

| CLINICAL RESEARCH STUDY ARCHIVING PLAN | |
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| Sponsor R&D No: 2016RC27 | REC No: 18-ES-0147 |
| EudraCT No (if applicable): 2018-001590-24 | Chief Investigator (CI): Professor James Chalmers |
| Retention period: 5 years/15 years or Other (Please specify) 5 Years as specified in the Protocol | Study Type: <input checked="" type="checkbox"/> CTIMP <input type="checkbox"/> NCTIMP <input type="checkbox"/> Paediatric |
| Study Archiving Contact Name: Fiona McLaren-Neil | Contact Details (email/phone): respiratorytrials@dundee.ac.uk |

| TMF/SMF Component | Paper or Electronic (Please specify) | Location (Please specify) | Contact |
|---|---|--|---|
| CTIMP Sponsor File (separate boxes) | Paper | NHS Tayside Off Site/Contracted Vendor | TASC Senior Research Governance Manager |
| TCTU/DM File Other DM File | Paper | NHS Tayside Off Site/Contracted Vendor | TCTU Clinical Trials Information Systems Manager <i>Or Specify</i> |
| TCTU Stats File (including programming) Other Stats File (including programming) | Paper | NHS Tayside Off Site/Contracted Vendor | TCTU Trial Statistician <i>Or Specify</i> |
| CTIMP PV File | Paper | NHS Tayside Off Site/Contracted Vendor | TASC Pharmacovigilance Monitor |
| Legal File | Paper | NHS Tayside Off Site/Contracted Vendor | TASC Head of Legal Services |
| Tayside ISF (including pCRFs, pICFs, training logs) | Paper | NHS Tayside Off Site/Contracted Vendor | CI/Study Archiving Contact |

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|---|--------------------|---|---------------------------------|
| CTIMP NHST CTP PSF | Paper | NHS Tayside Off Site/Contracted Vendor | NHST Clinical Trials Pharmacist |
| Electronic Correspondence | Paper & Electronic | Essential paper – on TMF; Other - electronic | N/A |
| CTIMP Tayside Pharmaceuticals | N/A | Tayside Pharmaceuticals | Tayside Pharmaceuticals |
| Other e.g. external CTU File, Regional Site Files, CRO File, UoD Pharmacy File, GP/GDP File, Vendor file <i>Specify</i> | Paper/Electronic | | |
| eCRF <i>Specify</i> | Electronic | Archived electronically according to local procedure | Principal Investigator |
| Trial Database (data/metadata) <i>Specify</i> | Electronic | | |
| Other data/bases (e.g. TRuST, PMS) <i>Specify</i> | Electronic | University of Dundee servers | HIC |
| Removable media <i>Specify media & data held</i> | N/A | | |
| Site Archiving | | | |
| ISFs (including pCRFs, pICFs, training logs) | Paper/ | Site Files are retained by the PI whilst the study is active. Archiving is the responsibility of each Site as per their local Policy and the exact location will be determined at study close out | Principal Investigator |
| CTIMP Site PSFs | Paper | Site Files are retained by the PI whilst the study is active. Archiving is the responsibility of each Site as per their local Policy and the exact location will be determined at study close out | Principal Investigator |

Please file this document in TMF/SMF/ISF

For CTIMPs please send this document and any updated versions to tay.tascarchiving@nhs.scot