
# MACRO User Guide – Data Entry Module


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# Contents

# Introduction

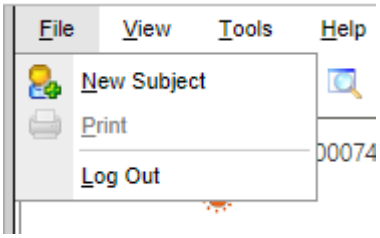
Welcome to the MACRO User Guide. MACRO is the database that the EBMT Registry is using to record clinical data, including aspects of the diagnosis and disease, first-line treatments, HSCT or cell-therapy-associated procedures, transplant type, donor type, stem cell source, complications and outcome. For instructions on how to get a MACRO User Account, please refer to our website, under The Registry / Data Submission: https://www.ebmt.org/registry/data-submission

**Logon page**'s link: https://eu1.macroedc.com/ebmt

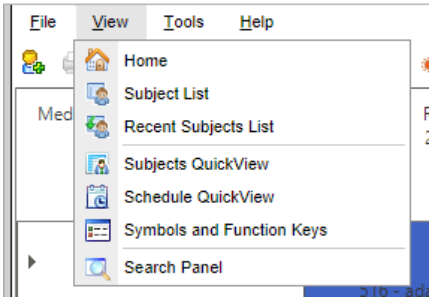
# Introduction to MACRO environment

## Menu Bar (drop down menus)

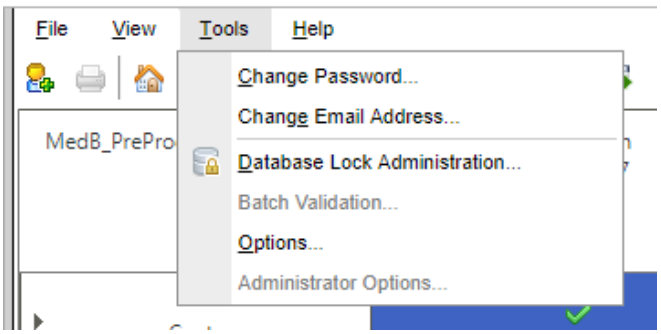
The Menu Bar is consisted of 4 options:

FILE 


The New Subject and the Print buttons can also be found in the Toolbar. PLEASE NOTE: there will be more options here, once inside a Subject (in relation to Save and Move between forms).

VIEW 

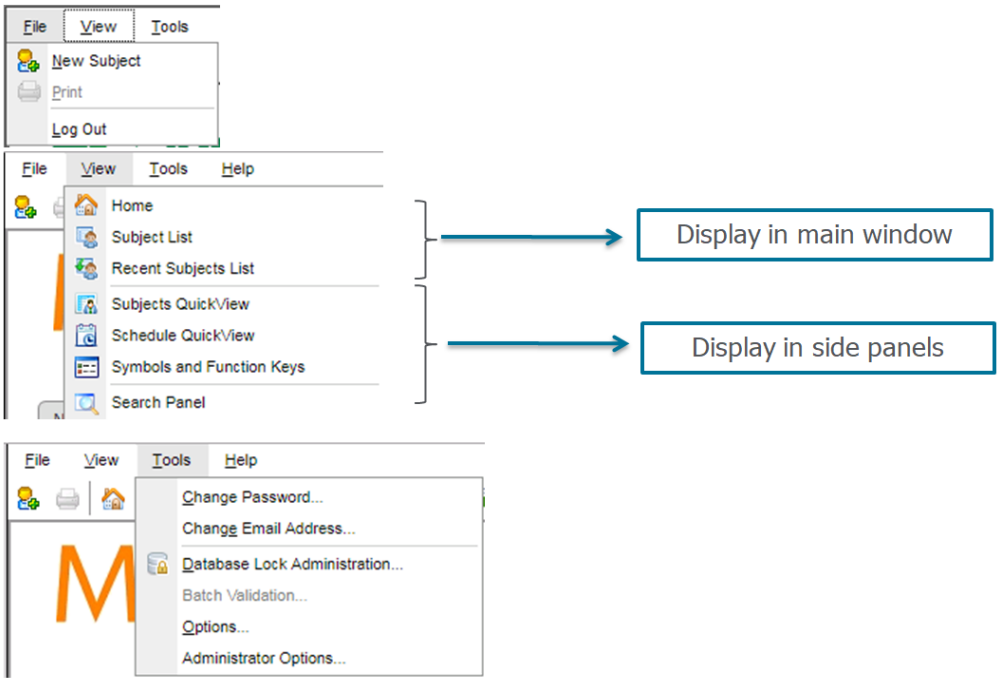
All of the available options above can also be found in the Toolbar (see Toolbar chapter below).

TOOLS 


PLEASE NOTE: none of the Tools options can be found in the Toolbar.

HELP 


The Help-Index can only be found in the above location. (PLEASE NOTE: MACRO help refers to radio buttons as "*option* buttons")



## **Toolbar** (where the Function Buttons are found)


You can hover over icons to see their descriptions. From left to right, the **Function Buttons** are:

- Create a new study subject
- Print the current screen
- Open your Home Page
- Open the Subject List page
- Open the Recent Subjects List page
- Open the Search Panel
- Open the Data Reporter
- Open the Subjects QuickView panel
- Schedule QuickView
- Symbols and Function Keys
- View Missing Data (n) {n= number of missing items}
- View planned SDVs (n) {n= number of planned SDVs}
- View queried SDVs (n) {n= number of queried SDVs}
- View raised DCRs (n) {n= number of raised SDVs}
- View responded DCRs (n) {n= number of responded SDVs}
- Recipients (Entire caseload that can be filtered by field(s))

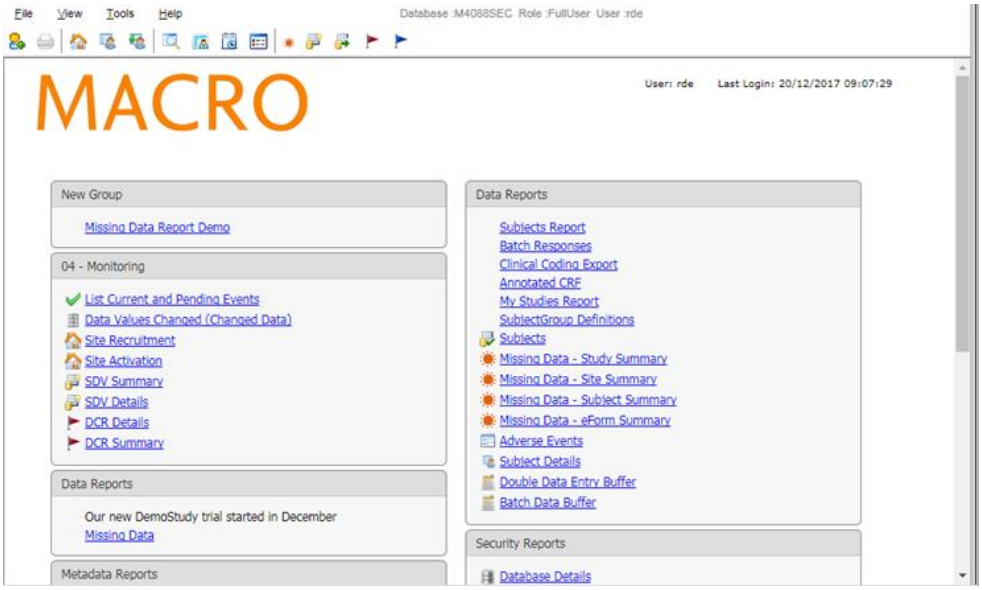
PLEASE NOTE: once you load a subject in MACRO, there will be more options available to you in the **Toolbar**, which are related to Data Entry:


which can also be found in the Menu Bar under FILE.

## **Home page** and available **Reports** (simple listings, quality reports, etc.)

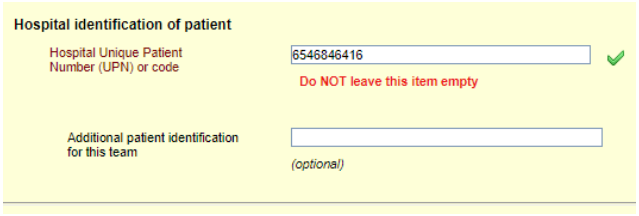
You can access the Home Page by clicking on the Home Button in the Menu Bar: 


*or* under **VIEW** in the Menu Bar. On the Home Page you can find a variety of useful reports in the form of hyperlinks.




## Forms' **colour coding** scheme

The Forms in MACRO are coloured coded, which means that you can tell what type of form you are filling in by its colour (for example, a certain Form is always one particular colour, regardless of which Visit it appears). The same stands for the Questions' font colour inside the forms (for example, mandatory questions appear in Dark Red, section headers are in Blue, etc.)




Please see all fonts appearing in MACRO below:

| | Description | Font (Type Face) | Style | Appearance |
|---|---|---|---|---|
| 1 | Form header 01/ Section headers Lvl 1 | Arial | Bold | Header 01 |
| 2 | Form header 01/ Section headers Lvl 2 | Arial | Bold | Header 01 |
| 3 | Form header 02/ Section sub-headers | Arial | Bold | Header 02 |
| 4 | Form question entries (responses) | Arial | Regular | Lymphoma |
| 5 | Optional Question (Q)caption (default) | Arial | Regular | Source |
| 6 | Derived Q style | Arial Black | Bold | Active |
| 7 | RQG captions | Arial | Bold | RQG caption |
| 8 | RQG Preset Core Questions font | Arial Black | Bold | Epirubicine |
| 9 | Hidden Q caption | Arial | Regular | Hidden |
| 10 | Mandatory Q caption | Arial | Regular | Mandatory |
| 11 | Derived Q caption | Arial | Regular | Derived |
| 12 | Form/ question comments | Arial | Italic | *Comments* |
| 13 | General/ Status Instructions | Arial | Bold | Active |
| 14 | Dynamic navigation information | Arial | Bold | Instruction |
| 15 | Dynamic navigation instructions | Arial | Bold | Instruction |
| 16 | Dynamic navigation caption | Arial | Bold | Instruction |
| 17 | Category list value | Arial | Regular | Value |
| 18 | Category list caption | Arial | Regular | Caption |
| 19 | Hyperlinks | Arial | Italic | *Study links* |

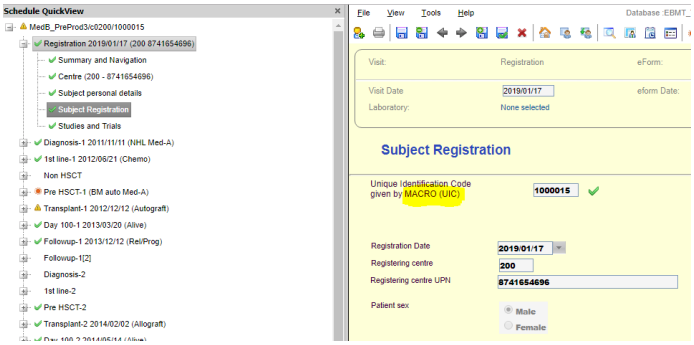
# How to search for an existing Subject (patient)

## Uniqueness Check

It is crucial to search for existing patients before starting your data entry. This is in order to avoid duplicating registrations. There is an inbuilt **Uniqueness Check** in Macro, which is a mechanism that reduces the risk of users creating duplicate subjects. However, we do recommend that you do a *Search* before you create a new subject. The questions that are related to the Uniqueness Check will have a font colour of their own (as per the Colour Coding Scheme above). The items that are being examined are: Date of Birth, Initials, UPN, Gender, HSCT Date, Country and CIC.

## Basic Terminology

The way to refer to patient records in MACRO is by using their "**Subject Label**", which is a *unique* number allocated to a patient record by the database the moment you first create a new subject ("Subject" = Patient Record). The Subject Label carries no information on the site or the subject, and can therefore be used as a *pseudonymised* key.




The **Subject ID** is *another unique* number that is incrementally increased, again allocated by the database, **but for each Site**. For example, the record 1234 could exist both for Site 222 and for Site 333. The Subject ID can be used to identify patient records, but *only* at a Site level.

PLEASE NOTE: the way that a patient record appears in data entry is by including the Study, the Site and the Subject Label.

The **UPN** stands for Unique Patient Number (or Hospital Number), which is the number allocated to patients by the centres (sites) where they were treated, and it is used as one of the basic identifiers of a patient (mandatory field in MACRO).

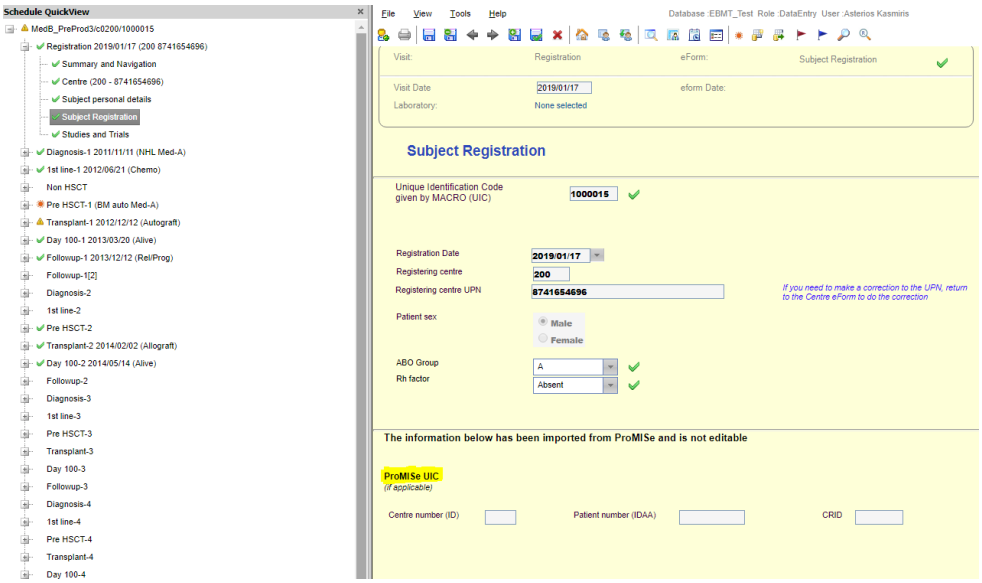
The **Study** is the way MACRO refers to what the EBMT is calling a Registry, meaning the database's project that has all the information on patient disease and treatment. The EBMT has 2 studies in MACRO: the patients' "study" and the donors' "study". (NOT to be confused with a Clinical Study (=trial) a patient may be participating in)

The **Subject Group** (Virtual Registry) is the way MACRO is *logically grouping* records, either of patients or of donors (depending on the Study), with a certain characteristic in common (e.g.: the same country for National Registries, the same disease for Working Parties, the same age for Paediatrics or for Adults, etc.). These are assigned via User Roles (Data Entry, Administrator, etc.).

The **Site** is the way MACRO refers to hospitals/centres performing treatments.

The **CIC** stands for Centre Identification Code and is a unique number allocated to sites/hospitals by the EBMT as an identifier of the centre.

The **ProMISe UIC** is the old patient number allocated to a patient record by the EBMT's previous database Promise, and it stands for Unique Identification Code (UIC). The UIC is relevant only to patient records that existed in the old database Promise and got migrated over to MACRO. For records that have been migrated from the previous database Promise, the number will be read-only at the bottom of the "Subject Registration" form:



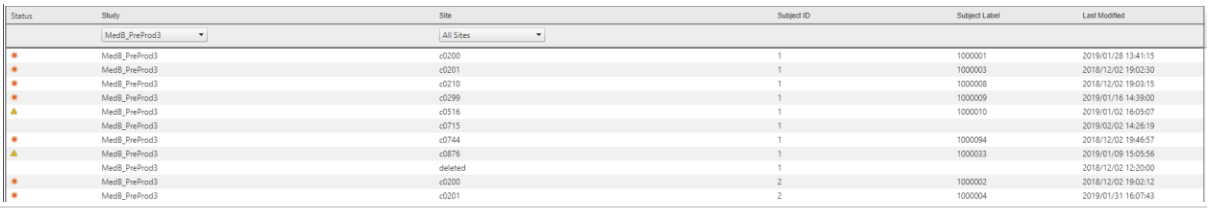

[Regarding any of the concepts described above, please refer to MACRO help.]

## How to **Search** for a subject / How to **Filter** your caseload / Quick access to subject records, including ***recent*** **subjects list** page

There are several ways/icons in MACRO by which you can **view** your caseload and **search** for subjects with certain characteristic(s). You can try them all and see what serves your purpose best.

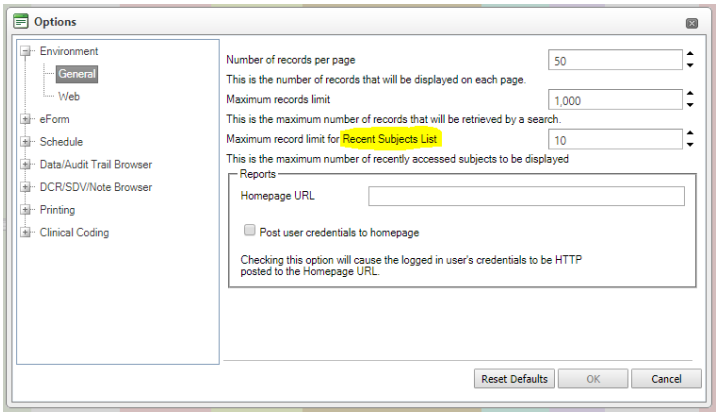
One way to **view** your caseload is to click on the button **Subject List** page:


which will open a list that shows the following pieces of information (subject per row):



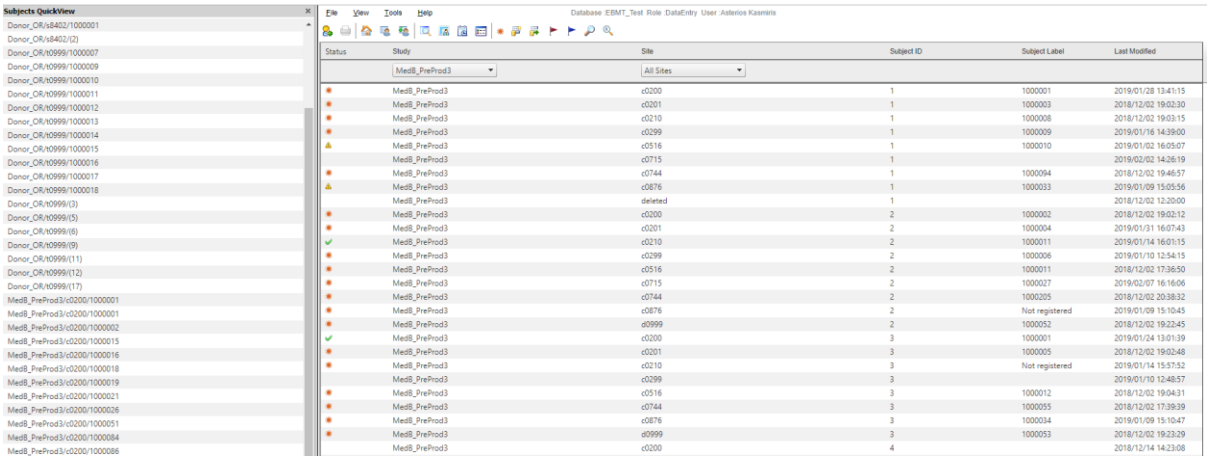
On the right side of the button above, you can find the same button, but with a green arrow pointing downwards, which is called **Recent Subject List** page (another way to **view** subjects):


This will load the 10 most recent subjects you have accessed. This number can be changed in your settings under Tools-Settings, according to your preferences:



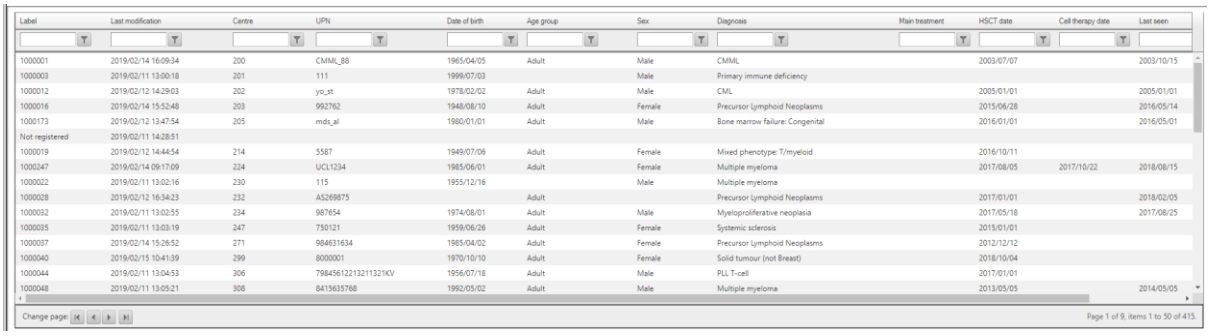

If you click on the icon below, which is called **Subject QuickView** panel:


a side panel appears on the left hand side (another way to **view** your subjects), that lists all your subjects for quick access, as shown below:



There is a variety of ways to **search** for subjects with certain characteristic(s). The one called **Recipients**, is found on the right hand side of the toolbar and is a magnifying glass with the letter R inside:


This is an *Index* of your entire caseload with the facility of performing a **search** by using subjects' main identifiers, such as subject label, date of birth, gender, diagnosis, HSCT date, etc.



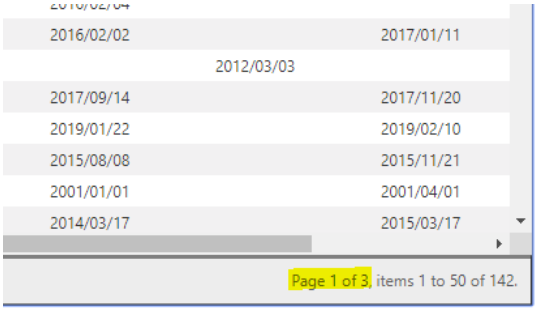
You can use it by typing on any of the items listed on the top row, and then pressing Enter. You can type only *part* of the label you are looking for, like for example in the Diagnosis, you can type "ML" and you will get in your results AMLs, CMLs, CMMLs, JMMLs, etc. as shown below:

| Date of birth | Age group | Sex | Diagnosis |
|---|---|---|---|
| | | | ML |
| 1965/04/05 | Adult | Male | CMML |
| 1978/02/02 | Adult | Male | CML |
| 1980/01/01 | Adult | Male | AML & Related Precursor Neoplasms |
| 1950/01/01 | | Male | AML & Related Precursor Neoplasms |
| 1965/08/15 | Adult | Female | CMML |
| 1965/04/05 | Adult | Male | JMML |
| 1965/05/02 | Adult | Male | JMML |
| 1965/04/05 | Adult | Male | AML & Related Precursor Neoplasms |

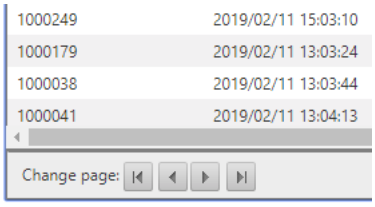
What is more, you can use more than just one item to filter your results even more. For example, in the search above, you can add the Sex filter as well (typed simply "fe" for females):

| Date of birth | Age group | Sex | Diagnosis |
|---|---|---|---|
| | | fe | ML |
| 1965/08/15 | Adult | Female | CMML |
| 1989/06/05 | Adult | Female | AML & Related Precursor Neoplasms |
| 1981/12/17 | Adult | Female | CML |
| 1956/07/08 | Adult | Female | CML |
| 1956/01/05 | | Female | AML & Related Precursor Neoplasms |
| 1989/06/05 | Adult | Female | AML & Related Precursor Neoplasms |
| 1965/10/20 | Adult | Female | CML |
| 1965/10/20 | Adult | Female | CML |
| 1981/12/17 | Adult | Female | CML |
| 1958/04/02 | Adult | Female | AML & Related Precursor Neoplasms |
| 1965/10/20 | Adult | Female | CML |
| 1989/06/05 | Adult | Female | AML & Related Precursor Neoplasms |
| 1964/11/05 | | Female | AML & Related Precursor Neoplasms |
| 1988/09/05 | Adult | Female | JMML |

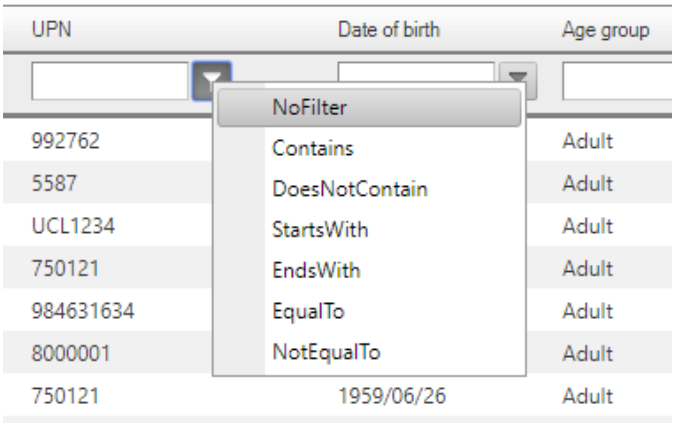
PLEASE NOTE: if your search's results are many, they will appear in many pages. You can see the number of pages produced at the bottom-right corner:




and you can navigate through the pages by clicking on the arrows on the bottom-left corner:



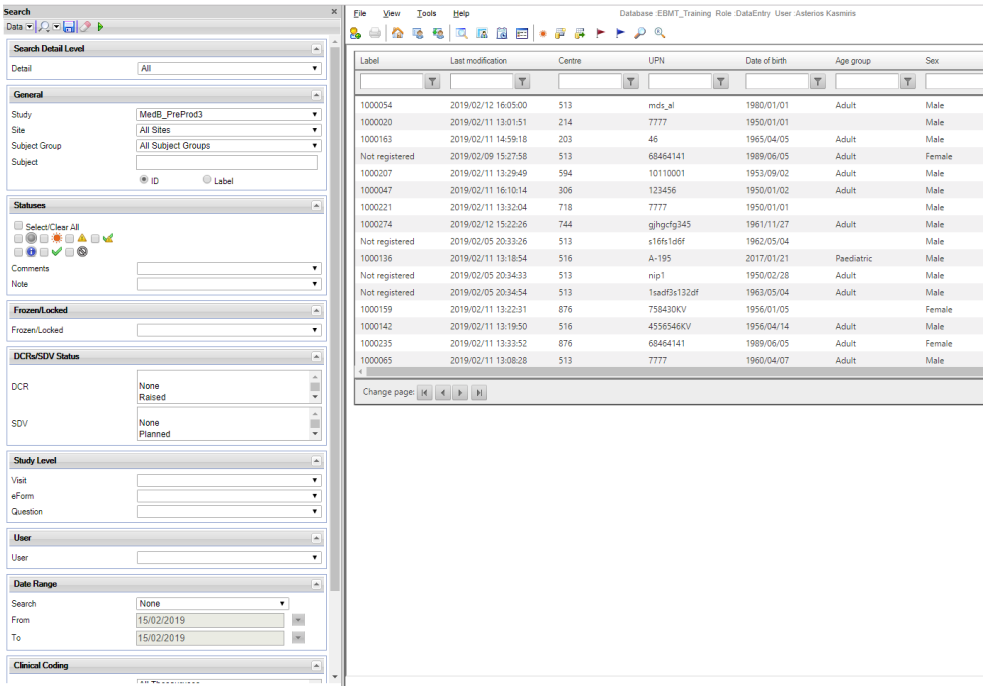

Another useful feature this search offers is the available options you get when you click on the funnel (Filter icon) found on the right side of each of the items:




For example, if you know the subject you are looking for was born 2010, but you do not know the month and day, you can type “2010” in the Date of Birth and select StartsWith. (Note that the dates’ format is always yyyy/mm/dd)

Another way to **search** for subjects with specific characteristics is by clicking on the icon called **Search Panel**, as shown below:

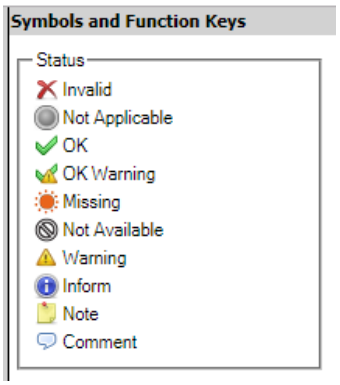

which opens a side panel on the left hand side of the screen:



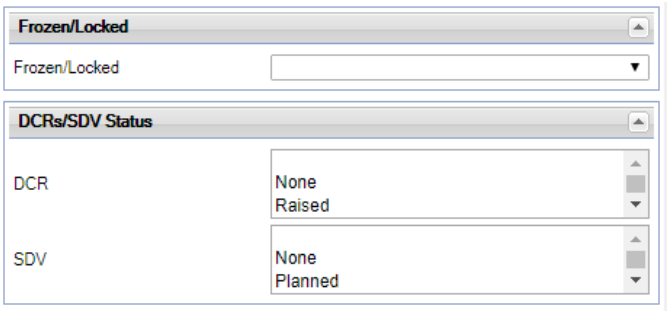

This MACRO inbuilt search function is to be used in particular when you are looking for subjects with a certain **Status**. As you can see below, there is section where you select the type of Status you are interested in (e.g.: Missing, Warning, OK Warning, etc.):


You can also search for subjects that have **Comments** or **Notes**. (For more on these please see chapter “Types of Questions” in this guide)

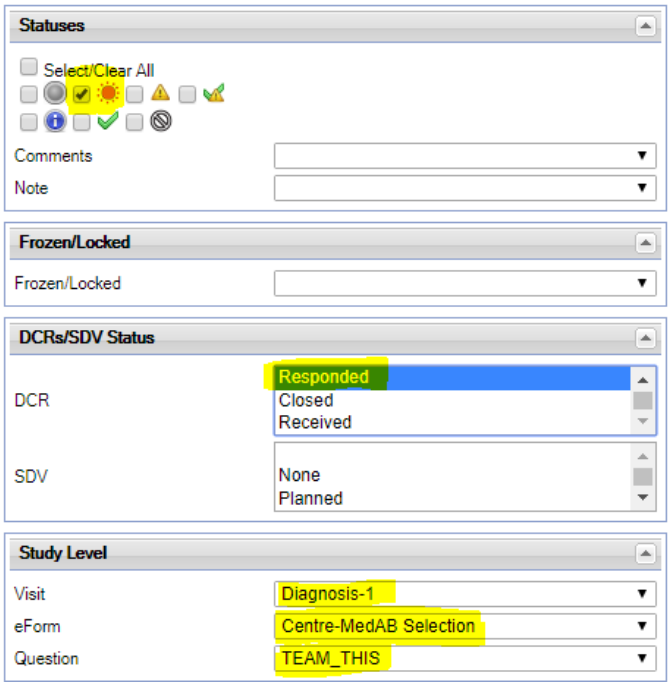
Possible indications for a Question’s **Status**:




Further down on the same panel, you can search for subjects that are Frozen or Locked, or that have DCRs or SDVs in them:

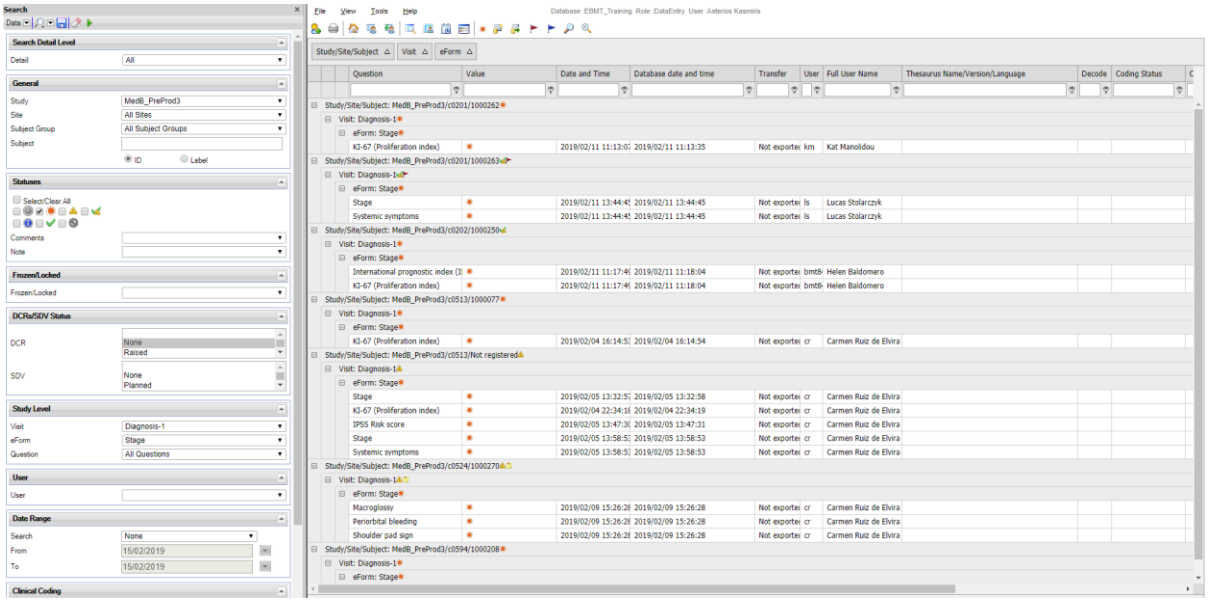



Of course, you can use combinations of these. For example, you can search for specific Visits or Forms that have at least one Missing item, or an unanswered DCR, or are Frozen or Locked:




After you select your criteria, you click on the green arrow pointing right, on the top of this panel:


and the results will appears on the main screen to the right:

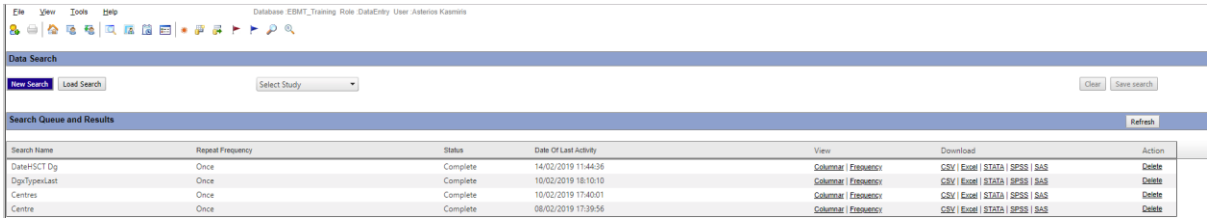


You can also Save a search of yours to use again in the future by clicking on the disk icon, or search for an already existing search of yours by clicking on the magnifying glass:

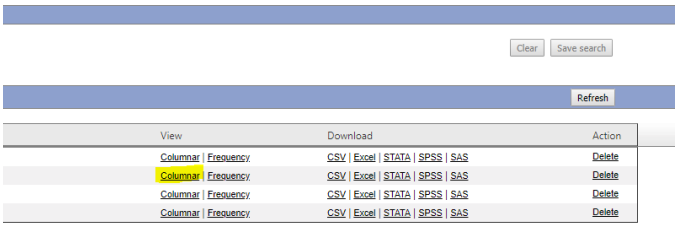

[Regarding any of the concepts described above, please refer to MACRO help.]

Another way to **search** for subjects with specific characteristics is by using the icon below:

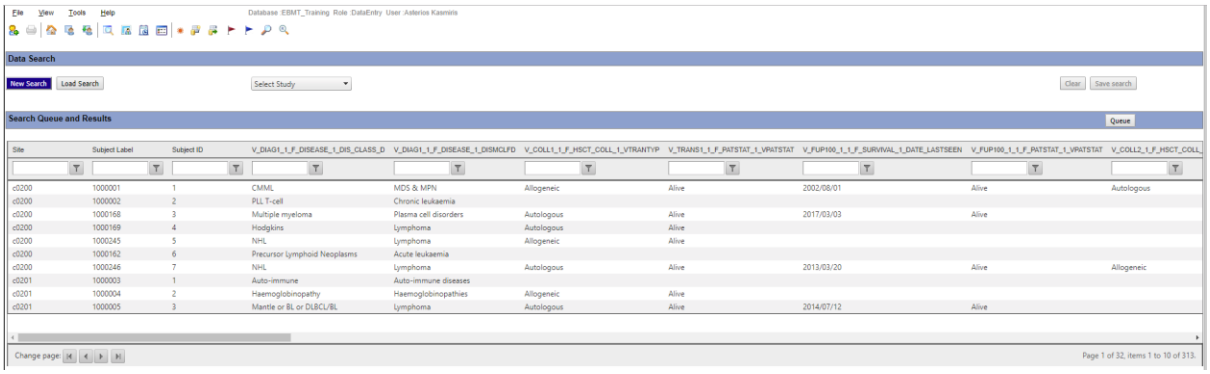

called **Data Reporter**, which opens a list of reports on the main screen:




This function is for more specialised searches/reports for subjects with even more specific characteristics, for example, with a certain diagnosis, a certain type of HSCT, a certain patient status, etc. The results of such reports will be produced in the format that the **Recipients** search mentioned above appears, if you click on the Columnar option found under View:




which you can then filter more:




## How to deal with a case of a "**Previous HSCT performed in another centre**" (use Access Request Form)

All data for a single patient should be entered under one Subject Label, including subsequent treatments (HSCTs, Cell Therapies, Additional treatment, etc.). This is to avoid creating duplications (2 patient records for the same patient). Patients transferred to other centres for further treatments (HSCTs or Cell Therapies) must always keep their original Subject Label. If your patient had a prior transplant or cell therapy elsewhere, please use the form titled "*Data Access Request Form for a Patient Given Previous Treatment in Other Centre*" to request access to their existing record, found in this webpage: https://www.ebmt.org/registry/data-submission

After the access to that specific patient record is granted to your Site, the new record will appear in your caseload (it might be that you need to refresh to make it appear).

PLEASE NOTE: this scenario is explained in more detail at the Chapter "Complex Cases (examples)".

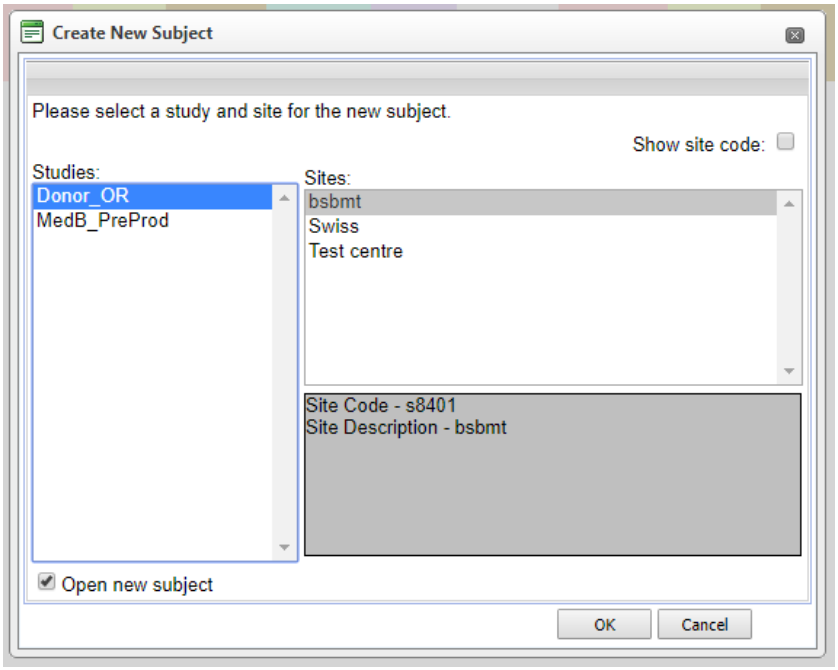
# Registration: How to create a new Subject (patient) → 1st HSCT

PLEASE NOTE: there is a separate chapter with cases of Subsequent HSCT. This chapter is for the case of a *1st* HSCT, where you are the centre that is creating a patient who does not exist in the database. It is assumed that you first Searched whether the patient record exists already, before you proceeded with the creation of a new Subject.

## Creating a **New Subject** using the icon or the toolbar menu

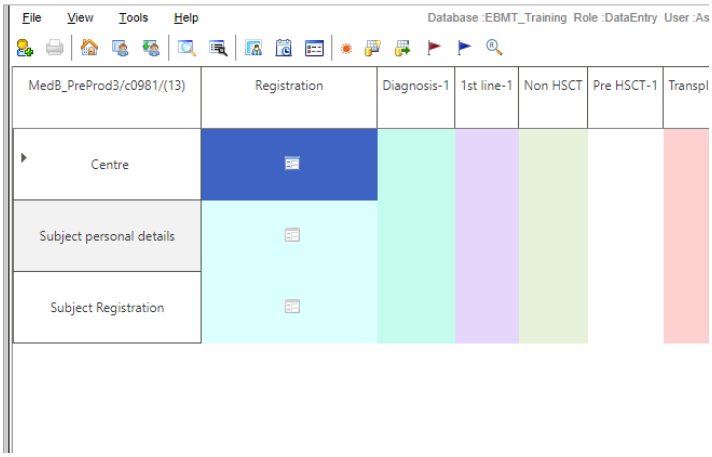
You can directly create a new subject by clicking on the first icon from your Toolbar:


Alternatively, you can use the Menu Bar, under File-New Subject. Following either method, a window appears where you select your Study (=not the normal behaviour for 90% of users) and your Site (most users will have access to 1 study and 1 site):

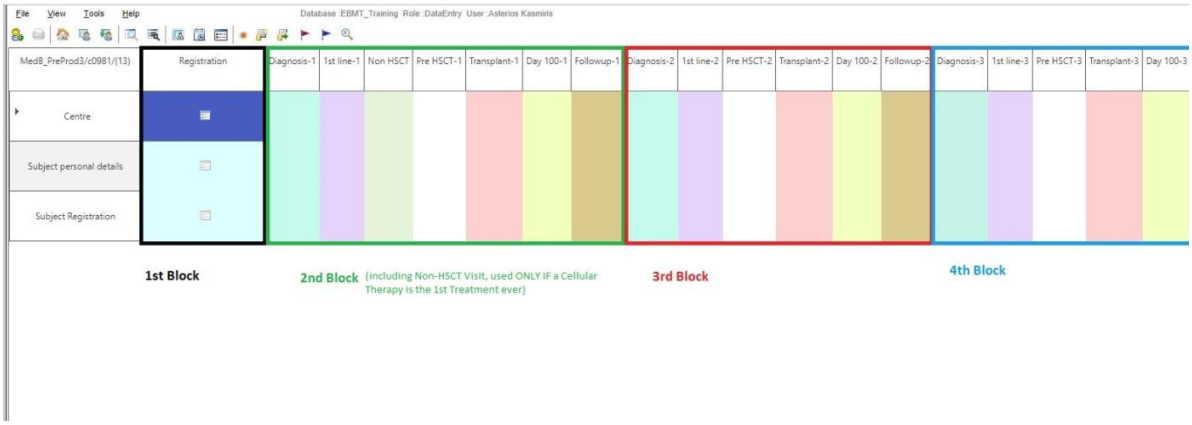



Once you click OK to confirm Study and Site selection, you are taken to the newly created patient's **Subject Visit Schedule**:

where the only active form you can use is the **Centre** Form from the **Registration** Block. Note that when a form is Active, it is coloured, but Not Active forms are greyed out:




Note that the hierarchical structure in MACRO is like this: Block → Visit → Form.

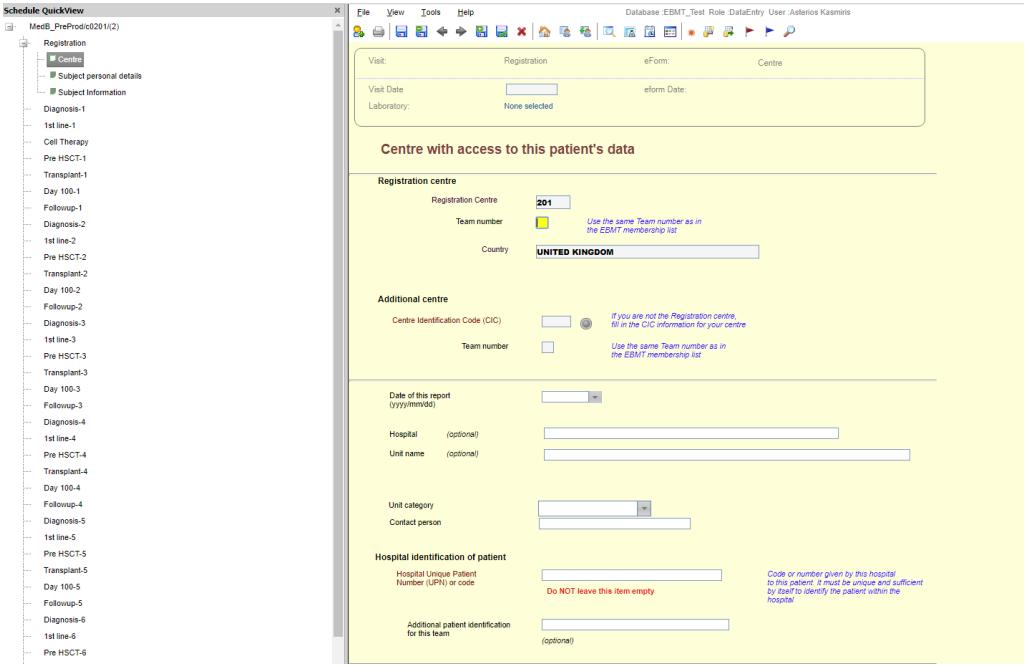



So, a Block is consisted of Visits and a Visit is consisted of Forms. The Visits are indicated by differently coloured columns and the Forms appear in rows, with their names showing in the left hand side column. Not all forms appear in all visits, as they may not be applicable, and some may appear in multiple visits.

PLEASE NOTE: the 2nd Block is different to any subsequent ones, in that it has an extra visit: the **Cell Therapy** visit, called **Non-HSCT**. The 1st Block is the Registration Block that appears only once at the very beginning of a newly created subject. The reason for this in only for the case where a patient is receiving their first treatment ever and it is a Cell Therapy; any other cell therapies that do not fit the above criteria will be reported using the Annual Follow Up.

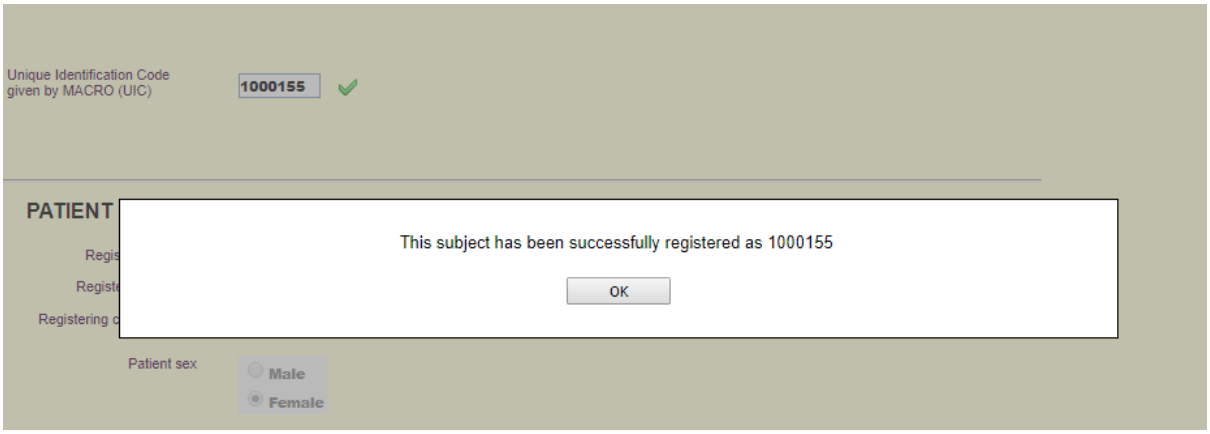
For a detailed description of the content and distribution of Blocks, please refer to the MACRO Help.

After you double-click on the Centre form of the Registration Visit in the Subject Visit Schedule above, the Form Centre opens, along with the Schedule QuickView in the left side panel.



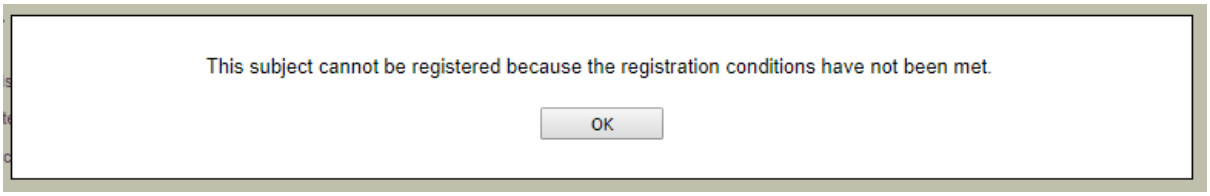

The **Schedule QuickView** is a summary of the patient's medical history in a tree form. Please read the next chapter below, which briefly explains its use.

After you fill in the Centre form above, and the following one, named Subject Personal Details, the patient is given a Subject Label by the system:



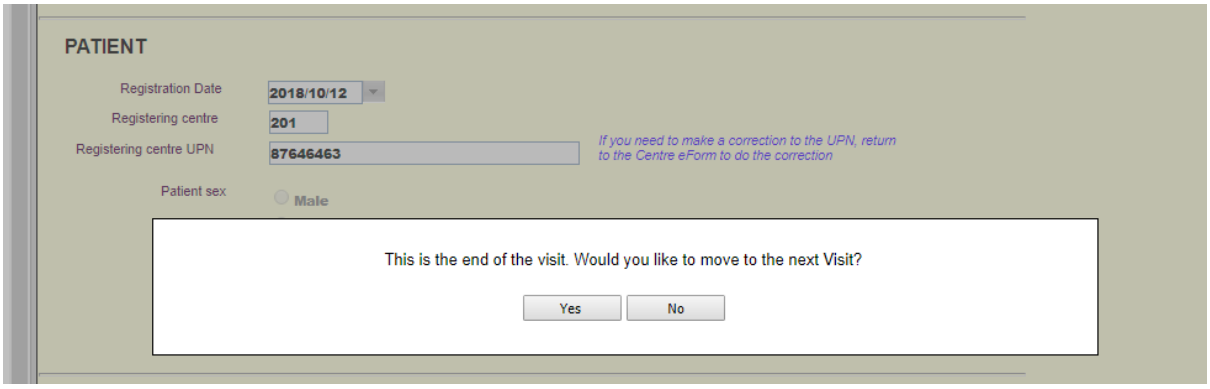

and then you can continue with the registration of the current form, named Subject Information.

