Common Technical Document [CTD]

The Common Technical Document (CTD) is an internationally agreed format for the preparation of marketing applications to regulatory authorities for new medicines approval. The CTD is divided into five modules, where modules 2 to 5 constitute the actual CTD; and module 1 differs according to the region. The modules are:

1. Administrative and prescribing information (these contents might differ based on national requirements),
2. Overview and summary of modules 3 to 5,
3. Quality (pharmaceutical documentation),
4. Non-clinical study reports (pharmacology/toxicology),
5. Clinical study reports– efficacy and safety (clinical trials).