



European Translational Information and Knowledge Management Services

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Sustainable Platform Organisation

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DELIVERABLE INFORMATION

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Executive Summary

The ability to offer a supported long term sustainable translational research platform for public use is dependent on two factors.

- 1) a stable, supportable platform
- 2) an environment on which the platform can be offered and maintained

The overall architecture of the eTRIKS KMP has been described in previous reports (D1.2, D1.4, D1.7) and is not repeated in detail here. The final supported platform for the core eTRIKS project is based on the eTRIKS KMP v4 which is an extension of tranSMART version 16.2. Extensive testing of the platform has been carried out.

In order to maintain the sustainability of the platform we have mirrored the initial CNRS service platform at the University of Luxembourg data centre. The long term strategy is to offer the hosting services to supported IMI projects via the ELIXIR node at the University of Luxembourg when support from IMI is no longer available. Some of the components of the platform are also maintained by related eTRIKS partners besides the ELIXIR Luxembourg node.

Inputs and Outputs from related deliverables

Inputs

- D1.2 Hosting and management environment of the eTRIKS KM Platform v1.0
- D1.4 Service Wrapper around eTRIKS
- D1.7 Publication of the current hosting model, hosting requirements and support plan for eTRIKS supported projects

Outputs

- D5.5 Business model for sustainable platform

Description sustainability strategy

Stable sustainable platform

The eTRIKS KMP is a suite of software and data management tools built around the TranSMART translational research exploration platform. In addition, the platform includes a number of supporting modules and middleware components. Last, but not least, the platform supports a number of data sets for public and project specific use.

The identified list of components in scope to be maintained is

- Online accessible public server and public data
- Downloadable version of the eTRIKS public server and data
- ABIRISK project server and data (when service agreement signed)
- Oncotrack project data (when service agreement signed)
- Training environment and training aids
- eTRIKS.org website
- Gitlab/GitHub platform code and documentation repository
- eTRIKS Labs (by multiple eTRIKS partners)
- eTRIKS bug reporting and tracking system will need to be maintained by the developer team
- All modules required to fully set up and run these services

Each eTRIKS developed component of the eTRIKS KMP is described by an Asset Maintenance Canvas that describes the asset and the support and maintenance plan for the asset after the eTRIKS project is completed.

Overview of eTRIKS asset maintenance

Maintenance of eTRIKS assets:

The approach for sustainability of the platform is driven by asset maintenance. In this report, we describe how we configure and monitor the assets we own and how we are able to make ongoing decisions through planning which allow us to adapt in this dynamic environment without losing quality.

Quality assurance:

The domain experts are enrolled in specific schemes for quality assurance with proficiency testing protocols and mentorship programs. This goes hand in hand with best practices and eTRIKS SOP's for internal quality control and service maintenance to make sure the best tools and services can be delivered.

Driving the community of practice:

The aim is to establish the data in a system that will allow for the maintenance of the data beyond the end of the project and to facilitate problem solving during data re-use. The eTRIKS Data Science Network (eDSN) coordination is enabled to solve problems related to the data infrastructure in order to ensure the maintain of assets.

The eTRIKS assets primarily results from the eTRIKS labs and are identified below, with an explanation of the sustainability measures taken aligned to each individual asset.

eTRIKS assets:

eTRIKS harmonization services (eHS):

eHS is hosted on the eTRIKS portal and on the Data Science Institute (DSI) website. The code is hosted publicly and on the internal eTRIKS GitHub repository. The asset is actively being developed by Imperial College London and will be further hosted and maintained at the DSI.

Hosting: DSI at Imperial College London

Further development work: In line with tranSMART developments and carried out by the DSI

Risk: Low – the asset is fully developed and requires adaption to tranSMART 17.1, as scheduled in the eTRIKS extension period

eTRIKS analytical engine (eAE):

Currently the eAE is in the process of being quality controlled with feedback being incorporated into the DSI code. These last steps are to be developed before testing and releasing back to the community. eAE will be fully available on GitHub. Work has been done on the adoption of eAE by ‘early adopter’ projects and IBM. The asset will be further maintained at the DSI.

Hosting: DSI at Imperial College London

Further development work: In line with interface developments and carried out by the DSI

Risk: Low – the asset needs more development and requires adaption to tranSMART 17.1, as scheduled in the eTRIKS extension period.

Weighted Gene Correlation Network Analysis (WGCNA):

WGCNA is suited to analyze any type of continuous biological omics data via the shiny app which implements the WGCNA R package in a user-friendly interface. The application is published as a package on the eTRIKS labs page (<https://portal.etriks.org/portal/>) with available demos and downloadable tutorials (<http://shiny.etriks.org/wgcna/>). The asset and corresponding R-package will be packaged on dedicated web repository (<https://cran.r-project.org/>). Further asset maintenance will occur through EISBM.

Hosting: EISBM

Further development work: carried out by the EISBM

Risk: Low – the asset is fully developed and requires no further adaptation.

Similarity Network Fusion (SNF):

A Shiny web app for SNF, where a user has the ability to integrate various data types, has been developed and is available at <https://snf-shiny.shinyapps.io/rtest/> . Similarly to WGCNA users are able to download the package, which has been made publically available (<https://portal.etriks.org/portal/>). Links to the demo inclusive of algorithm

description and deployment possibilities are shared with the crowd and will be placed at GitHub. EISBM will be further maintaining the asset.

Hosting: EISBM

Further development work: maintenance carried out by the EISBM

Risk: Low – the asset is fully developed and requires no further adaptation

Disease Maps:

The Disease Maps Project as a large-scale community effort was initiated by the Luxembourg Centre for Systems Biomedicine, the European Institute for Systems Biology and Medicine and the Institute Curie. Disease maps has a very dedicated website <http://disease-maps.org> which provides access to all information collaborating projects and new research projects in the pipeline. It depicts each and every published map and a variety of visualization tools and platforms that can be used to develop network modules. The asset will be maintained by the project leaders of the Disease Maps Project. They will further develop and refine the concept of disease maps, coordinate the activities of the community effort, help initiating new maps, advise on best practices and offer guidelines.

Hosting: LCSB/UL

Further development work: carried out by the LCSB/ UL – EISBM- Institute Curie

Risk: Low – the asset is fully developed and requires no further adaptation

Disease Networks:

The Disease Networks module is developed as a multi-scale framework (using the graph database approach) to facilitate management (integration, exploration, visualization, interpretation) of diverse types of biological and biomedical data. Disease Networks employ the popular graph database Neo4j, which provides a persistence mechanism that is robust and has powerful functionality (the Cypher query language) that allows the user to query networks, to find connections between particular data entries using graph traversal techniques. The two main frameworks are the protein framework and the metabolic framework. The first is available via:

<https://diseaseknowledgebase.etriks.org/protein/browser/>.

The Neo4j-based metabolic framework is freely available from:

<https://diseaseknowledgebase.etriks.org/metabolic/browser/>.

The java code files developed for this work are available from the following url:

<https://github.com/ibalaur/MetabolicFramework>.

The final versions of the neo4j-based applications are available on the public server that has been migrated to University of Luxembourg for further maintenance. The code is already available on Github repository; for example: URL Protein Framework:

<https://github.com/ibalaur/ProteinFramework>. All URLs are distributed and made publically available and maintained by EISBM.

Hosting: EISBM

Further development work: N/A

Risk: Low – the asset is fully developed and requires no further adaptation.

SmartR:

SmartR is aimed to provide a highly dynamic and interactive way of visualizing and analyzing data within transSMART. Access to the tool with necessary documentation is

provide via the eTRIKS portal <https://portal.etriks.org/portal/>. Also, a downloadable application on code and setup instructions, to report bugs and request feedback can be found at <http://etriks1.uni.lu/>. Further development of the asset will be monitored and guided for long term sustainability and maintenance at University of Luxembourg.

Hosting: LCSB/UL

Further development work: In line with tranSMART developments and carried out by the UL

Risk: Low – the asset is further developed at UL and requires adaption to tranSMART 17.1, as scheduled in the eTRIKS extension period.

HiDome:

The High Dimensional and omics data exploration project is an extension to tranSMART which allows the creation a gene set of interest across a sample population. This will be integrated in the latest tranSMART version with knowledge transfer from J&J and the Hyve. It is available on the eTRIKS portal (<https://portal.etriks.org/portal/>) and can be accessed for detailed documentation to optimal deployment. Users can try it on the Public Server

(<https://public.etriks.org/transmart/RWG>) and the asset will be maintained by J&J.

Hosting: J&J and the Hyve

Further development work: In line with tranSMART developments and carried out by the J&J and the Hyve

Risk: Low – the asset is further developed and requires adaption to tranSMART 17.1, as scheduled in the eTRIKS extension period.

Gene Set Variation Analysis (GSVA):

GSVA is a non-parametric, unsupervised method which estimates the relative enrichment of a gene set of interest across a sample population. It has been developed at ICL and is part of Bioconductor. There is a GSVA library package available via <http://shiny.etriks.org/gsva/> which informs clearly with full documentation and tutorial. The asset will be further maintained by J&J.

Hosting: J&J

Further development work: In line with tranSMART developments and carried out by the J&J

Risk: Low – the asset is fully developed and requires adaption to tranSMART 17.1, as scheduled in the eTRIKS extension period.

XNAT:

The XNAT viewer is its proper name (as there is also an "XNAT importer" plugin in tranSMART from a partner in the TraIT project. The XNAT viewer was delivered as a copy of the source code by the developers and included first in eTRIKS 3.0 and then in tranSMART 16.2. The source code is in the tranSMART repository:

<https://github.com/transmart/transmart-xnat-viewer> - so it has a secure long-term home beyond the end of eTRIKS. This repository was created on the 11th October 2016. The code was delivered in August 2016 by May Yong. Whenever eTRIKS partners like DSI, ICL or UL choose to make any changes for a future eTRIKS build (for example, bug fixes) it can be done by simply making a copy (a 'fork') of this repository

and use this for the next build of the full platform. A copy can similarly be maintained at ELIXIR Luxembourg if required.

Full documentation is on the tranSMART Foundation wiki at:

<https://wiki.transmartfoundation.org/display/transmartwiki/XNAT+Viewer+Plugin+Documentation>

Hosting: ICL/DSI

Further development work: In line with tranSMART developments and carried out by the ICL/DSI

Risk: Low – the asset needs more development and requires adaption to tranSMART 17.1, as scheduled in the eTRIKS extension period

Federated Data Integration:

Clinical data exploration from federated sources involves retrieving data from multiple sources. The asset can help to construct knowledge repository with a user-friendly search engine through a collection of molecular mechanisms with the option for visualization, exploration and data integration. The tool is under development at DSI / ICL. The code is available in GitHub <https://github.com/transmart/transmart-horde>. Potentially tranSMART could contribute to further developments and the FDI will be further maintained at the DSI.

Hosting: DSI at Imperial College London

Further development work: further developments and carried out by the DSI

Risk: Low – the asset requires further development as scheduled in the eTRIKS extension period

Standard Starter Pack:

IMI eTRIKS consortium has released an updated version of its 'Standards Starter Pack'. The aim of this document is to provide scientists, project managers and data custodians with a comprehensive overview of the landscape of standardization efforts in both the clinical and functional genomics areas. All information and documentation can be downloaded via: <https://zenodo.org/record/50825>. Biosharing database allows for a level of 'crowd sourcing', providing means for a community to 'claim and maintain' an asset: (<https://fairsharing.org/collection/eTRIKS?sort=best>). Biosharing site of Oxford University eResearch Centre (<https://biosharing.org/collection/eTRIKS>) provides the necessary tools and information. It will be open source and maintained via Oxford University eResearch Centre in the context of the ELIXIR UK node.

Hosting: Oxford

Further development work: carried out by the Oxford eResearch Centre

Risk: Low – the asset is fully developed

eTRIKS version of PLAY DECIDE:

eTRIKS, led by BioSci Consulting has created a multi-stakeholder discussion game "eTRIKS Play Decide". The main goal of this game version is to serve and outline the steps needed to promote the re-use of medical research data. A report on the EU Parliament event Oct 2016 can be found at: https://issuu.com/biosciconsulting/docs/etriks_play_decide_-_eu_parliament

Hosting: BioSci Consulting

Further development work: N/A

Risk: Low – the asset is fully developed

IMI Data Catalogue:

eTRIKS Data Catalogue is a metadata repository linking the massive data available in a global system that can be optimally leveraged to improve biomedical research. The Data Catalogue is interfaced with web-based software to enable remote, interactive data-mining such that important metadata and summaries of curated studies can be displayed. The idea is to have a 'one stop shop' to show the datasets that are available in IMI1, IMI2 and other published sources and let us help partners to promote the solution and encourage to share data. This creates value for public and private organizations/translational researchers and drive research collaboration formation towards convergence and precision medicine.

More information to bring in your metadata via:

<http://datacatalog.elixir-luxembourg.org/ckan/about>

[http://datacatalog-](http://datacatalog-dev.elixirluxembourg.org/limesurvey/?r=survey/index&sid=779596)

[dev.elixirluxembourg.org/limesurvey/?r=survey/index&sid=779596](http://datacatalog-dev.elixirluxembourg.org/limesurvey/?r=survey/index&sid=779596)

So far, 12 IMI projects have engaged and populated the database with study descriptions and a number of projects are in the process of completing the form. When eTRIKS funding period end ELIXIR /UL node will be full capacity to maintain the catalogue and drive sustainability. Similar to each eTRIKS asset, a sustainability canvas (Fig. 1) has been created by eTRIKS members.

Data catalogue sustainability canvas

| | | | | |
|---|--|--|--|---|
| <p>What obstacle (s) could be expected?</p> <p>The database can easily contain thousands of study descriptions over time. Development should anticipate on this and use a broad scale meta data catalogue management plan. ELIXIR /UL</p> <p>Awareness barrier</p> <p>Become the overarching repository of repositories</p> <p>Granularity of the template Addressing the right point of contact</p> | <p>What problem (s) does its solve?</p> <p>no such repository elsewhere that centralizes ongoing and past IMI project level metadata. bring power to the FAIR data concept starting with a focus on the findability of research study descriptions.</p> | <p>Unique Value Proposition</p> <p>Create value for public and private organisations/ translational researchers and create better opportunities to drive research collaboration formation towards convergence and precision medicine</p> <p>Promotion and awareness on the Preservation of research project results</p> <p>Increasing the impact of Medical Research Projects</p> | <p>Location?</p> <p>http://datacatalog.elixir-luxembourg.org/ckan/about http://datacatalog-dev.elixir-luxembourg.org/limesurvey/?r=survey/index&sid=779596</p> | <p>Supported by?</p> <p>It will be funded by the ELIXIR-LU budget</p> |
| | <p>Demands for potential customers?</p> <p>User friendly ness</p> <p>ONLY meta data</p> | <p>End users?</p> <p>Translational researchers</p> <p>Bioinformaticians</p> <p>Patients</p> | <p>How is the asset funded?</p> <p>It will be funded by the ELIXIR-LU budget</p> <p>There is a dedicated annual budget.</p> <p>Luxembourg government committed to long term activity.</p> | <p>Promotion:</p> <p>ETRIKS website UL IMI Social media Patient fora</p> |
| <p>Rough Costs for maintenance</p> <p>0,2FTE/yr is a rough estimate</p> <p>Hardware costs will be covered by the ELIXIR budget</p> | | <p>Road map for future development?</p> <p>We will continu the development of a more standardized template.</p> <p>Continue development of the interface and consolidate with other projects.</p> <p>The main objectives is that eTRIKS will try to populate the database with all IMI projects and Beyond...</p> | | |

Creative Commons license - derived from the Business Model Canvas as developed by WWW.BUSINESSMODELING.COM

Hosting: ELIXIR-LU /UL



Further development work: carried out by developers at UL

Risk: Low – the platform development will be furthered at UL as scheduled in the eTRIKS extension period

Galaxy Interface:

The Galaxy interface provides a tool for more user friendly and integrated access to existing bioinformatic datamining algorithms. This functionality is migrated to SmartR and will need no further development. It will be maintained on the eTRIKS public server environment and the code is available on the GitHub.

In case request support for any other assets and services that can help reduce the effort for data integration, sharing and re-use of medical research projects it is recommended to contact individual eTRIKS partners or the eTRIKS Data Science Network (<http://www.biosciconsulting.com/edsn/>).

Examples of these assets and services are:

1. eTRIKS/ tranSMART platform

- eTRIKS/ tranSMART data curation and i2b2 tree generation
- Deployment and admin training
- User training

Training as well as ‘train the trainer sessions ’will be organized keeping in touch with instructors, account managers to monitor reception, future needs.

Training model is enforced as eTRIKS compilation on training curriculum and is available to download from the public site.

- Research data curation training
- Analytical algorithms implementation training
- Analytical algorithms end-user training

2. ETL pipelines

Run ETL and training how to run the ETL

Development, as generation of code/pipelines to optimize ETL

Quality control

3. Support for curation, platform usage and system admin

4. Custom development

5. Data modelling

6. Architecture design and Sustainability planning as well as data hosting

7. Advice package on ethics, privacy and standards

This document and approach can lead to the generation of new assets that either or not can sustain existing assets as part of the maintenance work. Continuous improvement will go hand in hand with reliability and a customer centered approach.

Hosting: ELIXIR-LU /UL

Further development work: carried out by developers at UL

Risk: Low – the platform development will be furthered at UL as scheduled in the eTRIKS extension period

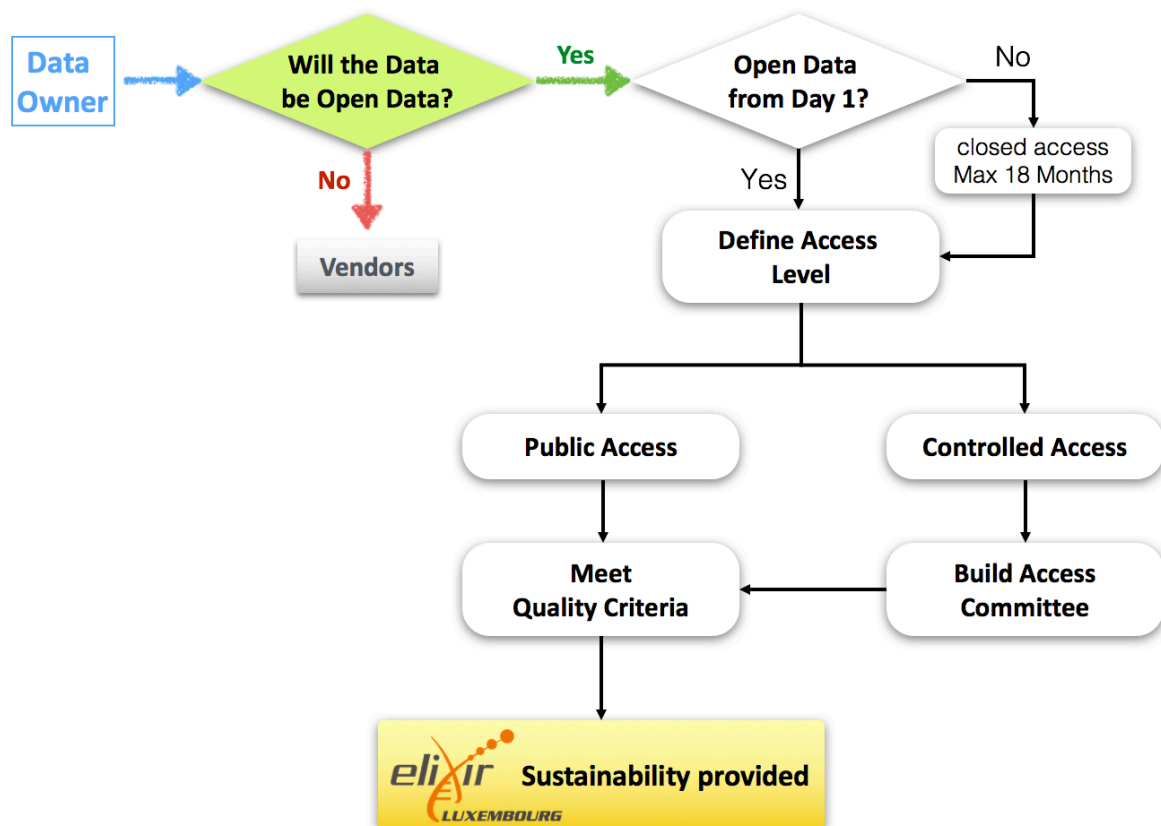
Elixir Node at University of Luxembourg

eTRIKS will provide data sustainability to all supported IMI projects via the ELIXIR-LU node as represented by University of Luxembourg. For the eTRIKS public platform, the server and data has been mirrored to ELIXIR-LU infrastructure and will be maintained for 10 years.

For all supported IMI projects, ELIXIR-LU offers two types of sustainability solutions:

- 1) tranSMART server hosting
- 2) data/file archiving

The conditions a supported IMI project will be sustained by ELIXIR-LU is defined in the service agreement (Appendix 1). Main points of the conditions are: data needs to be open access (with possibility of under the control of a Data Access Committee). A workflow for the sustainability model is shown in the following scheme:



List of abbreviations

eTRIKS KMP – eTRIKS Knowledge Management Platform
DSI – Data Science Institute, Imperial College London
UL – University of Luxembourg

Appendix 1: ELIXIR-LU SERVICES AGREEMENT (template)

ELIXIR-LU SERVICES AGREEMENT (the “Agreement”)

between

[...]
duly represented by [...], hereinafter “the Data Provider”

and

the University of Luxembourg, a Public Institution of Higher Education and Research, having its registered office at 162a, avenue de la Faïencerie, L-1511 Luxembourg, duly represented by its acting president Prof. Dr. Ludwig Neyses, acting for its Luxembourg Centre for Systems Biomedicine, Campus Belval, 7 avenue des Hauts-Fourneaux, L-4362 Esch-sur-Alzette, G.D. Luxembourg, duly represented by its director Prof. Dr. Rudi Balling, hereinafter “LCSB-UL”

Individually referred to as a “Party” or collectively referred to as the “Parties”.

Preamble

Whereas,

LCSB-UL disposes of a High Performance Computing infrastructure that allows hosting data;

LCSB-UL is the Luxembourg node (the “Luxembourg Node”) for the European Life-Science Infrastructure for Biological Information (“ELIXIR”) an intergovernmental consortium that brings together life science resources from across Europe;

the Data Provider is [PLEASE INSERT DESCRIPTION] and wishes to store biomedicine data and provide access to such data to third parties under the conditions listed in this Agreement and Terms of Use governing this Agreement;

each of the Parties recognises as a priority the need to respect the fundamental interests and rights of Data Subjects, including the need to preserve the security and privacy of the Data;

the infrastructure of data processing guarantees compliance with binding European legislation on the protection of individuals with regard to the processing of personal data and the free movement of such data (hereafter “the European data protection law”) that means the Data Protection Directive 95/46/EC that will be replaced by the General Data Protection Regulation (GDPR) on 25th May 2018. It is of high importance to process the Data in compliance with relevant applicable laws and regulations, including, without limitation, privacy and medical secrecy laws applicable to the activities of the Parties;

The Parties hereby agree as follows:

Clause 1: Definitions and Terms of Use

For the purposes of this Agreement, the terms used in this Agreement shall have the same meaning as attributed to them in the Terms of Use as attached in Annex A to this Agreement.

Terms of Use constitute an integral part of this Agreement. In case of any discrepancies between this Agreement and the Terms of Use, the terms of this Agreement shall prevail.

Clause 2: Scope of Services

The Data Provider opts for Services as described in Annex B.

The data transferred by the Data Provider concern the data listed in Annex B (the “Data”).

The Data Provider is responsible as a Data Controller for the management of Data within its organisation, while LCSB-UL is a Data Processor for the Data processing and sharing the Data on behalf of the Data Provider and its status is limited to data hosting services provider.

Clause 3: Financial provisions

[THE FINANCIAL PROVISIONS, IF ANY, SHOULD BE DESCRIBED]

Clause 4: Data Access

The Data Provider agrees to provide Open Access to the Data stored on Luxembourg Elixir Platform.

OR

The Data Provider agrees to provide Controlled Access to the Data stored on Luxembourg Elixir Platform.

Clause 5: Term

[If different from term established under the Terms of Use]

Made in two signed copies, each party having received one original.

| For the Data Provider | For University of Luxembourg / Luxembourg Centre for Systems Biomedicine (LCSB) |
|---------------------------------------|---|
| Name: Title: Date: Signature | Name: Prof. Dr. Ludwig Neyses Title: Acting President, University of Luxembourg Date: Signature Name: Prof. Dr. Rudi Balling Title: Director, LCSB Date: Signature |

- Annex A Terms of Services
- Annex B Services description
- Annex C Technical and organisational measures

ANNEX A

ELIXIR-LU TERMS OF SERVICES

The University of Luxembourg, a Public Institution of Higher Education and Research, having its registered office at 162a, avenue de la Faïencerie, L-1511 Luxembourg, acting for its Luxembourg Centre for Systems Biomedicine, Campus Belval, 7 avenue des Hauts-Fourneaux, L-4362 Esch-sur-Alzette, G.D. Luxembourg, hereinafter “**LCSB-UL or Luxembourg Node**” is the Luxembourg node for the European Life-Science Infrastructure for Biological Information (ELIXIR), an intergovernmental consortium that brings together life science resources from across Europe. These resources include databases, software tools, training materials, cloud storage and supercomputers. ELIXIR includes 21 member states and over 180 research organisations and is a research infrastructure of global significance.

ELIXIR is coordinated by the ELIXIR Hub hosted by the European Molecular Biology Laboratory with Nodes in member states and other countries with the aim to provide seamless and sustainable data infrastructures for research in the life sciences. The national nodes are constituted of bioinformatics centres of excellence that represent a national strength and priority and provide nationally coordinated services. LCSB-UL has been admitted as a Luxembourg Node to the ELIXIR.

These terms of use (the “**Terms of Use**”) govern the services provided by the LCSB-UL acting as a Luxembourg Node.

1. Definitions

Anonymisation shall mean the process of transforming Data into any information that does not relate to an identified or identifiable person or to personal data rendered anonymous in such a manner that the Data Subject is not or no longer identifiable.

LCSB-UL only receives anonymised data related to open access from the Data Provider.

Data shall mean biomedical data, including personal and anonymised data, provided by the Data Provider to the Luxembourg Elixir Platform.

Data Access Agreement shall mean the data access agreement that the LCSB-UL shall conclude on behalf of the Data Provider with User regarding the access of Data hosted on the Luxembourg Elixir Platform.

Data Access Policy shall mean access control policy established by the Data Provider on the basis of which LCSB-UL, acting on behalf of the Data Provider, grants controlled access to Data stored on Luxembourg Elixir Platform.

Data Access Committee shall mean the committee formed by the LCSB-UL, acting on behalf of the Data Provider, that reviews the application of access from User and

grants/declines access based on the Data Access Policy provided by the Data Provider. The Data Provider may mandate its representative to the Data Access Committee who will have a veto right on decisions regarding Data access within 10 days after the access request was submitted to the Data Provider.

Data Controller shall mean the natural or legal person which alone or jointly with others, determines the purpose and the means of the processing of Personal data. The Data Provider is the Data Controller as regards to the collection and the processing of Data provided to the Luxembourg Elixir Platform.

Data Processor shall mean the natural or legal person who processes Personal data on behalf of the controller. LCSB-UL is the Data Processor as regards the collection and the processing of Data provided to the Luxembourg Elixir Platform.

Data Subject shall mean any identified or identifiable natural person, whose data are provided by the Data Provider to the Luxembourg Elixir Platform. An identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his/her physical, physiological, mental, economic, cultural or social identity. As a rule, the subject whose data are processed within the Luxembourg Elixir Platform is the Data Subject.

Data Provider shall mean any private or public entity wishing to store its Data on the Luxembourg Elixir Platform and grant an open or controlled access to it to any User under the terms listed in these Terms of Services and the Services Agreement, as the case may be.

ELIXIR shall mean the European Life-Science Infrastructure for Biological Information, an intergovernmental consortium that brings together life science resources from across Europe.

Luxembourg Elixir Platform shall mean the platform hosted by LCSB-UL.

Personal data shall mean any information relating to an identified or identifiable natural person (the “Data Subject”).

Pseudonymisation shall mean the processing of Personal data in such a manner that the Personal data can no longer be attributed to a specific Data Subject without use of additional information, to keep separately the additional information and protect this information with technical and organisational measures to ensure that the Personal data are not attributed to a Data Subject.

LCSB-UL only receives pseudonymised data related to controlled access from the Data Provider.

Services shall mean secured Data storage Services provided by the LCSB-UL, including Luxembourg Elixir Platform.

Services Agreement shall mean the agreement concluded between the Data Provider and the LCSB-UL.

User shall mean any legal person registered with Luxembourg Elixir Platform wishing to access Data hosted on the Luxembourg Elixir Platform.

2. Services provided by LCSB-UL

In the context of ELIXIR programme, LCSB-UL acting as the Luxembourg Node provides the secured Data storing Services.

The Services chosen by the Data Provider shall be specified in the Services Agreement concluded with LCSB-LU.

Elixir Services provided by LCSB-UL are accessible to any Data Provider wishing to store Data on Luxembourg Elixir Platform and grant open or controlled access to such Data under conditions described in these Terms of Services.

LCSB-UL will make all reasonable effort to maintain continuity of the Services and provide adequate warning of any changes or discontinuities. However, LCSB-UL does not provide any warranty and accepts no responsibility for the consequences of any temporary or permanent discontinuity of the Services.

Only Data that is compatible with general Elixir European framework and goals shall be eligible for being hosted and transmitted to Luxembourg Elixir Platform. The Data Provider has to ensure that the Data provided to the Luxembourg Elixir Platform is provided in a structured manner, easily readable and usable format.

LCSB-UL retains a right to refuse storing/hosting Data on its Luxembourg Elixir Platform, if:

- the Data exceeds [PLEASE INDICATE THE LIMIT] the limit;
- the Data Provider fails to provide metadata;
- the Data Provider does not provide Data Access Agreement and Data Access Policy when the controlled access possibility is chosen;
- the Data Provider does not respect the other terms of these Terms of Services.

The role of the LCSB-UL within the Services is limited to the provision of hosting and sharing services, LCSB-LU itself does not have knowledge and does not control the quality of Data provided by the Data Providers.

Subject to applicable law, the LCSB-UL takes no responsibility and assume no liability for any Data or other materials posted, stored, or uploaded by Data Provider on the Luxembourg Elixir Platform or for any loss or damage to any of such Data. Although the LCSB-UL does not have an obligation to screen, edit, or monitor any Data posted or transmitted to Luxembourg Elixir Platform, the LCSB-UL reserves the right and have discretion to screen and remove any Data posted, stored, or transmitted on or through Luxembourg Elixir Platform at any time and without notice, where:

- it is notified by the Users or third parties about the illegal and infringing nature of Data;
- based on particular circumstance, the LCSB-UL may presume that Data is infringing third parties' rights or may otherwise be considered as illegal.

3. Data Access

By accepting these Terms of Services the Data Provider understands that the European ELIXIR initiative is based on open access and data sharing in order to establish sustainable infrastructure for research in the life sciences. Data Provider expressly **accepts to grant open or controlled access to Data** stored, hosted and/or transmitted to Luxembourg Elixir Platform under the conditions established in these Terms of Services.

The Data Provider may choose one of the below Data access options:

- **Open Access.** Open Access allows any User registered with Luxembourg Elixir Platform access Data in an unrestricted manner.
- **Controlled Access.** Controlled Access permits Data Provider to establish the Data Access Policy and in such a way control access of Data based on non-discriminating criteria. Based on the Data Access Policy the Data Access Committee shall perform the control of the access to Data and the LCSB-UL, acting on behalf of the Data Provider, shall enter into Data Access Agreements with Users. By accepting these Terms of Services, Data Provider mandates LCSB-UL to control on behalf of the Data Provider access to Data whenever the Controlled Access option is chosen and to enter on behalf of the Data Provider into Data Access Agreements with Users based on the requirements established in the Data Access Policy provided by the Data Provider.

If the Data Provider mandates its representative to the Data Access Committee, such a representative will have a right to exercise a veto right (by way of written/electronic notification) within 10 days after the notification about the access request is sent by LCSB-UL. If the veto right is not exercised within this time limit, it will be deemed that the Data Provider's representative tacitly consented to the access requested. The veto right may be only exercised if legitimate reasons exist.

In certain particular cases when for example Data may not be made public during certain limited period of time, the Data Provider may request the LCSB-UL to grant a limited closed access, which may not be longer than 18 months. The Data Provider shall reimburse LCSB-UL for the closed access storage period should the Data Provider fail to store the Data on the Luxembourg Elixir Platform for at least 5 years.

Data Access Policy established by the Data Provider should respect the following principles:

- contain clear and precise requirements for Data access;

- should not contain any discriminating criteria based on nationality, gender, race, political opinions;
- should contain Data access restrictions stemming from requirements applicable to personal data protection, ethics or other national legal requirements.

The Data Provider shall submit the Data Access Policy to the LCSB-UL for the latter's information.

4. Fees and payments

Luxembourg Elixir Platform is financed by the Government of the Grand Duchy of Luxembourg and the LCSB-UL, thus the Services presently are provided free of charge.

LCSB-UL reserves the right to apply the fees in certain particular situations where the amounts of the Data stored by the Data Provider are proportionately high in respect of the overall available space for the Luxembourg Elixir Platform. Such fees will be detailed in the Services Agreement.

Should the financing of the Luxembourg Elixir Platform be ceased, the LCSB-UL may implement the fees for the Services at any time by providing the Data Provider 30 days written notice. Upon such notification, the Data Provider will have a possibility to terminate Terms of Services and Services Agreement, if any. The use of Services after the expiry of the notification date shall be deemed as tacit acceptance of the fees notified.

