Document title: Sample and Data Usage	Document code/version no.: DM.003_V3.0

Status:	Life

Purpose

To define procedures and essential documents needed for sharing data and samples.

Scope

This Policy is of application to all the stakeholders who might be interested in performing a research project using EF CLIF data and/or samples within the framework of the EF CLIF research plan. Both academic and industrial partners can be considered.

Responsibility

All EF CLIF staff and associates.

Procedure

For each project that requires the use of EF CLIF clinical and omics data and/or samples an application will be required.
Basic contents required in the application:

- Proof-of-concept data (published or not published)
- Hypothesis to be explored
- Aims of the study
- Detailed description of required data
- Detailed description of material needed (incl. type of material, matrix, amount and processing)
- Sample size calculation and statistical consideration adapted to a given study
- A guarantee for sufficient funding (economic and/or human resources) to carry out the measurement and the statistical/bioinformatics analysis
- Proposed timelines to completion of the study

The application will be submitted to the Sample and Data Usage Committee (SDUC) for its approval.
The SDUC is constituted by:

- The Director
- The Scientific Director
- The General Manager
- The Head of the Clinical Operations
- The Head of Translational Operations
- The Head of the Data Management Center
- The Principal Investigator(s) of the EF CLIF study(ies) of the requested material

Features considered to obtain the approval:

- Alignment with the aim of the project which originated the sample/data collection and with the mission of the EF CLIF
- Technical viability and the scientific impact of the presented project.
- Current samples inventory:
  - After eventual retrieval of the samples, the remaining collection should still have at least 50% of the initially collected aliquots for a given sample type.
  - For those samples that are collected in a single tube and aliquots are not available, the sample usage is not possible unless it is for a core study or they are remnants from a core study.
- Ethical issues:
  - The Informed Consent Form signed by the donor might establish restrictions for sample/data sharing that need to be considered. It might be possible that samples/data can only be used by members of the EASL-Clif Consortium and the ENTR. In those cases, the principal investigator of the project requesting the samples will necessary be a part of the EASL-Clif Consortium or the ENTR.
- Commitment of the applicant with prior EF CLIF projects.
  - Projects presented by collaborating researchers who have included at least 10 patients in a given cohort will be prioritized.
- Overlapping with ongoing or planned core and ancillary studies.
  - It should be avoided.
- Reuse of samples and coordination with other centers/researchers for the usage are encouraged.
- Legal aspects:
  - DTA defining the framework to avoid leak of information on both sides.
  - MTA defining the intellectual properties, publication rights etc.

The application will be sent by completing the online Data and Sample Request Form (DSRF) (a paper template is included as Annex 1).

The SDUC will evaluate in a maximum of 30 days the application. Once the decision is taken, if it's positive, it will be followed by the DTA and MTA if applicable. Should conflict of interest arise among any of the members of the SDUC, this member should recuse himself from the evaluation.

The Committee will meet monthly in order to express its decision regarding the sample and/or data request.

Data required will be uploaded in the EF CLIF Data Hub. Authorized users specified in DSRF will receive login details in order to access to de Data Hub and download the data in a secure manner.

Definitions

Essential documents: Documents which permit the evaluation and implementation of the performance of a study and the quality of the data produced.

Document history

Version	Author / Job title	Date approved	Summary of main changes and reasons
00	Cristina Sánchez-Garrido	22 February 2022	Created
01	Anna Bosh	29 April 2022	Description of action in case of conflict of interest
02	Cristina Sánchez-Garrido	19 May 2022	Update DSRF
03	Cristina Sánchez-Garrido	28 November 2023	DSRF link embedded. Update submission calendar.

This document has been reviewed by:	This document has been approved by:
Anna Bosch, EF CLIF General Manager	Anna Bosch, EF CLIF General Manager on 28 November 2023

Annex 1: Data and Sample Request Form (DSRF)

Background

Please describe your project by completing this form and sending it to the Samples and Data Usage Committee (SDUC) to support your data access and/or samples request. The SDUC will evaluate your proposal. After approval, and having all the legal documents in place, data access will be granted via secure platform and samples if applicable will be sent.
Key aspects that will be evaluated include, among others, alignment with the aim of the project which originated the sample/data collection and with the mission of the EF CLIF, technical viability and scientific impact of the presented project.

