TOPIA
LIFE SCIENCES

e-CTD plus

Effortless **Regulatory Submissions**

CTD Plus simplifies the preparation, management, and submission of Common Technical Documents (CTD) and electronic CTDs (eCTD). Built to meet global standards, it ensures compliance for submissions to Europe, Japan, the US, and beyond.

What is **CTD Plus?**

Common Technical Document (CTD):
A global format set by the ICH.

eCTD:
The digital version of CTD, the following:
Content Standards: Defined by ICH.
Technical Standards: Implemented via software.

Key **Benefits**

Regulatory Compliance
Meets eCTD standards, reducing paper use.

Quick Tracking
Simplifies application searches for faster reviews.

Lifecycle Management
Easy updates for ongoing submissions.

Efficient Submissions
Supports both eCTD and NeeS formats.

Flexible Options
Handles electronic and paper formats.

Faster Approvals
Streamlines workflows to save time.

Improved Archiving
Enhances submission storage and handling.

Global Compatibility
Meets international submission standards.

Easy Access
Simplifies document sharing and collaboration.

Instant Acknowledgements
Electronic submissions get immediate confirmations.

CTD Plus Features

SPT Tool
Advanced tools for dossier preparation.

Validation Tools
Checks compliance with the latest standards. Ensures error-free submissions by adhering to updated validation criteria.

Compliant File Naming
Ensures adherence to regulations.

PDF Optimization
EnRegulatory-ready PDFs with hyperlinking tools. Optimizes files according to agency specifications, reducing errors and boosting productivity.
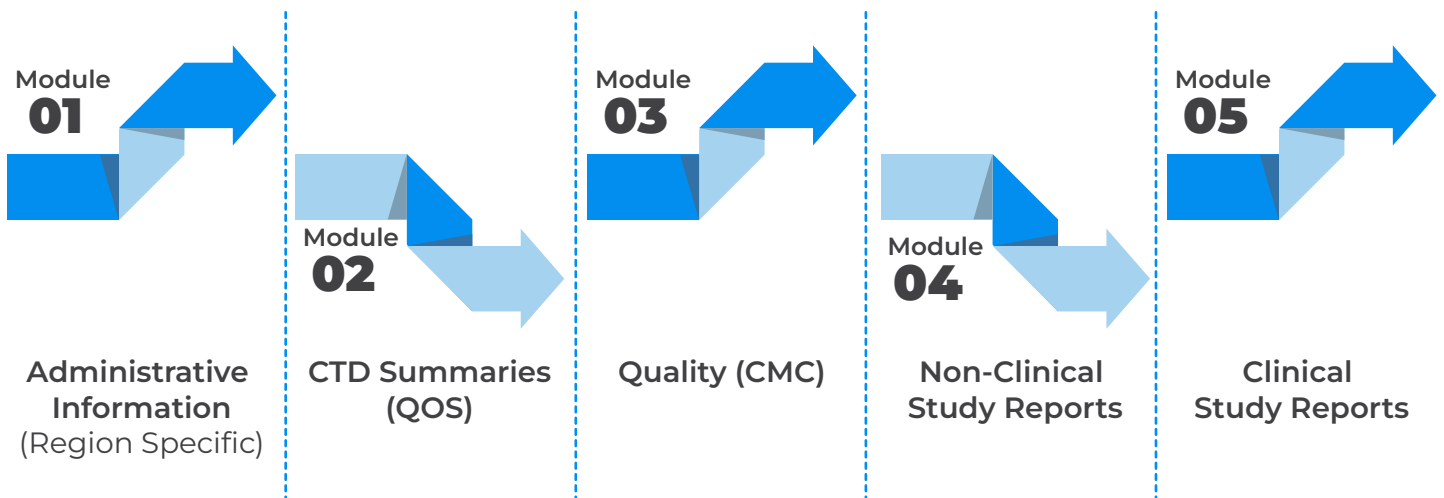
Flexible Document Preparation
Supports Word imports and PDF attachments.

Built-In Templates
Includes guidelines and templates for consistency.

Reporting Tools
Provides audit and submission insights.

Task Management
Defines roles for preparation, review, and publishing.

CTD Modules

Module 01
Administrative Information (Region Specific)

Module 02
CTD Summaries (QOS)

Module 03
Quality (CMC)

Module 04
Non-Clinical Study Reports

Module 05
Clinical Study Reports

For more information, visit our website or contact us directly.

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Simplify Submissions with CTD Plus
Achieve compliance and efficiency with CTD Plus.
Schedule a demo today!