Anexo 37. **Formato de Notificación de Sospecha de Reacción Adversa Grave e inesperada y/o Evento adverso grave**

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| **N° DE NOTIFICACIÓN:** |  |

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| **1. INFORMACIÓN SOBRE EL ESTUDIO** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Título abreviado y/o código del estudio:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Nombre y apellidos del Investigador principal:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Centro de investigación:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **2. INFORMACIÓN DEL SUJETO DE INVESTIGACIÓN** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **INICIALES DEL SUJETO DE INVESTIGACIÓN** | | | | | | | | | **EDAD (AÑOS)** | | | | | | | | | | **SEXO** | | | | | | | | | **ETNIA** | | | | | | **TALLA (CMS)** | | | | | **PESO (KG)** | | | | | | | | **Nº Código de Identificación del sujeto en investigación:** | | | | | | | | |
|  | | | | | | | | |  | | | | | | | | | | **F** | | | |  | **M** | | |  |  | | | | | |  | | | | |  | | | | | | | |  | | | | | | | | |
| **3. INFORMACIÓN SOBRE:**  **Reacción Adversa Grave e Inesperada (RAGI)**  **Evento Adverso Grave (EAG)** | | | | | | | | | | | | | | | | | | |  | | | | |  | | | | **Fecha inicio de la RAGI /EAG** | | | | | | | | | | | | | | | | | | **Fecha Fin de la RAGI/EAG** | | | | | | | | | |
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| **DESCRIPCIÓN DE LA RAGI /EAG (SÍNTOMAS, SIGNOS, LOCALIZACIÓN, GRAVEDAD):** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **DATOS RELEVANTES DEL SUJETO EN INVESTIGACIÓN (incluyendo exámenes de laboratorios relevantes):** | | | | | | | | | | | | | | | | | | | | | | | |
| **4. INFORMACIÓN DE MEDICAMENTO/EVENTO SOSPECHOSO** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **NOMBRE DEL PRINCIPIO ACTIVO** | | | | | **NOMBRE COMERCIAL** | | | | | | **LOTE** | | | | | | | | **FECHA INICIO**  día y hora de comienzo del tratamiento | | | | | | | **FECHA FIN**  día y hora de suspensión del tratamiento | | | | | | | | **DOSIS Y FRECUENCIA DIARIA** | | | | | | | | | **VIA DE ADMINIS.** | | | | **FORMA FARMACEUTICA** | | | | | | | **INDICACIÓN** | |
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| **5. TRATAMIENTOS CONCOMITANTES O TERAPIA CON OTROS PRODUCTOS** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **NOMBRE DEL PRINCIPIO ACTIVO** | | | | | **NOMBRE COMERCIAL** | | | | | | **LOTE** | | | | | | | | **FECHA INICIO**  día y hora de comienzo del tratamiento | | | | | | | **FECHA FIN**  día y hora de suspensión del tratamiento | | | | | | | | **DOSIS Y FRECUENCIA DIARIA** | | | | | | | | | **VIA DE ADMINIS.** | | | | **FORMA FARMACEUTICA** | | | | | | | **INDICACIÓN** | |
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| **6.TRATAMIENTOS PARA CONTRARRESTAR LA RAGI /EAG** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **NOMBRE DEL PRINCIPIO ACTIVO** | | | | | **NOMBRE COMERCIAL** | | | | | | **LOTE** | | | | | | | | **FECHA INICIO**  día y hora de comienzo del tratamiento | | | | | | | **FECHA FIN**  día y hora de suspensión del tratamiento | | | | | | | | **DOSIS Y FRECUENCIA DIARIA** | | | | | | | | | | **VIA DE ADMINIS.** | | | | | | | | | **INDICACIÓN** | | |
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| **7. RESULTADO DE LA REACCIÓN ADVERSA GRAVE INESPERADA O EVENTO ADVERSO GRAVE QUE SE REPORTA** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Lugar de ocurrencia de la RAGI/EAG** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Casa** | | |  | | | **Centro de Salud** | | | | | | | | | | | | |  | | | | **Hospital** | | | | | | |  | | | |  | | | **Otro** | | | |  | | | | **Especificar:** | | | | | | | | | | |
| **Nivel de atención médica que recibía el paciente cuando apareció el evento adverso:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Ingreso hospitalario** | | | | | |  | | **Ingreso en el hogar** | | | | | | | | | | |  | | | | **Ambulatorio** | | | | | | | |  | | | **Ninguno** | | | | | |  | | **Otro** | | | | | |  | **Especificar:** | | | | | | |
| **Relación de causalidad** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **¿La reacción adversa desapareció al suspender el medicamento?** | | | | | | **¿La reacción adversa desapareció al reducir la dosis del medicamento?** | | | | | | | | | | | | | **¿La reacción adversa reapareció al administrar de nuevo el medicamento?** | | | | | | | | | | | | | | | | | **Mortal** | | | | | | | | | | | | | | | | | | |  |
| **Amenaza la vida del paciente** | | | | | | | | | | | | | | | | | | |  |
| **Malformación congénita** | | | | | | | | | | | | | | | | | | |  |
| **Requirió o prolongí hospitalización** | | | | | | | | | | | | | | | | | | |  |
| **Si** |  | **No** | |  | | | **Si** | | |  | | | **No** | | | |  | | | | | **Si** | | |  | | | | **No** | | | | | |  | | | **Produjo incapacidad invalidez significativa o persistente** | | | | | | | | | | | | | | | | |  |
| **Se desconoce** | | | | | | | | | | | | |  | | | **Otro (especificar)** | | | | | | | | | | | | | | | | |  |
| **En caso de fallecimiento, ¿se realizó autopsia?** | | | | | | **¿Existe relación de causalidad con el producto en investigación?** | | | | | | | | | | | | | | | **Estado del sujeto en investigación** | | | | | | | | | | | | | | | | | | | **Acción emprendida en relación al producto en investigación** | | | | | | | | | | | | | | | |
| **Si** |  | **No** | |  | | | **Si** | | | | |  | | **No** | | | |  | | **Recuperado** | | | | | | | | | | | | | | | | |  | | | | **Ninguna** | | | | | | | | | | | | | | |  |
| **Fecha de la muerte:** | | | | | | **Se desconoce** | | | | | | | | | |  | | | | | **Recuperado con secuelas** | | | | | | | | | | | | | | | |  | | | **Posposición del tratamiento** | | | | | | | | | | | | | | | |  |
| **Día/mes/año** | | | | | |  | | | | | | | | | | | | | | | **Mejorado** | | | | | | | | | | | | | | | |  | | | **Interrupción del tratamiento** | | | | | | | | | | | | | | | |  |
| **Desconocido** | | | | | | | | | | | | | | | |  | | | **Modificación de la dosis** | | | | | | | | | | | | | | | |  |
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| **Especificar:** | | | | | | | | | | | | | | | |
| **8. INFORMACIÓN DEL NOTIFICADOR (INVESTIGADOR DEL ESTUDIO)** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **NOMBRE:** | | | | | | | | | | | | | | | **PROFESIÓN:** | | | | | | | | | | | | | | | | | | | **LUGAR DE TRABAJO:** | | | | | | | | | | | | | | | | | | | | | |
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| **DIRECCIÓN:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **TELÉFONO Y MAIL:** | | | | | | | | | | | | | | | | | | **FIRMA:** | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | |  | | | |
| **9. SOLO PARA USO DE ENTIDAD REGULADORA** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **IMPUTABILIDAD\*:**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Mp** | **Pr** | **Ps** | **Im** | **NR** | **NE** | | | | | | | | | | | | | | | | | | | | **GRAVEDAD:**   |  |  |  | | --- | --- | --- | | **L** | **M** | **G** | | | | | | | | | | | | | | | | **ÓRGANO AFECTADO:** | | | | | | | | | | | | | | | | **FECHA Y SELLO DE EVALUACIÓN** | | | | | |
| **Nº NOTIFICACIÓN:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **FECHA DE NOTIFICACIÓN:** | | | | | | | | | | | | | | | | | | | | | |
| **PROVINCIA:** | | | | | | | | | **EAG HA SIDO COMUNICADO POR OTRA VÍA:** | | | | | | | | | | | | | | | | | | | | | | | | | **TIPO DE NOTIFICACIÓN:** | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | **NO** | | | | | | | | | | | | | | | | | | | | | | | |  | **INICIAL** | | | | | | | | | | | | | | | | |  | | | | |
| **SI** | | | | | | | | | | | | | | | | | | | | | | | |  | **SEGUIMIENTO** | | | | | | | | | | | | | | | | |  | | | | |
| **Especificar:……………..** | | | | | | | | | | | | | | | | | | | | | | | | | **FINAL** | | | | | | | | | | | | | | | | |  | | | | |

