource for the requested report in the requested MIME type. The IDR Bundle shall conform to the specifications and guidance in 4.Y1.4.1.2.1.

4.Y3.4.2 Retrieve Response Message

The Responder sends the requested report to the Requester.

4.Y3.4.2.1 Trigger Events

The Responder receives a Retrieve Request Message from the Requester.

4.Y3.4.2.2 Message Semantics

The message is an HTTP GET response. The Requester is the User Agent. The Responder is the Origin Server.

The Responder SHALL return an HTTP GET response as specified by RFC2616.

The Responder SHALL respond with an HTTP Status Code 200 when it successfully returns the requested report to the Requester. The HTTP message-body SHALL be the IDR Bundle.

The Responder MAY return HTTP redirect responses (responses with HTTP Status Codes 301, 302, 303 or 307) in response to a request. See RFC7231 Section 6.4 Redirection 352.

See ITI TF-2x: Appendix Z.7 Guidance on Access Denied Results related to the use of 200, 403 and 404 response codes.

When the Responder returns an error response code, it SHOULD include a FHIR OperationOutcome with more details on the failure. See FHIR http://hl7.org/fhir/http.html and http://hl7.org/fhir/operationoutcome.html.

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4.Y3.4.2.3 Expected Actions

If the Responder returns an HTTP redirect response (HTTP status codes 301, 302, 303, or 307), the Requester SHALL follow the redirect, but may stop processing if it detects a loop. See RFC7231 Section 6.4 Redirection 352.

The Requester SHALL process the results according to application-defined rules.

4.Y3.4.3 CapabilityStatement Resource

Requesters and Responders implementing this transaction SHALL provide a CapabilityStatement Resource as described in ITI TF-2: Appendix Z.3 indicating the transaction has been implemented.

4.Y3.5 Security Considerations

The FHIR Resources conveyed typically constitute personal health information.

The FHIR Resources may contain external URLs (e.g. in presentedForm.url). The Requester SHOULD consider validating the URLs to ensure that they are valid URLs referencing a known legitimate host to avoid phishing attack.

4.Y3.5.1 Security Audit Considerations

This transaction is associated with a ‘Patient-record-event’ ATNA Trigger Event on both the Requester and the Responder. See ITI TF-2: 3.20.4.1.1.1.

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IHE Radiology Technical Framework Vol 3 (Content Specifications)

6.7 Imaging Diagnostic Report Content

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-3.html#67-imaging-diagnostic-report-content

…

6.7.2 Referenced Standards

- **DICOM: Digital Imaging and Communications in Medicine. https://dicomstandard.org**
- FHIR-R4: HL7 FHIR Release 4.0
- FHIR-R5: HL7 FHIR Release 5.0
- FHIR-R6: **HL7 FHIR R6 ballot3 (current build) https://build.fhir.org**
- **LOINC: Logical Observation Identifiers Names and Codes. https://loinc.org/**
- **RadLex: A Lexicon for Uniform Indexing and Retrieval of Radiology Information Resources. https://www.radlex.org/**
- **SCT: SNOMED CT (Systematized Nomenclature of Medicine—Clinical Terms). https://www.snomed.org/**
- ~~**FHIR ImagingSelection: ImagingSelection**~~
- ~~**LATER – Reference other FHIR Resources**~~

6.7.2.1 FHIR Versions and Extensions

This Profile/IG is written in terms of FHIR R6 resources.

Notes: 1. FHIR R6 (and R5) introduced specific elements to address key details of coded imaging diagnostic reports.

2. This work expects that HL7 FHIR R6 will be published as normative in 2027. Some prerequisites for this profile/IG to become Final Text include: HL7 FHIR R6 being published as normative, and the IHE Radiology Technical Committee reviewing any relevant changes to FHIR R6 during the HL7 ballot resolution process.

Implementations are permitted to be based directly on FHIR R6, or to be based on FHIR R4 and/or FHIR R5 resources with the incorporation of HL7 FHIR cross-version packages (See https://build.fhir.org/versions.html#extensions) as needed to provide the elements and behaviors specified in this Profile/IG.

LATER Confirm no glitches relevant to us in the cross-version packages.

~~**Implementations shall support the use of FHIR R4 resources.**~~

~~**Implementations may also be configurable to support the use of FHIR R5 and/or FHIR R6 resources.**~~

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~~**This profile depends on a number of extensions introduced in FHIR R5 and FHIR R6 to address key details for coded imaging diagnostic reports.**~~

~~**When encoding or parsing FHIR R4 resources, implementations shall support the additional elements specified in this Profile as extensions in the manner described here: https://build.fhir.org/versions.html#extensions**~~

~~**Implementers may find one or more "FHIR extension packs" available to facilitate the support of elements introduced in FHIR R5 (and/or eventually FHIR R6).**~~

~~**Update the text to more specifically describe the IDR-R4-to-R5-and-R6 extensions mechanism, and**~~

LATER Call out any IDR extensions (which go beyond R4/5/6)

6.7.3 Imaging Diagnostic Report Encodings

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-3.html#673-imaging-diagnostic-report-encodings

LATER <Check for Resource List edits>

…

This section describes requirements that are also represented in a companion IDR FHIR IG (Implementation Guide). Some of these requirements involve extensions to the FHIR Resources.

~~**TO: Since there is the risk that reiterated/duplicated content could diverge, any remaining content here will likely be reframed as informative and moved to Concepts, to an Informative Annex, to an IG Resource page, or dropped if all the discussion can be conveniently captured in the IG.**~~

~~***How should we handle the following? A: That's an IMR problem. IDR is fine.***~~

~~**In IMR, there is no Vol 3 Content Definition; the IMR Transactions reference directly to Profiled Resource pages in the IMR IG. Finding a way to splice FHIR IGs into Content Definitions might be another option. Discuss with JasonLynn/ITI.**~~

~~**This profile adds extension attributes (marked as "<new>" -** ***remove*****) to several existing resources.**~~

The following text describes how the necessary structure and content of an imaging diagnostic report, as described in IHE RAD TF-1:56.4.1.2, would be encoded in FHIR.

6.7.3.0 Diagnostic Report

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-3.html#6730-diagnostic-report

DiagnosticReport.text contains the fully rendered human-readable form of the diagnostic report as described in 6.7.3.11. It is often a compilation of the .text elements of resources that are

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components of the report as described in their component sections and in 6.7.3.11.2 Resources.text.

- (EUH) DiagnosticReport.resultsInterpreter: The**~~is is~~** imaging clinician(s) **who reported** the study **~~is reported by~~**. **Multiple~~Additional~~** report authors may **~~also~~** be referenced. **It is recommended to use** PractitionerRole resources **(which in turn reference Practitioner resources) rather than reference Practitioner resources directly, in order~~may be used~~** to **clearly** record **the** participants **role in the report,** such as resident**~~s~~**, **attending,** collaborating clinician**, etc~~s and the role they played~~**.
    - **PractitionerRole.code is suggested to contain a general code like (66862007, SCT, "Radiologist").**
    - **PractionerRole.specialty can optionally contain information like (1251547005, SCT, "Neuroradiology"). Try to use codes for specialties (like Neuroradiology) rather than codes for specialists (like Neuroradiologist).**
    - **PractionerRole.organization is expected to typically match the organization recorded in DiagnosticReport.performer.**
    - **PractionerRole.healthcareService.category and .healthcareService.type are not required to be populated in this context.**
- **DiagnosticReport.basedOn shall, if known, include each of the following:**
    - **A reference to** the imaging ServiceRequest **resource (i.e. the order)**.
    - **A Reference.identifier entry that encodes the accession number as done in ImagingStudy: https://build.fhir.org/imagingstudy.html#accession-number**
- DiagnosticReport.media **may contain** graphical elements such as charts and icons that appear in the presentedForm of the report **~~may go here~~** if they cannot be included inline in the format used (PDF, etc.).
    - The interpreted study is referenced from the .study element, not here. Those study images may be accessible as RESTful resources via DICOMweb (which includes parameterized renderings using the /rendered DICOMweb endpoint to adjust windowing and other parameters). Selected parts or points of those images are encoded as ImagingSelection resources. Comparison studies are referenced from the .comparison element.

Language and Translation

All FHIR resources have an optional .language element to communicate the language used for the text content of the resource.

The display text for codes, such as (80891009, SCT, "Heart") often reflects the local language where the data was encoded. Since the semantics are captured by the code value and the coding system, it is permitted to translate the display text into the equivalent text in the local language when presenting, localizing, or transcoding the information.

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FHIR provides several mechanisms to consider when text content is translated, for example to satisfy a clinical need or a legal requirement. See https://build.fhir.org/languages.html

Creating Provenance resources may be useful when systems creating persistent documents that are translations of other documents, and/or humans attest to the quality or accuracy of the translation.

6.7.3.1 Patient

…

6.7.3.3 History

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-3.html#6733-history

Patient History shall **be encoded as** reference**s to** resource items in **the~~<new>~~** DiagnosticReport.**supportingInfo~~patientHistory~~ attribute**. **(EUHO)**

Notes: 1. While the specification requires the ability to include coded history information, it does not specify **~~which or~~** how much history information is **~~en~~in** coded **form**. **The Patient History may be entirely text (See 6.7.3.6.2.6 Unstructured Observation).**

2. Reports do not include the entire medical history available but rather include history details determined to be relevant to the study, usually by the imaging clinician**~~,~~**. **This might include medical, surgical, social, and family history, as well as risk factors and allergies.** Also, the details are **~~coded~~** as known to the imaging clinician at the time of interpretation; different information may be available when any given reader reads the report, but the report will reflect what was known at interpretation.

3. Often this history will include **~~key~~** details that also serve as **~~the~~** indication(s) for the imaging study. The information coded in the ServiceRequest.reason (See 6.7.3.2 Order) **is** the **explicit~~definitive~~** record **of~~in~~** the indications, even if they are also duplicated here.

- **DiagnosticReport.supportingInfo.type shall use the code for PHX to indicate Patient History.**
- Condition resources shall be used **when~~to encode~~** past diagnoses **are encoded**.
- Observation resources shall be used **when~~to record~~** relevant observations **are encoded. E.g., those** from the referring physician, nursing notes, past care, and past diagnostics such as anatomic histopathology or clinical laboratory result values.
    - **An unstructured observation (see 6.7.3.6.2.6) can be a pragmatic way to include a block of narrative patient history if the implementation is unable to create corresponding coded entries.**
- **(EUH) AllergyIntolerance shall be used when patient allergies or intolerances are encoded.**
- Procedure shall be used **when~~to record~~** past procedures performed on the patient **are encoded. E.g.,** knee surgery, an appendectomy, or spinal fusion.
- FamilyMemberHistory shall be used **when~~to record~~** a person's relationship to the patient **is encoded**, along with the persons demographics, known conditions and procedures.

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Narrative text in the history section of the diagnostic report is a good candidate for auto-generation based on **a subset of** the coded content in the referenced resources, however the process of selecting the relevant subset will likely require input from the imaging clinician or a sophisticated algorithm.

- This narrative **can include~~is where~~** indications for the exam (if **provided~~any~~**) and clinical questions from the referring **~~are included~~**. **That text~~Information for those two items~~** will be **composed based on~~accessed via~~** the imaging ServiceRequest referenced in the .basedOn attribute rather than **resources referenced in the .supportingInfo~~this .history~~** attribute.
- Each referenced Condition, Observation, Procedure, and FamilyMemberHistory has a .text attribute which can contain a brief description which may be assembled into the narrative text for the History section.
- **The order of references in .supportingInfo represents the default order of presentation as selected by the Report Creator. Systems rendering this clinical content may choose a different order that is driven by their presentation needs.**
- **The order of references in .supportingInfo (and permission to choose a different order driven by presentation needs) may also apply if .text is re-rendered by Report Creators to reflect updates to the resource content.**
- See also the discussion of .text usage in Section 6.7.3.11.1 Resources.text.

6.7.3.4 Procedure

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-3.html#6734-procedure

Procedure and Materials information shall be encoded in Procedure resource(s) referenced in **~~a <new>~~** DiagnosticReport.procedure **and an ImagingStudy resource referenced in DiagnosticReport.study**.

Notes: The DiagnosticReport.procedure attribute mirrors the .specimen attribute to describe how the data being reported was obtained and prepared.

- **Only .status and .subject are required elements in the Procedure resource.**
- **Procedure.status will typically be "completed" when the report is being created.**
- **Procedure.subject is expected to be the same as DiagnosticReport.subject.**
- **ImagingStudy.note may be updated during reporting to contain an Annotation describing any limitations of the imaging data which might impact reporting, such as image artifacts, incomplete scan range, or inadequate contrast.**
    - **Annotation.author is expected to be the reading radiologist, either as a PractitionerRole or Practitioner reference.**

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- **In extreme cases, the radiologist might determine that the study quality is non-diagnostic, perhaps due to motion blur, resulting in a report with no findings and the statement in both the Procedure and Conclusion sections that the study quality was non-diagnostic.**
- **Observation-specific limitations might also be recorded in the corresponding Observation resource.**

Procedure resources describe a procedure that was performed. They provide details about technique and execution using clinical imaging language and codes and are created using information from the modality. In contrast, the ServiceRequest resource describes the order using orderable language and codes, which are typically more general and billing-oriented, and is created using information from the order placer. ~~**Further, t**~~**T**he ImagingStudy resource describes and provides links for the actual **Study** data produced **during or after**~~**by**~~ the procedure(s)~~**, and is referenced from DiagnosticReport.study**~~.

In the large majority of cases, one report will correspond to one study comprised of one procedure. Some studies do involve multiple procedures, e.g. a cardiac stress-rest workup, so systems shall be prepared to handle multiple procedures.

Procedure likely needs more profiling for imaging workflow and record-keeping, however that is out of scope for this Diagnostic Report Profile, and would be better addressed in concert with profiling imaging ServiceRequest. Until it is fully profiled, the current practice of user-generated text in the Procedure section of the DiagnosticReport.presentedForm will need to serve.

Narrative text in the procedure section of the diagnostic report is a good candidate for auto-generation, since it involves little to no interpretation. The text may be available in Procedure.text **and ImagingStudy.text**, which in turn would be based on a subset of the coded content in the referenced resource(s), usually the modality, date, **time,** procedure type, **performing facility,** and details such as technique, **patient positioning,** pulse sequences, contrast usage, radiation dose, and generated images/views. **(EUH-OK) The text might also mention patient allergies, to the extent they were noted and the procedure performed in a way that took them into consideration.** The content of the Procedure resource likely originated from the image header, MPPS, RDSR, and performed procedure protocols.

Recent FHIR IG work allows the Dose Reporter to provide the Report Creator with a formatted, locally-conformant block of text that assembles the correct subset of dose details for the specific procedure type for insertion into the report (typically to comply with local regulations).

(EUH-OK) During the diagnostic imaging procedure, it is possible that complications, such as allergic reactions to contrast, might occur. As part of clinical care documentation during the imaging procedure, these may be encoded in Procedure.complication, and/or AdverseEvent resources, and/or new or updated AllergyIntolerance resources with appropriate values for verificationStatus to allow management of the patient record. Such patient issues are generally managed long before the creation of the diagnostic report. The DiagnosticReport resource is not the primary record for those clinical care workflows; however, the Procedure section might describe and reference those resources, and the

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patient impact may also be captured in the Conclusion to bring it to the attention of the referring physician.

Procedure.outcome may include a reference to an Observation that contains the text block describing the radiation dose summary. This information sometimes needs to be included in the report to meet certain regulations. Applications which need more than summary information are referred to the detailed dose data that is commonly encoded and stored in the Imaging Study as DICOM Radiation Dose Structured Report objects.

During the imaging procedure, Observations might be created to capture things like nursing notes or technologist observations. Those would be associated with the Encounter for the imaging Procedure. Conveying those to the radiologist as inputs for interpretation is not addressed here since this profile is about encoding the resulting report. Future work on reporting workflow and managing inputs to the radiologist could address this.

6.7.3.5 Comparison

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-3.html#6735-comparison

Comparison studies shall be encoded in ImagingStudy resources referenced **in a List which is referenced** from **the~~a <new>~~** DiagnosticReport.comparison attribute.

Comparison reports shall be encoded in DiagnosticReport or DocumentReference resources also referenced in the same list referenced from the DiagnosticReport.comparison attribute.

- **List.emptyreason shall be used with a code for "unavailable" to indicate that no previous exams were available for comparison, in which case List.text will be populated with similar text.**
- **List.mode shall use the code for snapshot (since the list represents the point in time reporting took place and the list content is not maintained)**

This serves as the "library" of studies the imaging clinician took into consideration. Actual comparison observations **are encoded in DiagnosticReport.result (see 6.7.3.6), and may include** both new comparative statements and cited old statements from the prior study**~~, are encoded below with the findings~~**.

Narrative text in the comparison section of the diagnostic report is a good candidate for auto-generation based on enumerating the coded content in the referenced resources, usually the modality, date, and procedure type.

- Each referenced ImagingStudy resource has an **~~ImagingStudy~~**.text attribute which can contain a **brief~~one-line~~** description of the study **which may be assembled into the narrative text for the Comparison section**.
- **The order of references in .comparison represents the default order of presentation as selected by the Report Creator. Systems rendering this clinical content may choose a different order that is driven by their presentation needs.**

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- **The order of references in . comparison (and permission to choose a different order driven by presentation needs) may also apply if .text is re-rendered by Report Creators to reflect updates to the resource content.**

6.7.3.6 Findings

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-3.html#6736-findings

~~**Implementations are permitted to create reports where none of the findings in the narrative are encoded.**~~

Findings that **an implementation chooses to**~~**are**~~ encode~~**d**~~ shall use Observation **and/or Condition** resources referenced from DiagnosticReport.result. Implementations shall be capable of creating at least one Finding encoded as an Observation and**/or** referencing it from DiagnosticReport.result. **Implementations are permitted to create reports where none of the findings in the narrative are encoded.**

Notes: 1. Some Observations might not be referenced directly from .results, but rather might be referenced from .derivedFrom or .hasMember elements in another Observation which is part of a tree that is rooted in a reference from .results.

2. Some Observations and Conditions referenced from DiagnosticReport.result might also be referenced from DiagnosticReport.conclusionCode, particularly if they have high clinical significance. Such resources are not duplicated; rather their Resource.id is referenced from both locations. Conditions that are only referenced from DiagnosticReport.result likely represent conditions that are not clinically significant or actionable.

The scope and complexity of report findings can vary significantly. **See RAD TF-1:56.4.1.7 and 56.4.1.8 for terminology and concepts that will be helpful when reading this section.**

Narrative text in the finding section of the diagnostic report will potentially include text directly dictated by the reading radiologist and text generated from coded Observations.

- **Each referenced Observation resource has an Observation.text attribute which can contain a text rendering of the semantics of that Observation. These may be assembled into narrative text for the Findings section.**
- **Observations containing unstructured observation text (see 6.7.3.6.2.6) in the Observation.value string can duplicate that into Observation.text.**
- **Given the potential for findings to be organized (sequenced and grouped), more than one way, DiagnosticReport.text is considered to be the published organization. DiagnosticReport.composition can be used to encode another organization pattern. Similarly, DiagnosticReport.presentedForm can contain multiple additional organizations, as considered useful to potential consumers of the report. Report Reader systems might also make use of Observation metadata and user configurable logic to meet the needs of different users, for example grouping observations by finding site in a particular sequence.**

6.7.3.6.1 General Observation Metadata

The following **general** metadata shall be populated in the Observation**.**

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Notes: 1. Some of this information might be~~(despite being~~ referenced, or implicit, in the DiagnosticReport**~~). One reason for this is to~~but having the metadata here** facilitate**s** usage of the Observation resources beyond the direct context of the parent DiagnosticReport. For example, to perform Observation-level queries.

2. Several of the following bullets specify "if present". This reflects elements for which the FHIR cardinality permits zero (i.e. that the element may be absent) and this Profile is specifying constraints on the content but is not changing the cardinality (i.e. not requiring that they be present). (EUH-OK)

3. It is suggested that Observation elements that might sometimes be of interest for provenance, but are not normally used for searching or processing, can be omitted from the Observation resource since corresponding information is typically available in the DiagnosticReport resource from which they are referenced. These elements include details like .basedOn, .encounter, .issued, .performer, .device, and .partOf.

- Observation.subject shall reference the imaged Patient.
- Observation.category shall use the value "imaging"
- Observation.status shall use "final" for observations in the final report.
- **Observation.effective shall contain a datetime corresponding to the acquisition of the image on which the observation is made.**
    - **Since different images within a study are often acquired at different time points which can be clinically significant, this value is expected to be as precise and specific as possible; ideally, the exact frame time.**
    - **Observations from comparison imaging studies that are included in a current report, either by referencing existing Observation resources or creating new Observation resources based on prior report text, are generally distinguishable by the fact that their .effective datetime corresponds to the prior acquisition.**
- **Observation.identifier may include an observationUID as described in the DICOM SR to FHIR Resource Mapping IG. (https://build.fhir.org/ig/HL7/dicom-sr/en/)**
- **Observation.text shall contain a text summary of the observation for human interpretation (per FHIR DomainResource). Depending on how the observation was obtained and composed, the way this text is populated might differ. The observation might start with a line of dictated text in Observation.text and the other observation elements might be populated from that. Similarly, a line of observation text might be taken from an existing uncoded report, and again observation elements are populated from that. Conversely, the observation elements might be populated first from interacting with a radiologist or an AI tool, and then Observation.text is rendered from that coded/structured information.**
- **Observation.note, if present, may describe caveats about the reliability of this observation, such as limitations imposed by the nature or quality of the imaging. General statements about limitations of the study that are not specific to this observation may be described in the Procedure.**
- Observation.basedOn, **if present, ~~shall~~ may include a** reference **to the order for the imaging procedure that produced the data from which the observation is derived.**

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- Observation.encounter, if present, shall reference the ~~**imaging procedure**~~ Encounter **during which the imaging procedure took place**. *(EUHO granularity???)*
- Observation.partOf**, if present, shall reference the DiagnosticReport.**~~**shall reference t**~~**T**he interpreted ImagingStudy **is not typically referenced from each Observation since it is referenced from the DiagnosticReport.**
- **Observation.derivedFrom typically does not reference the ImagingStudy since that can be found via the DiagnosticReport that contains this Observation. ImagingSelection may be referenced from .derivedFrom as described in 6.7.3.6.2.**
- **Observation.performer, if present, shall reference the person or organization responsible for the validity of the observation content.** *(EUH-OK but looking at Provenance resource usage as a possible mechanism of interest here)*
- **Observation.device, if present, may reference the software Device (such as an AI model or clinical application) that generated the observation content.**
  - **This is not the device that produced the study image(s) unless that system also produced this observation.**
- **Observation.triggeredBy is typically absent in imaging observations.**
  - **It is primarily for lab observations. It should not be used to reference the ServiceRequest (which appears in .basedOn), or to include the reason for exam (which appears in the referenced ServiceRequest).**
- **Observation.interpretation is typically not present.**
  - **Radiologist interpretation is often driven by multiple observations, and are typically captured in Condition resources rather than .interpretation elements in individual Observations.**
  - **Further, interpretations, such as a qualitative breast density assessment of "very dense", may be provided on their own, in which case they would be encoded as an assessed characteristic observation (see 6.7.3.6.2.5). And a quantititative breast density could also be provided on its own and would be encoded as a measured property observation (see 6.7.3.6.2.4). If both are provided at once, the qualitative assessment could conceivably be put into the .interpretation of the measured property. However, that would require consumer applications to handle two different encoding patterns to find the qualitative information, so it is simpler to generate two observations.**
  - **If it is present, it will typically be driven by a statement by the radiologist rather than being automatically populated by a device or algorithm.**

~~**NOTE TO IMPLEMENTERS: Further profiling of the Findings section is deferred to future work.**~~

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~~**As a strategic scoping decision of this profile, the use cases focus on subsequent usage of imaging reports by referring physicians and patients, and clinical pathway automation such as recommendation follow-up, critical finding tracking, and clinical decision support for referring physicians. Those use cases depend primarily on the Impression and Recommendation sections which are the primary interest for referring clinicians. The imaging clinician has summarized all the most important clinical information in the Impression section where all conclusions and actionable findings should be represented.**~~

~~**Addressing the enormous range and variety of imaging findings will be a significant undertaking. One significant avenue for bringing structure to the problem will be exploring the use of CDE Sets, which are defined groups of common data elements (and values) for describing specific imaging findings.**~~

~~**Future work on Finding encoding will consider use cases centered on the interpretation process that leads to the report. This may bring together AI result review and transcoding, the IRA profile, selecting findings from prior reports for inclusion in the current report, using LLM technologies to compose and process blocks of text, and other automation functions for the imaging clinician. Such use cases will be helpful concrete drivers in resolving the many expected complexities. Such work will likely manifest in the form of a Findings Option to this Profile to avoid disrupting any existing implementations and data from this Trial Implementation draft of the IDR Profile.**~~

Findings that originated from AI models and the radiologist chose to include in the report can include related details in the metadata and/or provenance of that finding. Such details will be accessible to recipients of the report. Conversely, details about the reporting process, such as what AI models were or were not run, and what findings were not included in the report, may be documented by associated systems in relevant logs, but will not appear in directly in the report itself unless the radiologist chooses to include such details, for example by describing that in the Procedure/Technique section.

Add *the following new subsections as shown:*

6.7.3.6.2 Observation Type-specific Metadata

The following specifications address Observation details that vary depending on the type of observation. See RAD-TF-1:56.4.1.8.1 for discussion of observation types.

See Table B.3-1 for examples of the following encoding specifications.

6.7.3.6.2.1 Observation Finding Site (Anatomic Entity)

For an observation with a target that is an anatomic entity:

- Observation.bodyStructure.includedStructure.structure shall identify the anatomic entity that is target of the observation. The code shall be fully pre-coordinated except for the laterality.

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- It is recommended that an observation on multiple structures be encoded as multiple observations on individual structures. For example, see 6.7.3.6.3.5 Compound Observation.

- Observation.bodyStructure.includedStructure.laterality shall identify the laterality if .structure is a paired structure.
- Observation.bodyStructure.excluded is not typically used when encoding observations.

6.7.3.6.2.2 Observation Finding Site (Pathologic Entity)

For an observation with a target that is a morphologic abnormality:

- Observation.bodyStructure.includedStructure.morphology shall identify the type of morphologic abnormality that is the target of the observation. The code shall not unnecessarily pre-coordinate the associated anatomy.
- Observation.bodyStructure.includedStructure.structure shall identify the anatomy associated with the morphologic abnormality identified in .morphology. The code shall be fully pre-coordinated except for the laterality.
    - Typically, only a single structure will be referenced. It is permitted to reference multiple structures in the scenario where the position of morphologic abnormality is described relative to multiple landmarks, but that is very rare in practice.
- Observation.bodyStructure.includedStructure.laterality shall identify the laterality if .structure is a paired structure.
- Different Observation resources (and Condition resources) should reference the same BodyStructure resource when they are describing the same pathologic entity, particularly within a single DiagnosticReport. When multiple DiagnosticReports describe the same pathologic entity, they may or may not have access to, or be able to correlate or share, the same BodyStructure resource. In such cases, a Tracking UID may be used in the BodyStructure.identifier to correlate multiple observations on the same entity (e.g. a given lung nodule) or to distinguish between multiple observations on different similar entities (e.g. several lung nodules).
    - BodyStructure.identifier.type shall use the value (112039, DCM, “Tracking Identifier”) and/or (112040, DCM, “Tracking UID”) when encoding a DICOM Tracking Identifier and/or a DICOM Tracking UID, respectively.
    - It is possible that correlation might happen after the subsequent BodyStructure resources are created, in which case the matching Tracking UID might be added as a later entry to BodyStructure.identifier to relate the matched entities.
    - A morphological abnormality might be reclassified over time, such as a lesion that is elevated to a tumor in a subsequent study. Create a new BodyStructure with the new .morphology value that shares the same Tracking UID as the prior BodyStructure resource.

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- Two tumors might subsequently merge, perhaps while growing. Create a new BodyStructure which includes the Tracking UIDs of the two old BodyStructures.
- A tumor might subsequently split into two disjoint entities, perhaps while shrinking. Create two new BodyStructure resources with new Tracking UIDs and add references in the original BodyStructure to these. While the original BodyStructure could be modified to describe multiple disjoint entities, there would be no way to assign new measurements to the appropriate disjoint entity.

6.7.3.6.2.3 Observation Finding Site (Physical Object Entity)

For an observation with a target that is a physical object (such as a piece of shrapnel, or a stent):

- Observation.bodyStructure.includedStructure.morphology shall identify the type of physical object that is the target of the observation; preferably using an appropriate morphologic abnormality code from SNOMED, such as (840294004, SCT, "Retained metallic foreign body"). The code shall not unnecessarily pre-coordinate the associated anatomy.
- Observation.bodyStructure.includedStructure.structure, if present, shall identify the anatomy associated with the physical object. The code shall be fully pre-coordinated except for the laterality. E.g. the coronary artery in which the stent is located.

  Note: This differs from the situation where .focus identifies a fetus. In that case the bodyStructure is within the fetus, not the location of the fetus.
- Observation.bodyStructure.includedStructure.laterality shall identify the laterality if .structure is a paired structure.

6.7.3.6.2.4 Measured Property

For an observation of a property or feature in the image that is quantitative (typically determined using a measurement tool or application, although they could hypothetically be estimated):

- Observation.code shall identify the property measured. The code shall not pre-coordinate the associated anatomy.
  - Observation.bodyStructure identifies the associated anatomy where the measurement is taken and what entity is being measured.
  - Observation.code will sometimes need to distinguish between related properties of the measured entity or location. For example, one observation at the mitral valve using doppler ultrasound might use a code to indicate blood velocity is the property measured, while a second observation at the same location might use a different code to indicate tissue velocity is the property measured.
- Observation.value shall record the measured quantity. If the measurement is not unitless, the units shall be recorded.
  - Two different Observations might have the same .code but use different units in .value. Sites and observers may prefer different scales.

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- Comparative measurements such as volume change might be expressed in absolute terms (e.g. -22 mm3) or relative terms (e.g. -25%).

- Observation.method may be used to record details of how the property was measured, e.g., the left ventricle diameter was measured at end diastole, in the apical 4-chamber view, using B-mode.
- Observation.derivedFrom may reference a corresponding ImagingSelection that might include the specific coordinates and caliper shape used for the measurement. E.g. line coordinates in the ImagingSelection from which the diameter value in the Observation was derived.
    - The ImagingSelection coordinates are in the Frame of Reference of the Image on which they are placed.
    - DICOM Frame of Reference UID (0020,0052) uniquely identifies a spatial frame of reference for an image, but the origin and axes of the corresponding coordinate space are defined by the associated imaging data and metadata.
    - If ImagingSelection.bodySite is present, it is expected that the value be consistent with Observation.bodyStructure. Since the ImagingSelection should be considered supportive not primary, in the event the values are different, the value in Observation takes precedence when interpreting the Observation. E.g. the Observation.bodyStructure might identify a left breast mass for which a diameter is observed, while the ImagingSelection.bodySite might do the same, or might identify that it's coordinates are in the 5 o'clock region of the left breast.
    - Similarly, values of Observation.subject and Observation.focus take precedence over corresponding values (if present) in a referenced ImagingSelection.

When a property is computed from other measurements, instead of being measured directly, the base measurements can be encoded as described here and the computed property can be encoded as described in 6.7.3.6.3.6. For measurements that are taken using a caliper or other measurement tool, although some computation is involved, that is still considered a direct measurement.

When a property that is measurable is assessed qualitatively instead, it can be encoded as an assessed characteristic (see 6.7.3.6.2.5). E.g., instead of capturing that the main pancreatic duct width is 5 mm, in the absence of a measurement, the observation that the main pancreatic duct width is dilated. Similarly, an adrenal gland size might be recorded as being enlarged.

6.7.3.6.2.5 Assessed Characteristic

For an observation of a characteristic or feature in the image that is assessed qualitatively:

- Observation.code shall identify the characteristic assessed. The code shall not pre-coordinate the associated anatomy.
- Observation.value shall record the assessment.
- For the following commonly assessed characteristics, the recommended codes are:

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- Observation.code = (705057003, SCT, “Presence”) for assessment of whether or not a morphologic abnormality or other disorder is present, and Observation.value = (260373001, SCT, “Detected”) or (260415000, SCT, “Not detected”).
- Observation.code = (276800000, SCT, “Normality”) for assessment of whether or not an anatomic entity is normal, and Observation.value might include (263654008, SCT, “Abnormal”), (17621005, SCT, “Normal/Unremarkable”), (61350003. SCT, “Surgically acquired absence”)

- Observation.method may be used to record details of how the assessment was performed, e.g., the timing of the measurement, the guideline/criteria used.
- Observation.derivedFrom may, when the observation is localized to a particular image or spatial location, reference an ImagingSelection that includes the relevant image, frame, region, volume, and/or coordinates of the assessed feature.

6.7.3.6.2.6 Unstructured Observation

For an observation that is fully unstructured narrative:

- Observation.bodyStructure shall be absent.
- Observation.code shall use the code (newcode01, 99IHE, “Unstructured Observation”) *(EUHO) EU looking at .note and put a code on it that it is a finding?*
- Observation.value shall contain valueString text that describes the target image entity, the image feature and the observation result. The text is permitted to describe multiple observations, although it is not intended to contain an entire section or report. To the extent that it is practical, it is recommended to split multiple unstructured observations into multiple Observation resources. This recommendation is further supported by the fact that valueString is not supposed to contain formatting characters, and any markdown characters are treated as literal, not formatting.
- Unstructured observations might be particularly useful for complex sentences with advanced semantics that are challenging to encode.

For an observation that is unstructured narrative, but the finding site has been determined:

- Observation.bodyStructure shall encode the observation finding site as described above.
- Observation.code shall use the code (newcode02, 99IHE, “Unstructured Feature”)
- Observation.value shall contain text that describes the image feature and the observation result. The text may or may not reiterate the finding site. The text is permitted to describe multiple features and observation results. To the extent that it is practical, it is recommended to split multiple unstructured features into multiple Observation resources.

If both the observation finding site and the image feature can be coded and only the value is unstructured, it is recommended to encode it as an assessed characteristic (see above) and use a private code or a text value.

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6.7.3.6.3 Observation Relationship Encodinng

The following specifications address encoding relationships between Observations. See RAD-TF-1:56.4.1.8.2 for discussion of observation relationship patterns.

The following patterns are intended to illustrate how the relevant FHIR elements should be used to address the cases in RAD-TF-1:56.4.1.8.2. Implementations that need to address other cases may need to adopt additional patterns but are encouraged to be as consistent with the patterns here as possible.

6.7.3.6.3.1 Finding Set

For an observation that is part of a set of observations that collectively represent an assessment of a particular feature or pathology:

- The root finding shall be encoded in an Observation. The associated observations shall each be encoded in a separate Observations.
- Observation.code of the root finding shall identify the root of the finding set.
    - When encoding CDE Sets from radelement.org, it is preferred to use the CDE Set code here, such as (RDES195, *RadElement*, "Pulmonary Nodule").
- Observation.hasMember of the root finding shall reference the associated observations.
    - Associated observations are expected to follow the specifications for the CDE Set on radelement.org.
    - The associated observations do not reference the root finding. Given an associated observation, the root finding is found via a FHIR reverse chaining search.
    - The use of .hasMember is intended to carry a subtle implication here that subsequent viewers of this data may be interested in seeing the associated observations presented alongside the root finding. This differs slightly from .derivedFrom Observations which are less likely to be initially viewed unless there is a need to confirm the provenance of the referencing observation.
- Observation.organizer shall be absent or set to FALSE, since setting it to TRUE is only for grouping a subset and prohibits the parent observation from having a value.

See https://www.radelement.org for a large collection of Finding Sets.

For elements like Observation.device or Observation.derivedFrom, the associated observations may have different values from each other as appropriate (e.g. if observations were obtained from different pieces of software, or observations were made on different frames or pixels as recorded via ImagingSelections).

Note: Observation.component is not used here as FHIR limits it to observations that are not useful on their own, giving the example that a BMI Observation "… should not contain components for height and weight because they are clinically relevant observations on their own and should be represented by separate Observation resources." Further, "Components should only be used when there is only one method, one observation, one performer, one device, and one time." The use of component also has the potential to significantly complicate queries.

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6.7.3.6.3.2 Summary/Derived Observation

For an observation that summarizes other observations:

- The summary observation shall be encoded in an Observation. The sub-observations shall each be encoded in separate Observations.
- Observation.code of the summary observation shall identify the summary finding.
    - 6For *-RADS, this is a code for the top-level score, such as (146611000146107, SCT, “BIRADS Assessment Category”) and an Observation.value like (39714307,SCT,”3 – Probably Benign”)
- Observation.derivedFrom of the summary observation shall reference the underlying sub-observations from which the summary was derived. It is permitted to include all the observations that were a part of the summary assessment procedure, even if specific observations did not factor into the final summary value.
    - The associated observations do not reference the root finding. Given an associated observation, the root finding is found via a FHIR reverse chaining search.

6.7.3.6.3.6 Computed Property

For an observation that is computed from other observations, see Section 6.7.3.6.2 Measured Property.

- Observation.code shall identify the computed property. The code shall not pre-coordinate the associated anatomy.
- Observation.value shall record the computed quantity. If the measurement is not unitless, the units shall be recorded.
- Observation.derivedFrom shall reference the observations from which the property was computed. (There is no need to reference them from .hasMember). Any corresponding ImagingSelection(s) would be referenced from those other observations, not this one.

Note: The computation is not required to be strictly numerical. It might also involve Boolean or other logic.

6.7.3.6.3.7 Temporal Comparison

For an observation that captures the difference between a current and prior observation of the same property of the same entity (i.e. a change over time), treat this as:

- a computed property (See Section 6.7.3.6.6 Computed Property) for quantitative comparisons, or
- a summary/derived observation (See Section 6.7.3.6.2 Summary/Derived Observation) for qualitative comparisons, such as Increased/Decreased/Unchanged or Worsened/Improved/Unchanged.

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6.7.3.6.3.3 Hierarchical Target Entity

For an observation on a target entity that has hierarchical structure,

- The observations shall be organized as a Finding Set (see above).
- The root finding will relate to the "coarse end" of the hierarchical structure. The associated observations may be more specific in the anatomy or morphology of their BodyStructure as needed.

For example, a pulmonary nodule with observations of the presence and volumes of a solid component and a non-solid component could have:

- a root observation with
  - Observation.bodyStructure.includedStructure.structure is the anatomic site
  - Observation.bodyStructure.includedStructure.morphology indicates a nodule
  - Observation.code is (705057003, SCT, "Presence")
  - Observation.value is (260373001, SCT, "Detected")
  - Observation.hasMember references sub-observation A and B
- a sub-observation A with
  - Observation.bodyStructure.includedStructure.structure is the same anatomic site
  - Observation.bodyStructure.includedStructure.morphology indicates a nodule solid component
  - Observation.code is (705057003, SCT, "Presence")
  - Observation.value is (260373001, SCT, "Detected")
- a similar sub-observation B with the .morphology indicating the non-solid component.
- sub-observation A and sub-observation B each have a .hasMember sub-sub-observation (A1 and B1) with .code = volume and referencing the same BodyStructure to provide the corresponding volume measurements of the solid and non-solid component.

Note that while the hierarchy provides potentially useful structure to present and navigate the observations, each observation can still be parsed and understood all on its own.

This construction should be used judiciously. Medical concepts of anatomy are inherently hierarchical, but this pattern is not intended to be used to capture that. For example, observations on lobes of the liver are not intended to be organized under a parent observation of the entire liver just because there is an anatomical hierarchy.

Narrative text in Observation.text of each of the sub-observations reflect the semantics of that particular sub-observation. Observation.text of the root observation will reflect the combined semantics of the hierarchical set, which may or may not elide some details of the sub-observations based on clinical convention and preferences.

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6.7.3.6.3.4 SR Measurement Group

For a set of observations that correspond to a DICOM Measurement Group, but do not fit any of the other relationship patterns in this section:

- The observation group shall be encoded in an Observation. The associated observations shall each be encoded in an Observation.
- Observation.organizer of the observation group shall be set to true.
- Observation.code of the observation group shall identify the nature of the observation group. In some cases, the source object might not provide any information, in which case it might simply be (125007, DCM, "Measurement Group")
- Observation.hasMember of the observation group shall reference the associated observations.
- Per FHIR, Observation.value is absent for the observation group, and Observation.organizer may be absent or set to false for the associated observations.

6.7.3.6.3.5 Compound Statement

For an observation that was expressed as part of a compound statement,

- The observations shall each be encoded in separate Observations.
    - E.g. "The lungs are well expanded and clear. No focal consolidation, pleural effusion, or pneumothorax." The first sentence produces two observations and the second sentence produces three more observations. For all of them, the BodyStructure is lungs, bilateral.
    - E.g. "Liver, gallbladder, pancreas, and spleen are unremarkable." The sentence produces four observations.
    - E.g. "A 0.5 x 1.2 cm lesion in the bladder". The sentence produces two observations. It is recommended to use different property codes, such as major axis and minor axis, so the two observations do not appear to be a repeated measurement of a single diameter property.

If there is a need to persist the compound rendering, i.e. present a compound statement based on the atomic observations, coding similar to the SR Measurement Group may be used.

- A compound statement grouper observation may be created where,
    - Observation.code may use a code for "Compound Statement".
    - Observation.hasMember shall reference the associated observations.
    - Observation.organization shall be set to true.
    - Observation.value is absent, per FHIR.
    - Observation.text shall contain the compound statement text.

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Even if the compound rendering is persisted, clients are still permitted to present alternate formatting, such as atomic observation bullets, based on user preferences.

6.7.3.6.3.8 Conclusion Support

For an observation that was identified as supporting evidence for the presence of a Condition:

- Condition.evidence shall reference the Observation.
    - This evidence is not necessarily conclusive. This may be used to express relations like "<observed> opacity suggestive of infection <condition>".
    - This evidence is not necessarily complete. There may be other evidence considered that is not referenced here, and might not be coded in a machine readable form.

For an observation that was identified as supporting evidence for the absence of a Condition:

- This is encoded differently since FHIR guidance is that absent conditions are only encoded in a Condition resource if they have resolved, or were erroneously asserted and have been refuted, or were identified as entered in error. Otherwise, absent conditions are encoded in an Observation resource.
- Observation.derivedFrom in the Observation that encodes the absent condition shall reference the Observation that represents the supporting evidence.

6.7.3.6.3.9 Causal Relationship

For an observation on an entity whose existence or state is, at least in part, the result of another observed entity or state.

LATER – There is currently no etiology mechanism in FHIR Core. Discuss with FHIR Patient Care WG and Orders & Observations WG. Two observations that share a common cause is a related form of this kind of relationship.

https://build.fhir.org/ig/HL7/fhir-extensions/StructureDefinition-condition-dueTo.html

6.7.3.6.z Consumers of Findings

The observation types, relationships, and hierarchical structures described throughout section 6.7.3.6 are intended to provide predictable patterns that will make it easier for systems that consume the DiagnosticReport, Observation, and Condition resources. Such consumers might choose to "flatten out" the observation tree under DiagnosticReport.result to the extent that suits their needs.

Consumers should also consider that the above patterns might not cover all situations and should be prepared for some residual variability in the ways that Report Creators encode findings.

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6.7.3.6.y Query Patterns for Findings

The following are example query tasks that might be performed on a collection of observations. These were taken into consideration to confirm that they are reasonably practical given the observation encoding requirements and guidance of this profile.

Most queries will start with something like this:

- GET [base]/Observation?subject=Patient/{patient-id}&category=imaging

The rest of these examples will start with … instead of repeating the above.

Task: Constrain the results to the last 12 months

- …&date=ge2025-01-29 (choose a date 12 months ago)

Task: Obtain observations about a target anatomy of interest (e.g. liver)

- …&reference:BodyStructure.included_structure={anatomy code}
- Considerations:
    - By avoiding pre-coordination of the morphology or measured property, the query can obtain measurements, assessments, and morphological abnormalities with a single query without enumerating all the possible pre-coordinated codes.

Task: Anatomical search expansion - more specific results (e.g. liver + any parts of the liver)

- See Open Issue on “fuzzy matching” for anatomy
- E.g. Specific expansion of a search for Kidney would also return observations for Renal Capsule, Renal Artery, Medulla, etc.

Task: Anatomical search expansion - more general results (e.g. liver + things the liver is part of)

- See Open Issue on “fuzzy matching” for anatomy
- E.g. General expansion of a search for Left Kidney would also return observations for Kidneys, Abdomen and Whole Body.

Task: Anatomical search expansion - related results (e.g. liver + things related to the liver)

- See Open Issue on “fuzzy matching” for anatomy
- E.g. Related expansion of a search for Kidney would also return observations for Adrenal Gland, Ureter, Bladder.

Task: Obtain specific property observations of a target anatomy of interest (e.g. volume of liver)

- …&<see anatomy above>&code={property code}

6.7.3.6.x Other Coding Guidance

The following are recommendations, but not normative requirements for the profile.

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For paired anatomy, when an observation or finding applies to both, SNOMED recommends coding two observations, one for left one for right.

For coding the presence of a disorder, SNOMED recommends using values of Detected/Not detected rather than Present/Absent. This is a more accurate description of the situation in the imaging context. It is conceivable for something to be present but not visualized.

For coding interpretive concepts for a measurement, SNOMED recommends using values like above/within/below reference range rather than high/normal/low.

For pneumonia, SNOMED recommends reserving that code for infectious processes. When it is not clearly an infectious process, use pneumonitis.

For pulmonary embolisms, SNOMED recommends that the recorded finding site be a pulmonary artery rather than a region of the lung organ.

Modify the following sections as shown:

6.7.3.7 Impression / Conclusion

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-3.html#6737-impression--conclusion

Implementations shall be able to create at least one Condition and reference it in the DiagnosticReport.conclusionCode.

<Edit .category diagnostic-imaging-impression to become diagnostic-report-impression>

The following bullets focus on impression statements as structured coded data. The Report Creator is responsible for distinguishing and encoding dictated impressions, recommendations, and communications. **This is intended to facilitate workflow and clinical pathway automation, such as agentic tools, to support the referring physician tracking critical findings, accessing and applying relevant clinical guidelines and other forms of clinical decision support.**

- **An unstructured observation (see 6.7.3.6.2.6) is a pragmatic way to include a block of narrative impression if the system is unable to create corresponding coded entries. (EUH)**

Implementations shall be able to create Flag resources to identify specific findings as actionable. Usage of this capability will be at the discretion of the site. Individual flags are at the discretion of the imaging clinician.

- **Flag.subject shall be a reference to the Patient.**
- **Flag.status shall initially be active. The resource may have its status set to inactive when it is subsequently dealt with.**
- **Flag.category shall include a code for imaging-finding-followup. Per FHIR, category codes provide a means of filtering which Flags are displayed to particular users or in a given context.**

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- **Flag.category is recommended to also include**~~**Condition.actionable <new> shall, if present, contain**~~ a code to indicate the degree to which the Impression finding is actionable. Codes may be drawn from the RadLex codes for the ACR Actionable Finding Categories described in IHE Results Distribution (RD):
    - (RID49480, RadLex, "Cat 1 Emergent Actionable Finding") defined as requiring immediate medical attention within minutes.
    - (RID49481, RadLex, "Cat 2 Urgent Actionable Finding") defined as requiring medical attention within hours.
    - (RID49482, RadLex, "Cat 3 Non-critical Actionable Finding") defined as requiring medical attention within days to months.
    - ~~**(RID50261, RadLex, "Non-actionable") defined as not requiring follow-up actions.**~~
- **Flag.code shall include a code or text providing the recipient with a sense of what needs to be addressed. This might replicate the Condition.code in the referenced Condition resource, such as for an aortic aneurysm, or a pulmonary embolism, or a suspicious mass.**
- **Flag.supportingInfo shall reference the Condition or Observation that represents the actionable finding. Flag.supportingInfo might also reference an associated Recommendation or Communication.**
- **Flag.author, if present, may reference the imaging clinician, particularly if they want to facilitate the care team contacting them for more information, or to facilitate notification when the flag is addressed.**
- **Flag.period, if present, may indicate the time the actionable finding was published (typically the datetime the report was issued, or the datetime of a Communication with the care team) as the start of the period. Per FHIR, the end of the period should be unspecified until the status has changed to inactive.**

Note 1. The presence of a Recommendation for a given impression is an implicit indication that it is actionable. Having an explicit code can help with subsequent tracking and follow-up.

Note 2. Conversely, actionable findings do not always have a corresponding Recommendation. For example, an identified pneumothorax is a well-known entity to the referring clinician with standard actions to address it. The imaging clinician would be unlikely to re-iterate those actions in the report.

Note 3. Category 1 and Category 2 codes constitute "critical findings" which often result in direct Communications (see Section 6.7.3.9) due to the clinical urgency.

Note 4. The absence of a Flag referencing any given finding does not imply that the imaging clinician feels no action should be taken on that finding.

The narrative form of the Impression section is often directly dictated by the imaging clinician. Tools also exist that generate a draft of the Impression narrative based on the dictated Findings narrative. If the Impression narrative were built up from the coded Impression, the summary in Condition.text of each referenced Condition resource might be compiled into impression bullets sequenced according to the Condition.order.

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- **The order of references in .conclusionCode represents the default order of presentation as selected by the Report Creator. Systems rendering this clinical content may choose a different order that is driven by their presentation needs.**
- **The order of references in . conclusionCode (and permission to choose a different order driven by presentation needs) may also apply if .text is re-rendered by Report Creators to reflect updates to the resource content.**

In addition to rendering the Impression narrative as a section in the full report in the DiagnosticReport.text attribute, the Report Creator may also render the Impression narrative into DiagnosticReport.conclusion as a ~~**single**~~ markdown field. The Impression narrative **shall not**~~**may**~~ contain dictated text which goes beyond the semantics captured in the DiagnosticReport.conclusionCode references **since any additional narrative can be encoded in an unstructured Observation referenced from DiagnosticReport.conclusionCode**.

If/when one of these Conditions is added to the patient Problem List, either by the referring physician or because the Condition.verificationStatus is confirmed, that would likely create a new Condition resource that might point to the Impression Condition instance as Condition.evidence (or maybe the biopsy result instead). While the Problem List Condition instance would be updated over time, for example when the condition is abated, the Impression Condition persists as a medicolegal snapshot that is an integral component of the Report. If the Report is exported, that bundle would contain the Impression Condition at the time of the report, not any "current" version.

6.7.3.8 Recommendations

Recommendations, if any, shall be ~~**encoded as ServiceRequest, CommunicationRequest, or CarePlan resources**~~ referenced from the DiagnosticReport.recommendation attribute.

Recommendations for subsequent imaging**, or** lab tests~~**, or specialist consultations**~~ would be encoded as **new** draft ServiceRequests. Recommendations for **formal specialist consultations could also be encoded as draft ServiceRequests while** simpler communications ~~**w**~~could be encoded as draft CommunicationRequests. **In the event an imaging clinician chose to recommend a specific care plan in the report, that would be encoded as a draft CarePlan.**

Machine-readable recommendations are intended to facilitate workflow and clinical pathway automation, such as agentic tools, to support the referring physician doing things like placing orders based on the recommendations. If necessary, non-machine-readable text recommendations can be provided in DiagnosticReport.recommendation.concept.text entries since the .recommendation element is a CodeableReference. Similarly, a partially machine-readable ServiceRequest can populate ServiceRequest.code.concept.text with descriptive text.

These draft ServiceRequests and CommunicationRequests, when created, may omit various details that the imaging clinician would not know or would not be responsible for choosing. They are intended to serve as a skeleton that facilitates the referring provider adding any needed details and activating it as an order.

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…

- **The order of references in .recommendation represents the default order of presentation as selected by the Report Creator. Systems rendering this clinical content may choose a different order that is driven by their presentation needs.**
- **The order of references in . recommendation (and permission to choose a different order driven by presentation needs) may also apply if .text is re-rendered by Report Creators to reflect updates to the resource content.**

Although this Profile facilitates machine-readable encoding of the potential ServiceRequests, the narrative Recommendation text may also include conditional logic, e.g., if A is true then procedure X is recommended; if B is true then procedure Y is recommended; else procedure Z is recommended. This profile does not yet model this logic in the coded recommendations; as a placeholder, the condition text could be included in ServiceRequest.note, but this does not support automated tooling. In this example scenario, all three procedures would be included as referenced ServiceRequest resources (with status = draft, as described above) and the referring physician would apply the logic in the narrative to decide which to activate (by setting the status to active), if any.

6.7.3.9 Communications

Communications, if any, shall be encoded as Communication resources referenced from the DiagnosticReport.communication attribute.

This information is included in the body of the report, in part for medicolegal purposes. If future HIT infrastructure handles tracking such communications directly in the EMR, the practice of using the diagnostic report to implement such accountability and tracking might change, but for now it is expected to persist.

