

Cellular Therapy

Data collection handbook for Castor EDC

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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.

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.

Data Structure

Studies in Castor are organised in **phases**, **steps** and **reports** as illustrated in figure 3.1.

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



Figure 3.1: Castor structures

The Cellular Therapy study in Castor EDC is composed of the **phases** *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* and *Subsequent HSCT* still need to be reported on ProMISe.

3. Data Structure

Reports are specific sets of questions that can be nested in steps or exist independently and allow iteration. These are associated to a patient directly, or through a **step**. A patient record can have multiple **reports**.

At the moment, the following reports are 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 a **report**, as this needs to be filled in for every year a follow-up assessment with the patient has been performed, iteration is required. The *Death report* in the cellular therapy database is independent of the **phases**, as this can happen any time. Once a *Death report* has been filled, any new data entry is discouraged.

Account creation

An account for Castor can be created after receiving an invitation to do so (see figure 4.1). 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.

🧿 castor.

Hello,

You have been invited by Ignacio García to join Castor EDC, the electronic data capture platform. This concerns data collection for the Car T Main study. Please follow this link to complete your account registration.

Figure 4.1: 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.

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 4.2

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.

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

4. Account creation

			Two-factor authentication $\qquad imes \qquad$ activation
6 castor		Two-factor authentication $\qquad imes$ activation	Step 2 Scan the QR code or enter the following code:
grastor	윪 Structure	Step 1	ED:0000000
Studies	Forms	Open an authenticator app on your mobile phone	
Account ·	Settings	You may need to download an authenticator	
		or Microsoft Authenticator first.	
		Cancel Start	23 .8973
			Back Continue

Figure 4.2: Process to activate Two-Factor Authentication

After a successful login, the user should be able to see the Cellular Therapy study as per figure 4.3.

Live Cellular Therapy data collection

Linked Multicenter EU Server

Figure 4.3: Studies Overview

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.
- 3. **Data Entry**: Data managers from centers 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.

Administrator	Data Manager	Data Entry	Monitor
 Add View Edit Email Sign Lock Verify Query Archive Export Surveys 	 View Edit Sign Lock Query Export 	 Add View Edit Export 	ViewVerifyQuery

Table 5.1: Role capabilities overview

Login

To log in to Castor, go to https://data.castoredc.com/. 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.

Log in	Netherlands					
Email						
Password	Forgotten your password?					
â Log in	Remember me					

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).

Live Cellular Therapy data collection

Linked Multicenter EU Server

Figure 6.2: Study for Cellular Therapy data collection

Record Section

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

Re	cord 🗸	C	Exact match			+ New A	ctions 🗸	∇ Filters	٢
List	Phase Ste	ер							
	Record ID $\ \downarrow$	Institute 1	Progress ↑↓	Last opene ↑↓	Created on $\uparrow\downarrow$	Updated on $ \uparrow \downarrow $	Status ↑↓	⋳	Â
	000001	ZSIS Universitaetsklinikum Knappscl	naftskrankenha	Ignacio García	07 Feb 2022	16 Mar 2022	Not Set	⋳	:
	000002	ZSIS Universitaetsklinikum Knappscl	naftskrankenha	Ignacio García	07 Feb 2022	16 Mar 2022	Not Set	⋳	:

Figure 7.1: Castor Record 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 records using the tick boxes, or selecting all records using the tick box in the header of the table, after which records can be downloaded (See chapter 14).

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

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

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

7. Record Section

List	Phase	Step					
	Record ID	Institute	Pre-infusion Regist	Day 0	Day 100 - Follow up	6 Months - Follow	Annual - Follow
	000003-1	Test Institute					
	000004	Test Institute				-	
	110002	European Bo	n				
	110003	European Bo	n				
	110004	European Bo	n		_		
	110005	European Bo	n				

Figure 7.2: Castor Record phase view (With dummy patients and centre)

List	Phase	Step								
	Record ID	Institu	ite l	nformed consent	Centre identificati	Patient data	Indication for Cell	Basic CT informati	Donor	Infusion u
	000003-1	Test In	stitute							
	000004	Test In	stitute			_				
	110002	Europ	ean Bon	sDy		sby		SDW,	soy	
	110003	Europ	ean Bon		_					
	110004	Europ	ean Bon							
	110005	Europ	ean Bon							_
	110006	Europ	ean Bon							
•										×

Figure 7.3: Castor Record step view (With dummy patients and centre)

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.
- 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.
- 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 is unknown, it is suggested to select June as it is the middle of the year. 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 reports associated to steps as repeated measurements. 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.
- 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.

