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Onto-Med Report

The Onto-Builder Handbook Version 1.1

Barbara Heller
Kristin Lippoldt, Katrin Kuehn

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Institute for Medical Informatics,
Statistics and Epidemiology (IMISE)

University of Leipzig

Liebigstr. 27
04103 Leipzig
Germany

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Institute for Informatics (IfI)
Department of Formal Concepts

University of Leipzig

Augustusplatz 10/11
04109 Leipzig
Germany

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Ontologies   in Medicine

Contact address authors

Barbara Heller
Institute for Medical Informatics,
Statistics and Epidemiology (IMISE)
University of Leipzig
Liebigstrasse 27
04103 Leipzig
Germany
Email: barbara.heller@imise.uni-leipzig.de

Katrin Kuehn
Institute for Medical Informatics,
Statistics and Epidemiology (IMISE)
University of Leipzig
Liebigstrasse 27
04103 Leipzig
Germany
Email: katrin.kuehn@imise.uni-leipzig.de

Kristin Lippoldt
Institute for Medical Informatics,
Statistics and Epidemiology (IMISE)
University of Leipzig
Liebigstrasse 27
04103 Leipzig
Germany
Email: kristin.lippoldt@imise.uni-leipzig.de

Imprint

The Onto-Builder Handbook
Version 1.1

Part I: The Construction of Medical Terms

Technical Report

The *Onto-Builder* is a software tool developed by the Onto-Med research group at the University of Leipzig. The version described in this report is Onto-Builder Version 1.1.

Project leader: Dr. Barbara Heller, Prof. Heinrich Herre, Prof. Markus Loeffler

Developer team: Katrin Kuehn, Kristin Lippoldt, Gerald Muecke, Karin Quaas

In cooperation with: The Working Group for Quality Management (WG QM) of the Competence Network Malignant Lymphoma

Dr. Goetz Gelbrich, Coordination Center for Clinical Trials Leipzig

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1 Introduction

1.1 Motivation and Purpose

The rationale for the compilation of a *Data Dictionary for Clinical Trials* in the Competence Network Malignant Lymphoma is, among other things, to gather the terms and their definitional variants, which are relevant to clinical trials. In this connection, the different definitional variants from the relevant literature as well as the various uses of terms within the Competence Network Malignant Lymphoma are to be collected.

The purpose is to collect terms from the clinical trial context to reveal contradictory and/or ambiguous definitions and to reach a consensus with respect to the use of terms among the members of the Competence Network Malignant Lymphoma in order to create a uniform terminological base. To this end, a software tool called the *Onto-Builder* has been developed. The *Onto-Builder* is an interent-based tool for the development of data dictionaries.

1.2 Target Group and Contents

The present documentation is intended for all users who enter terms and descriptions into the *Onto-Builder*, engage in the moderation of terms, and/or make comments on the existing definitions.

In the *Onto-Builder Handbook Version 1.1* you will find a detailed description of the *Onto-Builder's* functionalities, including how the individual commands can be executed, e.g. the creation of a new term, performing a search for terms, etc.

Instructions for the entry of terms with respect to content can be obtained in Onto-Med Report No. 4 *Guideline for Creating Medical Terms* [Heller, Lippoldt, et al., 2003]. The *Guideline* contains general rules for the entry of terms, specific rules for certain groups of terms, and a detailed description of contexts. This document should be helpful for entering terms into the *Onto-Builder*. Careful work with the aid of the *Guideline* will contribute to a uniform procedure for the entry of data into the *Onto-Builder* and should lead to high-quality data content.

2 Preliminaries

2.1 Access

The demo version of *Onto-Builder Version 1.1* in German and English is accessible via the internet at www.onto-builder.de as of July 2003.

2.2 Technical Requirements

The *Onto-Builder* is an internet-based software tool that is available through all current browsers. The activation of cookies[1] is required for registration and login into the *Onto-Builder*.

