ICH Guideline E6

There are many ways to organize essential documents, and there is no gold standard for how to do this. For example, the ICH GCP E6 guideline recommends that the documents be grouped according to the stage of the trial, i.e. documents relevant to the trial before it commences, documents relevant to the trial during the conduct of the trial, and those documents relevant to the trial after completion or termination of the trial. But the most important thing is that the documentation is organized and that all of the necessary documents are present.

Essential Documents also serve a number of other important purposes. Filing essential documents at the investigator/institution and sponsor sites in a timely manner can greatly assist in the successful management of a trial. These documents are also the ones which are usually audited by the independent audits and inspected by the regulatory authority(ies) as part of the process to confirm the validity of the trial conduct and the integrity of data collected.

Another way to organize the essential documents into study binders is by the content of the binder. For example, many sites have a “source document binder,” a “case report form binder,” a “financial binder,” and a “regulatory binder.”

“Essential documents are those documents which individually and collectively permit evaluation of the conduct of the trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements”