**严重不良事件报告表（SAE报告表）**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 报告类型： □首次报告   □随访报告   □总结 报告时间：   年    月   日 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 临床试验项目名称 | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | 中心号 | | |  |
| 临床试验方案编号 | | | | | | | | |  | | | | | | | | | | 新药临床研究批准文号 | | | | | | | | | |  | | | |
| 医疗机构及专业名称 | | | | | | | | |  | | | | | | | | | | | | | | 试验科室电话 | | | | | |  | | | |
| 申办者名称 | | | | |  | | | | | | | | | | | | | | | | | | 申办者联系电话 | | | | | |  | | | |
| 试验用药品(器械）名称 | | | | | | | | | 中文名称： | | | | | | | | | | | | | | | | | | | | | | | |
| 英文名称： | | | | | | | | | | | | | | | | | | | | | | | |
| 药品注册分类及剂型 | | | | | | | | | 分类：□中药 □化学药 □治疗用生物制品 □其它 注册分类： 剂型： | | | | | | | | | | | | | | | | | | | | | | | |
| 临床研究分类 | | | □Ⅰ期 □Ⅱ期 □Ⅲ 期 □Ⅳ期  □生物等效性试验  □临床验证 | | | | | | | | | | | | | | | | | | 临床试验适应症 | | | | | |  | | | | | |
| **受试者基本情况** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 筛选号 |  | | | | | | | 姓名拼音缩写 | | | | |  | | | | | | | 民族 | | | | |  | | | 身高(cm) | | | |  |
| 入选号 |  | | | | | | | 出生日期 | | | | | **\_\_年 \_月\_\_\_日** | | | | | | | 性别：□男 □女 | | | | | | | | 体重(Kg) | | | |  |
| 饮酒史 | | | | ☐无 ☐有 | | | | | | | | 吸烟史 | | | | | | ☐无 ☐有 | | | | | | | 家族史 | | | ☐无 ☐有 | | | | |
| 肝病史 | | | | ☐无 ☐有 | | | | | | | | 肾病史 | | | | | | ☐无 ☐有 | | | | | | | 过敏史 | | | ☐无 ☐有 | | | | |
| **受试者合并用药使用情况 ☐不详 ☐无 ☐见下表**  **注：合并治疗是指SAE发生前开始使用，SAE发生时正在使用的药品；针对SAE的治疗用药，请填写在“SAE发生及处理的详细情况”栏。** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **药物名称** | | **使用原因**  **（合并疾病等）** | | | | | | | | | **剂量/剂量单位** | | | **剂型** | | | **频次** | | | | | **给药途径** | | | | **开始时间** | | | | | **结束时间** | |
|  | |  | | | | | | | | |  | | |  | | |  | | | | |  | | | | **\_\_年 \_月\_\_\_日** | | | | | **\_\_年 \_月\_\_\_日** | |
|  | |  | | | | | | | | |  | | |  | | |  | | | | |  | | | | **\_\_年 \_月\_\_\_日** | | | | | **\_\_年 \_月\_\_\_日** | |
|  | |  | | | | | | | | |  | | |  | | |  | | | | |  | | | | **\_\_年 \_月\_\_\_日** | | | | | **\_\_年 \_月\_\_\_日** | |
| **与SAE相关实验室检查项** | | | | | | | | | | | | | | ☐不详 ☐无 ☐见下表（可按实际项目自行增加行列） | | | | | | | | | | | | | | | | | | |
| **检查名称** | | | | | | | **检查日期** | | | | | | | | **检查结果** | | | | | | | | | **正常值范围** | | | | | | **备注** | | |
|  | | | | | | | **\_\_\_\_年\_\_\_月\_\_\_日** | | | | | | | |  | | | | | | | | |  | | | | | |  | | |
|  | | | | | | | **\_\_\_\_年\_\_\_月\_\_\_日** | | | | | | | |  | | | | | | | | |  | | | | | |  | | |
|  | | | | | | | **\_\_\_\_年\_\_\_月\_\_\_日** | | | | | | | |  | | | | | | | | |  | | | | | |  | | |
| **严重不良事件** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| SAE的医学诊断 | | | | | | 应填1个临床诊断，而非症状或者体征的描述；同时存在多个SAE应分别报告。 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| SAE情况 | | | | | | □死亡 \_\_\_\_\_\_年\_\_\_月\_\_\_日  □导致住院（不包括择期手术或常规的临床过程） □延长住院时间  □功能障碍/致残 □肿瘤 □致畸 □危及生命  □其它（包括计划外妊娠和试验方案中规定的需要报告的情况） | | | | | | | | | | | | | | | | | | | | | | | | | | |
| SAE发生时间 | | | | | | \_\_\_\_\_年 \_\_\_月\_\_\_日 | | | | | | | | | | 研究者获知SAE时间（研究者被告知或发现SAE的时间，此为第0天） | | | | | | | | | | | | | | \_\_\_\_年 \_\_\_月\_\_\_日 | | |
| 对试验药物采取的措施 | | | | | | | | | | □继续用药 □减小剂量 □药物暂停后又恢复 □停用药物 □破盲 □其它 | | | | | | | | | | | | | | | | | | | | | | |
| SAE转归 | | | | | | | | | | * 症状消失（后遗症  □有  □无）  □症状持续  □其他 | | | | | | | | | | | | | | | | | | | | | | |
| SAE与试验药的关系  （请尽可能根据临床所掌握证据，判断相关性） | | | | | | | | | | □肯定有关 □可能有关 □可能无关 □肯定无关 □无法判定  （相关性的判断须由研究者完成，对无关/可能无关的判定应谨慎） | | | | | | | | | | | | | | | | | | | | | | |
| SAE报道情况 | | | | | | | | | | 国内：□有 □无 □不详； 国外：□有 □无 □不详  （请根据研究者手册和既往研究经验进行填写） | | | | | | | | | | | | | | | | | | | | | | |
| 是否为SUSAR  （研究者的初步判定） | | | | | | | | | | 若研究者将SAE与试验药物的相关性判断为肯定有关/很可能有关/可能有关时，需初步判断此SAE是否为SUSAR并记录 | | | | | | | | | | | | | | | | | | | | | | |
| SAE发生及处理的详细情况： | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

报告单位名称：      报告人签名： 主要研究者签名：