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| 1. **NOTIFICATION FROM INVESTIGATOR TO SPONSOR** | |
| **Project identification** | |
| Project name/description |  |
| Investigator |  |
| Trial site |  |
| Sponsor's representative |  |
| Identification in continuous record of project activities |  |

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| --- | --- |
| **Information about the trial subject** | |
| Trial subject's ID in the project[[1]](#footnote-1) |  |
| Trial subject's age |  |
| Trial subject's gender |  |
| Date of inclusion in the project |  |

|  |  |
| --- | --- |
| **Information about the investigational medicinal product** | |
| Commercial name |  |
| Generic name (active substance) |  |
| Strength |  |
| Dosage |  |
| Date of administration of first dose of investigational medicinal product |  |
| Date of last administration of investigational medicinal product before the event took place |  |
| Information about any other treatment with a medicinal product |  |

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| --- | --- |
| **Information about the medical event** | |
| Event started on: (date) |  |
| Event first reported to Investigator |  |
| Event ended on : (date)[[2]](#footnote-2) |  |

**Description of the event**

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|  |

Is the event serious? Yes □ No □

Is the event assumed to be related to the investigational

medicinal product? Yes □ No □

Date dd.mm.yyyy (report sent to Sponsor by Investigator) Signature (Investigator)

1. **SPONSOR'S CLASSIFICATION AND REPORT OF THE EVENT**
2. See procedure 3, Chapter 3.21 and 3.22.

Is the event assumed to be related to the investigational medicinal product? Yes □ No □

Is the event unexpected? Yes □ No □  
Duty to inform Norwegian Medicines Agency Yes □ No □

Date dd.mm.yyyy Signature (Responsible for classification)

Date of report (if any) to the Norwegian Medicines Agency

dd.mm.yyyy

1. Pseudonymised, i.e. the subject's number or code in the project - not name [↑](#footnote-ref-1)
2. Or "ongoing" [↑](#footnote-ref-2)