Data Entry Manual
ProMISe 4

Date	Author	Action	Completed
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Introduction

ProMISe (Project Manager Internet Server) is an internet based application for the design, maintenance and use of (clinical) data management projects. By using ProMISe, the design and implementation of single and multi-centre data management projects can be performed without hardly any programming effort, thus allowing the project coordinators as well as the users to fully concentrate on the clinical contents and logistics of the study at hand.

This manual describes the basics of Data Entry in ProMISe. It includes descriptions of the logon procedure, navigation through the ProMISe interface, manipulation of the data index and the data entry procedure itself.

ADM

The section Advanced Data Management (ADM) is part of the Medical Statistics department of the Leiden University Medical Center. ADM is responsible for the design and maintenance of the database projects in the ProMISe application.

If there are problems in your ProMISe project or if you have questions about the ProMISe application, you can contact the ADM helpdesk: ADM@lumc.nl or via telephone: +31-71-5269726.

Note: all patient data in this document are fake.

Tips & trics

- By pressing [F1] a help screen will appear specific to the current screen or the location of the mouse cursor.
- In ProMISe dates are displayed as yyyy/mm/dd. Date formats are also accepted when entered as dd/mm/yyyy, dd-mm-yyyy or dd mmm yyyy (e.g. 13 oct 2016). ProMISe will convert this to yyyy/mm/dd.
- In some cases the info screen will appear. This screen can be moved by clicking and dragging, or be hidden by a right-click on the info button next to the info screen (Figure 1). The last contents of the screen will appear again by clicking the info button in the function button row.

Figure 1: Info button

Start using ProMISe

Start the application

ProMISe is an online application for Internet Explorer and Chrome. At this moment it cannot be loaded in other browsers. If you open ProMISe with a different browser or old version, a pop-up will appear and direct you to this page with more information: https://edu.nl/rncu4**.**

You can access a ProMISe project via the project specific login page. You will usually receive the link to the login page with your account. It is often useful to store the login page in your Favourites. The login page location is not indexed, meaning that it cannot be found using Google (or a different search engine). For convenience, a link to the login page can be placed on a project website. Some projects make use of the MSBI portal pages, which are maintained by ADM. The MSBI ProMISe website can be found at www.msbi.nl/promise. The projects that have an MSBI portal page can be listed by clicking 'Projects' in the upper navigation menu. This and other manuals can be downloaded on the MSBI page as well.

Configuration test

Proper functioning of the ProMISe application is dependent on several browser settings. Therefore, if you are working with ProMISe for the first time, it is recommended to test (and adjust) the settings of your PC. To do this click *on [How to make your PC ProMISe compatible and other important Tips and Tricks]* on the centre of the login page (Figure 2). In the expanded menu click on *[Interactive browser configuration checker]*.
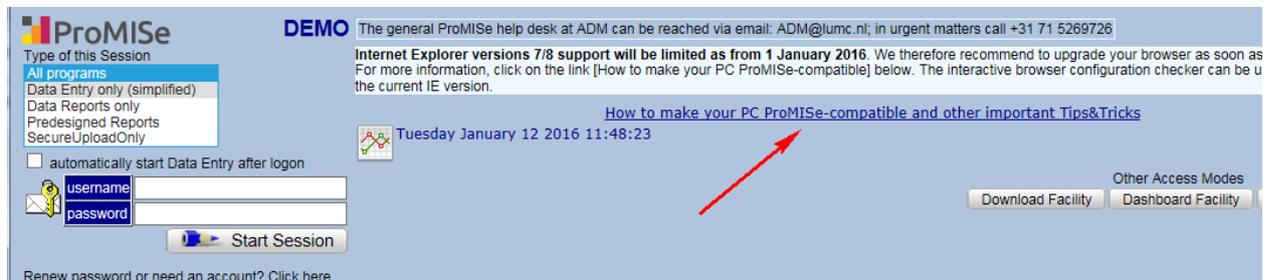
Figure 2: The login page. The red arrow indicates the configuration checker.

Figure 3: The configuration test. Before you start with ProMISe, it is recommended to check the settings of your PC in the Interactive browser configuration checker.

Click *[Run the Tests]*. You will get an overview of the settings of your browser, indicating possible problems and solutions (Figure 4).

Figure 4: Result of the configuration test. The column 'status' shows whether your computer settings are compatible with ProMISe or not.

The column 'Status' shows the status of that setting on your computer. The different figures and colours indicate whether the setting is properly configured (Figure 5).

Figure 5: Explanation status symbols.

The column 'Status' shows the result:

Red = could pose a problem

Yellow = suboptimal

Green = OK

Question mark = unknown or not applicable

What to do if ProMISe does not work

If ProMISe does not start properly there are several things you can try to fix it:

- Use an up-to-date version of Internet Explorer or Chrome. For more information see https://edu.nl/rncu4
- Add these websites to the list of trusted sites:
  - *.clinicalresearch.nl
  - *.lumc.nl
  - *.zorgttp.nl
  - *.msbi.nl
- Allow pop-ups from www.clinicalresearch.nl.
- Allow use of ActiveX.

In the column '*Information and Setup Instructions*' of the configuration checker (Figure 4, right side) links are provided to instructions on how to configure these options in Internet Explorer or Chrome (where applicable).

Login screen

When your pc is correctly configured you can proceed to login. Figure 6 and Figure 7 show examples of the login page. The lay-out, content and language (Dutch or English) of the login page can be different for each project, but these elements can normally be found on the login page.
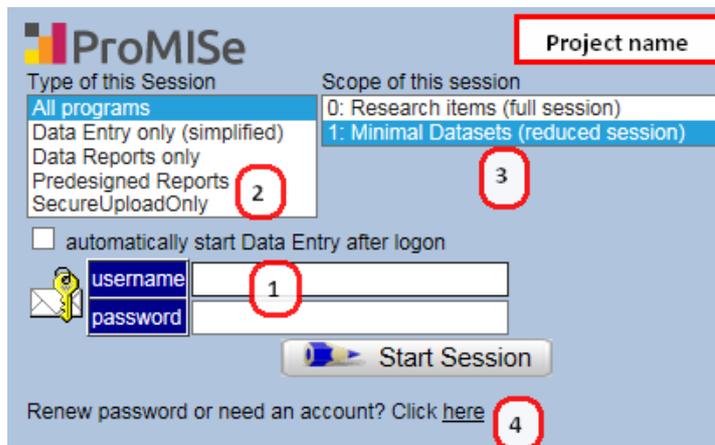

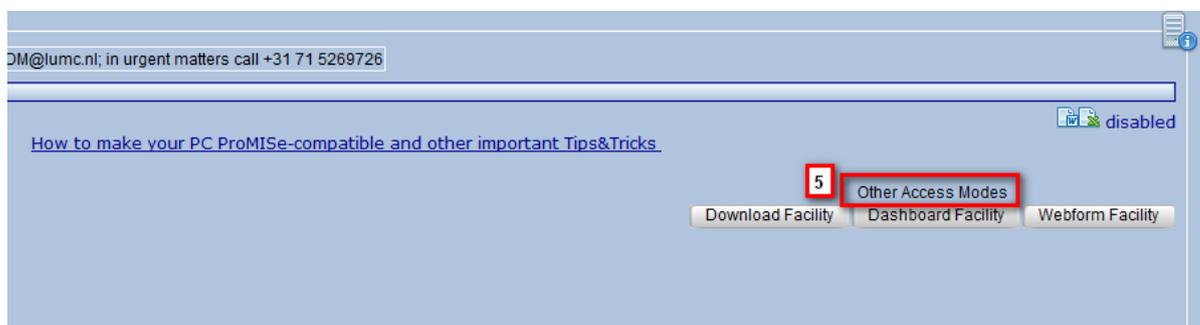Figure 6: The login page (left part).

Figure 7: The login page (right part).

The numbers in these figures correspond to the following options:

1. **Username en password:** here you fill in your username and password. Please contact your project manager if you did not receive a username (yet). For new passwords see the section 'Request and change a password'.

2. **Type of this Session:** here you can choose the type of your session. With this option you can reduce the <u>functionality</u> of the ProMISe session. If you select "All programs" ProMISe will load with full functionality. Other options will load ProMISe with only the one type of functionality, for example "Data Entry only (simplified)" will load ProMISe with only Data Entry functionality.

3. **Scope of this Session:** this option can reduce the <u>data scope</u> of the loaded ProMISe session. By selecting "Full Session", the complete data dictionary will be loaded. By selecting another session, the data dictionary will be limited to the variables in that scope, for example only adverse event data or only medication data. This option is not always visible on the login screen; it is only visible if different scopes have been defined for the current project.

4. **Renew password:** with these options you can change your password. The change password procedure is explained below.

5. **Other access modes:** the Webform, Dashboard or Download facility can be reached by clicking the corresponding button. You can request a separate manual for these options when they are available in your project.

To login fill in your username and password and select the relevant options. Then click the *[Start Session]* button to start ProMISe (or press enter when the cursor is in the password field).

Request and change a password

To request a new password or change a valid password, click "Renew password or need an account? Click here" (Figure 6 – option 4). The following screen will appear (Figure 8):

Figure 8: Password manager. In this screen you can request a new password or change a valid password.

If you do not have a password or if you have forgotten your current password, you can obtain a new password by clicking *[obtain new password]*. You are then asked to enter your username. After entering your username you can request a security code. Depending on both project- and account settings, this security code will be sent to the e-mail address or mobile number associated with your account.

Figure 9: Request Security Code.

The screen as shown in Figure 10 will open automatically. Fill in your username, the received security code and a new password of your own choosing (twice). The new password needs to adhere to some rules, which are stated on the next page. After confirming, your password has been set and you can login using the new password.

Figure 10: Setting a new password with a security code.

There are some cases in which a ProMISe password is considered expired. Expired passwords cannot be used to log in to the project, but can be used to set a new password. For example, if you receive a temporary password, this password is considered to be expired.

If you wish to change an expired password or if you wish to change your current password for another reason, you can click "change valid password" (Figure 8). A screen will appear as shown in Figure 11. To set a new password first fill in your username. Then fill in your current password. Finally, to change your password, fill in a new password in the NEW password fields. As per usual, this new password needs to adhere to the ProMISe password requirements. After you have confirmed the new password, your password has been changed. You can log in using the new password.

Figure 11: Set a new password

ProMISe passwords have the following requirements:

- At least 8 characters long
- At least 3 of the 4 following character types:
  - Lower-case letter
  - Upper-case letter
  - Numeric character
  - Special character, such as ! @ ? _

Your ProMISe account is strictly personal, therefore it is not allowed to share your password with anyone. If someone else needs to access your ProMISe database, ask the project manager for a new account for that person.

Password expiration

Passwords expire after a certain period. This can depend on the project, but usually passwords expire after 6 months. If your password has expired, ProMISe will prompt this information if you try to login. You can change an expired password by following the procedure described above.

Second authentication

Some projects make use of a second authentication via SMS; after authentication by username and password a code will be sent to your mobile phone. If your project makes use of a second authentication the screen in Figure 12 will appear when your session is starting.

Figure 12: second authentication by SMS

In the second authentication screen you need to fill in the code (or Session Key) you have received via SMS in the corresponding field (in the upper right). Then you can declare your current PC safe by checking the box (check to declare to safe). If you do this, the current IP address is stored and for future logins the second authentication will be skipped if logging in from that IP address. Please only check this option if your current PC is indeed safe. You are also asked to provide your email address. However, most often this is already known and is filled in.

After filling the code and providing the other options as appropriate, continue the logon procedure by clicking the button "Continue logon procedure". If successful, ProMISe will load completely and go to the data entry screen of the database.

Automatic lock

For security reasons, ProMISe automatically locks a session after 30 minutes of inactivity. To unlock the session you can enter your password. Unsaved data will be kept in memory during the lock and is available after unlocking. However, unsaved data are lost if you close the locked ProMISe screen.

ProMISe shows the minutes of inactivity next to time in the upper part of the screen (Figure 13). You can reset this counter by clicking it. After 25 minutes of inactivity, ProMISe starts producing audio warnings every minute. However, depending on browser and volume settings, this may not always be audible. After 24 hours a forced logout will take place. You will then lose any unsaved changes.
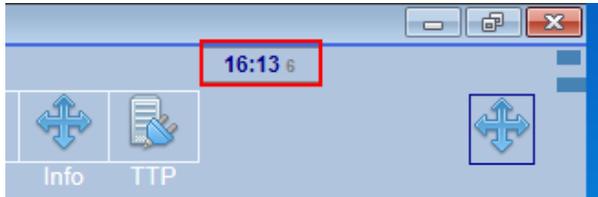
Figure 13: A counter with the number of minutes of inactivity is shown next to time dialog.

Full screen

The ProMISe layout is optimized to work in full screen mode. To remind you of this, a message is shown after you log on (Figure 14). You can activate the full screen mode with the button in the top right corner (explained in Figure 16). You can leave the full screen mode by pressing Esc or by switching to another window (using Alt+tab or the Windows key).
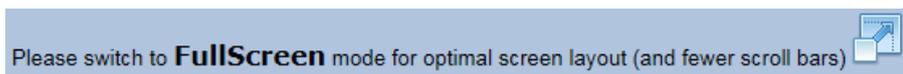
Figure 14: Full screen message

General ProMISe interface

After logging in the main screen of the database will appear (Figure 15).
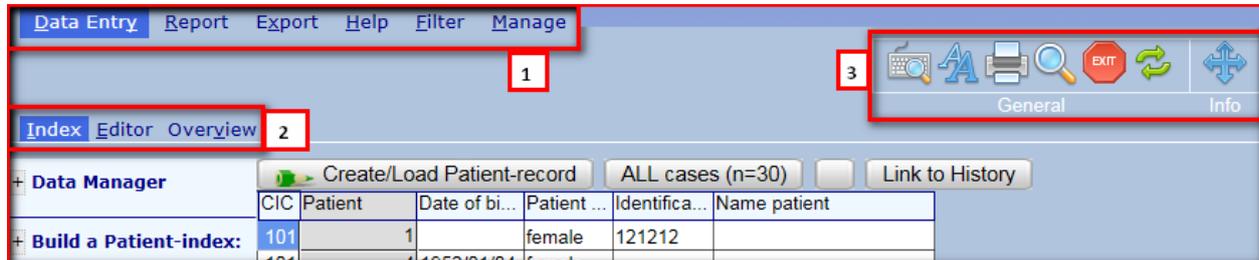
Figure 15: Main ProMISe screen. (1) Main tab navigation (2) Sub tab navigation (3) General Function buttons.

Navigation through ProMISe is partly tab based and partly button based. The main functionalities of ProMISe correspond to the different main tabs (1 in Figure 15). Depending on the type of session you have chosen and the restrictions to your useraccount, some options may not be visible. Each main function / tab in ProMISe is divided in several sub tabs (2 in Figure 15). To navigate through these different functionalities, simply click the tab(s).

Besides the tab navigation, there are several general function buttons in ProMISe (3 in Figure 15). The buttons labelled "General" are always visible. Some context-specific buttons are added in some situations. The general function buttons are described in Figure 16. The context-specific buttons are mentioned as required in the rest of this manual.

Figure 16: Main function buttons

The main function buttons as in Figure 16 have the following functions:

1. Shows keyboard shortcut keys relevant to the current screen
2. Cycle through different font sizes for the letters on the screen
3. Opens print- and export options for the contents of the current screen
4. Search for variables or labels
5. (Attempt to) exit the current ProMISe session
6. Restart current ProMISe session
7. Activates full screen mode
8. Show or hide the message frame that occasionally pops up

ProMISe contains several menus that can expand and collapse as required. These menus are marked by a "+" or "-" button. By left clicking on the button the menu will expand or collapse the current, single level ("+" expands, "-" collapses). By right clicking the button the menu will expand or collapse the current level and every underlying level of the menu (Figure 17).
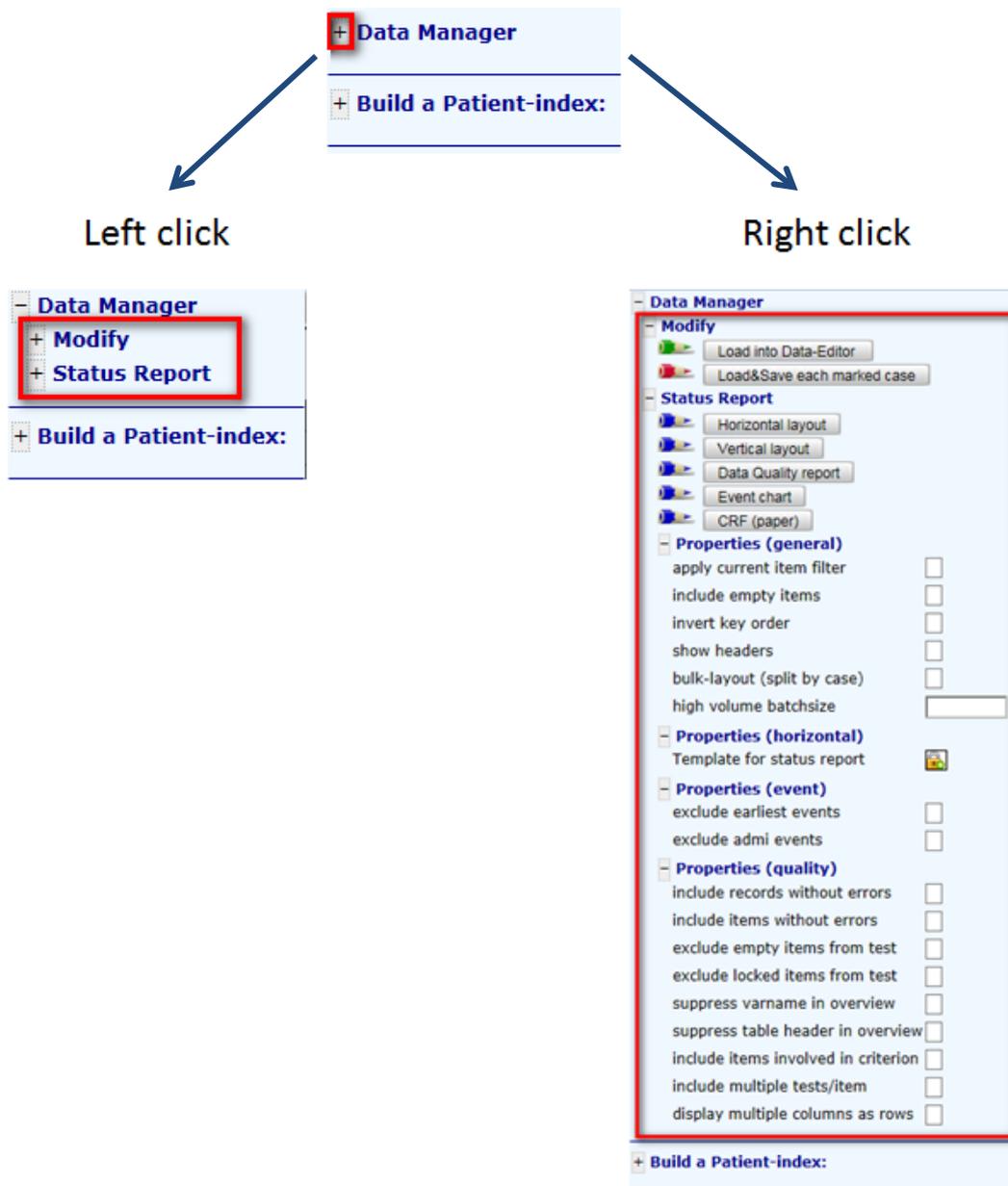
Figure 17: Expandable menus in the ProMISe interface. Left clicking a plus button will expand the current level of the menu. Right clicking will expand the current level plus all underlying levels of the menu.

The rest of this manual focusses on the Data Entry functionality. It deals with the selection of cases from the index and explains how to enter data for such a case.

Index

After ProMISe has loaded it will usually go to the index page. You can go to the index by selecting the Data Entry main tab and Index sub tab. The index contains an overview of all cases in the database that are within the scope of your account (Figure 18). The exact definition of a case depends on the project. Usually a case represents a patient, but it can also correspond to a medical procedure, a hospital visit, etcetera. Each case in the project has a unique key. This key consists of a Center code (CIC) plus a Case number.

Figure 18: The index screen. Each row corresponds to a case. The first two columns are the keys of the cases; a combination of a Center code (CIC) and Case number (Patient). The other columns show several variables and the values of these variables for each case. Which variables are shown is configured for each project separately.

The main function of the index screen is to find, select and/or create cases for which you want to perform data entry. If the case you wish to select is quickly identifiable in the index screen, you can load the case by right clicking on the grey square (second column) of the case you wish to load. However, often you will likely not be able to quickly identify the case you wish to load. For example, if the project contains a lot of cases (Figure 19). Therefore, ProMISe contains several options to find cases.

Figure 19: If more than a set number (usually 1000) cases are in the scope of your account, the index screen is divided in several sections (or blocks). You can load a section by clicking the appropriate section under the "More Entries Found" menu. The section numbers show the key (Center Code + Case number) of the first case in that section. For example, the first case in "Section 104|212|" has Center code 104 and Case number 212.

Find cases

The functions to find cases in the ProMISe index are listed in the Build a "Case"-index menu (the definition of case again depending on the project). The expanded options are shown in Figure 20.
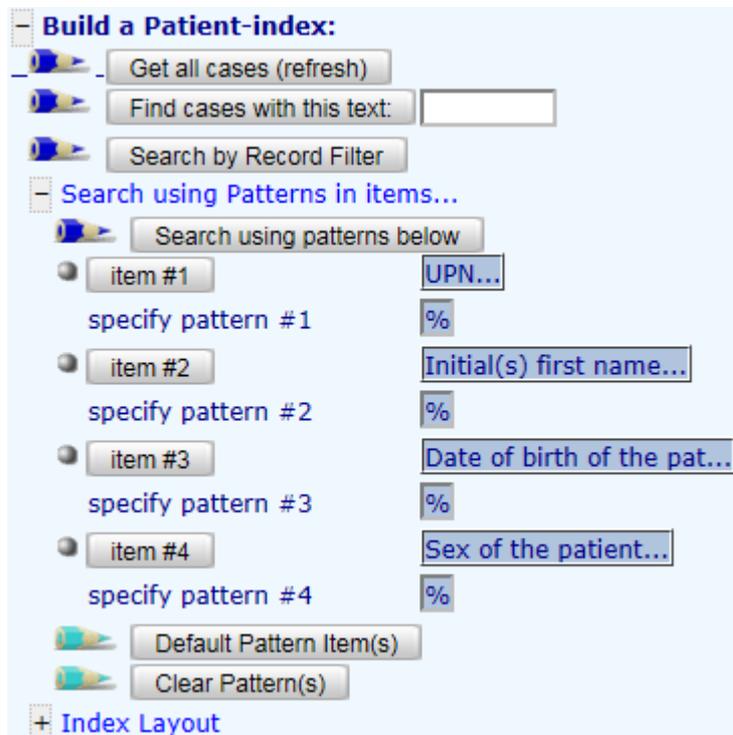
Figure 20: Search functions in the index.

