FHIR

Creation and Curation of FHIR Profiles

Profiling

- Localizations are manifestations of the ability of users to both extend and constrain the core FHIR specification.
- However, unregulated proliferation of localized artifacts will have a counter-productive effect on the ability for data to be passed between systems with no loss of meaning.
- Conformance statements are a mandatory part of FHIR. (xxx?xx)

Governance & Profiling

- Establishment of policies [around the creation and approval of profiles], and continuous monitoring of their proper implementation
  - It includes the mechanisms required to balance the powers of the members
- Two key processes
  1. The creation of new FHIR artifacts (e.g. profiles, implementation guides)
  2. The curation/vetting of FHIR artifacts developed by “others”

CREATION OF ARTIFACTS

HL7 International – Artifact Creation

draft

active

retired

Proposed new artifact
Acceptance by FMG (set of ciriteria exists)
Assign to HL7 Workgroup

FMM 0 – draft artifact

FMM 1 – untested artifact

Testing (e.g. connectathon)

FMM 2 – tested artifact

QA Guidelines; 1 STU ballot

FMM 3 – quality tested artifact

Prototype implementation

FMM 4 - implemented artifact

Changes require implementer feedback

Production use; >=2 STU ballots

FMM 5 – candidate for normative

Normative artifact = FMM 6

Issue tracker

Resolution by WGs

FGB monitors Process

ISO ballot rules

STU Ballot Full mbrship

Normative Ballot full mbrship

HL7 International

- Ballot comments “carry more weigth” than regular issues
- FMG (FHIR Management Group)
  - provides day-to-day oversight of FHIR-related work group activities including performing quality analysis, monitoring scope and consistency with FHIR principles and aiding in the resolution of FHIR-related intra and inter-work group issues
- FGB (FHIR Governance Board)
  - sets the strategic direction for the FHIR (Fast Healthcare Interoperability Resources) initiative in the HL7 organization and oversees the structures, rules and processes that govern the creation, maintenance and review of FHIR-related artifacts

France / HL7 Affiliate

- HL7 France is profiling FHIR resources for France
- Multiple working groups. Consist of main stakeholders: Industry and public agencies. The consensus is established within the WG
  - WG1: "Administration"
  - WG2: “Financial Management”
  - WG3: “Health actors”
- HL7 France membership will be solicited to express their feedback on WG products.

France / HL7 Affiliate

- 5 stage process developed by Interop'Santé for the production of FHIR Profiles...
  - 1. Use case inventory;
  - 2. Identify needs for constraints, value sets, extensions;
  - 3. Check profiles & extensions already available;
  - 4. Build (or adopt) ValueSet resources and Profiles (Forge);
  - 5. Publish on a FHIR Server (to be chosen)

HL7 Affiliate / France / – Artifact Creation

draft

Use case inventory (stage 1)
Identify need for constraints (stage 2)
Identify existing artifacts (stage 3, e.g. profiles, extensions)
Create profiles (stage 4, stage 5)

active

Draft artifact

Feedback from main stakeholders

Stakeolder reviewed artifact

WG Review

WG Consensus artifact

Membership ballot

Normative artifact

retired

Change request

WG Consensus process

Ballot full mbrship

Germany / HL7 Affiliate

- HL7 Germany are hosting their Profiles on Simplifier with an underlying GitHub.
- Any comments they get are documented as GitHub-issues
- They discuss the issues on Zulip and are planning to do the voting on zulip, too. For this purpose, they will announce all issues that are ready for voting over a mailinglist, to alert people who are not regularly active on zulip.
- When the votes are in, they document the result in the issue and update the profile on Simplifier according to the resolution.

US / Argonaut project

- US projects have been 'flexible'...a few ingredients that have been important in Argonaut/other projects
  - getting the major EHR vendors engaged early/often,
  - piloting through sprints and/or full blown connect-a-thons,
  - requesting formal clinician review.
- The profiles all include places to log issues.

Sprints / off-line connectathon

- Step 1 - hosted a call or two to propose set of requiremetns (http://argonautwiki.hl7.org/index.php?title=Patient). Discussed and improved on calls
- Step 2 - after completing a few profiles, we started a series of sprints (https://github.com/argonautproject/implementation-program/wiki/Server-Re-Sprint-1)
- Step 3 - based on feedback from sprints we built the formal IG (http://www.fhir.org/guides/argonaut/r2/)

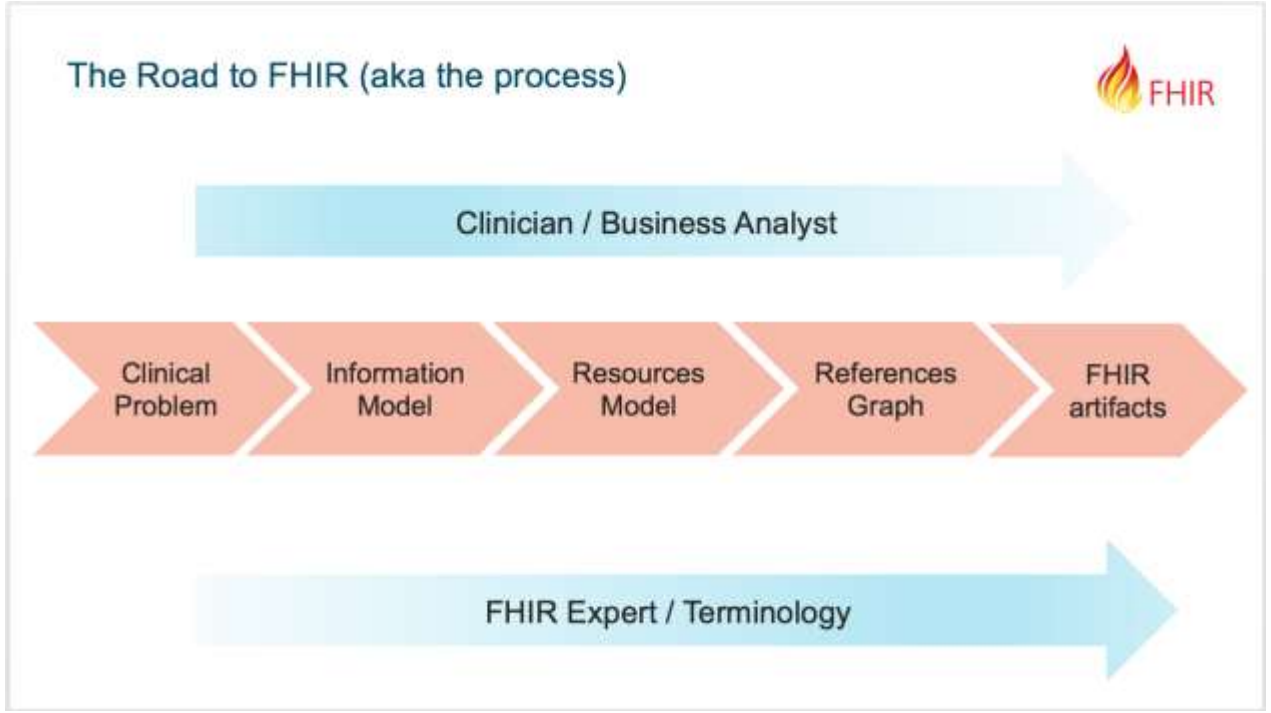
- They used term 'Sprint' to give folks 2-weeks to implement the profile in their system and test with another partner

Australia / HL7 Affiliate

- They are currently running FHIR localisation content through a minuted committee approval process
- 3 'working groups' Patient Administration, Orders and Observations and Medications - there are open community meetings, no membership check.
- This does not have a lot of formal governance at this stage; more of a general committee approval process for content to be worked on and included in IG publications
- They are expecting that there will be balloting with full AU membership at some stage but there are no firm plans for this.

New Zealand / HL7 Affiliate

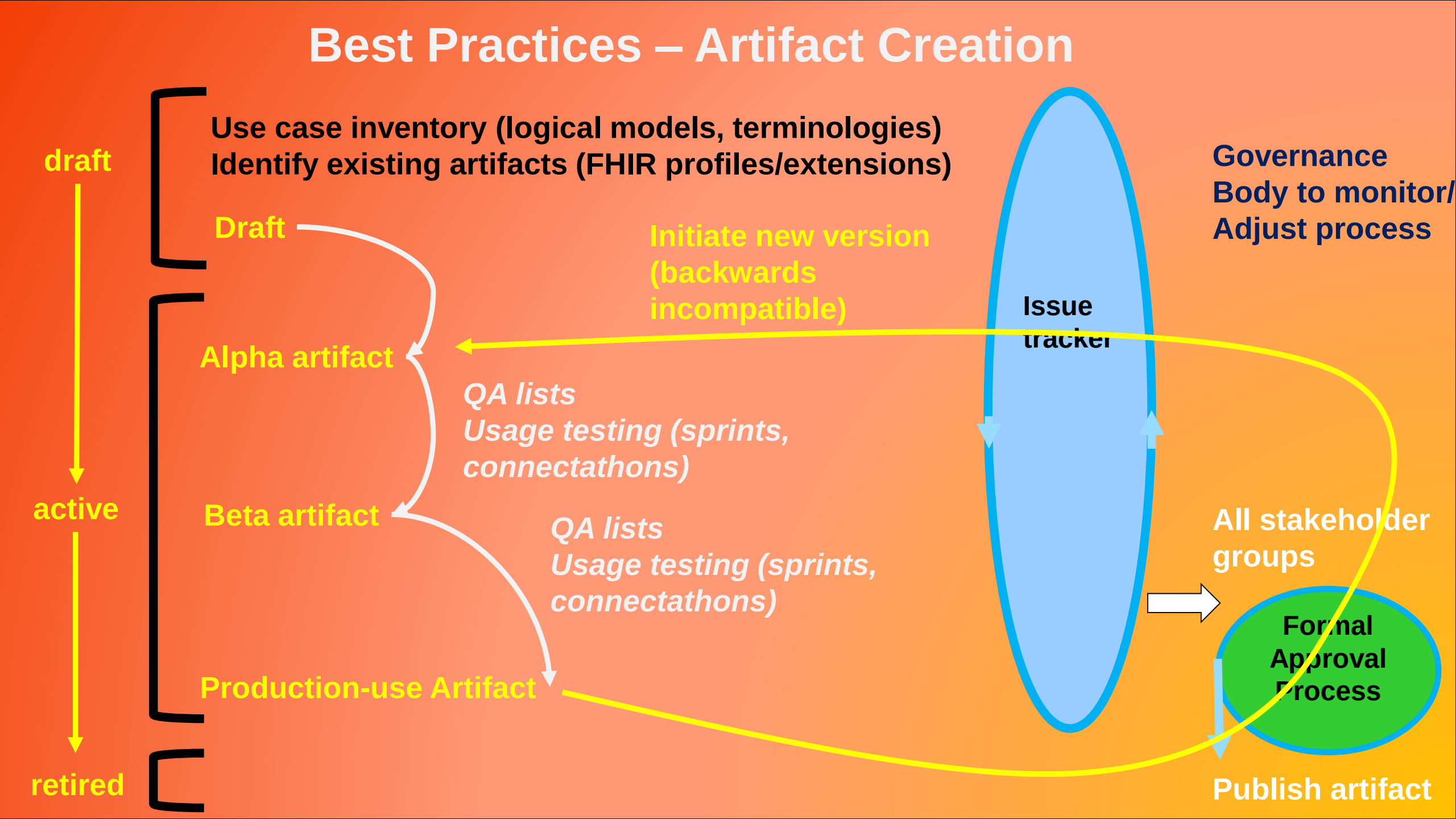
- A joint process has been agreed with the Health Information Standards Organisation (HISO) and this is awaiting formal ratification.
- Candidate NZ Naming System Identifiers have been posted on an HL7NZ Collaboration Site and discussed on the NZ Zulip Stream



