IReS Terminology Product Development Lifecycle

Published February 2018

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Document Management

Revision History

Version	Date	Summary of Changes
v0.1	28/09/2010	1st draft adapted from IHTSDO documentation (Jeremy Rogers)
v0.2	06/04/2011	2nd draft for approval by UK Edition Committee. Incorporates v0.1 review comments from Anne Casey and Steve Bentley, and discussions in April 2011 UKTC Edition Committee meeting.
v0.3	18/05/2011	Transferred to CFH document template
V0.4	27/12/2012	Updated following trial period and inclusion of section on deprecation (Ian Arrowsmith)
V0.5	14/03/2013	Updated following extensive comments
V0.6	08/05/2013	Further extensive content update, document restructure and rebranding to NHS DIGITAL (Jo Goulding)
V0.7	18/05/2013	Update to Status names further to feedback from UKTC Management Team
V0.8	25/05/2013	Minor updates for clarification further to UKTC Edition Committee feedback
V0.9	05/06/2013	Change name from Policy to Lifecycle (and amend body of text to reflect this change), updated scope to remove Classifications further to decision from UKTC Governance Board, new governance diagram (Appendix I)
V1.0	24/06/2013	Move to Approved
V1.1	22/08/2013	Minor updates and clarifications further to feedback from UKTC Governance Board
V2.0	09/02/2014	Sanctioned updates to hyperlinks for templates and uplift to 2.0 to reflect final version agreed by UKTC Governance Board
V2.1	09/05/2016	Update to TRUD Status, changing Legacy and Withdrawn with Deprecated and Retired to align with SCCI guidelines.
V2.2		Various groups reviewed (UKTC Mgmt., Ed Com and T&C Mgmt. group)
V3.0	5-Oct-2016	Final
V3.1	26-2-18	Revised for IReS/DSAS/SI structure & branding

Reviewers

This document must be reviewed by the following people:

Reviewer name	Title / Responsibility	Date	Version
Various	UKTC Edition Committee	08/06/2016	2.1
Various	UKTC Management Team	5-Oct-2016	2.2
Various	UK Edition Committee	13-3-18	3.1

Approved by

This document must be approved by the following people:

Name	Signature	Title	Date	Version
Various Groups	At meeting	Terminology and Classifications Development Management Group	5-Oct-2016	3.0
Various Groups	At meeting	UK IReS Strategy Board	Next meeting	3.1

Future Review Schedule

Review Frequency	To be reviewed by
At least every 2 years following approval	UK Edition Committee, and approval by the Terminology & Classifications Management Group and subsequent assurance by IReS Strategy Board

Glossary of Terms

Term / Abbreviation	What it stands for
dm+d	NHS Dictionary of Medicines and Devices
NHS Digital	trading name of the Health and Social Care Information Centre, which is the national provider of information, data and IT systems for commissioners, analysts and clinicians in health and social care in England,
IHTSDO	International Health Terminology Standards Development Organisation – trading name now SNOMED International
SNOMED CT®	Clinical health terminology product in the world, owned and distributed around the world by SNOMED International. [1]
TRUD	Technology Reference data Update Distribution (website)
IReS	UK Information Representation Services
DSAS	Data Standards Assurance Service

Contact Information

This document is produced by:	
Address:	NHS Digital Terminology and Classifications Delivery Service Information Representation Services I Trevelyan Square Boar Lane Leeds LS1 6AE
Telephone:	0300 30 34 777
Email:	information.standards@nhs.net
Internet:	www.digital.nhs.uk

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Contents

1 About this Document

1.1 Purpose

This document outlines the policy and underpinning processes that will be referenced by the Information Representation Services Terminology and Classifications governance bodies when exercising their oversight duties in relation to IReS Terminology products throughout their lifecycle and followed by developers, including their initial development, testing, maintenance, review and retirement. It also gives links to the procedures and document templates to support the policy and processes.

This document does not cover initial approval, only the status conferred on products once approval to proceed is given.

1.2 Audience

This document has been written for all those involved in the use and implementation of IReS Terminology products (and product derivatives). This includes authors, implementers, and end users.

2 Introduction

2.1 Background

New terminology products (and product derivatives) are typically developed in response to specific requests for new functionality. These new products are often accompanied by policies or guidance concerning their implementation and proper use.

Previously, it was common practice for some of these new products to be released with various undefined release status flavours including ‘Draft’, ‘Technology Preview’, ‘Value Added File’, ‘Test Data’, and ‘Bonus File’. The exact meaning of each status was not always

clear and the processes and timescales by which a product might progress between statuses equally unclear. There was also a lack of clarity around the mechanisms for managed withdrawal or retirement of historical products.

In order to enhance the current service and to ensure clarity this document defines the policy, processes and procedures for the IReS Terminology product lifecycle. It also specifies governance as coordinated through the Terminology & Classification Management Group, the UK Edition Committee and where necessary, through the IReS Strategy Board .

This document is divided into two core sections:

- IReS Terminology Product Development Policy
- IReS Terminology Product Development Process

The process is supported by document templates which are found on the NHS Digital Terminology and Classification Delen website:

http://systems.digital.nhs.uk/data/uktc/snomed/governance

or by direct approach to the IReS TerminologySenior Service Manager via the helpdesk (information.standards@nhs.net).

2.2 Aims and Objectives

The aim of this document is to fully describe the IReS product development lifecycle.

The objectives are to:

- Clearly outline the policy for terminology product development in IReS
- Provide a clear process for developers, maintainers and users to ensure all stakeholders understand and can engage in the product development lifecycle
- Outline the procedures underpinning the product development process noting how to perform the activities specified in the processes
- Provide document templates to guide users through the process and to support decision makers in assessing compliance with the policy in order to enable an informed decision on sign off.

3 IReS Terminology Product Development Policy

The IReS Terminology Product Development Policy sets out the lifecycle of IReS Terminology Products and defines each stage in that lifecycle. The policy only covers stages in the lifecycle and therefore starts after the approval to proceed has been granted.

For detailed information on progression between each status see Section 4 of this document – IReS Terminology Product Development Process.

3.1 The Lifecycle of IReS Terminology Products

3.1.1 Release Status

An IReS Terminology product ('product') shall exist in one of the following statuses:

1. In Development
2. Technology Preview
3. Draft for Trial Use
4. Supported Product
5. Deprecated
6. Retired

All releases of a product carrying other than 'In Development' status will be public releases (i.e. available to all, not only to the original requestors).

Decisions to progress a product from one status to another shall be the responsibility of the relevant editorial or governance authority who will need to be provided with sufficient evidence of utility and demand in the stakeholder community. (These decision points and decision makers are defined in Section 4). Each product will require an IReS owner to provide this information and manage the progression of any product through these statuses.

3.1.2 Interaction of product lifecycle with the DSAS

Additional to the product lifecycle statuses described in this document, an IReS Terminology product may **also** be approved as a DSAS standard. Typically, this could only occur to products within IReS's 'Supported Product' status – but note that not all IReS 'Supported Products' are necessarily DSAS standards.

Policies covering both when a product should be submitted to DSAS and whether DSAS should approve it as a standard are outside the scope of this document. However, note that the IReS cannot unilaterally move a product to 'Deprecated or Retired' status where it is also a DSAS standard.

3.2 Definition of Statuses

3.2.1 In Development

A product that has received agreement to proceed is conferred 'In Development' status and will subsequently either be abandoned, or progress through the remaining statuses as described below.

'In Development' status means:

1. Neither the release format specification nor the method of content preparation of the product are public or fixed
2. There is no obligation for public release of any In Development product though early iterations may be released to external collaborators including (but not limited to) e.g. the original external requestor/sponsor
3. Quality and safety assurance of the product may be ill-defined and/or absent
4. In the event that the product is found to be less useful than thought, or unsafe, or too costly to produce, then Terminology & Classification Management Group may determine that its development be abandoned.

3.2.2 Technology Preview

The first public release and typically also several early releases thereafter, will have 'Technology Preview' status and must be clearly labelled as such.

'Technology Preview' means:

1. The release format specification of the product is public but not fixed.
2. The method of product content preparation *may* be public (but is not required to be) but is not fixed
3. Quality or safety assurance of the product may be ill-defined and/or incomplete
4. So far as is possible within internal resourcing constraints and demonstrated demand, IReS undertakes to support the product and maintain it in synchronisation with the primary release data as required.
5. Trial implementation is encouraged to evaluate utility and safety, and to identify possible design improvements.
6. Live deployment is at the users own risk, where such risk is permitted by other governance processes.
7. Implementations may have to change if and when the product design changes in the light of experience
8. Product support will be available but not to any guaranteed service level
9. In the event that the product is found to be only minimally used or useful, or unsafe, then IReS is under no obligation to continue its support or maintenance (a move to deprecated/withdrawn is still subject to processes noted in Section 4.7 'Deprecated').

3.2.3 Draft for Trial Use

'Draft for Trial Use' means:

1. Both the release format specification of the product and the method of its content preparation shall remain fixed for a period of at least 3 years *unless* a significant safety risk is identified that cannot be mitigated without changing them.
2. IReS commits to continue supporting, maintaining and publishing the product against that fixed specification for a period of at least 3 years, subject only to the same safety considerations
3. Quality assurance may be ongoing but the product is approved for deployment in live clinical systems, subject to standard safety assessment procedures associated with deployment of any product into a live environment
4. The commitment to release against a stable specification does not preclude continued parallel evolution of the specification and consequent development of improved variants as new products

3.2.4 Supported Product

'Supported Product' means:

1. Both the release format specification of the product and the method of its content preparation shall remain fixed indefinitely *unless* a significant safety risk is identified that cannot be mitigated without changing them. Where changes are deemed necessary to improve a product then a formal consultation procedure will be undertaken which may include some or all parts of the product development process and may include an option for parallel running (i.e. support for both existing and new specification).
2. IReS commits to continue to support, maintain and publish the product against that fixed specification indefinitely, subject to the considerations above or proper product termination
3. Quality assurance may be ongoing but the product is approved for deployment in live clinical systems, subject to standard safety assessment procedures associated with deployment of any product into a live environment
4. The commitment to release against a stable specification does not preclude continued parallel evolution of the specification and consequent development of improved variants which may or may not be considered as new products

3.2.5 Deprecated

Deprecation is marking a product as obsolete to warn against use in the future so that the product may be phased out. Deprecation indicates that use should be avoided, typically (but not always) because the product has been superseded. Product continues to be supported by IReS for a specified period of time. The detail of the support will be provided with each IReS Terminology product.

3.2.6 Retired

Once a product is deprecated IReS may move towards full retirement of the product.

Retirement means that IReS will no longer support the product and will remove all the previous versions of the product from its publically available publishing portals in an agreed timescale with all internal and external stakeholders.

4 IReS Terminology Product Development Process

The IReS Terminology Product Development Process outlines the interaction between each of the six release statuses defined above. The Process is supported by the Product Development Document Templates which detail the procedures required to progress through the process.

The current procedures and templates can be found on the NHS Digital website:

Insert new link here

4.1 High Level Principles

- All items taken through the Product Development Process should be of national* applicability and will have identified product owners and if their status requires it, supporting documentation. Where the use is considered to be outside routine core product maintenance then evidence of sponsorship and funding is also required from the commissioners.

**national in this context refers to England. The Policy is also applicable to any work commissioned by the other home countries in order to assure best practice however the provenance of the commission may affect the process and decision making.*

- During the initial exploratory (or 'inception') phase the IReS Terminology Senior Service Manager will seek assurance that the proposed product owner is authorised to commence the work and that justification for the product is gained.

- Evidence to proceed between stages of development will be provided to the IReS Terminology Senior Service Manager for submission to the relevant governance function once all requisite information is submitted.

- The IReS Terminology Senior Service Manager will keep a log of all products subject to this policy and will be able to determine their current status and will have the audit trail of how they got to that status.

- The IReS Terminology Senior Service Manager will act as the quality gatekeeper to the approvals bodies and will ensure the evidence to support progression is complete, in a suitable format and available in a timely fashion.

