**GCP受试者争议处理简况**

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| **项目基本情况** | | | | | | | | | | | |
| 项目名称 |  | | | | | | | | | | |
| 申办方 |  | | | | | | | | | | |
| 承担科室 |  | | | | | | 项目PI | |  | | |
| 合同签署例数 | | |  | | | | 启动会时间 | | |  | |
| 筛选例数 |  | | | 入选例数 | |  | | 完成例数 | |  | |
| 首例受试者入组时间 | | |  | | | | 末例受试者出组时间 | | |  | |
| **涉及受试者基本情况** | | | | | | | | | | | |
| 受试者姓名 | | |  | | | | 性别 | |  | 年龄 |  |
| 签署知情同意时间 | | |  | | | | 签署知情同意书版本及日期 | | |  | |
| 随机号 |  | | 用药情况 | |  | | | | | | |
| 受试者试验期间AE情况 | | |  | | | | | | | | |
| 受试者试验期间SAE情况 | | |  | | | | | | | | |
| **事件过程** | | | | | | | | | | | |
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| **承担专业及申办方采取措施** | | | | | | | | | | | |
|  | | | | | | | | | | | |
| **审核签名** | | | | | | | | | | | |
| PI审核签名 | |  | | | | | | | | | |
| 申办方审核盖章 | |  | | | | | | | | | |