**(Serious Adverse Event (SAE), Serious Adverse Reaction (SAR), Adverse Device event (ADE), Serious Adverse Device Event (SADE),**

**Suspected Unexpected Serious Adverse Reaction (SUSAR) and Unanticipated Adverse Device Effect (USADE))**

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| **Study Title:** |  |
| **Chief Investigator (CI):** |  |
| **Sponsor Internal Reference:** |  |
| **EudraCT Number:** |  |

| **Event No.** | **Patient ID** | **Date**  **Site**  **Reporter** | **Number recruited at initial report** | **Description of Event** | **Summary of Event** | **Action** | **Reporting requirements; dates of any reports made.** |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | **Serious** 🞏 **Not serious** 🞏  **Expected** 🞏 **Not expected** 🞏  **Related** 🞏 **Not related** 🞏  **Assessed by:** |  |  |
|  |  |  |  |  |  |  |  |
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