This information may also **facilitate~~support~~** performance metrics such as the speed with which the Referring Physician is notified of key clinical results or other conformance to best practices for patient safety and quality of care.

- **Communication.text shall contain the narrative text describing the communication.**
  - **A minimal unstructured Communication resource can be created with just .status and .text populated.**
- **Communication.reason, if present, can reference particular Conditions or Observations that motivated the communication.**

The corresponding section narrative text may be created by concatenating the .text contents for each of the referenced Communication resources. This narrative often appears at the bottom of the report under the Impressions and Recommendations. **The narrative text often includes the date and time, the recipient (referring, patient, etc.), the mode of communication, the urgency, whether the communication was successful, and the nature of the information communicated.**

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- **The order of references in .communication represents the default order of presentation as selected by the Report Creator. Systems rendering this clinical content may choose a different order that is driven by their presentation needs.**
- **The order of references in . communication (and permission to choose a different order driven by presentation needs) may also apply if .text is re-rendered by Report Creators to reflect updates to the resource content.**

6.7.3.10 Signature

Signature of the report **is typically rendered as a line of text at the bottom of the report.**

The digital signature of the report shall be encoded as a Provenance resource.

- **It is up to the rendering system to coordinate including the signature line in human readable forms of the report (see 6.7.3.11) before finalizing the Provenance resource because doing it in the opposite order would invalidate the signature.**
- Provenance.target shall reference the DiagnosticReport resource. **Usually, it will also reference all other clinical resources created or updated as part of creating the report, such as Conditions and Observations.**
    - **Implementations might consider displaying a presented form of the report that has been rendered from the coded content for review and signature by the imaging clinician as a way to facilitate approval of the coded content and not just dictated narrative.**
- **The references are typically version-specific. Since contextual resources, like the Patient and ServiceRequest, existed prior to the report and were not updated, those are not usually referenced here. ~~(TO should it reference all the resources that would go in the bundle, or is there a more efficient way to do this? Need to list the other resources that were created as "components" of the report, but not everything that goes in the bundle. So the observations and conclusions would be referenced, but not the patient or servicerequest)~~**
- Provenance.signature.type shall have a value of ProofOfApproval.
- Provenance.agent.who and Provenance.signature.who (or Provenance.signature.onBehalfOf) shall be compatible with the person identified in DiagnosticReport.resultsInterpreter. See also Section 6.7.3.0.

While the DiagnosticReport does not reference Provenance resources, such as the one containing the digital signature, the relevant Provenance resources may be obtained with a query like:

- GET [base]/Provenance?target=DiagnosticReport/12345

Relevant Provenance can also be included in the response bundle when querying the DiagnosticReport in the first place using _revinclude:

- GET [base]/DiagnosticReport?[search parameters]&_revinclude=Provenance:target

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Note: Some resources include a .relevantHistory element that documents prior clinical states of the resource via references to prior corresponding Provenance resources. The "current" Provenance cannot be so referenced since it cannot exist until after the current version of this "target" resource has been created.

Narrative text for the signature typically appears at the bottom of the report text with a statement in a form similar to "This report was digitally signed by Dr. X at <time> on <date>".

Preliminary ("unsigned") reports may involve a DiagnosticReport resource being made available which references a DiagnosticReport.resultsInterpreter, but is not the target of a Provenance resource with a .signature.type of ProofOfApproval.

In the unprofiled DiagnosticReport resource, the signature appears to be implicit. It is left to receivers to presume that if the report status is final and there is an interpreter listed, that means that practitioner approved the content of the report at some point in time. …

6.7.3.11 Human-Readable Form

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-3.html#67311-human-readable-form

…

6.7.3.11.1 Presented Form

…

It is recommended that the Attachment.title for each presented form attachment be populated to facilitate the recipient being able to distinguish between multiple presented forms and select an appropriate one. **Attachment.language may also help labelling and selecting an appropriate form.**

In addition to the rendered report in .text, and the presented form in .presentedForm, the Report Creator may choose to reference Composition resources in DiagnosticReport.composition to provide additional arrangements and renderings of the imaging report content. See RAD TF-1: 56.4.1.4 for further discussion of Composition.

6.7.3.11.2 Resources.text

…

The .text.status is required to be present and contains codes that describe the extent to which the semantic content of .text covers or exceeds the coded content of the resource. **A value of "additional" indicates that the narrative may contain additional information not found in the structured data.** See https://www.hl7.org/fhir/R5/valueset-narrative-status.html

…

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6.7.3.12 Addendum (*placeholder*)

6.7.3.13 Bundle Resource Usage

The DiagnosticReport resource, like most FHIR resources, encodes references to other associated resources. Handling collections of related resources is typically done with the Bundle resource using one of several bundle types and handling patterns.

LATER When resolving the Bundling guidance, name the categories of resources which will have different inclusion, handling, and completeness requirements: e.g., Created/Updated Primary, Created/Updated Related, Existing Related, Existing Core.

As shown in the RAD-141 (Store Multimedia Report) transaction, when the report is initially created and stored, a transaction bundle (Bundle.type=transaction) is used to POST the newly created resources (DiagnosticReport, ImagingSelection, etc) as an integral set to be processed together and created on the server.

For these new reporting resources, the Report Creator is typically the "source of truth"; i.e. the information it provides is definitive.

Other resources are referenced by the DiagnosticReport but already existed prior to reporting; for example, the Patient that is the .subject, or the Practitioner that is the .resultsInterpreter. These are not expected to be in the transaction bundle during creation since they do not need to be created and other systems are the source of truth for those resources.

Some resources, such as the ServiceRequest referenced in .basedOn and the ImagingStudy referenced in .study, are in a grey zone where they might typically be expected to exist prior to creation of the report but there may be situations where they are being "backfilled" by the Report Creator. In such cases, they may be included in the transaction bundle to be created conditionally as indicated by the Bundle.entry.request.ifNoneExist element.

When creating a bundle, an implementation might also take into consideration the types of resources supported by the FHIR Server. If the server does not support some of the included resources, encoding them inline in the resource that references them might facilitate more complete storage.

As shown in the RAD-143 (Find Multimedia Report) transaction, when querying for a report, a searchset bundle (Bundle.type=searchset) is returned from the query. By default, the bundle contains matching DiagnosticReport resources and no referenced resources. The _include and _revinclude parameters can be used to have the searchset bundle in the response also contain other referenced resources. (See https://hl7.org/fhir/search.html#include).

Although out of scope for this profile, a future Export Imaging Diagnostic Report transaction may be created to handle the need to send DiagnosticReport resources to systems that will not necessarily have access to all the resources referenced in the DiagnosticReport (e.g., because the recipient is outside the IT boundary of the sender). That transaction will describe a push transaction that includes a "full set" of referenced resources in the message bundle.

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See RAD TF-2:4.Y1 Store Imaging Diagnostic Report for further discussion of the formation of bundles containing an imaging DiagnosticReport and associated resources.

…

Annex B - Example Imaging Diagnostic Report Content

These examples were prepared in support of the Imaging Diagnostic Report (IDR) Profile. See Section 6.7.3 Imaging Diagnostic Report Encodings for the encoding specifications.

This appendix provides some examples of report content, followed by some examples of encodings. This is a limited set of illustrative examples. Additional examples may be available in IHE Connectathons.

B.1 Example Semantic Content

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-3.html#b1-example-semantic-content

…

B.1.5 Example Findings Semantics

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-3.html#b15-example-findings-semantics

…

B.2 Example Usage

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-3.html#b2-example-usage

B.2.1 Presenting Comparison Studies

A report viewer might offer to display studies used as comparisons in the report.

- GET [baseURL]/DiagnosticReport/X?$elements=comparison
- (Parse returned ImagingStudy references; Select; Invoke display)

B.2.2 Ordering Recommended Followup

…

Add *the following sections as shown:*

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B.3 Example Finding Encoding Patterns

The following table provides example observation encodings of various types of findings. It is intended to span a range of modalities, specialties, pathologies, anatomies, characteristics, and styles of expression and specificity.

The values shown in cells represent the semantics; it is left to the reader to map those to corresponding codes from SNOMED or elsewhere. The table only addresses the elements specific to the different observation types. More general Observation Resource metadata elements are described in RAD TF-3:6.7.3.6. Some of the patterns of post-coordination are influenced by the expected query patterns for observations described in RAD TF-3.6.7.3.6.y.

Table B.3-1 Example Observation Encoding Patterns

Observation.text	**.bodyStructure.includedStructure**			**.code**	**.value**
	.structure	**.laterality**	**.morphology**		
Left cerebral ventricle frontal horn width is 30 mm	Cerebral ventricle frontal horn	Left		Width	30 mm
Pancreatic duct diameter is 2mm	Pancreatic Duct			Diameter	2 mm
Bladder wall thickness is 3 mm *when distended (normal)*	Bladder wall			Thickness	3 mm
Homogenous liver attenuation	Liver			Attenuation	Homogenous
Liver contour is smooth	Liver			Contour	Smooth
Aorta is tortuous	Aorta			Shape	Tortuous
Gallbladder wall is not thickened	Gallbladder wall		Thickening	Presence	Not Detected
Spiculated lesion in the lower lobe of the left lung	Lung lower lobe	Left	Lesion	Presence	Detected
	"	"	"	Shape	Spiculated
Echotexture of the spleen is normal.	Spleen			Echotexture	Normal
Mild coronary calcifications	Coronary arteries		Calcification	Severity	Mild
Kidneys enhance symmetrically	Kidney	Bilateral		Enhancement	Symmetric
Adrenal glands are normal in morphology	Adrenal gland	Bilateral		Size	Normal
	"	"		Shape	Normal
Uterus is anteverted and homogeneous	Uterus			Orientation	Anteverted
	"			Texture	Homogenous
Distal radius fracture displaced 4 mm *dorsally*	Distal radius		Fracture	Displacement	4 mm

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Pulmonary arterial trunk is normal in caliber	Pulmonary arterial trunk			Diameter	Normal
Free gas cannot be ruled out	Abdomen		Free gas	Presence	Indeterminate
No evidence of TMJ dislocation (Exam is insensitive)	Temporo-mandibular Joint		Dislocation	Presence	No evidence
	.note=Radiographs have limited sensitivity for TMJ dislocation				
200 mm3 lesion in the Liver	Liver		Lesion	Presence	Detected
	"		"	Volume	200 mm3
Mild cardiomegaly	Heart		Cardiomegaly	Presence	Detected
	"		"	Severity	Mild
Left ventricle internal diameter at diastole is 4.2cm	Left ventricle (See Note 1)			Diameter	4.2cm
Worsening Left pleural effusion	Lung	Left	Pleural Effusion	Presence	Detected
	"	"	"	Severity Change	Worsening
Lungs are clear	Lung	Bilateral	Abnormal Opacity	Presence	Not detected
Consolidation in the right lower lobe	Lung lower lobe	Right	Consolidation	Presence	Detected
Gallbladder is surgically absent	Gallbladder			Normality	Surgically acquired absence
0.9 x 0.9cm splenic hypodensity, not well characterized without iv contrast	Spleen		Hypodensity	Presence	Detected
	"		"	Major Axis Length	0.9 cm
	"		"	Minor Axis Length	0.9 cm
	.note=Splenic hypodensity not well characterized without IV contrast				
Atheromatous plaque noted in the aorta	Aorta		Atheromatous plaque	Presence	Detected
Right nephrostomy tube is in appropriate position	Renal pelvis	Right	Nephrostomy tube	Position	Normal
No lesions observed (in the chest)	Chest		Lesion	Presence	Not detected
[CDE Set: Pulmonary Nodule] .hasMember …	Upper lobe of lung	Left	Nodule	RDES195 - Pulmonary Nodule	
	"	"	"	Presence	Detected
	"	"	"	Composition	Solid
	"	"	"	Size	35.0 mm
	"	"	"	Morphology	Smooth
	"	"	"	Plurality	Single
	"	"	"	Microcystic Component	Absent
	"	"	"	Volume	18662 mm3

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	“	“	“	Change from priors	Larger than prior
	“	“	“	Suspicious	Yes
	“	“	“	Min density	45 HU
	“	“	“	Max density	62 HU

Notes: 1. Most cardiac features are not paired structures as they are not bilaterally symmetric. See DICOM PS3.16 Table L-5 https://dicom.nema.org/medical/dicom/current/output/chtml/part16/chapter_L.html#table_L-5

2215

LATER Create a Google Sheet for community list of examples

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Annex C – Guidance on Related Specifications

Several other profiles that relate to imaging reports have been published. This section provides some comparisons and transcoding guidance from the perspective of the IDR Profile.

C.0 HL7 ORU Messages

HL7 ORU messages are widely used to convey order results, such as diagnostic reports, within a hospital. The report content can be included in an OBX segment in the ORU message as a block of ASCII text, as XML, or even as a PDF. See RAD-128 for further details.

When communicating reports to such legacy HL7 ORU systems, the content of a DiagnosticReport resource could be rendered into such OBX segments, perhaps based on the content of DiagnosticReport.text, or DiagnosticReport.presentedForm. A Report Creator might even prepare a rendering specifically intended for ORU encapsulation as one of the entries in DiagnosticReport.presentedForm. This is not required or further specified by the IDR Profile.

C.1 Breast Radiology Report IG (2019-22)

https://build.fhir.org/ig/HL7/fhir-breast-radiology-ig/

This IG profiles the use of a Composition Resource that contains sections for overall report details, left, right, and bilateral findings, impressions, and recommendations.

Profile usage of the Composition Resource is reported to have been driven by a concern that the Diagnostic Report Resource might not continue to be available as a top-level resource.

Findings are profiled Observation Resources (USCoreObservationImagingResultProfile) and focus initially on x-ray mammography, with hooks in place for other modalities.

Conclusions and BI-RADS results are contained in a profiled DiagnosticReport Resource (USCoreDiagnosticReportProfileNoteExchange)

C.2 US Core Diagnostic Report Note IG (2017-25)

https://build.fhir.org/ig/HL7/US-Core/branches/master/StructureDefinition-us-core-diagnosticreport-note.html

This IG (now in version 9) profiles the use of a DiagnosticReport Resource for various diagnostic reports and notes including labs, ECGs, pathology, and radiology. Based on the radiology example in the IG:

- DiagnosticReport.text contains a (generated) rendering of the full report in XHTML.
- DiagnosticReport.result contains an Observation with a .code value for Finding and a .value string containing the full findings narrative text, and a second Observation with a .code value for Impression and a .value string containing the full impression narrative.
    - Inclusion of discrete data Observations is demonstrated in a DEXA example.
- DiagnosticReport.category distinguishes radiology, cardiology, and pathology reports.

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- DiagnosticReport.code identifies the specific type of report.
- DiagnosticReport.presentedForm contains an alternate XHTML rendering, or a PDF.
- DiagnosticReport.media references a jpeg image.

The goal of the IG appears to be to facilitate wrapping the content of reports in HL7 ORU messages into FHIR Resources for storage in a FHIR Server.

In principle, it should be possible to downgrade reports that are conformant with the IHE Imaging Diagnostic Report Profile to fit into a US Core Diagnostic Report Note.

Some points of caution to consider include:

- IDR uses .basedOn to reference ServiceRequest and/or Accession Number, linking the report to the order. IDR uses .encounter to reference the imaging encounter. US Core is somewhat ambiguous on the use of .encounter.
- IDR uses .media strictly for graphical media included in the report, such as diagrams. IDR uses .study to reference ImagingStudy for access to the managed diagnostic images via mechanisms such as DICOMweb. US Core promotes converting the diagnostic images into JPEG files, discarding the diagnostic metadata and PACS management, and accessing the JPEGs via .media references. US Core does permit the use of .study.

C.3 IHE Imaging Diagnostic Report – Phase I Public Comment (2024)

LATER if time permits, Summarize content

C.4 DICOM SR to FHIR Resource Mapping IG (2024-2025)

https://build.fhir.org/ig/HL7/dicom-sr/en/

LATER if time permits, Summarize content

This IG (now in version 9) profiles the use of a DiagnosticReport Resource for various reports including imaging/radiology.

- *Avoid being too conflicting. (Simplification and subsetting is OK)*
- *Note that SR is about captured data/information NOT about DiagnosticReport encoding*
- *SR data is inherently more "verbose" which can be a concern if "imported" into the Report.*
- *Need to be able to refer to the "source" SR that provided an Observation in DR.*

C.5 HL7 Europe Imaging Report IG (2025-2026)

https://build.fhir.org/ig/hl7-eu/imaging-r5/en/index.html

This IG (now in version 9) profiles the use of a DiagnosticReport Resource for various reports including imaging/radiology. Based on the radiology example in the IG:

LATER if time permits, Summarize content

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C.6 Japan - JP Core ImagingStudy Radiology Profile

https://jpfhir.jp/fhir/core/1.2.0/StructureDefinition-jp-diagnosticreport-radiology.html

2285 This IG (now in version 1.2.0) profiles the use of a DiagnosticReport resource in a FHIR R4 environment. It takes a similar approach to the US Core by primarily wrapping narrative text in a FHIR resource.

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IHE Radiology Technical Framework Vol 4 (National Extensions)

11 Regional Extensions for IHE Europe~~Japan~~ (UP)

https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/volume-4-eu.html#11-regional-extensions-for-ihe-japan

11.1 Imaging Diagnostic Report (IDR)

LATER Describe residual specification differences, if needed to harmonize with EHDS, here as an EU Regional Extension or in an EHDS Option in the Profile. This might include additional feature requirements and/or different representations.

FHIR IG Resource Pages

LATER Consider rebuilding this index
https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/index.html

DiagnosticReport -
https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/StructureDefinition-imaging-diagnosticreport.html

LATER Fix all the R6 FHIR Ticket updates

Observation -
https://build.fhir.org/ig/IHE/RAD.IDR/branches/TIDocMigration/StructureDefinition-idr-observation.html

LATER – Much of the new guidance and specification get transcribed here.

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