5. Privacy and Personal Data Processing

The Data Provider undertakes:

- to transfer to LCSB-UL only Data, for which the informed consent of the Data Subject and/or appropriate ethics approval for transfer and use in ELIXIR are obtained;
- to transfer to LCSB-UL the Data using securely encrypted transit channels;
- to comply while processing the Data with the applicable laws, including national data protection law applicable to the data transfer. LCSB-UL will not be liable in case of any issues arising from any deficiency in the consent of the patients, or non-notification of relevant national personal data protection authorities or local ethics bodies prior to the transfer of the data to LCSB-UL;
- to perform a secure pseudonymisation process on any Data transferred to LCSB-UL for controlled access service and a secure anonymisation process on any Data transferred to LCSB-UL for open access service on the basis of this Agreement. LCSB-UL only stores pseudonymised or anonymised data that it has implemented and follows appropriate technical and organisational security measures to protect the data against misuse and loss (including without limitation the measures stated in Annex C to this agreement) in accordance with the European data protection law;

- to provide all necessary information and documents that may be needed in case of any request by supervisory authorities;
- to inform LCSB-UL 7 working days before for any removal of Data due to Data Subject's consent withdrawal;
- to inform LCSB-UL when the Personal data have to be deleted or rendered anonymous in accordance with European data protection laws 10 working days before.

The LCSB-UL undertakes:

- to store and process the Data in compliance with applicable personal data protection laws and the terms of this Agreement;
- that it has implemented and follows appropriate technical and organisational security measures to protect the Data against misuse and loss (including without limitation the measures stated in Annex B to this Agreement), in accordance with the requirements of relevant provisions of European data protection law;
- that it shall not attempt to identify any Data Subject from the Data either by external matching of the Data or by any other means;
- that in the event of inadvertently identifying any Data Subject, it undertakes not to make any use of the identifying information for any purposes and to take all necessary steps to protect the interests of the Data Subject including so far as possible restoring their pseudonymised status;
- to grant access to Data to Data Provider whenever Data Provider shall require such access. Access rights of Users to the Data shall be regulated by article 3 of the Terms and Conditions;
- to process and store the Data for the duration of these Terms of Services excepted if other legal disposals requires shorter deletion or anonymisation.

The Parties agree that the data retention will be for the duration of these Terms of Services excepted if legal disposals or supervisory authorities require a shorter duration. In such case, the Data Provider undertakes to inform the LCSB-UL at least 10 working days after becoming aware of these legal disposals or after being notified by the supervisory authority of the removal or anonymisation of the Data. The Parties undertake to inform each other about a Personal data breach no later than 2 working days after becoming aware of it as soon as they are aware, even imperfectly, of the circumstances and the approximate volume of the Data concerned.

In such a case, the Parties shall exchange all relevant information to enable them to respond effectively to regulators or Data Subjects and shall endeavour to coordinate their crisis communication on this eventuality.

6. Ethics Policy

Data Provider also undertakes to adhere to general ethical principles, including those related to research integrity and use of human biospecimens and Data related to human subjects for research purposes. Specifically, Data related to human subjects, human blood samples and other tissue, if any, will be transferred to the LCSB-UL only to the extent that the Data Provider can ensure that the patient has agreed in

writing to its specific use for scientific purposes and the competent local ethical committee of the Data Provider has permitted such use.

7. Intellectual Property Rights

All intellectual property rights (including but not limited to author rights, trade marks, patents, know-how) on the infrastructure, software, documentation and other tools used for the provision of the Services will stay the ownership of the LCSB-UL.

By accepting these Terms of Use the Data Provider gives his/her consent for the LCSB-UL to use Data Provider's corporate name and/or logo when communicating about the Services provided as a part of ELIXIR programme.

8. Representations and Warranties

When transmitting Data to Luxembourg Elixir Platform Data Provider represents and warrants that:

- (1) it has a right to post such Data to Luxembourg Elixir Platform and the posting and access of such Data by Users does not infringe, violate or misappropriate any Intellectual Property Rights of third parties;
- (2) all applicable privacy and personal data laws and regulations are respected, notably that all consents, waivers, authorisations and/or approvals from Data Subjects and relevant public authorities have been obtained;
- (3) posting Data on Luxembourg Elixir Platform does not violate any rights of or cause injury to any person or entity and does not otherwise create any harm to third parties;
- (4) Data posted on Luxembourg Elixir Platform corresponds to the definition of Data provided above, notably that it results from or is related to biomedicine, and that it is presented in easily usable and structured form;
- (5) it shall not post on Luxembourg Elixir Platform any unsolicited or unauthorised advertising, promotional materials, junk mail, spam or any other form of solicitation (commercial or otherwise);
- (6) it shall not post, transmit or otherwise make available any virus, worm, spyware or any other computer code, file or programme that may or is intended to damage or hijack the operation of any hardware, software or telecommunications equipment or any hardware/software connected to Luxembourg Elixir Platform.

9. Disclaimer of Warranties

To the extent permissible pursuant to applicable law, the Services, any materials and third-party content, software, applications made available through or in relation to the Services, are provided on as "AS IS" basis without representations or warranties of any kind, either express or implied, including but not limited to accuracy, reliability or otherwise.

10. Limitation of Liability

To the fullest extent permissible pursuant to applicable law, the LCSB-UL, its officers, directors will not be liable for any indirect, incidental, special, consequential damages arising out of or in connection with the use of Services or access to Luxembourg Elixir Node, including without limitation, damages for loss of profits, goodwill or other tangible or intangible losses.

11. Termination and obligations of the parties after the termination

These Terms of Services will be valid for 10 years and may be renewed upon mutual written agreement of the Parties.

LCSB-UL may terminate the Terms of Services at any time before the end of the 10 years term by providing a prior 3 months' notice, in case:

- the Data Provider does not ensure effective access management to the Data as provided in these Terms of Services and/or the Services Agreement or in any other way commits a material breach of the Terms of Services and/or the Services Agreement. The Parties hereby expressly agree that the breach of the clauses 5 (Privacy and Personal Data Processing), 6 (Ethics Policy) and 7 (Intellectual Property Rights) will in all circumstances be deemed as a material breach of the Terms of Services;
- the Luxembourg Elixir Platform financing from the Government or European Union is ceased or substantially reduced;
- LCSB-UL is subject to restructuration, cessation of the activities or change of control;
- the Data Access Committee prevents the access of Data by delaying decisions and/or making decisions based on discriminating criteria;
- the Data transferred to the Luxembourg Elixir Platform is of very low quality in the way that it is hard to use it or access for the Users;
- the Data have not been accessed by any User for longer than [2] years.

The termination of these Terms of Services will result in permanent deletion of the Data from the Luxembourg Elixir Platform.

12. Miscellaneous

Modification of the Terms of Use

In case of changes to these Terms of Use, the Data Provider will be notified with a 30 days prior notice. If, after reception of such notice, the Data Provider does not notify its intention to terminate these Terms of Services and continues to use the Services, he will be deemed to have accepted the amendments to the Terms of Services.

Confidentiality

The Data Provider shall keep confidential all technical, business and financial information including, where appropriate and without limitation, all information, licenses, business plans, data, structures, models, techniques, processes,

compositions, and compounds disclosed by LCSB-UL or obtained by the Data Provider through observation or examination of information.

The Parties undertake to enforce the present clause to their staff, suppliers and any third party involved.

Each Party undertakes, furthermore, to limit the dissemination of confidential information relating to these Terms of Services and its execution to members of its staff or sub-contractors where the performance of their activities require access to such confidential information (need to know basis).

This obligation of confidentiality does not apply to cases where either of the Parties would need to prove to the tax authorities of past performance hereof or to enforce its legal rights under the present Terms of Services.

Confidentiality does not apply to information already known by the receiving Party prior to its communication, to those obtained from third parties by legitimate means, to information developed independently, or to information made public by the disclosing Party.

The obligations of non-disclosure undertaken under this article shall stay in force from the effective date, and shall last five (5) years after the termination of the Terms of Services.

Force Majeure

The Parties shall not be liable for failing to perform their obligations under these Terms of Services, if such non-performance is attributable to strikes, revolt, acts of God, act of terrorism, wars, disasters, legal regulation, interruption of the telecommunications network or of the electricity network or other circumstances beyond the control of, or otherwise unforeseeable by the defaulting Party (hereinafter referred to as “**Force Majeure**”). The obligations of such Party shall be suspended for the duration of such event of Force Majeure.

However, the Party affected by Force Majeure shall without delay inform the other Party about the estimated duration of the event of Force Majeure; moreover, the Party affected shall use its best efforts to remedy the effects of such Force Majeure without undue delay. If a case of Force Majeure is expected to last for more than two months, the Party not affected by Force Majeure may terminate these Terms of Services with immediate effect in writing, and the affected Party shall not be entitled to any compensation for loss or damage.

