|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Data Points to Be Verified for each subject** | **Verified with Source** | **Corrections Needed** | **Site Response** | **Verification of Complete** |
| **Subject ID:** |  |  |  |  |
| ICF Completion (fully signed before any study related procedures are completed) |  |  |  |  |
| IC/EX Check to ensure subject is eligible |  |  |  |  |
| List Specific Outcome Measures Data Points |  |  |  |  |
| List Specific Aims Measure Data Points |  |  |  |  |
| List Outstanding Queries in EDC |  |  |  |  |
| Review medical exams for each visit (ensure AEs were captured) |  |  |  |  |
| Review Labs and ensure all abnormalities were reviewed as NCS/CS |  |  |  |  |
| Review Labs were listed as CS- AE is created (subject informed/questions asked) |  |  |  |  |
| Review Compliance of test article (people are using the medication/as prescribed) |  |  |  |  |
| List each AE # in AE log and review separately (many of these will be completed when you review the labs and exams above) |  |  |  |  |
| *Retention of Samples is marked in consent and in EDC* |  |  |  |  |

Subject Data Monitoring Worksheet Table

TIP: Copy this template in an excel file to make it easier to utilize.