

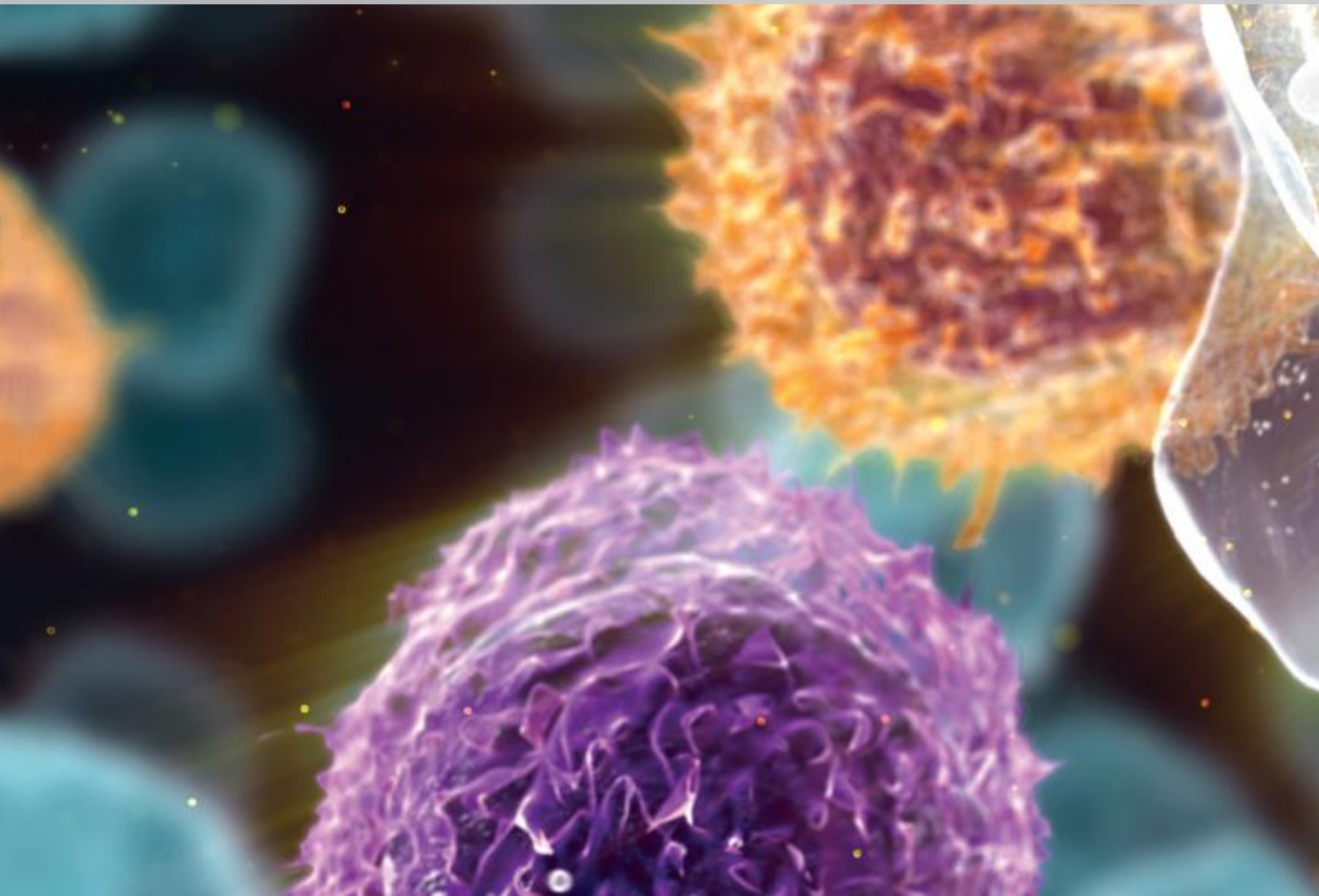


Cellular Therapy

Data collection handbook for Castor EDC

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CHAPTER 1

Introduction

The EBMT is a collaborative peer network of professionals working in the field of clinical bone marrow transplantation and cellular therapy. EBMT's biggest asset is clinical data, enabling many research possibilities with the goal of saving the lives of patients with blood cancers and other diseases.

Therefore, it is important to ensure adequate data collection and data management processes.

Over the years, data collection and data management tasks were performed through ProMISe. However, the increased complexity of ProMISe negatively affects its ability to cope with the evolving needs of EBMT.

To ensure quality during data collection, Castor is selected as the platform to collect and manage the new Cellular Therapy information.

The purpose of this handbook is to guide the user through Castor, and solve any potential doubts that may arise on the way. The entirety of the system will be explained and when needed, references will be provided for external consultation.

In order to read this document, no previous experience with Castor or Data Entry processes are needed.

CHAPTER 2

Castor EDC

Castor is a cloud-based clinical data collection management platform. Currently, Castor is the most used data capture tool in the market, with more than 85000 users collecting information about more than 2.8 million patients over 90 countries.

In addition to that, the platform is certified by the ISO 27001 and ISO 9001. Furthermore, it is adherent to General Data Protection Regulation (GDPR) and Good Clinical Practices. However, the main reason Castor was chosen to collect and manage the clinical data from Cell Therapy is its user-friendliness. The platform is designed to require minimal training in order to use it.

During the next chapters, the different sections of Castor will be explained as well as the overall procedure of data collection.

CHAPTER 3

Data Structure

Studies in Castor are organised in **visits**, **forms** and **Repeating data** as illustrated in figure 3.1.

Forms are the sections of the paper forms that are related to specific topics, for example *Patient data* or *Comorbid conditions*. Together, the **forms** form a **visit**. Using the previous example, the **forms** *Patient data* and *Comorbid conditions* would be part of **visit Day 0**.

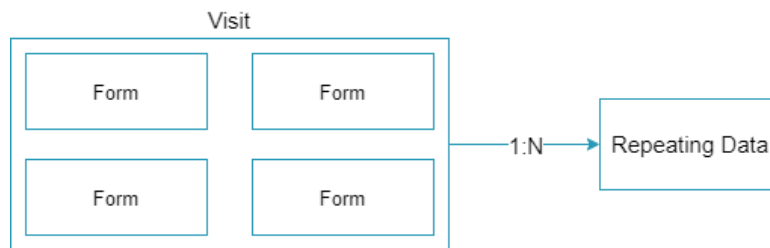


Figure 3.1: Castor structures

The Cellular Therapy study in Castor EDC is composed of the **visits** *Pre-infusion registration*, *Day 0*, *Day 100 - Follow up*, *6 Months - Follow up* and *Annual - Follow up* as seen in figure 3.2.

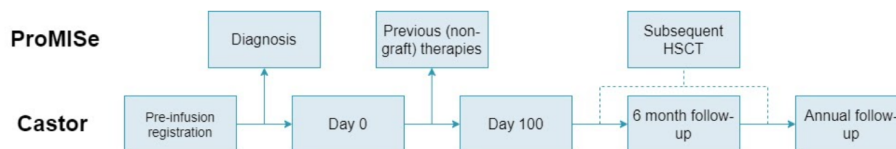


Figure 3.2: Castor Data Structure

On the other hand, as seen in figure 3.2, *Diagnosis*, *Previous treatment* (In particular, chemotherapy) and *Subsequent HCT* still need to be reported on ProMISe.

3. Data Structure

Repeating data are specific sets of questions that can be nested in forms or exist independently and allow iteration. These are associated to a patient directly, or through a **form**. A patient record can have multiple **repeating data**.

At the moment, the following **repeating data** is implemented in Castor EDC:

1. Cell Infusion Episode
2. Cell Infusion Unit(s)
3. Cell Therapy Infusion Unit - Manipulation
4. Complications - Infections
5. Other Complications
6. Other Treatment
7. Patient Preparatory Treatment
8. Post Therapy Treatment
9. Radiotherapy
10. Death Report
11. Annual Follow up

The *Annual follow-up* is **repeating data**, as this needs to be filled in for every year a follow-up assessment has been performed, iteration is required. The *Death Report* functioning is slightly different in the cellular therapy database as it is independent of the **visits**. It can happen any time. Once a *Death report* has been filled, any new data entry is discouraged.

CHAPTER 4

Account creation


An account for Castor can be created at <https://data.castoredc.com/> by clicking on **Sign up**. After selecting sign up, the only necessary step is fill the information displayed at figure 4.1. It is necessary to create an account to be able to access the data collection study and this process need to be done by the user.


Sign up

First name Last name

Email Address

Phone number (Optional)

Password 

Repeat password 

I declare that I have read [Terms of Use](#)*

By clicking here we will keep you up-to-date about our products, services, and webinars as well as educational materials

Figure 4.1: Sign up screen

Alternatively, you can also create and account after being invited to a particular study. You are invited to an study after receiving an invitation to do so (see figure 4.2). The email will contain a link, through which an account can be created. After setting up the account, two-factor authentication needs to be activated. This is the case for the cellular therapy data collection study.

4. Account creation

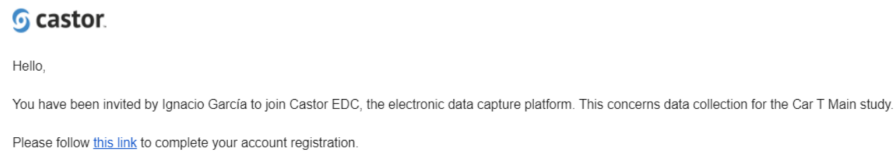


Figure 4.2: Example of invitation Mail for Castor

4.1 Two-Factor Authentication

Google authenticator, Authy or Microsoft Authenticator are apps that can be used to set up two-factor authentication for Castor. One of these needs to be installed on a tablet or smartphone. In addition to that, Authy can be installed in a desktop computer.

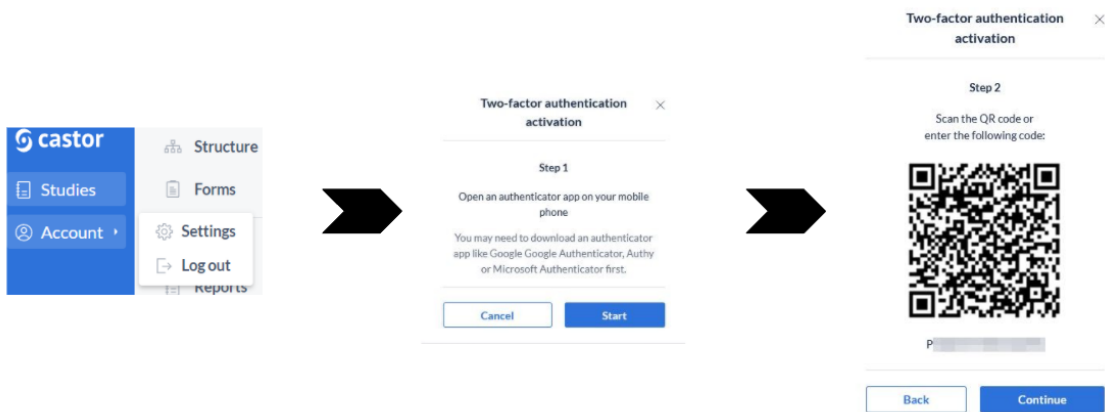


Figure 4.3: Process to activate Two-Factor Authentication

To turn on two-factor authentication, go to **Account** on the left side of the screen and click **Settings**. From the account settings, click **Password Security**. Select the box **Using two-factor authentication with this account** and click the blue button that says **Activate two-factor authentication**. The web page will ask to open the Authenticator app, as previously referred, and scan the QR code or enter the code that is provided (step 2). These steps can be visualized on figure 4.3. Despite this, it is known that sometimes there is a bug that prevents people from being able to activate the two factor authentication. In case the user experiences this situation, it can be solved by using a different browser and/or cleaning the cookies and cache of the current browser.

The Authenticator app will provide a code, which needs to be entered in the field on the Castor web page. After entering the code, click **configure**. Castor EDC will be added to the list of web pages that the Authenticator app is used for.

4.1. Two-Factor Authentication

For every login to Castor, the newest code in the app needs to be entered after logging in using the login credentials.

After a successful login, the user should be able to see the Cellular Therapy study as per figure 4.4.

Figure 4.4: Studies Overview

CHAPTER 5

Account types

In Castor, different roles for user accounts can be created. Roles can be edited and new ones can be created at any point during the study to suit the needs of potential special users, allowing flexibility. The type of role will depend on the functionalities the user needs to have access to.

1. **Administrator:** The study admin account oversees all other roles and has the possibility to change the study, add new users, and all functionalities other role types have.
2. **Data Manager:** This role can view and edit entered data, sign, lock, query and export. In addition to that, they are also able to archive data.
3. **Centre user:** This role is aimed at users from centres. They will have data entry accounts, allowing them to add, view, edit, and export data.
4. **Monitor:** Accounts for EBMT or external monitors can be created, which have the functionalities to view data, perform source document verification, and query.
5. **Internal User:** Accounts for EBMT personnel can be created, which have the functionalities to view data, add data and edit it in addition to Query rights. For specific authorised personnel export rights are also granted.
6. **National Registry:** This role is aimed at national registries. They will have data entry accounts, allowing them to add, view, edit, and export data.

5. Account types

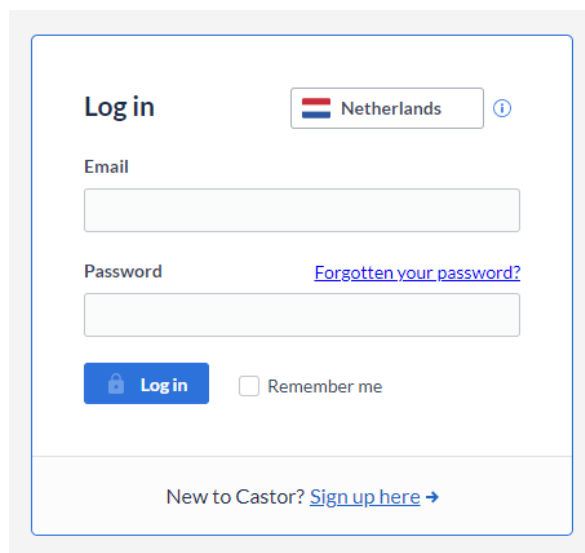
Administrator	Data Manager	Centre User	Monitor	Internal User	National Registry
<ul style="list-style-type: none"> • Add • View • Edit • Email • Sign • Lock • Verify • Query • Archive • Export • Surveys 	<ul style="list-style-type: none"> • View • Edit • Sign • Lock • Query • Export 	<ul style="list-style-type: none"> • Add • View • Edit • Export 	<ul style="list-style-type: none"> • View • Verify • Query 	<ul style="list-style-type: none"> • Add • View • Edit • Query • Export* 	<ul style="list-style-type: none"> • Add • View • Edit • Export

Table 5.1: Role capabilities overview

CHAPTER 6

Login

To log in to Castor, go to <https://data.castoredc.com/> once you have created your account. Type in the email address that was used to create the account, and the password. Castor will ask for the authentication code as provided by the authenticator app as described in chapter 4.



The screenshot shows a login form with the following elements:

- Log in** header
- Country selector: **Netherlands** (with a flag icon and an information icon)
- Email** label and an empty input field
- Password** label and an empty input field
- [Forgotten your password?](#) link
- Log in** button (with a lock icon)
- Remember me** checkbox
- [New to Castor? Sign up here →](#) link

Figure 6.1: Castor Log-In screen

6. Login

After successful login, the **My Studies** page will become visible, where Cellular Therapy data collection should be selected to enter cellular therapy data (See figure 6.2) if the invitation to the study has been received and accepted.

• Live Cellular Therapy data collection Linked Multicenter EU Server

Figure 6.2: Study for Cellular Therapy data collection

CHAPTER 7

Participant Section

After selecting the study, the study's participant section will become visible. All patients entered for your center are listed in this table. The participants section has different views and functionalities, which will be explained. By default the list view is selected, which is pictured in figure 7.1.

Participant...	Site	Progress	Last opened	Created on	Updated on	Status	
<input type="checkbox"/> 110001	European Bone Marrow Transplant Association	<div style="width: 100%;"><div style="width: 100%;"></div></div>	Jgnacio Garcia	19 May 2022	27 Sep 2022	Not Set	🔒
<input type="checkbox"/> 110002	European Bone Marrow Transplant Association	<div style="width: 50%;"><div style="width: 50%;"></div></div>	Jgnacio Garcia	01 Jun 2022	08 Sep 2022	Not Set	🔒

Figure 7.1: Castor participant list view (Default)

In the **List view**, it is possible to sort the cases based on the names in the columns (e.g. *Institute*, *Progress*, or *Updated on*). It also allows selecting participants using the tick boxes, or selecting all participants using the tick box in the header of the table, after which participants can be downloaded (See chapter 14).

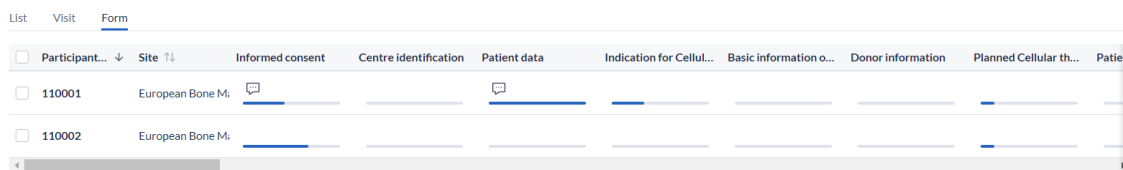
Another view option is by **Visit** (figure 7.2). Here all participants are listed with progress bars for completeness, outstanding queries and comments.

Participant...	Site	Pre-infusion Registr...	Day 0	Day 100 - Follow up	6 Months - Follow up	Annual - Follow up
<input type="checkbox"/> 110001	European Bone M:	<div style="width: 100%;"><div style="width: 100%;"></div></div>	<div style="width: 100%;"><div style="width: 100%;"></div></div>	<div style="width: 100%;"><div style="width: 100%;"></div></div>	<div style="width: 100%;"><div style="width: 100%;"></div></div>	<div style="width: 100%;"><div style="width: 100%;"></div></div>
<input type="checkbox"/> 110002	European Bone M:	<div style="width: 50%;"><div style="width: 50%;"></div></div>	<div style="width: 50%;"><div style="width: 50%;"></div></div>	<div style="width: 50%;"><div style="width: 50%;"></div></div>	<div style="width: 50%;"><div style="width: 50%;"></div></div>	<div style="width: 50%;"><div style="width: 50%;"></div></div>

Figure 7.2: Castor participant visit view (With dummy patients and centre)

A more detailed version of the **Visit** view is **View by form**, available in figure 7.3, where the progress per form of the study can be seen.

7. Participant Section



The screenshot displays the 'Form' view of the Castor participant section. At the top, there are navigation tabs for 'List', 'Visit', and 'Form', with 'Form' being the active tab. Below this, there is a header row with several tabs: 'Participant...', 'Site', 'Informed consent', 'Centre identification', 'Patient data', 'Indication for Cellu...', 'Basic information o...', 'Donor information', 'Planned Cellular th...', and 'Patient'. The main area shows two rows of dummy patients. The first row is for patient ID '110001' at 'European Bone M...', and the second row is for patient ID '110002' at 'European Bone M...'. Each row has a progress bar indicating the completion status of various data collection forms, with some bars being blue and others grey. There are also small comment icons next to the patient names.

Figure 7.3: Castor participant form view (With dummy patients and centre)

Depending on your objectives, different views will be more helpful. For example, when checking for completeness or queries/comments, the **Form** or **Visit** view will be more helpful than the **List** view.

7.1 Searching for patients

Sometimes, finding the appropriate patients is not an easy task. Among other reasons, the **Castor id** that serves as a unique identification is exclusive to Castor and assigned to each patient created automatically. As a result, it is not associated with the information filled in the data collection forms.

In order to find a specific patient, it is possible to filter by centre (*institute*) by selecting the correct option in **Filters**. In addition to that, it is possible to use the search bar located on the top left of the participant section to filter by the answer to any of the study's questions. It is recommended to use the Castor variable *ID_IDAA_PRE* also known as EBMT Unique Identification Code, *DATPATBD_PRE* known as Date of Birth or *UPN_PRE*, Hospital Unique Patient Number or Code.

CHAPTER 8

Castor Question's

Castor allows to add different types of questions. However, not all are used throughout this study. In this section, the used questions are described:

1. **Drop-down:** 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. If there are more than 25 options available, it is possible to write on the field and obtain suggestions.
2. **Radio buttons:** Used for questions where there is two options available but only one option can be selected. The question can be filled in by clicking the dot before the answer.
3. **Check-boxes:** Used for questions where more than two options are available and more than one option can be selected.
4. **Dates:** All dates in Castor are in DD-MM-YYYY format. When the day of the month is unknown, it is suggested to select the 1st of the month. In cases where the month and day is unknown, it is suggested to select the first of January to report the date. Nonetheless, in the Castor study questions that contain dates, more information will be available.
5. **Text-boxes:** Text boxes in Castor allow both text and numbers. It is important that text boxes to specify *Other* are only 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 recognized by the system.
6. **Tables:** Tables are **Repeating data** associated to **Visits**. Tables are not standalone questions, but cover different types of questions. The **Add measurement** button will allow the user to fill in the table. Multiple measurements can be added, for example in the case of multiple drugs or cell therapy infusion units. Any of the measurements added in a table can be edited by clicking on the cogwheel that appears on the right side of the measurements.
7. **Calculated Questions:** Calculated questions are used throughout the study to perform calculations such as number of cell infusions, or whether dates or numerical values are within reasonable limits. This particular use of the calculated questions will be explored in Chapter 10.

CHAPTER 9

Mandatory Questions

Questions in Castor can be made mandatory to fill in. The mandatory questions can be recognised by a bold font. Non-mandatory questions appear in a non-bold/normal font. An example of this can be seen in figure 9.1

The screenshot shows a data entry form with three questions. The first two are mandatory, indicated by bold text and an orange dot. The third is non-mandatory, indicated by normal text and a green dot. Each question has an information icon and a dropdown menu.

12.1.14 Peptic ulcer requiring treatment	(i)	<input type="text"/>
12.1.15 Psychiatric disturbance	(i)	<input type="text" value="No"/>
12.1.16 Specify other additional major clinical abnormalities not listed above and present prior to the preparative regimen:		<input type="text"/>

Figure 9.1: Mandatory and Non-Mandatory questions

The percentage in the completion bar visible in the top left corner of the data entry form only counts mandatory questions as seen in figure 9.2.

9. Mandatory Questions

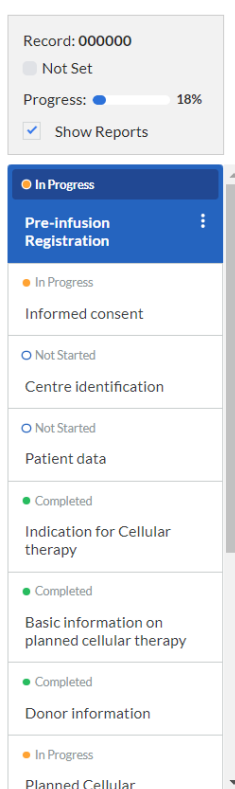


Figure 9.2: Record fulfillment tab

CHAPTER 10

Automated Checks

Answers to questions in Castor can be subject to automated checks. These automations cross-check different fields for correctness to improve data quality and prevent mistakes, or to check if the entered value conforms to the range set for the item.

1.1.1 Date informed consent (i) (DD-MM-YYYY)

1.2 Informed consent date validation check Check successful: Yes

Figure 10.1: Successful check example

Some checks are visible in between questions, as pictured in figures 10.1, 10.2, 10.3. This is the type of automation that cross-checks different fields. If a check appears to be incomplete (showing the text *Not all values for this calculation are available (yet)*), the field that is used for cross-checking has not been filled in yet. This message does not affect data entry and it is aimed to notify data managers and monitors in case information introduced at a later date is in conflict.

11.1.2 Date of cell infusion (i) (DD-MM-YYYY)

11.1.3 Date of cell infusion validity check Not all values for this calculation are available (yet).

Figure 10.2: Unfinished check example

For values that are expected to fall within set ranges or specific answers, a warning message can be displayed if the entered value does not match the range/expected value, as in figure 10.4. For example, if a value that is entered in percentages is higher than 100, or negative values for weight or height, or the consent is negative. Data entry can be continued after a warning message is displayed. However, a notification will be added to the record, allowing monitors and EBMT data managers to see that an unexpected value

10. Automated Checks

was entered in a field.

● 9.2 Date of this report (i) 05-10-2021 (DD-MM-YYYY)

● 9.3 Date of this report validity check. Check successful: No

(!) Date of this report cannot be prior to date of pre-registration report.

Figure 10.3: Unsuccessful check example

● 1.1 Consent to sharing data with EBMT? No ▼

(X) Informed consent not signed, no further data entry should be performed.

Figure 10.4: Automated validation example

CHAPTER 11

Audit Trail

In Castor, all actions are registered in the audit trail, accompanied by the type of action, the user responsible for it, and the date and record ID. Changes to the system are captured in the audit trail as well. The audit trail is only visible to study administrators. Figure 11.1 shows an overview of the Audit trail.

Filter on event type:

Filter on user:

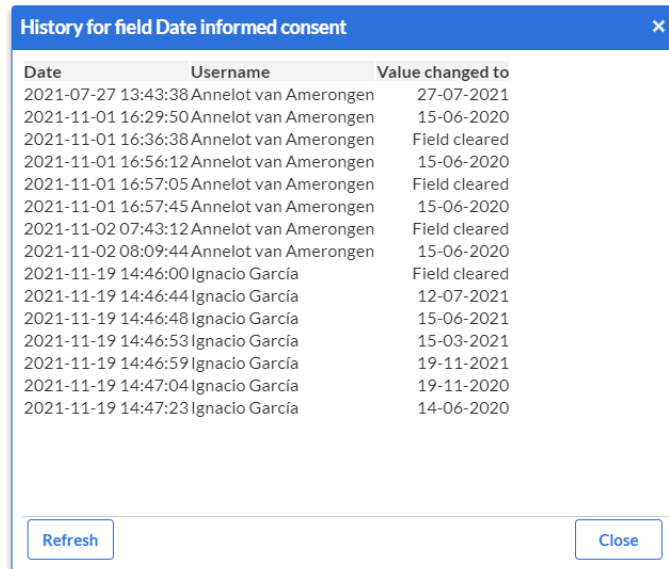
Filter on secondary information:

Username	Event type	Date	Record id	Primary information	Secondary information
Ignacio García (ignacio.garcía@...)	Audit trail viewed	2021-11-19 16:06:54			
Ignacio García (ignacio.garcía@...)	Record opened	2021-11-19 16:05:32	110005		
Name		Value			
Created By	Annelot van Amerongen (annelot.vanamerongen@ebmt.org)				
Created On	2021-11-01T16:19:12+0100				
Institute Id	European Bone Marrow Transplant Association				
Last Opened Step	E2C87F86-111C-4AE3-BBA0-916975E760E2				
Next Phase Visit					
Record Id	110005				
Status	open				
Updated By	Ignacio García (ignacio.garcía@ebmt.org)				
Updated On	2021-11-19T14:47:23+0100				
Ignacio García (ignacio.garcía@...)	Record opened	2021-11-19 16:05:31	110005		
Ignacio García (ignacio.garcía@...)	Study opened	2021-11-19 16:05:28			

Figure 11.1: Overview of Castor's Audit Trail

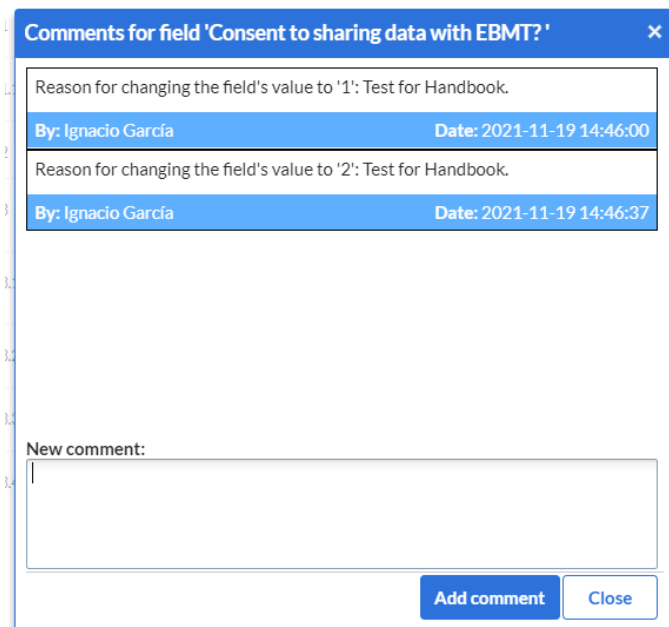
Additionally, the history of changes can be seen per item by clicking the cogwheel and selecting **History** as seen in figures 11.2, 11.3. Figure 11.2 shows what is displayed in a field where no comments were added for the changes. Figure 11.3 shows the history of changes on a field where reasons for change were added. This functionality is available for all users. In the Cellular Therapy study, it is mandatory to justify all changes in English.

11. Audit Trail



Date	Username	Value changed to
2021-07-27 13:43:38	Annelot van Amerongen	27-07-2021
2021-11-01 16:29:50	Annelot van Amerongen	15-06-2020
2021-11-01 16:36:38	Annelot van Amerongen	Field cleared
2021-11-01 16:56:12	Annelot van Amerongen	15-06-2020
2021-11-01 16:57:05	Annelot van Amerongen	Field cleared
2021-11-01 16:57:45	Annelot van Amerongen	15-06-2020
2021-11-02 07:43:12	Annelot van Amerongen	Field cleared
2021-11-02 08:09:44	Annelot van Amerongen	15-06-2020
2021-11-19 14:46:00	Ignacio García	Field cleared
2021-11-19 14:46:44	Ignacio García	12-07-2021
2021-11-19 14:46:48	Ignacio García	15-06-2021
2021-11-19 14:46:53	Ignacio García	15-03-2021
2021-11-19 14:46:59	Ignacio García	19-11-2021
2021-11-19 14:47:04	Ignacio García	19-11-2020
2021-11-19 14:47:23	Ignacio García	14-06-2020

Figure 11.2: Field History of changes



Reason for changing the field's value to '1': Test for Handbook.

By: Ignacio García Date: 2021-11-19 14:46:00

Reason for changing the field's value to '2': Test for Handbook.

By: Ignacio García Date: 2021-11-19 14:46:37

New comment:

Figure 11.3: Field History of reasons for change

CHAPTER 12

Data Entry Process

The starting point for data entry in Castor is the **Participant** section, as described in chapter 7.

12.1 Participant creation

A patient or participant should be registered in ProMISe before entering into Castor.

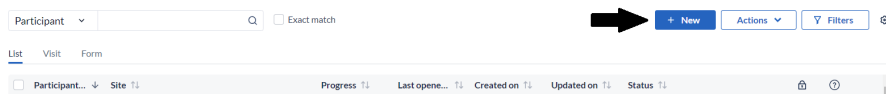


Figure 12.1: Participant creation

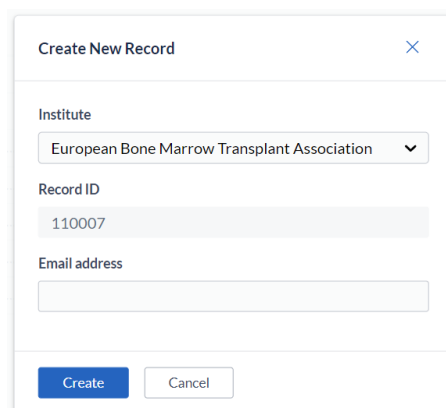
To create a new patient, click the blue button saying **+ New** that is visible on the right side above the participants table, as seen in figure 12.1. A pop-up will open, showing the institute the patient will belong to, the auto-generated participant ID, and a field for email address (figure 12.2). The e-mail address must be left empty and nothing should be changed in this popup. Click **Create**.

This will open the data entry fields for the newly created patients, as seen in figure 12.3. The ProMISe center number (CIC) and EBMT (ProMISe) unique identification code need to be entered in the **Patient data** form.

12.2 Filtering

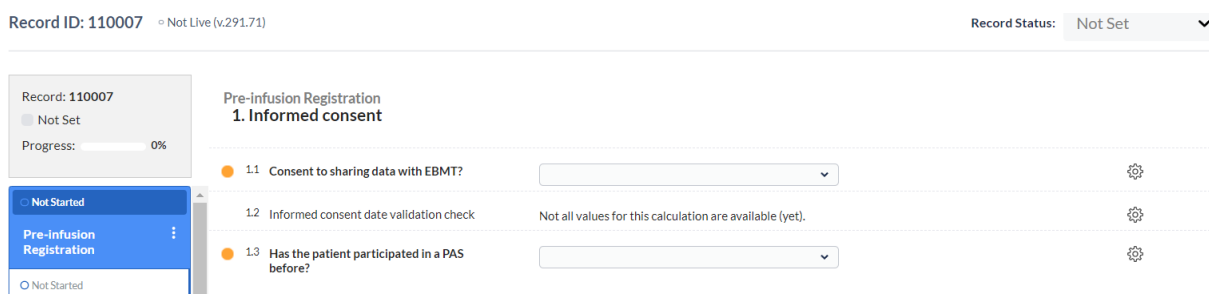
To open an existing patient, select the patient from the **Participant** section. This can be done by scrolling through the participants or by filtering, using the search bar on the left above the participants table (figure 12.4). To search for a patient using the EBMT patient number, select *EBMT Unique Identification Code* from the list. Searching based on the date of birth, hospital unique patient number, or any other variable is possible too.

12. Data Entry Process



A dialog box titled "Create New Record" with a close button (X) in the top right corner. It contains three input fields: "Institute" with a dropdown menu showing "European Bone Marrow Transplant Association", "Record ID" with the value "110007", and "Email address" which is empty. At the bottom, there are two buttons: "Create" (blue) and "Cancel" (white).

Figure 12.2: Participant creation confirmation



The screen shows the data entry interface for Record ID: 110007. At the top, it says "Record ID: 110007" and "Not Live (v.291.71)". On the right, "Record Status: Not Set" is shown with a dropdown arrow. On the left, a sidebar shows a progress bar for "Record: 110007" which is "Not Set" and "Progress: 0%". Below this, a list of visits is shown: "Not Started", "Pre-infusion Registration" (selected in blue), and "Not Started". The main area is titled "Pre-infusion Registration" and "1. Informed consent". It contains three assessment items: "1.1 Consent to sharing data with EBMT?" with a dropdown menu, "1.2 Informed consent date validation check" with the text "Not all values for this calculation are available (yet).", and "1.3 Has the patient participated in a PAS before?" with a dropdown menu. Each item has a gear icon for settings.

Figure 12.3: Data Entry start



A toolbar for filtering participants. It includes a "Record" dropdown menu, a search input field, an "Exact match" checkbox, a "+ New" button, an "Actions" dropdown menu, and a "Filters" button with a gear icon.

Figure 12.4: Filtering options in the Participants tab

12.3 Updating Participants

Adding data to existing patients can be done for the following reasons:

- New data was made available to update fields from previous assessments, or needs to be clarified after a query;
- A follow-up assessment was performed and can be added to the patient's participant.

Updating Data

Open the patient using the participant locator (see section 12.2).

The patient participant will open at the last step that was entered. The assessment that needs to be updated can be selected from the blue coloured visits, which open the forms as seen in figure 9.2, chapter 9. Select the form

from the visit to be updated. Change the value of the field of interest, this will trigger a pop-up, asking to confirm that the participant should be changed and provide a reason as in figure 12.5.

A reason for changing the data is required before continuing. A logical and valid explanation for changing the data should be entered, for example 'lab reports from other hospital were sent' or 'a mistake was made in entering the data'. Explanations should be written **exclusively** in English.

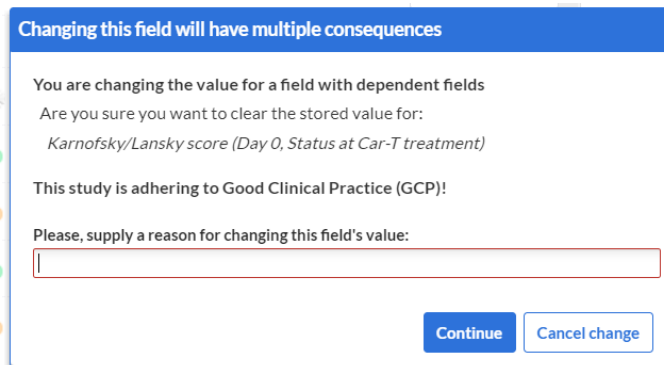


Figure 12.5: Change confirmation

After the change is confirmed and explained, the data can be updated.

14.4 Manipulation

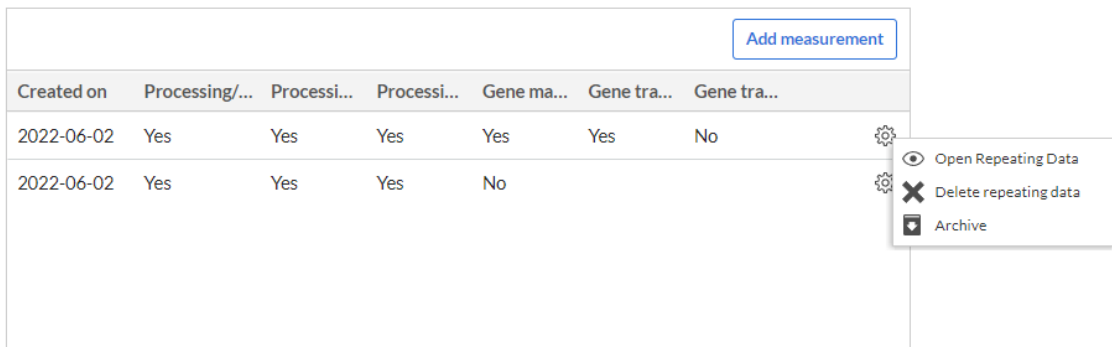


Figure 12.6: Repeating Data table overview

If the data that needs to be updated is in a table, the process is the same. After opening the form containing the table, clicking on the cogwheel at the right of the table row that needs updating will display the options seen in figure 12.6. Selecting open **Repeating data**, will redirect you to the report where you can perform the necessary changes. On the other hand, adding a new measurement would be as simple as clicking on the **Add measurement** button at the top of the table.

Follow Ups

Open the patient using the participant locator (see section 12.2).

The patient participant will open at the last form that was entered. In order to enter data for the *Day 100 Follow up* and the *6 Months Follow up*, clicking on the visits associated with those follow ups on the navigation bar to the left of the Data Entry screen is enough as seen in figure 12.7. However, the *Annual Follow up* works differently.

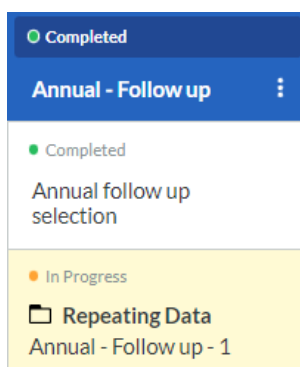


Figure 12.7: Phases available to fill

As *Annual Follow ups* can happen a different number of times based on the patient and the duration of the data collection process, normal phases and steps are not enough. In order to be able to generate as many *Annual Follow ups* as we may need, we use the **Repeating data**.

In order to create an *Annual Follow up* report, you need to select **Annual - Follow up** from the left tab on the Data Entry screen and click on the button that will appear, **Add annual follow up to the patient** (Figure 12.8).

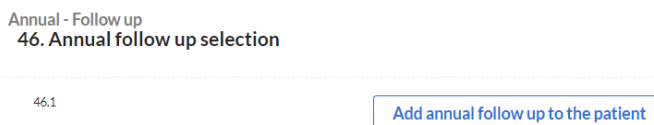


Figure 12.8: Add Annual Repeating Data screen

All the *Annual Follow ups* associated with a patient will appear as in figure 12.9.

Repeating Data

As seen throughout this document, **Repeating data** can be used for different purposes on Castor EDC. In order to have an overview of all the **Repeating data** (*Annual Follow ups*, *Tables*, and *Death reports*) associated with

12.4. Adding second treatments to a Participant

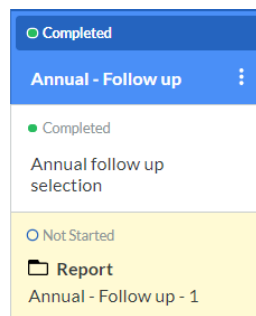


Figure 12.9: Annual Follow up report in Data Entry screen

a participant, you can access the **Repeating Data** tab. In the participant section (figure 12.10), after selecting a participant, we can see different options available on the left menu such as **Study** and **Repeating Data**.

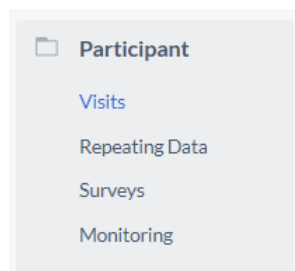


Figure 12.10: Participant Section options

By clicking on **Repeating Data**, the platform will redirect to the **Repeating data** tab, as seen in figure 12.11. In this tab, filters can be performed as in the **Participant** section to find the report you are looking for, such as measurement tables, the *Death report*, or a particular *Annual Follow-up* associated to that patient.

12.4 Adding second treatments to a Participant

Adding a second treatment directly to an existing participant is not possible in Castor. As one treatment comprises all the implemented forms, in order to register a second treatment for a patient it is necessary to create a new participant in the system. This new participant is filled with the same information in the **Patient Information** section as the original participant. The rest of the forms are filled with the information of the new treatment.

As a result, there would be *two* participants that represent the same patient in the platform, one for each treatment. The data and the two participants can be matched easily based on the **Patient Information** and each cellular therapy treatment can be differentiated based on milestone dates of the treatment such

12. Data Entry Process

Status	Repeating Data	Name	Type	Created on	Created by	Assigned to	
●	Annual - Follow up	Annual - Follow up - 1	Unscheduled visit	2022-05-31 10:43:53	Ignacio García	Annual - Follow up	⚙️
●	Cellular Therapy Infusion ...	Cellular Therapy Infusion ...	Repeated measure	2022-06-02 14:19:25	Ignacio García	Day 0	⚙️
●	Cellular Therapy Infusion ...	Cellular Therapy Infusion ...	Repeated measure	2022-06-02 14:19:44	Ignacio García	Day 0	⚙️
●	Post therapy treatment - ...	Post therapy treatment - ...	Repeated measure	2022-05-19 15:24:12	Ignacio García	Day 100 - Follow up	⚙️

Figure 12.11: Repeating Data section overview

as date of cell collection or cell infusion. This procedure can be repeated as many times as needed based on the amount of treatments for the patient.

CHAPTER 13

Query system

EBMT data managers and monitors will be able to add queries to data entered into Castor. A notification showing there is a query will be visible in the last column of the record section table if it is on list view, or at the applicable phase or step if the record section is set to those views.

If a query is added to an item, a red circle with a question mark will appear next to it. By clicking this, the query will become visible. If the query is added, it will be shown as 'New'. If the query is opened by the center, it will change to 'Open'.

11.3 Patient weight at cellular therapy (kg)

40



Figure 13.1: Query view from Data Entry perspective

A query can have the following statuses:

1. **New:** the query has been added, but not is not opened yet
2. **Open:** an EBMT data manager or monitor has added a query, and the center opened the query
3. **Unconfirmed:** the center does not agree with the query
4. **Confirmed:** the center agrees with the query and will update the field
5. **Resolved:** the center agreed with the query and updated the field appropriately
6. **Closed:** the EBMT data manager or monitor has seen the updated field and agrees, or accepts the 'unconfirmed' response from the center.

13. Query system

A query status can be updated by selecting the new status from the drop down menu, adding a remark (not mandatory but highly encouraged) and clicking the blue **Update** button (see figure 13.2). Monitors can see the queries and their statuses on the **Monitoring > Queries** page. A separate manual for monitors is available.

