



User Guide to ProMISe (Version 4)

For the MED-AB project

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■ ProMISe has been designed, written and implemented as a general tool for clinical data management by Ronald Brand, Professor of Biostatistics at the Leiden University Medical Center

PROMISE: Project Manager Internet Server

Version: 23/09/2020

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Introduction

ProMISe (Project Manager Internet Server) is the system used by the EBMT for MED-AB data entry and retrieval over a secure Internet connection. The MED-AB project was developed to collect and analyse the data required by the EBMT Registry.

The MED-AB project consists of the EBMT transplant registry database, where the data is stored, whilst the ProMISe system is used to manage and access the database.

All ProMISe users access the same copy of the entire database online, with the option of downloading their own centre data to other programs (MS Access, SPSS, Excel etc) for reference purposes. In addition to a statistical overview of the complete EBMT database, users are able to view, enter and analyse data for their own centre.

Checking that your PC can run Promise

To use ProMISe version 3 you will need Internet Explorer, a reasonably fast processor and at least 1 GB of Memory. You must also have access to a good internet connection. Your computer will have to meet some minimum technical requirements in order for you to use ProMISe efficiently. It is advisable to check that your PC specifications are compatible by using the interactive browser configuration checker before trying ProMISe. For convenience this web link contains full instructions and links for updating your computer's local settings. (Further information is in the Appendix)

Demo Version

If you would like to try the application, a DEMO project is available. The DEMO project has the same functionality as the MED-AB project but instead of accessing the EBMT registry database, it accesses a database filled with fake data. You can practice entering, erasing or modifying data in this project without restrictions. Note that any new data entered must be fake as the Demo can be seen by other users.

Please contact the Registry Helpdesk to request a Demo user name.

Entering Your Database

To enter data directly into the MED-AB project you should first apply to the EBMT Central Registry Office to request access. See "Password Access" below.

If you have sent transplant data to the EBMT in the past, these registrations will be present when you access your centre database.

Please check that your PC meets the hardware requirements and that you have the correct security settings in Internet Explorer. More information is available on the interactive browser configuration checker

ProMISe is located on the EBMT web site [http://www.ebmt.org].

- [Data management]
- Login to ProMISe

Password Access

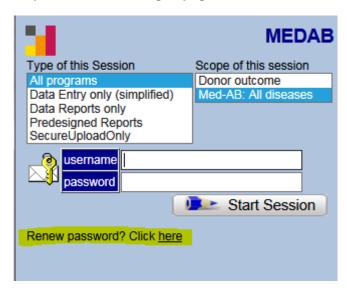
ProMISe usernames are assigned by the EBMT Central Registry Office in London. There are two different levels of access:

Data Entry: access to all functions: Data Entry; Statistical Reports; Patient Reports and Downloading Centre Data. We assign personal passwords to those entering data on behalf of their team (authorised by Principal Investigators). <a href="Profile: Profile: Profi

Data Download: access as Data Entry but data modification is disabled. Personal passwords are assigned as above. ProMISe personal password request form - data download.

Usernames and passwords are personal and non-transferable. Please do not disclose your password to anyone else, including other team members. ProMISe keeps a log of all modifications made in the database, identifying the user and the time in which the modification was performed. It is in your interest that the only modifications attributed to your username are those performed by yourself.

New users will receive their login details via email. When accessing ProMISe for the first time they must request a new password on the logon page.



Click here (highlighted above) in order to get a new password

On the next screen click [obtain new password]

Enter your username here:



(If you do not yet have a username, follow the instructions in the section above "Password Access")

Click [Request Security Code]

The security code will be sent to your registered email address

When you receive the security code enter it here and add a new password of your choice:



Note that your password must be strong, at least 8 characters long and must...

contain UPPER CASE character(s) contain lower case character(s) contain one or more digits

Enter your username and password exactly as shown. (Usernames and passwords are casesensitive: please enter capitals or lower case letters as shown).

Click on [START SESSION]

It may take a few minutes for the session to load fully. If it takes longer than a few minutes to initialise, the hardware specification or browser settings may not be correct.

Please contact the Registry Helpdesk if you experience problems or forget your username.

Renewing Your Promise password

For security reasons, you will need to renew your password occasionally, for example when your password expires or if you forget your password. To renew your password, click the link on the logon screen as shown above.

After you have logged in

Immediately after very first logon, ProMISe will take you to the data entry module. You will find yourself in the Index screen:



On the top left hand corner of the screen there is a series of tabs



These tabs indicate the main modules of ProMISe.

Below these tabs, there is another series of secondary tabs



With your mouse, click on any of the tabs present in the top layer ("Data entry", "Report", etc.). You will notice that the tabs available in the second layer change depending on which tab is highlighted in the top layer. These tabs are the main way the user has to navigate between the different modules or the options within each module.

In order to return to data entry go to Data entry – Index (click on the "Data entry" tab if not already highlighted, and then click on the "Index" tab if not already highlighted).

On the top right hand corner of your screen in Data Entry, you will see a collection of icons:



Font size

Click the following icon if you prefer to toggle between a smaller / larger font size:



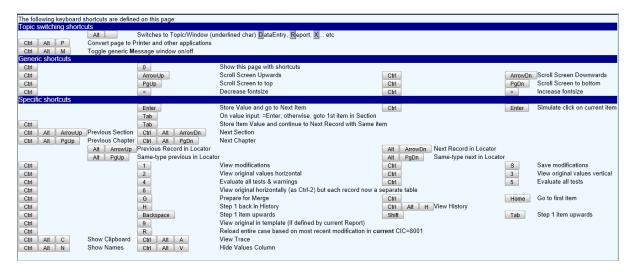
Shortcut keys: Ctrl < or Ctrl >

Keyboard Shortcuts

Click the following icon to view a list of shortcuts for the currently active tab:



Below is an example list of shortcuts available in the Data Entry – Editor tab:



All shortcuts in use in your currently active screen can be viewed when pressing the following icon or the shortcut itself: Ctrl-Ø. (Press again to remove the shortcut window):



We recommend you print the Shortcut screen (the Editor window as shown above has the most comprehensive list) and keep it by your computer for handy reference.

Shortcut key: Ctrl-0

Exit button



Use this button to properly close down your session

Refresh button



Use this button to restart or refresh your session in case of technical problems.

Full screen button



Use this button to switch to full screen if preferred. Press the [Esc] key to exit full screen mode and return to the standard screen.

The remaining icons will be explained later in this guide.

Data Entry

How to find and load a registered patient in Data Entry

It is crucial to search for existing patients before starting your data entry. This is in order to avoid duplicating registrations. We strongly recommend that you read the document Duplicate registrations: how to avoid them before you begin entering any data in Promise.

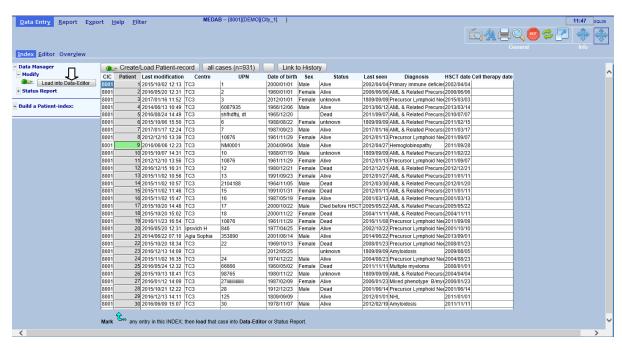
The index screen has a list of all the patients registered by your centre.



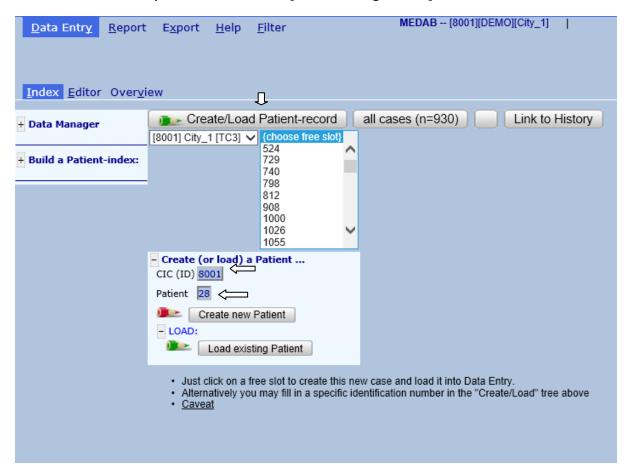
The Data Entry Index is sorted by the EBMT Patient Number by default. You can opt to sort by a different item such as UPN (Unique Patient Number at your hospital) or date of birth. Click on the column heading to choose your sort item and direction.

To load a patient located in the index, either right-click with your mouse on the EBMT Patient Number (as above), or left-click on a patient number to select it (highlighted in green when selected), then press [Load into Data-Editor]:

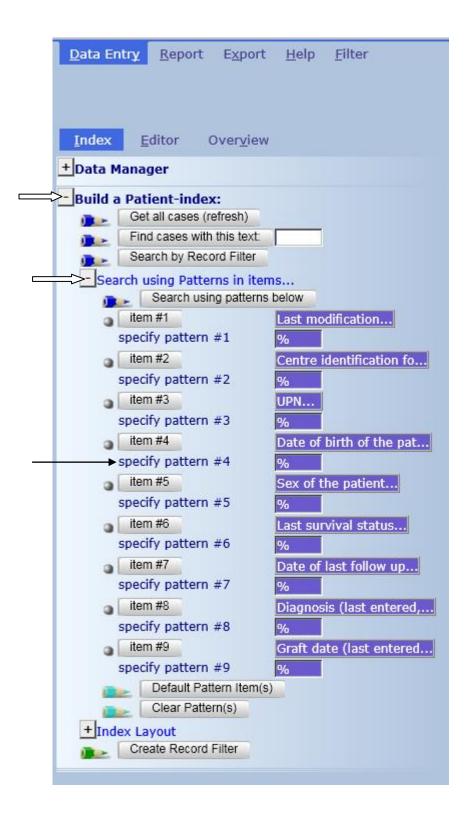
Shortcut keys: Ctrl-1



If you already know the EBMT Patient Number and you prefer to enter it manually, click the [Create / Load Patient Record] button above the Index. Select your CIC, enter the EBMT Patient Number in the patient box and click [Load existing Patient]:



You can also search for a patient by creating a pattern filter. Click on Build a Patient-index and open folder "Search using Patterns in items..."



Index: Search by Pattern

To search for a patient by date of birth for example, click on the corresponding 'specify pattern #' indicated above, and enter the date in the EBMT format yyyy/mm/dd

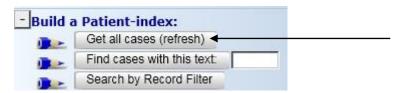
Example: to find a patient with the date of birth 1963/01/02

Click specify pattern # as indicated above and enter the date in format: 1963/01/02 or 1963-01-02 or 1963/01% (% can be used as a wildcard to find any unknown characters after), then press the button named Search using patterns below

After the Index results have loaded (when the central tab in the Index reads [Found Cases n=x]) you can load the individual patient into the Data Entry Editor by right-clicking on the patient ID, or left-clicking on the patient ID to mark it, then pressing [Load into Data Editor] in the Patient Data Manager:

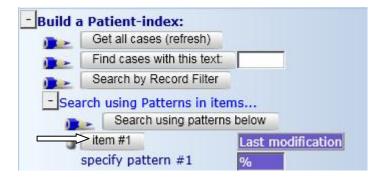


To restore your original index after carrying out a Search, or after entering a new patient select [Get all cases (refresh)]

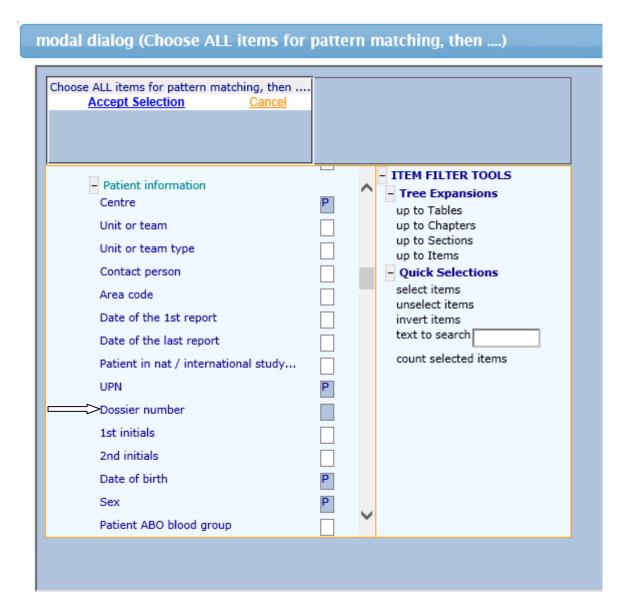


Choose Other Items for Search

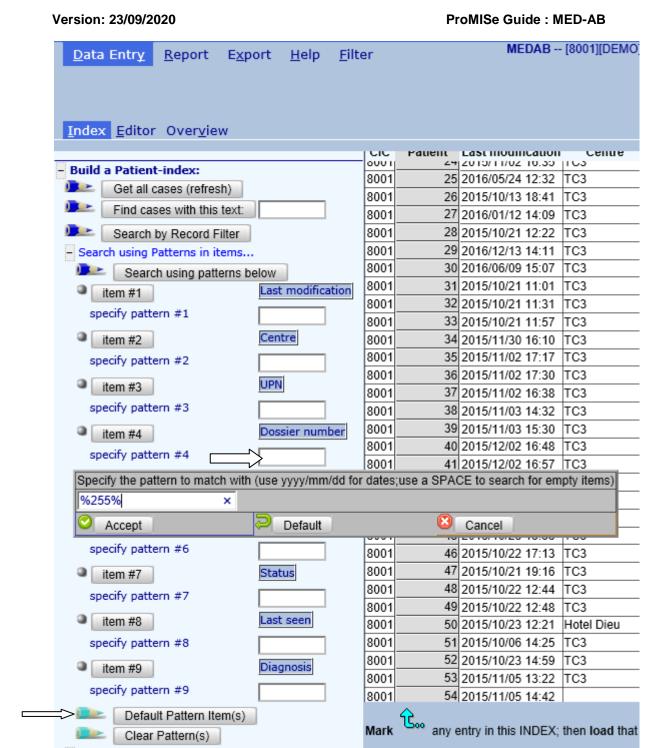
A selection of default items to search on has been pre-programmed by the designer. However, you can replace this selection at any time with other items of your choice in "Build a Patient index" – "Search using Patterns in items...". Click on the Item button that you wish to change, for example item #1:



The current list of marked items will display, where you can unmark or mark any other item(s) of your choice. Click on the item descriptions. When selected, the checkbox will be filled. Click [Accept Selection] to continue.



You can search on your new item in the corresponding specify pattern #. For example the search entry below will find all dossier numbers in your centre containing the digits 255:



(To restore the original items in the Index click [Default Pattern Item(s)])

Record Filters

In Data Entry you can also create an index restricted to a filtered group of records. For example, if you are collecting data for a study on AML, you can filter using a selection you have created or loaded from menu [Filter] – [Records].

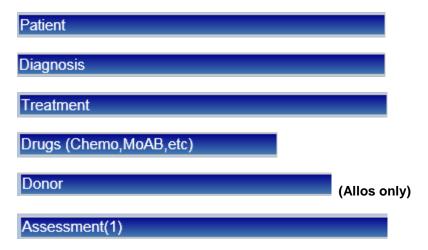
Navigation

Navigation is the term used for the movement of the cursor during data entry. The MED-AB project is designed so that navigation follows the MED-AB forms as closely as possible.

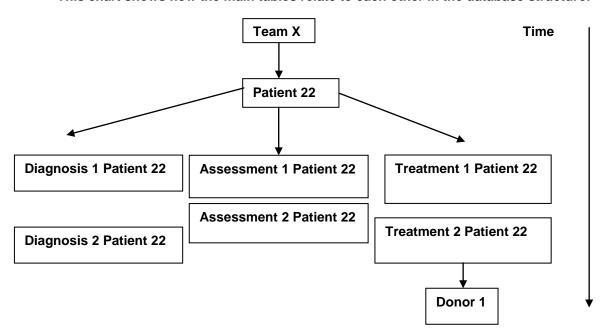
The EBMT database is a relational database with several levels and the data is stored in several tables.

It is recommended that for a better understanding of the navigation involved in entering data, you read the document The EBMT Registry Database

The basic (MED-A only) database structure contains 5-6 main tables, namely:

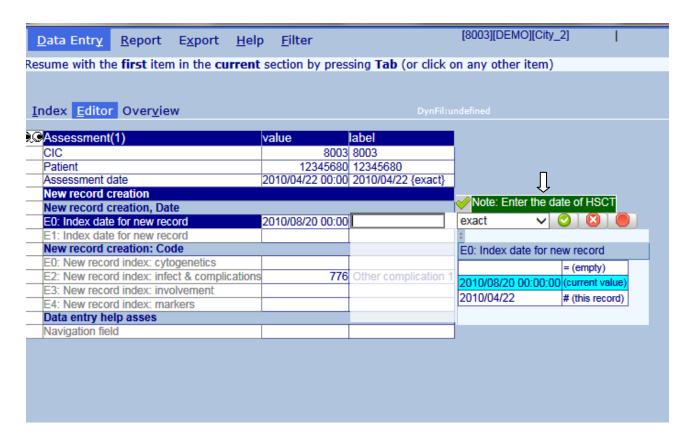


This chart shows how the main tables relate to each other in the database structure:



The tables Diagnosis, Treatment and Assessment1 are indexed by date. During the process of data entry, you will find that the cursor lands in fields named "New record creation" fields. If the records to be created at this point belong to one of the tables above, a note will then appear advising you which date has to be entered, for example the diagnosis date; transplant date.

Example of note indicating new record creation:

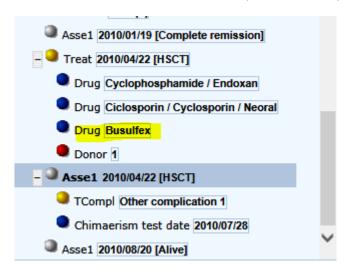


Events

In the Data Entry Editor you will see that each stored patient registration has a short abbreviation on the right in the Record Locator ('Main indication diagnosis', 'HSCT', 'Alive', etc). When the abbreviation belongs to the Diagnosis, Assessment1 or Treatment tables, this abbreviation represents the "Event" that took place on the date that warrants the collection of the data. The events are listed below

Code	Label
1	Main indication diagnosis
2	Non graft treatment
3	Alive
4	Collection
5	Worst disease status
6	Staging
7	HSCT
8	Myelosuppression
9	GvHD
10	Relapse/progression
11	Dead
12	Study entry
13	Complication
14	Support / Boosts
15	Complete remission
16	Other, non indication diagnosis
17	DLI
18	Cell Therapy (non HSCT/DLI)

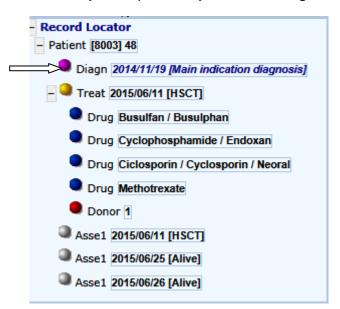
When the abbreviation belongs to any of the other tables, it is the main information stored in that table, whose code behaves as the unique index key for that record. For example, "Busulfex" as a label in the Record Locator would correspond to a drug that the patient received during their stem cell treatment on a certain date (event "HSCT") in the MED-AB:



Dates

As you can see in the Record Locator, some records are indexed by date so that each type of record is unique, and we can follow a chronological event chart for each patient. What happens if you do not know the exact date an event happened – how can a new record be created in Data Entry?

In ProMISe we have implemented "approximate dates" in case the exact date is not known when creating a new record for a patient (the example shows a Diagnosis date):



After saving, the record locator displays the date in italics to indicate it is approximate.

If you are unsure of the exact date, please give your best estimate, for example enter the approximate date and specify "this month" or "this year" depending on the information available to you.



If you know only that the event took place in 2004 for example, we recommend that you enter the 1st of the year, e.g. 2004/01/01 and select "This year" as the approximation.

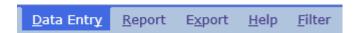
If you know only that the event took place in March 2000 for example, we recommend that you enter the 1st of the month, e.g. 2000/03/01 and select "This month" as the approximation.

If you have no date available we ask you to make an estimate based on the information available. For example if the patient was born in 2000 and had a transplant in 2004 but you do not have the date of diagnosis, you can enter 2002/01/01 and select "Within 5 years" as the approximation.

NB: this concept does help to solve the problem of unknown/imprecise dates, however, there is some concern regarding overuse of approximate dates when it is not strictly necessary. Where an exact date cannot be given this system allows a patient to be registered, although the record cannot be included in a statistical analysis. Please bear this in mind and do not abuse the system.

Approximate dates should be kept to a minimum and used only when strictly necessary.

Item Filters during Data Entry



Item filters in ProMISe are *dynamic*. This means that as soon as you enter/load the main diagnosis or type of graft for a patient, the filter will automatically exclude all irrelevant items. The programmed cursor jumps are designed to follow the MED-AB forms. For example, once you enter or load a diagnosis as Acute Leukaemia, only Acute Leukaemia items will be displayed. All items relating to other diseases will be excluded from your filter. Equally the filter will transform itself depending on the type of graft or treatment entered.

You will notice items appearing or disappearing depending on the type of patient record entered or loaded at the time. Therefore you do not normally need to manually apply any filters in Data Entry. To ensure that the correct dynamic filter is applied in terms of MED-A or MED-B, at day 0, day 100 or follow up, you must always fill the first question in the Data Entry Editor: "Form about to be entered". You will find more information on this item on page 25.

You can toggle dynamic filters on and off in menu Actions – Visibility – No DynFilters by unmarking / marking the blue checkbox:

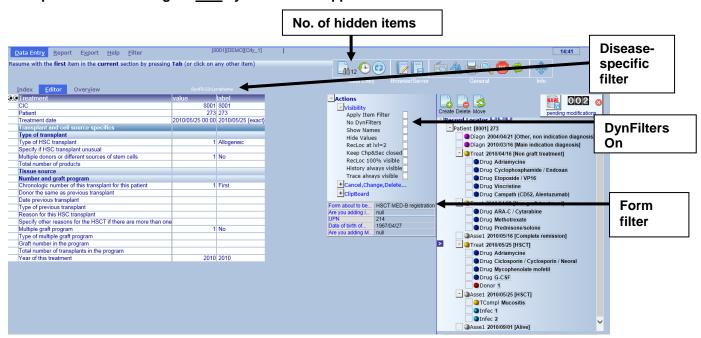


Alternatively you can click on the Binoculars icon to toggle these filters on and off:

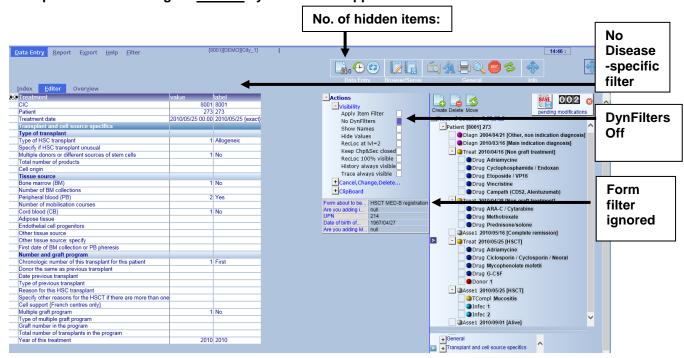


(The current number of hidden items will be displayed next to the Binoculars. If all items are visible, number '0' will display).

