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

**ATTENDEES AT INITIATION MEETING**

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

**AVAILABLE DOCUMENTATION AT THE INITIATION**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Document** | **Version** | **Approval date REK** | **Approval date NoMA** | **Comment no.:** |
| Protocol |  |  |  |  |
| Case report form (CRF) |  | NA | NA |  |
| Information and consent |  |  | NA |  |
| Signed agreements |  |  | NA |  |
| Documentation of investigational medicinal product |  | NA |  |  |
| Laboratory equipment | NA | NA | NA |  |
| Other necessary technical equipment | NA | NA | NA |  |

**COMMENTS**

|  |  |
| --- | --- |
| Comment 1 |  |
| Comment 2 |  |
| Comment 3 |  |
| Comment 4 |  |
| Comment 5 |  |
| Comment 6 |  |
| Comment 7 |  |

**TOPICS REVIEWED**

|  |  |  |
| --- | --- | --- |
| **Topic** | **Reviewed** | **Comments:** |
| 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 □ |  |
| Statutory requirements, including GCP | Yes □ No □ |  |

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