*Insert trial title* SAE Reconciliation Checklist

***Text in blue is for instruction only and should be deleted.***

***Text in black should be included if appropriate for the trial.***

|  |  |  |  |
| --- | --- | --- | --- |
| **Patient Identification Number** (PIN): |  | **SAE number**: |  |

|  |  |
| --- | --- |
| **Adverse Event** |  |
| **eCRF**  | **Original SAE Report** | **Match** | **Result** | **Follow up Query** |
| OK | If no, please document the data queries required  | **OK** |
| **Patient Identification Number** |  | Exact |  |  |  |
| **Patient Initials** |  | Exact |  |  |  |
| **Patient Sex** |  | Exact |  |  |  |
| **Patient DOB or Age** |  | Consistent |  |  |  |
| **Main diagnosis or symptom** |  | Consistent |  |  |  |
| **Associated symptoms** |  | Consistent |  |  |  |
| **CTCAE grade** |  | Exact |  |  |  |
| **Date of Onset** |  | Exact |  |  |  |
| **SAE Status** |  | Exact |  |  |  |
| **Date of death or resolution** |  | Exact |  |  |  |
| **Seriousness criteria** |  | Exact |  |  |  |
| **Treatment assigned**  |  | Exact |  |  |  |
| **Date of administration** |  | Exact |  |  |  |
| **Actual dose administered** |  | Exact |  |  |  |
| **Relationship to the study drug** |  | Exact |  |  |  |
| **Outcome** |  | Consistent |  |  |  |
| **Action taken** |  | Consistent |  |  |  |
| **Concomitant Medication** |  | All drugs present on the SAE Report form should be present in the eCRF but not vice versa.  |  |  |  |
| **Laboratory/diagnostic tests** |  | Consistent |  |  |  |

I hereby confirm SAE reconciliation and resolution of all data discrepancies have been satisfactorily completed:

|  |
| --- |
| **Local Data Manager** |
| **Name :**  |  |
| **Signature :**  |  |
| **Date :**  |  |