The following browsers have been tested successfully:

- Netscape 4.7 (Unix, Windows)

- Netscape 6.x (Windows)

- Internet Explorer 5.x (Windows)

2.3 Registration

There are two registration options for becoming an *Onto-Builder* user:

(a) Registration as a user of the demo version

Fill out the form entitled "New User for Demo Version" and request an account. Your data will be verified and you will receive an email with your access information (username and password) within two working days.

(b) Registration as a user of a project database (e.g. for members of the Competence Network Malignant Lymphoma or the Coordination Center for Clinical Trials Leipzig)

Please apply to use the *Onto-Builder* by email at admin@onto-builder.de. Your registration request will be processed according to the project specifications within two working days.

3 Functionality of the Onto-Builder

The functions of the *Onto-Builder* can be selected from the starting screen of the *Onto-Builder* (see Figure 1) and from the menu bar at the top of each screen. The available functionalities are dependent on the user group to which you are assigned (see below).

In the following sections the functionalities of *Onto-Builder Version 1.1* are described.

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[1] Cookies are small files that a web server automatically sends to your PC when you browse certain web sites. They contain information that identifies each user, e.g. login or username.

Figure 1: Starting Screen of Onto-Builder Version 1.1

4 User and Role Concept

The *Onto-Builder* supports a user and role concept in which the following user groups are defined:

- Reader

- Editor

- Moderator

- Administrator

In the following sections the privileges and responsibilities associated with each user group are elaborated.

4.1 Reader

The Reader can view the contents of the *Onto-Builder*, although all personal information will remain hidden (i.e. information pertaining to the authors of terms and descriptions, the names of Moderators, etc.). Readers have merely the option of entering comments; the Reader may neither supplement nor modify any other information contained in the *Onto-Builder*.

4.2 Editor

The Editor contributes to the construction of the compilation by entering terms and descriptions. By commenting on the definitions of terms, s/he participates in the discussion. The Editor can insert terms and descriptions, modify his/her own descriptions and context classifications, and record abbreviations, synonyms and comments.

4.3 Moderator

The Moderator has all the privileges and responsibilities of an Editor, and is additionally responsible for an assigned pool of terms corresponding to the Moderator's scientific area of expertise. The Moderator develops proposals for consensus on these terms and their definitions.

It is also the Moderator's task to initiate the deactivation of nonsensical descriptions, abbreviations, etc. within his/her pool of terms by emailing the Administrator.

4.4 Administrator

The Administrator is responsible for setting up new users (assignment to user groups). S/he assigns new terms to the Moderators and deactivates nonsensical entries in the database at their request.

5 Tasks for Editors

5.1 Creating a New Term

Figure 2: Input Window for a New Term in Onto-Builder Version 1.1

The creation of a new term into the *Onto-Builder* is associated with the following specifications:

    (a) Term (may not include the symbols ? or *)   [required]

    (b) Language of the term (German, English)   [required]

    (c) Abbreviation(s)   [optional]

    (d) Remarks   [optional]

    (e) Description   [optional]

- Text of the description
- Language of the description
- Source
- Context(s)

It is not strictly necessary to specify abbreviation(s), remarks and descriptions when creating a new term in the *Onto-Builder*. In Chapter 6 you will find a detailed description of the individual specifications. By saving your entry, the term and corresponding specifications will be stored in the database.

5.2 Search

The *Search* function allows you to search for terms and descriptions which are already saved in the *Onto-Builder*. A search is especially recommended when creating a new term. By performing a search you can make sure similar terms have already been saved, and find out whether your term has already been used in the existing descriptions.

Figure 3: Search Window in Onto-Builder Version 1.1

5.2.1 Using the Search Window

Simply enter one or more (partial) words and select whether these words should be searched for in the terms and/or descriptions. When specifying multiple words you can choose the combination type: select *and* to obtain a search result containing all words, or *or* to obtain a search result containing at least one word.

If descriptions are selected to be searched, you can restrict the search domain with the help of contexts.

