The FHIR for Jurisdictions Handbook

A Practical Guide to Developing FHIR Standards for your Country

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1.1 Why and how is this whitepaper useful?

HL7® FHIR® (hereafter simply "FHIR") has become a ubiquitous requirement for Health IT systems. Since the first ideas about FHIR were originated by a small group of visionaries within HL7, the not-for-profit global Standards Development Organization (SDO) and owner of FHIR, back in 2011, thousands and thousands of care providers, vendors, governments, software developers around the world consider FHIR to be key to solving or at least decreasing the "interoperability gap". This whitepaper sheds light on how to successfully implement Fast Healthcare Interoperability Resources (FHIR) within a "jurisdiction". A jurisdiction refers to regional or national bodies that are responsible for driving interoperability within their realm.

1.2 The do's, don'ts and best practices for developing FHIR standards for a specific realm

FHIR is a very forgiving standard. It allows adjustment to any use case by defining data models based on the core specification and extensions to this core specification. The upside of this built-in mechanism is the flexibility and broad application of the standard. The downside is that FHIR can introduce its own incompatibilities. That's why SDOs create guidelines, building blocks and standards to maintain a high level of interoperability within the use of FHIR in their realm or even between realms. These SDOs are typically HL7 Affiliate organizations or government agencies that are often linked to a country's Ministry of Health. This whitepaper is a window into how pioneering SDOs have ventured on this journey.

1.3 This whitepaper is useful for you if you are...

This whitepaper is useful for anyone involved in building FHIR specifications for their country. The focus is on practical application rather than on policy making. We expect readers with various backgrounds to be interested, such as:

- Active members of HL7 Affiliates[1]
- Project members, like standards experts, project managers, consultants and clinicians, who contribute to interoperability projects driven by the government or an SDO
- Industry representatives who depend on these national projects and who want to influence the outcome by participating in the development of FHIR standards
- Policy makers who want to understand the day-to-day business of standards development as a background for policy making

The focus of this whitepaper is on the practical implementation of FHIR standards rather than the policies and strategies regarding interoperability.

1.4 UK and Germany as exemplary jurisdictions

For this whitepaper we asked major players in the FHIR community to share their experiences and learnings on FHIR development within their jurisdictions. For the UK, we have asked David Crampin, FHIR Product Owner, and Kevin Sprague, Interoperability Team Lead at NHS Digital, to give their input on nationwide standards development. NHS Digital is the public body within England's National Health Service. They design and develop national IT and data services to support clinicians at work, help

[1] An HL7 Affiliate is a national branch of the HL7 International umbrella organization, responsible for HL7 standards in their realm.

patients get the best care, and use data to improve healthcare. NHS Digital has been one of the driving forces behind the development of the UK Core FHIR specification.

Simone Heckmann of **HL7 Germany** has also provided her expert insight in her role as the lead of the technical committee for FHIR. HL7 Germany is the country's HL7 affiliate and works on the promotion and dissemination of the HL7 FHIR standard in Germany. They focus on the further development of the standard based on German requirements, including the development of Implementation Guides (IGs) and other specifications, as well as training for users and system vendors. Simone founded the technical committee for FHIR back in 2015. Since then, she has been reelected as the chair of the committee. She is responsible for the development and maintenance of the German base profiles. Besides her involvement with HL7 Germany, she is also currently the Chief Technology Officer (CTO) at Gefyra.

Last but not the least, we are also contributing our expertise in implementing FHIR for jurisdictions. The team behind Firely has been heavily involved in the creation of the FHIR standard itself and continues to contribute to its development. Firely is also the creator of Simplifier.net, the leading HL7 FHIR development and collaboration platform. You can find the national base profiles for the following pioneering countries on Simplifier.net:

- United Kingdom: NHS Digital and HL7 UK
- Germany: HL7 Deutschland e.V.
- Netherlands: Nictiz
- Finland: Kanta / HL7 Finland
- Canada: Canadian FHIR Registry
- France: HL7 France and IHE France (part of Interop'Santé)
- Argentina: HL7 Argentina + DNSIS - Argentina
- Norway: HL7 Norway
- Poland: HL7 Poland
- New Zealand: New Zealand FHIR Registry
- Israel: Israeli Core

We have added our own observations from working with these and other HL7 affiliates, Ministries of Health and other SDOs from all over the world.

2 A practical roadmap for developing FHIR standards for your jurisdiction

In the world of FHIR a jurisdiction typically refers to a country. We will walk you through the entire lifecycle of a FHIR specification for a jurisdiction. The lifecycle begins by first setting up the right organizational structures. Once set up, it's time to define the use case for FHIR. Next you move into the exciting phase of developing FHIR resources and documentation and then to the publication and adoption phase. Let's go through each stage in more detail.

2.1 Setting up the organization

Before developing anything, it is adamant to assemble the right team within your organization and create a support group that represents the full diversity of your jurisdiction.

The development of a standard for a jurisdiction is a highly collaborative process. However, a *core team* with a high level of FHIR expertise is generally useful for developing a consistent data model that is aligned with the best practices in the industry. The team should have a combined expertise of stakeholder management, FHIR development and clinical practice. This team can be organized as the technical working group from the national HL7 Affiliate, like the 'Technisches Komitee FHIR' from HL7 Germany. It can also exist within an organization affiliated with the ministry of health, like Nictiz for the Netherlands or NHS Digital and its national counterparts in the UK.

Apart from the core team, it is common to hire HealthTech consultants with extensive experience in FHIR to contribute to the execution. Firely works with many standards organizations across the globe to give their specifications a strong foothold by aligning them with the best practices and latest developments from the FHIR community. Finally, it is highly recommended to assemble a sounding board composed of leaders from across the healthcare landscape. This board can provide feedback in all stages of development. They can supplement the knowledge of the core team and ensure buy-in from the wider community. While a wide diversity of backgrounds will help with adoption, it is also important to select people who will benefit most from the new standard and who are also open to change.