PLEASE NOTE: if you fail to fill in the Subject Personal Details Form in full, your subject will not be registered in the database and you will get the following message:



THE **EBMT WORKING PARTIES** WILL HAVE **NO ACCESS** TO THE FORM "**SUBJECT PERSONAL DETAILS**", WHICH WILL BE VISIBLE *ONLY* BY THE CENTRES/SITES THAT ARE *INVOLVED* WITH THIS PATIENT (either treating or following up, as they will already have this information in their records).

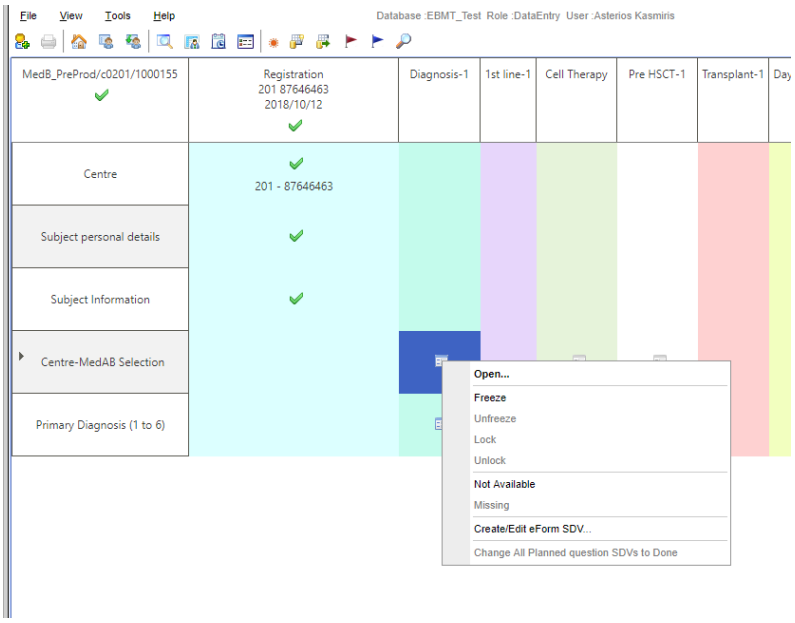
When you are done registering the 3rd and last Form of the Registration Block, you are asked if you want to continue to the Next Visit:




This Question is asked every time a Visit ends (at the end of the last question of its last Form) and a new one begins. In this case, after you finish with the last Visit of the 1st Block, you are taken to the 1st Visit of the 2nd Block.

PLEASE NOTE: the 1st Block has only one Visit: the Registration visit, consisted of 3 forms (= Centre, Subject Personal Details & Subject Information), unless you answer Yes to the Study question, which will then create a Study form as well. You can find more details in the "Entering Data" Chapter.

If you click Yes, you are taken to the 1st Form of the Diagnosis-1 Visit, but you can click No and work on a different patient. If you go back to that patient's **Subject Visit Schedule**, you can now see the completed forms marked with a Green Tick, and the following Active form is now coloured in the Diagnosis Visit:



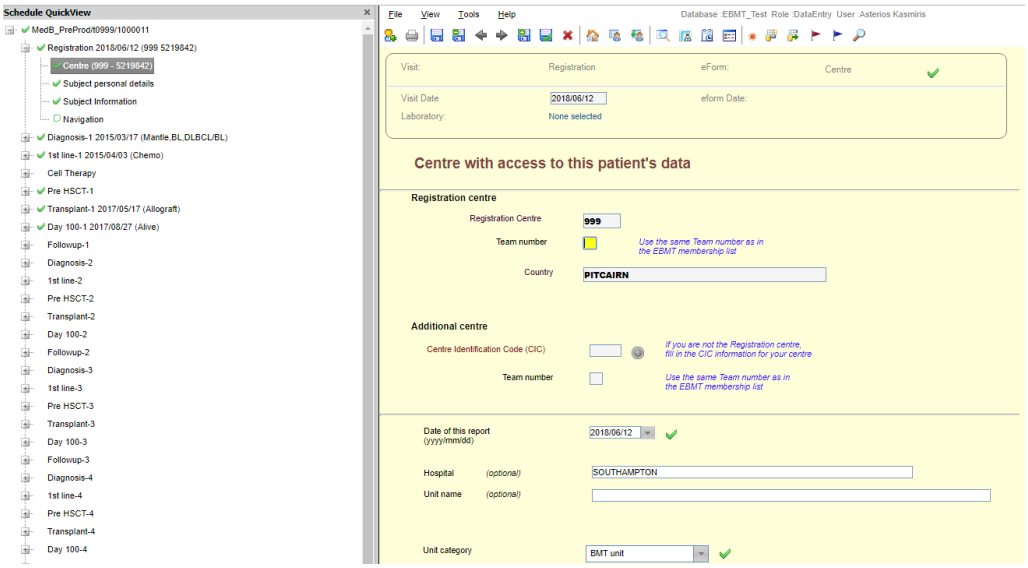
You can also right-click on an Active Form to see the available options.

When inside a Form, if you click on the Close Current Form button  , MACRO will take you back to the patient's **Subject Visit Schedule**.

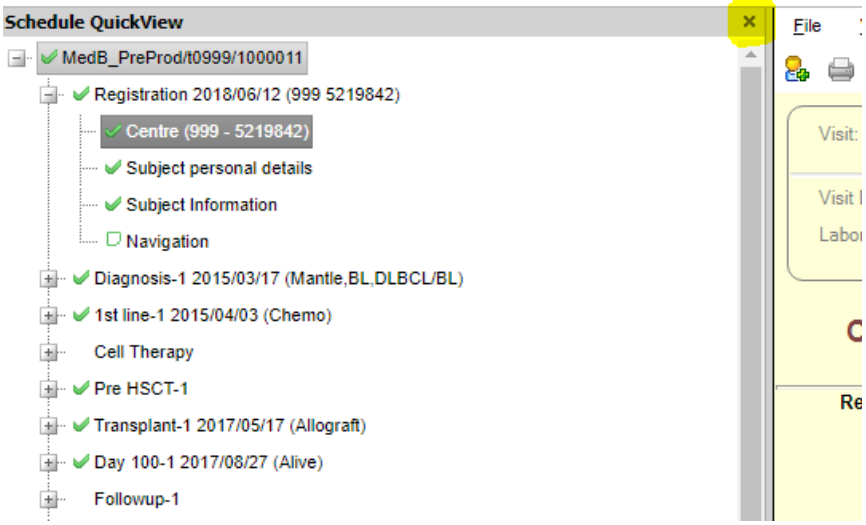
READ MORE about this in the Chapter "Entering Data" below.

## How to use the **Schedule QuickView**

Once you access any subject and double-click on any of its forms in the Visit Schedule to view/edit/record data, the Form opens along with the Schedule QuickView in the panel on the left side:

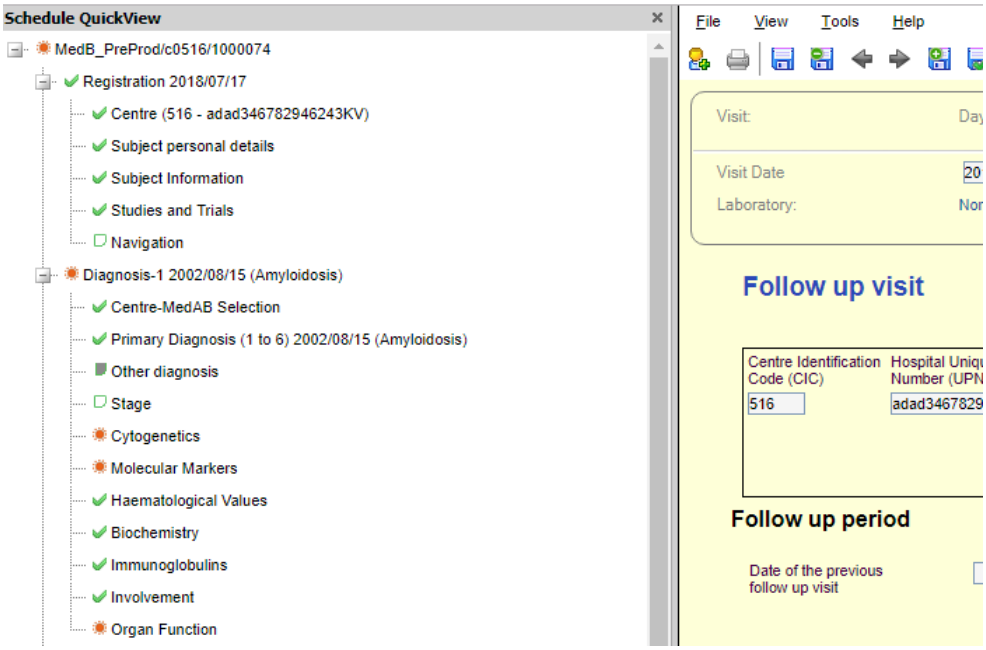



You can close the Schedule QuickView by clicking on the X on the top right corner of the panel:



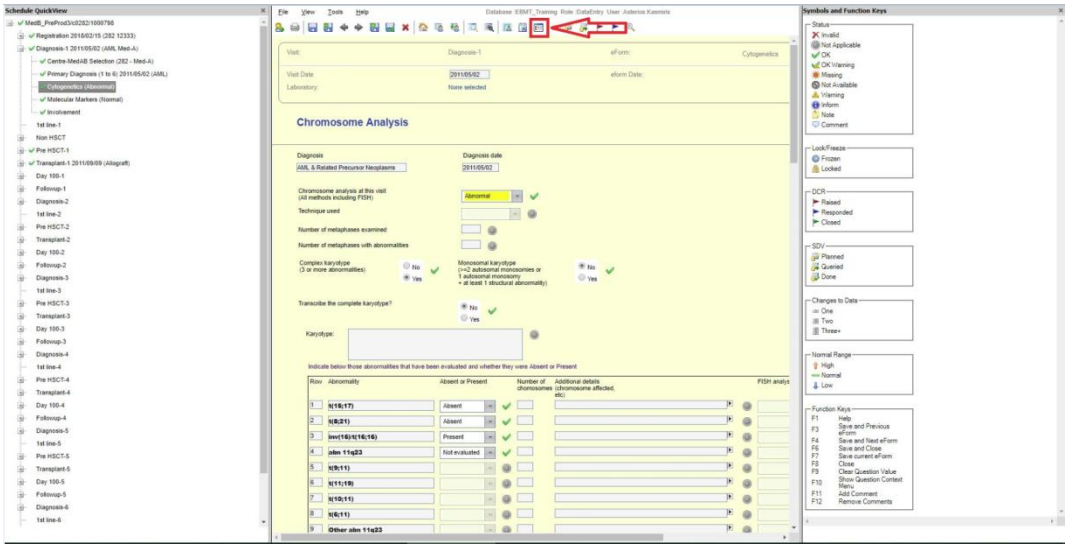
To re-open the panel click the Schedule QuickView icon:


You can click on the **+** on the left of any Visit to unfold its available Forms, and by *single* clicking on any Form, you can load it. Below you can see that if a Form is marked as Missing, then the Visit it is a part of, is also marked with the same Status Icon. This indicates that there is *at least one* form in this visit with this property:




Equally, a whole Subject is marked accordingly, if at least one visit is marked with any Status.

You can check the meaning of all Status Icons at any time by clicking on the icon **Symbols and Function Keys** to get the Icon Legend (which shows the Symbols' description):



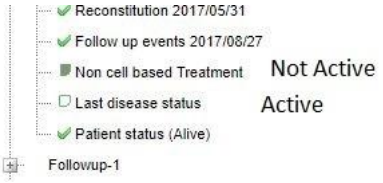
They will appear in the right side panel, along with a list of available **Shortcuts**. You can close this panel by clicking on the X button on the top right of the panel.

PLEASE NOTE (Question status priority): When a subject/visit/Form contains questions with differing statuses, the following hierarchy applies:

1. Warning
2. OK Warning
3. Missing
4. OK
5. Not Available

For example, if a Form contains questions with the statuses 'Warning' and 'Missing', it will always be represented by the 'Warning' icon as this has the highest priority.

PLEASE NOTE: some Forms in a Visit may not be Active, as they are not relevant to the Disease, the HSCT Type, etc. so you can see them being greyed out:




# Entering Data

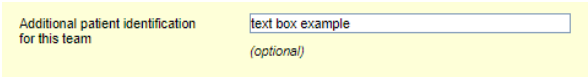
## Types of **Questions** (**Comments** and **Notes**)

There are several different types of question in MACRO. A question type determines how it is displayed on a Form and how it is to be answered.

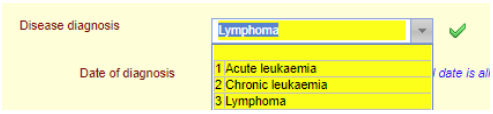
| **Type** | **Identified by** |
|---|---|
| Text | A text box requiring a textual answer, occasionally with an expand arrow to the right. Thesaurus questions are clinically significant text questions that can be coded against a medical dictionary. They are displayed as a text box with an orange border |
| Category | A set of option buttons (radio buttons), check boxes or a drop down list. |
| Number | A small text box requiring a numerical answer. |
| Date/time | A small text box requiring a date as an answer, occasionally with a drop down arrow to the right. |
| Multimedia | A paperclip icon or a magnifying glass icon if the question has already been answered. |

EXAMPLES:

Text:

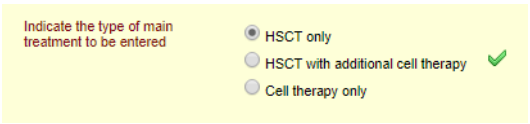



Drop-down Category question:

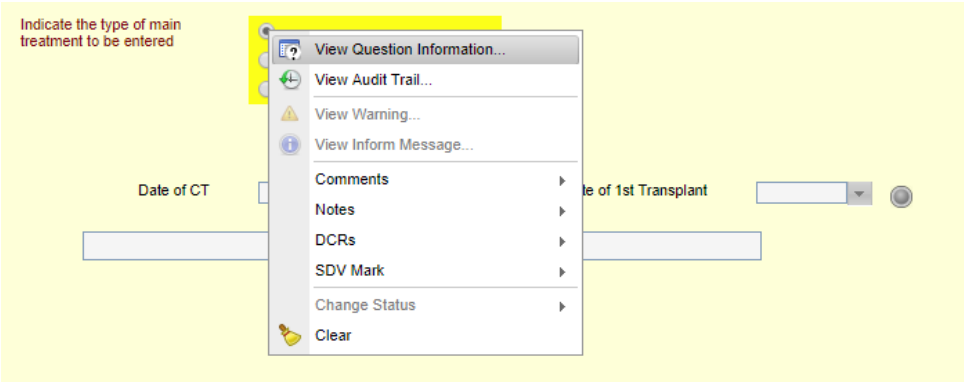



*SHORTCUT*: once you tab to a drop-down list category question, the options unfold automatically. You can use "ALT+Down Arrow" or "ALT+Up Arrow" to unfold it and fold it respectively.

Radio Button Category question:

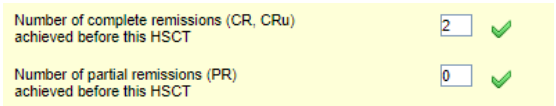



When you tab to a radio button category question, you can move down and up using the arrow keys on your keyboard to go through the options (you can also use the left and right arrow keys) and press SPACEBAR to select your choice. When you tab to any question, it is activated by turning Yellow (= how the cursor moves throughout the Data Entry). To remove an entry from a Radio Button category question, right-click on it and select the option **Clear**:

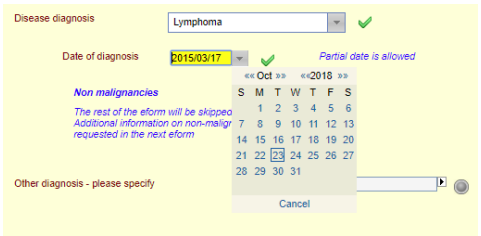



*SHORTCUT*: alternatively, you can press F9 when the cursor is on the question (Yellow).

Number:

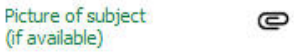



Date/Time:



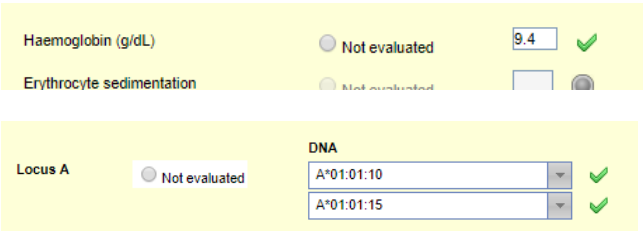

*SHORTCUT:* instead of typing the date, you can click on the drop-down option next to the date field, which unfolds a **Calendar**, where you can select the date from.

*SHORTCUT 2*: when inside a date question, the shortcut for **today's date** is letter "**t**".

Multimedia: 


If the Multimedia Question is answered, the Paperclip is then changed to a Magnifying Glass, which indicates that you are able to view its content:

PLEASE NOTE: there are some Questions with a *combination* of the above options of category questions, such as some Haematological Values, where you have the option to select either a radio button for Not Evaluated or a Numerical value field to enter the value. Also, you can have a radio button for Not Evaluated or a drop-down list category question with options to choose from or, such as the HLA.

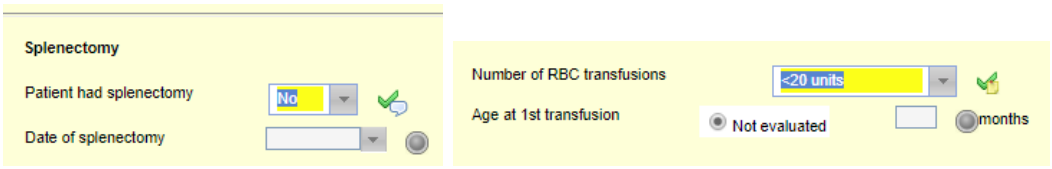



In terms of Data Entry, in cases such as the 2 examples above, you first tab to the NE Radio button and if you select it, it skips the following item (free text box or drop down list category question), but if you skip it, then it jumps to the following item (free text box or drop down list category question) for you to answer. Just a gentle reminder: if you want to **Clear** a selected Radio button category question, you press F9 or you right-click and you select the option Clear from the drop-down menu.

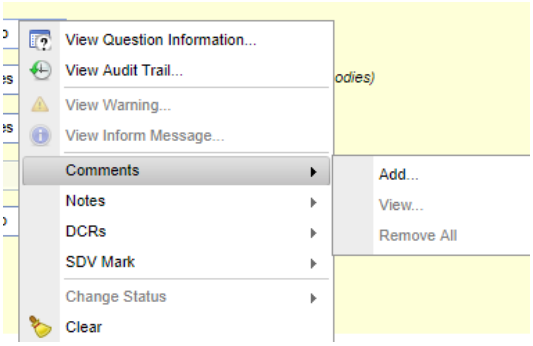
PLEASE NOTE: depending on the language you have set in your internet browser, the **Decimal and Thousands Separator** might be presented differently – it can be either Decimal Comma (**,**) or Decimal Point (**.**) and the opposite for the Thousands Separator. For example, in countries like the Czech Republic, Italy or Spain *ten thousands* would be written like this: 10.000,00 and in countries like the UK and the US like this: 10,000.00

In order to avoid possible mistakes, you must remember that it is your Internet Browser's language that defines what format you will be viewing your data in MACRO, and you should therefore choose the corresponding symbol (comma or point) when entering numerical values.

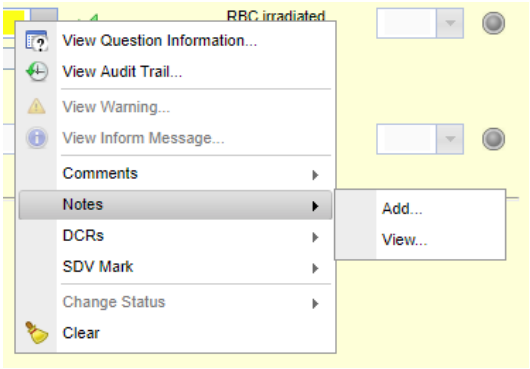
PLEASE NOTE: you can add **Comments** and/or **Notes** on any question. The Comments are clinically significant comments on a question. The Notes are more like a personal reminder, but they are visible both by data entry users and by data reviewers, so it is a way of communication between the two. The notes can also be downloaded. If any question has either a comment or a note, they are marked respectively as such:



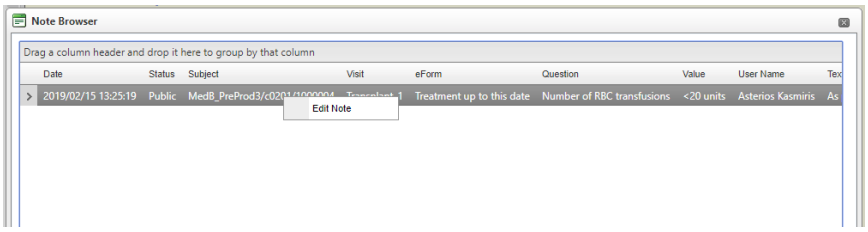

You can add either of the two by right-clicking on any question to get the drop-down options:



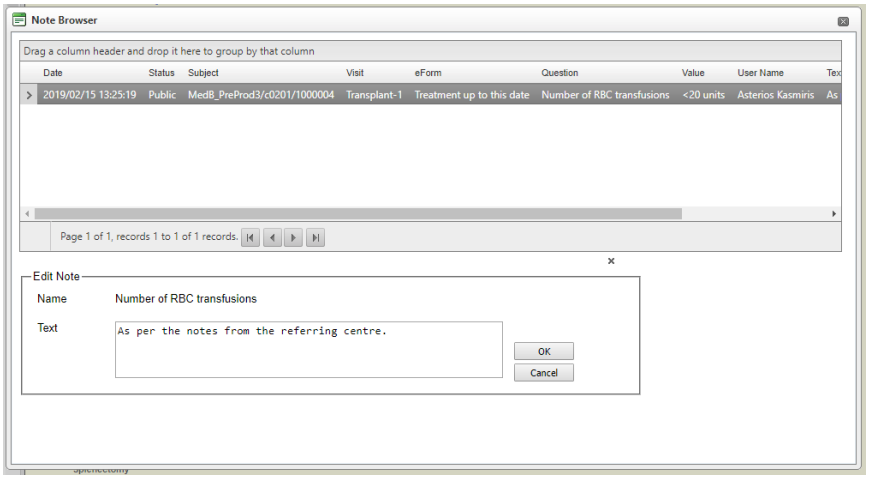

If at least 1 Comment exists already, the option view will be active (not greyed out as above). The same happens with Notes as shown below:



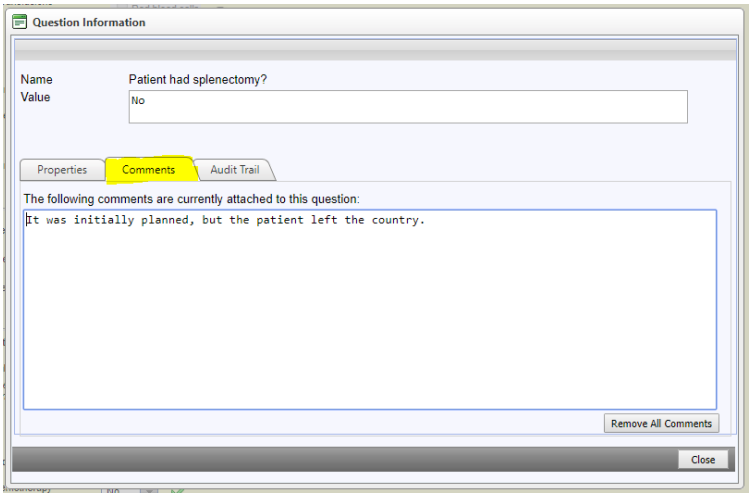

If you click on View a pop-up window appears to show the existing information. The **Notes** appear in rows on which you can right-click and select Edit Note:



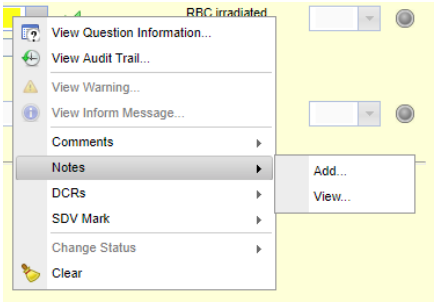

which will open the Note like this:




The **Comments** appear in the following window, but it is just 1 of the 3 available tabs:




The other 2 tabs – Properties and Audit Trail – can also appear by selecting their corresponding options on the drop down list of any question:




named: **View Question Information** and **View Audit Trail**.