Queries for field Patient weight at cellular therapy (kg) [X]

Current query status: ? Open

Change status to: Open [v]

Remarks:

This combination of height and weight does not match.

By: Ignacio García Date: 2021-10-28 18:05:04

New Remark:

[Text Area]

[Update] [Close]

Figure 13.2: Query options

CHAPTER 14

Data Export

Data can be exported from the **Participant** section. The patients that need to be exported can be selected using the tick boxes before the **Participant ID**. After selecting the patients for export, click the **Actions** button on the top right corner above the table, and select **Export selected**, **Export all**, or **Export filtered** depending on the goal.

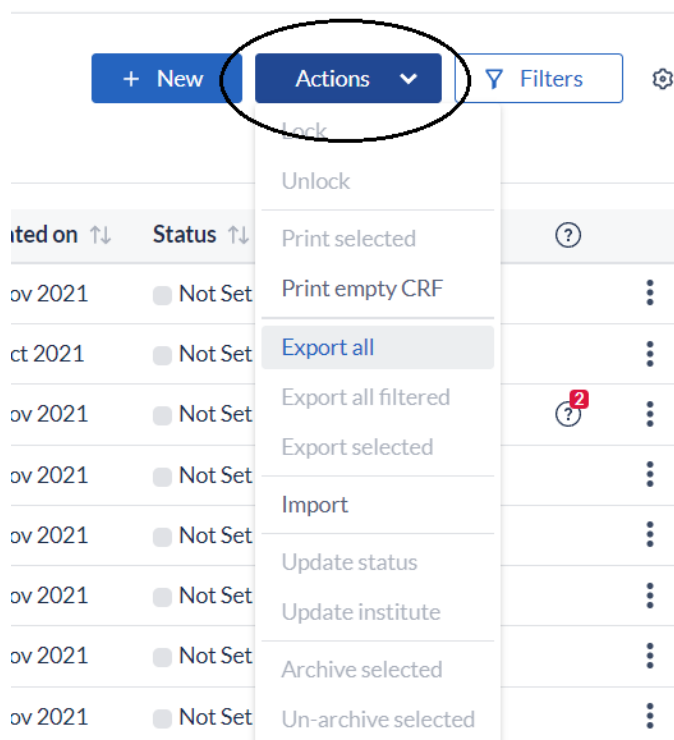
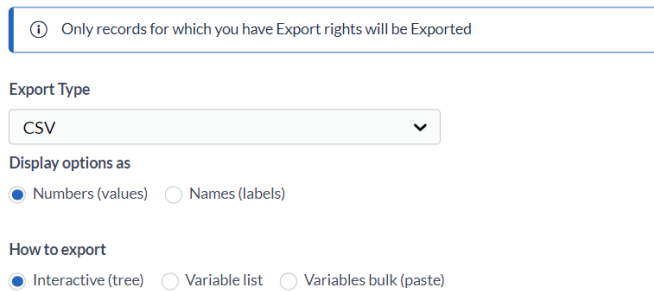


Figure 14.1: Export selection in Participants tab

A pop-up window will appear as shown in figure 14.2, where the details of the export can be specified. Exports can be performed in CSV, Excel, or SPSS format. The option *Upload files* is not applicable for this study. Furthermore,

14. Data Export

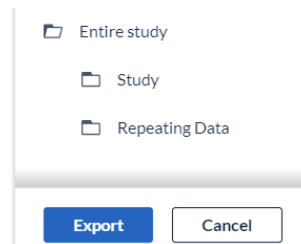
you can select whether the data should be exported using the labels of the fields or the values. In addition to that, you can select the variables you want to export by selecting or by writing its names of the text field.



The screenshot shows a dialog box for data export options. At the top, there is a warning icon and the text "Only records for which you have Export rights will be Exported". Below this, the "Export Type" is set to "CSV" in a dropdown menu. Under "Display options as", the "Numbers (values)" radio button is selected, with "Names (labels)" as an alternative. Under "How to export", the "Interactive (tree)" radio button is selected, with "Variable list" and "Variables bulk (paste)" as other options.

Figure 14.2: Different export options

Once you have selected the desired output and variables from the study, you can select which sections of the study you want to download. You can select up to *Form* level.



The screenshot shows a dialog box titled "Scope of the export". It contains a list of folders: "Entire study", "Study", and "Repeating Data". At the bottom, there are two buttons: "Export" (highlighted in blue) and "Cancel".

Figure 14.3: Scope of the export

In figure 14.4 you can see an example of CSV download selecting the *Entire Study* option. The default export includes all the repeating data (tables) available, as well as visits and forms. Moreover, it adds a data dictionary, queries, comments, and verifications.

The image is a screenshot of a file listing interface. It shows a vertical list of 15 CSV files. Each file name is preceded by a small blue icon that resembles a document with a magnifying glass. The file names are: Cellular_Therapy_data_collection_Annual_-_Follow_up_export_20220422.csv, Cellular_Therapy_data_collection_Cell_infusion_episode_export_20220422.csv, Cellular_Therapy_data_collection_Cell_therapy_infusion_unit(s)_export_20220422.csv, Cellular_Therapy_data_collection_Cellular_Therapy_Infusion_Unit_-_Manipulation_export_20220422.csv, Cellular_Therapy_data_collection_export_20220422.csv, Cellular_Therapy_data_collection_Patient_Preparative_Treatment_export_20220422.csv, Cellular_Therapy_data_collection_Post_therapy_treatment_export_20220422.csv, comments.csv, custom_verifications.csv, field_options.csv, report_variablelist.csv, source_data_verification_steps.csv, study_Cellular_Therapy_data_collection_queries.csv, and study_variablelist.csv.

Cellular_Therapy_data_collection_Annual_-_Follow_up_export_20220422.csv
Cellular_Therapy_data_collection_Cell_infusion_episode_export_20220422.csv
Cellular_Therapy_data_collection_Cell_therapy_infusion_unit(s)_export_20220422.csv
Cellular_Therapy_data_collection_Cellular_Therapy_Infusion_Unit_-_Manipulation_export_20220422.csv
Cellular_Therapy_data_collection_export_20220422.csv
Cellular_Therapy_data_collection_Patient_Preparative_Treatment_export_20220422.csv
Cellular_Therapy_data_collection_Post_therapy_treatment_export_20220422.csv
comments.csv
custom_verifications.csv
field_options.csv
report_variablelist.csv
source_data_verification_steps.csv
study_Cellular_Therapy_data_collection_queries.csv
study_variablelist.csv

Figure 14.4: CSV download file overview

