

The ICH defines a Clinical Trial as “any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or identify any adverse reactions to an investigational product(s), and/or study absorption, distribution, metabolism and excretion of an investigation product(s) with the object of ascertaining it’s safety and/or efficacy. The terms Clinical Trial and Clinical Study are synonymous.”

Where a clinical trial is concerned, document control is responsible for retaining documents that the ICH refers to as **“Essential Documents.”** ICH defines essential documents as “those documents that individually and collectively permit evaluation of the conduct of a 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 GCP and with all applicable regulatory requirements.**”

There are 2 types of files that the document control department should file essential documents in; the Site File and Trial Master File (TMF)

A **Site File** is a file that contains essential documents. Essential documents are documents that individually and

Collectively permit evaluation of the conduct of a trial and the quality of the data produced.

Document control is responsible for maintaining Essential Documents

Documents relevant to a Clinical Trial are retained in Document Control in either a Site File or a Trial Master File