

Visualizing STF Content in a Browser Using the ICH Stylesheet

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1. Summary

Currently we are receiving many support questions regarding an issue that arises when displaying STF study reports in a browser using the new stylesheet version 2-3. We would like to explain the background and why we need to wait until ICH issues another official stylesheet to correct this.

Background: In June 2017, the ICH M8 group issued a new STF stylesheet, [version 2-3](#), with the MD5 checksum "92BFEB4CB358A4AF786317A0DA2309C5". This stylesheet, which allows the visualizing of Study Tagging Files (STF) XML objects in a browser, was adopted by the USFDA on November 15, 2017, and is today a mandatory item when submitting eCTD submissions with STFs.

Under certain conditions, this new STF stylesheet generates an error and prevents the display of the complete STF study report in a browser.

It would be a technically easy task to modify the stylesheet; however, since the present stylesheet (with the MD5 checksum "92BFEB4CB358A4AF786317A0DA2309C5") is currently valid and "in-force", its modification will require a formal change by the ICH enabling a new official stylesheet to be used. Using a corrected but non-official version of the stylesheet will lead to validation errors.

That means we need to wait until ICH issues another official stylesheet to correct this issue.

The following sections explain the source of this error in more detail.



2. Display Method

To display the contents of a Study's STF in a browser requires the processing of three distinct files in different folder locations. To visualize a sample, the following folder structure is assumed.

Folder	File	Comment
ind123456\		Root (Application) folder
0000\	index.xml	Sequence folder where index.xml file is stored
m5\ 53-clin-stud-rep\ 532-rep-stud-pk-human-biomat\ 5321-plasma-prot-bind-stud-rep\ 555\	stf-555.xml	Module-level folder and path to location where the STF study report file is stored
util\ style\	ich-stf-stylesheet-2-3.xsl	Location where the STF Stylesheet is stored

The STF study report file, in this case, is "stf-555.xml" located in study id folder "555". This file contains the main study report information to be displayed in the browser.

Two additional files need to be accessed in order to properly display/render the STF in a browser: the stylesheet "ich-stf-stylesheet-2-3.xsl" with the display instructions, and the backbone file "index.xml" with further information of each individual document.

2.1 Locate Stylesheet

The STF study report file (in this sample "stf-555.xml") references in its header, the stylesheet as:

```
xml-stylesheet href="../../../../../../util/style/ich-stf-stylesheet-2-3.xsl"
```

From the study folder, "555", the reference specifies moving up 5 folder using the notation "../", until reaching the sequence folder "0000" and then going down 2 folders "util", "style\" to locate the file "ich-stf-stylesheet-2-3.xsl".

2.2 Identifying Backbone File

The STF study report file (in this sample "stf-555.xml") references for each document, a leaf element in the backbone file in one of 2 ways:



2.2.1 Option 1

```
doc-content href="../../../../../../index.xml#N0715"
```

This specifies moving 5 folders to the sequence folder to access the "index.xml" file, and locating the specific leaf (i.e. "N0715" in this example). This leaf contains document title and file location information.

2.2.2 Option 2

Alternatively the document leaf in the backbone file could be referenced as:

```
doc-content href="../../../../../../0000/index.xml#N0715"
```

This specifies moving up 6 folders to the application folder and then going down 1 folder to the sequence's folder (i.e. "0000"), to locate the backbone file "index.xml".

In syntax terms, both reference options are correct as relative file paths. However during execution, the browser will optimize the reference to a minimum level (i.e. to "../../../index.xml#N0715").

3. The Display Issue

In case the backbone file is referenced in the optimized way (Option1), the stylesheet "ich-stf-stylesheet-2-3.xsl" creates an error. This is a minor bug in the string coding that is not compliant with the W3C standard.

It would be a technically easy task to modify the stylesheet; however the current stylesheet (with the MD5 checksum "92BFEB4CB358A4AF786317A0DA2309C5") is considered valid and "in-force", and its modification will require a formal change by the ICH, so that a new official stylesheet can be used.

We need to wait until ICH issues another official stylesheet to correct this issue.