Example of a MED-B allograft with dynamic filters applied:



Example of a MED-B allograft without dynamic filters applied:



The dynamic filters are applied by default, so you do not need to change anything manually when following a MED-A or B form. The filters are designed to follow these forms. If you find that the cursor is not jumping to the correct place, always check first that the "No DynFilters" checkbox is not marked in blue (equivalent to hidden items: 0).

Remember to use the Tab or Enter key to move from item to item rather than clicking around the form with your mouse.

IMPORTANT: We strongly recommend that you enter your form in its entirety until the screen with a message prompting you to save appears (shown on page 41) This will ensure that all items have been filled, and calculations are made for automatic entry such as 'age at transplant'. This results in good data and saves you being contacted in future with requests for missing data.

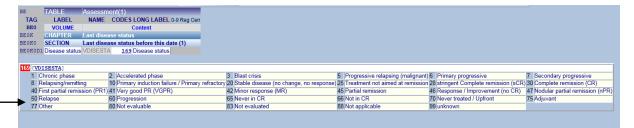
There are occasions where you may need to switch off dynamic filters manually. (Mainly if you need to enter data outside of MED-AB for your own use). More information is available in "Creating New Records Manually..." on page 51

Reduced Labelsets

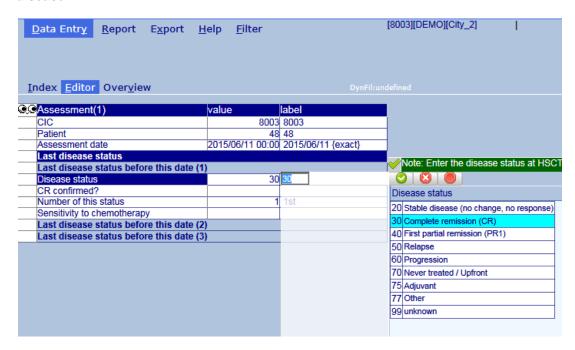
You should be aware that the labelsets also follow the dynamic behaviour in the same way as the item filters.

Example:

The full labelset for the question "Disease Status" is indicated below:



If you have, for example, a solid tumour patient loaded in the Data Entry Editor, the dynamic labelset will show a reduced number of options available depending on the relevance to the disease:



How to view the full list of codes for an item:

If a set of labels attached to an item has been reduced, press? on your keyboard to view the full labelset. (Your cursor will need to be placed in the input box).

NB: If you need to enter a code outside of the "reduced" labelset, this can still be entered manually as long as the code exists in the full labelset for that particular item. However, if you find this is necessary we advise you to seek advice from the Helpdesk. (To our knowledge, the visible codes should be sufficient for normal data entry.)

Creating a Data Entry Form for a New Patient

While in the Index screen, to view free EBMT Patient Numbers that have not already been assigned in the database click the [Create/Load Patient record] tab in the Index. (The combination of your centre number (CIC) and the patient number in the database forms the EBMT Patient Number.)

EBMT Patient Number:

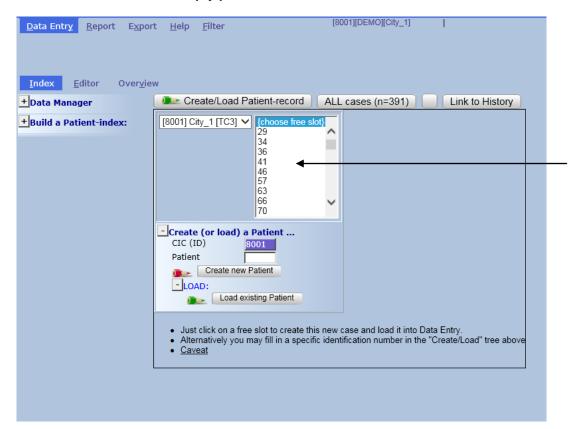
If you are entering a new patient in the EBMT database yourself, you can choose any free number suggested by the database, or enter a free number of your choice manually. The EBMT Patient Number is a unique database key and should <u>never</u> be changed. All data for a patient

should be entered under one number, including subsequent transplants. Patients transferred to other centres for further transplants must always keep their original number. If your patient had a prior transplant elsewhere please use this form to request access to their existing record:

http://www.ebmt.org/Contents/Data-

Management/Datasubmission/Documents/PatientGivenPreviousHSCTinOtherCentre.pdf:

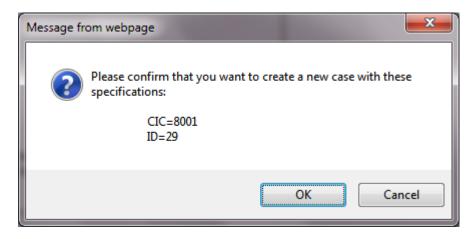
Select any free patient number (the number does not have to follow a chronological order) and click on it to create a new empty patient form:



NOTE: If the list with free slots doesn't appear, go to 'Build a Patient-index and select [Get all cases (refresh)] first

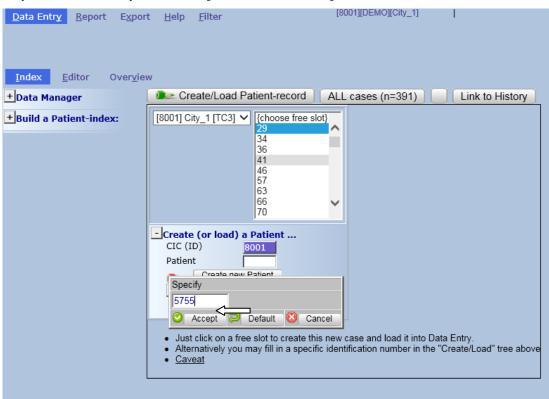


Press [OK] to confirm:



IMPORTANT NOTE: When you create a new patient in the database that has never been registered before, make sure you have an empty form loaded. You should never overwrite any patient details unless you are making corrections to an existing patient record.

If you prefer to enter your own number manually instead of choosing from the free slots, select your CIC from the drop-down list on the left, enter your chosen ID number in the patient box, accept and click [Create new Patient]:



(If your chosen ID number is already taken you will receive an error message.)

Starting Your Data Entry

It is crucial to search for existing patients before starting your data entry. Please see "how to find and load an existing patient" above.

Certain items must be filled in <u>at the very beginning</u> in the field "Form about to be entered" in order to follow the programmed navigation for the EBMT data collection forms. Entering a code in this field is vital. If you leave it empty, the cursor will not direct you to the correct place in the data entry form. By entering the code for day 0, day 100 or follow up (MED-A or B) the programmed navigation will follow your form order, while skipping any irrelevant questions for that particular patient characteristics or time point. When you want to add new information to an existing patient record, the code in this field should be overwritten with a new form code depending on the form you are entering at the time (please see 'Form about to be entered' below).

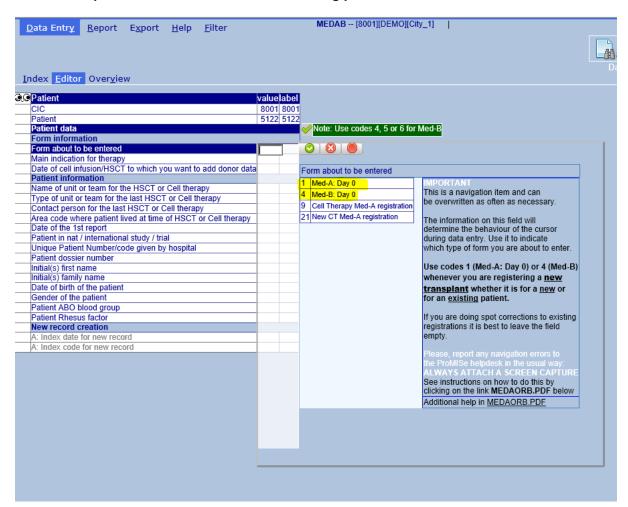
Notes during Data Entry

You will see a green 'Note' attached to certain items such as the image below. To the right you have a more detailed explanation. Please always read the explanations that appear next to an item before proceeding, as they contain important information or help.

a) Entering a new MED-AB registration

Form about to be entered:

Enter code 1 (MED-A day 0) or 4 (MED-B day 0) whenever you are registering a <u>new</u> transplant whether it is for a new or existing patient.



b) Entering a patient that died during the conditioning or transplant

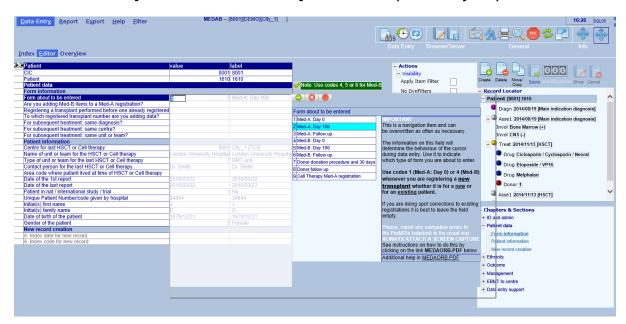
Enter code 1 (MED-A day 0) as above if you are registering a <u>patient that died during conditioning or transplant.</u> Enter the date of death as the date of HSCT. It is understood that this is not the date of HSCT since the transplant was never done. When you finish entering the planned transplant you will be asked the Patient Status: please select code 3 - Died before HSCT but after Conditioning was initiated

SHORTCUT: Press [Ctrl-Home] to return to the "Form about to be entered" question at any time during data entry.

c) Entering a MED-A day 100 report

Note that the day 0 report must already be entered and ensure the existing patient record is loaded

Go to the first field [Form about to be entered]. Enter code 2 (MED-A day 100)

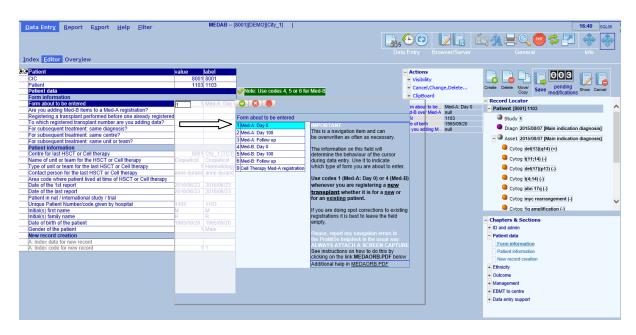


After entering the type of form, the system will recognise that a day 0 has already been entered. You will be asked which transplant you are editing (first, second..), and the most recent date of the report, then the cursor will go straight to the Neutrophil & Platelet recovery questions.

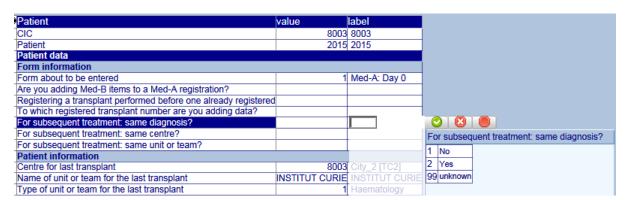
d) Entering a subsequent transplant for an existing patient:

Ensure that the existing patient record is loaded

Click on [Form about to be entered]



Enter code 1 (MED-A day 0) or 4 (MED-B) depending on the type of form you wish to enter. The system will recognise that a transplant has already been entered. You will be asked "For subsequent transplant: same diagnosis / same centre / same team?" If the answers are 'yes', you will not be asked for the diagnosis or centre / team data again. If the diagnosis, centre or team is different for the subsequent transplant, answer 'no' to the question and the navigation will prompt you to enter the new information:



While moving through the form you will be prompted to enter the new treatment date.

Note: If the first transplant for your patient took place in another centre, the new transplant must also be registered under the original ID number in the database. Please contact the Registry Helpdesk or your national registry before entering the new transplant in the database, so that they can give you access to the existing data and ID number. A request form to do so is available here (Access to patients given a prior HSCT in a different centre): http://www.ebmt.org/Contents/Data-Management/Datasubmission/Pages/Data-Submission.aspx#application

e) Entering a MED-B on top of a MED-A for the same transplant

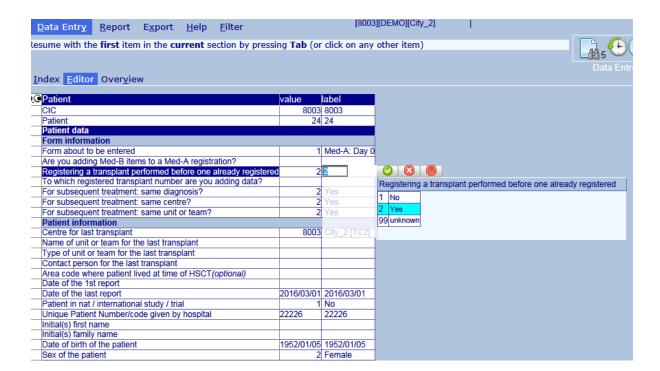
Enter code 4 (Med-B day 0) in Form about to be entered and answer yes to: "Are you adding Med-B items to a Med-A registration?". You can later proceed to the day 100 update in MED-B by using code 5 (Med-B day 100).



f) Entering a transplant performed before one already registered

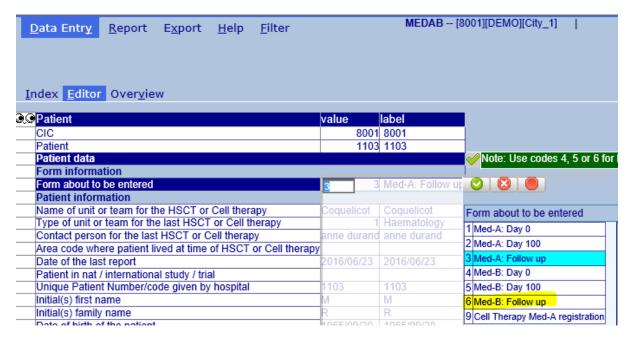
If you need to enter transplants in reverse order for any reason, enter the correct form code (e.g. MED-A or B day 0) for the transplant you are about to enter and go manually to the question

"Registering a transplant performed before one already registered?", then answer Yes. Answer the subsequent transplant questions, interpreting them as "prior treatment: same diagnosis, same centre, team". While moving through the form you will be prompted to enter the new (prior) treatment date.



g) Entering a follow up

Start at the same question (Form about to be entered) and enter the code for MED-A follow up (code 3) or a MED-B follow up (code 6). You may have to re-enter the same code again and again whenever you have new follow up data



You will be asked the date the follow up data was collected (Date of the last report), whether the patient is in a study and then the cursor will move straight to "Date last contact" where you enter the date the patient was last seen or the date of death and you can continue with the follow up entry

h) Entering a new donor registration (donation procedure at 30 days)

Please use code 7 in "form about to be entered". Note that the MED-A or B 100 day registration must be entered first with the Donor record. For more information please see Donor Outcome forms and manual. (The follow up for this Donatjon procedure can be entered using form code 8).



SHORTCUT: Press [Ctrl-Home] to return to the "Form about to be entered" question at any time during data entry.

i) Entering a non consenting patient

For patients who have not consented for their data to be viewed by the Registry, you have 2 options.

- 1. You can enter the minimal data set (so it is counted in your centre numbers)
- 2. Enter the full report for your own centre records but <u>ensure</u> you mark them as "Not to be seen by EBMT" and/or "Not to be seen by National Registry" (if applicable) before saving the data.

Option 1: Here is the minimal required data to be entered (No patient identifiers allowed):

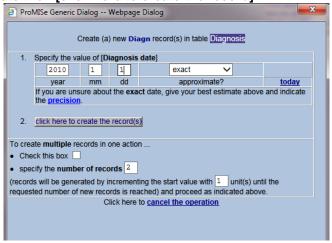
- Diagnosis (& Date)
- Date of Transplant
- Type of Transplant
- Chronological Number of the Transplant for this Patient

Create a new patient record in the Index. Create the diagnosis record manually by clicking [Create] and select Diagn:

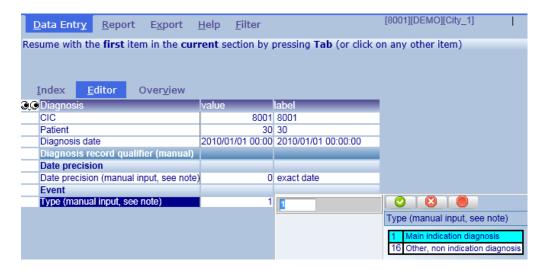




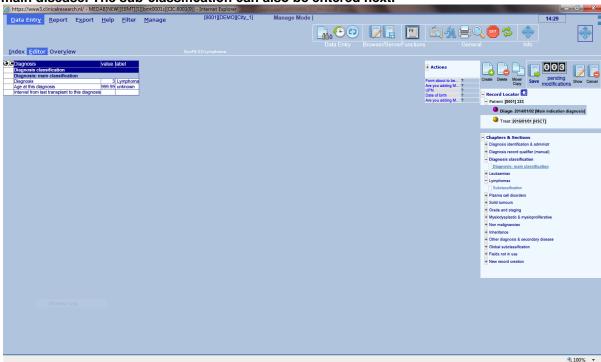
Enter the diagnosis date then [click here to create the record]:



Indicate the precision of the diagnosis date and code it as main indication diagnosis (code 1):

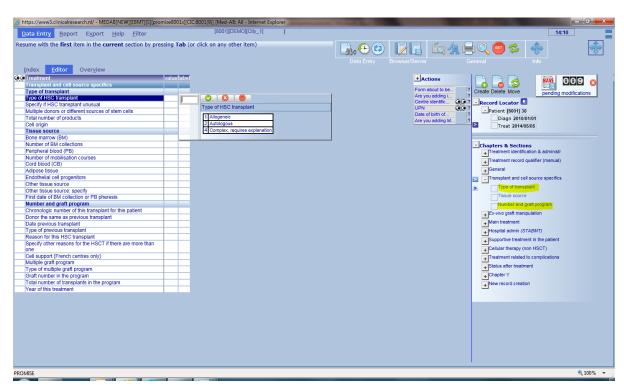


Open the chapter on Diagnosis classification – Main classification to enter the code for the main disease. The sub-classification can also be entered next.



Repeat similar steps to create the Transplant record. Click [Create], select Treat and enter the date of transplant. Code the context as HSCT (code 7).

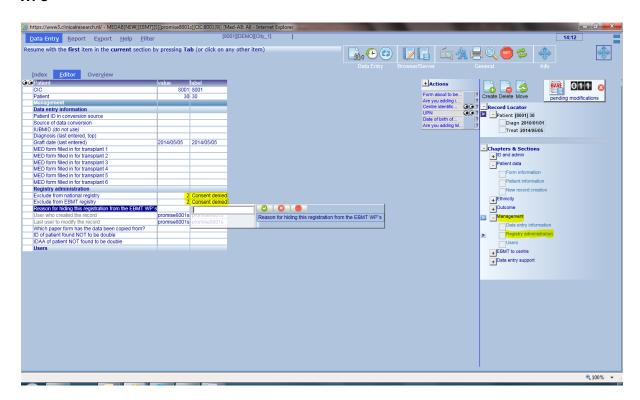
Open the chapter on Transplant and cell source specifics to enter the type and chronological number of this transplant:



To exclude this record from research analysis, go to Record Locator:

Patient - Management - Registry Administration

Enter "consent not asked/denied" to block access to National Registry, EBMT Registry and/or WPs



Option 2: Enter the full report if needed for your own centre records but <u>ensure</u> you mark them as "Not to be seen by EBMT" and/or "Not to be seen by National Registry" (if applicable) before saving the data. See screen above.

Entering and Editing Data

To move from item to item (and to activate the filters previously mentioned) during data entry use the [Tab] or [Enter] key.

Note: for all text fields e.g. additional comments, you need to use the [Tab] key to continue.

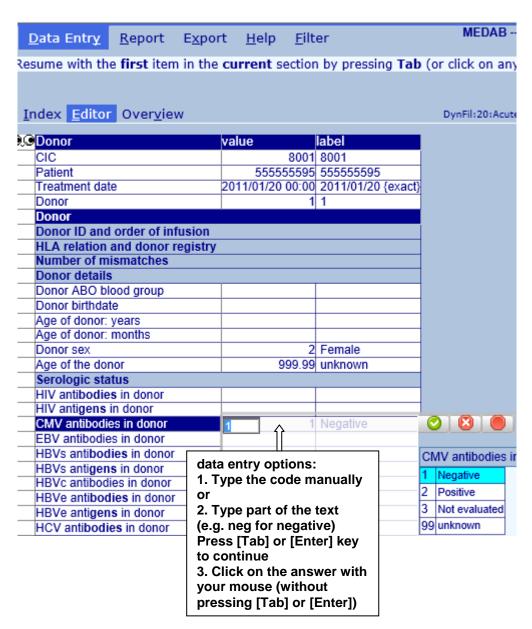
To enter data for coded items, you can enter the number manually, or (if you have a long list of codes to scroll through) type part of the text to find the corresponding code.

Alternatively you can click on the label itself with your mouse and it will jump automatically to the next item.

IMPORTANT: Please avoid using your mouse to jump from item to item, otherwise the preprogrammed navigation will not work / you will miss out relevant questions

A small selection of shortcuts is available when entering data:

١	Not applicable
?	Unknown
!	Today
#	Same date as this record



Record Locator, Chapter and Sections

At times you may need to use the Record Locator to edit an existing record, for example if you return and enter some items that were previously unanswered.

The interface in Promise operates as a tree-like structure. On the right hand side of the Data entry screen you will see two tree-like structures: the Record Locator and the Chapters & Sections.

In the Record locator you have a full description of the patient's records. Each patient may have one or more records in each of the main tables uniquely identified by a date or other index key. Depending on the information recorded, there may also be records in tables at deeper levels, such as Donor below a Treatment record, uniquely identified by a number.

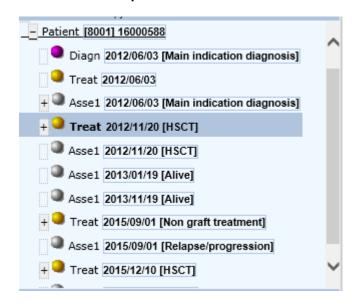
In the Chapters & Sections, you have all the items within the MED-AB project which can be found in the table that particular record belongs to.

To view different stages, and data, of the patient record in the Data Entry Editor you can click on a 'branch' of the Record Locator and in the desired 'branch' of the table as shown in the Chapters & Sections.

Using your mouse:

Open or close a **branch** by clicking on a — or — icon respectively.

Left-clicking on a date or index key in the Record Locator takes you to that record in the Data Entry form, e.g. the darker shading below shows a user has moved to HSCT treatment date 2012/11/20 of this patient:

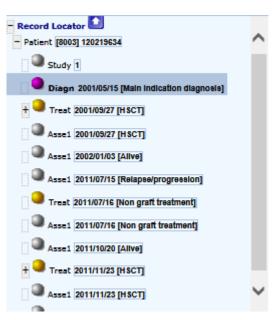


Records are listed in ascending date order. You can see this patient has had 2 transplants [HSCT] and multiple assessments.