Best practices

- Process
  - Create a maturity model
    - QA criteria, test events, input from specific stakeholder groups
  - Use test events to advance the maturity level
    - Sprints, connectathons, etc.
  - Use a 24/7 issue tracker
    - Resolve issues as they arise, short cycles
  - Occasionally Freeze a coherent set of artifacts
    - Versioning, formal approval process
- Governance
  - Monitor/adjust process
    - Ensure proper representation of all stakeholder groups

Best Practices – Artifact Creation

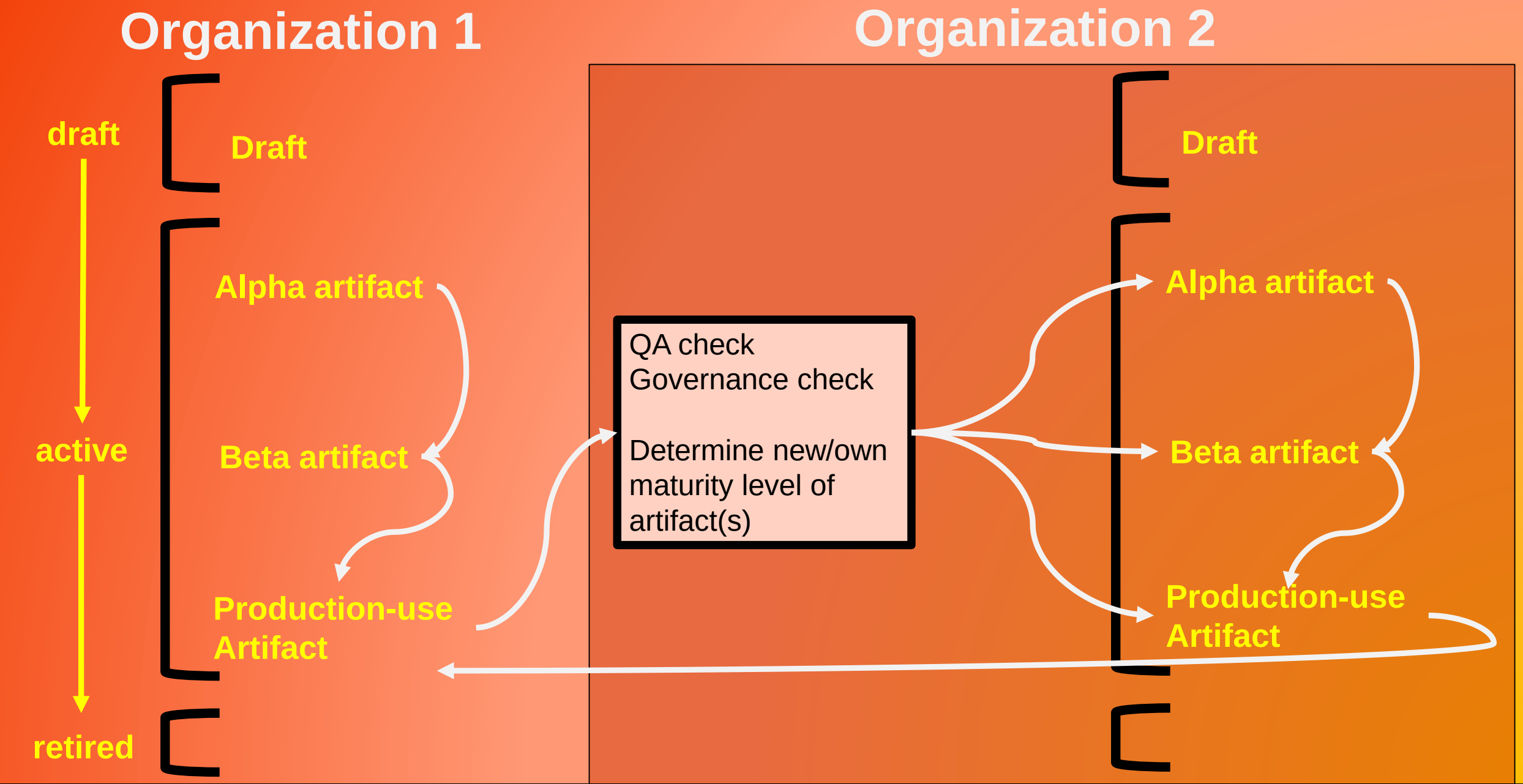


CURATION OF ARTIFACTS

Curation/vetting of profiles

- A process for curating profiles created by “others”
- Overlapping and duplicating profiles as well as incorrect profiles should be filtered out
  - May result in modifications to the artifacts brought forward
- Governance process to balance interests of the party (and its stakeholders) which brings forward the artifacts with the interests of the party (and its stakeholders) which intents to curate those artifacts.

