**临床试验项目进度报告表**

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|  | | | | | | | | | | | | 第 次进度报告 | | | | | | | | | | | | | | | |
| 填表人姓名： | | | | | | | | 联系电话： | | | | | | | | | | | | | | 填表日期： | | | | | |
| 临床试验题目 | | | |  | | | | | | | | | | | | | | | | | | | | | | | |
| 专业名称 | | | |  | | | | | | | | | | PI | | | |  | | | | | | | | | |
| 申办方 | | | |  | | | | | | | | | | CRO | | | |  | | | | | | | | | |
| 1. **项目进度** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 启动会日期 | | | | 人遗批件日期 | | | | | | 第1例受试者  签署ICF日期 | | | | | | | | 最后1例受试者完成日期4 | | | | | | 锁库日期4 | | | |
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| 计划入组人数 | | | | 筛选人数 | | | | | | 入组（随机化）人数 | | | | | | | | 完成试验人数 | | | | | | 未完成试验人数 | | | |
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| 1. **研究方案** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 版本号/版本日期 | | | | | 递交伦理日期 | | | | | 伦理批准日期 | | | | | | 备注 | | | | | | | | | | | |
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| 1. **知情同意书** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 版本号/版本日期 | | | | | 递交伦理日期 | | | | | 伦理批准日期 | | | | | | 备注 | | | | | | | | | | | |
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| 1. **其他受试者相关文件** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 文件名称 | 版本号/版本日期 | | | | | | | | 递交伦理日期 | | | | 伦理批准日期 | | | | | | | 备注 | | | | | | | |
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| 1. **研究人员：**研究人员有无变更 □无 □有；如有，请填写下表。 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | 姓名 | | | | | | 授权开始/结束日期 | | | | | | | | 职称 | | | | | | 分工 | | | |
| 新增授权人员 | | | |  | | | | | |  | | | | | | | |  | | | | | |  | | | |
| 终止授权人员 | | | |  | | | | | |  | | | | | | | |  | | | | | |  | | | |
| 1. **SAE：**有无SAE □无 □有；如有，请填写下表。 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| SAE名称 | | 受试者编号/姓名缩写 | | | | 研究者获知日期 | | | | | SAE发生日期 | | | | SAE结束日期 | | | | 与研究药物关系 | | | | SAE转归 | | | | 伦理签收日期 |
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| 1. **方案违背：**有无方案违背 □无 □有；如有，请填写下表。 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 受试者编号/姓名缩写 | | | 访视名称 | | | | 方案违背描述 | | | | | | | | | | | | 递交伦理日期 | | | | | | 伦理审查意见日期 | | |
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| 1. **试验用药物（包括试验药、对照药、安慰剂、急救用药等）** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 药物名称 | | | 批号 | | | | 有效期 | | | | 规格 | | | | | | 贮存条件 | | | | 用法用量 | | | | | 药检报告伦理备案日期 | |
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| 备注：1.方案和ICF有重大修改时，请括号备注**主要修改内容**。  2. 若事件尚未发生，请在单元格中填入“NA”。 | | | | | | | | | | | | | | | | | | | | | | | | | | | |