Safety information form ACTION-1 –study

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| --- | --- | --- | --- |
| Site number |  | Project name | ACTION-1 |
| Local investigator |  | Project number | NL66759.029.19 |
| Country |  | Sponsor | Dijklander ziekenhuis |
| Investigational Product (IP) | | Heparin / protamine | |
| Intervention | | ACT guided heparinization 5000 IU | |

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| --- | --- | --- | --- |
| **Subject information** | | | |
| Subject-number |  | Sex | F  M |

|  |  |
| --- | --- |
| **Informatie SAE** | |
| Event diagnosis |  |
| Date of notification (dd-mm-yyyy) |  |
| **Type of report** | **Initial report  Follow-up report \*** |
| To which category does the SAE relate? | An unexpected outcome of an expected  serious side effect.  A SAE related to research treatment or  study procedure (Surgery or  Heparin)  A SAE related to a medical device.  A SAE related to equipment failure.  Other |
| If answer above question is ‘Other’, specify? |  |
| If outcome of an expected serious side effect. To which IP? | Heparin Protamine Not applicable |
| Description of the SAE |  |
| On what date did the SAE occur? (dd-mm-yyyy) |  |
| To which of the categories does the SAE relate? | Mortality  Life threatening  (Prolongation of) hospitalization  Permanent disability of incapacity |

\*In case of a follow-up report only fill-out SUBJECTNUMBER and EVENT INFORMATION on page 2.

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| **Event information** | |
| If above question is not equal to ‘Mortality’:  Answer: Has the patient been recovered? | Yes  Is still recovering\*  No  Recovered with residual symptoms  Passed away  Unknown |
| If above question is equal to ‘Yes’:’  Answer: On what date was the patient recovered?  (dd-mm-yyyy) |  |
| Additional comments |  |

\*Provide follow-up report after recovering or patient passed away

If applicable: also provide a copy of the comprehensive report

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Name Investigator Signature Investigator (natte handtekening) Date (dd-mm-yyyy)

|  |  |
| --- | --- |
| To be completed by Dijklander Ziekenhuis | |
| Date safety information received ?  (dd-mm-yyyy) |  |
| Expectedness | Expected  Not expected |
| Causality | Related  Not related |
| Does this incident have consequences for the safety of the patients in this study? | Yes  No |
| If YES, what are the consequences for the conduct of the study? | Study on hold  End of study  Adaption of patient information letter  Adaption medication use  Adaption in/exclusion criteria  Another consequences |
| If ‘Another consequences’, specify? |  |
| Date of this report (dd-mm-yyyy) |  |

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Signature Dijklander Safety Responsible person: dr. A.M. Wiersema Date (dd-mm-yyyy)