Road to CERTAIN-LI Version 1.0 | May 2017



Transpl-Ant **INitiative** lver

Cooperative **EuRopeanPaediatric**

CERTAIN-LI FIRST STEPS

TECHNICAL REQUIREMENTS

The registry can be accessed and used with any of the common modern browsers (Internet Explorer, Mozilla Firefox & Google Chrome). The registry team recommends the usage of most recent Google Chrome or Mozilla Firefox versions as they both provide the best user experience during the work with the CERTAIN-LI registry. To access the system just go to https://certainli-registry.kikli.uniheidelberg.de

STEP 1: LOG IN

Type the registry address into the navigation bar of the web-browser of your cho

Enter your credentials into the log-in box and press "Log in" button.

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ENT	ER YOUR CF	EDENTIALS	
Username:			ort
		C	d d
Password:			S
	Log in		

STEP 2: ENTERING THE DATA OF A NEW PATIENT

Now you are logged into the registry application. On the right side, you can find the menu. To start the enrollment process, select **PATIENTS** and then **ENROLLMENT**.

You can enter the patient's data category by category – tab by tab, from left to right. Please ensure that all mandatory attributes are entered. Mandatory attributes are in **bold** type like e.g. First name and Date of LTx.

After you finished entering the data in each category (general, history, donor, recipient, complications etc.), you create/save the patient by clicking CREATE. However, it's recommended to create a patient directly after entering the gene data and saving data as often as possible in order to prevent data loss during the data entry.

rst name:	Nationality:
CERTAIN-LI	Germany
Last name:	Migration background:
TestPatient	No
Birth name:	Residence country:
-	Germany
Date of birth (dd.mm.yyyy):	Registration country:
01.01.2000	Germany
Gender:	Eurotransplant-No:
Male	123456
Ethnic origin:	Date of LTx (dd.mm.yyyy): ⑦
Caucasian	16.07.2015
	Age at Tx: 15 years

INTERNET ADDRESS:

https://certainli-registry.kikli.uniheidelberg.de

SUPPORTED BROWSERS:

- Google Chrome (recommended)
- Mozialle Firefox (recommended)
- Microsoft Edge

SSL CERTIFICATES:

Thanks to the usage of the HTTPS protocol the whole traffic between you and our system is encrypted – in some cases you may need to accept our SSL certificates.

TIPS&TRICKS:

You will discover that some input fields accept only valid numbers (e.g. Warm Ischemia Time) or only valid input (e.g. all clinical values). In case of clinical values, you can enter either:

- correct number
- (using . as the decimal separator),
- positive or negative,
- number in the 9.6x10e3
- (which equals 9.6 * 10²) notation,

 or < number and > number – e.g. <1000 or >5000.

To enter HLA values, you can either enter the broad, split and antigen by hand, or if you know only one of the values, you can use the HLA search functionality.

Some part of the patient's data set is organized as continuous entries which means that you can enter any amount of single entries (e.g. lab values or patient's medication) - these categories can be recognized by the table form and the

presence of the + button. By clicking the + button a pop-up window will be shown in which the entry's data can be specified.

The CERTAIN-LI Registry distinguishes between a minimal required and an extended optional data set, indicated by "MINIMAL" or "EXTENDED" respectively.



STEP 3: STORING THE DATA

After the data has been entered and the **CREATE** button been clicked, the patient object will be stored on our servers and a patient overview will be presented. If you click the FOLLOW UP button on the bottom you will be able to enter the next follow up data set (the application automatically chooses the correct type of the follow up). This process is fairly similar to the enrollment process. Each data entry time point, so called visit, can be accessed via the visits' list on the right side, as shown on the screenshot. You can always access all your patients through the menu items: PATIENTS/PATIENT'S LIST.

