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ENCePP Secretariat

ENCePP survey of EU Member States national legal requirements on data protection

Compilation of responses to ENCePP 2012 request to the PhVWP

1. Background

The European Network of Centres for Pharmacoepidemiology & Pharmacovigilance (ENCePP) is a pan-European initiative that brings together pharmacoepidemiology and pharmacovigilance expertise and resources in a functioning network. Participation in ENCePP is voluntary and the network aims to build capacity and take pharmacoepidemiology to the next level guided by the principles of transparency, scientific independence and robust methodologies.

The ENCePP Work Plan 2011 – 2012 defined the objectives and milestones for the period in the context of the operation and future development of the network. One of the essential deliverables of the work plan was the development of approaches to facilitate the conduct of multi-national studies in the context of differences at national level in the implementation of Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

To progress the deliverable, led by the ENCePP Working Group 'Data sources and multi-source studies' (WG 3), it was agreed to establish current status regarding meeting national legislative requirements for data privacy among individual EU Member States as a baseline for future work.

2. Survey of Member States National Competent Authorities

A request for Non Urgent Information (NUI) was therefore sent in May 2012 via the members of the Pharmacovigilance Working Party (PhVWP) to seek information from National Competent Authorities (NCAs) on their understanding of national requirements on data privacy for the conduct of pharmacoepidemiology research. The NCAs were, specifically, asked to identify:

- 1. national legislative requirements themselves (with links to the relevant documentation);**
- 2. national organisation(s) responsible for data protection;**
- 3. any associated issues they are aware of that have had or potentially have an important impact on timelines or even feasibility of the conduct of pharmacoepidemiological studies.**

Responses were subsequently received from PhVWP delegates from 13 European Union Member States: [Czech Republic](#); [Denmark](#); [Finland](#); [France](#); [Germany](#); [Ireland](#); [Latvia](#); [Netherlands](#); [Portugal](#); [Slovenia](#); [Spain](#); [Sweden](#); and the [United Kingdom](#).

However, over the course of reviewing the responses the WG3, in following the progress of the new General Data Protection Regulation through the European Parliament, [http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2012/0011\(COD\)#tab-0](http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2012/0011(COD)#tab-0) considered the revision of the legislation at EU level would supersede further synthesis.

WG3 decided, therefore, to disseminate the results of the survey by publishing the compiled responses as they were submitted in full on the ENCePP website for current information for interested researchers.

DISCLAIMER: Please be aware that the information provided has not been checked for accuracy or completeness and ENCePP/EMA does not accept responsibility for the contents.

3. Tabulated responses

NCA	Response
<p>Czech Republic</p>	<p>Sensitive data may be processed only:</p> <p>(a) if the data subject has given his express consent to the processing. When giving his consent, the data subject must be provided with the information about what purpose of processing, what personal data, which controller and what period of time the consent is being given for. The controller must be able to prove the existence of the consent of data subject to personal data processing during the whole period of processing. The controller is obliged to instruct in advance the data subject of his rights pursuant to Articles 12 and 21,</p> <p>(b) if it is necessary in order to preserve the life or health of the data subject or some other person or to eliminate imminent serious danger to their property, if his consent cannot be obtained, in particular, due to physical, mental or legal incapacity, or if the data subject is missing or for similar reasons. The controller shall be obliged to terminate data processing as soon as the above mentioned reasons cease to exist and must liquidate the data, unless the data subject gives his consent to further processing.</p> <p>(c) if the processing in question is in relation with ensuring health care, public health protection, health insurance, and the exercise of public administration in the field of health sector pursuant to a special Act, or it is related to assessment of health in other cases provided by a special Act,</p> <p>(d) if the processing is necessary to keep the obligations and rights of the controller responsible for processing in the fields of labour law and employment provided by a special Act,</p> <p>(e) if the processing pursue political, philosophical, religious or trade-union aims and is carried out within the scope of legitimate activity of a civil association, foundation or other legal person of non-profit nature (hereinafter referred to as the "association"), and which relates only to members of the association or persons with whom the association is in recurrent contact related to legitimate activity of the association, and the personal data are not disclosed without the consent of data subject,</p> <p>(f) if the data processed pursuant to a special Act are necessary to carry on sickness insurance, pension insurance (security), accident insurance, state social support and other state social security benefits, social services, social care, assistance in material need and social and legal protection of children, and if, at the same time, the protection of these data is ensured in accordance with the law,</p>

NCA	Response
	<p>(g) if the processing concerns personal data published by the data subject,</p> <p>(h) if the processing is necessary to secure and exercise legal claims, (ch) if they are processed exclusively for archival purposes pursuant to a special Act, or</p> <p>(i) if it is the processing under special acts regulating prevention, investigation, detection of criminal activities, prosecution of criminal offences and search for persons.</p> <p>(1) Whoever intends to process personal data as a controller or alter the registered processing pursuant to this Act, with the exception of the processing mentioned pursuant to Article 18, shall be obliged to notify in writing the Office of this fact prior to commencing personal data processing.</p> <p>(2) The notification must include the following information:</p> <p>(a) the identification data of the controller, i.e. in case of natural person who is not an entrepreneur his first name or names, surname, date of birth and address of permanent residence; in case of other subjects their trade, corporate or other name, seat and identification number if assigned, and name, eventually first names and surnames of persons that are their statutory representatives;</p> <p>(b) the purpose or purposes of processing;</p> <p>(c) the categories of data subjects and of personal data pertaining to these subjects; (d) the sources of personal data; (e) description of the manner of personal data processing; (f) the location or locations of personal data processing; (g) the recipient or category of recipients; (h) the anticipated personal data transfers to other countries; (i) the description of measures adopted for ensuring the protection of personal data pursuant to Article 13; (3) If the notification includes all essentials pursuant to paragraph 2 and no proceeding pursuant to Article 17(1) has been initiated, the personal data processing may start after the expiration of 30 days from the delivery of the notification. In such case the Office records the information stated in the notification into the register. (4) If the notification does not include all essentials pursuant to paragraph 2, the Office shall send without delay a reminder to the notifying subject in which he shall make reference to the missing or insufficient information and set a deadline for supplementing the notification. In case the notification is being supplemented, running to the time limit pursuant to paragraph 3 shall begin as of the day of delivery of the notification supplement. If the Office does not receive the notification supplement within the set deadline, the notification shall be regarded as if it has not been submitted. (5) Upon the request from the controller the Office shall issue a certificate which includes date of issuance, reference number, first name, surname and signature of the person by whom the certificate has been issued, official stamp, identification data of the controller and purpose of processing. (6) The Administrative Code shall not apply to the proceedings of the Office pursuant to paragraphs (1) - (5). The notification to the Office is also obliged in case of termination of the study. The preservation of personal data for archival purposes in case of pharmcoepidemiological studies is under the mentioned exception:</p> <p>Article 19 If the controller intends to terminate his activities, he shall be obliged to announce to the Office without delay how he handled personal data, if their processing is subject to the notification obligation.</p> <p>Article 20 Liquidation of Personal Data (1) The controller or, on the basis of his instructions, the processor shall be obligated to carry out liquidation of personal data as soon as the purpose for which personal data were processed ceases to exist or on the basis of a request by the data subject pursuant to Article 21.</p> <p>(2) A special Act shall provide exceptions relating to the preservation of personal data</p>

