

Connectathon 27: Ophthalmology track
Technically validating the “Eyes on FHIR®” Implementation Guide ([link](#))



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Use cases focus:

Demonstrating IG’s capability to enable FHIR-driven semantic interoperability between ophthalmic diagnostic devices / PACS <> EMR /EHRs



Endorsed and supported by:



Additionally (critical current context to the rationale for this use case):

- The American Academy of Ophthalmology (AAO) recently published a cardinal statement on its “Recommendations for Standardization of Images in Ophthalmology,”[1] which was subsequently endorsed by the National Eye Institute (NEI) and other other peak ophthalmic bodies globally [2–4].
- Similarly, “the Food and Drug Administration (FDA) recognizes that the progression to digital health offers the potential for better, more efficient patient care and improved health outcomes. To achieve this goal requires that many medical devices be *interoperable* with other types of medical devices and with various types of health information technology” - FDA, 2019 [5]

NB: this is a project sponsored by HL7® International Patient Care Work Group

- See “Eyes on FHIR®” confluence landing page [here](#)

NB: “Eve Bill” is a **made-up** (patient name, demographics and conditions etc.) for connectathon testing purposes

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1. Summary: what was the track trying to achieve

Project overview

The overarching goal of this initiative “Eyes on FHIR®” is to develop international standards that represent the comprehensive ophthalmic clinical lexicon in FHIR® format. This is to address a fundamental problem - there is no current implementation guidance (IG) for ophthalmology (nor almost all other other clinical specialties). Hence, FHIR's potential to significantly impact health service delivery and therapeutic discovery has limited capacity to develop, implement and adopt standardized interoperable solutions to solve real-world data exchange problems in these domains.

However, given the unprecedented opportunity FHIR® presents to leverage modern technology to improve healthcare outcomes and scientific research. Hence, we started “Eyes on FHIR®” over a year ago under the guidance of Dr. Stephen Chu, co-chair Patient Care Working group, HL7 International (dedicated confluence landing page [here](#).) The initiative has attracted engagement and active contribution from a range of key stakeholders in the ophthalmic community; clinicians, technical implementers (representing a variety of hardware and software vendors), peak medical societies and research bodies and a variety of other key affiliates (see IG [contributors page](#)). Our approach has adhered to the traditional FHIR® process of semi-structured, ‘use-case driven’ IG development (see: Figure 1, below.)

Figure 1: Ophthalmic use cases informing the IG development process.
(The blue box surrounding Oph-01-06 highlights the use cases tested and validated in this connectathon.)

Foundational ophthalmic elements	Oph-01:	Representing ophthalmic <u>clinical findings</u> in FHIR®
	Oph-02:	Representing ophthalmic <u>diagnoses</u> in FHIR®
	Oph-03:	Representing ophthalmic <u>tests & interventions</u> in FHIR®
EHR/EMR \diamond device	Oph-04:	(i) EHR + DICOM Modality Worklist (NO PACS integration)
	Oph-05:	(ii) EHR + DICOM Modality Worklist (+ PACS integration)
	Oph-06:	(iii) EHR with DICOM support; NO HL7 (+ PACS integration)
Exchanging data between 2 parties	Oph-07:	Referrals between providers with FHIR® messaging protocols
	Oph-08:	Referral from a clinic to a healthcare service (hospital/day surgery)
	Oph-09:	Sending data to a clinical registry (eg - FRB!) with mandatory fields
	Oph-10:	Sending clinical records in bulk to a clinical registry
Specific scenarios	Oph-11:	Sending select data elements from select patients (de-identified) in bulk to a research institute / life science body
	Oph-12:	The referral of a patient to a clinical trial
	Oph-13:	Automating prior authorization for anti-VEGF injections
	Oph-14:	Real time clinical trial recruitment using CDS hooks (eg new wet-AMD)
	Oph-15:	SMART on FHIR app to compile relevant clinical data single screen / application enabling ‘decision on a page’

Connectathon track aim

This [track](#)'s aim in the May '21 FHIR® technical connectathon was to test and formally validate the IG's artefacts in preparation for its submission to the upcoming September ballot '21 cycle. Activity centered around 2 highly practical ophthalmic clinical interoperable use cases that would meaningfully impact daily practice, which purposefully required the testing and validation of a wide range of the IG's profiles.

Ultimately, the scenarios (see below) were designed to evaluate the IG's function utility in enabling the real-world implementation of 6 pre-defined use cases (blue-box-bounded in Figure 1). Equally, we sought to demonstrate a number of novel world-first 'proofs-of-concept' and also identify and fix any errors within the IG in preparation for the September ballot cycle.

Scenarios:

These sought to demonstrate a bold, groundbreaking proof of concept: bidirectional, vendor implemented, FHIR-enabled data exchange between EMRs/EHRs and ophthalmic diagnostic devices / PACS.

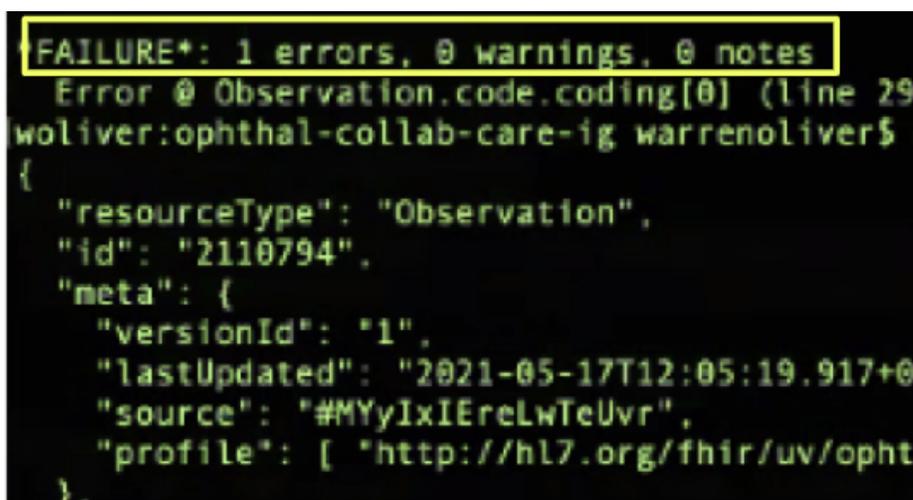
Scenario (i): sending clinical data from an EMR/EHR to a device / PACS

Scenario (ii) focused on sending clinical data from a device / PACS to an EMR/EHR

Methods:

- **Messaging:** data conversion and validation of FHIR® Resources against the IG used was facilitated by open source tools, including the HAPI FHIR server, the Mirth Connect cross-platform HL7 interface engine and the Postman API Client.
- **IG content testing:** the technical artefacts were validated against the IG, demonstrated by either:
 - Utilization of pre-prepared test scripts taken from the IG
 - Real-time Resources generated were validated using the Java jar FHIR validator (see screenshots below with yellow highlighted box showing examples of (a) failure and (b) success):

(a): failed



```
FAILURE+: 1 errors, 0 warnings, 0 notes
Error @ Observation.code.coding[0] (line 29)
woliver:ophthal-collab-care-ig warrenoliver$
{
  "resourceType": "Observation",
  "id": "2110794",
  "meta": {
    "versionId": "1",
    "lastUpdated": "2021-05-17T12:05:19.917+0
    "source": "#MYyIxIEreLwTeUvr",
    "profile": [ "http://hl7.org/fhir/uv/opht
  },
```

(b): successful

```
FHIR Validation tool Version 5.3.9 (Git# 265e2cebfe73). Built 2021-04-12T20:35:
Java: 11.0.1 from /Library/Java/JavaVirtualMachines/openjdk-11.0.1.jdk/Cont
Paths: Current = /Users/warrenoliver/Projects/FHIR/ophthal-collab-care-ig. P
Params: connectathon/2110798.json -version 4.0 -ig ./input/resources/
Loading
No such cached session exists for session id null, re-instantiating validator.
Load FHIR v4.0 from hl7.fhir.r4.core#4.0.1Creating Package manager?
- 4575 resources (00:05.0750)
Load hl7.terminology#2.1.0 - 3767 resources (00:01.0035)
Terminology server http://tx.fhir.org - Version 1.9.372 (00:04.0046)
Load ./input/resources/ - 38 resources (00:00.0167)
Get set... go (00:00.0180)
Validating
Validate connectathon/2110798.json 00:05.0147
Done. Times: Loading: 00:11.0614, validation: 00:05.0148
Success: 0 errors, 0 warnings, 1 notes
Information @ ?? : All OK
```

Endpoint success:

Successful accomplishment of this proof-of-concept in end-to-end communication for each scenario would demonstrate the “Eyes on FHIR ®” IG ability to enable:

- Breaking new, practical and translational ground in the mobilization, messaging and consumption of data that to date live in siloed digital systems
- The technical integrity of IG profiles used and hence, the legitimate power and utility of having assembled this IG, which addresses the intended “Eyes on FHIR ®” project’s goal of developing the standards required to guide implementers to develop FHIR® -based solutions and create truly systemic semantic interoperability.
 - Of note: the ‘universal’ application is unlikely due to regional differences in healthcare digital maturity, choice of clinical terminology etc.; however, in future connectathon/ballot cycles intend to address this by iteratively enhancing the IG’s maturity in both content and artefacts.
 - Future IG releases will add increasing jurisdictional guidance.
- If successful, real-world implementation feasibility of this critical use case (see below: “[EMRs and devices in ophthalmology: backdrop context and significance](#)”) holds strong translational capacity to showcase FHIR’s® potential to the non-technical, clinical world; it therefore stands to deepen engagement with clinicians, provider institutions, vendors, developers, researchers and peak medical bodies. It moves a conceptual possibility into a tangible reality.
- See section 4 “notable achievements” for the immediate potential clinical implications of this connectathon.

EMRs and devices in ophthalmology: backdrop context and significance

There are substantial limitations in current state device <> EMR/EHR workflow, connectivity and data exchange that adversely impact clinical care, increase healthcare system costs and inefficiencies and hinder biomedical research.

(i) Diagnostic devices

- Historically, ophthalmic diagnostic devices gather basic patient demographic information via an HL7v2 order (via an EHR/EMR/PMS). This information may be received by a Picture Archive and Communication System (PACS) and then sent to individual devices to populate the Digital Imaging and Communications in Medicine (DICOM) standard modality worklist workflow.
- This messaging has limited clinical utility as meaningful clinical data cannot either be sent (by an EHR) nor received (by the device) in HL7 V2.
- It is important to note that the investigation/test performed by ophthalmic diagnostic devices (eg - diagnostic imaging, automated perimetry) are distinct from radiology devices in that they generally have native software algorithms that automatically produce post-capture/post-test results or measurement outputs. For example:
 - (i) a 3-dimensional optical coherence tomography (OCT) near infra-red laser 'image' of the retina will generate algorithmically derived, post-capture key measurements of retinal thickness that accompany the image itself.
 - (ii) an automated perimetry / visual field test similarly outputs a report that quantifies both a series of 'performance metrics' (measures of how reliably one can interpret the test results), as well as numerous test scores of age-matched deviations from 'normal.'

(ii) EMRs/EHRs

- These systems generally have little to no DICOM support; meaning, any data captured in a diagnostic device (even in the event that it can be sent), cannot be consumed by the clinical system.

As ophthalmology is increasingly becoming an 'imaging-dependent' specialty, modern practices simply cannot function without these devices on site, as they are routinely used as part of the routine assessment of the majority of patients. As such, enabling interoperable exchange between output data from ophthalmic diagnostic devices and clinical data captured in the EMRs/EHRs hold immense potential to solve a significant and widely applicable real world problems that can enhance physician experience, improve clinical care, enrich digital referrals and unlock a powerful, virtuous cycle of data-driven biomedical research. For example:

- Currently, ophthalmologists spend wasted time and energy either moving between rooms, or switching screens to review images or other test results that do not reside within the EHR environment. These results are then often manually entered into the EHR (which may be captured in a structured or unstructured field). Success in this connectathon would eliminate the need for the inefficiency.
- Integrating DICOM metadata with clinical data will catalyze research, which holds substantial translational potential in the modern era, as the academic focus on imaging and artificial intelligence applications is growing exponentially.
- Enhance patient access to integrated information
- Accelerate clinical trial recruitment; in ophthalmology, these are increasingly driven by imaging parameters

2. List of active participants

Connectathon track leads:

- Ash Kras, MBBS (HONS), MBI, FRANZCO (“Eyes on FHIR®” project lead)
 - Consultant ophthalmologist
 - Senior Clinical Lecturer, Sydney University
 - Postdoctoral fellow, Massachusetts Eye and Ear Infirmary Retinal Imaging Lab, Harvard Medical School, MA, USA
 - Honorary fellow, Moorfields Eye Hospital
- Warren Oliver
 - CTO, Oculo

Clinical participants:

- Nigel Morlet, MBBS, FRANZCO, FRACS (see below - senior clinical ophthalmology advisors)
- Hemal Mehta, MBBS MD (Cantab.), FRCOphth, FRANZCO (see below - senior clinical ophthalmology advisors)

Ophthalmic technical implementer/ vendor representation:

- EHR/EMR
 - Warren Oliver (Oculo)
 - Ashley Ramsey (Oculo)
 - Leah King (MediSoft)
 - Adam Child (MediSoft)
- Diagnostic Device / PACS manufacturers
 - Alex Gogol (Heidelberg)
 - Regis Deshayes (Carl Zeiss Meditec)
 - Marita (Carl Zeiss Meditec)
- Big data / Registry / Clinical research
 - Marco Garcia ([Save Sight Registry](#))
- Major Endorser for the connectathon, IG development and the “Eyes on FHIR® Project”
 - Kerry Goetz (National Eye Institute, NIH, USA)
- Registered, but unable to participate (timezone incompatibilities)
 - Artur (Topcon)
 - Steven (Topcon)

Additional thanks to the following individuals supporting this endeavour in various capacities (non track participants):

HL7 / FHIR technical advisory

- Dr. Stephen Chu, MBBS, Co-Chair, Patient Care Working Working Group, HL7 International
 - Foundational and ongoing active member advocate of “FHIR for Ophthalmology”
- Grahame Grieve, PhD
 - Founder, FHIR® & product lead, HL7®

- Overarching directional guidance and support for “Eyes on FHIR”
- Rob Hausum
 - Co-Chair, Orders and Observations Working Group, HL7® International
 - Co-Chair, Vocabulary Working Group, HL7® International
 - Specific terminology advisory
- Imaging Integration (HL7 international) / DICOM (WG 20) collaboration:
 - Jonathan Whitbey (Co-Chair, Imaging Integration Working Group, HL7 International)
 - Chris Lindop (Co-Chair, Imaging Integration Working Group, HL7 International)
 - Elliot Silver (Facilitator - vocabulary, Imaging Integration Working Group, HL7 International)
 - Carolyn Hull (Secretariat, DICOM WG 20)

HL7 Working Group sponsorship for September ballot

- Patient Care WG (primary sponsor)
- EHR WG (co-sponsor)

Senior clinical ophthalmology advisors

- John Miller, MD
 - Assistant Professor of Ophthalmology, retina faculty, Massachusetts Eye and Ear Infirmary - Harvard Medical School (HMS) affiliate academic medical centre
 - Director, [Retinal Imaging Laboratory](#), HMS
 - Associate Director, HMS Vitreoretinal Fellowship
 - HMS Ophthalmology Residency Retina Curriculum Advisor
- Mark Gillies, MBBS, MD., Ph.D, FRANZCO
 - Head, Medical Retina Unit, Sydney Eye Hospital
 - Professor, Director of Research, University of Sydney, Save Sight Institute
 - Founder and director - [Fight Retinal Blindness!](#) project, Save Sight Institute, Sydney University
 - Chair, working group for the International Consortium for Health Outcomes Measurement (ICHOM) for [macular degeneration standards](#) (2014-2016)
- Thomas Hwang, MD
 - Chair, Medical Informatics and Technology Committee, [American Academy of Ophthalmology](#)
 - Professor of Ophthalmology, Casey Eye Institute-Oregon Health and Science University
 - Residency Program Director
 - Chief, Vitreoretinal Division
- Nigel Morlet, MBBS, FRANZCO, FRACS
 - Professor clinical epidemiology, School of Population and Global Health University of Western Australia
 - Consortium member in the development of [ICHOM for cataracts](#) Standards Set
- Hemal Mehta, MBBS MD (Cantab.), FRCOphth, FRANZCO
 - Advisor to RCOphth National Age-related macular degeneration Audit (UK)
 - Senior researcher and steering committee member, [Fight Retinal Blindness!](#), Save Sight Institute, Sydney University
 - Consultant ophthalmologist, Sydney Eye Hospital

3. Systems which have implemented the IG, Profile, or Resource, and approximate percentage covered (link to ConMan results if applicable)

- Though none of the participating systems have functionally implemented the FHIR capabilities to support the IG and its profiles in production to date, this connectathon prototyping was the first real world vendor endeavor at doing so - following the IG specifications. This was performed with considerable success (notwithstanding a few expected iterations along the way)
- SUCCESS: multiple digital systems (various EHRs, devices and PACS) were able to both produce and consume IG-validated FHIR resources. Numerous vendors were able to produce, map, consume and/or display these validated artifacts in various useful capacities (see 'screenshots' section below).
- Of equal significance, the FHIR profiles generated for communication and validated against the IG - poised for the upcoming ballot - came from a range of primary sources and file types, such as:
 - Different types of .dcm (DICOM) files originating from multiple systems
 - Various clinical terminologies
 - Various EHR backends and front ends
- The screenshot below and link ([here](#)) to CONMAN results captured some of this activity success

Asserter	Server	Result	Note	IG
Alexander Gogol	HAPI R4	pass	Procedure resource for OCT RNFL with codes for both CPT and SNOMED	
Alexander Gogol	HAPI R4	pass	Creation of Media resource for an OCT RNFL PDF to be referenced by a DiagnosticReport	
Alexander Gogol	HAPI R4	pass	"THE WORLDS FIRST" OCT RNFL Observation resource (referencing the LOINC thickness panel for right inferior RNFL thickness) - to be used in an OCT RNFL DiagnosticReport together with accompanying PDF	
Alexander Gogol	HAPI R4	pass	OCT RNFL DiagnosticReport containing a reference to PDF (Media) and an Observation (Inferior right RNFL thickness)	
Warren Oliver	HAPI R4	pass	Sent validated VA / IOP / Media / Refraction to the FHIR server from front end data entry	
Marita Bergmann	HAPI R4	pass	Retrieved validated IOP Observation data from FHIR server and displayed in PACS graphically (originally sent by Oculo)	
Adam Child	HAPI R4	pass	Mapped VA data from EMR database to Visual Acuity Observation resource, validated it, then uploaded it to the FHIR server.	

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Adam Child	HAPI R4	pass	Mapped refraction data from EMR database to an Observation resource, validated it, then uploaded it to the FHIR server.
Adam Child	HAPI R4	partial	Mapped IOP data from EMR database to an IOP Observation resource, validated it, then uploaded it to the FHIR server. Unable to map (Pascal) Dynamic Contour tonometry to a value in the IOP methods value set.
Adam Child	HAPI R4	pass	Mapped Central Corneal thickness data from EMR database to an Observation resource, validated it, then uploaded it to the FHIR server.

Adam Child	HAPI R4	pass	Mapped cup to disc ratio data from EMR database to an Observation resource, validated it, then uploaded it to the FHIR server.
Adam Child	HAPI R4	pass	Mapped general examination findings data from EMR database to an Observation resource, validated it, then uploaded it to the FHIR server.
Adam Child	HAPI R4	pass	Mapped diagnosis data from EMR database to a condition resource, validated it, then uploaded it to the FHIR server.

4. Notable achievements

This connectathon track was successful in achieving its aims; the proof-of-concept showcased the powerful translational capacity of the “Eyes on FHIR®” IG specifications, and can now be applied to real world ophthalmic practice (pending September ballot success).

-In collaboration with real-world implementers from the ophthalmic vendor community, ultimately, we succeeded in: Validating the technical artefacts themselves contained within the IG

-End-to-end (bidirectional) interoperable data exchange, as pre-defined by the use cases, using FHIR® messaging protocols and the IG’s Resources mediated via a HAPI FHIR server

==This was shown to be successful between multiple unique ophthalmic digital systems, which were able to convert and represent their data in validated FHIR format and communicate to other (and different) ophthalmic digital systems via a FHIR server

This stands to unlock exponential and unprecedented future possibilities for:

- Interoperability-driven improvements in ocular healthcare, particularly those outlined in the work group’s use cases
- Critical important ophthalmology data to support effective care coordination, collaboration, data-driven innovation and biomedical research.
- Notably, key ophthalmic EMR and diagnostic device vendors actively validated the IG’s implementation by demonstrating real-time data exchange between real world digital systems.

Most significantly:

- Through FHIR’s DiagnosticReport Resource, we created the world’s first mobilized, computer readable OCT RNFL report; this was generated from a DICOM object within a PACS, successfully validated against the IG’s specifications and then passed to EHRs vis FHIR servers (see screenshots above.)

Other key, unique and specialty-specific achievements:

- Specialty specified utilization of anatomical referencing (see [here](#) in the current IG; a post-connectathon modification; now using a combination of Body Site and BodyStructure with specifically clinically relevant ophthalmic extensions)
- Unique utilization of the DiagnosticReport Resource across multiple diagnostic tests, which capture *Observations* defined in value sets combined from various terminologies to enable the comprehensive transfer of test results in ophthalmology in combination with static PDF / other image reports generated, referenced as *Media*

Overall, this outcome strongly aligns with the strategic imperatives of the NIH and NEI (key endorsers) in promoting interoperability through utilisation of the FHIR® standards to advance biomedical research. Their endorsement is resoundingly demonstrated throughout the “Eyes on FHIR®” project and IG development process. and will continue to work collaboratively with other key stakeholders in the ophthalmic and research community to continue accelerating and expanding its adoption and impact.

5. Screenshots if relevant and interesting and/or links to further information about implementations/achievements

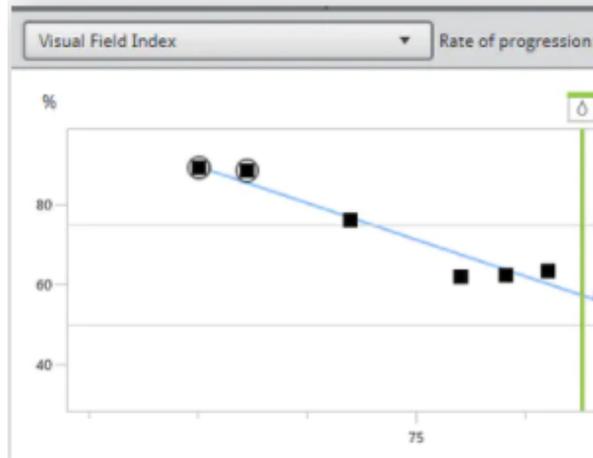
i) Scenario of transferring clinical data (IOP) → FHIR server (validated) → showcase consumption and display by PACS

(ia) Zeiss® Forum® PACS

- This depicts clinical data originating from an EHR (intraocular pressure, measured in mmHg) over 3 different time points
- This interface, until now, has not had the capability to consume and display clinical data
- Routinely, Forum® is used to visualize numerous diagnostic test results generated by Zeiss® diagnostic devices (see below - (ia), (ib))
- Hence, this is evidence of a truly groundbreaking world first in ophthalmology, showing evidence that FHIR® can enable *clinical* data to be visualized alongside diagnostic device generated data (traditionally only HL7 v2 has been receivable exclusively to prepopulate worklists etc. with *demographic* data).



(ib) [SAMPLE] The Zeiss Forum Glaucoma Workplace[®] graphically representing the visual field index (VFI) - an output parameter of a visual field test. This is *not* data that is generated by an EHR, rather by a visual field diagnostic device; here we are seeing serial results of the VFI over time, which demonstrates the rate of progression of glaucomatous damage to the optic nerve over time.



(ic) Medisoft's coded generation of sample Goldman IOP reading (July 7th; 11mmHg → validated in (ic) and the consumed and displayed by Zeiss Forms[®] in (ia)

```
"status": "final",
"category": [ {
  "coding": [ {
    "system": "http://terminology.hl7.org/CodeSystem/observation-category",
    "code": "exam",
    "display": "Exam"
  } ]
} ],
"code": {
  "coding": [ {
    "system": "http://snomed.info/sct",
    "code": "41633001",
    "display": "Intraocular pressure"
  } ]
},
"subject": {
  "reference": "Patient/ophthal-patient-example-0"
},
"effectiveDateTime": "2020-07-06T11:00:20+01:00",
"issued": "2020-06-07T11:00:00+01:00",
"valueQuantity": {
  "value": 11.0,
  "unit": "mm[Hg]",
  "system": "http://unitsofmeasure.org",
  "code": "mm[Hg]"
},
"method": {
  "coding": [ {
    "system": "http://snomed.info/sct",
    "code": "391939000",
    "display": "Goldmann applanation tonometer"
  } ]
}
```

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(id) Validation of this IOP FHIR resource against the IG, which was generated by the code in (ib) and subsequently messaged through FHIR servers and consumed by the Zeiss PACS (seen as the central of 3 data points - 11mmHG, July 6th 2020)

```
Validation IOP_OS
C:\_NAC\100_Projects\Connectathon_Fhir\Validator>java -jar validator_cli.jar C:
\_NAC\100_Projects\Connectathon_Fhir\Results\Patient_iop\Observation_IOP_OS.json -version 4.0 -ig C:
\_NAC\100_Projects\Connectathon_Fhir\ophthal-collab-care-ig-master\input\resources
FHIR Validation tool Version 5.3.11 (Git# 33fffe28ff6b). Built 2021-04-22T05:48:36.375Z (26 days old)
Java: 1.8.0_281 from C:\Program Files\Java\jre1.8.0_281 on amd64 (64bit). 3552MB available
Paths: Current = C:\_NAC\100_Projects\Connectathon_Fhir\Validator, Package Cache = C:
\Users\msmbe\.fhir\packages
Params: C:\_NAC\100_Projects\Connectathon_Fhir\Results\Patient_iop\Observation_IOP_OS.json -version
4.0 -ig C:\_NAC\100_Projects\Connectathon_Fhir\ophthal-collab-care-ig-master\input\resources
Loading
  Load FHIR v4.0 from hl7.fhir.r4.core#4.0.1Creating Package manager?
  - 4575 resources (00:04.0567)
  Load hl7.terminology#2.1.0 - 3767 resources (00:00.0861)
  Terminology server http://tx.fhir.org - Version 1.9.372 (00:03.0359)
  Load C:\_NAC\100_Projects\Connectathon_Fhir\ophthal-collab-care-ig-master\input\resources - 37
resources (00:00.0103)
  Get set... go (00:00.0082)
Validating
  Validate C:\_NAC\100_Projects\Connectathon_Fhir\Results\Patient_iop\Observation_IOP_OS.json
00:05.0335
Done. Times: Loading: 00:09.0159, validation: 00:05.0335. Memory = 289Mb

Success: 0 errors, 0 warnings, 1 notes
Information @ ?? : All OK
```

In summary: (i a→d) demonstrate how clinical data, represented in FHIR format and validated against the IG, can be successfully exchanged through FHIR-based messaging protocols from an EHR of one vendor to the PACS of another. This is a powerful display of a successful demonstration of scenario #1 (EHR >>>> PACS).

- It profoundly shows FHIR's® capability to impact daily ophthalmic practice
- This is a breakthrough proof concept that stands to powerfully enhance routine clinical workflows, but also mobilize and combine data from different sources to advance biomedical research in unprecedented ways.

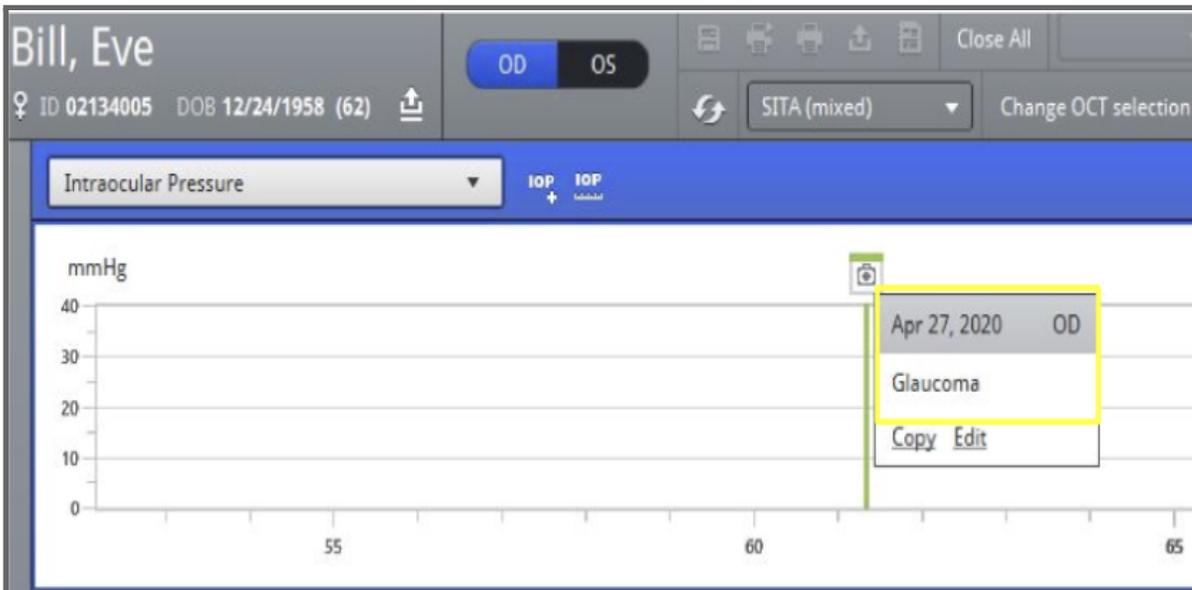
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The screenshot below shows a similar process, utilizing different content - the "Condition" resource - glaucoma

```
PUT {{HOST}}/Condition/condition-ophthal-glaucoma

Params Authorization Headers (9) Body Pre-request Script Tests Settings
none form-data x-www-form-urlencoded raw binary GraphQL JSON

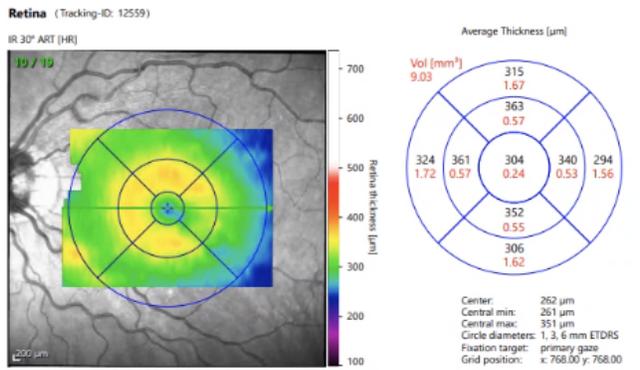
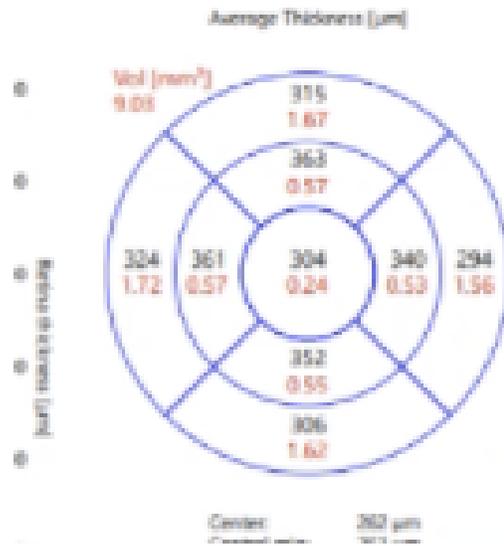
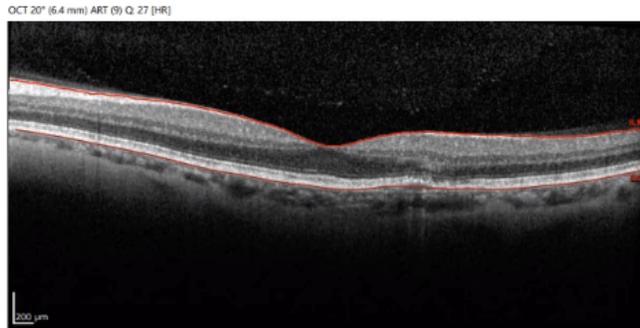
32 ..... "system": "http://terminology.hl7.org/CodeSystem/condition-category",
33 ..... "code": "encounter-diagnosis",
34 ..... "display": "Encounter Diagnosis"
35 ..... }
36 ..... ]
37 ..... }
38 ..... ],
39 ..... "code": {
40 .....   "coding": [
41 .....     {
42 .....       "system": "http://snomed.info/sct",
43 .....       "code": "23986001",
44 .....       "display": "Glaucoma"
45 .....     }
46 .....   ]
47 ..... },
48 ..... "onsetDateTime": "2020-04-27T17:04:21.643+04:00"
51 ..... }
52 }
```



