Opinion on a notification for prior checking received from the Data Protection Officer of the European Medicines Agency related to the "clinical study in the frame of the research project PROTECT WP4 "

Brussels, 29 November 2012 (Case 2012-0704)

1. Proceedings

On 21 August 2012, the European Data Protection Supervisor ("EDPS") received from the Data Protection Officer ("DPO") of the European Medicines Agency ("EMA") a notification for prior checking ("the notification") regarding the data processing operations relating to the research project PROTECT WP4[1].

Five annexes were joined to the notification.
- Annex I: Memorandum of Understanding between the members of the Consortium Protect WP4 on the responsibilities with regard to the protection of personal data of the 09/12/2011.
- Annex II: Protocol PROTECT Pregnancy: An explanatory study of self-reported medication use in pregnant women.
- Annex III: Copy of the Notification from Outcome Europe Sarl to the Information Commissioner Office of 3rd August 2012.
- Annex IV: Informed Consent Template.
- Annex V: Informed Consent Template (web version).

This notification follows a consultation Article 46(d) by the DPO of the EMA on the role of the Agency in the processing of personal data for the clinical study in the frame of the research project PROTECT (case 2010-0818). The EDPS concluded that the processing operations carried out by the EMA in the framework of the study project qualified for prior checking under Article 27(2)(a) of the Regulation. As was also stated in the consultation, the EDPS underlines that the legal assessment conducted is limited to the role of the EMA[2] in respect of the study carried out in WP4 of PROTECT, considering the nature of the Study which deals with sensitive medical information. Therefore, this assessment does not apply to other activities of the consortium. The EDPS provided specific recommendations in order to help the EMA prepare the notification and to ensure the respect of Regulation 45/2001. References to those recommendations are made in the analysis as to ensure that they have been implemented by the EMA.

The draft opinion was sent to the DPO for comments on 20 November 2012. These were received on 28 November 2012.

[1] http://www.imi-protect.eu/.
[2] "*The EDPS cannot draw conclusions as concerns the responsibilities of the other members of the consortium - and, eventually, of the consortium as a whole- and the degree in which they are controlling each or jointly the processing*". See Consultation 2012-0818.

2. Examination of the matter

2.1. The facts

The EMA is a member of a Research Consortium called PROTECT funded through the Innovative Medicine Initiative (IMI). In one of the Work Package, WP4, the EMA is acting, following the decision of the EDPS in his consultation 2010-0818 as "joint controller"[3] of the processing of personal data of women who voluntarily enrol in the study.

Based on the explanations from the notification, the Agency will not directly collect, store or access data of the subjects enrolled in the study in an identifiable manner.

All members of the PROTECT WP4 have signed a Memorandum of Understanding setting out different roles and responsibilities with regard to the processing of personal data (Annex I), as was recommended by the EDPS.

The **purpose** of the processing of personal data is for conducting scientific research under the funding of the IMI. The main research question for this study is "Is the quality and quantity of information collected directly from pregnant women without intervention of health care professionals suitable for research ?".

As a general statement, the Memorandum of Understanding (Annex I) states that the protection of personal data of the participants enrolled in the non-interventional prospective study is recognized as a fundamental and integral element of the scientific project which implies that any activity performed in the framework of this study shall not contravene the laws on the protection of personal data.

The processing is **automated** (web access and electronic phone system).

The **data subjects** are pregnant women residing in one of the four participating countries who must be above the legal age for providing informed consent and who voluntarily enrol in the study in 4 countries (UK, The Netherlands, Denmark and Poland). The approximate number is 5600.

In order to accomplish this task, **data** will be collected. The categories of data concern health, data revealing racial or ethnical origin, data concerning data subject's lifestyle (including use of drugs) and data in the form of personal identification numbers. These data are collected by another member of the Consortium - "OUTCOME Europe Sarl" under the terms and conditions of a Protocol (Annex II) agreed by all Consortium participants. The data to identify a patient are kept by Outcome during the study (phone number, e-mail address, social security number) and are kept separate from the rest of the data. They are exclusively accessed by the study personal of Outcome for study conduct purposes: sms, e-mail reminders sent to participants, technical support if the participant forgot their pin code, etc. The contact details of the participants will never be sent outside of Outcome and will be deleted at the end of the study.

[3] The decision making in relation to the overall management of the project is the responsibility of a Steering Committee that is composed of 14 consortium members and their alternates, the EMA representatives being two of them. The Steering Committee adopts the work programme of the work packages in PROTECT and decides on technical roadmaps. Normally it adopts decisions on a higher level than the implementation of practical issues related with the conduct of the research activities which are within the remit of the single work package. The WP4, in the frame of which the Study is carried, is composed of 25 members from 11 partners in the consortium; this includes the EMA.

The social security numbers and NHS numbers are used to link the information collected throughout the study to the information in the country databases of Denmark (to be used by the DHMA) and UK (to be used by established processes with Trusted Third Parties.) During the linkage, the social security number (DK) and NHS number (UK) identifier is replaced by the study number of the participant.

The data collected will be assessed and might eventually be linked to other data available from other databases (e.g. in the UK, THIN for the monitoring of prescription drugs).

The notification states that EMA has received confirmation from Outcome Europe Sarl on the 9th August 2012 that a notification has been filed to the UK DPA (Annex III).

As explained in the notification, the **processing** of the data is as follow:
- Outcome Europe Sarl collects the data, pseudonymizes them and then shares aggregated data with the rest of the WP4 partners.
- The Trusted Third Party (TTP) receives encrypted information solely of identifiers needed to link the data where possible. No medical data is included.
- Imperial College London will perform the analysis.
- The country lead from Denmark will receive a list of social security and study numbers from Outcome. The Danish lead will then link data from the various country registries and send this under the study number to Imperial College.
- The country leads from The Netherlands will receive data on their specific country with information such as postcode or only compare collected aggregated data with the appropriate regional/national information.

All data generated from the participants will be collected by a dedicated data management team (Outcome). For those patients who provide consent in the UK, linkage of study records with data held on a General Practitioner (GP) research database (THIN) will be attempted. The study team will provide a trusted third party with encrypted[4] identifiers which have been provided by the participant to the study. The trusted third party will link these encrypted identifiers where possible with encrypted identifiers provided from GP records. This will then be used to provide the GP research database (THIN) with linked study numbers and THIN database identifiers. THIN will then provide the study team with a derivative THIN identification number for each study number, and the study team will then extract the electronic medical records. It is stated that at each stage of the linkage process those undertaking these procedures will be unaware of patient identity.

The consent mentioned above in the case of the UK is a “specific” consent to allow Outcome to link the data collected in the framework of the interview with a GP research database through the use of a trusted “third party”. As a general rule of the project, all patients in the project provide a consent for the processing of the “medical” set for research purposes, however patients in some Member States such as in this case the UK (and also in Denmark) may provide another specific consent to the linkage of their data contained in other databases (THIN) always and exclusively for research purposes. This information on the consent is described in the protocol of the project (Annex II) and is provided to all participants in the UK. Also, information on consequence of not consenting to the second processing and the possibility to withdraw the consent is explained in the protocol.

[4] The protocol (Annex II) contains the following clarification: "Any encrypted identifiers provided for linkage purposes will be removed once linkage has taken place to ensure confidentiality and all data will be protected".

With regard to the mechanisms of linkage in UK and DK, it was further clarified by the EMA that the use of encrypted identifiers is envisaged only in the case of UK as this would be the secure option to link the data about a patient and in accordance with UK data protection legislation. With regard to the system used to link the data in DK, the Danish organization part of the Consortium intends to use the social security number, an identifier used frequently in transactions in DK, which is in line with Danish data protection legislation.

Moreover, although Outcome Europe Sarl might decide to use non-EU legal entities belonging to the same group of companies as processors of the data, it was clarified by EMA that it was clear that the subsidiary companies have to keep the same level of data protection. It is also foreseen in the consent forms (Annex IV and V) that some of the authorised persons involved in the study are located outside the European Union and that the data of the participants may be shared with those persons only as necessary to allow them to perform study services. It is also stated that they may be located in countries that do not have a level of protection for the data equal to the country of residence of the participants but that Outcome will make sure that the authorised persons comply with a level of protection at least equal to the country of residence of the respective participants, to the extent required by the applicable laws.

Regarding **storage and conservation** of data, all data collected on pregnant women starting from recruitment until end of participation in the study (either loss to follow up or three months after the end of pregnancy) will be archived in a database held by the central data collection facility in the UK. Data collected via the internet will be stored by electronic means; data related to the IVRS will be retained electronically. For each woman, a consolidated record enabling tracking of data provided at the times of each data entry, i.e. baseline, every 2-4 weeks follow up and final follow up upon end of pregnancy, will be kept.

The records will be linked to the women's respective study identifiers allocated during recruitment. This is in line with the Protocol PROTECT Pregnancy: An Explanatory Study of Self-reported Medication Use in Pregnant Women - Final Version 20th July 2012 (Annex II).

As explained above, personal identifiable data will only be kept in order to contact women in relation to their participation in the study, e.g. email/call reminders, informed consent, etc, and data linkage based on the women's permission to do so.

All study data will be retained for a minimum period of 5 years for research purposes including secondary analyses.

It is foreseen that anonymized and aggregated data will be kept for a longer period for historical and statistical purposes.

Based on the information provided by the EMA, the retained data do not contain any direct identifiers. The de-identified data only contain a study code. During the course of the study, this study code could be used to retrieve the participants' contact details or social security numbers as the link between the study code and the identifiers data exist in Outcome database. Once the study finishes, the specific participant identifiers that are necessary for the study conduct, will be deleted from the study files at Outcome in order to fully anonymize the data. The retained data will have a study code that will not be linked to any identifier, and thus be considered as fully anonymized.

As to the **information**, a data protection notice is provided directly to the data subjects at the point of enrolment in the study. It is included within the "Information Consent Form" which is

statutorily mandated for the enrolment of data subjects in a clinical study (See Annex IV and V). These consent forms foresee the identity of the principal controller collecting the data in the processing amongst the other partners of the project (i.e. Outcome), the purposes of the processing, the rights of access and rectification, information about the consent to be given, the recipients of the data, information on how the data are protected.

Data subjects have the **right** to review and correct data in accordance with different country's data protection legislation. Access and corrections may be limited to ensure the scientific accuracy of the study, as may be permitted by applicable laws and regulations.

As to blocking and erasure, Outcome Europe Sarl is responsible to ensure the rights for blocking and erasure in accordance with applicable data protection legislation.

As to the **security measures** [...]

2.2. Legal aspects

2.2.1. Prior checking

This prior checking Opinion relates to the processing of personal information carried out for the purpose of a scientific research.

In his consultation 2010-0818, the EDPS concluded that, "*as member of the consortium, the EMA shall be considered as a (one of the) controller(s) of the personal data processing undertaken for the Study*".

Furthermore, he stated that even if the EMA were not itself processing data relating to identified or identifiable individuals, this would not alter the conclusion that the EMA is one of the controllers of the initial personal data processing taking place in the context of the Study: "*As a controller who, together with others, determines the purposes and means of the processing, the EMA bears certain responsibilities under the Regulation in respect of the personal data processing that will be carried out for the Study*". In this case, it must be particularly taken into account that one of the controllers, Outcome, has means to identify the person to whom the information relates. Therefore, the data processed in the context of the Study will remain identifiable, through Outcome and must be considered as personal data.

Amongst others, as co-controller, the EMA is required pursuant to Article 27 of the Regulation to submit to the EDPS a notification of processing operations that present specific risks to the rights and freedoms of data subjects. Article 27(2)(a) specifies that data relating to health fall within this category. Since the data processing carried out by the EMA for the Study relates to health data, it is therefore subject to prior checking.

The notification also states that the processing operations are also notified under Article 27.2.(c) (processing operations allowing linkages not provided for pursuant to national or EU legislation between data processed for different purposes). On the basis of the elements provided, the EDPS does not consider that the planned processing should be covered by this legal basis. Although the data controller states that the data "might eventually be linked with other databases", the EDPS consider that such linkages would take place outside the scope of Regulation 45/2001 as such linkages are possible at the level of the member states involved in the project (namely in the UK).

Prior Checking. Since prior checking is designed to address situations that are likely to present certain risks, the Opinion of the EDPS should be given prior to the start of the processing operation. In this present case, the notification relates to a processing which has not yet taken place and therefore qualifies as **prior-checking.**

Notification and due date for the EDPS Opinion. The Notification was received on 21 August 2012.

Pursuant to Article 27(4) of Regulation (EC) No 45/2001, the two-month period within which the EDPS must deliver an Opinion was suspended for a total of 31 days to obtain additional information plus seven days to allow comments on the draft Opinion. The Opinion must therefore be adopted no later than 29 November 2012.

