User Guide for R-LIVER

Content

1. Registry Purpose

With the prospective R-Liver registries we aim to collect data and ultimately improve treatment for rare liver diseases within the European Union.

1.2 Populations of Interest

The goal is to include every patient newly presenting to your centre and who is being diagnosed or has received the diagnosis within the past 12 months. Patients of any age (including children), sex or ethnical background presenting with any of the following diseases will be included:

- Autoimmune Hepatitis (AIH)
- Primary Biliary Cholangitis (PBC)
- Primary Sclerosing Cholangitis (PSC)
- Polycystic Liver Disease [*in Quality Criteria Registry only*]

1.3 Data Collection Intervals

To better understand the long-term disease progression, an annual follow-up visit (+/- 3 months) after the initial diagnosis should be scheduled for each patient and recorded in the registry.

Additionally, for AIH patients a one-time 6 months (+/- 6 weeks) follow-up visit should be scheduled and recorded to help investigate the response to initial drug treatment in AIH.

2. Participating in R-LIVER

- Before data can be included into the registry, please provide the data management at UKE with the following documents:

- Data transfer agreement
- Ethics approval
- Local lab reference ranges
- Submit list of authorised personnel for registry access including:
  - Type of registry (research or quality criteria)
  - Name, occupation, email address
- Once the user accounts are created, the listed personnel will receive an email from no-reply@castoredc.com to complete your registration with R-LIVER

3. Access to R-LIVER

- Pseudonymise patient data according to local guidelines
- Login at https://castor.uke.de using the personal account provided by the data management at UKE
- For general questions on how to use Castor, refer to the Castor support pages at https://support.castoredc.com

4. Enter New Patient Record

- To create a new patient record, first select the *All records* Button in the study overview:
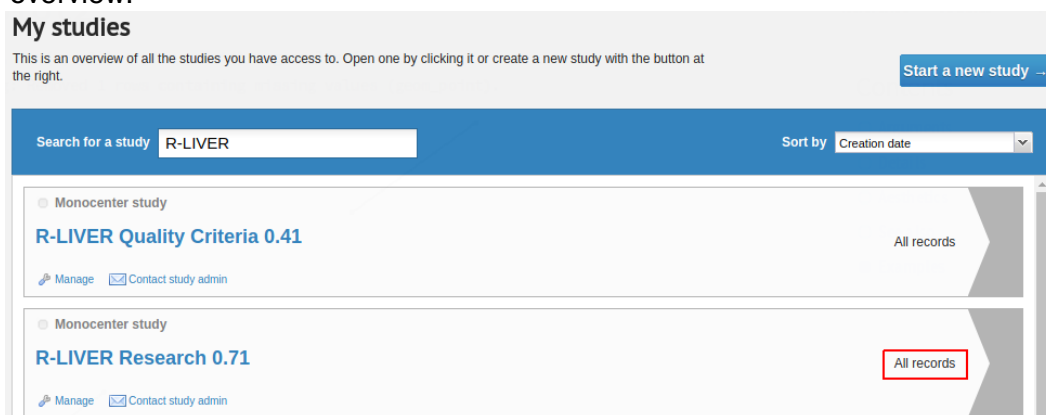
- Click the *Create a new record* button to enter the patient's data
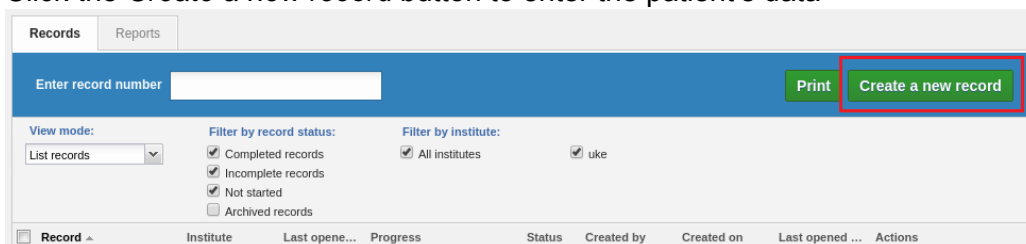
- Use patient's pseudonym as Record ID:
  - Prefix pseudonym with your centre abbreviation, e.g.: DE-UKE_DKSNDFJK
  - **Be extra careful:** The Record ID cannot be changed once created!

- o This step is **important** for data consistency and to prevent pseudonym collisions with other centres
- o You can find the prefix as part of your institute name when creating a new record. Resize the dialogue box by dragging one of its corners to reveal the complete prefix.

- After creating a new patient record, first select which disease population the patient belongs to:

- This will hide all study phases irrelevant to this disease
- Subsequently go through each step of the *Diagnosis* phase and enter the required data:
  - o See section Missing Data on how to handle missing data
  - o Your data is saved as soon as the spinning wheel next to the item disappears

  - o Clicking on the *info* icon reveals additional information on how to code the variable

o   If anything else is unclear, please contact us (see [Contact](#))

5. Enter Follow-up Visit Report

- In order to add a follow-up visit to an existing patient record:
  o   Open the appropriate study
  o   Open the matching patient record
    ▪ The record list can be filtered using the *Enter record number* field (the field filters by s*tarts with…*)

  o   Select the *Follow-up* Phase and click the *Add Follow-up Visit*-Button

  o   Leave the automatically generated custom name

- **Note:** The R-LIVER AIH Research database contains an **additional follow-up visit** six months after diagnosis

6. Missing Data

- If data for any item is missing, use the Castor missing data function:
  o   Click on the cogwheel next to the missing item

o Select an appropriate reason

7. Anonymising Records

Whenever patients request the anonymisation of their records, their entry in the local pseudonymisation database should be deleted, thus anonymising their records in the R-LIVER registries.

8. Removing Records

To remove patient records from the registry:

- Open the Record overview
- Click on the cogwheel next to the record to be deleted and select *Archive this record*

- Archived records do not show up in data exports and are by default filtered in the record overview
- Due to GCP regulations records cannot be deleted entirely

9. Contact

- General castor usage/support: https://www.castoredc.com/contact-us/
- R-LIVER registry related problems: Christian Casar, UKE, c.casar@uke.de

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- Organisational questions: Christoph Schramm, UKE, c.schramm@uke.de

Last updated: 2018-04-16