ii) Scenario of transferring OCT macula DICOM® ePDF → FHIR server → EHR backend → EHR front end display

ii) Regular 'static' OCT macula PDF report generated by an OCT machine; note here - the central number - 304 μm (visually expanded in the right image). NB: the accompanying ePDF.dcm was used to generate the individual Observation Resources that were linked to the DiagnosticReport Resource.

Numeric measurement report		HEIDELBERG SPECTRALIS	
OS	Patient: Bill, Eve Patient ID: 02134005	DOB: 12/24/1958 Exam: 3/7/2018	Sex: Male



Notes:
Date: 5/17/2021 2:38:06 PM Signature:
Software Version: SEDAF 1.0.15.0 HEYEX 2.5.4.1870 www.HeidelbergEngineering.com Page 1 / 1

ii) Front end EHR displaying the consumed data from a diagnostic device (OCT machine)

BILL, Eve
31 Pacquola Street, Blacktown, NSW, Australia, 2148

Born
24-Dec-1958 Hosp 02134005

Ophthalmology

OCT - macula 18-May-2021 Clinic, Hazelwood Hospital
Seen By Unknown UNKNOWN

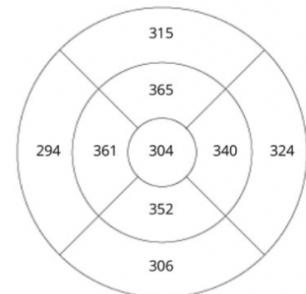
Macular Data

Right eye

Machine: Spectralis

Left eye

Average central 1mm thickness (μm) 304
Central point foveal thickness (μm) 262



iii) OCT RNFL DICOM object → Validated DiagnosticReport (Media + Observation) → EHR

This demonstration is not just a world first in the same way example (ii) above is; currently this also broke new ground in that:

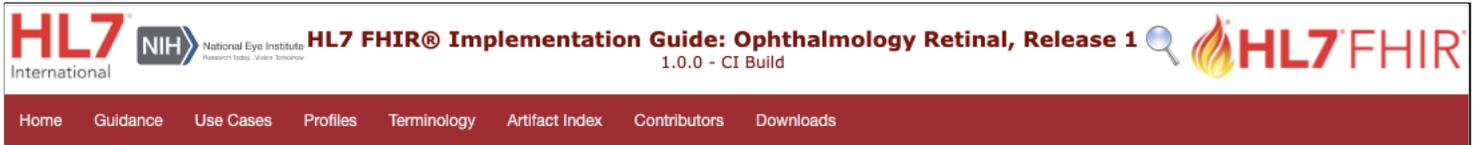
- a) There is no IHE / any other guidance for how to generate an ePDF DICOM report for an OCT RNFL scan
- b) There is no vendor that currently produces this DICOM object as an output
- c) Similar to example (ii) above, this data has also never been converted to a FHIR[®] Observation, linked to a DiagnosticReport, validated against the IG (which referenced an *existing* LOINC panel - [link](#) - code 86291-2 'Retina Retinal nerve fiber layer panel by OCT'), and transmitted to an EHR.

```
{
  "resourceType": "Observation",
  "id": "2118794",
  "meta": {
    "versionId": "1",
    "lastUpdated": "2021-05-17T12:05:19.917+00:00",
    "source": "#YyIxIErslwTeUvr",
    "profile": [ "http://hl7.org/fhir/uv/ophthalmology/StructureDefinition/observation-oct-rnfl" ]
  },
  "extension": [ {
    "url": "http://hl7.org/fhir/uv/ophthalmology/StructureDefinition/laterality",
    "valueCodeableConcept": {
      "coding": [ {
        "system": "http://snomed.info/sct",
        "code": "419465000",
        "display": "Unilateral right"
      } ]
    }
  } ],
  "status": "final",
  "category": [ {
    "coding": [ {
      "system": "http://terminology.hl7.org/CodeSystem/observation-category",
      "code": "exam",
      "display": "Exam"
    } ]
  } ],
  "code": {
    "coding": [ {
      "system": "http://loinc.org/",
      "code": "86283-9",
      "display": "Right retina Retinal nerve fiber layer.inferior thickness by OCT"
    } ]
  },
  "subject": {
    "reference": "Patient/ophthal-patient-example-0"
  },
  "effectiveDateTime": "2020-07-06T17:04:20+04:00",
  "issued": "2021-05-17T12:52:00.643+04:00",
  "valueQuantity": {
    "value": 152,
    "unit": "micrometer",
    "system": "http://unitsofmeasure.org",
    "code": "um"
  },
  "method": {
    "coding": [ {
      "system": "http://snomed.info/sct",
      "code": "392010000",
      "display": "Optical coherence tomography"
    } ]
  }
}
```

6. Discovered issues / questions (if there are any)

1. IG technical artefact issues noted during testing/validation

- a. IG rendering - update to use the 'hl7.fhir.template,' which is suggested in the 'Guidance for FHIR IG Creation' ([here](#))
- i. This also enables customization, such as including relevant logos (eg: NEI)



b. Observations (general); similarly applicable to Conditions and Procedures

- i. How and where to provide deeper levels of guidance either through commentary or profiling
- For instance, some Observations almost indispensably require mandatory accompanying data elements, otherwise their clinical relevance is significantly diminished, whereas others may be less clinically eg -
 - Observations / date-time
 - An IOP should always have an accompanying date-time
 - An observation of pseudophakia (artificial lens replacement) could reasonably have a preferred date-time binding
 - Considerations noted:
 - Primary issue is the tension between:
 - The ideal state - where every *Observation*, *Condition* and *Procedure* has an attached and accurate time-date stamp data element that is both generatable and consumable by digital systems exchanging FHIR data;
 - Variable clinical significance (ranging from indispensable → nice to have)
 - Enablement of data exchanges and integration with digital systems that are either: (i) legacy and never had this digital element intrinsically integrated, or (ii) simply do not support this, and those that (iii) may mandate accompaniment of a time-date stamp for any/all of the *Observation*, *Condition* and *Procedures* it represents.
 - Additional issues notes for consideration:
 - Time zones of both:
 - Variable locations where clinical encounters occur

