INFORMATION PAPER

Use of OIDs & UUIDs in ICH Messages

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Explanation of the use of OIDs and UUIDs in the message.

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Introduction

ICH E2B(R3), the "Electronic Transmission of Individual Case Safety Reports (ICSRs) Implementation Guide Data Elements and Message Specification," and ICH M8, the "Electronic Common Technical Document" are technical standards that incorporate code sets and namespaces using numeric Object Identifier codes (OIDs). Since OIDs may be a new concept to some implementers and users of these standards, this information paper is being released to provide more detail.

Background: OIDs & UUIDs

An Object Identifier, or OID, is a construct used to identify an object. In the context of Information Technology standards, OIDs are globally unique identifiers. Most international standards use the ISO ASN.1 data type which consists of a sequence of one or more non-negative integers, often referred to as arcs, which define a hierarchy, or tree, of object identifier values. These are represented using a form that consists only of numbers and dots (e.g., "2.16.840.1.113883.3.989"). OIDs are paths in a tree structure, with the left-most number representing the root and the right-most number representing a leaf.

Each OID is created by a Registration Authority. As explained by HL7,

> Each of these authorities may, in turn, delegate assignment of new OIDs under it to other registration authorities that work under its auspices, and so on down the line. Eventually, one of these authorities assigns a unique number that corresponds to a leaf node on the tree. The leaf

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ICH Secretariat c/o IFPMA, Chemin Louis-Dunant 15, P.O. Box 195, 1211 Geneva 20, Switzerland
Telephone: +41 (22) 338 32 06, Telefax: +41 (22) 338 32 30
admin@ich.org, http://www.ich.org

may represent a registration authority (in which case the OID identifies the authority), or an instance of an object. A registration authority owns the namespace consisting of its sub-tree. [1]

ICH is a Registration Authority under the arc of HL7 with responsibility to assign its own OIDs. ICH M2 ESTRI, the ICH Expert Working Group (EWG) responsible for the technical aspects of ICH standards for information transmission, acts on behalf of ICH to assign and maintain OID values in partnership with the particular topical ICH EWG developing a standard that may require code lists or namespaces. The E2B standard was the first of the ICH technical messaging standards to utilize this OID system for clear identification of the coding values for elements of the message.

OIDs provide unambiguous and clear identification of objects like code lists. A particular OID always refers to a distinct object. That OID will never refer to another object. No two parties can ever assign the same OID to two different objects. The OIDs assigned by any registrar are always distinct from those created by a different registrar. However under this distributed system it is possible for two different parties to assign different OIDs to the same object. This does not matter in practice, because using either of those OIDs will always point the user to the correct object. They would be analogous to synonyms, but never have different meanings.

OID Repositories, or OID Registries, are publicly accessible listings of OIDs to allow identification and translation of the numeric strings, and to provide information on the owner and registrar for a particular OID. To understand more about the role of OID registries or repositories please see the examples of the HL7 OID Registry at http://www.hl7.org/oid/index.cfm?ref=common or the OID Repository sponsored by FranceTelecom at http://www.oid-info.com/.[2] ICH will publicise its OIDs using these repositories, and also via its own ESTRI webpages on the www.ich.org site.

ICH, as a registrar, will maintain a structure or tree of values for identification of artefacts. Table 1: Overall OID Assignment Scheme (As Relevant) below illustrates a piece of that arc. The overall identifier for ICH is represented by the value **2.16.840.1.113883.3.989**. This numeric identifier represents a chain locating ICH in the global scheme of OID registration. It is extended by adding values on the end, separated by decimal points, to identify arcs. In the next position the digit 2 represents a standard, as illustrated by **2.16.840.1.113883.3.989.2**.

[1] http://www.hl7.org/oid/index.cfm?ref=common
[2] ICH is not officially recommending or sponsoring either of these sites. These are merely two easily accessible websites with comprehensive information on OIDs.

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ICH Secretariat c/o IFPMA, Chemin Louis-Dunant 15, P.O. Box 195, 1211 Geneva 20, Switzerland
Telephone: +41 (22) 338 32 06, Telefax: +41 (22) 338 32 30
admin@ich.org, http://www.ich.org

Table 1: Overall OID Assignment Scheme (As Relevant)

ICH Root OID:	**2.16.840.1.113883.3.989**					
Sub-Category	**Arc**	**Sub-Category**	**Arc**	**Sub-Category**	**Arc**	**Values (OIDs)**
General M2 / ESTRI Documents	1	Not applicable				
Standards	2	E2B(R3) ICSR	1	Code Lists / Vocabularies	1	…
				Documents	2	…
				Other NameSpaces	3	…
				Test Artifacts	4	…
		M8 eCTD V4	2	TBD		
(RESERVED)	3	Not applicable				
(RESERVED)	…	Not applicable				

Table 2 provides an illustration of how this works in practice. It shows individual OIDs, the numeric identifier, and what they identify.

Table 2: Overarching ICH OIDs Related to E2B(R3):

OID Name	**OID Value**	**Notes**
ich-estri	2.16.840.1.113883.3.989	The ICH registrar node, maintained by the M2 ESTRI EWG
ich-estri-msg-stds	2.16.840.1.113883.3.989.2	ICH Standards requiring OIDs
ich-estri-msg-stds-e2b-icsr	2.16.840.1.113883.3.989.2.1	The E2B Standard
ich-estri-msg-stds-e2b-icsr-code-lists	2.16.840.1.113883.3.989.2.1.1	Code lists from the E2B standard
ich-first-sender-of-this-case	2.16.840.1.113883.3.989.2.1.1.3	A particular code list
ich-estri-msg-stds-e2b-icsr-documents	2.16.840.1.113883.3.989.2.1.2	Documents that are part of the E2B standard
E2B(R3) Implementation Guide	2.16.840.1.113883.3.989.2.1.2.1	A particular document from the E2B standard
Step 2 Version 3.01	2.16.840.1.113883.3.989.2.1.2.1.1	A version of that document.
ich-estri-msg-stds-e2b-icsr-other-namespaces	2.16.840.1.113883.3.989.2.1.3	Namespaces referenced in the E2B message
ich-worldwide-case-identifier	2.16.840.1.113883.3.989.2.1.3.2	A particular namespace

A Universally Unique Identifier (UUID) is a different method of identifying an object that does not rely on central coordination. It is generated by the user and does not reference any generally accessible naming convention or catalogue. UUIDs are generally not easily interpreted by a human reader and are intended solely for machine comparison. (OIDs can be interpreted by humans, more so when alphanumeric naming schemes are used, but are relatively recognizable even in numeric form.)

Although a UUID does not provide absolute certainty that it is distinct (such as an OID), it provides enough certainty to clearly identify an object. The benefit of OIDs is that they can be looked up through the repositories, and can be accessed and referenced by anyone. UUIDs need to be transmitted between parties, but once identified can be used within the given implementation to identify objects. The benefit of UUIDs is that they do not require any central support or maintenance

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ICH Secretariat c/o IFPMA, Chemin Louis-Dunant 15, P.O. Box 195, 1211 Geneva 20, Switzerland
Telephone: +41 (22) 338 32 06, Telefax: +41 (22) 338 32 30
admin@ich.org, http://www.ich.org

(such as an OID registration process) and can be created and used instantly. There are many ways to generate UUIDs. For the ICH E2B message UUIDs are only used in two namespaces, ***int-references-to-reaction*** and ***int-references-to-substance-administration***. These are references that are used internally to the XML message as pointers and therefore do not need to be distinct across messages, only within them. They are used in the parsing and validation of a message, not in the creation or interpretation of content.

Code Lists & Namespaces Usage in the Messages

There are many elements within the messages requiring specific codes to reference defined values. In the past these codes were part of the standard and were specified directly within the ICH Implementation Guides, making alteration very difficult. By separating the code lists and the standard it becomes easier for code lists to be adapted, should this be necessary, without altering the technical message standard itself. Also, technical systems can be more readily adapted if the code lists are provided in a clearly identified, traceable manner.

Within E2B messages there are also elements which require transfer of coded values which are not derived from ICH code lists, such as MedDRA. The use of an OID ensures that systems always reference the appropriate external code list when creating or parsing these messages.