2.2 How it started in the UK

In the United Kingdom, the NHS Digital team started to see the need for a nationwide base standard that could underpin the various standards that existed per use case. This internal sentiment, combined with the fact that they possessed the right experience and resources to see it through, gave birth to the FHIR UK Core specification. It was an initiative that the organization took on with full force.

From the beginning, the team was set up virtually so that stakeholders all across the region could contribute to its development. NHS Digital involved peer organizations from other countries in the United Kingdom to join the project, like the NHS Wales. They also invited key vendors and consultants from the industry, as well as anyone who was willing to contribute to their vision.

At first, they considered allowing everyone to make direct edits to the core FHIR artefacts, but they soon realized that in order to deliver a more focused and coherent specification, a smaller, dedicated core team would be more efficient. In order to maintain the spirit of collaboration and inclusivity they put a mechanism in place for the rest of the community to provide feedback and raise issues.

Dave Crampin stresses that: “The most important part is showing from the beginning that this is really a nationwide effort and that we are truly listening to everyone’s requests and requirements and incorporating their feedback. We try to make this very clear in our communication and branding by placing the UK Core under the management of HL7 UK.”

2.3 How it started in Germany

Meanwhile in Germany the base profiles were initiated by HL7 Germany. There were multiple national initiatives that had received funding to create data standards for various use cases in the country. HL7 Germany wanted to harmonize the most commonly used parts of FHIR among these projects. The organizations involved in these initiatives include:

- The German National Association of Statutory Health Insurance Physicians, known as Kassenärztliche Bundesvereinigung (KBV)
- Gematik, a major Healthcare IT provider
- the Medical Informatics Initiative, or Medizininformatik Initiative

HL7 Germany’s technical committee for FHIR is responsible for the German base profiles. It is a relatively loose group of everyone who contributes to the profiles and the German FHIR chat. Contributions are done on a voluntary basis, like adding improvements and asking or answering questions. Within the committee is an even smaller group of committers. Around ten people have commit-rights for the German base profiles. They are volunteers who have both the initiative and the required skills to work on them. “We sometimes ask people directly for this, when we know they would be a great addition, and sometimes people volunteer themselves”, explains Simone Heckmann. The chair and co-chair decide on who gets these rights.

3 The FHIR Development Cycle

Once the right teams are set up, it is time to start the FHIR project development cycle.

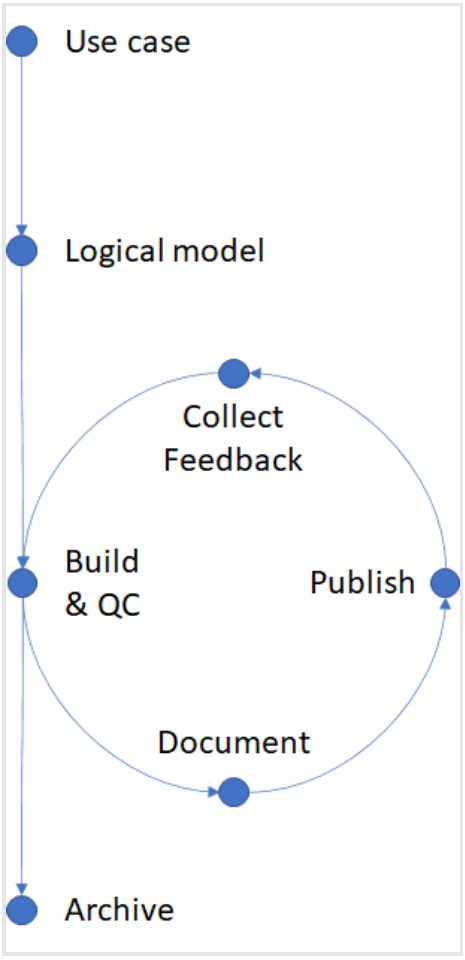

Figure 1: The life cycle of a FHIR project.

3.1 Defining the use case

The first step to developing FHIR standards is to define your use case and the short-term and long-term problems you are looking to solve. Often we'll see that Conway's law comes into play here: the organization of the implementation will reflect the way healthcare (IT) is organized in a jurisdiction. In the two jurisdictions described here, the UK has a central body (NHS England and NHS Digital) and is organized, while Germany, with its *Bundesländer*, has a federal model.

You can then simultaneously look at a top-down or bottom-up approach. In a top-down approach you select foundational data models that are standardized across use cases. In a bottom-up strategy multiple use cases are sourced from the jurisdiction's stakeholders to drive the criteria and prioritization for the base models.

For example, at Israel Core the Ministry of Health looked at international specifications, such as the US Core, to define the first set of models to take on. At the same time funding has been provided for a first

group of use cases that are willing to implement FHIR in a specific setting and guide further development of the Israel Core profiles based on these use cases.

3.2 Different approaches to the core national profiles

The UK Core started with five resource profiles in their first sprint to form a basis:
Location, Organization, Patient, Practitioner and PractitionerRole, along with other associated FHIR conformance assets such as Extension, CodeSystems, ValueSets and ConceptMaps. Based on available use cases, the team moved on to Allergy Intolerance in the second sprint and Medication and Immunization related resources in the third.

The German base profiles on the other hand, contain a very limited set of resource profiles. HL7 Germany focused on data type profiles for reuse, like identifiers that are commonly used, or a profile on the Address or HumanName data type, with typical extensions that are required in Germany.
"Over the years we have found that the full resources we created, like a profile on Patient, were not very useful. Since we didn't have a specific use case we left all cardinalities untouched, but we also added all extensions. And we found that people weren't keen on deriving from the core profiles because they were so bloated. They had to constrain all the extensions out of the profiles, so we only made their life harder," Simone Heckmann explains.

On top of data types, Simone and her team provide a registry of extensions that people can use and facilitate others to include them in their profiles. Currently the different standards organizations in Germany each have their own Patient profiles without a common German ancestor, but because they reuse the same German data types and extensions they are still very similar. Terminology is also a big topic in the context of national guidance, including which code systems and value sets to use.

The elements to work on are brought forward by the different organizations working on FHIR, but also often come from FHIR consultants that see the same work happening in multiple places. "In such cases we offer to take it out of their hands and define it once. In most cases people are happy with this, because using a German base profile gives them a seal of approval with respect to interoperability."

3.3 Defining the logical models

More often than not, organizations begin this process to solve an interoperability problem in their area of expertise. This is the time to concretize this problem, without worrying too much about the correct FHIR resources to use. Afterwards you can formalize the workflow using process descriptions and interactions diagrams based on business analysis and knowledge from the field.
When it comes to data modeling, logical models can be developed to formally describe the data objects, their attributes, the data types and the codes and values that can be used. Logical models can be described using simple spreadsheets with, for example, a sheet per data model with a row per model attribute.

The FHIR specification also provides a structured way of capturing these generic logical models, aptly called Logical Models. These resources allow you to define a fully customized data model that is not meant for direct data exchange, but it does let you capture all data modeling requirements. It allows you to do the modeling without having to worry about which FHIR base resource would be most applicable.

Logical models in the UK

On the topic of logical modeling, Kevin Sprague shares how they first look at specific use cases as their starting point: “We started with direct FHIR use cases in NHS Digital, like medication prescribing, and then looked at their overlap. Now we are working on aligning this with the clinical models from other core information standards. We look at dimensionalities, ambiguities and things that don’t match between them and trying to line them up.”

David Crampin also talks about his experience working with logical models for FHIR: “We’ve started to use FHIR Logical Models and have recognized they bring benefits, so we are looking to use them more often where there isn’t an underlying data standard yet or create one from where there is. We are really at a point where we think a logical model is the best starting point.” Both experts agree on the various benefits of using logical models before defining the data model. Kevin Sprague further expounds, “I have found logical models are both a good starting point for technical people to define requirements, and for communication with clinical people. This can even just be a mockup of a clinical model in a spreadsheet. FHIR insists on sending some extra fields that might not be in a clinician’s original data model. But if you can look at those together, click on them and explain what they are used for, it helps in building the understanding and appreciation for why they are there.”

Lastly, David concludes: “We do have layers of separation here and I think it also has value to not build it all closely to a specific technical solution like FHIR. There is data out there and the part that can be standardized should be able to be expressed in any logical model separate from whether that is in FHIR. And then, for us as FHIR implementers it would be helpful to also have a FHIR Logical Model based on those technology-independent data models, to be specific about our modeling requirements.”

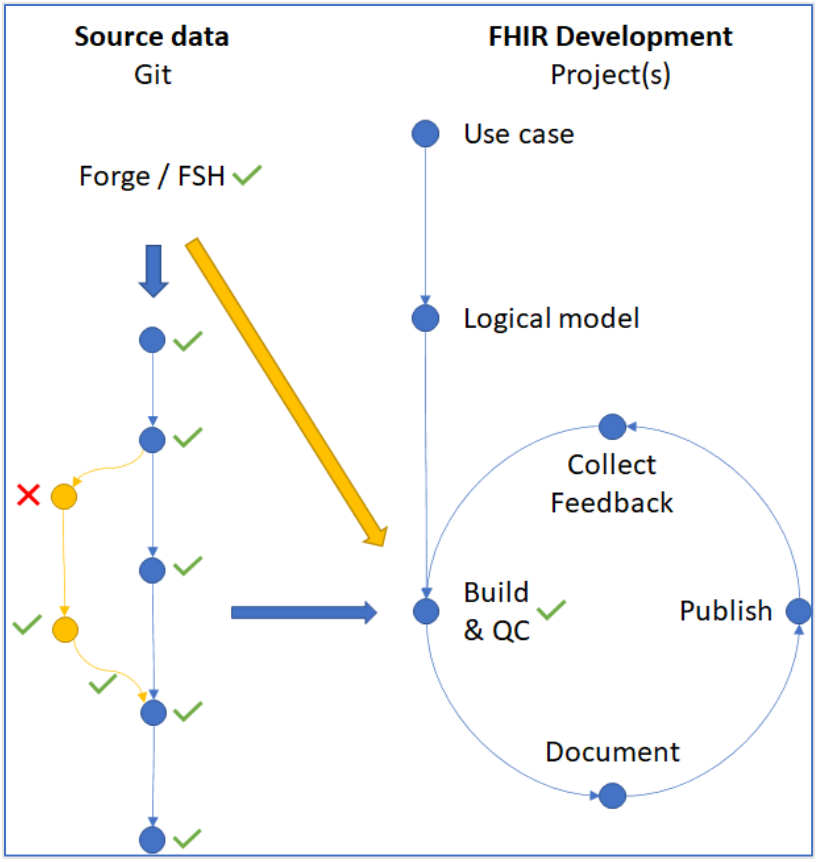

Figure 2: Development of FHIR resources.

Development of FHIR resources can be done with multiple tools and languages. The most common scenarios are creating JSON or XML resources directly in Forge, a FHIR data modeling editor, or creating FSH files with FHIR Shorthand which can then be converted to JSON and XML resources. These resources can be uploaded directly to a FHIR project or indirectly, by organizing the change and approval flow in an intermediary git repository. Quality Control can be applied to every step of this process.

3.4 Building the FHIR model

Now it's time to take the logical models and represent them as derived resources from the core FHIR specification. In this next section we will cover helpful tools for building your FHIR model, best practices in FHIR profiling and how to align with international FHIR initiatives.

