Lifebrain

D5.4. Exploitation and IP management strategy I

Project title:	Healthy minds from 0-100 years: Optimising the use of European brain imaging cohorts
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Executive summary

The **vision** of the Lifebrain Consortium is to enable targeted prevention of brain, cognitive and mental health problems at all stages in life in Europe and worldwide. This vision will be put into action by several different approaches.

This deliverable 5.4, describes the "**Exploitation and Intellectual Property (IP) management strategy" of Lifebrain**. Acknowledging the fact that if the vision of the Lifebrain Consortium is to be implemented, some commercial activities should provide better chances for success.

The Deliverable D5.4 describes the Background provided to the consortium by each partner, the nature of the Lifebrain partners, being either Academic or SME, in respect to how results from the Lifebrain project will be exploited by these two types of partners. Vitas, as the only SME, has a defined strategy to reach the market, and commercially exploit results during and after the Lifebrain project.

The current commercialisation strategy for Vitas will be developed during the project to a complete business plan.

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List of acronyms/ abbreviations

Lifebrain	Healthy minds from 0 to 100 years: Optimizing the use of European brain imaging cohorts
CA	Consortium Agreement
DBS	Dried Blood Spots
DEC	Dissemination, Exploitation and Communication
DWI	Diffusion-Weighted Imaging
EB	Executive Board
EC	European Commission
EU	European Union
GA	Grant Agreement
fMRI	Functional Magnetic Resonance Imaging
IP	Intellectual Property
IPR	Intellectual Property Right
LCBC	Centre for Lifespan Changes for Brain and Cognition
LB	Lifebrain
MEG	MagnetoEncephaloGraphy
M	Month
MRI	Magnetic Resonance Imaging
R&D	Research and Development
RTD	Research and technical development
SME	Small and Medium-size Enterprises
UiO	University of Oslo
WP	Work Package

1. Introduction

1.1. Deliverable description

Task 5.4.
An IP management strategy will be delivered considering the necessary and most appropriate consortium agreement to lead to effective exploitation opportunities post-project.

An integrated IP and exploitation strategy will be defined and implemented along with innovative communication channels developed.
A series of IP workshops will be held with all partners (i.e. on the back of AGM meetings) and provide insight and information on IP management steps for collaborative R&D projects and a strategy for the Lifebrain project (D5.4-5.7).
The task will also examine the 'results' achieved in the project and how this can lead to the up-take of products/services to the market place. As a minimum a business plan will be delivered for the exploitation of the advanced (VITAS) DBS – Home kits (D5.9) and how this will be launched into the market place post-project and for use in LCBC and other multidisciplinary research investigations.

D5.4. Exploitation and IP management strategy - I [24] An integrated IP and exploitation strategy will be defined and implemented along with innovative communication channels developed

1.2. Purpose of deliverable

The purpose of this deliverable is to produce, update, control, and revise the exploitation strategies of the Lifebrain consortium. In addition, an IP strategy will be evaluated, defined and finally implemented based on the outcome of internal agreements among the beneficiaries. In this document we present how the Lifebrain results will be used and exploited by project partners.

The Exploitation Plan has been created through consultations with the entire consortium in order to develop a strategy that fully accounts for its needs and expected benefits.

The exploitation plan is an important factor for the success of the project and all Partners will have specific roles according to their core businesses.

The exploitation strategy of partners is described regarding the following main points:

- How to use and receive commercial benefits resulting from the Lifebrain project defining who can sell and use it.

- How to manage the IPR generated in the project. e.g. how all partners could apply part of the Lifebrain results/knowledge in new products or RTD projects.

The present document should complement pre-existing instruments such as the Grant Agreement and the Consortium Agreement; it shows the plan for exploitation by partners, the overall exploitation towards external (to the consortium) organizations, and the exploitation agreement among the partners and the management of the Intellectual Property Right.

1.3. Exploitation strategy

Lifebrain exploitation strategy is based on the following two main pillars:

1. Exploitation Plan, which describes how partners are expected to generate benefits by the project results (Individual Exploitation Plan), and the agreement among partners on commercial exploitation of a potential "Lifebrain solution".
2. IPR Management, which addresses the ownership of the IPR, and the management of access rights to such IPR by the project partners.

These pillars are described in this document. The SME partner Vitas will exploit the project outcomes in terms of commercial use, whereas academic partners will exploit such results in terms of know-how in research activities (research projects, educational activities, Research and Development (R&D) on behalf of future industrial partners, SMEs in particular), and related Intellectual Properties (IP).
At the end of the project, the final exploitation plan will elaborate the future exploitation, based on the achieved results. This final delivery will also incorporate and elaborate a strategy on how to exploit the produced results optimally with respect to the partners' practices.

