附件：

**医疗器械临床试验数据自查表**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 试验名称 | |  | | | 临床备案号 | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | |
| 试验用医疗器械 | | 名称 | | |  | | | | | | | | | | | | | | 规格型号 | | | | | | | | |  | | | | | | | | | |
|  | | 分类 | | | 1.□境内Ⅱ类 □境内Ⅲ类 □进口Ⅱ类 □进口Ⅲ类  2.□有源 □无源 □体外诊断试剂  3.□植入 □非植入 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 注册 | | 需进行临床试验审批的第三类医疗器械 | | | | | | | | | | | | | | | | | | | | | | | | | | □是 □否 | | | | | | | | | |
| 试验方案版本号  及日期 | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **基本情况** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 申办者（企业名称） | |  | | | | | | | | | | | | | | | | | | | 申办者监查员 | | | | | | | | | | |  | | | | | |
| 申办者项目负责人 | |  | | | 电话 | | | | | |  | | | | | | | | | 手机 | | | | |  | | | | | | | 邮箱 | | | |  | |
| 申办者组织机构  代码 | |  | | | | | | | | | 申办者联系地址 | | | | | | | | | | | | | |  | | | | | | | | | | | | |
| CRO（如有） | |  | | | | | | | | | | | | | CRO监查员姓名 | | | | | | | | | | | | | | |  | | | | | | | |
| CRO注册地址 | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CRO项目负责人 | |  | | | 电话 | | | | |  | | | | | | | | | | 手机 | | | |  | | | | | | | | 邮箱 | | | |  | |
| 承担临床试验项目机构名称 | |  | | | | | | | | | | | 数据管理及统计单位 | | | | | | | | | | | | | | |  | | | | | | | | | |
| 项目实施科室 | |  | | | | | | | | | | | 主要研究者 | | | | | | | | | | | | | | |  | | | | | | | | | |
| 试验合同金额 | | 总金额 | | | | | | | 万元 | | | | | | | | | | | | |  | | | | | | | | | |  | | | | | |
| 医疗器械临床试验项目起止时间 | |  | | | | | | | | | | 至 | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **临床试验条件与合规性** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 是否为经资质认定且在有效期内的药物临床试验机构 | | □是 □否 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 其他情况： | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 是否具有与受试产品相适应的条件 | | | | □是 □否 | | | | | | | | 仪器设备是否具有使用记录，使用记录与临床试验是否吻合 | | | | | | | | | | | | | | | | | | | | | □是 □否 | | | | |
| **临床试验的伦理审查** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 是否有伦理审查记录 | | | | | | | □是 □否 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 审查的方案/知情同意书版本及内容是否与执行的版本及内容一致 | | | | | | | □是 □否 | | | | | | | | | | | 受试者受到伤害时是否给予及时救助和补偿 | | | | | | | | | | | | | | □是 □否 | | | | | |
| **临床试验批准或备案情况** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 需进行临床试验审批的第三类医疗器械，是否在临床试验前获得批准 | | | | | | | | | □是  □否 | | | | | 是否按规定向省级食品药品监督管理局提交备案 | | | | | | | | | | | | | | | | | | | | | | | □是  □否 |
| **临床试验协议/合同** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 是否签署临床试验协议/合同 | | | | | | | | | □是  □否 | | | | | 协议/合同内容与受试产品信息是否相符 | | | | | | | | | | | | | | | | | | | | | | | □是  □否 |
| 协议/合同内容是否明确各方责任 | | | | | | | | | □是  □否 | | | | | 是否在注册检测完成后开始临床试验 | | | | | | | | | | | | | | | | | | | | | | | □是  □否 |
| **临床试验准备情况** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 临床试验机构和实施者是否按规定的格式共同设计制定临床试验方案 | | | | | | | | | □是  □否 | | | | | 临床试验方案及其修改，是否经伦理委员会审查同意或者备案 | | | | | | | | | | | | | | | | | | | | | | | □是  □否 |
| 实施者是否对参加临床试验人员进行了培训，是否有培训记录 | | | | | | | | | □是  □否 | | | | | 临床试验机构是否保存受试产品及临床试验相关文件物品的交接记录 | | | | | | | | | | | | | | | | | | | | | | | □是  □否 |
| 实施者是否向临床试验机构提供《医疗器械临床试验须知》，内容是否符合有关要求 | | | | | | | | | | | | | | □是 □否 | | | | | | | | | | | | | | | | | | | | | | | |
| **知情同意情况** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 知情同意书签署 | | | | | | | | | 已签署  份 | | | | | 受试者信息登记表是否与临床试验报告中的病例数相符： | | | | | | | | | | | | | | | | | | | | | | | □是  □否 |
| 签署的知情同意书版本是否与伦理审查通过的版本一致 | | | | | | | | | □是  □否 | | | | | 伦理审查时间是否早于知情同意书签署时间 | | | | | | | | | | | | | | | | | | | | | | | □是  □否 |
| 知情同意书签署的内容是否完整、规范 | | | | | | | | | □是  □否 | | | | | 受试者签署知情同意书是否为受试者本人或其法定代理人签署 | | | | | | | | | | | | | | | | | | | | | | | □是  □否 |
| 其他情况： | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **临床试验实施情况** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 临床试验人员是否熟悉临床试验方案及相关资料，并熟悉受试产品的使用 | | | | | | | | | □是  □否 | | | | | 临床试验过程是否遵循临床试验方案,包括受试者入选与排除标准、病例数、对照品选择、试验周期、观察指标、不良事件处置和记录等 | | | | | | | | | | | | | | | | | | | | | | | □是  □否 |
| 各临床试验机构执行的试验方案是否为同一版本（多中心） | | | | | | | | | □是  □否 | | | | | 临床试验的原始数据收集、病例报告表是否由临床试验人员签字 | | | | | | | | | | | | | | | | | | | | | | | □是  □否 |
| 临床试验统计分析是否由试验方案规定的人员、按照规定的方法完成 | | | | | | | | | □是  □否 | | | | | 是否对临床试验实施监查，是否有监查记录 | | | | | | | | | | | | | | | | | | | | | | | □是  □否 |
| **临床试验数据管理** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 是否具有病例筛选入选记录及病例鉴认文件 | | | | | | | | |  | | | | | 病例筛选入选记录及病例鉴认文件中筛选、入选和完成例数是否与临床试验报告中信息相符 | | | | | | | | | | | | | | | | | | | | | | |  |
| 受试者鉴认文件或者筛选入选记录等是否可以溯源，并且具有关联性 | | | | | | | | |  | | | | | 试验中生成的检测报告或结果中的数据是否可以溯源 | | | | | | | | | | | | | | | | | | | | | | |  |
| 病例报告表填写是否完整 | | | | | | | | |  | | | | | 病例报告表中填写的内容是否在原始病历、检验记录等原始记录中可追溯 | | | | | | | | | | | | | | | | | | | | | | |  |
| 临床试验中发生的不良事件是否均按规定记录和处理，并与临床试验报告一致 | | | | | | | | |  | | | | | 严重不良事件是否按规定记录、报告监管部门，并与临床试验报告一致 | | | | | | | | | | | | | | | | | | | | | | |  |
| **受试产品的管理** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 是否有具备资质的检测机构出具的结论合格的产品检验报告 | | | | | | | | | □是 否 | | | | | | | 试验用医疗器械保存原始记录是否符合要求 | | | | | | | | | | | | | | | | | | □是 □否 | | | |
| 试验用医疗器械管理 | | | 接收量 | | |  | | | | | 使用量 | | | | | |  | | | | | | 剩余量 | | | |  | | | | 返还量 | | | | | |  |
| 运输条件、储存温度、储存条件、储存时间、安全有效期是否符合要求 | | | | | | | | | | | | | | | | | | | | | | | | | | □是 □否 | | | | | | | | | | | |
| **申报资料的情况** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 注册申请的临床试验方案版本及内容是否与临床试验机构保存的版本及内容一致 | | | | | | | | □是  □否 | | | | | | 注册申请的临床试验报告版本及内容是否与临床试验机构保存的版本及内容一致 | | | | | | | | | | | | | | | | | | | | | □是  □否 | | |
| 注册申请的临床试验报告中数据是否与临床试验机构保存的原始记录和原始数据一致 | | | | | | | | □是  □否 | | | | | | 注册申请的临床试验报告中临床试验人员签名及临床试验机构签章是否属实 | | | | | | | | | | | | | | | | | | | | | □是  □否 | | |
| **自 查 结 论** |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 申请人项目负责人（签名）： | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| 注册申请机构法人（签名）： | | | | | | | | | | | | | | | | 注册申请机构（公章） | | | | | | | | | | | | | | | | | | | | | |
| 临床试验机构负责人（签名） | | | | | | | | | | | | | | | | 临床试验机构（公章） | | | | | | | | | | | | | | | | | | | | | |
| 填表日期： | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |