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| **Chief Investigator:** <NAME>  **EudraCT Number:** <IF A CTIMP OTHERWISE DELETE>  **Site Number: □□□** < COMPLETE > | **REC Number:** <COMPLETE>  **R&D Number**: < COMPLETE >  **Participant ID: □□□** < COMPLETE > |

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| **< STUDY TITLE >** |

**Has the participant had any Adverse Events since signing the informed consent form?** **Yes  No *(If YES, please specify all AEs below)***

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| **What is the severity grade?** | **Is the AE related to the study treatment?** | **What action was taken regarding the study treatment?** | **What was the outcome of this Adverse Event?** | **Was the event serious?** | **Was the event expected?** |
| 0 = No AE (Within normal limits)  1 = Mild  2 = Moderate  3 = Severe | 1 = Definitely related  2 = Possibly related  3 = Probably related  4 = Not related | 1 = None  2 = Drug Discontinued permanently  3 = Drug Discontinued temporarily  4 = Reduced Dose  5 = Increased Dose  6 = Delayed Dose  7 = Not Applicable  7 = Unknown | 1 = Resolved, No Sequelae  2 = AE still present - no treatment  3 = AE still present - being treated  4 = Residual effects present - not treated  5 = Residual effects present - treated  6 = Death  7 = Unknown | 1 = Yes  2 = No  (If **YES**, complete a SAE form and **submit within 24hrs**) | 1 = Yes  2 = No |

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| **Adverse Event number and description.**  **(Diagnosis if known, signs/symptoms)** | **Start Date**  ***DD/MM/YYYY*** | **Stop Date**  ***DD/MM/YYYY*** | **Severity**  **Grade** | **Relationship to Study Treatment** | **Action Taken** | **Outcome**  **of AE** | **Serious Adverse Event?** | **Expected?** | **Initials** |
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| **Adverse Event number and description.**  **(Diagnosis if known, signs/symptoms)** | **Start Date**  *DD/MM/YYYY* | **Stop Date**  *DD/MM/YYYY* | **Severity**  **Grade** | **Relationship to Study Treatment** | **Action Taken** | **Outcome**  **of AE** | **Serious Adverse Event?** | **Expected?** | **Initials** |
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