Please read carefully the supportive text for each field in order to properly fill out the form.

Evaluation period will be the first week of every month (August excluded). Applications received during the last week of the month will be evaluated the second month after receiving the appliation.

Before SDUC evaluation, the EF CLIF Data Management Center could contact you in order to clarify some aspects of the application.

Calendar

Application period	**SDUC evaluation dates**
1 – 20 January	20 February
1 – 20 May	20 June
1 – 20 September	20 October

Research plan

Applicant/Project-specification		
	Date of request dd/mm/yyyy	**Title of the Project** Please add a descriptive project title here
	Principal Investigator Last name, name: Institution: Email:	
	Type of institution	○ Private Profit ○ Private Non-profit ○ Public

1.	**Participating scientist** Last name, name: Institution: Email:	
2.	**Participating scientist** Last name, name: Institution: Email:	
3.	**Participating scientist** Last name, first Institution: Email:	
	(Expected start date of the project data usage)	(dd/mm/yyyy): Data from cohorts with patients not cleaned for the Data Management center will be delivered once the data will be cleaned. If DTA and MTA are applicable, they should be signed before data transfer.The proposal should be aproved before the transfer.
	Expected send date of the project data usage	(dd/mm/yyyy): Final date should be reasonable according to the objectives of the project and it cannot be used for other purposes other than the specified in this application.
	Purpose of data/sample usage	☐ H2020 – specified project task → Specify project and task ☐ H2020 – work not specified as task ☐ Horizon Europe – specified project task → Specify project and task ☐ Horizon Europe – work not specified as task ☐ IWG Project *H2020 and Horizon Europe can be used only for partners of the specific European Project. IWG option can be used only for members of the Inspiring and Writing Group. Others option should be used for those applicants not included in the above groups.*

	If H2020/Horizon Europe selected	*Please specify WP and task*
	Select your cohort data needed for this project	CANONIC ☐ DECISION ☐ PREDICT ☐ A-TANGO ☐ ACLARA ☐ COBALT ☐ CHANCE ☐
	Proof-of-concept data	*Please indicate the scientific background (published or unpublished).*
	Primary and secondary objectives/aims of the study:	*Please add a short description of the general aim and hypothesis to be assessed.*
	Study design and methods	*Please add a short overview of the number of subjects needed, inclusion/exclusion criteria to be applied, techniques and tools to be used, overall approach as well as the analysis plan. It's important, if the applicant has a preexisting cohort, to differentiate between the existing data and the requested data. For example: Total sample size: 150 patients from the EF CLIF cohort, 50 patients needed. (Maximum 1500 words)*
	Relevance of potential results	*Please add a comment on the expected outcomes for this scientific question*
	(only read field)	**PAY ATTENTION: NOW SELECT WHAT YOU NEED FROM THE EF CLIF IN NEXT SECTIONS, PLEASE BE CONCISE. THANK YOU.**
	Clinical/Omics datasets needed	MEDICAL HISTORY & ETIOLOGY ☐ LAB DATA ☐ PRIOR DECOMPENSATIONS ☐ TREATMENTS ☐ CLINICAL EVENTS ☐ ACLF & SURVIVAL ☐ VITAL SIGNS ☐ OMICS ☐
	Material needed	SERUM ☐ PBMC ☐ PLASMA ☐ DNA ☐ URINE ☐ RNA ☐ ASCITIC FLUID ☐

	Detailed and specific description of variables and material needed.	*Please add sample size, specific clinical variables needed. Please remember also to include sample amount and processing, type of samples, sampling points and clinical variables needed.*
	Funds and resources available for the execution of the project	*Please add a comment on the expected funds (public or private) and available resources to perform the study.*
	Others	*Please add any other information you consider important for the evaluation of the project.*
	Drop file here	*Please add a file if you need to complement your request (word, excel, pdf)* *You can upload a supportive document of your project including supplementary materials such as figures, tables etc.*

I confirm to have all ethical and legal permissions for the performance of my study/experiment.

If data access is granted, the data will be used only for the purpose specified in this form.

Date _____ Signature _____