NCA	Response
	<p>for archival purposes and to the exercising of rights in civil judicial proceedings, criminal proceedings and administrative proceedings. Chapter III</p> <p>TRANSFER OF PERSONAL DATA TO OTHER COUNTRIES Article 27(1) Free flow of personal data shall not be restricted if data are transferred to a member state of the European Union. (2) Personal data may be transferred to third countries if the prohibition of restriction of the free movement of personal data is ensuing from an international treaty to the ratification of which the Parliament has given his assent and which is binding the Czech Republic, or if the personal data are transferred on the basis of decision of an institution of the European Union. The Office in the Official Journal publishes information about such decisions.(3) Where the condition pursuant to paragraphs 1 and 2 is not met, the transfer of personal data may be carried out if the controller proves that: (a) the data transfer is carried out with the consent of, or on the basis of an instruction by the data subject; (b) in a third country, where personal data are to be processed, has been created sufficient specific guarantees for personal data protection, e.g. by other legal or professional regulations and security measures. Such guarantees may be specified in particular by a contract concluded between the controller and the recipient, if this contract ensures application of these requirements, or if the contract contains contractual clauses for personal data transfer to third countries published in the Official Journal of the Office; (c) the personal data concerned are part of publicly accessible data files on the basis of a special Act or are, on the basis of a special Act accessible to someone who proves legal interest; in such case the personal data may be disclosed only in the scope and under conditions provided by a special Act; (d) the transfer is necessary to exercise an important public interest following from a special Act or from an international treaty binding the Czech Republic; (e) the transfer is necessary for negotiating the conclusion or change of a contract, carried out on the incentive of the data subject, or for the performance of a contract to which the data subject is a contracting party; (f) the transfer is necessary to perform a contract between the controller and a third party, concluded in the interest of the data subject, or to exercise other legal claims, or(g) the transfer is necessary for the protection of rights or important vital interests of the data subject, in particular for rescuing life or providing health care.4) Prior to the transfer of personal data to third countries pursuant to paragraph 3, the controller shall be obliged to apply to the Office for authorization to the transfer, unless provided otherwise by a special Act. When considering the application, the Office shall examine all circumstances related to the transfer of personal data, in particular the source, final destination and categories of personal data which are to be transferred, the purpose and period of the processing, with regard to available information about legal or other regulations governing the personal data processing in a third country. In the authorization to the transfer, the Office shall specify the period of time over which the controller may perform the data transfers. If a change of the conditions under which the authorization was issued occurs, in particular on the basis of a decision of an institution of the European Union, the Office shall alter or revoke this authorization</p> <p>The Act on Pharmaceuticals 378/2007 regulates the preservation of the personal data from the clinical and other studies. The link to this Act is: http://www.sukl.eu/sukl/act-on-pharmaceuticals.</p> <p>The Section 52 is dealing with the legal protection of trial subjects:</p> <p>Section 52 Protection of trial subjects (1) This Act shall apply without prejudice to the legal regulations governing the protection of trial subjects60) and Section 92 (11) The marketing authorisation holder must keep the documentation pertaining to pharmacovigilance for the minimum period of ten years, except for the documentation specified under a special legal regulation63). The implementing legal regulation stipulates the scope and method of maintaining and keeping records. The preservation of the documentation is adapted by the Decree No 385/2006 Coll. On Medical records, by its special amendment No 3: The time period for archiving is 15 years' time period for health data arising from CT or 10 years from the patient's death (if the human MP has not been put into the practice). The time period for archiving data from non-intervention studies is 10 years.</p>

NCA	Response
	<p>2. the national organisation(s) responsible for data protection; The Office for Personal Data Protection (UOOU) is the CZ organization responsible for data protection, the link to its English web site is http://www.uoou.cz/uoou.aspx?lang=en</p>
Denmark	<p>Processing of non-identifiable personal data is not covered by the Danish personal data protection laws. Data is usually considered identifiable if an individual can be expected to be identified by any means possible, e.g. if individuals can be recognized through correlating the given data set with a different set of data or if encoded unique identifiers can be decoded. Personal data may be processed for the purposes of scientific studies of significant public importance if the processing is necessary in order to carry out these studies, cf. section 10 in the Danish Act on Processing of Personal Data. An English version of the data protection act can be found through this link: http://www.datatilsynet.dk/english/. Further, sections 46-48 in the Danish Health Act provide that personal health data in patient files may be transferred to researchers if certain conditions are met and upon prior approval from certain governmental bodies. The Danish Health Act can be found through this link (Danish only): https://www.retsinformation.dk/forms/r0710.aspx?id=130455. Finally, section 41 of the data protection act stipulates that the controller shall implement appropriate technical and organizational security measures to protect data against accidental or unlawful destruction, loss or alteration and against unauthorized disclosure, abuse or other processing in violation of the provisions laid down in this Act. The same shall apply to processors.</p>
Finland	<p>The legal basis and available guidance on register-based research in Finland:</p> <p>One of the objectives of the Personal Data Act (523/1999) is to improve the opportunity of individuals to control the use of their personal data. It accommodates the constitutional reform and the EU Data Protection Directive (Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the personal data and on the free movement of such data). Also the Act on the Openness of Government Activities (621/1999), Statistics Act (280/2004), Medical Research Act (488/1999), the Act on the Status and Rights of Patients (785/1992) and acts on National Institute for Health and Welfare (556/1989), (409/2001), (668/2008) contain relevant information concerning different aspects of the questions included. These acts are available from www.finlex.fi. The Office of the Data Protection Ombudsman (www.tietosuoja.fi) is an independent authority operating in connection with the Ministry of Justice. It provides guidance and advice on issues related to the processing of personal data and controls the observance of the law. The Finnish Information Center for Register Research (www.rekisteritutkimus.wordpress.com) has published guidance for researchers concerning register-based research (also available in English). The National Committee on Medical Research Ethics (www.tukija.fi) serves as an expert on research ethics and advises regional ethics committees in matters of ethical principles related to medical research. Information on general aspects of register-based research can be found in the article "Finnish health and social welfare registers in epidemiological research" in <i>Norsk Epidemiologi</i> 2004; 14 (1): 113-120, by Mika Gissler and Jari Haukka. Also the chapter "Applying permissions to use register data for research in the REDD project" in "How to carry out register-based health service research in Finland?", <i>Stakes, Discussion paper 1/2006</i>, contains a description of the relevant procedure</p> <p><i>General aspects.</i></p> <p>From an international perspective Finnish legislation on data protection is relatively permissive. It allows the use of administrative data for scientific, historical and statistical research purposes. There are, however, strict provisions on the type of research which is appropriate, e.g. marketing research is not considered appropriate. Register-based studies can generally be performed without subjects' informed consents.</p> <p>The requirements include the following aspects: that the research cannot otherwise be carried out without identifying the person, the consent cannot be collected e.g. because of the quantity of the data, age or other justifiable reason an appropriate</p>

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	<p>research plan (a specific and clearly defined study, not a general request to use data in e.g. cancer research or , pharmacoepidemiological study, giving the names of the responsible persons and those with access to da, clarification on how the privacy of the study subjects in the personal data file is secured as the data cannot be disclosed to outsiders at any time (signed statement by those involved require, the data file is archived, destroyed or made unidentifiable after the study ends There are also provisions on enforcing authorities to make sure that individual rights are not violated in scientific research (i.e. the Office of the Data Protection Ombudsman).</p> <p>The practical steps in planning and performing a register-based study in Finland are:</p> <ol style="list-style-type: none"> 1. Preparing a detailed study plan showing the scientific nature of the study 2. Review by regional ethical committee (not officially required by register controllers, but may facilitate decision making, and journal review). Some of the register controllers like Social Insurance Institution and the National Institute for Health and Welfare have their own ethical committees that may also be used. 3. Application for permission from the register controller. When data from different register controllers (health registers) are to be combined the permission is applied from the Ministry of Social Affairs and Health 4. A formal data file description prepared and stored by study leader before the launch of the project with notification to the Office of the Data Protection Ombudsman (30 days before launch of the project 5. If register data will be linked with data or samples collected directly from the research subjects, consent is needed from the research subject. Also ethical committee approval is required. Most registers use a unique personal identification number (PIN) which facilitates the combination of data from different sources. Only some registers will pass on data with personal identification numbers still present (e.g. for longitudinal follow-up studies) and therefore a non-identification process will be done by some of the register controllers. When combined data is requested the process is done by one of the register controllers before the combined data is released to the applicant. Interpretation of 'identifiable' and 'non-identifiable' on national level is not specifically defined. Removal of PIN from the file and the holder of the key is determined on a case by case-approach. Even after the removal of PIN there may be possibilities to identify the individuals, e.g. rare disease in a small city, and therefore some of the data may be only available on an aggregate level. Researchers most often use 'non-identifiable' data in their daily work, and only those authorized to use the data would perform analyses on it. The national requirements are being enforced and scientists are in most cases compliant to the regulations and guidelines given by the authorities. Also the public still have high confidence in the system since very few violations by scientists have been recorded. <p>Answers to individual questions/scenarios</p> <ol style="list-style-type: none"> 1. Secondary use of collected 'non-identifiable' data without chart review/contact For this scenario there are no explicit requirements given, and the procedures depend on who is the user and for what purpose. A detailed study plan is necessary. The study plan would need to address ethical aspects of the study, how data protection is secured and how the study data is handled, stored, archived and destroyed. The permission to use the data would be given by the register controller and/or the responsible research leader who originally compiled the data. 2. Chart review in hospital of 'non-identifiable' data. In this scenario, a study plan is needed including issues mentioned above in scenario 1. Permission is usually given by the chief physician of the hospital after approval from department head if a certain department is specifically targeted. Ethical committee review is not mandatory, but may be necessary when publishing the results 3. Chart review with GP of 'non-identifiable' data If GP works in a health center the procedures and requirements are the same as in scenario 2. If data from the private sector is targeted permission from the Ministry of Social Affairs and Health is required 4. Information from patient ('non-identifiable') The procedures depend on where the patient is contacted, in hospital, at health center or at home. A study plan is always required. If contacted in hospital or other health care establishment, permission of the head of the establishment is needed to make the contact. The contact to the patient is

NCA	Response
	<p>done by the health care establishment and after consent has been given by the patient, the researchers can contact the patients. The patient consent is always required. Ethical committee review of study plan, the study questionnaire etc. and informed consent materials are required. This material would include: who is responsible for the study, who is the researcher, the organization and the sponsor, aim and objectives of the study, significance, how the research is performed, rights of the study subjects (volunteer, right for more information, possibility of withdrawing at any time), possible benefits and risks to the study subjects, data protection, use of research material and further use in the future, possible combination of register data, contact information</p> <p>5. Information from patient ('identifiable') Same as above – patient consent and ethical committee review of study plan and other information material to the patient.</p> <p>6. Collect materials (blood) of patient Same as above, study plan, patient consent, and information to the patient and ethical committee review.</p> <p>7. Linking of different data sources with a unique person identifier, The study plan would need to address ethical aspects of the study, how data protection is secured and how the study data is handled, stored, archived and destroyed. Depending on what registers are to be linked permission from Ministry of Social Affairs and Health might be needed. Ethical committee review is not generally required, but may facilitate the process and publishing.</p> <p>8. Linking of different data sources probabilistic ("non-identifiable" data) Same as above in scenario 7.</p>
<p>France</p>	<p>To conduct a pharmacoepidemiological research in France, legislative requirements depend on the nature of the study: an interventional study or a non-interventional study</p> <p>1) Interventional study. In agreement with article L.1123-6 of the Public Health Code, the interventional research protocol must be submitted to a Committee for the Protection of Persons (CPP). This committee's opinion is notified to the competent authority by the sponsor before initiating the research. If the research falls within the framework of the "Reference methodology" (MR-001) by application of the provisions of article 54, paragraph 5 of the modified data protection act of 6 January 1978, approved by decision of 5 January 2006, an authorisation request will be submitted to the French National Commission for Data Processing and Privacy (CNIL). If the research doesn't fall within the framework of the "Reference methodology", for example when full patient identity is requested, for genetic research with objective of patient identification or for researches with the principal objective to study behaviours, an authorisation request will be submitted to the Advisory committee on the processing of health research information (CCTIRS) and the French National Commission for Data Processing and Privacy (CNIL). Written consent shall be obtained from all persons participating in the research, prior to performing any procedures required by the research.</p> <p>2) Non-interventional study. If a study requires the collection of personal health data* for the purpose of research in the field of health, it is governed by chapter IX of the amended Data Processing and Privacy Law of 6 January 1978. *Personal data means any information relating to a natural person who is or can be identified, directly or indirectly, by reference to an identification number or to one or more factors specific to him. In order to determine whether a person is identifiable, all the means that the data controller or any other person uses or may have access to should be taken into consideration. It must be the subject of a request for approval from the Advisory committee on the processing of health research information (CCTIRS) and a request for authorization from the French National Commission for Data Processing and Privacy (CNIL). The CCTIRS's delay for approval is one month from reception of the full application. The CNIL's approval is two months from reception of the full application. The CCTIRS opinion needs to be enclosed to the application sent to the CNIL. A negative opinion of the CCTIRS regarding a study protocol precludes CNIL approval. The use of indirectly named data may be necessary when: There is a follow-up of patients, with collection of longitudinal information, It is essential to combine the data from the CRFs, patient questionnaires, and the adverse events diary for the statistical analysis.</p>

NCA	Response
	<p>These documents will therefore be identified by two numbers: physician number and patient number, Quality control of the data is planned The need for patient ethnic data collection needs to be justified in the study protocol. Without scientific justification, the collection of ethnic data will be refused by the CCTIRS. Pursuant to the amended "Data Processing and Privacy Law" of 6 January 1978, the patient is informed of his/her right of access, objection and correction of the data recorded during this study, and that this right may be exercised at any time through his/her physician. The physician will give the patient a patient information sheet at the inclusion visit. This form will contain information concerning the nature and purpose of the study, the collected data, the physical persons or legal entities who will be the recipients of these data, and the patients' right of access, correction or objection to the processing of these data (in accordance with the amended "Data processing and privacy" law of 6 January 1978). In case of collection of ethnic data, religion, political opinion or lifestyle, a written consent shall be obtained from all persons participating in the research prior to performing any procedures required by the study.</p> <p>See ANSM attachment on CNIL</p>
<p>Germany (BfARM)</p>	<p>The request of this NUI encompasses complex issues relating to German Law on Data Protection and access to personal data and routine data.</p> <p>We would like to point out that any response to this NUI exceeding a high-level compilation of information would be extremely burdensome due to the complexity of Data Protection in Germany. We will therefore provide a list of references dealing with data protection issues and conduct of epidemiological studies in Germany and will further include information on publications on this issue.</p> <p>As WG 3 contains German members and ENCePP has conducted several studies that included data from German resources, the members of ENCePP themselves might also be able to contribute more detailed information on this request.</p> <p>Reference to English translations of the cited documents is provided where available.</p> <ul style="list-style-type: none"> • The German Data Protection Act regulates collection, processing and use of personal data. It includes a definition of anonymisation and pseudoanonymisation (which has been translated as "aliasing" of data.) The German Data Protection Act can be found on the following link: http://www.gesetze-im-internet.de/bdsg_1990/_3.html An English translation is available via: http://www.bfdi.bund.de/clin_111/EN/DataProtectionActs/DataProtectionActs_node.html • Section 4 of the Data Protection Act refers to "lawfulness of data collection, processing and use" and defines when informed consent has to be provided from concerned persons and defines where exceptions from this rule apply. • The website of the German Federal Commissioner for Data Protection is available at: http://www.bfdi.bund.de/EN/Home/homepage_node.html This website provides also contact information for the data protection commissioners of the "Länder" (states). • The "Musterberufsordnung (medical professional code of conduct)" for German physicians can be found under (German version): http://www.bundesaerztekammer.de/page.asp?his=1.100.1143 This code of conduct is the basis for the professional codes of the German states ("Länder") as the concerned legislation falls under federal state law. Of relevance is section 10 detailing rules for documentation and processing of patient data. • SGB X - Book 10 of the German Social Code available at (German version): http://www.gesetze-im-internet.de/sgb_10/ Section 75 of SGB X details the rules for using social data for research purposes. Transmission of data has to be authorised by the supervising authority (the kind of supervising authority depends on the kind of data that will be used: e.g. if data from nationwide acting health insurance companies is

NCA	Response
	<p>involved, this is the German Ministry of Health, if data from regional health insurance companies is involved, this is the Social Ministry of the concerned State).</p> <ul style="list-style-type: none"> • SGB V - Book 5 of the German Social Code Sections 284-305 detail rules for transmission of health insurance data (German language): http://www.gesetze-im-internet.de/sqb_5/ • Access to data from German Cancer Registries is regulated in the Federal Cancer Registry Data Act (German language): http://www.gesetze-im-internet.de/bkrg/index.html http://www.krebsdaten.de/Krebs/EN/Home/homepage_node.html <p>Further information can be found in the following articles (majority in German language) and under the following links:</p> <ul style="list-style-type: none"> • Good Practice in Secondary Data Analysis - http://dqepi.de/fileadmin/pdf/leitlinien/gps-version2-final_ENG.pdf • The 'PMV Forschungsgruppe' has compiled literature relating to data protection (also for 'biobanks') and secondary data. <ul style="list-style-type: none"> ◦ http://www.pmvforschungsgruppe.de/ ◦ Literature on data protection issues: http://www.pmvforschungsgruppe.de/content/03_publicationen/03_b_thema_5.htm ◦ Literature relating to secondary data analysis with focus on German data sources: http://www.pmvforschungsgruppe.de/content/03_publicationen/03_b_thema_6.htm • "AGENS" is a Working Group of the German Society for Epidemiology that is concerned with usage of secondary data (site is only available in German): http://dqepi.de/arbeitsgruppen/ag-12.html • March S, Rauch A, Thomas D, Bender S, Swart E. [Procedures According to Data Protection Laws for Coupling Primary and Secondary Data in a Cohort Study: The lidA Study.] Gesundheitswesen. 2012 Feb 1. [Article in German] https://www.thieme-connect.com/DOI/DOI?10.1055/s-0031-1301276 • Ihle P. [Data protection and methodological aspects in compiling a routine database from statutory health insurance data for research purposes]. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2008 Oct; 51(10):1127-34. [Article in German]. http://www.springerlink.com/content/ux55608k38755130/?p=450b740052ae4d31b7f1268e5b1a6d74&pi=4&MUD=MP • Ihle P, Harnischmacher U. [Patient Informed Consent for Bio-Banks – Investment for the Future]. it - Information Technology 2007; 6: 345-351. [Article in German] http://www.oldenbourg-link.com/doi/abs/10.1524/itit.2007.49.6.345 • Eggert K, Wüllner U, Antony G, Gasser T, Janetzky B, Klein C, Schöls L, Oertel W. Data protection in biomaterial banks for Parkinson's disease research: the model of GEPARD (Gene Bank Parkinson's Disease Germany). Mov Disord. 2007 Apr 15; 22(5):611-8. [Article in German] http://onlinelibrary.wiley.com/doi/10.1002/mds.21331/abstract;jsessionid=7D9A0541582B48B6CEB5DB1F265F2062.d03t02 • Wellbrock R. [Data Protection and Biobanks]. it - Information Technology November 2007 : it - Information Technology November, Vol. 49, No. 6, pg(s) 360-366. [Article in German] http://www.oldenbourg-link.com/doi/abs/10.1524/itit.2007.49.6.352 • Pommerening K. [The TMF Data Protection Scheme for Biobanks]. it - Information Technology November 2007 : it - Information Technology November, Vol. 49, No. 6, pg(s) 352-359. [Article in German] http://www.oldenbourg-link.com/doi/abs/10.1524/itit.2007.49.6.360 • Weigelt E, Scherb H. Gesundheitswesen. [Data protection and data access (I): federal data protection law and the social welfare code with reference to carrying out occupational medicine epidemiologic studies in Germany]. 1992 Nov; 54(11):666-72. [Article in German] http://www.ncbi.nlm.nih.gov/pubmed/1286250

NCA	Response
	<ul style="list-style-type: none"> Weigelt E, Scherb H. [Data protection and data access (II): Physician's responsibility for confidentiality, federal statistics law and data collection by authorization with reference to implementing occupational medicine epidemiologic studies in Germany]. Gesundheitswesen. 1993 Jan;55(1):8-15. [Article in German] http://www.ncbi.nlm.nih.gov/pubmed/8435545
Germany (PEI)	As per BfARM response
Ireland	<p>1. The Irish legislation relating to data protection is listed below: Data Protection Amendment Act 2003 S.I. 6 of 2003 - http://www.irishstatutebook.ie/2003/en/act/pub/0006/index.html with links to related legislation as per below</p> <p>Data Protection Act 1988 1988, No. 25 Dentists Act 1985 1985, No. 9 Freedom of Information Act 1997 1997, No. 13 Interpretation Act 1937 1937, No. 38 Medical Practitioners Act 1978 1978, No. 4 National Archives Act 1986 1986, No. 11 Social Welfare (Consolidation) Act 1993 1993, No. 27 Statistics Act 1993 1993, No.</p> <p>2. The principal organisation with responsibility for data protection in Ireland is the Data Protection Commissioner. For further information see http://dataprotection.ie</p> <p>3. Any associated issues they are aware of that have had or potentially have an important impact on timelines or even feasibility of the conduct of pharmacoepidemiological studies: Information on this issue is not available at this time.</p>
Latvia	<p>1. the national legislative requirements themselves (with links to the relevant documentation); opportunity to implement and protect his or her rights and interests. The law contains provisions how to protect patient data.</p> <ul style="list-style-type: none"> The law contains provisions how to protect patient data.1.1. Personal Data Protection Law (http://www.dvi.gov.lv/eng/legislation/pdp/) includes the following terms that should be protected: <ul style="list-style-type: none"> personal data – any information related to an identified or identifiable natural person; sensitive personal data - personal data that indicate the race, ethnic origin, religious, philosophical or political convictions, or trade union membership of a person, or provide information as to the health or sexual life of a person; Personal data and sensitive personal data can be published or given to the third party only in the case if the person gave the approval for it. Moreover, if it refers to sensitive personal data, then the approval should be given in the written form only. <p>1.2. Law On the Rights of Patients (http://www.vvc.gov.lv/advantagecms/LV/tulkojumi/dokumenti.html?folder=%2fdocs%2fLRTA%2fLikumi%2f&currentPage=7)</p> <ul style="list-style-type: none"> This Law promotes favourable relationships between a patient and the provider of health care services, facilitating active participation of the patient in his or her health care, as well as to provide him or her with an opportunity to implement and protect his or her rights and interests. <p>2. the national organisation(s) responsible for data protection: Data State Inspectorate (http://www.dvi.gov.lv/eng/)</p>

