




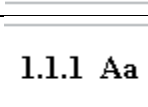
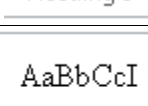

**PREPARATION OF eCTD COMPLIANT DOCUMENTS:  
AREAS TO FOCUS ON**

**General Comment:**

*Draft View* – How to view the formatting that has been applied to a document?

*Go to the View Tab, under Views Group, select ‘Draft’. If you cannot see the ‘Draft View’ on the left-hand side of the document, go to the File Tab, Options, Advanced: under Display update the ‘Style Area Pane Width in Draft and Outline views’ to be at least 1”. In addition, under General, make sure ‘Allow Opening a Document in Draft View’ is checked.*

1. **Use the Correct Font Styles:** Apply the following font styles to appropriate text and/or section headings. Applying the appropriate font style to all section headings will allow them to appear in the Table of Contents.

Font Style	Style Buttons in Word Toolbar	Font Specifications	Examples
Admin Title (not a default style setting in word, must be created)		Times New Roman, font size 16, bolded, center-aligned	Signature page, TOC, LOF, LOT, List of Abbreviations, Statement of Compliance, Protocol Summary
Heading 1		Times New Roman, font size 16, bolded, numbered, left-aligned	1. Background Information and Scientific Rationale 2. Objectives and Outcome Measures
Heading 2		Times New Roman, font size 14, bolded, numbered, left-aligned	2.2 Rationale, 3.1 Study Objectives
Heading 3		Times New Roman, font size 12, bolded, numbered, left-aligned	3.1.1 Primary, 6.1.1 Acquisition
Normal (important that this is set properly)		Times New Roman (TNR), font size 12, left-aligned	Non-numbered/non-bulleted general body text <b>How to set (as default):</b> Go to the Home tab, click the arrow in the lower right-hand corner of the Font Group. Select TNR 12. In the lower left-hand corner, select ‘set as default’. Choose ‘this document only’ or ‘all documents based on the Normal.dotm template?’ Click OK to apply the changes and save. This will automatically update your Normal Font Style in the Style Gallery.
List Paragraph		Times New Roman, font size 12, left-aligned, bulleted/numbered	Numbered/bulleted general body text

2. **Caption Tables and Figures:** Insert Captions for all tables and figures. This allows them to pull into a List of Tables (LOT) or List of Figures (LOF). You do not need to create an additional heading for your tables and figures if they are captioned.
  - *Navigate to the “References” tab and click on the “Insert Caption” option under the Captions group.*
  - *Select the appropriate Label (either Table or Figure)*
  - *To name the table, use a colon and enter the table name at the end of the field.*
  - *Select “Above Selected Item” for position*
  - **Optional:** *Under “Numbering” option, check box to “include chapter number”. This will include the section or ‘chapter’ number in your table caption.*
    - *Select Heading 1 in the “Chapter starts with style” field and click “OK”*
3. **Table of Contents:** Insert a Table of Contents (TOC) if the document is more than 5 pages. A TOC is generated only if the appropriate font styles are applied to section headings.
  - *Place cursor where you would like to insert the TOC*
  - *Navigate to the “References” tab and click on the “Table of Contents” option under the Table of Contents group.*
  - *Click to choose the appropriate table of contents template.*
4. **LOT and LOF:** Insert a List of Tables (LOT) and List of Figures (LOF). A LOT and LOF are generated only if the figures and tables are appropriately captioned.
  - *Place cursor where you would like to insert the LOT/LOF*
  - *Navigate to the “References” tab and click on the “Insert Table of Figures” option under the Captions group.*
  - *Under the “Table of Figure” tab, check the following boxes: “Show page numbers”, “Right align page numbers”, “Use hyperlinks instead of page numbers” and “Include label and number”.*
  - *Under the “General” section –*
    - *select the option ‘from template’ in the “Formats” field*
    - *select Figure/Table in the “Caption Label” field*
5. **Use Cross-References:** Insert in-text cross-references for all tables, figures, sections and appendices.
  - *Place cursor where you would like to insert the reference.*
  - *Navigate to the “References” tab and click on the “Cross-reference” option under the Captions group.*
  - *In the reference type field select Table, Figure or Heading from the drop-down menu.*

- *In the Insert reference to field, choose “Only label and number” when linking to Tables and Figures and “Heading text” and/or “Heading number” when linking to specific section Headings.*
  - *Select the entity you would like to insert and click Insert.*
6. **Set Table Dimensions:** Modify the table dimensions as follows, to 6.5 inches width for tables found on pages that are in portrait and 9 inches width for tables found on pages that are in landscape.
- *Select the appropriate table.*
  - *Right-click on the table and select the “Table Properties” option in the drop-down menu.*
  - *Under the “Table” tab, check the box associated with “Preferred width” option and select Inches in the “Measure in” field.*
  - *Select/Enter the width value (6.5 in - portrait and 9 in - landscape) in the “Preferred width” field.*
7. Delete any unrequired blank pages.
8. **Update TOC, LOT, LOF:** Select “Update field” for TOC, LOT and LOF before saving the document to reflect the changes that were made.
- *Select the appropriate table.*
  - *Step 1*
    - *Navigate to the “References” tab and click on the “Update table” option under the Table of Contents group (For TOC).*
    - *Right-click on the appropriate table and select the “Update field” option in the drop-down menu (For TOC and LOT/LOF).*
  - *Step 2*
    - *In the “Update Table of Contents” window, select “Update entire table” option and click “OK” (For TOC).*
    - *In the “Update Table of Figures” window, select “Update entire table” option and click “OK” (For LOT and LOF).*