Syntax of search entries

Examples:

art   –   finds all words containing the sequence `art` (e.g. part, participant, etc.)

g?ve   –   finds all words which contain exactly one letter in the place of the question mark (e.g. give, gave, etc.)

*   –   finds all entries in the *Onto-Builder*

In order to find spelling variants you should try to search for the shortest possible sequence of letters when entering search words.

Example:

You are searching for the term `serious adverse event`; enter the search word `serious`*.

By executing the search request with the *Search* button you will obtain the display of *Search results*.

5.2.2 Display of Search Results

After you have clicked the *Search* button, the search results will be listed and separated into results within the terms and within the descriptions (according to the option you selected in *Search in*). Each term found will be accompanied by a brief information summary (synonyms, number of descriptions, and date of last change to a description). By clicking on the hyperlinks you can reach the *Detailed display of a term / Detailed display of a description*.

5.2.3 Detailed Display of a Term

In the *Detailed display of a term* you can view the saved information pertaining to the selected term, and can change or add certain properties. In the default mode, only up-to-date descriptions will be displayed. All previously modified or deleted descriptions can be called up by using the *Display all descriptions* option in the heading.

It is possible to differentiate between up-to-date, out-of-date, and inactive variants by means of the following symbols, which are displayed for each alternative definition:

     Up-to-date description (status indicator)

     Out-of-date description (status indicator)

     Inactive description (status indicator)

The *Detailed display of a term* contains the following information:

- Name of the person who created the entry for the term
- Creation date of the entry
- Abbreviations of the term
- Remarks (see 5.2 Remarks)
- Alternative definitions

Every alternative definition contains the following information:

- Description (text description of the term)
- Source (source from which the definition originates)
- Author (name of the person who created the entry for the definition)
- Date (creation date of the entry)
- Status (up-to-date, out-of-date, inactive)
- Classification by context with weighting
- Optional: synonym(s)
- Optional: comments (remarks from users about the description)

The author of the context classification will be entered as well, since as a result of adding synonyms a situation can arise where the author of the description is different from the author of the context classification.

In connection with authorship of descriptions and/or context classification authors have various privileges which correspond to certain commands ("+" = permitted / "-" = not permitted):

		Neither the author of the description nor the author of the context classification	The author of the description but not the author of the context classification	The author of the context classification but not the author of the description	Both the author of the description and the author of the context classification
Modify a definition		-	+	-	+
Tag a definition for deactivation		-	+	-	+
Modify a context classification		-	-	+	+
Insert comments		+	+	+	+
Insert a description		+	+	+	+
Insert an abbreviation		+	+	+	+
Insert a synonym		+	+	+	+

Table 1 :   Privileges of authors

5.2.4 Detailed Display of a Description

In the *Detailed display of a description* you will find the saved information for the selected definition variants. You can also modify or add certain properties. The *Detailed display of a description* is just a different display of the definition in the database from the *Detailed display of a term* to which the description is associated.

Every definition variant contains the following information:

- Description (text description of the term)
- Source (source from which the description originates)
- Author (name of the person who created the entry for the description)
- Date (creation date of the entry)
- Status (up-to-date, out-of-date, inactive)
- Terms to which the description is associated (synonym(s))

If you are the author of a description, you can modify your description or tag it for deactivation. In any case you can always add synonyms (see section 6.7). By clicking on the hyperlinks you can reach the *Detailed display of a term*.

5.3 Modifying a Description / Initiating Deactivation

The *Modify* function displays all terms, descriptions and pairs for which you are the author, as it is only these that you are allowed to modify or tag for deactivation. You can select the term, description or pair which you want to modify. In the corresponding *Detailed display* you can use the following symbols to perform certain operations on the descriptions you have created:

modify (edit a description)

delete (tag a description for deactivation)

5.3.1 Modification

By clicking on the *Edit description* symbol you can access the *Modify the description of a term* window (see figure 4). Next, you can select the terms whose descriptions you want to modify (checkboxes). It is necessary to make this selection, as the description can be associated with multiple terms (synonyms).

