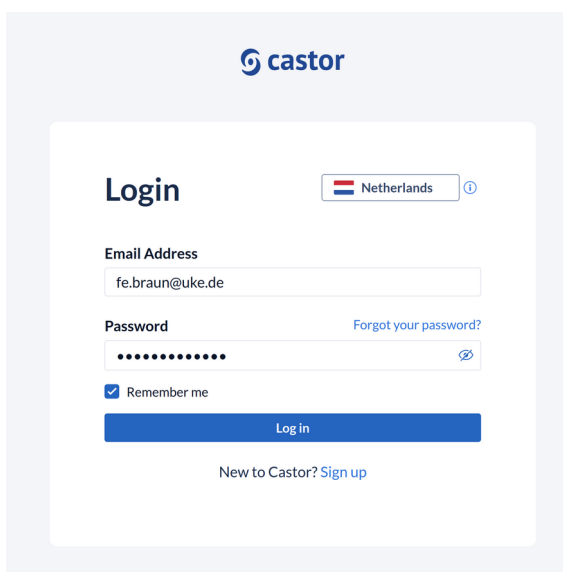# Protocol R-Liver Introduction – Process of introducing new participants

Login

For Login you'll need an account on data.castoredc.com. When registering, please choose the Netherlands as your region. Proceed with you login credentials:
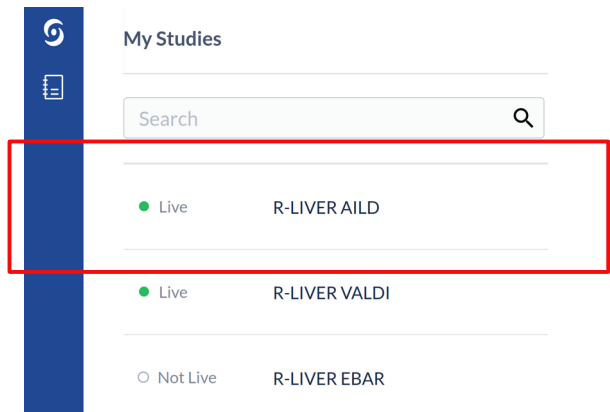

Registries

After login you'll get to choose from a list of registries you're invited to. The registries currently offered by R-LIVER are:

1. R-LIVER AILD: Autoimmune and polycystic liver diseases (AIH, PBC, PSC, PLD)
2. R-LIVER VALDI: Vascular liver diseases (PVT, BCS, NCPIH, SOS and others)
3. R-LIVER EBAR: Biliary Atresia

Depending on your interests and specializations, you may choose which registries you want to contribute to. Please provide us a list of e-mail addresses of your colleagues and the registries they should be invited to and we'll add them accordingly. This introduction will mainly cover the autoimmune liver disease registry AILD. Additional introductions for the other registries might follow. However, many points made in this introduction apply to all Castor registers.

Structure

The registries in castor are structured in Participants, Repeating Data and Surveys. In AILD, there are only follow-up reports to provide. The other registries offer additional reports to be collected for specific examinations.
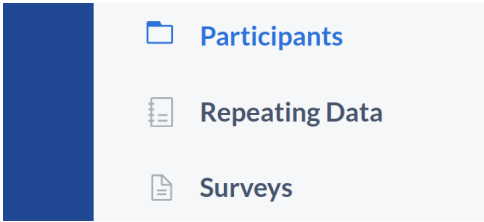
AILD is a prospective registry. Please only include patients with a relevant diagnosis no older than 12 months. For each patient create a new participant. The Participant ID will be assigned automatically and consists of a 2-letter country code, a 3-letter center code and a 5-digit number. Please only provide an e-mail address if the patient has signed a contact consent. For the use of the mobile application, which is currently under development, the e-mail address is mandatory. If you accidentally create a participant, please reuse it for your next patient as the Participant ID would go to waste otherwise.

AILD is structured in:

Patient population

Basic information about the patient such as his/her demographics are recorded here. For internal reference, a pseudonym can be entered here as well. It will not be shared with third parties in data exports used for scientific research. The list of participants can be filtered by individual fields such as the pseudonym, giving you quick access to all your cases.

Patient population
1. Base information

● 1.1 Pseudonym   ⓘ   ABCDEF

Diagnosis

The baseline data. It contains diagnostic information as well as examination reports and treatment at first onsite. If there's an overlapping autoimmune diagnosis such as AIH/PBC or AIH/PSC, please enter PBC or PSC as initial and AIH as additional diagnosis. If a AIH patient is later on diagnosed with PBC or PSC, it can be added in a follow-up report.

Participant: NA-TES_00003

Not Set

Progress: 3%

● In Progress

Patient population   ⋮

○ Not Started

Diagnosis   ⋮

○ Not Started

6 months follow-up   ⋮

● Completed

Yearly follow-up   ⋮

○ Not Started

End of Study   ⋮

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6 months follow-up

For all AIH patients a 6 months (+/- 12 weeks) follow-up visit should be scheduled. For the most part, the data entered here mirrors the baseline data.

Yearly follow-up

A follow-up report is expected every 12 months (+/- 3 months) for all autoimmune liver disease patients. A new report can be created by the click of a button:

Yearly follow-up
17. Add follow-up report

17.1   **Add follow-up**

The default name proposed by Castor is not mandatory and can be changed. There's no naming convention for the follow-up reports. We recommend something reflecting the yearly follow up structure like:

**Add a repeating data instance to participant NA-TES_00003**   ✕

Repeating data: Yearly follow-up

Custom name: ⓘ   1st yearly follow-up 2023

Attach to: Visit 4. Yearly follow-up

Create   Cancel

If an follow-up report is created on accident, please don't leave it empty and archive it right away. Before archiving, be sure to rename the report and add a prefix like "archived - <report name>". Castor does not allow for any differentiation between archived and valid follow-up reports in data exports, hence the effort. Options for renaming (Edit repeating data) and archiving (Archive repeating data) can be found in the Repeating Data list on the right:
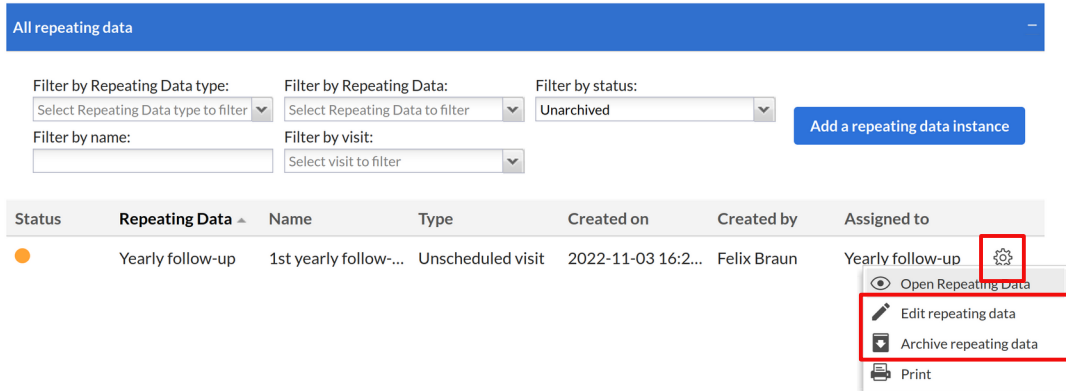
Similar to the 6 months follow-up, the yearly follow-up is intended to mirror the baseline data as far as applicable.

End of study

If the study ends for a patient, this is the last data sheet to be filled out. Criteria for termination are:

1. Liver transplantation
2. Death
3. Lost in follow-up
4. Opted-out
5. Other

It's up to you to choose when a patient is lost in follow-up. We recommend to consider him/her gone after 2-3 years. If a patient specifically asks for his/her data to be deleted, please send an informal request to ern.rareliver@uke.de. The data manager will then delete the data shortly.

Quality

Castor

To measure and evaluate data quality, a set of required data fields is defined within the collected fields. In Castor, required data fields can be identified by their bold lettering. Castor also has a built-in quality assurance feature checking the completeness and validity of the data. It highlights missing required fields in orange and ill-formatted values (dates, lab report values, etc.) in red. Completed fields are marked green.

If a required field can not be delivered, it should be marked explicitly. This will help the quality control (see section quality reports). To mark a field as missing, select the cog next to the data field, choose "User missing" and state a reason.

The color coding is applied on the structural overview on the left as well. The participant list can be sorted by progress, quickly guiding you to the gaps in your data.

Quality reports

As an additional layer of support, we prepare quality reports quarterly. They are intended to give you an overview of your data and highlight those parts that need your attention. In two separate Excel files, all your cases are listed and possible data gaps, in regard to completeness of required data fields and follow-up reports, are pointed out. An example table, as it can be found in the Excel file on your required data field completeness, is shown below:

record	section	expected	missing	field
NA-TES_00002		62	5	
	Patient population	2	0	
	Diagnosis	30	3	
				Additional signs of NASH?
				Additional signs of NAFLD?
				Type of bile duct affection
	1st yearly follow-up 2020	30	2	
				Bilirubin total
				Creatinine
NA-TES_00003		26	2	
	Patient population	2	0	
	Diagnosis	24	2	
				Height
				Weight

It basically lists all your Participant IDs (**record**) and all the data sheets (**section**) that have been started for this case. It will check how many required data field were expected (**expected**), how many of them weren't provided (**missing**) and the names of the missing data fields (**field**).

For the follow-up completeness reports a different table design is used. An example is shown below:

record	diagnosis	status	expected	found	month of diagnosis	2019	2020	2021	2022
NA-TES_00001	PBC	LostInFollowUp	2	0	02/2019	-	x	x	-
NA-TES_00002	AIH	Alive	3	2	09/2019	-	✓	✓	x
NA-TES_00003	PSC	Dead	1	1	04/2019	-	✓	-	-
NA-TES_00004	PBC	LiverTransplantation	3	2	02/2018	✓	o	x	-

The number of follow-ups expected (**expected**) for each patient (**record**) is determined based on the date of the initial diagnosis (**month of diagnosis**). The status of the patient (**status**) is considered as well and no more follow-ups are expected for closed cases (transplanted, dead, etc.). For each year after diagnosis, a follow-up report is expected (**2019**-**2022**). There are 4 different values to expect in these columns:

- = follow-up not expected

x = expected follow-up missing

✓ = expected follow-up found

o = follow-up found at unexpected date (every 12 months +/- 3 months)