

**SAE ASSESSMENT**

**FORM**

**FORM 3.4**

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| **IRB REFERENCE NO.** | |  | | |
| **PROTOCOL NO. & TITLE** | |  | | |
| **Site of reported SAE** | | **Type of SAE**  **(Number)** | | On-site SAEs | | | | | |
| **On-site**  **(Site in the country)** | **Off – Site**  **(Site in foreign countries)** | **SUGAR** | **Non-**  **SUGAR** | **Date of SAE** | **Date reported**  **To REC** | **Date Presented in REC meeting** | **Relation to Investigational New Drug** | **Action taken** | **Reviewed By** |
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