



## ICH M2 Expert Working Group

### TERMINOLOGY LIST MANAGEMENT PROCESSES

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## 1 EXECUTIVE SUMMARY

The ICH process has led to the definition of a number of technical standards that use terminology lists to manage commonly used terms. Terminology lists are otherwise described as controlled vocabularies, pick lists and code lists. The ICH M2 EWG has been mandated by the ICH Management Committee to define a process and points to consider for the selection and management of terminology lists to ensure that this can be done efficiently for the entire lifecycle of the ICH work items that employ them.

This document defines a number of concepts that are used in the process definitions. Three general roles for the people and groups involved are described. The specific tasks of the M2 EWG and the EWG/IWG leading the technical standard definition are also described. The document describes the key roles of Terminology List Points of Contact in both M2 and the EWG/IWG and the creation of a Service Level Understanding (SLU) document to define the details of the way the individual terminology lists used in the work item will be maintained.

The document describes the ICH preference for efficient terminology list maintenance. For dynamic lists that are liable to frequent change, the recommendation is to identify a terminology list maintained by a 3<sup>rd</sup> party Maintenance Organisation (MO) and use their processes to propose new terms, make changes to the list and remove obsolete terms. For lists of terms that are unlikely to change often then it may be appropriate to have the EWG/IWG act as the MO. Other methods of managing the lists can be proposed and agreed between M2 and EWG/IWG. The final decisions would be detailed in the SLU.

The document describes the 6 main processes associated with terminology lists:

1. Identifying the need for and selecting a terminology list and MO;
2. Creating a terminology list;
3. Creating the initial SLU;
4. Changing the terminology list contents;
5. Revising the SLU;
6. Changing the MO.

The documents appendices contain points to consider and template documents to accompany these process descriptions. In particular, the points to consider when selecting a terminology list and the accompanying MO and the considerations when changing the MO.

The document also contains a section detailing key points on the governance of the processes and the escalation of issues that might arise while running the processes.



## 2 PURPOSE

This document describes the key points to consider and outlines processes on the topic of terminology list definition and change management for ICH Expert/Implementation Working Groups. The ICH Management Committee charged the M2 EWG with the task of devising a change management process for terminology lists associated with ICH guidelines and other work items.

## 3 SCOPE

The ICH M2 EWG has produced these processes and points for consideration to ensure that all terminology lists used in ICH standards and guidelines are managed through a single process that pursues consistent terminology for equivalent concepts across ICH topics.

These processes and points to consider will apply to terminology lists arising from ICH guidelines that are used in electronic information transfer (e.g. terminology lists used in the E2B message and the M8 eCTD specifications). The change management process for ICH M1 work products (MedDRA®) are out of scope.

It is expected that these processes and points to consider can be applied to the terminology lists used by all ICH EWG/IWG, with specific issues identified in the Service Level Understanding (SLU) set up between ICH M2 and the EWG/IWG.

The management of local or regional modifications to ICH terminology lists are not specifically covered by this document and will be dealt with on a case- by-case basis where they exist within ICH guidelines (e.g., the ICH Study Tagging File specification). Where this is agreed, it will be documented in the SLU.

The management of purely regional terminology lists needed to support ICH specifications (e.g., Module 1 Context of Use terms for the eCTD) are also not covered by this document, but the points to consider may help the organisations tasked with managing these regional terminology lists.

This document uses the term “terminology list” throughout. This is used synonymously with “controlled vocabulary” “genericcode files” and “code list” which have been used in some other ICH documents.

## 4 KEY PRINCIPLES

### 4.1 Definitions: Governance, Owners and Stewards of the Terminology Lists

The following definitions are used in this document

**Terminology List Governance Group:** A group of individuals (or a hierarchy of groups) typically representing a cross-section of stakeholder groups. Together, they define a set of rules in the form of policies, standards, requirements, guidelines or data definitions. [Derived from the definition of a Data Governance Group in Governance, Stewardship, and Quality Roles and Responsibilities, The Data Governance Institute, 2009]



**Terminology List Owners:** Organizations that are in the position to obtain, create and have significant control over the content, access and distribution of Terminology Lists. [Derived from the definition of Data Owners in Governance, Stewardship, and Quality Roles and Responsibilities, The Data Governance Institute, 2009]

**Terminology List Steward:** The person responsible for managing the Terminology List in an organization in terms of integrated, consistent definitions, structures, calculations, derivations, etc. [Derived from the definition of a Data Steward in Data Stewardship: Process for Achieving Data Integrity, Claudia Imhoff, 1997]

In the ICH processes for terminology list management, the ICH M2 EWG will act as the Terminology List Governance Group, with input from the ICH EWG/IWG involved, as specified in the SLU.

The ICH processes for terminology list management are most impacted by who the Terminology List Owners are:

1. Terminology List Ownership is by external organization, usually referred to as a Maintenance Organisation (MO).
2. Terminology List Ownership is by an ICH EWG/IWG.

In all cases the ICH EWG/IWG is acting as the Terminology List Steward for the use of the terminology list for the specific ICH work item. In the second case above, the ICH EWG/IWG are both the Owners and Stewards of the Terminology List

It is possible that a selected Terminology List may have more than one specified Steward. For example, a particular Terminology List is owned by Organisation A but with the OIDs defined and managed by Organisation B. The ICH EWG/IWG chooses to use the Terminology List as managed by Organisation B in their work item as they need both the terms and the OIDs. In this example, Organisation A are the Owners of the Terminology List and Organisation B are the Owners of the OIDs and both Organisation B and the ICH EWG/IWG both have roles as Stewards.

It is considered good practice within the work of the ICH to adopt and use terminology lists already available and widely adopted that are maintained by an existing organisation (i.e. that another organisation should be the Owners and ICH are Stewards). In this case, the change management process defined by the organisation that owns the terminology list should be followed, after any necessary internal ICH review.

If no externally owned terminology list is available, then a terminology list can be created and defined by an ICH EWG/IWG. In doing so, the EWG/IWG also takes on the owners responsibility of maintaining and publishing this list.



## 4.2 Service Level Understanding

When the need for a terminology list is agreed between the ICH EWG/IWG and the M2 EWG then the details of the agreement will be specified in a Service Level Understanding (SLU) between the two groups. The process for defining and managing the SLU can be found in Sections 5.3 and 5.5 respectively.

The SLU will describe the key information about the terminology list or lists to be created and maintained. A template for the SLU is attached in Appendix 1. Alongside standard information there will also be a section where specific details for the terminology lists can also be documented.

It is not intended to “sign off” the SLU. The SLU should record the ICH EWG/IWG POC and the M2 EWG POC and the date that the agreement was first reached and then the dates of revision for any subsequent changes.

## 4.3 ICH Preferences for Terminology List Management

ICH recommends the following when managing Terminology Lists

1. For complex and changeable terminology lists we recommend trying to find externally owned and managed lists of terms. The EWG/IWG can then use the MOs processes for managing changes and making the updated lists available.
  - Ideally, the selected list is managed by the MO in a way that allows tools and systems managing the ICH message to interact directly via an interface to the terminology list (e.g. an API). If this is the case, the EWG/IWG needs to be sure that the list and all future changes can be used without the need for further review by the EWG/IWG.
2. For simple lists or lists with terms that are less likely to change (e.g. a fixed list of status values defined in the ICH work item) it may be easier to retain the ownership of the terminology list within the EWG/IWG as such lists will not require frequent updates.

## 4.4 Subject Matter Expertise

Each ICH EWG/IWG is considered to have the necessary Subject Matter Experts (SME) to be able to assess the need for changes to existing terms or to determine if additional terms are required or existing terms should be deleted or deprecated. It is noted that some ICH EWG/IWGs may need to work with other ICH experts to assess requests for new terms.

