**医疗器械临床试验人类遗传资源批准/实施情况汇总表**

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| 项目名称 | | |  | | | | | | | | | 合同编号 | |  | | 试验起止时间 | |  | 试验分期 | |  |
| 申办者/ CRO | | |  | | | | | | 外资单位 | | |  | | | | 专业科室 | |  | 主要研究者 | |  |
| 人类遗传材料 | | | | | | | | | | | | | | | | | | | | | |
| 序号 | 材料类型 | | | 获批数 | | 实际采集数 | | | | 检测单位 | | | | | | 是否超审批 | | 销毁地/方式  或存放地 | | 是否  出境 | 是否出境审批 |
| 管数 | ml/管 | 管数 | | ml/管 | |
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| 人类遗传资源信息 | | | | | | | | | | | | | | | | | | | | | |
| 数据信息类型 | | 获批数 | | | | | | | | | | | 实际产生 | | | | | 是否超审批 | | 是否出境 | 是否出境审批 |
| 筛选期MB/例 | | | 入组MB/例 | | 筛选例数 | | 入组例数 | | 合计数量 | | 筛选例数 | | 入组例数 | | 合计数量 |
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注：1.人类遗传资源材料类型：全血、血细胞、脑脊液、骨髓、骨髓涂片、 血涂片、组织切片、其他样本（附说明）； 2.人类遗传资源信息包括基因、基因组、转录组、表观组及ctDNA等核酸类生物标志物等数据信息，以及与此数据相关的疾病、人种等关联信息。