Instructions for Using the eCTD Quick Viewing Tool

Version 1.5

5/10/2002

The eCTD Quick Viewing Tool (ViewXML.xml) provides a basic interface for viewing an instance of the Electronic Common Technical Document (eCTD) or Regional document rendered in Extensible Markup Language (XML). The viewing interface displays an XML Stylesheet Language Transformation (XSLT) of the file contents, rather than a physical transformation of the file itself.

The eCTD Quick Viewing Tool works with Microsoft Internet Explorer (IE) 5.0 or above and will only function correctly when:

- 1) The selected XML instance consists of well-formed XML.
- 2) The syntax of the target XML instance conforms to a recognized International Conference on Harmonisation (ICH) standard. The target XML instance must include the proper eCTD or Regional document element. If a Document Type Definition (DTD) is referenced, the XML syntax must strictly conform to the referenced DTD.

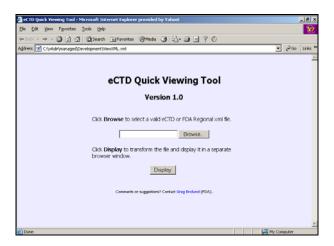
The eCTD Quick Viewing Tool is NOT designed to isolate formatting errors in an eCTD or Regional XML document.

1.1 VIEWING AN ECTD XML INSTANCE

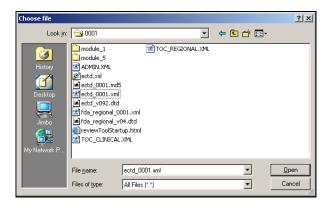
The eCTD Quick Viewing Tool can be associated with any existing eCTD or Regional XML file. To do this,

- 1) Locate the ViewXML.xml file. The ViewXML.xml file should reside on a **local** drive. If the ViewXML.xml file is currently located on a non-local network drive, please copy the file to a local drive.
- 2) Open the ViewXML.xml file. The launch screen is displayed:

¹ Version 1.5 of the eCTD Quick Viewing Tool has been baselined on guidance provided in the ICH eCTD Specification V 2.0 February 12, 2002.



- Click the Browse button.
- 4) Select the XML file you want to transform and click the **Open** button:



Alternatively, you can simply type the full-qualified name of the file into the field next to the **Browse** button.

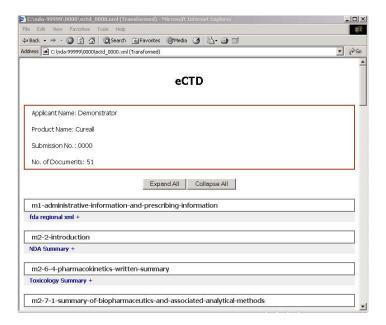
5) On the launch screen, click the **Display** button.

A transformed version of the selected file should now be displayed in a secondary window.

The eCTD Stylesheet displays submission summary information, provided:

- 1) The Regional XML file indicated in the eCTD XML file exists and the indicated Regional path is valid (normally the same directory).
- 2) The Regional XML file includes the appropriate information.

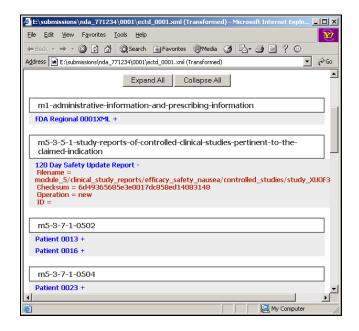
The eCTD Stylesheet instructs IE to display only the headings associated with actual document nodes. The corresponding file links are displayed directly below the node headings. For example:



Clicking on a blue file name below a header opens the indicated file and displays the file contents in a separate browser window, provided:

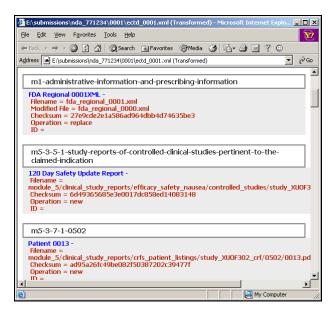
- 1) The file path included in XML file is valid.
- 2) IE can understand the format of the indicated file.

Clicking once on the plus sign to the right of the file name displays included summary information for the file, causing the plus sign to change to a minus sign, as shown below:



Clicking on the minus sign removes the summary information, restoring the file name to its original appearance.

Clicking the **Expand All** button will display all of the summaries in the document, as shown below:

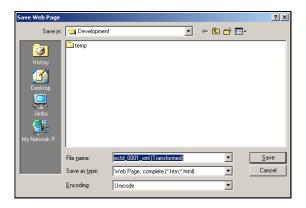


Clicking the **Collapse All** button removes the summary information, restoring all file names to their original appearance in the file. For large XML files, both processes may take several seconds.

1.2 SAVING A TRANSFORMATION IN PORTABLE HTML FORMAT

To save a transformation in portable HTML format, do the following:

1) Select **Save As** from the **File** menu. The Save Web Page dialog window is displayed:



2) Select Web Page, HTML Only (*.htm,*.html) as the file type. Saving the transformation as a complete web page produces an unusable file.

- 3) Select a directory location from the **Save in** drop-down list at the top of the window.
- 4) Click the **Save** button.

The resulting file will include all of the functionality available in the display window. To keep the same look and feel as the display version, simply include a copy of ViewXML.xml in the directory that includes the new transformation file.