附件Appendix67:EC-B-019-05-A01-V1.0

试验/研究结题报告 the summary report of trial/ research

|  |  |  |
| --- | --- | --- |
| 研究项目名称Name | |  |
| 研究组长单位The head site | |  |
| 研究组长单位主要研究者The PI of the head site | |  |
| 本中心主要研究者The PI of this site | |  |
| 申办方 Sponsor | |  |
| 试验/研究结题情况（填写本中心的情况）the summary(in this site) | | |
| 1 | 研究开始日期the start date： | |
| 2 | 研究结束日期the finish date： | |
| 3 | 计划入组例数the No. of the subjects planed to enroll： | |
| 4 | 已经入组例数the No. of the subjects having to enroll： | |
| 5 | 随机进入各组的实际病例数、完成随访/观察例数、脱落例数及脱落原因 the No. of the subjects of all groups, No. of the subjects finishing the follow-up, No. of the withdraws and the reason： | |
| 6 | 是否发生与研究干预相关的，非预期的严重不良事件 If there is SAE which is relevant and unexpected to the research？  □否No  □是Yes，请描述please describe： | |
| 7 | 是否发生严重不良事件或方案规定的必须报告的重要医学事件Do the SAE and the important events that must be reported take place ？  □否No  □是Yes，请继续填写please continue：  是否已经及时上报Do the SAE and the important events that must be reported have reported timely？  □是Yes  □否No，请描述原因，please describe the cause： | |
| 8 | 试验/研究中是否存在影响受试者安全及权益的问题Is there questions which affected the safety and rights of the subject？  □否No  □是Yes，请描述please describe： | |
| 9 | 试验/研究中有无投诉 Is there complaints during the trial/research？  □无No  □有Yes，请详细描述投诉的数量、处理过程、处理结果等内容please describe the No.of the complains, the treatment , the treatment result and so on in detail ： | |
| 10 | 试验/研究中是否存在各方利益冲突Is there conflict interest, during the trial/research？  □无No  □有Yes，请详细描述利益冲突数量、处理结果等内容please describe the No.of the conflict interest, the treatment result and so on in detail： | |
| 11 | 初步疗效评价 the preliminary evaluation of curative effect： | |
| 12 | 初步安全性评价the preliminary evaluation of safety（包含不良事件、严重不良事件、安全性信息等。对本中心发生的不良事件建议分类描述和评价，对于本中心的严重不良事件详细描述和评价，对于其他中心发生的不良事件和严重不良事件建议分类描述和评价。例如建议描述不良事件以及严重不良事件的名称、严重程度、是否采取相关措施、是否为预期的、与试验药物的关系、是否影响试验/研究的开展、转归等。Including AE,SAE and safety information. For the AE taking place in this site, please describe and evaluation according to the classification, For the SAE taking place in this site, please describe and evaluation, For the SAE taking place in other sites, please describe and evaluation according to the classification. For example, please describe the name, degree, the treatment measement, expected or unexpected, relation to the research, influence, outcome and so on）： | |
| 13 | 初步研究结果（疗效和安全性等方面）the preliminary research result（curative effect、safety and so on ）： | |
| 14 | 有无其他需要说明的问题Is there other question to describle？  □无No  □是Yes，请描述please describe： | |
| 主要研究者签字The signature of the PI：  日期Date： | | |