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	<p>3. any associated issues they are aware of that have had or potentially have an important impact on timelines or even feasibility of the conduct of pharmacoepidemiological studies: We are not aware of conduct of pharmacoepidemiological studies in Latvia.</p>
Netherlands	<p>1. the national legislative requirements themselves (with links to the relevant documentation): The MEB needs to adhere to the provisions Dutch Data Protection Act (Wet Bescherming Persoonsgegevens) and the Dutch Freedom of Information Act (Wet openbaarheid van bestuur) with respect to the active and passive disclosure of Personal Data of patients. The Court of Amsterdam (Rechtbank Amsterdam) ruled in its judgement of 19 July 2011 (LJN: BR3104) that the MEB needs to redact and redacted the personal data of patients in accordance with the Acts mentioned above.</p> <p>Dutch Data Protection Act (Wet Bescherming Persoonsgegevens) http://www.dutchdpa.nl/Pages/en_wetten_wbp.aspx</p> <p>Dutch Freedom of Information Act (Wet openbaarheid van bestuur) http://wetten.overheid.nl/BWBR0005252/geldigheidsdatum_04-06-2012</p> <p>2. the national organisation(s) responsible for data protection: The Dutch Data Protection Authority (DPA)</p> <p>3. any associated issues they are aware of that have had or potentially have an important impact on timelines or even feasibility of the conduct of pharmacoepidemiological studies: Section 2 (Article 21) of the Dutch Data Protection Act lays down criteria with respect to the processing of health data of patient.</p> <p>Article 21</p> <p>1. The prohibition on processing personal data concerning a person's health, as referred to in Article 16, does not apply where the processing is carried out by:</p> <ol style="list-style-type: none"> medical professionals, healthcare institutions or facilities or social services, provided that this is necessary for the proper treatment and care of the data subject, or for the administration of the institution or professional practice concerned; insurance companies as referred to in Article 1(1)(h) of the Insurance Supervision Act 1993 (Wet toezicht verzekeringsbedrijf 1993), insurance companies as referred to in Article 1(c) of the Funeral Insurance Supervision Act (Wet toezicht natuura-uitvaartverzekeringsbedrijf), and intermediaries and sub-agents as referred to in Article 1(b) and (c) of the Insurance Mediation Act (Wet assurantiebemiddelingsbedrijf), provided that this is necessary for: 1° assessing the risk to be insured by the insurance company and the data subject has not indicated any objection thereto, or 2° the performance of the insurance agreement; schools, provided that this is necessary with a view to providing special support for pupils or making special arrangements in connection with their state of health; institutions for probation, child protection or guardianship, provided that this is necessary for the performance of their legal duties; Our Minister of Justice, provided that this is necessary in connection with the implementation of prison sentences or detention measures, or administrative bodies, pension funds, employers or institutions working for them, provided that this is necessary for: 1° the proper implementation of the provisions of laws, pension regulations or collective agreements which create rights dependent on the state of health of the data subject, or 2° the reintegration of or support for workers or persons entitled to benefit in connection with sickness or work incapacity. <p>2. In the cases referred to under (1), the data may only be processed by persons subject to an obligation of confidentiality by virtue of office, profession or legal provision, or under an agreement. Where responsible parties personally process data and are not already subject to an obligation of confidentiality by virtue of office, profession or legal provision, they are required to treat the data as confidential, except where they are required by law or in connection with their duties to communicate such data to other parties who are authorised to process such data in accordance with (1).</p> <p>3. The prohibition on processing other personal data, as referred to in Article 16, does</p>

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	<p>not apply where this is necessary to supplement the processing of personal data concerning a person's health, as referred to under (1)(a), with a view to the proper treatment or care of the data subject.</p> <p>4. Personal data concerning inherited characteristics may only be processed, where this processing takes place with respect to the data subject from whom the data concerned have been obtained, unless: a. a serious medical interest prevails, or b. the processing is necessary for the purpose of scientific research or statistics. In the case referred to under (b), Article 23(l)(a) and (2) shall likewise be applicable.</p> <p>5. More detailed rules may be issued by general administrative regulation concerning the application of (1)(b) and (e).</p>
Portugal	<p>1. 1. Law no. No. 67/98 of 26 October: Law on the Protection of Personal Data (transposing into the national).</p> <p>2. The national organisation responsible for data protection in Portugal is "Comissão Nacional de Proteção de Dados" available at: http://www.cnpd.pt/</p> <p>3. N/A (no information available). legislation the Directive 95/46/EC of the European Parliament and of the Council, of 24 October 1995, on the protection of individuals with regard to the processing of personal data and on the free movement of such data). Available at http://www.cnpd.pt/bin/legis/nacional/lei_6798.htm</p>
Slovenia	<p>1. the national legislative requirements themselves (with links to the relevant documentation); Zakon o varstvu osebnih podatkov/ Personal data protection Act: https://www.ip-rs.si/index.php?id=339 Ustava Republike Slovenije/ Constitution of the Republic of Slovenia: http://www.dz-rs.si/wps/portal/Home/PoliticniSistem/URS/UstavaRepublikeSlovenije Zakon o pacientovih pravicah/ Patient's rights Act: http://www.uradni-list.si/1/objava.jsp?stevilka=455&urlid=200815 Zakon o zdravilih /Medicinal products Act: http://zakonodaja.gov.si/rpsi/r00/predpis_ZAKO4280.html Zakon o kakovosti in varnosti človeških tkiv in celic, namenjenih za zdravljenje/ Act on quality and safety of human tissues and cells, for the Purposes for medical treatment: http://www.uradni-list.si/1/objava.jsp?urlid=200761&stevilka=3297 Zakon o preskrbi s krvjo/ Supply of Blood Act: http://www.uradni-list.si/1/objava.jsp?urlid=2006104&stevilka=4461</p> <p>2. the national organisation(s) responsible for data protection; Information Commissioner : https://www.ip-rs.si/?id=195 National Medical Ethics Committee: http://www.kme-nmec.si/</p> <p>3. any associated issues they are aware of that have had or potentially have an important impact on timelines or even feasibility of the conduct of pharmacoepidemiological studies: We suggest you to contact Information Commissioner or National Medical Ethics Committee.</p>
Spain	<p>1. In Spain, data protection is regulated by the following legislation:</p> <ul style="list-style-type: none"> - Law 15/1999, of 13 December, of protection of personal data - Royal Decree 1720/2007, of 21 December, approving the regulation of development of the Law 15/1999, of 13 December, of protection of personal data - Law 41/2002, of 14 November, basic regulation of patient autonomy and rights and obligations of information and clinical data. - Order SAS 3470/2009, of 16 December, by adopting guidelines on post- authorisation non-interventional studies for human medicines - Law 14/2007, of 3 July, of biomedical research. - Royal Decree 1716/2011, of 18 November, laying down the basic requirements for authorization and operation of Biobanks in biomedical research and treatment of biological samples of human origin, and regulates the operation and organization of the National Registry of Biobanks for medical research. In Spain, the following

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	<p>information is considered identifiable data: Name; Surname; Initials; Telephone number; Address; National identification number, number of clinical records, etc.</p> <p><i>2. The specifications of the Spanish Regulation regarding data protection can be summarized as follows:</i></p> <p>Informed Consent: In clinical research, it is necessary to obtain the informed consent of the participants (independently if the data collected is referred to the past, present or future). If a pre-existing anonymized clinical database is used for the research, obviously this consent cannot be obtained. If the participant is less than 12 years, parents or legal representative should give their consent. If the participant is over 12 years and less than 18 years, their consent should be also obtained. If the participant is disabled, the legal representative should give the consent. In some situations, a waiver could be given by an Ethic Committee and the informed consent could not be obtained, The content of the informed consent document will depend on the kind of research (with identifiable data or with dissociated data). The participants may withdraw their consent in any time, without any justification, and without any prejudice. The informed consent document should be kept in the archive of the center, and a copy should be given to the participant. All the participants can exercise, at any time, their rights regarding access to their collected data, rectification of their collected data, cancellation of their consent and opposition to the use of their data.</p> <p>Research with dissociated data: The sponsor won't have access to the identifiable data of the participants. The center of the investigator should declare a "Clinical Investigation File" (CIF) to the Spanish Agency of Data protection. It is not necessary to declare a CIF for each research. One CIF declared per Center is considered enough, and could be applicable to multiple researches. The investigator is responsible of the obtaining of the informed consent, and keeping it in the CIF. Also, the investigator is responsible of the dissociation of data</p> <p>Research with personal identifiable data: - The sponsor will have access to the identifiable data of the participants. - The center of the investigator should declare a "Clinical Investigation File" (CIF) to the Spanish Agency of Data protection. It is not necessary to declare a CIF for each research. One CIF declared per Center is considered enough, and could be applicable to multiple researches. The investigator is responsible of the obtaining of the informed consent, and keeping it in the "Clinical Investigation File". The sponsor should declare to the Spanish Agency of Data Protection the file of case report forms (CRFF). This CRFF is different from the CIF, and both files should be declared. International transmission of information: If the destination is a Country with an adequate level of data protection, the transmission should only be notified to the Data Protection Registry. If the destination is a Country with an inadequate level of data protection, the transmission should be authorized by the Spanish Agency of Data Protection Director.</p> <p>Research with biological samples: Genetic analysis and data: Prior to the consent of the participants, they should be informed about the purpose of the genetic analysis, place where the analysis will be done, persons that will have access to the analysis results, a warning about the possibility of unexpected findings, a warning about the implication it may have to their family, and commitment to provide genetic counselling once the results are obtained. A specific consent of the participants should be obtained (additional to the consent to be included in the clinical research). Genetic data from deceased could be obtained, provided they have not rejected previously.</p> <p>Biomedical research: The consent to the use of biological samples could be given at their collection or after, but specifically for a particular clinical research. If the samples will not be anonymized, the subject should be informed, among other things, about the purpose of the research, expected benefits, disadvantages, responsible of the research and place where the analysis will be done. - Biobanks: The establishment</p>

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	<p>and operation of a biobank should be authorized by the Competent Authorities. The biobank should be supervised by two Committees (ethic and scientific).</p> <p>2. The national organisation(s) responsible for data protection: The Spanish Agency for Data Protection is the organisation responsible for data protection. Ethic Committees are the institutions that guarantee the protection of citizens and participants in clinical research, including their personal data. They ensure that regulation regarding data protection is fulfilled. In Spain, all the studies with medicines (interventional or non-interventional) should obtain the favourable opinion of an Ethic Committee (except research with pre-existing anonymized clinical databases).</p> <p>3. Any associated issues they are aware of that have had or potentially have an important impact on timelines or even feasibility of the conduct of pharmacoepidemiological studies: Regarding confidential data, the following issues should be considered to determine timelines or feasibility of clinical research:</p> <ul style="list-style-type: none"> - Informed consent in retrospective follow-up studies: In these cases, the consent should be also obtained. Sometimes, this consent is difficult to obtain, and even this issue could prevent the research. These considerations should be notified to the Ethic Committee that evaluates the study, requesting exemption. The Ethic Committee can accept or refuse the request. - Use of clinical data of deceased: To prove that deceased have no rejected the use of their data or samples, the "File of Previous Instructions" should be consulted (falling that, the criterion of close relatives should be followed). - Safety measures of high level: In addition to declare the files used in clinical research (CIFs and CRFFs), it is necessary to apply some measures that should be taking into account if a clinical research is planned: <ul style="list-style-type: none"> o Storage: The access to the location of the archive should be closed and restricted. o Copies: Only can be done under the supervision of authorised personal. o Access: Mechanism to identify all the authorised persons that access to the documentation should be implemented. o Transfer: If the documentation is transferred, measures to prevent the access or manipulation should be implemented. <p>See AEMPS attachment</p>
Sweden	<p>1. National Legislation on Data Protection</p> <p><u>The Personal Data Act, the Medicinal Products Ordinance and the Medicinal Products Act</u></p> <p><i>Identifiable and non-identifiable data:</i> In Sweden the <i>Personal Data Act</i>¹ defines non-identifiable and identifiable data in the following way. The data is recognized as <i>identifiable</i> data when it directly or indirectly is attributable to an individual that is alive, according to section 3. According to the Act, all information that "may" be attributed to an individual is defined as personal data. In determining whether a person is identifiable one should take into account all information that is available to the controller of personal data or any other person. Encrypted data is thus covered by the Act as long as <i>someone</i> can make the data readable and thereby identify the individual. It is not enough that the controller temporarily or permanently disposes of the encryption key. Even the content of genetic information is personal data. All data that may not be attributed to an individual is defined as <i>non-identifiable</i> data.</p> <p><i>General provisions:</i> The controller of personal data shall, according to section 9,</p> <ul style="list-style-type: none"> • ensure that personal data is processed only if it is lawful, • make sure that personal data is only collected for specific, explicitly stated and justified purposes and

¹ Personuppgiftslag (1998:204), see <http://www.sweden.gov.se/content/1/c6/01/55/42/b451922d.pdf> for English provisions, note that section 19 is not up to date)

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	<ul style="list-style-type: none"> ensure that this collected data is not processed for any purpose that is incompatible with that for which the information is collected. <p>Personal data may be processed only if the registered person has given his/her consent to the processing or if the processing is necessary in order to fulfil some, in the Act, named goals, according to section 10.</p> <p><i>Sensitive personal data and the deviation from the Personal Data Act</i> It is prohibited to process personal data that reveals information of, for example, an individual's health, according to section 13 in the <i>Personal Data Act</i>. If another act or ordinance contains provisions that deviate from the <i>Personal Data Act</i>, those provisions shall apply, according to section 2.</p> <p>According to chapter 4 section 4 in the <i>Medicinal Products Ordinance</i>² the Medical Products Agency (MPA) is allowed to process information on individual's health, for the purposes given in the Ordinance or in the <i>Medical Products Act</i>, despite section 13 in the <i>Personal Data Act</i> that forbids the processing of sensitive information. According to this provision the MPA is entitled to receive information that is essential for the purposes specified in section 9 in the <i>Medicinal Products Act</i> and for the production of statistics and for research. The purposes in section 9 in the <i>Medicinal Products Act</i> are, among other things, to scientifically evaluate data on adverse effects of medicinal products.</p> <p>According to chapter 4 section 5 in the Ordinance the MPA is allowed to maintain health data directories according to section 1 in the <i>Act on Health Data Directories</i>³. According to section 6 and section 3 in the <i>Act on Health Data Directories</i>, health care providers are to hand over information to the authorities that are entitled to maintain health data directories and the information they are to hand over is stated in <i>The Medicinal Products Ordinance</i>, i.e. information on adverse reactions of medicinal products.</p> <p>Sensitive personal data may even be processed for research if the conduct has been authorized according to the <i>Act of Ethical Review of Research Involving Humans</i>⁴ according to section 19 in the <i>Personal Data Act</i>.</p> <p><u>Public Access to Information and Secrecy Act</u></p> <p>The <i>Public Access to Information and Secrecy Act</i>⁵ states that it is not entitled to hand over information from one authority to another if the information is regulated as confidential, according to chapter 8 sections 1 and 3.</p> <p>Confidentiality applies on an individual's health care data that comprises of information on the individual's health or other personal circumstances, if it is not clear that the data can be disclosed without the individual or someone close to him/her suffering harm, according to chapter 25 section 1 in the Act. The presumption is therefore that this data is confidential and that it may not be disclosed. If the data is <i>non-identifiable</i> it can be disclosed, as no-one can be considered to suffer from the disclosure.</p> <p>Chapter 10 section 28 states that confidentiality does not prevent data from being provided to another authority, if the obligation to provide data is required by law or ordinance. This is the case for the MPA, as the health care providers need to disclose information of adverse reaction to medical products to the MPA, according to the <i>Act on Health Data Directories</i> and the <i>Medicinal Products Ordinance</i>.</p>

² Läkemedelsförordning (2006:272), see <http://www.notisum.se/rnp/sls/lag/20060272.HTM> for the Swedish provisions

³ Lag (1998:543) om hälsodataregister, see <http://www.notisum.se/rnp/sls/lag/19980543.htm> for the provisions, only available in Swedish

⁴ Lag (2003:460) om etikprövning av forskning som avser människor, see <http://www.notisum.se/rnp/sls/lag/20030460.htm> for the Swedish provisions

⁵ Offentlighets- och sekretesslag (2009:400), see <http://www.notisum.se/rnp/sls/lag/20090400.htm> for the Swedish version, for information in English, see <http://www.sweden.gov.se/content/1/c6/13/13/97/aa5c1d4c.pdf>

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	<p>According to chapter 21 section 7 the public authority that will disclose information has to assume that the recipient won't process the disclosed information in violation with the <i>Personal Data Act</i>. Therefore the authority has to know how the recipient is going to use the information in question.</p> <p>2. The national organisation responsible for data protection All controllers of personal data are responsible for processing the data in accordance with the <i>Personal Data Act</i>, according to section 9 of the Act. According to chapter 4 section 4 of the <i>Medicinal Products Ordinance</i> the MPA is a controller of personal data. According to sections 43-47 of the <i>Personal Data Act</i> the Swedish Data Inspection Board supervises that the controllers follow the provisions. The Swedish Data Inspection Board (Datainspektionen) is responsible for protecting the individual's privacy in the information society. The Board supervises that authorities, companies, organisations and individuals follow, for example, the <i>Personal Data Act</i>.⁶</p> <p>3. Issues that potentially impact the conduct of pharmacoepidemiological studies It is generally difficult to state which issues that can arise when conducting pharmacoepidemiological studies, as all different cases arise different provisions and different issues.</p>
<p>United Kingdom</p>	<p>Summary of Data Protection Legislation – UK. The overall legislation governing Data protection is the Data Protection Act 1998 http://www.legislation.gov.uk/ukpga/1998/29</p> <p>The National Organisation responsible for Data Protection is The Information Commissioners Office http://www.ico.gov.uk/</p> <p>Subsequent to this, there have been further pieces of legislation. In particular, in the Health and Social Care Act 2001, specifically Section 60. http://www.legislation.gov.uk/ukpga/2001/15/section/60</p> <p>Further Guidance on Section 60 can be found here: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/document/s/digitalasset/dh_4066384.pdf</p> <p>This has subsequently been replaced by Section 251 of the NHS Act 2006 http://www.legislation.gov.uk/ukpga/2006/41/section/251</p> <p>Specific governance of Section 251 is now undertaken by the National Information Governance Board for Health and Social Care http://www.nigb.nhs.uk/nigb</p> <p>and in particular further information is to be found here: http://www.nigb.nhs.uk/s251/abouts251/index.html</p> <p>Further details of Applications that have been approved under Section 251 can be found in the Excel Spreadsheet linked to from this site. http://www.nigb.nhs.uk/s251/registerapp</p> <p>The vast majority of MHRA pharmacoepidemiology research is conducted through CPRD (previously GPRD). There have been no specific issues that we can recall with respect to the impact that data privacy has had on timelines or feasibility of studies.</p>

⁶ More information on the Board can be found on their website, <http://www.datainspektionen.se/in-english/>.