|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| STUDY SCHEDULE SAMPLE | | | | | | | | | | |
| Test/Procedures | Screening | Treatment Period | | | | | | Follow-Up Period | | |
| Study Visit Number | **1** | **2** | **3** | **4** | **5** | **6** | **7 (EOT) 11** | **8** | **9** | **10** |
| Week | -2 | 0 | 4 | 8 | 12 | 24 | 48 | 60 | 72 | 96 |
| Day (window) | - 14 days | 1 | 28 (+/-7) | 56(+/-7) | 84(+/-7) | 168 (+/-7) | 336 (+/- 7) | 420 (+/- 7) | 504 (+/- 14) | 672 (+/-14) |
| Informed Consent 1 | X | X | X | X | X |  |  |  |  |  |
| HIPAA 2 | X |  |  |  |  |  | X |  |  |  |
| Medical History | X | X | X | X | X |  |  |  |  |  |
| Confirm Eligibility |  | X |  |  |  |  |  |  |  |  |
| Randomization |  | X |  |  |  |  |  |  |  |  |
| Physical Exam 3 | X |  | X |  | X |  | X |  |  | X |
| Vital Signs 4 | X | X | X | X | X | X | X | X | X | X |
| 12 – lead EKG | X |  |  |  |  | X | X |  | X |  |
| Laboratory Tests 5 | X | X | X | X | X | X | X |  |  | X |
| Adverse Event |  |  | X | X | X | X | X | X | X | X |
| Genomic Sample Collection 6 | X | X |  |  |  |  | X |  |  | X |
| Clinical Assessment of Intervention 7 |  | X | X |  | X |  | X |  |  | X |
| Study Questionnaire | X | X | X |  | X |  | X |  | X | X |
| Quality of Life Questionnaire | X | X | X | X | X |  | X |  |  |  |
| Review of Patient Medication List | X | X | X | X | X | X | X | X | X | X |
| Review Patient Study Diary 8 | X | X | X | X | X | X | X | X | X | X |
| Dispense Study Medications |  | X | X | X | X | X | X |  |  |  |
| Drug Accountability 9 |  | X | X | X | X | X | X |  |  |  |
| Dispense Patient Study Diary 8 | X | X | X | X | X | X | X | X | X |  |
| Review Patient Contact Information | X |  |  |  | X |  | X |  | X | X |
| Request Outside Medical Records 10 | X |  |  |  |  | X | X |  |  |  |
| Annotations:   1. All patients must sign an informed consent consistent with ICH-GCP guidelines prior to participation in this trial, which includes performing any screening procedures, medication washout and any restrictions. 2. HIPAA authorization must be obtained on all patients participating in the study at Visit 1, Visit 7 and must cover through Final Study Visit (Visit 10). 3. Physical Exam- A complete Physical Exam is required at Screening Visit 1, Visit 3, End of Treatment- Visit 7, and Final Study Visit 10. Symptom-directed Physical Exam can be done at all other visits as determined as needed by treating Investigator. 4. Vital signs include Height (required only at V1), Weight, Blood Pressure, Pulse, and Temperature. 5. Laboratory Tests- Refer to protocol for specific Lab Tests to be performed at each study visit. Visit 1 and Visit 7 - patient must be fasting. 6. Genomic Sample Collection is to be collected only for those patients that sign the separate Genomic informed Consent Form. 7. Clinical Assessment must be completed per protocol instructions and by the treating investigator for that specific patient. 8. Patient Study Diary – At Screening Visit 1, instructions for completion are to be reviewed with the patient prior to providing the Patient Diary to complete. At each subsequent study visit, the Study Diary is to be reviewed by the study personnel during the visit with the patient to determine and record any changes in medications or reported symptoms that may be considered as adverse events. The treating Investigator must review any changes in medications and potential adverse events during study visit. The Patient Study Diary is to be collected at each study visit and a new Patient Study Diary provided to the patient. 9. Drug Accountability - At Visit 2 prior to dispensing study medication, the instructions for recording study drug administration in study diary are to be reviewed with the patient. Drug Accountability is to be reviewed and assessed at each subsequent treatment visit (Visits 3-7) with the patient and further instructions and counseling provided as needed. 10. Request Outside Medical Records- Outside medical records are to be obtained from patients PCP to confirm eligibility and medical history prior to Randomization at Visit 2. Subsequent requests for medical records for patient’s primary physician are to be requested every 6 months during the treatment phase of the study to ensure changes in health status, medications, or potential adverse events. Additionally, outside medical records are to be requested for any hospitalizations during the patient’s participation in the study. 11. End of Treatment (EOT)- The procedures required at Visit 7 are to be performed at the end of treatment or in the event of a premature discontinuation from study treatment. | | | | | | | | | | |