ROSETTA *Phoenix* Server Product White Paper

ROSETTA *Phoenix* Server™, developed by DoubleBridge Technologies, Inc., is a web-based eCTD and NeeS reviewing system that not only allows the viewing of regulatory submissions prepared in the Electronic Common Technical Document (eCTD) format after eCTDs were submitted to health authorities but also enables collaboration between submission publishers and reviewers during the final stage of compiling eCTDs before they are submitted.

ROSETTA *Phoenix* Server provides a single web interface for users to navigate electronic document repositories and locate eCTD submissions that are stored on file share, EMC Documentum dobases or Microsoft SharePoint sites. Even if the eCTDs are mixed with other types of electronic documents, ROSETTA *Phoenix* Server intelligently determines whether a folder contains an eCTD application and provides users an option to launch the ROSETTA *Phoenix* eCTD Viewer to view the full lifecycle of the eCTD application.

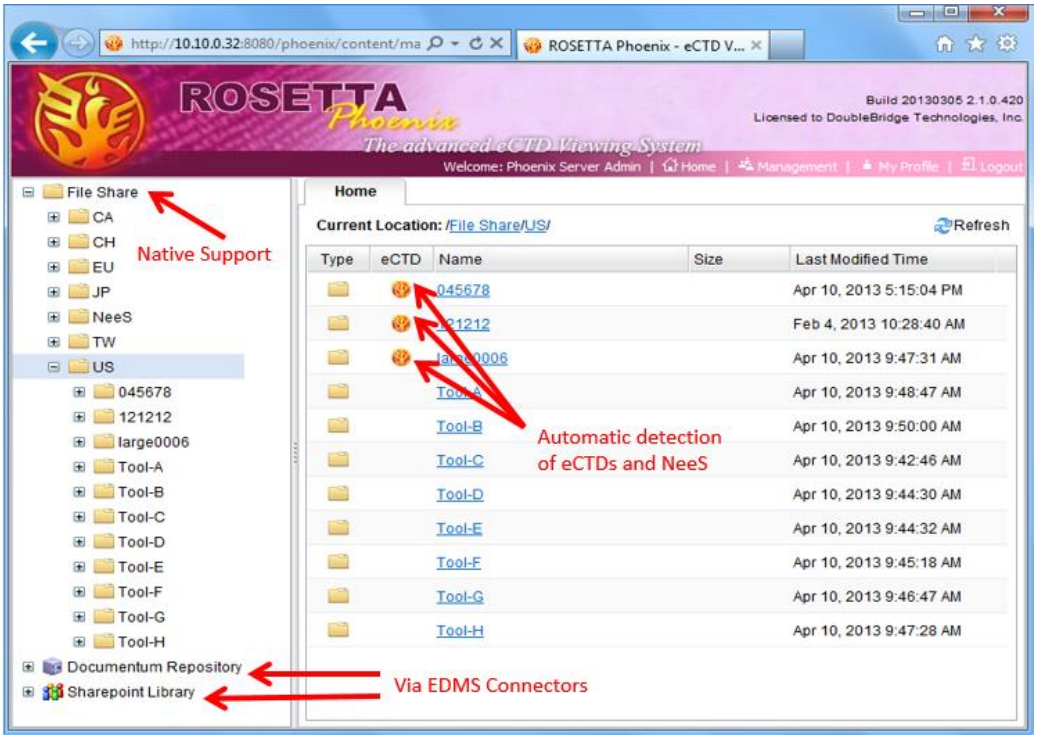


Figure 1: ROSETTA Phoenix Server's Web User Interface

Launch the ROSETTA Phoenix eCTD Viewer

When a user clicks on a Phoenix icon that signifies an eCTD or NeeS submission or application, ROSETTA *Phoenix* Server responds with an HTTP/S handshake message to launch the ROSETTA *Phoenix* eCTD Viewer pre-installed on the end user's computer and load the eCTD/NeeS submission's cumulative Table of Contents (ToC). The user can navigate the ToC to locate and open documents of his/her interest stored in the document repositories (such as file share, Documentum docbases and SharePoint sites) connected to the Phoenix Server.

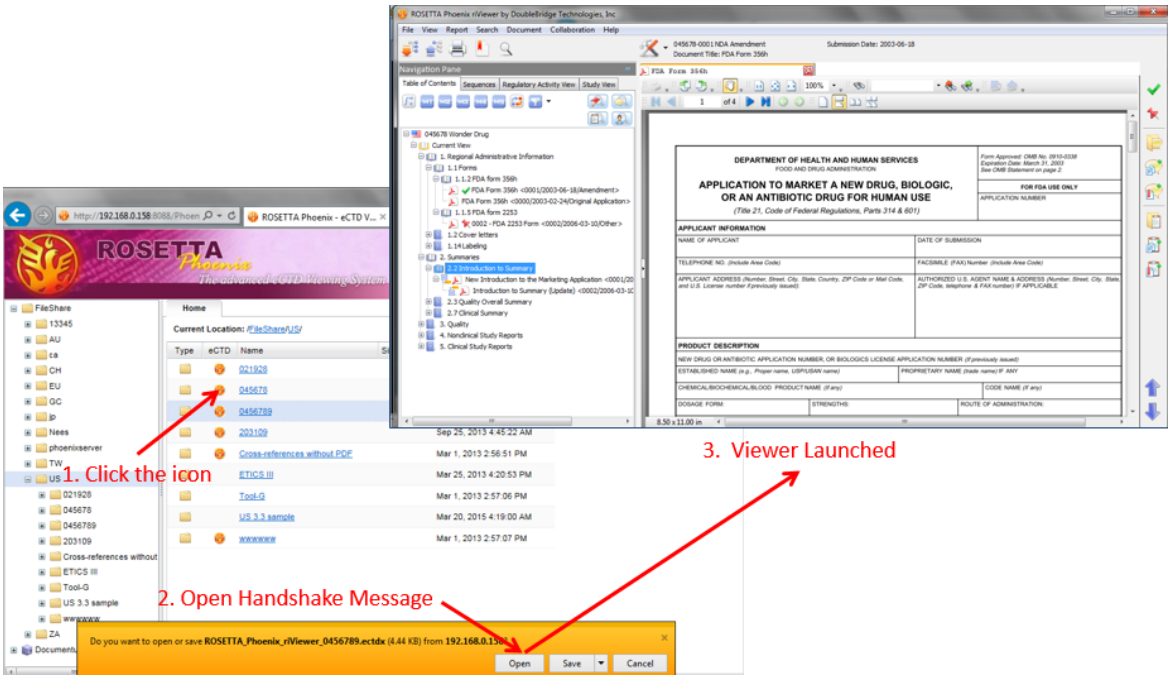


Figure 2: Two clicks to load ToC into the ROSETTA Phoenix Viewer

Architecture Design

ROSETTA *Phoenix* Server's web-based client-server architecture provides the best performance and user experience possible. An eCTD application's Table of Contents is hierarchical and it can go as deep as six or more levels. A "chatty" communications protocol like HTTP or HTTPS and the Hyper Text Markup Language (HTML) are inefficient to deliver the ToC and perform the Expand All function on the ToC hierarchy. In a so-called pure web or no-footprint system, it is likely to require a user to click and expand the ToC hierarchy repeatedly, one level a time, before the user can examine a submission document's title and open the document. One the contrary, **inside ROSETTA Phoenix Server, an eCTD application's entire ToC is transferred to and loaded in the Phoenix Viewer by a single request to the server.** Once the ToC is loaded in the Phoenix eCTD Viewer, all the navigation operations, such as Expand/Collapse All functions, are performed in a native Windows application, the ROSETTA Phoenix eCTD/NeeS Viewer, that provides the speediest performance and best user experience that a pure web application simply cannot deliver. In addition, advanced compression,

caching and other optimization techniques are utilized during the transmission and processing of ToC, behind the scenes to achieve the best response time.

Even though ROSETTA *Phoenix* Viewer must be pre-installed on an end-user's computer, there are no configurations needed on the client side at all. All the information needed by the client-side Phoenix Viewer to communicate with the Phoenix Server is contained in a handshake message that is delivered to the client side when a user clicks on a Phoenix icon in the Phoenix Server's web user interface. A Phoenix Server's handshake message contains service URLs and parameters required when the client-side Phoenix Viewer requests a service from the server (e.g. Transfer ToC and open a document). The front-end Phoenix eCTD Viewer never has to establish direct connections to the backend database or document repositories. The Phoenix Server acts as the proxy to retrieve documents stored in the repositories configured on the server. A handshake message also includes system-enforced security configurations, user permissions, software update policy and user preferences stored on the server.

ROSETTA *Phoenix* Server's web-based, client-server architecture design also isolates and confine all front-end eCTD related functions within the Phoenix eCTD Viewer application and hence shield it from browser incompatibility issues that many pure web/HTML systems often encounter, especially when a new version of a web browser is made available to end users. This means it is easier for IT or application support personnel to maintain the system. Furthermore, since the client-side **ROSETTA *Phoenix* Viewer is a native Windows application, it does not depend on either .NET framework or Java run-time libraries.** This, again, makes IT and application support personnel's job a lot easier when they want to upgrade client machines' .NET framework or Java run-time libraries. They can freely upgrade .NET framework and Java run--time libraries without having to worry about Phoenix eCTD Viewer's compatibility.

The server-side of ROSETTA Phoenix Server is developed in Java and runs on Java Run-time v1.7 or later versions. It natively supports file share as a document repository and can optionally connect to EMC Documentum Content Server and Microsoft SharePoint sites via EDMS connectors developed by DoubleBridge Technologies, Inc.

Annotation and Collaboration Services

Besides the read-only consumptions of eCTD submission information, ROSETTA *Phoenix* Server also offers an optional module called ROSETTA Annotation and Collaboration Services (RACS). The RACS module provides users capabilities to review, quality check, comment, annotate and collaborate on eCTD submission documents during the final stage of preparation eCTD submissions.

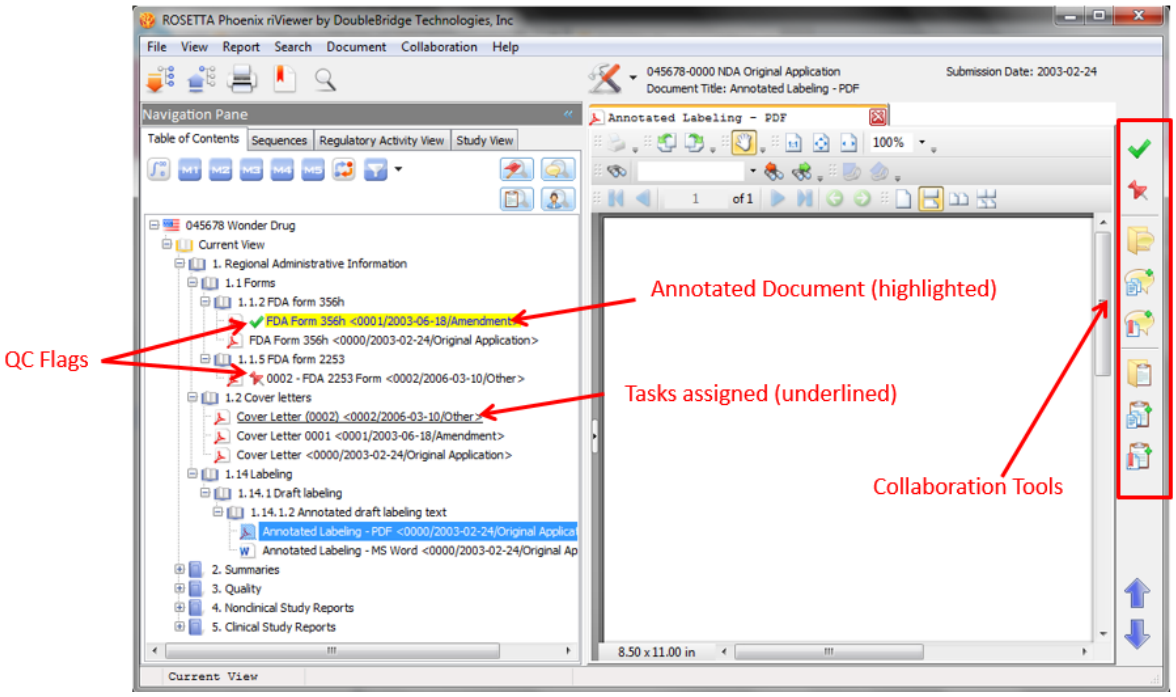


Figure 3: Annotation and Collaboration Capabilities

During the final stage of preparing an eCTD submission sequence, the ROSETTA Phoenix Viewer lets you preview what the regulatory application will look like cumulatively after all lifecycle operations (new, append, delete, replace) are all accounted for. With the RACS module, each submission document can be reviewed and tagged with quality check flags to indicate whether a document is submission-ready or needs additional attention. Annotations can be made and associated with a submission document. Tasks can be created, communicated and assigned to team members to address issues found during the review and quality checks process.

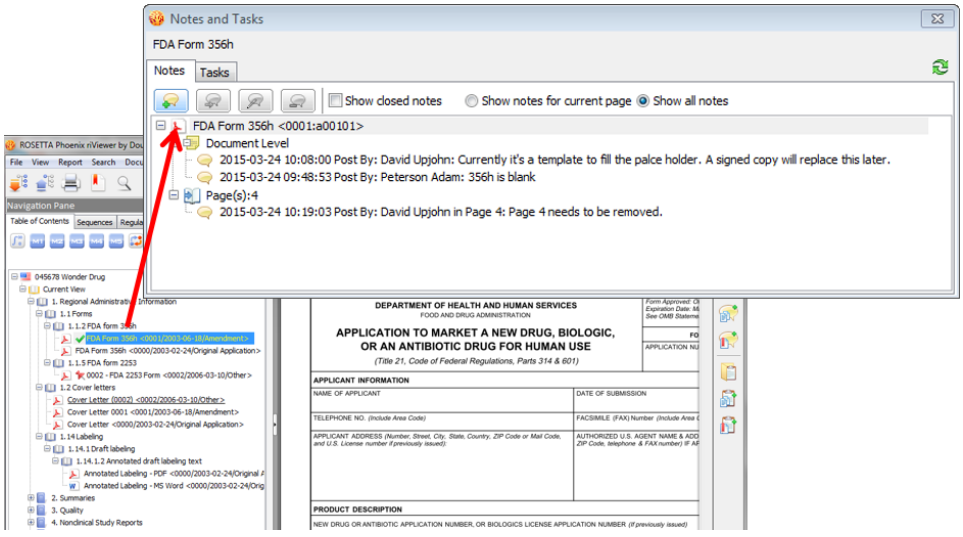
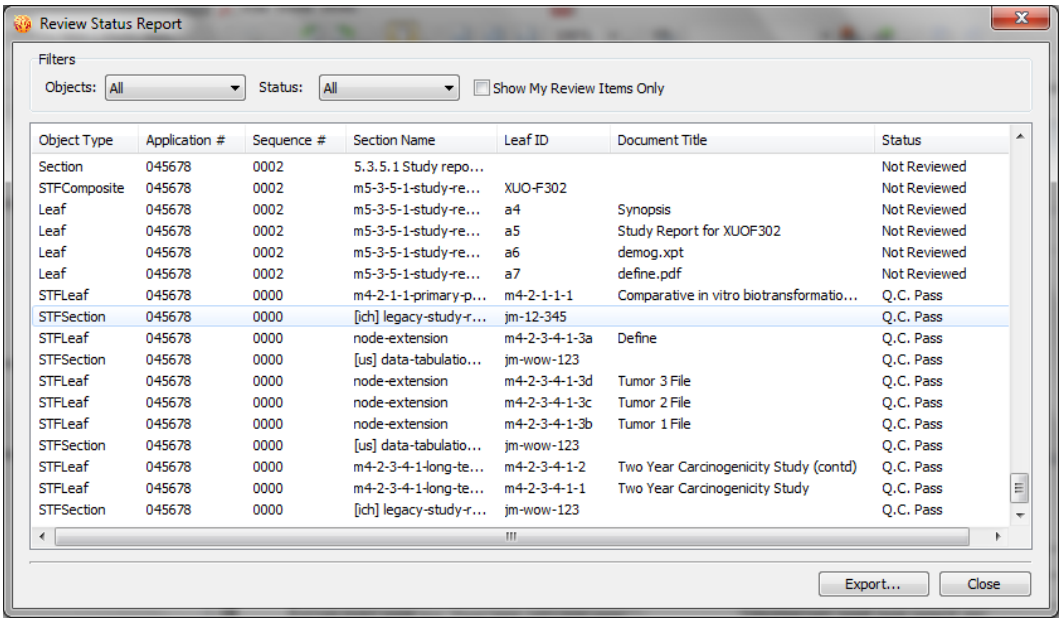


Figure 4: Annotations and Tasks associated with a submission document

Reporting Capabilities

Reports are available for monitoring the status and progress of submission preparation and review. Reports include Review Status Report, Review Tasks Report and Review Notes by Individuals.



Object Type	Application #	Sequence #	Section Name	Leaf ID	Document Title	Status
Section	045678	0002	5.3.5.1 Study repo...			Not Reviewed
STFComposite	045678	0002	m5-3-5-1-study-re...	XUO-F302		Not Reviewed
Leaf	045678	0002	m5-3-5-1-study-re...	a4	Synopsis	Not Reviewed
Leaf	045678	0002	m5-3-5-1-study-re...	a5	Study Report for XUOF302	Not Reviewed
Leaf	045678	0002	m5-3-5-1-study-re...	a6	demog.xpt	Not Reviewed
Leaf	045678	0002	m5-3-5-1-study-re...	a7	define.pdf	Not Reviewed
STFLeaf	045678	0000	m4-2-1-1-primary-p...	m4-2-1-1-1	Comparative in vitro biotransformatio...	Q.C. Pass
STFSection	045678	0000	[ich] legacy-study-r...	jm-12-345		Q.C. Pass
STFLeaf	045678	0000	node-extension	m4-2-3-4-1-3a	Define	Q.C. Pass
STFSection	045678	0000	[us] data-tabulatio...	jm-wow-123		Q.C. Pass
STFLeaf	045678	0000	node-extension	m4-2-3-4-1-3d	Tumor 3 File	Q.C. Pass
STFLeaf	045678	0000	node-extension	m4-2-3-4-1-3c	Tumor 2 File	Q.C. Pass
STFLeaf	045678	0000	node-extension	m4-2-3-4-1-3b	Tumor 1 File	Q.C. Pass
STFSection	045678	0000	[us] data-tabulatio...	jm-wow-123		Q.C. Pass
STFLeaf	045678	0000	m4-2-3-4-1-long-te...	m4-2-3-4-1-2	Two Year Carcinogenicity Study (contd)	Q.C. Pass
STFLeaf	045678	0000	m4-2-3-4-1-long-te...	m4-2-3-4-1-1	Two Year Carcinogenicity Study	Q.C. Pass
STFSection	045678	0000	[ich] legacy-study-r...	jm-wow-123		Q.C. Pass

Figure 5: Review Status Report

Where are annotations and collaboration information stores?

ROSETTA Annotation and Collaboration Services let users annotate on submission documents and their metadata and collaborate on tasks associated with them. **These quality check, annotation and collaboration activities do not modify submission documents in any way**. They are captured and stored in a backend database and information is displayed in ROSETTA Phoenix Viewer by "overlaying" the information when requested by an end user. In other words, no annotated copies of submission documents are created during the process. Annotations and collaboration activities can be easily purged without affecting original submission documents.

Additional Information

For more information about ROSETTA *Phoenix* Server, ROSETTA *Phoenix* eCTD Viewer and ROSETTA Annotation and Collaboration Services, visit website www.rosettaectd.com or send inquiries to rosetta@doublebridge.com.