I. ICH GCP 8.3 – Essential Documents collected during the Conduct of a Clinical Trial.

What essential documents need to be collected and filed (investigator and/or sponsor file) during the conduct of a clinical trial?	
Essential Documents	8.3 In addition to having on file (investigator and/or sponsor file) the documents required before the clinical trial starts, the following should be added to the files during the trial as evidence that all relevant information is documented as it becomes available: ☐* Investigator's brochure (IB) updates (investigator and sponsor file) ☐* Any revisions to protocol/amendments (investigator and sponsor file) ☐* Any revisions to Case Report Form (CRF) (investigator and sponsor file) ☐* Any revisions to any written information provided to subjects (investigator and sponsor file) ☐* Any revisions to advertisements for subject recruitment (if used) (investigator and sponsor file) ☐* Any revision to advertisement for subject recruitment (if used) (investigator and sponsor file) ☐* Dated, documented approval/favourable opinion of IRB/IEC of protocol amendments, revisions of ICF, any other written information to be provided to the subject, advertisement of subject recruitment (if used) and any other documents given approval/favourable opinion and continuing review of the trial (where required) (investigator and sponsor file) ☐* Regulatory authority(ies) authorisations/approvals/notifications where required for protocol amendment(s) and other documents (investigator and sponsor file) ☐*Curriculum Vitae for new investigator(s) and/or sub-investigator(s) (investigator and sponsor file)

Essential Documents	☐* Updates to normal value(s)/range(s) for medical/laboratory/technical procedure(s)/test(s) included in the protocol (investigator and sponsor file) ☐* Updates of medical/laboratory/technical procedures/tests (investigator and sponsor file) ☐* Documentation of investigational product(s) and trial-related materials shipment (investigator and sponsor file) ☐* Certificate(s) of analysis for new batches of investigational products (sponsor file) ☐* Monitoring visit reports (sponsor file) ☐* Relevant communications other than site visits, like letters, meeting notes, notes of telephone calls (investigator and sponsor file) ☐* Signed informed consent forms (investigator file) ☐* Source documents (investigator file) ☐* Signed, dated and completed case report forms (copy in investigator file and original in sponsor file) ☐* Documentation of CRF corrections (copy in investigator file and original in sponsor file) ☐* Notification by originating investigator to sponsor of serious adverse events and related reports (investigator and sponsor file) ☐* Notification by sponsor and/or investigator, where applicable, to regulatory authority(ies) and IRB(s)/IEC(s) of unexpected serious adverse drug reactions and of other safety information (investigator and sponsor file) ☐* Notification by sponsor to investigators of safety information (investigator and sponsor file) ☐* Interim or annual reports to IRB/IEC and authority (ies) (investigator and sponsor file) ☐* Subject screening log (investigator and sponsor file) ☐* Subject identification code list (investigator file) ☐* Subject enrolment log (investigator file) ☐* Investigational products accountability at the site (investigator and sponsor file) ☐* Signature sheet (investigator and sponsor file) ☐* Record of retained body fluids/tissue sample (investigator and sponsor file)