



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 May 2016
EMA/337294/2016
Inspections and Human Medicines Pharmacovigilance Division

European Medicines Agency policy on access to EudraVigilance data for medicinal products for human use **Annex D - confidentiality undertaking for academia**

This Confidentiality Undertaking is aimed principally at ensuring the protection of personal data. It governs the access and use by academia of the ICSR data set Level 2A as defined in chapter 5.2.5.4. of the European Medicines Agency policy on access to EudraVigilance data for medicinal products for human use (Doc. Ref. EMA/759287/2009 Revision 2) ("Policy"). By signing the Confidentiality Undertaking, ICSR access to the data set Level 2A will be granted to the academic institution by the Agency.

Access to the ICSR data set Level 2A under the policy

The academic institution acknowledges that the ICSR data set level 2A will be made available in the most suitable electronic format based on the research request submitted to the EMA. Before being granted access to the ICSR data set level 2A, the academic institution shall provide the EMA with:

- An e-mail address;
- A place of address in the European Union. In the event that the academic institution does not have a place of address in the European Union and wishes to avail itself of the services of a third party resident or domiciled in the European Union, such third party shall be considered a representative of the academic institution for the purpose of the Confidentiality Undertaking and shall comply with all the terms hereof;
- Elements concerning the identity of the person nominated by the academic institution requesting access to the ICSR data set Level 2A under the policy (i.e. name, date of birth, passport or ID card number, expiry date of the document; the affiliation and position within the organisation);
- A signed copy of the Confidentiality Undertaking (signed by the person nominated by the academic institution and requesting access to the ICSR data set Level 2A under the Policy and all members of the research team).



Confidentiality Undertaking

As a condition of my access to the EudraVigilance database, for the purpose of ensuring the protection of personal data therein, I agree to the following terms:

- I agree at all times to treat as confidential all information related to the ICSR data set Level 2A and to use it according to the conditions set in this Undertaking and in compliance with applicable data protection legislation. In particular, I agree not to seek to identify, profile, contact or target the data subjects from the ICSR data set Level 2A.
- I agree not to transfer or dispose of the ICSR data set Level 2A for which access is provided under the condition of this Confidentiality Undertaking to any third party. I shall not permit any third party to access, study, analyse, refer to or otherwise use the data or permit any party to reproduce any ICSR data.
- I agree to access and use only the minimal amount of personal data that is necessary for the performance of my research activities and I acknowledge that the source of the data is the EudraVigilance database.
- I agree to ensure that any publications or reports based on the use of EudraVigilance database do not contain personal information. Personal information mean any recorded information that could, either by itself or in combination with other information, be used to link or associate the information to a particular individual.
- I agree to maintain adequate technical and security measures to prevent unauthorised or unlawful access, disclosure, dissemination, alteration, destruction, accidental loss or copying of the ICSR data set Level 2A in accordance with applicable data protection legislation and to immediately notify the Agency of a breach of security leading to any thereof.
- I agree to use the data only for the purposes of bona fide research activities and for no other purpose. I agree to provide a copy of any article using this ICSR data to the Agency for information at least 5 business days before its publication. I acknowledge that this Undertaking will be in effect from the date of my signature and that the terms of this Undertaking will apply to any subsequent research projects I perform using EudraVigilance data.
- I understand that compliance with this Confidentiality Undertaking is a condition of my access to the EudraVigilance database and that failure to comply may result in immediate termination of my right to access or possess the data.

I have read, understood and I agree to comply with the terms stated above at all times.

Note: the person nominated by the academic institution and requesting access to the ICSR data set Level 2A under the Policy and all members of the research team must sign this form.

Name: _____ Title: _____

Signature: _____ Date: _____