**SAE/Pregnancy Reporting Form**

**Please report any SAE within 1 day (i.e. immediately but no later than   
the end of the next business day) of receiving the information.**

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| 1. **Study Information** | | | |
| **Study title:** |  | **Site ID:** |  |
| **Study No.:** |  | **Country:** |  |
| **Sponsor** (if applicable): |  | **Responsible Person:** |  |
| **E-Mail Sponsor:** |  | **Phone Sponsor:** |  |

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| 1. **Patient Description** | | | |
| **Subject initials:** |  | **Age or year of birth**  (YYYY): |  |
| **Patient ID:** |  | **Weight (kg):** |  |
| **Height (cm):** |  |
| **Ethnicity:** | Asian  Black  Caucasian  Other | **Gender:** | Female  Male  Diverse |

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| 1. **Serious Adverse Event (SAE) / Pregnancy Information** | | | | |
| **Event term**  (please only enter a diagnosis, if applicable): |  | | | |
| **What kind of report** | Initial  Follow-Up | | **Detection Date** (Date when investigator became aware that event was a SAE) |  |
| **SAE Start Date**  (DD-MM-YYYY) |  | | **SAE Stop Date**  (DD-MM-YYYY) |  |
| **Date of hospitalisation** (DD-MM-YYYY) |  | | **Date of discharge** (DD-MM-YYYY) |  |
| **The event is serious due to**  (t**ick one or more criteria):** | | Death  Life threatening  Requires or prolongs hospitalisation  Leads to permanent or severe handicap or disablement  Leads to congenital anomaly or congenital defect  Is an important medical event | | |
| **Description of SAE** (Symptoms, course, treatment of SAE, response to dechallenge and/or rechallenge, etc.) | | | | |
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| 1. **Investigational Medical Product (IMP) Information** | | | | | | | |
| **Trade- generic or product name** | **Batch No.** | | **Route**  (e.g. oral) | **Daily Frequency** (e.g. 1x, 2x...) | **Total Daily Dose**  (specify unit) | **Duration of Therapy** | |
| **Start Date** (DD-MM-YYYY) | **Stop Date** (DD-MM-YYYY) |
| **1.** |  | |  |  |  |  |  |
| **2.** |  | |  |  |  |  |  |
| **3.** |  | |  |  |  |  |  |
| **Is there a causality to the IMP:**  NO  YES (if yes, please comment below) | | | | | | | |
| **Comments regarding Causality** (e.g. timing, dechallenge or other cause detected) | | | | | | | |
| **IMP Action taken** | | NA = Not applicable  Dose changed  Temporarily interrupted  Generally stopped  Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |

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| 1. **Further Information** | | | | | | | |
| **Existing relevant medical history:**  NO  YES (if yes, please specify below) | | | | | | | |
| **Comments relevant medical history** (e.g. concurrent diseases, previous history of present condition): | | | | | | | |
| **Concomitant drug therapy:**  NO  YES (if yes, please specify below) | | | | | | | |
| **Trade- generic or product name** | **Indication** | **Route**  (e.g. oral) | **Daily Frequency** (e.g. 1x, 2x...) | **Total Daily Dose**  (specify unit) | **Duration of Therapy** | |
| **Start Date** (DD-MM-YYYY) | **Stop Date** (DD-MM-YYYY) |
| **1.** |  |  |  |  |  |  |
| **2.** |  |  |  |  |  |  |
| **3.** |  |  |  |  |  |  |
| **4.** |  |  |  |  |  |  |
| **5.** |  |  |  |  |  |  |
| **6.** |  |  |  |  |  |  |

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| 1. **SAE related assessments** | | | | | | | | | |
| **Patient received SAE related drugs:**  NO  YES (if yes, please document below) | | | | | | | | | |
| **Trade- generic or product name** | **Indication** | | **Route**  (e.g. oral) | **Daily Frequency** (e.g. 1x, 2x...) | | **Total Daily Dose**  (specify unit) | | **Duration of Therapy** | | |
| **Start Date** (DD-MM-YYYY) | **Stop Date** (DD-MM-YYYY) |
| **1.** |  | |  |  | |  | |  |  |
| **2.** |  | |  |  | |  | |  |  |
| **3.** |  | |  |  | |  | |  |  |
| **4.** |  | |  |  | |  | |  |  |
| **Additional SAE related Procedures were done:**  NO  YES (if yes, please document below) | | | | | | | | | |
| **Assessment date** | | **Procedure or test name** | | | **Result** (incl. unit) | | **Ref. Range** (only for lab) | | |
| **1.** | |  | | |  | |  | | |
| **2.** | |  | | |  | |  | | |
| **3.** | |  | | |  | |  | | |
| **4.** | |  | | |  | |  | | |

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| 1. **SAE Outcome** | |
| **Outcome** | Recovered/Resolved without sequelae  Recovered/Resolved with sequelae  Ongoing at the end of study  Death |
| **If fatal outcome:** | Date of death (DD-MM-YYYY) \_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **Additional Information** |
| Please add any additional information, if applicable: |

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| **Reporting Investigator** | | | |
| **Name in block letters:** |  | | |
| **Address:** |  | | |
| **Phone:** |  | | |
| **Investigator’s signature:** |  | **Date:**  (DD-MM-YYYY |  |

**>>Please send this SAE reporting form to the E-Mail** [**xxxxx@xx.at**](mailto:xxxxx@xx.at)**<<**