D4.3 Establish Data Privacy and Ethics Committees (DPECs)

IMI2 Project ID – DO->IT

Big Data for Better Outcomes, Policy Innovation and Healthcare System Transformation

WP4 – Minimum Data Privacy Standards for ICFs and Supporting Materials

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Version	Date	Description
V1.1	01/05/2017	First Draft
V1.2	10/05/2017	Additional comments
V1.3	12/05/2017	Version submitted to Managing Board
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Contents

Publishable Summary

As a part of the DO→IT consortium, Work Package 4 focuses on an important aspect of Big Data: personal data protection. This WP4 team aims to develop harmonized provisions regarding data protection for informed consent forms to facilitate the use of health data and biosamples while also respecting the rights of "data subjects" (legal wording), meaning participants/patients providing/sharing their data. Following a collaborative approach, the resulting standard provisions will be discussed with data protection authorities, ethics committees and further stakeholders throughout Europe and beyond, thus leading to enhanced progress in Big Data research of health data, while keeping up ethical standards to protect patient/subject rights.

In order to ensure that the development of the standard provisions is based on sound consultation of multiple stakeholders as well as data protection and ethics experts, the DO→IT sub-team has formed two expert teams: one team consists of business representatives and other stakeholders who routinely use personal data for research and thus have to implement the Informed Consent Forms (ICFs) and act within the boundaries of the given consent (DPEC-Operational), whereas the other expert team consists of representatives of data protection authorities and ethics committees throughout Europe (DPEC-Review). In the course of this two years, these experts will be asked to provide their unique perspectives and expertise as the Work Package 4 team drafts the proposed templates. In addition, they will be invited to attend at least one face to face (F2F) meeting in order to discuss the results in this consulting process.

Methods for selecting members for the Data Privacy and Ethics Committees

The aim to develop data protection provisions, which are accepted by multiple stakeholders who routinely use personal data for research and thus have to implement the Informed Consent, as well as by representatives of data protection authorities and ethics committees throughout Europe is certainly a huge challenge. The overarching aim of the DPECs is to base the development of the standard data protection provisions on a wide acceptance of the multiple stakeholders using research data on the one hand and of the supervising authorities being Data Protection Authorities (DPAs) as well as Ethics Committees (ECs) on the other hand. This is crucial to ensure, that the documents are effectively used in practice. Due to the limited resources and to the fact, that working groups should not be too large, WP4 had to find a way to carefully choose the DPEC members in order to ensure, that they represent a wide range of stakeholders for the DPEC-O and the most important positions regarding data protection law in Europe for the DPEC-R. To find the most relevant organisations and appropriate representatives to be invited the DPECs has therefore been the major challenge. Therefore it was crucial to get those people on board, who are actually working in the field and have great experience as well as expertise in their field. To achieve this goal, much care has been used to find out, whom to invite to the two DPECs. WP 4 included all members of the WP in the finding process in order to provide insight in the landscape of stakeholders on the one hand and in the national systems of authorities on the other hand. The WP 4 members proposed names for a preliminary list of invitees. This list was then discussed several times within the dedicated task group (task 4.3.1 and task 4.3.2) in order to make sure, that only those people who represent their stakeholder group or their national DPA and/or ECs landscape and that they have the power to support the regular usage of the ICFs would be invited,. Finally, the WP 4 members were asked to reach out to their respective contact persons in order to make sure, that they would be interested in participating. As a last step, the invitations have already been for DPEC-O members and will be sent out at the latest in October 2017 for the DPEC-R members.

List of organisations invited to be members of the DPEC-O

Stakeholder Group	Country	Entity	Sector
Public Biobank	EU	Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) ERIC	EU Research Infrastructure: Biobanking
Public Biobank	Germany	German Centre for Cardiovascular Research (DZHK), located at the German Research Center for Environmental Health	Research group
Public Biobank	Germany	German Centre for Cardiovascular Research (DZHK)	Research group
Public Biobank	Germany	Indivumed GmbH	Biobanking CRO
Public Biobank	USA	BioMarin Pharmaceutical Inc.	Biobanking
Patient Organization	Canada	Global Alliance for Genomics and Health	GA4GH brings together 400 institutions working in healthcare, research, disease advocacy, life science and information technology to create common framework and harmonized approaches for topics of interest. Adrian led the working group on consent policy and tools
Academia	UK	Imperial College Faculty of Medicine, School of Public Health	Chair of Environmental Epidemiology at Imperial College
Academic Research Group	EU	ELIXIR (~ERIC)	EU Research Infrastructure: Public Health databases/ Big Data
Academic Research Group	EU	European Clinical Research Infrastructure Network (ECRIN)	EU Research Infrastructure for clinical studies
Patient Organization	EU	European Organisation for Treatment of Cancer (EORTC)	
Investigator	Germany	German Cancer Research Center (DKFZ)	Hospital/Ethics
CRO	Global	Parexel International Corp.	CRO
CRO	Global	Covance, Inc.	CRO

