# IND Review Model

May 14, 2001:  The subject of this download is software that contains the material presented at the Electronic Investigational New Drug Application: Cumulative Table of Contents; Public Meeting on January 26, 2001. It is also in part a copy of the web site for Electronic Investigational New Drug (IND) Cumulative Table of Contents (CTOC) development project (http://www.fda.gov/CDER/REGULATORY/ERSR/CTOC/Default.htm).

The CTOC navigation and Life Cycle Management model represents the current thinking for how a reviewer would access information provided by application sponsors to the agency.  The specification for how files are submitted to the agency may be different from what is in this development model.  Those specifications will be developed from agreements reached within the International Conference on Harmonization (ICH).

The CTOC model download is available at the web site referenced in the first paragraph.  With the download you can run and edit the CTOC model at your desktop without Internet access.  Look for the "CTOC Model Download" hyperlink at the web site referenced in the first paragraph.  Place the downloaded zip file into a folder at the drive root named "CTOC_Download_Beta_0.4" and extract the contents (for example, the path to the new folder may be C:\CTOC_Download_Beta_0.4\).  After extraction of the zip file you will find a copy of this document, a file named "StartModel.htm", and two folders named "IND_12345" and "Resource".

> NOTE:  The reason for the specific folder name and placement is so that the destination for  the start file will work properly.

Run the file named "StartModel.htm" and the model will start automatically.

> The model is a frames based web network that starts from a file named "Main_v500.htm".  For the download described above, the filename and path is:

> > [drive]:\ CTOC_Download_Beta_0.4\Resource\Tools\ Main_v500.htm.

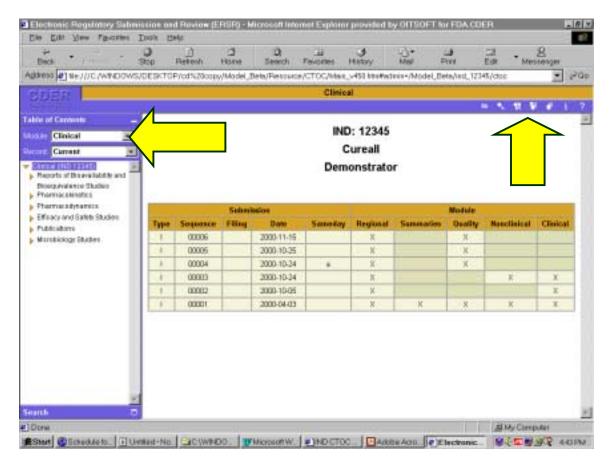> If you run the "Main_v500.htm"  file directly it will ask for the location of the "admin.xml" file.  If the download were done on the "C:" drive, the correct response to the prompt is the following path:

> > C:\ CTOC_Download_Beta_0.4\IND_12345\0005\

> > Notice that the filename should not be included.

> > Notice that this information is provided to the computer automatically when the StartModel.htm file is used.

When the model is successfully started, either from the Internet site or from the download, it will look like the following picture (except for the yellow arrows):



Notice the pull-down boxes for "Module" and for "Record" near the end of the blue arrow on the left. You can select different modules by clicking the "Module" pull-down arrow and then clicking the module in which you are interested (Clinical is the default). You can select the record view you are interested in by clicking on the "Record" pull-down arrow and selecting whether you want to view a individual submission (by date), all submissions together, or only the ones that remain current since they were submitted and have not changed (default). I recommend selecting "all submissions" to see everything in the model.

Notice the tool bar items near the end of the blue arrow on the right. These are various search tools best learned by experimentation. The "related documents" tool finds all the files that are related through the "updates" attribute in the <document> element. If you need help send me a message at clarkjo@cder.fda.gov. Refer to them by the name appearing on the pop-up that occurs during mouseover.

If you want to participate in a demonstration of this model contact Jon Clark at Clarkjo@CDER.FDA.gov