Curation of Artifacts – general principles



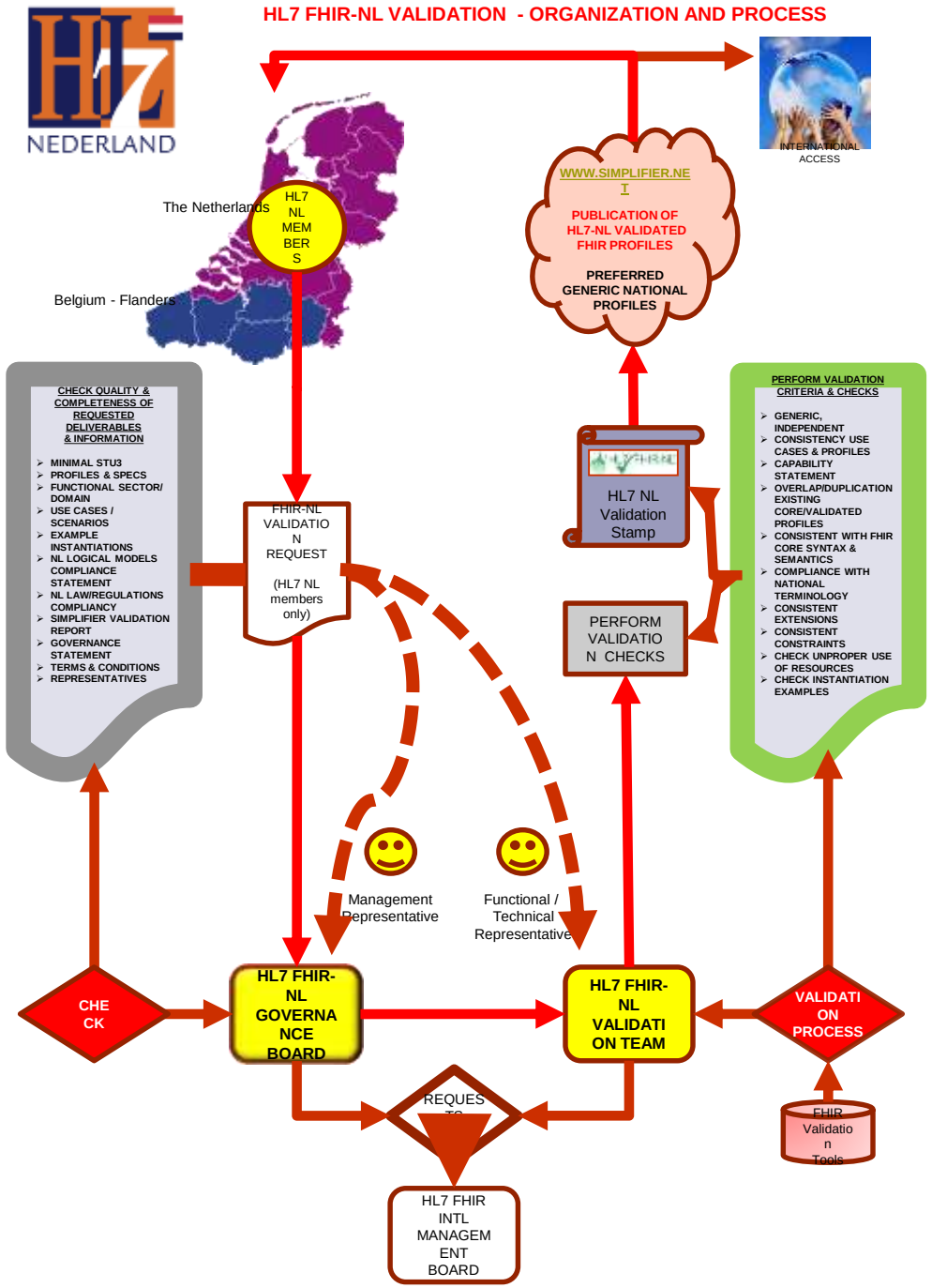
HL7 International

- Work created by third parties (not joint with HL7) can be brought to HL7 International for inclusion in its standard.
  1. An HL7 work group would create an HL7 project to bring in the material.
  2. The ARB would review project scope & external content
  3. The material would come in as DRAFT or STU, and have to follow the established rules for balloting and where appropriate assignment of maturity level.
  4. It would have to be brought into the HL7 build process and pass all verification.
- The fact that the material has been tested and implemented outside of HL7 is no guarantee that it would build/test within HL7.

Norway / Nasjonal IKT / HL7 Norway

As a project looking to use FHIR in Norway, one should

- Capture requirements
  - Scenario/use-case, data exchange requirements
- Apply checklist
  - Do artifacts (in Norway, elsewhere) already exist? If artifacts already exist, let HL7 Norway know you're using them
- Development
  - Create and publish profile
- Review
  - HL7 Norway will review, provides feedback for changes; start using updated profile
- *No formal governance process as of yet*



HL7® FHIR-NL®

FHIR

FHIR Governance Board

- define general and specific validation criteria and requirements
- judge on validation readiness of validation requests
- manage the validation team

Each organization who wishes to have their profiles validated and published as a “national HL7-FHIR-NL profile” should (must) send a representative to this board.

Validation Team

- define detailed validation criteria, validation sets & req’rements
- conduct and execute the validation procedure
- report the validation results including advice re: improvements
- maintenance and publication of validated profiles

Each organization who wishes to have their profiles validated and published should (must) send a functional/technical representative to this team.

HL7 NL – Governance Board

- CHECK QUALITY & COMPLETENESS OF REQUESTED DELIVERABLES & INFORMATION
  - MINIMAL STU3
  - PROFILES & SPECS
  - FUNCTIONAL SECTOR/ DOMAIN
  - USE CASES / SCENARIOS
  - EXAMPLE INSTANTIATIONS
  - NL LOGICAL MODELS COMPLIANCE STATEMENT
  - NL LAW/REGULATIONS COMPLIANCY
  - SIMPLIFIER VALIDATION REPORT
  - GOVERNANCE STATEMENT
  - TERMS & CONDITIONS
  - REPRESENTATIVES

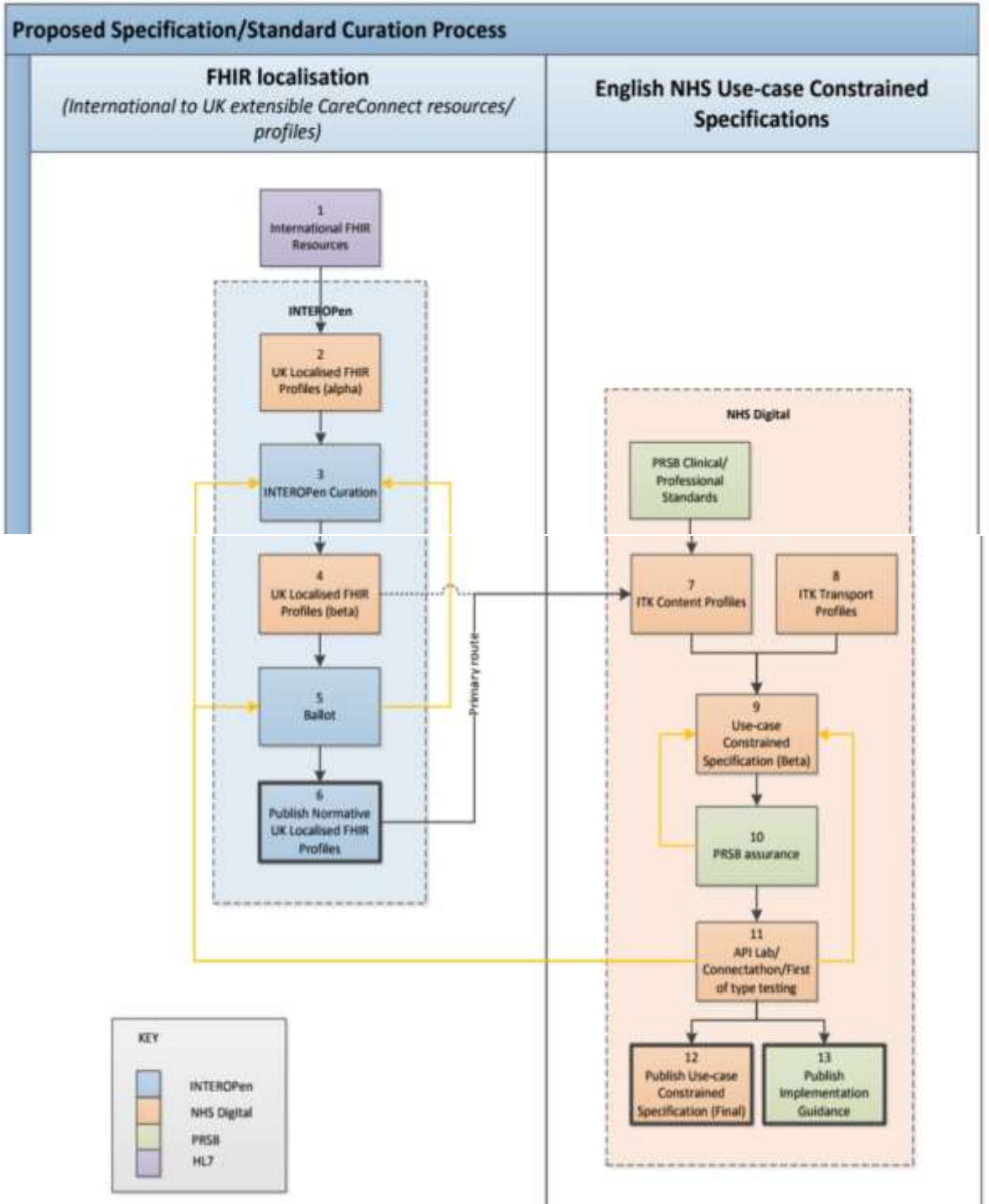
HL7 NL – Validation team

- PERFORM VALIDATION CRITERIA & CHECKS
  - GENERIC, INDEPENDENT
  - CONSISTENCY USE CASES & PROFILES
  - CAPABILITY STATEMENT
  - OVERLAP/DUPLICATION EXISTING CORE/VALIDATED PROFILES
  - CONSISTENT WITH FHIR CORE SYNTAX & SEMANTICS
  - COMPLIANCE WITH NATIONAL SPECS
    - Terminology, Clinical Building Blocks (CBB), non-HL7 standards
  - CONSISTENT EXTENSIONS
  - CONSISTENT CONSTRAINTS
  - CHECK UNPROPER USE OF RESOURCES
  - CHECK INSTANTIATION EXAMPLES

UK InterOPEN

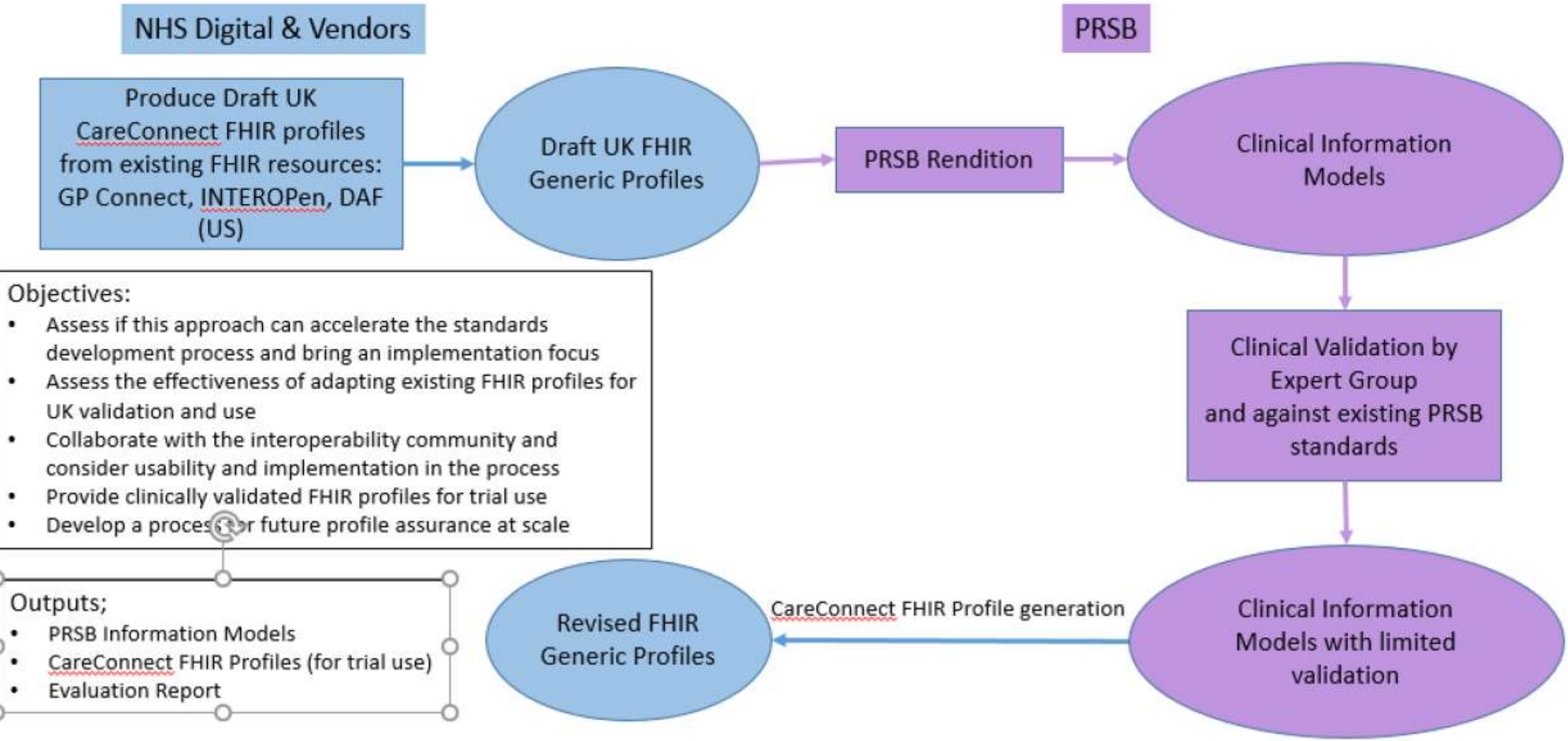
- Adoption of UK CareConnect FHIR profiles requires a collaborative process that brings together the interests of NHS Digital, Code4Health, PRSB, INTEROPen, HL7 UK, and all local implementers including health and social care practitioners.
- From the outset, CareConnect FHIR profiles need to be co-produced by health and social care practitioners and information modellers.

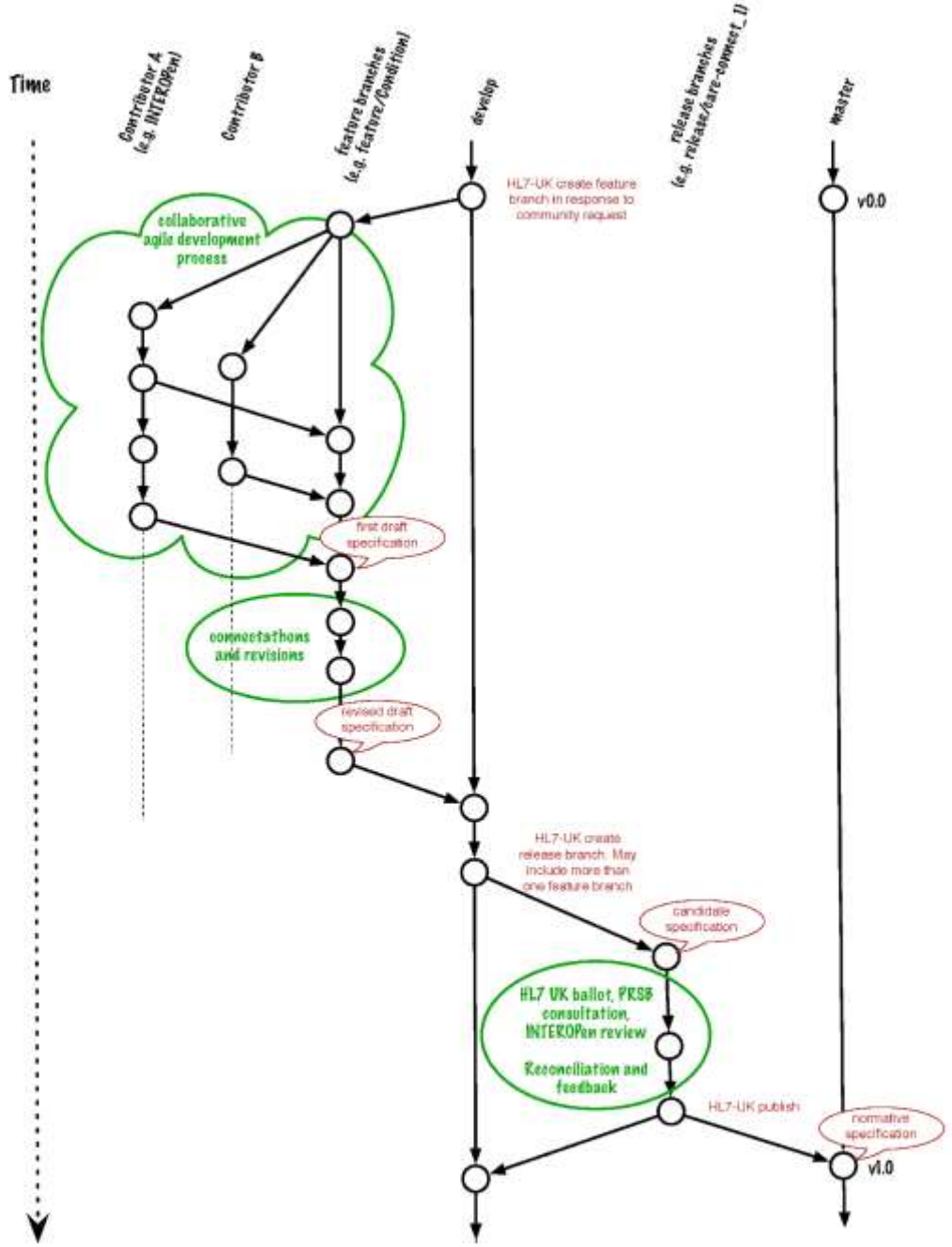
InterOPEN


Proposed Specification/Standard Curation Process
FHIR localisation
(International to UK extensible CareConnect resources/ profiles)
English NHS Use-case Constrained Specifications
1 International FHIR Resources
INTEROPen
2 UK Localised FHIR Profiles (alpha)
3 INTEROPen Curation
4 UK Localised FHIR Profiles (beta)
5 Ballot
6 Publish Normative UK Localised FHIR Profiles
Primary route
NHS Digital
PRSB Clinical/ Professional Standards
7 ITK Content Profiles
8 ITK Transport Profiles
9 Use-case Constrained Specification (Beta)
10 PRSB assurance
11 API Lab/ Connectathon/Fiest of type testing
12 Publish Use-case Constrained Specification (Final)
13 Publish Implementation Guidance
KEY
INTEROPen
NHS Digital
PRSB
HL7

FHIR Profile Development Flow – Proof of Concept Work

PRSB
Professional Record Standards Body
for health and social care

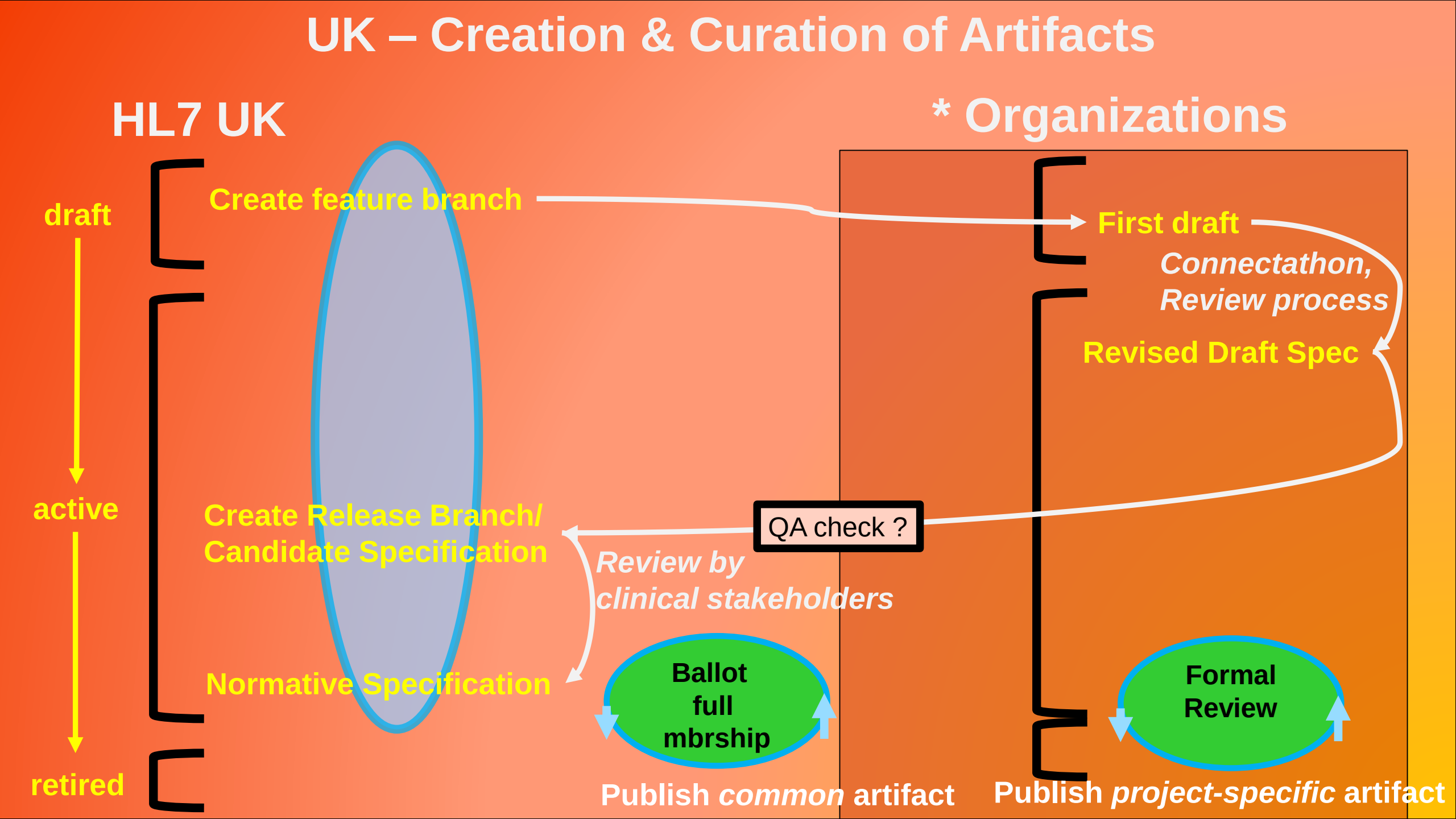




Process perspective

- Based on GitHub (hosted by HL7 UK)
- The repository uses the gitflow pattern [http://nvie.com/posts/a-successful-git-branching-model/]
- Balloted versions of assets are published on the master branch. Latest versions of assets are available on develop branch.

UK – Creation & Curation of Artifacts



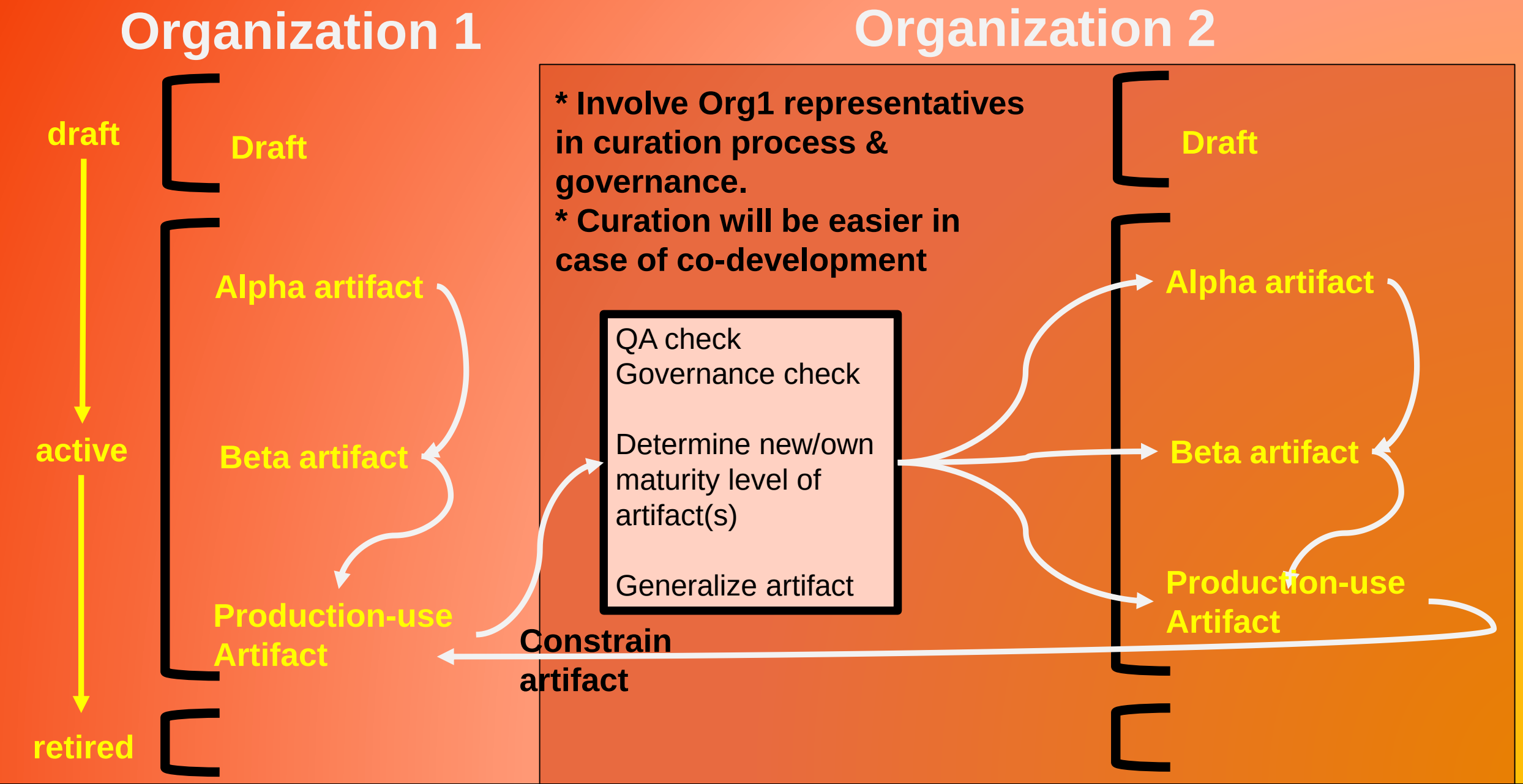
UK – API Lab (late 2017)

- API Lab to be run by NHS Digital in partnership with INTEROPen community members
- The Lab is expected to accelerate the development of open source APIs designed to improve system integration across the NHS and social care.
- It is anticipated that developers from industry and care sector organisations will participate in the work of the Lab on a pro bono basis.
- The APIs and associated tools and guidance will be made available under a permissive open source licence.

Best Practices

- Ensure participation of those proposing acceptance of an artifact (“third-party”) in the curation process itself (both governance & actual curation)
- Decide: co-development (get involved early), or curate ‘final version’ created by third-party
- Curated/accepted artifact may differ from the one used by third-party
  - third-party to use constrained version of accepted artifact

Best Practices - Curation of Artifacts



QUESTIONS?

References

- HL7.org process/governance
  - http://wiki.hl7.org/index.php?title=FHIR_Maturity_Model
  - http://wiki.hl7.org/index.php?title=FHIR_Conformance_QA_Criteria
- HL7 Affiliate process/governance
  - http://wiki.hl7.org/index.php?title=Affiliate_Governance_of_Localised_FHIR_Artefacts
  - Contains links to HL7 Netherlands process materials
- InterOPEN
  - https://docs.google.com/document/d/1n0SXC9BqN-ROjJvpdhceFCPOg5hzqmPq4B8DJxlrbMU/edit#heading=h.peqy9ui2tdlw