**The Diabetes Virus Detection and Intervention Trial (DiViD Int)**

**Serious Adverse Event**

**Project manager and medical officer:**

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**Coordinating Investigator, principal investigator for Norway, and back-up medical officer:**

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* Please complete form, sign and then e-mail form within 24 hours of awareness to coordinating investigator.
* Coordinating investigator to be contacted as soon as possible by mobile telephone **+47 922 33 550.**
* Original completed form to be stored in Trial Master File/ Investigator Site File.
* Please ensure event to be recorded in patient medical journal in hospital, and eCRF where applicable.

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| Initial report |  |

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| Follow-up report |  |

Report information

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| Follow-up report number: |  |

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| --- | --- | --- |
| Date of birth (dd-mm-yyyy): | Male: | Female: |

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| --- | --- | --- | --- | --- | --- |
| **INVESTIGATIONAL MEDICINAL PRODUCT (IMP)** | | | | | |
| Name of IMP: | | | | Indication: | Participant in DiViD Int. |
| **Pleconaril** | Dosage: | Dosage form:  Oral solution | Dose/ unit:  40 mg/ml | Route:  X 2 | Frequency:  Morning + evening |
| **Ribavirin** | Dosage: | Dosage form:  Oral solution | Dose/ unit:  40 mg/ml | Route:  X 2 | Frequency:  Morning + evening |
| **Placebo** | Dosage: | Dosage form:  Oral solution | Dose/ unit:  40 mg/ml | Route:  X 2 | Frequency:  Morning + evening |
| Date of first dose IMP: | | | | | |
| Date of most recent dose IMP: | | | | | |

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| **MAIN SERIOUS ADVERSE EVENT** | | | | | | |
| **SAE term:**  Clearly related sign/symptoms should preferably be recorded as a single diagnosis or syndrome. Please describe symptoms of the diagnosis in the narrative field. | | | | | | |
| Start date: | | | | Stop date: | | |
| **Intensity:** | | **Relatedness to study drug:** | | | **Outcome:** | |
|  | Mild |  | Not related | |  | Ongoing |
|  | Moderate |  | Unlikely related | |  | Recovering |
|  | Severe |  | Possible related | |  | Recovered |
|  | Life-threatening |  | Probable related | |  | Recovered with sequelae |
|  | |  | Definitely related | |  | Death |
|  | |  | | |  | Unknown |

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| **Narrative and comments**  Description of event, including presenting symptoms, pertinent risk factors specific to the event(s), treatment, procedure, final diagnosis and event outcomes. Please note that the description may be written in Norwegian. | | | | | | |
| **Action taken regarding the IMP due to this event** | | | **Seriousness criteria** | | | |
|  | | None |  | A congenital anomaly or birth defect | | |
|  | | Dose reduced |  | Persistent or significant disability/ incapacity | | |
|  | | Drug interrupted |  | Hospitalization/ prolongation of hospitalization | | |
|  | | Drug discontinued |  | Life-threatening | | |
|  | | NA |  | Death | | |
|  | | |  | Other important medical event  (is medically significant or require intervention to prevent one or other of the outcomes listed above) | | |
|  | | | Date of death: | | | |
| **Did event abate after stopping IMP?** | | | **Could patient original condition, or other illness, account for the adverse event?** | | | |
|  | Yes | |  | | No | |
|  | No | |  | | Yes | If Yes, please specify: |
|  | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Concomitant medications ongoing at time of event(s), (exclude those used to treat event):** | | | |
| Drug name/ Strength | Indication for use | Start Date  dd.mm.yyyy | Stop Date  dd.mm.yyyy |
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| **Reporter information** | | | |
| Name (signature) | Name (block capitals) | Title | Date |
|  |  |  |  |

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| --- | --- | --- | --- | --- | --- | --- |
| **SPONSOR EVALUATION** | | | | | | |
| Name (signature) | Name (block capitals) | Relationship to IMP | | Was this event | | Date |
|  |  |  | Not related |  | Expected |  |
|  | Unlikely related |  | Unexpected |
|  | Possible related |  | |
|  | Probable related |
|  | Definitely related |

|  |  |
| --- | --- |
| Investigator signature: | Date: |