EHDEN

EUROPEAN HEALTH DATA & EVIDENCE NETWORK

806968 – EHDEN

European Health Data & Evidence Network

WP7 – Project Management and Dissemination

D7.7 Ethics Advisory Board nomination

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DOCUMENT HISTORY

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V1.0	25 Mar 2019	First draft
V1.1	29 Apr 2019	Second draft including all CVs
V1.2	10 May 2019	Final version for consortium review
V1.3	20 May 2019	Final version after comments from consortium review

DEFINITIONS

Participants of the EHDEN Consortium are referred to herein according to the following codes:

EMC	Erasmus Universitair Medisch Centrum Rotterdam- The Netherlands **(Project Coordinator)**
Synapse	Synapse Research Management Partners S.L. - Spain
UOXF	The Chancellor, Masters and Scholars of the University of Oxford - United Kingdom
UTARTU	Tartu Ulikool - Estonia
UAVR	Universidade de Aveiro – Portugal
The Hyve	The Hyve BV – the Netherlands
Odysseus	Odysseus Data Services SRO – Czech Republique
EPF	Forum Europeen des Patients (FPE) - Luxembourg
NICE	National Institute for Health and Care Excellence – United Kingdom
UMC	Stiftelsen WHO Collaborating Centre for International Drug Monitoring - Sweden
ICHOM	International Consortium for Health Outcomes measurement LTD - United Kingdom
Janssen	Janssen Pharmaceutica NV - Belgium **(Project Lead)**
Pfizer	Pfizer Limited – United Kingdom
Abbvie	AbbVie Inc - United States
IRIS	Institut De Recherches Internationales Servier - France
SARD	Sanofi Aventis Recherche & Developpement - France
Bayer	Bayer Aktiengesellschaft - Germany
Lilly	Eli Lilly and Company Limited – United Kingdom
AZ	AstraZeneca AB - Sweden
Novartis	Novartis Pharma AG - Switzerland
UCB	UCB Biopharma SPRL - Belgium
Celgene	Celgene Management SARL - Switzerland

Grant agreement	The agreement signed between the beneficiaries and the IMI JU for the undertaking of the EHDEN project (806968).
Project	The sum of all activities carried out in the framework of the Grant Agreement.
Consortium	The EHDEN Consortium, comprising the above-mentioned legal entities.
Consortium agreement	Agreement concluded amongst EHDEN participants for the implementation of the Grant Agreement. Such an agreement shall not affect the parties' obligations to the Community and/or to one another arising from the Grant Agreement.

PUBLISHABLE SUMMARY

This deliverable gives an overview of the Ethics Advisory Board nomination, detailing the responsibilities of the Board, the procedure to select the candidates, and including a short bio sketch of the final External Experts forming this Board.

1. ETHICS ADVISORY BOARD

EHDEN has planned the creation of an Ethics Advisory Board composed by external experts with detailed knowledge of ethical policies and expertise in privacy protection policies of data sources.

The Consortium Agreement, agreed and signed by all EHDEN partners, includes a detailed description of the responsibilities of this Board:

"The EAB is an advisory board to the Action, and the General Assembly and ExCom in particular. The EAB will advise the General Assembly and the ExCom upon request of the Project Leader together with the Coordinator and provide non-binding subject matter advice to the General Assembly and the ExCom as decision-making support. It will aim at ensuring that all Project activities are ethically sound and comply with all due rules and regulations, including data privacy considerations, in accordance with the Ethical Code of Practice ("ECoP") developed in the IMI1 The European Medical Information Framework (EMIF) Project, under grant agreement n° 115372.

The EAB will be responsible for:

a) reviewing the proper application of the ethical rules and privacy protection of the data sources by the Beneficiaries;
b) providing advice and expertise in privacy protection of data sources and on ethical issues to the Beneficiaries, the General Assembly and the ExCom; and
c) providing advice on the compliance with European ethical laws and regulations and with different guidelines, laws and regulations of countries where activities are being performed."

2. ETHICS ADVISORY BOARD NOMINATION

In order to nominate the candidates to participate in this Board, all project members have been requested to provide suggested names to be members of the Ethics Advisory Board. The Project Lead has contacted all suggested names enquiring their willingness to become members of the EHDEN EAB.

After this process, five external experts have been appointed to take part as Ethics Advisory Board, namely:

1. Amelia Martín Uranga
2. Giuseppe D'Acquisto
3. Joerg Hasford
4. Richard Milne
5. Nathan Lea

All project members have been informed of the final selection, and no objection was received. All the members of the EAB will sign an Advisory Agreement, based on the template included in the Consortium Agreement agreed by all partners.

3. ETHICS ADVISORS BACKGROUND

Amelia Martín Uranga

Dr Martin is PHD in Law. She joined FARMAINDUSTRIA in 2006 to manage the Spanish Technological Platform for Innovative Medicines, as Innovative Medicines Initiative mirror. She also is in charge of the coordination of different Biomedicine Project such as: BEST Project, as a strategic initiative promoted by the pharmaceutical industry with the aim of integrating all stakeholders, both public and private, to create an

excellence based platform for clinical research in Spain. She is the coordinator of different working group in Farmaindustria to the main goal is to promote de biomedicine research in the country. Amelia is member of the Data Protection Working Group of EFPIA and the IMI working group of EFPIA. She was member of two IMI Projects such as: EUPATI and DO-IT. She participates, as key note speaker, in numerous international and national Congresses, Seminars and Events in relation with the promotion of Biomedicine in Spain.

Furthermore, she is an active member of Innovative Medicines Initiative Forum in Spain, not only to promote the Spanish participation in different IMI calls but to also make the IMI rules and procedures Known to different stakeholders.

She has a broad professional experience of more than 20 years teaching graduated and post graduate courses related with legal and ethical aspects in Biomedicine in prestigious national and international universities. She has developed her research work in the Interuniversity Chair in Law and the Human Genome -of which she is a scientific advisor, the UNED and the Sheffield Institute of Biotechnological Law and Ethics in the Sheffield University (UK). She has published several papers on legal and ethical aspects of Biomedicine.

Giuseppe D'Acquisto

Dr D'Acquisto is currently working as technology advisor for the Italian Data Protection Authority (the Garante). He represents the Authority within the Technology Subgroup of the European Data Protection Board and the International Working Group on Data Protection in Telecommunications (the Berlin Group), being rapporteur in various opinions and working documents (e.g. anonymization techniques, cloud computing, Collaborative Intelligent Transport Systems). He is member of the Technical Anonymization Group of the European Medicines Agency. He holds a degree in telecommunications and a PhD in computer science. He authored scientific articles and books on technical-regulatory topics (net and search neutrality, right to be forgotten, privacy by design).

Joerg Hasford

Born in 1950 in München, training in medicine at Ludwig-Maximilians-Universität München and Freie Universität Berlin from 1972-1979. Since 1994 Professor for medical informatics, biometry and epidemiology at the medical faculty of the Ludwig-Maximilians-Universität, München.

Dr. Hasford's main research interests include clinical trials methodology, drug risk assess-ment and patients' safety issues, prognostic research, patients' compliance and persistence, pharmacoepidemiology and public health. Since more than 30 years he serves as the responsible biostatistician for the German CML Study Group. He is a member of the European LeukemiaNet and was responsibly involved in the development of the New CML and the EUTOS score. There are more than 195 Medline-listed publications. From 2008-2015 he served as Editor for Europe of Pharmacoepidemiology and Drug Safety, a Medline listed journal. In 2000 he received the Paul Martini Prize for his research. In 2008 he became Fellow of the Society for Clinical Trials.

He currently acts as chairman of the Ethics Committee of the Physicians' Chamber of the Free State of Bavaria and as president of the Association of the Research Ethics Committees in Germany. Since 2010 he is a member of the Expert Group on Clinical Trials of the European Commission. He coauthored the Ethical considerations for clinical trials on medicinal products conducted with minors which were made public in EUDRALEX in 2017. Finally, he is a member of the Munich Center for Ethics since many years.

Richard Milne

Dr Richard Milne is a sociologist of science, technology and medicine. He is Senior Social Scientist in the Society and Ethics Research group at the Wellcome Genome Campus and researcher in the Institute of Public

Health at the University of Cambridge. Dr Milne received his PhD from University College London in 2010 and has held posts at UCL, the University of Sheffield, Birkbeck University of London and at the PHG Foundation health policy think tank.

Dr Milne's research examines social and ethical questions associated with biomedical science and technology, particularly associated with changing approaches to the diagnosis and treatment of Alzheimer's disease. He holds a Wellcome Trust seed award to research ethical challenges associated with the development of data-driven diagnostics for dementia, and co-leads work on ethics within the European Prevention of Alzheimer's Dementia (EPAD) and AMYPAD projects. He is also member of the ethics group for the MRC Dementias Platform UK and previously co-ordinated the Ethics of Big Data research group at CRASSH, University of Cambridge.

Nathan Lea

Dr Lea is a Senior Research Associate at the UCL Institute of Health Informatics (IHI) and an honorary Data Science Facilitator at UCLH NHS Foundation Trust, working on projects in clinical care and research. His research focus is on the role of information systems in supporting healthcare delivery and empowering patients. He is also the GDPR Taskforce lead for the European Institute of Innovation through Health Data and works as an independent information governance and eHealth consultant.

He has a particular interest in the role Information Governance and wider regulatory oversight in the use of genetic, health and social care records in clinical research, particularly with the advent of omics, machine learning and artificial intelligence to drive innovation and improve care. His work includes understanding of the role of the General Data Protection Regulation and forthcoming Clinical Trials Regulation to enable safer, more robust and effective software and interventions.

He has co-developed and deployed clinical information systems used at Whittington Health for Cardiovascular care and Dementia registries in partnership with the West London Mental Health Trust and UCL's Dementia Research Centre. He is the chair of the IHI Ethics Committee and is a member of the IHI Athena SWAN Self Assessment Group, UCL GDPR Preparedness Board, Consultative Committee and Security Working Group. He teaches on the Information Law and Governance In Clinical Practice and eHealth modules of the IHI's Health Informatics MSc and courses in UCL's MBBS.