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| --- | --- |
| **Date of review** |  |
| **Sponsor Reviewer** |  |
| **Total number of SAEs for study** |  |
| **Initial review period (monthly, quarterly, etc)** |  |
| **Current review period (monthly, quarterly, etc)** |  |
| **No of SAEs since last review** |  |

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| --- | --- | --- | --- |
| **SAE ID** | **Issues identified?** | **Minor/Major issue** | **Action required?** |
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| --- | --- |
| **Number of SAEs reviewed during this period** |  |
| **Number of minor issues** |  |
| **Number of major issues** |  |

Are there any changes to the QC review process following this review? Yes [ ]  No [ ]

If Y, please specify:

Signed: Position: Date of QC review