The ICH M2 EWG is considered to have the Subject Matter Expertise in the process for managing terminology lists but not in the content of the lists.

The role of ICH M2 EWG is noted below in Section 4.4.1. The role of the ICH EWG/IWG is noted below in Section 4.4.2.



#### 4.4.1 Role of the M2 EWG in Managing ICH Terminology Lists

The ICH M2 EWG has the following roles and responsibilities with regard to managing terminology lists.

- The M2 EWG will contact the ICH EWG/IWG during the development phase of their work items and set up a meeting to determine if there is a need for terminology lists. This contact should be made in the first 6 months of the setup of the EWG. The M2 EWG will also contact existing ICH EWG/IWGs approaching Step 4 to check if there are any needs for Terminology Lists within their work items.
- The M2 EWG will act as Subject Matter Experts on the topic of terminology lists and can be consulted by any other EWG/IWG for advice in identifying existing candidate terminology lists, working with the Maintenance Organisations (MO), etc.
- The M2 EWG will identify a Terminology List Point of Contact to perform certain tasks associated with the management of terminology lists. This role will be referred to as the M2 POC in this document.
- The M2 POC will maintain a list of all of the terminology lists (The ICH Master List of Terminology Lists) identified in all of the ICH EWG/IWG documents (Appendix 2). The ICH Master List of Terminology Lists will identify:
  - The EWG/IWG which owns the ICH work item
  - The EWG/IWG that owns the terminology list (if this is not the same as the owner of the ICH work item)
  - The ICH EWG/IWG Point of Contact for all issues associated with maintaining the terms in their terminology lists (if applicable)
  - The work product name and type (e.g. guideline, guideline addendum, points to consider document, etc.)
  - Each terminology list defined within the Group's work product, if any. For each identified terminology list the following items will be identified
    - The name of the list (and a brief description of the content, if needed)
    - The organisation maintaining the list, including contact information
    - The location of the master list for the terminology
    - Whether there are any regional extensions to the terminology list (As noted in the Scope section, the SLU will include details of whether the regional extensions are managed by the ICH process)
- The M2 POC will provide oversight and tracking of all requests made by ICH EWG/IWG for changes to terminology lists on a master list of terminology change requests (Appendix 3).
- The M2 EWG manage the relationships with the external organisations that own terminology lists used in ICH work items.
- The M2 EWG owns the process and this document
- The M2 EWG will create the draft SLU for discussion with the EWG/IWG and maintain the final agreed SLU (see Section 5.3).
- The M2 EWG has the responsibility to maintain the consistency and alignment of terminology lists used by ICH EWG/IWG groups.





#### 4.4.2 Role of the ICH EWG/IWG in Managing ICH Terminology Lists

The ICH EWG/IWG has the following roles and responsibilities with regard to managing terminology lists.

- The ICH EWG/IWG will be the Subject Matter Experts about the work item from which the need for a terminology list arises. They will identify and describe the terms needed to support the technical specification.
- The EWG/IWG will determine the specific needs for the management of the terminology list and describe this in the SLU (see Sections 5.1 and 5.3)
- The EWG/IWG will review and approve the final SLU
- The EWG/IWG will identify a Terminology List Point of Contact to manage issues associated with identified Terminology Lists, known as the EWG/IWG POC

#### 4.5 The EWG/IWG Terminology List Point of Contact

As noted above, each ICH EWG/IWG with an agreed need for terminology lists to support a technical specification should appoint a Terminology List Point of Contact (EWG/IWG POC). Someone in the EWG/IWG should be named to this role while the working group is in operation but this should continue also after it has been closed. The process steps below identify what the EWG/IWG POC needs to do.

Even when the EWG/IWG is closed, the EWG/IWG POC plays an important role in ensuring an appropriate level of expertise is available to support the maintenance activities for the terminology lists. If a particularly complex request associated with a terminology change arises, the EWG/IWG POC can approach the ICH Management Committee to request additional experts to be nominated from each party. However, for simple changes it is expected that the EWG/IWG POC can deal with requests on behalf of all of the parties and without the need to reach all-party consensus. It is recommended that if the EWG/IWG POC has any questions or concerns about the need for a change then they should request the MC for additional experts to be nominated.

It is expected that the name and contact information for the EWG/IWG POC will be continuously available through the ICH Secretariat. Thus, in the normal course of transition to a new EWG/IWG POC, the Secretariat must be informed of the change immediately. This is the task of the EWG/IWG POC and their Assembly or MC representative.

#### 4.6 Locations of Documents Associated with this Process

The following locations are used to store documents referred to in this document:

ICH Groups, M2 Technical References for WGs web page (<https://groups.ich.org/shared-section/page/m2-technical-references-ich-working-groups>) (Note: This is a restricted access website only available to members of ICH WGs)

- Terminology List Management Processes (this document)





- Considerations and Standards for Creating and Maintaining an ICH Owned Terminology List
- Copies of the agreed SLUs
- The ICH Master List of Terminology Lists
- Blank Terminology List Change control form
- Completed Terminology List Change Control Forms
- List of all Terminology List Change Control requests

ICH Electronic Standards web page (<http://www.ich.org/products/electronic-standards.html>)

- Information Paper: Use of OIDs and UUIDs in ICH Messages

Individual ICH EWG/IWG pages

- Change control forms and details for the individual EWG/IWG
- Final versions of the Terminology Lists to be used for the individual standard or other ICH work item

ICH Secretariat

- List of EWG/IWG Terminology List POCs

## 5 PROCESSES

### 5.1 Identifying the Need and Selecting a Terminology List

When a new EWG is formed it is the responsibility of the M2 EWG to contact the EWG Rapporteur and have an initial discussion about the need for terminology lists. This contact should be made within the first 6 months of the EWG being formed.

1. When a new EWG is formed, the M2 Rapporteur will contact the new EWG Rapporteur to discuss any support they may need with regard to technical issues within the remit of the M2 group. This should include the need to develop or define any terminology lists to support a technical message standard.
2. If a possible need is identified, members of the M2 EWG should meet with members of the new EWG to help clarify and confirm the support needed, including terminology list requirements.
3. The confirmed need for a terminology list or lists should be recorded in the ICH Master List of Terminology Lists and the new EWG should be trained on the processes and points to consider in this document.



4. The EWG/IWG should identify their Terminology List Point of Contact, described as the EWG/IWG POC in this document. See also Section 4.5.

If an ICH EWG/IWG needs a terminology list, the steps below should be followed. If more than one terminology list is required then the steps should be followed for each required terminology list:

1. The EWG/IWG POC notifies the M2 POC of the need and gets any guideline or help. The EWG/IWG may propose a terminology list that they would prefer to use.
2. The M2 EWG, through the M2 POC, will work with the EWG/IWG POC to review the current list of M2-maintained ICH terminology lists to evaluate if an existing terminology list could meet the need, along with the identified MO
  - If a suitable list is identified then the details of the list and MO should be documented in the SLU.
3. If no terminology list meeting the need is already being used by another EWG/IWG, the M2 EWG will scan for external lists that may exist, with assistance from the EWG/IWG; if selecting a list from an MO that has not been used before by ICH, the M2 EWG will review the points to consider for selecting an MO (Appendix 4)
  - If a suitable list is identified then the details of the list and MO should be documented in the SLU.
4. If no suitable external list is found and an internal ICH list must be developed, follow the steps below (Section 5.2)

Note that if several terminology lists are required it could be the case that some are owned externally and others are owned by the EWG/IWG

## **5.2 Process for Creating a Terminology List**

This process should be followed when an ICH EWG/IWG, with assistance from the ICH M2 EWG, has reviewed the available externally managed terminology lists and determined that no suitable lists are available. In this case, the ICH EWG/IWG will create their own terminology list. The primary contacts for the work will be the M2 POC and EWG/IWG POC. Note also that the decision to become the owners of a terminology list places a responsibility on the EWG/IWG to maintain the list for the life of the ICH guideline or standard.

The process steps are as follows;

1. The EWG/IWG creates the terminology list
  - The ICH M2 POC will work with the EWG/IWG to ensure that the necessary requirements are met for the creation and maintenance of the terminology list. These considerations will be published in a separate document that the ICH M2 EWG will create and that can be found on the ICH Groups site (see Section 4.6).
    - As a minimum, the terminology list should have a name, a change control section (to track changes to the list), a version number and a



list of valid terms but other considerations are identified in the separate document cited above.

- Where necessary, the EWG/IWG should add brief comments alongside individual values to explain their usage, reference should be made back to the ICH guideline as needed.
  - To assist with future change management, the EWG/IWG must think ahead as to how to show the status of values, particularly those that are no longer valid and how they will be identified in the list.
2. Approve the list within the EWG/IWG
  3. The EWG/IWG posts the list, with version control information, to the ICH website in the EWG/IWG's own section.
  4. The EWG/IWG POC should notify the M2 POC that the list has been approved and posted so that the master list can be updated.

The details of the terminology list will be listed in the SLU.

### 5.3 Process for Creating the SLU

As noted in Section 4.2, the SLU is a key document for understanding the way in which the identified terminology lists will be maintained over the life of the ICH work item. It is recommended that a separate SLU should be created for each EWG/IWG work item. Information for different work items can be combined but this may bring challenges in managing the information over the lifecycle of each individual work item.

Each SLU should list all of the terminology lists associated with the work item, whether the maintenance task is considered simple (e.g. the list is not likely to change over the life of the work item) or more complex. The SLU should identify all the necessary steps to update and make public to the work item users the associated terminology list terms and to ensure the terminology list is up to date for the life of the work item.

1. Once the terminology list(s) is identified then ICH M2 POC will create a draft SLU for the creation and management of the terminology list(s).
2. The draft SLU will be sent to the EWG/IWG POC and then reviewed by the EWG/IWG and the final wording agreed.
3. The final SLU will be accepted by both parties and the agreed SLU archived by the M2 POC.

It is possible that the SLU will detail specific steps or considerations about the management of the identified Terminology Lists. In this case the SLU supersedes or supplements the relevant sections of this document.

### 5.4 General Process for Changing a Terminology List

As noted, the expertise and knowledge about the individual ICH guidelines and their associated terminology lists lies with the ICH EWG/IWG responsible for them. As the EWG/IWG plays the role of Terminology List Steward they will determine if a proposed change to a terminology list is implemented.



The process steps for changes to the terminology lists associated with ICH guidelines should be as detailed below. It is possible that specific update considerations for the terminology list are detailed in the SLU, in this case the details in the SLU supersede or supplement the process detailed below.

The process steps below assume that every EWG/IWG that has implemented a technical specification which employs terminology lists has also implemented their own change control process, including a form to make requests to the EWG/IWG. The M2 POC will recommend to the EWG/IWG to establish a change control process if they do not have one.

1. A request for a change, or a notification of a change, is received by the EWG/IWG via their own change control form.  
Note: if the EWG/IWG work item references a terminology list owned by another organisation, the EWG/IWG must determine how they will be informed of changes to the terminology list that are requested by other users of the list. This communication route may serve as notification of a planned change that is not made on the EWG/IWG change control form.
2. The EWG/IWG POC will assess the change request for impact on their uses of Terminology Lists and accept or reject the requested change. If insufficient information is available to make the final decision, the EWG/IWG POC may contact the requestor for additional information. In circumstances where the EWG/IWG POC is unable to make the final decision due to the complexity of the request, they may request additional help from other experts in the EWG/IWG.
3. Changes assessed as impacting a terminology list should be documented on the ICH Terminology List Management Process Change Control Form by the EWG/IWG POC, available on the ICH M2 website (see also Appendix 5). Requests must include the details of the terminology list being changed, a description of the proposed change, a justification for the proposal and contact details of the requestor.
4. The EWG/IWG POC should inform the M2 POC that a request has been received and send the completed ICH Terminology List Management Process Change Control Form. The M2 POC should assess potential impact on other EWG/IWGs if they also use the same terminology list. The M2 POC should contact the EWG/IWG POC for any other EWG/IWG and they should also follow these process steps.
5. The M2 POC will update the log of all change requests with the details provided by the EWG/IWG POC.
6. The M2 POC will further update the log with details of the outcome of the review and the final decision. The M2 POC should ensure approved changes are consistent and aligned with the usage of the terminology within ICH and may need to hold a wider discussion with other members of the M2 EWG. The M2 POC may need to refer back to the EWG/IWG if there is an issue.
7. For requests that are accepted to be made to the terminology list, the EWG/IWG POC will initiate the relevant process for an externally owned list (Section 5.4.1) or an ICH EWG/IWG owned list (Section 5.4.2).
8. The EWG/IWG POC should inform the requestor of the final outcome (if applicable) and copy the M2 POC on the response.



#### **5.4.1 Making Changes to an Externally Owned Terminology List**

As noted above, the change management process followed should be defined by the organisation that owns and manages the terminology list. The ICH EWG/IWG should make requests using this change management process.

The ICH EWG/IWG that has selected the terminology list should interact directly with the organisation that owns the terminology list if they want to propose changes or updates to the list.

#### **5.4.2 Making Changes to ICH EWG/IWG Owned Terminology Lists**

It is usually expected that the EWG/IWG will provide the resource and expertise to maintain the lists and assess proposed changes. In this case the following points should be considered. It is possible that the SLU will detail specific steps or considerations when making these changes. In this case the SLU supersedes or supplements the points identified below.

1. The EWG/IWG POC should make a determination about the complexity of the change received
  - a. Simple changes (e.g. correction of spelling mistakes) may be made and released by the EWG/IWG POC
  - b. Complex changes will usually need wider input from experts from the EWG/IWG and the EWG/IWG POC may need to make a request for experts from all parties to be nominated if the EWG/IWG is currently disbanded.
2. The change to the terminology list should be made and approved by EWG/IWG POC or EWG/IWG. The updated list should be appropriately version controlled and a change log included on the list to identify approved changes made to the list.
  - a. Note that care should be taken with changes that request values to be “deleted” or otherwise removed from the list of valid values. In this case the list should retain the old term but identify it as no longer valid (rather than deleting the value completely). This ensures people reviewing legacy data can still check the validity of old data.
3. The updated terminology list should be made available via the ICH website and the change communicated to users of the associated guideline.
4. The EWG/IWG POC should inform the M2 POC that the change has been completed.

#### **5.5 Revisions to the SLU**

The SLU may need to be revised as a result of activities by either the M2 EWG or the EWG/IWG. The following steps should be taken:

1. The M2 POC or IWG/EWG POC will identify the need to revise the SLU. They will contact the other POC with details of the proposed change.
2. The POCs will discuss and document the changes. If needed, the POCs may include a wider group of experts from the M2 EWG or the ICH EWG/IWG or both to discuss and document the changes
3. The final SLU will be reviewed and approved by both parties



4. A copy of the final SLU will be archived by the M2 POC

## **5.6 Process to Change the MO**

There may be circumstances where a selected MO may need to be changed. The impact of the change may be different whether the MO is the owner of the Terminology List or is acting in a stewardship role in the process of maintaining the Terminology List. Some points to consider are listed in Appendix 6.

In general, it is recommended that a change to the MO is treated as any other change to the Terminology List and the general process in Section 5.4 should be followed.

## **6 ISSUE ESCALATION AND REVISION**

In general, the IWG/EWG has responsibility to provide the expertise in managing a terminology list and its applicability to the work item, to maintain the overall quality of the list values and to determine if the list continues to be fit for purpose. ICH M2 EWG has the responsibility to provide the technical expertise about terminology lists, their development and maintenance and other associated topics, such as liaising with MOs.

When an issue is identified then, in line with the responsibilities described above, one party will be designated as responsible for resolving the issue. The other party will be consulted in resolving the issue. Members of the both parties should work to find a resolution with the responsible party taking the lead to clarify the issue and seek options for resolution which can be discussed. The final resolution should be agreed by both parties.

Should the groups be unable to reach a mutually acceptable resolution, issues should be escalated to the ICH Management Committee. The groups should provide information about the issue and the positions of the two groups in dispute with a request for the MC to help find a resolution.



## APPENDICES

### Appendix 1 Sample SLU

EWG/IWG:

EWG/IWG Work Item:

EWG/IWG POC (Name and ICH Party):

M2 POC (Name and ICH Party):

Date of Agreement:

[Repeat the following details for each Terminology List in the EWG/IWG Work Item]

Terminology List Name:

Terminology List OID (if applicable):

Terminology List Description (if needed):

MO for the Terminology List

MO Contact Information:

Location of the Master Terminology List:

Are there any Regional Extensions?

(Give details if they are being managed under this SLU):

Agreed conditions for the maintenance of the Terminology List:

Revision Dates:

Date of Revision	Description of Revision	POC for Change (from Change Request)





**INTERNATIONAL COUNCIL FOR HARMONISATION OF  
TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE**

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Appendix 2 The ICH Master List of Terminology Lists (The List of Controlled Terminologies used in ICH Guidelines) (Example)

<b>EWG/IWG that owns the ICH Work Item</b>	<b>ICH Work Item Name</b>	<b>ICH Work Item Type</b>	<b>EWG/IWG that owns the Terminology List</b>	<b>EWG/IWG POC</b>	<b>Terminology List Name</b>	<b>Terminology List Contents Description (if needed)</b>	<b>MO for the Terminology List</b>	<b>MO Contact Information</b>	<b>Location of the master list for the terminology</b>	<b>Are there any regional extensions?</b>



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Appendix 3 Master List of Change Control Requests (Example)

<b>EWG/IWG</b>	<b>EWG/IWG Work Item</b>	<b>Date of Change request</b>	<b>Terminology List Name</b>	<b>Terminology List Description</b>	<b>MO for the Terminology List</b>	<b>Proposed Change for the Terminology List</b>	<b>Proposed Implementation Date for the Change</b>	<b>Status</b>



#### Appendix 4 Points to Consider When Selecting a Terminology List Owned by an External Maintenance Organisation

When selecting a terminology list owned by an external Maintenance Organisation (MO) the following points should be considered:

- Well established organisation with a record of owning and managing terminology lists
- A published process for requesting changes to their terminology lists
  - It is possible that the MO that owns the list uses a separate MO to run the change control process (acting as stewards for the list). In this case, the same considerations should be applied to the steward organisation.
- A published appeal process exists for new terms that are not approved by the normal procedure
- A means to identify the version of the terminology list used at a certain time (e.g. through the use of specific version number associated with changes made to the list at any one time or by date/time stamping of changes made). It may be the case that the identification of the “versioning” is managed on the individual terms, rather than on the complete list.
- It should be possible to see a change history for a specific term
- It should be possible to look up a single term and determine its status and the date that the status changed. In some cases the statuses may only be valid or invalid, but other lists may have other statuses (e.g. legacy, proposed, accepted, retired).
- The terminology list should be available to users in an easily usable and readily accessible form, for example:
  - The list can be downloaded in full from the MO source in an electronic form that does not require re-keying for use in the users own tools, or;
  - The list is available electronically via a web service so it can be linked into the users’ own tools
  - The strong preference is for the list format to be Genericode (see the ESTRi recommendations)
  - There should not be a cost associated with the use of the terminology list. This may include costs to access the list and use the terms or costs associated with modification of the terms.
  - If any of these considerations are not met (e.g. the full terminology list is only available to MO members or the list is not available in genericode) then the benefits and issues should be discussed between the M2 POC and the ICH EWG/IWG.
- When ICH uses an externally maintained terminology list, the MO defines the frequency and approach to updating the terminology. Each ICH member party and any other adopter of the ICH standard using the terminology will be responsible for its own schedule for refreshing its internal copy of the list. If the refresh frequency is longer than the MO’s update schedule, the party must be aware that the possibility exists that a new term is used that is not in the downloaded version. If this occurs, the first step should be to check the term against MO’s master list, and to refresh the downloaded list accordingly.



- A preferred requirement of terminology maintenance organizations is to include vocabulary governance – i.e., nothing is deleted, only deprecated and an alternative term is provided. Also some notification or method of determining when terms are deprecated should be considered.
- A terminology list should usually be available in English. Arrangements for the list to be available in other languages are at the discretion or requirements of the EWG/IWG that is requesting the list.
- If the MO list has terms not required by ICH, it will be up to the EWG/IWG to provide the additional guideline on the valid values on the list for ICH use.

The details of the terminology list selected and the MO will be listed in the SLU.



Appendix 5 ICH Terminology List Management Process Change Control Form

Requestor Information

EWG/IWG:

EWG/IWG Work Item:

EWG/IWG POC (Name and ICH Party):

Date of Change request:

Proposed Implementation Date for the Change:

[Repeat the following details for each change in a Terminology List in the EWG/IWG Work Item]

Terminology List Name:

Terminology OID (if applicable)

Terminology List Description (if needed):

MO for the Terminology List

MO Contact Information:

Proposed Change for the Terminology List:



Appendix 6 Points to Consider When Changing Maintenance Organisation for a Terminology List

The following points to consider should be reviewed when considering changing the maintenance organization responsible for managing a terminology list. This could be a change from one external MO to another external MO. However, this could also be when changing from a terminology list maintained by an ICH EWG/IWG to a list maintained by an external MO.

- The points to consider when identifying a MO (Appendix 4) should be reviewed when selecting a new MO for a specific terminology list. The EWG/IWG should liaise as needed with the M2 EWG if they need support for this activity.
- Review the terms on the current list and the terms on the list from the new MO.
  - If terms are similar but not identical, the EWG/IWG will need to give guidance on mapping the terms from the current list to the terms on the new list
  - If terms on the current list are not available on the new list, the EWG/IWG will need to follow the process for adding new terms in this document (Section 5.4)
  - If terms on the new list should not be used in connection with the ICH use of the terminology list then the EWG/IWG will need to give guidance. Constraints on the use of the list may be made by the external MO on ICH's behalf, or the ICH EWG/IWG may issue details after the list is adopted.
- The concerned EWG/IWG and the M2 EWG must approve the new list, as well any supplemental explanatory materials, prior to its adoption for use in support of the respective ICH guideline. Note that there may be a requirement for guidance that would support use of both the former and the new terminologies simultaneously for a period of time. In addition, there may be a requirement for mapping or conversion (backwards and forwards) from one terminology to the other.
- If the maintenance of a list is being passed from an ICH EWG/IWG to an external MO then consideration about the retirement of the ICH maintained list should be made by the EWG/IWG. This should include detailing any transition period and the necessary steps to retire the old list and remove from the ICH website and any other reference locations.

Any changes to the MO for a terminology list must be detailed in a revised SLU.