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

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| 1. **Patient Description**
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| **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**
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| **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**
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| **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**
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| **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**
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| **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****<<**