Timeline and Flowchart for IND Document eCTD Formatting Compliance Assessment

CPMs/ Document Authors

IND Documents are processed through the protocol review tool and are considered final.

Step 1:
Ensures eCTD compliance of IND documents before sending them to TRI for an eCTD Compliance Assessment. Sends documents to the RAM as they are finalized, rather than batched, so the assessment can start A.S.A.P.

CPMs receive eCTD-compliant protocol documents and list of changes made from the RAM, and share with the site and/or Document Authors.

Regulatory Affairs Manager (RAM)

RAM receives eCTD-compliant documents from CPMs/Document Authors.

RAM receives eCTD-compliant documents and list of changes made from TRI. RAM sends documents and list to the CPM to share with the site and/or document authors.

TRI

Step 2:
TRI performs compliance checks and corrects IND documents, as necessary. *If extensive corrections are required, extra time is needed to ensure compliance.*

Factors that Impact Timeline:
- *Total number of documents*
- *Timing of receipt*
- *Page count per document*
- *Quality of Documents*

Step 3:
Once assessment is complete, TRI sends an email to the RAM with the attached eCTD-compliant protocol documents and **a list of eCTD formatting changes that were needed to correctly format each document for eCTD compliance.**

Up to 5 to 10 Days