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| Research Project Submission Form |
| REal world dAta in LYmphoma and Survival in Adults |



**Thank you for submitting your project with the REALYSA cohort!**

In order for us to process your project submission, we would need you to fill in this form and send it back to the LYSARC. You will find below more details on the submission process. If you have any questions or need more information, please feel free to contact our teams.

If you would like to get this Submission Form in French, please contact our teams.

Contact:[realysa.projets@lysarc.org](mailto:realysa.projets@lysarc.org)

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**Merci de votre proposition de projet avec la cohorte REALYSA !**

*Afin de nous permettre de considérer votre soumission, veuillez renseigner les informations demandées dans ce formulaire et de le renvoyer aux équipes du LYSARC. Vous trouverez ci-dessous plus d’information sur les modalités de soumission. Si vous souhaitez plus de renseignements ou pour toute question, n’hésitez pas à nous contacter.*

*Si vous avez besoin du formulaire de soumission en français, celui-ci est disponible sur demande auprès de nous équipes.*

*Adresse de contact :* [realysa.projets@lysarc.org](mailto:realysa.projets@lysarc.org)

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| **Name of the study (Acronym):** |

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| **Complete title of the project:** |

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| **Project holder:** |

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# Submission modalities

Thank you for submitting a project with the REALYSA cohort. In order for us to be able to consider your submission, we ask you to fill in this form. Please note that this document is only a support to describe your project and can be modified as needed to best reflect the scope of the project. If your project is not concerned by some of the aspects mentioned, please indicate "Not applicable". On the other hand, if it seems to you that information important for the proper review of your project is not explicitly covered in the sections below, please feel free to add a section to cover the subject.

## REALYSA Access to Resources Charter

A Charter governing the access to REALYSA resources has been created. It is available in French and describe the conditions to access REALYSA data and biological samples. For people who are not French native speakers, we invite you to contact our teams for more information before any project submission.

## Définitions

In this section you will find a reminder of some of the definitions used in the Access to Resources Charter, which will be used in this form, during the submission process and for the evaluation.

**Project holder:** the **legal person**, generally part of an industrial or academic entity, **responsible for the PROJECT**, in particular in charge of formalities with the Authorities in accordance with the applicable regulations. In the case of a mixed unit or PROJECT associating several academic actors, the PROJECT holder will indicate to the Executive Group a single body as administrative manager of the PROJECT which will be in charge of the distribution of its share with any academic actors involved in the realization of the PROJECT. The Project Owner will identify **one person as the main interlocutor who will have the scientific responsibility of the PROJECT.**

**Executive Group:** The role of the Executive group is to ensure the implementation and operational follow-up of the REALYSA study and the related PROJECTS, as well as to managing the governance of REALYSA and the submission process for new projects. Its members and missions are defined in the REALYSA Charter of Governance.

## Submission process and evaluation procedures

The PROJECTS are evaluated on the basis of the information completed in this Submission Form by the Executive Group and the Scientific Committee of REALYSA, in conjunction with the Office of the LYSA Scientific Board. The evaluation process aims to assess the technical and scientific aspects of the project.

Depending on the date on which the PROJECT is submitted, applications will be reviewed at the next REALYSA Scientific Committee meeting. A minimum of six weeks is requested for the evaluation process to allow enough time for reviewers of the REALYSA Scientific Committee to review the PROJECT proposal.

An accelerated procedure may be considered by the Executive Group and approved by the reviewers of the Scientific Committee for descriptive PROJECTS, without major scientific, strategic or resource demands.

At each stage of the process, the decision is notified by email to PROJECT Holder by the Executive Group.

During the PROJECT evaluation, you can use the following address to contact the LYSARC teams and share any documents needed for the evaluation process: [realysa.projets@lysarc.org](mailto:realysa.projets@lysarc.org).

## Aspects reglementaires

Depending on your project (data required, analyses requested, etc.), the control of the data processing related to the PROJECT will be determined by the LYSARC DPO (Data Protection Officer) in conjunction with the REALYSA Executive Group. The PROJECT Holder will be informed of the decision by the Executive Group. The PROJECT Holder may be in charge of some of the regulatory procedures (in addition to those carried out by the LYSARC) before the initiation of project.

You will find more information on these regulatory aspects in the REALYSA Access to Resources Charter.

# PROJECT description

## Administrative information

|  |  |
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| **Project holder (legal person)** | |
| Organization | Name of the organization: …………………………………………………….  Type:  academic  Industrial - if yes, specify the type of partnership with the REALYSA cohort:  Non-Partner  Bronze Silver Gold |
| **Contact Person** |  |
| Title | Prof. Dr. Mr. Mrs. |
| Name |  |
| Forename |  |
| Function |  |
| Address |  |
| Email address |  |
| Telephone number |  |

|  |  |
| --- | --- |
| **Scientific leader of the project (natural person)** | |
| **Same as Project Holder** | |
| Title | Prof. Dr. Mr. Mrs. |
| Name |  |
| Forename |  |
| Function |  |
| Address |  |
| Email address |  |
| Telephone number |  |
| Organization | Name of the organization: …………………………………………………….  Type:  academic  Industrial - if yes, specify the type of partnership with the REALYSA cohort:  Non-Partner  Bronze Silver Gold |

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| **Is/will the project be carried out in collaboration with other organizations?**   1. YES NO |

If yes, specify (this *section should be duplicated as many times as needed*):

|  |  |
| --- | --- |
| **Other partners involved in the project** | |
| Title | Prof. Dr. Mr. Mrs. |
| Name |  |
| Forename |  |
| Function |  |
| Address |  |
| Email address |  |
| Telephone number |  |
| Organization | Name of the organization: …………………………………………………….  Type:  academic  Industrial - if yes, specify the type of partnership with the REALYSA cohort:  Non-Partner  Bronze Silver Gold |

## Scientific summary of the PROJECT

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| **Detailed title of the project:** |

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| **Keywords (5 max):** |

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| **Project Timeline:**  Desired start date: .............../........./................  Desired end date: .............../........./................  If there is a specific constraint for the end date (e.g., file to be submitted to the authorities, submission to a congress, publication), please specify: ................................  *A provisional project schedule will be proposed by LYSARC, based on scientific elements and internal constraints of the LYSARC.* |

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| **Purpose**  Dossier for submission to the health authorities  Internal use  External or commercial use. Please detail: ....  Submission to a congress. Please detail: ....  Publication. Please detail: ....  Other: .... |

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| **Project summary (5 pages max) (Calibri 11):**  Context, rationale and hypothesis(s)  Objectives  Methods  - Study design (cross-sectional analyses, cohort, control case, retrospective, prospective study, etc.)  - Population(s)  Statistical analysis  **-** Number of patients needed or minimum number of patients (if relevant)  - Type of analyses  Expected results  Expected format  Statistical report  Medically annotated statistical report  Clinical Study Report (CSR)  N/A (the LYSARC will not be asked to do the analyses)  Other: ........ |

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| **Type of data/material requested**  *This is to specify the type of data and/or biological samples you need for the realization of the PROJECT.*  Data already collected in REALYSA:  Clinical data  Epidemiological data  *Please complete the Appendix (which contains the list of data available in REALYSA).*  Do you need to collect additional data *that is not already collected in REALYSA*?  YES  NO  If yes, specify (type of data, on what medium, prospective or retrospective...): .......................................................  Biological material collected within REALYSA:  Biological samples  Anatomo-pathological samples  *Please complete the Appendix (which contains the list of biological samples available in REALYSA).*  Do you need to collect additional biological material *that is not already collected in REALYSA?*  YES  NO  If yes, specify (e.g. nature, quantity, biological and technical characteristics, method of conservation): ........................................................................................................................................................................................................................................................................................................................................................................................................................................................................................ |