1.0-RC1 (16. July 2015) egister menu Hide	Showing patient						Log out	FATIENT S VISIT LIFECTULE
atients) ata analysis) ocuments)	Identification Patient:	Eurotransplant-No: 123456	Visits No.	Туре:	Created on:	A Scheduled on:	Status:	After a visit has been stored it must
sers) upport)	Date of birth (dd.mm.yyyy): 01.01.2000 (15 years) Treating centres: /	Date of Tx: 16.07.2015 Next visit:	1	Discharge visit	03.08.2015	16.07.2015	NOT_APPROVED	
og out	DE_Heidelberg Signed PICS T	16.07.2018 Ongoing studies 🥕	3	3 months visit	03.08.2015	16.10.2015	INCORRECT NOT APPROVED	completed before it will be ma
	Schedule	Patient's data export	4	6 months visit	03.08.2015	16.01.2016	INCORRECT NOT_APPROVED	accessible for the quality assurance in
			5	1.0 year visit	03.08.2015	16.07.2016	INCORRECT NOT_APPROVED	accessible for the quality assurance in
			6	2 di savare sisit	01.08.2015	16.07.2817	NCORECT +	registry headquarters. Once the d
0.5	Bedside GFR calculation - Schwart	z Clearance		Height [cm]				
	0.5			150				quality has been reassured by
								rogistry's staff the visit will be accord
	0.0			100				registry's starr, the visit will be accep
								as research data.
	-0,5			50				
-								
	Serum creatinin [mgidl]			Weight [kg]				
	0.5			65				
							Lost to follow up Follow up	Stored
	Beaking All rights researed Legal inform	mation / Imposessum						Storeu

STEP 4: LOGGING OUT

After you finished working with the system please do not forget to log out (using the menu LOG OUT button). As long as you are logged into the system you will not be able to access it from any other browser.

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Completed

Accepted

AUTOMATIC LOG OUT

If you will be inactive for more than 15 minutes, the system will conduct an automatic log out to prevent any abuse.

SUPPORT

Further information regarding the Registry usage can be found by using the tutorial function indicated by "Take a tour" buttons and magic wand symbols at dedicated locations within the CERTAIN-LI Registry.

Regular online instructions by our medical staff will give a better insight into the usage of CERTAIN-LI Registry and the opportunity for questions.

In case of questions, feedback or problems you can contact the CERTAIN-LI Registry headquarter at any time. Please contact certainli.registry@med.uni-heidelberg.de or a person directly, listed on our website https://certainliregistry.kikli.uni-heidelberg.de.

DEMO VERSION

In order to give the CERTAIN-LI Registry a try, you can use the demo application.

URL https://certainli-registry.kikli.uniheidelberg.de/DemoApp

Username certainli.test1 (certainli.test2) Password testPassword#

WELCOME TO THE CERTAIN-LI FAMILY

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GIGOLO PARTICIPATION

ANALYSIS PARTICIPATION

After the patient is created as described above, it can be included into several analyses or studies. In order to activate the GIGOLO-specific forms, go to the patient's overview via **PATIENTS/PATIENT'S LIST**. The patient's overview reveal a pen symbol next to the label **ONGOING ANALYSES**. Click on the pen-symbol and a popup will appear as shown right side. Choose **GIGOLO** for study participation and select the transplantation, if more than one.

If the patient was included to GIGOLO before, you are able to add the previous so called **PT code** by clicking on **PROVIDE ID**. At the end, click on **ADD** in order to mark the patient for GIGOLO. If no PT code is available, you may skip the setting of an ID.

Specific forms can now be found within each appropriate visit in the section **ANALYSES** -> **GIGOLO**.

SEARCH FOR PATIENT

It is possible to search for a patient by patient ID or PT code. Via **DATA ANALYSIS** / **SHOW PATIENT DATA** it is possible to search for a patient by entering the patient ID or PT code.

Ongoing analyses	
Study participation	
GIGOLO	
Analysis specific forms for following transplantation(s)	?
12.04.2017 ×	
Provide ID Add	

PATIENT ID / PT CODE

Every patient in the CERTAIN-LI registry owns a unique patient code or in case of GIGOLO eventually a PT code. The patient code is shown in the patient's overview directly beneath the patient's name.

In case of support queries provide the patient id, no names or other identifying data.

GIGOLO DOCUMENTATION

As mentioned above, **GIGOLO-specific forms**, like the pathology scoring, are designed for the project. Next to the **basic CERTAIN-LI data set**, these forms have to be documented. The basic CERTAIN-LI data set covers the entire basic GIGOLO data set.

As mentioned above in "Patients' visit lifecycle", the basic data set has to be **COMPLETED** and **ACCEPTED** in order to process the complete data validation and quality assurance. The GIGOLO-specific data set has to be completed and accepted in the same manner.

Visits which are not part of the GIGOLO data entry time points (transplantation, discharge and 5 yearly) can be skipped by clicking on **SKIP** within the not required visit.