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

**PARTICIPANTS AT FINAL VISIT**

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

**TOTAL NUMBER OF TRIAL SUBJECTS**

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

**CHECKED, FINISHED AND ARCHIVED UNDER FINAL VISIT**

|  |  |  |  |
| --- | --- | --- | --- |
| **Element** | **Yes** | **No** | **Comment (or "No deviation")** |
| Signed consents |  |  |  |
| Copies of complete CRF |  |  |  |
| Form for delegation of tasks |  |  |  |
| Source documentation |  |  |  |
| Investigational medicinal devices accountability |  |  |  |
| SAE reports |  |  |  |
| Code break  Envelopes |  |  |  |
| Other trial documentation |  |  |  |

**TOPICS DISCUSSED WITH PROJECT TEAM MEMBERS**

|  |  |  |
| --- | --- | --- |
| **Topic** | **Reviewed** | **Comments (e.g. "not relevant")** |
| Information to trial subjects after completion | Yes □ No □ |  |
| Destruction/return of investigational medicinal devices | Yes □ No □ |  |
| Retention of source data | Yes □ No □ |  |
| Further use of technical/measuring equipment  procured for the trial | Yes □ No □ |  |
| Possibility of audit/inspection | Yes □ No □ |  |
| Further follow-up of serious adverse events/reactions | Yes □ No □ |  |
| Further handling of samples by biobank | Yes □ No □ |  |
| Forwarding and/or analysis of stored samples | Yes □ No □ |  |
| Archiving of trial documentation | Yes □ No □ |  |
| Retention of subject identity list (list of trial subjects) | Yes □ No □ |  |

Date dd.mm.yyyy Signature (Monitor)

Comments from Sponsor's representative:

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