**药物临床试验严重不良事件报告表**

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| **新药临床研究批准文号：**  **申办方临床研究方案号**： | | | | | | | | | | | | | | | | | **中 心 号：**  **受试者编号**： | | | | | | | | | | | | **报告类型：** ☐ 首次  ☐ 随访 ☐ 总结报告  **报告编号：** | | | | | | | |
| **研究项目及报告单位信息** | | | | | | | | | | | | | | | | | **报告时间** | | | | | | | | | | | | 年 月 日 | | | | | | | |
| **医疗机构及专业名称** | | | | | | |  | | | | | | | | | | **电话** | | | | | | | | | | | |  | | | | | | | |
| **申报单位名称** | | | | | | |  | | | | | | | | | | **电话** | | | | | | | | | | | |  | | | | | | | |
| **研究方案名称** | | | | | | |  | | | | | | | | | | **临床试验适应症** | | | | | | | | | | | |  | | | | | | | |
| **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 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **报告者信息** | | | | | | | | | | | | | | | | | | | | | | | | **获知时间** | | | | | | 年 月 日 | | | | | | |
| **报告姓名** | |  | | | | | | **报告者职业** | | | | | |  | | | | | | | | | | **电话** | | | | | |  | | | | | | |
| **报告者地址** | |  | | | | | | | | | | | | | | | | | | | | | | **邮箱** | | | | | |  | | | | | | |
| **患者信息** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **受试者编号** | |  | | | | | | **民族** | | |  | | | **发生SAE时年龄** | | | | |  | | | | | **受试者是否退出研究** | | | | | | ☐是 ☐否 | | | | | | |
| **患者死亡** | | ☐是 ☐否 | | | | | | **死亡时间** | | |  | | | **死亡原因** | | | | |  | | | | | **是否尸检** | | ☐是 ☐否 | | | | | | | | **尸检结果** | |  |
| **相关病史与治疗** | | | | | | | | ☐不详 ☐无 ☐见下表 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **现病史** | | 试验用药适应症以外，SAE发生时未恢复的疾病 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **疾病名称** | | **开始时间** | | | | | | | **是否持续** | | | | | | **结束时间** | | | | | | **治疗药物通用名称** | | | | | | | | | | **用法用量** | | | | | |
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| **既往病史** | | 试验用药适应症以外，SAE发生时已经恢复的疾病 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **疾病名称** | | **开始时间** | | | | | | | **是否持续** | | | | | | **结束时间** | | | | | | **治疗药物通用名称** | | | | | | | | | | **用法用量** | | | | | |
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| **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 | | | | | |
| **与SAE相关实验室检查项** | | | | | | | | | ☐不详 ☐无 ☐见下表 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **检查名称** | | **检查日期** | | | | | | | **检查结果** | | | | | **正常值上限** | | | | | | | **正常值下限** | | | | | | | | | | **备注** | | | | | |
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| **合并用药**  ☐不详 ☐无 ☐见下表  注：合并用药是指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** | | | | | **剂量/剂量单位** | | | | | | | **剂型** | | | | | **频次** | | **给药途径** | | | | | | | **开始时间** | | | | | | | | **结束时间** | |
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| **试验用药品使用情况 （如有多个试验用药品，请复制此表格添加）**  （若有除试验用药品外的怀疑药品及相互作用的药物，请复制并添加此表格；如果是盲态试验请填写研究药物名称/对照药品名称） | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **试验用药品中文名称** | | | | |  | | | | | | | | | | | | | | | | | **研究设计** | | | | | |  | | | | | | | | |
| **试验用药品英文名称** | | | | |  | | | | | | | | | | | | | | | | | **用药原因** | | | | | |  | | | | | | | | |
| **是否已给药** | | | | | ☐ 是 ☐否 | | | | | | | | | | | | | | | | | **药物编号** | | | | | |  | | | | | | | | |
| **是否已破盲** | | | | | ☐ 否 ☐是，破盲日期： | | | | | | | | | | | | | | | | | **破盲原因** | | | | | |  | | | | | | | | |
| **对试验用药品采取的措施** | | | | | ☐继续用药 ☐减小剂量 ☐停用药物 ☐停用药物又恢复 ☐不适用 □不详 ☐增加剂量 | | | | | | | | | | | | | | | | | | | | | | | **采取措施时间** | | | | | | |  | |
| **剂量详情** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **剂量/剂量单位** | | | | **给药途径** | | | | | | **频次** | | | | | | **剂型** | | | | | | | | | **开始日期** | | | | | | | **结束日期** | | | | |
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| **严重不良事件(此表可复制）** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | **SAE1** | | | | | | | | | **SAE2** | | | | | | | | | | | **SAE3** | | | | | | | | | | **SAE4** | | | |
| **不良事件名称（诊断）** | | |  | | | | | | | | |  | | | | | | | | | | |  | | | | | | | | | |  | | | |
| **开始日期** | | |  | | | | | | | | |  | | | | | | | | | | |  | | | | | | | | | |  | | | |
| **结束日期** | | |  | | | | | | | | |  | | | | | | | | | | |  | | | | | | | | | |  | | | |
| **研究者获知SAE时间** | | |  | | | | | | | | |  | | | | | | | | | | |  | | | | | | | | | |  | | | |
| **严重性标准** | | | **☐**导致死亡  **☐**致残/致功能丧失  **☐**危及生命  **☐**导致住院或延长住院时间  **☐**致畸/致出生缺陷  **☐**其他重要医学事件 | | | | | | | | | **☐**导致死亡  **☐**致残/致功能丧失  **☐**危及生命  **☐**导致住院或延长住院时间  **☐**致畸/致出生缺陷  **☐**其他重要医学事件 | | | | | | | | | | | **☐**导致死亡  **☐**致残/致功能丧失  **☐**危及生命  **☐**导致住院或延长住院时间  **☐**致畸/致出生缺陷  **☐**其他重要医学事件 | | | | | | | | | | **☐**导致死亡  **☐**致残/致功能丧失  **☐**危及生命  **☐**导致住院或延长住院时间  **☐**致畸/致出生缺陷  **☐**其他重要医学事件 | | | |
| **严重程度** | | | **☐**轻度**☐**中度**☐**重度 | | | | | | | | | **☐**轻度**☐**中度**☐**重度 | | | | | | | | | | | **☐**轻度**☐**中度**☐**重度 | | | | | | | | | | **☐**轻度**☐**中度**☐**重度 | | | |
| **CTCAE 分级** | | |  | | | | | | | | |  | | | | | | | | | | |  | | | | | | | | | |  | | | |
| **国内SAE报道情况** | | | ☐有 ☐无 ☐不详 | | | | | | | | | ☐有 ☐无 ☐不详 | | | | | | | | | | | ☐有 ☐无 ☐不详 | | | | | | | | | | ☐有 ☐无 ☐不详 | | | |
| **国外SAE报道情况** | | | ☐有 ☐无 ☐不详 | | | | | | | | | ☐有 ☐无 ☐不详 | | | | | | | | | | | ☐有 ☐无 ☐不详 | | | | | | | | | | ☐有 ☐无 ☐不详 | | | |
| **不良事件结果** | | | ☐不详  ☐死亡  ☐未好转  ☐好转  ☐痊愈  ☐痊愈伴有后遗症 | | | | | | | | | ☐不详  ☐死亡  ☐未好转  ☐好转  ☐痊愈  ☐痊愈伴有后遗症 | | | | | | | | | | | ☐不详  ☐死亡  ☐未好转  ☐好转  ☐痊愈  ☐痊愈伴有后遗症 | | | | | | | | | | ☐不详  ☐死亡  ☐未好转  ☐好转  ☐痊愈  ☐痊愈伴有后遗症 | | | |
| **是否针对SAE进行治疗** | | | ☐不详 ☐无  ☐是，需在事件描述说明 | | | | | | | | | ☐不详 ☐无  ☐是，需在事件描述说明 | | | | | | | | | | | ☐不详 ☐无  ☐是，需在事件描述说明 | | | | | | | | | | ☐不详 ☐无  ☐是，需在事件描述说明 | | | |
| **相关性评价**  **(不良事件--怀疑药物)**  **研究/怀疑药物名称1：** | | | ☐肯定有关  ☐很可能有关  ☐可能有关  ☐可能无关  ☐肯定无关  ☐无法评价 | | | | | | | | | ☐肯定有关  ☐很可能有关  ☐可能有关  ☐可能无关  ☐肯定无关  ☐无法评价 | | | | | | | | | | | ☐肯定有关  ☐很可能有关  ☐可能有关  ☐可能无关  ☐肯定无关  ☐无法评价 | | | | | | | | | | ☐肯定有关  ☐很可能有关  ☐可能有关  ☐可能无关  ☐肯定无关  ☐无法评价 | | | |
| **停用研究/怀疑药品1后SAE是否消失？** | | | ☐是  ☐否  ☐不详  ☐不适用 | | | | | | | | | ☐是  ☐否  ☐不详  ☐不适用 | | | | | | | | | | | ☐是  ☐否  ☐不详  ☐不适用 | | | | | | | | | | ☐是  ☐否  ☐不详  ☐不适用 | | | |
| **再次使用研究/怀疑药品1后，时间是否再次出现？** | | | ☐是  ☐否  ☐不详  ☐不适用 | | | | | | | | | ☐是  ☐否  ☐不详  ☐不适用 | | | | | | | | | | | ☐是  ☐否  ☐不详  ☐不适用 | | | | | | | | | | ☐是  ☐否  ☐不详  ☐不适用 | | | |
| **SAE发生及处理的详细情况** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **研究者签名： 日期：** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |