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| **BEFORE TRIAL INITIATION** | | | |
| 1.1 | Advance internal submission of the project | See Procedure description 3 point 4.5 and Procedure description 2, Appendix 2.1 , *Project planning form* |  |
| 1.2 | Insurance of trial subjects | See Procedure description 3 point 4.4 |  |
| 1.3 | Documentation of quality, safety and efficacy of investigational medicinal product | For example Investigator's Brochure or approved summary of product characteristics (SPC) |  |
| 1.4 | Trial protocol | Final version, signed and dated |  |
| 1.5 | Reference values | For analyses and measures |  |
| 1.6 | Documentation laboratories and equipment | Measures of significance for the trial result |  |
| 1.7 | Labelling of investigational medicinal product |  |  |
| 1.8 | Instructions for handling investigational medicinal product |  |  |
| 1.9 | Investigational medicinal product accountability | See Procedure description 3 Appendix 3.11 Investigational medicinal product accountability form |  |
| 1.10 | Case report form  (CRF) | Or electronic system |  |
| 1.11 | Information to trial subjects  Informed consent form | Version sent to REC for approval  Final version, approved by REC |  |
| 1.12 | Qualifications of Principal Investigator and co-investigators | CV or the equivalent. |  |
| 1.13 | Application to REC | Copy of full application with appendices or reference to appendices |  |
| 1.14 | Correspondence with REC | Including any appendices |  |
| 1.15 | Approval from REC |  |  |
| 1.16 | List of REC members | At the time of REC's assessment |  |
| 1.17 | Application to NoMA | Copy of full application with appendices or reference to appendices |  |
| 1.18 | Correspondence with NoMA | Including any appendices |  |
| 1.19 | Approval from NoMA |  |  |
| 1.20 | Notification and assement from NSD | A copy of the notification with appendix as well as the assessment from NSD |  |
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| 1.21 | Contracts with business partners | Final version, signed and dated |  |
| 1.22 | Contracts with subcontractors | Final version, signed and dated |  |
| 1.23 | Form for subject identity list and list of trial subjects | See Procedure description 6 Appendix 6.3. *Subject identity list and list of trial subjects* |  |
| 1.24 | Randomisation list | N.B. in blinded trial design this must not be openly accessible to project team members, including the Project Manager |  |
| 1.25 | Project-specific procedure for blinding the investigational medicinal product | For blinded clinical trial design |  |
| 1.26 | Research Biobank form | If relevant  See Procedure description 5 and Appendix 5.1. Checklist for Research Biobank |  |
| 1.27 | Form for handling and storage of data | See Procedure description 6 and Appendix 6.1 *Checklist for handling and storage of data in the individual project* |  |
| 1.28 | Appendix 3.1 Form for documentation of Principal Investigator and trial site | See Appendix 3.1 *Form for documentation of Principal Investigator and trial site* |  |
| 1.29 | Initiation meeting form | See Appendix 3.4 Initiation meeting form |  |
| 1.30 | Form for Principal Investigator's delegation of tasks | See Appendix 3.2 *Form for Principal Investigator's delegation of tasks* |  |

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| **DURING THE PROJECT** | | | |
| 2.1 | Updated documentation quality, safety and efficacy of investigational medicinal product |  |  |
| 2.2 | Signed consents | Dated and signed by trial subjects |  |
| 2.3 | Completed case report form(s) | Or reference to electronic system. see Procedure description 6 |  |
| 2.4 | Completed subject identity list | To be kept separately |  |
| 2.5 | Amendments to trial protocol | Final version, signed and dated |  |
| 2.6 | Amended information to trial subjects  Amended informed consent form | Version sent to REC for approval  Final version, approved by REC |  |
| 2.7 | Amended applications to REC | Copy of application with appendices or reference to appendices |  |
| 2.8 | Correspondence with REC | Including any appendices or reference to appendices |  |
| 2.9 | Approval of amendments from REC |  |  |
| 2.10 | Applications for amendments to NoMA | Copy of application with appendix/ices or reference to appendix/ices |  |
| 2.11 | Correspondence with NoMA | Including any appendices or reference to appendices |  |
| 2.12 | Approval of amendments from NoMA |  |  |
| 2.13 | Notification of amendment to NSD | A copy of the notification with appendix as well as the assessment from NSD |  |
| 2.14 | Updated reference values |  |  |
| 2.15 | Updated documentation laboratories and equipment |  |  |
| 2.16 | Updated investigational medicinal product accountability |  |  |
| 2.17 | Contracts with subcontractors | Updated or new |  |
| 2.18 | Source documentation/raw data | See Procedure description 6 |  |
| 2.19 | Serious adverse event reports | See Appendix 3.12 *Form for reporting and classifying serious adverse events / adverse reactions* |  |
| 2. 20 | Monitoring reports |  |  |
| 2.21 | Completed case report forms (CRFs) |  |  |
| 2.22 | Completed form for subject identity list and list of trial subjects |  |  |

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| **After completed trial** | | | |
| 3.1 | Completed case report form(s) (CRPs)  Or reference to electronic system | Complete set; See Procedure description 6 |  |
| 3.2 | Signed consents | Complete set  See Procedure description 6 |  |
| 3.3 | Notification of close-out to REC |  |  |
| 3.4 | Notification of close-out to NoMA |  |  |
| 3.5 | Source documents/raw data | Complete set  See Procedure description 6 |  |
| 3.6 | Complete subject identity list | To be kept separately  See Procedure description 6 and Procedure description 3, point 4.18 |  |
| 3.7 | Statistical calculations |  |  |
| 3.8 | Final report |  |  |
| 39 | Publication |  |  |
| 3.10 | Research Biobank form (if relevant) | Completed see *Appendix 5.1 Checklist for research biobank* |  |
| 3.11 | Form for handling and storage of data | Completed See Procedure description 6 and Appendix 6.1 *Checklist for handling and storage of data in the individual project* |  |
| 3.12 | Serious adverse event reports | See Appendix 2.6 *Form for reporting serious adverse events* |  |
| 3.14 | Closed out investigational medicinal product accountability |  |  |
| 3.15 | Project completion | See Appendix 3.10 Project completion form |  |