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| **LYSARC's involvement in this project**  Are you asking for support from the LYSARC for this PROJECT?  YES  NON  If yes, please specify:  Data management (only in case of a collection of additional data)  Statistical analysis\*  Analysis of biological samples – LYSA-Biology  Analysis of anatomo-pathological samples – LYSA-Pathology  Analysis of medical imaging data – LYSA-Imagery  \*If the data analysis is not done by the LYSARC, please specify the name of the structure that will be doing the analysis*):* .................................................................................................................................................... ...................................................................................................................................................... |

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| **Financial aspects**  The project will be fully financed from own funds:  YES  NO  If not, have you already identified potential sources of funding:   * Own funds:  YES  NO * Call for Project Proposal:  YES  NO * Other financial support sources:  YES  NO   Detail (e.g., identified call for projects, duration, submission dates, expected amount): ................................ ......................................................................................................................................................................................................................................................................................................................................... |

**Date of first submission of the synopsis to the Executive Group and signature of the project leader**

Done at:

The:

Signature:

*I acknowledge that any access to REALYSA's resources is subject to compliance with the REALYSA charters. In the absence of compliance with the Charters, the right of access and use of said resources may be withdrawn from me by decision of the REALYSA Executive Group.*

# Appendix: List of REALYSA biological data and samples

This Appendix lists the clinical, epidemiological, and biological data collected in REALYSA. Please indicate in this section the data you would like to have access to for the realization of the PROJECT. For the biological data, please detail the quantities needed as well as the analyzes you would like to carry out on the samples. From these elements, the LYSARC will determine the feasibility and send you a quote.

## Clinical and epidemiological data

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| **Data Collected at baseline** | **Check the box if the data is needed for the project** |
| Demographics (such as Age, Sex, Department of residency) |  |
| Participation to CEVI program (human viable cell collection) |  |
| Participation to LYSATOMIC program (Biological project for T-cell NHL) |  |
| Prior cancer history and other relevant medical history |  |
| Concomitant treatments at inclusion |  |
| Details of the patient's care pathway such as type of healthcare facility and medical specialty where the diagnosis was performed and the treatment was given, review in initial Multidisciplinary Team Meeting (RCP) |  |
| Characteristics at initial diagnosis such as date, clinical/biological details of the pathological diagnosis (including the pathology report), nodal/extra-nodal involvement; exams performed (clinical, date of CT/PET scans), staging, hematology, and biochemistry laboratory data, serologies |  |
| Auto-Questionnaire: History of residences (including complete addresses) |  |
| Auto-Questionnaire: History of occupations (including addresses of the companies, main activities...) |  |
| Questionnaire in interview: Medical History (including personal history of infectious diseases, allergies, cancers, chronic diseases, treatments, imaging, and family history of hematological malignancies) \* |  |
| Questionnaire in interview: Professional, domestic exposures, lifestyle, and women health\* |  |
| Self-Questionnaire: Quality of life (QLQ C 30 + lymphoma specific modules) |  |
| Auto-Questionnaire: Social support SSQ6 (measures the availability of the social support and the satisfaction of the patient regarding this support) |  |
| G8 questionnaire: Geriatric screening: Appetite, Weight loss, BMI, Mood, and cognition –medications – Patient-related health – Age categories |  |

\*data collected in certain REALYSA centers only

With regard to follow-up, the following information is collected at the following time-points (calculated from the date of the patient's diagnosis):

|  |  |  |  |  |  |  |  |  |  |  |  |  |
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|  | **6 m** | **12m**  **1Y** | **18m** | **24m**  **2Y** | **30m** | **36m**  **3Y** | **4Y** | **5Y** | **6Y** | **7Y** | **8Y** | **9Y** |
| **Standard FU** | X | X | X | X | X | X | X | X | X | X | X | X |
| **Morbidities** | X |  | X |  | X |  | X | X | X | X | X | X |
| **Lifestyle** | X |  | X |  |  |  | X |  | X |  | X |  |
| **Professional (including work stress)** |  | X |  | X |  |  |  | X |  | X |  | X |
| **Quality of life** |  | X |  | X |  | X |  |  | X |  |  | X |
| **Social Support** | X | X |  | X |  | X | X | X | X | X | X | X |
| **Fertility** |  |  |  |  | X |  |  |  |  |  |  |  |
| **Health Behavior** |  |  |  |  |  | X |  |  | X |  |  | X |

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| **Data Collected during follow-up *(see table above for precise collection time-points)*** | **Check the box if the data is needed for the project** |
| Disease status at the last hematology consultation, number of consultations and imaging exams |  |
| Initial and additional treatment lines, including detailed therapies, start/end dates, dose modality (full/reduced in chemotherapy), amount of Gray if radiotherapy, transplant, and other surgeries |  |
| Response to treatment (with the method(s) of evaluation used) as evaluated by the hematologist |  |
| Permanent treatment discontinuation (and AE related) |  |
| Relapses/progressions/transformations: dates, involvement, method of evaluation used, staging |  |
| New malignancy: type and date of diagnosis |  |
| Date and cause of death |  |
| End of study, reasons for early termination |  |
| Self-Questionnaire: New morbidities, including new cancers |  |
| Self-Questionnaire: Lifestyle (consumption of food, alcohol, tobacco, physical activities) |  |
| Auto-Questionnaire: Professional activities (change in working conditions and/or salary, work-related stress) |  |
| Self-Questionnaire: Quality of Life (QLQ C 30 + lymphoma specific modules) |  |
| Auto-Questionnaire: Social support SSQ6 (measures the availability of the social support and the satisfaction of the patient regarding this support) |  |
| Self-Questionnaire: Fertility, woman health, pregnancies, attempt to have children |  |
| Auto-Questionnaire: Health behaviors, including use of alternative medicine and of screening (cancer and non-cancer) |  |

## Biological samples

*Any sample taken for REALYSA is traced with a traceability sheet from collection to freezing. Each Biological Resource Center (CRB) keeps a database with all the information characterizing the samples. Additional data on available samples and DNA concentrations in samples can be obtained from the LYSARC upon request.*

Access to samples depends on their availability. For samples with high demand, the scientific interest of the desired analyses, and the adequacy between these analyses and the samples requested, will be thoroughly evaluated by the REALYSA Scientific Council, in order to assess the feasibility of the project and to best guide the PROJECT Holders in their choice of samples.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Nature** | **Sampling collection date** | **Description** | **Check the box if** **samples requested** | **Quantity or volume (in μL)** | **Requirements (freezing time, sterility, etc.)** |
| Serum | Baseline | 2 aliquotes of 1.8 mL on dry tube |  |  |  |
| C3J1 | 2 aliquotes of 1.8 mL on dry tube |  |  |  |
| Plasma | Baseline | 3 aliquots of 1.8 mL on cell free DNA BCT tube |  |  |  |
| C3J1 | 3 aliquots of 1.8 mL on cell free DNA BCT tube |  |  |  |
| End 1st line | 3 aliquots of 1.8 mL on cell free DNA BCT tube |  |  |  |
| Relapse | 3 aliquots of 1.8 mL on cell free DNA BCT tube |  |  |  |
| DNA | Baseline | 1 aliquot on PAXgene DNA tube |  |  |  |
| CeVi living cells | Baseline | PBMC to DMSO |  |  |  |
| *Baseline* | *Ganglion to DMSO* |  |  |  |
| *C3J1* | *PBMC to DMSO* |  |  |  |
|  | *Relapse* | *PBMC to DMSO* |  |  |  |
|  | *Remote – 24 months* | *PBMC to DMSO* |  |  |  |

CeVi: collection of cryopreserved living cells on the platforms of the CeVi network (future web page)

## Anatomo-pathological samples

***Reminder****: REALYSA has set up a virtual tumour library: biopsy samples at diagnosis are not centralized, only the information about these biopsies has been collected for each patient. We cannot commit to ensuring that the biopsies listed in the REALYSA eCRF are still available for your project. Requests will be made by LYSA-P and any information regarding the availability of the biopsies will be shared to you as soon as possible.*

Please specify here any information that may be useful to LYSARC and LYSA-P to better understand the biological material you need and analyses you would like to carry out on these biopsies.

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| Additional information(s): |