INVESTIGATORS' STUDY FILE INDEX

SECTION	CONTENTS
	o Protocol Summary o Protocol for team perusal o CD containing training presentations, CRFs, patient leaflet/consent form, Adverse event form, Screening log, Randomisation log, Drug accountability sheet, Delegation log
CONTACTS	o Contact information: at site, coordinating centre, randomisation etc.
PROTOCOL	o Trial Protocol version submitted to local ethics committee – this is for record of submission so should not be removed from study file. A separate copy of the protocol is provided for team use. o Protocol amendments
TRIAL DRUGS	o Drug accountability log – to be completed every time treatment packs are received, used, lost/damaged or destroyed due to expiry or end of trial o Drug administration guidance – detailed information about the storage, allocation, administration and expiry of the treatment drugs o Drug receipts / shipping documents – file here all relevant documents o Investigator Brochure / SmPC – for information
TRAINING	o Training presentations o ICH GCP Guidelines Summary; guidance on where to find complete guidelines
PATIENT INFORMATION SHEETS / CONSENT FORMS	o Consent procedure – country specific approved procedure o Spare patient / representative information sheets o Spare patient / representative consent forms o Original signed consent forms to be filed here
DATA COLLECTION	o Trial instructions o Randomisation flowchart o Patient screening log – to be completed each time a patient is considered for the trial but not randomised o Patient randomisation log – to be completed for each randomised patient and returned to the coordinating centre when requested to do so o CRF guidance – detailed instructions about completing the data collection forms o Spare forms o Completed CRFs – original forms to be filed here o Data queries / corrections – all relevant correspondence
ADVERSE EVENTS	o Adverse Events reporting guidance o AE/SAE forms o Completed forms – originals to be filed here o Notification of SAE/SUSAR by co-ordinating centre o Reports from PI to Local Ethics Committee
CORRESPONDENCE	o Correspondence, emails

ETHICS	o Copy of application submitted o Correspondence with ethics committee o Ethics committee approval o Approvals of Protocol amendments o Annual reports to ethics committee
REGULATORY	o Copy of application submitted o Correspondence with national regulatory authority o National regulatory approval o Approvals of protocol amendments o Reports to regulatory authority
OTHER APPROVALS & INDEMNITY	o E.g. hospital director's approval letter; UK R&D approval o Sponsor's indemnity letter
SITE RESPONSIBILITIES	o Hospital information sheet o Delegation of responsibilities / signature log – to be kept up to date with the changes in the trial team o CV of principal investigator o CVs of trial team members who have been delegated responsibilities o GCP & other training certificates
AGREEMENTS	o Principal investigator & financial agreement – a signed copy to be filed here o Agreement of Trial Responsibilities (if applicable) – this may be relevant in EU countries or with National Coordinators who are delegated some sponsorship responsibilities
TRIAL MONITORING	o Site visit log – to be signed each time a representative of the coordinating centre visits for any reason o Site monitoring report – to be completed at monitoring visits o Completed site visit reports to be filed here o Guidance on data discrepancy; protocol violations; deviations o Guidance on monitoring procedures o Audit reports / certificates o Close out monitoring report
REPORTS AND PUBLICATIONS	o Final & other trial reports o Publication(s) o Log of patients who have requested the study results
FAQ	o Frequently asked questions o Participating sites – this is a requirement but can also be provided via the trial website