



Deliverable D2.3

PROPOSAL for AMENDMENTS to the Draft Personal Data Protection Legislation

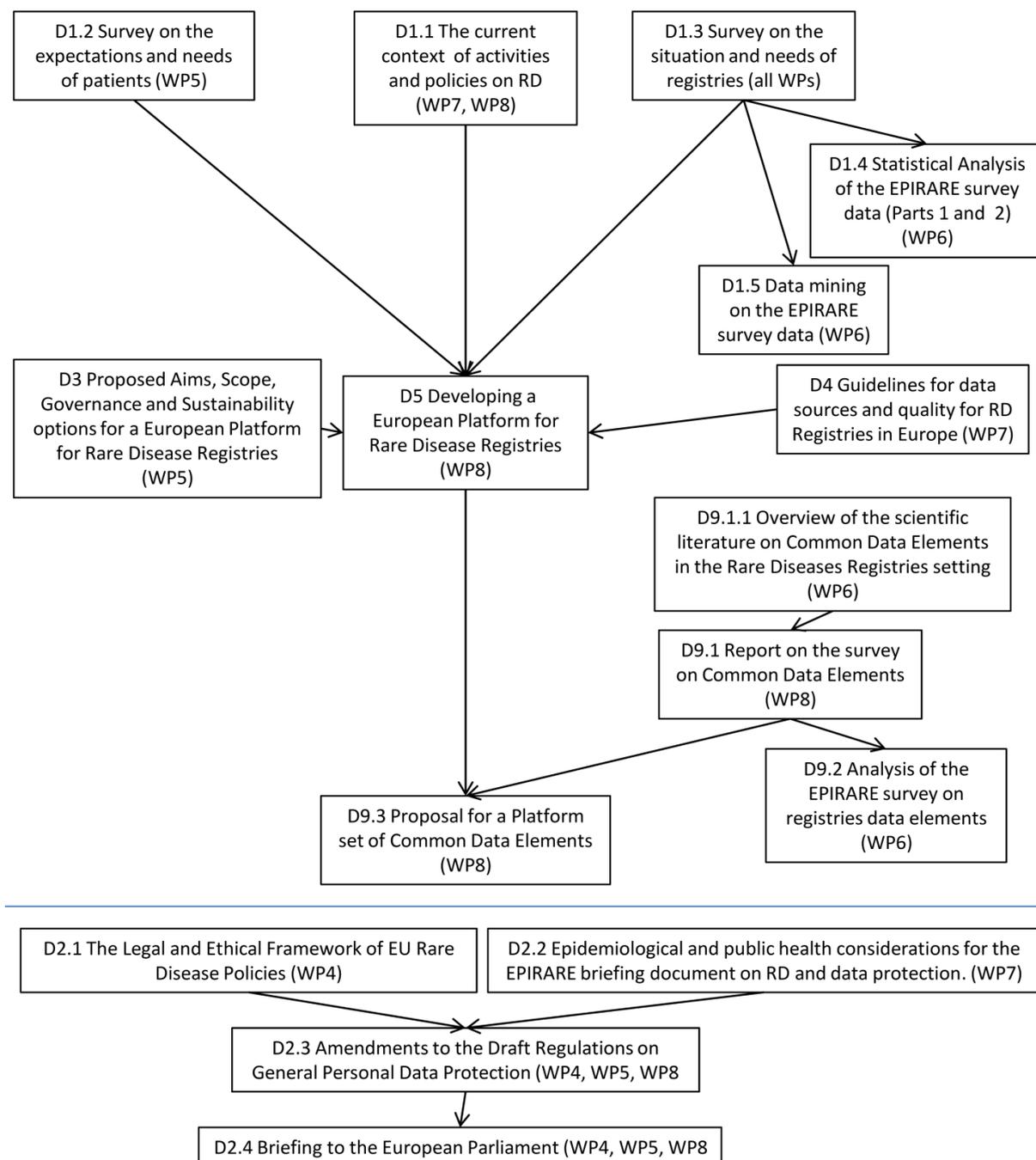
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Amendment n. 1	
Compatibility of Medical and Public Health Research with other purposes	
Recital 122	
Text proposed by the Commission (as amended in the draft dated 22 June 2012)	Amendment
<p>(122) The processing of personal data concerning health, as a special category of data which deserves higher protection, may often be justified by a number of legitimate reasons for the benefit of individuals and society as a whole, in particular in the context of ensuring continuity of cross-border healthcare. Therefore this Regulation should provide for harmonised conditions for the processing of personal data concerning health, subject to specific and suitable safeguards so as to protect the fundamental rights and the personal data of individuals. This includes the right for individuals to have access to their personal data concerning their health, for example the data in their medical records containing such information as diagnosis, examination results, assessments by treating physicians and any treatment or interventions provided.</p>	<p>(122) The processing of personal data concerning health, as a special category of data which deserves higher protection, may often be justified by a number of legitimate reasons for the benefit of individuals and society as a whole, in particular in the context of ensuring continuity of cross-border healthcare. Therefore this Regulation should provide for harmonised conditions for the processing of personal data concerning health, subject to specific and suitable safeguards so as to protect the fundamental rights and the personal data of individuals. This includes the right for individuals to have access to their personal data concerning their health, for example the data in their medical records containing such information as diagnosis, examination results, assessments by treating physicians and any treatment or interventions provided. Medical research, in particular in relation to rare diseases or biobanking, may require the use personal data of individuals that has been collected for other purposes. With appropriate alternative safeguards, the processing of such data for medical scientific research should be presumed to be compatible with the original purpose for the processing. Likewise where there are appropriate alternative safeguards, processing personal medical data for rare diseases in the interests of public health purposes should be presumed to be compatible with the purpose of its original collection.</p>
Justification	
<p>It is important for Rare Diseases (and for other modern medical research techniques reliant upon large-scale data processing, for example in biobanking), that secondary processing of personal data can be undertaken under the original route to fair, lawful and transparent processing. In order to balance the interests of the data subject and other rights holders in the community, alternative safeguards must be in place to justify the appeal to compatibility with original purposes, for example, approval by an independent research ethics committee. It does not remove the separate requirement to inform the data subject about the processing (under Article 14), but it does not imply that a new specific informed consent is required. Notification under the information principles could in these circumstances be satisfied by for example the publication of information in a newspaper, and on a dedicated website.</p>	
Amendment n. 2	
Compatible Processing: Removing the Ambiguity	

of the Current Directive's wording. Article 5(b)	
Text proposed by the Commission (as amended in the draft dated 22 June 2012)	Amendment
(b) collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes; further processing of data for historical, statistical or scientific purposes shall not be considered as incompatible subject to the conditions and safeguards referred to in Article 83;	(b) collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes;
Justification	
Amending Article 5(b) to reinstate the wording of the current Directive [95/46/EC, Article 6(1)(b)] reintroduces the ambiguity of the current law. This would hinder harmonisation. Article 5(b) should be kept without amendment to the proposal of 25-01-2012.	
Amendment n. 3	
Lawfulness of Compatible Processing of Personal Data Article 6(4)	
Text proposed by the Commission (as amended in the draft dated 22 June 2012)	Amendment
Where the purpose of further processing is incompatible with the one for which the personal data have been collected, the processing must have a legal basis at least in one of the grounds referred to in points (a) to (e) of paragraph 1. This shall in particular apply to any change of terms and general conditions of a contract.	Where the purpose of further processing is not compatible with the one for which the personal data have been collected, the processing must have a legal basis at least in one of the grounds referred to in paragraph 1. This shall in particular apply to any change of terms and general conditions of a contract.
Justification	
Whereas the current Directive (95/46/EC) Article 6(1)(b) is ambiguous about compatible processing, the proposal for the Regulation from 25-01-2012 removes the ambiguity. The Draft Regulation's Article 6(4) makes it clear that processing for compatible purposes is possible. Article 6(4) should be kept to the form of the Regulation published on 25-01-2012; it should include processing for (medical) scientific research by avoiding specifying the particular elements of paragraph 1 that should be included.	
Amendment n. 4	
Lawfulness of Compatible Processing of Special Categories of Personal Data Article 9	
Text proposed by the Commission (as amended in the draft dated 22 June 2012)	Amendment
1. The processing of personal data, revealing race or ethnic origin, political opinions, religion or philosophical beliefs, trade-union membership, and the processing of genetic data or data concerning health or sex life or criminal convictions and offences or related security measures shall be prohibited. 2. Paragraph 1 shall not apply if one of the following applies:	Addition of the following: (i-bis) further processing of special categories of data is carried out where appropriate safeguards are in place and in accordance with Articles 81 and 83 for purposes compatible with the original processing of the data; or

(a) the data subject has given consent to the processing of those personal data, subject to the conditions laid down in Articles 7 and 8, except where Union law or Member State law provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject; or

(b) processing is necessary for the purposes of carrying out the obligations and exercising specific rights of the controller in the field of employment law in so far as it is authorised by Union law or Member State law providing for adequate safeguards; or

(c) processing is necessary to protect the vital interests of the data subject or of another person where the data subject is physically or legally incapable of giving consent; or

(d) processing is carried out in the course of its legitimate activities with appropriate safeguards by a foundation, association or any other non-profit-seeking body with a political, philosophical, religious or trade-union aim and on condition that the processing relates solely to the members or to former members of the body or to persons who have regular contact with it in connection with its purposes and that the data are not disclosed outside that body without the consent of the data subjects¹⁴⁰; or

(e) the processing relates to personal data which are manifestly made public by the data subject; or

(f) processing is necessary for the establishment, exercise or defence of legal claims in court proceedings or otherwise; or

(g) processing is necessary for the performance of a task carried out in the public interest, on the basis of Union law, or Member State law which shall provide for suitable measures to safeguard the data subject's legitimate interests; or

(h) processing of data concerning health is necessary for health purposes and subject to the conditions and safeguards referred to in Article 81; or

(i) processing is necessary for historical, statistical or scientific (...) purposes subject to the conditions and safeguards referred to in Article 83; or

(j) processing of data relating to criminal convictions or related security measures is carried out either under the control of official authority or when the processing is necessary for compliance with a legal or regulatory obligation to which a controller is subject, or for the performance of a task carried out

<p>for important public interest reasons, and in so far as authorised by Union law or Member State law providing for adequate safeguards. A complete register of criminal convictions shall be kept only under the control of official authority.</p> <p>3. [The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria, conditions and appropriate safeguards for the processing of the special categories of personal data referred to in paragraph 1 and the exemptions laid down in paragraph 2].</p>	
Justification	
<p>Whereas the text of Article 9 implies that the restriction on the processing of special categories of personal data can be lifted in the circumstances listed in 9(2) and so should include the further processing of special categories of personal data for purposes that are compatible with the original purposes for processing, making it explicit that paragraph 1 is also lifted in relation to processing for purposes that are compatible with the original purpose for processing will ensure that this is clear. This is important for much of modern health research and public health work.</p>	
Amendment n. 5	
<p>Ensuring the Inclusion of Delegated Powers to the Commission to develop “Best Practices” Article 86 (generally) and, for example, Article 83(3) specifically</p>	
Text proposed by the Commission (as amended in the draft dated 22 June 2012)	Amendment
<p>The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria and requirements for the processing of personal data for the purposes referred to in paragraph 1 and 2 as well as any necessary limitations on the rights of information to and access by the data subject and detailing the conditions and safeguards for the rights of the data subject under these circumstances.</p>	<p>NO AMENDMENT TO THE WORDING, but the importance of including these powers should not be underestimated in ensuring effective trust and confidence in particular areas of practice.</p>
Justification	
<p>The proposals to delegate powers to the Commission to specify criteria and requirements for processing are enormously important in developing best practices in particular areas, and these powers should be included in the Regulation, as they allow for the development of ‘best practice’ protocols under the Regulation. Rare Disease research and public health processing should be a focus for these powers and best practice development in the early rounds of this process.</p>	
Amendment n. 6	
<p>Developed Definition of Health Data Article 4(12)</p>	
Text proposed by the Commission (as amended in the draft dated 22 June 2012)	Amendment
<p>‘data concerning health’ means any information which relates to the physical or mental health of an individual, or to the provision of health services to</p>	<p>‘data concerning health’ means any information which relates to the physical or mental health of an individual, or to the provision of</p>

<p>the individual;</p>	<p>health services to the individual, including all elements related to health, namely health status, morbidity and disability, the determinants, <i>including genetic data</i>, having, or suspected to have, an effect on that health status, health care needs, resources allocated to health care, the provision of, and access to, health care as well as health care expenditure and financing, and the causes of mortality.</p>
<p>Justification</p>	
<p>The extended definition reflects the current scientific understanding of the term. Wording is based on definitions recalled in recital 123. Together with other individual's characteristics, genetic factors are important determinants of health in general; gene variants are the cause of by far most rare diseases. Research into diseases, and, in particular, rare diseases, needs to address the association among the disease and selected genes.</p>	

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