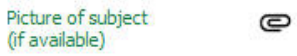
[Regarding any of the concepts described above, please refer to MACRO help.]

## **Help** provided (Contextual texts, Help Files, Multimedia, Hyperlinks)

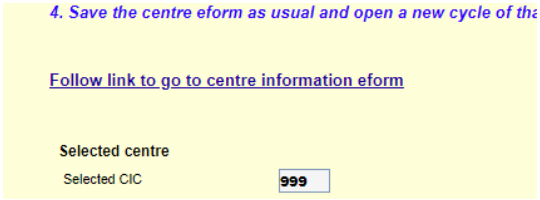
For the easiness of the Data Entry process, MACRO offers the capacity of some explanatory notes (Contextual Text) appearing on the Forms in blue colour, found next to the Questions they refer to:


Please make sure to read these, as they are designed to facilitate your work.

What is more, MACRO offers the possibility of attaching documents, known as Multimedia files, which are indicated with a paperclip icon (or a magnifying glass if the question is answered):




Moreover, you can find Hyperlinks, for moving to another form *within* MACRO, such as the one below:




Finally, additional help can always be found on the EBMT Website under the Registry tab:

https://www.ebmt.org/registry/how-use-registry

https://www.ebmt.org/registry/data-collection

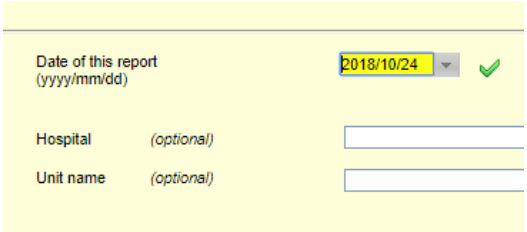
https://www.ebmt.org/ebmt/documents/med-ab-forms-manual

https://www.ebmt.org/registry/data-submission

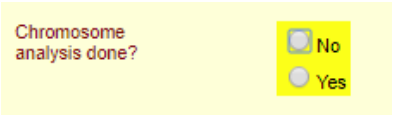
You can also contact the **Registry Helpdesk** at all times → registryhelpdesk@ebmt.org We aim to get back to you within 24 hours upon receipt of your query.

## Data Entry

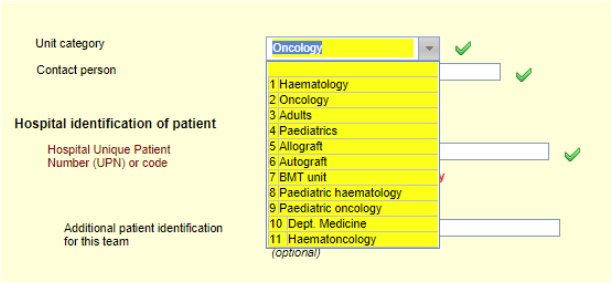
*Cursor*: the cursor indicates which question you are answering at any given moment during data entry. It is highlighted in Yellow, if it is a free text box:


if it is a Radio button category question, the whole area of options is highlighted instead:




and if it is a Drop-down list category question, the options expand automatically and all of them are highlighted:

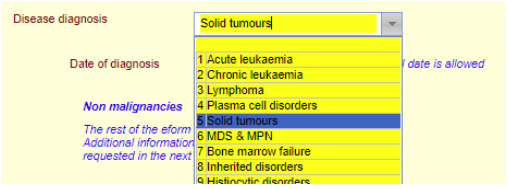



PLEASE NOTE: the Blue highlighting happens when you go back to a question that has already been answered.

*Y*ou can do the entire Data Entry using solely the **keyboard**, which is *recommended*, as it ensures you answer all the questions in the order specified by the study designer. The TAB key is the key that moves the cursor from one question to the following one.

- If the question is a free-text box, you can click TAB after you are done typing your entry.

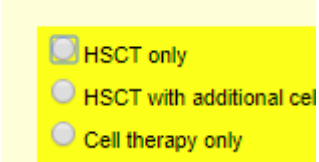
- If it is a drop-down list category question, you can use the Down and Up arrows to move to the preferred of the available options and then TAB to accept it. The option you are about to choose is highlighted in Blue:




You can fold and unfold the options of a drop-down list category question by using the ALT+Up and ALT+Down shortcut respectively.

PLEASE NOTE: in Drop-down lists category questions, such as the one above, you can alternatively type the **Code** that appears next to the label and press TAB or ENTER.

- If it is a Radio button category question, again you use the Down and Up arrows (or the Left and Right arrow keys) to move to the preferred of the available options and then click SPACEBAR to accept it. A grey square is indicating which option you are about to select:




In all of the 3 options above, if you click TAB, the cursor will jump to the next question without any answer selected ("tabbing out" of a question). But if a selection is made, the cursor automatically jumps to the following question.

PLEASE NOTE: MACRO does *not accept* the following characters when entering data **" ` ~ |**

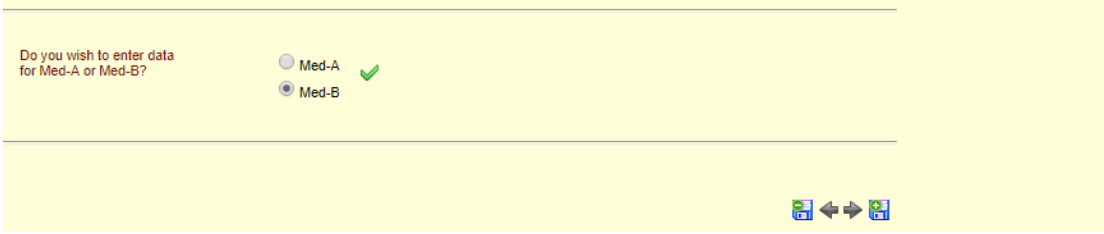
For more information on this, please refer to MACRO Help, under "Navigating through an eForm".

> *Mouse*: Using the mouse is **not** recommended during normal registration as it may lead to essential data items being skipped or validations being triggered in the wrong order. However, the mouse may be useful when filling missing items *ad hoc* or making point corrections. You can choose one of the options by *left* clicking on the preferred answer (either in a Radio button or an option in a Drop-down list of a category question) and once the selection is made, the cursor moves automatically to the following question. If you are typing in a free text box, you can click anywhere outside of the box and your value/text will be accepted.

## Saving data and moving between Forms

Data is not saved until you click a Save button or move to another Form. You will always be warned if you attempt to save a Form containing unanswered mandatory questions or if you attempt to leave a Form containing unsaved data. You can also choose to see a warning message if you attempt to save a Form without having made any changes to it. Set this via Tools > Options > eForm.

At the end of each Form and after you have answered its last question, the cursor will jump to the option Save and Move to the Next Form, which you can select by clicking SPACEBAR:

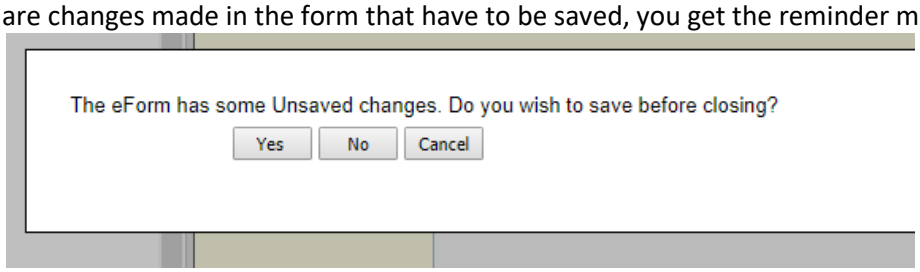


Alternatively, you can use the arrow keys to select another of the 3 options there (Move to next Form in schedule without saving, Move to previous Form in schedule without saving & Save and move to previous Form in schedule).

*SHORTCUT*: click the F4 key for the option “Save and move to next Form in schedule”.

| Icon | Keyboard shortcut | Action | Description |
|---|---|---|---|
|  | F7 | Save current screen | Use this to save data at any time whilst keeping the Form open. Any question derivations and validations will be updated. This icon appears in the tool bar at the top of the screen. |
|  | F3 | Save and move to previous Form in schedule | Use this to save and close the current Form and open the previous Form in the schedule. The icon appears at the bottom right of the Form and in the tool bar at the top of the screen. |
|  | | Move to previous Form in schedule without saving | Use this to close the current Form without saving it and to open the previous Form in the schedule. The icon appears at the bottom right of the Form and in the tool bar at the top of the screen. |
|  | | Move to next Form in schedule without saving | Use this to save and close the current Form and to open the next available Form in the schedule. The icon appears at the bottom right of the Form and in the tool bar at the top of the screen. |
|  | F4 | Save and move to next Form in schedule | Use this to close the current Form without saving it and open the next available Form in the schedule. The icon appears at the bottom right of the Form and in the tool bar at the top of the screen. |
|  | F6 | Save and close current Form | Use this to save and close the current subject. Note that this will close all Forms and the schedule for this subject. This icon appears in the tool bar at the top of the screen. |
|  | F8 | Close current Form | Use this to close the current subject tab without saving. Note that this will close all Forms and the schedule for this subject. If you have any unsaved data on the Form, you will be asked if you wish to save it before closing. |

PLEASE NOTE: if you click on the button “Move to next Form in schedule without saving”, but there are changes made in the form that have to be saved, you get the reminder message below:



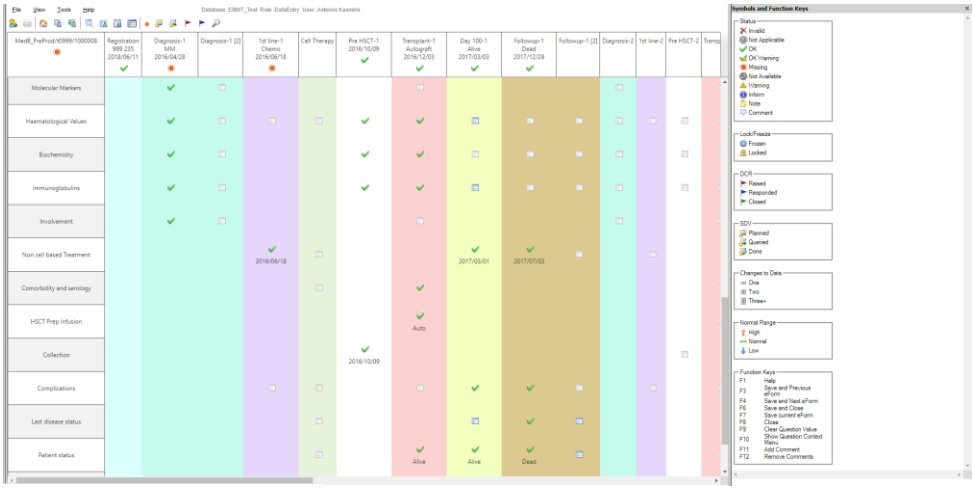
The above options will also appear in the Toolbar, once you have loaded any Form:


PLEASE NOTE: every time you **SAVE** a Form in MACRO the patient record reloads itself and certain Forms that are applicable (depending on the Disease or some answers that you have provided) will then appear after the patient is reloaded.

## Shortcuts

You can get the list of available Shortcuts in MACRO by clicking on the icon **Symbols and Function Keys:**  and the Icon Legend appears in the right side panel:





| Function Keys | |
|---|---|
| F1 | Help |
| F3 | Save and Previous eForm |
| F4 | Save and Next eForm |
| F6 | Save and Close |
| F7 | Save current eForm |
| F8 | Close |
| F9 | Clear Question Value |
| F10 | Show Question Context Menu |
| F11 | Add Comment |
| F12 | Remove Comments |

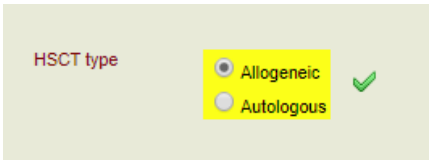
In addition, you can use the usual shortcuts CTRL+C, CTRL+V, CTRL+A and CTRL+Z that are used in Windows for Copy, Paste, Select All and Undo respectively, but NOT the CTRL+S for Save. The shortcut for Save is the F7 key.

PLEASE NOTE: CTRL+Z is only applicable inside a free-text box to Undo what you typed, but it will not work if you try to deselect a Radio button or a Drop-down list selection you have just made in a category question.

## Navigation (answering Questions inside the Forms)

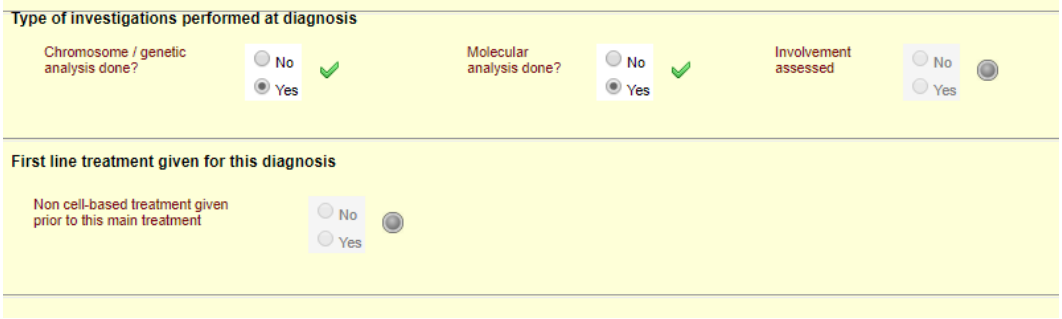
As mentioned before, there could be some Forms that are Active and some that are not. This depends on some questions, typically asked at the beginning of a Registration, and they depend both on the type of Diagnosis you choose and some of the answers you have already provided. For example, at some point you are asked if you are recording a MedA or a MedB form:


and depending on your answer, some Questions or Forms will become active or not. Equally, when selecting the HSCT Type:



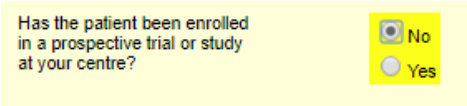

if you select an Allogeneic, the Donor's relevant Forms and HLA Forms will get activated, which will not be the case if you select Autologous. Another example would be Cytogenetics or Molecular Markers. So, if you select to register an AML, you will be asked the corresponding *screening* questions:


to which if you answer Yes the Cytogenetics Form will be activated; if you answer No, it will not. Another example is a *screening* question about Involvement Assessed or about Pre-HSCT Treatment, which are also disease dependent:

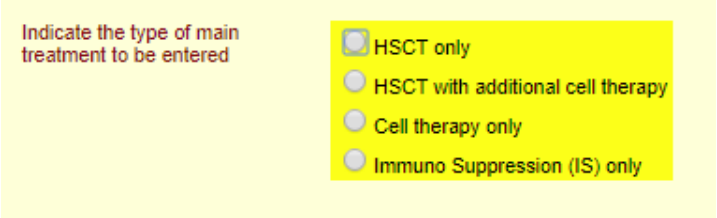



PLEASE NOTE: in the above screenshot the Questions "Involvement Assessed" and "Non cell-based treatment given prior to this transplant" are Not Active (marked with a greyed circle and with the answers greyed out as well), as they are not a requirement of the pre-selected disease (depending on the corresponding Working Party's decision). They will be active in certain diseases where they are considered a requirement.

Another *screening* question that you will have to answer has to do with whether the patient has participated in a Clinical Study or not:




Or with the type of treatment you are reporting:



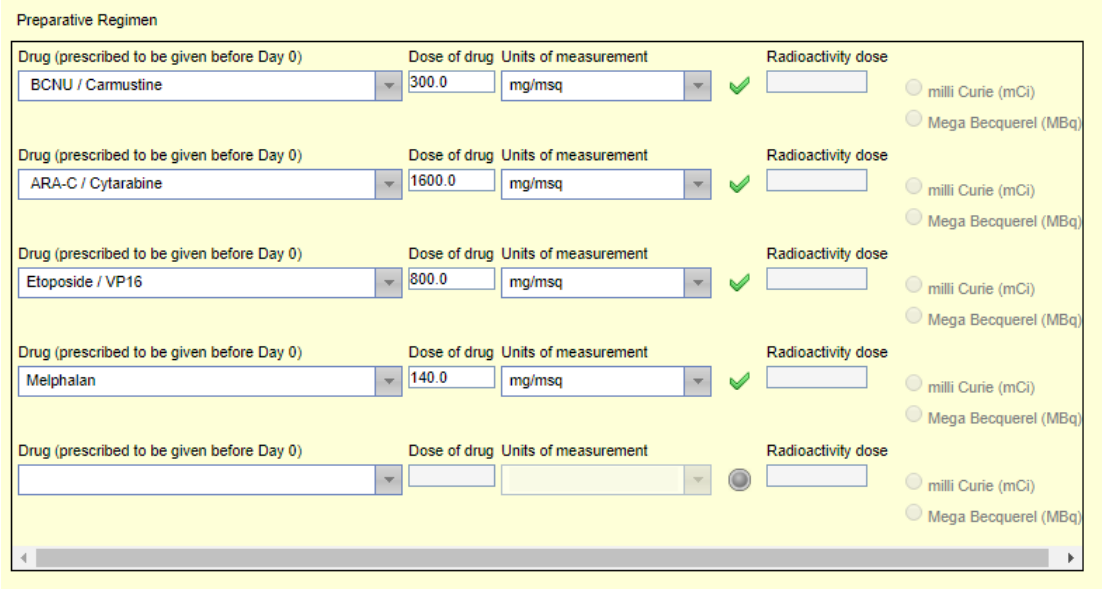

PLEASE NOTE: the "Immuno Suppression (IS) Only" option above is applicable only for Bone Marrow Failures.

The Forms will not appear at first, but they will appear once you **SAVE** the Form. Every time you SAVE a Form in MACRO the patient record reloads itself, which makes any new Forms appear, depending on your answer to this type of Questions.

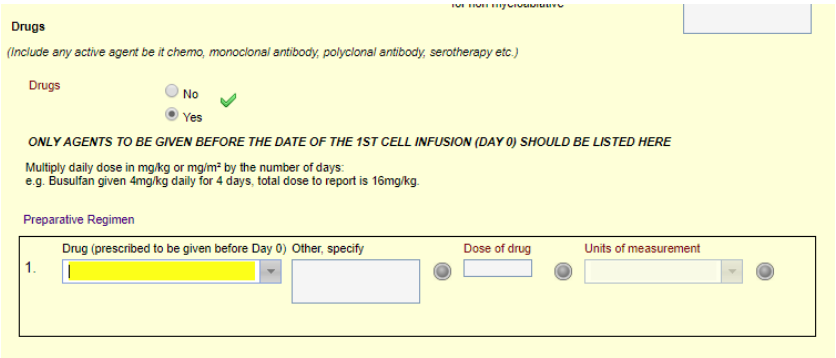
There is another section in this Chapter called **Navigation (how to continue or finish a registration)**, but it has to do with how you continue to or how you finish a Day 0, a Day 100 or a Follow Up registration.

## Repeating Question Groups (RQGs)

In certain occasions in MACRO there are some types of Questions that are *repeating* and appear in the form of tables. Such examples are the cytogenetics, the molecular markers or the drugs:




Once you answer the corresponding Question that activates the above Repeating Question Group, you are first taken to select the Drug name from the drugs' list. There will only be one row showing inside the table:




PLEASE NOTE: at this point, and at the moment you select your first drug and accept the value, MACRO will automatically SAVE, Reload the form, and generate the second row, where the following drug can be added. This behaviour is the same throughout all RQGs.

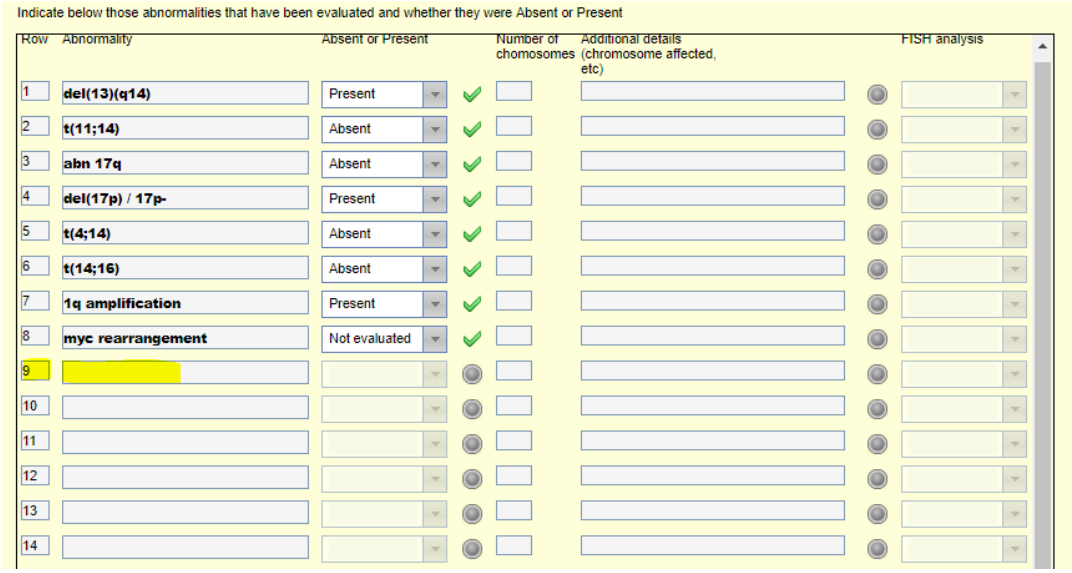
Once you select the first drug, you are taken to the next question (dose), and once you answer that, to the Unit of Measurement. After that you are automatically taken to select the next drug.

PLEASE NOTE: at this point MACRO will SAVE and Reload the form, so that the following row is created.

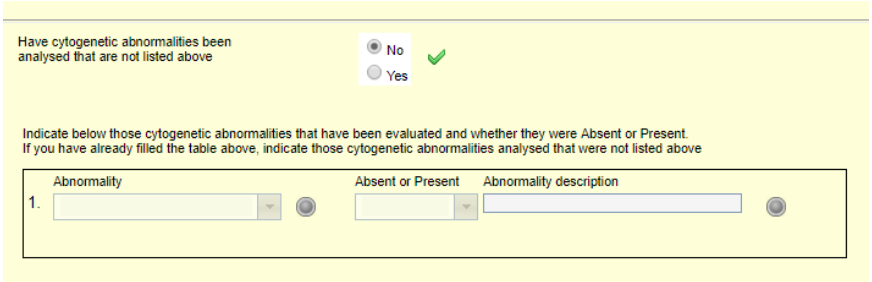
If you do not have more drugs to report, you simply leave this question blank by tabbing out of it, which should take you to the following question, outside the table. Otherwise you continue entering drugs until you report them all.

Therefore, note that there will *always be a row left blank* at each and every one of tables of any RQG found in MACRO.

PLEASE NOTE: in some case you may find some pre-defined options selected for you (either because it is the corresponding Working Party's requirement or because they are commonly used). You cannot add more data underneath the pre-defined ones:




Instead, there will be another table (RQG) that follows, where you can add any other choices that are not included in the pre-defined ones:




## Validation (Warning and Rejection messages)

Validation rules can be attached to individual questions by the study designer in the form of conditions. If you enter a value that satisfies the condition, a validation message may be displayed. You might see two types of validation; Rejection and Warning.

1. *Rejection*

An explanation of the rejection is present within the popup and should help you to re-enter the correct data. Your only option is to click OK and enter a different value. Your original entry will automatically be removed.

2. *Warnings*

An explanation of the warning is present within the popup and should help you to either re-enter the correct data or overrule this warning.

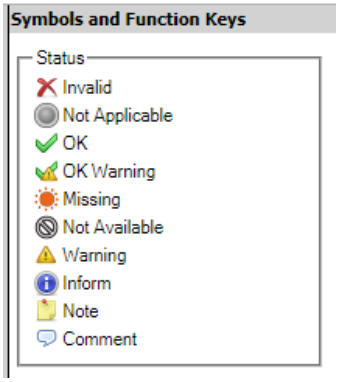
You have 3 options:

I. If you have entered an incorrect value, click **CLOSE** and enter a different value.
II. If you wish to ignore the warning, click **CLOSE** and leave your original entry in place. The Warning status will be assigned to the question. (see Examples below)
III. If there is a valid reason for entering the value, enter your reason in the **Overrule** text box (using up to 255 characters) or select a predefined reason from the drop down list and click OK. This will leave your original entry in place and assign the OK Warning status to the question.

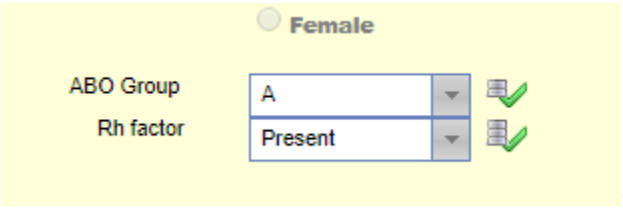
PLEASE NOTE: if multiple validations have fired for a question, you will see them all listed but you will only be able to respond to the one at the top of the list.

