

HL7® FHIR® Implementation Guidance Checklist

This checklist is intended for CDC programs to assist in navigating available resources for the adoption of HL7® FHIR® standards and API-based approaches to interoperability. The resources listed are meant to be used as guidance to ensure CDC programs are taking advantage of existing HL7® FHIR® standards and other resources to reduce implementation burden and ensure key questions and considerations are addressed before choosing to develop a new resource or IG.

This checklist assumes that these efforts are planning to conform to or be aligned with the Cures Act Final Interoperability Rule and to use Health IT (e.g. EHR systems) certified by the ONC Health IT Certification Program

- Final Rule: <https://www.healthit.gov/curesrule/>
- Conformance Testing and Certification: <https://infernophl.com/inferno/>

Implementers should evaluate their data exchange requirements for consistency and alignment with the US Core Data for Interoperability (USCDI) data elements updated by ONC yearly:

- O USCDI versions: <https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>
- O The USCDI is represented in FHIR as the “FHIR US Core Implementation Guide” using provided profiles and extensions: <http://hl7.org/fhir/us/core/> (current version)

- Standards Version Advancement Process (SVAP): <https://www.healthit.gov/isa/standards-version-advancement-process>
- Interoperability Standards Advisory (ISA): <https://www.healthit.gov/isa/>

In addition to FHIR US Core, FHIR Accelerator projects have started to develop IGs, profiles, and extensions that may be applicable to future national requirements and certification criteria:

- HL7 FHIR Accelerator Program: <http://www.hl7.org/about/fhir-accelerator/>

It is important to meet all requirements for gathering and systematic documentation and what available templates are available for current use before moving forward in the creation of a new Implementation Guide. Please take the necessary steps and research within this document to ensure these needs are met before moving forward.

REQUIREMENTS GATHERING AND PREPLANNING

Note: During this analysis you may identify specific capabilities that are out-of-scope for your API or intended to be part of future requirements. You may also identify an existing data exchange that can be re-purposed, have a second form of use, or be extended to meet your needs. See <http://www.fhir.org/guides/registry/> to search existing FHIR IGs.

- Identify the community of interest (COI): business champions, domain users, interoperability subject matter experts, clinical, administrative, and terminology experts, and other potential stakeholders;
- Describe problem/need that will be met by the implementation of the FHIR IG.
- Collaborate with the COI to describe the benefits that will accrue to patients and practitioners who use the health IT systems that produce or consume information using APIs. Consider return-on-investment; policy barriers or facilitators.

Note: Do not start an IG without identifying a COI with support from business modeling expertise, and interoperability expertise.
- With the assistance of the COI, define the business and interoperability requirements; prepare use cases.

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- Identify health IT system types and their roles to produce or consume information.
- Describe the interoperability scenarios or workflows that define how information exchanges are initiated. These triggers must be consistent with FHIR Exchange Module;

Note: It is recommended that the FHIR Release 4.0.1 or later should be used to scope out the project.
- For each use case, describe the information exchange and acceptance criteria for a successful exchange.
- Determine how successful interoperability will be measured.
- Identify a project facilitator with expertise in HL7 project initiation, balloting, and reconciliation.
- Identify a profile and IG modeler with experience in one or more of the FHIR IG development tools.
- Identify regulations when considering the clinical workflows
- For each information exchange, identify the mandatory data elements used as input or created as an output.

Note: As you analyze your requirements, harmonize them with the USCDI to ensure alignment. If alignment is not possible you may identify issues that need to be addressed by the HL7 FHIR Core. Pay attention to any data elements that are mandatory but do not appear in USCDI. For these data elements you need to identify the structure, data type, and terminology, if applicable.
- To facilitate planning, review the FHIR Implementation Guide Process Flow at <https://confluence.hl7.org/display/FHIR/FHIR+Implementation+Guide+Process+Flow>.

PREPARATION

- What is the plan to increase adoption of this new HL7® FHIR® standard (e.g., incentive policies, cooperative agreement requirements)?
- Determine the purpose/need for interoperability
- Determine the information to be exchanged.
- How will we measure interoperability?
- Determine the cost to hospitals and providers.
- Can data be derived from existing workflows and operations rather than require a custom data collection?
- Can data be inferred from other activities that are already recorded?
- Determine the costs to keep this running.
- Can an existing data exchange be re-purposed or have a second form of use? Can you extend an existing exchange to meet your needs?
- Are there any policy barriers for implementing the HL7® FHIR® standard?
- Determine the plan to increase adoption of this new HL7® FHIR® standard (e.g., incentive policies, cooperative agreement requirements)?
- Check for existing specification IGs to help determine if a new IG is needed/How you may use API's in an architecture? <https://build.fhir.org/ig/FHIR/ig-guidance/best-practice.html>
- Can you utilize existing FHIR Profiles that EHRs and other systems may already be producing, e.g. FHIR US Core? This reduces your barriers to adoption /Check for content IG's: https://wiki.hl7.org/FHIR_IG_Framework
- Check for additional resources to see if they align with the scope

DETERMINE THE PURPOSE OF DATA EXCHANGE

Once you complete your requirements analysis you may evaluate existing implementations to determine whether your project can reuse, expand, or constrain existing FHIR implementation guides that were balloted and published by HL7 as Standard for Trial Use (STU) or Normative specifications: <http://www.fhir.org/guides/registry/>

INITIATE A NEW HL7 PROJECT

Note: Before initiating a new Implementation Guide, please check make sure data are currently not flowing (or soon to flow) through regulated APIs, CCDs, ADT feeds, etc. You should also consider a cost-benefit analysis and opportunity cost of developing a new implementation guide.

FHIR IGs may be balloted using the HL7 development process. A new Project Scope Statement (PSS) is required to start a new FHIR IG project that will result in a balloted specification.

- Identify an HL7 work group that focuses on the same domain as the IG or project (e.g. Medications would be addressed by the Pharmacy Work Group, Transfer of Care would be addressed by Patient Care Work Group). There is a list of Work Groups and a link to their respective Confluence Pages here: <https://confluence.hl7.org/>

Note: If your IG is intended to expand FHIR APIs in the US, the Cross-Group Projects Work Group (<https://confluence.hl7.org/display/CGP/Cross-Group+Projects+Home>) may need to be involved. The US Realm Steering Committee can provide guidance to US-based projects.

- Draft a PSS using the HL7-provided guidance: <https://confluence.hl7.org/display/PSS>
Note: Typically, a FHIR IG is balloted as a “Standard for Trial Use” (STU) to ensure the experience of implementers can be added to the IG prior to its Normative status.

- Follow the HL7 process to create a ballotable FHIR IG that can be approved; see

<https://confluence.hl7.org/display/FHIR/Designers>

<https://build.fhir.org/ig/FHIR/ig-guidance/best-practice.html>

<https://confluence.hl7.org/display/FHIR/Home>

<https://confluence.hl7.org/display/FHIR/Designers>

- Address terminology gaps by reaching out to HL7 Vocabulary or HTA, Regenstrief, or the National Library of Medicine.

Note: Terminology should be defined and approved through the vocabulary maintenance process with the vocabulary Work Group;

<https://confluence.hl7.org/display/VOC/Vocabulary+Work+Group+and+the+HL7+Terminology+Authority> <https://confluence.hl7.org/display/TA>

AUTHORING TOOLS

- Visit the Confluence pages listed here:

<https://www.hl7.org/fhir/downloads.html>

<https://confluence.hl7.org/display/FHIR/Home#a0c8f2d8-9087-48ba-8b78-49a16dd5bc2f-35718280>

<https://confluence.hl7.org/display/FHIR/FHIR+Tooling+Ecosystem>

- Sign up to the FHIR Committers Zulip chat at <https://chat.fhir.org/#narrow/stream/committers>

- Register on <https://chat.fhir.org> to be able to ask for help from the FHIR Community.

- Terminology Capabilities <https://hl7.org/fhir/terminologycapabilities.html>

- MITRE provides FHIR SUSHI (<https://fshschool.org/docs/sushi/>) tools for FHIR IG development using HL7® FHIR® Shorthand: <https://build.fhir.org/ig/HL7/fhir-shorthand/>

- Forge + Simplifier.NET- Windows application for authoring HL7® FHIR® profiles:
<https://simplifier.net/>
 - Trifolia-on-FHIR, is a free, web-based, open source tool for creating HL7® FHIR® profiles and IGs
 - To validate your IG you may use the FHIR IG validator :
<https://confluence.hl7.org/display/FHIR/Using+the+FHIR+Validator>
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EXPLORE HL7® FHIR® RESOURCES & EXTENSIONS

- Cures Act Final Rule webinars: <https://www.healthit.gov/curesrule/resources/webinars>;
 - Cures Act Final Rule fact sheets: <https://www.healthit.gov/curesrule/resources/fact-sheets>;
 - Check for content IG's: https://wiki.hl7.org/FHIR_IG_Framework
 - Check for existing specification IGs to help determine if a new IG is needed:
<https://build.fhir.org/ig/FHIR/ig-guidance/best-practice.html>
 - Reference HL7® FHIR® Getting Started Link: <https://hl7.org/fhir/modules.html>
 - HL7® GitHub Web page: <https://github.com/CDCgov>
 - Examples of balloting: <http://hl7.org/fhir/us/vrdr/2019May/>
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CONFORMANCE AND PROFILING REFERENCES

- Check System Profile, Use-cases Profile, and Check Global Profiles
 - Identify what other related profiles exist in other IGs
 - HL7 Downloads <https://www.hl7.org/fhir/downloads.html>
 - HL7 Profiling Link: <https://www.hl7.org/fhir/profiling.html>
 - EPIC HL7® FHIR® Tutorial: <https://fhir.epic.com/Documentation?docId=fhir>
 - Using Profiles: <http://hl7.org/fhir/uv/cpg/2019Sep/documentation-profiles.html>
 - Profiling HL7® FHIR®: <http://hl7.org/fhir/R4/profiling.html>
 - Extension Registry: <http://hl7.org/fhir/STU3/extensibility-registry.html>
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HL7 IG REVIEW

- Apply the FHIR IG Checklist (<https://confluence.hl7.org/display/FHIR/FHIR+IG+Review>) during IG development and prior to formal reviews and publication. Key areas of concern:
 - Check clarity and appropriateness of purpose, realm, and dependencies.
 - Check notes to balloters/readers, history and quality report (qa.html).
 - Check the actors and exchange protocol(s) for alignment with the business needs statements.
 - For all profiles and extensions check: search, conformance, slicing, terminology binding and strength, cardinality, definitions and comments.
 - Check for valid and comprehensive Capability Statement.

- Check for a Must Support definition, correct inheritance and usage within profiles.
- For all new terminology ensure the need then check: copyright, version and registration in the HL7 Unified Terminology Gateway (<https://build.fhir.org/ig/HL7/UTG/>).
- Check for business appropriate Privacy and Security guidance and requirements.
- Check for relevance and completeness of examples.
- Submit all gathered work for the proposal of the new or recreated IG to the appropriate parties before submitting for a ballot.

TESTING REFERENCES

- HL7® Connectathon: <https://confluence.hl7.org/display/FHIR/Connectathons>
 - IHE Connectathon: <https://www.iheusa.org/>
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HOW TO GET INVOLVED?

- Become an HL7® member [here](#).
 - Join the CDC HL7® FHIR® Community of Practice
 - Join the HL7® FHIR® chat <http://chat.fhir.org> (Sometimes referred to as “Zulip”)
 - Build a community through HL7 Work Groups.
 - Subscribe to the HL7® FHIR® Foundation Calendar (<http://www.fhir.org/calendar>)
 - Watch #FHIR on twitter
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OTHER RESOURCES

- EPIC HL7® FHIR® Tutorial: <https://fhir.epic.com/Documentation?docId=fhir>
- Cerner SMART on FHIR Tutorial: <https://engineering.cerner.com/smarter-on-fhir-tutorial/#introduction>
- Mapping Tutorials: <https://www.hl7.org/fhir/mapping-language.htm>
- National Academy of Medicine Special Report on Procuring Interoperability: <https://nam.edu/event/procuring-interoperability-special-publication-webinar/>