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| **REPORTE DE EVENTO ADVERSO SERIO EN PERÚ**   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | 1. **INFORMACIÓN GENERAL DEL ENSAYO CLÍNICO** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **Título del Ensayo Clínico** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **Patrocinador (es)** | | | | | | | | | | | | **Empresa / Institución / Otro ejecutora** | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | **Fase Clínica del Estudio** | | | |  | | | | | | | | **Código de Protocolo** | | | | | | | | | | | |  | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1. **IDENTIFICACIÓN DEL REPORTE DE EVENTO ADVERSO SERIO** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **Tipo de Reporte** | | | * Inicial * Seguimiento N°\_\_\_\_\_ * Final | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1. **INFORMACIÓN SOBRE EL PACIENTE** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **Código de Identificación del Paciente** | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | **Sexo** | | | * Femenino * Masculino | | | | | | | | | | | **Edad** | | | | | | | |  | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1. **INFORMACIÓN SOBRE EL EVENTO ADVERSO SERIO** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **Categorías** | | | | | | | | | | | **Diagnóstico CIE – 10** | | | | | | | | | | **Relación de causalidad con el producto de investigación** | | | | | | | | | * Fatal * Puso en grave riesgo la vida del paciente * Requirió hospitalización y/o atención al servicio de emergencia * Prolongó hospitalización * Produjo discapacidad o incapacidad permanente o importante * Anomalía o malformación * Congénitas. * Otros: evento médico importante Especificar:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | |  | | | | | | | | | | * Si Relacionado * No Relacionado * Por Determinar | | | | | | | | | **Fecha de Inicio de EAS** | | | | | | | | | | | \_\_\_/\_\_\_/\_\_\_\_ | | | | | **Fecha de Fin de EAS** | | | | | | | | | \_\_\_/\_\_\_/\_\_\_\_ | | | | | **Descripción detallada del EAS** (con los datos obtenidos hasta la fecha) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **Desenlace de EAS (a la fecha del reporte)** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | * Completamente recuperado | | | | | | | | Fecha de recuperación**:** \_\_\_/\_\_\_\_/\_\_\_ | | | | | | | | | | |  | | | | | | | | | | | * Recuperado con secuela | | | | | | | | Fecha de recuperación**:** \_\_\_/\_\_\_\_/\_\_\_ | | | | | | | | | | | Especificar tipo de secuela: | | | | | | | | | | | * Condición mejorada | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | * Condición aún presente y sin cambios | | | | | | | | | * Condición deteriorada | | | | | | | | | * Muerte | | | | | | | | Fecha de muerte:  \_\_\_/\_\_\_\_/\_\_\_ | | | | | | | Causa básica de muerte: | | | | | Autopsia   * Si * No | | | | | | Adjuntar Certificado de Defunción | | | | **Si el EAS no está relacionado al producto en investigación, indicar si está asociado a:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | * Procedimiento del estudio | | | | | | | | | | | | * Otro medicamento (Especificar en información sobre medicación concomitante) | | | | | | | | | | | | | | | | | | * Progresión de la enfermedad subyacente | | | | | | | | | | | | * Otra condición o enfermedad. * Especificar: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1. **INFORMACIÓN SOBRE EL PRODUCTO EN INVESTIGACIÓN** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **Medidas Tomadas con el Sujeto de Investigación** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | * Se dio terapia de soporte. Especificar:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | * Se dio terapia medicamentosa. Especificar: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | | | | | | | * No se tomó acción alguna | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | **Medidas Tomadas con el producto en Investigación** | | | | | | **¿Cuál es el tipo de medida tomada con el producto en Investigación?** | | | | | | | | | | | | **Evolución del Caso** | | | | | | | | | | | | * Se suspendió | | | | | | * Se suspendió temporalmente | | | | | | | | | | | | Si hubo suspensión temporal ¿el evento adverso reaparece al administrar nuevamente el producto en investigación?   * Si * No | | | | | | | | | | | | * Se suspendió definitivamente | | | | | | | | | | | | Si hubo suspensión definitiva ¿Qué sucede con el evento adverso serio?   * Mejora * No Mejora | | | | | | | | | | | | * No se suspendió | | | | | | * Ningún cambio, continúa * Otra medida tomada Especificar:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | ¿Qué sucede con el sujeto de investigación?   * Mejora por tolerancia * Mejora por tratamiento | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1. **INFORMACIÓN SOBRE MEDICACIÓN CONCOMITANTE** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **Listar los medicamentos concomitantes que estaba tomando en la fecha del EAS**  (No incluir los medicamentos usados para el tratamiento del EAS) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ¿Recibió medicación concomitante?   * Si * No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Medicamento Concomitante | | Dosis, frecuencia  y vía | | | | | Indicación de uso | | | | | | | | Fecha de Inicio | | | | | | Fecha de Finalización | | | | | | ¿Es sospechoso del EAS? | | |  | |  | | | | |  | | | | | | | | **\_\_/\_\_/\_\_\_** | | | | | | **\_\_/\_\_/\_\_\_**   * continúa | | | | | | * Si * No | | |  | |  | | | | |  | | | | | | | |  | | | | | | **\_\_/\_\_/\_\_\_**   * continúa | | | | | | * Si * No | | |  | |  | | | | |  | | | | | | | |  | | | | | | **\_\_/\_\_/\_\_\_**   * continúa | | | | | | * Sí * No | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1. **OTROS DATOS RELEVANTES DE LA HISTORIA CLINICA** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Listar los antecedentes médicos relevantes, diagnósticos o condiciones médicas pre-existentes, por Ej. Alergias, insuficiencia renal o hepática, etc. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **¿Tiene antecedentes médicos relevantes, diagnósticos o condiciones médicas pre-existentes?**   * Sí * No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **Enfermedad / condición médica** | | | | | | | | | **Fecha inicio** | | | | | | | | **Fecha término(año)** | | | | | | | | | | | | |  | | | | | | | | |  | | | | | | | |  | | | | | | | | | | | | |  | | | | | | | | |  | | | | | | | |  | | | | | | | | | | | | |  | | | | | | | | |  | | | | | | | |  | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1. **EXÁMENES DE LABORATORIO U OTRAS PRUEBAS DIAGNÓSTICAS** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Listar todos los exámenes de laboratorio u otras pruebas diagnósticas realizados para establecer o descartar la causalidad de EAS. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **¿Se realizaron exámenes de laboratorio u otra prueba diagnóstica?**   * Sí * No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Examen de laboratorio / prueba diagnóstica | Fecha dd/mm/aaaa | | | | Resultados | | | | | valores normales | | | Fecha de prueba previa a la ocurrencia del EAS | | | | Resultados de la prueba previa a la ocurrencia del EAS | | | | | | Relación con el EAS | | | | | Observaciones | |  |  | | | |  | | | | |  | | |  | | | |  | | | | | | * Sí * No | | | | |  | |  |  | | | |  | | | | |  | | |  | | | |  | | | | | | * Sí * No | | | | |  | |  |  | | | |  | | | | |  | | |  | | | |  | | | | | | * Sí * No | | | | |  | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1. **FIRMA DEL INVESTIGADOR PRINCIPAL** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  ***Firma del Investigador***  *(Apellidos y Nombres)*  **Fecha:** \_\_\_/\_\_\_\_/\_\_\_ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |