



As more and more pharmaceutical and biotechnology sponsors move toward electronic submissions for new drug approvals, the eCTD has emerged as the guidance standard they must follow.

Organizations continue to seek an application that will enable them not only to submit new drug applications to regulatory agencies worldwide, but one that will facilitate review, compilation, publishing and archiving, as well as the re-use of all information involved in the drug development lifecycle.

eCTDXPress allows you to satisfy all of these requirements, and contains everything you need to create, edit and manage eCTDs in one sophisticated easy-to-use solution.

eCTDXPress is also available in a number of different configurations depending on your requirements. It can be configured as an enterprise solution, a desktop solution, or as a packaged, scalable entry-level solution that includes validation and consulting services to assist you with your first eCTD submission. With eCTDXPress, all technical processes are generated automatically, without requiring users to know XML or coding.

ISI's eCTDXPress is made more flexible through the ISI Solutions Platform, which leverages Microsoft's .Net architecture. The ISI Solutions Platform provides a foundation for integration and interoperability that can help Life Science organizations reduce costs, improve quality and dramatically streamline the drug development lifecycle.

If you're looking for a system that makes it easy to ensure compliance and submission readiness while focusing on building submissions, eCTDXPress is the solution.

The ISI Solutions Platform allows for a fully integrated set of capabilities that can be used to solve problems at all stages within the Life Science business information life cycle. This integrating framework makes assembly of an eCTD and a related paper CTD for Europe and other countries a seamless process.

From a technology standpoint, ISI offers a flexible platform that enables companies to rapidly accommodate changing business requirements and global regulations without investing in entirely new technologies. Companies can invest once and be assured of a platform that can expand and scale as their needs do.

New Capabilities

A Complete Document Management/Submissions Solution

Through tight integration with document management systems, ISI's eSubmissions solutions also help ensure that documents compiled in the earlier stages of the drug life cycle can be used at later points in the submission's process—automatically. The newest version of eCTDXPress allows for full integration with all of the leading Document Management Systems, including EMC's Documentum and Open Text's Livelink ECM, as well as vertically focused DMS such as FCG's FirstDoc. Companies now have a complete system to manage regulatory documents and publish submissions.

Integrated paper/electronic system

With the ISI Solutions Platform, the industry now has a fully integrated paper/electronic system and process, as well as a state-of-the-art rendering capability that simplifies submission publishing that can be deployed throughout the enterprise at a lower cost. Initially, the PDF rendition capability will be added to ISIPublisher, but other ISI applications will be able to create PDF renditions as needed from source documents.

Common Features and Ease of Use

The solution suite has common features including document viewing, publication-structure tree navigation, and access to regulatory repositories to create a flexible set of applications that work together for the creation of electronic submissions in any language, compliant with many country-specific regulations. An intuitive user interface can be customized to suit preferences, information needs and work habits, significantly improving global workflow while boosting productivity.

Virtual Link Management

Publishers can create hyperlinks between documents without knowing where the final document will reside in a publication as hyperlinks are updated with subsequent versions of the document. Together with ISI's support for Named Destinations in PDF documents, it is simple and straightforward to maintain cross-document hyperlinks even when both the source and target documents have changed. In 2007, ISI will offer Virtual Link Management capabilities outside of core publishing applications so that hyperlinks can be designated between documents that are not yet part of any submission or publication.

Built on the ISI Solutions Platform

The ISI Solutions Platform contains common components not visible to the workers using the applications, but transparently provide capabilities across multiple solutions. Because of this, the installation footprint of our applications is smaller because the common components are only installed once. This can cut down on the effort for Installation Qualification and Operation Qualification.

Primary among these is ISI's Façade™ Content Management Interface system. This enables all ISI Solutions Platform applications to work with documents on any supported repository, including multiple repositories. Initially, this is limited to Documentum, Livelink and the Windows File System, but will be expanding to additional content management systems (CMS).

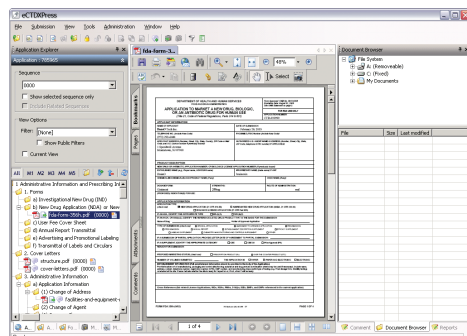
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Features and Functionality

Create and Assemble eCTDs

Featuring a flexible interface, eCTDExpress makes it simple to create and manage submissions. And best of all, the intuitive web-based interface is easily accessible – whether it's from the office or anywhere else around the globe.

eCTDExpress makes it easy to create eCTDs for compliance with multi-region support (EU, US, JP, CA). Easy-to-use wizards guide you through applications while automatically adding metadata for the appropriate DTDs. Metadata can be preset and stored in a database for users to share and select information (substance, manufacturer, dosage forms, strengths, etc.) when needed.



