DMID eCTD Templates and Resources

The electronic Common Technical Document (eCTD) is the standard format for submitting applications, amendments, and reports to FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER). All IND documents for submission to the FDA must be eCTD compliant as of May 2017, www.fda.gov/ectd.

To assist with eCTD compliance of IND documents, IND application preparation and submission for a new clinical trial sponsored by the Division of Microbiology and Infectious Diseases (DMID), please refer to the DMID IND SOP and tracking worksheet for a list of documents needed for the IND application, Modules 1-5, and resources listed below.

eCTD formatted and compliant templates are available by request for:

- Module 1, 1.14 Investigator's Brochure (IB)
- Module 1, 1.2 General investigational plan (GIP)
- Module 2, 2.2 Introduction
- Module 2, 2.3 Quality Overview Summary (QOS)
- Module 2, 2.4 Clinical overview (CO)
- Module 3, Chemistry, Manufacturing and Controls (CMC)
- Module 5 Protocol and ICF templates posted here.

Resources listed below and found here are available for your reference when ensuring eCTD formatting and compliance of protocols, ICFs, or any other IND documents for submission to the FDA.

1. Microsoft Word Quick Reference Guide for Preparation of eCTD Compliant Documents
2. Preparation of eCTD Compliant Documents- Areas to Focus on
3. Preparing eCTD Compliant PDF Documents
4. Videos:
   - Using Document Styles
   - Copying and Pasting Content and Tables
   - Captioning Tables and Figures
   - Using Cross References
   - Creating and Updating Table of Contents and Lost of Figures/Tables
   - Setting Table Dimensions

5. Best practices for collaborating on documents. This document provides three options:
   - How to merge documents properly; also provides further information on how to work with tracked changes, comments etc.
   - How to copy/paste into one properly formatted document.
   - Other options such as Share Point, Google docs etc.

The FDA also has a resource page here.

A dedicated email address for questions and issues related to eCTD formatting is also available. Please use this email and copy your RAM when you have specific eCTD related questions, DMID-RASeCTD@tech-res.com.

Please note that the ORA contractor, TRI, can provide training and assistance to the CPMs and/or sites on how to properly format IND documents for eCTD compliance. Requests can be made using the email address listed above.