



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

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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). [ProMISe personal password request form - data entry.](#)

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

Username 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:

Your username	<input type="text"/>
Security code (required to continue)	<input type="text"/> Request Security Code

(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:

As soon as we have verified your account, a security code will be sent to your mobile number or email address. If you do not receive this code and you are sure you entered the correct information, please contact the helpdesk.	
Your username	<input type="text"/>
Security code	<input type="text"/>
Your own NEW password	<input type="text"/> Info
Repeat your own NEW password	<input type="text"/>
<input type="button" value="Confirm"/>	

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 case-sensitive: 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.

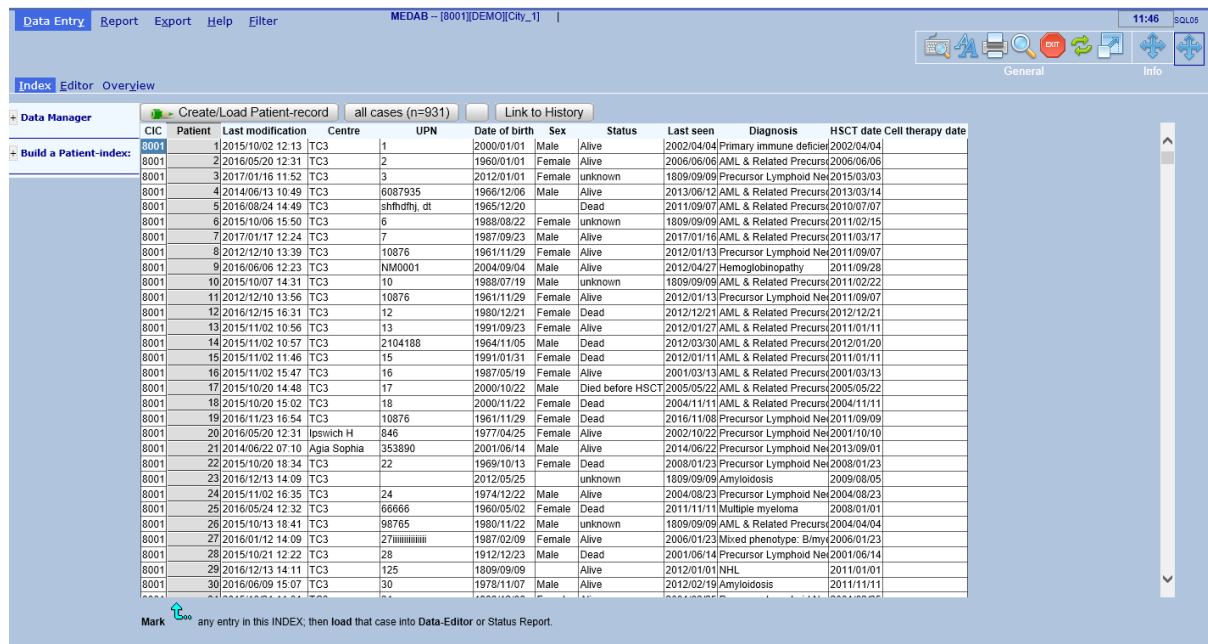
Please contact the [Registry Helpdesk](#) if you experience problems or forget your username.

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.

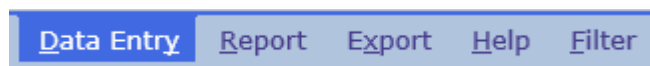
After you have logged in

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



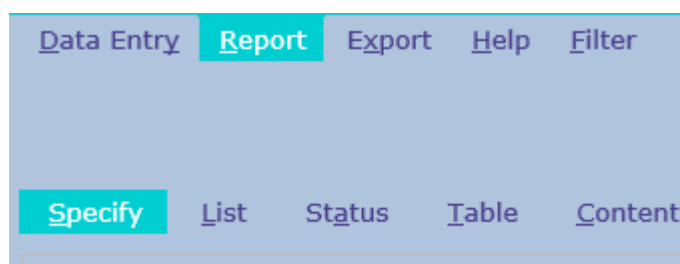
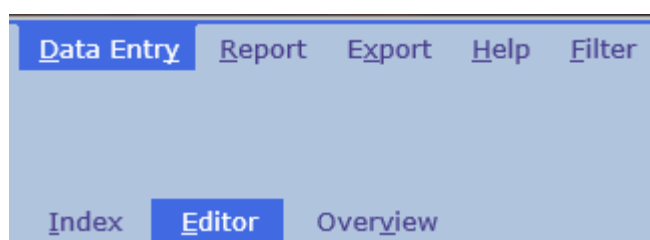
CIC	Patient	Last modification	Centre	UPN	Date of birth	Sex	Status	Last seen	Diagnosis	HSCT date	Cell therapy date
8001	1	2015/10/02 12:13	TC3	1	2000/01/01	Male	Alive	2002/04/04	Primary immune deficiency	2002/04/04	
8001	2	2016/05/20 12:31	TC3	2	1960/01/01	Female	Alive	2006/06/06	AML & Related Precurs	2006/06/06	
8001	3	2017/01/16 11:52	TC3	3	2012/01/01	Female	unknown	1809/09/09	Precursor Lymphoid Ne	2015/03/03	
8001	4	2014/06/13 10:49	TC3	6087935	1966/12/06	Male	Alive	2013/06/12	AML & Related Precurs	2013/03/14	
8001	5	2016/08/24 14:49	TC3	shfhdthj_d	1965/12/20		Dead	2011/09/07	AML & Related Precurs	2010/07/07	
8001	6	2015/10/06 15:50	TC3	6	1988/08/22	Female	unknown	1809/09/09	AML & Related Precurs	2011/02/15	
8001	7	2017/01/17 12:24	TC3	7	1987/09/23	Male	Alive	2017/01/16	AML & Related Precurs	2011/03/17	
8001	8	2012/12/10 13:39	TC3	10876	1961/11/29	Female	Alive	2012/01/13	Precursor Lymphoid Ne	2011/09/07	
8001	9	2016/06/06 12:23	TC3	NM0001	2004/09/04	Male	Alive	2012/04/27	Hemoglobinopathy	2011/09/28	
8001	10	2015/10/07 14:31	TC3	10	1988/07/19	Male	unknown	1809/09/09	AML & Related Precurs	2011/02/22	
8001	11	2012/12/10 13:56	TC3	10876	1961/11/29	Female	Alive	2012/01/13	Precursor Lymphoid Ne	2011/09/07	
8001	12	2016/12/15 16:31	TC3	12	1980/12/21	Female	Dead	2012/12/21	AML & Related Precurs	2012/12/21	
8001	13	2015/11/02 10:56	TC3	13	1991/09/23	Female	Alive	2012/01/27	AML & Related Precurs	2011/01/11	
8001	14	2015/11/02 10:57	TC3	2104188	1964/11/05	Male	Dead	2012/03/30	AML & Related Precurs	2012/01/20	
8001	15	2015/11/02 11:46	TC3	15	1991/01/31	Female	Dead	2012/01/11	AML & Related Precurs	2011/01/11	
8001	16	2015/11/02 15:47	TC3	16	1987/05/19	Female	Alive	2001/03/13	AML & Related Precurs	2001/03/13	
8001	17	2015/10/20 14:48	TC3	17	2000/10/22	Male	Died before HSCT	2005/05/22	AML & Related Precurs	2005/05/22	
8001	18	2015/10/20 15:02	TC3	18	2000/11/22	Female	Dead	2004/11/11	AML & Related Precurs	2004/11/11	
8001	19	2016/11/23 16:54	TC3	10876	1961/11/29	Female	Dead	2016/11/08	Precursor Lymphoid Ne	2011/09/09	
8001	20	2016/05/20 12:31	Ipswich H	846	1977/04/25	Female	Alive	2002/10/22	Precursor Lymphoid Ne	2001/10/10	
8001	21	2014/06/22 07:10	Agia Sophia	353890	2001/06/14	Male	Alive	2014/06/22	Precursor Lymphoid Ne	2013/09/01	
8001	22	2015/10/20 18:34	TC3	22	1969/10/13	Female	Dead	2008/01/23	Precursor Lymphoid Ne	2008/01/23	
8001	23	2016/12/13 14:09	TC3		2012/05/25		unknown	1809/09/09	Amyloidosis	2009/08/05	
8001	24	2015/11/02 16:35	TC3	24	1974/12/22	Male	Alive	2004/08/23	Precursor Lymphoid Ne	2004/08/23	
8001	25	2016/05/24 12:32	TC3	66666	1960/05/02	Female	Dead	2011/11/11	Multiple myeloma	2008/01/01	
8001	26	2015/10/13 18:41	TC3	98765	1980/11/22	Male	unknown	1809/09/09	AML & Related Precurs	2004/04/04	
8001	27	2016/01/12 14:09	TC3	27	1987/02/09	Female	Alive	2006/01/23	Mixed phenotype: B/my	2006/01/23	
8001	28	2015/10/21 12:22	TC3	28	1912/12/23	Male	Dead	2001/06/14	Precursor Lymphoid Ne	2001/06/14	
8001	29	2016/12/13 14:11	TC3	125	1809/09/09		Alive	2012/01/01	NHL	2011/01/01	
8001	30	2016/06/09 15:07	TC3	30	1978/11/07	Male	Alive	2012/02/19	Amyloidosis	2011/11/11	

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



These tabs indicate the main modules of ProMISe.

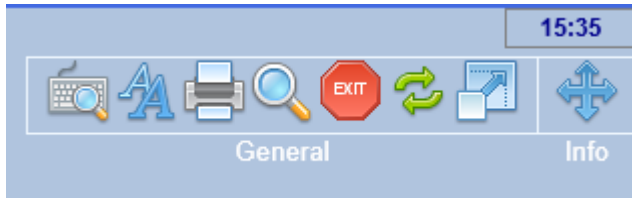
Below these tabs, there is another series of secondary tabs



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:

The following keyboard shortcuts are defined on this page:			
Topic switching shortcuts			
Ctrl Alt P	Alt	Switches to Topic/Window (underlined char) DataEntry, Report, X... etc	
Ctrl Alt M		Convert page to Printer and other applications	
		Toggle generic Message window on/off	
Generic shortcuts			
Ctrl	0	Show this page with shortcuts	
Ctrl	ArrowUp	Scroll Screen Upwards	Ctrl ArrowDn Scroll Screen Downwards
Ctrl	PgUp	Scroll Screen to top	Ctrl PgDn Scroll Screen to bottom
Ctrl	<	Decrease fontsize	Ctrl > Increase fontsize
Specific shortcuts			
	Enter	Store Value and go to Next Item	Ctrl Enter Simulate click on current item
	Tab	On value input: =Enter; otherwise: goto 1st item in Section	
	Tab	Store Item Value and continue to Next Record with Same Item	
Ctrl	Alt ArrowUp	Previous Section	Ctrl Alt ArrowDn Next Section
Ctrl	Alt PgUp	Previous Chapter	Ctrl Alt PgDn Next Chapter
	Alt ArrowUp	Previous Record in Locator	Alt ArrowDn Next Record in Locator
	Alt PgUp	Same-type previous in Locator	Alt PgDn Same-type next in Locator
Ctrl	1	View modifications	S Save modifications
Ctrl	2	View original values horizontal	Ctrl 3 View original values vertical
Ctrl	4	Evaluate all tests & warnings	Ctrl 5 Evaluate all tests
Ctrl	6	View original horizontally (as Ctrl-2) but each record now a separate table	
Ctrl	G	Prepare for Merge	Home Go to first item
Ctrl	H	Step 1 back in History	Ctrl Alt H View History
Ctrl	Backspace	Step 1 item upwards	Tab Step 1 item upwards
Ctrl	9	View original in template (if defined by current Report)	
Ctrl	R	Reload entire case based on most recent modification in current CIC=8001	
Ctrl Alt C		Show Clipboard	
Ctrl Alt N		Show Names	
Ctrl Alt A		View Trace	
Ctrl Alt V		Hide Values Column	

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.

Right-click with your mouse to load a single patient form in one click

CIC	Patient	Last modification	Centre	UPN	Date of birth	Sex	Status	Last seen	Diagnosis	HSCT date	Cell therapy date
8001	1	2015/10/02 12:13	TC3	1	2000/01/01	Male	Alive	2002/04/04	Primary immune deficiel	2002/04/04	
8001	2	2016/05/20 12:31	TC3	2	1960/01/01	Female	Alive	2006/06/06	AML & Related Precurs	2006/06/06	
8001	3	2017/01/16 11:52	TC3	3	2012/01/01	Female	unknown	1809/09/09	Precursor Lymphoid Ne	2015/03/03	
8001	4	2014/06/13 10:49	TC3	6087935	1966/12/06	Male	Alive	2013/06/12	AML & Related Precurs	2013/03/14	
8001	5	2016/08/24 14:49	TC3	shhdthj, dt	1965/12/20	Male	Dead	2011/09/07	AML & Related Precurs	2010/07/07	
8001	6	2015/10/06 15:50	TC3	6	1988/08/22	Female	unknown	1809/09/09	AML & Related Precurs	2011/02/15	
8001	7	2017/01/17 12:24	TC3	7	1987/09/23	Male	Alive	2017/01/16	AML & Related Precurs	2011/03/17	
8001	8	2012/12/10 13:39	TC3	10876	1961/11/29	Female	Alive	2012/01/13	Precursor Lymphoid Ne	2011/09/07	
8001	9	2016/06/06 12:23	TC3	NM0001	2004/09/04	Male	Alive	2012/04/27	Hemoglobinopathy	2011/09/28	
8001	10	2015/10/07 14:31	TC3	10	1988/07/19	Male	unknown	1809/09/09	AML & Related Precurs	2011/02/22	
8001	11	2012/12/10 13:56	TC3	10876	1961/11/29	Female	Alive	2012/01/13	Precursor Lymphoid Ne	2011/09/07	
8001	12	2016/12/15 16:31	TC3	12	1980/12/21	Female	Dead	2012/12/21	AML & Related Precurs	2012/12/21	
8001	13	2015/11/02 10:56	TC3	13	1991/09/23	Female	Alive	2012/01/27	AML & Related Precurs	2011/01/11	
8001	14	2015/11/02 10:57	TC3	2104188	1964/11/05	Male	Dead	2012/03/30	AML & Related Precurs	2012/01/20	
8001	15	2015/11/02 11:46	TC3	15	1991/01/31	Female	Dead	2012/01/11	AML & Related Precurs	2011/01/11	
8001	16	2015/11/02 15:47	TC3	16	1987/05/19	Female	Alive	2001/03/13	AML & Related Precurs	2001/03/13	
8001	17	2015/10/20 14:48	TC3	17	2000/10/22	Male	Died before HSCT	2005/05/22	AML & Related Precurs	2005/05/22	
8001	18	2015/10/20 15:02	TC3	18	2000/11/22	Female	Dead	2004/11/11	AML & Related Precurs	2004/11/11	
8001	19	2016/11/23 16:54	TC3	10876	1961/11/29	Female	Dead	2016/11/08	Precursor Lymphoid Ne	2011/09/09	
8001	20	2016/05/20 12:31	Ipswich H	846	1977/04/25	Female	Alive	2002/10/22	Precursor Lymphoid Ne	2001/10/10	
8001	21	2014/06/22 07:10	Agia Sophia	353890	2001/06/14	Male	Alive	2014/06/22	Precursor Lymphoid Ne	2013/09/01	
8001	22	2015/10/20 18:34	TC3	22	1969/10/13	Female	Dead	2008/01/23	Precursor Lymphoid Ne	2008/01/23	
8001	23	2016/12/13 14:09	TC3		2012/05/25	unknown		1809/09/09	Amyloidosis	2009/08/05	
8001	24	2015/11/02 16:35	TC3	24	1974/12/22	Male	Alive	2004/08/23	Precursor Lymphoid Ne	2004/08/23	
8001	25	2016/05/24 12:32	TC3	66666	1960/05/02	Female	Dead	2011/11/11	Multiple myeloma	2008/01/01	
8001	26	2015/10/13 18:41	TC3	98765	1980/11/22	Male	unknown	1809/09/09	AML & Related Precurs	2004/04/04	
8001	27	2016/01/12 14:09	TC3	27	1987/02/09	Female	Alive	2006/01/23	Mixed phenotype: B/my	2006/01/23	
8001	28	2015/10/21 12:22	TC3	28	1912/12/23	Male	Dead	2001/06/14	Precursor Lymphoid Ne	2001/06/14	
8001	29	2016/12/13 14:11	TC3	125	1809/09/09	Female	Alive	2012/01/01	NHL	2011/01/01	
8001	30	2016/06/09 15:07	TC3	30	1978/11/07	Male	Alive	2012/02/19	Amyloidosis	2011/11/11	

Mark any entry in this INDEX; then load that case into Data-Editor or Status Report.

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

Data Entry Report Export Help Filter MEDAB -- [8001][DEMO][City_1] | 11:47 SQL05

Index Editor Overview

- Data Manager
 - Modify
 - Load into Data-Editor
 + Status Report
 + Build a Patient-index:

Create/Load Patient-record all cases (n=931) Link to History

CIC	Patient	Last modification	Centre	UPN	Date of birth	Sex	Status	Last seen	Diagnosis	HSCt date	Cell therapy date
8001	1	2015/10/02 12:13	TC3	1	2000/01/01	Male	Alive	2002/04/04	Primary immune deficiency	2002/04/04	
8001	2	2016/05/20 12:31	TC3	2	1960/01/01	Female	Alive	2006/06/06	AML & Related Precurs	2006/06/06	
8001	3	2017/01/16 11:52	TC3	3	2012/01/01	Female	unknown	1809/09/09	Precursor Lymphoid Ne	2015/03/03	
8001	4	2014/06/13 10:49	TC3	6087935	1966/12/06	Male	Alive	2013/06/12	AML & Related Precurs	2013/03/14	
8001	5	2016/08/24 14:49	TC3	shhdthj dt	1965/12/20	Male	Dead	2011/09/07	AML & Related Precurs	2010/07/07	
8001	6	2015/10/06 15:50	TC3	6	1988/08/22	Female	unknown	1809/09/09	AML & Related Precurs	2011/02/15	
8001	7	2017/01/17 12:24	TC3	7	1987/09/23	Male	Alive	2017/01/16	AML & Related Precurs	2011/03/17	
8001	8	2012/12/10 13:39	TC3	10876	1961/11/29	Female	Alive	2012/01/13	Precursor Lymphoid Ne	2011/09/07	
8001	9	2016/06/06 12:23	TC3	NM0001	2004/09/04	Male	Alive	2012/04/27	Hemoglobinopathy	2011/09/28	
8001	10	2015/10/07 14:31	TC3	10	1988/07/19	Male	unknown	1809/09/09	AML & Related Precurs	2011/02/22	
8001	11	2012/12/10 13:56	TC3	10876	1961/11/29	Female	Alive	2012/01/13	Precursor Lymphoid Ne	2011/09/07	
8001	12	2016/12/15 16:31	TC3	12	1980/12/21	Female	Dead	2012/12/21	AML & Related Precurs	2012/12/21	
8001	13	2015/11/02 10:56	TC3	13	1991/09/23	Female	Alive	2012/01/27	AML & Related Precurs	2011/01/11	
8001	14	2015/11/02 10:57	TC3	2104188	1964/11/05	Male	Dead	2012/03/30	AML & Related Precurs	2012/01/20	
8001	15	2015/11/02 11:46	TC3	15	1991/01/31	Female	Dead	2012/01/11	AML & Related Precurs	2011/01/11	
8001	16	2015/11/02 15:47	TC3	16	1987/05/19	Female	Alive	2001/03/13	AML & Related Precurs	2001/03/13	
8001	17	2015/10/20 14:48	TC3	17	2000/10/22	Male	Died before HSCt	2005/05/22	AML & Related Precurs	2005/05/22	
8001	18	2015/10/20 15:02	TC3	18	2000/11/22	Female	Dead	2004/11/11	AML & Related Precurs	2004/11/11	
8001	19	2016/11/23 16:54	TC3	10876	1961/11/29	Female	Dead	2016/11/08	Precursor Lymphoid Ne	2011/09/09	
8001	20	2016/05/20 12:31	TC3	846	1977/04/25	Female	Alive	2002/10/22	Precursor Lymphoid Ne	2001/10/10	
8001	21	2014/06/22 07:10	TC3	353890	2001/06/14	Male	Alive	2014/06/22	Precursor Lymphoid Ne	2013/09/01	
8001	22	2015/10/20 18:34	TC3	22	1969/10/13	Female	Dead	2008/01/23	Precursor Lymphoid Ne	2008/01/23	
8001	23	2016/12/13 14:09	TC3	23	2012/05/25	unknown	unknown	1809/09/09	Amyloidosis	2009/08/05	
8001	24	2015/11/02 16:35	TC3	24	1974/12/22	Male	Alive	2004/08/23	Precursor Lymphoid Ne	2004/08/23	
8001	25	2016/05/24 12:32	TC3	66666	1960/05/02	Female	Dead	2011/11/11	Multiple myeloma	2008/01/01	
8001	26	2015/10/13 18:41	TC3	98765	1980/11/22	Male	unknown	1809/09/09	AML & Related Precurs	2004/04/04	
8001	27	2016/01/12 14:09	TC3	27	1987/02/09	Female	Alive	2006/01/23	Mixed phenotype: Bmy	2006/01/23	
8001	28	2015/10/21 12:22	TC3	28	1912/12/23	Male	Dead	2001/06/14	Precursor Lymphoid Ne	2001/06/14	
8001	29	2016/12/13 14:11	TC3	125	1809/09/09	Alive	Alive	2012/01/01	NHL	2011/01/01	
8001	30	2016/06/09 15:07	TC3	30	1978/11/07	Male	Alive	2012/02/19	Amyloidosis	2011/11/11	

Mark any entry in this INDEX; then load that case into Data-Editor or Status Report.

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]:

Data Entry Report Export Help Filter MEDAB -- [8001][DEMO][City_1] |

Index Editor Overview

+ Data Manager
 + Build a Patient-index:

Create/Load Patient-record all cases (n=930) Link to History

[8001] City_1 [TC3] {choose free slot}

524
 729
 740
 798
 812
 908
 1000
 1026
 1055

Create (or load) a Patient ...

CIC (ID) 8001

Patient 28

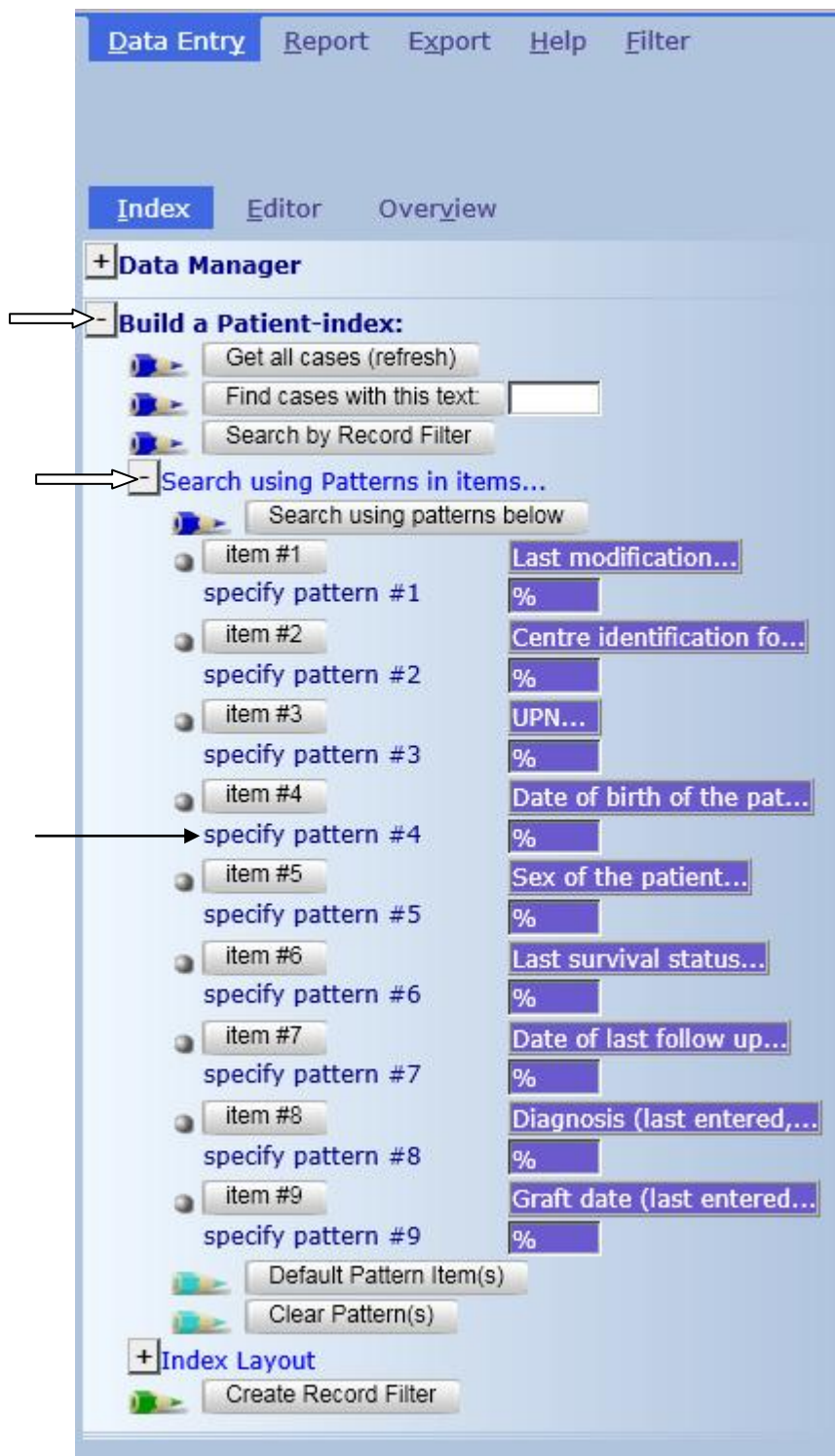
Create new Patient

LOAD:

Load existing Patient

- Just click on a free slot to create this new case and load it into Data Entry.
- Alternatively you may fill in a specific identification number in the "Create/Load" tree above
- Caveat

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..."



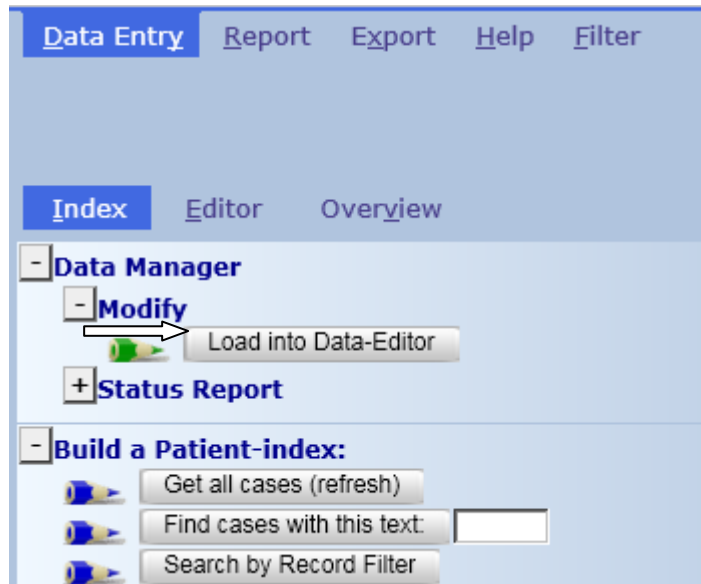
Index: Search by Pattern

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.

modal dialog (Choose ALL items for pattern matching, then)

Choose ALL items for pattern matching, then
[Accept Selection](#) [Cancel](#)

Patient information
Centre
Unit or team
Unit or team type
Contact person
Area code
Date of the 1st report
Date of the last report
Patient in nat / international study...
UPN
Dossier number
1st initials
2nd initials
Date of birth
Sex
Patient ABO blood group

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ITEM FILTER TOOLS
Tree Expansions
up to Tables
up to Chapters
up to Sections
up to Items
Quick Selections
select items
unselect items
invert items
text to search
count selected items

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:

Data Entry **Report** **Export** **Help** **Filter** MEDAB -- [8001][DEMO]

Index **Editor** **Overview**

Build a Patient-index:

Get all cases (refresh)

Find cases with this text:

Search by Record Filter

Search using Patterns in items...

Search using patterns below

item #1 Last modification

specify pattern #1

item #2 Centre

specify pattern #2

item #3 UPN

specify pattern #3

item #4 Dossier number

specify pattern #4

Specify the pattern to match with (use yyyy/mm/dd for dates; use a SPACE to search for empty items)

%255%

☒ Accept

specify pattern #6

item #7 Status

specify pattern #7

item #8 Last seen

specify pattern #8

item #9 Diagnosis

specify pattern #9

Mark any entry in this INDEX; then load that

CIC	Patient	Last modification	Centre
8001	24	2015/11/02 10:35	TC3
8001	25	2016/05/24 12:32	TC3
8001	26	2015/10/13 18:41	TC3
8001	27	2016/01/12 14:09	TC3
8001	28	2015/10/21 12:22	TC3
8001	29	2016/12/13 14:11	TC3
8001	30	2016/06/09 15:07	TC3
8001	31	2015/10/21 11:01	TC3
8001	32	2015/10/21 11:31	TC3
8001	33	2015/10/21 11:57	TC3
8001	34	2015/11/30 16:10	TC3
8001	35	2015/11/02 17:17	TC3
8001	36	2015/11/02 17:30	TC3
8001	37	2015/11/02 16:38	TC3
8001	38	2015/11/03 14:32	TC3
8001	39	2015/11/03 15:30	TC3
8001	40	2015/12/02 16:48	TC3
8001	41	2015/12/02 16:57	TC3
8001	42	2015/10/22 17:13	TC3
8001	43	2015/10/21 19:16	TC3
8001	44	2015/10/22 12:44	TC3
8001	45	2015/10/22 12:48	TC3
8001	46	2015/10/23 12:21	Hotel Dieu
8001	47	2015/10/06 14:25	TC3
8001	48	2015/10/23 14:59	TC3
8001	49	2015/11/05 13:22	TC3
8001	50	2015/11/05 14:42	

(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.

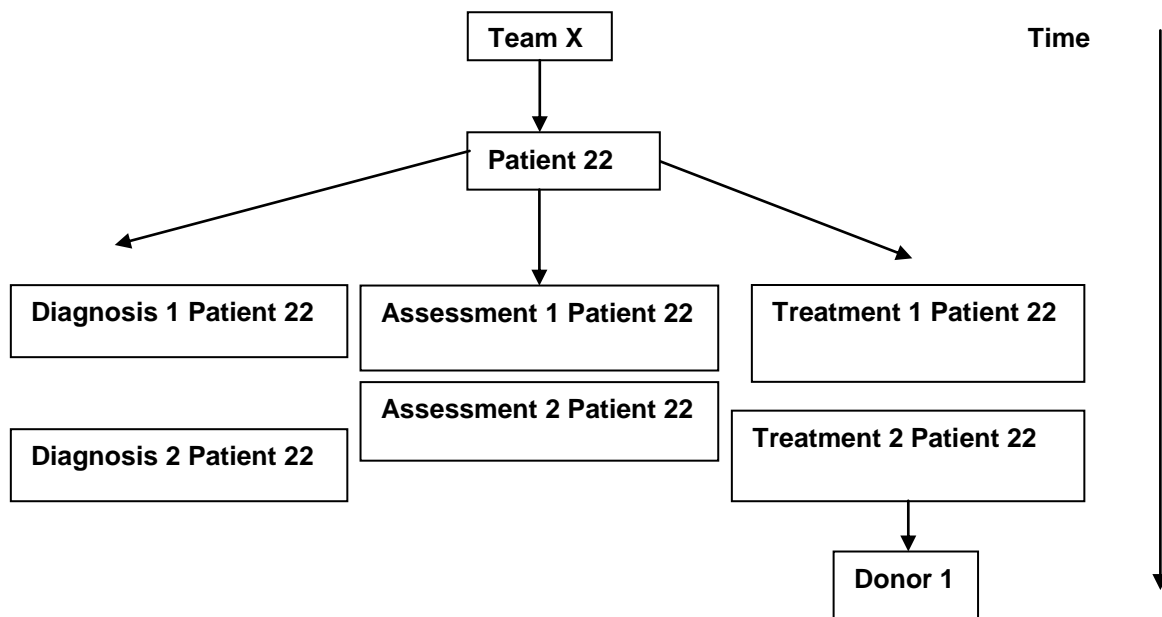
The EBMT database is a relational database with several levels and the data is stored in several tables.

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:

Data Entry Report Export Help Filter [8003][DEMO][City_2] |

Resume with the **first** item in the **current** section by pressing **Tab** (or click on any other item)

Index **Editor** Overview DynFil:undefined

Assessment(1)	value	label
CIC	8003	8003
Patient	12345680	12345680
Assessment date	2010/04/22 00:00	2010/04/22 {exact}
New record creation		
New record creation, Date		
E0: Index date for new record	2010/08/20 00:00	
E1: Index date for new record		
New record creation: Code		
E0: New record index: cytogenetics		
E2: New record index: infect & complications	776	Other complication 1
E3: New record index: involvement		
E4: New record index: markers		
Data entry help asses		
Navigation field		

Note: Enter the date of HSCT

exact

E0: Index date for new record

= (empty)

2010/08/20 00:00:00 (current value)

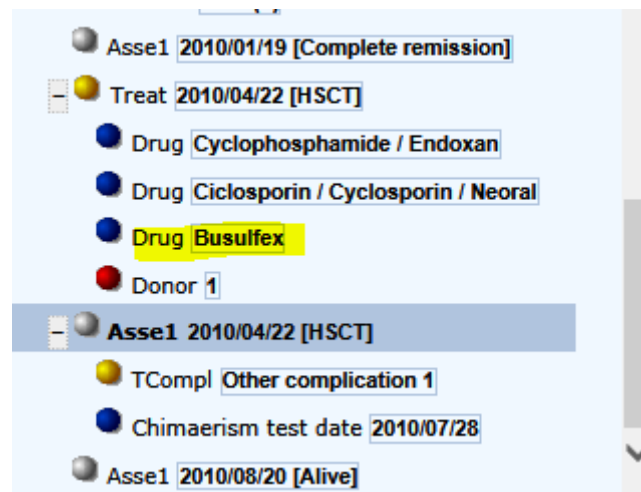
2010/04/22 # (this record)

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)

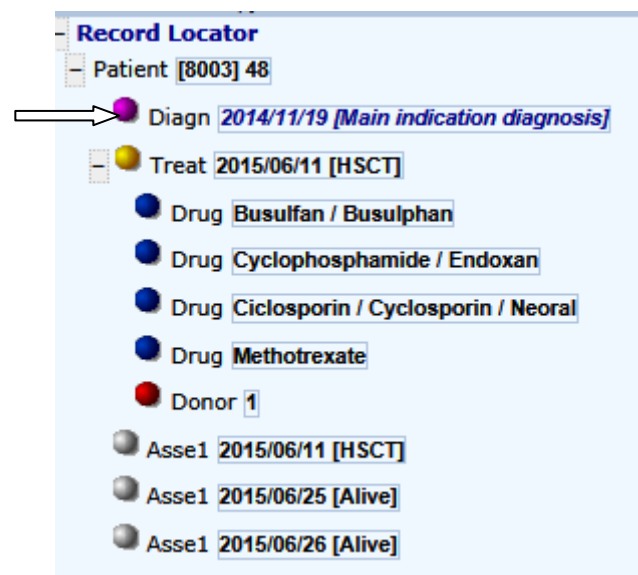
When the abbreviation belongs to any of the other tables, it is the main information stored in that table, whose code behaves as the unique index key for that record. For example, “Busulfex” as a label in the Record Locator would correspond to a drug that the patient received during their stem cell treatment 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.

Sex of the patient	1 Male	Note: Enter date of initial diagnosis for this subsequent transplant This month
New record creation		
A: Index date for new record	2014/11/19	
A: Index code for new record		

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

Data Entry	Report	Export	Help	Filter
------------	--------	--------	------	--------

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:

	value	label
CIC	8003	8003
Patient	48	48
Patient data		
Form information		
Form about to be entered	1	Med-A: Day 0
Main indication for therapy		
Are you adding Med-B items to a Med-A registration?		
Registering a transplant performed before one already registered		
To which registered transplant number are you adding data?		
Date of cell infusion/HSCT to which you want to add donor data		
For subsequent treatment: same diagnosis?	1	No
For subsequent treatment: same centre?	2	Yes
For subsequent treatment: same unit or team?	2	Yes
Patient information		
Centre for last transplant		
Name of unit or team for the last transplant		
Type of unit or team for the last transplant	7	BMT unit
Contact person for the last transplant		
Area code where patient lived at time of HSCT (optional)		
Date of the 1st report	2015/06/27	2015/06/27
Date of the last report		
Patient in nat / international study / trial		
Unique Patient Number/code given by hospital	CHUAC048	CHUAC048
Patient dossier number (Optional)		

Actions

- ☐ Visibility
- ☐ Apply Item Filter
- ☐ No DynFilters
- ☐ Show Names
- ☐ Hide Values
- ☐ RecLoc at lvl=2
- ☐ Keep Chp&Sec closed
- ☐ RecLoc 100% visible
- ☐ History always visible
- ☐ Trace always visible
-
-

Form about to be: Med-A: Day 0
 Are you adding M... null
 UPN CHUAC048
 Date of birth 1953/06/07
 Are you adding M... null

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:

No. of hidden items

Disease-specific filter

DynFilters On

Form filter

	value	label
Treatment	8001	8001
CIC	273	273
Patient	2010/05/25 00:00	2010/05/25 (exact)
Transplant and cell source specifics		
Type of HSC transplant	1	Allogeneic
Specify if HSC transplant unusual		
Multiple donors or different sources of stem cells	1	No
Total number of products		
Tissue source		
Number and graft program		
Chronologic number of this transplant for this patient	1	First
Donor the same as previous transplant		
Date previous transplant		
Type of previous transplant		
Reason for this HSC transplant		
Specify other reasons for the HSCT if there are more than one		
Multiple graft program	1	No
Type of multiple graft program		
Graft number in the program		
Total number of transplants in the program		
Year of this treatment	2010	2010

Actions

- ☐ Visibility
- ☐ Apply Item Filter
- ☐ No DynFilters
- ☐ Show Names
- ☐ Hide Values
- ☐ RecLoc at lvl=2
- ☐ Keep Chp&Sec closed
- ☐ RecLoc 100% visible
- ☐ History always visible
- ☐ Trace always visible
-
-

Form about to be: HSCT MED-B registration
 Are you adding I... null
 UPN 214
 Date of birth of 1957/04/27
 Are you adding M... null

Record Locator: 5-15-15-1

Patient [8001] 273

- Diagn 2004/04/21 [Other, non indication diagnosis]
- Diagn 2010/03/16 [Main indication diagnosis]
- Treat 2010/04/16 [Non graft treatment]
- Drug Adriamycine
- Drug Cyclophosphamide / Endoxan
- Drug Etoposide / VP16
- Drug Vincristine
- Drug Campath (CD52, Alemtuzumab)
- Asse1 2010/05/16 [Complete remission]
- Treat 2010/05/25 [HSCT]
- Drug Adriamycine
- Drug Ciclosporin / Cyclosporin / Neoral
- Drug Mycophenolate mofetil
- Drug G-CSF
- Donor 1
- Asse1 2010/05/25 [HSCT]
- TCompl Mucositis
- Infec 1
- Infec 2
- Asse1 2010/09/01 [Alive]

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

No. of hidden items:

No Disease-specific filter

DynFilters Off

Form filter ignored

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:

BE	TABLE	Assessment(1)
TAG	LABEL	NAME CODES LONG LABEL 0-9 Reg Cen
BE0	VOLUME	Content
BE0K	CHAPTER	Last disease status
BE0K0	SECTION	Last disease status before this date (1)
BE0K0D1	Disease status	VDISESTA 169 Disease status

169 [VDISESTA]						
1 Chronic phase	2 Accelerated phase	3 Blast crisis	5 Progressive relapsing (malignant)	6 Primary progressive	7 Secondary progressive	
8 Relapsing/remitting	10 Primary induction failure / Primary refractory	20 Stable disease (no change, no response)	25 Treatment not aimed at remission	28 stringent Complete remission (sCR)	30 Complete remission (CR)	
40 First partial remission (PR1)	41 Very good PR (VGPR)	42 Minor response (MR)	45 Partial remission	46 Response / Improvement (no CR)	47 Nodular partial remission (nPR)	
50 Relapse	60 Progression	65 Never in CR	66 Not in CR	70 Never treated / Upfront	75 Adjuvant	
77 Other	80 Not evaluable	83 Not evaluated	88 Not applicable	99 unknown		

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:

The screenshot shows the 'Data Entry Editor' window for a patient with ID [8003][DEMO][City_2]. The 'Editor' tab is active, displaying a table of patient data. The 'Disease status' field is highlighted, and a dynamic labelset is shown on the right. The labelset lists various disease statuses, with '30 Complete remission (CR)' selected. A note indicates that the disease status should be entered at HSC.

Assessment(1)	value	label
CIC	8003	8003
Patient	48	48
Assessment date	2015/06/11 00:00	2015/06/11 {exact}
Last disease status		
Last disease status before this date (1)		
Disease status	30	30
CR confirmed?		
Number of this status	1	1st
Sensitivity to chemotherapy		
Last disease status before this date (2)		
Last disease status before this date (3)		

Note: Enter the disease status at HSC

Disease status

20	Stable disease (no change, no response)
30	Complete remission (CR)
40	First partial remission (PR1)
50	Relapse
60	Progression
70	Never treated / Upfront
75	Adjuvant
77	Other
99	unknown

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 never 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>:

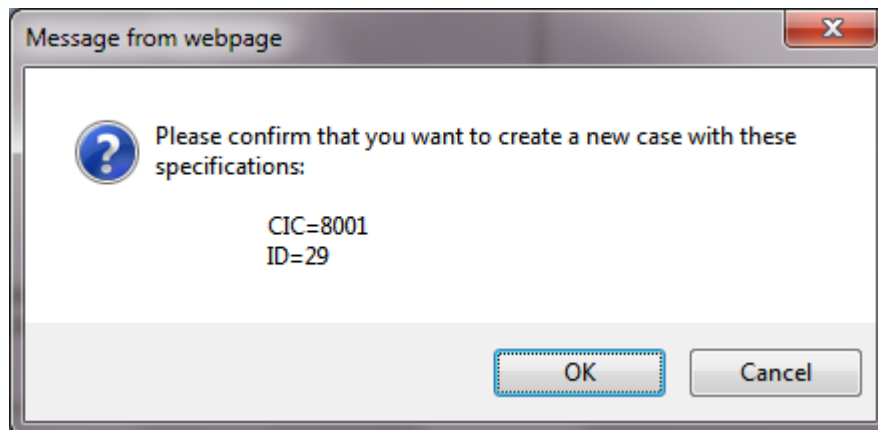
Select any free patient number (the number does not have to follow a chronological order) and click on it to create a new empty patient form:

The screenshot shows the ProMISe Data Entry interface. The 'Data Entry' menu is at the top. The 'Index' tab is selected. In the 'Data Manager' section, the '+ Build a Patient-index:' button is visible. The 'Create/Load Patient-record' tab is active, displaying a dropdown menu for '[8001] City_1 [TC3]' and a list of free slots: 29, 34, 36, 41, 46, 57, 63, 66, 70. A blue arrow points to the 'choose free slot' header. Below the list, there is a section titled 'Create (or load) a Patient ...' with fields for 'CIC (ID)' (8001) and 'Patient'. There are buttons for 'Create new Patient' and 'LOAD: Load existing Patient'. At the bottom, there are instructions: 'Just click on a free slot to create this new case and load it into Data Entry.', 'Alternatively you may fill in a specific identification number in the "Create/Load" tree above', and 'Caveat'.

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

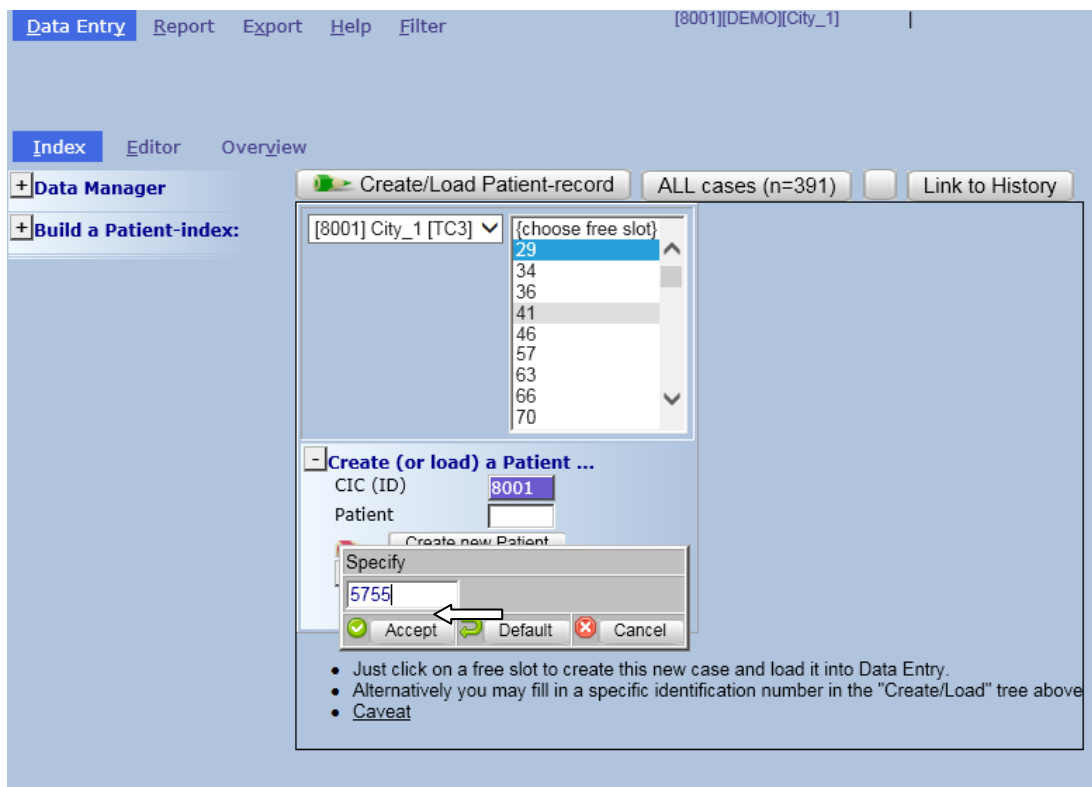


Press [OK] to confirm:



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 at the very beginning 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 new transplant whether it is for a new or existing patient.

The screenshot shows the MEDAB data entry interface. The top menu bar includes 'Data Entry', 'Report', 'Export', 'Help', and 'Filter'. The title bar indicates 'MEDAB -- [8001][DEMO][City_1]'. Below the menu bar, there are tabs for 'Index', 'Editor', and 'Overview'. The main area displays a list of patient data fields, including 'Patient', 'Patient data', 'Form information', and 'Form about to be entered'. A green note is visible: 'Note: Use codes 4, 5 or 6 for Med-B'. The 'Form about to be entered' section shows a table with codes and descriptions:

Code	Description
1	Med-A: Day 0
4	Med-B: Day 0
9	Cell Therapy Med-A registration
21	New CT Med-A registration

To the right of the table, an 'IMPORTANT' message is displayed:

IMPORTANT
This is a navigation item and can be overwritten as often as necessary.
The information on this field will determine the behaviour of the cursor during data entry. Use it to indicate which type of form you are about to enter.
Use codes 1 (Med-A: Day 0) or 4 (Med-B) whenever you are registering a new **transplant** whether it is for a new or for an existing patient.
If you are doing spot corrections to existing registrations it is best to leave the field empty.
Please, report any navigation errors to the ProMISe helpdesk in the usual way: **ALWAYS ATTACH A SCREEN CAPTURE** See instructions on how to do this by clicking on the link [MEDAORB.PDF](#) below
Additional help in [MEDAORB.PDF](#)

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 patient that died during conditioning or transplant. 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)

The screenshot shows the MEDAB data entry application. The main window has a menu bar (Data Entry, Report, Export, Help, Filter) and a toolbar with icons for Data Entry, Browser/Server, General, and Info. The 'Form about to be entered' dropdown menu is open, showing options: 1 Med-A Day 0, 2 Med-A Day 100 (selected), 3 Med-A Follow up, 4 Med-B Day 0, 5 Med-B Day 100, 6 Med-B Follow up, 7 Donor donation procedure and 30 days, 8 Donor follow up, and 9 Cell Therapy Med-A registration. The 'Patient data' section on the right shows a patient record for 'Patient [8001] 1610' with various fields like 'Diagn 2014/08/19', 'Asse1 2014/08/19', 'Invol Bone Marrow (+)', 'Invol CNS (-)', 'Treat 2014/11/13 [HSCT]', 'Drug Ciclosporin / Cyclosporin / Neoral', 'Drug Etoposide / VP16', 'Drug Melphalan', and 'Donor 1'. The 'Chapters & Sections' panel on the bottom right lists various sections like 'ID and admin', 'Patient data', 'Form information', 'Patient information', 'New record creation', 'Ethnicity', 'Outcome', 'Management', 'EBMT to centre', and 'Data entry support'.

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]

Form about to be entered

Note: Use codes 4, 5 or 6 for Med-B

Form about to be entered

- 1 Med-A: Day 0
- 2 Med-A: Day 100
- 3 Med-A: Follow up
- 4 Med-B: Day 0
- 5 Med-B: Day 100
- 6 Med-B: Follow up
- 9 Cell Therapy Med-A registration

IMPORTANT

This is a navigation item and can be overwritten as often as necessary.

The information on this field will determine the behaviour of the cursor during data entry. Use it to indicate which type of form you are about to enter.

Use codes 1 (Med-A: Day 0) or 4 (Med-B) whenever you are registering a **new** transplant whether it is for a **new** or for an **existing** patient.

If you are doing spot corrections to existing registrations it is best to leave the field empty.

Please, report any navigation errors to the ProMISe helpdesk in the usual way/ ALWAYS ATTACH A SCREEN CAPTURE See instructions on how to do this by clicking on the link [MEDAORB.PDF](#) below Additional help in [MEDAORB.PDF](#)

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:

Form about to be entered

Form about to be entered

- 1 Med-A: Day 0
- 2 Med-A: Day 100
- 3 Med-A: Follow up
- 4 Med-B: Day 0
- 5 Med-B: Day 100
- 6 Med-B: Follow up
- 9 Cell Therapy Med-A registration

IMPORTANT

This is a navigation item and can be overwritten as often as necessary.

The information on this field will determine the behaviour of the cursor during data entry. Use it to indicate which type of form you are about to enter.

Use codes 1 (Med-A: Day 0) or 4 (Med-B) whenever you are registering a **new** transplant whether it is for a **new** or for an **existing** patient.

If you are doing spot corrections to existing registrations it is best to leave the field empty.

Please, report any navigation errors to the ProMISe helpdesk in the usual way/ ALWAYS ATTACH A SCREEN CAPTURE See instructions on how to do this by clicking on the link [MEDAORB.PDF](#) below Additional help in [MEDAORB.PDF](#)

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).

The screenshot shows the MEDAB form interface. The top bar includes 'Data Entry', 'Report', 'Export', 'Help', and 'Filter'. The main title is 'MEDAB -- [8001][DEMO][City_1]'. Below the title are tabs for 'Index', 'Editor', and 'Overview'. The 'Editor' tab is active, showing a list of fields with 'value' and 'label' columns. The 'Form about to be entered' field has the value '4' and label 'Med-B Day 0'. A confirmation dialog is open on the right, asking 'Are you adding Med-B items to a Med-A registration?' with options '1 No', '2 Yes', and '99 unknown'. The '2 Yes' option is selected.

Field	value	label
Patient		
CIC	8001	8001
Patient	1103	1103
Patient data		
Form information		
Form about to be entered	4	Med-B Day 0
Are you adding Med-B items to a Med-A registration?		
Registering a transplant performed before one already registered		
To which registered transplant number are you adding data?		
For subsequent treatment: same diagnosis?		
For subsequent treatment: same centre?		
For subsequent treatment: same unit or team?		
Patient information		
Centre for last HSCT or Cell therapy	8001	City_1 [TC3]

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.

The screenshot shows the MEDAB form interface. The top bar includes 'Data Entry', 'Report', 'Export', 'Help', and 'Filter'. The main title is '[8003][DEMO][City_2]'. Below the title are tabs for 'Index', 'Editor', and 'Overview'. The 'Editor' tab is active, showing a list of fields with 'value' and 'label' columns. The 'Form about to be entered' field has the value '1' and label 'Med-A: Day 0'. A confirmation dialog is open on the right, asking 'Registering a transplant performed before one already registered' with options '1 No', '2 Yes', and '99 unknown'. The '2 Yes' option is selected.

Field	value	label
Patient		
CIC	8003	8003
Patient	24	24
Patient data		
Form information		
Form about to be entered	1	Med-A: Day 0
Are you adding Med-B items to a Med-A registration?		
Registering a transplant performed before one already registered	2	
To which registered transplant number are you adding data?		
For subsequent treatment: same diagnosis?	2	Yes
For subsequent treatment: same centre?	2	Yes
For subsequent treatment: same unit or team?	2	Yes
Patient information		
Centre for last transplant	8003	City_2 [TC2]
Name of unit or team for the last transplant		
Type of unit or team for the last transplant		
Contact person for the last transplant		
Area code where patient lived at time of HSCT (optional)		
Date of the 1st report		
Date of the last report	2016/03/01	2016/03/01
Patient in nat / international study / trial	1	No
Unique Patient Number/code given by hospital	22226	22226
Initial(s) first name		
Initial(s) family name		
Date of birth of the patient	1952/01/05	1952/01/05
Sex of the patient	2	Female

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

The screenshot shows the MEDAB software interface. At the top, there are tabs: Data Entry, Report, Export, Help, and Filter. The title bar indicates 'MEDAB -- [8001][DEMO][City_1]'. Below the tabs, there are buttons for Index, Editor, and Overview. The main area displays a form titled 'Patient data'. The form has several sections: 'Form information' (Form about to be entered), 'Patient information' (Name of unit or team for the HSCT or Cell therapy, Type of unit or team for the last HSCT or Cell therapy, Contact person for the last HSCT or Cell therapy, Area code where patient lived at time of HSCT or Cell therapy, Date of the last report, Patient in nat / international study / trial, Unique Patient Number/code given by hospital, Initial(s) first name, Initial(s) family name, Date of birth of the patient), and 'Form about to be entered'. The 'Form about to be entered' dialog box is open, showing a list of codes for follow-up: 1 Med-A: Day 0, 2 Med-A: Day 100, 3 Med-A: Follow up (highlighted in blue), 4 Med-B: Day 0, 5 Med-B: Day 100, 6 Med-B: Follow up (highlighted in yellow), and 9 Cell Therapy Med-A registration. A green note at the top right of the dialog box says 'Note: Use codes 4, 5 or 6 for'. The background form shows patient data for a patient with CIC, value 8001, label 8001, and patient data value 1103, label 1103.

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).

The screenshot shows the MEDAB software interface. At the top, there are tabs: Data Entry, Report, Export, Help, and Filter. The title bar indicates 'MEDAB -- [8001][DEMO][City_1]'. Below the tabs, there are buttons for Index, Editor, and Overview. The main area displays a form titled 'Patient data'. The form has several sections: 'Form information' (Form about to be entered), 'Patient information' (Name of unit or team for the HSCT or Cell therapy, Type of unit or team for the last HSCT or Cell therapy, Contact person for the last HSCT or Cell therapy, Area code where patient lived at time of HSCT or Cell therapy, Date of the last report, Patient in nat / international study / trial, Unique Patient Number/code given by hospital, Initial(s) first name, Initial(s) family name, Date of birth of the patient, Gender of the patient), and 'Form about to be entered'. The 'Form about to be entered' dialog box is open, showing a list of codes for follow-up: 1 Med-A: Day 0, 2 Med-A: Day 100, 3 Med-A: Follow up, 4 Med-B: Day 0, 5 Med-B: Day 100, 6 Med-B: Follow up, 7 Donor donation procedure and 30 days (highlighted in blue), 8 Donor follow up, and 9 Cell Therapy Med-A registration. A green note at the top right of the dialog box says 'Note: Use codes 4, 5 or 6 for Med-B'. The background form shows patient data for a patient with CIC, value 8001, label 8001, and patient data value 1112, label 1112. The form also shows 'Date of cell infusion/HSCT to which you want to add donor data' as 2012/06/08, 'Centre for last HSCT or Cell therapy' as 8001 City_1 (TC3), 'Date of the 1st report' as 2012/06/08, 'Date of the last report' as 2012/06/08, 'Unique Patient Number/code given by hospital' as 654, 'Date of birth of the patient' as 1981/12/29, and 'Gender of the patient' as 1 Male.

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

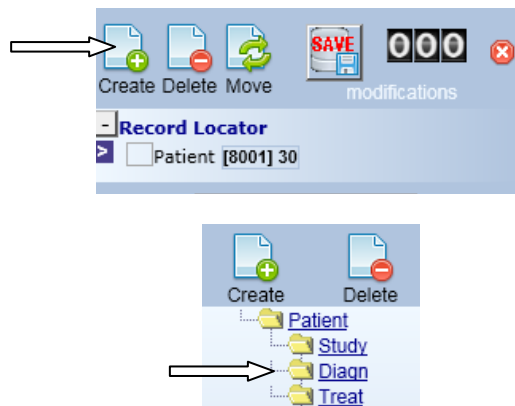
i) Entering a non consenting patient

For patients who have not consented for their data to be viewed by the EBMT and/or your National Registry (if your country has one), you can enter the minimal data set below (so it is counted in your centre numbers) or *preferably* contact us at the registryhelpdesk@ebmt.org to record your case for you.

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

- Diagnosis Type (Main Disease and Subclassification)
- Diagnosis Date (just the Year = yyyy/01/01 and approximation Unknown)
- Transplant Type (autologous or allogeneic)
- Transplant Date (just the Year = yyyy/01/01 and approximation Unknown)
- Chronological Number of the Transplant for this Patient
- Exclude from National Registry: Consent denied
- Exclude from EBMT: Consent denied

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



Enter the diagnosis date (yyyy/01/01 and approximation Unknown) then [click here to create the record]:

Create (a) new **Diagn** record(s) in table **Diagnosis**

1. Specify the value of [Diagnosis date]

2010	01	01	Unknown	
year	mm	dd	approximate?	today

If you are unsure about the exact date, give your best estimate above and indicate the [precision](#).

2. [click here to create the record\(s\)](#)

To create multiple records in one action ...

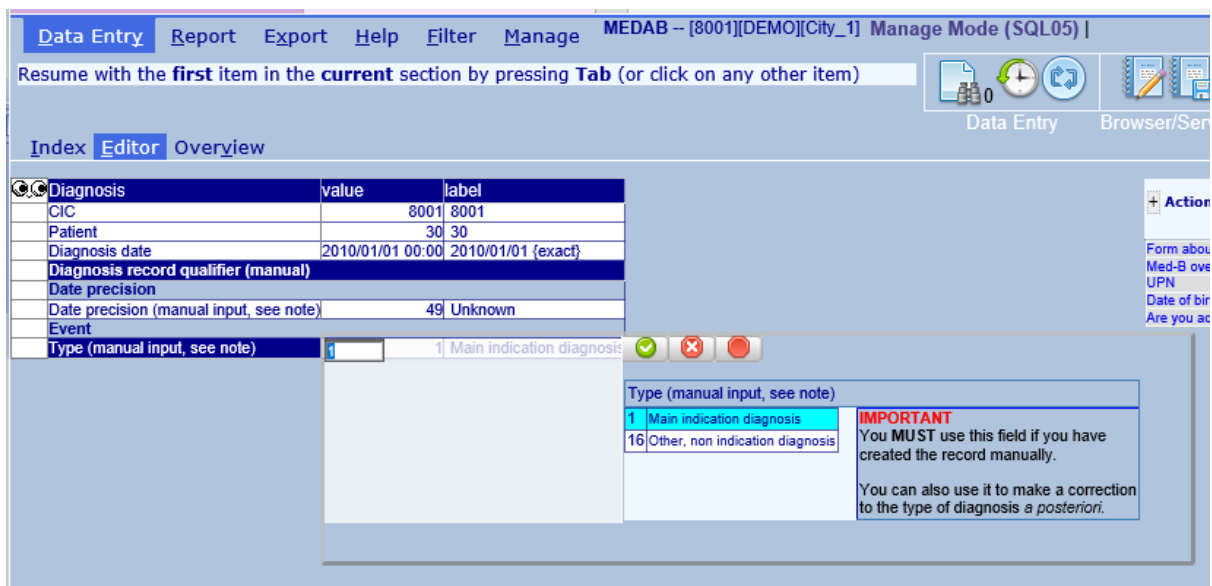
• Check this box ☐

• specify the number of records

(records will be generated by incrementing the start value with unit(s) until the requested number of new records is reached) and proceed as indicated above.

[Click here to cancel the operation](#)

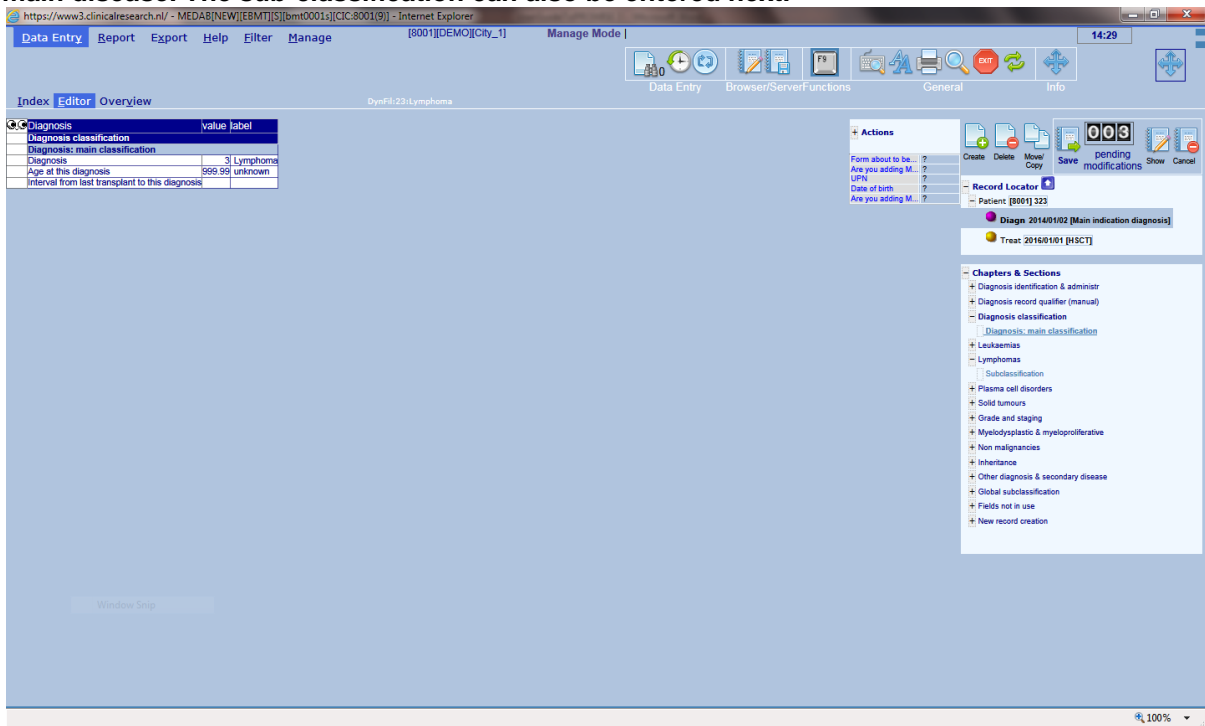
Indicate the precision of the diagnosis (code 49 for Unknown) date and code it as Main indication diagnosis (code 1):



Diagnosis	value	label
CIC	8001	8001
Patient	30	30
Diagnosis date	2010/01/01 00:00	2010/01/01 {exact}
Diagnosis record qualifier (manual)		
Date precision		
Date precision (manual input, see note)	49	Unknown
Event		
Type (manual input, see note)	1	Main indication diagnosis

IMPORTANT
You MUST use this field if you have created the record manually.
You can also use it to make a correction to the type of diagnosis *a posteriori*.

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



Diagnosis classification	value	label
Diagnosis: main classification		
Diagnosis	3	Lymphoma
Age at this diagnosis	999	unknown
Interval from last transplant to this diagnosis		

Record Locator
Patient: [8001] 323

Diagnosis
Diagn 2010/01/02 [Main indication diagnosis]

Treat
Treat 2010/01/01 [HSCT]

Chapters & Sections

- Diagnosis identification & admin
- Diagnosis record qualifier (manual)
- Diagnosis classification
 - Diagnosis: main classification
- Leukemias
- Lymphomas
 - Subclassification
- Plasma cell disorders
- Solid tumours
- Grade and staging
- Myelodysplastic & myeloproliferative
- Non malignancies
- Inheritance
- Other diagnosis & secondary disease
- Global subclassification
- Fields not in use
- New record creation

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:

Resume with the **first** item in the **current** section by pressing **Tab** (or click on any other item)

Index **Editor** **Overview**

Transplant and cell source specifics

Type of transplant

Specify if HSC transplant unusual

Multiple donors or different sources of stem cells

Total number of products

Cell origin

Tissue source

Bone marrow (BM)

Number of BM collections

Peripheral blood (PB)

Number of mobilisation courses

Cord blood (CB)

Adipose tissue

Endothelial cell progenitors

Other tissue source

Other tissue source: specify

First date of BM collection or PB pheresis

Number and graft program

Chronologic number of this transplant for this patient

Donor the same as previous transplant

Date previous transplant

Type of previous transplant

Reason for this HSC transplant

Specify other reasons for the HSCT if there are more than one

Cell support (French centres only)

Multiple graft program

Type of multiple graft program

Graft number in the program

Total number of transplants in the program

Year of this treatment

Actions

Form about to be... ?

Are you adding L... ?

Centre identific... ?

UPN ?

Date of birth of... ?

Are you adding M... ?

Record Locator

Patient (8001) 30

Diagn 2010/01/01

Treat 2014/05/05

Chapters & Sections

Treatment identification & administr

Treatment record qualifier (manual)

General

Transplant and cell source specifics

Type of transplant

Tissue source

Number and graft program

Ex-vivo graft manipulation

Main treatment

Hospital admin (STABM7)

Supportive treatment in the patient

Cellular therapy (non HSCT)

Treatment related to complications

Status after treatment

Chapter Y

New record creation

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

Resume with the **first** item in the **current** section by pressing **Tab** (or click on any other item)

Index **Editor** **Overview**

Patient

CIC

Patient

Management

Data entry information

Patient ID in conversion source

Source of data conversion

UBMID (do not use)

Diagnosis (last entered_top)

Graft date (last entered)

MED form filled in for transplant 1

MED form filled in for transplant 2

MED form filled in for transplant 3

MED form filled in for transplant 4

MED form filled in for transplant 5

MED form filled in for transplant 6

Registry administration

Exclude from national registry

Exclude from EBMT registry

Reason for hiding this registration from the EBMT WP's

User who created the record

Last user to modify the record

Which paper form has the data been copied from?

ID of patient found NOT to be double

IDAA of patient NOT found to be double

Users

Actions

Form about to be... ?

Are you adding L... ?

Centre identific... ?

UPN ?

Date of birth of... ?

Are you adding M... ?

Record Locator

Patient (8001) 30

Diagn 2010/01/01

Treat 2014/05/05

Chapters & Sections

ID and admin

Patient data

Form information

Patient information

New record creation

Ethnicity

Outcome

Management

Data entry information

Registry administration

Users

EBMT to centre

Data entry support

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 pre-programmed navigation will not work / you will miss out relevant questions

A small selection of shortcuts is available when entering data:

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

Data Entry Report Export Help Filter MEDAB --

Resume with the **first** item in the **current** section by pressing **Tab** (or click on any

Index **Editor** Overview DynFil:20:Acute

Donor	value	label
CIC	8001	8001
Patient	555555595	555555595
Treatment date	2011/01/20 00:00	2011/01/20 {exact}
Donor	1	1
Donor		
Donor ID and order of infusion		
HLA relation and donor registry		
Number of mismatches		
Donor details		
Donor ABO blood group		
Donor birthdate		
Age of donor: years		
Age of donor: months		
Donor sex	2	Female
Age of the donor	999.99	unknown
Serologic status		
HIV antibodies in donor		
HIV antigens in donor		
CMV antibodies in donor	1	1 Negative
EBV antibodies in donor		
HBVs antibodies in donor		
HBVs antigens in donor		
HBVc antibodies in donor		
HBVe antibodies in donor		
HBVe antigens in donor		
HCV antibodies in donor		

data entry options:

1. Type the code manually or
2. Type part of the text (e.g. neg for negative) Press [Tab] or [Enter] key to continue
3. Click on the answer with your mouse (without pressing [Tab] or [Enter])

CMV antibodies in

1	Negative
2	Positive
3	Not evaluated
99	unknown

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.

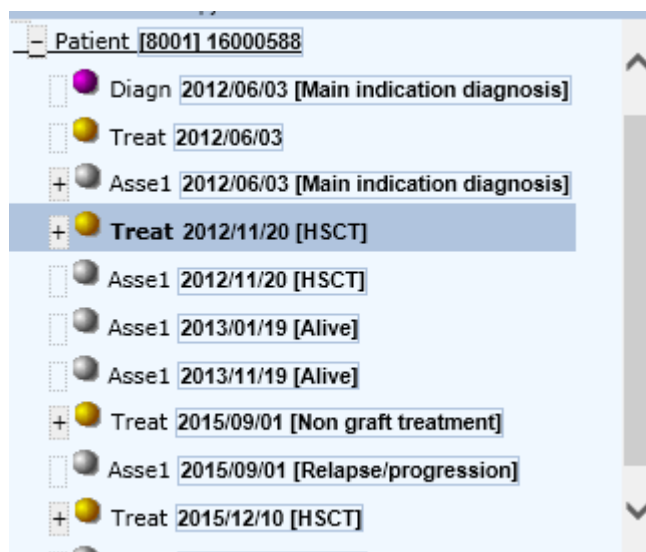
In the Chapters & Sections, you have all the items within the MED-AB project which can be found in the table that particular record belongs to.

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):

Record Locator

- Patient [8003] 120219634
 - Study 1
 - Diagn 2001/05/15 [Main indication diagnosis]
 - + Treat 2001/09/27 [HSCT]
 - Asse1 2001/09/27 [HSCT]
 - Asse1 2002/01/03 [Alive]
 - Asse1 2011/07/15 [Relapse/progression]
 - Treat 2011/07/16 [Non graft treatment]
 - Asse1 2011/07/16 [Non graft treatment]
 - Asse1 2011/10/20 [Alive]
 - + Treat 2011/11/23 [HSCT]
 - Asse1 2011/11/23 [HSCT]

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

Chapters & Sections

- + Diagnosis identification & administr
- + Diagnosis record qualifier (manual)
- + Diagnosis classification
- + Leukaemias
- **Lymphomas**
 - Subclassification
- + Plasma cell disorders
- + Solid tumours
- + Grade and staging
- + Myelodysplastic & myeloproliferative
- + Non malignancies
- + Inheritance
- + Other diagnosis & secondary disease
- + Global subclassification
- + Fields not in use
- + New record creation

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	BMT
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	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

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).

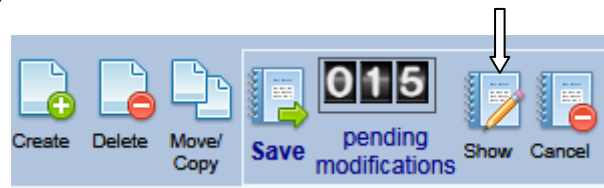
Record Locator shortcuts

Ctrl	Alt	ArrowDn	Next Section
Ctrl	Alt	PgDn	Next Chapter
	Alt	ArrowDn	Next Record in Locator
	Alt	PgDn	Same-type next in Locator
Ctrl	Alt	ArrowUp	Previous Section
Ctrl	Alt	PgUp	Previous Chapter
	Alt	ArrowUp	Previous Record in Locator
	Alt	PgUp	Same-type previous in Locator

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:

[Data Entry](#) [Report](#) [Export](#) [Help](#) [Filter](#) [8003][DEMO][City_2]

you can click on any data cell to return to data entry on that particular record/item!

[Index](#) [Editor](#) [Overview](#) DynFil:undefined

click here to save all pending modifications after reviewing the report below

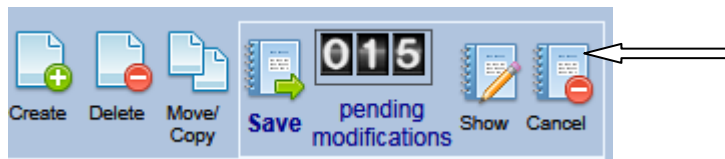
	erased	filled	modified:new	modified:old
TABLE Patient				
CHAPTER ID and admin				
SECTION Patient identification				
A000001	ID	CIC	8003	
A000002	IDAA	Patient	24	
CHAPTER Patient data				
SECTION Form information				
A000003	MEDAORB	Form about to be entered	1 Med-A: Day 0	
			2 Med-A: Day 100	
SECTION Patient information				
A000004	DATLSTRE	Date of the last report	2016/03/01	
CHAPTER Data entry support				
SECTION Navigation items				
A000005	AACOD7	Last dated record created	2015/12/30	
			2016/02/15	
A000006	LASTITEM	Last item visited	VPATSTAT	
			ADDPROT	
TABLE Treatment				
CHAPTER Treatment identification & administr				
SECTION Patient ID and treatment date				
C000001	ID	CIC	8003	8003
C000002	IDAA	Patient	24	24
C000003	IDAABC	Treatment date	2015/12/30 00:00:00	2016/02/15 00:00:00
SECTION Treatment database administration				
C000004	BC_FUZ	How approximate is the Index Date		NaN
C000005	BC_EVD	Context of this treatment		2 Non graft treatment
CHAPTER General				
SECTION Location				
C000006	AACOD2T	Diagnosis (enforced formula)		23 PPL
C000007	INTDIAG	Interval from last diagnosis to this treatment (enforced formula)		1385
C000008	AGETRT	Age at this treatment (enforced formula)		64.11
CHAPTER Transplant and cell source specifics				
SECTION Graft program				
C000009	YEAR	Year of this treatment (enforced formula)		2016
CHAPTER Supportive treatment in the patient				
SECTION Disease treatment				
C000010	ADDPROT	Additional disease treatment	3 Yes, not planned	
CHAPTER Cellular therapy (non HSCT)				
C000011	SECTION	Cellular therapy (non HSCT)		
C000012	VADCELLT	Other cell therapy (non HSCT)	1 No	

Example:

In the Overview screen click on [Yes, not planned] to switch back to the Editor and change it to 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

TraceBack of cursor movements:			
Type of HSC transplant	Treat	2014/01/03	12:40:02
Karnofsky or Lansky status	Asse1	2014/01/03	12:39:58
Performance system used	Asse1	2014/01/03	12:39:56
Number of this status	Asse1	2014/01/03	12:39:54
CR confirmed?	Asse1	2014/01/03	12:39:49
Disease status	Asse1	2014/01/03	12:39:41
CR confirmed?	Asse1	2014/01/03	12:39:38
Disease status	Asse1	2014/01/03	12:39:29
B: Index date for new record	Diagn	2012/05/04	12:39:15
Lymphoma WHO subclassification	Diagn	2012/05/04	12:39:11
Diagnosis	Diagn	2012/05/04	12:39:07
A: Index date for new record	Patient	[8001] 29	12:38:58
Sex of the patient	Patient	[8001] 29	12:38:56
Date of birth of the patient	Patient	[8001] 29	12:38:49
Initial(s) family name	Patient	[8001] 29	12:38:48
Initial(s) first name	Patient	[8001] 29	12:38:46
UPN	Patient	[8001] 29	12:38:44
Patient in nat / international study / trial	Patient	[8001] 29	12:38:42
UPN	Patient	[8001] 29	12:38:40
Patient in nat / international study / trial	Patient	[8001] 29	12:38:39

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:

Finding a Specific Item

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):

TAG	TABLE	LABEL	NAME	CODES	LONG LABEL	0-9 Reg Cen
BE0	VOLUME		Content			
BE0C	CHAPTER		Diagnostics (cont.)			
BE0C6	SECTION		Clinical status			
BE0C6G1		Test used for maternal engraftment	ENGRTST	114	Test used for maternal engraftment	
BE0H	CHAPTER		Haematopoeitic recovery & chimaerism			
BE0H1	SECTION		Cell count recovery (engraftment)			
BE0H1X1		Haematopoeitic recovery (engraftment)	ENGRAF	350	Haematopoeitic recovery (engraftment)	
BE0H1X1		Interval to neutrophil recovery (engraftment) (days)	INTENGR	503	Interval to neutrophil recovery (engraftment) (days)	
BE0H2	SECTION		Graft function / Chimaerism			
BE0H2B1		Date full T-cell recovery (engraftment) achieved	DFTCENG		Date full T-cell recovery (engraftment) achieved	

114	[ENGRTST]					
1	HLA typing	2	Microsatellite	3	IL2 T-cell line	4
						99 unknown
350	[ENGRAF]					
1	No engraftment	2	Engrafted	3	Lost graft	77
						not evaluated
88						not applicable
99						unknown
503	[INTENGR]					
888						Not evaluated
999						unknown

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 – Haematopoeitic 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).

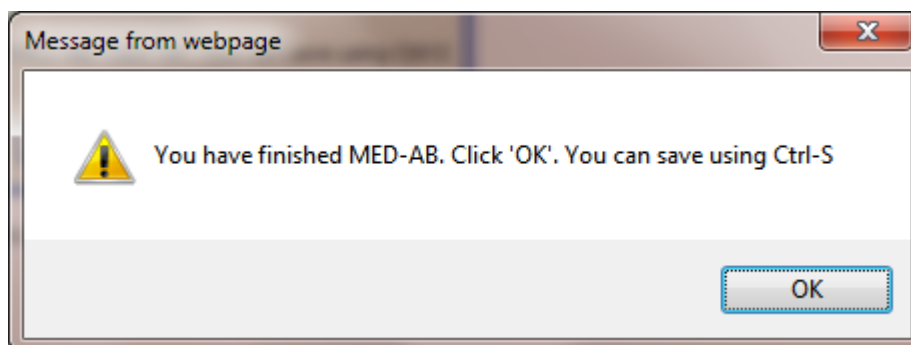
You will be directed to the correct place in the Editor after clicking on the item in your search results:

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

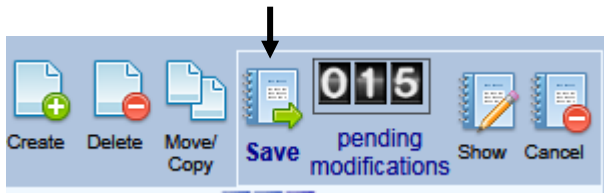
You are advised to save your work regularly while in data entry mode. You can do so by clicking on the Save button or pressing Ctrl-S on your keyboard.

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

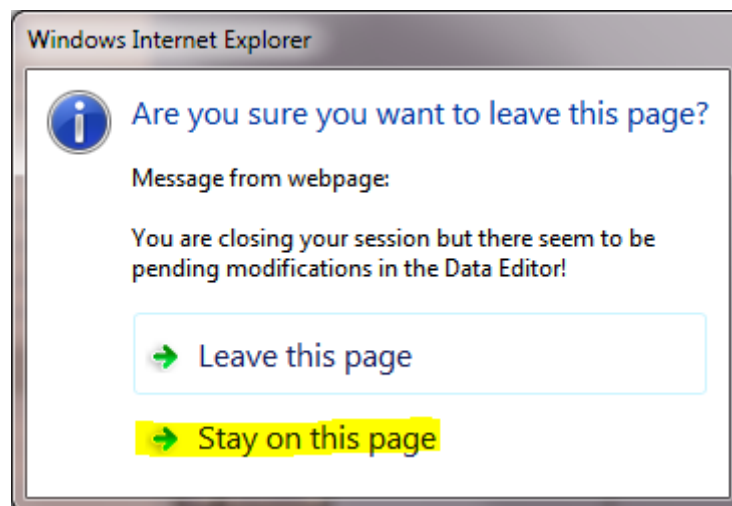
or click on the icon to save:



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 not saved and you need to press Save again):

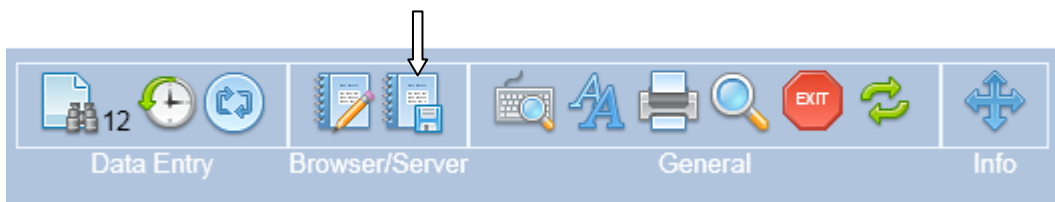
Emergency Save Procedure

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.



Shortcut key: Ctrl-2

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”:

The screenshot shows the MEDAB Overview screen for patient [8003][DEMO][City_2]. The interface includes a menu bar (Data Entry, Report, Export, Help, Filter) and a toolbar with icons for Browser/Server, General, and Info. A status bar at the top right shows the time 17:31. The main area displays a table of patient information, including ID and admin, Patient identification, Database administration, and Patient data. A right-hand panel titled "LAYOUT DISPLAY" contains checkboxes for "Current Display Properties", "Show empty cells", "Show only values in cells", "Suppress values when labelled", "Invert key order", "Show headers", "Show Date Tracker", "Apply current Item Filter", and "Show Item Names". An arrow points from the "Show headers" checkbox to the "Show headers" option in the table.

Horizontal or Vertical overview of all values currently stored on the Server.	
Patient	
ID and admin	
Patient identification	
CIC	8003
Patient	24
Database administration	
Authorized CIC	8003 City_2 [TC2]
Country	NLKingdom of the Netherlands
Record creation date	2016/01/26 11:34:00
Last modification	2016/03/01 15:57:00
(SQL Server autonumber field)	29683
Record creation type	Q created during data entry
User that created this record	bmt0001s
User most recently modifying this record	promise8003s
Patient data	
Form information	
Form about to be entered	1 Med-A: Day 0
Patient information	

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

The screenshot shows the MEDAB Overview screen for patient [8001][DEMO][City_1]. The interface includes a menu bar (Data Entry, Report, Export, Help, Filter) and a toolbar. A status bar at the top right shows the time 17:31. The main area displays a table of transplant and cell source specifics. A right-hand panel titled "LAYOUT DISPLAY" contains checkboxes for "Current Display Properties", "Show empty cells", "Show only values in cells", "Suppress values when labelled", "Invert key order", "Show headers", "Show Date Tracker", "Apply current Item Filter", and "Show Item Names". An arrow points from the "Show headers" checkbox to the "Show headers" option in the table.

Transplant and cell source specifics			
Type of transplant			
HSCT type	2 Autologous		2 Autologous
Tissue source			
Bone marrow (BM)	2 Yes		1 No
Peripheral blood (PB)	1 No		2 Yes
Cord blood (CB)	1 No		1 No
Number of the transplant			
HSCT number	2 Second		1 First
Previous transplant			
Date previous transplant	2012/11/20 {exact}		
Type of previous transplant	2 Autologous		
Graft program			
Multiple graft protocol (program)	1 No		1 No
Year of this treatment	2015	2015	2012
Ex-vivo graft manipulation			
Ex vivo manipulation			
Ex-vivo manipulation of the cells	1 None		1 None

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):

Treatment	value	label
CIC	8003	8003
Patient	24	24
Treatment date	2015/12/30 00:00	2015/12/30 {exact}
Transplant and cell source specifics		
Type of transplant		
Type of HSC transplant	2	Autologous
Specify if HSC transplant unusual		
Tissue source		
Bone marrow (BM)	1	No
Peripheral blood (PB)	2	Yes
Cord blood (CB)	1	No
Number of the transplant		
Chronologic number of this transplant for this patient	1	First
Date previous transplant		
Type of previous transplant		
Was last HSCT at different institution?		
Other centre in which this treatment was given		
Name of different institution if CIC unknown		
City of different institution		
City of different institution if not listed		
Cell support {French centres only}		
Graft program		
Multiple graft protocol (program)	1	1
Type of multiple graft protocol		
Graft number in the protocol		
Total number of transplants in the protocol		
Year of this treatment	2015	2015

✓
✗
⌂

Multiple graft protocol (program)

1	No
2	Yes
99	unknown

Data Entry Actions

Data Entry

Browser/Server

General

Info

1 Registry default

Actions

- + Visibility
- + Cancel, Change, Delete...
- + ClipBoard

Create

Delete

Move

pending

Record Locator

Visibility:

Actions

- Visibility**
 - Apply Item Filter ☐
 - No DynFilters ☒
 - Show Names ☐
 - Hide Values ☐
 - RecLoc at lvl=2 ☐
 - Keep Chp&Sec closed ☐
 - RecLoc 100% visible ☐
 - History always visible ☐
 - Trace always visible ☐
- + Cancel, Change, Delete...
- + ClipBoard

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:

Treatment	value	label	TABLE
CIC	8003	8003	ID
Patient	24	24	IDAA
Treatment date	2015/12/30 00:00	2015/12/30 (exact)	IDAAABC
Transplant and cell source specifics			BC0C
Type of transplant			BC0C0
Type of HSC transplant	2	Autologous	VTRANTYP
Specify if HSC transplant unusual			VEXTYPE1
Tissue source			BC0C1
Bone marrow (BM)	1	No	VBMSC
Peripheral blood (PB)	2	Yes	VPBSC
Cord blood (CB)	1	No	VCBSC
Number of the transplant			BC0C2
Chronologic number of this transplant for this patient	1	First	BMTNR
Date previous transplant			MPREVDG
Type of previous transplant			VPASTGRF
Was last HSCT at different institution?			DIFFINST
Other centre in which this treatment was given			DIFFCNTR
Name of different institution if CIC unknown			OTHINSTN
City of different institution			INSTCITY
City of different institution if not listed			OTHICITY
Cell support (French centres only)			CELLSUPP
Graft program			BC0C3
Multiple graft protocol (program)	1	No	VMULGRAF

Actions
 Visibility
 Apply Item Filter ☐
 No DynFilters ☐
 Show Names ☒
 Hide Values ☐
 RecLoc at lvl=2 ☐
 Keep Chp&Sec closed ☐
 RecLoc 100% visible ☐
 History always visible ☐
 Trace always visible ☐
 + Cancel, Change, Delete...
 + ClipBoard
 Form about to be... Med-A: Day 0
 Are you adding M... ?
 UPN 22226
 Date of birth 1952/01/05
 Are you adding M... ?

Record Locator options

Actions
 - Visibility
 Apply Item Filter ☐
 No DynFilters ☐
 Show Names ☐
 Hide Values ☐
 RecLoc at lvl=2 ☒
 Keep Chp&Sec closed ☐
 RecLoc 100% visible ☐
 History always visible ☐
 Trace always visible ☐
 + Cancel, Change, Delete...
 + ClipBoard

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 lvl=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 lvl=2 off:

Record Locator

- Patient [8003] 24
 - Diagn 2012/05/01 [Main indication diagnosis]
 - Asse1 2012/05/01 [Main indication diagnosis]
 - **Treat 2015/12/30 [HSCT]**
 - Drug Carboplatin
 - Drug Etoposide / VP16
 - Asse1 2015/12/30 [HSCT]

Record locator with RecLoc at lvl=2 option on:

Record Locator

- Patient [8003] 24
 - Diagn 2012/05/01 [Main indication diagnosis]
 - Asse1 2012/05/01 [Main indication diagnosis]
 - + **Treat 2015/12/30 [HSCT]**
 - Asse1 2015/12/30 [HSCT]

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

+ **Chapters & Sections**

Keep Chp&Sec closed: on

- **Chapters & Sections**

- + Treatment identification & administr
- + Treatment record qualifier (manual)
- + General
- **Transplant and cell source specifics**
 - Type of transplant
 - Tissue source
 - Number of the transplant
 - Graft program
- + Ex-vivo graft manipulation
- + Main treatment
- + Hospital admin (STABMT)
- + Supportive treatment in the patient
- + Cellular therapy (non HSCT)
- + Treatment related to complications
- + Status after treatment
- + New record creation

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

TraceBack of cursor movements:				
Patient Rhesus factor	Patient [8001] 1225		13:02:30	
Initial(s) family name	Patient [8001] 1225		13:02:28	

Trace always visible

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

TraceBack of modifications:	
1 [A]	Patient ABO blood group
2 [Female]	Sex of the patient

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):

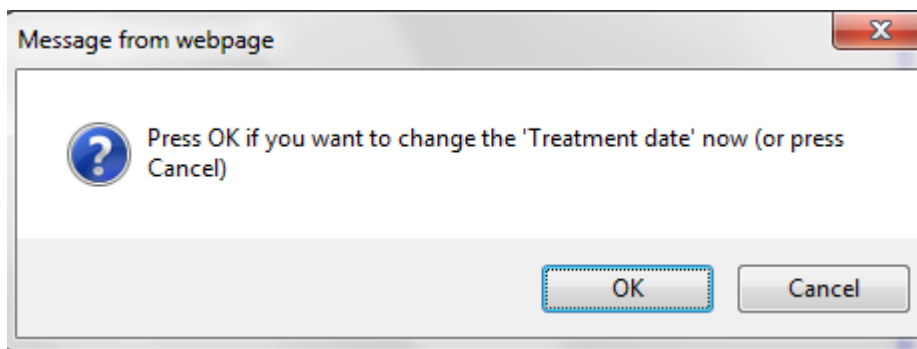
- Record Locator	
- Patient	[8003] 24
	Diagn 2012/05/01 [Main indication diagnosis]
	Asse1 2012/05/01 [Main indication diagnosis]
	Treat 2015/12/30 [HSCT]
	Drug Carboplatin
	Drug Etoposide / VP16
	Asse1 2015/12/30 [HSCT]

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:

Data Entry | Report | Export | Help | Filter | [8003][DEMO][City_2]

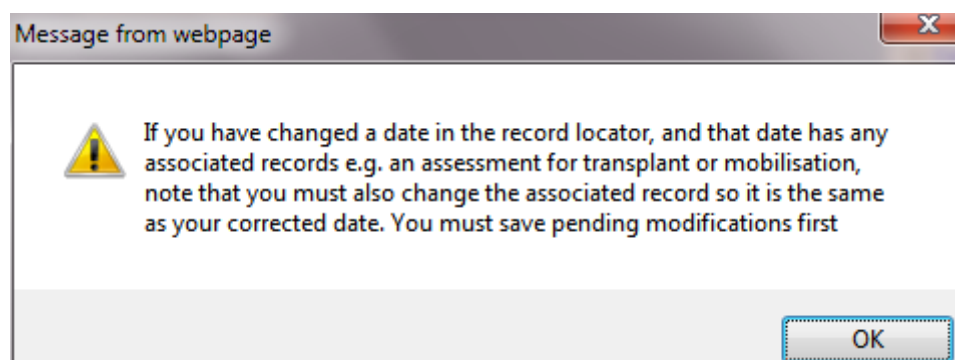
Index | **Editor** | Overview | DynFil:undefined

Treatment	value	label
CIC	8003	8003
Patient	24	24
Treatment date	2015/12/03 00:00	2015/12/03 {exact}
Treatment record qualifier (manual)		
Date precision		
Date precision (manual input, see note)	0	exact date
Event		
Context (manual input, see note)	7	

Context (manual input, see note)

2	Non graft treatment
4	Collection
7	Hematopoietic stem cell transplant
14	Support / Boosts
17	Donor lymphocyte infusion
18	Cell therapy (non HSCT/DLI)

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



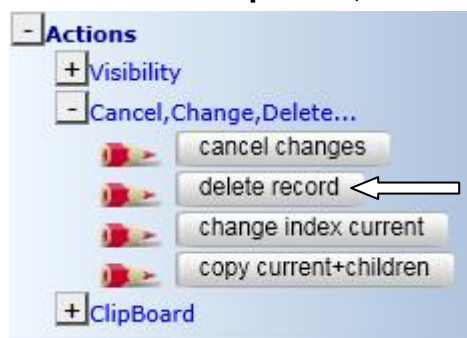
If there is another record associated with the revised date, remember to change this at the same time. For example an assessment for HSCT will have been created automatically and it will have the same date as the HSCT date before it was revised. This will often be true for other events e.g. when changing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

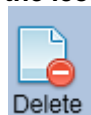
Record Locator

- Patient [8003] 24
- Diagn 2012/05/01 [Main indication diagnosis]
- Asse1 2012/05/01 [Main indication diagnosis]
- Treat 2015/12/03 [HSCT]
 - Drug Carboplatin
 - Drug Etoposide / VP16
 - Asse1 2015/12/30 [HSCT]

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

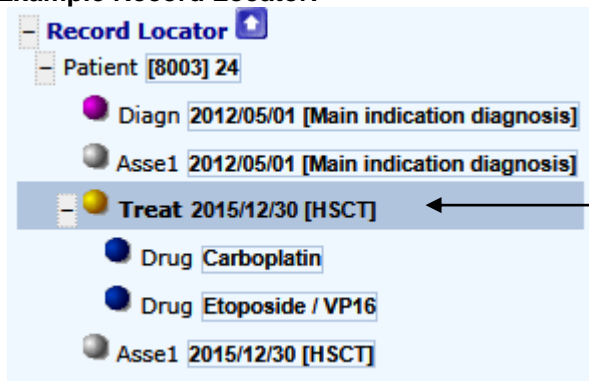


If you have registered a record by mistake, it is possible to delete the entire patient record or a subset of records for a patient, by clicking the option [delete record] in “Actions”, or by using the icon above the Record Locator:



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.

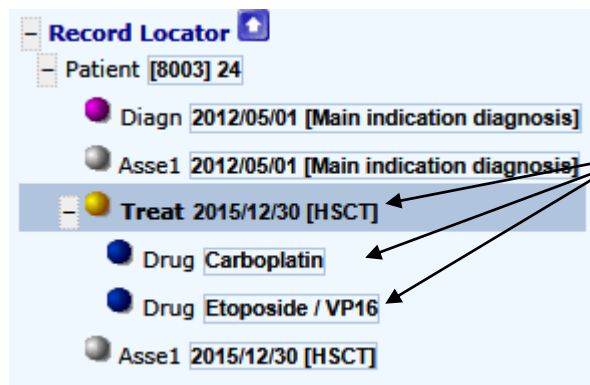
Example Record Locator:



When records are selected they will be highlighted with a darker blue

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.)

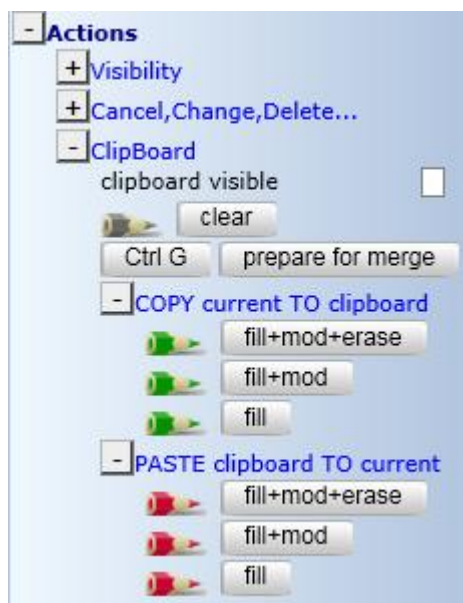


Delete this Treatment (and associated drugs) by highlighting the record and clicking the action [delete record], or the delete icon, as indicated above

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

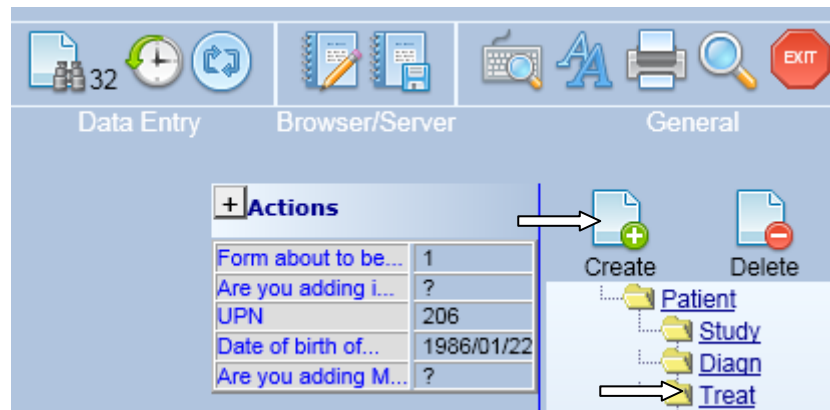
fill+mod: this will copy and replace only filled items

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

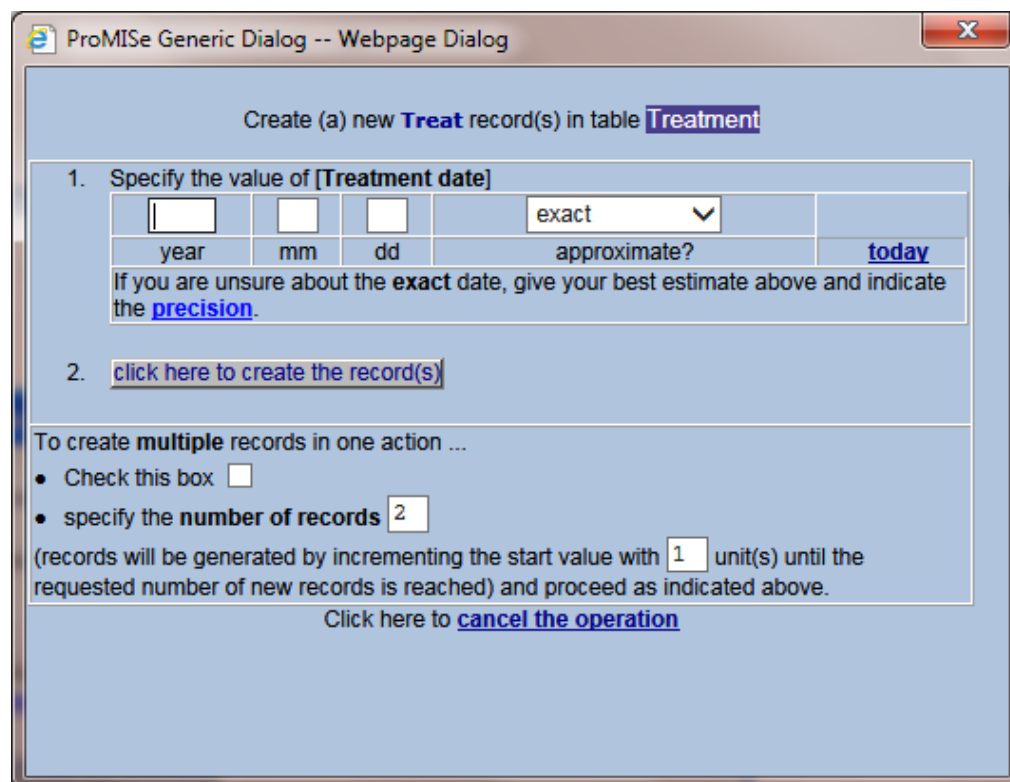
You may wish to create new records manually if, for example, you need to enter additional data to an existing MED-A or B registration. You can create records to register data that is not requested in the MED-AB forms. For example, the EBMT is not requesting the data at this timepoint but you need to 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 imperative that you enter this code. For example, a new record for a non transplant treatment must be coded as '2' non graft treatment:

Data Entry Report Export Help Filter [8001][DEMO][City_1]

Resume with the **first** item in the **current** section by pressing **Tab** (or click on any other item)

Index Editor Overview DynFile:27:Aplastic anaemia

Treatment	value	label
CIC	8001	8001
Patient	1220	1220
Treatment date	2012/01/01 00:00	2012/01/01 00:00:00
Treatment record qualifier (manual)		
Date precision		
Date precision (manual input, see note)	0	exact date
Event		
Context (manual input, see note)	2	

Context (manual input, see note)

2	Non graft treatment
4	Collection
7	Hematopoietic stem cell transplant
17	Donor lymphocyte infusion
18	Cell therapy (non HSCT/DLI)

IMPORTANT
You **MUST** use this field if you have created the record manually.
You can also use it to make a correction to the context of this treatment *a posteriori*.

Actions

Form about to be...	1
Are you adding i...	?
UPN	206
Date of birth of...	1986/01/22
Are you adding M...	?

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:

Data Entry Report Export Help Filter [8001][DEMO][City_1] 16:08

Index Editor Overview DynFile:27:Aplastic anaemia

Treatment	value	label
CIC	8001	8001
Patient	1220	1220
Treatment date	2012/01/01 00:00	2012/01/01 00:00:00
Main treatment		
Collection		
General		
Preparative (conditioning) treatment		
Regimen intended to be myeloablative (full intensity)		
Reason for non myeloablative (reduced intensity) regimen		
Other or additional reason for non myeloablative		
Sequential number of this treatment		
Reason for this treatment		
Other reason, specify		
Drugs / chemo and TBI		
Date conditioning chemo started	2	
TBI		
Total body irradiation, details		
Date conditioning TBI started		
CIC Radiophysics group		
Hospital of radiophysicist group		
Radiophysicist unit		
Radiophysicist phone/fax		

Drugs or chemotherapy

1	No
2	Yes
99	unknown

Actions

Form about to be...	1
Are you adding i...	?
UPN	206
Date of birth of...	1986/01/22
Are you adding M...	?

Record Locator

Patient [8001] 1220

- Diagn 2006/01/01 [Main indication diagnosis]
- Asse1 2006/04/20 [HSCT]
- Asse1 2006/08/01 [Alive]
- Treat 2006/10/20 [HSCT]
- Donor 1
- Treat 2012/01/01

Chapters & Sections

- Treatment identification & administr
- Treatment record qualifier (manual)
- General
- Transplant and cell source specifics
- Ex-vivo graft manipulation
- Main treatment

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:

Data Entry Report Export Help Filter [8001][DEMO][City_1] 16:10

Index Editor Overview DynFile:27:Aplastic anaemia

Treatment	value	label
CIC	8001	8001
Patient	1220	1220
Treatment date	2012/01/01 00:00	2012/01/01 00:00:00
Treatment related to complications		
GvHD prevention & immunosuppression		
GvHD prevention in the patient		
Drugs or chemotherapy (immunosuppression)		
Extracorporeal photopheresis (ECP)		
Other therapy for GvHD prevention		
Other GvHD prevention: specify		
Treatm for failure or complications		
Growth factor for failure or complications		
Subsequent transplant for failure or complications		
Type of transplant used for failure or complications		
Date subsequent transplant		
Autologous PBSC re-infusion (not transplant)		
Autologous BM re-infusion (not transplant)		
Other treatment for failure or complications		
Other treatment for failure or complications: specify		
Treatment for aGvHD		
Treatment for aGvHD		
Chemoidrug treatment for aGvHD (including MoAB, etc)		
Other treatment for aGvHD		
Other treatment for aGvHD: specify		

Treatment for failure or complications

1	No
2	Yes
99	unknown

Actions

Form about to be...	1
Are you adding i...	?
UPN	206
Date of birth of...	1986/01/22
Are you adding M...	?

Record Locator

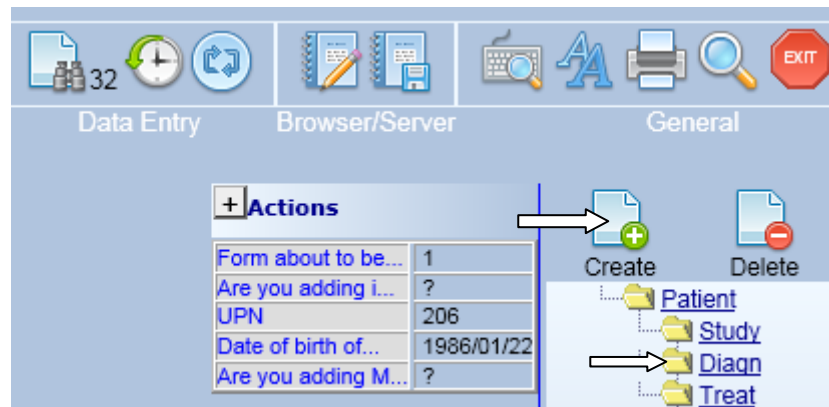
Patient [8001] 1220

- Diagn 2006/01/01 [Main indication diagnosis]
- Asse1 2006/04/20 [HSCT]
- Asse1 2006/08/01 [Alive]
- Treat 2006/10/20 [HSCT]
- Donor 1
- Treat 2012/01/01

Chapters & Sections

- Treatment identification & administr
- Treatment record qualifier (manual)
- General
- Transplant and cell source specifics
- Ex-vivo graft manipulation
- Main treatment
- Hospital admin (STAEMT)
- Supportive treatment in the patient
- Cellular therapy (non HSCT)
- Treatment related to complications
- GvHD prevention & immunosuppression
- Treatment for failure or complications

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).

The dialog box is titled 'ProMISe Generic Dialog -- Webpage Dialog'. It contains the following sections:

Create (a) new **Diagn** record(s) in table **Diagnosis**

1. Specify the value of [Diagnosis date]

<input type="text"/>	<input type="text"/>	<input type="text"/>	exact <input type="button" value="v"/>	
year	mm	dd	approximate?	today

If you are unsure about the **exact** date, give your best estimate above and indicate the [precision](#).

2. [click here to create the record\(s\)](#)

To create **multiple** records in one action ...

- Check this box ☐
- specify the **number of records**

(records will be generated by incrementing the start value with unit(s) until the requested number of new records is reached) and proceed as indicated above.