2.2.2. Lawfulness of the processing

Personal data may only be processed if legal grounds can be found in Article 5 of Regulation (EC) No 45/2001. The notification does not make a specific reference to Article 5 of the Regulation.

However, the EDPS consider that the grounds that may justify the processing operation at stake are based on Article 5(a) where personal data may be processed if the processing is "*necessary for the performance of a task carried out in the public interest on the basis of the Treaties establishing the European Communities or other legal instruments adopted on the basis thereof* (...)".

The purpose of the declared data processing (to provide for the elaboration of a study for purpose of determining how to improve the collection of information on medication use and other risk factors during pregnancy) is integrated in the framework of the EMA's tasks and appears to be specific, determined and legitimate, according to article 5(a) of the Regulation. This participation to the project is defined in the research contract that has been signed with the other partners, its additional protocol as well as in a Memorandum of Understanding applicable among the partners.

As to the necessity of the processing, the EDPS takes notes that although the EMA does not directly collect the personal data, it participates in scientific research projects concerning the monitoring of medicinal products within its official capacity of an EU institution concerned with public health protection. In this respect, the EDPS considers that the necessity of the processing could be considered as justified.

The lawfulness of the processing is also based on Article 5(e) *"the data subject has unambiguously given his or her consent"*. Indeed, the lawfulness of the processing of the personal data of pregnant women is based on the unambiguous consent provided at the time of enrolment.

2.2.3. Data quality

Adequacy, relevance and proportionality. Pursuant to Article 4(1) (b) of Regulation (EC) No 45/2001, personal data must be collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes. Furthermore, based on

Article 4(1) (c) they must be adequate, relevant and non excessive in relation to the purposes for which they are collected and/or further processed. This is referred to as the data quality principle.

Among the recommendations in the consultation, the EDPS stated that the EMA should notably require that Outcome only processes the data for the specified, explicit and legitimate purpose of the study. The protocol (Annex II) contains a chapter 7.4 on data protection that states that "*personally identifiable information will only be used for the purpose of contacting women at pre-determined intervals to remind them about the need to provide follow-up [...]. No personally identifiable data will be maintained beyond what is needed to complete the study*".

Furthermore**,** the Memorandum of Understanding (Annex I) foresees under its point IV that "*Outcome will process the personal data only for the specified, explicit and legitimate purposes of the study [...]".*

As to the data that are collected, these have been described in the facts above and are stated in the protocol (Annex II) as data on use of prescription and non-prescription medications, as well as on use of herbals and homeopathic medications. They were developed from a review of best practice documents and with the participation of a patient organisation.

Finally, by coding the data and only allowing identification at Outcome level, the EDPS considers that the EMA fulfils his recommendation that data are not excessive in relation to the purpose for which they were collected.

From this point of view, the data collected could be considered adequate, relevant and non excessive for the purposes of the processing.

Fairness and lawfulness. Article 4(1)(a) of the Regulation requires that data be processed fairly and lawfully. The issue of lawfulness was analyzed above (see Section 2.2.2). The issue of fairness is closely related to what information is provided to the data subjects who is further addressed in Section 2.2.8.

Accuracy. According to Article 4(1)(d) of the Regulation, personal data must be *"accurate and, where necessary, kept up to date",* and *"every reasonable step must be taken to ensure that data which are inaccurate or incomplete, having regard to the purposes for which they were collected or for which they are further processed , are erased or rectified".*

In his recommendations the EDPS underlined that EMA should require that Outcome enables data subjects to effectively exercise their rights (Articles 13 to 18 of the Regulation). Based on the informed consent forms that are provided to any participants (Annex IV and V) data subjects have the right to review and correct data in accordance with the different countries' data protection legislation (depending on the country where the study is conducted).

However, the EDPS notes that "*access and corrections may be limited to ensure the scientific accuracy of the study, as may be permitted by applicable laws and regulations*". This point will be analysed under the right of access (2.2.6) below.

2.2.4. Conservation of data

Pursuant to Article 4(1)(e) of Regulation (EC) No 45/2001 personal data may be kept in a form which permits identification of data subjects for no longer than necessary for the purposes for which the data are collected and/or further processed.

In his consultation, the EDPS asked EMA to require from Outcome that it destroys personal data at the end of the agreed retention period. As stated in the notification, all study data will be retained for a minimum period of five years for research purposes including secondary analyses and the Memorandum of Understanding (Annex I) foresees under its point IV that "*Outcome will process the personal data only for the specified, explicit and legitimate purposes of the study, and will destroy all personal data at the end of the agreed retention period*".

As to the deletion of personal data, the EDPS takes note that it is also clarified in the consent forms (Annex IV and V) that contact details are kept in a separate, secure system from the medical and lifestyle information that is given by the participants. Furthermore, as explained in the facts, based on the information provided by the EMA, the retained data do not contain any direct identifiers. The de-identified data only contain a study code. During the course of the study, this study code could be used to retrieve the participants' contact details or social security numbers as the link between the study code and the identifiers data exist in Outcome database. Once the study finishes, the specific participant identifiers that are necessary for the study conduct, will be deleted from the study files at Outcome in order to fully anonymize the data. The retained data will have a study code that will not be linked to any identifier, and thus be considered as fully anonymized

The EDPS agrees with the proposed retention period of the data, which seems justified in the context of the research being conducted.

As to the conservation for longer period, the EDPS agrees that the EMA has foreseen that only anonymized and aggregated data will be kept for a longer period for historical and statistical purposes.

2.2.5. Transfers of data

As already explained above the participants in the study are co-controllers. Besides, the EDPS notes that various recipients may receive data collected by Outcome, among which the EMA. Indeed, the co-controllers share data amongst themselves so they are therefore also recipients of the data.

Therefore, the EPDS considers that the project partners in the study are both co-controllers and recipients.

In this respect, Directive 95/46/EC, which is applicable in this case, ensures the free flow of personal data among Member States.

As to transfer outside the EU, the EDPS takes note that Outcome will ensure that the subsidiary companies have to keep level of data protection equals to the one of the country of residence of the participants. However, the EDPS considers that Outcome should provide verifiable guarantees as to this commitment.

2.2.6. Rights of access and rectification

As a co-controller, EMA must ensure that data subjects' rights are effectively granted and respected in accordance with applicable data protection law(s), in particular as provided in Regulation (EC) No 45/2001 and in Directive 95/46/EC. The EDPS has verified that the privacy notice/consent form contains appropriate information for the exercise of the rights and that the MoU contains appropriate clauses ensuring respect of these obligations by Outcome. The EDPS also takes note of specific limitations as permitted by applicable laws and regulations based on Article 13 of Directive 95/46/EC. The EDPS notes that such limitation is foreseen in the consent forms (Annex IV and V) as explained in the facts that access and rectifications can be limited as may be permitted by applicable laws and regulations.

In such case however, the EDPS would like to stress that he agrees that such limitation can take place on the basis of the applicable law but the fact that the processing of data is based on the consent of the participants does not limit the rights of access and rectification to one's personal data. Moreover, such limitation should only be taken following a case by case analysis of the reasons of the limitation on the access and corrections. This was confirmed by the EMA which confirmed that any decision to deny access or correction on the basis of the specific exception foreseen by the applicable legislation will be duly motivated and the data subjects will be also informed about the remedies to dispute the decision, in accordance with applicable national legislation.

2.2.7. Information to the data subject

As co-controller, EMA must ensure that data subjects are appropriately informed, in accordance with applicable data protection law. In his consultation, the EDPS stated that EMA should ensure that Outcome provides data subjects with appropriate notice at the moment of collection.

The EDPS has checked that appropriate steps have been taken to inform data subjects and is satisfied that EMA has taken necessary steps in this regard.

2.2.8. Security measures

According to Articles 22 and 23 of Regulation (EC) No 45/2001, the controller and the processor must implement appropriate technical and organizational measures to ensure a level of security appropriate to the risks represented by the processing and the nature of the personal data to be protected. These security measures must in particular prevent any unauthorized disclosure or access, accidental or unlawful destruction or accidental loss, or alteration and prevent all other forms of unlawful processing.

[...], the EDPS considers that the EMA has fulfilled the recommendation made with regards to this aspect.

3. Conclusion

The proposed processing operation would not appear to involve any breach of the provisions of Regulation (EC) No 45/2001, provided that account is taken of the observations made above. In particular, the EMA should:

- ensure that if a data subject is refused access or rectification to his or her personal data, this is decided only on a case by case basis;

- ensure that Outcome provides verifiable guarantees as regards the protection of personal data in the case of international transfer(s) of data.

Done at Brussels, 29 November 2012

(**signed**)

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