To overrule a warning, you need both the 'Change data' and 'Overrule warnings' **permissions**

Possible indications for a Question's **Status**:




In addition to the above, you may see the symbol below, which indicates the number of changes that each Question had:



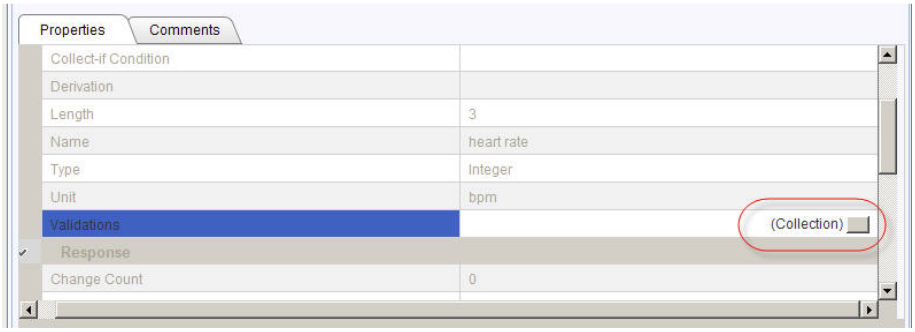

(e.g.: 2 for ABO Group and 3 for Rh factor)

Viewing the validation rules for a question

You can view any validation rules that have been attached to a question:

a) On an eForm, right click the question field or status icon (or press **F10**) and select **View Question Information**. The Question Information window is displayed.
b) Within the Properties tab, click in the Validations row then click the **Collection** button.

c) The validation rules associated with the question are listed.



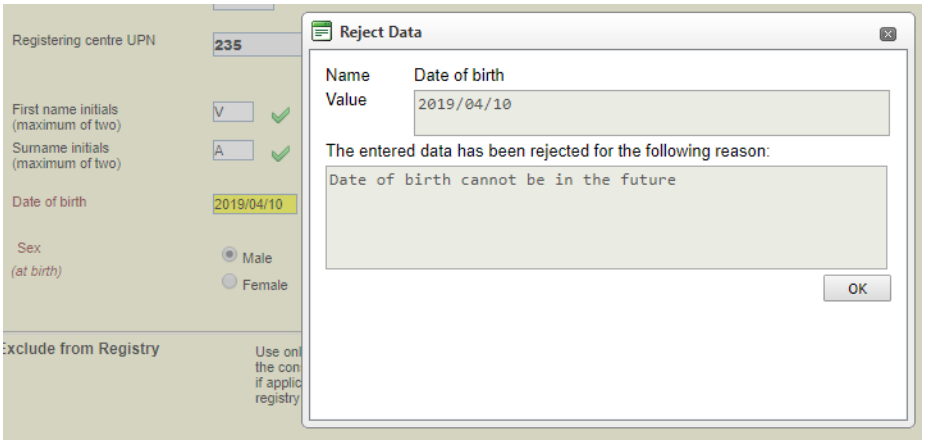

For each rule, you will see the type of validation, the condition itself and the message that will be displayed if the condition is not met.

If the question has the status of Warning, OK Warning or Inform, you will be able to right click it and select **View Warning** or **View Inform Message** from the popup menu to view the validation message attached to the condition that has been met. Before the eForm is saved, it is possible to view all the fired validations but after the eForm has been saved, only the first validation will be shown.

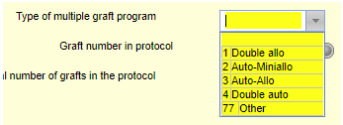
Validation takes place automatically every time an eForm is opened by a user with the Change Data permission and every time that it is saved.

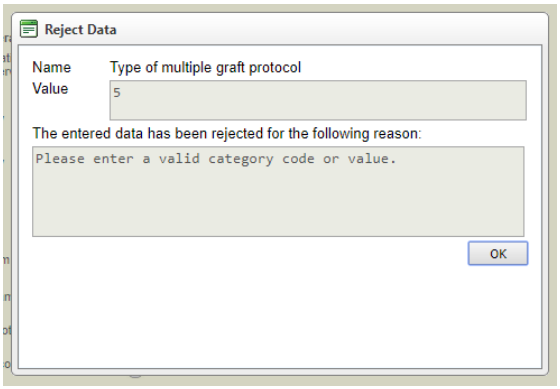
EXAMPLES:

1.**Rejection** messages



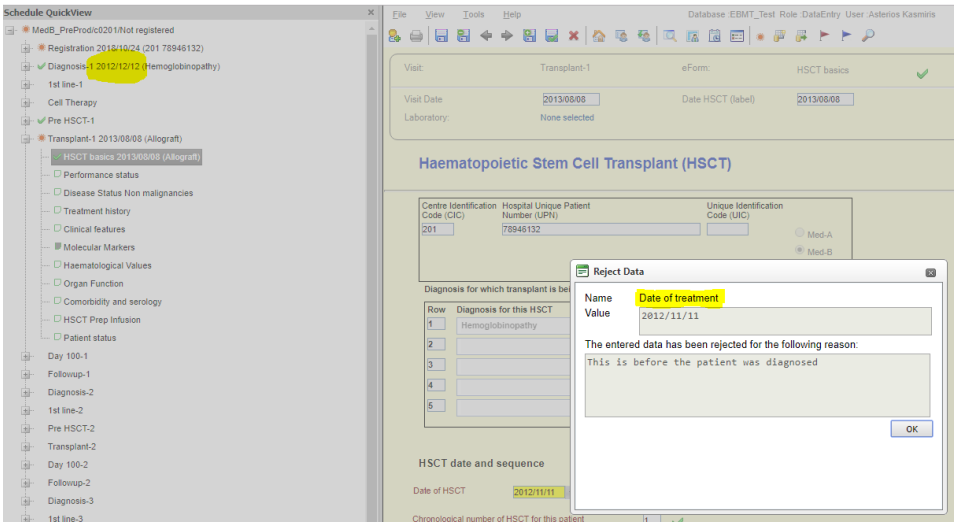

In the question of Multiple Graft Protocol where the options are 4:



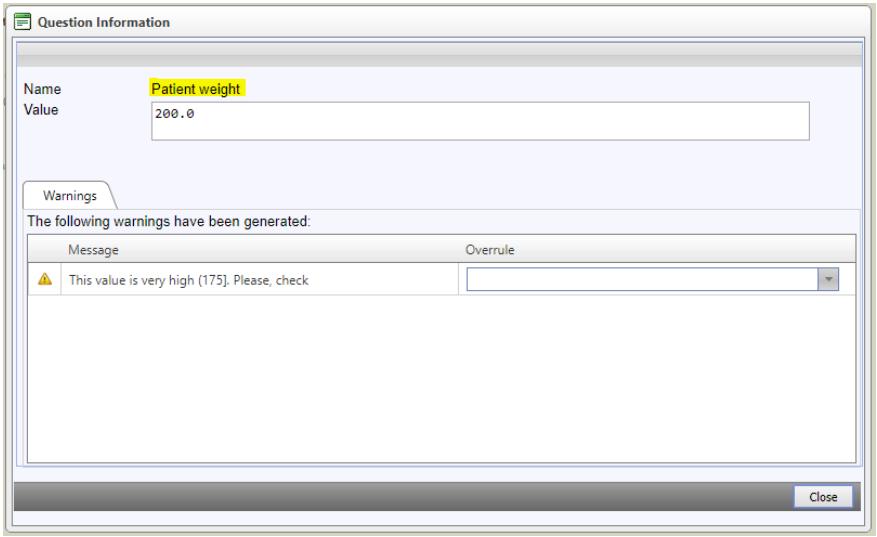



if you type 5 you get a **Rejection** message:

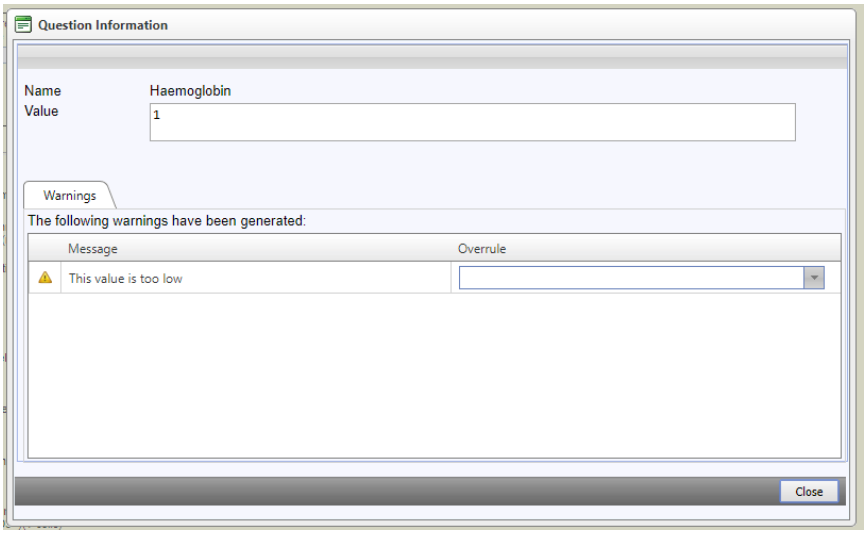
Another example would be if the HSCT Date is before the Diagnosis Date, your value will be rejected:



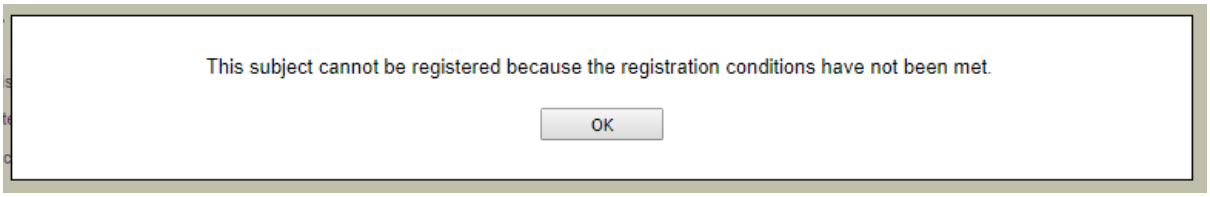

2. **Warning** messages



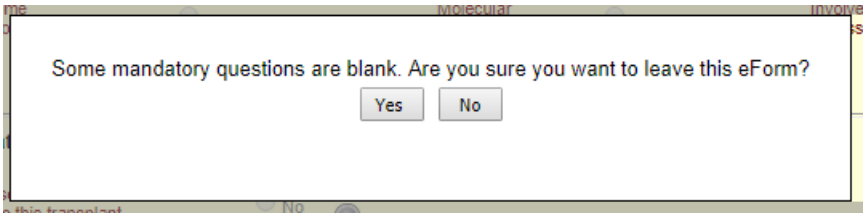

A value can exceed the maximum, like the patient's Weight above, or it can be less than the minimum requirement, like the Haemoglobin below:




In a scenario where you have not filled in the Subject Personal Details Form in full, the registration will not be completed and you will get the following Warning message:

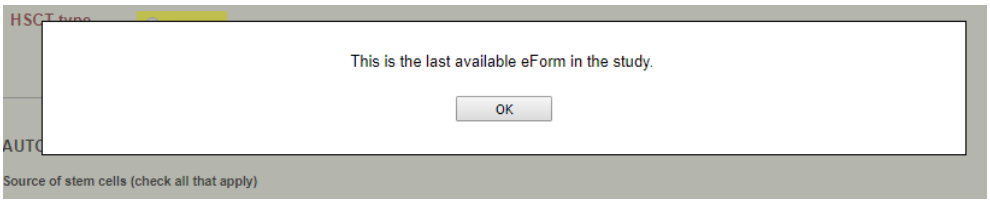



If a Form contains some **Mandatory** questions, which you left unanswered, you get this message:



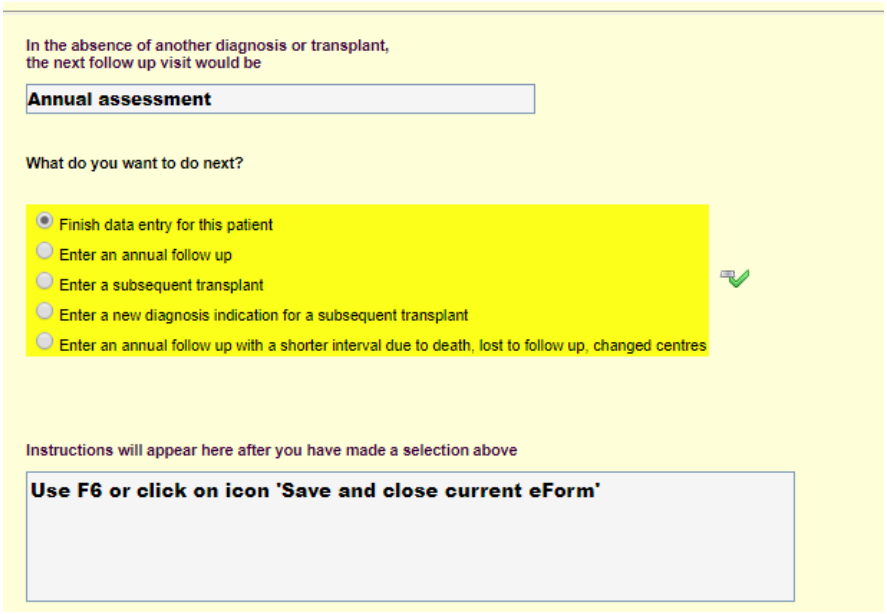

PLEASE NOTE: the above message appears before the Form is saved, therefore you click No and the Missing items will then be marked with the Missing Status symbol, so that you know which ones they are and you can then go and fill them in, before you leave the Form.

If you choose to ignore the warning and answer Yes to the question, the following Form or Visit will **fail to activate**. Therefore, MACRO will not be able to continue and you will be presented with the following message:



## Navigation (how to continue or finish a registration)

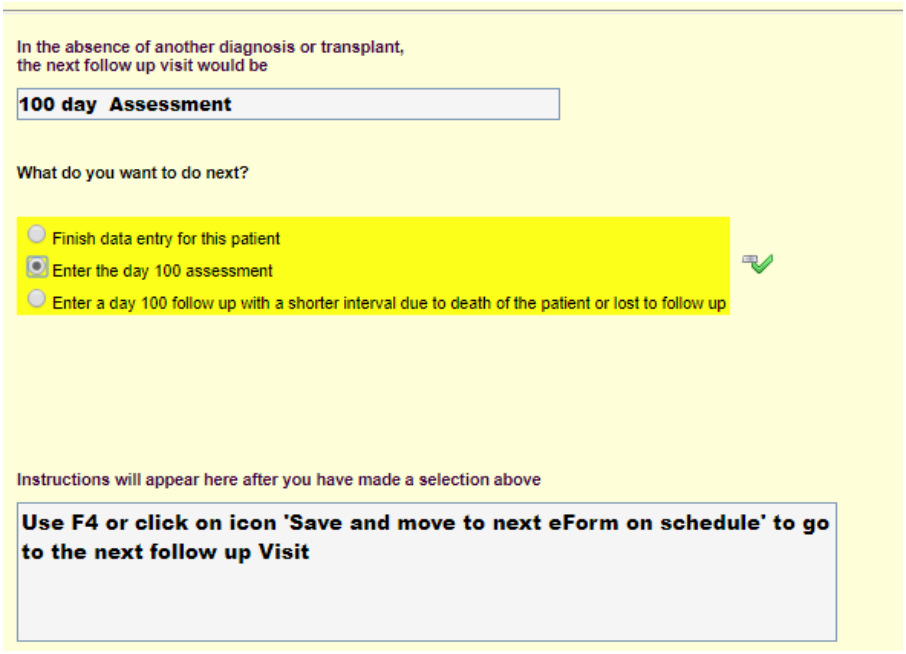
The requirements for a registration may change depending on the type of treatment you are reporting. For an **HSCT** you are required to report a Day 0, a Day 100 and an Annual Follow Up report, but for a **Cell Therapy**, besides the 3 above, you are additionally required to report a 6 Month report as well. Each time you are finishing a registration for any of the above, you will be asked by MACRO how you want to proceed. This happens at the last Form of the last Visit of each registration:




You can see in the above Form that you are presented with certain options:

- Finish data entry for this patient
- Enter an annual follow up
- Enter a subsequent transplant
- Enter a new diagnosis indication for a subsequent transplant
- Enter an annual follow up with a shorter interval due to death, lost to follow up, changed centres

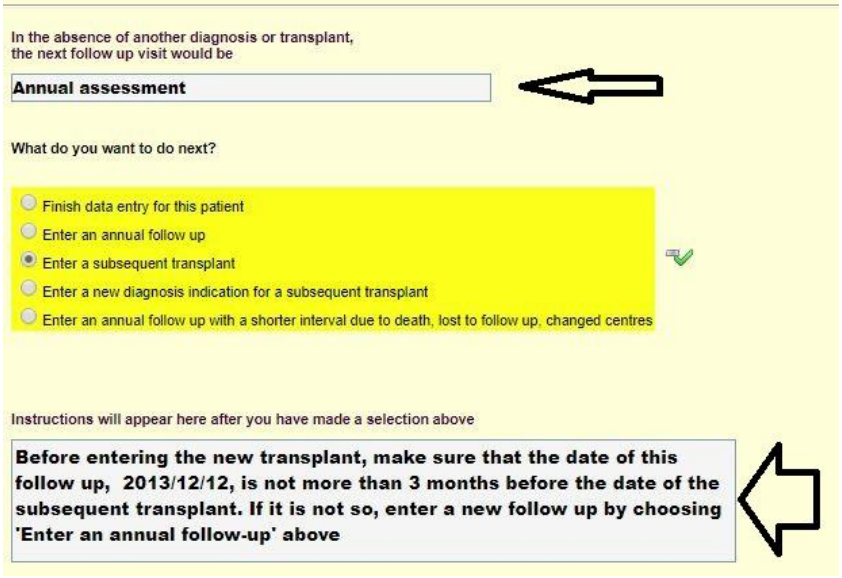
PLEASE NOTE: the options that will be offered will depend on the type of the Visit you are at. For example, at the end of a Day 0 registration you are presented with the following options:




Accordingly, at the end of a Day 100 registration these 2 options will not appear, as they are not applicable:

- Enter the 100 day assessment
- Enter a 100 day follow up with a shorter interval due to death of the patient or lost to follow up

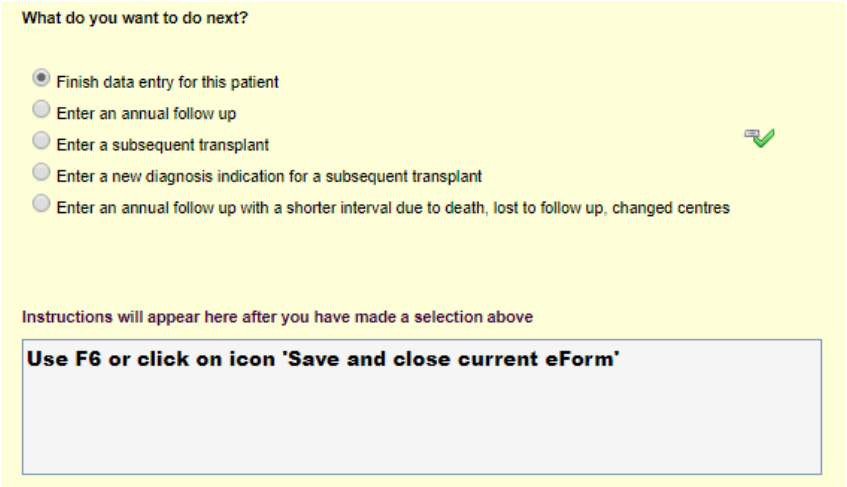
PLEASE NOTE: in the box above these options, you are advised as to what is likely to follow. And underneath these options you are advised as to what Save option you need to select. These instructions underneath change depending on the choice you made from one of these options. Please make sure you read and follow them.



*Explanations:*

- Finish data entry for this patient

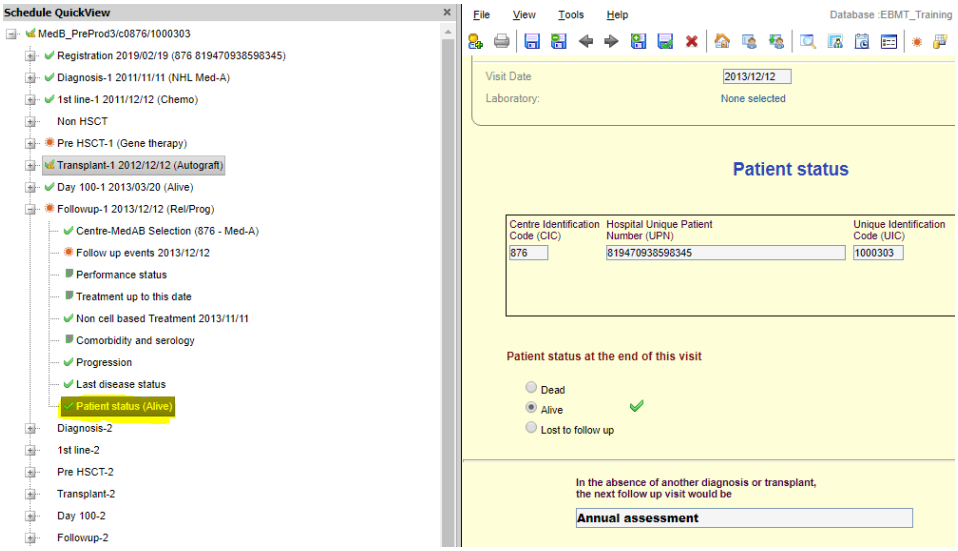
This should be the most common choice to make at the end of any registration. The reason for this is that if you are reporting on time, you will not be able to choose any of the rest of the options, as they would all refer to the future (either 100 days later or a year later, depending on whether you wanted to report Day 0 or Day 100 respectively). However, if you are reporting retrospectively, you might want to continue with any registration that follows, which is why all these options are there.



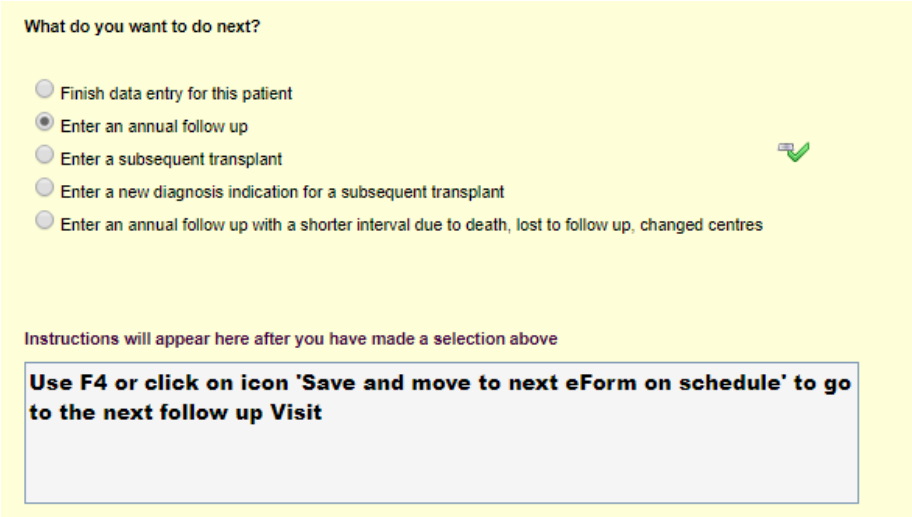

- Enter an annual follow up

This option should appear only after the latest registration is a Day 100 or a previously reported Annual Follow Up. Logically, it should not appear when you have finished a Day 0, but instead you should have 2 Day 100 available options. The **time restriction** in reporting an annual follow up is from 2 months before to 2 months after the 1 year post transplant. You will not be allowed to record a Follow Up outside this 4-month timeframe.

This is also the way to report a patient who is **Lost to Follow Up**, if you have a new date to report this. Alternatively, you can amend an already existing follow up's Patient Status from Alive to Lost to Follow Up, found in the Form called Patient Status:

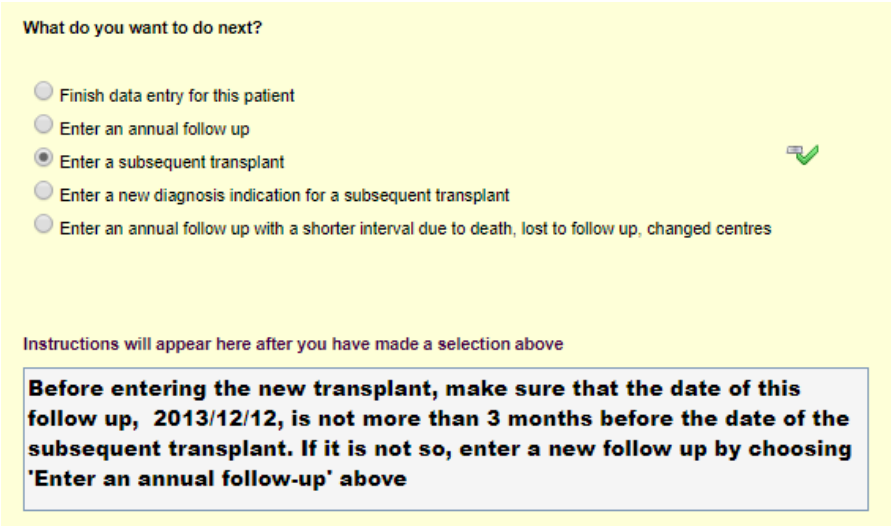



PLEASE NOTE: this <u>not</u> the option to select if you are reporting a <u>Death</u>, which is *outside* the 4 months timeframe mentioned above. For this case read below the **Shorter Interval** option.



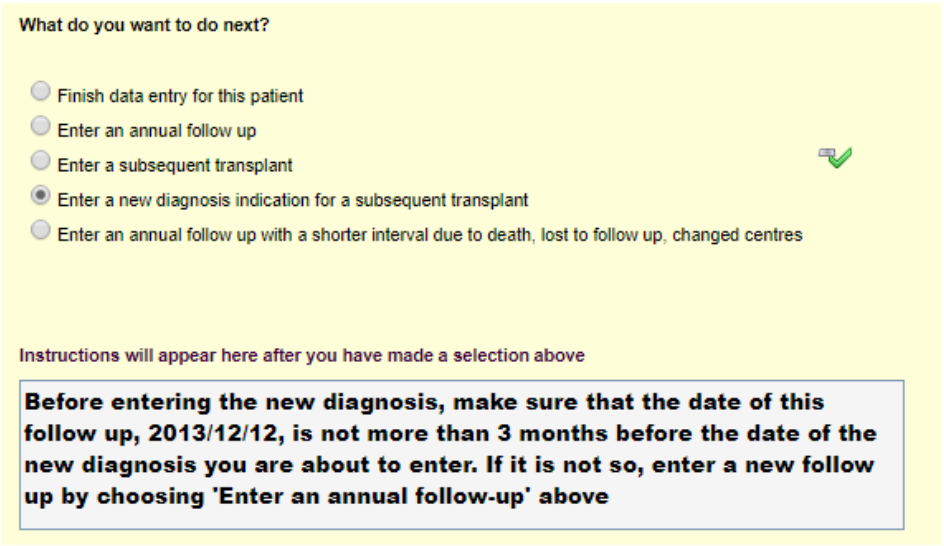

- Enter a subsequent transplant

This option is offered for the case where a subsequent transplant is taking place before the passing of a 3 months' period. If the new transplant is over 3 months since the most recent Visit, then you are requested to add a Follow Up first, and then select this option to record the new treatment. As it is explained in the message below, when you select this option:



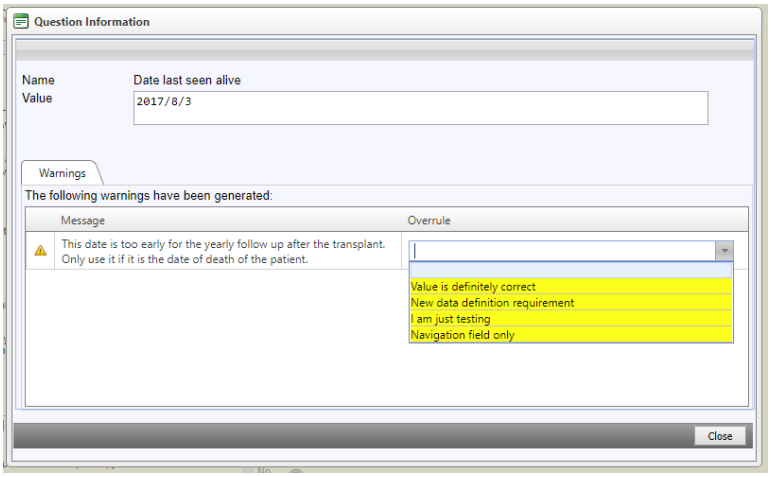

- Enter a new diagnosis indication for a subsequent transplant

Same as the option "Enter a subsequent transplant", you will be requested to enter a follow up first, if there has been over 3 months, since the most recent Visit. Again, it is explained in the message below:

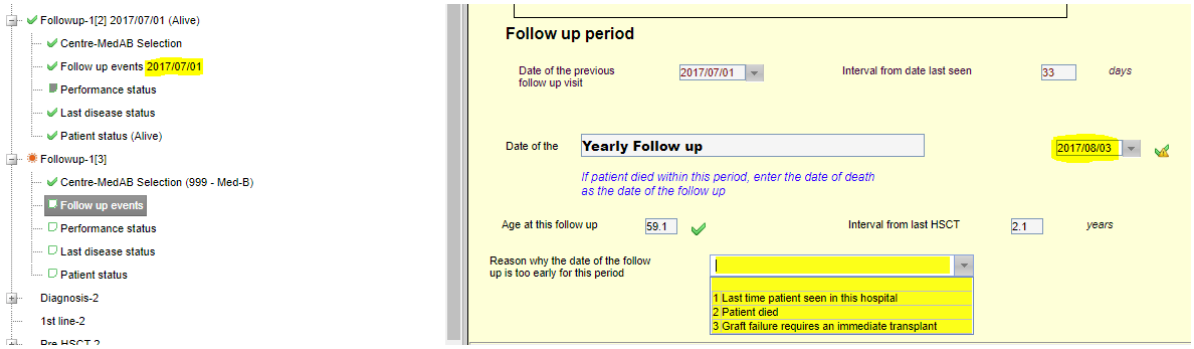



- Enter an annual follow up with a **shorter interval** due to death, lost to follow up, changed centres

This option is offered so that you are allowed to "skip" the time-restrictions mentioned in the 4 options above. If you choose to select it, you will be asked for the reason why the **Shorter Interval**, before you are able to continue. The key element in this option and the reason of its existence is only the time that has passed since the most recent Visit. Of course, a valid reason to select this option would be the **Death** of the patient. If you choose to select it, a new Follow Up Visit will be created, and the moment you give the new date (which would be less than 3 months), you will first get a Warning message with options for why you are Overruling this rule:



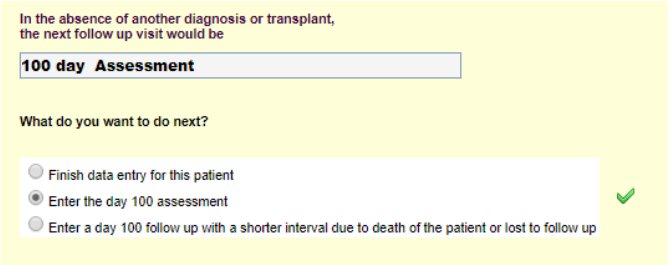

And then you will have to provide a "Reason why the date of the follow up is too early for this period":




- Enter the 100 day assessment

This option is offered only at the end of a Day 0 registration, as it is not applicable elsewhere. The **time restrictions** applied here are from 80 days post-HSCT to 150 days post-HSCT.

PLEASE NOTE: this is <u>not</u> the option to select if you are reporting a <u>Death</u>, which is *outside* the 70 days timeframe mentioned above. For this case read below the **Shorter Interval** option.




- Enter a 100 day follow up with a **shorter interval** due to death of the patient or lost to follow up

Same as for the annual follow up, this option is offered so that you are allowed to "skip" the time-restriction mentioned in the option above. If you choose to select it, equally you will be asked for the reason why the **Shorter Interval**, before you are able to continue. The reason of its existence is again

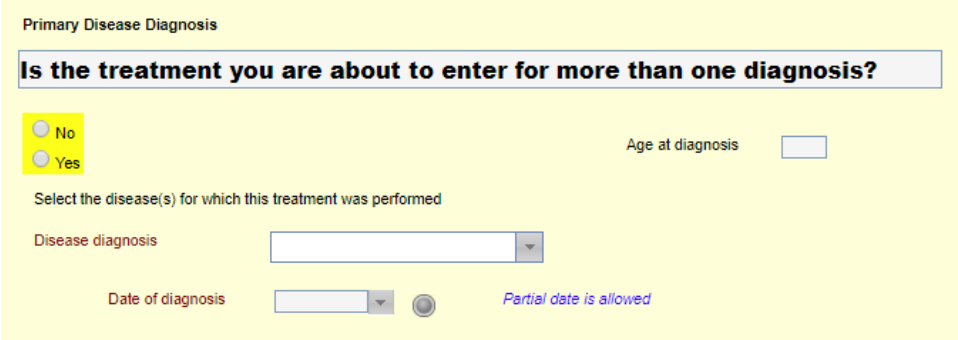
only the time that has passed, since the most recent Visit. A valid reason to select this option would be the **Death** of the patient. If you choose to select it, a new Follow Up Visit will be created, and the moment you give the new date (which would be less than 80 days), you will first get a Warning message with options for why you are Overruling this rule, and then the "Reason why the date of the follow up is too early for this period".

# Diagnosis Visit

## Diagnosis Visit

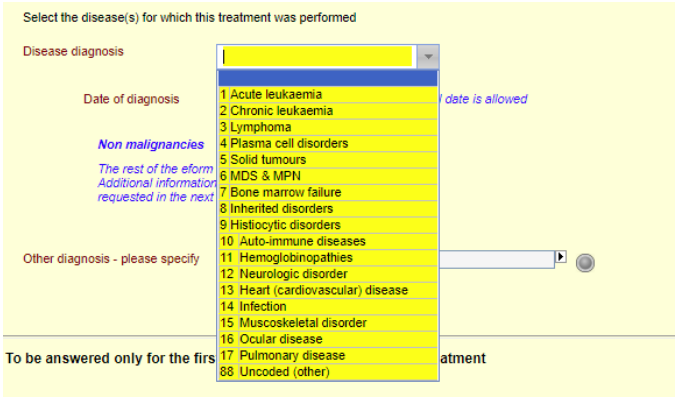
The first Question from the first Form (**Centre**) you have to answer in the Diagnosis Visit is the type of form you are about to use: either MedA or MedB:


After you answer the above, you are taken to the Question below, which is the first one in the **Primary Diagnosis** Form:




Usually the answer to this would be No, but there are rare cases of what is called **Simultaneous Diagnosis** and there is a special section about this in the Chapter called "Complex Cases (examples)".

The following Question is naturally the **Main Disease Classification**, where you select one of the available options below:




PLEASE NOTE: the first 11 of the above options are applicable *only* to **HSCT**s, whereas if you are reporting a **Cell Therapy**, you can choose any of the 17.

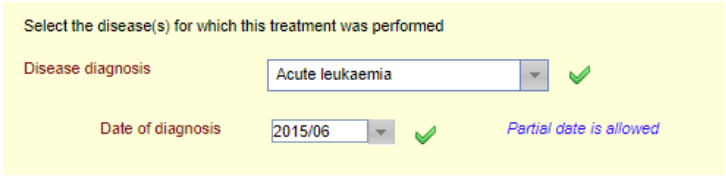
The code 88 for "Uncoded (other)" is *extremely rare* that will be needed, as we make sure that we update our lists with all possible diagnoses, in accordance with the WHO Classifications. What is more, we have a help file on our website called "List of Disease Classifications":

https://www.ebmt.org/ebmt/documents/dismclfd-list-disease-classifications

found under The Registry/ Data Collection: https://www.ebmt.org/registry/data-collection

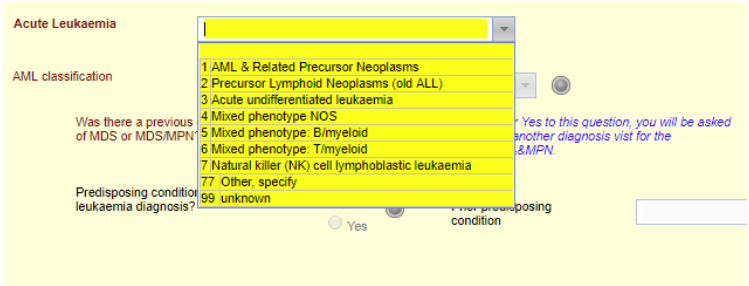
where you can see how *diagnoses and their sub-classifications* can be coded in MACRO. If you are uncertain about how to record a diagnosis, and before you select the option Uncoded, please contact our Registry Helpdesk at: registryhelpdesk@ebmt.org

PLEASE NOTE: for the Diagnosis' dates a "Partial date is allowed", as occasionally the exact date of when a disease was diagnosed is not easy to pinpoint:



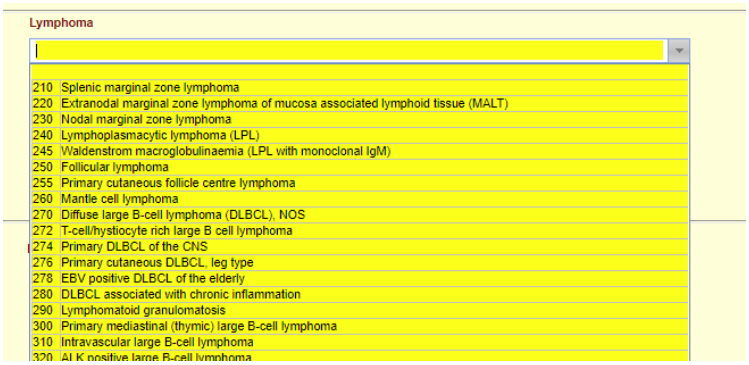

For example, you can enter just the Year and the Month, or just the Year.

Depending on your choice of a Main Disease Classification, and after you also provide the Date of Diagnosis, MACRO will take you to the corresponding **Sub-Classification** Question. For example, if you select Acute Leukaemia, you will be asked to choose from the following options:



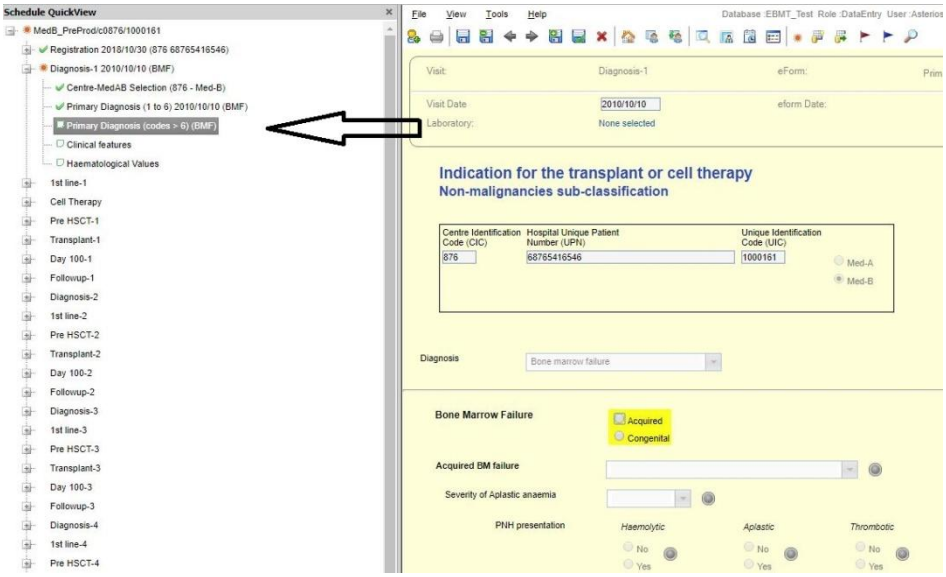
and then its corresponding sub-classification (or not), depending on your choice.

If you select Lymphoma, it will ask you for the Lymphoma Sub-Classification:




PLEASE NOTE: in some Main Disease Classifications there will be another Primary Diagnosis Form created (for codes 7 to 11), where you will record the corresponding Sub-Classification.

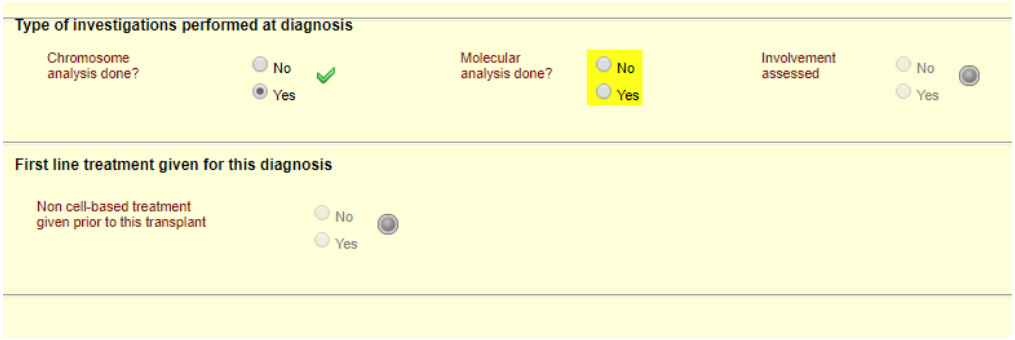
Some of the diseases will be recorded it the form called “Primary Diagnosis (1 to 6) and some will be recorded in the one called “Primary Diagnosis (codes > 6), as shown in the screenshot below. This is reflecting your choice of the Main Indication Diagnosis (“Disease Diagnosis” question) that you choose first.




ALSO NOTE that if you create the Form “Primary Diagnosis (codes >6)” in error and you do not want to use it, you cannot delete it and it will then appear as Missing. The way to amend this is found in the Chapter of this manual called: “Modifying Existing Data”.

## Chromosome Analysis – Molecular Markers – Involvement – Non cell-based treatment (note that the Non-Cell Based Treatment is recorded in the following Visit (**1st line**))

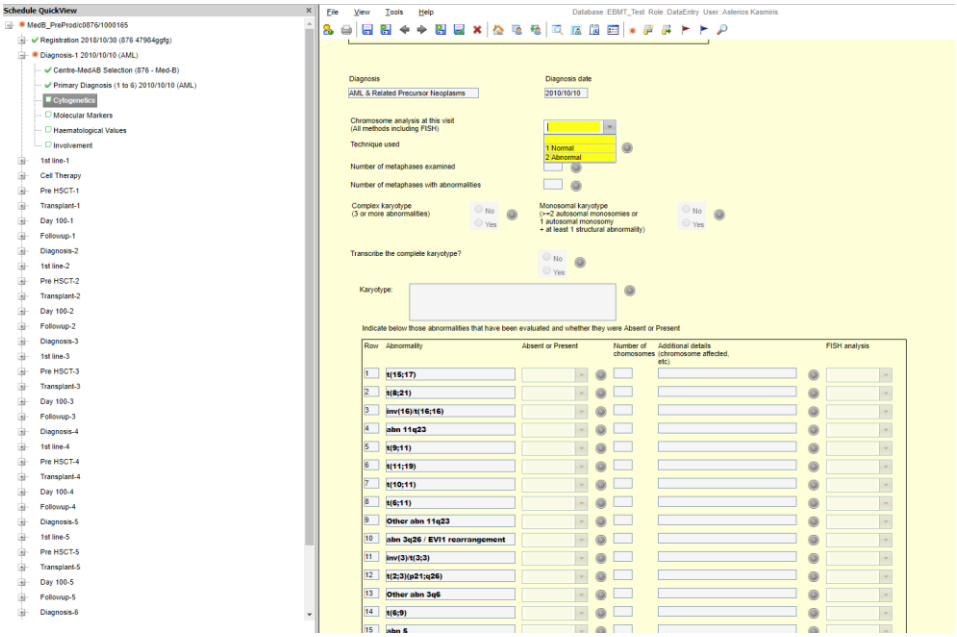
These Forms that are found in the Diagnosis Visit are activated by answering their corresponding Questions found at the end of the Form “Primary Diagnosis (1 to 6)”:



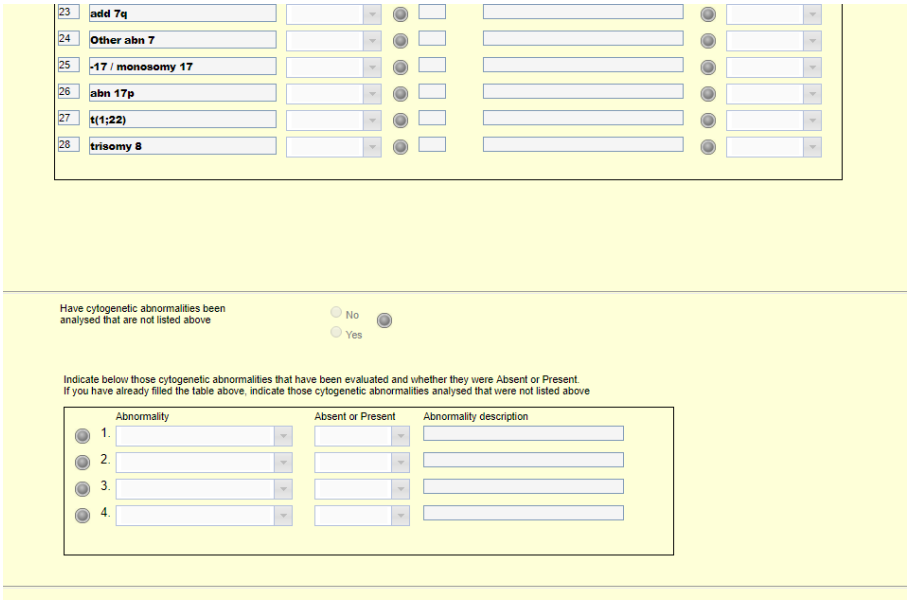

These Questions are activated or not depending on the diagnosis you have just selected, and will activate or not their corresponding forms in the Diagnosis Visit. This happens after the Form is saved and the patient record reloads itself.

*Chromosome Analysis (Cytogenetics)*

The first Question you have to answer if you have activated this Form is whether your result was Normal or Abnormal. You can also see in the screenshot below that some options in the RQG are pre-selected for you, but note that which options will be active depends the on disease you have selected, as each one has its own likelihoods.



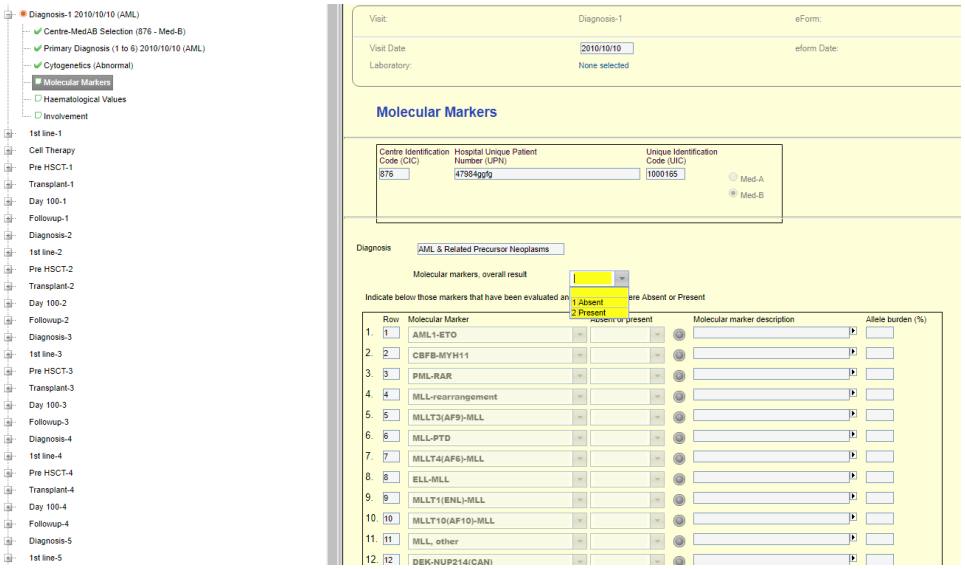

If however in your results you have found any that do not appear on this list, there will be another RQG underneath, where you can enter them:




which you can access by answering Yes to the Question "Have cytogenetic abnormalities been analysed that are not listed above".

*Molecular Markers*

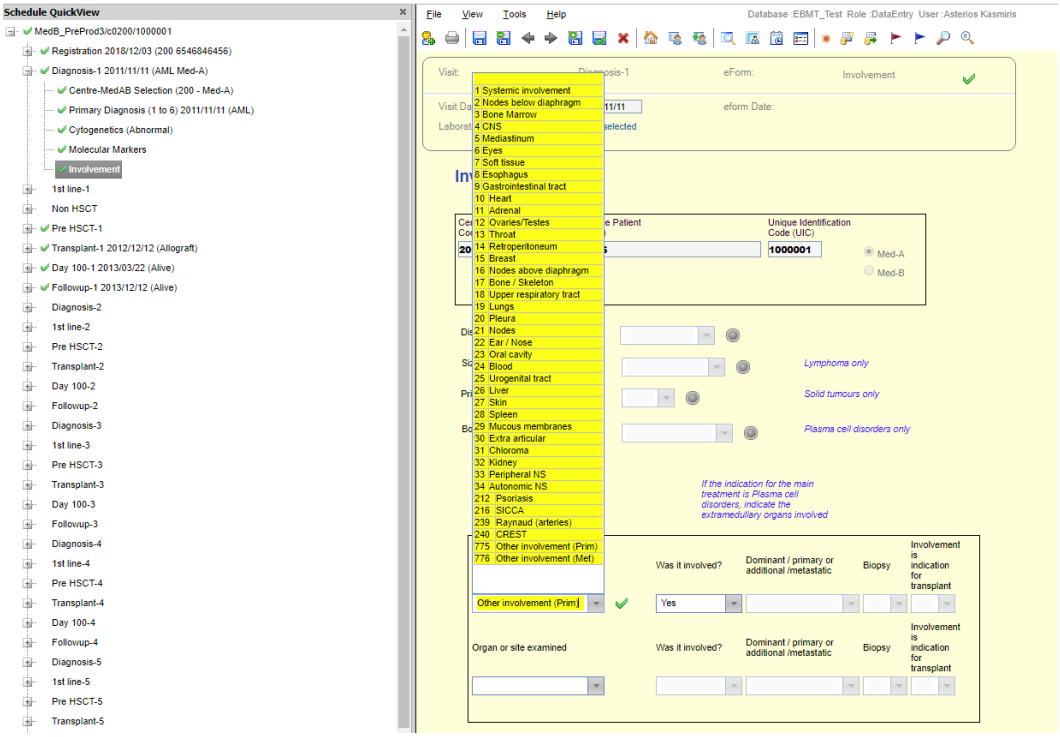
Same as the Cytogenetics' Form, but instead you first have to answer Present or Absent:



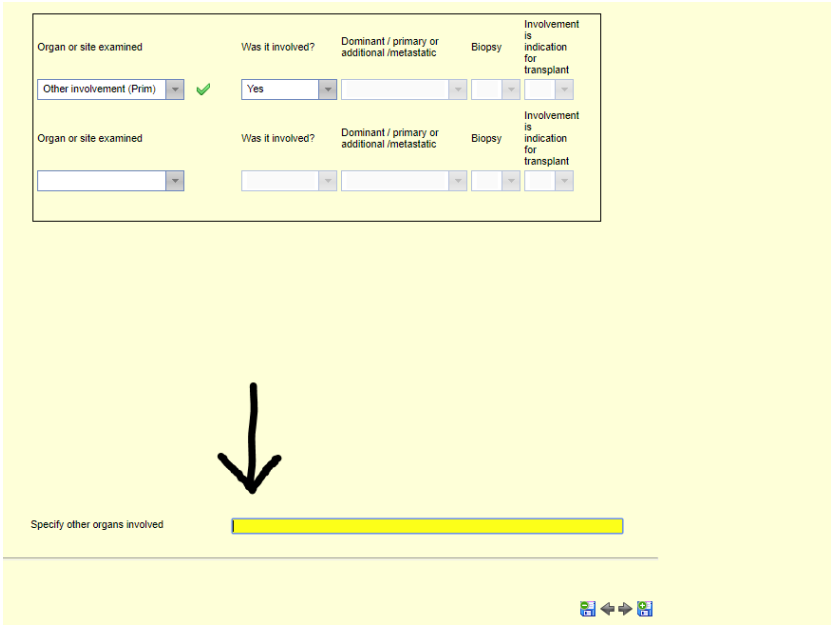

Again, like above, if your results are not included in the listed ones, you are given the option to add them underneath.

*Involvement*

In the Involvement Form, instead of a screening question you are first selecting the organ assessed and then whether it was involved or not:

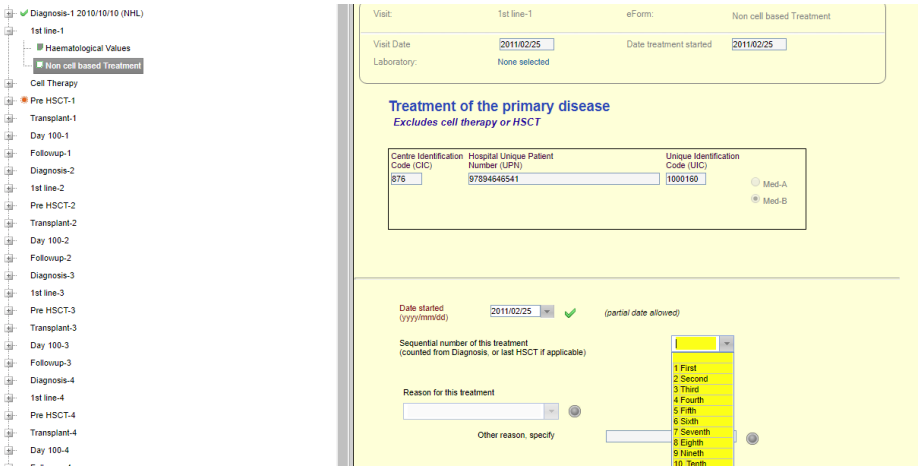



The other difference is that instead of having a separate RQG for those that are not listed, you are offered a few options of "Other Involvement" to select from( codes 775 and 776), and you can then type them in the field provided underneath, called "Specify other organs involved":




*Non cell-based treatment*

If you answer Yes to this screening question, this Form will be active in the "1st line" Visit. This is where any Pre-HSCT Treatment(s) is/are recorded and it is again disease dependent (for certain diseases it is not required). First you provide the date it started and then its sequential number:




Please read the following Chapter for more details.

PLEASE NOTE: this question is *Disease dependent* (certain Working Parties do not consider it a requirement).

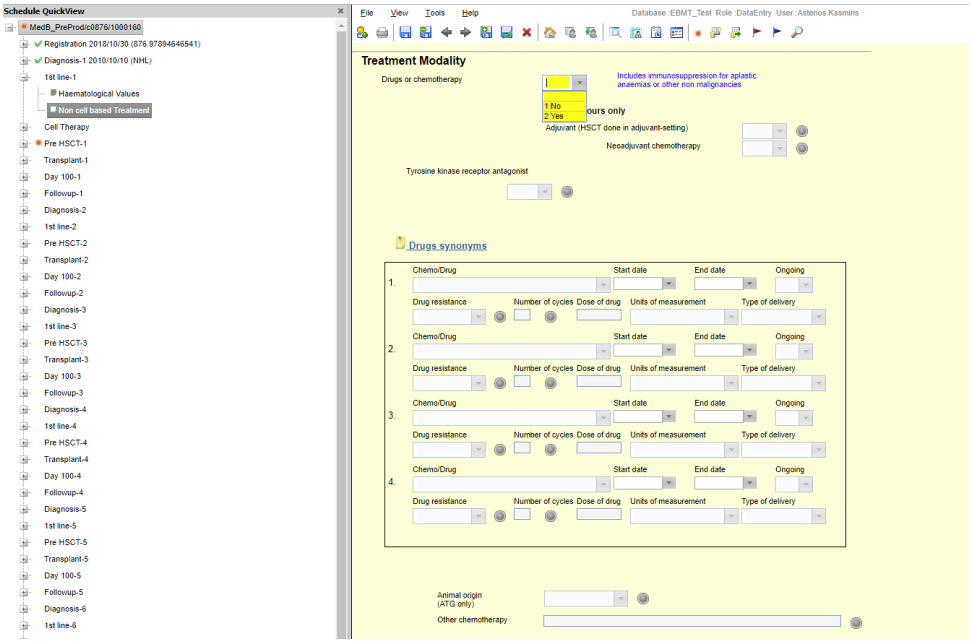
## 1st line (Pre-HSCT) Visit – Non-cell based Treatment Form

As continued from above, after you answer the Date Started and the Sequential Number, you are taken to the Drugs RQG. On a clinical note, this is where you indicate whether the patient has been treated before the treatment procedure (transplant or cell therapy). This will be the case for practically all patients (unless, for example, the diagnosis is AML, where this is not a requirement). However if it is precursor lymphoid neoplasm you should complete it. For more information on this, please refer to our Manual:

https://www.ebmt.org/ebmt/documents/med-ab-forms-manual

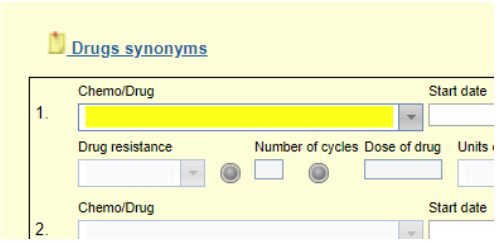
on sections like “Pre-HSCT Treatment” or “First Line Therapy”.

PLEASE NOTE: for certain diseases, this Question is not a requirement and will therefore be skipped. Moreover, for certain cases there could be NO 1st line treatment given, in which case you simply answer No to the screening question mentioned in the previous chapter.




If you answer Yes to the question “Drugs or Chemotherapy”, you will then be asked for the drugs administered, but if you answer No, the section Treatment Modality of this Form will be skipped and you will be taken to the Other Modality section underneath.

PLEASE NOTE: on top of the Drugs RQG there is a hyperlink that should take you to our document “**Med-AB List of Drug Names and Synonyms**”:



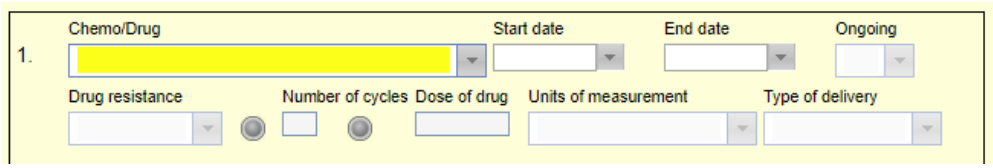

where you can find alternative names for drugs depending on the country they are used, along with their codes for MACRO. The list also includes **Protocols** (and their codes) and the drugs they are consisted of.

You can also find the same document on the EBMT website, under the Registry- Data Collection:

https://www.ebmt.org/ebmt/documents/med-ab-list-drug-names-and-synonyms

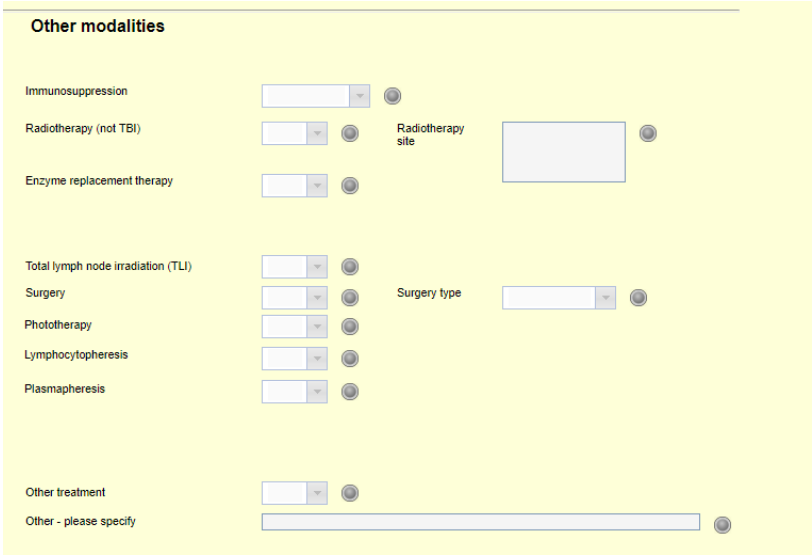
PLEASE NOTE: although the **Protocols** can be used in the Non Cell-based Treatment, they should *not be used* when reporting the **Conditioning** (preparative regimen), as in the conditioning the doses and their units of measurements are also required, which cannot be indicated just by selecting the protocol name. For more details on the Conditioning, please read the corresponding section in the Transplant Visit Chapter further down.

The Drugs RQG offers you a range of options for reporting:

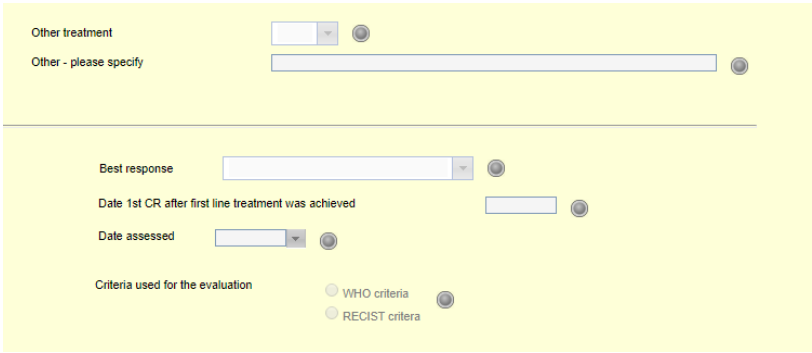



But note that not all drugs will be available, as it will depend on the type of form you are reporting (MedA or MedB), the type of treatment (for example, in conditioning the dose and unit of measurement are activated), the Disease, etc.

This form's following section, Other Modalities, offers a selection of other types of treatments like Total Body Irradiation (TBI), Total Lymph node Irradiation (TLI), Surgery, Phototherapy, etc.

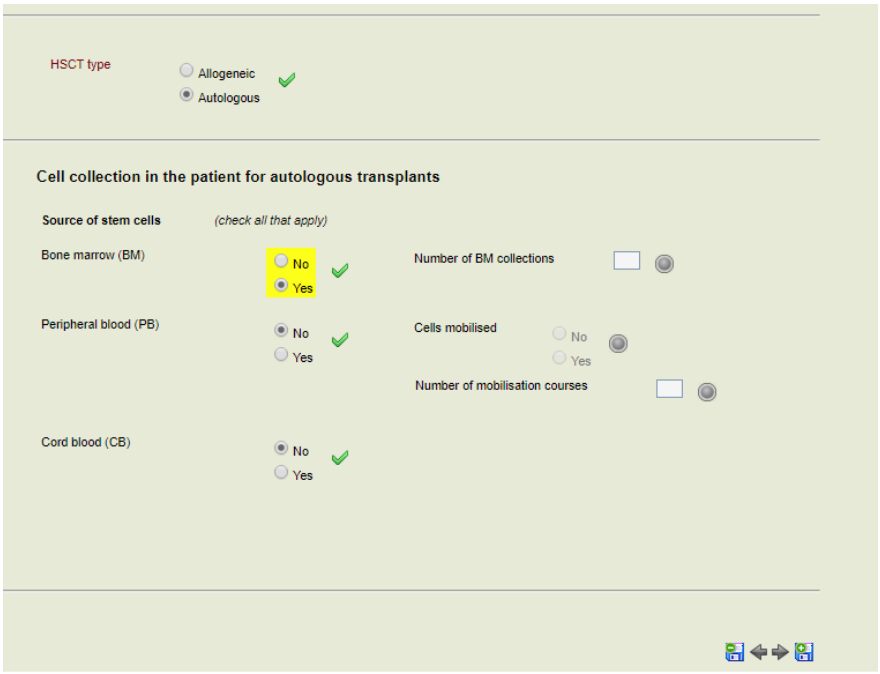



At the end of a treatment you also need to provide its **Best Response**, but it's again disease dependent:

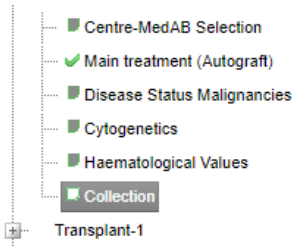



## Pre-HSCT Visit (Mobilisation / Collection Form)

The main Question that is mandatory in this Visit is the **HSCT Type** (allogeneic / autologous):



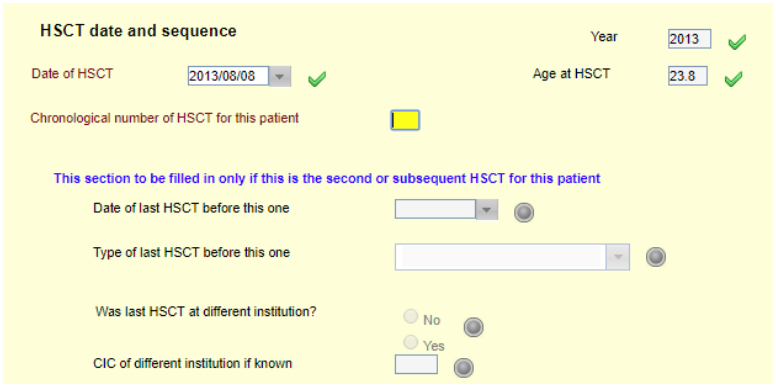

Note that the section underneath has to do with autologous transplants, so by selecting Allogeneic this whole section will be skipped. What is more, depending on the Source of Stem Cells chosen, corresponding forms will become active. For example, the form Collection:



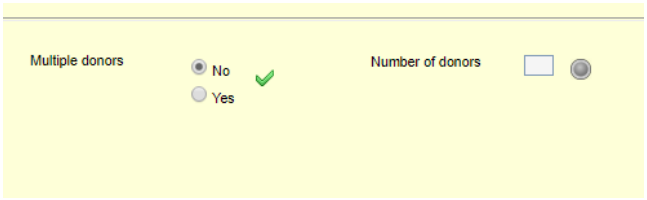

where you may record any cells' or genes' **Manipulation**, **Mobilisation** details, etc.

## Transplant Visit

The first 2 questions of the first Form (HSCT basics) are mandatory (marked in Red font):



Then follows the section on Multiple Treatment Programs, and then, if you are reporting an Allogeneic treatment, follows the question about Multiple Donors:




where if you answer Yes, you are asked for the number of donors.

PLEASE NOTE: for a single treatment you can have multiple donors providing 1 or more products each, or you can have 1 donor providing 1 or more products, and there can be any possible combinations. For example, you can have 2 donors: the 1st providing BM and PB and the 2nd one providing cord blood. This is the reason why there is a separate question, found in the form Donor Registration, where you are asked for the number of products:


The *Transplant Visit* can have a range of forms that may or may not get Activated depending on the case you are reporting.

The form **Disease Status Malignancies** is used to record the status of the disease **at** HSCT. You will be taken to the corresponding section of this form depending on the disease you have selected.

The **HSCT Prep Infusion** Form is where the Conditioning (Preparative Regimen) is recorded.

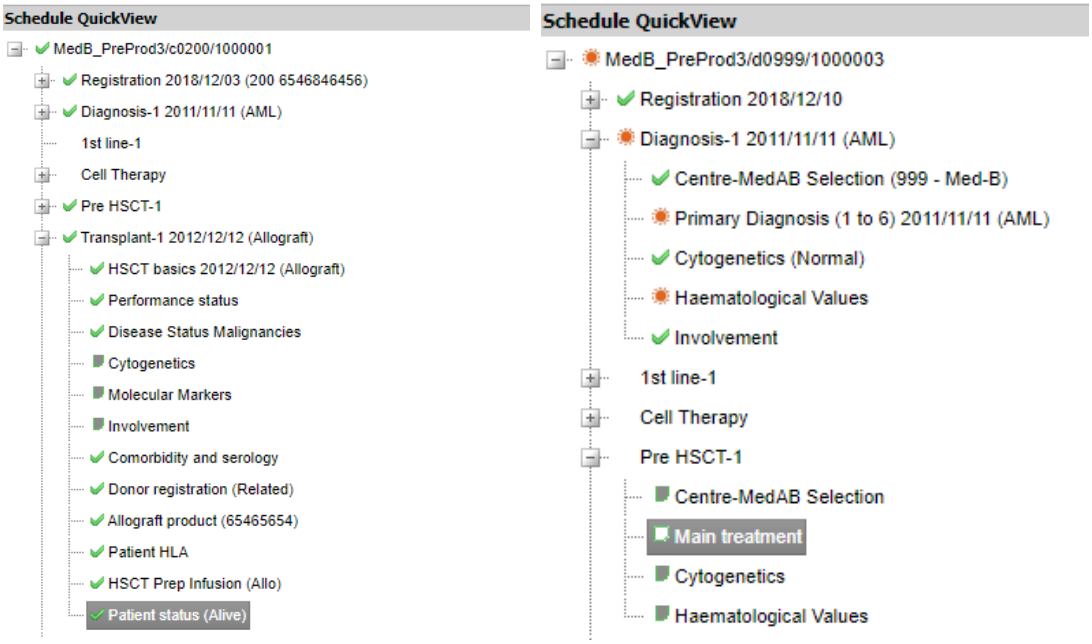
PLEASE NOTE: it is Mandatory to report the drug names individually, along with their Dose and Unit of Measurement (as opposed to Pre-HSCT Treatment, where you only provide either individual drug names or Protocols).

The **Patient Status** form appears at the end of *every* visit (except the Registration one), as you need to answer whether the patient is alive, dead or lost to follow up. For more information on this form, please refer to the chapter of this manual called: "Navigation (how to continue or finish a registration)".

PLEASE NOTE: the Patient Status form of the Transplant Visit (i.e.: Day 0), besides the options Dead or Alive, there is also a 3rd option for patients who die after conditioning has started, but before the treatment was performed, should also be reported. (MACRO users should register those patients

entering 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 for the Patient Status: please select the option "**Died before cell infusion started but after preparative regimen was initiated**").

If all of the forms of a Visit have no Missing items (or otherwise marked; e.g.: Warning, OK Warning, etc.) a green tick appears on the left of the visit (please see the screenshot on the left side below). If there is at least one form that has at least one missing item then the whole visit is marked as Missing too (screenshot on the right below).

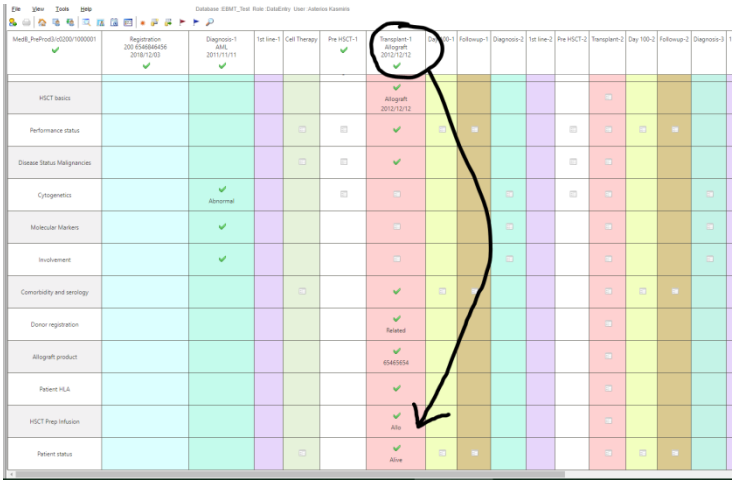



For more information on options of labelling of a question/form/visit and the hierarchy in which they appear, please refer to the chapter "How to use the Schedule QuickView" of this manual.

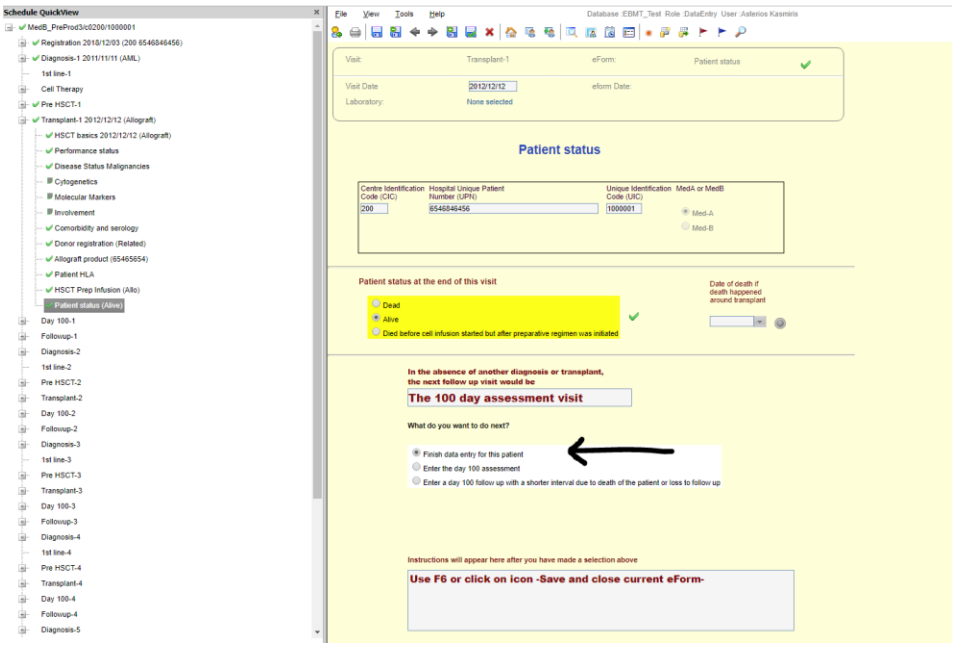
## Day 100 Visit

For the implemented **time restrictions** on when to report the Day 100, please refer to the chapter "Navigation (how to continue or finish a registration)" of this User Guide.

In the Subject Visit Schedule you scroll down until you see the last Form called Patient Status in the most recent **Transplant Visit**:



You then double-click on this Form to open it (the above screenshot has the form marked with a Green Tick (OK), but it can be other symbols appearing instead), which should look like this:




The option already chosen will be the one you had selected the last time you had entered data on this form (normally the option shown above). You can now see that since you are at the Transplant Visit, you are presented with the option to record the Day 100 report (for example, the Annual Follow Up is not available, since you need to record a Day 100 before you report an Annual Follow Up). You then select the option “Enter the Day 100 Assessment” and you can see that the text below, that advises you what you need to do next, has changed:

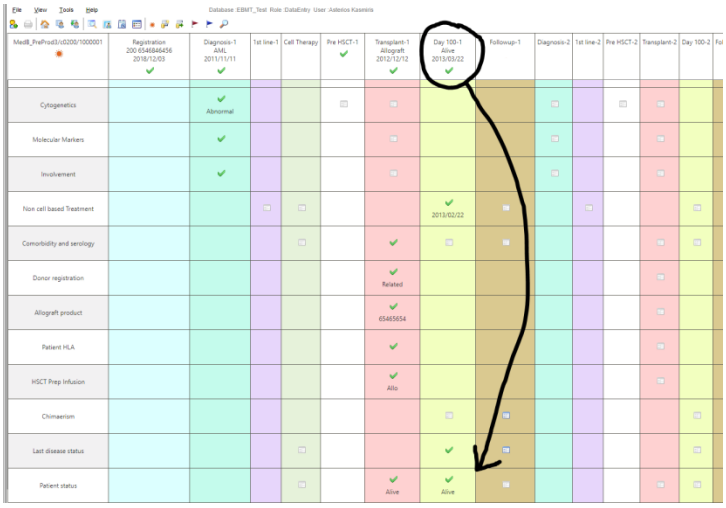

Once you Save and move to the next form, the Day 100 Visit will have been activated. You will be asked whether you want to move to the next visit or not like normally.