Tooling and development "out in the open"

NHS Digital develops their FHIR profiles with Forge and shares this development publicly on Simplifier.net via a GitHub repository. Forge is a downloadable FHIR profile editor while Simplifier.net is the leading collaboration platform for FHIR developers, where they can share and access FHIR projects and various resources. Both tools are well integrated and support many aspects of working with FHIR, from conception to implementation. David Crampin says that, "One of the reasons we are developing on Simplifier.net is because we want to develop publicly, as part of a bigger collaborative space."

The use of GitHub, or a different git-based platform, as the storage mechanism between the FHIR profile authoring on the one hand, and publication on the other hand, is a very common workflow. Given the

text-based nature of the FHIR resources, they are better managed in a source control system that is already widely used by developers around the world, allowing for complicated scenarios like branching and merging.

HL7 Germany also uses Forge to develop their profiles, and GitHub and Simplifier.net to store and publish their ongoing developments. Sharing their development out in the open is an important point for Simone Heckmann: "When someone has a project and they have barely even started on it, I always encourage them to use a free Simplifier.net account, create a project page and just edit the description to explain what they are going to do. I tell them to add an email address so people can see that there is a group that is going to do something and they can reach out if they are working on something similar."

Kevin Sprague echoes that sentiment with, "We are definitely getting more interaction because what we build is transparent for everyone. People reach out to us by email because they find our specification online."

UI based profiling and FHIR Shorthand

Development in FHIR Shorthand is gaining popularity with standards developers because of the powerful way it allows you to write resources in common text editors and include common elements in many profiles at once. With FHIR Shorthand it is also easier to compare resources in git.

At the Israeli Ministry of Health they are combining the use of Simplifier.net and FHIR Shorthand. The Israel Core Methodology Principles explains that, "Once the model is formulated in Excel, the technical profile is written in FHIR Shorthand, and compiled with SUSHI to JSON. After validation with the FHIR server the profile is uploaded to Simplifier.net, where descriptions and examples are added."

Simone sees enthusiasm in the German community to work with FHIR Shorthand too: "In my training sessions, I always recommend everyone getting into FHIR development and those not working with FHIR every day, to use Forge. But people who are working on profiles every day and who have a clear mental model of what is in a structure and element definition can save time by using FHIR Shorthand. You can also always change your position. These things are interoperable, you can always transform FHIR Shorthand to JSON and the other way around so you are not locked into either."

Open profiling

Once the tooling infrastructure is set up, an important choice to make is how specific you need your profiling approach to be. Kevin Sprague from NHS Digital admits that it is always difficult to strike a balance between how generic or specific a profile should be. On the one hand, keeping the profiles generic means risking people sharing low quality content that is technically accepted by the validation. On the other hand, a more specific profiling approach has historically produced too many different profiles for conceptually similar use cases. For a great overview of the benefits and drawbacks of open versus closed profiling, you can check out the profiling guidelines of Nictiz, the Dutch standards organization.

So far an effective the approach is to take one concept, like medication or allergies, and then start with a generic profile with many optional attributes and extensible value sets. As more and more feedback is collected from users the profiles are tightened over time, making elements and terminology mandatory and adding "Must Support" flags where appropriate.

3.5 International FHIR standards and discovery

When trying to achieve interoperability within your jurisdiction, it is important to try and reuse what is already available internationally. This can greatly improve sharing across jurisdictions and will make the lives of vendors that work across regions much easier. Not only will it save you time reinventing the wheel, but it also avoids potential and unnecessary incompatibility between standards.
You can start by looking first and foremost at the base FHIR specification and using what is already available where possible. This includes the core FHIR resources and the common extensions available in the FHIR Extensibility Registry. Everyone is encourages to reuse or collaborate, on existing resources that have been developed by other, well-respected organizations. You can search for these on the FHIR Package Registry, which is also powered by Simplifier.net and includes all the publicly available FHIR resources in the world.

IPS and IPA
There are two FHIR specifications that are specifically under development for being reused in an international context:

- The International Patient Summary (IPS) intends to model an essential export of a patient's healthcare information from an electronic health record.
- The International Patient Access API (IPA), which describes how an application acting on behalf of a patient can access information about the patient from a clinical records system using a FHIR-based API. It has been described as an internationalized version of the US Core specification. Although it is currently still a work in progress, it already has support from large vendors and governments.

The two key markets that we have been using as an example throughout these paper, Germany and UK, are also anticipating these international FHIR specifications. In the UK, NHS Digital plans to align with the international specifications more closely. On this topic David Crampin says, "We want to increasingly reduce our differences with international standard approaches and align with the international community. There will absolutely need to be localizations for different countries, but why should international vendors working in healthcare have to implement a completely different approach everywhere."

In Germany, HL7 Germany itself is not currently looking at them since they only have a limited set of profiles in their project. However, the National Association of Statutory Health Insurance Physicians, more commonly known as the Kassenärztliche Bundesvereinigung (KBV), is presently looking at the International Patient Access API (IPA) for their Patientenkurzübersicht (PKÜ).

3.6 Quality control

Developing high quality specifications depends on the continuous validation, review and enforcement of clear profiling guidelines.

Validation
While building your specification, the tooling you use should actively support you in creating high quality content. A profiling tool like Forge will provide you with best practices and warn you whenever you are making a change that is breaking a FHIR rule or one of the parent resources. Command line tools like Firely Terminal, SUSHI and the IG Publisher will output detailed quality reports and can be combined to

provide a wide arrangement of assurances. With an automation framework like GitHub Actions, pipelines like the Firely Terminal pipeline can be run on every commit and pull request in your source control.

On top of validation against the core FHIR specification, validation of example data against your specification is essential to ensure it behaves as intended. Examples are widely used by implementers to base their own work on, so it is most convenient that validators like the Java or .NET validator will validate conformance to every profile an example claims to conform to. With unit testing in Quality Control you can even create 'negative examples' that are deliberately designed to test whether your profiles exclude behavior you are looking to prevent.

Profiling guidelines

Developing valid FHIR specifications is the first bar to clear, but on top of that you are also looking for consistent implementation within your jurisdiction according to the custom rules you have agreed on.

Ardon Toonstra, a FHIR consultant at Firely, is deeply involved in the FHIR development at the Dutch standards organization Nictiz. He always recommends his customers to start by writing down their profiling guidelines. The profiling guidelines for Nictiz are available online for FHIR R4 and STU3 and cover jurisdiction-specific decisions on versioning, naming conventions, slicing and much more.

NHS Digital has also defined their own profiling guidelines and formulated them in a UK Core Design and Development Approach, Implementation Guide. These rules include high-level data modeling guidelines like "never remove an element, unless it is agreed upon across the UK", or "make sure that extensions are only made for data items that are not in in the FHIR standard yet." The team makes sure to review these guidelines against any data models that are added to the project.

Besides manual validation, Quality Control also allows you to automatically check many of these custom profiling guidelines by formulating them as FHIRPath rules. Running these checks in every step of your development ensures not just FHIR compliance, but also consistent, high-quality specifications.
This is what HL7 Germany learned in the process. They used to write their style guides in documents but have added these rules as quality checks in their pipelines. The HL7 affiliate runs both the .NET validation and the Java validation using the Firely Terminal pipeline in GitHub Actions. According to Simone Heckmann, "Whenever we encounter an issue post-release, like 'Oh, there is a version missing here or a context missing on an extension', we add that as a step to our quality control rules."

Test server

An additional step you can take to make sure the API specification behaves as intended is to set up a test FHIR server in which any newly released specification can be tested. You can easily install a HAPI or free trial instance of Firely Server as a Docker instance and load it with a published (or in development) specification to test against a live FHIR API.
You could even go one step further and create a series of tests to validate whether a FHIR server has correctly implemented your specification. Nictiz does this to certify Personal Health Environments for the correct implementation of the MedMij standard. Some popular platforms for doing this are Aegis' Touchstone and MITRE's Crucible.

Document your model

Adding quality documentation to a great data model and API model will bring you one step closer to the right implementation. Every Simplifier.net project already gives you a large amount of visualizations for every resource without any additional work but to provide full guidance, the FHIR community leverages Implementation Guides (IG). There are three main ways to create these informational websites:

- Using the IG Publisher command line tool, as seen in the US Core Implementation Guide
- Using the interactive Guide editor in Simplifier.net, as seen in the Implementation Guide for Digital Medicines by NHS Digital
- Or a custom website as seen in the MedMij FHIR Implementation Guide by Nictiz.

Simone Heckmann talks about her experience working on Implementation Guides using Simplifier.net. "What I like about Implementation Guide development on Simplifier.net is that it makes the editing accessible for people who have no technical understanding of how FHIR works or how the tooling works. They do have domain know-how or know about a specific terminology. We can easily onboard people who are not FHIR experts and say: You can write this part of the Implementation Guide. Even for things as simple as spellchecking, so they don't need to report an issue for each typo they find. That is taking a lot of work off everyone's plates."

NHS Digital is using two ways of publishing their guides. Kevin Sprague explains, "For STU3 we still generate documentation on our GitHub Pages, for R4 we create and publish them on Simplifier.net."
The team that works on this is largely the same as the development team: technical modelers and FHIR developers with input from clinical and terminology teams. "They all had technical authoring training. The most important part is that their writing is human-readable, clear and precise."
All Implementation Guides developed by the team use either the UK Core or NHS Digital master template, which can be copied to start new guides. David adds, "This serves two purposes: To align new developments with the rest, but also to have something we can keep on improving over time to improve our documentation across the board."

For both Germany and the UK, deploying these out in the open from the beginning helps to convey the message that the development is open to everyone.

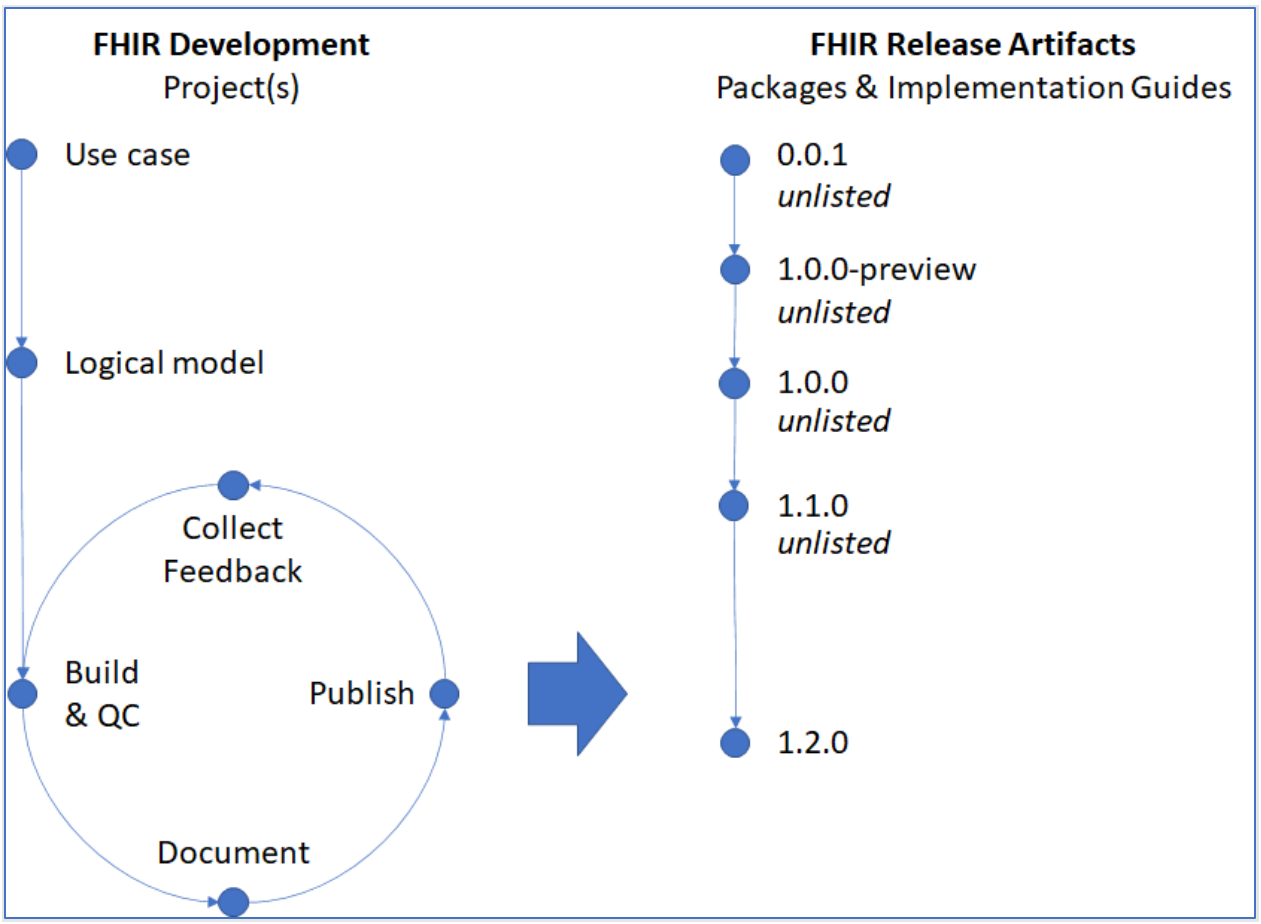

Figure 3: Development versus stable versions

FHIR development projects can publish stable versions of their FHIR resources, called a FHIR package, and their documentation, called Implementation Guides. These versions are stable artifacts that customers can build and depend on because they will always remain available and never change. Authors can indicate when they should no longer be used by "unlisting" older versions.

3.7 Publish your first drafts

It is generally recommended to keep your FHIR development transparent from the very beginning. However, once your specifications are ready to be tested by others it is good practice to give the test team a stable release to work with. In the FHIR world, this is done with FHIR packages. Packages are a version of your specification that are frozen in time and that will always be around for users to use and build on. Using a version number, the author is able to set an expectation of the maturity and by unlisting a specific version, the author can recommend against its further use. In a similar manner, accompanying documentation will refer to specific published versions of a FHIR specification to provide stable documentation over time.

At NHS Digital, Kevin Sprague says that, "We used to publish our releases to an internal website with links to individual resources on a FHIR server. That didn't work in the long run. Our vendors told us they would strongly prefer one package with everything they need in it. That is one of the reasons we started to use Simplifier.net, because it does the packages for us." To look further into their process, the UK

Core Design and Development Approach IG contains plenty of information in their release cycle and versioning strategy.

Meanwhile at HL7 Germany, Simone Heckmann says that, “Simplifier.net has grown into the central German FHIR repository because everyone, including the organizations above, are using it. So it makes sense to use Simplifier.net for our publications, since everyone is familiar with it and already there.” Some of these releases are also sent to the German HL7 affiliate for official balloting, serving as a formal consensus approval on the release. “We do have ballots regularly, but they used to be for-comment ballots. HL7 UK are currently running their first UK Ballot on the UK Core” (December 2021).”

4 Continuously collecting feedback

Interoperability requires your jurisdiction specification to actually be used. For this to happen it is crucial to get input and feedback from the full spectrum of implementers in your realm to learn whether the specification works for them. You can facilitate this via a structured feedback cycle, a strong community and tools that enable feedback collection.

4.1 Structured feedback cycle

NHS Digital calls this the clinical and technical assurance phase which all profiles will have to go through. Once the UK Core profiles, ValueSets and documentation have been created by the team, the resources go through a series of three meetings. These sprint reviews can be attended by anyone interested in FHIR in the UK, clinicians and (FHIR) informaticists alike.

Only during these meetings can profiles can be tightened over time. Kevin Sprague gives the handling of extensions as an example. “We don’t hardcode them in the profiles in the beginning. We just say, here are extensions you could use. But after reviewing them we agree on which ones should be there by default.”

Interested parties are invited two to three months in advance via the channels of standards organization PRSB, the INTEROPen chat app, Simplifier.net news items and more. Everyone is welcome. Currently around sixty people join and the number increases every time. Even so their biggest challenge remains, “How do we reach everyone doing FHIR within the UK?”

In the German market Simone Heckmann shares that concern. “It is easy to think you are reaching out if you send messages back and forth with a few people. But there might be hundreds more people out there who are working on a competing specification and reinventing the wheel, leading to FHIR artefacts that are not interoperable.”

Besides the aforementioned regular balloting of the Simplifier.net-based Implementation Guide for formal consensus, the German technical committee for FHIR also reaches out informally to everyone in the German channels of the publicly available FHIR chat, where people can give a thumbs-up to proposed changes.

4.2 Feedback tools

The German team uses GitHub issues to collect errors that they find or to look for suggested additions. This allows them to close these issues directly with git commits.

The UK Core collects feedback from issues directly from the Simplifier.net project, where anyone with a free account is allowed to create issues. This keeps the feedback directly linked to the concerned resource. The Clinical and Technical Assurance sprint documentation provides detailed instructions on how to add UK Core feedback.

