|  |
| --- |
|  |
| **Project identification** |
| Project name/description |  |
| Identification in continuous record of project activities |  |
| Investigator |  |
| Trial site |  |
| Sponsor's representative |  |
| Monitor |  |
| Date of monitoring visit |  |

**PARTICIPANTS AT MONITORING VISIT**

|  |  |
| --- | --- |
| **Name** | **Part played in the trial** |
|  |  |
|  |  |
|  |  |
|  |  |

**RECRUITMENT OF TRIAL SUBJECTS**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Number planned** | **Number screened** | **Number included** | **Number discontinued** | **Number finished** |
|  |  |  |  |  |

**CHECKED DURING MONITORING VISIT**

|  |  |  |  |
| --- | --- | --- | --- |
| **Element** | **Yes** | **No**  | **Comment (or "No deviation")** |
| Consents |  |  |  |
| Compliance with protocol |  |  |  |
| Completion of CRF |  |  |  |
| Source documentation |  |  |  |
| Project documentation |  |  |  |
| Equipment accountability |  |  |  |
| Reporting of SAE\* |  |  |  |
| Handling of biological material |  |  |  |

\*Serious adverse events

**DEVIATION FRON CONSENT PROCESS AND DOCUMENTATION**

|  |  |
| --- | --- |
| **Trial subject number** | **Deviation** |
|  |  |
|  |  |
|  |  |

**DEVIATION FROM PROTOCOL**

|  |  |
| --- | --- |
| **Deviation** | **Comment** |
|  |  |
|  |  |
|  |  |
|  |  |

**DEVIATION IN VERIFICATION OF SOURCE DOCUMENTATION**

|  |  |  |
| --- | --- | --- |
| **Trial subject number** | **CRF page** | **Deviation** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**DEVIATION IN PROJECT DOCUMENTATION**

|  |  |  |
| --- | --- | --- |
| **Document** | **Deviation** | **Comment** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**DEVIATION IN INVESTIGATIONAL MEDICINAL PRODUCT ACCOUNTABILITY**

|  |  |  |
| --- | --- | --- |
| **Trial subject number** | **Control no.** | **Deviation** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**FAILURE TO REPORT SERIOUS ADVERSE EVENTS**

|  |  |  |
| --- | --- | --- |
| **Trial subject number** | **Date of event** | **Description of event and further action** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**DEVIATION IN HANDLING OF BIOLOGICAL MATERIAL**

|  |  |  |
| --- | --- | --- |
| **Trial subject number** | **CRF page** | **Deviation** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**TOPICS DISCUSSED WITH PROJECT TEAM MEMBERS**

|  |  |  |
| --- | --- | --- |
| **Topic** | **Reviewed** | **Comments (e.g. "not relevant")** |
| Protocol and process for obtaining informed consent  |  Yes □ No □ |  |
| Recruitment of trial subjects | Yes □ No □ |  |
| Handling of investigational medicinal product | Yes □ No □ |  |
| Blinding and possibly unblinding | Yes □ No □ |  |
| Monitoring plan and monitoring | Yes □ No □ |  |
| Verification of source data | Yes □ No □ |  |
| Use of technical/measuring equipment in the trial | Yes □ No □ |  |
| Audit/inspection | Yes □ No □ |  |
| Reporting of serious adverse events/reactions | Yes □ No □ |  |
| Completion and correction of CRF | Yes □ No □ |  |
| Sampling and forwarding of samples | Yes □ No □ |  |
| Archiving of trial documentation | Yes □ No □ |  |

**ACTION LIST FOR NEXT MONITORING VISIT**

|  |  |
| --- | --- |
| **Action** | **Responsible** |
|  |  |
|  |  |
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**CRF SENT FOR DATA HANDLING**

|  |  |  |
| --- | --- | --- |
| **Trial subject number** | **Pages** | **Comments:** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

Date dd.mm.yyyy Signature (Monitor)

**Comments from Sponsor's representative:**

Date dd.mm.yyyy **Signature (Sponsor's representative)**