VirtualBrainCloud

Personalized Recommendations for Neurodegenerative Disease

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Public deliverable report

Deliverable 2.2
Establishment of contact with relevant stakeholders

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1. Abbreviations

#	Acronym/abbreviation	Description/Definition
	AD	Alzheimer's Disease
	AE	Alzheimer Europe
	AI	Artificial Intelligence
	EAB	External Advisory Board
	GA	Grant Agreement
	GDPR	General Data Protection Regulation
	NDD	Neurodegenerative Diseases
	TVB-Cloud	The VirtualBrainCloud Project
	UNIVIE	University of Vienna

2.   Background

The annual worldwide cost of Alzheimer's disease (hereinafter, 'AD') was 777.81 billion Euro in 2015. This number will rise to 7.41 trillion Euro in 2050. Early diagnosis would save up to $7.9 trillion in medical and care costs by 2050 in the US alone.[1] However, the emergent pathology varies substantially between individuals, necessitating individualized diagnostics and interventions for people living with AD. The VirtualBrainCloud project, an EU project funded by Horizon 2020, addresses this need by bridging the gap between computational neuroscience and subcellular systems biology, integrating both research streams into a unifying computational model that supports personalized diagnostics and treatments in Neurodegenerative Diseases (hereinafter, 'NDD').

The VirtualBrainCloud project not only integrates existing software tools, it also merges the efforts of two big EU initiatives, namely The Virtual Brain (the large-scale simulation platform of the Flagship EU Human Brain Project) and the European Prevention of Alzheimer's dementia project (EPAD; an Innovative Medicines Initiative consortium project).TheVirtualBrainCloud will develop and validate a decision support system that provides access to high quality multi-disciplinary data for clinical practice. The result will be a cloud-based brain simulation platform to support personalized diagnostics and treatments in NDD. The EU PRACE (Partnership for Advanced Computing in Europe) initiative will provide the required computing infrastructure. The VirtualBrainCloud will develop robust solutions for legal and ethical matters by interacting with EU projects such as European Open Science Cloud (EOSC), 'cloud4health', Alzheimer Europe patient organisations and ELIXIR, an organization that manages and safeguards EU research data. Our software developers have already produced highly successful brain simulation and clinical decision support tools. The resulting software will be a cloud based computational modelling system that is tailored to the individual, and bridges multiple scales to identify key mechanisms that predict NDD progression and serves as Precision Decision Support System.

TVB-Cloud project is aimed to target stakeholders such as experts from the public and private Health sectors, Academic (research) and international organizations, experts from the fields of privacy, data protection, information technology law from European and non-European countries. This document focuses on the following two groups that are deeply involved in the VirtualBrainCloud Project (hereinafter, 'TVB-Cloud'): an external ethical advisory board and relevant external stakeholders.

3.   Introduction

Deliverable 2.2 (hereinafter, 'D2.2') of the TVB-Cloud describes the establishment of contact with relevant stakeholders for TVB-Cloud. Specifically, D2.2 has established an external legal/ethical advisory board (hereinafter, the 'EAB'), and has initiated contact with a network of relevant stakeholders from various organisations and countries.

The aim for establishing a legal and ethical EAB and creating a stakeholder network is two-fold. First, by establishing the EAB, and interacting with stakeholders through the activities described in section 5.3 below, we will enhance the overarching legal and ethical framework applicable to TVB-Cloud through discussions with legal and ethical experts in the fields of medicine scientific research and privacy. Second, identifying relevant stakeholders, will give stakeholders and other parties interested the

opportunity to engage with the TVB-Cloud project. The expected engagement of stakeholders is materialized at different levels, giving the TVB-Cloud project the possibly to:

- gain input and expertise from the experts on the health and data protection field,
- involve experienced experts in the TVB-Cloud conferences and dissemination activities,
- exchange past and current knowledge and experiences of other similar projects and endeavours,
- gain impartial input on legal and ethical framework, and
- promote best practices to be employed within the framework of TVB-Cloud project.

4. Partners involved

UNIVIE, AE

5. Description of work performed

This document provides an overview of the legal and ethical EAB (section 5.1 below), and initially outlines some of the relevant stakeholders for the TVB-Cloud project (section 5.2 below). Additionally, this report also describes recent activities that the TVB-Cloud partners of the Work Package 2 (hereinafter, 'WP2') have led or taken part in to make contact with external stakeholders (section 5.3 below).

