15 May 2024

EMA/99666/2016

Data Analytics and Methods

EudraVigilance Human Sponsor Registration Form

Appointment of a 'Responsible Person for EudraVigilance' (RP) by a sponsor organisation

This form is part of a set of [EudraVigilance Registration Documents](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/eudravigilance-registration-documents_en.pdf). These documents are required in support of the registration process of authorised users of EudraVigilance Human, which is further described in the [EudraVigilance Registration Manual](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/eudravigilance-registration-manual_en.pdf).

This form is completed on behalf of the sponsor of the clinical trial.[[1]](#footnote-1)

**Notes:**

For **Commercial and Non-commercial Sponsors NOT established in the Union/Community**, a Legal Representative[[2]](#footnote-2) for the Sponsor organisation should be established in the Union/Community and also needs to complete and sign this form.

For **Commercial and Non-commercial Sponsors established in the Union/Community**, the section of the Legal representative should be left blank.

As per the EMA’s internal procedures and in order to safeguard the accuracy of the information in EudraVigilance, the Agency reserves the right to contact, if applicable, the former RP of the organisation so as to clarify the scope of the change and to validate the change being requested.

The personal data submitted in this form is processed in accordance with Regulation (EU) 2018/1725, and as explained in the data protection notice for EudraVigilance Human and for the [EMA Account Management system](https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-privacy-statement-ema-account-management-system_en.pdf).

Table 1. Contact details of the Sponsor, the RP and the Sponsor’s Legal Representative

|  |  |  |
| --- | --- | --- |
| **Sponsor’s contact details** | **Sponsor’s Legal Representative in the Union/Community+** | **Contact details of nominated RP#** |
| Sponsor’s organisation name[[3]](#footnote-3):  | Organisation Name (if applicable):  | Organisation Name (if applicable):  |
| Contact point within the organisation: | Contact point within the organisation: | Contact point within the organisation: |
| Full Name:  | Full Name:  | Full name:  |
| Address[[4]](#footnote-4):  | EU/EEA Address[[5]](#footnote-5):  | Address:  |
| Postcode:  | EU/EEA Postcode:  | Postcode:  |
| Country:  | EU/EEA Country:  | Country:  |
| Telephone number:  | EU/EEA Telephone number:  | Telephone number:  |
| E-mail address:  | E-mail address:  | E-mail address:  |
| Date:  | Date:  | **#** **Note**: this column should be populated whenever the Sponsor’s contact person does **NOT** act as the RP; otherwise, it should be left blank. |
| **I confirm that** *(please select 1 option)***:**[ ]  I will be the Responsible Person (RP) for EudraVigilance**Or**[ ]  I will **NOT** act as the nominated RP for EudraVigilance *(in this situation, please complete the 3rd column of this table with the contact details of the nominated RP)*. | Signature (by signing this document I, the undersigned person, confirm that I am authorised to act, as the Union/Community Legal Representative for the sponsor named on this form and that **I AM ESTABLISHED IN THE Union/Community**, as per the provisions of Article 74 of Regulation (EU) 536/2014 and Article 19 of Directive 2001/20/EC, as applicable): |
| Signature (by signing this document I, the undersigned person, confirm that I am authorised to act on behalf of the Sponsor organisation):  | **+****Note**: For Sponsors not established in the Union/Community, this column should be populated with the details of the Sponsor’s Legal Representative in the Union/Community; otherwise, this column should be left blank for Sponsors established in the Union/Community. |

1. As defined in Article 2(14) of Regulation (EU) 536/2014 and Article 2(e) of Directive 2001/20/EC as applicable. [↑](#footnote-ref-1)
2. In accordance with Article 74 of Regulation (EU) 536/2014 and Article 19 of Directive 2001/20/EC as applicable. [↑](#footnote-ref-2)
3. This should match the information provided in the Clinical Trial Application form provided as part of the trial registration. [↑](#footnote-ref-3)
4. The address should be provided for the sponsor of the clinical trial. [↑](#footnote-ref-4)
5. Address of the organisation acting as the Legal Representative in the EU/EEA (where the sponsor is not established in the EU/EEA). [↑](#footnote-ref-5)