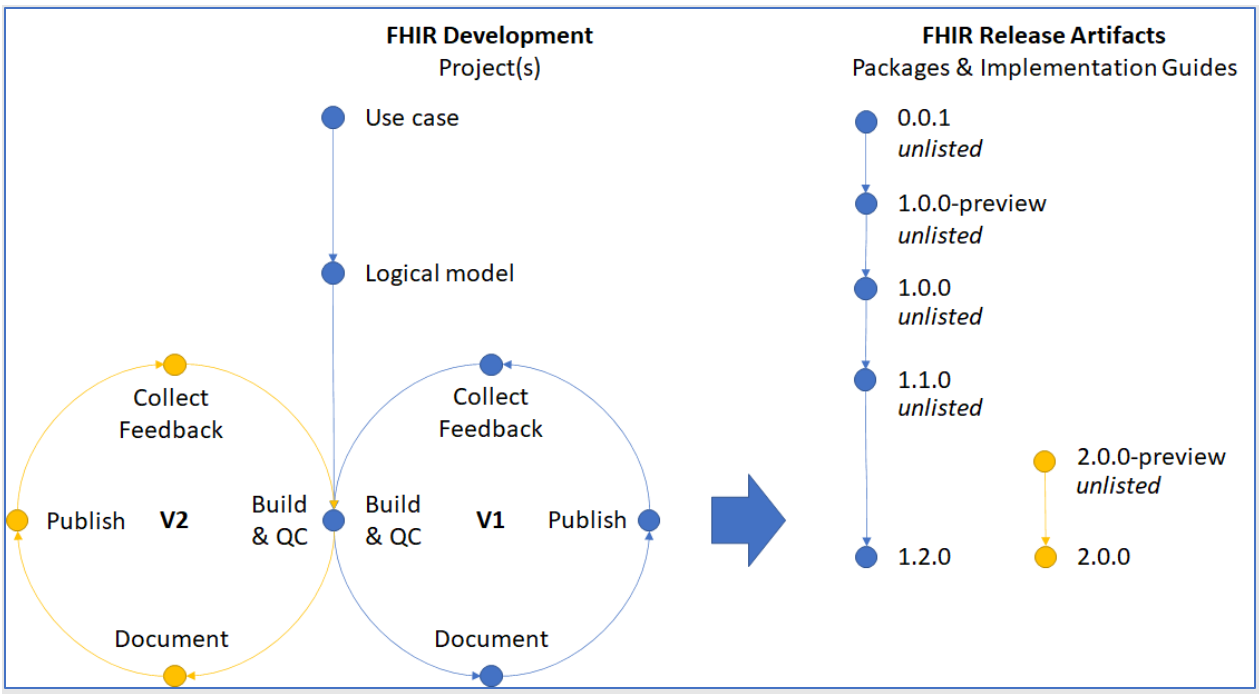

Figure 4: Parallel versions

When multiple versions of the standard need to be developed in parallel, extra development projects can be used. Both projects can be published to the same package line.

5 Long term support and breaking changes

Congratulations! Now we have completed the first full circle of our FHIR release cycle and it's time to enter the state of continuous improvement. With more uses cases and feedback coming in, we can continue to improve our data models, API models, and documentation, and release new versions to the public.

5.1 Versioning

When making changes, it is important to consider the current state of your specification and managing expectations of your users by evaluating whether or not major changes can be introduced with or without warning.

Simone Heckmann shares the German practice of versioning. "Breaking changes are usually only done after community consultation. We make announcements in our community channels, explain why and what is going to break, and then we collect opinions. For example, during our latest ballot we made a major breaking change to how we were doing our ICD coding, because the way we were doing post-coordinated codes interfered with other modifiers, like laterality or severity. We explained the issue, and luckily no one disagreed with the change."

FHIR releases use Semantic Versioning to make it easier to communicate the expected impact of an update. Semantic version numbers consist of three numbers separated by a dot, respectively named the major, minor and patch version number. As long as the version number is lower than 1.0.0 it is not yet considered to be production-ready, which will make it easier for authors to introduce major changes.

"With the 1.0 version, we are giving an expectation that we are reasonably certain of the models we have made. We are going to be a lot more careful in how we are going to make breaking changes from then on. We will have a more strict way to document changes, to document release notes. Changes will now require community consensus and agreement from the large organizations that are using our profiles," says Simone.

From the 1.0.0 version onwards, releases will need to be clear on whether they only make non-consequential fixes (updating the patch version number, e.g. *1.0.1*), make major additions but are still compatible with the previous release (updating the minor version number, e.g. *1.1.0*), or create changes that might break previous implementations (updating the major version number, e.g. *2.0.0*).
Preview releases can always be made, signified by an additional label behind the version number (e.g. *1.0.0-preview*) and should not be considered ready for production.

5.2 Individual resource versioning

"We originally debated whether the version of an individual FHIR resource should reflect whether it has been changed, or whether it should indicate that the resource belongs to a FHIR Package with a certain version," Simone continues. "We eventually decided to go with the latter, because it was much easier to maintain. Versioning per resource would require us to decide whether it is a major or minor change every time and that manual process is very hard to get right. People will forget or have different opinions on what is a significant change, so we decided not to do that."

5.3 Release notes

Release notes are an important part of versioning, as in all software development projects. “Our release notes are captured per package version with the package releases, but also shown as a full list of all versions in the Implementation Guide,” says Simone. “We are inspired by how the Trusted Health Apps project in Simplifier.net is keeping their changelog in the DiGA-API Implementation Guide. This nicely describes which profiles were added or changed and whether a change is just an addition, a non-consequential technical fix or whether it actually broke something. This is inspired by the Keep a Changelog guidance.”

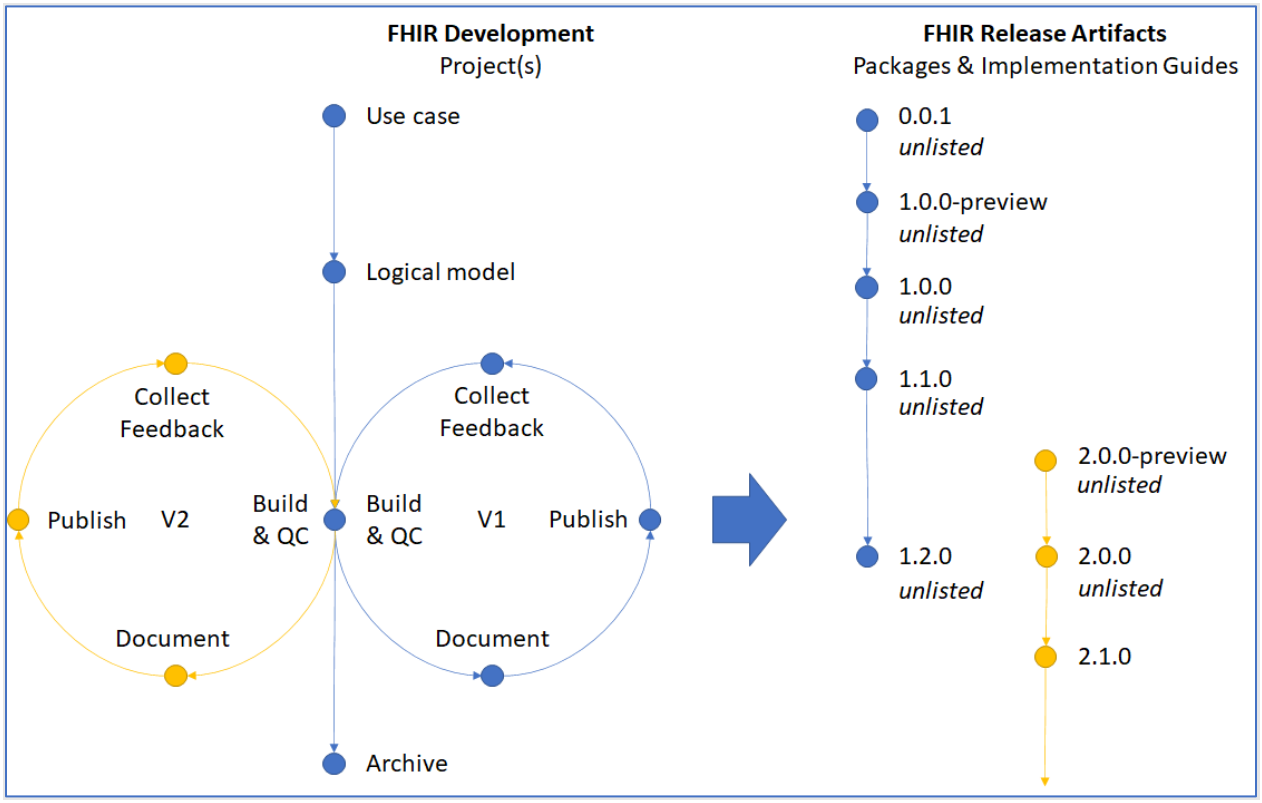

Figure 5: Archiving projects

Development projects that no longer need updating can be archived. This will make them read-only and prevents them from counting against a project limit on the Simplifier.net plan.

6 Driving adoption

Despite all the technical details, both standards leaders from the United Kingdom and Germany stress that building a strong community by being collaborative and helpful is the key to driving adoption.

NHS Digital finds it crucial to show from the beginning that you truly want to get feedback from everyone to make sure the specification works for a wide audience. While there were already many use cases within NHS Digital that would benefit from a nationwide set of base profiles, the team made sure to work closely with other stakeholders, like peer organizations from other countries within the UK, the strategic funding organization NHS X, the UK affiliate of HL7, the industry collaboration group called INTEROPen, and other volunteers from the field.

As Dave puts it, “The fact that we are putting effort and development into the UK Core is because we recognize the benefit of it. We do not want it to be ‘our’ data models, we prefer them to be UK-wide. It is all about stakeholder engagement and understanding their challenges. You need to demonstrate that you genuinely take their feedback to heart.” He continues, “Using Simplifier.net, FHIR itself is the technical part. But delivering interoperability using those technical solutions is actually about the people, their processes and their personal goals and aims. You are trying to align everybody to that common purpose and then the technical work can follow.”

The German market also recognizes that nurturing a strong community is the key to driving adoption. Simone concludes, “We do see a lot of people using the German base profiles. The most important advice I would give to organizations who are just getting started in their jurisdiction is to create a community and advertise it. We reach out to everyone working on FHIR and encourage them to share their use case and discuss their needs.”

We asked David whether the proverbial stick of mandating a FHIR specification also has a role to play. To this he was clear to say, “While eventually financial incentives can come into play, since funders logically will want to get the benefit of jurisdiction-wide interoperability with their grants, you don’t want to mandate from an ivory tower. Mainly it is about trying to be helpful, even outside the part that NHS Digital itself strictly needs. The UK Core is a key building block, but it is no good without delivering results on the ground.”

7 Acknowledgements

We are grateful to everyone in the FHIR community and to our customers without whom we could not have written this whitepaper. Their wisdom, tips, suggestions, feedback and comments over the years have resulted in this whitepaper. We are especially grateful for the contributions made by NHS Digital and HL7 Germany. More specifically we want to thank David Crampin and Kevin Sprague from NHS Digital, and Simone Heckmann from HL7 Germany for their invaluable insights.

8 About the authors

Firely provides all the software, training and expertise needed to bring FHIR to life. We are also the authors of one of the two main open source FHIR libraries: Firely .NET SDK. Our software powers FHIR APIs and systems around the world. Many governments, hospitals, payers and MedTech companies rely on our software for their FHIR capabilities. Firely provides FHIR training courses and workshops, and is the organizer of HL7 FHIR DevDays, the largest and foremost FHIR event in the world. In 2019, we were among the founding members of the FHIR Business Alliance. More information on our solutions, services and education can be found on our website (https://fire.ly).

Contact us

Any feedback on this whitepaper is very welcome. Please send your comments, kudos or questions to info@fire.ly.

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