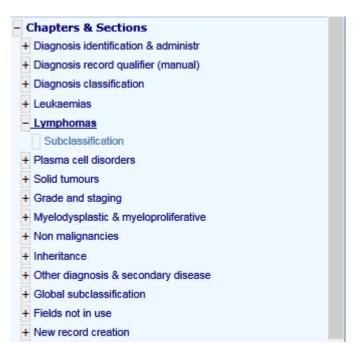
Therefore it is important to look at events e.g. [Diagnosis] or [HSCT] or [Non graft treatment], if you want to modify or view data at a certain timepoint

Using Chapters and Sections to move to other parts of the form

You can click on a Record, then Chapter & Section to move to a field of your choice. For example, to view or edit the specifics on the Diagnosis classification in Data Entry, first left-click with your mouse on the Diagnosis record in the Locator (when loaded it will be highlighted with a darker shade of blue):



Next left-click on the relevant section in the Chapter/Section below. In this example: Lymphomas – Subclassification.



This will take you to the part of the form where the sub-classification is located for this disease.

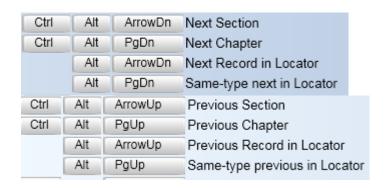
You can also right-click on a record in the Record Locator and move directly to an item by clicking on it within the mini-overview.

To change the TBI item from 'no' to 'yes' for example, right-click on the Treatment [HSCT] record in the Record Locator (check you have the correct transplant date if there is more than one) and click on the response TBI in the mini overview. You will be taken to that item in the Data Entry Editor where you can change it.

A click below will go to		
that item on that record	Show empty items	
CIC	8003	
Patient	120219634	
Treatment date	2011/11/23 {exact}	
Record creation type	created during data entry	
Record creation date	2015/04/09 15:28:00	
Record modification date	2015/04/09 15:29:00	
(SQL Server autonumber field)	39595	
Context of this treatment	Hematopoietic stem cell transplant	
User that created this record	promise8003k	
User most recently modifying this record	promise8003k	
Centre in which this treatment was given	City_2 [TC2]	
Country of the centre	Netherlands, The	
Unit or team	ВМТ	
Type of unit or team	Haematology	
Contact person	GLAISNER	
UPN for this patient for this centre	12021634	
Last diagnosis before this treatment	NHL	
Interval from last diagnosis to this treatment	3844	
Age at this treatment	46.86	
Country (> 10 centres)	Netherlands, The	
Chronologic number of this autograft for this patient	Second	
Type of HSC transplant	Autologous	
Bone marrow (BM)	No	
Peripheral blood (PB)	Yes	
Cord blood (CB)	No	
Chronologic number of this transplant for this patient	Second	
Date previous transplant	2001/09/27 {exact}	
Type of previous transplant	Autologous	
Multiple graft protocol (program)	No	
Year of this treatment	2011	
Ex-vivo manipulation of the cells	None	
Drugs or chemotherapy	Yes	
TBI TBI	No -	
TLI / TNI / TAI	No	
Additional disease treatment	No	
Other cell therapy (non HSCT)	No	
Best response	CR	
Date response achieved or assessed	2012/02/15 {exact}	
C: Index date for new record	2012/02/15 {exact}	
C0: Index code for new donor	First	
C2: Index code for new drug/agent	ARA-C / Cytarabine	
<u> </u>		

The programmed navigation (dynamic filters) will be switched off when you edit the form in this way, but you can switch the filter back on again afterwards (see page 45).

Record Locator shortcuts



How to make corrections to data

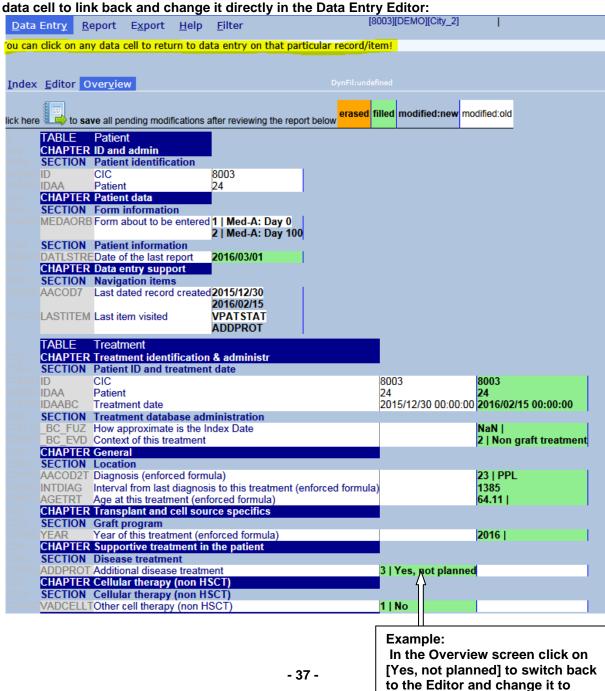
Before Saving

There are various ways to modify items in Data Entry before you have saved your data on the server. An efficient way is to use the Show Modifications icon:



Shortcut key: Ctrl-1

While editing, you can click the Show Modifications icon to see your changes before you save them to the server. If you see a specific item in the Overview needs amending, click on any data cell to link back and change it directly in the Data Entry Editor:



Additional Treatment = No

How to cancel pending changes

If you have modified data but wish to cancel all pending modifications, click [cancel] next to the pending changes counter. After confirming you will return to the beginning of your form.



Moving back to a previous field

Click on the History icon to go back 1 step



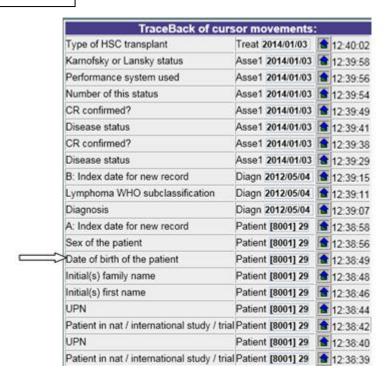
You can click to go back one step in history

Shortcut key: Ctrl-H

The navigation implemented to follow the MED-AB forms may skip items present in the screen because they are not relevant (drugs given for conditioning if conditioning has been answered "no", for example). You can rewind your exact step using the History feature.

You can also see an overview of the entire history since last saving, and click on an item to move back to it in the data entry form

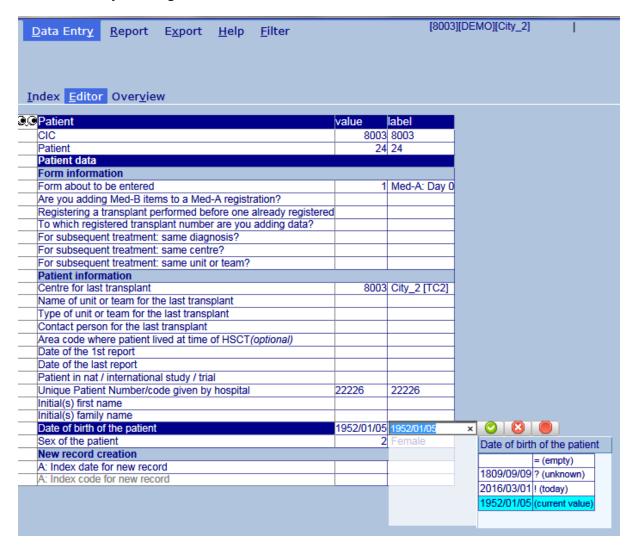
Shortcut key: Ctrl-Alt-H



Please note:

The history contains only those items that your cursor has visited. It is valid only for the patient record currently in the Editor screen. To move back one item at a time (including items that your cursor has not visited) then you would use shortcut [Ctrl-Backspace]. Once you save your data, the history is automatically emptied.

Clicking on the item in the "TraceBack of cursor movements" (above) directs you to the field in the data entry form e.g. date of birth:





This search tool can be used to locate a specific item in the full database dictionary.

Example: you want to look for the item "engraftment" but you are not sure where to find it within the Data Entry Editor.

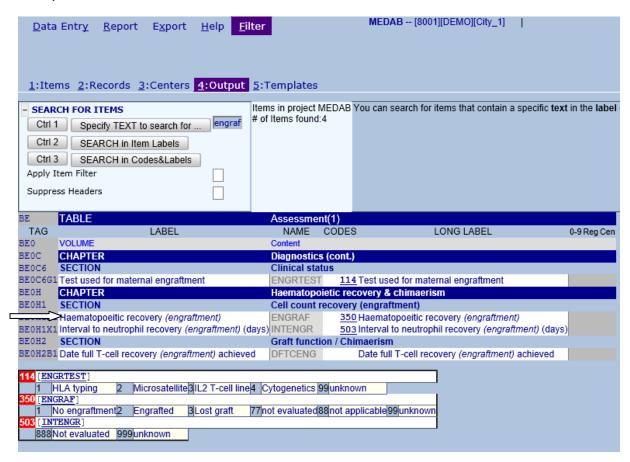
Click on the above 'magnifying glass' icon and press Ctrl-1 or click the button [specify TEXT to search for...] and type the partial or full text, for example 'engraf' or 'engraftment''.

Alternatively if you know the database item name, e.g. ENGRAF you can also type this in the Search.

Next press Ctrl-2 to search in Item Labels (MED-AB questions). If you need to search the Codes&Labels (MED-AB answers), press Ctrl-3.



It is possible to link back directly to that item in the Editor by clicking on the item label (see arrow):



The Table / Chapter / Section titles in the data entry form will show the location of the item in the database structure. In this case, you can see that the engraftment question is located in

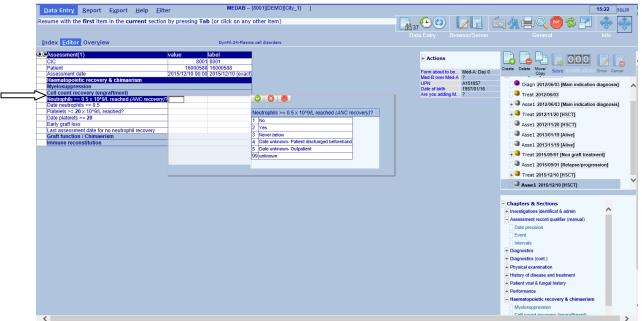
Record - Assessment

Chapter – Haematopoietic recovery & chimaerism

Section - Cell count recovery (engraftment)

NOTE: If you want to modify data using this search output, we advise you to either empty the first field "Form about to be entered", or enter the relevant code in the first field if you know which form contains the data question. (Shortcut to return to this field no matter where you are in the form is [Ctrl-Home].) If you know that the item you need to correct is in MED-A day 100 for example, ensure the code for the MED-A day 100 form is entered in this field. (If you do this, remember to switch the dynamic filter back on when you have finished your corrections. Please see page 25 for more info on filters).

You will be directed to the correct place in the Editor after clicking on the item in your search results:

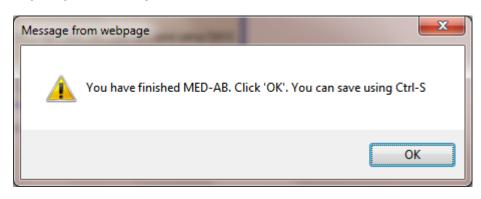


Before editing, check that you are first on the correct record (and date) in the Record Locator if the patient has had multiple HSCT.

Saving Data

You are advised to save your work regularly while in data entry mode. You can do so by clicking on the Save button or pressing Ctrl-S on your keyboard.

When you reach the end of the form and press [Tab] in the additional comments field, you will be prompted to save your data:



Shortcut key: Ctrl-S

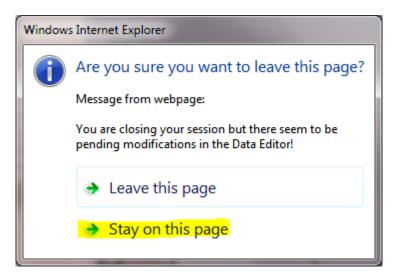
or click on the icon to save:



The data has been saved to the server when the pending modifications counter returns to '000' after pressing Save. (If the counter still shows pending changes then your data has <u>not</u> saved and you need to press Save again):

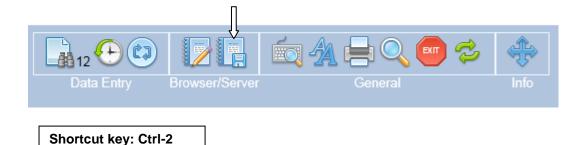
Emergency Save Procedure

In case you accidentally close down / or are forced to close your Promise session before saving modifications, a warning message will appear allowing you to "Stay on this page" and save your pending changes.



Making corrections to saved data

If you are familiar with the database structure, you can move to the item you wish to edit by using the Record Locator and clicking on the Record, Chapter and Section. Alternatively, in the same way as using the 'Show Modifications' icon, you can click the Original Values icon to obtain a complete overview of the stored patient data.

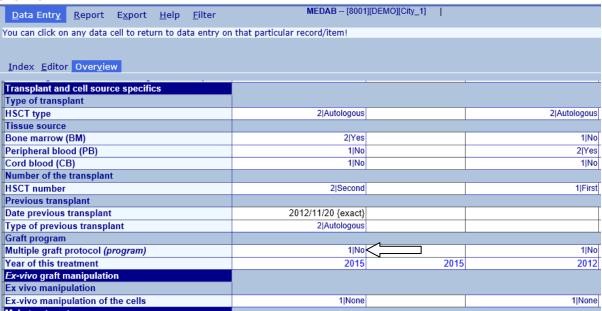


If you want to modify data using this overview, we advise you to enter the relevant code in the first field "Form about to be entered". (Shortcut to return to this field no matter where you are in the form is [Ctrl-Home].) If you know that the item you need to correct is in MED-B day 0 for example, ensure that code for a MED-B day 0 form is entered in this field. Alternatively, if you are not sure which form code to use, then you can leave this field empty and all items will be visible. (If you do this, remember to switch the dynamic filter back on when you have finished your corrections. Please see page 25 for more info on filters).

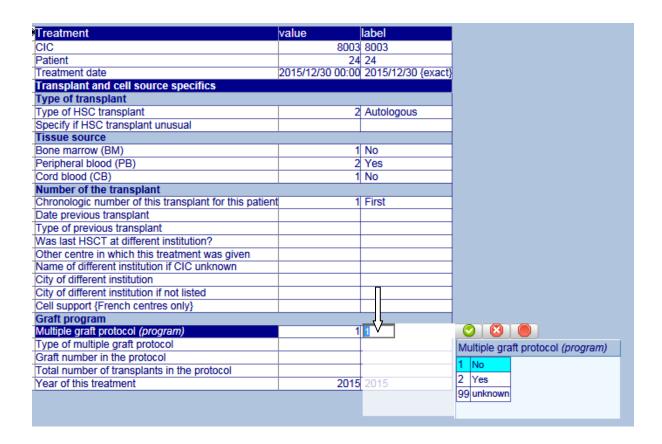
To view or modify a stored item click on the Original Values icon or press [Ctrl-2] in tab [Data Entry] – [Editor]. You will be taken to the Overview screen. A quick way to locate an item in the overview is to use shortcut [Ctrl-F] instead of scrolling. You may also prefer to switch the Headers on, so it is easier to interpret the overview. In the Layout Display select "Show Headers":



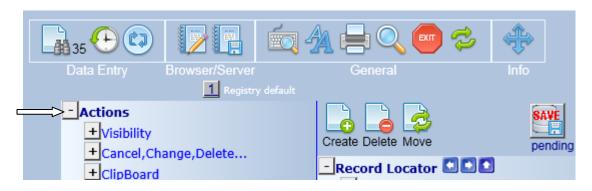
To change for example, multiple graft program from No to Yes, click on the code or label in the overview:



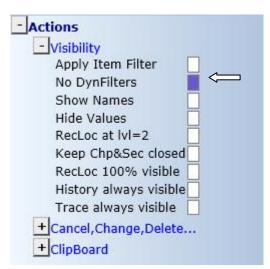
You will be taken back to the same field in the Editor where you can change the code. (You would need to change it for each transplant in the multiple program):



Data Entry Actions



Visibility:



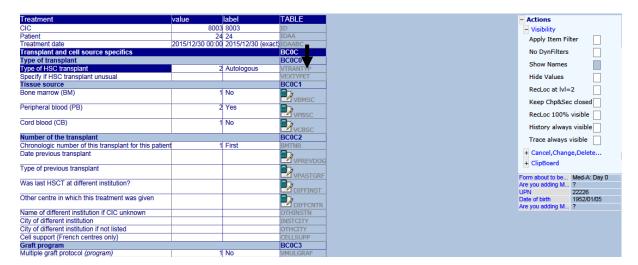
No Dynamic Filters

Item Filters are dynamic. If you load a patient with a certain diagnosis or type of transplant, then the item filter will change automatically depending on your patient selection. If for any reason you want this dynamic behaviour to be ignored, for example when creating a record manually, please select "No DynFilters". For general information on Item Filters please go to page 19. You can switch the dynamic filter on and off in menu Actions – Visibility – No DynFilters. (When the checkbox is filled, dynamic filters are turned off. Alternatively you can click on the Binoculars icon to toggle between visible and hidden items):

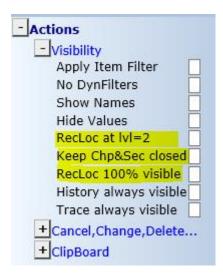


Show Names

It is possible to show/hide the database item names. This example has the item names shown, for example VTRANTYP is the item name in the database for Type of Transplant (see column indicated below). This feature in "Actions" in the Editor can be turned on if you need to view the item names for programming, data exports, error reporting etc:



Record Locator options

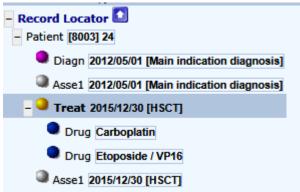


There are 3 options here (mainly useful to MED-B users). You may have noticed that the Record Locator can become very long, particular if a patient has a long history of treatments and follow up. To improve visibility and reduce scrolling, you can mark:

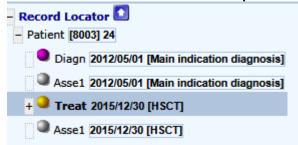
RecLoc at IvI=2

Toggle the checkbox on and off to hide/view the level 2 tables in the record locator, for example:

Record locator with RecLoc at IvI=2 off:



Record locator with RecLoc at IvI=2 option on:

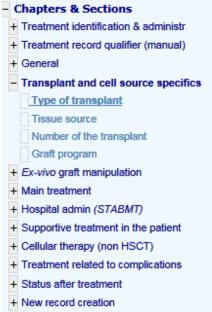


Keep Chp&Sec closed

Toggle the checkbox on and off to hide/view the Chapters & Sections below the record locator, for example: Keep Chp&Sec closed: off



Keep Chp&Sec closed: on

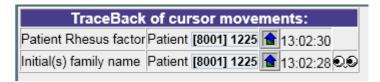


RecLoc 100% visible

Mark this option to view the Record Locator in full

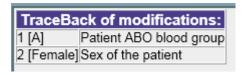
History always visible

Mark this option to continuously show the *clickable* History of data entered for the current record. For more information on the History function please see page 38



Trace always visible

Mark this option to continuously show the traceback of cursor movements in the current record for reference.



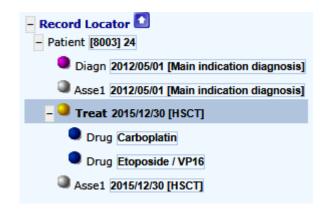
Change or Delete

How to change the date/index key of a record for a patient

If you need to correct a date / index key for a record within a patient record (for example date of diagnosis, HSCT, or a code for a drug) you need to change this manually. NB: first you must save any pending changes before changing an index key.

Index keys and dates can be changed using the Record Locator. For example, the correct HSCT date should be 2015/12/03:

Click on the corresponding record in the locator (it will be highlighted in darker blue):

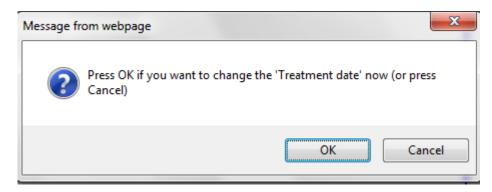


In the "Actions" menu (folder Cancel, Change, Delete) click [change index current]



(You will be prompted to save changes first if there are any modifications pending)

Alternatively, you can click directly on an index date in the data entry form to change it. Click on the date, you will see the following message:

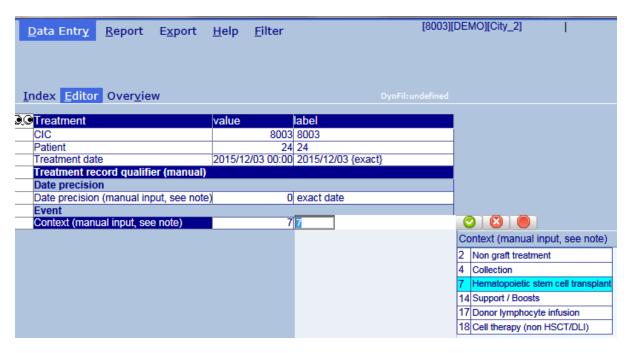


To enter the correct treatment date click [ok].

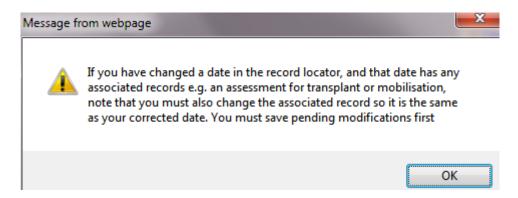
Enter the correct date in the dialog box and press [click here to recode the key of this record]. Press [ok] to confirm.



Whenever you change the date key of a record, you must enter the precision of the date and the context. In this example we have confirmed that it is the exact date, and code 7 (HSCT) must be entered in the field 'Context' because it is the date of the transplant:

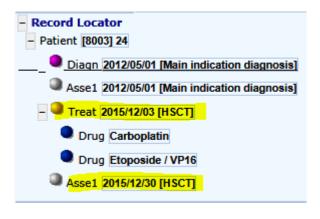


IMPORTANT: Please pay attention to this note that appears whenever index dates are being changed:

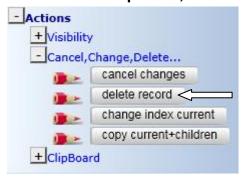


If there is another record associated with the revised date, remember to change this at the same time. For example an assessment for HSCT will have been created automatically and it will have the same date as the HSCT date before it was revised. This will often be true for other events e.g. when changing the diagnosis or collection dates in certain forms.