With eCTDExpress, you can:

- Create and Assemble eCTDs
- Easily Build STFs
- Add and Modify Hyperlinks
- Compile, Validate and Verify
- Review and Comment Globally
- Manage eCTD Lifecycles
- Clone for Other Regions
- Archive into EDMS

Build Study Tagging Files (STFs) the Easy Way

Adding files to your eCTD is a snap with eCTDExpress drag-and-drop technology. Add files from anywhere - whether it's from a file share, local computer or DMS. With advanced features such as folder mapping, you can automatically move study report files to the appropriate study folders. In addition, you can map DMS attributes to eCTDExpress - automatically tagging study files and building STFs as files are dropped into the submission.

Add and Modify Hyperlinks Efficiently

eCTDExpress also lets you create links and build eCTD submissions at the same time. The flexibility to create links directly within eCTDExpress allows you to create cross-document links as submissions are being assembled - eliminating costly errors and ensuring reliability. Links go to submission-ready files regardless of source (file share, DMS, etc.), giving you the assurance that links will never break or point to an invalid destination.



With the hyperlinking tools provided in eCTDExpress, you can create hyperlinks between documents using PDF bookmarks or named destinations. Through an advanced file browser, you can navigate through your submission files' bookmarks and named destinations without having to open a single file.

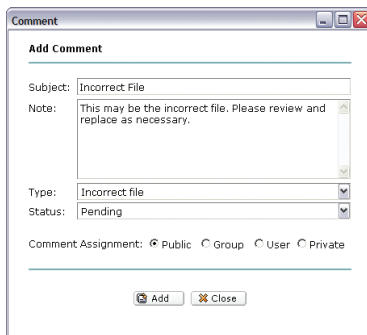
Compile, Validate and Verify

With eCTDExpress, you'll breeze through compiling, validating and reviewing submissions. Organize submission files into an eCTD folder structure while eCTDExpress automatically validates the XML against the DTD - ensuring compliance with regional and ICH guidance. In addition, eCTDExpress validates SPL files and checks for broken links and bookmarks.

Review and Comment Globally

Enhance your review process with convenient global commenting that leverages the latest advances in technology. Save time and boost your efficiency as you track comments, manage changes, and follow the progress of eCTDs as they mature.

With eCTDXPress you'll get superior management, efficient reviews and the most comprehensive information about your eCTDs. Hide unneeded information for faster review and have the ability to review compiled submissions anywhere around the world. Even view complete eCTDs with all associated lifecycle sequences, search across multiple eCTDs, and display and review multiple documents simultaneously. Track the progress of eCTD lifecycles with a review list and viewing history for quality assurance.



Manage eCTD Lifecycles

Organize, manage and prioritize eCTD lifecycles without disrupting your workflow. Every aspect of lifecycle management is under your control. With the Submission Wizard, you can easily create new sequences and relate them to existing submissions. Even append, replace and delete documents from earlier submissions by dragging and dropping files without having to worry about compatibility; eCTDXPress automatically sets the appropriate operation in the XML backbone. And, built-in lifecycle control allows you to keep submissions accurate and up-to-date, keeping you ahead of the latest version to come through the pipeline.

Archive and Clone for Other Regions

Backup, organize, import and clone eCTDs quickly and easily with eCTDXPress. Turn a US submission into an EU submission in a few simple steps. With support for US, EU, CA, and JP regions, you can clone all or part of an application for other regions easily. Also clone link management hyperlinks and comments, and import previously created eCTDs from the database for other regions. You'll experience a seamless transfer of links, submission formats and content from one submission to another.

Comprehensive Reports

Track everything you need to know - all through comprehensive reports. Stay on top of the entire lifecycle: correct errors after they happen, stop new ones before they occur, track comments, previous versions and submission statuses.

Flexible Control of Permissions

Set permissions for users around the world for maximum collaboration. Organize users, assign privileges and control access down to the modular level. Easy to set and extraordinarily flexible, eCTDXPress gives you the most control over your eCTDs - no matter where they're being worked on.



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