REGISTER NUMBER: 889

NOTIFICATION FOR PRIOR CHECKING

Date of submission: **21/08/2012**

Case number: **2012-0704**

Institution: **EMA**

Legal basis: article 27-5 of the regulation CE 45/2001(1)

(1) OJ L 8, 12.01.2001

INFORMATION TO BE GIVEN(2)

(2) Please attach all necessary backup documents

1/ Name and address of the controller

Noel Wathion Head of Unit Patient and Health Protection 7 Westferry Circus Canary Wharf E14 4HB London e-mail: noel.wathion@ema.europa.eu

2/ Organisational parts of the institution or body entrusted with the processing of personal data

Head of Unit Health and Patient Protection

3/ Name of the processing

PROTECT WP4

4/ Purpose or purposes of the processing

The EMA is a member of a Research Consortium called PROTECT and funded through the Innovative Medicine Initiative (IMI). In one of the Work Package, WP4, the EMA is acting as "joint controller" of processing of personal data of women who voluntarily enrol in the study. The Agency will not directly collect , store or access data of the subjects enrolled in the study in a identifiable manner. Th EMA has consulted the EDPS with regard to the interpretation of its controllership under Art. 46(d) of Regulation 45/2001 and has received the EDPS' Opinion on 21 March 2011 (Your Ref. C 2010-0818). 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). The purpose of processing 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? " In order to accomplish this task, data will be 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. Data will be collected from pregnant women in four different countries (UK, The Netherlands, Poland, Denmark). The data collected will be assessed and might eventually be linked to other data available from other databases (e.g. in the UK, the THIN for the monitoring of prescription drugs) The EMA has received confirmation from Outcome Europe Sarl on the 9th August that a notification has been filed to the UK DPA (Annex III)

5/ Description of the category or categories of data subjects

Pregnant women who voluntarily enrol in the study in 4 countries (UK, The Netherlands, Denmark, Poland). Approximate number: 5600 in total.

6/ Description of the data or categories of data *(including, if applicable, special categories of data (article 10) and/or origin of data)*

Data concerning 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.

7/ Information to be given to data subjects

Data Protection Notice is provided directly to the data subjects at the point of enrollment in the study. It is included within the "Information Consent Form" which is statutorily mandated for the enrollment of data subjects in a clinical study (See Annex IV and V)

8/ Procedures to grant rights of data subjects *(rights of access, to rectify, to block, to erase, to object)*

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. See "Informed Consent Forms" Annex IV and V

9/ Automated / Manual processing operation

Automated

10/ Storage media 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 secure 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 (Annex II)
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 (see Section 4.5.4 "Informed Consent").
All study data will be retained for a minimum period of 5 years for research purposes including secondary analyses.

11/ Legal basis and lawfulness of the processing operation

The EMA participates in scientific research projects concerning the monitoring of medicinal products within its official capacity of an EU institution concerned with public health protection. The Legal Basis for the processing of the data of pregnant women is unambiguous consent provided at the time of enrollment.

12/ The recipients or categories of recipient to whom the data might be disclosed

Outcome Europe Sarl (collect data), Trusted Third Party (received encrypted information), Kings College London will perform the anaysis, country leads from The Netherland and Denmark will receive data on their specific country with information such as postcode or social security number only to perform data linkage with 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, linkage of study records with data held on a GP research database (THIN) will be attempted. The study team will provide a trusted third party with encrypted 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. At each stage of the linkage process those undertaking these procedures will be unaware of patient identity.

13/ retention policy of (categories of) personal data

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

13 a/ time limits for blocking and erasure of the different categories of data
(on justified legitimate request from the data subject)
(Please, specify the time limits for every category, if applicable)

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

14/ Historical, statistical or scientific purposes
If you store data for longer periods than mentioned above, please specify, if applicable, why the data must be kept under a form which permits identification,

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

15/ Proposed transfers of data to third countries or international organisations

Under para. IV and V of the Memorandum of Understandings, Outcome Europe Sarl is legally responsible to ensure the confidentiality and security of the personal data. In particular Outcome Europe Sarl might decide to use non-EU legal entities belonging to the same group of companies as processors oif the data

16/ The processing operation presents specific risk which justifies prior checking (*please describe*):

Article 27.2.(a)

Processing of data relating to health and to suspected offences, offences, criminal convictions or security measures,

Article 27.2.(c)

Processing operations allowing linkages not provided for pursuant to national or Community legislation between data processed for different purposes,

17/ Comments

Annexes 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 II) Protocol PROTECT Pregnancy: An explanatory study of self-reported medication use in pregnant women III) Copy of the Notification from Outcome Europe Sarl to the Information Commissioner Office of 3rd August 2012 IV) Informed Consent Template V) Informed Consent Template