2. Location of the servers where data may be collected or consumed - these may not necessarily align with the timezone of the clinical encounter, where the data was recorded
 - c. Potential solutions discussed
 - i. Could *potentially* link to an *Encounter*:
 1. This could denote the date-time of the *Encounter* itself where the Resource was recorded, but not the specific *time* of a clinically significant relevant activity or *Event*
 2. For example, if a patient presented with a particularly high IOP (acute glaucoma) that required urgent intervention for symptomatic relief and prevention of sight threatening sequelae - it would be critical to note:
 - a. The time of presentation and recording of the initial IOP
 - b. The time/s of any/all therapeutic interventions (*Medication/Procedure*)
 - c. The time of all all subsequently recorded IOPs following treatment commencement
 3. Rob Hausem consulted:
 - a. Agrees that particular clinical scenarios should be considered on a case-by-case basis
 - i. Unless deemed clinically significant, opt for a *preferred* binding to enable optimal digital system interoperability; otherwise can either (i) mandate a *required* date-time binding, or (ii) comment that this would be the ideal method of communication for that particular scenario
 - ii. Alternatively, could consider creating 2 different profiles for; (i) legacy / non-supportive systems and (ii) date-time supportive systems
 1. Note: this carries the risk of minimizing interoperability (inconsumable data, which may still carry some clinical significance), as well as the potential absence of clinically accuracy/relevant information exchanged
 - b. Ultimately, these nuanced, important issues should be accounted for through accompanying documented clinical guidance; be explicit in this commentary.
 4. Conclusion: (**IG commentary**) is required:
 - a. Particularly with respect to those Resources where date-time stamp is mandatorily required - wherever possible, this should at least be noted as *required* as the preferential optional (as opposed to *preferred*), if not mandated as *required* binding strength, particularly if deemed absolutely critical clinically.
 - b. Time-zone matter noted above (place of clinical encounter *and* physical location of server where the data is stored, which may not be co-located)
- c. Re: "status" of an *Observation* - consider making this code limited to "final" and "amended" only (see screenshot below; pink highlighted box).

Figure: Observation status

status	?! Σ	1..1	code	registered preliminary final amended +
category	0..*		CodeableConcept	Classification of type of observation

d. Observations (specific)

i. VA

1. Address aforementioned general terminology issues
2. Written / documented guidance to be added to the IG (**IG commentary**)
3. VA result in logmar - explain rationale (**IG commentary**)
4. Need to add Monoyer VA method to the VA valueset
5. Need to include a conversion table (**IG commentary**)
 - a. Link to [this](#) (R package) computation converter and/or [this](#) DICOM conversion table

ii. IOP

1. Add upper and lower limit
2. Limit values to 0 → 99
3. Add units of measure
4. mmHg (convert to this) - existing
5. And also commentary regarding other units of measurement:
6. For non mmHg (eg - kPa and hPa) → convert at system (similar to Logmar by analogy)
7. Include conversion table / method etc

e. Laterality extension - not supported by HAPI server

i. Note: FHIR servers do not support any extensions

1. This relates exclusively to searchability; it does not impact receipt of Resource / transmission / validation etc.

ii. Current approach:

1. We do not use the data element *BodySite*
2. Rather, a unique ophthalmic laterality extension has been created, which is designated for application to the following Resources contained within the IG:
 - a. *Condition*
 - b. *Observation*
 - c. *Procedure*
 - d. *DiagnosticReport*
3. Note: expansion displayed in the screenshot below is based on the updated SNOMED CT International edition 31-Jan 2021 (this was updated following the connectathon, during which the terminological update was noted)

Figure: ophthalmology laterality extension

Code	Display	Definition
419161000	Unilateral left	
419465000	Unilateral right	
51440002	Bilateral	
261183002	Upper	
261122009	Lower	
264217000	Superior	
261089000	Inferior	
255551008	Posterior	
255549009	Anterior	
255570003	Temporal	
260540009	Nasal	

4. The rationale for this approach is:
 - a. The existing *Observation.BodySite* value set for ocular laterality includes SNOMED-CT code "Left eye - 8966001," which descends from the 'Body Structure' concept
 - b. However, there are numerous concepts in ophthalmology that are clinically relevant to record and comment that are not specific to the eye; for example - eyelid, forehead, facial cranial and brain structures
 - i. It may be equally reasonable to reference these anatomical structures wherever relevant
 - ii. However, the concept of laterality (and other relative anatomical locations noted in the screenshot above) is so critically and intrinsically relevant to ophthalmology practice, this specific value set was deemed to be sufficiently justifiable, as it can be uniformly applied to each of the aforementioned Resources, and enables the most accurately intended conceptual meaning of the codified clinical representation
 - iii. *Discussed the lack of extension support (in this case, 'laterality') with Rob Hausem - suggests:*
 1. Raise/consult independently with relevant server how to support it - eg - start with HAPI
 - iv. NOTE: will need to code/note a workaround if we stick with this method of representing laterality
 1. Give example of how this could be done (**IG commentary**)
 - v. Additional consideration: this extension currently carries a *required* binding strength
 1. Whilst this would be optimal in almost all clinical scenarios, similar considerations should be given as noted above with date-time
 2. Any which way, ensure there is adequate accompanying (**IG commentary**)
- f. Medication Resource - should be added into IG (**IG ADD**)
 - i. Note different terminologies that may be required for different jurisdictions, eg -
 1. USA ([US core - FHIR R4](#)):
 - a. [RxNorm](#)
 - b. [HCPCS](#) (Healthcare Common Procedure Coding System)
 - i. HCPCS is a collection of standardized codes that represent medical procedures, supplies, products and services. The codes are used to facilitate the processing of health insurance claims by Medicare and other insurers.
 1. It is maintained by the US Centers for Medicare and Medicaid Services (CMS) available for public use;
 2. Note - used with the CMS Blue Button 2.0 FHIR [API](#) for medicare beneficiaries
 - ii. In ophthalmology, often used in combination with a [CPT](#) (clinical procedure terminology code); eg - in the case of intravitreal injection administration
 1. See - American Academy of Ophthalmology (AAO) [webpage](#) for details
 2. Note - when Value Sets include CPT codes, the copyright element should include the text "CPT copyright 2014 American Medical Association. All rights reserved."
 2. United Kingdom:
 - a. Note: [UK Core](#) -
 - i. As of June 28 2021 "UK Core Profiles (are) in development and should be considered as "work in progress""

- b. [DMD](#) (Dictionary of medicines and devices)
 - c. [MIMS](#) - “the essential prescribing and clinical reference for UK general practice.”
3. Australia:
- a. [AU base medication for FHIR](#), includes:
 - i. [PBS Item Code](#) - Pharmaceutical Benefits Scheme coding, claiming context is not relevant as medicine coding.
 - ii. [GTIN](#) - Global Trade Item Number, physical product reference.
 - iii. [AMT Code](#) - Australian Medicines Terminology, national drug terminology.
 - iv. [MIMS Package](#) - commonly used medicine coding.

g. *DiagnosticReport*

- i. For ALL Diagnostic report profiles:
 - 1. Need to change code cardinality from (0..*) to (1....1)

h. Note: Procedure billing terminology variance between jurisdictions

- i. For US: use [CPT](#)
 - 1. Relevant ophthalmic CPT codes are detailed in the “use case” document
 - 2. Per above, note - when Value Sets include CPT codes, the copyright element should include the text "CPT copyright 2014 American Medical Association. All rights reserved."
- ii. For UK: use jurisdictional guidance, provided in UK core
- iii. For Aus: suggest to include [MBS](#) (note: not in [AU base profile](#)) (**IG commentary**)

2. Handling multiple code systems

- i. Is there an optimal solution to enabling the message transfer of multiple code systems? As different digital systems capture and support variable and potentially numerous code systems to represent clinical concepts, and this conformance information is not always known upfront between systems desiring to interoperably exchange data, we see a role in offering guidance regarding the clinical and technical considerations implementers may confront
 - i. There are a number of issues and potential solutions, which may be highly variable and be uniquely situation dependent.
 - ii. Of note:
 - 1. One particular limitation is the current inability to formally validate profiles (eg - our base Procedure) where there are 2 (or more) code systems sent, eg:
 - a. Eg: (CPT + SNOMED) / (ICD + LOINC + SNOMED) etc.
 - 2. Note: recipient system will ‘ignore’ a code system it does not support or a code it does not recognize; this will *not* prevent it accepting an accompanying code transmitted if this code system *is* supported
 - iii. Potential solutions discussed:
 - 1. With guidance for which codes are suited to conceptually represent particular clinical situations, indicating a particular preference if/where applicable, we could enable the transfer of multiple codes if suitable/desired ; hence, when ‘validating’ a given code/profile combination, this can be done 1 code by 1 (**IG commentary**).
 - a. For example: “codes ‘a’, ‘b’ and ‘c’ could be used to represent concept ‘d’; code ‘a’ is preferred where possible, but ‘b’ and ‘c’ could be alternatives.” Sending multiple codes would not be prevented. (**IG commentary**)

- ii. Consultation with Rab Hausum (with thanks) led to the following conclusions.
- i. It is feasible to send multiple code systems as elements within a single Resource (confirmed). This is best achieved using 'slicing' - as many slices can be used as appropriate
 - ii. It is feasible to mandate that ≥ 1 code be transmitted if there are multiple sliced options.
 - iii. The recommended approach is:
 1. At the code.coding level (slice definition):
 - a. [use cardinality of $1..*$ \rightarrow at *least* 1 code will be sent]
 2. For each code.coding 'slice' \rightarrow binding strength "*required*" & cardinality $0..1/*$; this will enable
 - a. Any associated accompanying text to be transmitted, if it is intrinsically related to the terminological definition
 - b. Note: the '*required*' binding strength is what programmatically determines that a given code from a particular code system, should match this code system, eg -
 - i. A CPT slice should transmit CPT codes
 3. In addition to the multiple coding slices that can exist at the code.coding elemental level of the profile, a *single* independent free text string can accompany this (*code.text* - a "plain text representation of the concept"), but this is not baked into the expression of each individual slice
 4. "*Pattern*" should not be used *unless* it is specified which specific code value should be sent; in this situation, "*pattern*" enables anything else to be sent along with this, such as a 'random' unassociated text string (an alternative to *pattern* is a fixed constraint)
 - a. Note: it is also possible to use *pattern* as part of a slice for specific code, but not when using a value set with multiple options (eg the whole CPT terminology)
 5. Re: '*preferred*' binding strength with slices (as opposed to recommended '*required*,' as noted above):
 - a. This will not enable validation of the *Resource*
 - b. This necessitates that each slice is required to be included
 - iv. (IG amendments):
 1. Change *code*. cardinality $\rightarrow 0..*$
 2. Change *code.coding* for each slice $\rightarrow 0..*$
 3. Maintain *code.text* @ $0..1$
 - v. (IG commentary):
 1. Ensure that any accompanying free text that is not associated with a sliced code system is placed in *code.text* (note: as above, only 1 string of free text is allowed for every *code* element, no matter how many slices of *code.codings* there may be sliced within it.

Figure below: existing *Procedure* base profile, as an example \rightarrow to be amended as described above

code	Σ	0..1	CodeableConcept	Identification of the procedure Binding: ProcedureCodes(SNOMEDCT) (example): A code to identify a specific procedure .
id		0..1	string	Unique id for inter-element referencing
extension		0..*	Extension	Additional content defined by implementations Slice: Unordered, Open by value:url
coding	Σ	0..*	(Slice Definition)	Code defined by a terminology system Slice: Unordered, Open by pattern:\$this
coding:cpt	Σ	1..1	Coding	CPT codes for ophthalmic procedures Binding: Ophthalmology CPT Procedures ValueSet (preferred)
coding:snomed	Σ	1..1	Coding	SNOMED codes for ophthalmic procedures Binding: Ophthalmology SNOMED Procedures ValueSet (preferred)
text	Σ	0..1	string	Plain text representation of the concept

3. **Vocabulary issues noted** (eg - updated vocabularies since IG authorship; absence of clinically relevant concepts)

a. SNOMED international updates identified:

- i. Updated *laterality* codes (see screenshot below); noted above in more detail

Figure: updated SNOMED laterality terminology

Description	
The valueset http://hl7.org/fhir/ValueSet/bodystructure-relative-location contains obsolete SNOMED CT codes	
419161000 ↗	Unilateral left
419465000 ↗	Unilateral right
They have been superseded, probably by	
7771000 Left	
24028007 Right	

b. Insufficient guidance and vocabulary support for ePDF DICOM objects ®

- i. In order to support clinically critical results derived from diagnostic tests that have been represented as *DiagnosticReport* Resources. *This is a fundamental issue we encountered in authoring our IG to meet the needs of the use case requirements; equally, once addressed, this represented one of the most significant and novel achievements of the connectathon.* There were a number of matters identified -
- ii. First, regarding the diagnostic tests identified as highest priority for IG *DiagnosticReport* Resource / value set definition in preparation for this connectathon, particularly given the frequency of use and modern clinical indispensability, there were substantially insufficient existing appropriate codes and coordination guidelines contained within mainstream clinical terminology and implementation vocabularies and documentation (eg - Loinc, SNOMED, IHE) etc [6–8].
1. Hence, for each of the investigations enumerated below, unique value sets were created to fill this gap, coded into the IG and successfully tested and validated during the connectathon. These value sets contained a combination of existing (sometimes multiple) vocabulary references, in addition to new codes created where needed.
 2. In any event, there was no existing comprehensive guidance for how this compiled information can and should be universally represented in FHIR format so that it can be interoperably exchanged and combined with clinical data. Enabling this functionality enhances clinical care quality and workflow, biomedical research and will serve as a critical underpinning to ophthalmic artificial intelligence (AI) tools that draw upon inputs *both* clinical and imaging data, that produce outputs that can equally be consumed by a variety of digital systems.
- iii. Second, it was also noted that, perhaps due to this noted ‘guidance gap’, there was inconsistent and / or absent availability of ePDF DICOM ® objects routinely produced and made accessible by industry for the aforementioned key diagnostic tests.
1. Hence, as highlighted in the “*notable achievements*” section of this document, a novel accomplishment was the compilation of an ePDF report of an OCT RNFL.
- iv. It should be noted that one important diagnostic test that was not brought into these clinical scenarios does have an ePDF - biometry

4. **Unique patient identification**

- a. This issue was discussed, but we note that this critical issue is currently being addressed by FHIR's [Patient Administration](#) work group
- i. The R4 *Patient* Resource notes that “fields vary widely between jurisdictions and often have different names and value sets for the similar concepts, but they are not similar enough to be able to map and exchange.”
 - ii. According to the [US core Patient profile](#), the following data-elements must always be present, or must be supported if the data is present in the sending system. They are presented below in a simple human-readable explanation. Profile specific guidance and examples are provided as well. The Formal Profile Definition below provides the formal summary, definitions, and terminology requirements.
 1. Each Patient must have:
 - a. a patient identifier (e.g. MRN)
 - b. a patient name
 - c. a gender*
 2. Each *Patient* must support:
 - a. a birth date
 - b. an address
 3. Additional USCDI v1 Requirements
 - a. Each Patient must support the following additional elements. These elements are included in the formal definition of the profile. The patient examples include all of these elements.
 - i. contact detail (e.g. a telephone number or an email address)
 - ii. a communication language
 - iii. a race
 - iv. an ethnicity
 - v. a birth sex*
 - vi. previous name
 - vii. Suffix
 4. Additionally, commissioned by the ONC, [FAST](#) (FHIR at Scale Taskforce), is also addressing the matter of unique patient identification
 - iii. Note: in the Australian context, a *Patient* StructureDefinition provides a structure, guided by the below, but this profile does not force conformance to core localised concepts. It enables implementers and modellers to make their own rules.
 1. Common data elements within the *Identifier* Resource
 - a. Individual Healthcare Identifier (IHI)
 - b. Medicare Card Number
 - c. Department of Veterans' Affairs (DVA) Number
 - d. Health Care Card Number, Pensioner Concession Card Number, Commonwealth Seniors Health Card Number
 - e. Medical Record Number - ABN scoped, HPI-O scoped
 - f. Private Health Insurance Member Number
 2. Additional extensions:
 - a. Birth Place (Core Extension)
 - b. Indigenous Status

- c. Closing the Gap registration
- d. Mother's Maiden Name (Core Extension)
- e. Interpreter Required (Core Extension)
- f. Date of Arrival in Australia
- g. Ethnicity
- h. Gender Identity (Core Extension)
- i. Patient.birthDate: Birth Time (Core Extension)
- j. Patient.birthDate, Patient.deceasedDateTime: Date Accuracy Indicator

5. Unique identification of a healthcare provider or service

- a. This issue was discussed, but note that it is currently being addressed by:
 - i. This issue was discussed, but we note that this critical issue is currently being addressed by FHIR's [Patient Administration](#) work group
 - 1. According to the [US Core Practitioner StructureDefinition](#)- each *Practitioner* must have:
 - a. An identifier which must support an NPI if available.
 - b. A name
 - 2. Note, in Australia, a [provider directory](#) is defined in the AU base profile as an identifier that defines a "Medicare Provider Number in an Australian context" - this [code system](#) defines numerous extension value sets, including the Medicare Provider Number directory and the AHPRA registry (Australian Health Practitioner Regulation Agency Registration Number)

7. Now what?

1. **IG updates** (denoted above by **(IG amendment)**) determined by the issues identified in the connectathon
 - a. Address all aforementioned issues noted (particularly as outlined in section 6 - 'discovered issues') prior to the September ballot submission with sufficient time to receive adequate feedback from the participating community, including all collaborating multidisciplinary contributors and vendors; in addition -
 - i. Include/reference all contributions / acknowledgements in a distinct section of the IG
 1. Include relevant additional endorsing peak ophthalmic medical organizations
 2. Continue to bring increasing stakeholders within the ophthalmic community into the conversation for endorsement, review, contribution and most importantly - implementation
 - ii. Add and update relevant clinical and technical commentary / content to IG
 1. For a certain profile, place this in the 'text summary' table
 - iii. VF Observations - haven't specified how to report the numerical data (% , fraction etc)
 - iv. Address the laterality extension to reflect updated SNOMED codes (eg - unilateral, left → left)

PROPERTY	VALUE
System	http://snomed.info/sct
Code	7771000
Fully specified name	Left (qualifier value)
Preferred	Left
Synonym (acceptable)	Lt - Left
	Levo-
	Left side
	Left lateral
	Left
Effective Time	20020131
Primitive	true

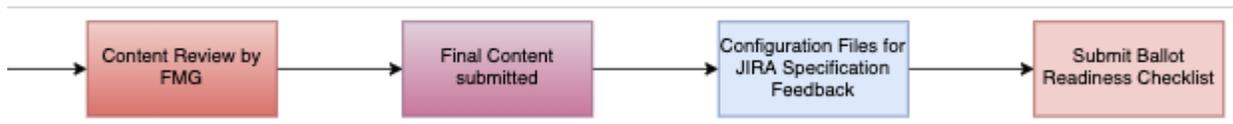
PROPERTY	VALUE
System	http://snomed.info/sct
Code	419161000
Fully specified name	Unilateral left (qualifier value)
Preferred	Unilateral left
Synonym (acceptable)	Unilateral left
Effective Time	20180731
Primitive	false
Inactive	true
Module ID	900000000000207008

Possibly Equivalent To	7771000
Inactivation Reason	Ambiguous

2. Proceed successfully to ballot September '21

In addition to making updates recognised in the connectathon, the next steps to do so are →

1. Complete NiB by due date
2. Present to PCWG (Friday 30 July) prior to September ballot for review and address any suggested amendments necessary to proceed to ballot with PCWG sponsorship (see “Sept ‘21 ballot update documentation”)
3. Submit IG to FMG by the 12th of August with all issues addressed and QA performed
 - a. Complete checklist found in [this](#) link to the ballot submission confluence page (which also outlines the steps required for ballot submission)



3. Outward terminology update recommendations:

- a. SNOMED
 - i. IOP methods:
 1. Add to parent “391932009” (Tonometer), the following conceptual child codes for -
 - a. “Rebound tonometry” - as a concept, with children:
 - i. In office, eg -
 1. “Icare”
 - ii. Remote, eg -
 1. “iCare-home”
 - b. “Dynamic Contour”
 - c. “Contact lens”
 - i. Triggerfish
 - ii. Anatomical regions
 1. Retinal nerve fibre layer
 2. Macula
 - iii. Tests
 1. Visual field: *fixation losses*

- b. IHE (Integrating the Healthcare Enterprise) - Key Measurements in DICOM® Encapsulated PDF [6]
i. Recommend to update the following report contents -

1. OCT RNFL

a. Currently:

Code Value (0008,0100)	Code Meaning (0008,0104)	Definition
400400	Retinal nerve fiber layer average thickness	Average measurement approximating the distance related to the structure between the internal limiting membrane (ILM) and the outer border of the retinal nerve fiber layer (RNFL) in all regions, as microns.
400401	Retinal nerve fiber layer inferior thickness	Average measurement approximating the distance related to the structure between the internal limiting membrane (ILM) and the outer border of the retinal nerve fiber layer (RNFL) in the inferior region, as microns.
400402	Retinal nerve fiber layer superior thickness	Average measurement approximating the distance related to the structure between the internal limiting membrane (ILM) and the outer border of the retinal nerve fiber layer (RNFL) in the superior region, as microns.
400403	Retinal nerve fiber layer temporal thickness	Average measurement approximating the distance related to the structure between the internal limiting membrane (ILM) and the outer border of the retinal nerve fiber layer (RNFL) in the temporal region, as microns.
400404	Retinal nerve fiber layer nasal thickness	Average measurement approximating the distance related to the structure between the internal limiting membrane (ILM) and the outer border of the retinal nerve fiber layer (RNFL) in the nasal region, as microns.
400405	Retinal nerve fiber layer symmetry	Percent symmetry of the retinal nerve fiber layer (RNFL) thickness between the two eyes, as percent.

b. Suggest including (at least):

- i. Conceptual parameters from LOINC panel 86291-2 (linked [here](#)), which references 21 parameters for each eye (42 total)
- ii. Additional parameters routinely calculated and produced on a static PDF report by major vendors

2. OCT macula

a. Currently (note - these are LOINC code references):

LN	57109-1	Macular Grid Center Subfield Thickness	microns
LN	57118-2	Macular Grid Total Volume	millimeter cubed

b. Suggest including (at least):

- i. Conceptual parameters from LOINC panel 57119-0 (linked [here](#)), which references 11 macular measurement parameters
- ii. In addition to this, the Heidelberg DICOM conformance statement has 22 key measurement values

- c. USCDI (United States Core Data for Interoperability) - recommend that the mandatory (must support) data elements include the ophthalmic data contained within the Ophthalmology FHIR® Implementation Guide

- i. Recommendations can be submitted through the USCDI ONDEC (ONC New Data Element and Class) Submission System - linked [here](#) - reviewed and updated annually

4. Other upcoming activity

a. September cycle connectathon;

- i. Test and validate additional profiles created for additional use cases
- ii. Deepen connectivity and participate in connectathon activity coordinated by the following Working Groups and HL7® accelerators:
 1. Work Groups: DICOM 20 / Imaging Integration; Patient Administration
 2. Accelerators: Gravity (SDoH); Vulcan (translational research); Argonaut (SMART apps, bulk API etc.

HL7 FHIR Connectathon 27:
Ophthalmology track - Report Out

- b. Explore expansion of accomplishments to date either through additional offline connectathons or real world trials/pilots in test clinical environments (demonstrating bidirectional interoperable data exchange between diagnostic devices and EHRs)
 - i. Real world testing is planned to follow with 2 large digital vendors at a large US-based AMC
- c. Continue to develop IG to support our additional use cases
- d. Seek funding to accelerate activity
- e. Implementer engagement; explore utilizing this guide practically (presuming passes through the ballot successfully) to build out e.PDF DICOM structured reports for OCTs utilizing DiagnosticReport
- f. Expand device types in IG (eg - include biometry)
- g. Explore Artificial Intelligence applications (see here: FHIR[®] - DICOM integrated proposed workflow solution for a real world deployment of algorithms requiring both imaging and clinical/demographic inputs)