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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 = Mild2 = Moderate3 = Severe | 1 = Definitely related2 = Possibly related 3 = Probably related4 = Not related | 1 = None2 = Drug Discontinued permanently3 = Drug Discontinued temporarily4 = Reduced Dose5 = Increased Dose6 = Delayed Dose7 = Not Applicable7 = Unknown | 1 = Resolved, No Sequelae2 = AE still present - no treatment3 = AE still present - being treated4 = Residual effects present - not treated5 = Residual effects present - treated6 = Death7 = Unknown | 1 = Yes2 = No(If **YES**, complete a SAE form and **submit within 24hrs**) | 1 = Yes2 = 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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