1. Overall approach to consortium exploitation plan

1.1. General approach

Specific commercial and other benefits achievable by results from the Lifebrain project are regulated in the Exploitation Plan in the following way:

- Definition of the marketable results and of individual exploitation strategies;
- Definition of the access rights of the partners to the project Background and Results for internal use.
- How to manage the IPR generated in the project. This includes the definition on how to treat the Results generated in the project. In this sense, the classical IPR approach of cooperative projects will be applied; the inventor of the IPR remains owner of the IPR generated. When the Results are result of joint efforts, the partners contributing will be co-owners of the Results created.

Lifebrain partners have different backgrounds and core businesses. There are only two types of partners in Lifebrain; academic institutions and one SME (Vitas).

The academic partners are interested in using newly gained Results as input to further research, scientific publications, and advanced teaching purposes as well as to initiate further research projects.

The SME partner will focus on network building, raising its profile and seeking opportunities for commercial linking and co-exploitation of project results or provision of innovative services in their current area of operation. They will be able to exploit the project activities to leverage company growth through an improved high-tech reputation for the company, new opportunities for collaboration and new service offers that can open new markets and serve the European populations in terms of better health service as well as economic growth based on scientific evidence.

1.2. Definition of marketable results

As the only SME, Vitas AS will be the only partner with interests in marketing commercial products and services based on the activities in the Lifebrain Consortium. Academic partners will focus on using newly gained Results as input to new research projects, scientific publications and advanced teaching purposes.

1.3. Exploitation plan for the SME partner Vitas

A unique innovative aspect of Lifebrain is related to the blood biomarker analyses from dried blood spots, where Vitas expects to develop a DBS home-kit after generation of results from additional samples from the different Lifebrain cohorts. This will be a unique service at moderate cost. The idea is to monitor beneficial and negative factors in blood for brain function, providing an opportunity to improve diet, exercise and other lifestyle factors, in addition to evaluate potential drug treatments where this would be appropriate. Thus, the analytical service might turn out to have very marked effects on the society level.

Novel methods have been developed (will be finalized by the end of 2018 and early 2019, See D3.5. DBS assays for relevant biomarkers for data enrichment, due December 2018) for biomarker analyses that can be applied in future academic projects and exploited in various business models where decentralized collection of blood via DBS for biomarker analyses are needed. Typical examples for future use will be personalized nutrition, medicine and programs to improve lifestyle and health on an individual level.

The unique datasets on brain imaging and cognitive functions will be related to results from analyses of blood samples collected in the studies already performed among several partners in Lifebrain. These blood samples will be selected for analyses of many nutrients, hormones, signal molecules and lipids with state-of-the-art technology, after development and validation of certain analytical methods relevant for characterization of brain status.

The WP1 study focused on: “Are people ready to endorse personalised brain health? - viewpoints from the Lifebrain consortium,” will also contribute to the exploitation plan by revealing preferences and attitudes to brain health tests and lifestyle changes in general.

Vitas will use the Lifebrain results to expand its product portfolio and target new markets and customers:

- Public health – population screening. Currently we do not have specific measurements to reveal conditions like neuro-degenerative diseases, but we have considered to screen school children for high concentrations of cholesterol and glucose (HbA1c). These measurements have predictive values for neurodegenerative diseases like dementia and Alzheimer’s disease. This approach will be evaluated depending on what we find in the specific Lifebrain analyses.
- Personal nutrition services are increasingly in focus of many health providers. Life insurance companies represent one group that may be of importance as future customers.
- Pharmaceutical companies like Glaxo Smith Kline, Roche, Nycomed, PharmaQ, Weifa, Photocure, Celgene, Aker Biomarine, PCI Biotech, Algeta, Receptos, and Anokion USA are also customers for hundreds of different analyses linked to specific pharmaceutical agents in association with evaluation of stability, storage, metabolism, and synthesis.
- Multi-marketing providers like Zinzino and Ecology have submitted about 100000 samples for fatty acid analyses on DBS in 2018. The samples are submitted from many different countries and the dominant amount of samples are coming from abroad. These analyses are bundled to purchase of certain oil products and are linked to repeated measurements.
- Food industries such as Nestlé, Orkla, Stabburet, Tine, Nortura, and Smartfish are customers mostly concerning measurements of different nutrients and food components.