The following specifications of one or more selected terms can be modified independently of one another:

- Context classification
- Description (incl. Source)

After saving the modification(s) you will see the confirmation message *The description was successfully modified.*

Figure 4: Modification Window in Onto-Builder Version 1.1

5.3.2 Tagging for Deactivation

You can delete a description by clicking on the *Deactivate description* symbol. You will be asked whether you are sure you want to delete the definition. With your confirmation *Deactivate* the description is tagged and appears with the inactive descriptions.

5.4 History

The function *History* allows you to display recent modifications and additions. Choose the time period (1 day to 1 year) for which you would like to view changes with respect to terms, descriptions and comments. By clicking on the hyperlinks you can reach the corresponding *Detailed display*.

5.5 Printing

The *Onto-Builder* provides the user with the option of printing the current web page or multiple results of a search request.

5.5.1 Printing the Current Page

In the Competence Network portal there is a printer symbol in the top right corner of the browser window. By clicking on this symbol a new web page with the same contents but in printable form will be generated. It is now possible to print this page using the print function of your browser.

5.5.2 Printing Multiple Results of a Search Request

This printing functionality allows you to print the results of a search in a unified manner according to terms, descriptions, or comments. By using the print options you can adjust the content of the printout according to your needs.

5.5.2.1 The Print Version of Search Results

After executing a search request by clicking the *Search* button, the results of your search will be listed. Depending on which search option you selected, a screen listing *Results of a search in the terms*, *Results of a search in the descriptions*, or *Results of a search in the comments* will appear. In each of these summary screens you will find a link labeled *To the print version of the terms* (*To the print version of the descriptions, To the print version of the comments*), by means of which you can access the print version of the relevant search results.

5.5.2.2 Setting the Print Options

After clicking on the links *To the print version of the terms/descriptions/comments*, you will see a window displaying your search parameters and search results. In this window you can select the terms (descriptions/comments) which you would like to print. Check the *Print all results* box if you would like to print the *Detailed displays* of all search results. If you only want to print the *Detailed display* for individual search results, un-check the *Print all results* box and instead check the selection boxes of the terms (descriptions/comments) which you would like to print. Additional print options are available in the displays of search results for terms and comments, which allow you to further refine the print version of the *Detailed displays*.

Figure 5: Print Options in Onto-Builder Version 1.1

Example:

> You need a print version of all valid descriptions available for the term `Cytocines`. Enter `*cines` in the search window. In the *Search results* screen click on the link *To the print version of the terms*. Select *Print all results* and check the *Display comments* box if you want to print the comments for the individual descriptions.

5.5.2.3 Printing

Once you have fixed the settings, click on the *Display printable pages* button. You will be taken to a page showing the *Detailed displays* for all the search results you selected with the help of the print options. Using the print function of your browser you can now print this page.

5.6 Exit

You can quit the *Onto-Builder* with the command *Exit*.

6 Specifications of a Term or Description

6.1 Abbreviations

It is possible to enter abbreviations when creating a new entry as well as in the *Detailed display*. Multiple abbreviations for a single term can be entered, separated by a semicolon. Abbreviations cannot be deleted. Abbreviations for terms are displayed in the detailed display as well as in search results.

Example:

> »adverse event«; Abbreviation: »AE«

6.2 Remarks

Remarks can only be entered while a term is being created. A remark should contain, for example, the source of a term — especially when no description is provided at the time the term is entered. In this way the origin of the term can be reconstructed later.

Example:

> `Application` Remark: case report form (CRF) This remark makes clear that `Application` is understood in a medical context, and has nothing to do with a software application.

6.3 Descriptions

Describing a term serves on the one hand to collect existing term definitions from the literature or from personal suggestions for definitions. On the other hand, the various usages of terms should be revealed, e.g. based on usage in case report forms or clinical trial protocols. Several definitions can be entered for a single term — by the same or a different author — which along with additional information can be called up in the *Detailed display of a term*.

If a consensus suggestion is available for a term, it will be displayed at the end of the list of definition variants with the heading "Moderator's consensus suggestion".

Note: If you are going to copy descriptions into the *Onto-Builder* input field from another document, please remove any list number characters which may be present. These characters will not be recognized in the input field and will be displayed as special ASCII characters.

6.4 Sources

Every term description must be accompanied by a source entry from one of the following categories:

- Journal article
- Book
- Case report form
- Personal definition
- Law
- Guideline
- Other clinical trial material
- SOP (Standard Operating Procedures)
- Clinical trial protocol

Once a source has been entered it can be used again; thus, when you add a new term you can choose one of the sources already entered.

Figure 6: Selection Window for Sources in Onto-Builder Version 1.1

To select an existing source:

    (a) Choose the desired category from the list of categories.

    (b) Press the *Select* button.

    (c) Choose the desired source from the summary of sources.

If you select *Personal definition*, two text fields will appear (first name, last name), which are pre-set to your name. You can change the name if the definition comes from a different person.

Entering a new source:

    (a) Choose the desired category from the list of categories.

    (b) Press the *Select* button.

    (c) If you cannot find the desired source in the summary of sources, press the *Create a new source in this category* button.

    (d) A form will appear. Fill in the requested source information.

    (e) When you send the form, the source will be stored in the database, and your current definition will be classified.

In the source information you will find the *Page(s) where the description is located* text field. Here you should enter the *exact* page number(s) within the source (e.g. 12 or 12f or 12ff) where the description can be found. Please take note of the difference in the *Page* field with respect to journal articles; here the page numbers of the article should be entered. By recording the exact page numbers where the description was found, it will be easier for the Moderator to locate the term description.

6.5 Contexts

Terms can have different meanings according to the context in which they are used. A simple example is the German term Bank, which can mean either Sitzgelegenheit (bench) or Geldinstitut (financial institution). Thus, it is often impossible to create a description for a term without stating the context to which the description refers. For this reason, it is necessary to specify for each term description the context(s) in which you think the description is valid. This will make it possible to expose ambiguities when evaluating a term.

Selection of a context:

    (a) Select the context(s) with the help of the checkboxes.

    (b) If multiple contexts are selected, you can weight each one using the selection fields (1 to 5, 1=most important). If only one context is selected, enter the value 1.

    (c) If another appropriate context occurs to you which is not available in the checkboxes, you can select *Other* and enter the context in the text field.

    (d) For temporal or spatial limitations on the validity of a context (see the *Guideline* [Heller, Lippoldt, et al., 2003]), use the text fields to enter the nature of the limitation.

In the *Guideline for Creating Medical Terms* you will find, in addition to instructions for the creation of terms and term descriptions, an explanation of contexts. For every context, a description and sample term are cited.

Example:

```
informed consent
```

Description: A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

Source: International Conference on Harmonisation, Guideline for Good Clinical Practice, 1996 [ICH., May 1996].

Context (1): Administration / Management / Documentation
Context (2): Event / Process / Action

→ (1) means that the term is primarily classified in the context "Administration / Management / Documentation" (primary context) and secondarily classified in the context "Event / Process / Action" (secondary context).

Context classifications can be modified later by the author. This option is left open in order for corrections to be incorporated after consultation with other users.

6.6 Comments

Figure 7: Display of Comments in Onto-Builder Version 1.1

Comments can be entered for each description in order to discuss terms, term definitions and consensus suggestions. Every user can thus enter instructions and suggestions which are useful for reaching a consensus.

From the *Detailed display of a term* you can read as well as add comments. By clicking on the *Insert a comment* symbol you will cause an input window to appear in which you can enter your comments on the description. The author and date of comments will be entered as well. You can also respond to existing comments. If you want to view all the definition variants without comments, you can hide the comments with the corresponding symbol.

6.7 Synonyms

While entering definition variants, all synonyms should be considered to have equal value, i.e. there is no preferred term at this stage. Preferred terms will be identified later in the consensus suggestions. Two terms can only be synonyms with respect to a description. If two terms share a common description, then they are synonyms with respect to that description. The rationale for this method of representing synonyms is that the meaning of terms, as elaborated in section 6.5, is usually context-dependent. Thus, the German term Geldinstitut (financial institution) is a synonym of Bank only in the financial world. It must be determined for every description individually which terms (and thus which synonyms) are appropriate.

Synonyms are displayed in the *Detailed display of a term* and in the *Detailed display of a description*, and new synonyms can be defined there. While inserting a synonym it is possible to select a term that has already been saved and enter it as a synonym. In this case, the description for the synonym will be stored as an additional definition variant. Otherwise, the synonym should be entered into the database as a new term, and assigned the corresponding description. Please be sure to enter the language (German/English) and the context classification of the synonym.

7 Tasks for Moderators

In order to reach a consensus with respect to uniform term definitions and uniform term usage, it is necessary to evaluate the various definition variants assigned to a term and to develop a consensus suggestion. Due to the nature of this task, individual Moderators will be responsible for a certain pool of terms, according to their specific expertise.

7.1 Consensus Suggestion (My Terms)

In the *My terms* window you will find the terms that have been assigned to you as a Moderator, divided into two lists. The upper list contains those terms for which no consensus suggestion exists at present; the lower list shows all the terms assigned to you, for which a consensus suggestion has been entered — either by you or by another Moderator. The situation where another Moderator has entered a consensus suggestion for a term assigned to you arises when s/he enters your term as a synonym for one of his/her own terms.

Example:

Term 1: `informed consent` – Moderator = Person A

Term 2: `patient's declaration of consent` – Moderator = Person B

Moderator B enters a consensus suggestion for `patient's declaration of consent` with the synonym `informed consent`. `Patient's declaration of consent` is assigned preferential status.

7.2 Entry of Consensus Suggestions

Select the term for which you want to enter a consensus suggestion in the *My terms* window. By clicking on the term you will be taken to the *Detailed display of a term* where all the definition variants are displayed. At the end of the list you can enter a consensus suggestion by selecting *Insert a consensus proposal*.

In the *Make a consensus proposal for this term* window, the following information should be provided:

- Text of the description
- Language of the description
- Source
- Context(s)

By executing the *Save* command, the consensus suggestion is entered and you can insert synonyms in the *Detailed display of a term*. Synonyms are also part of consensus suggestions.

8 Tasks for the Administrator

8.1 Creating New User Accounts

The creation of new user accounts is outlined in internal documentation.

8.2 Assigning Terms to Moderators

8.2.1 Assigning New Terms to Moderators

By selecting the *Reassign Moderators* menu item you can assign terms to Moderators. All terms will be displayed on the vertical axis and all Moderators on the horizontal axis. By using the horizontal radio button, this matrix permits you to assign each term to exactly one Moderator. Unassigned terms can be identified easily since the corresponding radio button is set to *No Moderator* column.

8.2.2 Changing a Moderator Assignment

By selecting the *Change Moderators* menu item you can display all assigned terms in the matrix view and the assignment of terms to Moderators can be modified. Such changes are necessary, e.g. when a person changes his/her role within the project or is no longer available as a Moderator.

8.3 Deactivating Nonsensical Content

The deactivation of nonsensical content at the request of Moderators should take place directly in the database. Every change to the database should be recorded.

9 Summary of Symbols and their Meanings

Symbol	Meaning
	insert an abbreviation, description, synonym
	insert a consensus suggestion
	insert a comment
	respond to this comment
	tag a description for deactivation
	out-of-date description (status display)
	up-to-date description (status display)
	inactive description (status display)
	show details
	change a description

Table 2 :   Symbols and their meaning in Onto-Builder Version 1.1

10 Future Development of the Onto-Builder

The *Onto-Builder Version 2.0* will be based on a more flexible underlying model and will be available in 2004. For example, the following extensions are planned: context-dependent relations between terms, hierarchies of concepts, separation of generic and domain-specific concepts.

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