- Determination of success criteria and quality metrics will need to be established in advance to enable effective assessment of progression to next stage. They will include information on:
    1. Due process followed to date
    2. All appropriate documentation submitted
- The approval (or otherwise) of any product going through this process must be recorded in the minutes by the approval body.

- Information to consumers of products covered by this Policy will be made available publicly in appropriate form and via appropriate channels whenever the products are released and whenever there is a status change.

- Feedback on the usefulness or implementability will usually be received by the Information Standards Helpdesk (information.standards@nhs.net) or through formal consultation though it may sometimes be appropriate for the product owner to receive the feedback directly (particularly at 'In Development' status). It may be appropriate to adopt a formal survey mechanism for particularly important products or significant changes to existing products.

- Appendix I gives a graphical representation of the Development Process

4.2 Indicative Timelines

The product management described in this document assumes that a 'typical' timeline for progression would be broadly as follows:

Status	Type	Typical timescales
In Development	Initial design	3-6 months
Technology Preview	alpha testing	**Up to** 2 years
Draft for Trial Use	beta testing	**Up to** 3 years
Supported Product	Deployment	

This timeline is influenced by the following observations:

- Most new IReS Terminology products likely to be managed by this Policy will be derivatives of IReS's underlying core products in the Integrated (or "*combined*") Terminology Release
- Much of the risk from such derivatives – particularly with respect to the safety or utility of their content, or IReS's capacity to produce and QA them – arises from the content changes occurring within the core products themselves

- The released core product content only changes every six months (more frequently for medicines and devices)

- Therefore, more than one successive release of the core product may be required to pass before designers and users can be reasonably confident that new derivative products can cope with the underlying changes in those core products

4.2.1 Fast-track

The Policy does also allow for rapid progression where this is required and appropriate. In theory, a terminology product could progress from ‘In Development’ to ‘Supported Product’ in less than 12 months, if IReS request it and the UK Edition Committee supports it.

Examples where a rapid progression to ‘Supported Product’ can be supported may include product development in response to safety concerns or when the new product is largely similar to existing products. For example subsets: where the release format is already a fixed part of the SNOMED CT standard whilst the content – particularly for very small subsets – might be judged fit for purpose very quickly.

4.3 In Development

Once approval to proceed is granted (this initial approval process is outside the scope of this Policy) the initial product design will typically be drafted and tested by staff internal to IReS, optionally in closed consultation with the original requestor and other invited stakeholders. This original scoping and documentation of the product and supporting information can be referred to as ‘inception’ or the ‘inception phase’ of development.

To move from an internal prototype to a recognised ‘In Development’ product an application must be made to the Terminology & Classification Management Group.

This application should be made using the ‘In Development’ template found on the NHS DIGITAL website:

Insert new link here

or by direct approach to the IReS Terminology Senior Service Manager via the helpdesk (information.standards@nhs.net).

Evidence supporting an application for an ‘In Development’ product includes:

1. A statement of the use case(s) and letters of support from one or more potential users (*evidence of utility*)
2. Identification of the required expertise and resource to complete the design and build of the prototype. This would normally include evidence that IReS had internal management approval to commit the required resources. (*evidence of capability)*
3. Identification of a Sponsor for the product *(evidence of support*)*

**Once the approval of the nature of the product is gained then sponsorship from e.g. NHS England (or other sponsor) should be sought where the development is found to be outside normal core product maintenance efforts.*

The Terminology & Classification Management Group will then decide to:

Approve – the product will be conferred In Development Status

Defer – acceptance that there may be a requirement for the product but not all the evidence is in place to make an informed decision. The applicant will be given opportunity to re-submit.

Reject – the product is rejected. Grounds for rejection must be clearly stated and minuted.

All decisions must be appropriately minuted by the Terminology & Classification Management Group secretariat to provide a full audit trail of decisions.

The community of practice should be notified when development of a new product is approved in order to seek support for development and potential partners for testing etc. Methods of notification may include:

- presentation at existing IReS stakeholder forums
- by direct communication to the potential narrow user community or,

- more broadly to all known consumers of all related IReS Terminology products (e.g. to particular sub-pack subscribers from IReS distribution portal).

NOTE – *A product that has received agreement to proceed is conferred 'In Development' status and will subsequently either be abandoned, or progress through the remaining four statuses as described below.*

4.4 Technology Preview

Once initial work has been undertaken during 'In Development' stage, the feasibility and usability of the new product (or derivative), and consequently any progression to a subsequent stage, will be a decision for the UK Edition Committee.

To move from 'In Development' status an application should be made to the relevant editorial authority using the 'Technology Preview' template found on the NHS Digital Terminology and Classification Delen website:

Insert new link here

or by direct approach to the IReS Terminology Senior Service Manager via the helpdesk (information.standards@nhs.net).

Evidence supporting an application for a product to acquire 'Technology Preview' status shall typically include:

1. EITHER a successful trial implementation (including only internally within IReS) OR evidence of intent to deploy (*evidence of utility*)
2. Documentation describing the current quality assurance status of the product and the processes for maintaining and improving its quality (*evidence of quality*)
3. Documentation describing the current safety assurance status of the product and describing the future clinical governance regime for the product and its associated deployments (*evidence of safety*)
4. Assurance from IReS that it has planned the resource to honour the maintenance commitment and has also secured management agreement to commit it (*evidence of capability)*

NOTE – *Any product that has remained at '*Technology Preview' *status for more than 3 years must be referred to the UK Edition Committee for consideration of a change of status*

4.5 Draft for Trial Use

At any time, the Terminology & Classification Management Group may request the relevant UK Edition Committee to upgrade a product from 'Technology Preview' to 'Draft for Trial Use' release status. At the discretion of this editorial authority, other stakeholders may make the same request directly to it, although they are normally encouraged to make their case through the IReS Terminology Senior Service Manager (who in turn will submit to the UK Edition Committee via the Terminology & Classification Management Group).

As noted above, any product that has remained at 'Technology Preview' status for more than 3 years must be referred to the UK Edition Committee for consideration of a change of status. If no change in status is recommended after an application to the UK Edition Committee, the product shall be automatically re-referred at least every 12 months thereafter or considered for direct progression to a legacy product.

To move from 'Technology Preview' status an application should be made to the relevant editorial authority using the 'Draft for Trial Use' template found on the NHS Digital Terminology and Classification Delen website:

Insert new link here

or by direct approach to theIReS Terminology Senior Service Manager via the helpdesk (information.standards@nhs.net).

Evidence supporting this application to the UK Edition Committee for a product to acquire 'Draft for Trial Use' status shall typically include:

1. More than one successful trial implementation, optionally including deployments within live systems. Evidence only of intent to deploy would not normally be considered sufficiently strong evidence. (*evidence of utility*)
2. Documentation of an open stakeholder consultation, occurring within the preceding 9 months (typically), to provide:
    a. comprehensive review of the product specification
    b. agreement on any changes to the product specification thought likely to ensure its fitness for purpose and stability over a period of at least 3 years. (*evidence of stability*)
    c. completion of one release cycle incorporating those changes
    d. significant levels of engagement with the major product stakeholders
3. Documentation describing the current quality assurance status of the product and the processes for maintaining and improving its quality (*evidence of quality*)
4. Documentation describing the current safety assurance status of the product development and describing the future clinical governance regime for the product and its associated deployments (*evidence of safety*)
5. Assurance from IReS that it has the resource to honour the maintenance commitment (*evidence of capability)*
6. Documentation describing implementation guidance for the product (ease of implementability)

Note – *Any product that has remained at 'Draft for Trial Use' status for more than 5 years must automatically be referred to the UK editorial authority for consideration of a change of status.*

4.6 Supported Product

At any time, but usually after a minimum of 3 years as a 'Draft for Trial Use', IReS *may* request the UK Edition Committee to consider upgrading a product from 'Draft for Trial Use' to 'Supported Product' release status.

A request to progress to 'Supported Product' after less than 3 years as a 'Draft for Trial Use' may be considered in exceptional circumstances.

As noted above, any product that has remained at 'Draft for Trial Use' status for more than 5 years must automatically be referred to the UK Edition Committee for consideration of a change of status. If no change in status is recommended after an application to the UK Edition Committee, the product shall be automatically re-referred at least every 12 months thereafter or considered for cessation.

At the discretion of this editorial authority, other stakeholders may make the same request directly to it, although they are normally encouraged to make their case through the IReS Terminology Senior Service Manager (who in turn will submit to the UK Edition Committee via the Terminology & Classification Management Group).

To move from 'Draft for Trial Use' status to 'Supported Product; an application should be made to the relevant editorial authority using the 'Supported Product' template found on the NHS Digital Terminology and Classification Delen website:

Insert new link here

or by direct approach to the IReS Terminology Senior Service Manager via the helpdesk (information.standards@nhs.net).

Evidence supporting an application for 'Supported Product' status includes:

1. More than one sufficiently credible live deployment (*evidence of utility*)
2. Completion, within the preceding 9 months (typically), of an open consultation with stakeholders to comprehensively review the product specification and deployment experiences. This consultation should have agreed any changes to the product specification required to ensure its fitness for purpose and lasting stability. At least one release of the product shall have been made incorporating the changes. The consultation process must also have demonstrated significant levels of engagement with the major product stakeholders (*evidence of stability*)
3. Documentation describing the current quality assurance status of the product and the processes for maintaining and improving its quality in perpetuity (*evidence of quality*)
4. Documentation describing the current safety assurance status of the product and describing the future clinical governance regime for of the product and its associated deployments (*evidence of safety*)
5. Assurance from IReS that it has the resource to honour the maintenance commitment (*evidence of capability)*

Once a product reaches supported status it will then be reflected as such in any IReS Terminology product portfolio or catalogue prevalent at that time.

4.7 Deprecated

At any time the Terminology & Classification Management Group *may* request the UK Edition Committee to consider that a product ceases to be supported and/or maintained (except those only at 'In Development' status, where no formal switch-off is required), following which production will either be continued or move through the product cycle to deprecated and eventually retired.

Where it is proposed that a previously 'supported' product be deprecated then the IReS Strategy Board approval must also be sought.

Any decision to withdraw support for a previously supported product should not be taken lightly. It is essential that full consultations are undertaken appropriate to the product being withdrawn.

To move to 'Deprecated Product' an application should be made to the relevant editorial authority (and IReS Strategy Board where applicable) using the 'Deprecated Product' template found on the NHS Digital Terminology and Classification Delen website:

http://systems.digital.nhs.uk/data/uktc/snomed/governance

or by direct approach to the IReS Terminology Senior Service Manager via the helpdesk (information.standards@nhs.net).

This evidence in support of the application to take the product to 'deprecated' status includes:

1. 'Technology Preview' or 'Draft for Trial Use':
   EITHER evidence that the product is unsafe
   (*evidence of risk*)
   OR evidence that there are no live deployments
   OR evidence that nobody has received or taken recent update releases
   (*evidence of non-utility*)
   OR evidence of insufficient capability to continue production
   (*evidence of incapacity*)

2. 'Supported Product':
   a. EITHER evidence that the product is unsafe*
      (*evidence of risk*)
      OR evidence that there are no live deployments
      OR evidence that nobody has received or taken recent update releases
      (*evidence of non-utility*)
   b. Approval from the DSAS where a supported product has *also* become part of a standard
      (*evidence of stakeholder engagement*)

***Note –** where a product is found to be unsafe then immediate steps must be taken to move the product to ‘Deprecated Product’ status and where it has previously been considered as a supported product there should also be plans to consider provision of an alternative (which may just be improvements to an existing) product. Communication to all stakeholders must be a key part of the activity.

4.8 Retired

After the deprecation notification period of a product, the product will move to “Retired” and removed from publically available publishing portals.

The retirement of a product generally follows Data Standards Assurance Service (DSAS) guidelines. The product is usually available for 18 months after deprecation but this may be shorter or longer depending on business justifications.

It is important to note that the data may still be available through other mechanisms (e.g. the Service Desk) but justification needs to be provided detailing the reasons for the request, this may include data to be used for research purposes.

APPENDIX I – Diagrammatic summary of policy framework