Severability

If any term hereof is held invalid, void or unenforceable by any court or body of competent jurisdiction or by virtue of any legislation to which it is subject or by virtue of any other reason whatsoever, it shall be void or unenforceable to that extent only and no further and the validity and enforceability of any of the other provisions herein shall not be affected thereby to the extent allowed by law.

Governing law and jurisdiction

These Terms of Services shall be governed by and construed in accordance with the laws of Grand Duchy of Luxembourg.

Any controversy or claim arising out of or relating to these Terms of Services shall be submitted to the exclusive jurisdiction of the competent courts of the city of Luxembourg.

ANNEX B TO THE SERVICES AGREEMENT

[SERVICES AND TRANSFERRED DATA SHOULD BE DESCRIBED].

ANNEX C

TECHNICAL AND ORGANISATIONAL MEASURES

Both LCSB-UL and Data Provider will take appropriate technical and organisational measures (while taking into account the costs of the measures and State of the Art) to protect the Data provided to the Luxembourg Elixir Platform against misuse and loss, in accordance with European data protection rules, including all necessary and reasonable precautions:

- to prevent unauthorised persons from gaining access to data processing systems with which the Data are processed or used (**physical access control**),
- to prevent data processing systems from being used without authorisation (**denial of use control**),
- to ensure that persons entitled to use a data processing system can gain access only to the Data to which they have a right of access, and that the Data cannot be read, copied, modified or removed without authorisation in the course of processing or use and after storage (**data access control**),
- to ensure, including through use of secure encryption, that the Data cannot be read, copied, modified or removed without authorisation during electronic transmission, transport or storage and that it is possible to examine and establish to which bodies the transfer of Personal data by means of data transmission facilities is envisaged (**data transmission control**),
- to ensure that it is possible retrospectively to examine and establish whether and by whom the Data have been inputted into data processing systems, modified or removed (**input control**),
- to ensure that the Data being processed on commission are processed solely in accordance with the directions of the Data Controller (**contractual control**),
- to ensure that the Data are protected against accidental destruction or loss including backup copies (**availability control**),
- to ensure that other Data collected for different purposes is processed separately (**separation rule**).

ELIXIR-LU SERVICES AGREEMENT (the “**Agreement**”)

between

[...]
duly represented by, hereinafter “**the Data Provider**”

and

the University of Luxembourg, a Public Institution of Higher Education and Research, having its registered office at 162a, avenue de la Faïencerie, L-1511 Luxembourg, duly represented by its acting president Prof. Dr. Ludwig Neyses, acting for its Luxembourg Centre for Systems Biomedicine, Campus Belval, 7 avenue des Hauts-Fourneaux, L-4362 Esch-sur-Alzette, G.D. Luxembourg, duly represented by its director Prof. Dr. Rudi Balling, hereinafter “**LCSB-UL**”

Individually referred to as a “Party” or collectively referred to as the “Parties”.

Preamble

Whereas,

LCSB-UL disposes of a High Performance Computing infrastructure that allows hosting data;

LCSB-UL is the Luxembourg node (the “**Luxembourg Node**”) for the European Life-Science Infrastructure for Biological Information (“**ELIXIR**”) an intergovernmental consortium that brings together life science resources from across Europe;

the Data Provider is [PLEASE INSERT DESCRIPTION] and wishes to store biomedicine data and provide access to such data to third parties under the conditions listed in this Agreement and Terms of Use governing this Agreement;

each of the Parties recognises as a priority the need to respect the fundamental interests and rights of Data Subjects, including the need to preserve the security and privacy of the Data;

the infrastructure of data processing guarantees compliance with binding European legislation on the protection of individuals with regard to the processing of personal data and the free movement of such data (hereafter “the European data protection law”) that means the Data Protection Directive 95/46/EC that will be replaced by the General Data Protection Regulation (GDPR) on 25th May 2018. It is of high importance to process the Data in compliance with relevant applicable laws and regulations, including, without limitation, privacy and medical secrecy laws applicable to the activities of the Parties;

The Parties hereby agree as follows:

Clause 1: Definitions and Terms of Use

For the purposes of this Agreement, the terms used in this Agreement shall have the same meaning as attributed to them in the Terms of Use as attached in Annex A to this Agreement.

Terms of Use constitute an integral part of this Agreement. In case of any discrepancies between this Agreement and the Terms of Use, the terms of this Agreement shall prevail.

Clause 2: Scope of Services

The Data Provider opts for Services as described in Annex B.

The data transferred by the Data Provider concern the data listed in Annex B (the “Data”).

The Data Provider is responsible as a Data Controller for the management of Data within its organisation, while LCSB-UL is a Data Processor for the Data processing and sharing the Data on behalf of the Data Provider and its status is limited to data hosting services provider.

Clause 3: Financial provisions

[THE FINANCIAL PROVISIONS, IF ANY, SHOULD BE DESCRIBED]

Clause 4: Data Access

The Data Provider agrees to provide Open Access to the Data stored on Luxembourg Elixir Platform.

OR

The Data Provider agrees to provide Controlled Access to the Data stored on Luxembourg Elixir Platform.

Clause 5: Term

[If different from term established under the Terms of Use]

Made in two signed copies, each party having received one original.

| For the Data Provider | For University of Luxembourg / Luxembourg Centre for Systems Biomedicine (LCSB) |
|---------------------------------------|---|
| Name: Title: Date: Signature | Name: Prof. Dr. Ludwig Neyses Title: Acting President, University of Luxembourg Date: |

| | |
|--|---|
| | <p>Signature</p> <p>Name: Prof. Dr. Rudi Balling Title: Director, LCSB Date: Signature</p> |
|--|---|

- Annex A Terms of Services
- Annex B Services description
- Annex C Technical and organisational measures

ANNEX A

ELIXIR-LU TERMS OF SERVICES

The University of Luxembourg, a Public Institution of Higher Education and Research, having its registered office at 162a, avenue de la Faïencerie, L-1511 Luxembourg, acting for its Luxembourg Centre for Systems Biomedicine, Campus Belval, 7 avenue des Hauts-Fourneaux, L-4362 Esch-sur-Alzette, G.D. Luxembourg, hereinafter “**LCSB-UL or Luxembourg Node**” is the Luxembourg node for the European Life-Science Infrastructure for Biological Information (ELIXIR), an intergovernmental consortium that brings together life science resources from across Europe. These resources include databases, software tools, training materials, cloud storage and supercomputers. ELIXIR includes 21 member states and over 180 research organisations and is a research infrastructure of global significance.

ELIXIR is coordinated by the ELIXIR Hub hosted by the European Molecular Biology Laboratory with Nodes in member states and other countries with the aim to provide seamless and sustainable data infrastructures for research in the life sciences. The national nodes are constituted of bioinformatics centres of excellence that represent a national strength and priority and provide nationally coordinated services. LCSB-UL has been admitted as a Luxembourg Node to the ELIXIR.

These terms of use (the “**Terms of Use**”) govern the services provided by the LCSB-UL acting as a Luxembourg Node.

1. Definitions

Anonymisation shall mean the process of transforming Data into any information that does not relate to an identified or identifiable person or to personal data rendered anonymous in such a manner that the Data Subject is not or no longer identifiable. LCSB-UL only receives anonymised data related to open access from the Data Provider.

Data shall mean biomedical data, including personal and anonymised data, provided by the Data Provider to the Luxembourg Elixir Platform.

Data Access Agreement shall mean the data access agreement that the LCSB-UL shall conclude on behalf of the Data Provider with User regarding the access of Data hosted on the Luxembourg Elixir Platform.

Data Access Policy shall mean access control policy established by the Data Provider on the basis of which LCSB-UL, acting on behalf of the Data Provider, grants controlled access to Data stored on Luxembourg Elixir Platform.

Data Access Committee shall mean the committee formed by the LCSB-UL, acting on behalf of the Data Provider, that reviews the application of access from User and grants/declines access based on the Data Access Policy provided by the Data Provider. The Data Provider may mandate its representative to the Data Access

Committee who will have a veto right on decisions regarding Data access within 10 days after the access request was submitted to the Data Provider.

Data Controller shall mean the natural or legal person which alone or jointly with others, determines the purpose and the means of the processing of Personal data. The Data Provider is the Data Controller as regards to the collection and the processing of Data provided to the Luxembourg Elixir Platform.

Data Processor shall mean the natural or legal person who processes Personal data on behalf of the controller. LCSB-UL is the Data Processor as regards the collection and the processing of Data provided to the Luxembourg Elixir Platform.

Data Subject shall mean any identified or identifiable natural person, whose data are provided by the Data Provider to the Luxembourg Elixir Platform. An identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his/her physical, physiological, mental, economic, cultural or social identity. As a rule, the subject whose data are processed within the Luxembourg Elixir Platform is the Data Subject.

Data Provider shall mean any private or public entity wishing to store its Data on the Luxembourg Elixir Platform and grant an open or controlled access to it to any User under the terms listed in these Terms of Services and the Services Agreement, as the case may be.

ELIXIR shall mean the European Life-Science Infrastructure for Biological Information, an intergovernmental consortium that brings together life science resources from across Europe.

Luxembourg Elixir Platform shall mean the platform hosted by LCSB-UL.

Personal data shall mean any information relating to an identified or identifiable natural person (the "Data Subject").

Pseudonymisation shall mean the processing of Personal data in such a manner that the Personal data can no longer be attributed to a specific Data Subject without use of additional information, to keep separately the additional information and protect this information with technical and organisational measures to ensure that the Personal data are not attributed to a Data Subject.

LCSB-UL only receives pseudonymised data related to controlled access from the Data Provider.

Services shall mean secured Data storage Services provided by the LCSB-UL, including Luxembourg Elixir Platform.

Services Agreement shall mean the agreement concluded between the Data Provider and the LCSB-UL.

User shall mean any legal person registered with Luxembourg Elixir Platform wishing to access Data hosted on the Luxembourg Elixir Platform.

2. Services provided by LCSB-UL

In the context of ELIXIR programme, LCSB-UL acting as the Luxembourg Node provides the secured Data storing Services.

The Services chosen by the Data Provider shall be specified in the Services Agreement concluded with LCSB-LU.

Elixir Services provided by LCSB-UL are accessible to any Data Provider wishing to store Data on Luxembourg Elixir Platform and grant open or controlled access to such Data under conditions described in these Terms of Services.

LCSB-UL will make all reasonable effort to maintain continuity of the Services and provide adequate warning of any changes or discontinuities. However, LCSB-UL does not provide any warranty and accepts no responsibility for the consequences of any temporary or permanent discontinuity of the Services.

Only Data that is compatible with general Elixir European framework and goals shall be eligible for being hosted and transmitted to Luxembourg Elixir Platform. The Data Provider has to ensure that the Data provided to the Luxembourg Elixir Platform is provided in a structured manner, easily readable and usable format.

LCSB-UL retains a right to refuse storing/hosting Data on its Luxembourg Elixir Platform, if:

- the Data exceeds [PLEASE INDICATE THE LIMIT] the limit;
- the Data Provider fails to provide metadata;
- the Data Provider does not provide Data Access Agreement and Data Access Policy when the controlled access possibility is chosen;
- the Data Provider does not respect the other terms of these Terms of Services.

The role of the LCSB-UL within the Services is limited to the provision of hosting and sharing services, LCSB-LU itself does not have knowledge and does not control the quality of Data provided by the Data Providers.

Subject to applicable law, the LCSB-UL takes no responsibility and assume no liability for any Data or other materials posted, stored, or uploaded by Data Provider on the Luxembourg Elixir Platform or for any loss or damage to any of such Data. Although the LCSB-UL does not have an obligation to screen, edit, or monitor any Data posted or transmitted to Luxembourg Elixir Platform, the LCSB-UL reserves the right and have discretion to screen and remove any Data posted, stored, or transmitted on or through Luxembourg Elixir Platform at any time and without notice, where:

- it is notified by the Users or third parties about the illegal and infringing nature of Data;
- based on particular circumstance, the LCSB-UL may presume that Data is infringing third parties' rights or may otherwise be considered as illegal.

3. Data Access

By accepting these Terms of Services the Data Provider understands that the European ELIXIR initiative is based on open access and data sharing in order to establish sustainable infrastructure for research in the life sciences. Data Provider expressly **accepts to grant open or controlled access to Data** stored, hosted and/or transmitted to Luxembourg Elixir Platform under the conditions established in these Terms of Services.

The Data Provider may choose one of the below Data access options:

- **Open Access.** Open Access allows any User registered with Luxembourg Elixir Platform access Data in an unrestricted manner.
- **Controlled Access.** Controlled Access permits Data Provider to establish the Data Access Policy and in such a way control access of Data based on non-discriminating criteria. Based on the Data Access Policy the Data Access Committee shall perform the control of the access to Data and the LCSB-UL, acting on behalf of the Data Provider, shall enter into Data Access Agreements with Users. By accepting these Terms of Services, Data Provider mandates LCSB-UL to control on behalf of the Data Provider access to Data whenever the Controlled Access option is chosen and to enter on behalf of the Data Provider into Data Access Agreements with Users based on the requirements established in the Data Access Policy provided by the Data Provider.

If the Data Provider mandates its representative to the Data Access Committee, such a representative will have a right to exercise a veto right (by way of written/electronic notification) within 10 days after the notification about the access request is sent by LCSB-UL. If the veto right is not exercised within this time limit, it will be deemed that the Data Provider's representative tacitly consented to the access requested. The veto right may be only exercised if legitimate reasons exist.

In certain particular cases when for example Data may not be made public during certain limited period of time, the Data Provider may request the LCSB-UL to grant a limited closed access, which may not be longer than 18 months. The Data Provider shall reimburse LCSB-UL for the closed access storage period should the Data Provider fail to store the Data on the Luxembourg Elixir Platform for at least 5 years.

Data Access Policy established by the Data Provider should respect the following principles:

- contain clear and precise requirements for Data access;
- should not contain any discriminating criteria based on nationality, gender, race, political opinions;
- should contain Data access restrictions stemming from requirements applicable to personal data protection, ethics or other national legal requirements.

The Data Provider shall submit the Data Access Policy to the LCSB-UL for the latter's information.

4. Fees and payments

Luxembourg Elixir Platform is financed by the Government of the Grand Duchy of Luxembourg and the LCSB-UL, thus the Services presently are provided free of charge.

LCSB-UL reserves the right to apply the fees in certain particular situations where the amounts of the Data stored by the Data Provider are proportionately high in respect of the overall available space for the Luxembourg Elixir Platform. Such fees will be detailed in the Services Agreement.

Should the financing of the Luxembourg Elixir Platform be ceased, the LCSB-UL may implement the fees for the Services at any time by providing the Data Provider 30 days written notice. Upon such notification, the Data Provider will have a possibility to terminate Terms of Services and Services Agreement, if any. The use of Services after the expiry of the notification date shall be deemed as tacit acceptance of the fees notified.

5. Privacy and Personal Data Processing

The Data Provider undertakes:

- to transfer to LCSB-UL only Data, for which the informed consent of the Data Subject and/or appropriate ethics approval for transfer and use in ELIXIR are obtained;
- to transfer to LCSB-UL the Data using securely encrypted transit channels;
- to comply while processing the Data with the applicable laws, including national data protection law applicable to the data transfer. LCSB-UL will not be liable in case of any issues arising from any deficiency in the consent of the patients, or non-notification of relevant national personal data protection authorities or local ethics bodies prior to the transfer of the data to LCSB-UL;
- to perform a secure pseudonymisation process on any Data transferred to LCSB-UL for controlled access service and a secure anonymisation process on any Data transferred to LCSB-UL for open access service on the basis of this Agreement. LCSB-UL only stores pseudonymised or anonymised data that it has implemented and follows appropriate technical and organisational security measures to protect the data against misuse and loss (including without limitation the measures stated in Annex C to this agreement) in accordance with the European data protection law;
- to provide all necessary information and documents that may be needed in case of any request by supervisory authorities;
- to inform LCSB-UL 7 working days before for any removal of Data due to Data Subject's consent withdrawal;
- to inform LCSB-UL when the Personal data have to be deleted or rendered anonymous in accordance with European data protection laws 10 working days before.

The LCSB-UL undertakes:

- to store and process the Data in compliance with applicable personal data protection laws and the terms of this Agreement;

- that it has implemented and follows appropriate technical and organisational security measures to protect the Data against misuse and loss (including without limitation the measures stated in Annex B to this Agreement), in accordance with the requirements of relevant provisions of European data protection law;
- that it shall not attempt to identify any Data Subject from the Data either by external matching of the Data or by any other means;
- that in the event of inadvertently identifying any Data Subject, it undertakes not to make any use of the identifying information for any purposes and to take all necessary steps to protect the interests of the Data Subject including so far as possible restoring their pseudonymised status;
- to grant access to Data to Data Provider whenever Data Provider shall require such access. Access rights of Users to the Data shall be regulated by article 3 of the Terms and Conditions;
- to process and store the Data for the duration of these Terms of Services excepted if other legal disposals requires shorter deletion or anonymisation.

The Parties agree that the data retention will be for the duration of these Terms of Services excepted if legal disposals or supervisory authorities require a shorter duration. In such case, the Data Provider undertakes to inform the LCSB-UL at least 10 working days after becoming aware of these legal disposals or after being notified by the supervisory authority of the removal or anonymisation of the Data. The Parties undertake to inform each other about a Personal data breach no later than 2 working days after becoming aware of it as soon as they are aware, even imperfectly, of the circumstances and the approximate volume of the Data concerned.

In such a case, the Parties shall exchange all relevant information to enable them to respond effectively to regulators or Data Subjects and shall endeavour to coordinate their crisis communication on this eventuality.

6. Ethics Policy

Data Provider also undertakes to adhere to general ethical principles, including those related to research integrity and use of human biospecimens and Data related to human subjects for research purposes. Specifically, Data related to human subjects, human blood samples and other tissue, if any, will be transferred to the LCSB-UL only to the extent that the Data Provider can ensure that the patient has agreed in writing to its specific use for scientific purposes and the competent local ethical committee of the Data Provider has permitted such use.

7. Intellectual Property Rights

All intellectual property rights (including but not limited to author rights, trade marks, patents, know-how) on the infrastructure, software, documentation and other tools used for the provision of the Services will stay the ownership of the LCSB-UL.

By accepting these Terms of Use the Data Provider gives his/her consent for the LCSB-UL to use Data Provider's corporate name and/or logo when communicating about the Services provided as a part of ELIXIR programme.

8. Representations and Warranties

When transmitting Data to Luxembourg Elixir Platform Data Provider represents and warrants that:

- (1) it has a right to post such Data to Luxembourg Elixir Platform and the posting and access of such Data by Users does not infringe, violate or misappropriate any Intellectual Property Rights of third parties;
- (2) all applicable privacy and personal data laws and regulations are respected, notably that all consents, waivers, authorisations and/or approvals from Data Subjects and relevant public authorities have been obtained;
- (3) posting Data on Luxembourg Elixir Platform does not violate any rights of or cause injury to any person or entity and does not otherwise create any harm to third parties;
- (4) Data posted on Luxembourg Elixir Platform corresponds to the definition of Data provided above, notably that it results from or is related to biomedicine, and that it is presented in easily usable and structured form;
- (5) it shall not post on Luxembourg Elixir Platform any unsolicited or unauthorised advertising, promotional materials, junk mail, spam or any other form of solicitation (commercial or otherwise);
- (6) it shall not post, transmit or otherwise make available any virus, worm, spyware or any other computer code, file or programme that may or is intended to damage or hijack the operation of any hardware, software or telecommunications equipment or any hardware/software connected to Luxembourg Elixir Platform.

9. Disclaimer of Warranties

To the extent permissible pursuant to applicable law, the Services, any materials and third-party content, software, applications made available through or in relation to the Services, are provided on an "AS IS" basis without representations or warranties of any kind, either express or implied, including but not limited to accuracy, reliability or otherwise.

10. Limitation of Liability

To the fullest extent permissible pursuant to applicable law, the LCSB-UL, its officers, directors will not be liable for any indirect, incidental, special, consequential damages arising out of or in connection with the use of Services or access to Luxembourg Elixir Node, including without limitation, damages for loss of profits, goodwill or other tangible or intangible losses.

11. Termination and obligations of the parties after the termination

These Terms of Services will be valid for 10 years and may be renewed upon mutual written agreement of the Parties.

LCSB-UL may terminate the Terms of Services at any time before the end of the 10 years term by providing a prior 3 months' notice, in case:

- the Data Provider does not ensure effective access management to the Data as provided in these Terms of Services and/or the Services Agreement or in any other way commits a material breach of the Terms of Services and/or the Services Agreement. The Parties hereby expressly agree that the breach of the clauses 5 (Privacy and Personal Data Processing), 6 (Ethics Policy) and 7 (Intellectual Property Rights) will in all circumstances be deemed as a material breach of the Terms of Services;
- the Luxembourg Elixir Platform financing from the Government or European Union is ceased or substantially reduced;
- LCSB-UL is subject to restructuration, cessation of the activities or change of control;
- the Data Access Committee prevents the access of Data by delaying decisions and/or making decisions based on discriminating criteria;
- the Data transferred to the Luxembourg Elixir Platform is of very low quality in the way that it is hard to use it or access for the Users;
- the Data have not been accessed by any User for longer than [2] years.

The termination of these Terms of Services will result in permanent deletion of the Data from the Luxembourg Elixir Platform.

12. Miscellaneous

Modification of the Terms of Use

In case of changes to these Terms of Use, the Data Provider will be notified with a 30 days prior notice. If, after reception of such notice, the Data Provider does not notify its intention to terminate these Terms of Services and continues to use the Services, he will be deemed to have accepted the amendments to the Terms of Services.

Confidentiality

The Data Provider shall keep confidential all technical, business and financial information including, where appropriate and without limitation, all information, licenses, business plans, data, structures, models, techniques, processes, compositions, and compounds disclosed by LCSB-UL or obtained by the Data Provider through observation or examination of information.

The Parties undertake to enforce the present clause to their staff, suppliers and any third party involved.

Each Party undertakes, furthermore, to limit the dissemination of confidential information relating to these Terms of Services and its execution to members of its staff or sub-contractors where the performance of their activities require access to such confidential information (need to know basis).

This obligation of confidentiality does not apply to cases where either of the Parties would need to prove to the tax authorities of past performance hereof or to enforce its legal rights under the present Terms of Services.

Confidentiality does not apply to information already known by the receiving Party prior to its communication, to those obtained from third parties by legitimate means, to information developed independently, or to information made public by the disclosing Party.

The obligations of non-disclosure undertaken under this article shall stay in force from the effective date, and shall last five (5) years after the termination of the Terms of Services.

Force Majeure

The Parties shall not be liable for failing to perform their obligations under these Terms of Services, if such non-performance is attributable to strikes, revolt, acts of God, act of terrorism, wars, disasters, legal regulation, interruption of the telecommunications network or of the electricity network or other circumstances beyond the control of, or otherwise unforeseeable by the defaulting Party (hereinafter referred to as “**Force Majeure**”). The obligations of such Party shall be suspended for the duration of such event of Force Majeure.

However, the Party affected by Force Majeure shall without delay inform the other Party about the estimated duration of the event of Force Majeure; moreover, the Party affected shall use its best efforts to remedy the effects of such Force Majeure without undue delay. If a case of Force Majeure is expected to last for more than two months, the Party not affected by Force Majeure may terminate these Terms of Services with immediate effect in writing, and the affected Party shall not be entitled to any compensation for loss or damage.

Severability

If any term hereof is held invalid, void or unenforceable by any court or body of competent jurisdiction or by virtue of any legislation to which it is subject or by virtue of any other reason whatsoever, it shall be void or unenforceable to that extent only and no further and the validity and enforceability of any of the other provisions herein shall not be affected thereby to the extent allowed by law.

Governing law and jurisdiction

These Terms of Services shall be governed by and construed in accordance with the laws of Grand Duchy of Luxembourg.

Any controversy or claim arising out of or relating to these Terms of Services shall be submitted to the exclusive jurisdiction of the competent courts of the city of Luxembourg.

ANNEX B TO THE SERVICES AGREEMENT

[SERVICES AND TRANSFERRED DATA SHOULD BE DESCRIBED].

ANNEX C

TECHNICAL AND ORGANISATIONAL MEASURES

Both LCSB-UL and Data Provider will take appropriate technical and organisational measures (while taking into account the costs of the measures and State of the Art) to protect the Data provided to the Luxembourg Elixir Platform against misuse and loss, in accordance with European data protection rules, including all necessary and reasonable precautions:

- to prevent unauthorised persons from gaining access to data processing systems with which the Data are processed or used (**physical access control**),
- to prevent data processing systems from being used without authorisation (**denial of use control**),
- to ensure that persons entitled to use a data processing system can gain access only to the Data to which they have a right of access, and that the Data cannot be read, copied, modified or removed without authorisation in the course of processing or use and after storage (**data access control**),
- to ensure, including through use of secure encryption, that the Data cannot be read, copied, modified or removed without authorisation during electronic transmission, transport or storage and that it is possible to examine and establish to which bodies the transfer of Personal data by means of data transmission facilities is envisaged (**data transmission control**),
- to ensure that it is possible retrospectively to examine and establish whether and by whom the Data have been inputted into data processing systems, modified or removed (**input control**),
- to ensure that the Data being processed on commission are processed solely in accordance with the directions of the Data Controller (**contractual control**),
- to ensure that the Data are protected against accidental destruction or loss including backup copies (**availability control**),
- to ensure that other Data collected for different purposes is processed separately (**separation rule**).