The first form that gets activated is the **Response to Main Treatment**, as it is an important part of the follow up procedure, followed by the form **Reconstitution**, which is a Day 100 requirement. Then you report any Complications (GvHD and/or Relapse) and/or Additional Treatment (chemotherapy, radiotherapy, cell therapy) in the form **Follow up events**. Note that certain forms either will or will not be activated, depending on your answers in the forms above. The form **Patient Status** will appear at the end of each type of a visit created in MACRO.

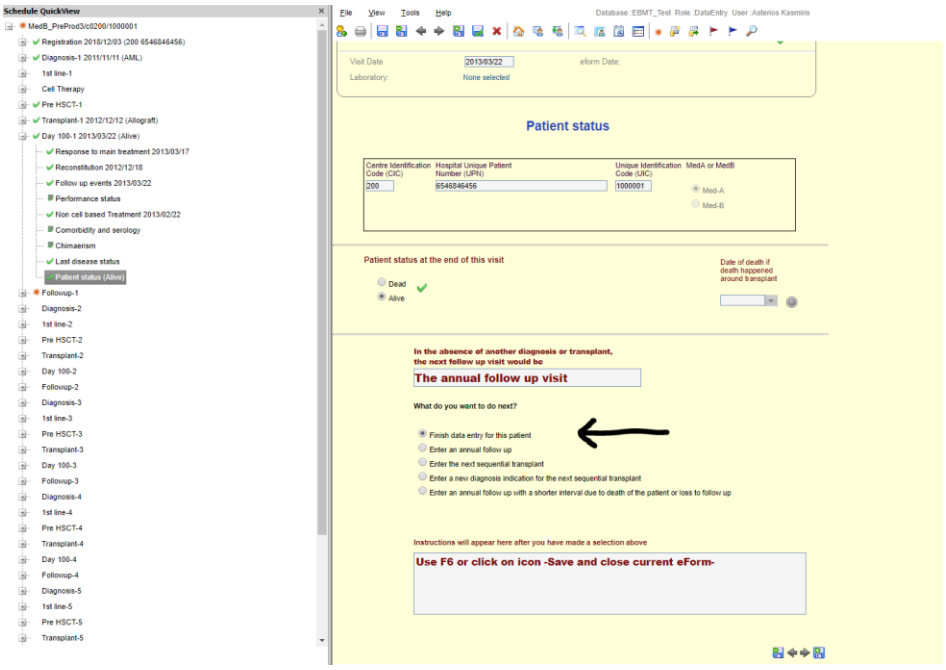
## Annual Follow Up Visit

For the implemented **time restrictions** on when to report the Annual Follow Up, please refer to the chapter “Navigation (how to continue or finish a registration)” of this User Guide.

In the Subject Visit Schedule you scroll down until you see the last Form called Patient Status in the **Day 100 Visit**:



You then double-click on this Form to open it (the above screenshot has the form marked with a Green Tick (OK), but it can be other symbols appearing instead), which should look like this:

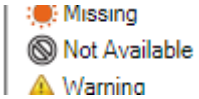



You can now see that, since you are at the Day 100 Visit, you are presented with the option to record an Annual Follow Up report (for example, the Day 100 one is not available, since it can only be recorded right after the Transplant Visit).

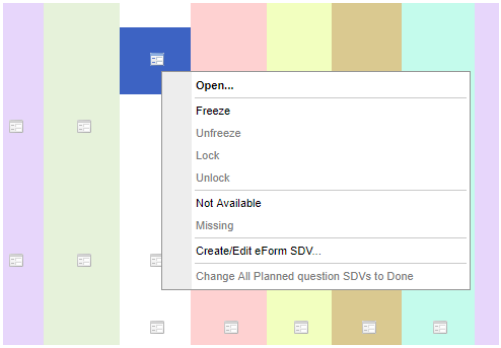
In the form **Follow Up Events** you are, like in the Day 100 form, asked to provide any Complications (GvHD and/or Relapse) and/or Additional Treatment (chemotherapy, radiotherapy, cell therapy). However, you are also asked some questions that did not appear in the Day 100 form (e.g.: Secondary Malignancy or Conception questions are also asked). The form **Performance Status** appears here too, as it did in the Transplant visit. The form **Patient Status** will appear at the end of each of the following visits created in MACRO: Day 0, Day 100 and Annual Follow Up, but please note that the end of a Day 0 would be the Transplant Visit.

# Modifying existing data

The diagnosis forms in the Diagnosis Visit are 2: the 1st one includes codes from 1 to 6, which is also the default (it appears always automatically), but if you select diagnosis code 6 or higher, then a 2nd form is created, where you would record its sub-classification with its specifics. If you create by mistake a Primary Diagnosis Form for codes >6 (e.g. BMF), but you actually wanted to report a Multiple Myeloma (which is code 4.Plasma Cell Disorders), you can *MARK* the already created "Primary Diagnosis >6" as Not Available:

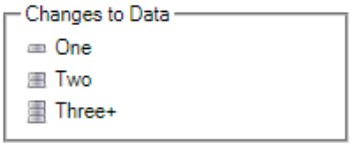



You can mark it as such from the SCHEDULE (not the Schedule QuickView) by right-clicking on it:

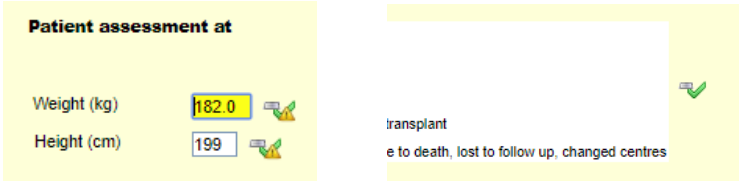



PLEASE NOTE: when you do that, the option SAVE will be activated, and then after you save the Form, it will be marked as OK (Green Tick) and relabelled to the correct Diagnosis (e.g. MM).

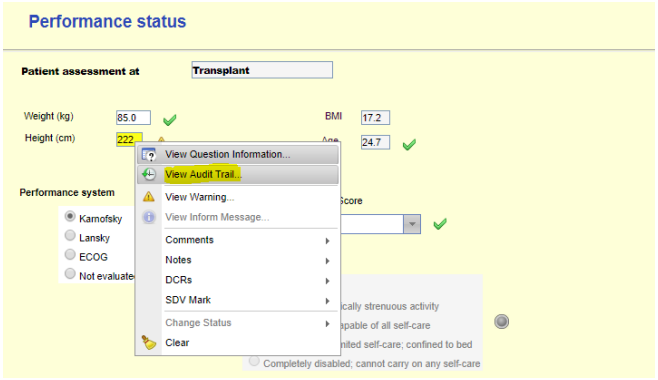
In terms of changes you make to a specific question, there is a symbol to indicate the number of changes found next to each question that has been modified:



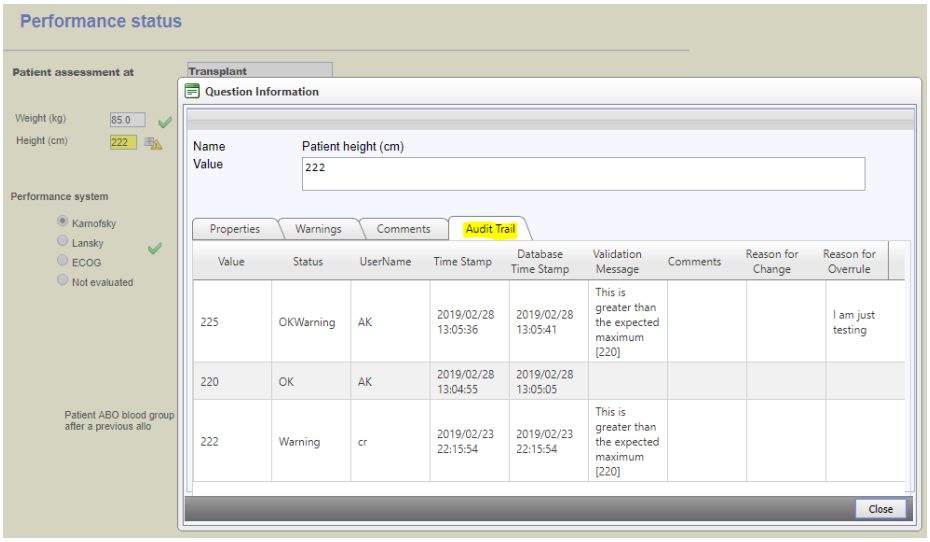

The above symbols will appear along with the Status symbol of the question (e.g.: OK, Warning, Missing, etc.):



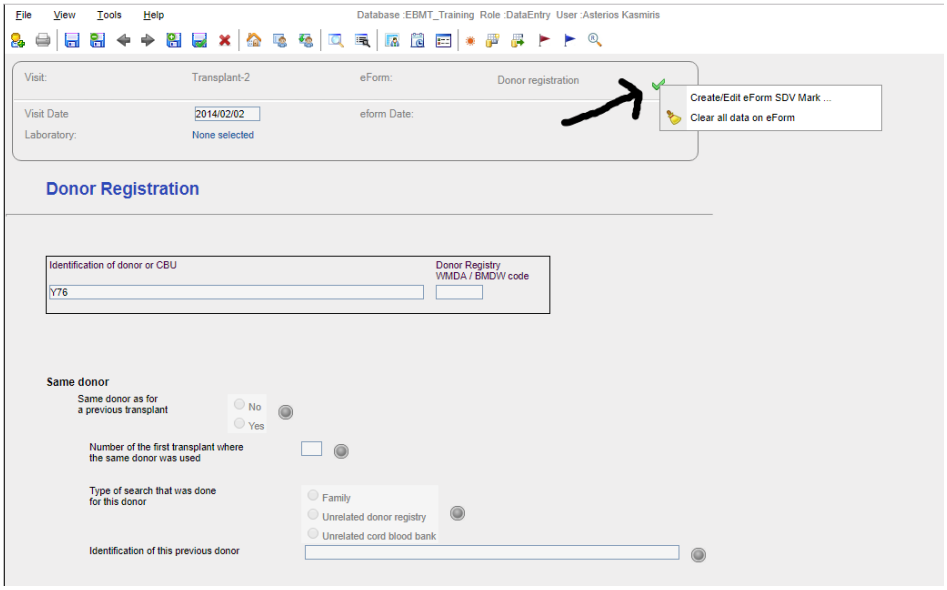

In addition, you can right-click on the actual question and you select the option View Audit Trail:




which will then open a window, where you can see who made what change, when, etc.:




To remove all existing responses on a Form, click on the Form status icon at the top right (this icon is only visible after saving the Form) and select "**Clear all data on a Form"**.



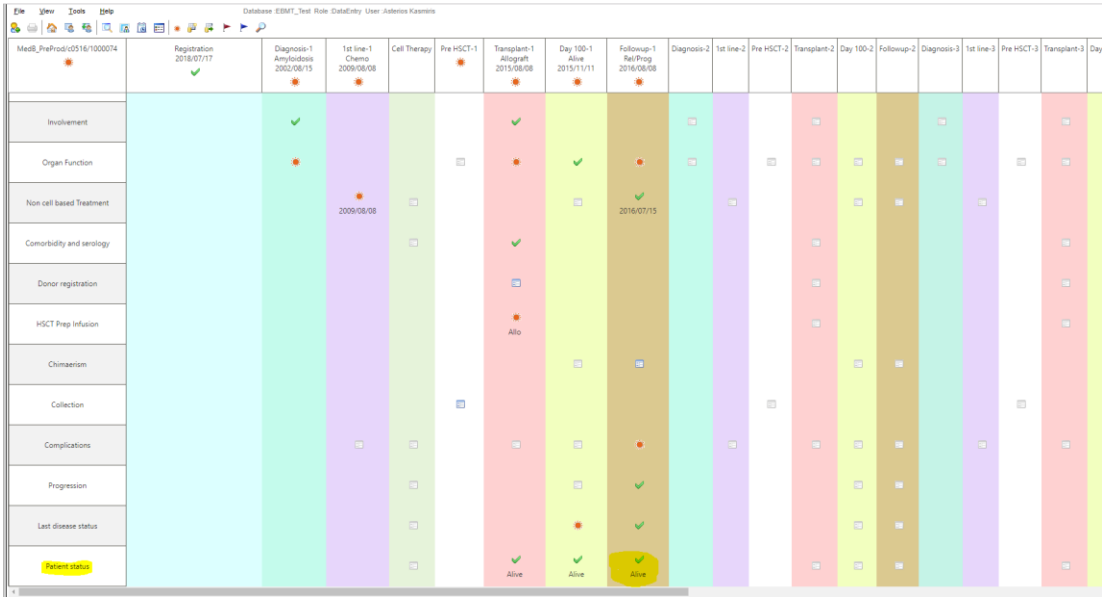
If this option appears greyed out, either the Form is locked or frozen, or you do not have the required permission. You cannot clear questions that are locked, frozen, or derived from values on another Form.

## Complex Cases (examples)

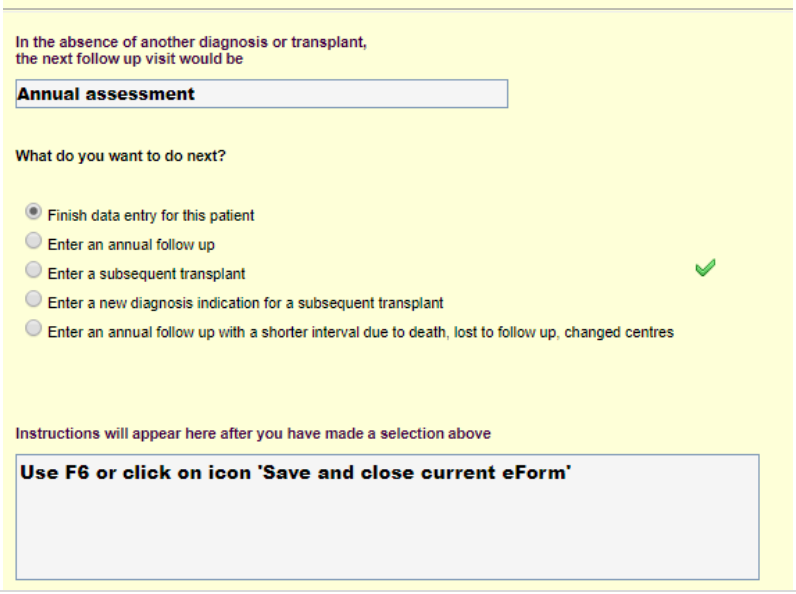
### Centre/Site with **Access** to a Subject that was created in another centre

In the case where a Site/Centre is granted with access to a Subject record that had a treatment in a different Site, after you are given access, you have to provide the information of your own Site in the first Form called **Centre**.

In the Subject Visit Schedule you scroll down until you see the last Form called Patient Status in the most recent Follow-Up Visit:



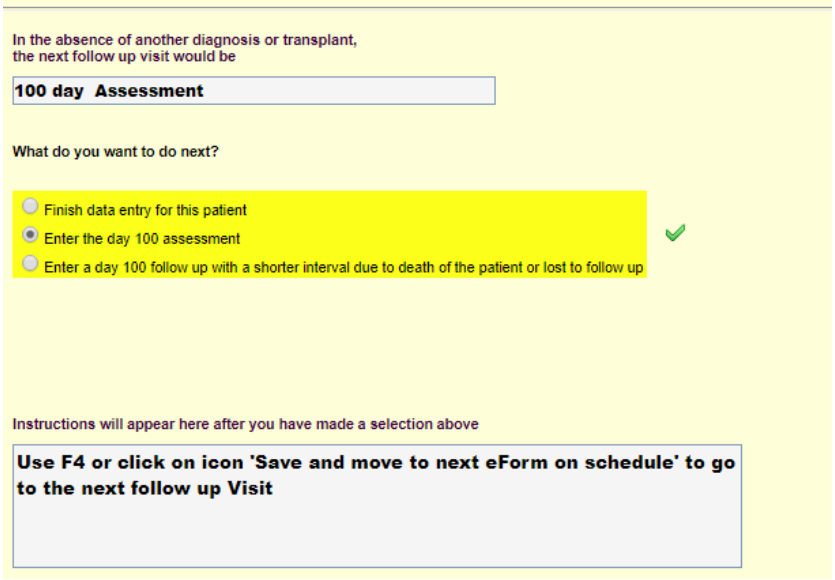

and you double-click on it to open the actual Form:



You can see in the above Form that you are presented with certain options:

- Finish data entry for this patient
- Enter an annual follow up
- Enter a subsequent transplant
- Enter a new diagnosis indication for the next transplant
- Enter an annual follow up with a shorter interval due to death, lost to follow up, changed centres

PLEASE NOTE: the options above may vary depending on the type of the Visit you are. For example, at the end of a Day 0 registration you are presented with the following options:




Accordingly, in a Day 100 Visit the 2nd from the above options will not appear as it is not applicable.

EXAMPLES:

If you were given access to this Subject because you are the new Follow-Up Site for this patient, then you select the option “Enter an annual follow up”.

If you were given access to this Subject because you are the new Site for a subsequent treatment (transplant or cell therapy), then you select the option “Enter a subsequent transplant” for an HSCT or “Enter Annual Follow Up” for a Cell Therapy. This means that the subsequent treatment is performed for the same indication diagnosis.

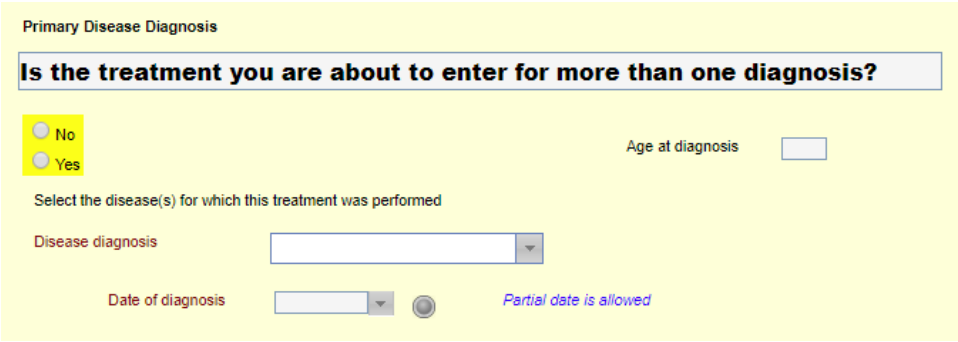
If you were given access to this Subject because you are the new Site for a subsequent treatment, but there has been a new diagnosis in the meantime, then you select the option “Enter a new diagnosis indication for the next transplant”.

For how to use the option “Enter an annual follow up with a shorter interval due to death, lost to follow up, changed centres”, please refer to the section “Navigation (how to continue or finish a registration)”.

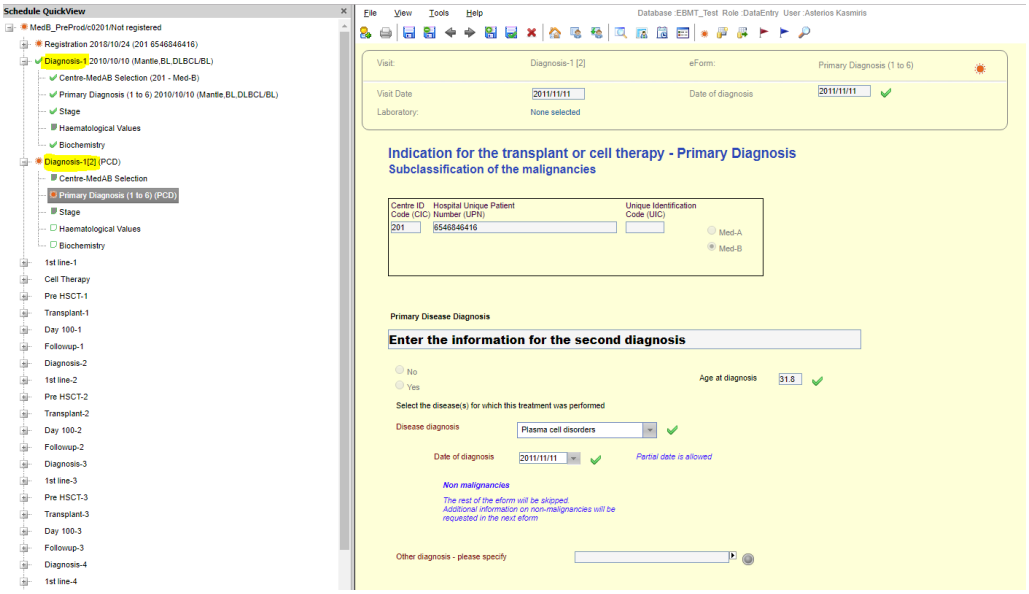
Finally, the option “Finish data entry for this patient” is used for when you are ending the registration of a Visit and you want to Save and Close the record, as you have no more reporting to do (for example, the previous treatment (transplant or cell therapy) took place 4 days ago, and you will re-visit the patient record in 100 days to report the Day 100). This option is not applicable for the scenario we are describing in this section, as it will already be chosen when you access the Patient Status form. You will need to select it *after* you finish your current reporting.

## How to record a **Simultaneous Diagnosis**

What defines whether a Diagnosis is considered a Main Indication or an Other, Non-Indication Diagnosis is whether a treatment was given to treat it or not. In some cases, an HSCT is performed to treat more than just one diagnosis, where both of the recorded Diagnosis would be considered as Main Indication, even if they were diagnosed with a few years of difference. This is known as **Simultaneous Diagnosis**. In MACRO, after you finish the patient’s information in the Registration Block and you move to the Diagnosis Visit, the first Form you fill in is the Centre and then you move to the “**Primary Diagnosis**” Form. On the very top of this form, you are first asked this:

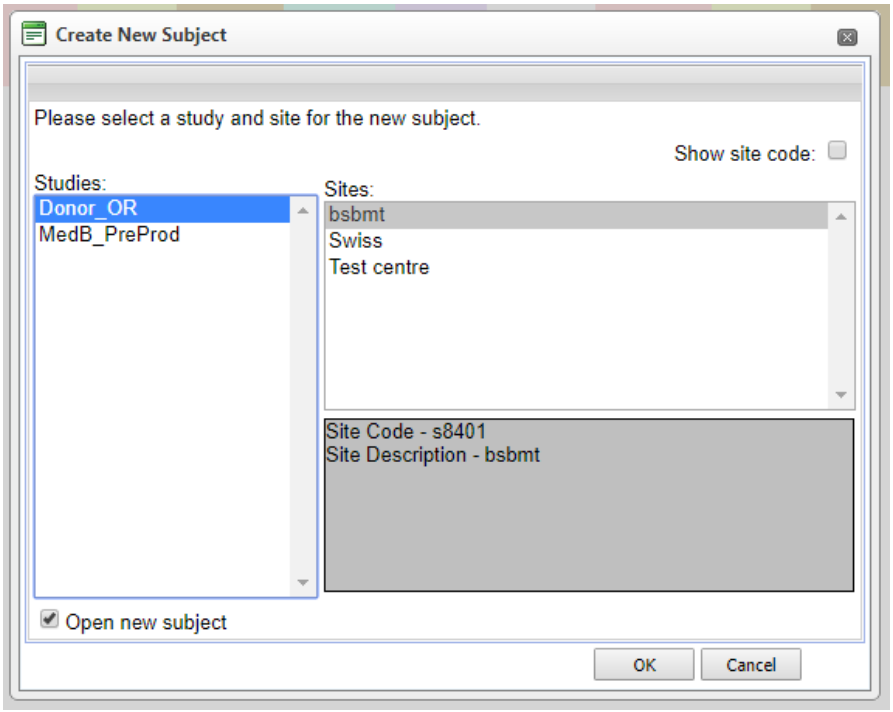



If you answer No, you will be allowed to record only 1 diagnosis. If you answer Yes, then you will first have to provide all the information related to the 1st Diagnosis (that is, all the Forms that will be Active, depending on the Main Indication you chose), and at the end of the last Form of the 1st Diagnosis Visit, after you Save and Move to the next Form, the 2nd Diagnosis will appear:




PLEASE NOTE: the 1st Diagnosis is labelled "Diagnosis 1", but the 2nd Diagnosis will be labelled "Diagnosis 1[2]". This is because they are both part of the First Diagnosis Block. Equally, you can have a Simultaneous Diagnosis at the 3rd block, which would be labelled "Diagnosis 3" & "Diagnosis 3[2]".

## Special case for users with **Access to more than one Site or Study**




PLEASE NOTE: depending on your Role, you might have access to more than just one Subject Group (e.g.: Study Coordinator in a Working Party or Data Manager in a National Registry) or Site.