RLP manager

EXTEDO
eRegulatory Affairs

Product Information

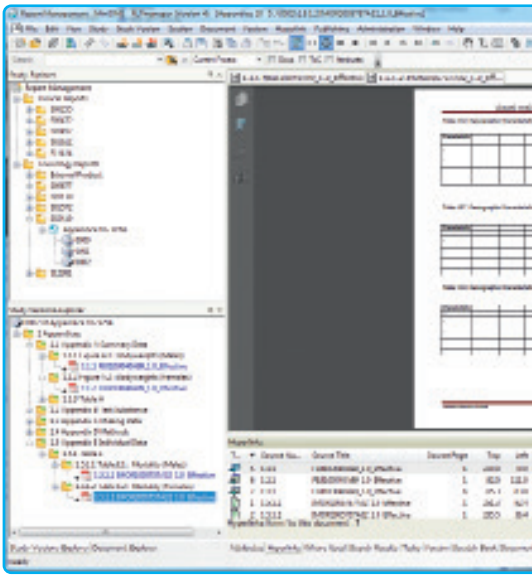
RLPmanager™

Automating the creation of clinical and non-clinical studies

Whether you are a pharmaceutical company or a clinical research organization (CRO), the process of creating, compiling and integrating clinical and non-clinical studies into eCTD or NeeS submissions is the same. The need to collate large numbers of different documents can be a complex and expensive process to manage.

Benefits

- Maximized flexibility in study creation
- Reduced approval time & time to market
- Cost efficient
- Lower logistics overhead
- Improved document quality
- Increased value of eCTD ready studies
- Enhanced cooperation between clinical study and regulatory affairs departments



Efficient creation of clinical study reports

EXTEDO's RLPmanager is designed to eliminate the most common challenges associated with Report Level Publishing. It optimizes your pre-publishing work and supports clinical study departments with the management and publishing of clinical and non-clinical study reports that ultimately become part of eCTD or NeeS submissions.

Simplified study creation & publishing

RLPmanager's extensive report compilation capabilities enable you to automate the processes of creating study structures and assigning documents, simplifying it down to just a few simple steps:

1. **Create new study**
2. **Build the study structure**

   RLPmanager enables you to create and save commonly used structures as templates that can be used across multiple submissions.
3. **Add documents**

   With a defined study structure, you can quickly and easily add documents from a report administration system or local life system with a simple a drag-and-drop or copy-paste operation.
4. **Publish**

   Once the structure has been defined and all documents are appropriately assigned, entire documents sets or subsets can be published either electronically or to paper.

Functional Overview

RLPmanager provides the following functionality:

- Flexible creation of ToC, ToT and ToF
- Table of Contents created based on the existing document bookmarks
- Automated document assignment
- Consistent integration of studies and other multiple document structures
- Fast access to documents from other electronic dossiers
- Hyperlinking and studies with associated Study Tagging Files (STF) can be included
- Entire sets or subsets of documents can be published electronically or on paper
- Strong bookmark and hyperlink generation functionalities
- Folder cover pages
- Advanced archiving capabilities

RLPmanager as a stand-alone solution

RLPmanager can be deployed stand-alone or as part of an integrated eCTDmanager-based solution. When used alone, RLPmanager enables you to readily merge multiple PDF documents into a single file. Once you have a complete series of documents compiled, the entire study can be published either to paper or into an electronic format. Electronic study files can be exported to your local file system or to your chosen Document Management System (DMS).

RLPmanager is also able to produce an ePaper output ready for use within any third-party electronic submission management tool. Publishing to the ePaper format automatically creates eCTD-ready files containing hyperlinks, bookmarks, and all metadata required by the eCTD standard.

An integrated study management solution

When deployed together as part of a broader electronic submission management solution RLPmanager and eCTDmanager provide you with support throughout the complete study creation, compilation and publication process. You can author, merge and finalize clinical and non-clinical studies within RLPmanager, then with a simple drag & drop you can move individual sections or the entire study over to eCTDmanager ready for further preparation and publication. Together, RLPmanager and eCTDmanager close the gap between your clinical study and regulatory affairs departments.

If you create or manage clinical study reports, RLPmanager is the most effective way to optimize your Report Level Publishing process.

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About us

EXTEDO is a leading solutions and services provider in the field of Regulatory Information Management (RIM). We focus on optimizing our clients' eRegulatory business processes and are the only vendor that provides solutions covering the entire regulatory landscape. Today, EXTEDO enables more than 35 regulatory authorities and over 850 maintained customers across 60 countries to deliver Effortless Compliance™.

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