# EBMT Registry

## User manual for data editors and data viewers

April 2025, v3

**EBMT Registry**
EBMT Clinical Research & Registry Department

Co-funded by the European Union

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# New EBMT Registry

If not stated otherwise, in the context of the current manual, the term EBMT Registry is used to describe the web application created to collect, view, edit and retrieve data and associated with the application databases.

**IMPORTANT NOTE:** the EBMT Registry is in an ongoing development process. Screenshots in this manual might be slightly different from the live application. We strive for having the most up-to-date information.

## Objectives

The purpose of the EBMT Registry is to provide a pool of data to EBMT members to perform studies, assess epidemiological trends and ultimately improve patients' lives. The EBMT Registry underpins extensive European research that translates into changes in clinical practice and improvements in patient outcome and care. With constant development of the field, the data set to be collected changes, thus the database also needs to change and adapt to reflect the latest trends. In recent decades, EBMT members used services such as ProMISe (Project Manager Internet Server) and Castor to collect, enter and use information of their patients and donors. Unfortunately, these services could not accommodate all the needs of EBMT members, thus it was decided that a completely new EBMT Registry should be created.

EBMT involved their staff, software developers, analytical specialists, doctors, representatives of different medical centres, regional and national organisations and other stakeholders to ensure that the new EBMT Registry satisfies everyone's needs.

It is important to note that after extensive data quality checks and cleaning, the data collected by EBMT since 1974 is transferred to the new EBMT Registry where it can be used by users within their access rights.

## EBMT Registry database structure

The EBMT Registry is a flexible data entry web application, connected to a fast and responsive live application database, enabling users to enter and retrieve data. The application database is then connected to the analytical database where all the data is restructured and organised according to the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) (for more details on OMOP CDM please refer to https://ohdsi.github.io/CommonDataModel/).

Splitting the databases has allowed EBMT to separate and accommodate the data entry needs from the analytical needs. A lot of work has been done for the EBMT Registry database to acquire an internationally recognised standardised OMOP CDM analytical database which is patient-centric, flexible and extendable. This is deemed to cover EBMT requirements and will offer new possibilities in terms of data analysis to EBMT partners and stakeholders.

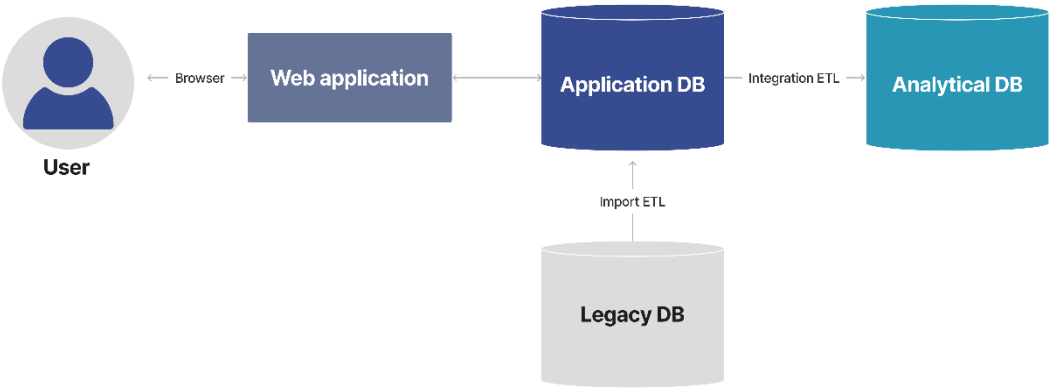



Image 1, schematic view of EBMT Registry application setup

Data entered by users through EBMT Registry web application is recorded in the application database, which always reflects the latest state of data, and then it is copied, transformed and transferred into the analytical database according to a predefined schedule (currently once per 24 hours), thus there is expected delay to have data changes reflected in the analytical database. Otherwise the data is considered to be equivalent, only organised in two different ways: the application database is event centric while the analytical database is patient centric.

The EBMT Registry is still accessible and fully running while synchronisation of the application and analytical databases is running, while the MicroStrategy analytical tool is not accessible during this process.

EBMT legacy data (i.e. all the data collected by EBMT before the EBMT Registry went live) was extracted from ProMISe and Castor, transformed and loaded into the EBMT Registry application database and then, through integration ETL, also loaded to the analytical database. ETL is a type of data integration that refers to the three steps: extract, transform and load; it is used to organise data from multiple sources.

The information shown via the user interface of the EBMT Registry is always the latest! Export (extraction) of data (via MicroStrategy analytical export tool) is done from the analytical database. It is recommended to wait 24 hours from the last data entry or edit before exporting data if a user wants to have these changes included into data export.

## Technical requirements and specifications

In order to access and work smoothly with the EBMT Registry, the users need to comply with the following technical requirements:

1. Computer with a stable internet connection. The EBMT Registry is a web-based application and requires access to the internet to load web pages. Large exports might require noticeable download time if the user's connection is slow.
2. Computer with a mouse, touchpad, touchscreen or similar device to navigate around the screen interface.
3. One of the following supported internet browsers:
   - ***Google Chrome***: the latest 2 versions of the browser on all operating systems.
   - ***Mozilla Firefox***: the latest 2 versions of the browser on all operating systems.

- ***Microsoft Edge***: the latest 2 versions of the browser on Windows operating system.
- ***Safari***: the latest 2 versions of the browser on iOS and macOS operating systems.

It is expected that other browsers also work correctly with the EBMT Registry, but it was not possible to perform sufficient testing and guarantee its high performance.

4. A screen that has a resolution of 1080p or higher. Screens with lower resolution were not tested, thus the correct layout of the web pages cannot be guaranteed.
5. A personal work email address to which the user has access. Shared emails must not be used.
6. Authenticator application: it can be MFA for smartphone, tablet or computer. (see Multi-factor authentication).

## Multi-factor authentication

Multi-factor authentication (MFA) with an authenticator application is mandatory to enter the EBMT Registry. It is a security feature that requires users to provide multiple forms of identification to access EBMT Registry and patients/donors information. One of the MFA applications must be installed on the user's computer, tablet, or smartphone. The list below includes examples of MFA applications that can be used:

- Google authenticator (both app and extension to the web browser);
- Twilio Authy;
- Microsoft Authenticator;
- 1Password (desktop app);
- Symantec VIP Access app;
- LastPass Authenticator;
- 2FAS;
- Duo Mobile;
- Dashlane (desktop app);
- Bitwarden (desktop app);
- Authenticator App by 2Stable (app for iPhone, iPad, iPod, Apple Watch and Mac);
- Step Two;
- TOTP Authenticator (desktop app, this is a browser extension).

This means that this MFA device shall be always available and used when a user needs to Sign in to the EBMT Registry. In case an MFA device becomes unavailable (e.g. lost, stolen, broken, replaced by a new device), the user should contact the EBMT Registry Helpdesk by email registryhelpdesk@ebmt.org to reset MFA settings for this user.

## User session

It is essential to note, that once a user signed in and entered the EBMT Registry, the user session remains active. For the security reasons, the user session will expire automatically and the user will be signed off after 20 minutes without activity. Termination of the user's session means that the user is signed out and the sign in page is shown on the screen.


Image 2, warning on automatic termination of user session due to inactivity

Important: EBMT Registry does have active termination of a user's session after 20 minutes of inactivity, it means that during that time, the information on the web page remains visible. Thus, users are strongly advised to use the Sign out process and lock the computer screen even for short periods of time to prevent unauthorised access to the data.

## Data ownership and protection

EBMT is strongly committed to protecting the privacy of personal data that we maintain about patients, donors, members and users of the EBMT Registry. The EBMT ensures that all personal data under its responsibility is processed according to the EU General Data Protection Regulation (GDPR).
For more information on Data Protection and Privacy, please refer to the EBMT website https://www.ebmt.org/registry/data-privacy.

## Audit trail

Audit trail is an important feature of the EBMT Registry to track changes made to data of patients and donors, users, centres and other registered entities. All actions are registered in the audit trail. The Audit trail information is not available to users of any roles but for a minimal number of specialists from EBMT Registry. This section describes its general overview and setup.

The audit trail is implemented with two main concepts in the EBMT Registry:

1. The **audit trail entries** provide an explicit event log of initiated actions and the circumstances in which they took place (who did what when).
2. The **version histories** provide a detailed history of data fields throughout its lifetime - what data was added/changed and why. Version histories cannot be used to back up or cancel changes. It is used purely for trackability of actions.

Audit trail and version histories can be used separately or together.

This division was established to satisfy the regulatory requirements without impacting performance or compromising audit trail readability. Here below is a short summary of its specifications:

- Version histories contain data points which may describe sensitive data that is not to be shared outside of exceptional circumstances;
- Version histories represent data entities in their entirety, which makes it simpler to reconstruct what has happened after the change;
- The audit trail entries focus on what actions took place and can just refer to the new version of a data field that was created as a result;
- The audit trail entries do not contain sensitive material and can therefore be more easily exported or even shared, if required.

Note: further improvements are planned to be done to the Audit trail access in the future versions of the system.

## Wiki

The EBMT Registry includes a link to the specifically designed Wiki platform. Wiki is a document platform where EBMT Registry users can find useful information they might need in the process of data entry or interaction with the system, such as:

- EBMT Registry user manual for data viewer and data editor;

- Reference to Data collection forms and completion guidelines;
- FAQ: frequently asked questions.


Image 3, the Wiki icon in the EBMT Registry navigation menu

Users can search for the topics through the content, keywords or tags.

## MicroStrategy

EBMT Registry is linked to the MicroStrategy tool designed to enable data access, enhancement of data analysis and visualisation for the end users of the EBMT Registry. More information on MicroStrategy can be found on the EBMT website.


Image 4, the MicroStrategy icon in the EBMT Registry navigation menu

MicroStrategy is accessible only when no data synchronisation between the application and analytical database is running. The estimated time for the MicroStrategy tool to be available for the EBMT Registry users is from 7:00 AM CET till 22:00 PM CET.

## Demo environment

All users enrolled into the EBMT Registry training in the e-learning will be able to access the EBMT Registry Demo environment (also referred to as Demo) before they are granted access to the real system. Demo is a training environment and copy of the system for training purposes only, thus no real patient's or donor's data must be entered, only fake data can be used.

To access the EBMT Registry Demo, users should follow the following process:

1. Open https://demo.registry.ebmt.org/ in their web browser.
2. Sign up (register and create username and password), please make sure you use the email specified in the *EBMT Registry User Account Request form.*

Important: do not use ebmtshared email address or any other personal email address other than the one, indicated in the EBMT Registry User Account Request form for your user.

3. Set up MFA

Note: the Username and Password, as well as the MFA device and MFA set up a user creates to access the Demo will also be used and valid later when the user gains access to the EBMT Registry.
Thus, EBMT recommends setting up all these parameters having in mind that they will be used in the future to access the real EBMT Registry. The user may request settings it to be reset by emailing the Helpdesk, but it will cause some delays in gaining access to the system after completion of the training.

The Demo environment has the same system version as the real EBMT Registry, but the events are configured separately. The fake data entered into the demo environment cannot be exported or extracted via MicroStrategy analytical tool.

**IMPORTANT NOTE:** the EBMT Registry is in an ongoing development and improvement process. The configurations of event forms in the demo environment might be slightly different from the live application. The demo environment might be cleaned (wiped out) from time to time. Only one version per event form is used in Demo, this should be taken into account while training (e.g. while training or practising filtering).

The demo environment is clearly marked to avoid users to confuse it with the real system: there is a label Demo environment in the top part (visible in all sections of the system).

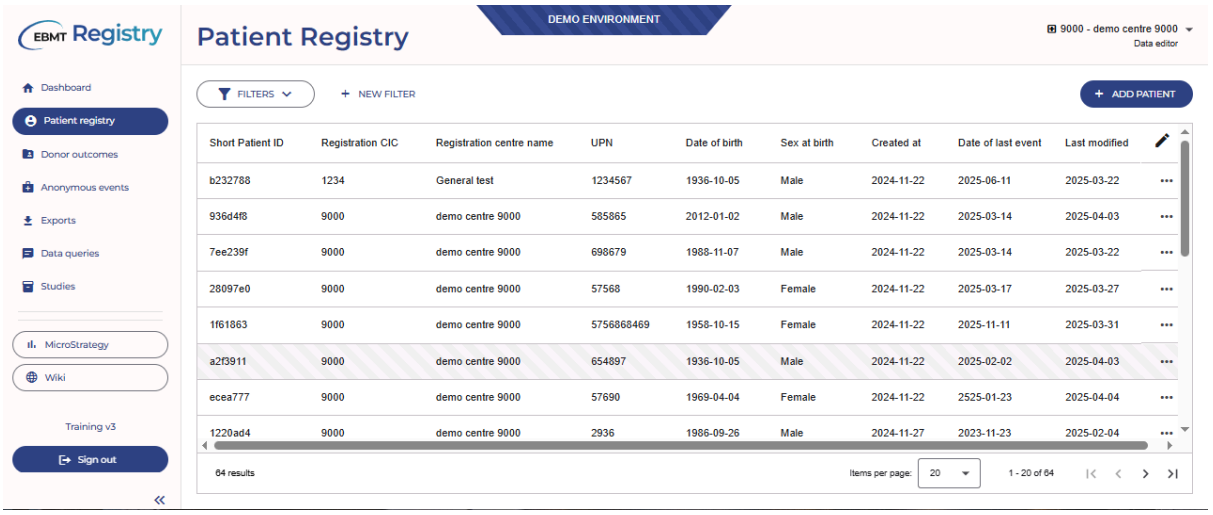



Image 5, EBMT Registry Demo environment

# Patients and Donors

## Patient

A **Patient** is a person who received a haematopoietic cell transplantation (HCT) procedure; an individual with bone marrow failures receiving immunosuppressive therapies; and/or a person receiving cellular or gene therapy.

The **EBMT Patient Registry** collects pseudonymised clinical data of consenting patients, including aspects of the diagnosis and disease, first-line treatments, HCT, cellular or gene therapy-associated procedures, transplant type, donor type, stem cell source, complications and outcome. Patients are followed-up indefinitely or as defined by EBMT (see Data collection). Once registered, patients may only be deleted by the Administrator of the system if they withdraw their consent and specifically request their data to be removed from the EBMT Registry (see Edit Patient consent).

Every Patient in the EBMT Registry is registered as a unique individual and assigned with:

- EBMT patient ID;
- EBMT short patient ID.

**EBMT patient ID** (long ID) - a unique patient identifier in the EBMT Registry that is generated automatically by the system in GUID / UUID format at the moment of patient registration in the EBMT Registry. It is a long code that contains letters (English alphabetic characters: a to z) and numbers (Arabic numerals: 0 to 9) for internal system use. It is not expected that users need to use it while interacting with

EBMT Registry, but in case needed, the EBMT patient ID is shown in the Edit patient details section of the Patient menu .


Image 6, the long EBMT patient ID shown in the patient menu-Edit patient section

**EBMT short patient ID** (short ID) - shortened version of the long EBMT patient ID for the convenience of the users to be used to find patients in the system. The EBMT short ID consists of the last seven digits of the EBMT patient ID, it is shown in the patient page.

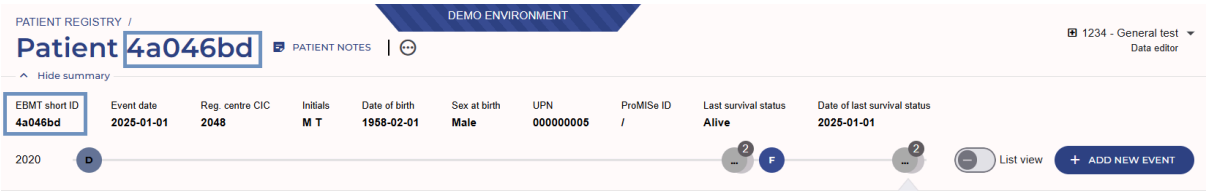



Image 7, the EBMT short patient ID shown in the Patient page

**UPN** (unique patient number) - the number/code used by the transplant centre or other entity to uniquely identify this patient. The organisations that input patient data have their own internal patient identifiers that should be entered into the EBMT Registry at patient creation and are used for the duplicate check, the users can also use UPN in order to search for patients.


Image 8, the patient UPN shown in the Patient page

In case of an error or change of UPN number, data editors are able to correct the UPN through the user interface (see Edit Patient UPN).

All patients in the EBMT Registry are **linked** to one or more centres. This means that centres have access to the patient data.

For the users' convenience, the EBMT Registry will still keep the record of ProMISe ID for patients who were registered in ProMISe system and later migrated into the EBMT Registry. However, this field is not relevant and will be empty for patients registered in the new EBMT Registry.

Every Patient is registered with some general data (see Add Patient) and associated medical events (see Add new event), more details on data collection are provided on the EBMT website under the Data

collection. If a patient does not consent to share their data with EBMT, said Patient cannot be registered in the EBMT Registry and only minimal data on performed treatment can be collected (see Anonymous events).

### Patient event

A patient event represents a significant occurrence related to a patient's medical condition. Every event in the EBMT Registry corresponds to a specific Data Collection Form (DCF). An event definition provides a way to document and track a patient's medical history over time. Registered events provide a comprehensive picture of the patient's health status and treatment progress or outcome.

The latest versions of DCFs can be found on EBMT website together with their respective completion guidelines.

### Patient event category

Since EBMT has a high number of patient events, they are grouped into the following **patient event categories**:

- ***Diagnosis***: it includes forms for primary diagnosis that was an indication for the treatment and other non-indication diagnosis that may directly or indirectly influence the outcome of the treatment;
- ***Treatment:*** it includes treatment specific forms (Autologous HCT, Allogeneic HCT, Cellular therapy, Gene Therapy, Immunosuppressive Treatment), and Disease status at HCT/CT/GT/IST;
- ***Follow-up:*** all follow-up (FU) forms, e.g. HCT Day 100 FU, HCT Annual and unscheduled FU, CT FU, GT FU, etc.

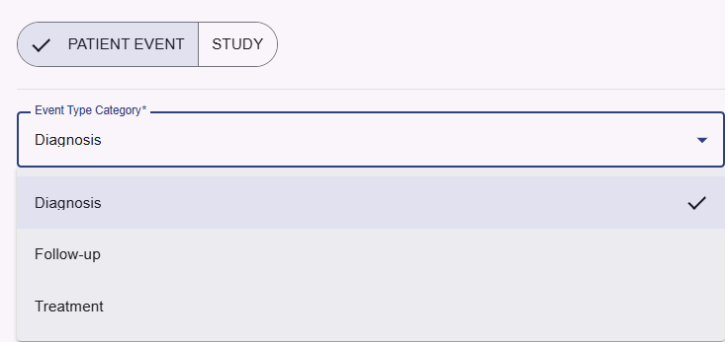



Image 9. Patient event categories shown upon clicking *Add new event* button in the EBMT Registry

Study events are also used to collect patient data required for specific studies. Each study has unique study event form. They are not grouped into any categories, but study event forms available for specific CIC are shown separately in the Create a new event modal window. If there are no study events available for the context the user is working in, the Study dropdown will be empty.

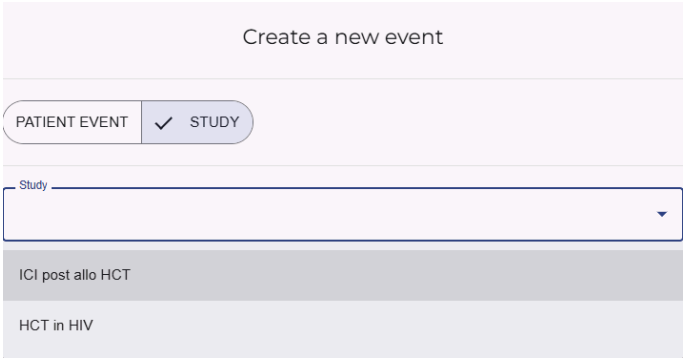



Image 10. Example of study event forms shown to data editor when adding new event to a patient timeline

Thus, every patient event contains a specific set of data (data fields) as per the corresponding Data Collection Form.

Some patient events also contain questions on donors and donated material, but this information is collected purely for the completeness of the specific Patient treatment and cannot be considered as donor registration (see **Donor outcome registry**).
When a new patient is being registered in the EBMT Registry, an automated duplicate check is performed: registration data of the new patient is compared to data of existing patients in the database. When a duplicate is suspected, the system warns the user and marks the new patient with a **tentative patient status**.

### Extended dataset

The data collected in the EBMT Registry can be divided into the core dataset and the extended dataset. In the EBMT Registry, the users can open an event form and then choose to fill in the extended dataset fields in addition to the core dataset fields using the toggle-button in the top right corner of each of the sections. Additionally, extended dataset fields are clearly marked in the event form (see Extended dataset data fields).
It means that there are no separate event forms to report extended dataset, the event form is the same, but it becomes a longer and more detailed variant of the form should the user choose to report extended dataset fields. The users are able to choose to fill in extended dataset fields per each section of an event form separately (see Extended dataset data fields)

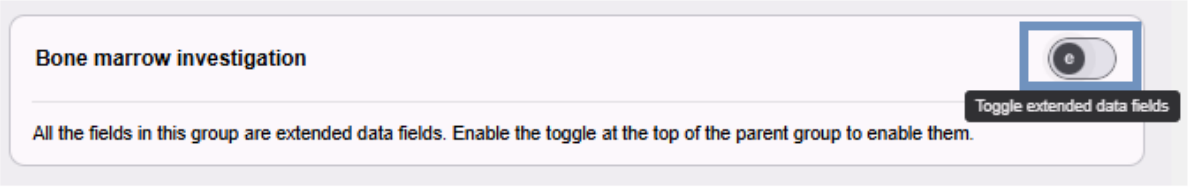



Image 11, extended dataset toggle icon

### Tentative patient

A Tentative patient is a temporary status automatically assigned to the patient by the system, to mark that it is a possible duplicate to an existing patient earlier registered in the system. Only an Administrator can remove tentative status from the patient record after more comprehensive and thorough evaluation.

An Administrator will revise the tentative patient record and follow-up with the centre on such cases, if needed. If the new patient is confirmed to be a duplicate of an existing one - the new patient will be deleted from the system. If it is confirmed that this is a unique patient, the Administrator will remove the tentative patient status and the patient will then appear as a regular patient in the system.

Tentative patient status is assigned by the system to *possible* duplicates while comparing patient birthdate, initials, sex at birth, blood group, rhesus factor to the data of existing patients (registered by any centre within the same country). If the existing and the new patient have the same UPN within the same centre, this is not considered as a possible duplicate but an *exact* duplicate, thus the system will not allow registration of a duplicate showing the corresponding error message (see Duplicate check).

Note: if the patient is marked by the system as tentative, but the registering centre is sure that this is a unique patient who has never been registered in the EBMT Registry, the centre (user) can send an email to the EBMT Registry helpdesk specifying patient short ID and centre CIC to speed up the removal of the tentative status for this patient.

## Donor

A **Donor** is a person who is the source of cells or tissue for allogeneic HCT or cellular therapy product.
**EBMT Donor outcome registry** is a separate independent section of the EBMT Registry. It focuses on the collection of information on the health outcomes of consenting individuals who have donated their bone marrow cells or other cellular material for allogeneic HCT or immune cells for cellular therapy. Donors are registered in the EBMT Registry as separate individuals and do not have any system links with the recipients (patients). This was a specific requirement in order for the EBMT Registry to fulfil the European requirements for the donor registries.
Some Donor data is registered in the Patient registry (as mentioned above) to provide a complete set of data on transplant or product used for treatment. It may even contain some data fields as in the Donor outcome registry. Since the two databases are not linked, it was not possible to avoid registering some information twice (see respective data collection forms for more details).

Every Donor registered in the EBMT Registry represents a unique individual and is assigned with:

- EBMT donor ID;
- EBMT short donor ID.

**EBMT donor ID** - a unique donor identifier in the EBMT Registry that is generated automatically by the system in GUID / UUID format at the moment of donor registration in the EBMT Registry. It is a long code that contains letters (English alphabetic characters: a to z) and numbers (Arabic numerals: 0 to 9) for internal system use. It is not expected that users need to use it while interacting with EBMT Registry, but in case needed, the EBMT donor ID is shown in the Edit donor details section of the Donor menu.

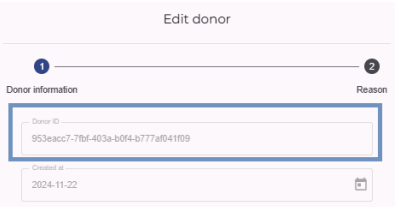



Image 12, the long EBMT donor ID shown in the Donor menu-Edit donor section

**EBMT short donor ID** - shortened version of the EBMT donor ID for the convenience of the users to be used to find donors in the system. The EBMT short donor ID consists of the last 7 digits of the EBMT donor ID and is shown in the Donor page.

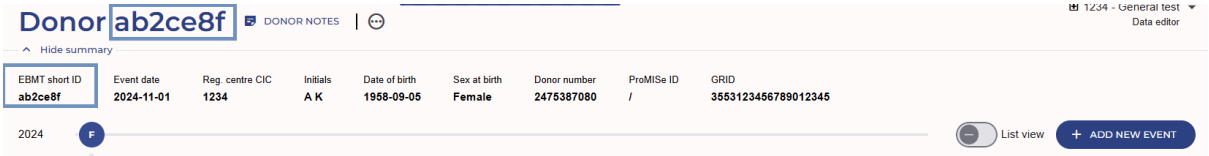



Image 13, the EBMT short Donor ID shown in the Donor page

**Donor ID (donor number)** - identification given to a donor by the collection centre or centre responsible for follow-up. This field may be empty, in case only GRID is used for this donor as an identifier.
If donor ID is entered, it is shown in the Donor page.


Image 14, the Donor ID number shown in the Donor page

In case of error or change of Donor ID number, data editors are able to correct the Donor ID number through the user interface (see Edit Donor ID number).

**Global registration identifier for donors** (GRID) - see https://wmda.info/ for more details on GRID. GRID is used mostly for unrelated donors. Some donors, who do not have GRID assigned, will have this data field empty and only Donor ID will be used as explained above.

Note: The concept 'GRID for life' was withdrawn in 2017. Every issuing organisation (IO) is currently allowed to assign a new GRID to an existing but relocated donor.


Image 15, the Donor GRID shown in the Donor page

In case of error or change of Donor GRID, data editors are able to correct it through the user interface (see Edit Donor GRID).

Every Donor is registered with some general data as requested in the Donor Registration form and associated donor events.

## Donor event

There are 2 donor events: the one to report details on the donation procedure and 30 days follow up and another one for long term follow-up. All donations of a particular individual are registered under the same donor. Information on donors is entered into the EBMT Registry by the transplant centre (or Donor Registry in case of unrelated donors).

# Users

## Users

The EBMT Registry is designed to be used by various individuals with different necessities and tasks, including, but not limited to:

- Principal Investigators;
- Data Managers;
- Other authorised staff members of a centre or hospital;
- National registries in the field of blood and/or bone marrow transplantation and IEC therapy (upon request and based on signed agreement);
- Donor centres and registries authorised staff members;
- EBMT research staff;
- Registry support team;
- Authorised auditors or data monitors (perform source document verification).

A **User** is an EBMT member listed on a centre's team member list or EBMT staff who interacts with or makes use of the EBMT Registry. This includes individuals who browse content, perform searches, input or export data, or engage in any other activity within the application.

Users are registered in the EBMT Registry based on the information provided by the PI in the ***EBMT Registry User Account Request form*** that includes the following data: user's first name, last name (surname), email address, details of organisation/entity they represent, etc. The request forms as well as procedure to gain access to the EBMT Registry is explained on the EBMT website.

Note: To access the new EBMT Registry database, Principal Investigators (PIs) need to submit the request on behalf of their staff members using ***EBMT Registry User Account Request form***. Only requests on behalf of EBMT members listed on the centre's team member list will be accepted, all individuals must register using their professional email addresses.

**User ID** - is a unique user identifier in the EBMT Registry that is generated automatically by the system at the moment of user registration in the EBMT Registry. It contains 7 digits and is used when it is needed to provide a reference to a particular user within the system without sharing their personal information (e.g. in data queries conversation). User ID can be found in *the User profile*.

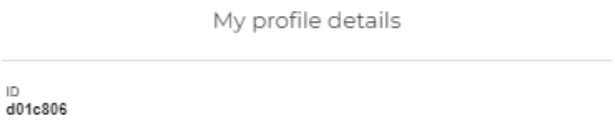



Image 16, the user ID in the EBMT Registry

Users are linked to one or multiple Centres and/or Virtual Registries (VR), this means that they represent this organisation/entity and that this organisation/entity authorises this individual to access a particular set of data and perform some tasks (see Context for more details). A separate request form must be submitted for each centre/VR the user requires access to.

When a user Signs up and Signs in to the EBMT Registry, they should indicate the following data:

### Username

This username can be used for login purposes only. It is created by the user and can contain letters, numbers and/or special characters and cannot contain any white spaces. This is not the user's first and last name, though it can contain it if the user prefers.

### Email

This is a work personal user email, specified in the ***EBMT Registry User Account Request form***. In case the user inputs any other personal email, they will not be able to access the requested context and will need to go through the first sign up process once again (as a new user) with the email specified in the *EBMT Registry User Account Request form.*

Note: User email addresses registered in the EBMT Registry user account cannot be changed. If a previous email becomes unavailable, the user should contact EBMT Registry helpdesk by emailing registryhelpdesk@ebmt.org to deactivate the previous user account and submit a properly signed and filled *EBMT Registry User Account Request form* with the updated email so that the new user account can be set up.

### Password

This is the personal password that the user will use to enter EBMT Registry. It must satisfy all the requirements as explained under the password field, and it must:

- contain a lowercase letter;
- contain an uppercase letter;
- contain a number;
- contain at least 8 characters;
- contain a special character or a space;
- not contain a leading or trailing space.

The password can be changed, if needed (see Change password).

## Active/inactive users

The users in the EBMT Registry may be set as *Active* or *Inactive* by the EBMT Registry administrator or automatically.

**Inactive users** cannot get access to any data in the database. They are able to Sign in (if they have registered their username/email and created a password), but will see the message notifying them that they do not have an active account.

**Active users** can sign in to the EBMT Registry (if they registered their username/email and created a password) and then can see/access data of patients or donors linked to their centre/VR only if they have active context (if their centre or VR are set as active). If they do not have a context assigned by the administrator, or if they are linked to one inactive centre or VR, they will see an error message.

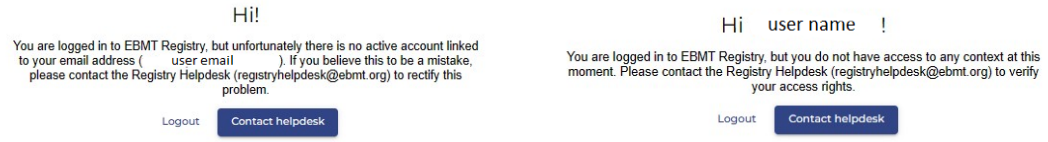



Image 17, the warning message for inactive users (L) and the message for active users with no linked context (R)

Important: The EBMT Registry will automatically change the user account from Active to Inactive when a user tries to log in after **three** or more months of not entering the system. Users should contact the EBMT Registry Helpdesk by emailing registryhelpdesk@ebmt.org to reactivate their user.

## User role

The User role refers to the set of permissions granted to a user in the EBMT Registry. Depending on their **role**, users will have access to a different set of functionalities necessary to perform their duties.

In other words, the user role defines what a user can and cannot do within the EBMT Registry.

The following roles are used in the EBMT Registry:

1. **Data viewer**: can view and export entered data (via MicroStrategy) within their context.
2. **Data editor**: can view, add, edit and export data (via MicroStrategy) within their context; can see and answer data queries.
3. **Administrator**: oversees all other roles and manages the links between a user and centre/VR, between centre and VR, manages users (adds new users, activates or deactivates users). Administrator has access to all the functionalities other role types have.
4. **Data monitor**: this role is designed for EBMT or external monitors and allows to view data, perform source document verification (SDV), and/or manage data queries. By managing queries it is understood that a data monitor can open, answer or close a query on a particular data field from a patient event.
5. **Query manager + viewer**: this role is designed for EBMT staff mainly and is similar to the data monitor role, but excludes source document verification (SDV). It allows users to view data, and/or manage data queries. By managing queries it is understood that a query manager can open, answer or close a query on a particular data field from a patient event.
6. **Query manager + editor**: this role is designed for EBMT staff mainly and is similar to the data monitor role, but excludes source document verification (SDV). It allows users to edit data, and/or manage data queries. By managing queries it is understood that a query manager can open, answer or close a query on a particular data field from a patient event.
7. **Study manager**: this role is designed for EBMT staff to manage EBMT studies within EBMT Registry application
8. **Helpdesk manager**: this is a designated role for the EBMT Helpdesk staff to perform user management (add new users, activates or deactivates users), patient management (provide access to the patient record to the new treating centre) and other helpdesk-related tasks.

### EBMT Registry User Account Request form

The roles are assigned by the EBMT Registry administrator within each user context (see Context) based on submitted *EBMT Registry User Account Request form* and in line with established user management procedures explained on the EBMT website.

The user role can be changed at any point to suit the needs of the user's work, allowing flexibility. If the user needs to change the role, the *EBMT Registry User Account Request form* has to be filled-in with the new requested role, properly signed and sent to the EBMT Helpdesk. The user also needs to complete the EBMT training for the required role.

Note: if the personal work email of a user changes, the EBMT Registry User Account Request form with updated email must be filled and submitted to the EBMT Helpdesk (see Email).

### Data viewer

The data viewer role allows the user to access minimal functionality in the EBMT Registry and thus users require minimum training.
It is an important role and should be used/requested for users who do not perform data entry, as this is the major functionality not available for data viewers. Instead, the data viewer focus is on accessing the patient/donor data ((within the scope of patients or donors they received authorisation to access), on reviewing and analysing the data that has already been entered. They can also print and export data.
Data viewers cannot:

- Add or edit data;
- answer data queries, if any (see Query);
- view tentative patients (see tentative patients).

### Data editor

The data editor role allows users to access the functionality for data viewers and additionally data entry-related ones in the EBMT Registry.
It is an important role and should be used/requested for users who perform data entry (enter or edit data). As a data editor, such users have the ability to access, modify, and enter patient or donor data into the system, print and export data (within the scope of patients or donors they received authorisation to access). This role requires a high level of attention to detail and accuracy. This means users with a data editor role require more advanced training compared to data viewers.

## Centres and virtual registries

The users receive access to the scope of data through the organisation/entity they represent. There are the following two main types of such organisations/entities:

- EBMT member centres (including donor centres);
- Virtual registries.

### Centre

**Centres** use the EBMT Registry to enter and store their patients' and donors' data, while simultaneously making it available to the EBMT. Members submitting data can access and use their own data for their own purposes; they do not require permission and do not need to notify the EBMT. Member centres users have access to their own data at all times. Every user can see in the EBMT Registry only pseudonymised data of patients they have access to.

**Registration centre** is the centre that created the patient or donor record in the EBMT Registry. This centre will have access to the patient/donor record and patient events data even if later the patient continues the treatment in another centre or donor is being followed-up by another centre. Every patient/donor is linked to one or more centres. The registration centre is always marked in the patient/donor details. In case the registration centre disappears as an organisation (it is closed, merges with another centre, etc.), the new centre responsible for this patient will be identified and marked in the EBMT Registry as the patient registration centre. All such changes are reflected in the audit trail and can be done only by the EBMT Registry administrator.

In many cases a patient or donor is being followed-up by multiple centres, all these centres are called **reporting centres**. Thus the access to the patient or donor record is granted to other centres involved in the data collection process through the specific form available on the EBMT website. Access to the patient/donor record is provided for an indefinite period.

Note: When referring to 'patients of a centre', it is understood all patients the centre has access to, even if this centre is not a registration centre for some of these patients.

**Centre Identification Code (CIC)** - is a unique 3-4 number code (Arabic numerals: 0 to 9) assigned to every centre in the EBMT Registry. This code is used in official communications between the EBMT and the respective centre. This item is essential for proper registration of the data, submitted by the centre, as well as for other processes in the application.

## Virtual registry

**Virtual registry (VR)** is a term used to describe a number of organisations that require access to the EBMT Registry for their users and include:

- Centre based VR (CBVR);
- Filter based VR (FBVR);
- Hybrid VR (HVR).

**CIC** term is also used to define a unique 3-4 number code (Arabic numerals: 0 to 9) assigned to every Virtual registry in the EBMT Registry. This code is used in official communications between the EBMT and respective VR. This item is essential for the proper registration of the data and correct setting of access rights.

### Centre-based VR (CBVR)

It is a group of users that require access to certain centres' patient/donor data. Usually it is an organisation that unites a number of centres based on certain criteria (regional registries, national registries, group of centres, etc.).

Representatives of centre-based VRs require access to data of patients that belong to their member centres only. For some countries it is also a legal requirement for the national registries to have access to the data of the centres in their territory and supervise and control their activities.

### Filter-based VR (FBVR)

FBVR is a group of users that require access to patients' and/or donors' data based on certain filtering criteria (it does not matter what centre the patient belongs to). For example, a group of scientists studying a specific topic who require access to pseudonymised patients data in the EBMT Registry that satisfies a very particular set of criteria (patients with particular diagnosis, that underwent particular treatment, born in specific period, etc.).

Practical example: EBMT Study group as a Filter-based VR will have access to the patients' data from different centres based on their research target group criteria (e.g. age, diagnosis, transplantation type, etc.).

**Hybrid VR (HVR)**

HVR is a combination of centre and filter-based VR, when a group of users requires access to a specifically filtered pool of patients and/or donors from a certain list of centres.

Practical example: EBMT recognised study group focused on analysis of data of patients from particular territory is seen as Hybrid VRs. They will have access to a pool of patients' data that satisfy specific criteria from a certain list of centres.

## Active/inactive centre or VR

Administrators only can set the centre or VR status as **active** or **inactive**. Centre/VR can be set as inactive in some rare cases, for example in order to protect the security of their data, as per legal requirements or if centre/VR does not exist anymore.

Note: Centres/VRs are not deactivated automatically by the system due to inactivity. Deactivation is always done by the EBMT Registry administrator.

If the centre/VR is inactive: users linked to this centre/VR cannot choose it as their context, thus they are not able to access the patients or donors within this context.

If the centre/VR is set as active: users linked to this centre/VR can see it in the list of their context (in context menu), choose this centre as their context and thus they are able to access the patients or donors within this context.

If a centre/VR as an organisation is to be closed, merged with another one, or the structure changes and splits, this should be reported to the EBMT Registry helpdesk as soon as possible so that the EBMT Registry administrator can link the patients (registered by this centre) to the correct centres/VRs and make all necessary amendments. This will ensure a smooth and continuous data access and data entry process.

# Context

**Context** - is a section of the database (data of a specific list of patients/donors linked to a centre or VR) that the user can access to perform their duties in the EBMT Registry.

The name of the context is the CIC and the name of a centre or VR that authorised the user to access their patients' data. Context is always linked to the user role.

Every patient in the system is linked to one or more centres (registration centre, reporting centre, etc.). Patients may also be linked to some VRs. Context is the scope of patients a centre or VR has access to and their data. Users cannot be linked to any patient directly. They can only use the Centre-patient or VR-patient link.


Image 18, schematic view of patient linking to a centre

If a user does not have access to any context or their context Centre/VR is inactive, they are still able to sign in, but they will see the message notifying them about this at the homepage of the application. All users should submit a properly filled and signed *EBMT Registry User Account Request form* and pass training certification to have their user activated and context assigned. If a user has already fulfilled all the steps, but sees an error stating (s)he does not have access to any Context, the user should contact the EBMT Registry Helpdesk.

There are users that, due to their work particularities, have **multiple roles** and need different permissions and functionality within the EBMT Registry (e.g. they are doing patient data entry in one centre, work in a national registry and at the same time are doing a research study in the EBMT working party). In this case, the user uses the system in different contexts. For each context the user might have the same or different role and thus a different set of rights and permissions (see the diagram below as an example).

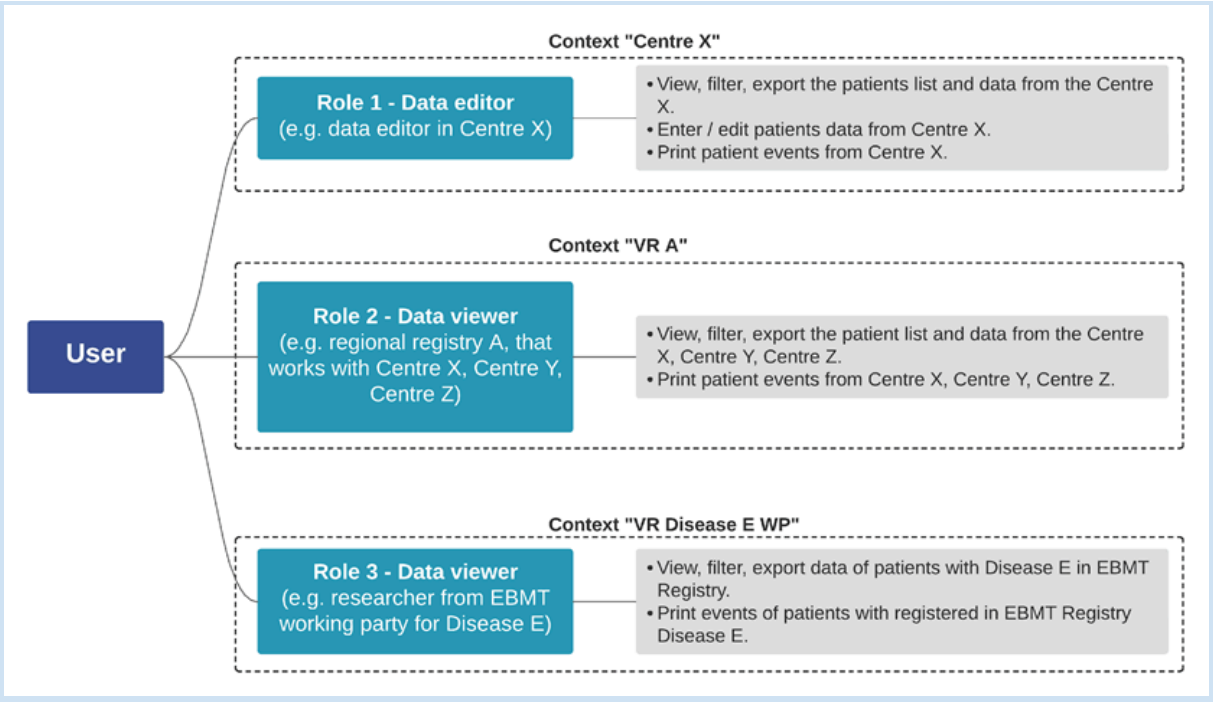



Image 19, description of a user that has multiple roles in multiple contexts

Important: in case a user has access to multiple contexts, these contexts exist independently and the user is assigned a role per each context, the rights and permissions of the user might be different in each context and are not combined.

Every user can have only one user account, which means this user is registered with one email and username and uses one password to enter the EBMT Registry. In case of multiple roles, a user logs into the system and the last used context is loaded, the user can change the context (s)he wants to work.

Only users with access to multiple contexts can switch between the contexts and can choose in which context to work without the need to log out. This can be done through the Context menu.

# Interface and screen layout

The EBMT Registry layout is designed to provide a seamless user experience. The screen is divided into the following sections:

1. The EBMT Registry logo is always shown on the left top corner of the screen.
2. The header displaying the name of the section the user is currently viewing (displayed on the main screen).
3. Context menu showing the current context name and the role of the user in this context.
4. Navigation menu for accessing different sections of the application quickly and easily.
5. EBMT Registry version.
6. The main screen is where the content of the opened section is displayed.

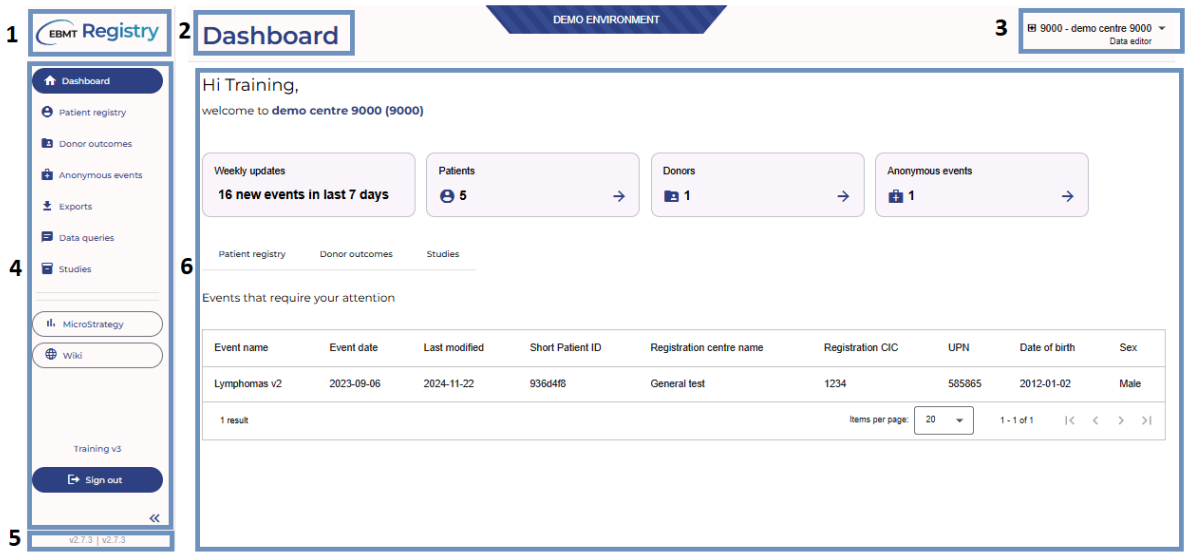



Image 20, landing page of the EBMT Registry after logging in

For sections and main screens where the overviews and long list of items is shown (like Patient registry overview, Donor outcomes overview, Data queries overview, etc.) there is also used Pagination at the bottom of the main screen.

## Context menu

Context menu is always shown in the top right corner of the screen, regardless of what part of the EBMT Registry the user is currently in. By default, it shows the name of the Context, the user currently in and the user role in this Context (see image 21).


Image 21, context menu

Users with access to multiple contexts can click on any part of the menu, and a dropdown list with all available contexts for the user will open. This list will contain only active centres or VRs and show the CIC and the name of the Centre/VR. The User role is not visible in the dropdown list.

For users with access to one context, the context menu will always show the name of the context they have access to. They cannot see the dropdown list.

## Navigation menu

Navigation menu is always displayed in the application on the left side of the screen. It includes the following navigation buttons:

| Name (in full view) | Icon | Description |
|---|---|---|
| **Dashboard** |  | A button to go to the dashboard, which is the homepage of the EBMT Registry (see Dashboard). |
| **Patient registry** |  | A button to open the patients overview list in the user's current context (see Patient registry). |
| **Donor outcomes** |  | A button to open the donors overview list in the user's current context (see Donor outcome registry). |
| **Anonymous events** |  | A button to open a registry of treatments for non-consenting patients (see Anonymous events). |
| **Exports** |  | A button to open the exports overview list. |
| **Data queries** |  | A button to open the overview of queries (see Queries). |
| **Studies** |  | A button to open the overview of EBMT study-related event forms. |
| **Wiki** |  | A button to open Wiki portal. |
| **MicroStrategy** |  | A button to open the MicroStrategy analytical tool library. |
| **User profile** | [user initials] | A button with the user full name or initials to open *My profile details*. |
| **Sign out** |  | A button to sign out (log out) from the EBMT Registry. |
| |  | A button to switch from Navigation menu full view to compact view. |
| |  | A button to switch from Navigation menu compact view to full view. |

Table 1, icons used in the EBMT Registry navigation menu and their descriptions

When the section is opened in the main window, the button is highlighted, e.g.  turns into  .

The navigation menu can be shown in ***full*** or ***compact view*** (see image 22), the users can switch between them at their convenience by pressing the double arrow button. The compact view was designed to display more information on a user's main screen while working with the database.

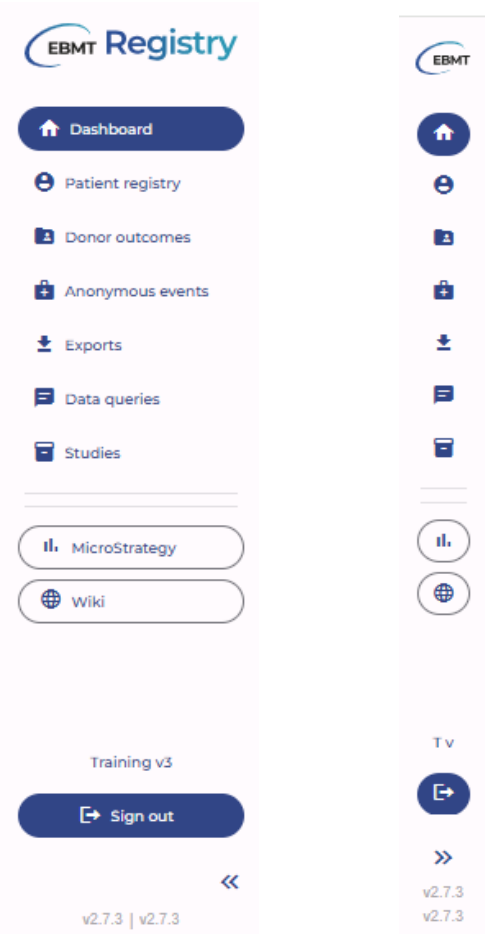



Image 22, Navigation menu in full (Right) and compact (Left) view

## Dashboard

The dashboard is the home page of the EBMT Registry application. It always shows a greeting message with the user name and the context the user is currently in.

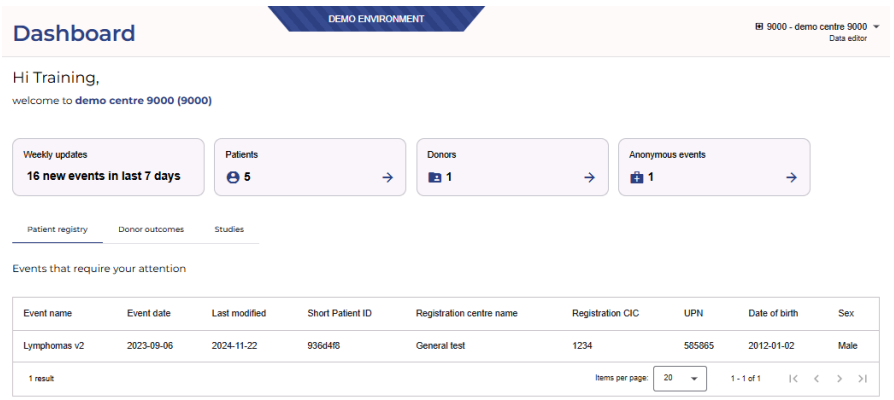



Image 23, the dashboard

Whenever the user changes their context, they are always redirected to the dashboard with the greeting message containing the chosen context.

In the current version of the EBMT Registry, the dashboard will contain some general information about the patients/donors recently registered in the user context as well as useful links to data, requiring user's attention, e.g. patients records with errors or warnings and some other.

Additional information and functionality will be added to the dashboard in the next versions of the application.

## Patient registry

The patient registry is part of the EBMT Registry that contains information on patients registered in the EBMT Registry and their events.

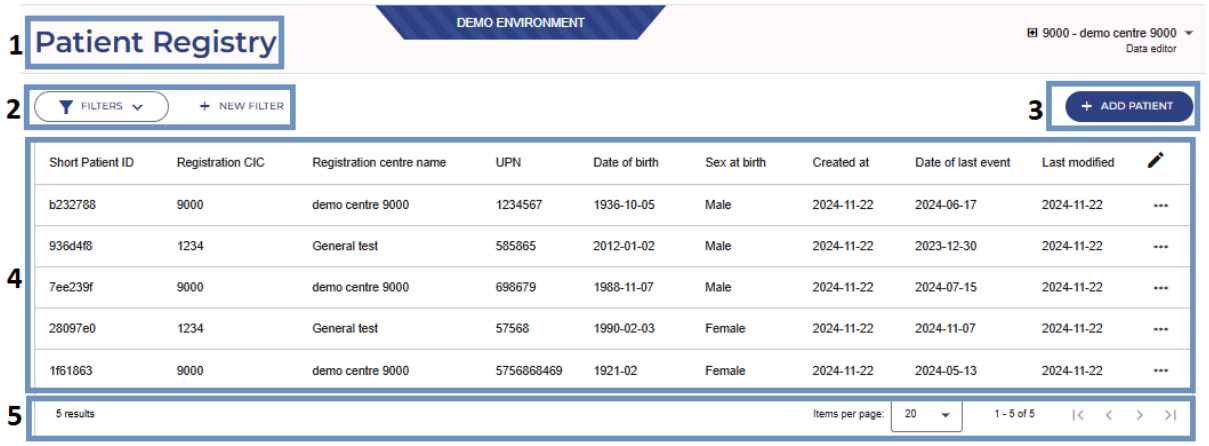



Image 24, the patient registry overview page (data editors view)

**Patient registry overview page**

Patient registry overview page shows:

1. The patient registry title.
2. The buttons to set up/apply filtering of the patient list (see Filters).
3. *Add patient* button to add or create a new Patient in the EBMT Registry (see Add Patient).

This button is only visible to users with data editing permissions.

4. The list of registered patients (in the chosen user context) with their data summary. The information in the Patient registry overview page is presented in the table 2, where each row corresponds to a separate patient, and columns provide the following details:

| Column name | Column can be used for sorting | Description |
|---|---|---|
| Short ID | Yes | EBMT patient short ID. |
| Registration centre CIC | Yes | The CIC of the centre that registered the patient in the EBMT Registry. |
| Registration centre name | Yes | The name of the centre that registered the patient in the EBMT Registry. |
| UPN | Yes | • If the context is a VR - the UPN for the registration centre is shown.<br>• If the context is a centre - the UPN for the context centre is shown. |
| Date of birth | Yes | Patient date of birth as per Patient registration data. |
| Sex at birth | Yes | Patient sex at birth as per Patient registration data. |
| Created at | Yes | The date the patient was created/added to the system. |

| Column name | Column can be used for sorting | Description |
|---|---|---|
| Date of last event | No | Date of the last registered event for this patient (the event with the most recent date). The event that is shown last (to the right) in the Patient timeline. |
| Last modified | No | Date the latest changes were done to any of the patient data/events. |

Table 2, items in the patient registry overview

5. Pagination section.

Tentative patients are marked in the patient overview list, the line that corresponds to a tentative patient is greyed-out (see image below) and visible to users with data editing permission and administrators.

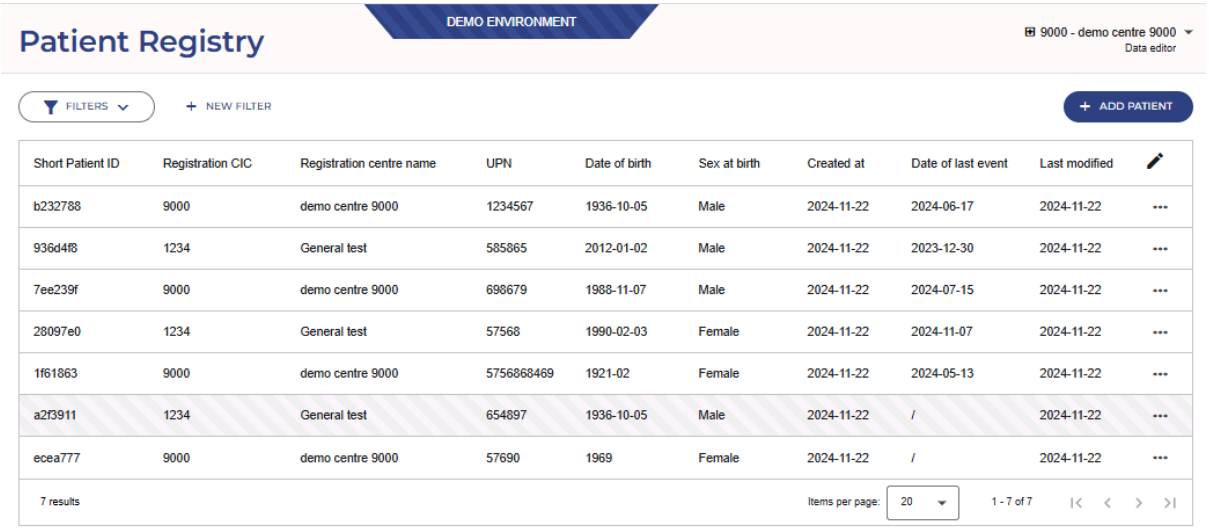



Image 25, Patient registry overview: registered patients versus tentative patients

The details on patient specific page layout and content are explained in the Patient page section.

## Donor outcome registry

The donor outcome registry is part of the EBMT Registry that contains information on donors registered in the EBMT Registry and associated with these donors events .

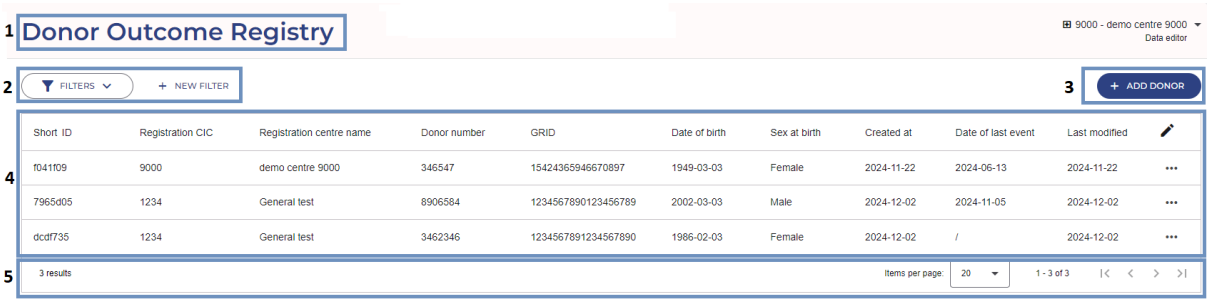



Image 26, donor outcome registry overview page (data editors view)

**Donor outcome registry overview page**

Donor outcome registry overview page shows:

1. The donor outcome registry title.
2. The buttons to set up/apply filtering of the donor list (see Filters).
3. The *Add donor* button to add or create a new Donor in the EBMT Registry (see Add Donor).
This button is not visible for users without data editing permissions.
4. The list of registered donors (in the user context) with their data summary. The information in the Donor outcome registry overview page is presented in the table, where each row corresponds to a separate donor, and columns provide the following details:

| Column name | Column can be used for sorting | Description |
|---|---|---|
| Short ID | Yes | EBMT donor short ID |
| Registration CIC | Yes | The CIC of the centre that registered the donor in the EBMT Registry. |
| Registration centre name | Yes | The name of the centre that registered the donor in the EBMT Registry. |
| Donor ID | Yes | Donor ID given to a donor by the collection centre or centre responsible for follow-up. |
| GRID | Yes | GRID |
| Date of birth | Yes | Donor date of birth as per Donor registration data. |
| Sex at birth | Yes | Donor sex at birth as per Donor registration data. |
| Created at | Yes | The date the donor was created/added to the system. |
| Date of last event | No | Date of the last registered event for this donor (the event with the most recent date). The event that is shown last (to the right) in the Donor timeline. |

| Column name | Column can be used for sorting | Description |
|---|---|---|
| Last modified | No | Date the latest changes were done to any of the donor data/events. |

Table 3, items in the donor outcome registry overview

5. Pagination section.

### Anonymous events for non-consenting patients

If the patient did not give their consent to share their data with the EBMT, it means that only minimal essential data on the performed treatment can be entered into the EBMT Registry according to instructions available on the EBMT website.

**Anonymous events** - is the term used to define the scope of data concerning the centre's activities related to non-consenting patients.

Important: In the current version of the application, the anonymous events are visible only to users in a centre context or Centre-based VR context.

**Anonymous events** are records, created in the EBMT Registry to report the centre's activities concerning non-consenting patients and they include the following information:

- diagnosis: date, classification, subclassification;
- treatment: year, type, chronological order (sequence) of this type of treatment for this patient;
- cell source: autogenic or allogeneic.

Each anonymous event has a unique identifier (7 digits) automatically created by the EBMT Registry.

**The anonymous event page** contains the following information:

1. Anonymous event unique identifier;
2. Anonymous event summary section. It also contains buttons *Save changes* to save changes (if changes were made to the saved form) and *Print* button to print the current anonymous event form.
3. Anonymous event data fields.

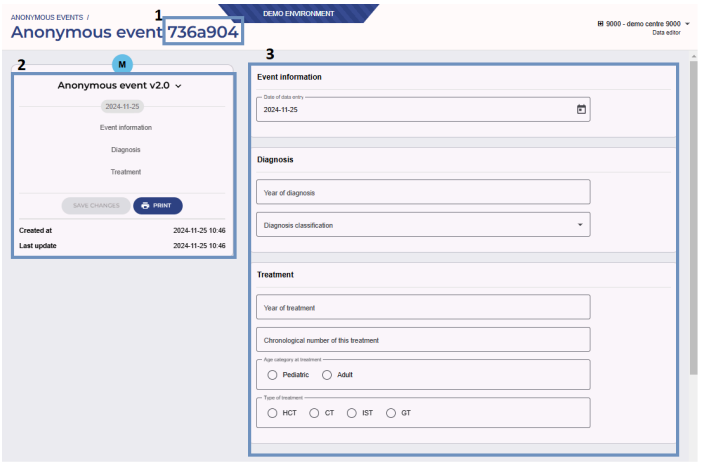



Image 27, an anonymous event page

Note: CBVR can view the anonymous events of their member centres.

Important: If a patient was registered in the EBMT Registry but withdrew their consent and requested their data to be removed from the EBMT Registry, the data is removed completely and is not automatically transferred into Anonymous events. From this point, the patient is considered a non-consenting patient. A centre should report the minimum essential data for this patient via an anonymous event.

**Anonymous events overview page**

The anonymous events overview page (see image 28) can be open through the Navigation menu and it contains:

1. The title: anonymous events.
2. The list of registered anonymous events (in the user context) with their data summary.
3. The button *Export anonymous events* to request export of data reported as Anonymous events.
4. The button *Add new event* to add or create a new anonymous event in the EBMT Registry (see Add anonymous event). This button is hidden for users without editing permissions (see image 29).
5. Pagination section.

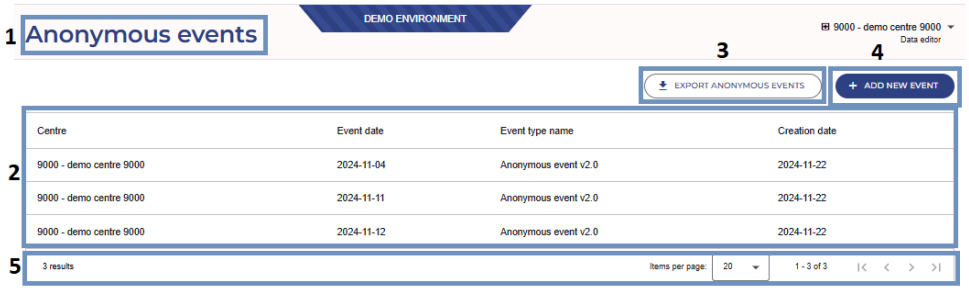



Image 28, anonymous events overview page (data editor view)


Image 29, anonymous events overview page (data viewer view)

The information in the anonymous events overview page is presented in table 4, with each row corresponding to a separate anonymous event and columns providing the following details:

| Column name | Description |
|---|---|
| Centre | The centre that registered treatment for a non-consenting patient. |
| Event date | The date specified by the used as event date |

| Column name | Description |
|---|---|
| Event type name | Name of the event form used. Users will be able to see the form version in this column. |
| Creation date | The date the anonymous event was created in the EBMT Registry to report minimal essential data for a non-consenting patient. |

Table 4, columns in the anonymous events overview and their descriptions

**Anonymous events export**

Note: the export of anonymous events was modified in 2.8 version of the EBMT Registry. This functionality is explained in the Exports section of this manual.

## Exports

Export of anonymous events data can be done via EBMT Registry built-in export functionality.

Data extraction from EBMT Registry patients registry and donor outcome registry is currently done via MicroStrategy analytical tool. Please refer to the MicroStrategy user manual for more details.

**Data export** - is a process of extracting (copying) data from the EBMT Registry and saving it in one of the requested formats.
**Export** - is the file created by the system that contains anonymous events data from the EBMT Registry. Anonymous events data is not stored in the analytical database, thus it cannot be extracted via MicroStrategy analytical tool. It is only stored in the EBMT Registry application database and can be extracted through the EBMT Registry application export functionality.

Users can request generation of an export file that contains all anonymous events in the current context using the *Export anonymous events* button in the Anonymous events overview page.

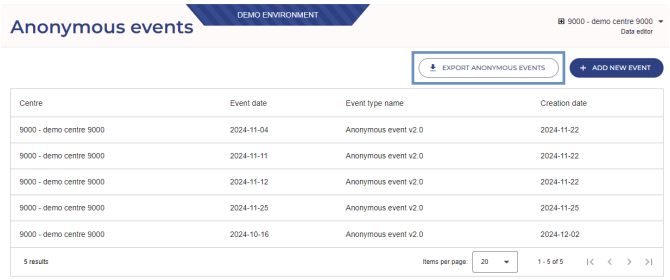



Image 30, the *Export anonymous events* button in the Anonymous events overview page

Once EBMT Registry generates the export file for anonymous events, it is stored in the server for 7 days and is available for download from the EBMT Registry only to the user who requested its creation. After 7 days the file expires and cannot be downloaded. If a new export with the same information is required after the expiration date, the request can be created again though the Anonymous events overview page.

**Export file status**

Data export requests are listed in the Exports section of the Navigation menu and may have one of the following statuses:

| Export status | Description |
|---|---|
| Requested | The user requested data export, the export file creation has not started and is awaiting the system to pick up this request. The export is not ready to be downloaded yet. |
| Started | The export file creation has started, but has not been completed yet. |
| Ready | The data export request was successfully processed. The export file is created and ready to be downloaded. |
| Expired | The export file is expired and is not available for download any more. |
| Error | The data export request failed. It was not possible to create the export file. |

Table 5, Export file statuses with descriptions

Note: data export requests may fail and show Error status due to various reasons. In case of error, It is recommended to repeat the attempt. If a user keeps experiencing this problem, they should contact the Registry helpdesk providing all the details of the case, including the details on the scope of data they tried to export.

**Export security**

Important: data exported from the EBMT Registry (including MicroStrategy reports/dossiers/tables) contain sensitive patient and/or donor data, and thus must be protected from unauthorised access and/or use by taking appropriate security measures.

It is expected that, among other security measures, Users will ensure that:

1. Data export files are downloaded, located and stored in an encrypted local disk on their devices.
2. The dedicated directory will not back up automatically to any Cloud storage facility or external drive.
3. All data export files are deleted promptly, once Users finish working with them.

All users of the EBMT Registry must comply with the EBMT Registry Conditions of Use, Data Protections laws in existence in each individual country, and the General Data Protection Regulations (GDPR 2016/679). Please visit the EBMT website for more information on Data privacy and the EBMT Registry Conditions of Use.

Every time users request generation of an export file or download export file, they have to confirm by clicking 'I understand' button that they are aware of and will comply with these security requirements

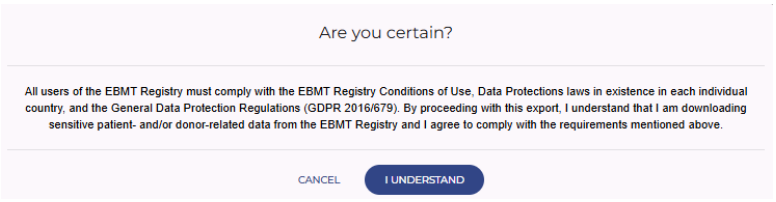



Image 31, download export file confirmation notification (warning)

**Exports overview page**


Image 32, Exports overview page

Exports overview page shows:

1. The title of the page: Your exports. The export file list is for the current user and it is not accessible to other users of EBMT Registry.

2. The list of the data export files requested by the user in the EBMT Registry. If a user has access to multiple contexts, this list will contain all requests for all user contexts. The information is presented in the table, where each row corresponds to a separate export file, and columns provide the following details:

| Column name | Description |
|---|---|
| Requested | Date and time the user requested to create an export file. |
| Name | Name of the file the user indicated while initiating this data export. |
| Expiration date | The date this data export expires. This means that the file will be available for download up till the specified date. |
| Status | Status of the data export file. |
| File type | The format of the data export file requested by the user for this data export. |

Table 6, columns in the Exports overview

3. Download button(s): the download button can be shown in two modes as described in the table below:

| Download button mode | Description |
|---|---|
| DOWNLOAD | *Download* button is highlighted to indicate that the download of the data export file is available to the user. |
| DOWNLOAD | *Download* button is greyed out to indicate that the download of the data export file is not possible. |

Table 7, Download button modes with description

4. Pagination section.

## Data queries

**Query** or **Data query** - is a conversation between a data editor and data monitor or query manager initiated by a data monitor/query manager/study manager and related to a specific field in a patient or donor event (or to patient/donor registration or consent data field) in the EBMT Registry. It is important that all data editors and all data monitors/query managers/study managers with access to the specific patient can take part in this conversation. Data viewers with access to the specific patient can view the query conversation but can not participate in it.

| Data query status | Description |
|---|---|
| **Open** | Data monitors/query managers/study managers can review patients' data, in particular specific questions (data fields) and **open a query**, which means start a conversation with data editors on a specific field; data query status becomes **Open**. |
| **Resolved** | Once data monitor(s)/query manager(s)/study manager(s) receive required feedback from data editor(s), they will **resolve a query** (in other words, close a query), which marks that the issue is resolved; data query status becomes **Resolved**. |
| **Closed** | This special status is used to mark the data queries which were automatically closed by the system due to the fact that the data field they refer to is no longer included into the event. This may happen if the answer in a parent question was edited and thus the dependent question was not relevant any more and removed (due to visibility conditions), if the visibility conditions were changed and the field is no longer visible, if the query was added on a field that is part of a repeatable group and the group was removed by a data editor, etc. |

Table 8, data query statuses and their explanation

A query cannot be reopened, past queries, regardless of their status (open or resolved) remain visible on the field. Multiple data queries may be open per field at the same time.

Data queries can be accessed through the query overview page (Data queries in the Navigation menu) or through an event form (query icon next to each data field).

| Data query icons next to a data field | Meaning |
|---|---|
|  | There is no query on this data field. |
|  | There is an open query on this data field. The conversation between the data monitor/query manager and data editor started and has not finished yet. |
|  | There is a resolved (closed) data query on this field. |

Table 9, data query icons and their descriptions

Data queries related to the patient or donor consent are shown in the queries overview page, but the query modal window has a fast link to the patient page only (not to the data field directly), thus users should find them through the patient/donor menu: Manage consent section

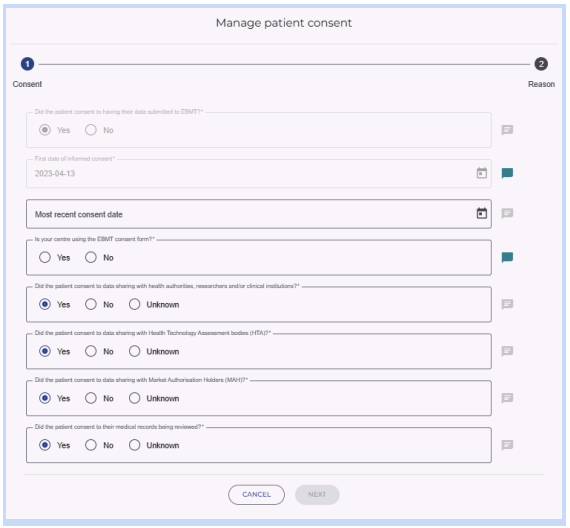



Image 33, data query open icon next to consent-related data field

Data queries related to the patient or donor registration data are shown in the queries overview page, but the query modal window has a fast link to the patient page only (not to the data field directly), thus users should find them through the patient/donor menu: Edit patients details/Edit donor details sections

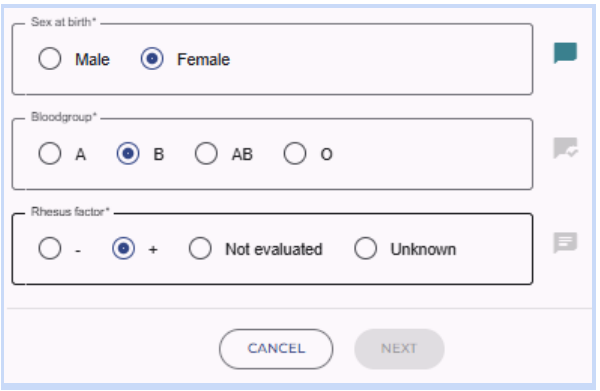



Image 34, Data query open icon, resolved icon next to patient-related data fields

Practical example: query may be used by data monitors/query managers in various ways, including but not limited to the following:

- to call attention of a data editor to any inconsistency with entered field value;
- to call extra attention of a data editor that the information is missing in the field;
- to point out that there is an error and request correction of it;
- to request correction of the value if entered information does not correspond to source document (see SDV below);
- to request some extra information, required for the verification check.

Queries (except closed queries) are visible to all users that have access to the patient record: data viewers, data editors, data monitors, query managers (including query manager and editor), administrators. But the functionality related to queries depend on the user role (see table below).

| Functionality | Data monitor/query manager | Data editor | Data viewer |
|---|---|---|---|
| Open query | Yes | No | No |
| Answer query | Yes | Yes | No |

| | | | |
|---|---|---|---|
| Close query | Yes | No | No |
| See open query | Yes | Yes | Yes |

Table 10, data query functionality per user role

**Data queries overview page**

Data queries overview page allows users to see all the data queries opened on fields related to patients in the current user context, the patient ID, event, field name, date query was added and updated, the status of the query, etc. Users can also use sorting and filtering to better navigate through their queries.

From the query overview page, users can have fast access to each query modal window to read the conversation and reply, if needed, or navigate to the event form using fast link buttons.

EBMT recommends data editors to check this section of the system regularly in order to react to the new queries from Query managers or data monitors.

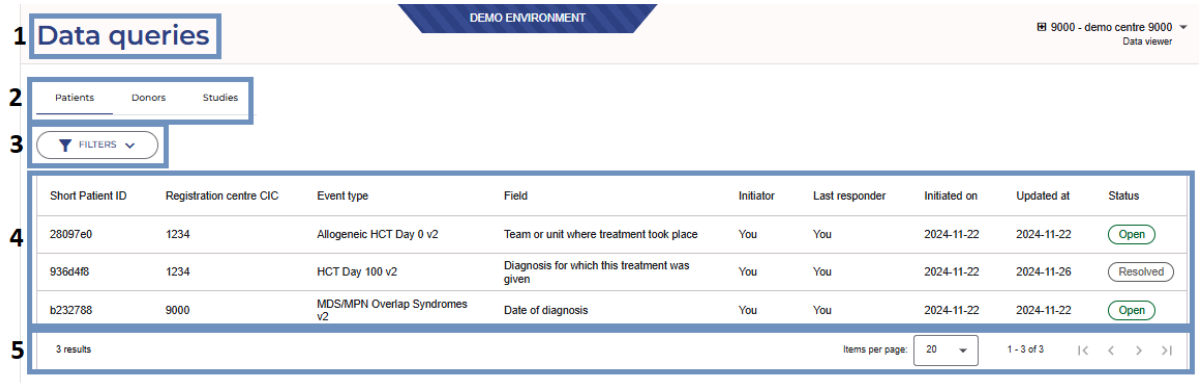



Image 35, the data query overview page

The data queries overview page can be open through the Navigation menu and it contains:

1. The page title: Data queries.

2. Patient / Donor / Studies tabs: to indicate whether the user wishes to view queries related to patients, donors or study specific forms in their selected context.

3. Filters: to filter the list of queries. It is possible to filter the list of queries by various parameters, e.g. by status, event type, patient short ID, date, etc. (see image 36)
4. The list of queries related to patients/donors in the user context. The information is presented in the table, with each row corresponding to a separate query, and columns providing the following details as explained in the Table 11.

5. Pagination section.

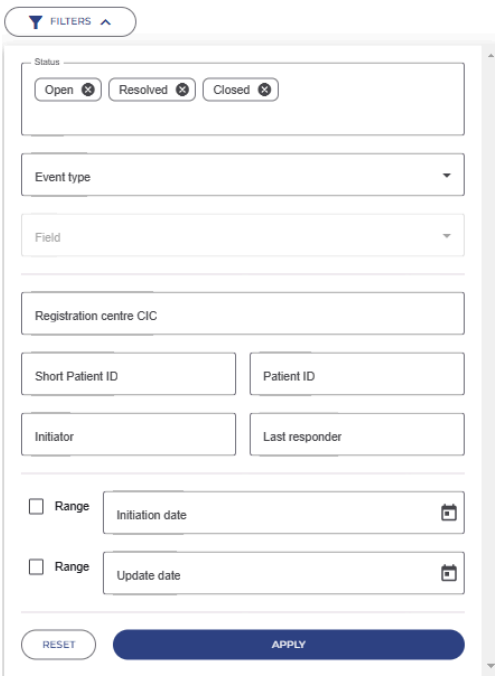



Image 36, the data query filter example

| Column name | Description |
|---|---|
| Patient short ID/Donor short ID | EBMT short ID, relating to the data field for whom the query was opened. |
| Registration centre CIC | The CIC of the centre, that registered the patient, in relation to whose data field the query was opened. |
| Event type | The event the query refers to. |
| Field | The name of the data field the query refers to. |
| Initiator | User's ID, who initiated (opened) the query. |
| Last responder | User's ID, who last responded to the query message. |
| Initiated on | The date the query was opened. |
| Updated at | The date the last message was sent in the query or the date its status was updated, whichever happened last. |
| Status | The status of the query: *open* or *resolved*. Closed status is used to filter the queries that were automatically closed by the system due to the field being removed (repeatable group that was removed or hidden due to visibility conditions). |

Table 11, items in the query overview

While in the Query overview page, users can click the row and open the corresponding data query window (see image 37), read the conversation, and see if the value of the field was updated during the conversation. They can also see the information as to what data field this data query refers to.

If the query is on a data field from any event form: this window also contains a link to open the event form with the data field the data query refers to.

If the query refers to the patient/donor registration data or consent: this window contains a link to open the patient/donor page and the user then has to open the patient/donor menu section to find the data this query refers to.

Note: Multiple queries may be open for the same data field. This means that in the data query overview page, each query will be shown as a different line.

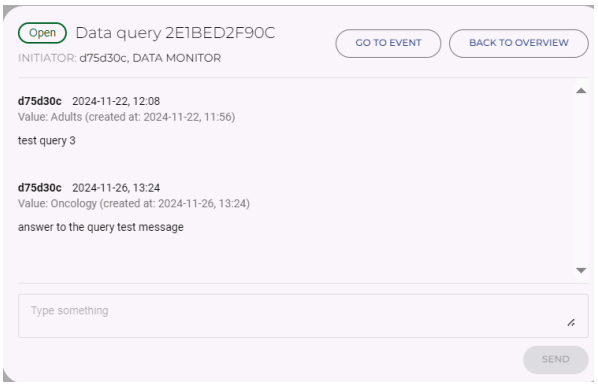



Image 37, a data query window

When opening a query from the patient or donor event form, the user will have to choose what query to enter (see image 38). It is possible to view and enter both open and resolved queries.

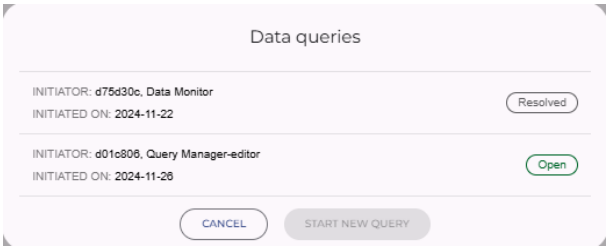



Image 38, a window to select data queries related to one data field

## Studies

One of the purposes of the EBMT Registry is to provide a pool of data to EBMT members to perform studies. The studies are carried out by the dedicated EBMT staff who works for one of the EBMT working parties. For some studies it is sufficient to use the data collected via the core and/or extended dataset, however for some studies additional data collection is required (see Study-related event forms).
In the past, such study-related data collection was carried outside the main EBMT data collection tool (ProMISe), using Excel sheets or PDF forms.

From the EBMT Registry version 2.7 and onwards, EBMT starts gradually moving to study data collection within the EBMT Registry. New functionalities and improvements related to this section of the system are added and explained in more details once available.

For data editors and data viewers it is important to know that study-related event forms are event forms added to the patient timeline, they can be filled-in, saved and submitted as explained further in more details.

### Studies overview page

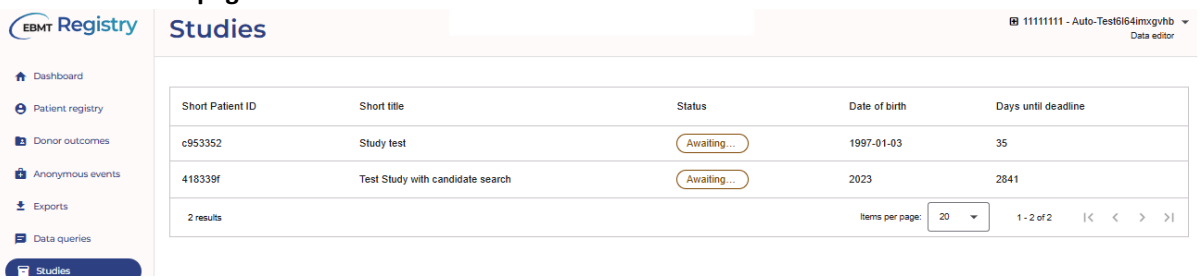



Image 39, example of a studies overview page

Studies overview page will show:
1. The title: Studies.
2. The list of study-related event forms (not submitted yet) for patients taking part in the EBMT studies (in the chosen user context) with their data summary. The information in the Studies overview page is presented in the table below, where each row corresponds to a separate study-related event, and columns provide the following details:

| Column name | Description |
|---|---|
| Short patient ID | EBMT patient short ID. |
| Short title | EBMT study name (short title) |
| Status | Status of the study-related event form: if it is awaiting data submission or data has been submitted already.<br>Note: in future versions of the system here will be listed also submitted study-related event forms |
| Date of birth | Patient date of birth as per Patient registration data. |
| Days until deadline | The number of days left until the deadline for submitting study-related data. If the study phase to submit the data has passed, it is marked as (Study ended).<br>Note: in future versions of the system the study event form will be removed from the study overview list and from the patient timeline if it was not filled in until the deadline. |

Table 12, items in the studies overview

3. Pagination section.

It is important, that Study overview page only lists the patients already enrolled into any study. In case the centre was invited to participate in a study without specific patients identified or if it is up to the centre to add the study event form (questionnaire) to some patients timeline, such patients are not listed in this tab by default. EBMT Study representative may provide further instructions and explanations for their studies.

### User profile

Users can access and view their profile information by clicking the button with their name and surname (when the navigation menu is in full mode) or initials (when the navigation menu is in compact view) from the navigation menu to call the *My profile details* modal window.

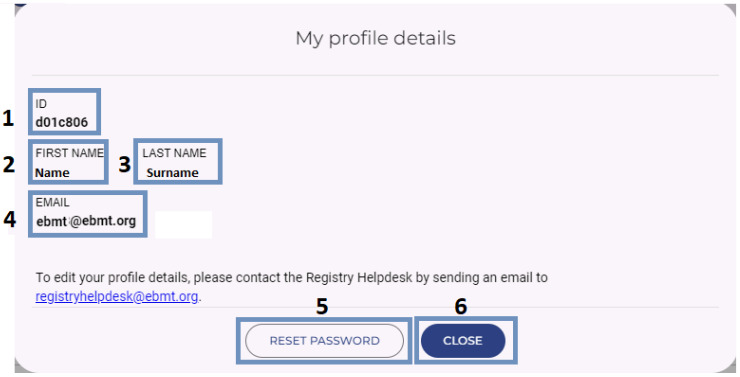



Image 40, *My profile details* modal window

*The My profile details* modal window appears on top of any previously opened section of the EBMT Registry. It shows the following information:

1. User's ID - ID number automatically assigned to the user in the EBMT Registry.
2. User's first name.
3. User's last name (surname).
4. User's email address, used for registration in the EBMT Registry.
5. Button *Reset password* - used to request a password reset.

6. Button *Close* - used to close *My profile details* modal window.

A user cannot change any information displayed in the *My profile details* modal window. If changes are required to the user's first or last name, the user can contact EBMT Registry helpdesk by email.

Note: User email addresses cannot be changed. If a previous email becomes unavailable, the user should contact EBMT Registry helpdesk to deactivate the previous user account and submit a properly signed and filled *EBMT Registry User Account Request form* with the updated email so that the new user account can be set up.

## Pagination

Main screens that show a long list of items with big datasets (like Patient registry overview, Donor outcomes registry overview, Data queries overview, etc.) will include pagination at the bottom of the main screen to navigate through the list of available items.

The EBMT Registry uses an offset pagination method to manage large datasets and display them on a webpage. It is a method to split a large amount of data into smaller, more manageable chunks. With offset pagination, only a portion of the data is loaded at a time, making the web page load faster and reducing the load on the system.

In the current version of the EBMT Registry (due to offset pagination) the system loads up to 1,000 items (10 pages of up to 100 items) at a time. This can be changed without prior notice to adjust system performance.


Image 41, footer showing the pagination

In case of large datasets when only some items were loaded, the system will perform the calculation of the number of filtered results with set up time out in order not to slow down the interface and system performance. In case the number of filtered results is too high and the system could not calculate it within a few seconds time out, unknown or # sign will be displayed instead of the exact number.


Image 42, footer showing the pagination with unknown number of results in the overview page

The pagination section includes:

1. The total number of items in the overview list (equivalent to the number of table rows).

The system will calculate this number over 1 second, and display where possible. Please be aware that very big datasets my not show the total number of items to ensure it does not decrease the general system performance.

2. The number of items (table rows) shown per page. There is also a dropdown for the user to choose whether to show 5, 10, 15, 20 or 100 items per page.

3. Indication as to what rows are currently being shown on the main screen (e.g.1-100 of 1,000 represents that out of over 1,000 items in the database, items 1 to 100 are currently being shown).
4. Button to go to the first page of the list of loaded items.
5. Button to go to the previous page with the list of items.
6. Button to go to the next page with the list of items.
7. Button to go to the last page with the list of loaded items.

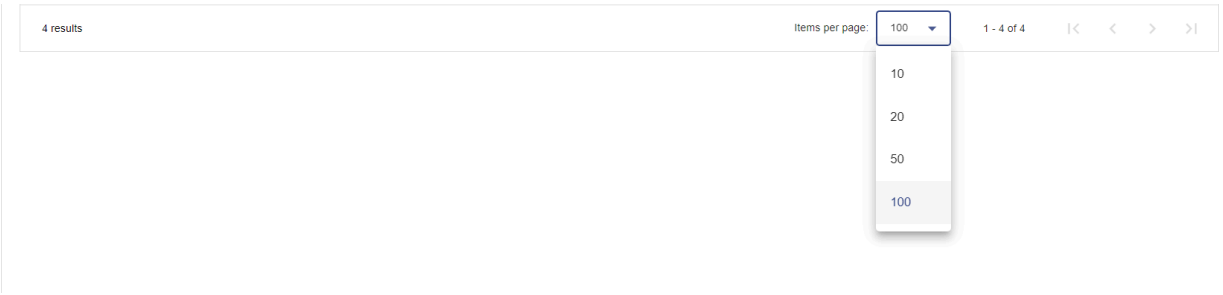



Image 43, dropdown to view more patients per page

## Sorting

Main screens showing tables with datasets also offer users sorting functionality for some columns. Sorting allows the user to organise and view data more meaningfully: in ascending or descending order based on a specific column.

Ascending order:

- If sorting a column of numbers, the smallest number appears first, followed by larger numbers;
- If sorting a column of text, the values are arranged alphabetically, with the first letter of the alphabet appearing first, followed by subsequent letters;
- If sorting dates, the earliest date appears first, followed by later dates.

Descending order is the opposite of ascending order.

| Sorting icon | Description |
|---|---|
|  | Ascending order icon is not highlighted to mark that the sorting is not used for this column. |
|  | Ascending order icon is highlighted to mark that the sorting is applied for this column. The items in this column are shown in ascending order. |
|  | Descending order icon is highlighted to mark that the sorting is applied for this column. The items in this column are shown in descending order. |

Table 13, icons for sorting columns in the EBMT Registry

It is important to note that sorting is not available for all table columns. Users can hover their mouse/cursor over the column header. If one of the sorting icons appears, this column can be used for sorting.

Note: sorting is done within the whole list of items in the EBMT Registry database (not only within a loaded chunk of data as per offset pagination).

## Filters

The EBMT Registry has various filtering options that allow users to filter the large datasets within their context to find the required data, narrow down the search, or define the list of patients or donors that meet certain filter criteria.

There are two types of filters in the EBMT Registry patient and donor overview pages:

- System filters;
- Personal filters.

There is also a separate filter available in the queries overview page, allowing filtering queries.

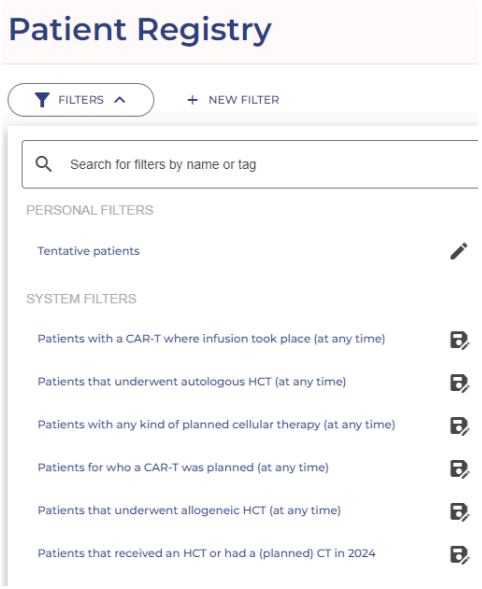



Image 44, example of a list of personal and system filters in the Patient registry overview

### System filters

System filters are the same for all users of the EBMT Registry. They are set up in order to facilitate everyday operation of the users, based on their needs. The list of system filters may change with the new editions of the EBMT Registry.

System filters are configured by EBMT separately for Patients Registry and for Donors outcome registry and may be applied to the patients or donors overview lists. Users may use system filters for filtering or use them as a template to edit and create their own personal filters.

It is not possible for users to edit any system filter. Users may save system filters as their personal filter and then edit it as needed (see Save system filter as personal filter).

### Personal filters

Personal filters are user-specific filters. They may be created and applied by a specific user to filter the list of items in the user context. Users can also save their filter, if they wish to keep it and/or use it again in the future. Any saved personal filter can also be edited or deleted by the user, if the filter is no longer relevant for the user.

Users can create their own personal filter in the following ways:

- Enter all the filtering criteria manually from scratch;
- Open a saved personal filter and modify it.
- Save system filter as personal filter and modify it further if needed.

It is possible to save personal filters with tags, in order to find them easier. A user may enter a tag or filter name in the search field to find the filter in the filter list.

**Filter results** - is the list of items received after applying all criteria defined in the filter. Suppose the initial filter results do not fully meet the user's needs. In that case, the user can refine or modify the

filter: adjust the criteria, remove some existing criteria or add new criteria to narrow down the displayed list further. The user can also remove the applied filter to return to an unfiltered list of items, which is the complete list of patients or donors in their context.

### Filter criteria

Filter criteria are the rules used to narrow the search results. E.g., If a user wants to filter data only to show patients born in a specific period.

To define the filter criteria, a user must specify three key components: parameter, condition and value (see image below).

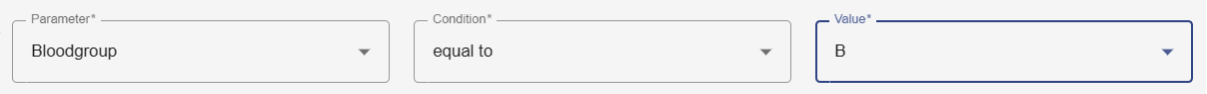



Image 45, example of a filter criteria (includes parameter, condition and value)

### Parameter

A filter parameter is the data field from an event a user wants to search for in the database.

Filters can be applied to various data fields thus filter parameters can be related to:

- Patient/Donor (data fields related to the patient/donor registration form e.g. Blood group, Sex at birth, etc.); or
- Patient events/Donor events: user also specifies the filter criteria that is related to what event type category and to what exact event (the Data Collection Form).

Since patients may have repeated events (e.g. multiple auto-HCT), it is also possible to narrow the search and specify whether it refers to the First event type, Last event type or Any event type (Image below).


Image 46, event type - Any, First, Last

Parameters are grouped based on the event form, where they are reported. Thus, to find a parameter, users should follow the logic below:

1. Specify the category of a patient event (DCF) and select if it is related to:
    - Patient (patient registration data);
    - Diagnosis;
    - Treatment;
    - Follow-up.

When filtering donors users should specify if the condition is related to Donor (donor registration data) or donor follow-up.

2. Choose the event form (DCF) that contains the data field which is the filtering parameter.
3. Choose the version of the event form (there are currently 2 versions for the majority of event forms). (see Event form versioning)
4. Select the parameter from the dropdown list or enter it (if it is text field).

### Condition

A filter condition is the type of comparison a user sets up. The list of conditions used for parameters that are dates differ from those used for other parameters (see table 14)

| Condition used for dates | Condition used for numerical values or items from a dropdown list, radio button groups or checkbox fields |
|---|---|
| Equal to<br>Not equal to<br>Before<br>Before or equal to<br>After<br>After or equal to<br>Is empty<br>Is not empty<br>Is not evaluated<br>Is ongoing<br>Is unknown | Equal to<br>Not equal to<br>Is empty<br>Is not empty<br>Is not evaluated<br>Is ongoing<br>Is unknown |

Table 14 conditions used in EBMT Registry depending on the type of parameter it refers to

See table 15 below for the list of conditions used in the EBMT Registry with some examples.

| Condition | Example |
|---|---|
| Equal to | Tentative (patient) equal to true. |
| Not equal to | Blood Group not equal to B |
| Greater than | Age (at treatment) is greater than 30 |
| Greater than or equal to | Age (at treatment) is greater than or equals to 30 |
| Less than | Age (at diagnosis) is less than 70 |
| Less than or equal to | Age (at diagnosis) is less than or equals to 70 |
| Is after | Treatment year is after 2000 |
| Is before | Treatment year is before 2020 |

Table 15, filter conditions and examples

### Value

Value is the reference value of the data field.
See table 16 below for the types of data field values used in the EBMT Registry with some examples.

| Data field value type | Example |
|---|---|
| Date |  |
| Number |  |
| Answer options (radio buttons or checkboxes in a data field) |  |
| Text |  |

Table 16, filter values and examples

Note: filtering value must be exact match to the data field value. Partial match is not included into the filter results. Text field values are not case sensitive thus both upper or lower case can be used.

### Complex filters

Users can filter the list of patients or donors within their context based on a number of **filter criteria** to search for patients/donors, create a filtered list of patients or work with it at their own discretion. Filtering of the patient/donor list may be based on many criteria, which may be grouped into **filter groups** for user convenience. It is possible to use either statement AND or statement OR inside each group of criteria (see example below).

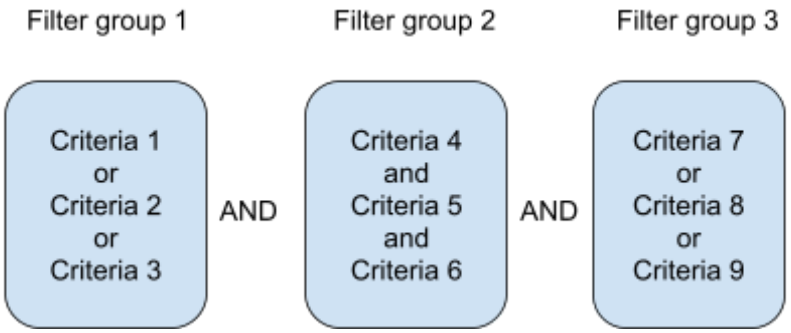



Image 47, example of a filter with 'and' groups

The statement between groups of criteria is always the same and is either AND or OR. It cannot be a combination of both (see example above and below).

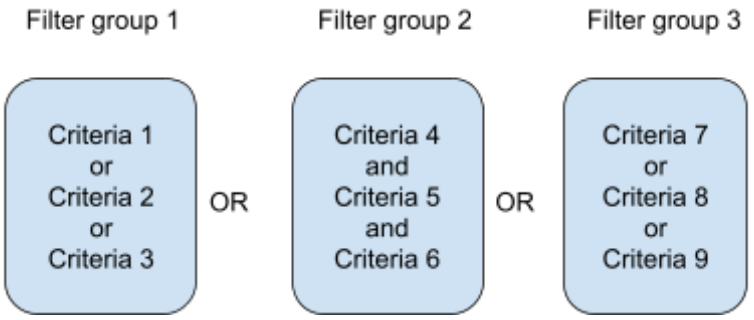



Image 48, example of a filter with 'or' groups

By default, the statement AND is always shown, but the statement can be changed at any time while setting the filter both inside the group and between groups.

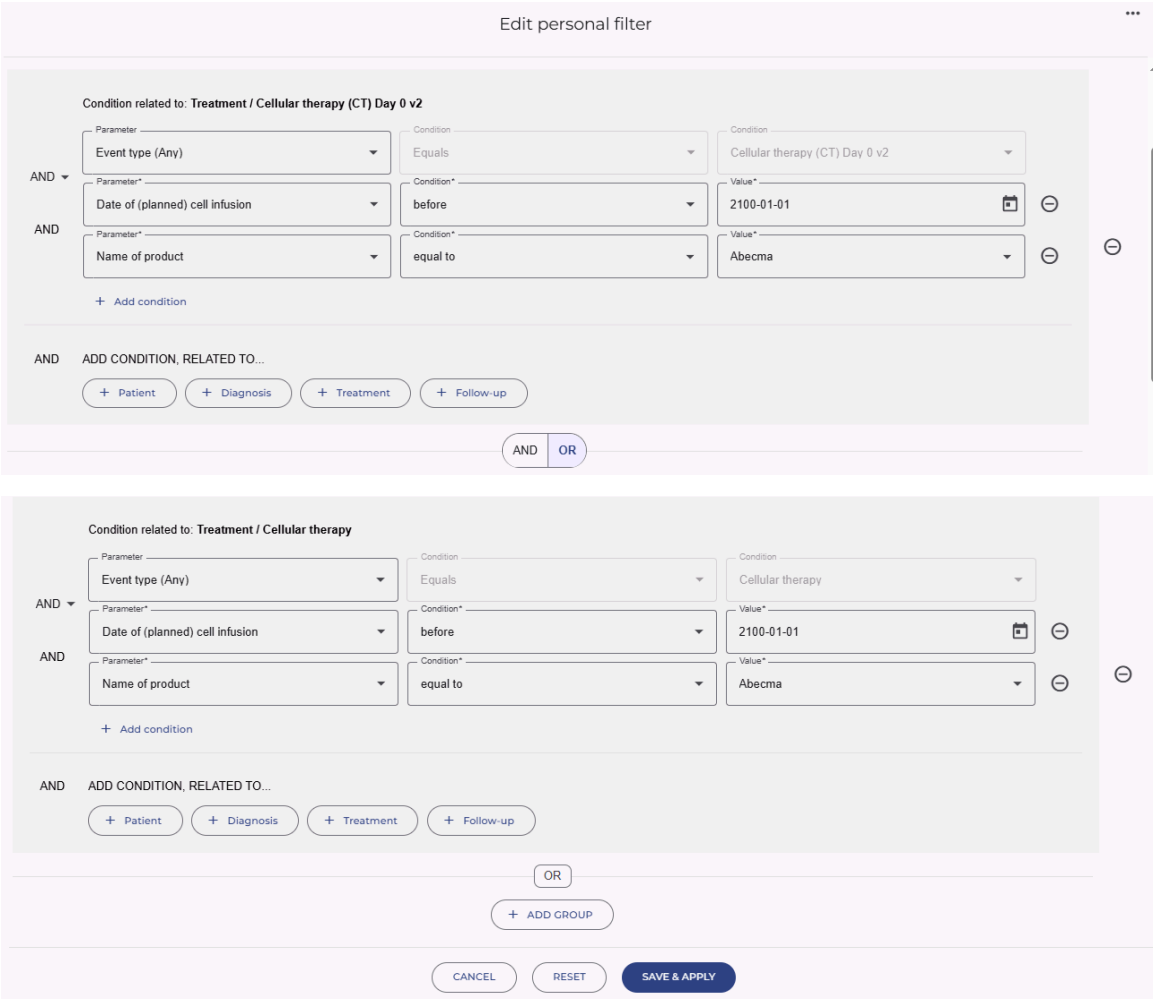



Image 49, example of a complex filter in the EBMT Registry

## Data queries filter

There is a separate filter available to filter the queries shown in the data queries overview page.

Users first need to select a patient, or donor, or studies tab, to define if they wish to view the queries that refer to patients data, or to donors data (registered in the Donors outcome registry), or queries in the study event forms.

Clicking the filter button in the top part of the queries list will open the window to define the filtering criteria:

1. Status: by default all query statuses are shown (open, resolved, closed). Users can click the cross sign in the right upper corner of the status to remove it.
2. Event type: this is a drop down list (with a search bar) of the event forms and their versions available in the system (e.g. Lymphomas v2 and Lymphomas).
3. Field: this parameter becomes active only once the event type is specified, and it is a dropdown list (with a search bar) of all data fields in the mentioned event form. The fields are grouped in the same way they are shown in the event form. It is possible to use a search bar to easier find the field or the field group name. Besides field names, there are also indicated field ID codes, which are used by internal EBMT staff in their tasks (see image below).

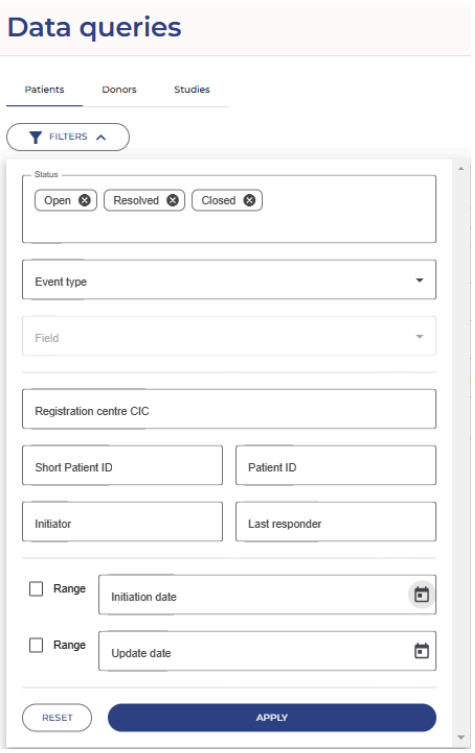



Image 50, filter in Data queries overview

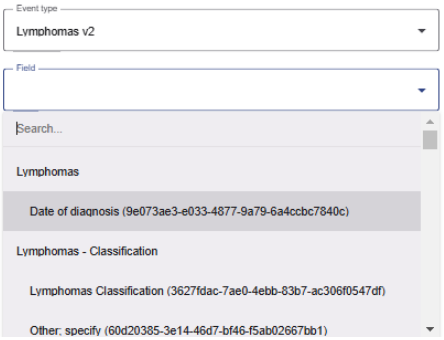



Image 51, example of a field to be indicated while filtering queries

4. Registration centre CIC: this is a number field to indicate the CIC of the centre marked as registration centre for this patient or donor.
5. Short ID: this is the field to enter EBMT short patient ID or EBMT short donor ID. It is possible to specify only one patient or donor in this field.
6. Patient ID/Donor ID: this is the field to enter EBMT patient ID (long ID) or EBMT donor ID. It is possible to specify only one patient or donor in this field.

7. Initiator: this is the field to enter the ID of the user who started this data query.
8. Last responder:  this is the field to enter the ID of the user who last responded in this data query.
9. Initiation date: this is a date picker to specify the exact date, when the query was open. If the exact date is not known, users can tick the range check box
    a. Range: this check box enables specifying the date range when the query was opened.


Image 52, example of date range specified for when the query was opened

10. Update date: this is a date picker to specify the exact date, when the query was las updated (answered, closed). If the exact date is not known, users can tick the range check box
    a. Range: this check box enables specifying the date range when the query was last updated.

# Patient/Donor page

All patients and donors registered in the EBMT Registry have their own page. The table below lists sections and explains the structure of each patient and donor specific page.

| | Patient page | Donor page |
|---|---|---|
| 1 | Hyperlink ***PATIENT REGISTRY*** used to come back to the Patient registry overview page. | Hyperlink ***DONOR OUTCOME REGISTRY*** used to come back to the Donor outcome registry overview page. |
| 2 | EBMT patient short ID is always shown in the header. | EBMT donor short ID is always shown in the header. |
| 3 | Patient notes icon is only shown when any information was saved in the Patient notes | Donor notes icon is only shown when any information was saved in the Donor notes |
| 4 | Patient menu | Donor menu |
| 5 | Patient summary | Donor summary |
| 6 | Timeline, by default it is shown in graphic view | |
| 7 | ***List view*** toggle button to switch the Timeline from the graphic view to the list view and vice | |
| 8 | ***Add new event*** button - not visible for users without data editing rights. | |
| 9 | Event form - the most recent event form in the timeline is loaded by default. | |
| 10 | Event form summary for the loaded event form. | |

Table 17, sections in the patient and/or donor pages

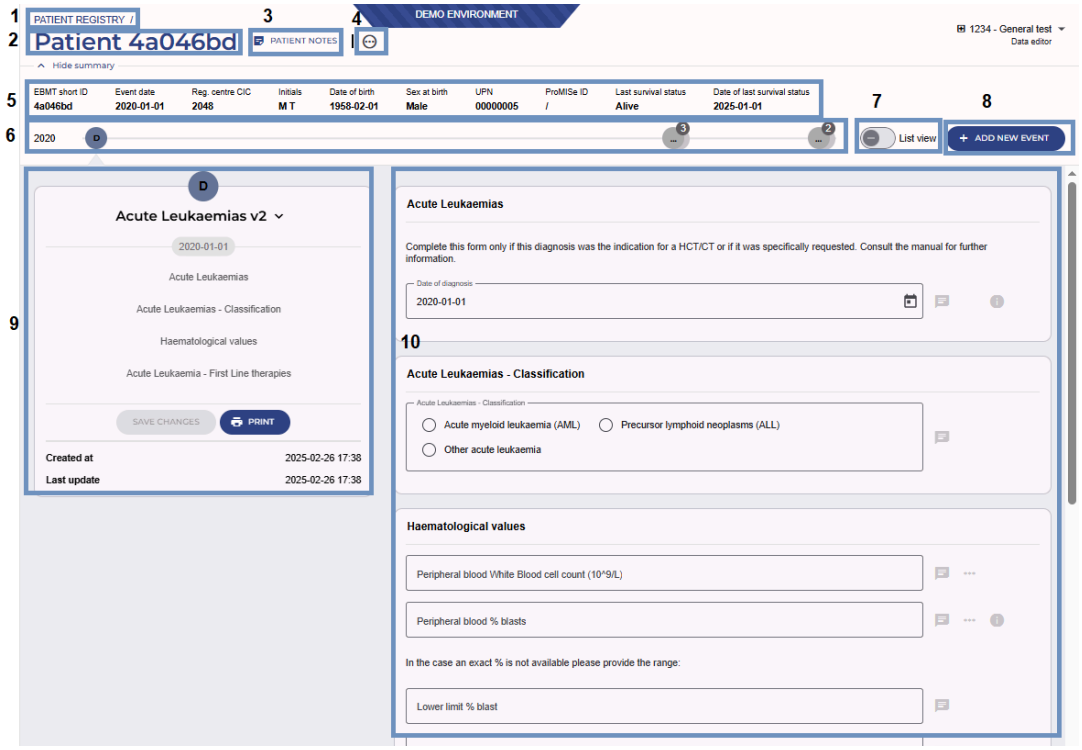



Image 53, patient page

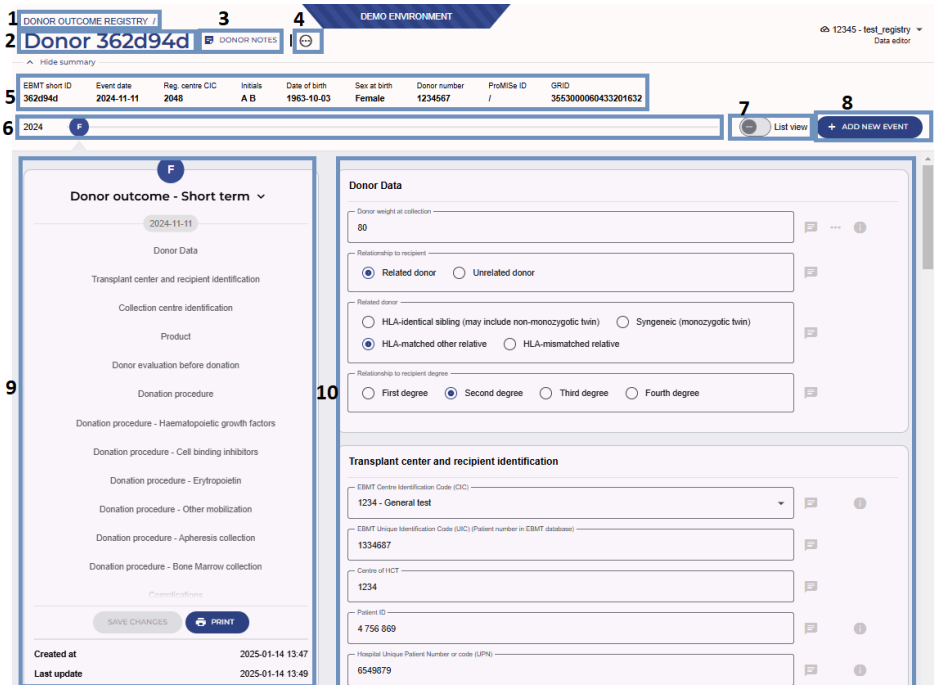



Image 54, Donor page

The patient and donor page may display the notes icon (see image 55). This icon is only shown for patients or donors with registered notes. Whenever the notes for the patient or donor are empty (deleted), the notes icon is hidden automatically.


Image 55, example of a patient page with notes

Important note: the information entered into patient/donor notes is a free text that is not part of the core dataset, and it is the responsibility of the centre to ensure no sensitive or confidential information is stored there. Notes can be accessed only via the EBMT Registry application interface, data from Notes is not stored in the analytical database. Thus, it is not possible to export data from patient/donor notes in the current version of the EBMT Registry.

## Tentative patient page

Tentative patient pages are marked to call data editor and administrator users attention to the tentative status (image 56):

- there is a word warning next to the patient menu stating *Pending verification*;
- all the top part of the main screen except event form and event form summary is greyed out.

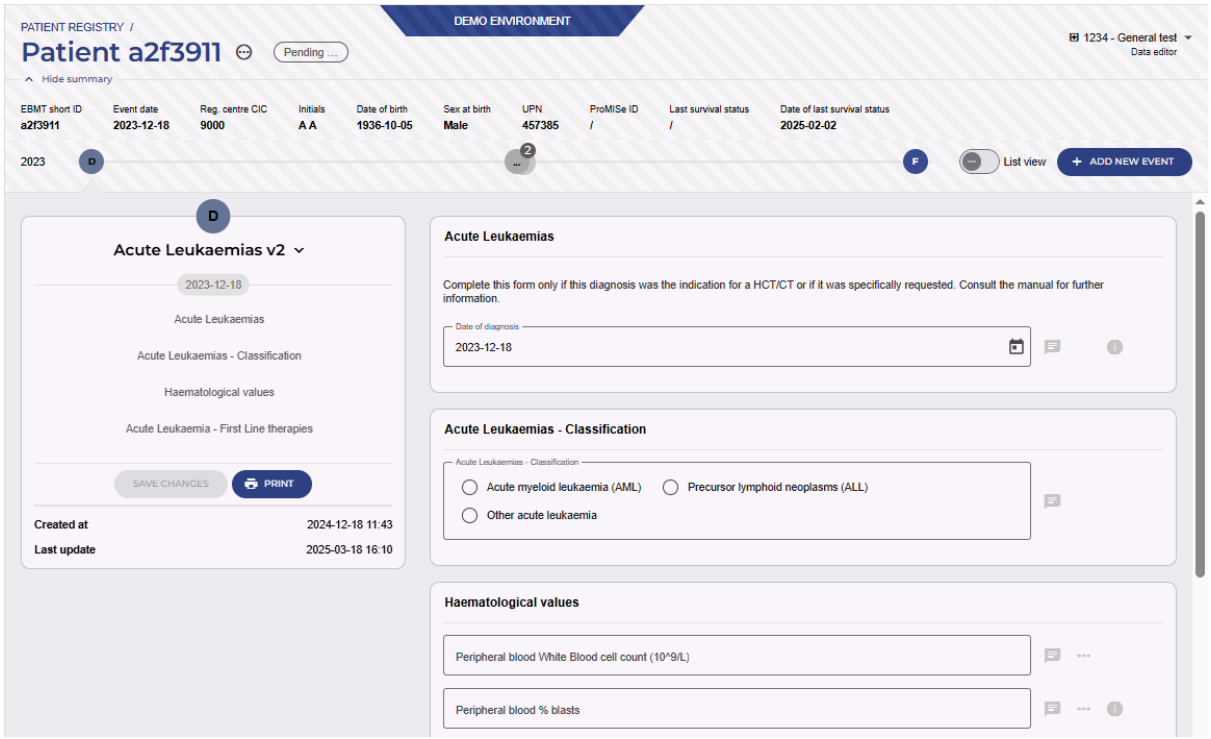



Image 56, example of a tentative patient page

Remember: Only data editors and administrators can see Tentative patient(s) in the system. This means that Data viewers and Monitors/Query managers cannot open Tentative patient pages.

## *Patient/Donor menu*

The **Patient/Donor menu** may be opened with the three dots button next to the Patient short ID (image 57 below) or Donor short ID (image 58 below). It is used to edit or update patient/donor registration information, consent, information on studies, update notes. The functionality available for a user role is always highlighted. The functionality that is not available to a user is greyed out.

Patient/Donor menu includes the following items:

- ***Edit patient details*** section includes information about EBMT patient ID and the patient registration data (initials, date of birth, sex at birth, blood group, rhesus factor, etc.), where it can be updated, if required (see Edit patient details). ***Edit donor details section*** includes information about EBMT donor ID and the donor registration data (initials, date of birth, GRID, sex at birth, etc.), where it can be updated, if required (see Edit donor details).
- ***Manage centres*** section allows viewing what centres are linked to the patient or donor and to update patient UPN/donor ID, if required.
- ***Manage consent*** section includes information on the date of initial patient or donor consent and the latest informed consent signed, as well as responses to all consent-related questions (see Edit patient consent and Edit donor consent).
- ***Manage studies*** section includes information on both non-EBMT and EBMT studies the patient is involved in. This section is not shown for donors in the current version of the system.
- ***Update notes*** section is used to edit or view any comments for this patient or donor. Comments are captured as a free text and are not part of core dataset, it is often used by centres/VRs users for their internal notes.

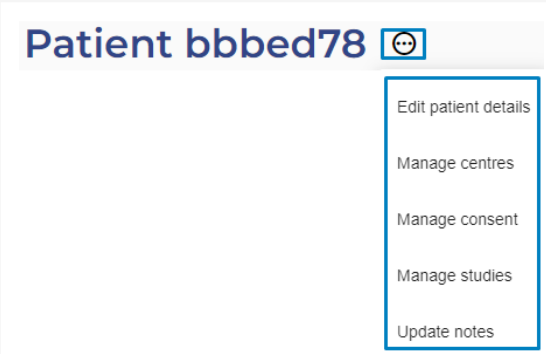



Image 57, patient menu


Image 58, donor menu

| Patient menu item/User role | Data viewer /Monitor/ Query manager+viewer | Data editor | Administrator |
|---|---|---|---|
| Edit patient details | Read only | Editable | Editable |
| Manage centres | Read only | Read only for linking centres Editable to update UPN | Editable |
| Manage consent | Read only | Editable | Editable |
| Manage studies | Read only | Editable | Editable |
| Update notes | Read only | Editable | Editable |

Table 18, items in the patient menu and users' editing or read only rights

| Donor menu item/User role | Data viewer /Monitor/ Query manager+viewer | Data editor | Administrator |
|---|---|---|---|
| Edit donor details | Read only | Editable | Editable |
| Manage centres | Read only | Read only for linking centres<br>Editable to update Donor ID | Editable |
| Manage consent | Read only | Editable | Editable |
| Update notes | Read only | Editable | Editable |

Table 19, items in the donor menu and users' editing or read only rights

## Patient/Donor summary

**Patient/Donor summary** is a section showing summary information about the patient/donor to provide users with some contextual details about the patient/donor while they are viewing events information. The content of this section may slightly change between the versions of the EBMT Registry application.


Image 59, patient summary full view

Patient/donor summary can be shown (in full view) as in image 59 or hidden as in image 60 to leave more screen space for the event form. *Hide summary* and *Show summary* are toggle buttons to switch between these two modes.


Image 60, patient summary hidden

## Patient/Donor timeline

**Patient and Donor timeline** represents a summary of registered events for the particular patient or donor. The timeline can be shown in the graphic view (see Image 61) or in the list view (see image 64).

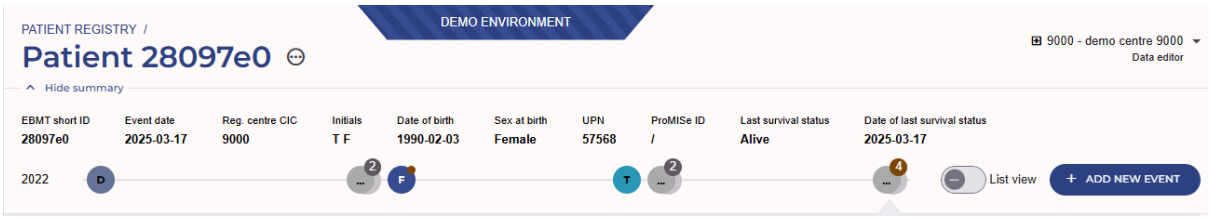



Image 61, example of a graphic timeline view

By default, the graphic view is shown. In default view, events are represented with coloured circles (see Image 61) in the timeline based on the registered event date (e.g. for patients: date of diagnosis, date of follow-up, etc.) in chronological order with the earliest events shown on the left side and all subsequent events to the right. It allows users to see the entire registered medical history and intensity of patient/donor events over time at a glance. Events may be grouped for patients with extended medical history. The groups of events are shown as a grey circle with the number of events it contains  . Event forms with the same event date (e.g. Treatment and Disease status at HCT/CT/GT/IST) are always grouped in the current version of the EBMT Registry. User should click on the group circle to see the list of events it contains (see image below)

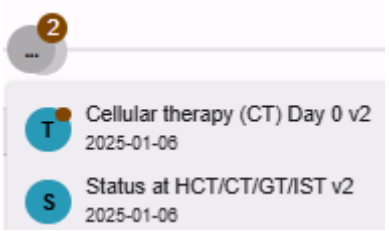



Image 62, example of a list of events shown upon clicking the event group in the timeline

When a user hovers the mouse over the event circle in a timeline, the user can see some summary information that includes:

1. Coloured circle representing an event with a letter(s) representing the category of the event (e.g. D for the diagnosis, T for treatment, F for Follow-up, etc).

S letter is used both for the Status at HCT/CT/GT/IST event and for study-related event forms (questionnaire), but the icons will appear with different colours to be easily distinguished.

2. Name of the event.
3. Date of the event.
4. The date when the event form was created in the EBMT Registry.
5. The date when the event form was last updated in the EBMT Registry.
6. How much time has passed since the event took place:
    a. It is shown in months for events dated less than a year ago;
    b. It is shown in full years for events dated over a year ago.

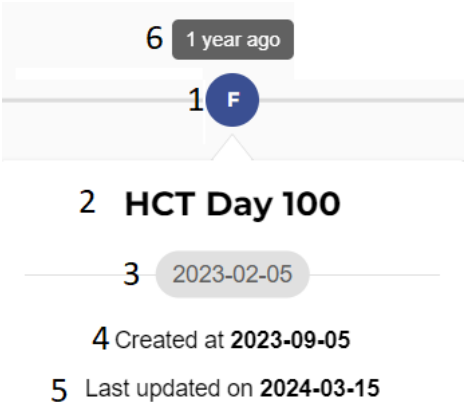



Image 63, example of summary information for an event

The timeline can be switched to the list view instead of the default graphic, using the list view toggle button.

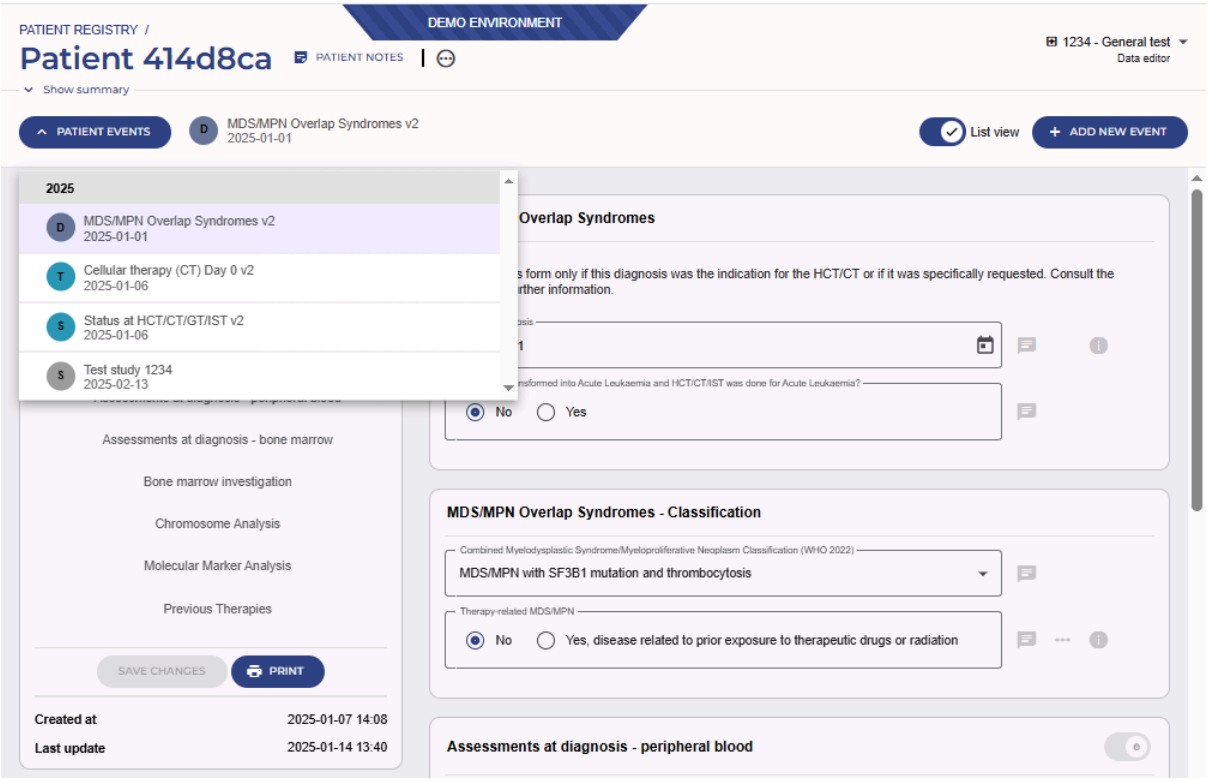



Image 64, example of a timeline in list view

Patient or donor timeline enables users navigating between registered events by clicking on the events in the timeline (see View Patient event).

## Event form summary

**Event form summary** (event summary) is an area to the left of the opened event form, that contains some summary information about the respective event form and important buttons for the event form management. It also allows navigating between event form sections.

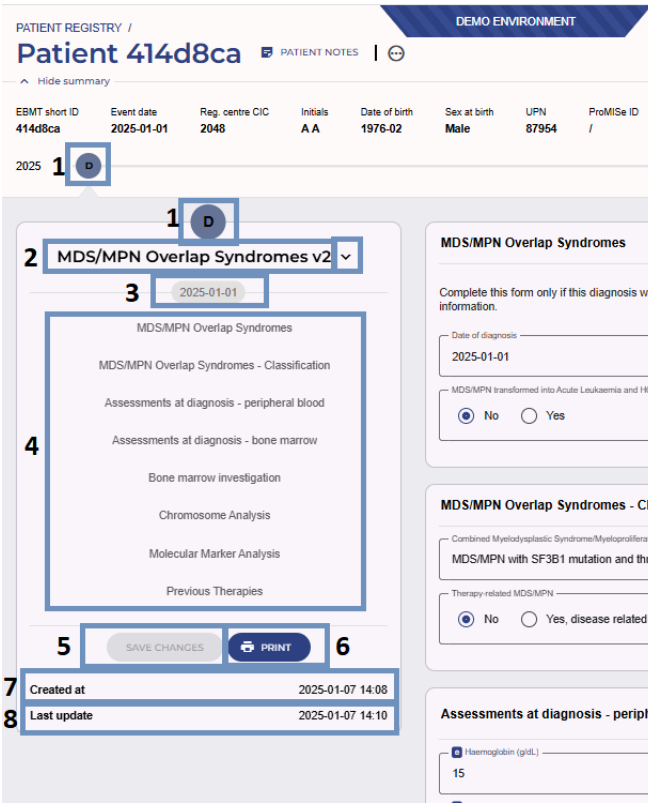



Image 65, example of an event form summary

It includes the following elements:

1. Event icon (coloured circle) representing an event with a letter specifying the event category (e.g. D for the diagnosis, T for treatment, F for follow-up, S for study-related event form, etc). It is equal to the one used in the Patient timeline.

Note: if an event form contains warning or error, the circle in the timeline (event icon) will also be marked with an error or warning dot. The event icon in the event form summary never contains any error or warning mark (see image below), since error/warning mark is shown next to the title of section it refers to.

2. Name of the event.
3. Date of the event.
4. Titles of the sections from the event form.

The titles of sections from the event form are listed one under another as a list. When a user scrolls through an event form, the section currently displayed in the event form is shown as selected (highlighted in bold in the event form summary).

Every title of sections in the event form summary is clickable, it works similar to interactive content. Once a user hovers the mouse over the title of the section in event form summary - it becomes highlighted.

Once a user clicks on it (selects), the title in the event form summary becomes highlighted and in bold and the corresponding section is being scrolled to and shown in the event form (see image below).

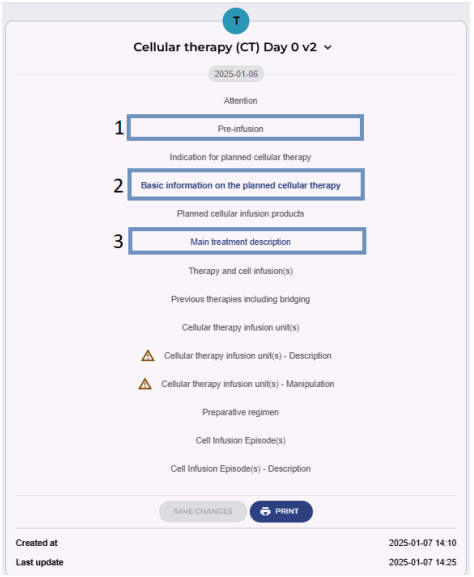



Image 66, event summary showing titles of sections: regular (1), selected/currently shown (2), highlighted upon hover (3)

If there are any field warning or error in any section of patient/donor event form, the corresponding icon will also be shown next to each title of the section (see Field warnings and Field errors)

5. ***Save changes*** button

*Save changes* button may be shown in active or inactive mode as described in a table below

| Button | Description |
|---|---|
| SAVE CHANGES | Active *Save changes* button signifies that there were some changes done in the currently opened event form by data editor.<br>If the user clicks the button, the changes will be saved to the database. |
| SAVE CHANGES | Inactive *Save changes* button signifies that the user role does not allow editing event form and saving changes (e.g. data viewer); or<br>there were no changes done in the currently opened event form by the data editor.<br>Inactive button cannot be clicked. |

Table 20, views of the save changes-button

6. ***Print*** button

*Print* button is used to create a printable version of the event form (see Print event).

7. Created at

It is the date and time when the loaded to the screen event form was created (registered) in the EBMT Registry by a data editor.

8. Last update

It is the date and time when the loaded to the screen version of the event form was last saved by an data editor in the EBMT Registry.

9. Event menu

Event menu can be called with the icon ⌄ which is to the right of the event form name. It is used to archive (delete) patient or donor events (see Delete event).

## Event form

**Event form** corresponds to the Data Collection Form (DCF) of the respective event with some adjustments due to electronic format and EBMT Registry design. Patient and/or donor **event form** contains a series of data fields (questions). It provides a structured and organised way to capture and manage information that refers to the same event in a patient or donor timeline.

Tables, which are reports associated with repeated measurements that are similar for multiple items, are not used for the current version of the EBMT Registry. Thus, the tables from the EBMT Data Collection Forms are represented with a group of questions.

Events are configured in the EBMT Registry in such a way that depending on answers given in some data fields, relevant sub-questions are shown (visibility conditions). There are also used buttons to add repeatable groups of questions (for example drugs, lines of treatments, etc.) in the EBMT Registry.

**Data entry field** (data field) is a designated space (field) where data can be input/viewed/edited. It is designed to capture a specific piece of information. More details on data fields can be found in the Data entry section.

Data fields are grouped by topic, similar to sections in the EBMT Data Collection Forms; in event forms this is visually represented as a group of fields displayed on the same white square background. Each section is displayed in a separate white square background.

There are usually-used titles for each section, which is also reflected in the event form summary.

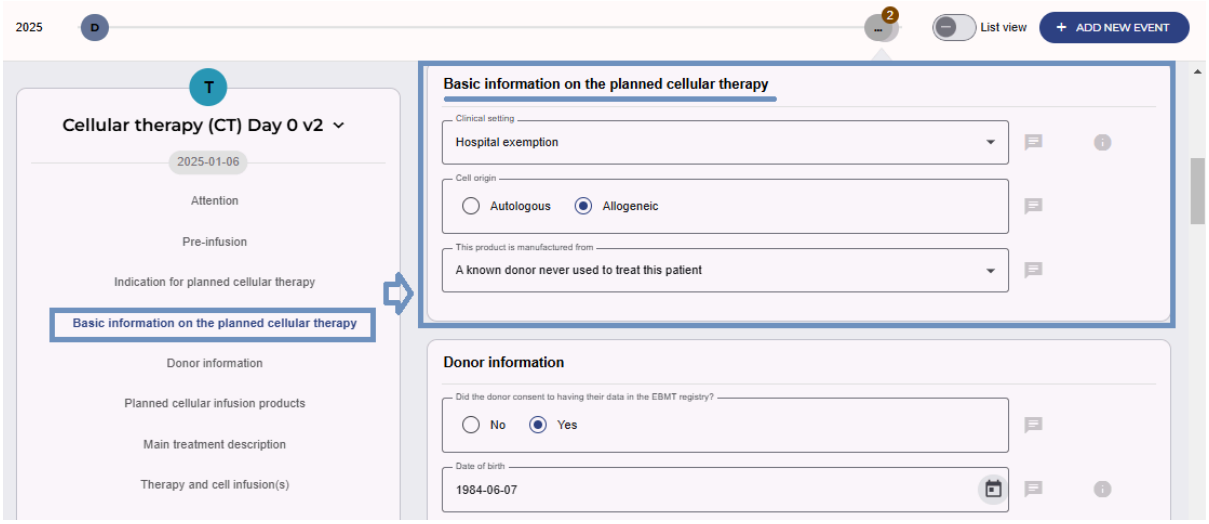



Image 67, data entry view with titles highlighted

Due to the high number of data fields within an event form, users need to scroll through the event form or use the event form summary to open the required section of the form.

Event forms are versioned, which means that the EBMT Registry keeps track of changes saved (e.g. user, who saved changes, date, time). It is recorded in the audit trail.

When a user opens an event form, the EBMT Registry loads the latest saved version of this event form. Event form is displayed both for data editors and data viewers. Users without editing right will see the information, but it is greyed out to reinforce that it is in read-only mode.

Only users with editing rights are able to edit values, but all such changes remain purely visual until they are saved. Any changes are recorded and saved to the database only when a Data editor saves changes - clicks active *Save changes* button. The system will then create a new version of the form that will become the most recent event form version.

Important: If the data editor leaves the event form without saving it or the user session expires, all unsaved entered data or changes will be lost and not recorded to the database or audit trail. Thus it is important to save changes done in the event form before a user:

- Navigates away from this particular event form (e.g. opens any patient menu section, goes to other patient events or to other parts of the EBMT Registry);
- Leaves web browser tab with unsaved edited event form in the EBMT Registry;
- Closes web browser tab or web browser with unsaved edited event form in the EBMT Registry;
- Switches off computer;
- Leaves the EBMT Registry web page without activity for 20 minutes or more (see User session).

## Event form versioning

Data collection process must be flexible to reflect the latest trends and changes in the treatments and diseases EBMT is collecting data. Data collection forms are regularly revised by EBMT experts and working parties, which leads to creation of new versions of DCFs and event forms as their equivalents in the EBMT Registry.
Once a new version of an event form is configured and published in the EBMT Registry - it becomes effective immediately and replaces its previous version (if any). Users cannot use the previous version of such event form to submit (register) new data, but they can open patient or donor event submitted at the time such version was active, edit/update active data fields, if needed.

The version of an event form is usually mentioned in the event name (see image 68)

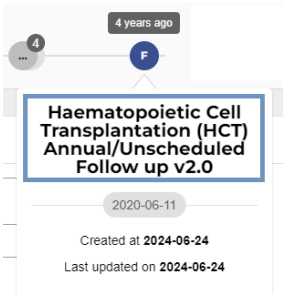



Image 68, example of an event form version specified in the event title

Since content of event forms differs in various versions, form versions should be taken into account while working with exported data and in order to filter data in the EBMT Registry.

While filtering data, users should specify what versions of event form the filter should be applied to.
For example, to filter all patients with blood group A that underwent Cellular therapy treatment, the user should configure the filter with the following logic:

1. Patient has CT treatment reported (any date of treatment) in CT treatment form v.1 **and** patient blood group is A.
2. **OR**
3. Patient has CT treatment reported (any date of treatment) in CT treatment form v.2 **and** patient blood group is A.

When such a filter is configured in the EBMT Registry, it will look as appears in the image 69.

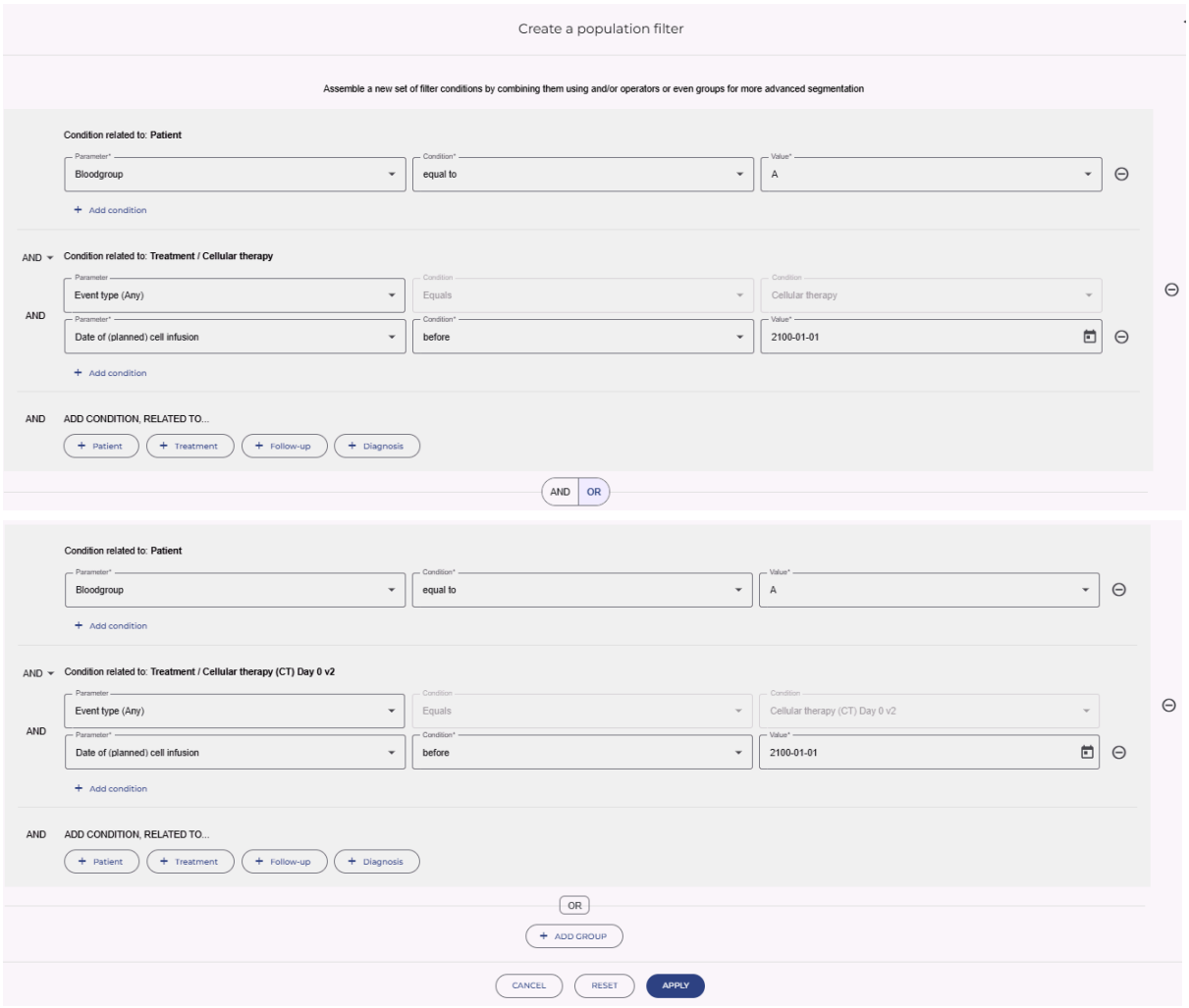



Image 69, example of a configured filter with form versions specified

## Possible editing conflict

If two or more users are opening any patient or donor event form at the same time or with 15 (fifteen) minutes difference, the EBMT Registry will show a warning, notifying them about **possible editing conflicts.** It is important to note that if the same form is opened or edited by multiple users, the user that presses the *Save changes* button last will create the latest event form version; this means that data entered by other users will be lost and only the data as displayed on the main screen of this last user will be saved to the database. This is a crucial point to remember if multiple users open or edit the same form.

Note: It is recommended that the users avoid situations of potential editing conflicts and return to such event records later.

Practical example:

- User A and User B open the same patient event form at the same time at 12:00 (or within 10 minutes of each other). The system shows a warning about a possible editing conflict. The event form is loaded on each user screen and looks exactly the same.
- User A enters data into data field 1, then presses the *Save changes* button at 12:11. The event form version 1.0 is created in the database.

- User B leaves data field 1 empty, enters data into data field 2 and data field 3, then presses the *Save changes* button at 12:15. The event version 2.0 replaces (overwrites) the event version 1.0 in the database.
- The information displayed on the User B screen will be captured in the database. The changes to data field 1 made by User A are lost, as version 1.0 has been overwritten by event version 2.0.
- Any user who enters this patient event form from 12:16 onwards will see that data field 1 is empty and data fields 2 and 3 are as entered by User B.

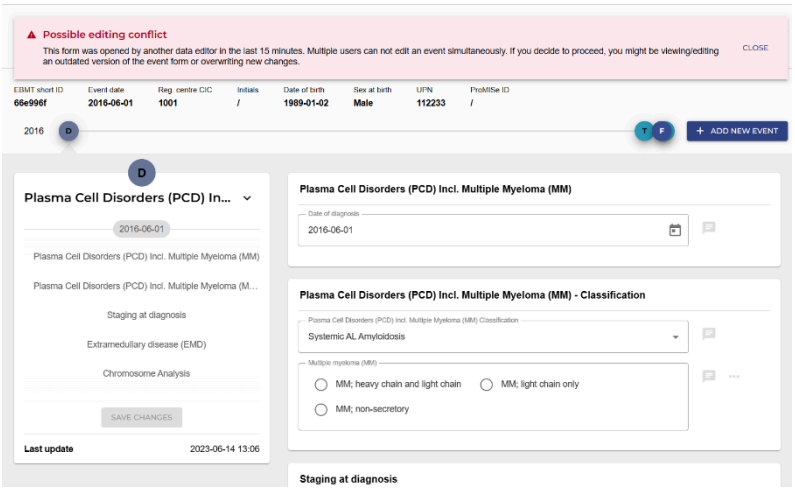



Image 70, the message shown in case of a possible editing conflict

## Hidden patients (embargo status)

There are cases when patients should be temporarily hidden from other EBMT Registry users and be excluded for studies until a certain date. E.g. data of CAR-T patients included into PAS studies should be hidden and not considered for EBMT studies for a certain period of time.

The EBMT Registry v2.5.2 and further versions allow assigning a special *Embargo status* to the patient to mark that the patient and all patient events data cannot be considered for studies.
Users with editing rights will be able to add and/or remove the Embargo status to their patient via the patient menu following steps described below.

1. Open the patient that needs to be Embargoed in the EBMT Registry.
2. Open Patient menu and select Edit patient details.
3. Add Embargo end date to the corresponding field of the Edit patient modal window
4. Click Next, specify the reason for the introduced changes to the patient record. Click Update patient to save and apply changes.


Image 71, the embargo status shown in the patient page.

The embargo status is removed automatically from the patient in the EBMT Registry once the Embargo end date is reached.
Users can remove Embargo end date in the Edit patient modal window, if it was entered by mistake.

## Study-related event forms

Besides regular event forms to record patient data (diagnosis, treatment, follow-up), patients enrolled into EBMT studies in their timeline will also be shown study-related events icons.
Study-related event forms contains a series of data fields (questions) to collect data required for studies.
This includes:
Study candidate search event forms, such form aims to collect data in order to select candidates for a study. This type of event forms are shown in the patient timeline as a smaller dot, comparing to other patient events.
Study event form (study questionnaire). This event form aims to collect data required for studies that is not included into regular patient events (core dataset).

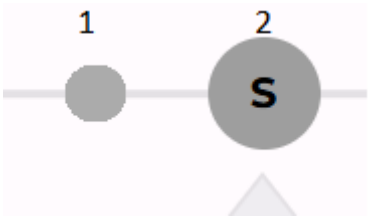



Image 72, study-related event form in a patient timeline: 1 study candidate search form , 2 study event form

## Data entry field

Data entry field (data field) has the following elements:

1. **Label** describes in short what data should be provided in the data field. Label design differs slightly depending on the data entry field type.

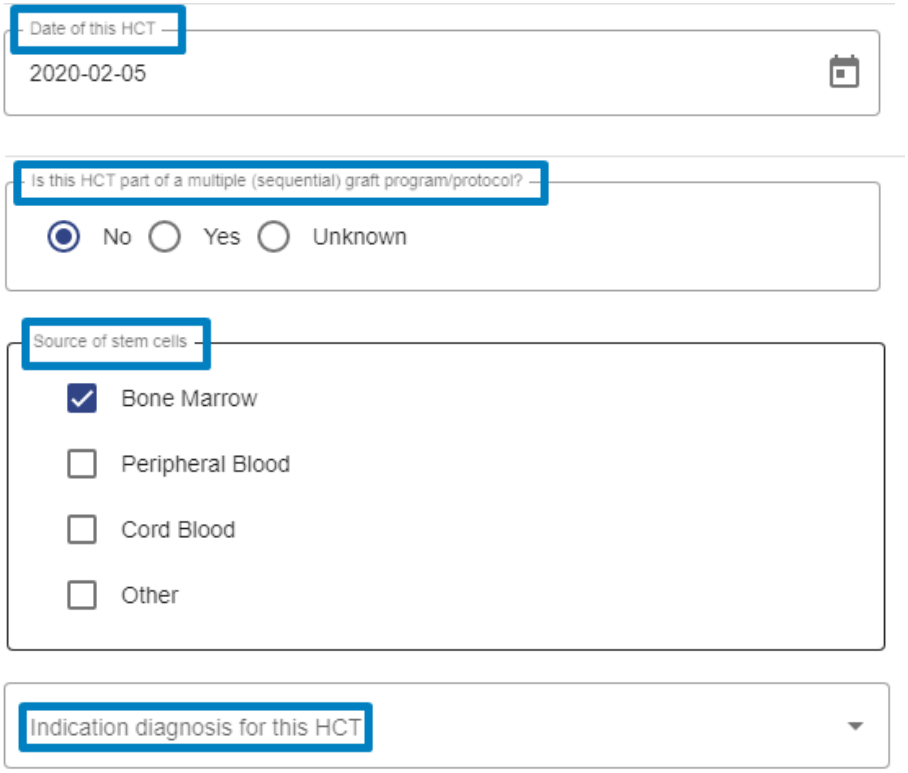



Image 73, labels in an event for data entry

2. Area to enter data or answer options to select from (see Data entry field types)
3. Help **text** - some of the fields also have help text; it provides some extra details, such as the data to be entered into the data field.

The following icons may be shown to the right of a data entry field:


Image 74, items shown next to data entry fields

1. Data query icon.
2. Three dots icon to mark the data field menu, it is used to mark that the answer is unknown/not evaluated.

Note: the data field menu icon is shown only for data fields, where it is possible to indicate unknown, not evaluated and/or ongoing status. If the icon is not visible, this means that for this data field it is not possible to select any of these statuses.

3. Hint - help text that is not shown by default. It appears when a user hovers a mouse or cursor over the information icon to the right of the data field.


Image 75, example of a hint

## Mandatory fields

Majority of data fields are considered to be mandatory for completion in the event form, a few may be optional. Optional fields are always marked. Data items should be filled in if specifically stated in the definition or in the Completion guidelines to the relevant DCF.
Some key data fields will also be configured to show a warning or error if they are left blank.

## Unknown/Not evaluated/Ongoing status

For some data fields, it is possible to indicate that information is unknown or not evaluated, or the date is not known because the process was not finished (ongoing).

There is a three dots icon ••• to the right of some data entry fields to mark the data field menu (see image below). The data field menu is a dropdown that includes one or more options that vary depending on a data field, e.g. not evaluated, unknown, ongoing.


Image 76, marking a field as not evaluated or unknown

It is used when needed to state that information is not available and cannot be entered into the database, thus assigning this status to a data field. When a data editor selects an answer option from the data field menu, the field is marked with the respective status.


Image 77, example of how a not evaluated field looks like after selecting 'Not evaluated'

In case it was done by mistake or information becomes available at a later stage, data editors may remove such status from this data field:

- For fields previously marked as *Unknown,* data editor users can enter the field value and unknown status will be removed automatically, or they can remove this status through the data field menu, clicking *Mark as Normal.*


Image 78, removing the 'unknown' status

- For fields marked as *Not evaluated*, data editor users should open the data field menu and click *Mark as Normal* to remove the Not evaluated status and enable editing, and then enter field value if needed.


Image 79, removing the 'not evaluated' status

Ongoing status may be indicated for some date fields, as shown in the image below:


Image 80, ongoing status on a data entry field

Depending on a data entry field, ongoing may also be a regular answer option as shown in the image below:

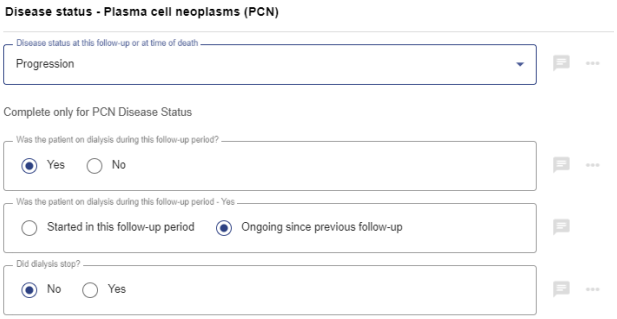



Image 81, ongoing as an answer option for a data entry field

## Data fields visibility conditions

The data fields in the EBMT Registry event forms have strictly defined visibility conditions: depending on the answer given in one data field, only relevant dependant fields are shown to capture data; irrelevant data fields, based on established visibility conditions, are not visible and cannot contain any data. This ensures that every event form remains as compact as possible, the collected data does not contain contradictions and is properly structured.

In case a user changes the main field value, the list of dependent fields is automatically updated to show only relevant ones, any previously entered data into dependent fields that are not visible and not relevant any more is emptied. The user will be notified in this case, to ensure that the main field value is not changed by mistake and to avoid such mistake leading to data loss.

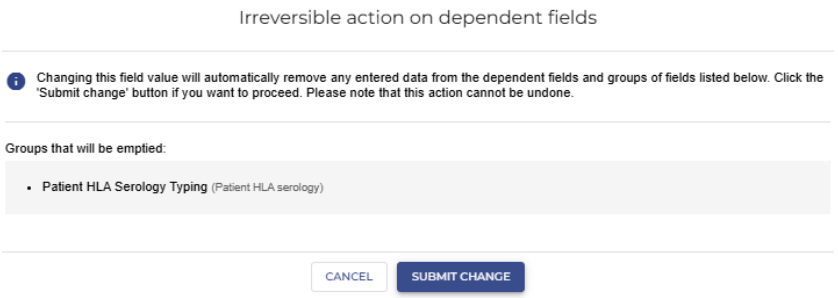



Image 82, example of a warning about removing data in dependant fields due to the main data field value change

## Data entry field types

Below is the short summary and some details on data entry fields used for online data entry. There are different types of inputs used for data fields in the EBMT Registry.

### 1. Drop-down

Drop-down is mostly used for questions with more than three answer options. The answer options will appear after clicking the field. An option can be selected from the list. For long lists, please scroll to navigate through and see all the items. Some of the drop-down lists also have a search field. In this case, it is possible to type the text on the field and obtain suggestions from the list of options available.

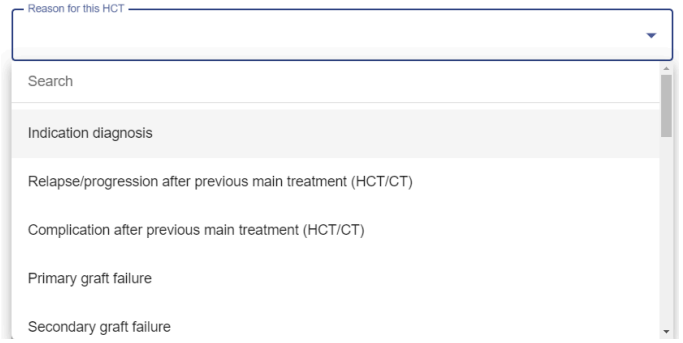



Image 83, example of a dropdown menu

### 2. Radio buttons

**Radio buttons** are used for questions where there are a few options available but only one option can be selected. The question can be filled in by clicking the dot before the answer.


Image 84, example of radio buttons

### 3. Check-boxes

**Check-boxes** are used for questions where more than one option can be selected at the same time. Check-boxes can be selected and unselected, if needed.

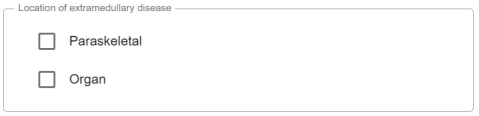



Image 85, example of check boxes

**4. Dates**

All dates in the EBMT Registry are in YYYY-MM-DD format, where YYYY represents 4 number digits of the year, MM - 2 number digits of the month, DD - 2 number digits for the day of the month. Date fields have calendar graphics on the right.

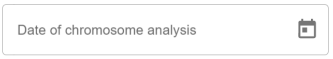



Image 86, example of a date field

Users can enter the date manually by typing it in the format YYYY-MM-DD or click the calendar graphics to open the calendar window and select the date (year, month and date).

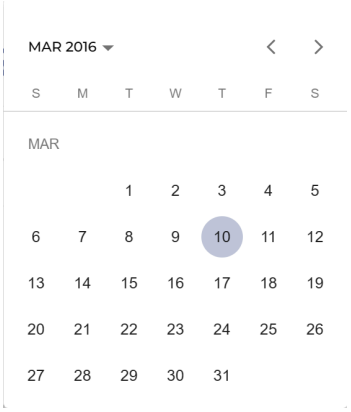



Image 87, calendar view after clicking the date field

It is not possible to mark the date reported as approximate in the current version of EBMT Registry, thus all dates are considered as exact dates. In case the exact day of the month is unknown, or day and month is unknown, please follow the instructions as stated for the Introduction to the EBMT Registry Completion Guidelines available at the EBMT website.

In rare cases, indicating a **partial date** (e.g. Patient date of birth) is possible. In this case, another date field format is used, allowing a user via separate dropdown to specify year only, or year and month, or year and month and day.

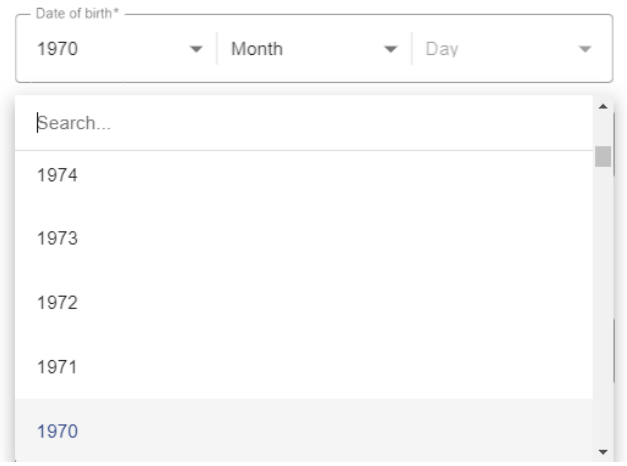



Image 88, example for adding a partial date

**5. Text**

Text fields in the EBMT Registry accept both text and numbers. In case the field is aimed to enter a numerical value, there might be also set up automatic data check to make sure entered value is within expected range. Text boxes that specify Other answer options in the forms must only be used if no alternative from the dropdown or radio buttons is available. It is mandatory to answer in English, as other languages can create codification problems with letters not recognised by the system.


Image 89, example of a text box field

**6. Calculated fields**

Calculated fields are quite rare and are used to perform calculations such as the exact age at the time of an event. These calculations are done based on the information entered into the database in previous forms. Calculated fields cannot be edited.


Image 90, example of a calculated field

If the value in the data field is shown wrongly, this can happen due to a mistake in the date of birth or date of the event registered in the EBMT Registry . Please check both data fields.

**7. Remote field**

Remote fields in the EBMT Registry are marked with the  icon, it is a data field (question) answered in the earlier submitted forms that is repeated in subsequent forms.

Remote fields are shown with the following information:

1. Remote field icon
2. Details of the source event form where this data field was entered, followed by the date of the event.
3. Name of the data field (label).
4. Event field value.

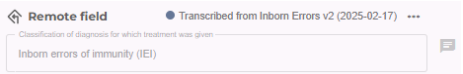



Image 91, Remote field

Remote field value can not be edited. If the data editor notices that the data value is incorrect in the remote field, they need to open the source form where it was initially entered (source field) and correct it. By clicking the three dots icon to the right from the source event form (see image below), users will see the possible actions in regard to the remote field they may take:

1. Go to event type selection - will scroll the current event form to the field, where they indicated the source event form.
2. Edit (in original event) - will show a warning message about leaving the current form and opening the source event form in the browser.

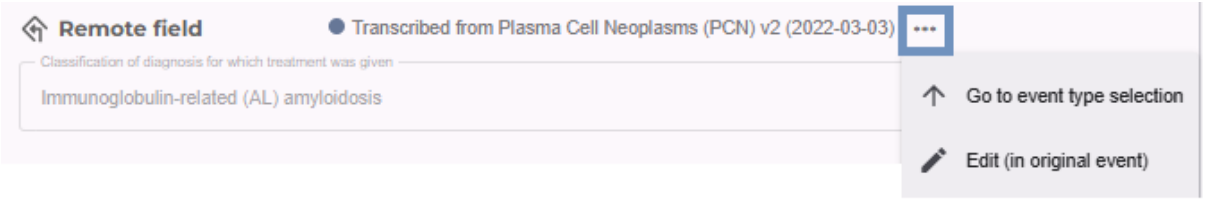



Image 92, the three dots icon to call fast actions in regard to the remote field

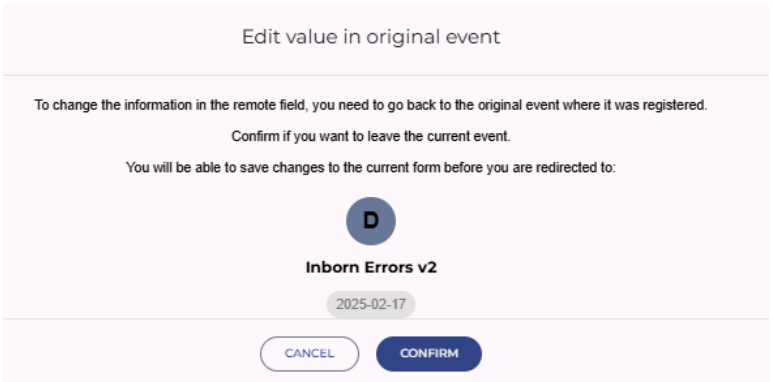



Image 93, warning pop-up window when navigating away from the event form to change the source event form to update the value in the remote field

## Repeating group of question

A repeating group of questions is a set of data entry fields (questions) that are repeated multiple times within a single data entry form (event form).

A button for *adding* the whole group of questions is often used in case it is not known the exact number of repetitions the user needs to report data. Such a button is placed at the end of the last added group of questions, it has ***+ Add*** at the beginning of its name.


Image 94, example of a repeating group of questions

The group of questions may also be removed (deleted) with the help of *remove* button icon ⊖ to the right from the group of questions title.

Important: Once the user deletes the group of questions, the data that was entered into there is deleted and this action is not reversible. That is why users are advised to be careful and check that there is no data to be lost by this action

For users convenience, each group of questions may be shown in full view or compact (collapsed) view in order to manage screen space. Users can use arrows (see table 21) to the left from the Repeated group name which are toggle buttons to switch between these views.


Image 95, collapsed and expanded questions in a repeating group

| Icon | Description |
|---|---|
| ^ | Repeated group of questions is shown in full view, which means there are shown all its data entry fields and values, if any.<br>Once a user presses this button, it switches to collapsed view. |
| v | Repeated group of questions is shown in a collapsed view, which means there is only the title of the group of questions. Data entry fields and their values, if any, are not visible to free more space for other data fields and information on the user screen.<br>Once a user presses this button, it switches to full view. |

Table 21, icons used in repeating groups of questions

Do not confuse:

- the ⊖ icon button deletes group of questions and entered into these fields data, while
- the ^ and/or v icon buttons are hiding/unhiding a group of questions on the user main screen (no data is deleted and it remains in the event form).

### Inactive data entry fields

Some data entry fields may be set as inactive to mark that they are not relevant any more (deactivated) and data editors do not need to enter information into these fields. Nevertheless, all information already submitted in deactivated fields (when they were active) remains in the database and is shown in the patient/donor event form as legacy data (historical data).

Inactive data entry fields are not shown to users unless they contain some data.

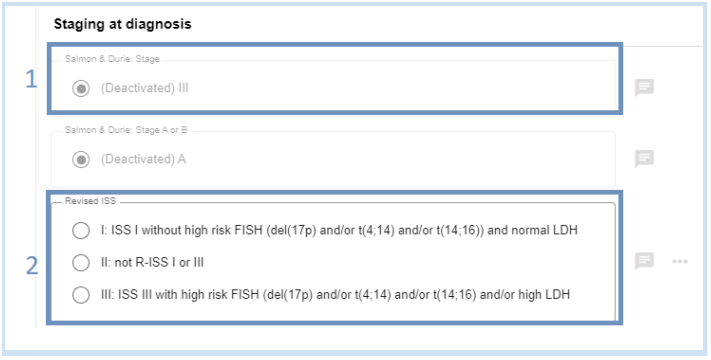



Image 96, example of inactive data entry field with entered data

### Data entry fields to link data in the EBMT Registry

Some of the patient event forms include a number of data fields that are not present in the corresponding Data collection form. The fields differ depending on the event form type:

- In Allo HCT, Auto HCT, CT, GT and IST treatment event forms, the users must add information on Indication diagnosis for this treatment.

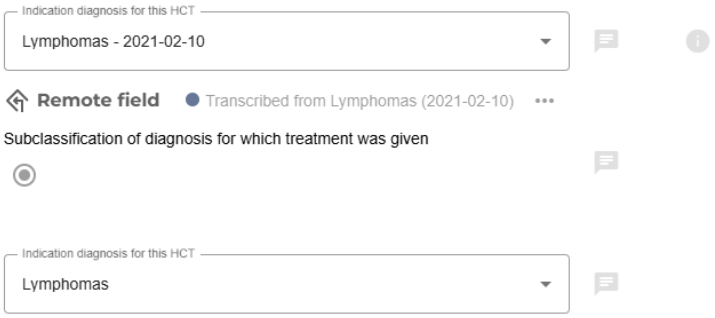



Image 97, example of data entry fields to link treatment and diagnosis events

- In Status at HCT/CT/GT/IST form the users must add information on Indication diagnosis for this treatment as well as treatment to which this event form refers to.

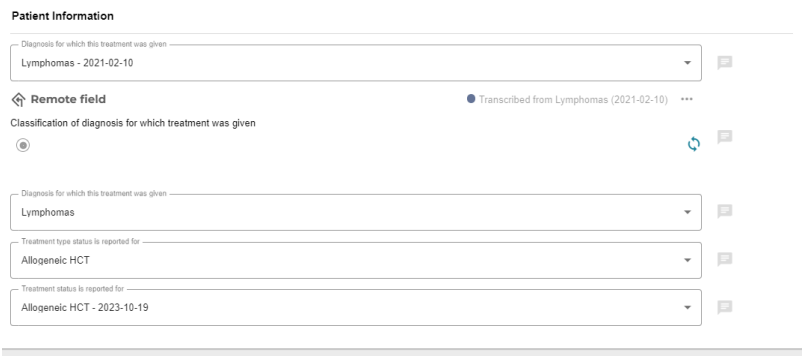



Image 98, example of data entry fields to link Status at HCT/CT/GT/IST form and treatment and diagnosis events

- In follow-up forms users must specify the indication diagnosis for this treatment and the exact treatment event the follow-up refers to

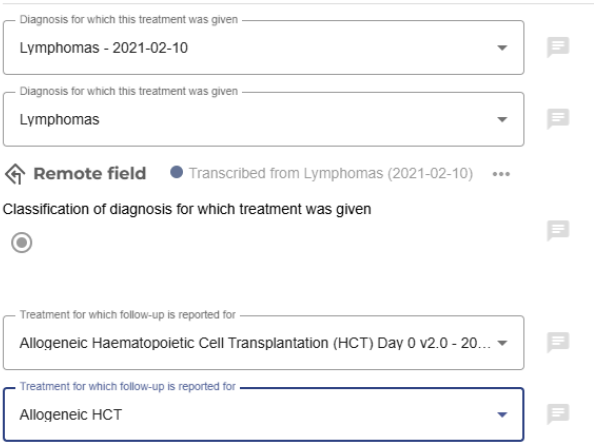



Image 99, example of data entry fields to link follow-up event and treatment and diagnosis events

There are two fields for users to enter the indication diagnosis for the reported treatment:

1) Drop down to select the main indication diagnosis for this treatment. The drop-down list includes all registered indication diagnosis events in the patient timeline with the date of each registered event. This data field is used to ensure the events are properly linked in the database and the data is correctly structured in OMOP.
2) Drop down to select the name of the main indication diagnosis for this treatment. This data field is used to ensure the visibility conditions for further data fields in this event form work correctly.

There are two fields for users to specify the treatment, the follow-up form refers to:

1) Drop down to select the treatment event in the patient timeline. The drop-down list includes all registered treatment events in the patient timeline with the date of each registered event. This data field is used to ensure the events are properly linked in the database and the data is correctly structured in OMOP.
2) Drop down to select the treatment type. This data field is used to ensure the visibility conditions for further data fields in this event form work correctly.

Mentioned above fields are mandatory and must be filled-in in order the data is properly organised in the EBMT Registry database and is included into the appropriate export file/table/dossier.

It is important to remember that if any event was archived (deleted) from the patient timeline, the data editor needs to open all the subsequent events, where archived (deleted) event could be mentioned in linking, and correct or update links.

If the date of transplant (treatment) was edited or changed, data editor should open the Status at HCT/CT/GT/IST form and update the data there as well.

### Delayed migration status

Due to the fact that data migration from previously used systems will happen in stages, in the current version of the EBMT Registry users will see a notification in the affected data field(s) to mark that field value has not been migrated yet. Any field type may have such a status.

Data fields with delayed migration status are marked with the  icon. Once the migration is done, data field value (if any) will appear and the delayed migration status will be removed from the data field.

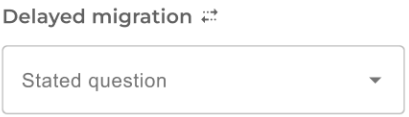



Image 100, a data field for which migration of data is still pending

Important: These fields are editable as any other field (except remote and calculated data fields). If data editor users enter the field value before the migration happens, it is recorded as the latest registered data field value. Data field value from the migration will be logged in the audit trail as historical data once the migration is complete.

### Unknown migration

Since systems previously used by EBMT to collect data did not have strict visibility conditions and dependencies, in some cases the main data fields were left empty and only dependent fields contained information. In order to migrate such data correctly and not to lose submitted information respecting new EBMT Registry visibility conditions, the empty at migration main (parent) fields that had dependant fields with entered data were marked as *Unknown migration*.

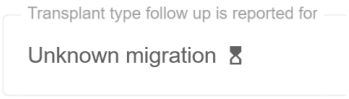



Image 101, the unknown migration field label

Unknown migration field value should not be edited by the users, and it is only present in the first version of the event form. Moreover, some of the answer options could be deactivated already. See image below as an example of Unknown migration status used to enable inclusion of dependent fields as legacy data.


Image 102, example of an Unknown migration field with data in the dependent fields

If a user marks the field with Unknown migration status as Normal, the migrated data in the dependent fields will be deleted. The user will be able then to enter the data into the main (parent) and dependent fields manually from available at the moment answer options (some answer options might be already inactive and will not be available).

### Interdependent fields

Besides dependent fields within one event form explained above (see visibility conditions), there are also **interdependent fields** in the database across various event forms (e.g. calculated field and remote field), and if the field value is edited in one form, the EBMT Registry cannot apply the correction automatically in all the forms it is used at one time. Nevertheless, suppose a data editor corrects the field value in the source field, once the subsequent form (with dependent field) is opened, the system will apply these changes and mark the affected field with the icon .

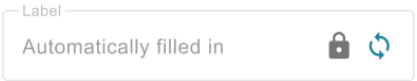



Image 103, example of a remote field that is refreshed

Updates to the affected field(s) are applied automatically when a form containing this data field is opened, but a data editor has to click the Save changes button so that these changes are saved into the database. To reinforce that a user with editing rights needs to save changes, the Save changes button is shown as active until the changes are properly saved and the new version of the event form is recorded into the audit trail.

## Extended dataset data fields

Extended dataset data fields are part of extended data set. Since in the EBMT Registry, users may choose to add the extended dataset-related data within regular patient events (see Extended dataset), such fields are marked with e icon.

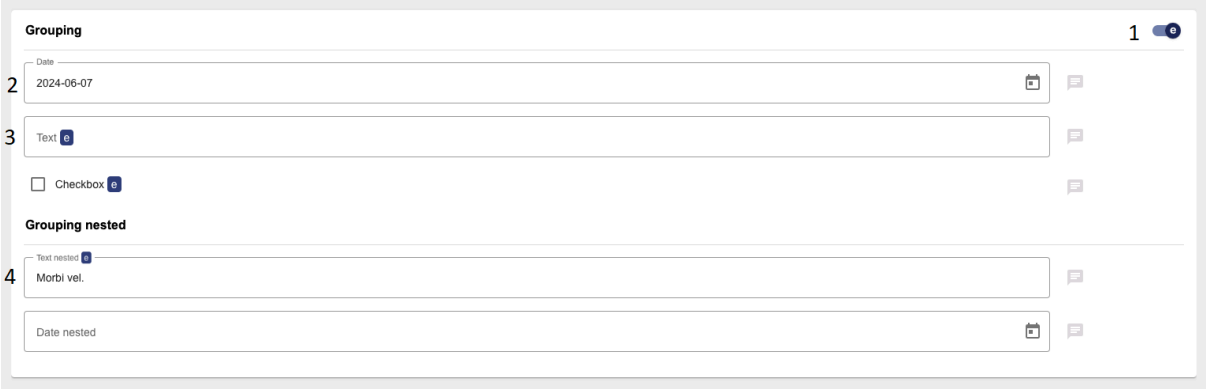



Image 104, extended and core dataset data fields: 1 toggle to show extended dataset data fields, 2 core dataset data field, 3 extended dataset data field without entered value, 4 extended dataset data field with entered value.

Extended dataset data fields are not shown by default upon creation of a patient event. Users should use the toggle switch button in the top right corner of an event section to show or hide extended dataset fields in a particular section of an event form.
Extended dataset toggle button may be as follows:

| Icon | Description |
|---|---|
|  | Extended dataset switch button is off.<br>Extended dataset data fields are hidden (not visible), only core dataset data fields are shown in the particular section of an event form (see image 105 ). |
|  | Extended dataset switch button is on.<br>Both core dataset and extended dataset data fields are visible (see image 106).<br>It is possible to switch the button off to hide extended dataset fields. |
|  | Extended dataset switch button is on but disabled.<br>Both core dataset and extended dataset data fields are visible.<br>It is not possible to switch the button off to hide extended dataset fields because some of the extended data fields contain data (see image 107). |

Table 22, Extended dataset toggle button icon

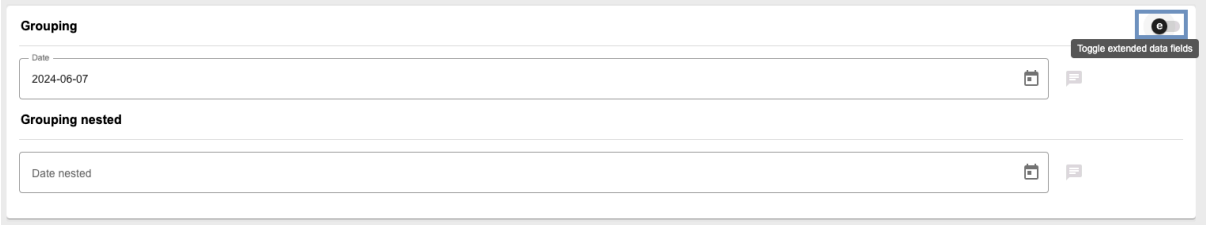



Image 105, extended dataset toggle button is off - no extended dataset fields are shown

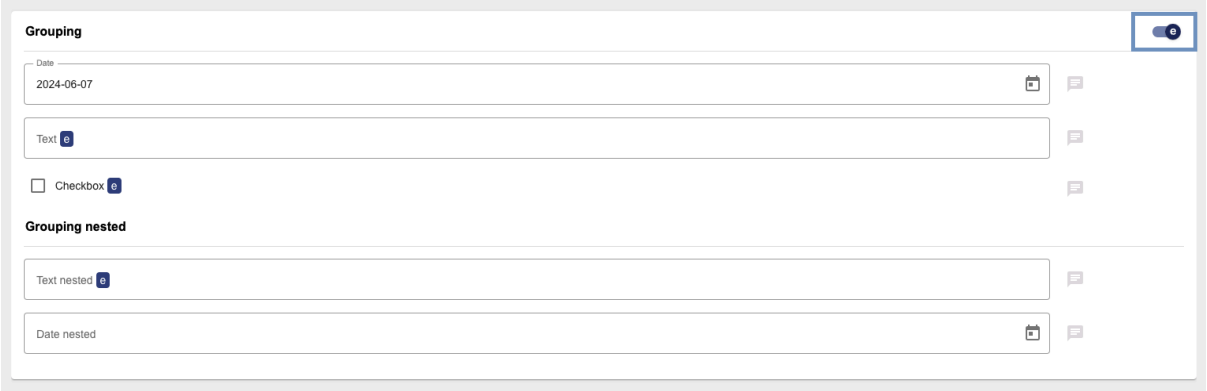



Image 106, extended dataset toggle button is on - extended dataset fields are shown

Note: once a data editor added information into extended dataset field(s), it is not possible to switch the extended dataset toggle button off and hide external data field. Users should remove data from extended dataset fields first to be able to hide them.

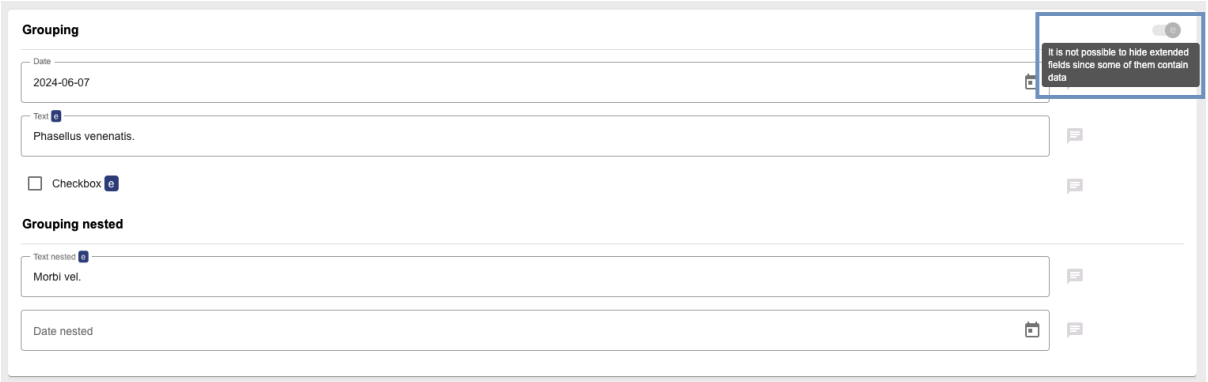



Image 107, extended dataset toggle button is on but disabled

# System notifications and data check

In the current version of the EBMT Registry, the system notifications are implemented in various ways to inform the user and provide adequate support while using the system. Here are some of the most common ones:

**Success notifications** are displayed when an action is successfully completed (e.g. when a user saves changes in the event form, thereby creating a new version in the system). It is usually a short message on a dark grey background, which is shown for a few seconds at the bottom of the user web page and then automatically disappears, allowing the user to continue using the application.

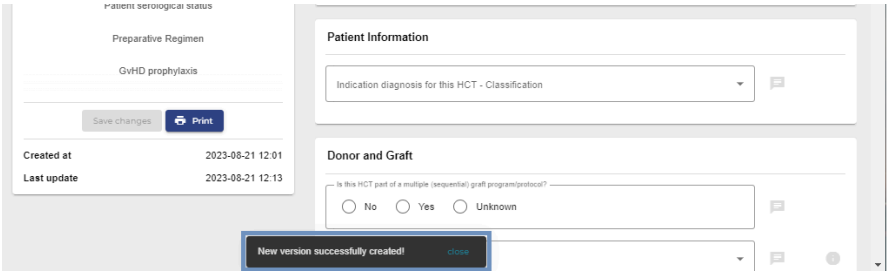



Image 108, an event with success screen visible at the bottom

**System error notifications** are displayed when an action fails, such as when a user tries to access the data of a patient who is not in the user's context. It is usually a modal window with a text explaining the issue.

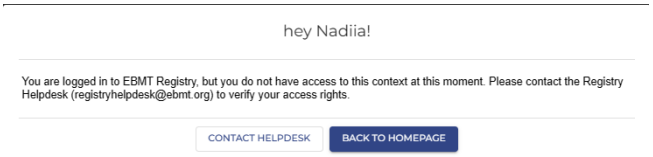



Image 109, access error due to no assigned context

Note: Field errors are different from system errors, they are described further in this section.

**Warning notifications** are displayed when there is a potential issue that needs to be addressed, such as when a data editor is entering a patient or donor that was opened by another data editor within the last 15 minutes. The system will warn the user about possible editing conflict. This type of notification is shown in the interface next to the element it refers to.

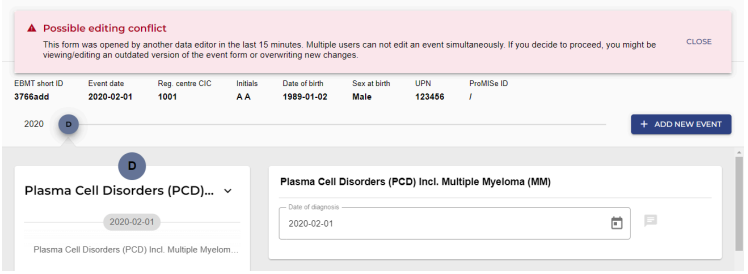



Image 110, possible editing conflict warning

Note: The field warning has a slightly different representation in the interface, and they are described in detail in the Automated data check section.

**Confirmation notifications** are usually displayed in a modal window. They typically contain a message explaining the action to be performed and asking the user to confirm or cancel the action. They often have two options, one for confirming the action and one for cancelling it. The user will see a window about unsaved changes when trying to leave an event form without saving changes (see image below). The user may choose to click *Confirm* button to proceed and leave the event form (the changes in the event form will not be saved) or click *Cancel* and return to the event form editing mode.

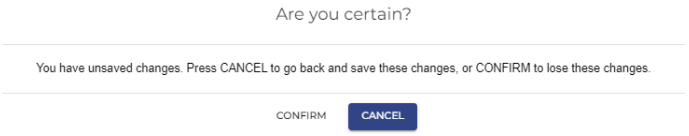



Image 111, confirmation on leaving the form without saving changes in the event

Some confirmation dialogues may also include additional options, such as stating a reason for the specific action being confirmed (e.g. stating a reason for making a change in an already submitted event form).


Image 112, confirmation on the reason for changes in the event

## Scheduled maintenance notification

The notification about any upcoming maintenance of the EBMT Registry, when the system will not be available for user access, is shown in the top part of the user interface regardless of the section (see image below). EBMT will also inform users about scheduled maintenance through the website.

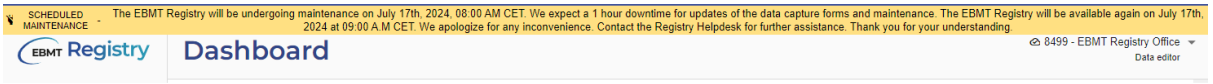



Image 113, example of a scheduled maintenance notification banner

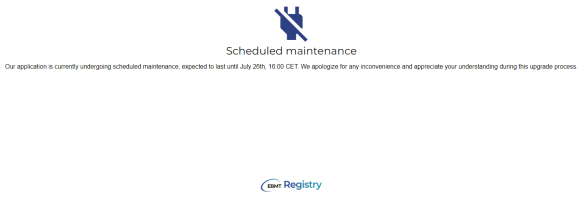



Image 114, example of a scheduled maintenance notification, when the system is not accessible due to maintenance

## Page unresponsive

The EBMT Registry is a web application and if it takes too long to load the webpage, the system may show the notification as in the image below.

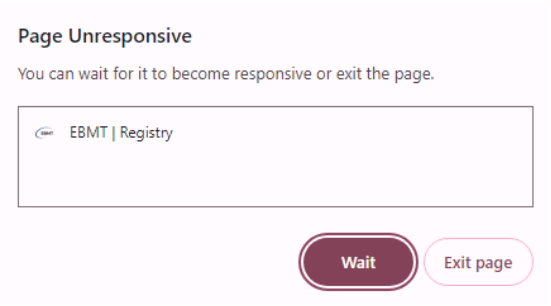



Image 115, notification on the EBMT Registry page unresponsive

Such messages may appear if the user internet connection is very slow. The users are advised to check their internet connection speed. The user may click the 'Wait' button to wait more time for the page to be loaded or exit the page to navigate away.

## Automatic termination of user session due to inactivity

If the user is being inactive in the EBMT Registry web page or does not reload the web page for 20 minutes, the user will be shown the warning about the upcoming session termination (see image below). The user may click *Remain signed in* button to keep the user session active, otherwise the user will be signed out of the EBMT Registry.


Image 116, warning on automatic termination of the user session due to inactivity (if the EBMT Registry web page is open in the user screen)

Note: entering data into data fields without clicking *Save changes* button is considerate as inactivity by the system since the web page is not updated or reloaded in the web browser during such edits. The users are advised to save data frequently to avoid it being lost if automatic sign out happens.

If the user has an active session in the EBMT Registry and is inactive there for 20 minutes, but the web browser tab with the EBMT Registry is not open or currently displayed at the user screen, the system will show the warning on possible loss of unsaved data due to automatic sign out (see image below). Should the user wish to keep the EBMT Registry session active, they are advised to click *Cancel* button and open the EBMT Registry in the browser tap. Otherwise, the user will be signed out automatically.


Image 117, warning on automatic termination of the user session due to inactivity (if the EBMT Registry web page is not open in the user screen, but in one of the browser tabs)

## Irreversible action notification or warning

While working with groups of questions or with data entry fields with dependencies, the users may get the warning as shown in the image below if they edit data that was entered previously. The reason and details of the warning and consequences of the action are explained in the warning window. The user may choose to click *Cancel* button and cancel the action that leads to data deletion, or may click *Submit change* button to proceed.

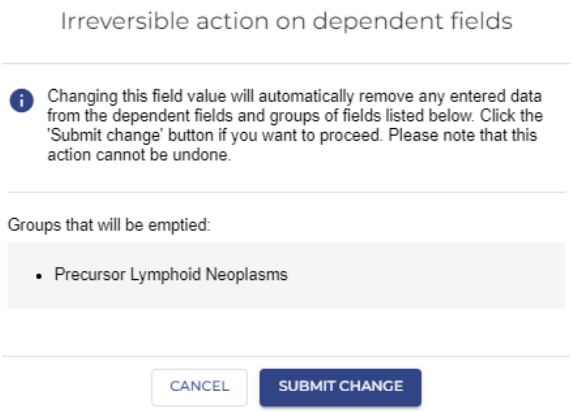



Image 118, example of a warning about deletion of data from dependent fields due to change in the main field answer (see visibility conditions)

While legacy data was prepared for migration to the EBMT Registry, it was noticed that in previous data collection systems used by EBMT it was possible for users to include contradictory data in the main and dependent fields (e.g. patient was reported as alive and there was also entered cause of death). Due to the fact that dependencies between data fields were changed/updated in the EBMT Registry compared to previous systems, some of the migrated data does not match the new dependencies and visibility criteria. For example, in ProMISe the user could report absence of GvHD and also record the aGvHD grade 0 (none). If the answer to the first question (GvHD present: yes or no) is answered 'no' in the EBMT Registry (no observed GvHD), the user is not able to register detailed information about aGvHD and cGvHD due to the introduced visibility conditions (these fields are not shown and thus cannot be filled in).

In case of such inconsistencies after data migration or due to new visibility rules, the information in the main data fields will stay as migrated and information in the dependent fields will be removed. The users will be shown the notification as in the image below. Users cannot cancel such action (*Cancel* button is disabled and there is an explanation shown upon mouse hover) and must click *Submit changes* button. If they fail to do it, the notification will be shown every time the event form is loaded to the user screen until the changes are saved and a new version of the event form without contradictory data is created.

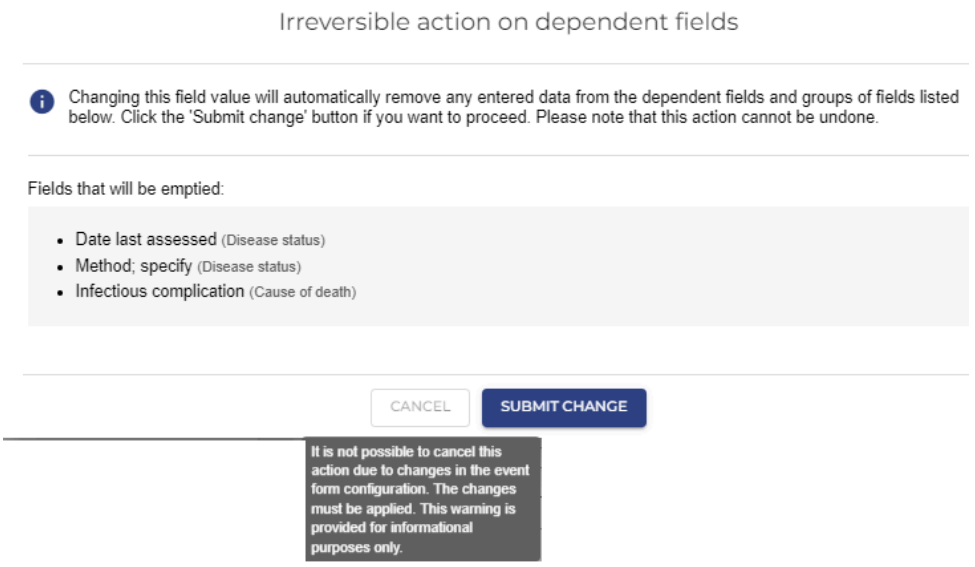



Image 119, example of a notification about deletion of data from dependent fields due to inconsistency with the main field answer

Note: if in the previous system the main data entry field was left empty, but dependent data entry field had data entered, the information from dependent fields will not be lost (see Unknown migration).

## Automated data check

The automated data check, warning and error messages are important features of the EBMT Registry and are designed to improve data quality and to prevent mistakes.

With **automated data check**, the system automatically verifies the data entered by users, comparing it to established standards (validation rules and reference values) or previously entered data, flagging any inconsistencies or errors. This helps prevent common mistakes such as typos, missing information, incorrect formatting, etc.

The automated data check is set up by the EBMT Registry team and is not visible to the end user. In case of possible issues or concerns, users should contact the EBMT Registry helpdesk by emailing registryhelpdesk@ebmt.org.

**Field warning and error messages** are another important feature, providing real-time alerts to users about any issues or concerns that arise during data entry. Most of them do not affect or block data entry processes. However, the message will remain visible, allowing monitors and other users (both data viewers and data editors) to see that the field/event form/patient data contains an unexpected value.

Practical example: for values that are expected to fall within set ranges or specific answers, a warning/error message may be displayed next to a data entry field if the entered value does not match the range/expected value: e.g. if a value is entered in percentages higher than 100, or for negative weight or height values.

Note: The process of EBMT Registry improvements is expected to be a continuous one. This means that new validation checks, warnings and errors will be added to consistently improve the data quality and to support users in the process of data entry.

## Field warnings

Warnings are used to inform EBMT Registry users that there is an issue with the entered field value, or a missing field value. It is shown in the following way:

1. the field is highlighted in yellow;
2. there is a message text under the field to explain the warning;
3. an exclamation mark in a triangular box is shown in the right top corner of the question group;
4. an exclamation mark in a triangular box next to the title of the event form section in the event form summary.

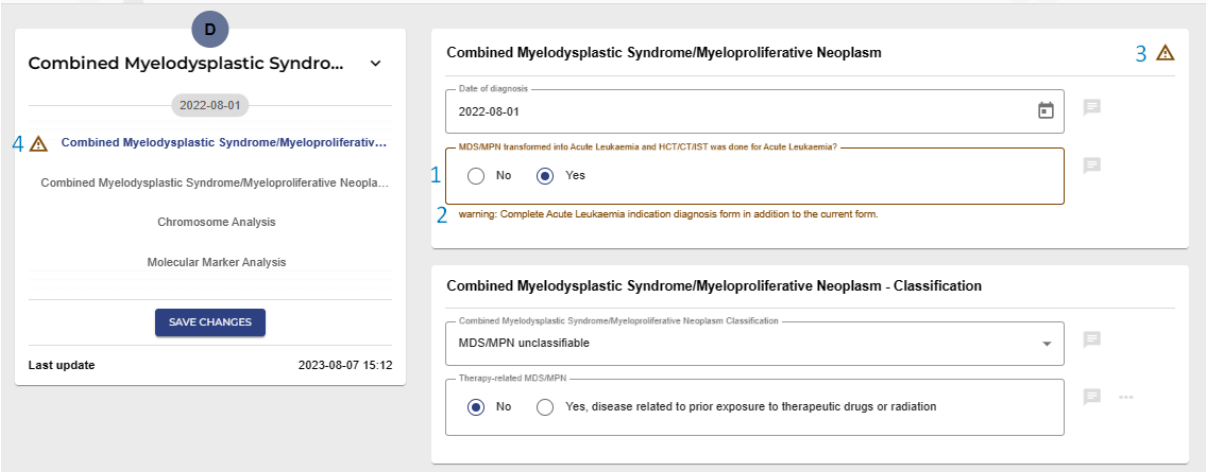



Image 120, example of a field warning

## Field errors

Error messages are used to inform EBMT Registry users that there is an error in the entered field value, or a missing field value. It is shown in the following way:

1. the field is highlighted in red;
2. there is a message text under the field to explain the error;
3. an exclamation marks in the circle is shown in the top right corner of the question group;
4. an exclamation mark in the circle is next to the title of the event form section in the event form summary.

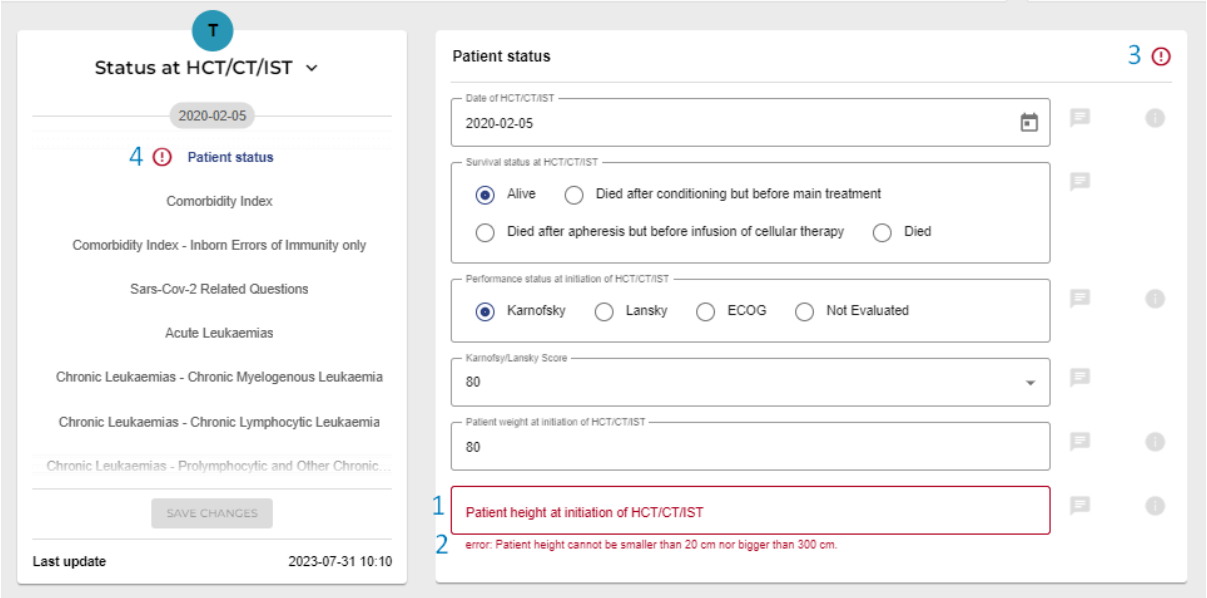



Image 121, example of a field error

Note: that there are some data fields in the EBMT Registry that must be answered and cannot be left blank. For example, the event date. The system will not allow the form to be created/saved without entering value into such a crucial field.

In case error is triggered, but saving the form is still allowed, the user will see an extra message next to the Saving changes button (see image below)

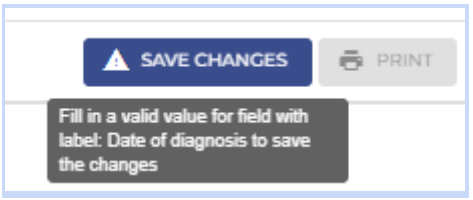



Image 122, example of a message next to Save changes button about a field error

## Duplicate check

The EBMT Registry performs the duplicate check when a user creates a new patient in the system. This ensures:

- Avoiding duplicate entries: by identifying existing patient records, it helps to prevent the creation of duplicate entries in the database. It ensures that each patient has a unique and single record, improving data management.
- Data accuracy: by highlighting potential duplicates, the application assists users and EBMT staff in reviewing and verifying patient information.

When a user enters new patient information during the patient registration process, the application performs the following steps:

1. Data check: The application validates the entered information for completeness and correctness, ensuring that all mandatory fields are filled accurately.
2. Matching Criteria UPN (the same UPN at the same centre)

3. The application compares the entered data against existing records in the system using the predefined matching criteria (duplicate check algorithm).
    a. In case it is suspected to be a duplicate, system requires user entering the indication diagnosis name and the date as additional data to compare new patient with existing ones.

***Case 1:*** if the new patient UPN is identical to an UPN of an existing patient at this centre, these records are considered as definite duplicates - creation of a new patient is not allowed. The user will receive a corresponding error message and a summary of patient details (see screenshot below). The user can either cancel the new patient creation and continue working in the existing patient page, or the user can modify the data of the patient under creation and try registering it again.

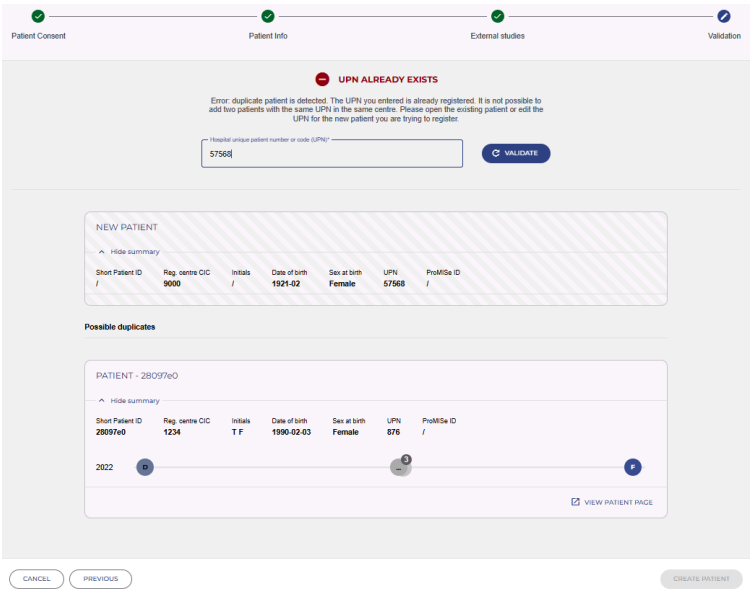



Image 123, the error message if a duplicate UPN is entered

4. Potential duplicates: If the application finds records that closely match the entered data, it displays a warning message. The duplicate check matching criteria include:

- Birthdate;
- Sex at birth;
- Blood group;
- Rhesus factor;

Note: the duplicate check is currently limited to the patient country only: this means that the new patient data will be only compared to data of patients registered in the same country.

The duplicate check algorithm is set up in such a way that the system compares the data value of the new patient (Pn) and existing in the database patient (Pe) in the following order:

1. **Date of birth** match - this is done by progressively deepening into the comparison:
    - First, the year of birth is compared;
        - If they match, the system proceeds to compare the next parameter;
        - If they don't match, Pe and Pn are not considerate being duplicates (comparison stops).

- Second, the month of birth is compared:
    - If it is specified for both patients, proceed to compare the next parameter;
    - If it is specified for both patients and don't match, Pe and Pn are not considerate being duplicates (comparison stops).
    - If in one or both patients the month of birth is not specified, the system will consider them matching and proceed to compare the next parameter.
- Third, the day of birth is compared:
    - If it is specified for both patients and match, the rule is satisfied. The system proceeds to compare the next parameter.
    - If it is specified for both patients and don't match, Pe and Pn are not considerate being duplicates (comparison stops).
    - If in one or both patients the day of birth is not specified, the system will consider them matching and proceed to compare the next parameter.

2. **Sex at birth** match
    - If in one or both patients records the sex is not specified (patients registered through the previous system sometimes do not have this data), the system will consider them matching and proceed to compare the next parameter.
    - If it is specified for both patients and don't match, Pe and Pn are not considerate being duplicates (comparison stops).
3. **Blood group** match
    - If the blood group is not specified for one patient, the system will consider them matching and proceed to compare the next parameter.
    - If it is specified for both patients and don't match, Pe and Pn are not considerate being duplicates (comparison stops).
4. **Rhesus factors** match:
    - If in one or both patients records the rhesus factor is not specified (patients registered through the previous system sometimes do not have this data), the system will consider them matching and proceed to compare the next parameter.
    - If it is specified for both patients and don't match, Pe and Pn are not considerate being duplicates (comparison stops).
5. **Initials** match
    - If it is specified for both patients and match, the match should be exact, disregarding the lower/upper case: e.g. A/G match a/g, while NN/S do not match N/S.
    - If it is specified for both patients and don't match, patients are not considerate being duplicates.
    - If in one or both patients the initials are not specified, the system will consider them matching and proceed to compare the next parameter.

The following cases may arise in case EBMT Registry identifies possible duplicate(s):

**Case 2:** The user is trying to create a patient that is a possible duplicate of an existing patient. The user has access to an existing patient data and thus can review data and check whether patients are actually duplicates or not. The EBMT Registry shows the list of potential duplicates for the user's review (see screenshot below).

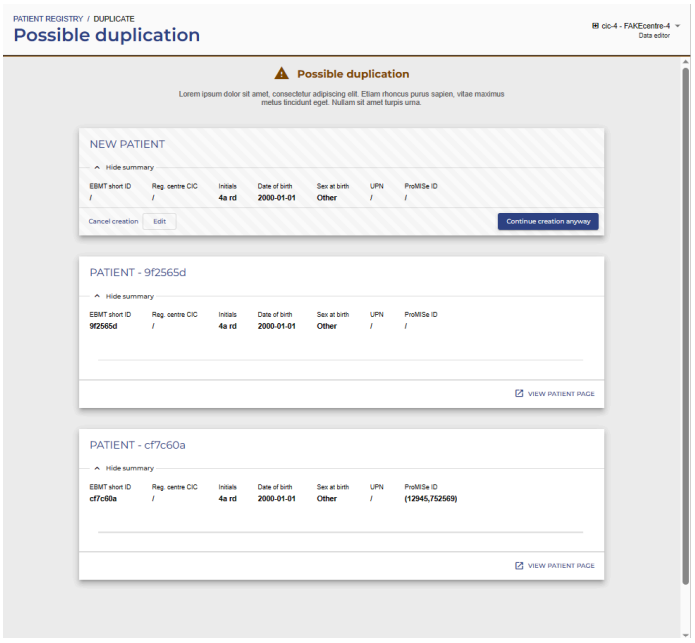



Image 124, the warning for a possible duplicate patient where the user has access to the possible duplicate

Possible actions for the user:
The user carefully examines the potential duplicate records to determine whether they correspond to the same patient or if they are indeed separate individuals.
Final action: Based on the user's evaluation, the application allows the user to either:

- proceed with the registration of a new patient (by clicking *Continue creation anyway*): the new patient will be registered but marked as tentative pending administrator review;
- cancel the new patient creation (by clicking *Cancel creation*) and select an existing patient record to register or edit data.

**Case 3:** The user is trying to create a patient that is a possible duplicate of an existing patient. The user does not have access to the data of an existing patient (this patient is not in the user Context) and thus cannot review data and check if the patients are actually duplicates or not. The EBMT Registry shows the respective warning (see screenshot below). The data of patients outside of the user context are not visible.

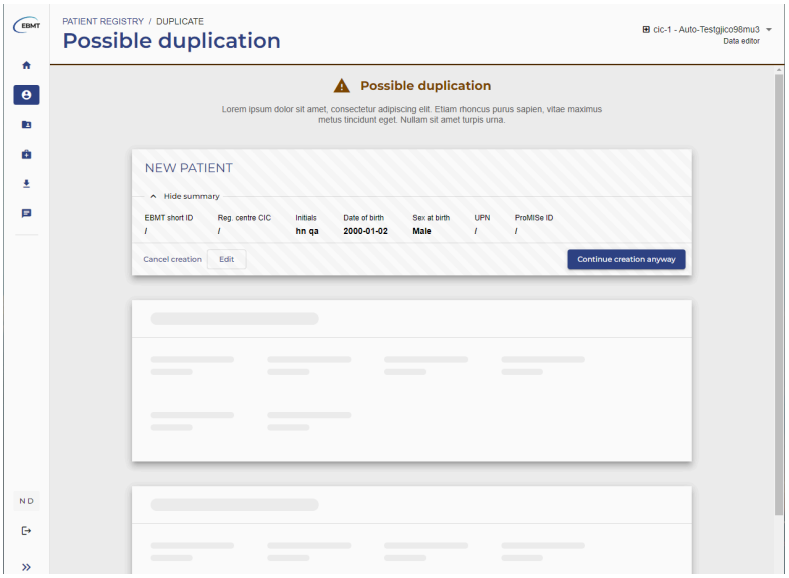



Image 125, the warning for a possible duplicate patient where the user does not have access to the possible duplicate

Possible actions for the user:

Based on the user's evaluation, the application allows the user to either:

- proceed with the registration of a new patient (by clicking *Continue creation anyway*): the new patient will be registered but marked as tentative pending Administrator review;
- cancel new patient creation (by clicking *Cancel creation*).

If the EBMT Registry does not suspect a new patient under creation as a possible duplicate, the patient is registered in the system and appears immediately in the patient overview list.

# Source data verification (SDV)

Source data verification (SDV) is a process performed by a data monitor to ensure that the data entered into the EBMT Registry corresponds to the original source documents of the patient and thus it is reliable and accurate.

Note: data viewers and data editors do not have access to see the SDV status of any data field. These are the EBMT Registry monitors internal processes and is part of a data quality check.

SDV refers to the data field value (answer), only the data monitor can see and update the SDV. The SDV is done only by data monitors and only if a patient consented to provide access to their original source documentation (see Patient consent).

# Access to the EBMT Registry: all users HOW TO

Here is a step-by-step for a user to get access to the EBMT Registry:

1. **Submit the *EBMT Registry User Account Request form* to the EBMT Registry Helpdesk by emailing registryhelpdesk@ebmt.org.**

It is important to note that the user role will be already indicated at this stage. The form must be properly filled in and signed by the PI of the centre or VR.
If a user requires access to multiple contexts, the form needs to be filled in per each context.

2. **Complete the EBMT Registry training in the EBMT E-learning platform.**

EBMT will activate access to the EBMT Registry only for the individuals who have successfully completed the specifically designed training and passed the exam in the EBMT E-learning. This is in order to ensure that the users are able to work with the new web- application and the database.

Access to the E-learning training will be provided to all users, who submit the *EBMT Registry User Account Request form.*
In case a user requires access to multiple contexts with different roles, the following should be taken into account:
Completed Data viewer training - is valid only for users to be granted a Data viewer role.
Completed Data editor training - is valid for both Data viewer and Data editor roles.

Only certificates on successful completion of the respective course in the EBMT E-learning will be recognised and considered while setting a user account in the EBMT Registry.

Additional online or face-to-face training course(s), questions and answers sessions, and other events provided by EBMT, National Registries or other stakeholders may be organised to support the users but cannot substitute the E-learning training.

It should be expected that new functionalities will be developed and added to the EBMT Registry application in the future, which will be announced to the EBMT members and stakeholders accordingly. In case of major changes, the users might be asked to undergo additional specific training and pass exams.

Note: the EBMT will require some time to process the confirmation on successful completion of the EBMT E-learning course and for the administrator to create/activate the user in the system and link to a correct context. Until this is completed, when a user Signs up or Signs in to the EBMT Registry, they may experience the following problems:

- Warning message that there is no active user with such email; or
- Required centre/VR is not shown in the Context menu (as requested in the *EBMT Registry User Account Request form*).

3. **Sign up and Sign in to the EBMT Registry application.**

The sign in (log in) to the EBMT Registry web-based application is currently done through the *AWS Cognito* service, which is an external service to manage the identity and authentication of users for the EBMT Registry and for its demo environment.

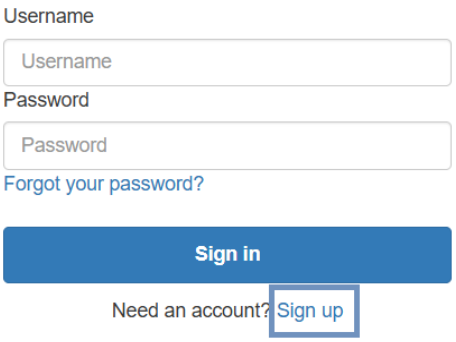
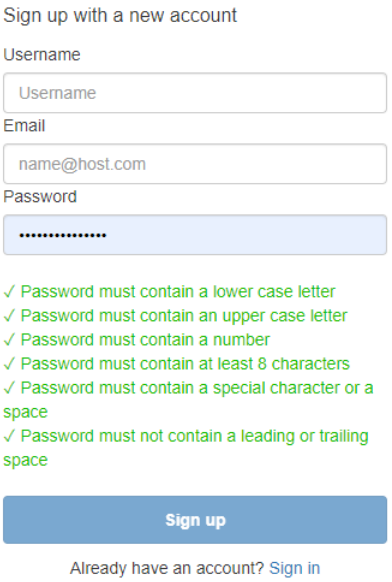
Note: Sign up process must be followed only once by every user. It ensures that the user created username and password that is used both to enter the real system and its training environment.

All Users need to set up and pass 2-factor authentication, which means that every time they want to sign in to the EBMT Registry, they not only enter their login and password but also need to confirm the entry through an additional MFA authenticator program. The MFA is used both to enter the EBMT Registry and its training environment.

Details on Sign up, Setting up the MFA, Sign in and other related processes will be further explained in the current section of the Manual.

## First time sign up - how to create login and password

Please follow the following step-by-step to create a username and password to access the EBMT Registry for the first time:

<table>
<tr><th>Step</th><th>User actions</th><th>EBMT Registry</th></tr>
<tr><td rowspan="4">1</td><td>Open the app in your browser.</td><td>The regular Log in page opens.</td></tr>
<tr><td colspan="2"> 
</td></tr>
<tr><td rowspan="2">2</td><td>Click the Sign up text button at the bottom of the form.</td><td>The Sign up with a new account form opens.</td></tr>
<tr><td colspan="2"> 
</td></tr>
<tr><td>3</td><td>Fill-in the Sign up with a new account form:<ul><li>Create Username;</li><li>Input Email (it must be the same email as in the EBMT Registry User Account Request form);</li><li>Create Password, check that password requirements are met</li></ul></td><td>The Confirm your account form opens.</td></tr>
</table>

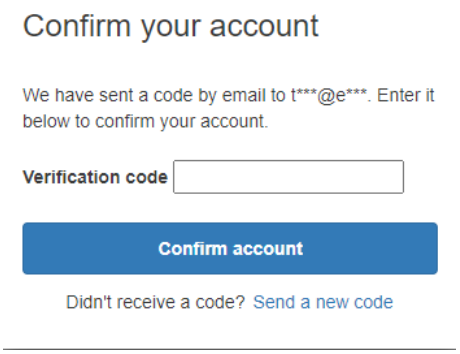
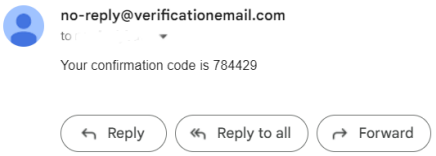
| | | |
|---|---|---|
| | and thus all highlighted in green; and<br>• Click the ***Sign up*** button. | |
| |  | |
| 4 | Check the mailbox specified in Step 2. There will be a new email from no-reply@verificationemail.com with the confirmation code that contains six digits. If you cannot find such an email in your Inbox, please check the Spam folder.<br>  <br>If the mail still has not arrived after a few minutes, please go to the *Confirm your account* window and press ***Send a new code*** text button, which is located at the bottom of this modal window. The system will send a new code to the entered email address. | |
| 5 | Enter the confirmation code from the email to ***Confirm your account*** form and click the ***Confirm account*** button.<br><br>Important: Sign up confirmation code is valid for 24 hours. After that, it expires. Please make sure to enter received code into the required field of ***Confirm your account*** form and complete the Sign up process at your earliest and before this deadline. | If the code is entered correctly, the system will proceed to Set up MFA process.<br><br>If the code is entered incorrectly, the system will show an error: *Invalid verification code provided, please try again*.<br><br>Try entering the code again or request a new code to be sent with ***Send a new code*** text button. |

Table 20, steps on setting up your credentials (username and password)

## Set up MFA

Instructions on setting up the authenticator application MFA are displayed on the screen (Image 1). It includes the following steps:

1. Install an authenticator application on your mobile device.
   OR
   Install an authenticator application on your computer.

Important: remember that this device must always be available when a user tries to sign in to the EBMT Registry. It is not possible to use different devices.

2. Scan the QR code displayed on the screen (Image 111) with your authenticator app - this will automatically add your account to the authenticator app.
   OR
   Alternatively, you can click the ***Show secret key*** text button and manually enter the shown secret key (combination of letters and numbers) into your authenticator app. Depending on the app, you might also be asked to enter the name of the account and the type of code.

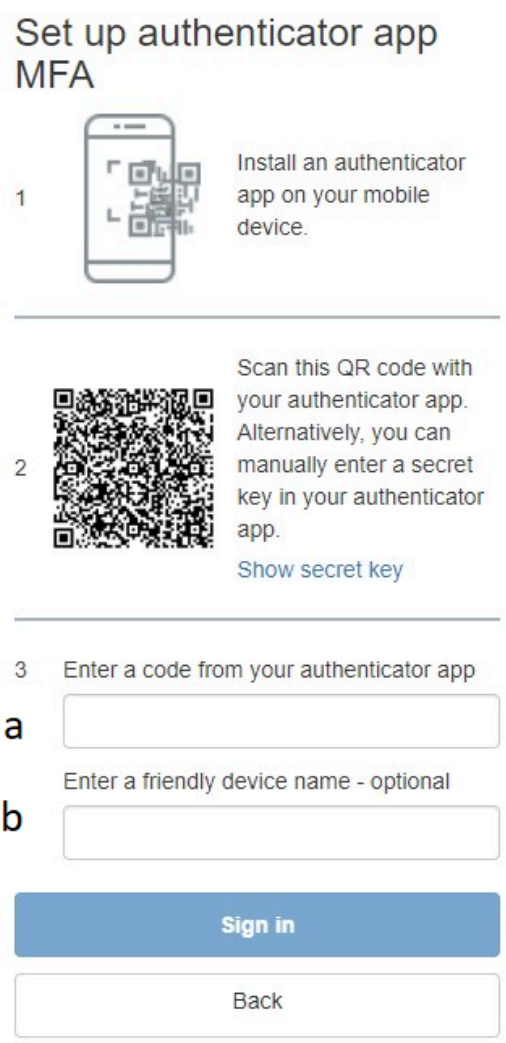



Image 111, setting up authenticator app MFA

3. a) Verify your account: once you have added your account to the authenticator app, you will need to verify it. This involves entering a code that is generated by the app into the field **a** on Image 72. This code changes every few seconds, so make sure you enter the correct code at the right time.
   b) Enter an MFA device name into the field **b** on Image 76 to remember which device you use for entering the EBMT Registry. This field is optional. If you leave it blank, you will be shown in the future instructions with default text *Please enter the code from passcode app*.

4. Click the ***Sign in*** button at the bottom of *Set up of authenticator application MFA* form. If the authenticator app was verified correctly and you entered a correct code, you will be signed in to the EBMT Registry and see the Dashboard.

   Note: If the authenticator app was not verified correctly or you entered an incorrect code, you will see an error message *Invalid or expired code entered. Try again.* You can try entering the code from your authenticator app once again, as explained in Step 3. If the sign-in failed again, try to remove the account from your authenticator app and set it up again, as explained in Step 2.

## Regular Sign in

This section explains the process of entering the EBMT Registry for the users that have already done the first time Sign up (created their username and password) and Set up MFA. This means that such users have entered the EBMT Registry in the past:

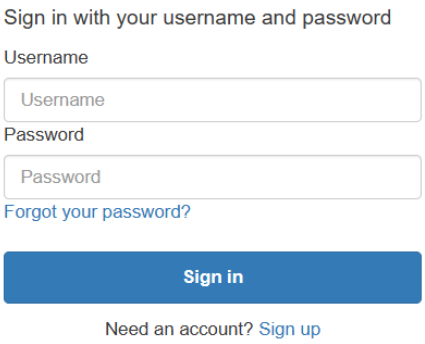
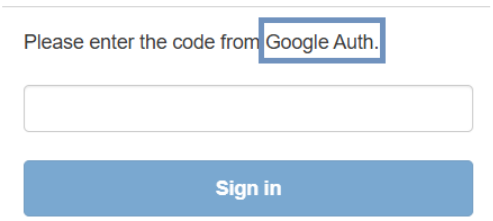
| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | Open the app in your browser. | The regular Sign in page opens. |
| |  | |
| 2 | Fill-in the *Sign in* form:<br>**Username** - you can enter here the email address or your username registered at the first time Sign up.<br>**Password** - enter the latest password you registered.<br>Click the ***Sign in*** button. | If you entered the correct username and password, the *MFA Code* form to enter the code from your authenticator device opens.<br><br>Name of the device is displayed as registered in Step 3b of Set up MFA.<br><br>If you entered incorrect username and/or password, the error message *Incorrect username or password* will be shown. |
| |  | |
| 3 | Enter the code from your authenticator app into *MFA Code* form and click the ***Sign in*** button. | If you entered a correct code, you will be signed in to the EBMT Registry and see the Dashboard.<br><br>If you entered an incorrect code, you will see an error message *Invalid or expired code entered. Try again*. You can try entering the code from your authenticator app again. |

Table 23, signing in after setting up your account

Important: after five consecutive failed login attempts, regardless of the reason (wrong username, wrong password, etc), there is an enforced lockout time for that user. A lockout time is a period in which the user cannot make any more attempts for authentication. Users should not try to sign in for a minimum of 15 minutes, after that, the user can do a normal sign -in attempt again or reset their password through the

*Forgot your password* functionality. If the issue still persists, users should contact the Registry Helpdesk registryhelpdesk@ebmt.org.

| Possible error messages: | Error related to topic | How to resolve |
|---|---|---|
| No active user with this email found in the system | Inactive user | 1. Make sure you have submitted an *EBMT Registry User Account Request form* with the same email address.<br>2. Make sure you have successfully completed the EBMT E-learning training.<br>3. Contact the EBMT Registry Helpdesk providing details of the user experiencing the problem (user registered email address must be indicated). |
| No context assigned to a user | Context or Inactive Centre/VR | Contact the EBMT Registry Helpdesk providing details of the user experiencing the problem (user registered email address must be indicated) and CIC number of the centre/VR. |

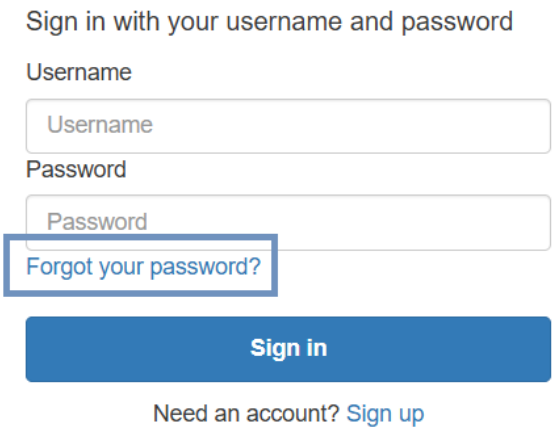
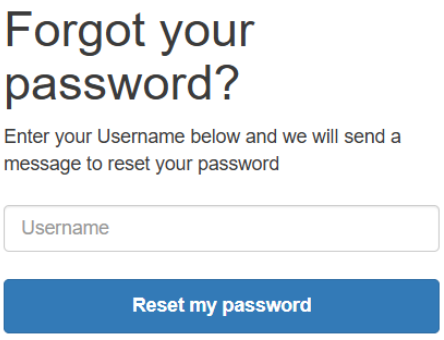
Table 24, common error messages and steps to resolve them

## Password change

Users can change their password in two ways:

1. from the EBMT Registry login page;
2. from the User profile when the user is in the EBMT Registry (signed in).

1. Here is step by step to change the password from the EBMT Registry login page:

| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | Open the app in your browser. | The regular *Sign in* page opens. |
| |  | |
| 2 | Click ***Forgot your password?*** text button at the *Sign in* page. | The *Forgot your password* page opens. |
| |  | |
| 3 | Enter your Email or Username into the field at *Forgot your password* page and press ***Reset my password*** button. | The system will send the code for the password change to the registered email.<br><br>The *Change password* page opens. |

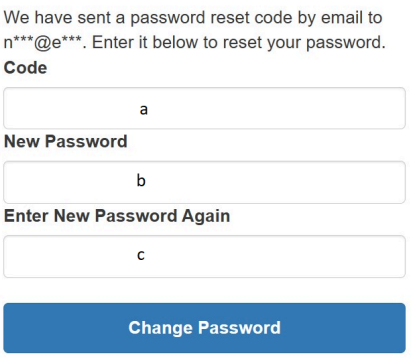
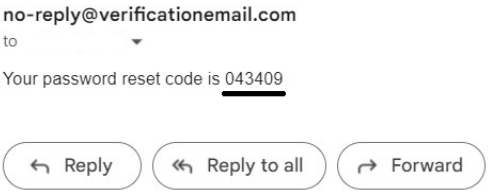
<table>
<tr><td></td><td colspan="2"> 
</td></tr>
<tr><td></td><td colspan="2">Check the mailbox specified on Step 2. There will be a new email from no-reply@verificationemail.com with the confirmation code that contains six digits. If you cannot find such an email in your Inbox, please check the Spam folder.<br> 
</td></tr>
<tr><td>4</td><td>Fill in fields a, b and c in Change password page:<br>- enter the confirmation code from the email to the field a;<br>- enter a new password to the field b;<br>- enter a new password again to the field c; check that password requirements are met and thus all highlighted in green.<br><br>Click the Change password button.<br><br>Important: password reset code is valid for 1 hour only. After that it expires. Please make sure to finalise Password change/reset before this deadline.</td><td>The regular Sign in page opens.<br><br>The new password is now saved and should be used.<br><br>Follow the regular Sign in process to enter the EBMT Registry.</td></tr>
</table>

Table 25, steps after a user forgets their password for the EBMT Registry

2. When the user is signed in to the EBMT Registry they can change their password in the following way:

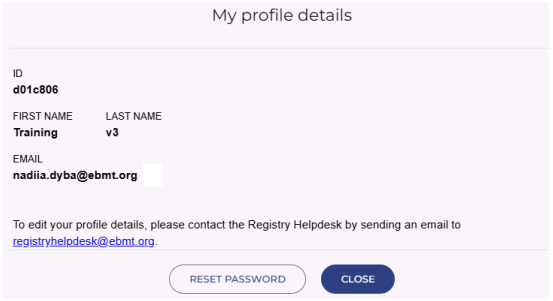
| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | Open *User profile* at the Navigation menu and click the ***Reset password*** button. | The *Forgot your password* page opens. |
| |  | |
| | Follow the **Steps 2-4** as described above to change the password from the EBMT Registry login page.<br><br>Important: password reset code is valid for 1 hour only, after that it expires. Please make sure to finalise Password change/reset before this deadline. | |

Table 26, changing the password for the EBMT Registry

## Reset MFA

Reset MFA is required in some cases, including but not limited to:

- user needs to change the MFA device or authentication application;
- previously used MFA device is not secure or lost.

Reset of MFA settings will also require the user to change both the password to the EBMT Registry and Set up MFA once again. The process for MFA reset is described in the following step by step:

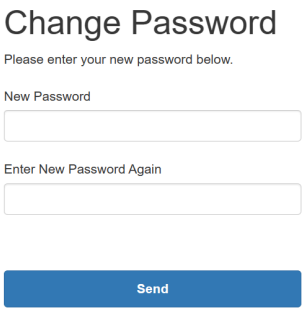
| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | Contact the EBMT Registry Helpdesk (registryhelpdesk@ebmt.org) to notify that the MFA device is lost or needs to be changed. Provide details. | Administrator resets users settings for MFA.<br><br>Important: MFA settings reset involves multiple parties and may take up to 7 working days. |
| | Check the mailbox. There will be a new email from no-reply@verificationemail.com with the information as provided in the example below. If you cannot find such an email in your Inbox, please check the Spam folder.<br><br>*Dear,*<br>*Your account to the EBMT Registry has been reset by an administrator. You can log in using your original username and the temporary password below to (re-)configure MFA.*<br>*Username: [**username**]*<br>*Temporary password: [**temporary password**] (e.g. 2%vqDea0)*<br>*Kind regards*<br><br>Important: temporary password from MFA reset email is valid for 24 hours. After that, it expires. Please make sure to complete Steps 2-4 as soon as possible and before this deadline. | |
| 2 | Open the app in your browser. | The regular *Sign in* page opens. |
| 3 | Enter the **Username** and ***temporary password*** received by email (in Step 1). | The *Change Password* page opens. |
| |  | |
| 4 | Enter a new password to the fields in the *Change Password* page.<br>Check that password requirements are met and thus all highlighted in green**.**<br>Click the ***Send*** button. | The *Set up an authenticator app MFA* window opens.<br>Follow the Set up MFA process. |

Table 27, resetting your multi-factor authentication

## Sign out

Signing out of a web application is essential to ensure the security and privacy of sensitive data. By signing out, the user terminates the session of the web application. This means that once logged out, the user has to go through the Sign in process, including MFA, to enter the system again.

Signing out from the EBMT Registry is essential for several reasons, including:

- Security: Signing out from the application ensures that sensitive medical data is protected from unauthorised access by others who may have access to the user's computer or device.
- Privacy: Signing out of the application helps to protect user privacy.
- Compliance: Signing out of the application is necessary to comply with various regulations and standards governing the handling and storage of medical data, such as HIPAA and GDPR.

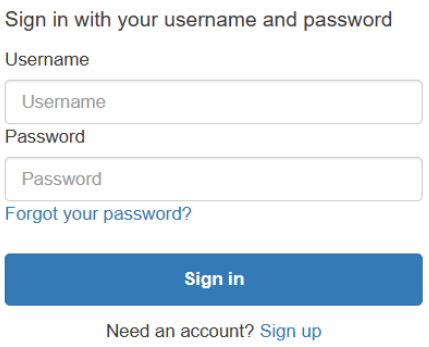
| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | From anywhere in the EBMT Registry, click the *Sign out* button or icon in the Navigation menu. | The regular *Sign in* page opens. |
| |  | |

Table 28, logging out

Note: simply closing the user's browser window or tab is not considered secure enough and does not substitute the sign out (logout) process. If a user does not sign out properly, the user's session may remain active in one of the open browser tabs, potentially allowing unauthorised access to the data.

If EBMT Registry was open in multiple tabs of the browser and the user terminates the session in one of the tabs (signs out), the information already loaded in the still open tab with EBMT Registry web app will remain visible, but upon reloading the EBMT Registry tab(s) (or any activity on the web page) the user will see the Sign in page.

If, for any reason, a user is using two or more browsers (not tabs) to work in the EBMT Registry simultaneously, The Sign-out process (session termination) should be done separately for each browser. It is not recommended, though, to work in multiple browsers to avoid confusion or editing conflicts.

## Change Context

The process below explains how to change the Context for users that have access to multiple contexts.

| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | From anywhere in the EBMT Registry, click the Context menu. | Dropdown list with the list of all available for the user active contexts will be open under the Context menu. |
| 2 | Click the context you want to be opened. | The Dashboard for the user in the selected context is loaded.<br>The Context menu displays the name of the context and user role. |

Table 29, changing contexts

# Viewing data

Once the user with access to one or multiple contexts enters the EBMT Registry, they can navigate around and view the data available within their context.

Use the Navigation menu to open the Patient registry or Donor outcome registry.
Click the Patient in the Patient Registry or Donor in the Donor outcome registry to open and view the Patient/Donor page, see summary data, timeline and events.
From the Patient page, users can also open the Patient menu to see the following information about this patient:

- Patient registration data and related details.
- Consent data - responses to EBMT Informed Consent questions.
- Studies - summary on any EBMT and non-EBMT studies the patient was/is enrolled in.
- Centres - Information on the patient registration centre as well as centres that have access to the patient record and the UPN for each of these centres.
- Notes - text field for the users notes. This information is for users information only. It is not included into analytical database.

From the Donor page, users can open the Donor menu to see the following information about this donor:

- Donor registration data and related details.
- Consent data - responses to EBMT Informed Consent questions.
- Centres - Information on the donor registration centre as well as centres that have access to the donor record and the Donor ID for each of these centres.
- Notes - text field for the users notes. This information is for users information only. It is not included into analytical database.

This section provides simplified step-by-step instructions to find and view various types of data within EBMT Registry user context for users of all roles.

## View Patient/Donor Event

Please follow the below step-by-step to access and view Patient/Donor events.

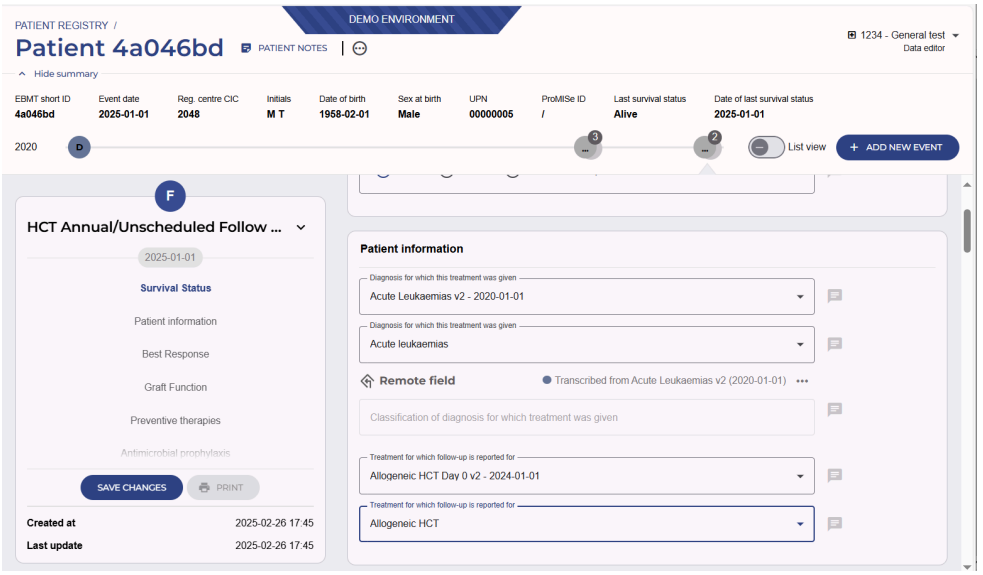
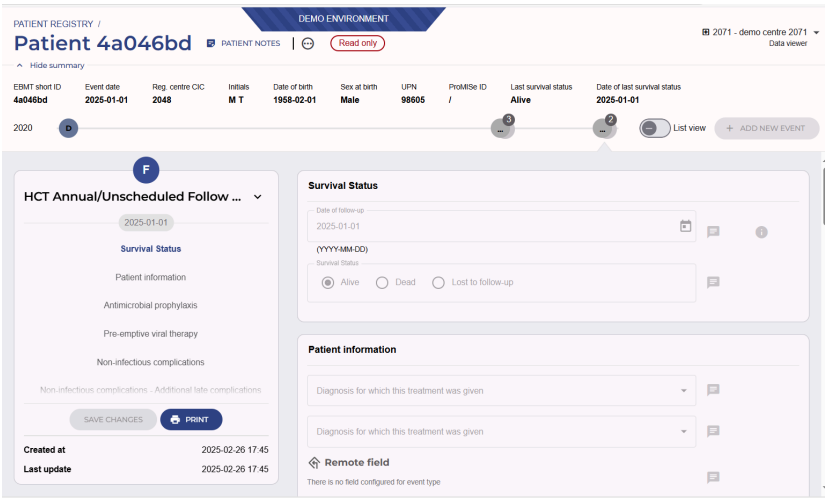
| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | Click on the Event in the *Patient/Donor timeline (*Patient or Donor page*)*. | *Patient/Donor event form* and *Patient/Donor event form summary* is loaded and shown on the Main screen. |
| |  | |
| | Patient/Donor event form includes:<br>● Patient/Donor event form data.<br>● ***Print*** button - to print the event form currently open in the Main screen;<br>● ***Save changes*** button - to save any introduced changes to the event. This button is disabled for data viewers/monitors. | |
| |  | |

Table 30, viewing a patient/donor events

## View Patient/Donor Details

Please follow the step-by-step below in order to access and view patient or donor general registration data fields and their EBMT patient ID or EBMT donor ID.

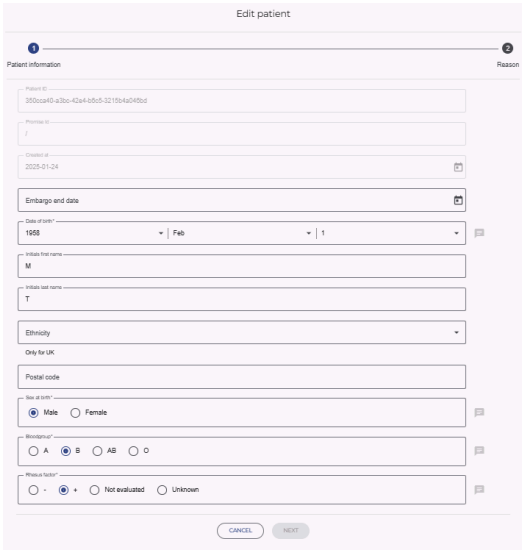
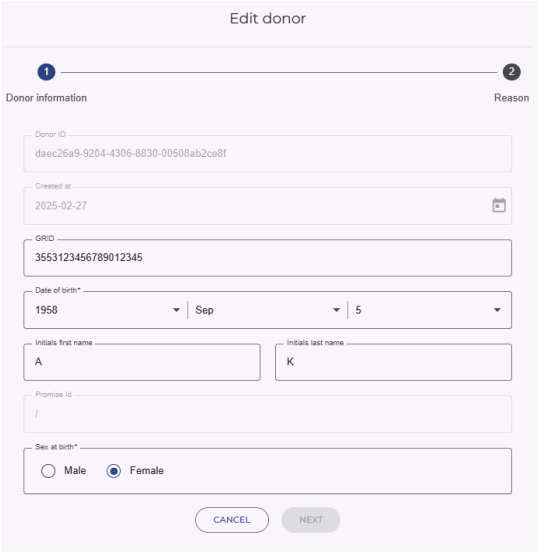
| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | Click *Edit patient details* in the *Patient menu*.<br>Or<br>Click *Edit donor details* in the *Donor menu*. | The *Edit patient* window opens.<br>Or<br>The *Edit donor* window opens.<br><br>For Data editors all editable fields are highlighted.<br>For Data viewers the fields are visible but greyed out to emphasise that they are not editable and disabled. |
|  | |  |
| The *Edit patient* window contains:<br>● EBMT patient ID;<br>● information from the Patient registration Data Collection Form;<br>● ProMISe ID for patients registered via the previously used system;<br>● ***Cancel*** button - to close the window and discard changes;<br>● ***Update patient*** button - to save any introduced changes to Patient details. | | The *Edit donor* window contains:<br>● EBMT donor ID;<br>● information from the Donor registration Data Collection Form;<br>● ProMISe ID for donors registered via the previously used system;<br>● ***Cancel*** button - to close the window and discard changes;<br>● ***Update donor*** button - to save any introduced changes to Donor details. |

Table 31, viewing and editing patient/donor details

## View Patient/Donor Consent

Please follow the following step-by-step in order to access and view Patient or Donor informed consent-related data fields from the Patient registration DCF or Donor registration DCF:

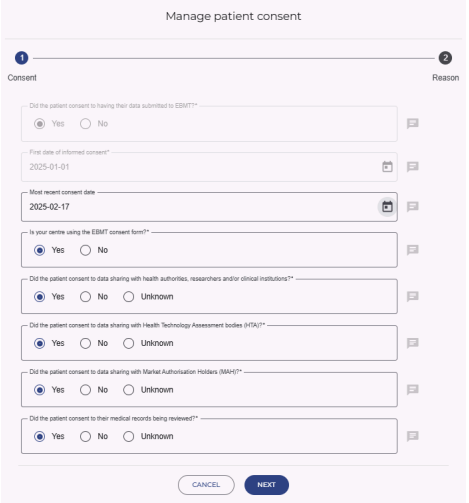
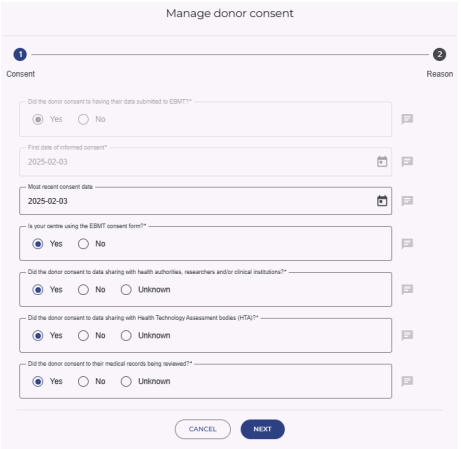
| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | Click *Manage consent* in the *Patient menu* or in *Donor menu*. | The *Manage Patient Consent* or *Manage Donor Consent* window opens.<br>The fields are visible but greyed out to highlight that they are not editable and disabled.<br>For changing consent information, contact the helpdesk. |
|  | |  |
| The *Manage patient consent* window contains:<br>● Patient answers to the consent questions;<br>● ***Cancel*** button - to close the window and discard changes;<br>● ***Update consent*** button - to save any introduced changes to consent questions. | | The *Manage donor consent* window contains:<br>● Donor answers to the consent questions;<br>● ***Cancel*** button - to close the window and discard changes;<br>● ***Update consent*** button - to save any introduced changes to consent questions. |

Table 32, viewing patient and donor consent in the EBMT Registry

## View Patient Studies

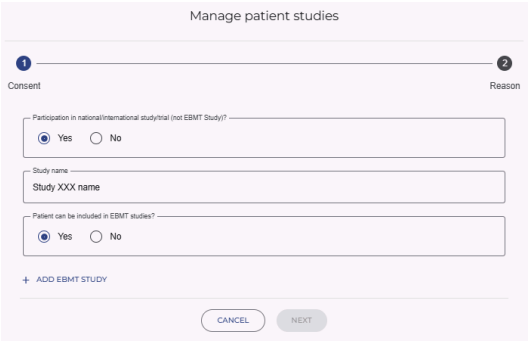
| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | Click *Manage studies* in the *Patient menu*. | The *Manage patient studies* window opens. |
| |  | |
| | The *Manage patient studies* window contains:<br>● Information on any non-EBMT studies of the Patient as indicated in the Patient registration form;<br>● Statement if the Patient can or cannot be included into EBMT studies;<br>● *+ADD EBMT STUDY* button - to add information about EBMT Study once the patient is enrolled. This button is disabled for data viewers. (this button should be used only by EBMT staff)<br>● ***Cancel*** button - to close the window and discard changes;<br>● ***Update studies*** button - to save any introduced changes to Patient studies questions. This button is disabled for data viewers. | |



Table 33, viewing patient studies

## Save system filter as personal filter

Users may save system filter as their personal filter (e.g. to further edit or reuse it). Follow the following step-by-stem to perform such action.

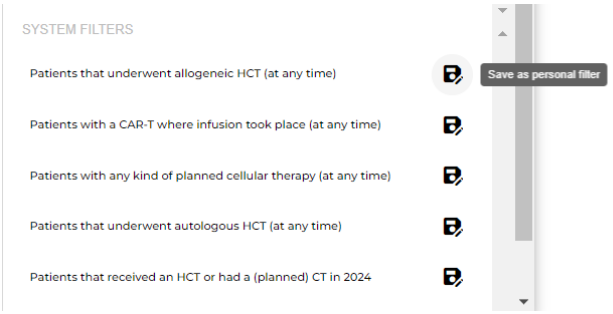
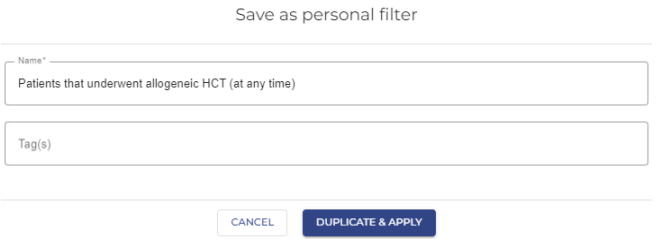
| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | In the Patient overview click *Filters* button to open the list of personal and system filters. Hover the mouse over the icon to the right from the system filter you want to reuse | The hint will be shown for the system filter |
| |  | |
| | Click the icon | Save as personal filter window appears.<br>It contains two fields:<br>Name - to name the personal filter to be created, by default it contains the name of the source filter.<br>Tags - to add tags the user wishes for the personal filter to be created.<br><br>It also contains the following buttons:<br>***Cancel*** - to close the window and cancel the creation of new personal filter;<br>***Duplicate and apply*** - to confirm the action and create a new personal filter with specified in the window name and tags. |
| |  | |
| | Fill-in fields as required and click *Duplicate and apply* button | The personal filter is saved and applied to the Patients registry list. Filtered list of patients is displayed. |

Table 34, saving system filter as a user personal filter

## Set up personal filter

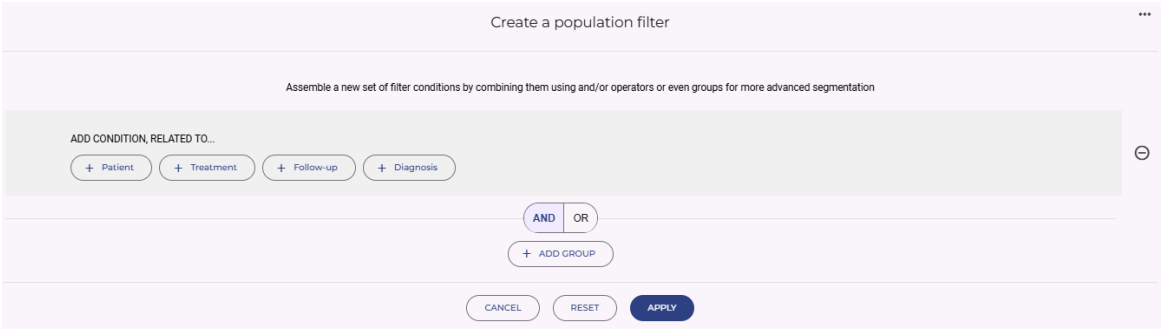
Creating or setting up a personal filter to filter or search for Patients or Donors follows the below logic:

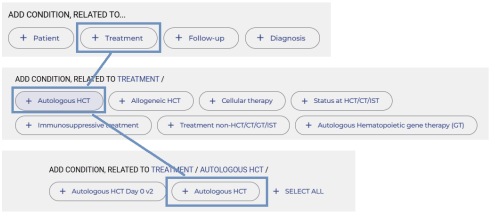
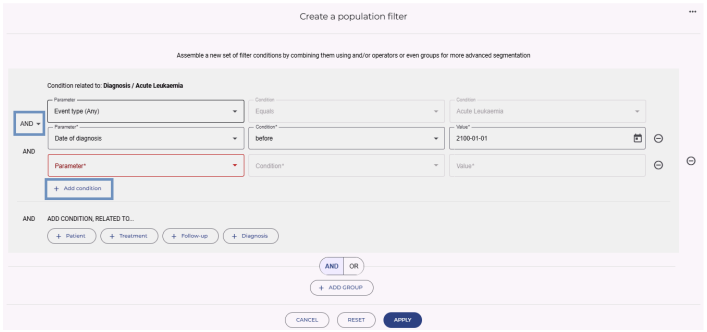
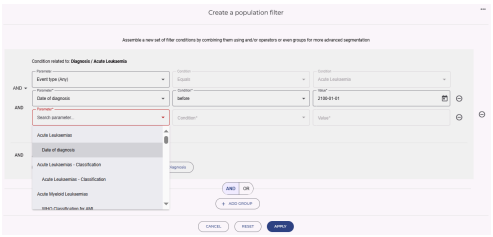
1. Identify all the data fields that will be Parameters for the User's personal filter.
    a. For each data field, identify the event (Data collection form) that contains this data field.

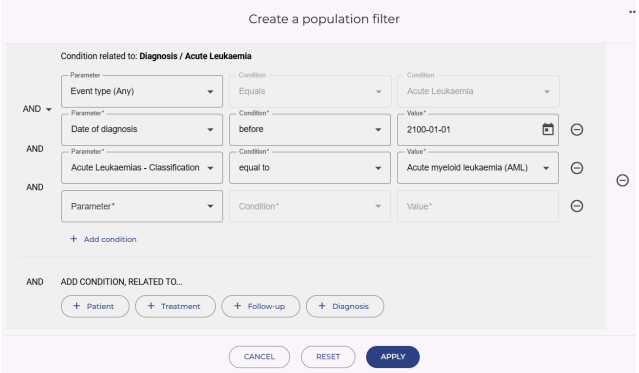
Due to event versioning in the EBMT Registry, it is also important to identify if the filtering should be done only in one or multiple versions of the event form, the versions should be stipulated at filter creation..

    b. For each Patient event, identify the event category (if it refers to Patient Diagnosis, Treatment, Follow-up or Other category). There are no event categories for Donors and this step can be skipped.
    c. For each Event, if there are multiple event types (e.g. Patient underwent multiple auto HCT treatments), will the filter consider all events or only a specific event? If only a specific event is to be considered for this filter, specify if it is the first or the last event from the respective patient timeline.
2. Identify the Condition and reference Value for each Parameter (data field). Parameter +Condition + Value will detail filter Criteria.
3. What are the relationships between the filter Criteria? It can be either:
    a. *and:* e.g. Criteria A and Criteria B and Criteria C;
    b. *or:* e.g. Criteria A or Criteria B or Criteria C.
4. Will the filter Criteria be divided into separate groups? If yes, how many groups and what are the relationships between the filter groups? It can be either:
    a. *and:* e.g. (Criteria A and Criteria B) and (Criteria C or Criteria D or Criteria E);
    b. *or:* e.g. (Criteria A and Criteria B and Criteria C) or (Criteria A and Criteria D and Criteria E).