We also consider development of an application including lifestyle advice concerning physical and cognitive training programs, quitting smoking, improving diet, reducing consumption of alcohol and drugs affecting brain functions, and plotting of results from biomarker analyses of importance for general health and brain health in particular.

2. IPR evaluation

The management of Intellectual Property Rights has been regulated in detail by the Consortium Agreement, which has been focused on the following main points:

- Licensing of pre-existing know-how and refinements thereof (Background);
- Ownership of the knowledge gained within the project (Results/Foreground);
- Confidentiality for dissemination of project results.

According to Section 9.3 of the CA, Access Rights to Results and Background needed for performing their own work a Party under the Project shall be granted on a royalty-free basis, unless otherwise agreed for Background excluded.

During the project, specific actions have been and will be undertaken for properly addressing issues related to ownership, protection and guarantee of knowledge inside the Lifebrain Consortium:

- Discussions of the IP strategy among all partners in the Lifebrain Executive Board
- It has been communicated to all 14 partners that knowledge generated in the Lifebrain Consortium may represent potential new commercial activities that should be first suggested by the different partners specifically coming up with new discoveries.
- Introduction of a specific subgroup on our internal communication named
- Future plenary Lifebrain meetings will have sections allocated for discussions about commercial exploitation of findings in our research or business activities.

2.1. Background

To enable a trustful and reliable cooperation (i.e. avoid disputes on the property of specific information) the partners of the Lifebrain Consortium defined their project Background at the beginning of the project. Pre-existing know-how remains the property of the partner that brings it into the project, but pre-existing know-how needed for carrying out the activities of the Lifebrain project shall be granted on a “royalty-free” basis, unless it is agreed otherwise by the concerned partners before signature of the Contract (especially in the case where the “exchanges” are unbalanced).

According to the Grant Agreement (Section 3, Article 24.1) Background is defined as “data, know-how or information (...) that are needed to implement the action or exploit the results.” Because of this need, access rights have to be granted in principle, but Parties must identify and agree amongst them on the Background for the project.

This section provides an overview of the background ownership and access rights included and excluded defined in The Lifebrain Consortium Agreement and updated by each partner.

BACKGROUND INCLUDED	Specific limitations and/or conditions for implementation (Article 25.2 Grant Agreement)	Specific limitations and/or conditions for Exploitation (Article 25.3 Grant Agreement)
University of Oslo (UiO)		
Expertise in processing of MRI imaging data by use of FreeSurfer. Data for ≈3500 participants, with cognitive scores and background information, ≈3000 MRI scans. Preprocessed data from American databases, e.g. PING, ADNI, VETSA, RUSH, NACC		
University of Oxford (UOXF)		
Whitehall II MRI Substudy data.	Access to Whitehall II MRI Substudy data shall be granted to Lifebrain partners whose requests are reviewed and approved by the Whitehall II MRI Substudy Steering Committee and in accordance with the Whitehall II data sharing policy.	Access to Whitehall II MRI Substudy data shall be granted Lifebrain partners whose requests are reviewed and approved by the Whitehall II MRI Substudy Steering Committee and in accordance with the Whitehall II data sharing policy.
Max Planck Institute (MPIB)		
Access Rights to data of the studies, Berlin Aging Study (BASE) and Berlin Aging Study II (BASE-II), will be granted by the BASE and BASE II Steering Committees, respectively, who have to approve the corresponding data analysis requests made by Lifebrain. The terms and conditions of these requests pre-date this agreement, and have to be complied with. All of the brain imaging data and some of the behavioral data of BASE-II participants have been assessed directly by MPIB, and not by BASE-II. Hence, these data are not under the authority of the BASE-II Steering Committee. The MPIB grants access rights to these data to members of the research group who are directly participating in Lifebrain for the purpose of carrying out research activities described in this agreement		
University of Barcelona (UB)		
University of Barcelona grants access to any Background created by the research group lead by Dr. David Bartrés and owned by UB or its third party Hospital Clinic, and which is needed to the project, except for any Background	UB grants access rights (subject to the Provisions of this Consortium Agreement and the Grant Agreement) to the Background included by the members of the research group who are directly participating in the Project	UB shall grant access to Background needed to use the Results of the Project under fair and reasonable conditions to be agreed with the Party or Parties that need access to use the Results of the Project.

excluded hereafter and, in particular, which is already subject to any third party agreement. Data for ≈ 315 participants (age range 38-89 y) with cognitive scores, MRI and fMRI, 148 of whom with a 2-year follow-up data. APOE and BDNF polymorphisms are available for 182 and 178 volunteers, respectively	Lifebrain and which are strictly needed for carrying out activities under the project Lifebrain, provided that there are no conflicting third-party rights. Approval from the local Ethics Committee required.	Approval from the local Ethics Committee required.
Region Hovedstaden		
Expertise in longitudinal multimodal image analyses HUBU project data contains: Longitudinal T1, T2, DWI (12 assessments, N= 94 at study start, MRI > 800) and rs-fMRI (6 assessments) images, cognitive and behavioral data, questionnaires, demographic background and genetics. LISA project data contains: Baseline (expected finished summer 2017) and followup (expected finish summer 2018) (N~450) T1, T2, FLAIR images. Three subtests of Intelligence Structure Test (IST-R). Demographic data.	Access Rights to the cognitive data in the LISA study, will only be granted after obtaining the necessary agreements with the data owners at the Faculty of Health and Medical Sciences, Copenhagen University. For the LISA project only brain measures derived from MRI images, using Lifebrain image analyses pipelines, will be shared Access Rights to HUBU and LISA data is for non-commercial use only	Access Rights to the cognitive data in the LISA study, will only be granted after obtaining the necessary agreements with the data owners at the Faculty of Health and Medical Sciences, Copenhagen University. For the LISA project only brain measures derived from MRI images, using Lifebrain image analyses pipelines, will be shared Access Rights to HUBU and LISA data is for non-commercial use only
Medical Research Council/University of Cambridge		
Expertise in processing of MRI, fMRI, DWI and MEG data Approx 700 MRI, fMRI, DWI and MEG datasets from the CamCAN cohort, together with cognitive performance on a range of tasks. Approx 470 cognitive datasets and 150 MRI, resting-state fMRI and DWI datasets from the CALM cohort of children aged 6-12 y, identified by specialist children's professionals as having difficulties with attention, memory, language and/or learning. Expertise in processing of MRI, fMRI, DWI and MEG data. Approx 700 MRI, fMRI, DWI and MEG datasets from CamCAN, together with cognitive performance on a range of tasks.	Participants consented to data only being used by researchers for similar ethically approved projects. Participants consented only to MRI data being used by researchers for similar ethically approved projects (ethics amendment awaited for sharing cognitive data). Participants consented to data only be used by researchers for similar ethically-approved projects.	Participants consented to data only being used by researchers for similar ethically approved projects. Participants consented only to MRI data being used by researchers for similar ethically approved projects (ethics amendment awaited for sharing cognitive data). Participants consented to data only be used by researchers for similar ethically-approved projects.

Vitas AS	Specific limitations and/or conditions for implementation (Article 25.2 Grant Agreement)	Specific limitations and/or conditions for Exploitation (Article 25.3 Grant Agreement)
VITAS grants access to any Background related to biomarker analysis and that is created by VITAS and owned exclusively by VITAS, and which is strictly needed to execute the project, except for any Background excluded hereafter and, in particular, which is already subject to any third party agreement.	No additional limitations than in Article 25.2 Grant Agreement	No additional limitations than in Article 25.2 Grant Agreement
University Medical Centre Amsterdam (VUmc)		
Specific structural neuroimaging data from the Netherlands Study of Depression and Anxiety (NESDA)	Access Rights to data of the NESDA study - that is only those data relevant for the Lifebrain project as described in the original project proposal - will only be granted if the requirements of NESDA, which pre-date this agreement, to access such data are complied with. This includes that the data can only be used after an analysis plan has been submitted to and has been approved by the NESDA Steering Group. Any use of these data is restricted to the policies of NESDA and/or approval of the NESDA Board. See website www.nesda.nl for details.	Access Rights to data of the NESDA study - that is only those data relevant for the Lifebrain project as described in the original project proposal - will only be granted if the requirements of NESDA, which pre-date this agreement, to access such data are complied with. This includes that the data can only be used after an analysis plan has been submitted to and has been approved by the NESDA Steering Group. Any use of these data is restricted to the policies of NESDA and/or approval of the NESDA Board. See website www.nesda.nl for details.
University of Cambridge		
CamCan data	No additional limitations than in Article 25.2 Grant Agreement.	Exploitation subject to the agreement of a license with UCAM.

Table 1. Background of Lifebrain

2.2. Access rights to results

Right to access in Lifebrain is described in Section 9 of the CA, and section 3 of the GA. Knowledge (results) arising from work carried out under the Lifebrain project shall be the property of the participant carrying out the work leading to that (ref GA Section 3, Article 26.1). If, during the activities required by the Lifebrain project, two or more participants have jointly carried out work generating invention, design or knowledge, and if the features of such joint work are such that their respective share of the work cannot be ascertained, the concerned participants agree that they may jointly apply to obtain and/or maintain the relevant rights and shall strive to set up amongst themselves appropriate agreements in order to do so (ref. GA Section 3, Article 26.2).

As long as any such rights are in force, such participants shall be entitled to use, without owing any financial compensation to or requiring the consent of the other participants, and to license such rights in accordance with the set-up agreements.

All results developed before the accession of the new Party shall be considered to be Background with regard to said new Party.

Access Rights granted to a Defaulting partner and such Party's right to request Access Rights shall cease immediately upon receipt by the Defaulting Party of the formal notice of the decision of the EB to terminate its participation in the Consortium. A non-defaulting Party leaving voluntarily and with the other Parties' consent shall have Access Rights to the results developed until the date of the termination of its participation. Any Party leaving the Project shall continue to grant Access Rights pursuant to the GA and this Consortium Agreement as if it had remained a Party for the whole duration of the Project. Where no joint ownership agreement has yet been concluded:

- Each of the joint owners shall be entitled to use their jointly owned results on a royalty-free basis, and without requiring prior consent of the other joint owner(s), and
- Each of the joint owners shall be entitled to grant non-exclusive licenses to third parties, without any right to sub-license, subject to the following conditions:
  - at least 45 days prior notice must be given to the other joint owner(s); and
  - fair and reasonable compensation must be provided to the other joint owner(s).

2.3. Confidentiality for dissemination of project results

Specific Non-Disclosure Agreement has been undertaken at the beginning of the project among partners on the confidentiality of the results. This particularly concerns the dissemination phase from the viewpoint of publications (ref. section 10 of the Consortium Agreement): specific agreement guarantee on the one hand the right scientific dissemination (and visibility acquisition), in particular for the academic partner; on the other hand, that sensitive information are maintained confidential within the consortium.

The Parties have agreed to the following for a period of 4 years after the end of the Project:

- Not to use Confidential Information otherwise than for the purpose for which it was disclosed
- Not to disclose Confidential Information without prior written consent by the Disclosing Party
- To ensure that internal distribution of Confidential Information by a Recipient shall take place on a strict need to know basis; and to return to the Disclosing Part, or destroy, on request all Confidential Information that has been disclosed to the Recipients including all copies thereof, and to delete all information stored in a machine-readable form to the extent practically possible. The Recipients may keep a copy to the extent it is

required to keep, archive or store such Confidential Information because of compliance with applicable laws and regulations or for the proof of on-going obligations provided that the Recipient comply with the confidentiality obligations herein contained with respect to such copy for as long as the copy is retained.

The above shall not apply for disclosure or use of Confidential Information, if and in so far as the Recipient can show that:

- The Confidential Information has become or becomes publicly available by means other than a breach of the Recipient's confidentiality obligations;
- The Disclosing Party subsequently informs the Recipient that the Confidential Information is no longer confidential;
- The Confidential Information is communicated to the Recipient without any obligation of confidentiality by a third party who is to the best knowledge of the Recipient in lawful possession thereof and under no obligation of confidentiality to the Disclosing Party;
- The disclosure or communication of the Confidential Information is foreseen by provisions of the Grant Agreement;
- The Confidential Information, at any time, was developed by the Recipient completely independently of any such disclosure by the Disclosing Party;
- The Confidential Information was already known to the Recipient prior to disclosure, or
- The Recipient is required to disclose the Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, subject to the provision Section 10.7 in the Lifebrain CA hereunder.

3. Future commercial exploitation of IPR

A future commercial exploitation plan of IPR will be drafted by asking Lifebrain partners to provide feedback about their foreseen exploitation activities. A questionnaire will be prepared for this purpose and its results will be published in the final exploitation plan (D5.7).

We will when appropiate examine the 'results' achieved in the project and describe how this can lead to the up-take of products/services to the market place. A business plan will be delivered for the exploitation of the advanced (VITAS) DBS – Home kits (D5.9) and how this will be launched into the market place post-project and for use in LCBC at UiO and other multidisciplinary research investigations. This will be communicated to all LB partners via our established internal communication channels like Slack, e-mail and electronic meeting places (Skype & OneDrive).