To quickly find a case, fill in a value (characters, numbers, dates) in the "Find cases with this text:" field and click the corresponding button. This function will scan the entire index for the value of the "Find cases with this text" field and return only those cases that match this value in any of the fields in the index.

The option "Search using Patterns in items…" allows for a more precise specification of the search action. It allows you to search in items specifically. You can change the item by clicking an item button. This also allows the selection of items that are not currently in the index; these items will be temporarily added to the index during the search function. For example, you could add the item "Diagnosis" to the list by clicking one of the item buttons in Figure 20 and selecting the diagnosis field. This then allows you to look for cases with a specific diagnosis.

After specifying the items you wish to search you can specify the patterns you want to find by entering the pattern in the specify pattern field. This goes on a per item basis, so pattern #1 will find matches in item #1, pattern #2 in item #2, etcetera. The percent (%) sign is the wildcard character in ProMISe; it will match zero or more characters of any kind. For example, the pattern "%/05/%" will match any date in May. Please note that some items in the index show labels and that matching will be performed on the corresponding values. For example, in Figure 18, Gender is coded as follows: 1 = Male, 2 = Female. The search using patterns function will try to match the values (1 or 2 in this case) and not the labels. More on values and labels is explained in the Editor section below.

The default pattern is only the wildcard character and will match every case. Therefore it is not necessary to remove items you do not wish to search in; simply specify the pattern as "%" and it will

match every case in the index. It is not possible to use logic operators (AND, OR) in the search pattern. If you wish to use logic operators you can use the "Search by record filter" option. However, record filters are beyond the scope of this manual and are discussed in the Data Retrieval manual.

If you have specified the items and patterns to your liking click the button "Search using patterns below". This will recreate the index to show only the cases that match the search criteria.

The button "Default Pattern Item(s)" and "Clear Pattern(s)" will reset the default values for, respectively, the items and the patterns. To return to the original (complete) index click the "Get all cases (refresh)" button.

Sort cases

By default cases are sorted on CIC (Center) and case number. To sort the cases using another item, simply click the header of the item you wish to sort on (Figure 21). Additional options for sorting can be found in the Index Layout menu (Figure 22).

Figure 21: Sort on an item by clicking the item name in the header of index. Sort items are marked by a green arrow. To reverse the sorting order, click the item again.
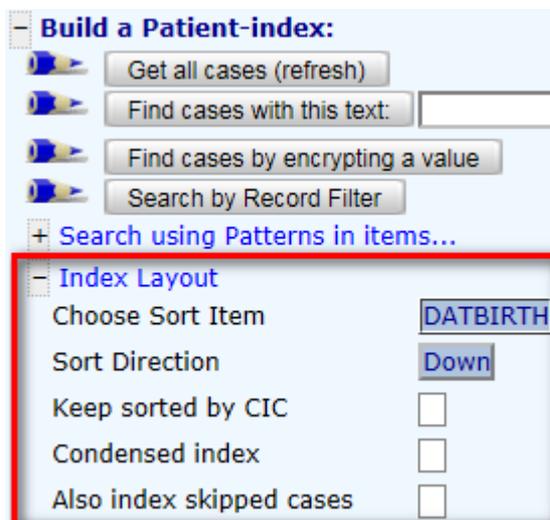
Figure 22: The Index Layout menu contains additional options for sorting the index.

The options in the Index Layout menu allow you to select an item to sort on, "Choose Sort Item". This opens a list with items in the database. Similar to the pattern searches, an item can be chosen that is not in the index; this will temporarily add this item to the index. The "Sort Direction" option sets the sort direction and the "Keep sorted by CIC" checkbox sets whether the index should also be sorted by CIC, which ProMISe does by default. The other options are in all if not most cases not useful. If the sorting options are set to your liking, click the "Get all cases (refresh)" option to reload the index in the desired order.

Loading and creating patients

As mentioned before, right clicking the grey square with the case number in the Index loads that case in the Editor, which is where data entry is performed. Alternatively, you can select the case by left-clicking the grey square and then clicking the "Load into Data-Editor" button in the "Data Manager" menu.

If you wish to create a new case, click the "Create/Load Patient-record" above the index. This will open a new menu, replacing the index (Figure 23).
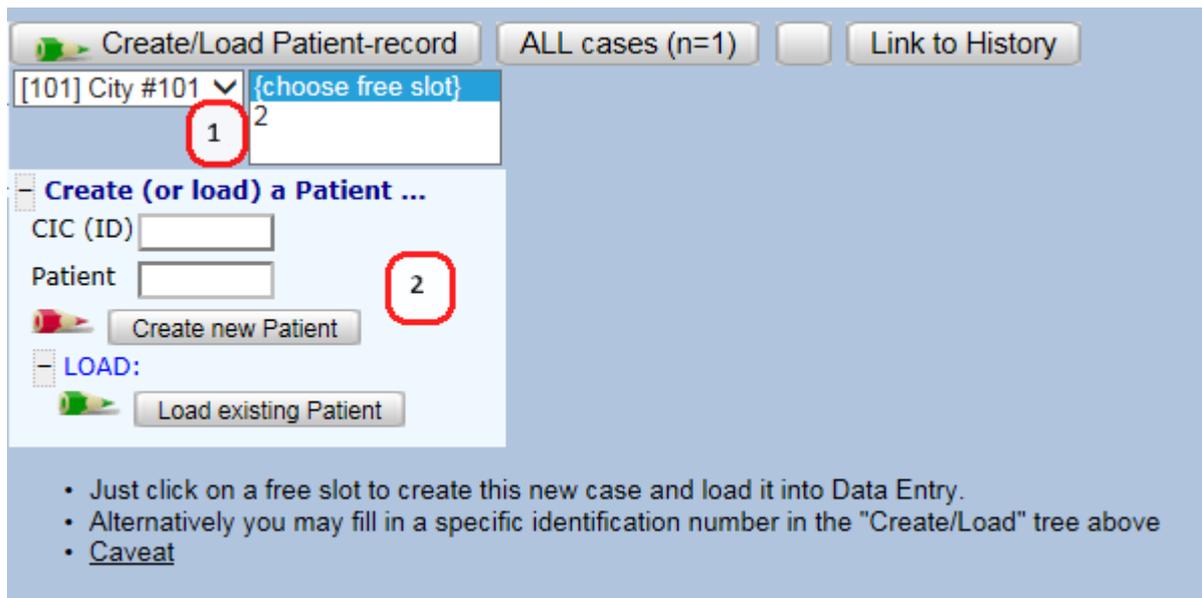
Figure 23: The create new case menu.

In the Create New Case menu, there are two options for creating a new case (Figure 23):

1. Select the appropriate Center and click a free slot number (ProMISe lists the next unused case number for that Center). A dialog will appear that asks for confirmation for the creation of a new record with the specified CIC and case numbers.