In this example, record Asse1 2015/12/30 [HSCT] also needs to be changed manually to match the revised HSCT treatment date:



How to delete a patient, or record(s) for a patient

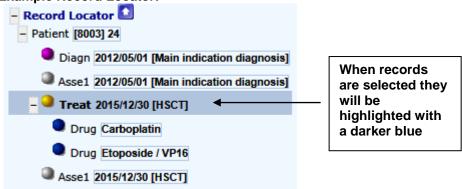


If you have registered a record by mistake, it is possible to delete the entire patient record or a subset of records for a patient, by clicking the option [delete record] in "Actions", or by using the icon above the Record Locator:



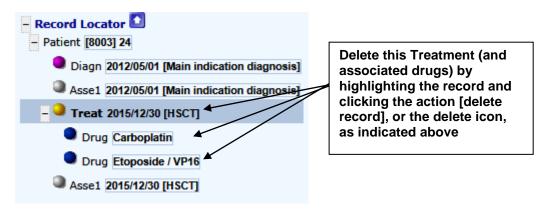
Warning: please take care when you delete a record: all children records belonging to tables which are dependent on the erased record (ie: drug records sitting under a treatment record) for that patient will also be erased. Therefore you must check the active record selected in the Record Locator. If the top record (patient) is selected when you press [delete record], the entire patient will be erased.

Example Record Locator:



To delete a specific record for a Patient, click on the record you want to delete and follow the steps above. Click on the Patient ID number to delete a full patient record.

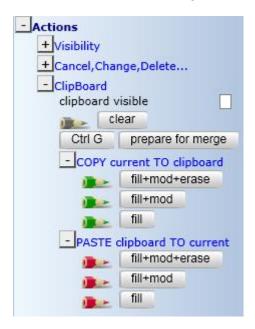
Or click on the Treatment record to delete the Treatment only for example. (Remember that you will also be deleting the level below, for example, deleting a Treatment with a Donor registered will delete both the Treatment and the Donor record.)



Clipboard

To copy/paste data from one record to another you can use the Clipboard function. Select the record to Copy in the Record Locator, then choose one of the copy actions to copy it to Clipboard. Select the record you want to paste the data to in the Record Locator, then choose one of the paste actions below. To paste data to a new record, you will need to create the record first with the correct date or index key. (For more information on creating records manually please see page 51.)

Go to the menu: Actions: ClipBoard



Copy/Paste Options:

fill+mod+erase: this will copy and replace both filled and empty items

fill+mod: this will copy and replace only filled items

fill: this will copy and paste filled items, but only to empty fields in the new record.

Creating New Records manually for an existing Patient

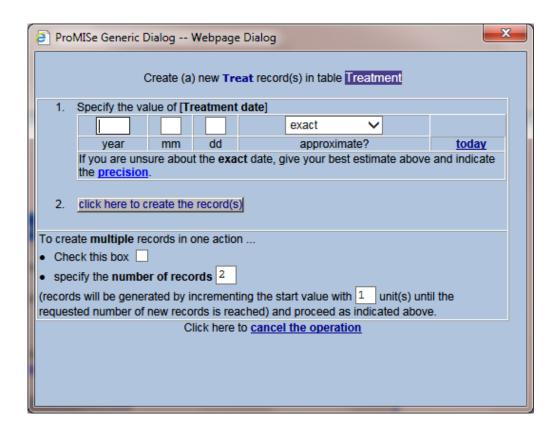
You may wish to create new records manually if, for example, you need to enter additional data to an existing MED-A or B registration. You can create records to register data that is not requested in the MED-AB forms. For example, the EBMT is not requesting the data at this timepoint but you need to register it for your own reference. As long as the table exists in the database structure, you can create it manually. Before using the [Create] button in the Data Entry Editor, be aware that this will override all programmed navigation. You will therefore have to direct yourself to the correct place within the database structure. We recommend you follow first the instructions on page 25 to add more information to an existing patient.

If you are confident in finding your own way in the database structure, new records can be created manually by clicking on a table in the tree-like structure. Any tables in the structure below can be created manually. (To create tables at a deeper level, for example Cells, you will need to create the corresponding Treatment record first if it is not already present.)

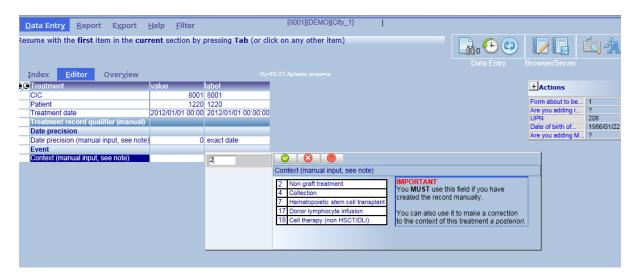


Example 1: To add a new (non graft) treatment record for a patient

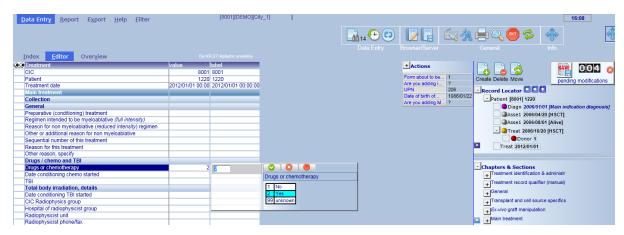
Click on the [Create] button (above) and then the "Treat" table. You will be prompted to enter the treatment date (1), then click the button to create the record (2).



After creating the manual record you will be prompted to confirm if the date is exact or approximate, then you will be asked to enter the context of the record. When creating records manually it is <u>imperative</u> that you enter this code. For example, a new record for a non transplant treatment must be coded as '2' non graft treatment:

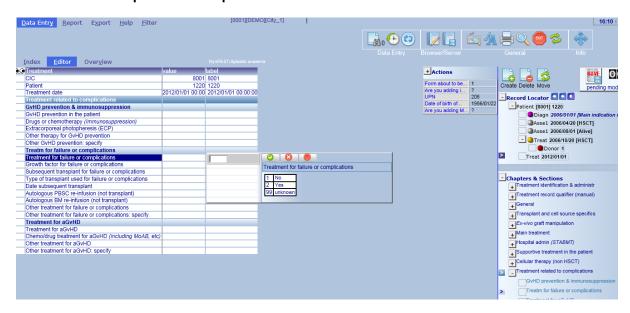


IMPORTANT: Please indicate details of this non graft treatment as well as creating the record. If the patient received additional drugs for example, you must enter "drugs given = yes" in the Main Treatment chapter:



You will then be prompted to enter the drug codes and doses.

If the patient received a non graft treatment due to complications, please answer "Yes" to Treatment for Complications chapter:



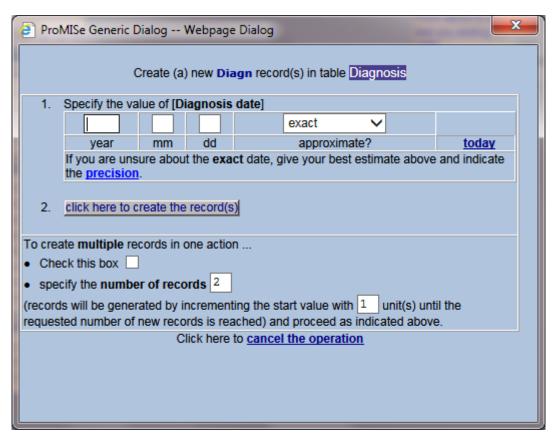
and provide the details e.g. growth factor. Press [save] or Ctrl-S to add the new changes.

Example 2: To add a (non transplant) diagnosis record for a patient

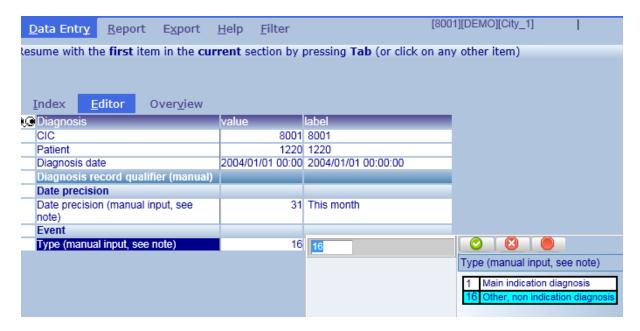


Click on the [Create] button (above) and then the "Diagn" table:

You will be prompted to enter the diagnosis date (1), then click the button to create the record (2).



After creating the manual record you will be prompted to confirm if the date is exact or approximate, then you will be asked to enter the context of the record. When creating records manually it is <u>imperative</u> that you enter this code. For example, a new record for a diagnosis that is not the main indication diagnosis must be coded as '16' Other, non indication diagnosis:



Please enter the details of the diagnosis using the Record Locator – Chapter "Diagnosis classification". Press [save] or Ctrl-S to add the new changes.

NOTE: If the patient developed a secondary disease after HSCT, this should be entered using the MED-A or B follow up form navigation, where you can answer "yes" to the question on "secondary malignancy after transplant" and give the date and disease classification.

Example 3: To add a cytogenetic record manually for a patient

To add the Cytogenetics data to a Diagnosis Assessment record, set the form filter to code 1 at the beginning (Day 0 MED-A) then go straight to:

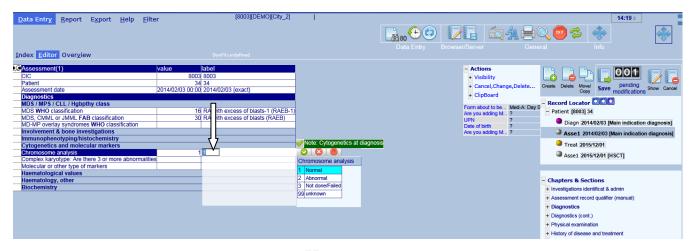
Record: Asse1 (in Diagnosis)

Chapter: Diagnostics

Section: Cytogenetics and molecular markers

Item: Chromosome analysis

Enter code '1' for Normal results



If the cytogenetics were abnormal, enter code '2'.

You will be prompted to enter the cytogenetic abnormalities, absent/present.

When they are all complete press [save] or Ctrl-S to add the new changes.

Example 4: To add TBI data only to a registered patient

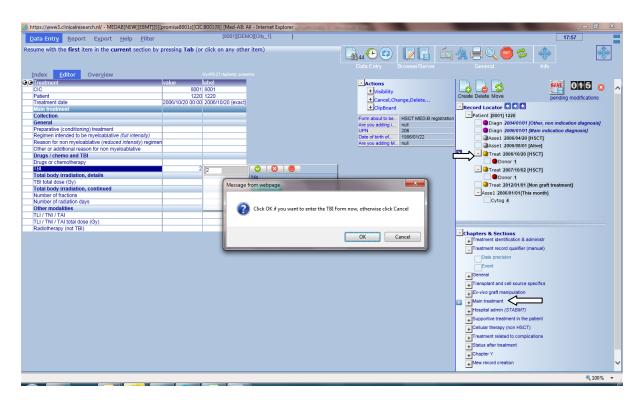
Ensure you have the first field "Form about to be entered" as code 4"Med-B Day 0"

Go directly to the Treatment [HSCT] record in the Record Locator, for which you want to enter the TBI.

Then go to:

Chapter: Main treatment **Section:** Drugs / chemo & TBI

Field: TBI



A message will appear, giving you the option to complete the TBI data now.

Example 5: To add a relapse

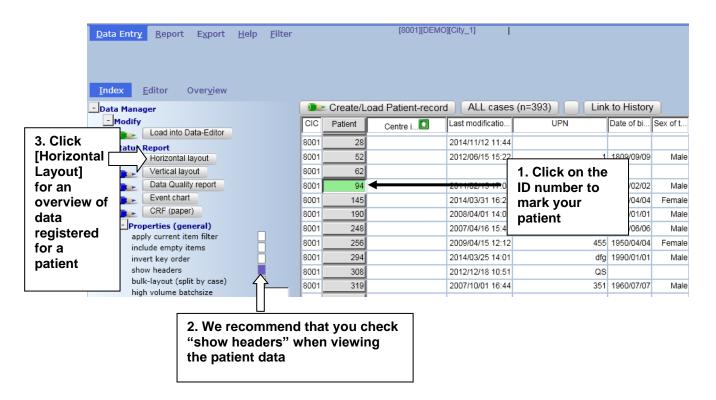
We recommend that this is not added manually, instead users should add relapse data using the MED-A follow up form (code 3) in the first field "Form about to be entered".

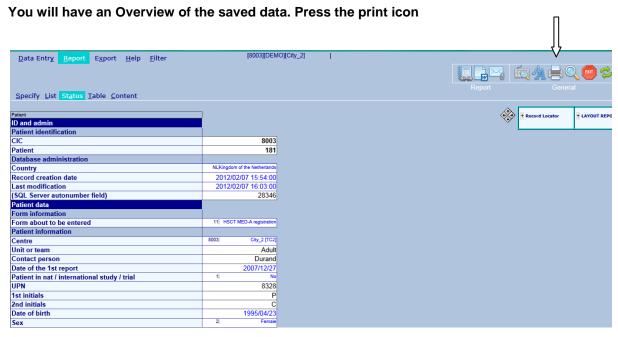
Viewing and Printing Individual Patient Data from the Index

Individual patient records stored on the server can be viewed and printed from the Data Entry Index.

Data Entry – Index

It is possible to view and print data from the Index for a single patient. Mark the patient in the Index and select Status Report - Horizontal layout.

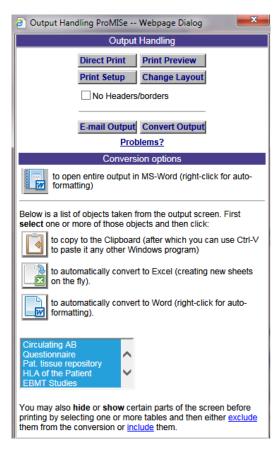




Your patient overview will be transferred to the Output window after you press the Print icon or shortcut Ctrl-Alt-P. If you want to check how the data will print you can first select [Print Preview] in the Output handling window, before pressing [Direct Print]:



Note that you can also convert the output to Word, Excel or the clipboard. The data will appear as a series of tables with rows, rather than displaying like a form with headers. Select [Convert Output] and select from the options below. (By default, all items will selected, or you can opt to select only parts of the overview to be converted):

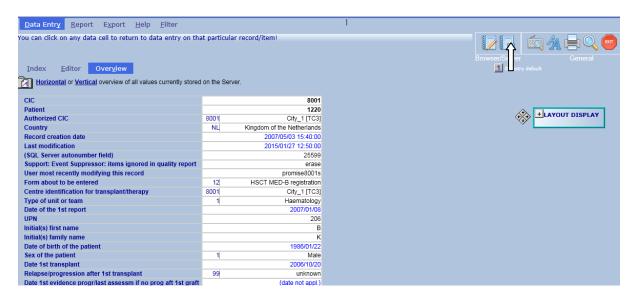


Viewing and Printing Individual Patient Data from the Editor



It is possible to view and print data from the Editor for a single patient using these Shortcuts:

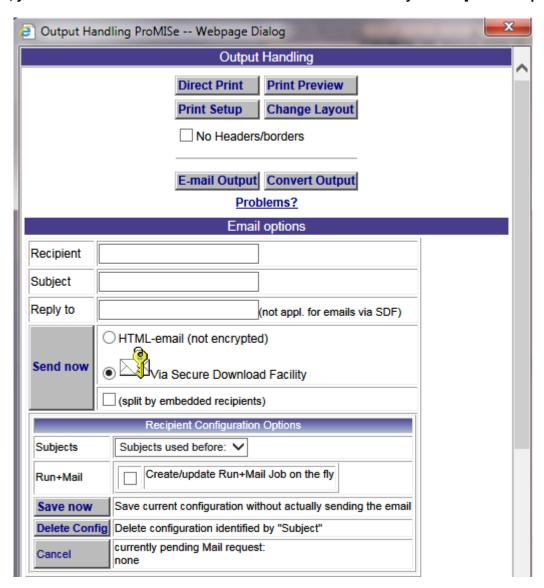
Pressing [Ctrl-2] or the [Show Original values] icon in the [Editor] gives you an overview in Horizontal Layout for the patient in the Editor:



(Pressing [Ctrl-6] in the [Editor] gives you a horizontal overview with each record as a separate table)

Sending Individual Patient Data by Email

Following the instructions on viewing and printing individual patient data from the Index or Editor, you can also send these data via the Secure Download Facility. Select [Email Output]



Enter the recipient email address or ProMISe username. Select to send it via the Secure Download Facility. Provided the recipient has a Promise account or Secure Download account, they can log on and access the download. For more info on Downloads and the Secure Download Facility, please see the manuals on www.ebmt.org – Data Management – Data Retrieval.

Printing MED-A for a group of patients

To extract MED-A for a group of patients, we recommend using the <u>MED-A Merge program (MS Office 2007)</u>. Please contact <u>registryhelpdesk@ebmt.org</u> if you need any assistance with this program.

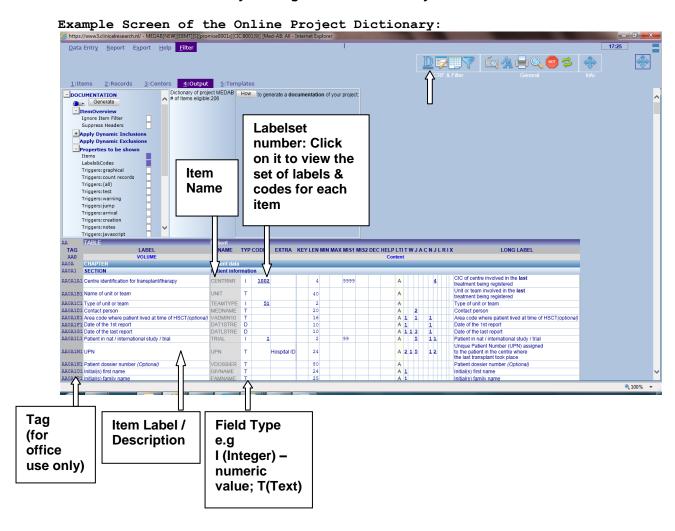
Viewing the Project Dictionary



If you wish to view the structure and dictionary of the database used in ProMISe you can access the Project Dictionary in the Filter tab. Click the above Dictionary icon to view the item; code, description and label in the database.

Within the "Documentation" folder, select the items and properties you want to show in the dictionary. Scroll down and mark "items" and "labels&codes" under "properties to be shown" (plus any other properties if necessary). You can ignore the current item filter, or select or create an item filter of your choice in Menu [Filter] – [Items].

NB: To activate the dictionary click again on the Dictionary icon.



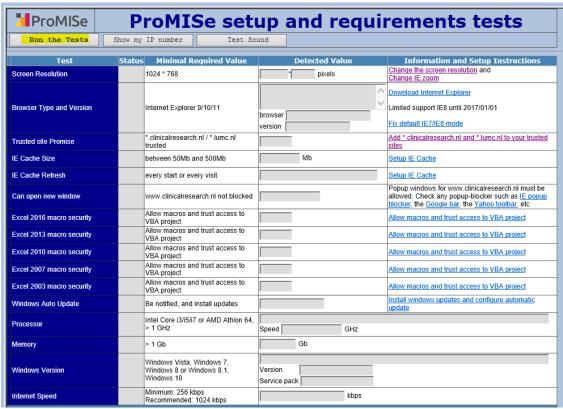
Appendix

Troubleshooting

ProMISe is an Internet Explorer-based application. It cannot be loaded in other browsers, however the developers are working on compatibility with more browsers in the near future.

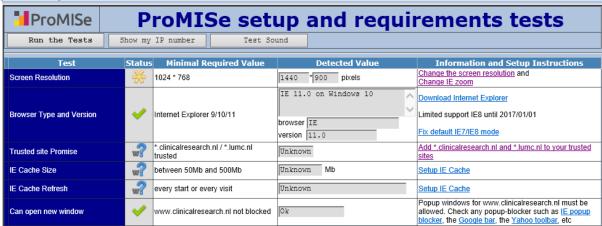
Configuration test

Proper functioning of the ProMISe application is dependent on some Internet Explorer settings. Therefore, if you are working with ProMISe for the first time or you experience technical problems, it is recommended to test (and adjust) the settings of your PC. To do this click on the <u>interactive browser configuration checker</u>. The following page will appear

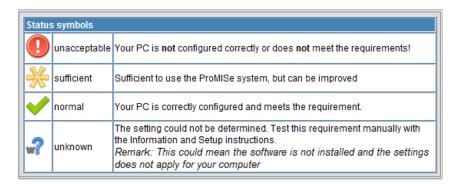


Press the [Run the Tests] button.

When you [Run the Tests]. You will get an overview of the settings of your browser, indicating possible problems and solutions:



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



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.

Add *.clinicalresearch.nl to the list of trusted websites.

Allow pop-ups of *.clinicalresearch.nl ***

Check your Internet Explorer settings as shown in the <u>interactive browser configuration</u> checker

If you cannot log in with your username and password, or you experience any problems after trying the above, please contact the <u>Registry Helpdesk</u> and give details of the error message or provide a screenshot.

How to Clear your Cache

Users may be instructed to clear their Internet Explorer cache in case of technical problems, or if a major update to the program has been implemented:

Step one: Open the Delete Browsing History box by 1) clicking Ctrl-Shift-Del or 2) clicking the gear in the top-right corner > Safety > Delete browsing history.

Step two: Be sure the box next to "Preserve Favorites website data" is unchecked. Conversely, make sure the box next to "Temporary Internet files and website files" is checked. Then click "delete" at the bottom.

^{***}If you see a blank screen after logging in, check that pop-ups are allowed for

^{*.}clinicalresearch.nl and that you do not have a pop-up blocker switched on.

Security Issues

ProMISe is a web application so all information travels back and forth through web pages. If the URL or address displayed at the top of the screen show https://, this shows that data between the PC and ProMISe is secure. (You will also see a padlock symbol on the bottom toolbar). Our secure server site uses state-of-the-art encryption to prevent anyone from accessing your patient data online. When you log on, you'll be asked to provide us with your personal username and password before you can view and access any individual patient data.

As technology is changing all the time, the designer will carry out security enhancements to ensure it remains this way.

On request we can send you a summary from the ProMISe designer outlining the security measures used in ProMISe. If you have specific questions, please send them to the <u>ProMISe</u> Helpdesk.

Glossary

DATA: Piece of information collected and formatted in a specific way

INDEX KEY: identifies Records in a Table. Usually in the EBMT database a date or a number identifies the Record. For example 1999/05/05 [Transplant] or 2000/09/09 [Transplant] and Donor 1 and Donor 2 help to identify multiple records of the same type.

FIELD: A location for a single piece of data in the database. (The columns of a Table)

ITEM NAME: abbreviation of a field in the database, for example PATSEX is the item name for "Patient Sex"

LABELS: Each field has its own set of labels. For example the labels for field "Donor Sex" and "Patient Sex" are: "male", "female", "unknown"

QUERY: A request for information from the database. Queries consist of questions presented to the database in a predefined format

RECORD: in a relational database, records correspond to rows in each Table

TABLE: in a relational database, a pre-defined data structure that organises the information about a single topic into rows and columns.

ProMISe Helpdesk

Please contact the Helpdesk at the Central Registry Office if you have any questions, comments or problems relating to ProMISe:

EBMT Central Registry Office 4th Floor Tabard House Guy's Hospital Great Maze Pond LONDON SE1 9RT UK

Phone: (+44) (0) 20 7188 8409

Fax: (+44) (0) 20 7188 8411

E-mail: registryhelpdesk@ebmt.org