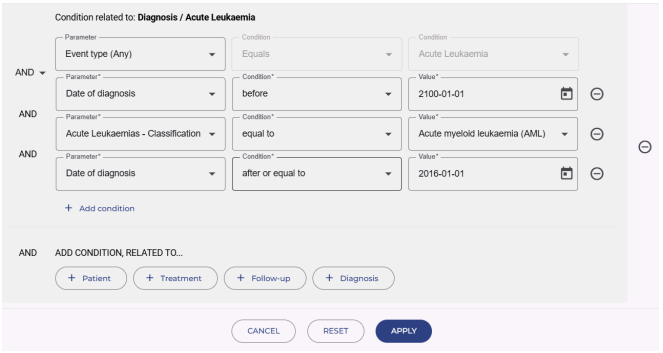
The process below explains how to set up a personal filter manually from scratch and filter Patients list. For Donor outcome registry follow the same logic choosing Donor-related filter conditions.

| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | From the Patient registry overview page click *+New filter*. | The *Create a population filter* window opens. |
| |  | |

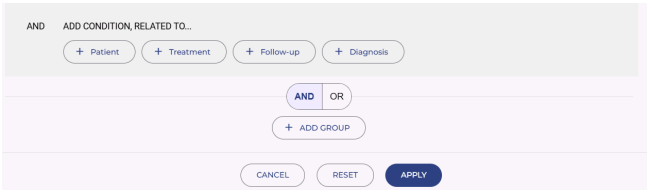
| | | |
|---|---|---|
| 2a | Click ***+ Patient*** under *Add condition, related to…* to specify that data field of interest (filter parameter) that refers to Patient Registration information.<br><br>If the data field refers to another event category (not to Patient Registration but to Treatment, Diagnosis, Follow-up), choose the correct one by clicking ***+ [Name of Event Category]*** button and then specify the form and form version. Example below<br>  | The filter Criteria 1 is shown (Parameter, Condition, Value are 3 dropdown fields) to specify criteria that refer to the chosen event.<br><br>1. The minus icon ⊖ is shown to the right from the filter criteria. It can be used to delete/remove this whole filter criteria regardless of whether it is empty or filled in with data.<br><br>2. *+Add condition* button is shown under filter criteria and can be used to add one more filter criteria that refers to Patient Registration<br><br>3. Use *and/or* toggle button to the left from filter Criteria 1 to specify the relationship between this condition and the following ones in the same group. This toggle is shown when 2 or more criteria are shown. |
| |  | |
| 3a | Specify filter Criteria using the dropdowns with answer options (Parameter, Condition, Value).<br>  | Selected Parameter, Condition and Value are displayed in filter Criteria.<br>These fields remain active and can be amended at any point of setting up the filter.<br>  |
| 4a | Click **+Add condition** under displayed filter Criteria if you need to add one more filter Criteria that refers to the same event or DCF.<br>Note: pay attention to the version of the form while configuring filter criteria. | A new filter Criteria (Parameter, Condition, Value are 3 dropdown fields) to specify criteria that refers to the chosen event is shown. |

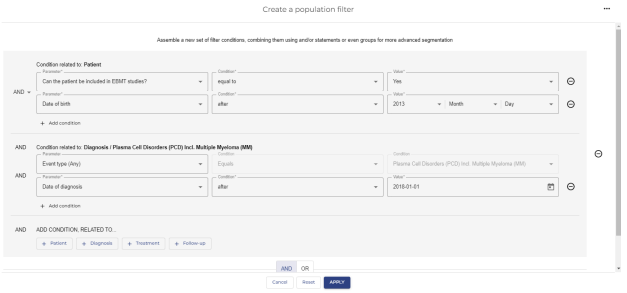


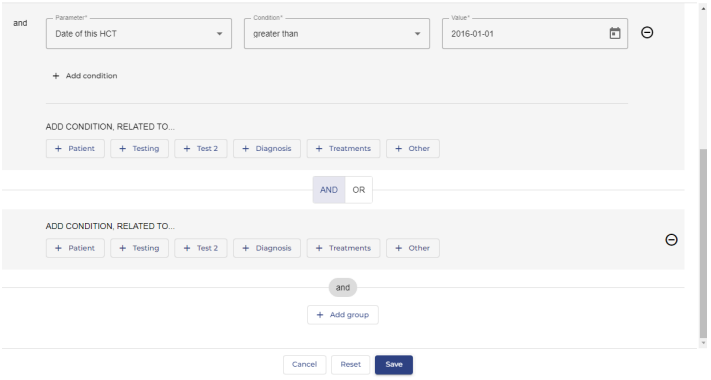

| | | |
|---|---|---|
| | Specify filter Criteria using the dropdowns with answer options (Parameter, Condition, Value). | Selected Parameter, Condition and Value are displayed in the filter Criteria.<br>These fields remain active and can be amended at any point of setting up the filter. |




| | | |
|---|---|---|
| 2b | Click the ***+ [Name of Event Category]*** under *Add condition, related to..* to specify to which event category the Event with a data field of the interest (filter parameter) belongs. Event Categories are shown as buttons with the plus sign before the name. | The list of events in the chosen Event category is shown.<br><br>The Event category name is clickable and can be used to go 1 Step back. |



| | | |
|---|---|---|
| 3b | Click ***+ [Name of Event]*** under *Condition related to [Name of the event category]* to specify what event contains the data field of interest (filter parameter). Events are shown as buttons with plus sign before the name. | Filter Criteria 3 is shown (Parameter, Condition, Value are 3 dropdown fields) to specify the criteria that refers to the chosen Event.<br><br>An additional line under *Condition related to: [Name of Event] is displayed* with a field that describes the Event type. Answer ***Any*** is chosen by default, use the dropdown to select from the answer options: Any, First, Last, if needed to specify that the Criteria refer only to one particular event from the Patient timeline.<br><br>  |
| |  | |
| 4b | Specify filter Criteria 3 using the dropdowns with answer options (Parameter, Condition, Value). | Selected Parameter, Condition and Value are displayed in filter Criteria 3.<br>These fields remain active and can be amended at any point of setting up the filter. |
| | Follow the **Steps 3a** - **4a** to add and specify more condition(s) that refer to the chosen Event, if needed. | |
| | Follow the **Steps 2b-4b** to add and specify more conditions that refer to any *other Event*, if needed. | |
| 5 | Click the ***+Add group*** button at the bottom of the window to add one more group of conditions, if needed. | The new Group of conditions for set up is shown.<br><br>1. Use the *AND/OR* toggle button shown before the group of conditions 2 to specify the relationship between these groups. |



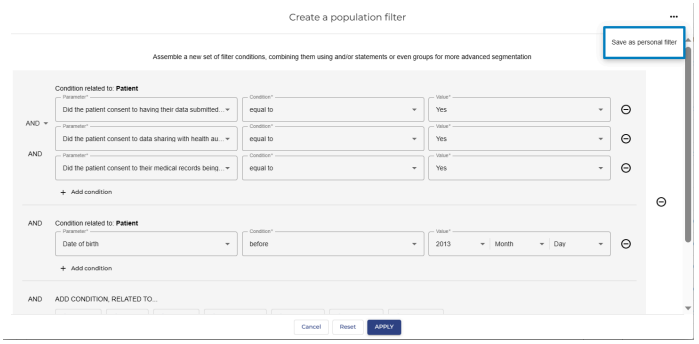

| | | |
|---|---|---|
| | For the New group of Conditions follow the **Steps 2a-4a or 2b-4b** to add and specify conditions that refer to the Patient registration form or Patient Event. | |
| 6 | Click the *Apply* button to apply the filter. | Patient Registry overview page shows filtered list of Patients. |

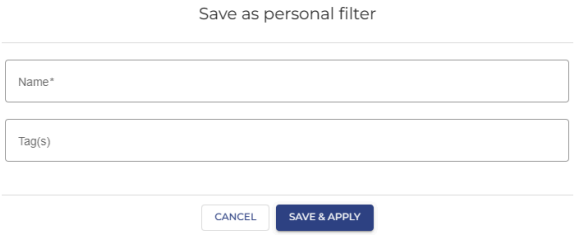
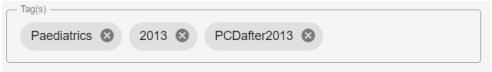
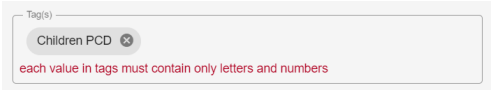
Table 35, making a personal filter and saving it

## Save personal filter

The process below explains how to save an already set up personal filter.

| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | *Set up personal filter that you would like to save.* | Click on the three dots icon to call the menu. |



| | | |
|---|---|---|
| 2 | Click ***Save as personal filter*** in the appeared menu. | *Save as personal filter* window appears. It contains two fields:<br>*Name* - to specify the name of filter. It will be later shown in the dropdown list of saved personal filters.<br>*Tag(s)* - to enter and save some tags, later to find this filter more easily in the list of saved filters.<br>It also contains the following buttons:<br>*Cancel* button- to cancel the action and close the window.<br>*Save and Apply* button - to save the personal filter and apply it filtering the list. |
| |  | |
| 3 | Enter the Name you want to assign to this filter into the 1st field Name.<br><br>Enter tags into the 2nd field Tag(s): type the tag name and press Enter every time you want to have it entered as a tag.<br>  <br>Tags may include letters and numbers without space. If a space is used while naming a tag, the system will show an error. Such tag needs to be removed and entered again in the correct format<br>  <br><br>Click *Save and Apply* button to save the filter. | *Save as personal filter* window closes. The filter is saved and applied to the overview list.<br>Filtered list is loaded in the main screen.<br><br>The name of the filter and number of conditions it contains is shown above filtered list.<br><br>The filter is now shown in the list of saved personal filters. |

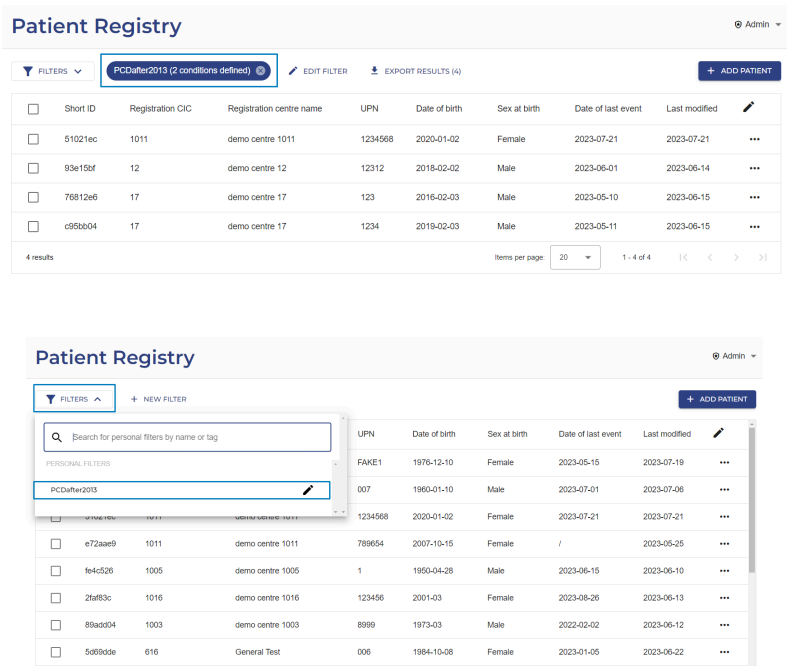
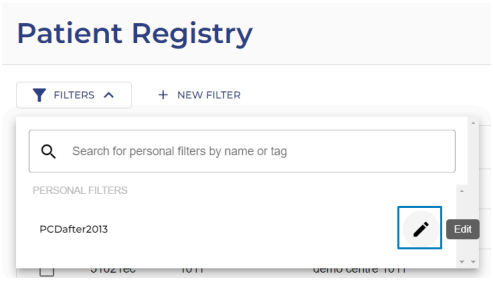
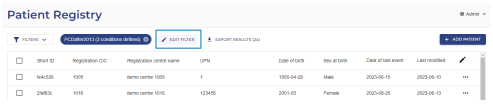
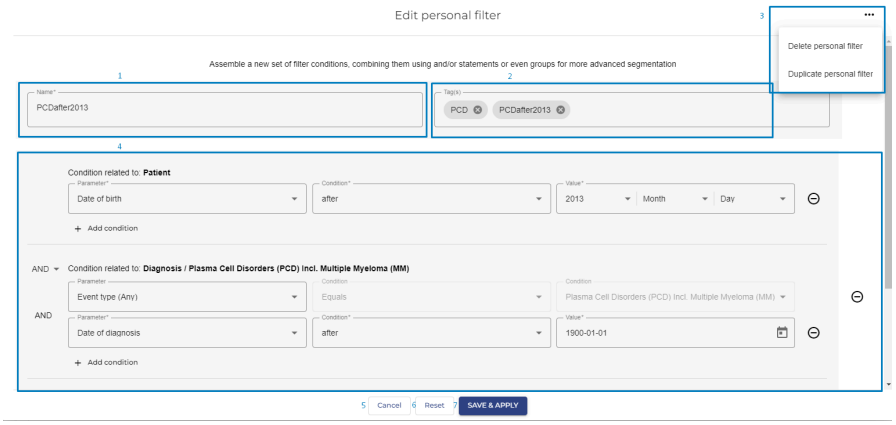



Table 36, making a personal filter and saving it

# Edit personal filter

The process below explains how to edit an already saved personal filter.

| Step | User actions | EBMT Registry |
|---|---|---|
| 1a | Open the list of saved personal filters and find the filter you would like to edit.<br>Click Edit icon button next to this filter name.<br>  | Edit personal filter window opens.<br><br>It contains:<br>1. Filter name field<br>2. Filter tag(s) field<br>3. Filter menu<br>4. Filter condition(s)<br>5. *Cancel* button - to cancel the request and close the window without applying changes.<br>6. *Reset* button - to resent and empty filter condition(s).<br>7. *Save and Apply* button - to save any introduced changes into the filter and apply this filter to the overview list. |
| 1b | When the filter you want to edit is applied to the overview list, click Edit button above the filtered list.<br>  | |
| |  | |
| 2 | Edit the personal filter as required by introducing changes into available fields.<br><br>Click *Save and Apply* button to save the changes into this personal filter and apply it filtering the overview list. | *Edit personal filter* window closes. The filter is saved and applied to the overview list.<br>Filtered list is loaded in the main screen.<br><br>The name of the updated filter and number of conditions it contains is shown above filtered list. |

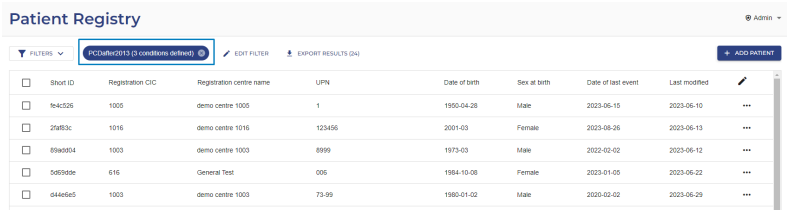



Table 375, editing a personal filter

## Delete personal filter

Note: deletion of a personal filter is not reversible action. It is not possible to restore deleted filters.

The process below explains how to delete any saved personal filter.

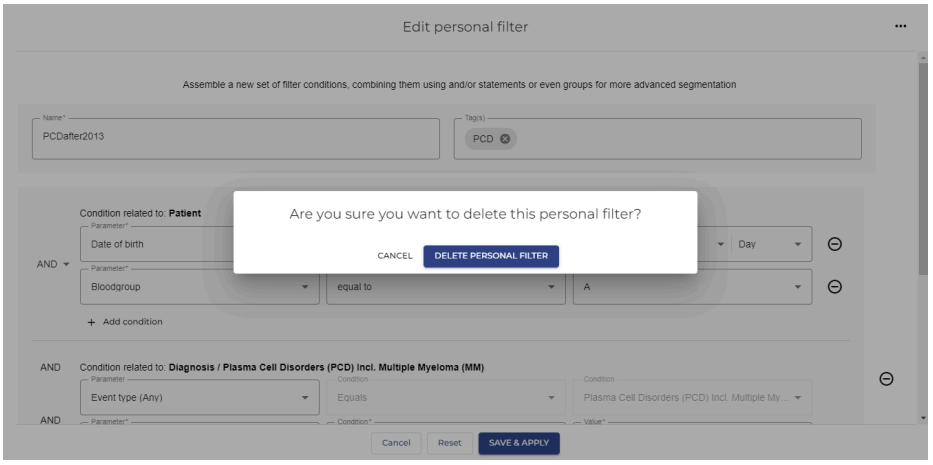
| Step | User actions | EBMT Registry |
|---|---|---|
| 1a | Open the Edit personal filter window as explained here.<br>Click Filter menu icon and then Delete personnel filter option.<br>  | The warning window will appear asking for confirmation on requested action.<br>It contains:<br>*Cancel* button - to cancel the request and return to Edit personal filter window.<br>*Delete personal filter* button - to confirm the deletion of this personal filter. |
| |  | |
| 2 | Click the *Delete personal filter* button to confirm the deletion. | This personal filter is deleted from the system and thus removed from the list of saved personal filters. Unfiltered overview list is loaded in the main screen |



Table 38, deleting a personal filter

## Duplicate personal filter

The process below explains how to duplicate or create a copy of any saved personal filter.

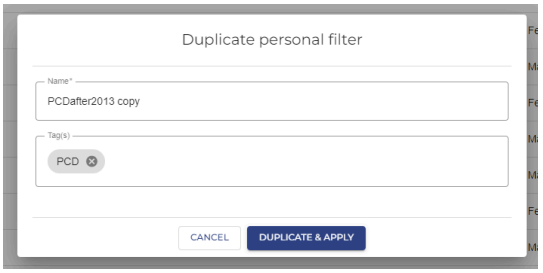
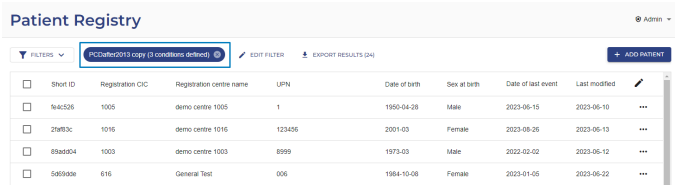
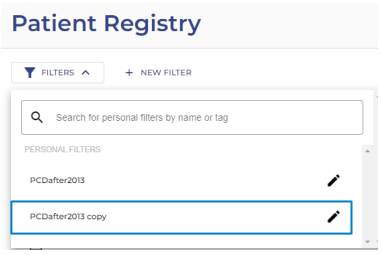
| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | Open the Edit personal filter window as explained here.<br>Click *Filter menu* icon and then *Duplicate personnel filter* option.<br>  | The *Duplicate personal filter* window will appear.<br>It contains:<br>*Name* field - to enter the name of duplicate filter. By default this field contains the name of the original filter followed by the word copy.<br>*Tags* field - to enter the tags for the duplicate filter. By default this field contains the tags of the original filter.<br>*Cancel* button - to cancel the request and return to *Edit personal filter* window.<br>*Duplicate personal filter* button - to confirm saving the duplicate of this personal filter with entered into the *Duplicate personal filter* window name and tags. |
| |  | |
| 2 | Edit the Name and Tag(s) fields of the *Duplicate personal filter* window as required.<br><br>Click *Duplicate personal filter* button to confirm the action. | The duplicate filter is saved and applied to the overview list. Filtered list is loaded in the main screen.<br><br>The name of the filter and number of conditions it contains is shown above the filtered list.<br><br>The filter is now shown in the list of saved personal filters. |
| |  <br>  | |

Table 39, duplicating a personal filter

## View anonymous events

The process below explains how to access and view anonymous events in the user Context.

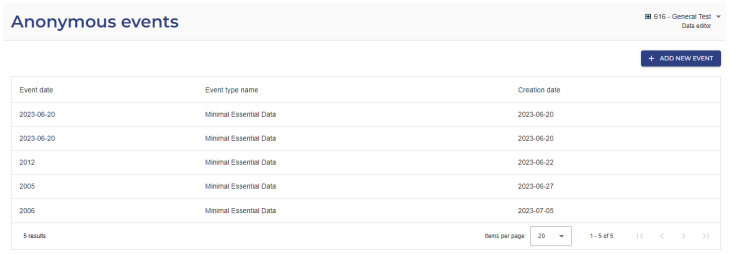
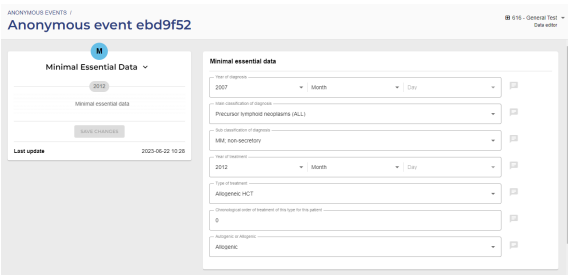
| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | Click *Anonymous events* in the Navigation menu. | Anonymous events overview page opens |
| |  | |
| 2 | Click the event you wish to open and view. | The Anonymous event is loaded and shown on the main screen. |
| |  | |





Table 40, viewing anonymous events

## Print Patient or Donor Event

Since the EBMT Registry is a web application, users are always able to print the webpage through the toolbar of their web browser or a keyboard shortcut.
The process below explains how to print a Patient or Donor Event form as displayed in the system user interface with EBMT Registry built-in functionality. The print document produced by the EBMT Registry is more user-friendly compared to the standard browser one.

Remember that printing document contains sensitive patient or donor data and all security measures should be applied.

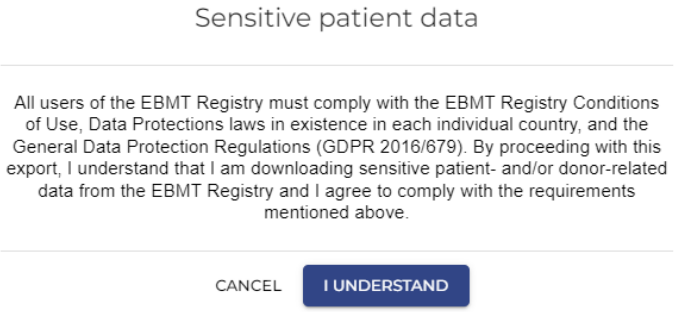
| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | Open the Patient event that you wish to print.<br>Click on *Print* in the Event form summary. | The confirmation warning appears.<br>It contains the following buttons:<br>*Cancel* - to cancel the printing request and return to the patient event form.<br>*I understand* - to confirm the user agrees and understand the shown warning and agrees to comply with the mentioned statement. |
| |  | |
| 2 | Read carefully the warning and click *I understand* to confirm and proceed to printing.<br>Or click Cancel to cancel the printing. | The event form is transformed into a file in pdf format and downloaded to the users computer. (into Downloads folder) ready to be printed. |

Table 41, printing patient or donor events

The printed version of an event received as a result of the currently explained process is not identical to the paper version of a Data Collection Form because it does not show answer options to data fields, does not display questions dependent on other factors than entered values, etc.

# Data Editor-related functionality

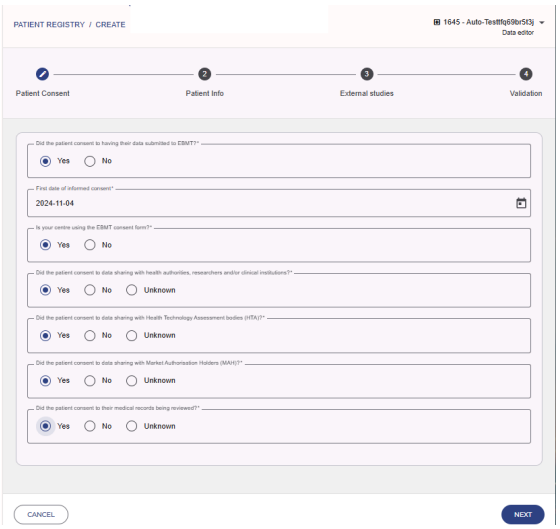
The EBMT Registry was designed so that users can fill a paper Data Collection Form first and then enter the information into the EBMT Registry, or fill the information online directly. The use of the EBMT Registry online platform is preferred, as it saves time, avoiding mistakes while transferring data from paper to the EBMT Registry, the system will also check for potential errors (validation checks) and navigate the user through the required fields (depending on answer to a question, dependant sub questions appear).

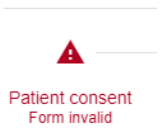
Reminder: It is important to save changes regularly during the data entry process.

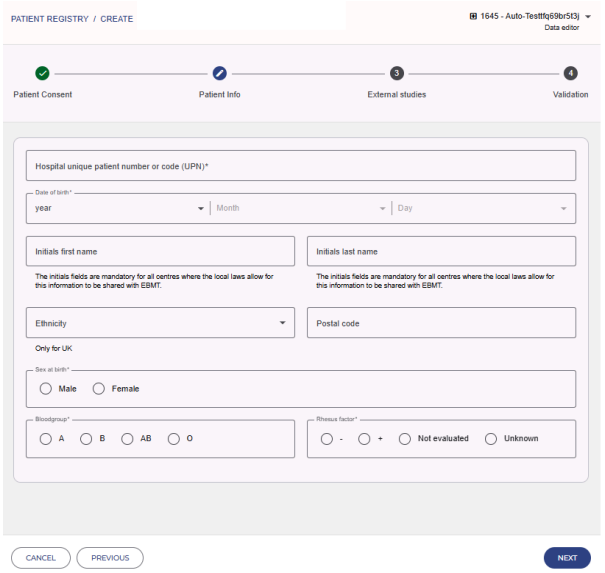
## Add Patient

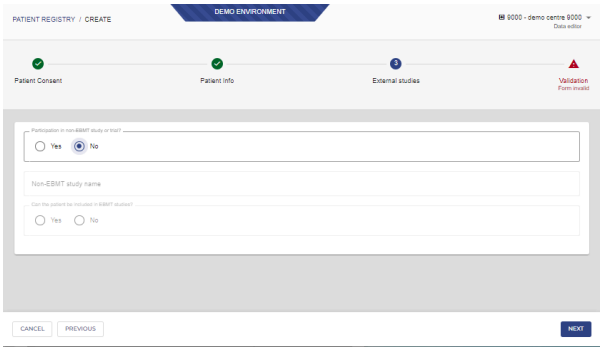
The process below explains how to register (add) a new patient to the EBMT Registry.

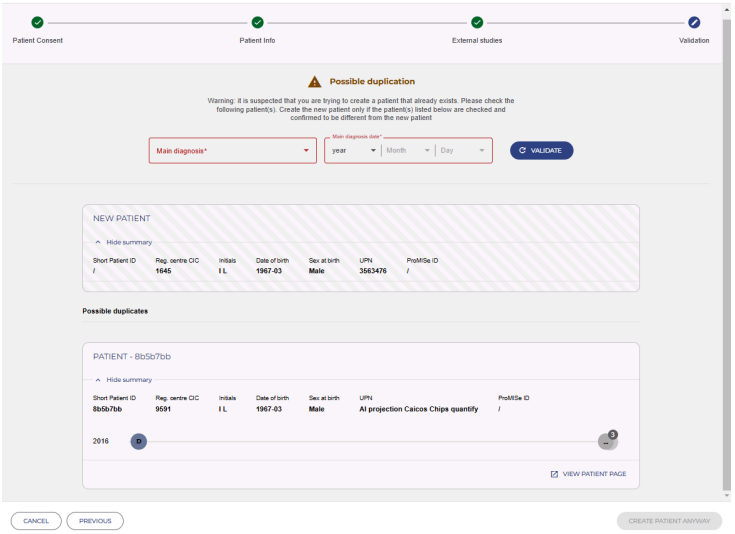
| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | From the Patient Registry overview page click *Add patient* button.<br>  | *Add a new patient* window opens.<br>It contains data fields from the a Patient registration form and is represented as 3 steps form (it can be considerate as 3 pages or sections of the same form):<br>1. **Patient consent** - contains data fields related to the Patient Informed consent.<br>2. **Patient Info** - includes data fields related to the general patient registration data (UPN, birthdate, initials, etc.).<br>3. **External studies** - data fields to inform if a patient is part of any non-EBMT study and study-related data.<br>4. **Validation** - in case of suspected duplicate, the warning is shown and extra data is requested to be entered (indication diagnosis and the date of the indication diagnosis) for the duplicate check.<br><br>At the bottom of the form there are shown the following buttons:<br>***Cancel*** - use this button to cancel new Patient creation. The Add a new patient window will be closed, already entered information, if any, will be lost.<br>***Next*** - use this button to proceed to the next step (page) of the registration form. |

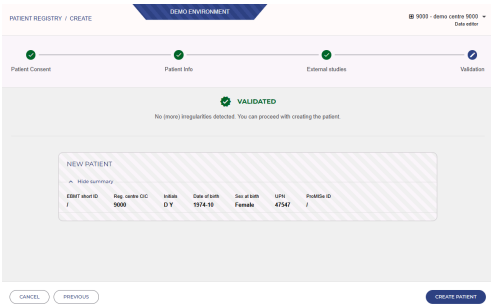



| | | |
|---|---|---|
| 2 | Answer questions in the Patient consent section. Remember to add the Date of the Patient informed consent.<br>Click the *Next* button at the bottom of the *Add a new patient* window.<br>It is important that all questions of this section are mandatory and shall not be left blank. If a user proceed to next sections of the *Add a new patient*, the title of the Patient consent section will be marked with an Error and shown as following<br>  | The Patient registration section will be shown in the *Add a new patient* window.<br><br>At the bottom of the form there are shown the following buttons:<br>***Cancel*** (explained in the Step 1).<br>***Previous*** - use this button to go back to the previous section Patient consent (Step 1).<br>***Next*** - use this button to proceed to the next step (page) of the registration form.<br><br>Data editors in VR context that Add a new patient will see one extra data field ***Centre***, where they must specify the registration centre for this Patient. |



| | | |
|---|---|---|
| 3 | Answer questions in the Patient registration section.<br><br>Click the *Next* button at the bottom of the *Add a new patient* window.<br><br>UPN number is a very important data field that should be entered correctly at this step. Please check it is correct before proceeding.<br><br>All data fields (except Ethnicity and Postal code) are shown as mandatory and shall be filled in. If a user proceeds to the next section of the *Add a new patient* or returns to a previous one, the title of the Patient registration section will be marked with an Error and shown as following:<br>  <br><br>Due to legal restrictions in some countries, in rare cases patients initials may not be reported, the field will still be highlighted with an error, but it will not block Adding a new Patient to the EBMT Registry. | The Patient studies section will be shown in the *Add a new patient* window.<br><br>At the bottom of the form there are shown the following buttons:<br>***Cancel*** (explained in the Step 1).<br>***Previous*** - use this button to go back to the previous section Patient consent (Step 1).<br>***Next*** **-** use this button to proceed to the next step (page) of the registration form. |
| |  <br> | |

| | | |
|---|---|---|
| 4 | Answer questions in the Patient studies section.<br><br>Click the *Create patient* button at the bottom of the *Add a new patient* window.<br><br>From EBMT Registry version 2.11 it will be possible to enter more than 1 non-EBMT studies, if required. | If all mandatory fields were filled in the *Add a new patient* window, the patient duplicate check will be performed and, if it is successful, the new Patient is successfully created in the EBMT Registry and the Patient page is shown in the main screen.<br><br>If there is missing information in the mandatory fields, the corresponding section of the form is highlighted with an error, the data field is highlighted in red. *The Create patient* button may be clicked, but the *Add a new patient* window remains open. Add information to the mandatory fields and click the Create *patient* button.<br><br>If the data of the patient the user is trying to register is matching the data of an existing patient, there will be shown the warning or error message as explained in details in the Duplicate check section and user might be asked to enter the patient diagnosis and the diagnosis date for further Duplicate check. |
| |  | |

| | | |
|---|---|---|
| | Once all mandatory fields are filled-in and data is validated, click Create patient button in the right bottom corner of the screen.<br>  <br>***Create patient*** - the button to confirm Adding a new patient to the EBMT Registry with registration data entered in the *Add a new patient* window. | The patient is added to the database and Patient page is loaded to the user screen. |

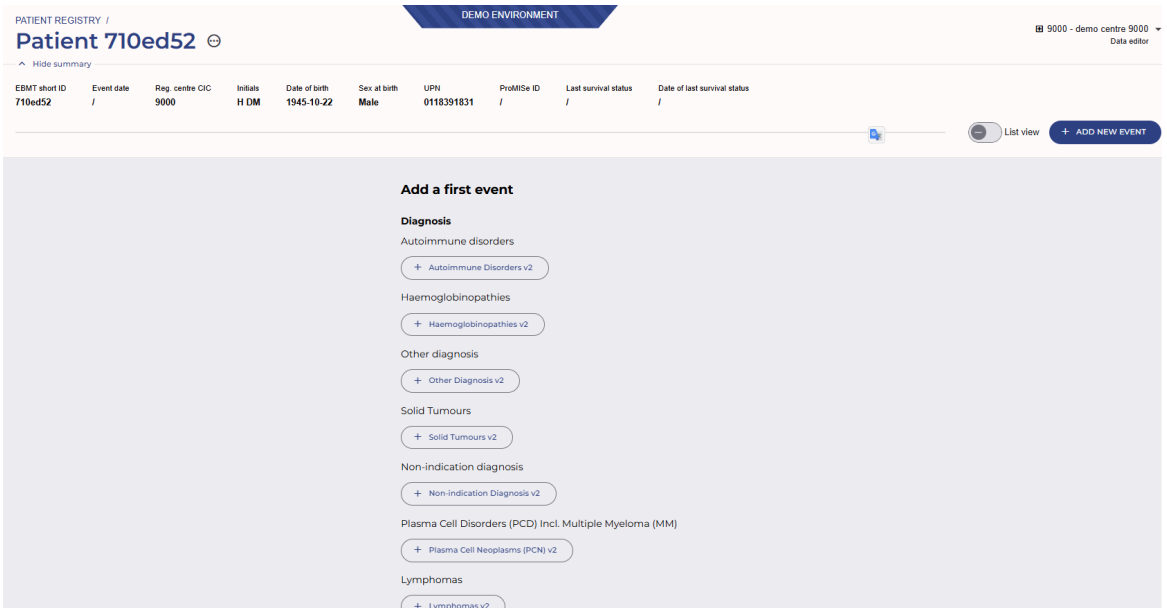
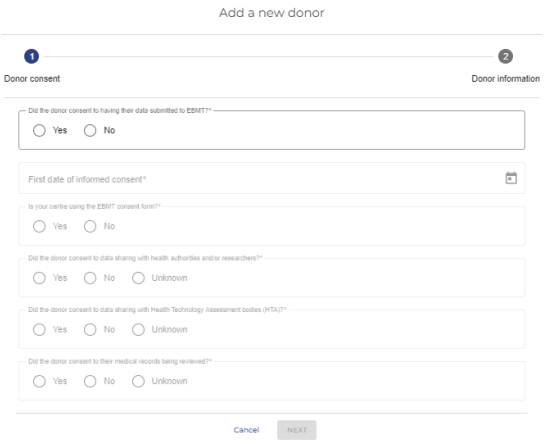


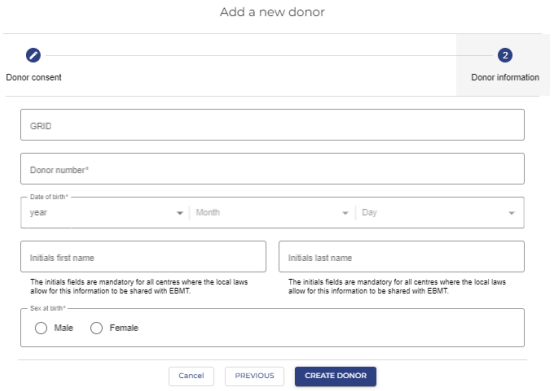

Table 42, instructions on how to add a patient to the EBMT Registry

## Add Donor

The process below explains how to register (add) a new donor to the EBMT Registry.

| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | From the Donor outcomes registry overview page click *Add donor*. | *Add a new donor* window opens.<br>It contains data fields from the a Donor registration form and is represented as 2 steps form (it can be considerate as 2 pages or sections of the same form):<br>1. **Donor consent** - contains data fields related to the Donor Informed consent.<br>2. **Donor information** - includes data fields related to the general donor registration data (GRID, Donor ID, birthdate, initials, etc.).<br><br>At the bottom of the form there are shown the following buttons:<br>***Cancel*** - use this button to cancel new Donor creation. The Add a new donor window will be closed, already entered information, if any, will be lost.<br>***Next*** - use this button to proceed to the next step (page) of the registration form. |
| |  | |

| | | |
|---|---|---|
| 2 | Answer questions in the Donor consent section. Remember to add the Date of the Donor informed consent.<br>Click the *Next* button at the bottom of the *Add a new donor* window.<br><br>It is important that all questions of this section are mandatory and shall not be left blank. If a user proceeds to the next section of the *Add a new donor*, the title of the Donor consent section will be marked with an Error and shown as following<br><br>Donor consent<br>Form invalid | The Donor information section will be shown in the *Add a new donor* window.<br><br>At the bottom of the form there are shown the following buttons:<br>***Cancel*** (explained in the Step 1).<br>***Previous*** - use this button to go back to the previous section Donor consent (Step 1).<br>***Create donor*** - the button to confirm Adding a new donor to the EBMT Registry with registration data entered in the *Add a new donor* window.<br><br>Data editors in VR context that Add a new donor will see one extra data field ***Centre***, where they must specify the registration centre for this Donor. |



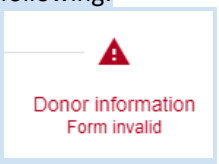
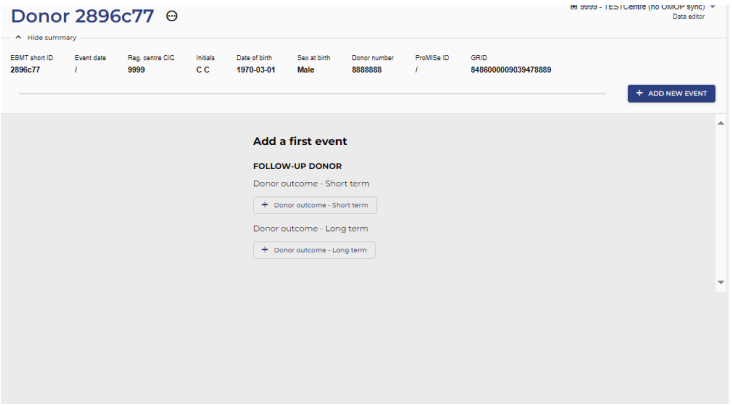
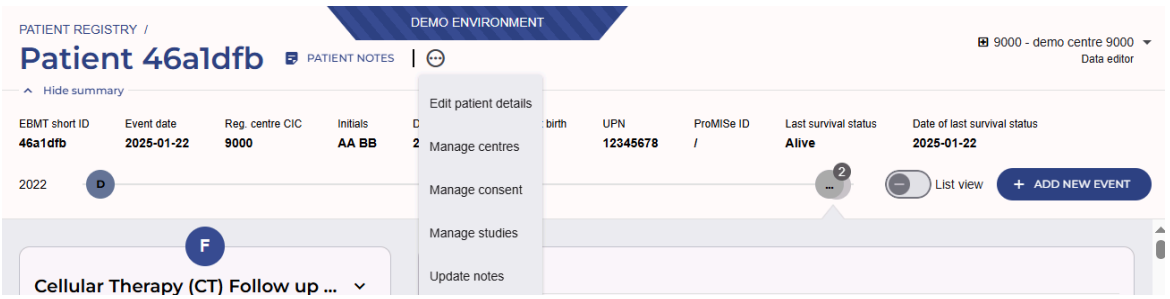
| | | |
|---|---|---|
| 3 | Answer questions in the Donor information section.<br><br>Click the *Create donor* button at the bottom of the *Add a new donor* window.<br><br>If a user returns to a previous section, the title of the Donor registration section will be marked with an Error and shown as following:<br>  <br><br>Due to legal restrictions in some countries, in rare cases donor initials may not be reported, the field will still be highlighted with an error, but it will not block Adding a new donor to the EBMT Registry. | If the data is entered correctly, the new Donor is successfully created in the EBMT Registry and the Donor page is shown in the main screen.<br><br>If there is missing information in the mandatory fields, the corresponding section of the form is highlighted with an error, the data field is highlighted in red. *The Create donor* button may be clicked, but the *Add a new donor* window remains open. Add information to the mandatory fields and click the Create *patient* button. |
| |  <br> | |

Table 43, instructions on how to add a donor to the EBMT Registry

## Edit Patient details

Please follow the following step-by-step in order to edit Patient general details-related data fields from the Patient registration DCF:

A. date of birth;
B. initials for name;
C. initials for surname;
D. Ethnicity; (should be entered only for UK centres)
E. postal code; (should be entered only for UK and France centres)
F. sex at birth;
G. blood group;
H. rhesus factor.

| Step | User actions | EBMT Registry |
|---|---|---|
| **1** | In the Patient page click on the three dots button to the right from the Patient short ID to call the Patient menu. | The **patient menu** will open. |
| |  | |
| **2** | Click on ***Edit patient details*** in the Patient menu. | The *Edit patient* window will appear.<br><br>It is 2 steps form (it can be considerate as 2 pages or sections of the same form):<br>1. **Patient information** - includes data fields related to the general patient registration data (UPN, birthdate, initials, etc.).<br>3. **Reason** - data field to inform about the reason for the change.<br><br>At the bottom of the form there are shown the following buttons:<br>***Cancel*** - to discard the changes. Use this button to close the Edit patient window without saving any changes done.<br>***Next*** - use this button to proceed to the next step (page) of the form. The button is active only if data editor edited any field of the form. |

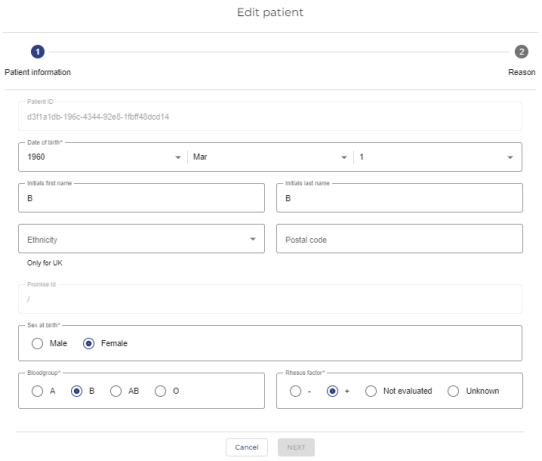
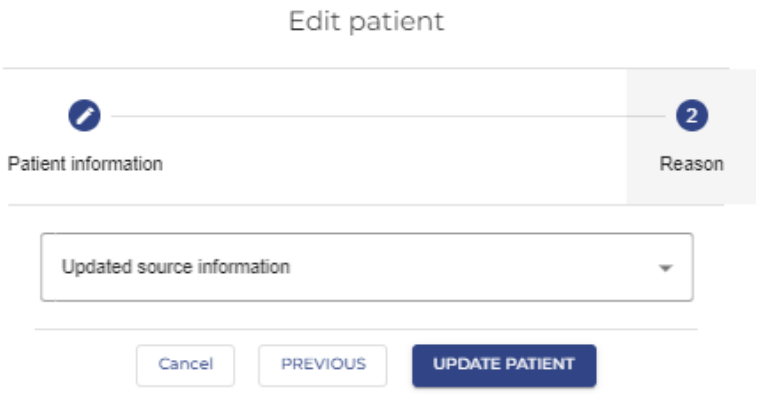
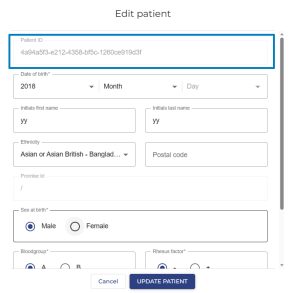
| Step | User actions | EBMT Registry |
|---|---|---|
| |  | |
| **5** | Edit required fields.<br>Click the *Next* button to proceed to the next step. | The *Edit patient* window: reason for changes will be shown.<br>There are shown the following buttons at the bottom of the window:<br><br>***Cancel*** - to discard the changes. Use this button to close the Update this patient window without saving any changes done.<br>***Previous*** - to go back to editing patient information.<br>***Update patient***- to save changes and close Edit patient window. |
| |  | |
| **6** | Enter the reason for the changes:<br>● Updated source information<br>● Data entry error/mistake<br>Click the *Update patient* button. | The *Edit patient* window disappears.<br>Patient page is displayed at the main screen. |



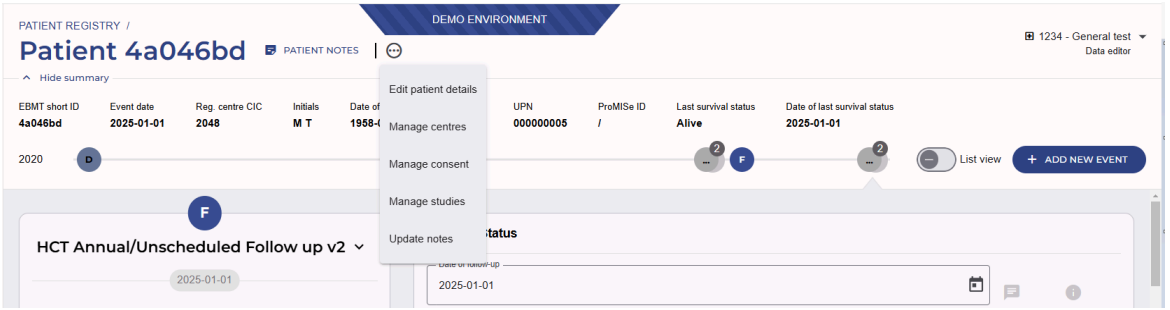
Table 44, instructions on how to update patient information

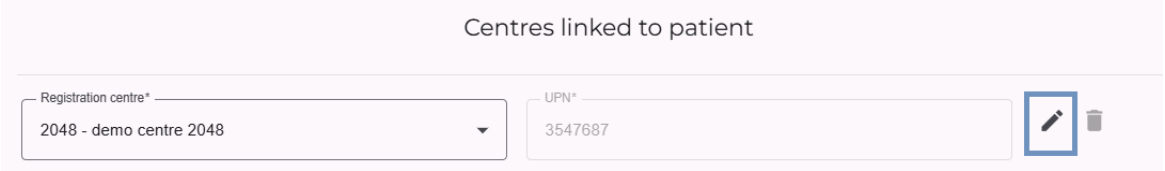
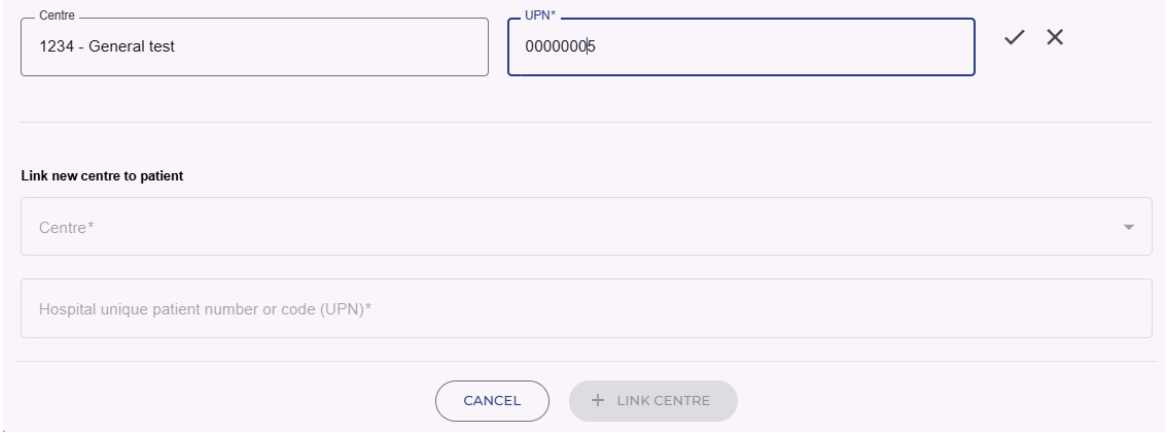
Note: The Edit patient window also shows the EBMT Patient ID (log ID) if it is required to see this information through the user interface. This field is not editable but for information purposes only.




## Edit Patient UPN

Data editors can update the patient UPN, if needed. Follow the instructions below to update or edit the Patient UPN

| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | In the Patient page click on the three dots button to the right from the Patient short ID to call the Patient menu. | The **patient menu** will open. |
| |  | |
| 2 | Click on ***Manage centres*** in the Patient menu. | The *Centres linked to patient* window will appear.<br><br>There are listed centres linked to this patient and UPNs per centre.<br>The UPN field is shown as disabled (greyed out). Next to the UPN field there are shown edit icon and delete icon .<br>Note: data editors cannot delete the patient UPN or the link between the centre and the patient. Should data editor click this button, the system will show an error.<br><br>The *Centres linked to patient* window also contains administrator-related fields to link a new centre to the patient. For data editors it is not possible to link new centres, thus such fields should not be used. |

| Step | User actions | EBMT Registry |
|---|---|---|
| | | At the bottom of the form there are shown the following buttons:<br>***Cancel*** - to discard the changes. Use this button to close the *Centres linked to patient* window.<br>***+Link centre*** - data editors are not able to link new centres to a patient, thus clicking this button will cause system showing an error to data editors. |
| |  | |
| 3 | Click the edit icon next to the patient UPN in the *Centres linked to patient* window. | The UPN field is shown in edit mode, there are icons to confirm and save changes ✓ or to cancel and close the field without saving any changes ✕ . |
| |  | |
| 4 | Edit the patient UPN as required and click confirm icon ✓ | The Updated UPN is saved in the UPN field. The field is shown as disabled. |

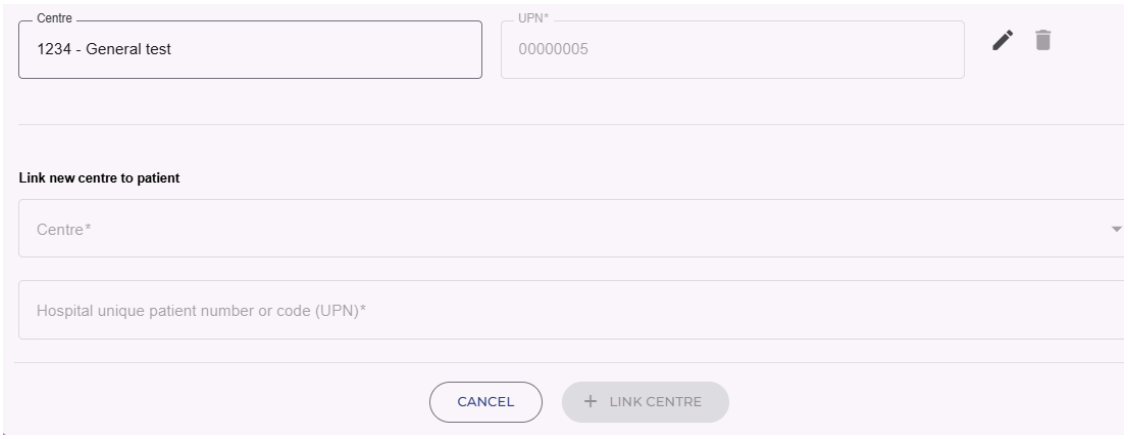
| Step | User actions | EBMT Registry |
|---|---|---|
| |  | |
| 5 | Click Cancel button at the bottom of the *Centres linked to patient* window. | The *Centres linked to patient* window disappears. The patient page is updated. New patient UPN is shown in the Patient summary. |

Table 45, editing patient UPN in the EBMT Registry

## Edit Patient consent

Follow the instructions below to update or edit the Patient informed consent related data, in particular:

1. Remove consent to having patient data submitted to EBMT

Important: if the patient withdraws the consent (answer is changed to No), the application will ask for the date of the patient consent withdrawal, the patient page will be turned to Read only mode. This means that already submitted data will remain visible, but it will not be possible to add new events data.

Patient data and events are not removed from the EBMT registry in this case. If this action happened accidentally, please contact EBMT Registry Helpdesk to request reversing such action and explaining all the details of the case.

2. Change the informed consent date:

At patient registration, a data editor enters the **First informed consent date**. This is the date the first informed consent was given (with signed informed consent form) by the patient or their legal guardian to having their data submitted to EBMT. (Please see more details in the Guide to the completion of the EBMT data collection form: Patient_registration_v2.0 available on the EBMT website)

In the scenario that a patient has been transferred from another hospital where consent was already collected, the new centre is responsible for obtaining the patient's consent (its date shall be recorded in the data field the Most recent informed consent date) and providing evidence of the consent acceptance following GDPR and their local regulations. The first date of consent from the previous hospital will be maintained since it is when the patient-EBMT relation was authorised.

Note: once First date of informed consent is added to the EBMT Registry, this field cannot be edited. Please contact EBMT Registry helpdesk if it is required to correct this data field, specifying all the details and the reason for such change.

**Most recent informed consent date** - is the date the latest informed consent form was signed by the patient or their legal guardian.

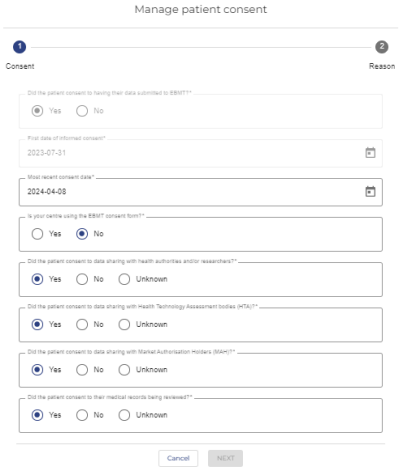
In the EBMT Registry initially this field is pre-populated with the date entered into the First informed consent date and it shall be edited/updated by the centre in case the patient or their legal guardian signed an informed consent form different from the form registered in the first informed consent field above.

For some patients this field is empty, this is due to the fact that this data field was added to the database after patient was created. Please note, that the system logic is not affected in this case.

Note: this date shall be edited in the EBMT Registry whenever the patient or their legal guardian signs a new informed consent form. The remaining questions of this section below should always reflect the patient details as per the most recent informed consent form signed.

3. Update or edit other consent-related questions.

| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | In the Patient page click on the three dots button to the right from the Patient short ID to call the Patient menu. | The ***Patient menu*** will open. |

| Step | User actions | EBMT Registry |
|---|---|---|
| |  | |
| 2 | Click on ***Manage consent*** in the Patient menu. | The *Manage patient consent* window will appear. There are shown the following buttons at the bottom of the window:<br>***Next*** **-** to proceed to the next step of updating patient consent data. The button is active (enabled) only if any field in the form was edited.<br>***Cancel*** - to discard the changes. Use this button to close the Manage patient consent window without saving any changes done. |
| |  | |
| 3 | Edit required fields.<br>Click the *Next* button to proceed with the changes.<br><br>If the changes due to signing a new ICF, make sure to enter the date into the field ***Most recent consent date***. | The Manage patient consent window: reason for changes will be shown.<br>There are shown the following buttons at the bottom of the window:<br>***Cancel*** - to discard the changes. Use this button to close the Manage patient consent window without saving any changes done.<br>***Previous*** **-** to go back to the editing of the patient consent data.<br>***Update consent*** - to save changes and close Manage patient consent window. |

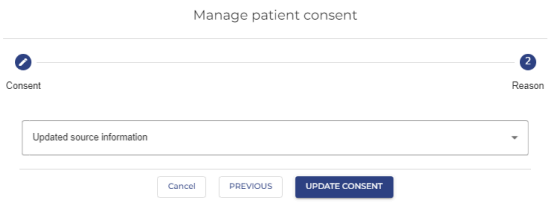
| Step | User actions | EBMT Registry |
|---|---|---|
| |  | |
| 4 | Enter the reason for the changes:<br>● Updated source information<br>● Data entry error/mistake<br>Click the *Update consent* button. | The patient consent-related data is updated.<br>The *Manage patient consent* window disappears.<br>Patient page is displayed at the main screen. |

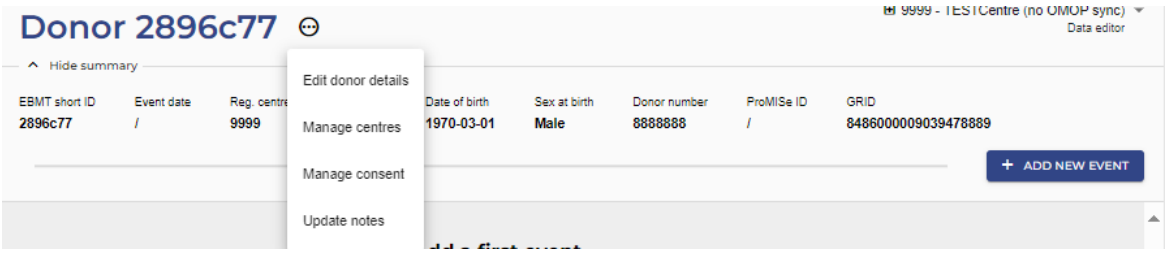
Table 46, editing patient consent in the EBMT Registry

Note: If a patient or donor besides removing the consent to share data with EBMT specifically requests that their data is removed from EBMT Registry, please contact EBMT Registry Helpdesk. Only Administrator can delete patient or donor from the database.

## Edit Donor details

Please follow the following step-by-step in order to edit Donor general details and related data fields from the Donor registration DCF:

A. Donor GRID
B. date of birth;
C. initials for name;
D. initials for surname;
E. sex at birth.

| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | In the Donor page click on the three dots button to the right from the Donor short ID to call the Donor menu. | The **donor menu** will open. |
| |  | |
| 2 | Click on ***Edit donor details*** in the Donor menu. | The *Edit donor* window will appear.<br><br>It is 2 steps form (it can be considerate as 2 pages or sections of the same form):<br>1. **Donor information** - includes data fields related to the general donor registration data (Donor ID, birthdate, initials, etc.).<br>3. **Reason** - data field to inform about the reason for the change.<br><br>At the bottom of the form there are shown the following buttons:<br>***Cancel*** - to discard the changes. Use this button to close the Edit donor window without saving any changes done.<br>***Next*** - use this button to proceed to the next step (page) of the form. The button is active only if data editor edited any field of the form. |

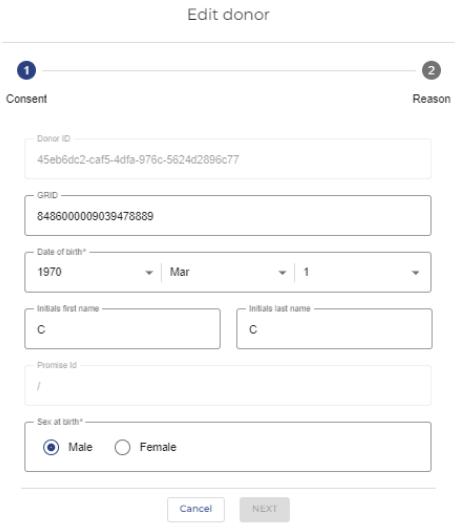
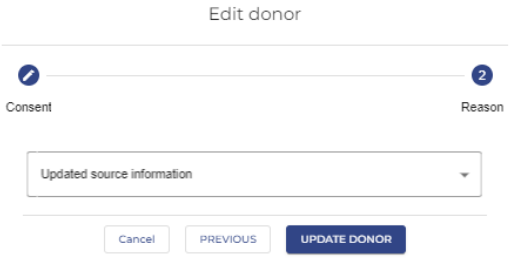
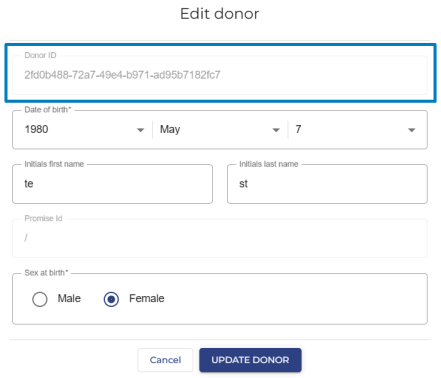
| Step | User actions | EBMT Registry |
|---|---|---|
| |  | |
| 3 | Edit required fields.<br>Click the *Next* button to move to the next step. | The *Edit patient* window: reason for changes will be shown.<br>There are shown the following buttons at the bottom of the window:<br><br>***Cancel*** - to discard the changes. Use this button to close the Update this patient window without saving any changes done.<br>***Previous*** - to go back to editing patient information.<br>***Update patient***- to save changes and close Edit patient window. |
| |  | |
| 4 | Enter the reason for the changes:<br>● Updated source information<br>● Data entry error/mistake<br>Click the *Update donor* button. | The *Edit donor* window disappears.<br>Donor page is displayed at the main screen. |

Table 47, editing donor details in the EBMT Registry

Note: The Edit donor window also shows the EBMT Donor ID if it is required to see this information through the user interface. This field is not editable but for information purposes only.


Edit donor
Donor ID
2fd0b488-72a7-49e4-b971-ad95b7182fc7
Date of birth*
1980
May
7
Initials first name
te
Initials last name
st
Promise Id
/
Sex at birth*
Male
Female
Cancel
UPDATE DONOR

## Edit Donor ID number

Data editors can update the Donor ID, if needed. Follow the instructions below to update or edit the Donor ID.

| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | In the Donor page click on the three dots button to the right from the Donor short ID to call the Donor menu. | The **Donor menu** will open. |
| |  | |
| 2 | Click on ***Manage centres*** in the Donor menu. | The *Centres linked to donor* window will appear.<br><br>There are listed centres linked to this donor and Donor ID per centre.<br>The Donor ID field is shown as disabled (greyed out). Next to the Donor ID field there are shown edit icon and delete icon .<br>Note: data editors cannot delete the Donor ID or the link between the centre and the donor. Should data editor click this button, the system will show an error.<br><br>The *Centres linked to donor* window also contains administrator-related fields to link a new centre to the donor. For data editors it is not possible to link new centres, thus such fields should not be used.<br><br>At the bottom of the form there are shown the following buttons:<br>***Cancel*** - to discard the changes. Use this button to close the *Centres linked to donor* window.<br>***+Link centre*** - data editors are not able to link new centres to a donor, thus clicking this button will cause system showing an error to data editors. |

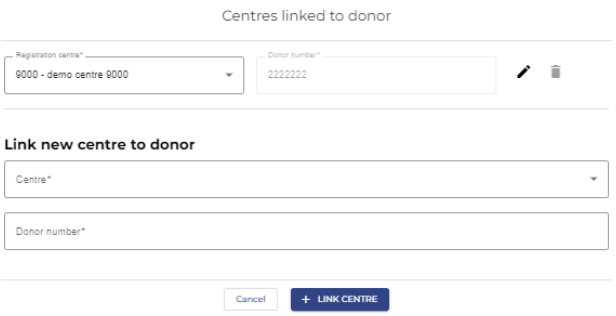
| Step | User actions | EBMT Registry |
|---|---|---|
| |  | |
| 3 | Click the edit icon next to the Donor ID in the *Centres linked to donor* window. | The Donor ID field is shown in edit mode, there are icons to confirm and save changes ✓ or to cancel and close the field without saving any changes ✗ . |
| |  | |
| 4 | Edit the Donor ID as required and click confirm icon ✓ | The updated Donor ID is saved in the Donor ID field. The field is shown as disabled. |
| |  | |
| 5 | Click *Cancel* button at the bottom of the *Centres linked to donor* window. | The *Centres linked to donor* window disappears. The Donor page is updated. New Donor ID is shown in the Donor summary. |

Table 48, editing donor ID number in the EBMT Registry

## Edit Donor GRID

Please follow the Edit Donor details process to update or add Donor GRID.

## Edit Donor consent

The process below explains how to update or edit the Donor informed consent related data.

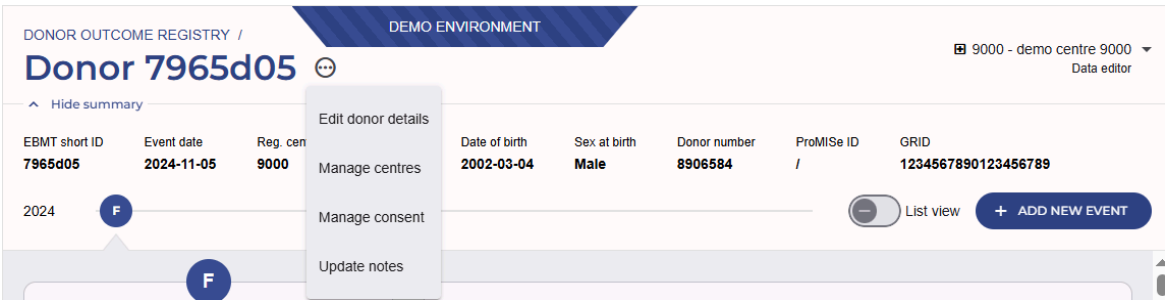
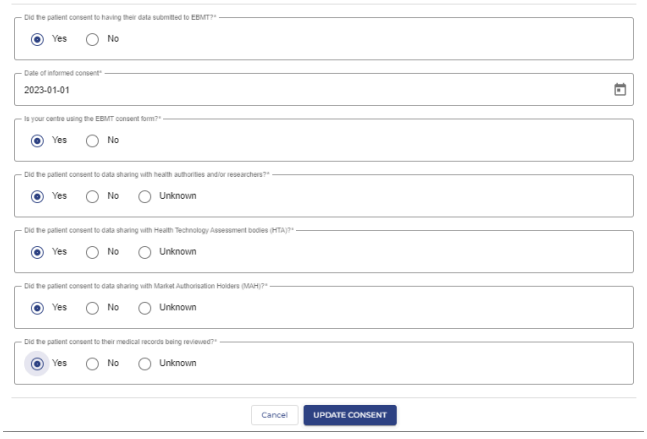
| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | In the Donor page click on the three dots button to the right from the Donor short ID to call the Donor menu. | The ***Donor menu*** will open. |
| |  | |
| 2 | Click on ***Manage consent*** in the Donor menu. | The *Manage donor consent* window will appear. There are shown the following buttons at the bottom of the window:<br>***Update consent-*** to apply and save the changes in shown data fields.<br>***Cancel*** - to discard the changes. Use this button to close the Manage patient consent window without saving any changes done. |
| |  | |
| 3 | Edit required fields.<br>Click the *Update consent* button to apply the changes. | The donor consent-related data is updated.<br>The *Manage donor consent* window disappears.<br>Donor page is displayed at the main screen. |

Table 49, editing donor consent in the EBMT Registry

## Edit Patient studies

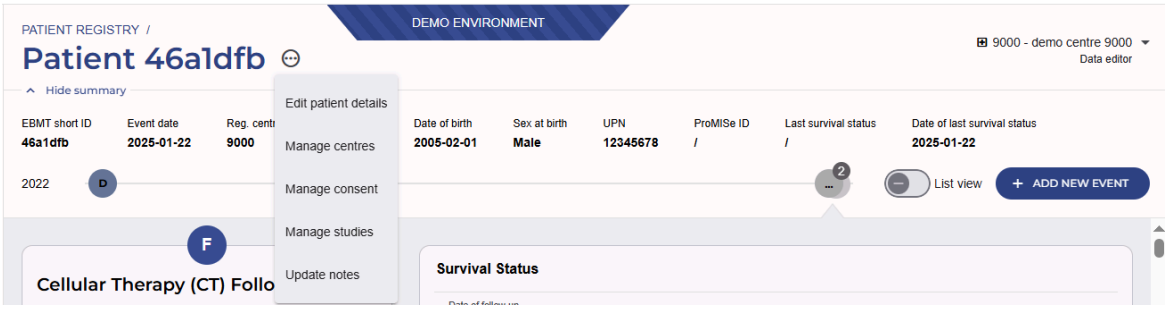
Follow the instructions below to edit patient data related to non EBMT studies, in particular:

**a.** Edit information as to whether the patient is participating in any non-EBMT study or trial and if answered Yes, to add study name;

**b.** Indicate whether the patient can be included into the EBMT studies.

Information on patient enrolment into EBMT studies is managed by EBMT staff and shall not be added or edited by users from Centres or National registries.

EBMT staff will add every EBMT study related information (E.g. *Working group*; *Study name*; *Study number*; *Study type*; *Patient ID number*).

| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | In the Patient page click on the three dots button to the right from the Patient short ID to call the Patient menu. | The ***Patient menu*** will open. |
| |  | |
| 2 | Select ***Manage studies*** from the patient menu. | The ***Manage patient studies*** window will appear.<br>There are shown the following buttons at the bottom of the window:<br>***Update studies*** **-** to apply and save the changes in shown data fields.<br>***Cancel*** - to discard the changes. Use this button to close the Manage patient consent window without saving any changes done. |

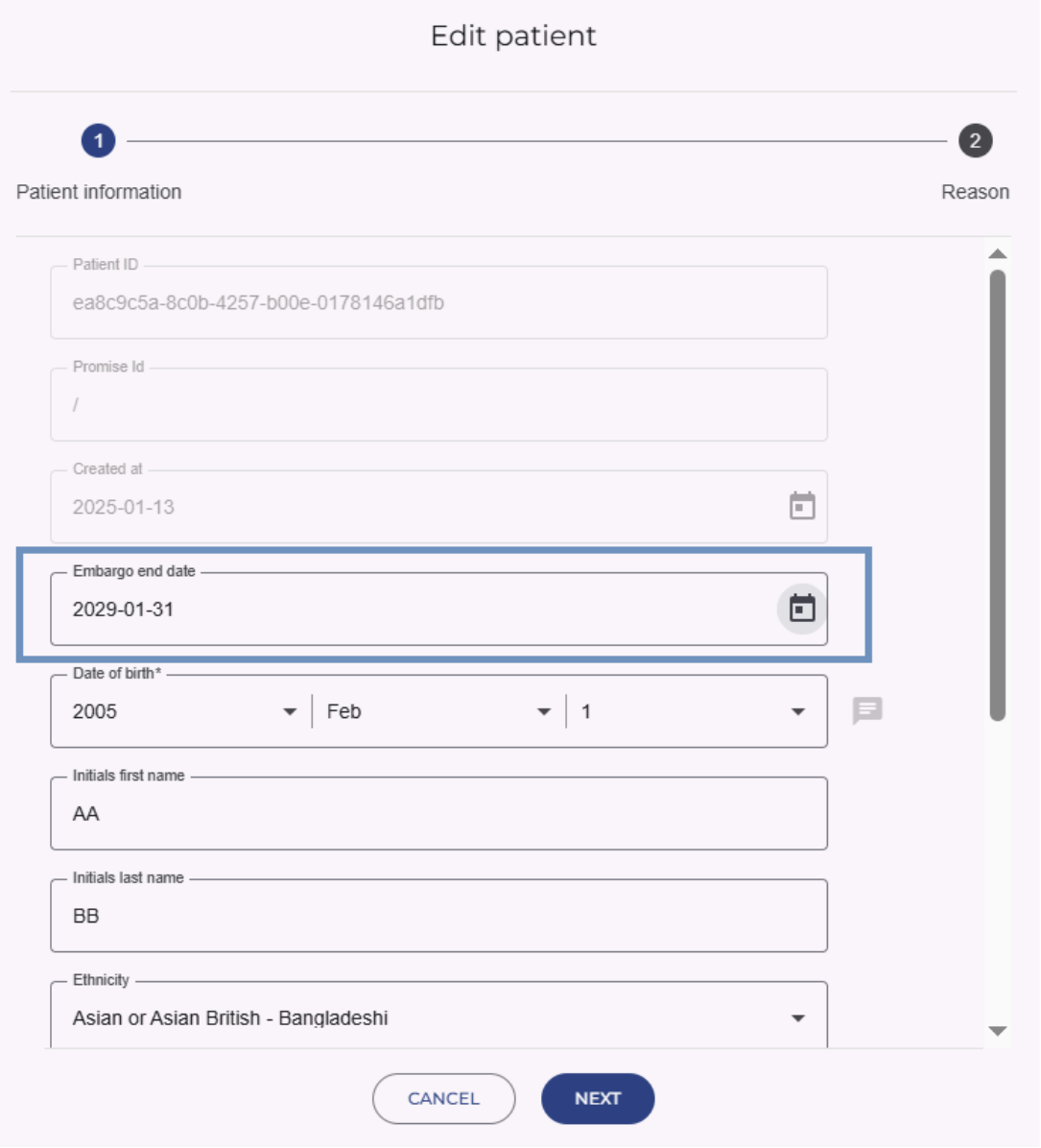
| Step | User actions | EBMT Registry |
|---|---|---|
| |  | |
| 3 | Edit required fields.<br>Click the *Update studies* button to apply the changes. | The patient study-related data is updated.<br>The *Manage patient studies* window disappears.<br>Patient page is displayed at the main screen. |

Table 50, editing patient studies in the EBMT Registry

## Add embargo status to a patient

In order to hide patient data temporary from EBMT studies and comply with clinical trial/non-EBMT studies conditions or other relevant agreements and documentation, data editors should remember to add the Embargo status to the patient.

| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | In the Patient page click on the three dots button to the right from the Patient short ID to call the Patient menu. | The ***Patient menu*** will open. |
| |  | |
| 2 | Click on ***Edit patient details*** in the Patient menu. | The *Edit patient* window will appear.<br><br>It is 2 steps form (it can be considerate as 2 pages or sections of the same form):<br>1. **Patient information** - includes data fields related to the general patient registration data (UPN, birthdate, initials, etc.).<br>3. **Reason** - data field to inform about the reason for the change. |

| Step | User actions | EBMT Registry |
|---|---|---|
| | | At the bottom of the form there are shown the following buttons:<br>***Cancel*** - to discard the changes. Use this button to close the Edit patient window without saving any changes done.<br>***Next*** - use this button to proceed to the next step (page) of the form. The button is active only if data editor edited any field of the form. |
| 3 | Enter embargo end date into the dedicated data field and click button Next on the bottom of the modal window. | The second step is shown to indicate the reason for changes. |
| |  | |

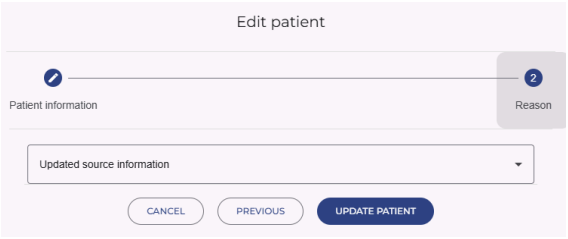
| Step | User actions | EBMT Registry |
|---|---|---|
| 3 | Specify the reason for changes and click Update patient button.<br>  | The embargo end date is saved, the Embargo icon is displayed on the patient page and will disappear automatically after the embargo period is over. |
| |  | |

Table 51, add embargo end date

## Delete Patient/Donor

Only the Administrator can delete a patient or donor in exceptional circumstances.
Data viewers and data editors cannot delete any patient or donor.

## Add new event

Follow the instructions below to add a new patient or donor event.

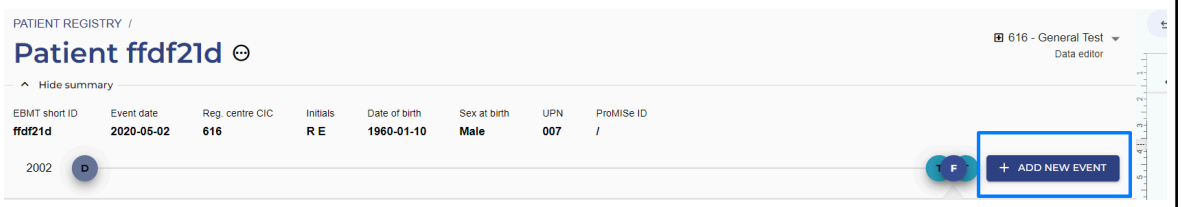
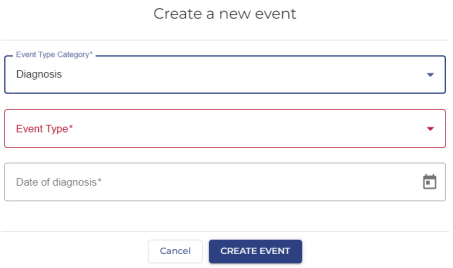
| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | In the *Patient page (or Donor page)* click the ***Add new event*** button located on the right from the patient timeline. | The ***Create a new event*** window will appear. |
| |  | |
| 2 | Fill in the ***Create a new event*** form, specifying:<br>**a.** Event type category: *Diagnosis/Treatment/Follow Up/Other*; (this field is not shown for Donor events)<br>**b.** Event type (name of the data collection form for the event you want to register);<br>**c.** Event date.<br>  | |
| 3 | Once fields are filled in correctly, click the ***Create event*** button. | The event is created in the Patient/Donor page, event form is shown in the main screen. |
| | | |

Table 52, adding new patient or donor event

## Edit event

Follow the instructions below to edit any registered patient or donor event.

| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | In the *Patient page (or Donor page)* open the event form you wish to edit (add new data or edit data, etc.).<br>Make edits in the required data fields.<br>Click Save changes button in the Event summary. | The warning message asking for confirmation and to state the reason for this change.<br>It is possible to indicate the following reasons:<br>● Updates source information;<br>● Data entry err/mistake.<br>The window also contains the buttons:<br>*Cancel* - to cancel the request to save introduced changes. Use this button to cancel saving the changes to the database.<br>*Save changes* - use this button to confirm saving changes to EBMT Registry database. |
| |  | |
| 2 | Indicate the reason for introduced changes from the dropdown list and click *Save changes* button | The changes are saved to the EBMT Registry database. The new version of the event form is created and recorded in the Audit log.<br>The event form with introduced changes is displayed in the main screen. |

Table 53, editing patient and donor event in the EBMT Registry

## Delete event

Follow the instructions below to remove the patient's or donor's event from the timeline.

The event is not deleted from the system in full. Data from the event is removed from the database, but it remains in the Audit trail, that is why in the user interface this action is called Archive event.

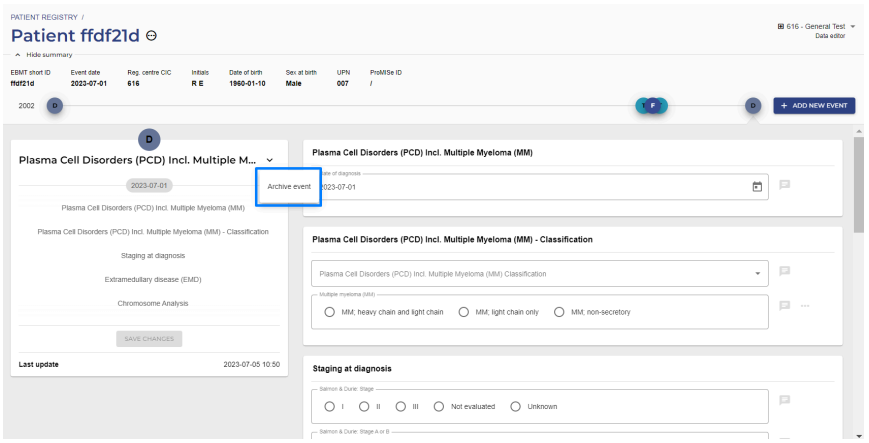
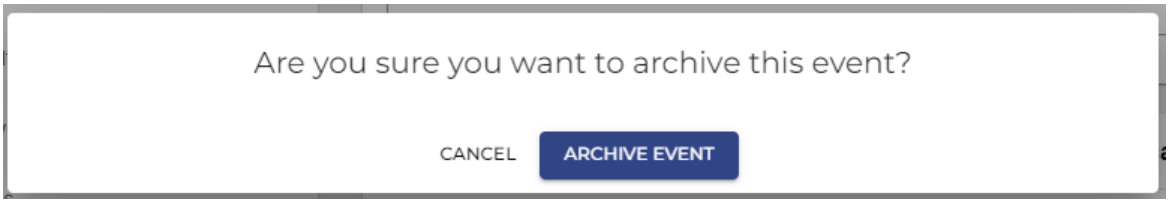
| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | In the *Patient page (or Donor page)* open the event you wish to delete.<br>Click the icon ⌄ to the right from the event form name to call the event menu. | The event menu will appear. |
| |  | |
| 2 | Click Archive event. The warning message asking to confirm the action will be shown. It includes the following buttons:<br>*Archive event* button - to remove the event from the Patient/Donor page and event data from the database.<br>*Cancel* - to cancel this request and leave the event in the Patient/Donor page and event data in the database.<br>  | |
| 3 | Click *Archive event* button. | The event disappears from the Patient/Donor timeline. The event with the latest date is loaded and shown in the main screen. |

Table 54, instructions on how to delete (archive) an event

## Study event form

After the study event appears in the patient timeline, data editors can start entering data. The study events will look like normal patient events on the timeline and should be filled-in in the same way, but next to the normal options in the event summary, they can click *Save changes* (if any data was entered and has not been saved yet) or *Submit questionnaire* (if data was entered and has been saved) buttons.

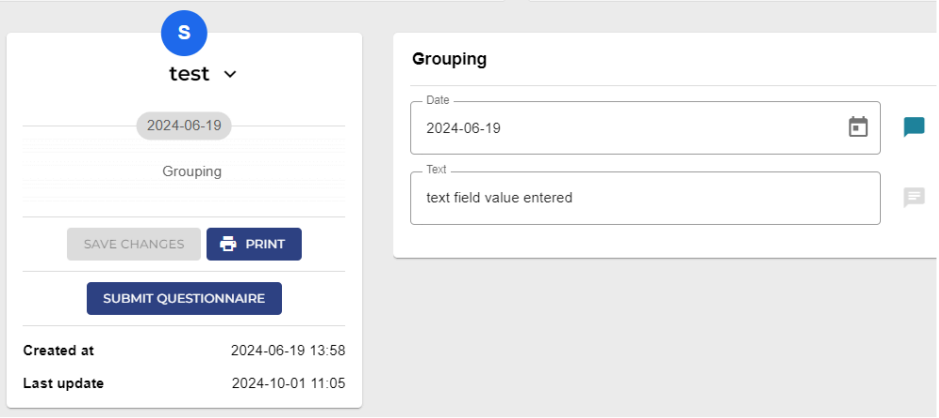



**Image 126. Example of an event summary as shown to data editors for a study event that has not been submitted yet**

The difference between saving changes and submitting a questionnaire is that saving changes can be used while working on the event. Submitting the questionnaire will inform the study manager that a study event has been submitted by a centre.

Once data editor enters data into the study event form, saves it and submits the questionnaire, this study event remains visible in the patient timeline, but the form can not be re-submitted or edited any more, thus the buttons *Save changes* and *Submit questionnaire* are disabled in the event form summary (image 127).

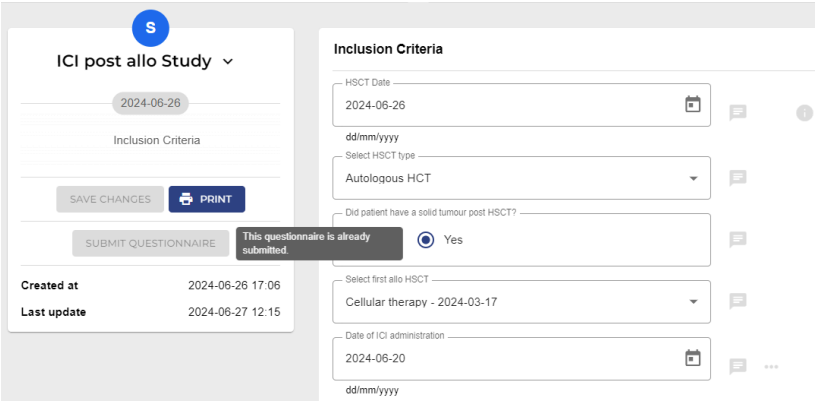



**Image 127. Example of an event summary as shown to data editors for a study event that has already been submitted**

## Add anonymous event

The process below explains how to add an anonymous event to register minimum essential data on treatment of non-consenting patients in the user Context.

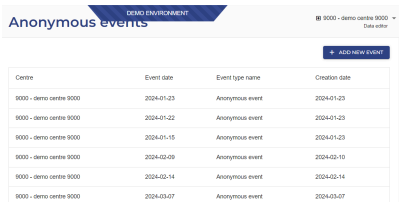
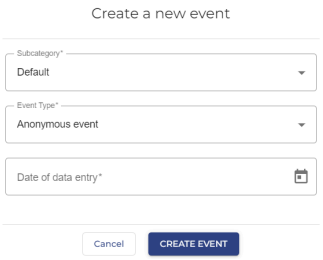
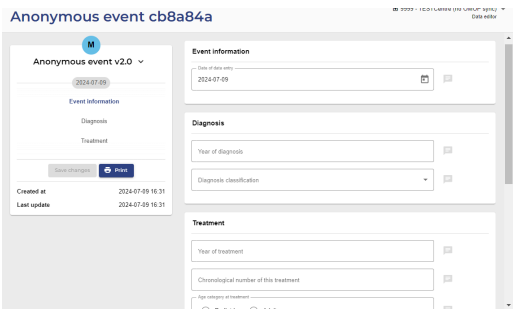
| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | Click *Anonymous events* in the Navigation menu. | Anonymous events overview page opens. |
| |  | |
| 2 | Click *Add new event* button. | The *Create a new event* window will appear. It contains:<br>Date field - to enter the date of the treatment<br>Cancel button - to cancel anonymous event creation and go back to Anonymous events overview page.<br>Create event button - to create an anonymous event in the system |
| |  | |
| 3 | Fill in the date of the anonymous event and click the *Create event* button. | New anonymous event with a unique number is created in the system and is loaded on the screen. |
| |  | |
| | Fill-in the data in the data fields and click the *Save changes* button. | The data is saved for the anonymous event in the database. |

Table 55, instructions on how to add anonymous events

## Edit anonymous event

Follow the instructions below to edit any registered anonymous event.

| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | In the Anonymous events overview page open the event form you wish to edit.<br>Make edits in the required data fields.<br>Click *Save changes* button in the Event summary. | The warning message asking for confirmation and to state the reason for this change.<br>The window also contains the buttons:<br>*Cancel* - to cancel the request to save introduced changes. Use this button to cancel saving the changes to the database.<br>*Save changes* - use this button to confirm saving changes to EBMT Registry database. |
| |  | |
| 2 | Indicate the reason for introduced changes from the dropdown list. It is possible to indicate the following reasons:<br>● Updates source information;<br>● Data entry err/mistake.<br>Click *Save changes* button. | The changes are saved to the EBMT Registry database. The new version of the event form is created and recorded in the Audit log.<br>The anonymous event form with introduced changes is displayed in the main screen. |

Table 56, instructions on how to edit anonymous events

## Delete anonymous event

Follow the instructions below to remove any anonymous event from the system.

The anonymous event is not deleted from the system in full. Data from the event is removed from the database, but it remains in the Audit trail, that is why in the user interface this action is called Archive event.

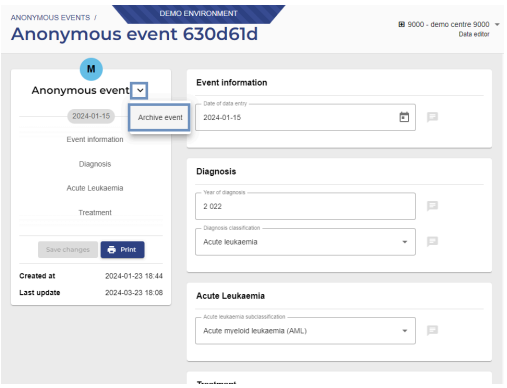
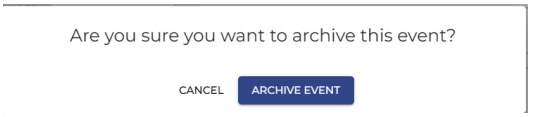
| Step | User actions | EBMT Registry |
|---|---|---|
| 1 | Open the page of the Anonymous event page you wish to delete.<br>Click the icon ⌄ to the right from the event form name to call the event menu. | The event menu will appear. |
| |  | |
| 2 | Click Archive event. | The warning message asking to confirm the action will be shown.<br><br>It includes the following buttons:<br>*Archive event* button - to remove the Anonymous event from the system.<br>*Cancel* - to cancel this request and leave the event in the database. |
| |  | |
| 3 | Click *Archive event* button. | The Anonymous event disappears from the system. Anonymous events overview page is shown on the main screen with the updated list. |

Table 57, instructions on how to delete anonymous events

# Abbreviations

| Abbreviation | Full term |
|---|---|
| EBMT | European Society for Blood and Marrow Transplantation |
| Allo-HCT | Allogeneic HCT |
| Auto-HCT | Autologous HCT |
| CT | Cellular therapy |
| IST | Immunosuppressive therapy |
| MFA | Multi-factor authentication |
| OMOP CDM | Observational Medical Outcomes Partnership Common Data Model |
| DCF | Data collection form |
| VR | Virtual registry |
| UPN | Unique patient number (see Patient) |

Table 58, abbreviations