CRO	Global	Medidata Solutions, Inc.	IT company
CRO	Global	Quintiles IMS	CRO
Hospital	Sweden	National Quality Registries, Sweden	
Academic Research Group	UK	Centre for Health, Law and Emerging Technologies (HeLEX)	
Academic Research Group	Germany	Medizinische Hochschule Hannover (MH-Hannover)	
Investigator	Spain	Oncology Data Science (ODysSey) Group	
Hospital	France	Assistance Publique - Hôpitaux de Paris (AP-HP)	Hospital
Trade Association	Belgium	European Biopharmaceutical Enterprises	Trade Association
Public Database	UK/global	Wellcome Trust	

This list corresponds to the invitation sent mid of April to each of the dedicated contacts. The personal contact details have been removed from this table.

List of organisations invited to be members of the DPEC-R

Country	Entity	Sector
Belgium	TBD	DPA
Finland (instead of Estonia)	Finnish Data Ombudsman	DPA
France	CNIL	DPA
France	Institutional Review Board (IRB of INSERM)	Ethics Committee
Germany	Arbeitskreis Medizinischer Ethik-Kommissionen in der Bundesrepublik Deutschland e.V. (Chairman of Managing Board)	Ethics committee
Germany	DPA Hessen	DPA
Hungary	National Ethics Committee	Ethics Committee
Hungary	National Data Protection Authority	DPA
Italy	Italian Data Privacy Authority	DPA
Italy	TBD	Ethics Committee
Norway	The National Committee for Medical and Health Research Ethics	Ethics Committee
Spain	Asociación Nacional de miembros de Comités de Ética de la Investigaciôn (ANCEI)	Ethics Committee
Spain	Spanish Data Protection Agency (Agencia Española de Protección de Datos- AEPD):	DPA
Sweden	Data Inspektionen	DPA
UK	UK ICO	DPA
UK	The National Research Ethics Advisors’ Panel (NREAP) at NHS	Ethics Committee
UK	NHS Health Research Authority	

This list corresponds to the first identified organisations and it will be completed at the latest before the end of June 2017. The priority has been made to the DPEC-O members to be invited as the DPEC-O meeting is scheduled in October 2017, while the DPEC-R meeting is planned for the end of 2018. The personal contact details have been removed from this table.

Conclusion

The selection process has taken even more time than expected. It was therefore decided, that the list of invitees for the DPEC-O will be prioritised, since the F2F meeting is scheduled for October 2017, whereas the DPEC-R meeting will take place in late 2018.

The procedure to establish the DPEC-O could be finished and almost all invited members have already confirmed their contribution. The date of the F2F meeting has been scheduled for October 19/20, 2017. This date has already been published in order to make sure, that most of the members are able to take part. The CDA basis is still pending.

A preliminary list of representatives from Data Protection Authorities (DPAs) and Ethics Committees (ECs) that should be invited to join the DPEC-R is ready, as well as an invitation letter approved by the Managing Board of DO->IT project. However, it is critical to ensure that the different national approaches to privacy encountered in the European countries are reflected in the composition of the DEPC-R. It is known that approval bodies across Europe often have different perspectives towards retention time, removal of data. For instance, ECs often act in a locally independent manner to protect patient/participant rights. However, these bodies play an important role in the adoption of new informed consent templates within health care systems. Furthermore, a balanced representation of European EC and DPA bodies as well as positions in terms of restrictions regarding Data Protection clauses should be taken into account. Therefore, a decision was made to postpone the selection of DPEC-R members to June 2017. Additional TCs are to be held and the plan is to send the invitations before end of June 2017.