**STUDY FLOWCHART SAMPLE**

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| Prior to  Enrollment  Visit 1  **Screening** | **Total N:.……..**  Obtain informed consent and HIPAA Authorization. Screen potential subjects by inclusion and exclusion criteria; obtain medical history, document informed consent and confirmation of eligibility in source records. |
|  | **Randomize** |
| Visit 2  **Baseline** | **Perform Baseline Assessments**  Obtain Complete Physical exam, vital signs, blood samples for laboratory tests, blood samples and genomic analysis, patient to complete study questionnaires, dispense patient diary, dispense study medication, administer study medication, and complete baseline clinical assessment. |
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| Visits 3 - 6  **Treatment** | **Perform On-Treatment assessments**  Obtain symptom-directed PE as needed, vital signs, laboratory tests, assess changes in medications, adverse events, drug accountability, dispense patient diary, dispense study medication, provide patient instruction and complete clinical assessments of safety of efficacy. |
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| Visit 7  **End of**  **Treatment** | **Perform End- of-Treatment assessments**  Obtain symptom-directed PE as needed, vital signs, blood samples for laboratory tests, assess changes in medications, adverse events, drug accountability, patient to complete study questionnaires, review patient contact information, and complete clinical assessments of safety of efficacy. |
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| Visit 8 - 9  **Follow-up** | **Perform Follow-Up assessments**  Obtain symptom-directed PE as needed, vital signs, assess changes in medications, adverse events, patient to complete study questionnaires, review patient contact information. |
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| Visit 10  **Final Study Visit** | **Final Assessments**  Complete PE vital signs, laboratory tests, assess changes in medications, adverse events, and complete clinical assessments of safety of efficacy. |