There are elements within the E2B (R3) message that require codes which are not part of global centrally maintained or publicly accessible code lists, such as the Sender's Safety Report Unique Identifier or the various Patient Medical Record Numbers. When these codes are transmitted they need to be clearly identified to the systems that are parsing the messages. This is done by referencing a distinct "namespace."

A namespace is a general term for an identifier that provides the context for identifying a set of values. In the HL7 framework it is essential to qualify any code that is provided in a message. For certain types of values, such as patient medical record numbers, there is no central repository that spans all potential coding systems – for example, all clinical institutions do not use the same system for numbering records – so it is not feasible to maintain an actual code list. The namespace informs the parsing system of the context of the coded value. A pertinent example from the ICSR message is the Unique Identifier assigned to a report by the sender. There is no global repository of all ICSR report identifiers for all ICSRs ever created by, or submitted to, all regulatory authorities and reporters. The namespace ***ich-senders-safety-report-identifier*** is used in the XML instance to inform the receiving system that the code being transmitted is not from a defined code list but is instead a code created by the sender according to the ICH process as defined in the Implementation Guide.

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ICH Secretariat c/o IFPMA, Chemin Louis-Dunant 15, P.O. Box 195, 1211 Geneva 20, Switzerland
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The full list of the Code Lists to be used in the messages, including both ICH- and externally-maintained lists, are contained in the Implementation Guide along with instructions as to which code list to use for each relevant element. The ICH-created code lists have now been assigned OIDs for use in the construction of the technical messages. Those values are listed in the reference section of this document, and will be available on the ICH web site. The Implementation Guide will contain the up-to-date OIDs and code list names.

Namespaces are a product of the technical construction of the message using the constrained HL7 standard schemas. These OIDs do not appear in the instructions for entering content into the elements as 'pick-lists' of values. They do appear connected to elements which are intended to contain codes which are not maintained by the ICH. They are also illustrated by example within the reference instance XML examples.

Use of Placeholders in a Step 3 Implementation Guide

As mentioned in the previous section, the Implementation Guide identifies various elements which required values from specified code lists that are referenced by OIDs. These are listed in Section 3.2 of the Implementation Guide in the various tables describing internal and external code lists.

The externally created and managed code lists have object identifiers due to their use in other systems and implementations that require OIDs. For example, in the excerpt below, the IG identifies that the MedDRA code list is used in element B.1.7.1.r.a.2. MedDRA has an internationally recognised OID which is given in the table.

Element id	Element Name	OID Name	OID Reference
B.1.7.1.r.a.2	Structured Medical History Information (disease / surgical procedure / etc.)	MedDRA	***2.16.840.1.113883.6.163***

Similarly, in another related table in Section 3.2, element A.2.r.1.3, the Reporter's Country Code is completed using the ISO International 2-letter alpha-numeric country code, which also already has an internationally recognised OID.

Element id	Element Name	Coding Scheme Name	OID Reference
A.2.r.1.3	Reporter's Country Code	ISO 3166 Part 1 (alpha-2)	***1.0.3166.1.2.2***

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ICH Secretariat c/o IFPMA, Chemin Louis-Dunant 15, P.O. Box 195, 1211 Geneva 20, Switzerland
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However, at the time that Implementation Guides are written and released for public consultation, the M2 (ESTRI) Expert Working Group has not yet created and registered OIDs for the code sets created by ICH for use in the various messages.

Therefore, in order to identify the elements requiring ICH internally-created code lists, placeholders are created and used both in the text of the Implementation Guide and in the reference XML instance examples. The actual numeric OIDs do not yet exist. These placeholders are derived from the element or code list name in a short-hand form and the text "**-oid**" to identify that the placeholder represented a numeric object identifier.

For example, from Section 3.2:

Element id	Element Name	ICH Placeholder OID
M.1.1	Type of Messages in Batch	***ich-type-of-message-in-batch-oid***

The difference is the "ICH Placeholder OID" instead of the actual "OID Reference" in the third column.

These placeholders will be replaced by the actual numeric OIDs when an Implementation Guide becomes final.

For example, the above excerpt from Section 3.2 will look like this in the final Implementation Guide:

Element id	Element Name	OID Reference
M.1.1	Type of Messages in Batch	2.16.840.1.113883.3.989.2.1.1.1

The number in this example is the actual value that will be used. The placeholder texts were only used for the purpose of the earlier drafts of the Implementation Guide.

