Essential Documents Label List

Signed protocol signature page	To document investigator and sponsor agreement to the protocol/amendment(s) and CRF
FDA 1572/DAIDs Investigator of record form for Non-IND	To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects
IRB Approval	To document that the trial has been subject to IRB/IEC review and given approval/favorable opinion. To identify the version number and date of the document(s)
IRB Membership List	To document that the IRB/IEC is constituted in agreement with GCP
CV – PI	To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects
Subject Screening Log	To document identification of subjects who entered pre-trial screening
Monitoring visit report	To document site visits by, and findings of, the monitor
Investigational product(s) accountability at site	To document that the investigational product(s) have been used according to the protocol. To documents the final accounting of investigational product(s) received at the site, dispensed to subjects, returned by the subjects, and returned to sponsor