[Click here to cancel the operation](#)

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 imperative 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:

Data Entry Report Export Help Filter [8001][DEMO][City_1]

Resume with the **first** item in the **current** section by pressing **Tab** (or click on any other item)

Index Editor Overview

Diagnosis	value	label
CIC	8001	8001
Patient	1220	1220
Diagnosis date	2004/01/01 00:00	2004/01/01 00:00:00
Diagnosis record qualifier (manual)		
Date precision		
Date precision (manual input, see note)	31	This month
Event		
Type (manual input, see note)	16	

Type (manual input, see note)

1 Main indication diagnosis
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

Data Entry Report Export Help Filter [8003][DEMO][City_2]

Index Editor Overview

Assessment(1)	value	label
CIC	8003	8003
Patient	34	34
Assessment date	2014/02/03 00:00	2014/02/03 (exact)
Diagnostics		
MDS / MPS / CLL / Hgbpthy class		
MDS WHO classification	16 RA	with excess of blasts-1 (RAEB-1)
MDS, CMML or JMML FAB classification	30 RA	with excess of blasts (RAEB)
MD-MP overlay syndromes WHO classification		
Involvement & bone investigations		
Immunophenotyping/histochemistry		
Cytogenetics and molecular markers		
Chromosome analysis	1	
Complex karyotype: Are there 3 or more abnormalities		
Molecular or other type of markers		
Haematological values		
Haematology, other		
Biochemistry		

Note: Cytogenetics at diagnosis

Chromosome analysis

1 Normal
2 Abnormal
3 Not done/Failed
99 unknown

Actions

- + Visibility
- + Cancel, Change, Delete...
- + Clipboard

Form about to be... Med-A: Day 0

Are you adding M... ?

UPN ?

Date of birth ?

Are you adding M... ?

Record Locator

Patient [8003] 34

Diagn 2014/02/03 [Main indication diagnosis]

Asse1 2014/02/03 [Main indication diagnosis]

Treat 2015/12/01

Asse1 2015/12/01 [HSCT]

Chapters & Sections

- + Investigations identifiat & admin
- + Assessment record qualifier (manual)
- + Diagnostics
- + Diagnostics (cont.)
- + Physical examination
- + History of disease and treatment

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

The screenshot shows the MED-AB software interface. On the left, the 'Index' tab is active, displaying a list of fields for a patient record. The 'TBI' field is highlighted. In the center, a 'Message from webpage' dialog box is displayed with the text: 'Click OK if you want to enter the TBI Form now, otherwise click Cancel'. On the right, the 'Record Locator' tab is active, showing a list of records. The 'Treat 2006/10/20 [HSCT]' record is selected. Below the 'Record Locator', the 'Chapters & Sections' tab is active, showing a tree view of the record structure. The 'Main treatment' section is expanded, and the 'TBI' field is highlighted. The 'Form about to be entered' field is set to '4' (Med-B Day 0).

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.

3. Click [Horizontal Layout] for an overview of data registered for a patient

1. Click on the ID number to mark your patient

2. We recommend that you check "show headers" when viewing the patient data

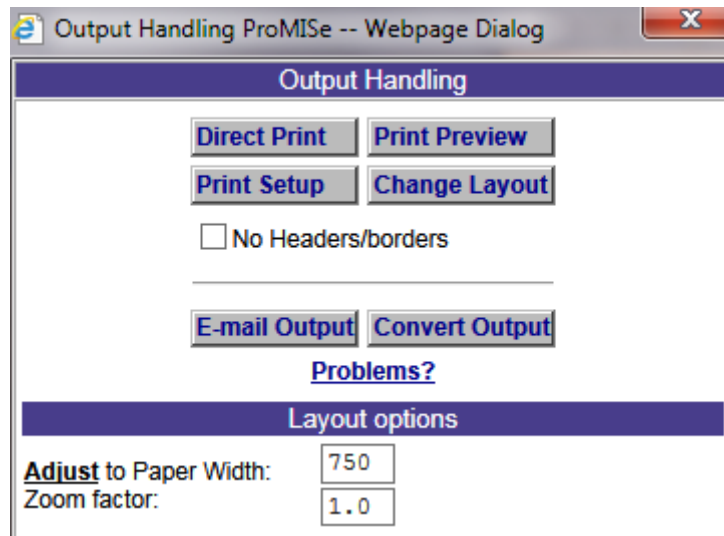
CIC	Patient	Centre i...	Last modificatio...	UPN	Date of bi...	Sex of t...
8001	28		2014/11/12 11:44			
8001	52		2012/06/15 15:22		1809/09/09	Male
8001	62					
8001	94		2011/02/15 11:00		02/02	Male
8001	145		2014/03/31 16:20		04/04	Female
8001	190		2008/04/01 14:00		01/01	Male
8001	248		2007/04/16 15:40		06/06	Male
8001	256		2009/04/15 12:12	455	1950/04/04	Female
8001	294		2014/03/25 14:01	dfg	1990/01/01	Male
8001	308		2012/12/18 10:51	QS		
8001	319		2007/10/01 16:44	351	1960/07/07	Male

You will have an Overview of the saved data. Press the print icon

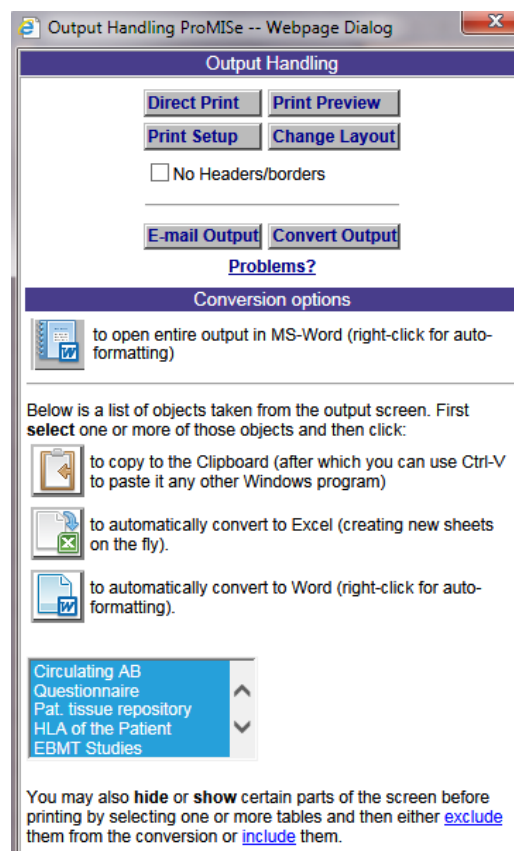
Print icon

Patient	
ID and admin	
Patient identification	
CIC	8003
Patient	181
Database administration	
Country	NL Kingdom of the Netherlands
Record creation date	2012/02/07 15:54:00
Last modification	2012/02/07 16:03:00
(SQL Server autonumber field)	28346
Patient data	
Form information	
Form about to be entered	11 HSCT MED-A registration
Patient information	
Centre	8003 City_2 (TC2)
Unit or team	Adult
Contact person	Durand
Date of the 1st report	2007/12/27
Patient in nat / international study / trial	1 No
UPN	8328
1st initials	P
2nd initials	C
Date of birth	1995/04/23
Sex	2 Female

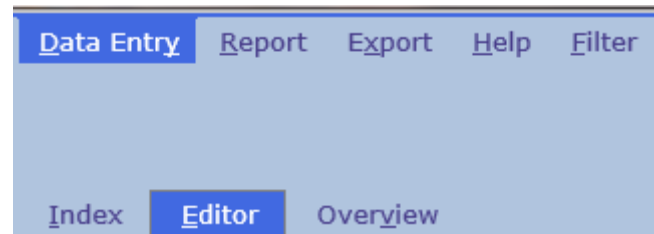
Your patient overview will be transferred to the Output window after you press the Print icon or shortcut Ctrl-Alt-P. If you want to check how the data will print you can first select [Print Preview] in the Output handling window, before pressing [Direct Print] :



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 be selected, or you can opt to select only parts of the overview to be converted):

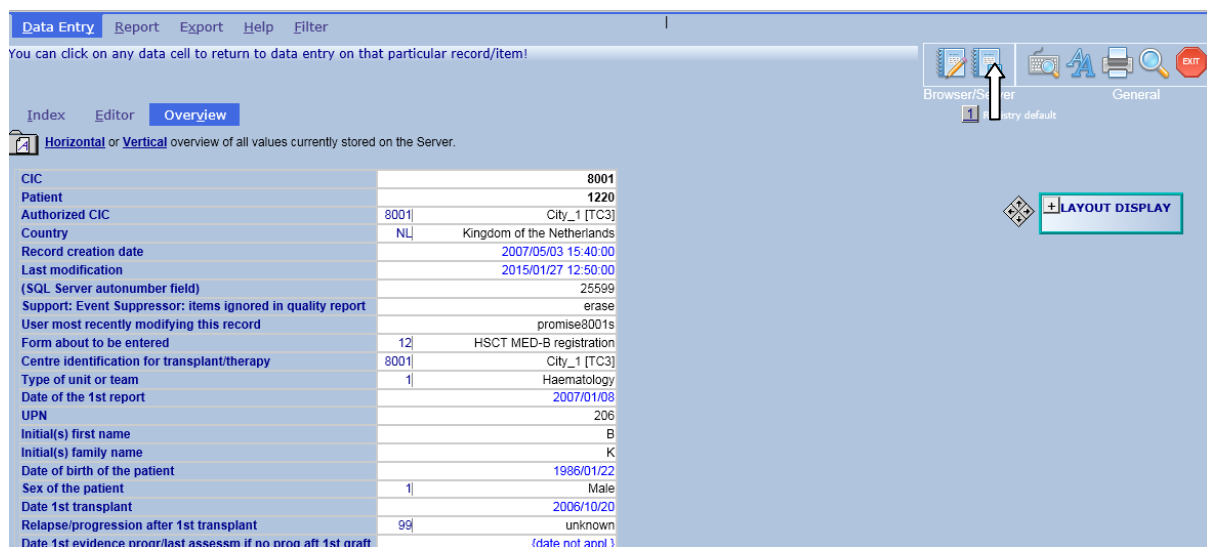


Viewing and Printing Individual Patient Data from the Editor



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 [MED-A Merge program \(MS Office 2007\)](#) . Please contact registryhelpdesk@ebmt.org 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.

Example Screen of the Online Project Dictionary:

Labelset number: Click on it to view the set of labels & codes for each item

Item Name

TAG	TABLE	LABEL	NAME	TYP COD	EXTRA	KEY LEN	MIN	MAX	MIS1	MIS2	DEC	HELP	L	T	W	J	A	C	N	J	L	R	I	X	LONG LABEL
AA0A	CHAPTER	SECTION																							
AA0A1A1			Centre identification for transplant/therapy	CENTRNR	I	1002		4		9999							A					4			CIC of centre involved in the last treatment being registered
AA0A1B1			Name of unit or team	UNIT	T			40									A								Unit or team involved in the last treatment being registered
AA0A1C1			Type of unit or team	TEAMTYPE	I	51		2									A								Type of unit or team
AA0A1D1			Contact person	MEDNAME	T			20									A	2							Contact person
AA0A1E1			Area code where patient lived at time of HSCT (optional)	VADMIN10	T			16									A	1	1						Area code where patient lived at time of HSCT (optional)
AA0A1F1			Date of the 1st report	DAT1STRE	D			10									A	1							Date of the 1st report
AA0A1G1			Date of the last report	DATLSTRE	D			10									A	1	3						Date of the last report
AA0A1L1			Patient in nat / international study / trial	TRIAL	I	1		2		99							A	5		1	1				Patient in nat / international study / trial
AA0A1M1			UPN	UPN	T			24									A	2	1	5		1	2		Unique Patient Number (UPN) assigned to the patient in the centre where the last transplant took place
AA0A1N1			Patient dossier number (Optional)	VDOSIER	T			80									A								Patient dossier number (Optional)
AA0A1O1			Initial(s) first name	GNNAME	T			24									A	1							Initial(s) first name
AA0A1P1			Initial(s) family name	FAMNAME	T			25									A	1							Initial(s) family name

**Tag
(for
office
use only)**

**Item Label /
Description**

**Field Type
e.g
I (Integer) –
numeric
value; T(Text)**

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 [interactive browser configuration checker](#). The following page will appear





ProMISe		ProMISe setup and requirements tests		
Run the Tests		Show my IP number	Test Sound	
Test	Status	Minimal Required Value	Detected Value	Information and Setup Instructions
Screen Resolution		1024 * 768	<input type="text"/> pixels	Change the screen resolution and Change IE zoom
Browser Type and Version		Internet Explorer 9/10/11	<input type="text"/> browser version <input type="text"/>	Download Internet Explorer Limited support IE8 until 2017/01/01 Fix default IE7/IE8 mode
Trusted site Promise		*.clinicalresearch.nl / *.lumc.nl trusted	<input type="text"/>	Add *.clinicalresearch.nl and *.lumc.nl to your trusted sites
IE Cache Size		between 50Mb and 500Mb	<input type="text"/> Mb	Setup IE Cache
IE Cache Refresh		every start or every visit	<input type="text"/>	Setup IE Cache
Can open new window		www.clinicalresearch.nl not blocked	<input type="text"/>	Popup windows for www.clinicalresearch.nl must be allowed. Check any popup-blocker such as IE popup blocker , the Google bar , the Yahoo toolbar , etc
Excel 2016 macro security		Allow macros and trust access to VBA project	<input type="text"/>	Allow macros and trust access to VBA project
Excel 2013 macro security		Allow macros and trust access to VBA project	<input type="text"/>	Allow macros and trust access to VBA project
Excel 2010 macro security		Allow macros and trust access to VBA project	<input type="text"/>	Allow macros and trust access to VBA project
Excel 2007 macro security		Allow macros and trust access to VBA project	<input type="text"/>	Allow macros and trust access to VBA project
Excel 2003 macro security		Allow macros and trust access to VBA project	<input type="text"/>	Allow macros and trust access to VBA project
Windows Auto Update		Be notified, and install updates	<input type="text"/>	Install windows updates and configure automatic update
Processor		Intel Core i3/i5/i7 or AMD Athlon 64, > 1 GHz	Speed <input type="text"/> GHz	
Memory		> 1 Gb	<input type="text"/> Gb	
Windows Version		Windows Vista, Windows 7, Windows 8 or Windows 8.1, Windows 10	Version <input type="text"/> Service pack <input type="text"/>	
Internet Speed		Minimum: 256 kbps Recommended: 1024 kbps	<input type="text"/> kbps	

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:

ProMISe		ProMISe setup and requirements tests		
Run the Tests		Show my IP number	Test Sound	
Test	Status	Minimal Required Value	Detected Value	Information and Setup Instructions
Screen Resolution		1024 * 768	1440 * 900 pixels	Change the screen resolution and Change IE zoom
Browser Type and Version		Internet Explorer 9/10/11	IE 11.0 on Windows 10 browser <input type="text"/> version <input type="text"/>	Download Internet Explorer Limited support IE8 until 2017/01/01 Fix default IE7/IE8 mode
Trusted site Promise		*.clinicalresearch.nl / *.lumc.nl trusted	Unknown	Add *.clinicalresearch.nl and *.lumc.nl to your trusted sites
IE Cache Size		between 50Mb and 500Mb	Unknown Mb	Setup IE Cache
IE Cache Refresh		every start or every visit	Unknown	Setup IE Cache
Can open new window		www.clinicalresearch.nl not blocked	Ok	Popup windows for www.clinicalresearch.nl must be allowed. Check any popup-blocker such as IE popup blocker , the Google bar , the Yahoo toolbar , etc

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

Status symbols		
	unacceptable	Your PC is not configured correctly or does not meet the requirements!
	sufficient	Sufficient to use the ProMISe system, but can be improved
	normal	Your PC is correctly configured and meets the requirement.
	unknown	The setting could not be determined. Test this requirement manually with the Information and Setup instructions. <i>Remark: This could mean the software is not installed and the settings does not apply for your computer</i>

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 [interactive browser configuration checker](#)

If you cannot log in with your username and password, or you experience any problems after trying the above, please contact the [Registry Helpdesk](#) and give details of the error message or provide a screenshot.

***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.

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.

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 [ProMISe 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