2. In some situations you can or may wish to freely specify the CIC and case number. Which centers you are allowed to create cases in depends on your account. The case number can be selected freely. If you specified a key (CIC + case number combination) that already exists, ProMISe will warn you accordingly. To create a new case, click the "Create new Case" button. A confirmation dialog will appear as above.

Some projects ask for another variable when creating a new case (besides CIC and case number). This variable will appear in the create new case menu. The variable has to be unique for all cases in the project; usually it is a social registration or unique (local) patient number. Before creating a new case in such a project, you will have to provide the value of the asked variable for the case you wish to create. ProMISe will then check whether a case with the same value exists in the project. If so, the case creation is aborted, if not, the case is created. This option prevents duplicate cases to be (unknowingly) entered in the database.

Editor

After a case has been created or selected, ProMISe will open the Data Editor. Tab-navigation-wise the editor is located in the Data Entry main tab and the Editor sub tab. The exact layout of the editor screen may differ slightly depending on the configuration of the project, but a general overview is shown in Figure 24.
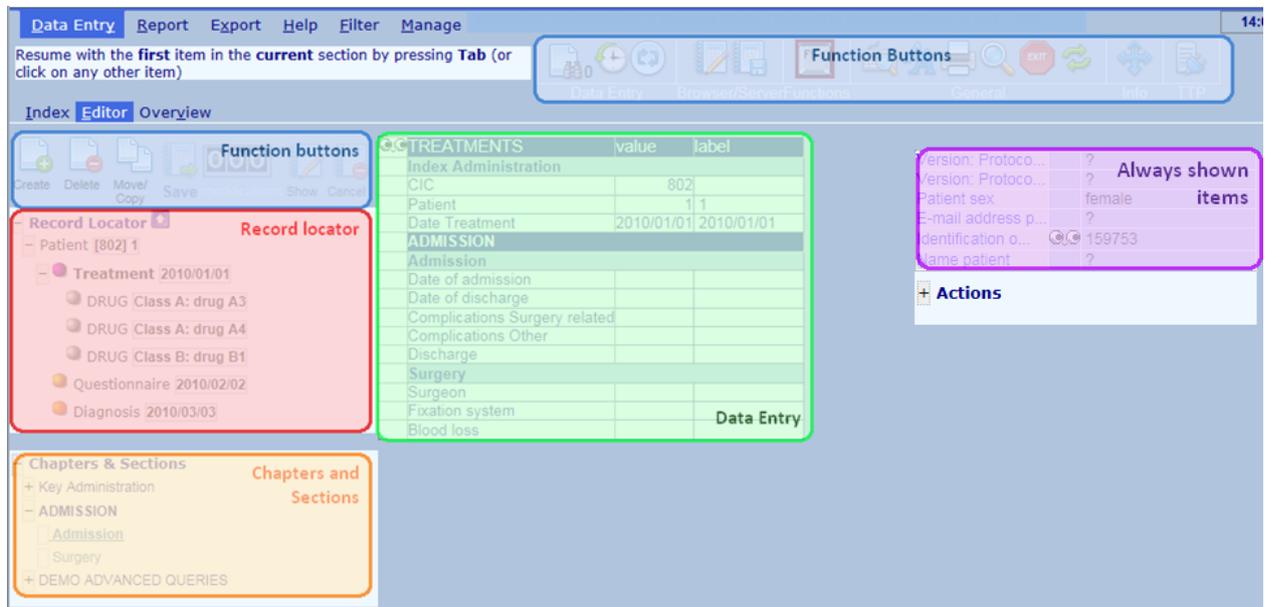
Figure 24: Overview of the editor screen. The layout may differ per project, but the ingredients are always the same: two blocks with functions buttons, a Record Locator, Chapters and Sections menu, Data Entry fields, Always shown items and the Actions menu.

Navigation through a loaded case

For every case in the database the data is structured in the same way. One case can contain several records of several types. A record is divided in chapters and sections. The editor shows the records of a loaded case in the record locator. The Chapters and Sections menu contains the different chapters and section of the currently selected record.

Record Locator

Each case contains one, and only one, main record. This is the upper most record in the record locator. Subrecords can be created that are related to the main case. These subrecords usually represent a collection of related data that can occur multiple times for a case, for example medication or adverse event data. To navigate to a record in the loaded case, simply click the record in the record locator. An example of a collection of records for a single case in the record locator is shown in Figure 25.
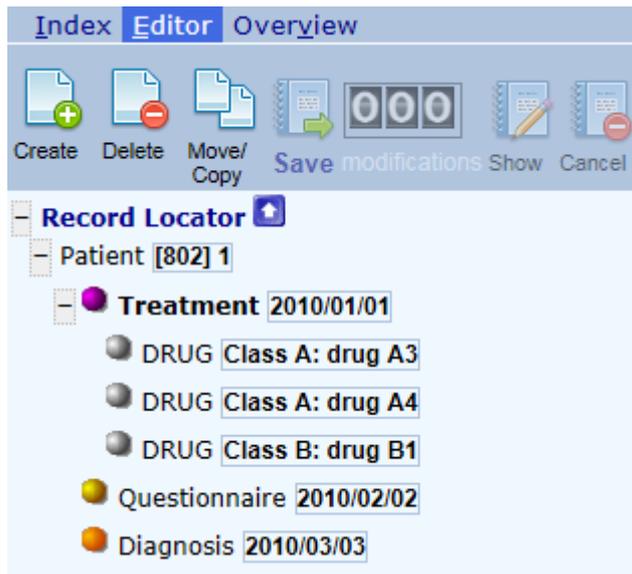
Figure 25: Record locator. The main case record is the uppermost record. Subrecords that are "related" to this main record can be created, deleted or moved with the corresponding function buttons above the record locator. The currently selected record is shown in a bold font. Please note that subrecords can be related to other subrecords (such as DRUG in the figure).

Chapters and sections

On a record, data is divided in chapters and sections. The chapters and sections of the currently selected record in the record locator are shown in the Chapters and Sections menu of the Editor screen (Figure 26).
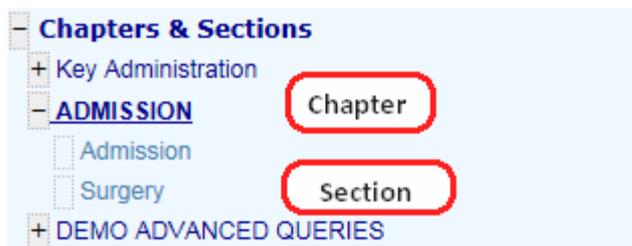
Figure 26: Chapters and Sections menu in the editor. The currently selected chapter is shown in bold font.

The data entry part of the screen shows the variables of a single chapter. To navigate to a different chapter, click the chapter in the Chapters and Sections menu.

Data entry

To start data entry, select the record and subsequently the chapter for which you wish to enter data. If the record does not exist yet, a new record has to be created (see below for instructions on how to do this). Then click a variable in the variable table or press the "tab" button to open the data entry popup (Figure 27). In this popup there are a data entry field and three buttons. In addition, there can be extra information in the popup, such as information on units, minimum and maximum values. During database design several rules are attached to an item. For example, numeric or text data, length, minimum and maximum values. The value entered in the data entry field needs to adhere to

these rules. If the value is not allowed based on these rules, an error will pop up and inform you that the value entered is not allowed and will not be accepted.

The three buttons in the data entry popup correspond to the following three options: accept, cancel and stop. Accept accepts the input and continues to the next item, cancel ignores the input (leaving the original value) and continues to the next item, and stop ignores the input and closes the data entry popup. (It is probably easier to use the keyboard shortcuts for accept, cancel and stop, which are, respectively: "tab", "esc" and "ctrl+end").
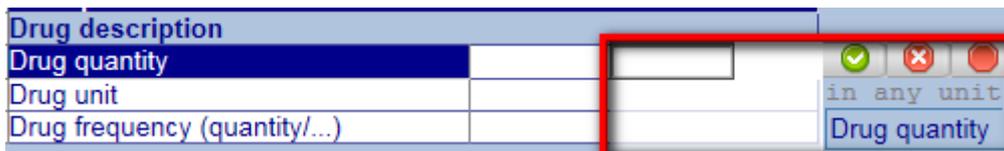
Figure 27: The data entry popup (highlighted). The buttons correspond to, from left to right: accept, cancel and stop.

As mentioned before, items must adhere to several rules, as per the design of the database. Two somewhat special item types may require some additional information: date items and labelset items.

Labelsets

Labels are used to add extra information in a database to an entered value. For example, gender is often encoded as 1=male, 2=female. The values are then 1 and 2, the corresponding labels are male and female. Therefore, the data entry table in ProMISe has both a value column and a label column. If a labelset is attached to an item, only values can be entered that are defined in that labelset, unless minimum and maximum values are defined (see below). The labelset that is attached to an item is shown in the data entry popup (Figure 28). To enter a value in such an item, you can either type the value, type the label or click the correct value-label in the data entry popup. For large labelsets it is recommended to type (part of) the desired label, because ProMISe will automatically filter the label options to match the entered text.
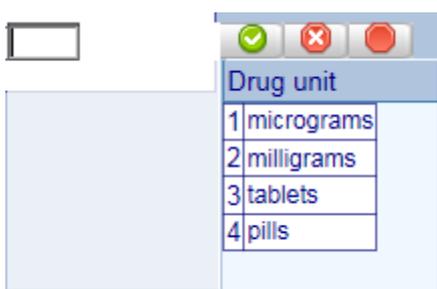
Figure 28: An item with a labelset.

If, in addition to a labelset, a minimum and maximum value are defined for an item, values can be entered that are not in the labelset. In such a case, you can enter all values in the minimum - maximum range, or values in the labelset (Figure 29).
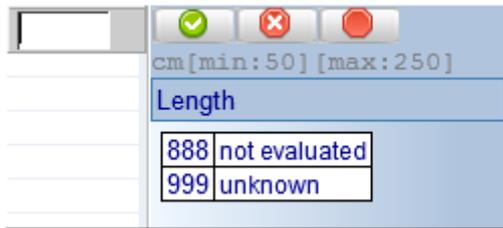
Figure 29: An item with a labelset, and a maximum value. Values can be entered that are in the min – max range or in the labelset.

Date items

Dates in ProMISe are stored as yyyy/mm/dd (ie. sortable date, for example: 2014/08/18). Date items in ProMISe come with a standard labelset with predefined dates for not applicable, unknown and today, as shown in Figure 30 (tip: type \ , ? or ! to quickly select the corresponding options).
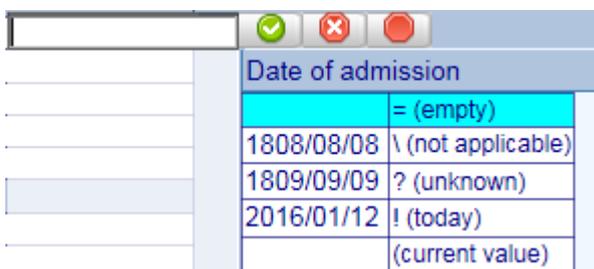
Figure 30: A date item.

Dates can also contain a time component. In these cases, the time is appended to the date as yyyy/mm/dd **hh:mm**. In addition, date items can contain fuzziness. Fuzziness is a measure of uncertainty that is added to the date value. An example is shown in Figure 31. Besides entering a date and a time, you can select a fuzziness for the entered date, for example 2014/08/18 00:00 plus or minus 1 day.
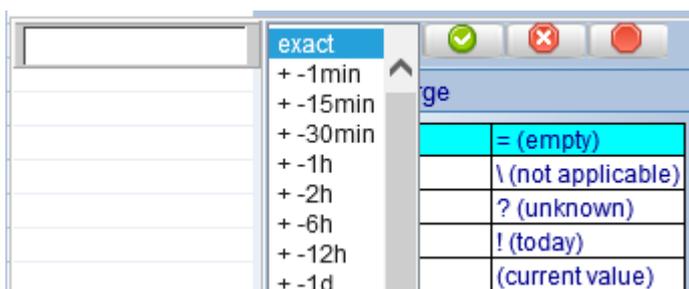
Figure 31: Fuzzy date options.

Saving data

It is very important to note that the data entered in the browser is not automatically stored in the database on the server. In order to save the data on the server you have to explicitly give the command to save the data, which is done by clicking the Save button above the record locator (Figure 32) or by using the shortcut ctrl + s. If you wish to cancel all pending modifications, you can click on the corresponding button in the save dialog.

The save dialog also shows a counter with the number of pending modifications. Pending modifications count the number of items that were modified, filled or erased since the last save. You

can review the pending modifications by using the function buttons shown in Figure 33. These allow you to either view the pending modifications or view the original, unmodified data of the current case as stored on the server. The current case as on the server can also be viewed by selecting the Overview sub tab in Data Entry main tab and clicking <u>Horizontal</u> or <u>Vertical</u>.

Figure 32: The save dialog. Clicking the save button will save all pending modifications to the server. To cancel pending modifications, click the cancel button. The show button will generate an overview of all pending changes.

Figure 33: Buttons for browser to server comparison. Clicking (1) will show a list of all pending (unsaved) modifications. Clicking (2) will show an overview of the current, unmodified data of the current case as on the server (without pending modifications).

Data entry logic

Most databases contain data entry logic that guide the user through the items and records. In this section several types of such logic are discussed that you can encounter in a ProMISe project.

Hidden items and jumps

Not all items are always relevant in a particular case. For example, you cannot enter the number of cigarettes per day if a patient is not smoking. In ProMISe, items that are not relevant can be automatically skipped or hidden. In some cases you may find items suddenly appearing, because some items may become relevant (again) depending on some newly entered data.

The number of items that is currently hidden is shown in the upper right function bar in Data Entry (Figure 34). Clicking this button will reveal (unhide) all items. This can be useful if you wish to see all items on a record. However, revealing all items will prevent hide logic from being used. To re-hide all hidden items you can click the same button.

Figure 34: Button for hidden items. The number next to the button shows the number of currently hidden items. Clicking this button will unhide all hidden items. If the button is clicked again, items are re-hidden again.

Errors and warnings

Besides the standard restrictions on items that were discussed above, additional restrictions can be put on items. For example, a date of a complication cannot be in the future or the age of patients must be above 18. To restrict inputs to items ProMISe makes use of errors and warnings. Both errors and warnings test whether an entered value is valid and show a popup if it is not. The difference is

that an error will refuse (and clear) the entered data for the item, while a warning accepts the input; a warning can be ignored during data entry. An example of both types is shown in Figure 35.
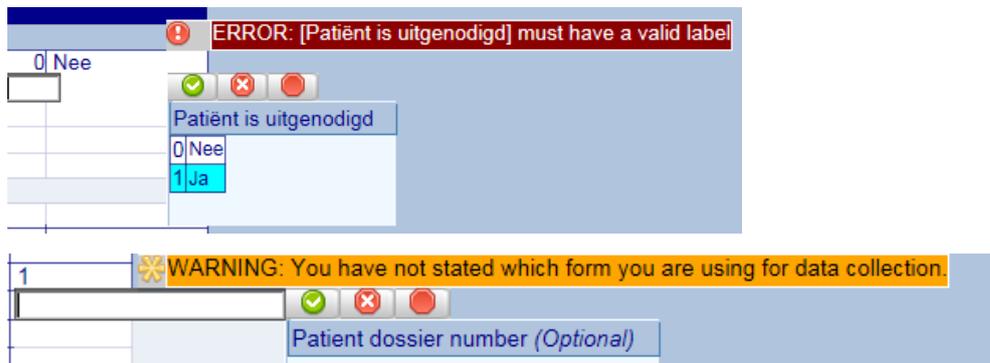

Figure 35: Examples of an error (in red) and a warning (in yellow). Note that in the case of the warning the entered value is accepted and is now a pending modification. An error will flat-out refuse the input.

Required items

Required items are a special case of warnings. If a required item is selected for data entry (if the data entry popup is opened for a required item) a valid entry is required; it should not be left empty. If no valid value is entered, ProMISe will generate a warning. There are three types of icons for (potentially) required items (Figure 36).

 An item marked by this icon is always required to enter.

 ProMISe projects can contain conditionally required items. An item marked by an orange icon is currently required to enter.

 A green icon also marks a conditionally required item, but one that is currently not required to enter.

Figure 36: Required items in ProMISe.

Create new record

As discussed, a case in ProMISe can consist of multiple records. There are two ways to add records to a case. Some projects make use of automatic record creation. New records are then automatically created as a result of entering certain data. For example, there may be an item "Add a complication", which, if "Yes" is entered, will add a Complication record to the current case. Alternatively, the data entry user can or must create records manually.

To add a record manually, first load the appropriate case into the Editor. Then click the Create button in the Editor Function Button Bar (Figure 37). A list will then appear with the type of records that can be created (this list includes the top / main record, which can also be created with this option). Please note that if you wish to create a subrecord of a subrecord, you also need to select the relevant parent record in the record locator. Based on the example of Figure 37, if you wish to create a record for a new "DRUG", you first need to select the "Treatment" record in the record locator to which the new "DRUG" record belongs.
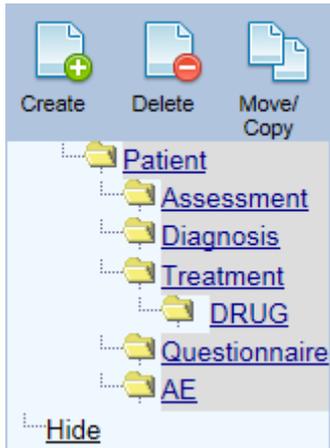
Figure 37: Function buttons to add, delete or recode records for the currently loaded case.

After you have selected the correct new record type a dialog will appear. In this dialog you will have to enter the key for the new record. If the record has a numbered key, a suggestion for the next available number will be done. If the record has a date key, an option to automatically enter the date of today will be supplied. To create the record, fill in a new key and click "Click here to create the record". When a new record is created, the Data Entry Editor screen will automatically go to the new record. Note that record creation is a (pending) modification and will have to be saved.

Deleting and recoding records

It is possible that an entire record has been incorrectly entered. Therefore ProMISe provides two options to deal with this: deletion and recoding / moving (Figure 37). To delete an entire record, first select the record in the record locator. Then click on the delete button. A dialog will appear that asks for confirmation for the deletion of the specified record. The dialog can contain more records than the one selected in the record locator; all subrecords of the currently selected record will be deleted as well (Figure 38). To confirm the deletion click "click here to delete the record(s) on the Server". In contrast to creating records, deleting records is instantaneous and will not be stored as pending modification.

Figure 38: Deleting the selected Treatment record will also delete all DRUG subrecords that are related to this Treatment record.

Recoding a record means to change its key; the other contents of the record will remain unchanged. To recode a record, select the record in the record locator and click the move button. Alternatively, in the Editor, click the key item of the currently selected record. A dialog will appear that allows you to specify a new key value for the item. Note that you can only move a record within a case; the moved record always has the same top record. It is not possible to move a subrecord to another

case. However, you can copy the contents of a subrecord to another case with the ProMISe clipboard.

ProMISe Clipboard

In some cases it could be convenient to be able to copy the contents of a record to another record. Therefore, ProMISe has a clipboard function. To activate the clipboard, open the Actions menu in the Editor Screen and open the ClipBoard menu (Figure 39). This menu contains several options.

- ▪ "clipboard visible" toggles the visibility of the clipboard in a popup screen.
- ▪ "clear" removes all data from the clipboard
- ▪ "prepare for merge" is a more complicated function of the clipboard and is beyond the scope of this manual
- ▪ "COPY current TO clipboard" will copy the contents of the currently selected record to the clipboard. The three different options will be discussed below.
- ▪ "PASTE clipboard TO current" will paste the contents of the clipboard to the currently selected record. This will only do anything if the contents of the clipboard are items of the same record type.

Both the Copy and Paste actions come in three flavours. They are the same options for both, but the targets are different; data goes to clipboard for Copy and to selected record for Paste. The different options are (in reverse order):

- ▪ "fill": will transfer the value of filled items to the target, but only if the corresponding item is empty on the target; items with existing data will not be modified.
- ▪ "fill+mod": will transfer the value of filled items to the target; filled items can be modified.
- ▪ "fill+mod+erase": will transfer the value of the all items (including empty) to the target; filled items can be modified and erased. For example, if an item is empty on the clipboard, but filled on the target record, the item on the record will be emptied during a paste action.
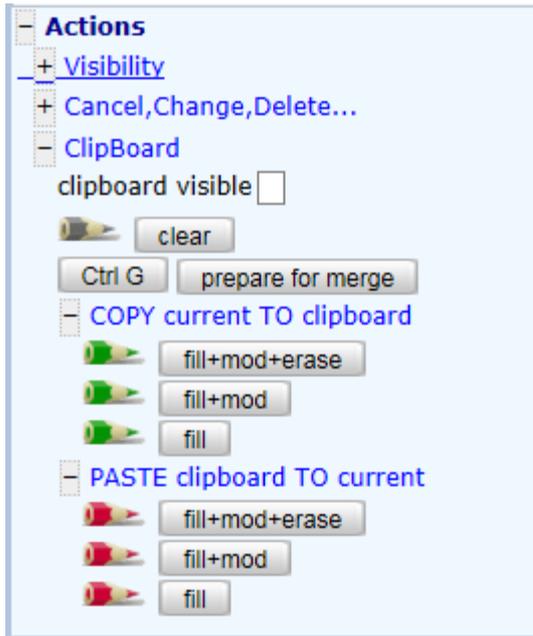
Figure 39: The clipboard menu.

If performing multiple copy-paste actions it is good practice to clear the clipboard after each paste; pasting data will not automatically clear the clipboard. It is easy to mix up data when the clipboard is used several times.

There is a shortcut button for the clipboard (Figure 40). If you left-click this button, the currently selected record will be copied to the clipboard. In addition, playback mode is activated; the icon of the button will change accordingly. To stop playback mode, left-click the same button. Right-clicking the button will clear the clipboard.

Figure 40: Shortcut button for the clipboard. Clicking this button will copy the selected to the clipboard and activate playback mode.

As long as playback mode is activated, ProMISe will suggest data entry options for items on the clipboard. For example, if "side of procedure" is an item on the clipboard and is labelled "left", the next time the "side of procedure" item is encountered in data entry ProMISe will suggest to enter "left". You have still have to confirm this entry in the usual way.

Close ProMISe session

Finally, after a data entry session, you may wish to close the ProMISe application. To close the session, click the exit button in the upper right bar of the screen (Figure 41). ProMISe will warn you if there are unsaved changes and give an option to save these changes before closing. You can also use the "x"-button on the browser window to close ProMISe, but then ProMISe is not able to give warning messages with regard to unsaved data.

There may arise situations in which you wish to restart the session. To restart the session, click the refresh session button next to the exit button (Figure 41). This will close the current session and build a new session. This option is not available if there are unsaved changes; you must first save or discard all pending modifications.

Figure 41: The Exit and Refresh session buttons

Appendices

ProMISe contains some other data entry features, but these are not used by every project. The following appendices explain several of these features.

Appendix A: Encryption

Encryption is the process of encoding certain data in order to make it unreadable without a decryption key. ProMISe projects can make use of encryption to protect sensitive data, usually data that makes patients identifiable (name, address, etc.). If encryption is enabled, ProMISe only stores the encrypted values of the encrypted items. It is impossible to decrypt these values without the use of a decryption key. This key is stored on another server than the database server; it is stored on the server of a so-called trusted third party (TTP). Therefore, in order to make use of the encryption / decryption possibilities in ProMISe, a user has to log in on two servers.

Whether an account has permission to decrypt and encrypt is configured by the project managers. Permissions can be set per center in the database and separately for decryption and encryption. The accounts for the TTP server are different from the ProMISe user accounts. Although it is common practice to use the same username for both ProMISe and TTP accounts, they are separate entities. For example, changing the password of a ProMISe account has no effect at all on a TTP account. It is possible to use the same password for both accounts.

Logging in the TTP server in ProMISe

To make use of encryption in ProMISe you have to log in on the TTP server during a ProMISe session. There are two ways to start this login procedure. You can either click on an item for which encryption is enabled or you can click on the TTP button in the upper right function bar (Figure 42). The login procedure starts with a popup that asks for the usual credentials (Figure 43). To login, supply both your username and password (of your TTP account) and click Log On. If login on the TTP server is successful, encryption and decryption services of your account will be enabled.

Figure 42: The TTP button. Click this button to open the TTP login dialog. The icon of this button will change after successfully logging in.
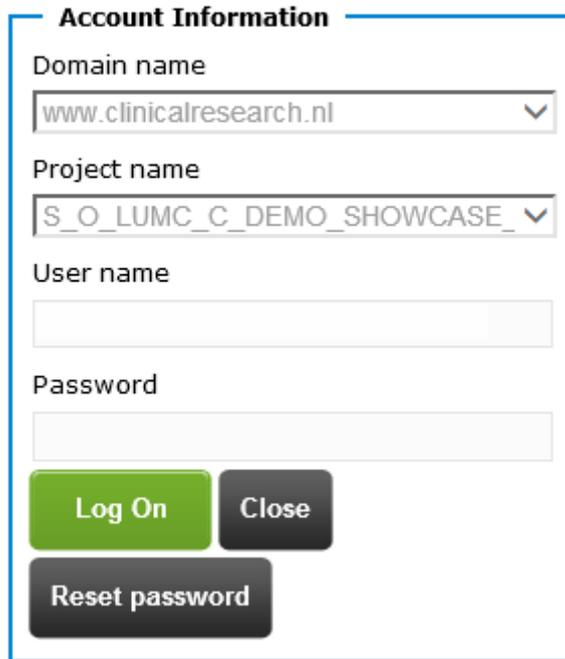
Figure 43: The TTP login screen. Domain- and project are usually auto-selected. If not, select the appropriate domain and project from the list. Then, fill in you username and password, and click Log On to enable encryption services. You can reset a password by clicking the Reset password button.

If you do not have a password for your TTP account or want to change it for another reason, click the Reset password button (Figure 43). A confirmation dialog will appear with again the domain name, project name and username. If these are correct, confirm the password reset by clicking the button "Reset password". An email will be sent to the email address linked with the account. This email contains a link, which if clicked leads to a website with a dialog to set a new password. Enter your desired new password (twice) and click the "Change password" button. The password has now been set and can be used to login to the TTP server in the ProMISe session.

Data Entry for encrypted items

Encrypted items in ProMISe are marked by an "{encrypted}" value (Figure 44). The labels of these items in the Data Entry Index and Editor depends on the TTP status of the current user. There are three possibilities:

- "Not connected to TTP": there is no connection to the TTP server in the current ProMISe session, so the decrypted value cannot be shown. Log in on the TTP server first to enable encryption services.
- "No decrypt permission": there is a connection with the TTP server, but the permissions for the current user do not allow the user to see decrypted values (for the selected case).
- The decrypted value: if logged in on the TTP server and decrypt permissions are enabled, the decrypted value is visible in the label column.

Figure 44: An encrypted item in ProMISe is marked by the value "{encrypted}". If you have logged in on the TTP server and have decryption rights, the label will change to the decrypted value of this entry.

To enter data for an encrypted item, select the item for which you wish to enter data. A dialog will appear in which you can enter the data for that item (Figure 45). If you click the "Encrypt" button, the data is first encrypted. This encrypted value is then automatically entered into ProMISe as a pending modification.

Figure 45: Enter data for an encrypted value.

Searching and encrypted items

Because ProMISe only stores encrypted strings and due to the nature of encryption, it is not possible to use standard search functionality on encrypted items, but for a single exception. An encrypted item can be marked searchable by project designers. To use these searchable, encrypted items in a search, you have to use the option "Find cases via encrypted value" in the Index (Figure 46). This option allows you to specify a value to search for in encrypted items, but will only show <u>exact</u> matches (no pattern search). For example, if you search for "bcd" in a certain encrypted item, the function will only return items with the (decrypted) value "bcd", and not "abcd" or "bcde".

Figure 46: Use the "Find cases via encrypted value" to search encrypted items.

Appendix B: Multiple-response items

Some projects use multiple-response items. A multiple-response item is a single item, but contains multiple data fields. An example is shown in Figure 47. As seen in the figure, a multiple-response item is basically a number of yes/no statements. To enter data in a multiple-response item you can set each statement to yes/no/??? by clicking the appropriate box. Alternatively, if you prefer to use the keyboard, you can press the letter before each statement to toggle the responses for that statement. In some cases it may be useful to set all statements in one go to a desired value. This can be done by clicking the yes/no/??? field in the lowest row of the response table. Again, if you prefer to use the keyboard, pressing 1 will set all statements to yes and pressing 0 will set all statements to no.

Figure 47: A multiple response item.

Appendix C: Logging and reason for change

GCP requirements state that projects should have an audit trail. Therefore, ProMISe logs the time, user and new + old data of every change that is made in the database. The logs can be accessed by project managers. Some projects require to log a reason for change if filled items are changed. Therefore, ProMISe can ask for a reason for change if modifying data; if you enter data in a non-empty field. The data entry dialog will then have an extra field, in which you have to specify the reason for changing the selected item (Figure 48).
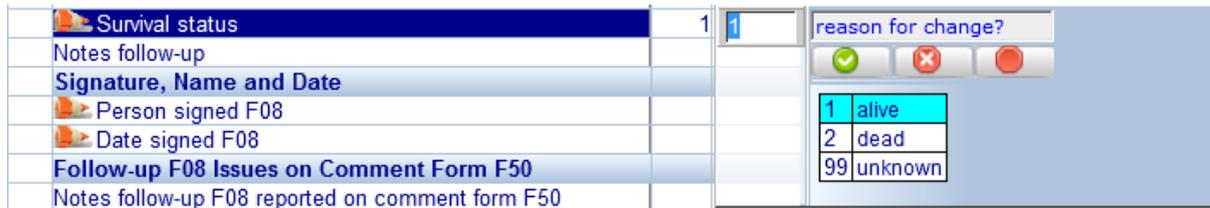

Figure 48: Reason for change. Some projects require the user to enter reason for change when modifying existing data.