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

e 12.1.14	Peptic ulcer requiring treatment	()	•	
12.1.15	Psychiatric disturbance	()	No 🗸	
12.1.16	Specify other additional major clinical abnormalities not listed above and present prior to the preparative regimen:			11

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

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) 15-06-2020 (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	()	12-06-2017	•	(DD-MM-YYYY)
11.1.	³ Date of cell infusion validity check		Not all values for this	calo	culation 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	(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 							
S Informed consent not signed, no further data entry should be performed.							

Figure 10.4: Automated validation example

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: All event types	~				Filter on user: Filter on secondary information:	All users	*
Username	Event type	Date 👻	Record id	Primary information	Secondar	y information	
Ignacio García (ignacio.garcia@	Audit trail viewed	2021-11-19 16:06:54					^
∃ Ignacio García (ignacio.garcia@	Record opened	2021-11-19 16:05:32	110005				
Name	Value						
Created By	Annelot van Ameronge	n (annelot.vanamerongen@	@ebmt.org)				
Created On	2021-11-01T16:19:12	+0100					
Institute Id	European Bone Marrov	w Transplant Association					
Last Opened Step	E2C87F86-111C-4AE3	3-BBA0-916975E760E2					
Next Phase Visit							
Record Id	110005						
Status	open						
Updated By Ignacio García (ignac		.garcia@ebmt.org)					
Updated On 2021-11-19T14:47:2		+0100					
Ignacio García (ignacio.garcia@	Record opened	2021-11-19 16:05:31	110005				
Ignacio García (ignacio.garcia@	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.

History for fi	eld Date informed consent		×
Date	Username	Value changed to	
2021-07-27 1	13:43:38 Annelot van Ameronger	27-07-2021	
2021-11-011	16:29:50 Annelot van Ameronger	15-06-2020	
2021-11-011	16:36:38 Annelot van Ameronger	 Field cleared 	
2021-11-011	16:56:12 Annelot van Ameronger	15-06-2020	
2021-11-011	16:57:05 Annelot van Ameronger	 Field cleared 	
2021-11-011	16:57:45 Annelot van Ameronger	15-06-2020	
2021-11-020	07:43:12 Annelot van Ameronger	 Field cleared 	
2021-11-020	08:09:44 Annelot van Ameronger	15-06-2020	
2021-11-191	14:46:00 Ignacio García	Field cleared	
2021-11-191	14:46:44 Ignacio García	12-07-2021	
2021-11-191	14:46:48 Ignacio García	15-06-2021	
2021-11-191	14:46:53 Ignacio García	15-03-2021	
2021-11-191	14:46:59 Ignacio García	19-11-2021	
2021-11-191	14:47:04 Ignacio García	19-11-2020	
2021-11-191	14:47:23 Ignacio García	14-06-2020	
Refresh			Close

Figure 11.2: Field History of changes

Comments for field 'Consent to sha	aring data with EBMT?'
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:	
I	

Figure 11.3: Field History of reasons for change

Data Entry Process

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

12.1 Record creation

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

Record 🗸	Q Exact match	+ New Action	ns 🕶 🛛 🍸 Filters 💿
List Phase Step			
$\begin{tabular}{ccc} Record ID \ \psi & Institute \ \uparrow \downarrow \end{tabular}$	Progress $\uparrow \downarrow$ Last opene $\uparrow \downarrow$ Created by	↑↓ Created on ↑↓ Updated on ↑↓ Status ↑↓	d (7)

Figure 12.1: Record creation

To create a new patient, click the blue button saying **+ New** that is visible on the right side above the records table, as seen in figure 12.1. A pop-up will open, showing the institute the patient will belong to, the auto-generated record 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** step.

12.2 Filtering

To open an existing patient, select the patient from the **Record** section. This can be done by scrolling through the records or by filtering, using the search bar on the left above the records 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

Institute		
European Bo	one Marrow Transplant Association	~
Record ID		
110007		
Email address		



Record ID: 110007 • Not	Live (v.291.71)			Record Status:	Not Set 🗸
Record: 110007 Not Set Progress: 0%	Pre-infusion Registration 1. Informed consent				
11081035.	1.1 Consent to sharing data with EBMT?		~		Ś
O Not Started	1.2 Informed consent date validation check	Not all values for this calculation are available (ye	t).		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
Pre-infusion : Registration	 1.3 Has the patient participated in a PAS before? 		•		୍ଦିତ
O Not Started	Figure 1	2.3: Data Entry start	+ Nour		
Record 🗸	Q Exact match		+ New	Actions ♥	٢

Figure 12.4: Filtering options in the Records tab

12.3 Updating Records

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 record.

Updating Data

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

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

phase to be updated. Change the value of the field of interest, this will trigger a pop-up, asking to confirm that the record 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 in English.

Changing this field will have multiple consequences						
You are changing the value for a field with dependent fields						
Are you sure you want to clear the stored value for:						
Karnofsky/Lansky score (Day 0, Status at Car-T treatment)						
This study is adhering to Good Clinical Practice (GCP)!						
Please, supply a reason for changing this field's value:						
Continue Cancel change						

Figure 12.5: Change confirmation

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

15.2 Cell infus	ion episodes							
						Add mea	surement	
Created on	Date of ce	Date of ce	Where w	Where w	Person in	Route of i		
2021-10	23-10-20	Check suc					503	
							×	Open report Delete report
							₽	Archive report

Figure 12.6: Report table overview

If the data that needs to be updated is in a table, the process is the same. After opening the step containing the table, clicking on the cogwheel at the right of the table you need to amend will display the options seen in figure 12.6. Selecting open report, 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 record locator (see section 12.2).

The patient record will open at the last step that was entered. In order to enter data for the *Day 100 Follow up* and the *6 Months Follow up*, clicking on the steps 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.

O Not Started	
Pre-infusion Registration	
O Not Started	
Day 0	
O Not Started	
Day 100 - Follow up	
O Not Started	
6 Months - Follow up	
O Completed	
Annual - Follow up	

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 reports.

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).

Annual - Follow up 46. Annual follow up selection	
46.1	

Figure 12.8: Add Annual Report screen

Add annual follow up to the patient



Figure 12.9: Annual Follow up report in Data Entry screen

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

Reports

As seen throughout this document, reports are used for different purposes on Castor EDC. In order to have an overview of all the reports (*Annual Follow ups, Tables*, and *Death Reports*) associated with a record, you can access the **Report** tab. In the record section (figure 12.10), after selecting a record, we can see different options available on the left menu such as **Study** and **Reports**.

Record
Study
Reports
Surveys
Monitoring

Figure 12.10: Record Section options

By clicking on **Reports**, we will be redirected to the **Report** tab, as seen in figure 12.11. In this tab, filters can be performed as in the **Record** 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. Data Entry Process

All reports							
Filter by repor Select report t Filter by name	rt type: ype to filter	Filter by report: Select report to filter Filter by phase: Select phase to filter	Filter by status: Unarchived	Y			Add a report
Status	Report 🔺	Name	Туре	Created on	Created by	Assigned to	
0	Annual - Follow up	Annual - Follow up - 1	Unscheduled phase	2021-11-02 11:05:49	Annelot van Amer	Annual - Follow up	ŝ
•	Cell infusion episo	de Cell infusion episode	Repeated measure	2021-10-24 18:34:46	Ignacio García	Day 0	\$ <u>0</u> ;
•	Cell therapy infusion	on Cell therapy infusion	Repeated measure	2021-10-27 15:51:44	Ignacio García	Day 0	ŝ

Figure 12.11: Report section overview

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	ξ.) } ?	Ð

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)					
	Current query status: (?) Open					
5	Change status to: Open 🗸					
	Remarks:					
	This combination of height and weight does not match.					
1	By: Ignacio García Date: 2021-10-28 18:05:04					
1						
2						
2						
3						
4						
5						
	New Remark:					
-	Update Close					

Figure 13.2: Query options

Data Export

Data can be exported from the **Record** section. The patients that need to be exported can be selected using the tick boxes before the **Record 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.

-	+ New	Actions 🗸 🕥 🏹	7 Filters	¢
		Lock		
		Unlock		
ited on ↑↓	Status ↑↓	Print selected	?	
ov 2021	Not Set	Print empty CRF		:
ct 2021	Not Set	Export all		:
ov 2021	Not Set	Export all filtered	?	:
ov 2021	Not Set	Export selected		:
ov 2021	Not Set	Import		:
ov 2021	Not Set	Update status Update institute		:
ov 2021	Not Set	Archive selected		:
ov 2021	Not Set	Un-archive selected		:

Figure 14.1: Export selection in Records 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.

(i) Only records f	or which you have Export rights will be Expo
Export Type	
CSV	~
Display options as	
Numbers (values)	 Names (labels)
How to export	
 Interactive (tree) 	Variable list Variables bulk (paste

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 *Step* level.

🗖 Entire study			
🗅 Study			
Reports			
Export	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 reports (tables) available, as well as phases and steps. Moreover, it adds a data dictionary, queries, comments, and verifications.

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
- a comments.csv
- 3 custom_verifications.csv
- ঌ 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