**APPENDIX A**:

Sample Schedule of

Study Visits and Evaluation

**SAMPLE SCHEDULE OF STUDY VISITS AND EVALUATION**

|  |  |  |
| --- | --- | --- |
| **Visit Description** | **Screening** | **Treatment and Follow-up** |
| **Study Visits/ Study days (or weeks)** | **Visit -1****Day -14 to****Day -1** | **Visit 1****Day 0****Randomization** | **Visit 2****Week 2** | **Visit 3****Week 4** | **Visit 4****Crossover****Week 8** | **Visit 5****Week 10** | **Visit 6****Week 12** | **Visit 7****Week 16****End of Study** |
| Informed Consent | X |  |  |  |  |  |  |  |
| Demographics |  |  |  |  |  |  |  |  |
| Joint Exam |  | X |  |  | X |  |  | X |
| Medical History | X | X | X | X | X | X | X | X |
| Prior Medications | X |  |  |  |  |  |  |  |
| Physical Exam | X |  |  |  |  |  |  | X |
| Blood Pressure | X | X | X | X | X | X | X | X |
| Height | X | X | X | X | X | X | X | X |
| Weight | X | X | X | X | X | X | X | X |
| Muscle Strength Test | X | X | X | X | X | X | X | X |
| Chemistries | X | X |  | X | X | X | X | X |
| Liver and Kidney FunctionTests | X | X | X | X | X | X | X | X |
| Hematology | X | X | X | X | X | X | X | X |
| Pregnancy Test | X | X |  |  | X | X | X | X |
| Randomization |  | X |  |  |  |  |  |  |
| Intervention Administration |  | X | X | X | X | X | X |  |
| Concomitant Medications | X | X | X | X | X | X | X | X |
| Adverse Events |  | X | X | X | X | X | X | X |
| Study Completion |  |  |  |  |  |  |  | X |