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 [ ]  |

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| **Informatie SAE** |
| Event diagnosis |  |
| Date of notification (dd-mm-yyyy) |  |
| 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. [ ]  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 |

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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 |  |

If applicable: also provide a copy of the comprehensive report

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

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| 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)