As mentioned, this is also true for the example XML text in the reference instances. The text released used the placeholder codes, as below:

```
<inboundRelationship typeCode="CAUS">
  <act moodCode="EVN" classCode="ACT">
    <code code="B.4.k.8" codeSystem="ich-action-taken-with-drug-oid"/>
  </act>
</inboundRelationship>
```

This was intended to illustrate that the element B.4.k.8 would need to reference an OID which points to the ICH code list named the *ich-action-taken-with-drug* when a real message was created. And the

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ICH Secretariat c/o IFPMA, Chemin Louis-Dunant 15, P.O. Box 195, 1211 Geneva 20, Switzerland
Telephone: +41 (22) 338 32 06, Telefax: +41 (22) 338 32 30
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value B.4.k.8 in parenthesis in the example would be replaced by a value from that code list which represented the content of the element (an integer between 1 and 6 as per the Implementation Guide).

The text in the new reference XML instance will appear like this now that the numeric OIDs are released:

```
<inboundRelationship typeCode="CAUS">
  <act moodCode="EVN" classCode="ACT">
    <code code="B.4.k.8" codeSystem="2.16.840.1.113883.3.989.2.1.1.15"/>
  </act>
</inboundRelationship>
```

This is closer to a real-life message. The Code System reference is now correct. The value for the code would still be replaced by an integer between 1 and 6 from the ***ich-action-taken-with-drug*** code list; however an actual ICSR message will contain the numeric string indicated here to tell the receiving system that the integer value in the field should be looked up in a table referencing this code list.

In the case of the internal references relating to the organization of the message (the structured references to allow multiple reactions or administration of substances) the reference instance indicated 'TBD' for the observation value grouping (the ich-organiser-code) and used an OID placeholder for the internal id used to reference related observations:

```
<organizer>
   <code code="drugInformation" codeSystem="TBD"/>
   <component typeCode="COMP">
   <substanceAdministration moodCode="EVN" classCode="SBADM">
   <id extension="1" root="oidInternalReferencesToSubstanceAdministration"/>
   <consumable>
```

In the corrected reference instance the correct numeric OID is provided for the ich-organizer-code, and the expression of the internal id has been demonstrated using a UUID:

```
<organizer classCode="CATEGORY" moodCode="EVN">
   <code code="drugInformation" codeSystem="2.16.840.1.113883.3.989.2.1.1.20"/>
   <component typeCode="COMP">
   <substanceAdministration classCode="SBADM" moodCode="EVN">
   <id root="6bffaf56-7af9-4d1a-a268-6195ca3c1de9"/>
   <consumable>
```

(Note: This UUID has no meaning and is only an example of what a typical UUID may look like.)

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ICH Secretariat c/o IFPMA, Chemin Louis-Dunant 15, P.O. Box 195, 1211 Geneva 20, Switzerland
Telephone: +41 (22) 338 32 06, Telefax: +41 (22) 338 32 30
admin@ich.org, http://www.ich.org

Distribution of ICH Code Lists

The values for the ICH Code Lists are being distributed in an electronic format rather than solely as text within the Implementation Guide.

The format for distribution of the values is based on an OASIS standard known as genericode.[3] The description of the overall code set, connected to the version of the Implementation Guide, is contained in a file named "ICH E2B(R3) Codelist Set.gc.xml" for the E2B(R3) IG as an example.

This file provides the name and version of the Implementation Guide, and provides the name and associated OID of each ICH provided code list in a simple XML format. It will allow for any future changes to code list sets to be properly associated with a particular version of the standard. At the current time this is not in use.

The individual code list are provided in separate XML files which code a table format associating a numeric value to an English and a Japanese term. This is done by defining a set of columns, and then placing the associated values in a row.