\*MP = Muy probable; Pr= probable; Ps = posible; Im= Improbable; NR = No relacionado; Ne = No evaluable, no clasificable.

**CRITERIOS PARA ESTABLECER LA RELACIÓN DE CAUSALIDAD ALGORITMO DE NARANJO**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **PREGUNTA** | | **SÍ** | **NO** | **NO SE SABE** | **PUNTAJE** |
| ¿Existen notificaciones concluyentes sobre esta reacción? | |  |  |  |  |
| ¿Se produjo la reacción adversa después de administrar el fármaco sospechoso? | |  |  |  |  |
| ¿Mejoró la reacción adversa tras suspender la administración del fármaco o tras administrar un antagonista específico? | |  |  |  |  |
| ¿Reapareció la reacción adversa tras la readministración del fármaco? | |  |  |  |  |
| ¿Existen causas alternativas (diferente del fármaco) que podría haber causado la reacción por sí mismas? | |  |  |  |  |
| ¿Reapareció la reacción adversa tras administrar un placebo? | |  |  |  |  |
| ¿Se detectó el fármaco en la sangre (o en otros fluidos) en concentraciones tóxicas? | |  |  |  |  |
| ¿Fue la reacción más severa al aumentar la dosis o menos severa al disminuirla? | |  |  |  |  |
| ¿Tuvo el paciente alguna reacción similar causada por el mismo fármaco u otro semejante en cualquier exposición anterior? | |  |  |  |  |
| ¿Se confirmó el acontecimiento adverso por cualquier tipo de evidencia objetiva? | |  |  |  |  |
| **PUNTUACIÓN TOTAL** |  |  |  |  |  |

**Puntuación:**

***Definida*** 9 o más puntos.

***Probable:*** 5 a 8 puntos.

***Posible:*** 1 a 4 puntos.

***Dudosa:*** 0 o inferior.

Formato de la Agencia Nacional de Regulación, Control y Vigilancia Sanitaria, “Formulario de notificación de sospecha de reacción adversa grave inesperada y/o evento adverso grave en ensayos clínicos”