5.1. External Advisory Board on Legal/Ethical Issues

TVB-Cloud aims to create a cloud-based brain simulation platform to support personalised diagnostics and treatments in NDD. The creation of a brain simulation platform raises ethical and legal issues at many different levels including privacy, security, and ethical matters. These issues have already been identified in a previous deliverable (D2.1, 'Analysis of relevant legal, ethical and regulatory framework'). Consequently, establishing close interactions with experts in the field of law and ethics is advisable, and has been identified as a requirement for the TVB-Cloud project. The creation of an EAB is aimed at meeting this requirement. The role and composition of the EAB will be further detailed in the sections below.

5.1.1. Role of the EAB

TVB-Cloud has foreseen the involvement of the EAB in a supervisory role, in particular for the work package on ethical and legal issues. The main responsibilities of the EAB will be to draft a short annual report on legal and ethical issues for the TVB-Cloud project, and to act as a group of expert consultants in the execution of WP2 tasks. It is foreseen that the EAB should consist of four members. Given the nature of these tasks, each of the four members of the board should have extensive professional experience and expertise in the areas of health data, ethics, data protection and privacy amongst others.

5.1.2. Composition and Selection of the EAB

As foreseen under the framework of the TVB-Cloud, the four members of the EAB should have extensive expertise and experience as detailed above. The selection procedure for the EAB members, agreed by the TVB-Cloud partners, consisted of three phases:

1) Proposal of candidates

2)   Unanimous agreement by all consortium partners

3)   Invitation and acceptance of EAB members

After the unanimous agreement by all consortium partners, invitations were sent and were all accepted – see Annex for the invitation letters. The EAB is comprised of four members coming from the public academic sector, all of them with extensive professional experience in the respective legal and ethical fields concerned. The names, professional backgrounds and affiliation of the members have been made available to the members of the consortium.

5.2.   Relevant External Stakeholders

As previously mentioned in the introductory notes of D2.2, the aim for establishing and expanding a network of external stakeholders is twofold. First, it enhances the overarching legal and ethical framework applicable to TVB-Cloud by establishing and fostering interactions with legal and ethical experts in the fields of medicine, scientific research and privacy. Second, this will facilitate the engagement of potential stakeholders and interested parties in the conferences that are planned under D2.4 (Stakeholder conference on GDPR-impact) and D2.6 (Stakeholder Conference: Specific issues of Neurodegenerative diseases: The patients' perspective) which will take place by November 2020.

With these aims in mind, contact has been established with the following organisations/legal entities and natural persons affiliated with organizations/legal entities from:

-   the public and private Health sectors, Academic (research) and international organizations

-   the fields of privacy, data protection, information technology law

-   in European countries (Belgium, Germany, Malta, Norway, Switzerland, United Kingdom)

-   in countries outside Europe (Australia, Argentina, United States)

Additionally, internal communications have been enhanced and maintained with the Data Protection Officers and/or legal departments of the following TVB-Cloud partners:

-   Charité Universitaetsmedizin Berlin (Charite)

-   Codemart SRL (Codemart)

-   Forschungszentrum Julich Gmbh (FZJ)

-   Institut National de Recherche Eninformatique et Automatique (IRNIA)

-   Universidad Complutense de Madrid (UCM)

-   Universite D'Aix Marseille (AMU)

-   Universita degli Studi di Genova (UNIGE)

-   Fundacio Institut de Bioenginyeria de Catalunya (IBEC)

In the future communicating with the with Data Protection Officers and legal departments will provide TVB-Cloud with valuable input from Data Protection/legal experts in different institutions and will create communication channels that will facilitate a harmonised approach on ethical and legal issues between TVB-Cloud partners.

5.3.   Activities – External Stakeholders

The involvement and/or participation of TVB-Cloud project partners in the following activities have been key to the identification of pertinent legal and ethical issues, which will be considered during the lifetime of the TVB-Cloud project.

5.3.1.   Alzheimer Europe Public Affairs Meeting

Alzheimer Europe (hereinafter, 'AE') and the University of Vienna (hereinafter, 'UNIVIE') discussed TVB-Cloud during AE's annual Public Affairs Meeting, which took place on 26 June 2019 and was attended by representatives from AE member organisations. AE is a non-governmental organisation (NGO) aiming to provide a voice to people with dementia and their caregivers, to make dementia a European priority, to promote a rights-based approach to dementia, to support dementia research and to strengthen the European dementia movement. AE has 42 member organisations from 37 countries and in 2012 has created the European Working Group of People with Dementia, which is composed entirely of people with dementia who have been nominated by their national organisations.

At the AE Public Affairs Meeting, TVB-Cloud was exemplified as a data-rich research project focusing on AD and other NDDs. In the course of this meeting UNIVIE has given a presentation on the application of the GDPR in health research. Representation of TVB-Cloud at this meeting has enabled future conversations between TVB-Cloud and member organisations of AE, providing an excellent basis for cooperation with patient organisations in the prevention and treatment of AD.

5.3.2.   International Consultation on the United Nations Draft Recommendation on the Protection and Use of Health-Related Data[2]

From the 11th to 12th of June 2019 in Strasbourg, an international consultation on health data was led by the United Nations Special Rapporteur on the right to privacy, Joe Cannataci, and was chaired by Nikolaus Forgó with the support of the UNIVIE team. The international consultation aimed to collect and exchange input for the draft Recommendation on the Protection and Use of Health Data. The purpose of this recommendation is to "provide guiding principles concerning data processing of health-related data and to emphasise the importance of a legitimate basis of data processing of health-related data by all sectors of society including public authorities and commercial organisations".[3] The recommendation also addresses general guidance on the protection of personal data in Artificial Intelligence (AI), and the liability attached to, as well as the use of health data in scientific research.

UNIVIE's involvement in the development of this recommendation assists UNIVIE not only in obtaining the state-of-the-art legal developments in the area of health data, scientific research and AI, but also creates links to a number of international stakeholders relevant to the TVB-Cloud, such as European and non-European national Data Protection Authorities, representative of European Data Protection

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[2] 'Call for contributions: Draft Recommendation on the Protection and Use of Health-Related Data' (United Nations Human Rights Office of the High Commissioner) <https://www.ohchr.org/EN/Issues/Privacy/SR/Pages/HealthRelatedData.aspx >accessed 12 July 2019.

[3] Draft Recommendation on the Protection and Use of Health-Related Data. United Nations Special Rapporteur on the Right to Privacy – Task Force on Privacy and the Protection of Health-Related Data. <https://id.univie.ac.at/en/news-and-events/en-detailansicht/news/health-data-taskforce-of-the-un-special-rapporteur-on-the-right-to-privacy-1st-draft-of-annex-3/?cHash=05e9c2070ce9b122f5a6dae67ce1dde1&tx_news_pi1%5Baction%5D=detail&tx_news_pi1%5Bcontroller%5D=News> accessed 12 July 2019

Supervisor, Data Protection Unit of the Council of Europe, health-related journals, NGOs representing patients' rights.

5.3.3. Annual Privacy Forum – ENISA - 2019

By participating in the Annual Privacy Forum – ENISA – 2019, UNIVIE aimed to be involved in the latest developments of privacy law in Europe, whilst also establishing strategic contacts for the benefit of the TVB-Cloud. The theme of the two-day conference was as follows:

"The recalibrated legal framework in the EU, as manifested by the promulgation of the General Data Protection Regulation (GDPR), is key in an effort to better control the processing of personal data. Additionally, the forthcoming Regulation on Privacy and Electronic Communications is expected to give new impetus to the way privacy is protected in electronic communications. Even the best legislative efforts cannot keep up to speed with the pace of innovative technology and business models that challenge the way personal data is processed and privacy is protected across the EU and beyond; therefore, examining what is at stake and where threats thereto originate from becomes of paramount importance"[4].

This high-level expert conference attracted stakeholders from the public sector (national data protection authorities and units) and the private sector (e.g. law firms specialized in data protection) as well as renowned academics and researchers in the fields of health data and AI. UNIVIE will continue to strengthen this network of contacts for the purposes of the TVB-Cloud project.

5.3.4. IMI Stakeholder Forum 2019: Brain Health and Disease in the Digital Era – 2020 & beyond

UNIVIE was also invited to speak at the 2019 IMI Stakeholder Forum in Brussels on June 12, 2019. The theme - Brain health and diseases in the digital era - 2020 & beyond - addressed how the digital revolution has contributed to digital health technologies and how they are allowing us to acquire and handle big biological data and mine this data with computational tools. The IMI Stakeholder Forum aimed at identifying cutting edge brain health solutions that are preventative, as opposed to reactive. UNIVIE contributed to the discussion with regard to ensuring compliance with legal, regulatory and ethical requirements when developing and promoting digital health technologies; a strategic exercise for the benefit of the TVB-Cloud.

5.3.5. i~HD GDPR for Health Data Innovation Task Force

UNIVIE is involved in the work of the i~HD GDPR Taskforce; which was established in early 2018 in anticipation of the new GDPR being implemented across the EU Member States, and is formed by the information and communication technology, legal and pharmaceutical industries, academia and most importantly the patient engagement and advocacy community. The aim of the Taskforce is, among others, to deploy a number of information and dissemination activities aimed at addressing developments of GDPR in regard to health, and ways in which the GDPR is affecting heath data innovations. UNIVIE involvement in the Taskforce is key to foster the exchange of latest developments of the GDPR on health data and new technologies, having a direct link with the legal and ethical framework applicable to TVB-Cloud.

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[4] <https://www.enisa.europa.eu/events/apf-2019/annual-privacy-forum-2019> accessed 25 July 2019

6.   Conclusion and Next Steps

As part of D2.2 and as outlined in this report, the EAB has successfully been established and contact has been initiated with the four EAB members. Moreover, contact with a number of different external stakeholders has been made, facilitating the creation of the legal and ethical framework applicable to TVB-Cloud and of the engagement of external stakeholders with the planned stakeholder conferences. The next steps will be to consult with the EAB on legal and ethical questions that are raised during the course of the TVB-Cloud project, and intensify interactions with relevant stakeholders for, in particular, TVB-Cloud outreach activities, including the two planned stakeholder conferences lead by WP2.

ANNEX

VirtualBrainCloud

Personalized Recommendations for Neurodegenerative Disease

Exploiting the full potential of in-silico medicine research for personalised diagnostics and therapies in cloud-based environments

Work Package 2- Leader
Prof. Dr. Nikolaus Forgó
University of Vienna

A European project, funded by the European Commission

01.12.2018 – 30.11.2022

Invitation letter to join the VirtualBrainCloud External Advisory Board on legal and ethical issues

Type of funding scheme: **RIA**
Grant Agreement No. **826421**
H2020 Societal Challenges – Health, demographic change and wellbeing

Dear colleague,

The Work Package 2 (WP2) of the European Commission funded project "VirtualBrainCloud Project – Grant Agreement No. 826421" (the "Project") is responsible for ensuring compliance with the legal and ethical framework, and serves as single point of contact for all internal and external stakeholders on legal and ethical issues.

As the WP2 leader, I would kindly like to invite you to join the VirtualBrainCloud Project as a honorary member of the VirtualBrainCloud External Advisory Board on legal and ethical issues (the "EAB").

The EAB will be a three/four-member board, and will support the work of WP2. Its main tasks will be to:

- draft an annual short report on legal and ethical issues, and
- be consulted in regard to the work on WP2.

The EAB membership is an honorary position. The effort to be mobilised as a board member is estimated to be two to three days per year.

Please refer to the Annex to find further information about the Project.

It would be a great honour to have you as a member of the EAB, and I would kindly appreciate if you reply to this invitation not later than 15 April 2019.

I am looking forward to your reply.

Sincerely,

Prof. Dr. Nikolaus Forgó

Annex to the invitation letter

to join the

VirtualBrainCloud External Advisory Board on legal and ethical issues

Summary

The annual worldwide cost of Alzheimer's dementia was 777.81 billion Euro in 2015. This number will rise to 7.41 trillion Euro in 2050. Early diagnosis would save up to $7.9 trillion in medical and care costs by 2050 in the US alone. However, the emergent pathology is highly variable across people, necehighly variable across people, necessitating individualized diagnostics and interventions. The VirtualBrainCloud addresses this by bridging the gap between computational neuroscience and subcellular systems biology, integrating both research streams into a unifying computational model that supports personalized diagnostics and treatments in NDD. TheVirtualBrainCloud not only integrates existing software tools, it also merges the efforts of two big EU initiatives, namely The Virtual Brain large scale simulation platform of the EU Flagship Human Brain Project and IMI-EPAD initiative (European prevention of Alzheimer's dementia consortium). VirtualBrainCloud will develop and validate a decision support system that provides access to high quality multi-disciplinary data for clinical practice. The result will be a cloud-based brain simulation platform to support personalized diagnostics and treatments in NDD. The EU PRACE (Partnership for Advanced Computing in Europe) initiative, will provide the required computing infrastructure. The VirtualBrainCloud will develop robust solutions for legal and ethical matters by interacting with EU projects such as European Open Science Cloud (EOSC), 'cloud4health', Alzheimer's Europe patient organizations and ELIXIR, an organization that manages and safeguards EU research data. Our software developers have already produced highly successful brain simulation and clinical decision support tools. The resulting software will be a cloud based computational modeling system that is tailored to the individual, and bridges multiple scales to identify key mechanisms that predict NDD progression and serves as Precision Decision Support System.

For further information on the Project, please refer to the following link: https://cordis.europa.eu/project/rcn/219020/factsheet/en.