Columns are defined as such within each code set:

```
<ColumnSet>
    <Column Use="required" Id="code">
        <ShortName>numeric-code</ShortName>
        <Data Type="unsignedShort"/>
    </Column>
    <Column Use="optional" Id="en">
       <ShortName>english-label</ShortName>
       <Data Type="string" Lang="en"/>
    </Column>
    <Column Use="optional" Id="jp">
        <ShortName>japanese-label</ShortName>
        <Data Type="string" Lang="jp"/>
    </Column>
</ColumnSet>
```

Then subsequent codes within the file provides the actual values:

```
<SimpleCodeList>
<Row>
     <Value ColumnRef="code"><SimpleValue>1</SimpleValue></Value>
     <Value ColumnRef="en"><SimpleValue>Spontaneous Report</SimpleValue></Value>
     <Value ColumnRef="jp"><SimpleValue>自発報告</SimpleValue></Value>
  </Row>
```

[3] Further details on genericode are available at http://www.oasis-open.org/committees/tc_home.php?wg_abbrev=codelist, and also background information at www.genericode.org

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ICH Secretariat c/o IFPMA, Chemin Louis-Dunant 15, P.O. Box 195, 1211 Geneva 20, Switzerland
Telephone: +41 (22) 338 32 06, Telefax: +41 (22) 338 32 30
admin@ich.org, http://www.ich.org

</SimpleCodeList>

We are providing the codes in this manner so that there is an unambiguous link from the Implementation Guide OID to the actual codes and there is no necessity for hand coding of pick-lists in applications. We believe this will open up potential advantages in the future for system developers and for preventing coding errors.

However, it is not necessary to know XML to access the code values. The genericode files can be viewed using any XML enabled software, including common internet browsers. This is done by ensuring that the schema file, "genericode.xsd," and the xsl viewing file, "Mod Crane-gc2html.xsl,[4]" are present in the directory that the code list files are placed. The screenshot below in Figure 1 is an example of how to open a code list using a web browser.If the file is opened with the .xsd file and the .xsl file in the directory the code list will be displayed in a tabular format, along with the identifying information relating to the code list name and OID. This is illustrated in Figure 2.

As you can see in these figures below, the ICH E2B ICSR code lists are now released in a bi-lingual format. Although the ICH Guidance is normally only released officially in English, these code list files are intended to support system development internationally across the ICH region and are therefore also linked to the Japanese translation of the ICH documents.

[4] This xsl file is an interim file supplied to allow easy viewing of the code lists. It will be replaced with a more suitable view at Step 4.

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ICH Secretariat c/o IFPMA, Chemin Louis-Dunant 15, P.O. Box 195, 1211 Geneva 20, Switzerland
Telephone: +41 (22) 338 32 06, Telefax: +41 (22) 338 32 30
admin@ich.org, http://www.ich.org

Figure 1: Opening a Code List file for viewing

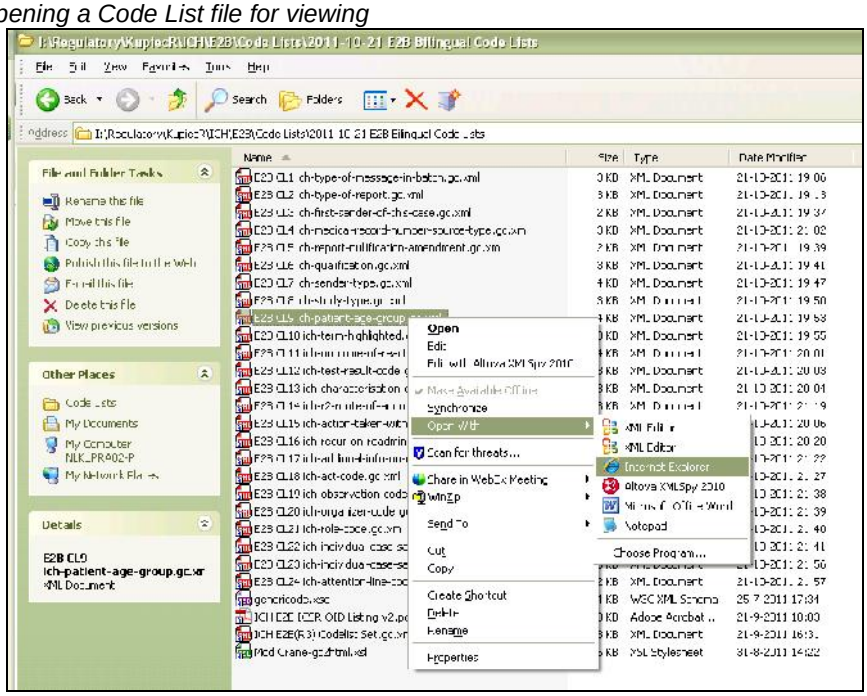

Figure 2: Code List viewed in a Web Browser window

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ICH Secretariat c/o IFPMA, Chemin Louis-Dunant 15, P.O. Box 195, 1211 Geneva 20, Switzerland
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admin@ich.org, http://www.ich.org

The code lists will be distributed by ICH via the ESTRI section on the ICH web site. The Code Set file (listing each code list and OID associated with this version of the standard), the individual code list files, the genericode schema and the .xsl viewer will be packaged as a .zip file and made available for download.

The full list of OIDs for code lists and namespaces will be also posted on the website for reference.

Further Resources

More information regarding OIDs may be found at:

Object Identifier (OID) Repository	OID listing service, sponsored by France Telecom at http://www.oid-info.com/index.htm
HL7 OID Registry	OID Registry and listing service provide by HL7 at http://www.hl7.org/oid/index.cfm?ref=common
ICH Web Page	http://www.ich.org/
ICH M2 Web Page	http://www.ich.org/products/electronic-standards.html
ICH ICSR Public Consultation	http://estri.ich.org/new-icsr/index.htm

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Telephone: +41 (22) 338 32 06, Telefax: +41 (22) 338 32 30
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Reference: ICH OID Scheme for E2B

ich-estri	2.16.840.1.113883.3.989
ich-estri-msg-stds	2.16.840.1.113883.3.989.2
ich-estri-msg-stds-e2b-icsr	2.16.840.1.113883.3.989.2.1
ich-estri-msg-stds-e2b-icsr-code-lists	2.16.840.1.113883.3.989.2.1.1
ich-estri-msg-stds-e2b-icsr-other-namespaces	2.16.840.1.113883.3.989.2.1.3

Full details of the use of these code lists are available in the ICH ICSR Implementation Guide.

OID Name (Code Lists)	OID Number
ich-type-of-message-in-batch	2.16.840.1.113883.3.989.2.1.1.1
ich-type-of-report	2.16.840.1.113883.3.989.2.1.1.2
ich-first-sender-of-this-case	2.16.840.1.113883.3.989.2.1.1.3
ich-medical-record-number-source-type	2.16.840.1.113883.3.989.2.1.1.4
ich-report-nullification-amendment	2.16.840.1.113883.3.989.2.1.1.5
ich-qualification	2.16.840.1.113883.3.989.2.1.1.6
ich-sender-type	2.16.840.1.113883.3.989.2.1.1.7
ich-study-type	2.16.840.1.113883.3.989.2.1.1.8
ich-patient-age-group	2.16.840.1.113883.3.989.2.1.1.9
ich-term-highlighted	2.16.840.1.113883.3.989.2.1.1.10
ich-outcome-of-reaction-event	2.16.840.1.113883.3.989.2.1.1.11
ich-test-result-code	2.16.840.1.113883.3.989.2.1.1.12
ich-characterisation-of-drug-role	2.16.840.1.113883.3.989.2.1.1.13
ich-r2-route-of-administration	2.16.840.1.113883.3.989.2.1.1.14
ich-action-taken-with-drug	2.16.840.1.113883.3.989.2.1.1.15
ich-recur-on-readministration	2.16.840.1.113883.3.989.2.1.1.16
ich-addional-info-on-drug-code	2.16.840.1.113883.3.989.2.1.1.17
ich-act-code	2.16.840.1.113883.3.989.2.1.1.18
ich-observation-code	2.16.840.1.113883.3.989.2.1.1.19
ich-organizer-code	2.16.840.1.113883.3.989.2.1.1.20
ich-role-code	2.16.840.1.113883.3.989.2.1.1.21
ich-individual-case-safety-report-type	2.16.840.1.113883.3.989.2.1.1.22
ich-individual-case-safety-report-criteria	2.16.840.1.113883.3.989.2.1.1.23
ich-attention-line-code	2.16.840.1.113883.3.989.2.1.1.24

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ICH Secretariat c/o IFPMA, Chemin Louis-Dunant 15, P.O. Box 195, 1211 Geneva 20, Switzerland
Telephone: +41 (22) 338 32 06, Telefax: +41 (22) 338 32 30
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Use of the namespace OIDs are illustrated in the reference instances and Implementation Guide. These OIDs are technical requirements in order to specify and ICH ICSR using the HL7 schema and messaging framework.

Namespaces used as roots in message	OID Number
ich-senders-safety-report-identifier	2.16.840.1.113883.3.989.2.1.3.1
ich-worldwide-case-identifier	2.16.840.1.113883.3.989.2.1.3.2
ich-other-case-identifier	2.16.840.1.113883.3.989.2.1.3.3
ext-authorisation-number-namespace	2.16.840.1.113883.3.989.2.1.3.4
ext-sponsor-study-number-namespace	2.16.840.1.113883.3.989.2.1.3.5
ext-study-registration-number-namespace	2.16.840.1.113883.3.989.2.1.3.6
ext-gp-medical-record-number-namespace	2.16.840.1.113883.3.989.2.1.3.7
ext-specialist-medical-record-number-namespace	2.16.840.1.113883.3.989.2.1.3.8
ext-hospital-medical-record-number-namespace	2.16.840.1.113883.3.989.2.1.3.9
ext-investigation-medical-record-number-namespace	2.16.840.1.113883.3.989.2.1.3.10
ich-message-sender-identifier	2.16.840.1.113883.3.989.2.1.3.11
ich-message-receiver-identifier	2.16.840.1.113883.3.989.2.1.3.12
ich-batch-sender-identifier	2.16.840.1.113883.3.989.2.1.3.13
ich-batch-receiver-identifier	2.16.840.1.113883.3.989.2.1.3.14
ich-ack-sender-identifier	2.16.840.1.113883.3.989.2.1.3.15
ich-ack-receiver-identifier	2.16.840.1.113883.3.989.2.1.3.16
ich-ack-batch-sender-identifier	2.16.840.1.113883.3.989.2.1.3.17
ich-ack-batch-receiver-identifier	2.16.840.1.113883.3.989.2.1.3.18
ich-local-report-number	2.16.840.1.113883.3.989.2.1.3.19
ich-ack-batch-number	2.16.840.1.113883.3.989.2.1.3.20
ich-ack-local-message-number	2.16.840.1.113883.3.989.2.1.3.21
ich-sender-batch-identifier	2.16.840.1.113883.3.989.2.1.3.22
int-references-to-reaction	UUID
int-references-to-substance-administration	UUID

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ICH Secretariat c/o IFPMA, Chemin Louis-Dunant 15, P.O. Box 195, 1211 Geneva 20, Switzerland
Telephone: +41 (22) 338 32 06, Telefax: +41 (22) 338 32 30
admin@ich.org, http://www.ich.org

Reference: ICH OID Scheme for eCTDv4

ich-estri	2.16.840.1.113883.3.989
ich-estri-msg-stds	2.16.840.1.113883.3.989.2
ich-estri-msg-stds-m8-ectd	2.16.840.1.113883.3.989.2.2
ich-estri-msg-stds-m8-ectd-code-lists	2.16.840.1.113883.3.989.2.2.1
Ich-estri-msg-stds-m8-ectd-documents	2.16.840.1.113883.3.989.2.2.2
ich-estri-msg-stds-m8-ectd-other-namespaces	2.16.840.1.113883.3.989.2.2.3

Full details of the use of these code lists are available in the ICH RPS Implementation Guide.

OID Name (Code Lists)	OID Number
ich-context-of-use	2.16.840.1.113883.3.989.2.2.1.1
ich-context-of-use-status	2.16.840.1.113883.3.989.2.2.1.2
ich-document	2.16.840.1.113883.3.989.2.2.1.3
ich-species	2.16.840.1.113883.3.989.2.2.1.4
ich-route-of-administration	2.16.840.1.113883.3.989.2.2.1.5
ich-duration	2.16.840.1.113883.3.989.2.2.1.6
ich-type-of-control	2.16.840.1.113883.3.989.2.2.1.7
ich-substance-name-types	2.16.840.1.113883.3.989.2.2.1.8

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