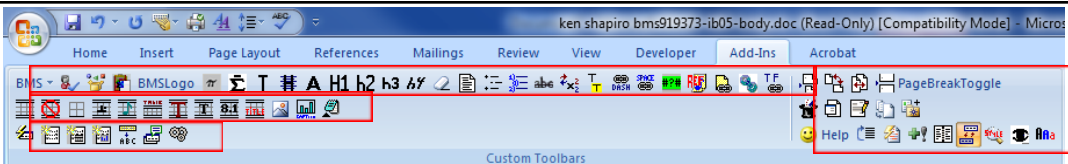
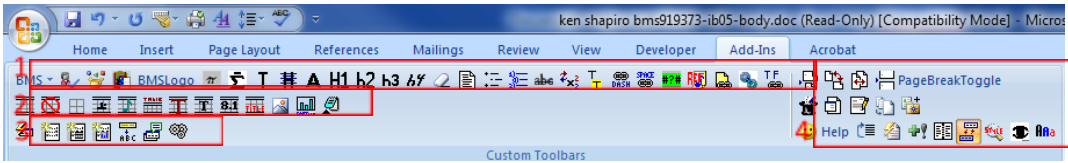


eLearning Storyboard

Module 2: Authoring a Model Document	
Slide	
Screen Title	What's Next
Screen Text	<p>In the previous module we discussed:</p> <ul style="list-style-type: none">• The CoreTemplate• Model Documents• Installation <p>In this module we're going to begin exploring</p> <ul style="list-style-type: none">• The CoreTemplate Toolbar• Entering information into a Model Document <p>Click Next to Continue</p>
Narration	<p>(1) In the previous module we discussed what the CoreTemplate and Model Documents are, and their relationship to each other. We also briefly discussed (3) installation of the CoreTemplate.</p> <p>(2) In this module we're going to begin exploring the CoreTemplate toolbar and how it is used to enter information into a Model Document.</p>
Programming Note	Synch audio to text.
Reviewer Name	
Reviewer Note	

eLearning Storyboard


Module 2: Authoring a Model Document	
Slide	
Screen Title	Navigating the Core Template BMS Toolbar
Screen Text	<div data-bbox="381 373 1458 535"></div> <p>After opening your document you'll find the CoreTemplate toolbar located in the Add Ins tab.</p> <p>The CoreTemplate Toolbar is organized by function.</p> <ol style="list-style-type: none">1. Text Style and Formatting tools2. Table and Figures tools3. TOC and Fields tool4. Page Setup and other tools <p>We'll explore specific buttons in the toolbar in greater detail a little later in this course. First, let's start entering text into our document.</p> <p>Click Next to explore entering text into a document.</p>
Narration	<p>After opening your document remember that you'll find the CoreTemplate toolbar located in the Add Ins tab of the MS Word ribbon at the top your window. (1) The Toolbar is organized by function. (2) Text Style and Formatting tools adjust the style and formatting of selected text. (3) Table and Figures tools allow authors to add and edit tables and figures. (4) The BMS TOC and Fields tools allow authors to insert and update the table of contents; lists of tables and figures and to work with fields such as Prompt for Fill-Ins. (5) Finally, additional tools such as section break, Page Setup, help, and many other tools are grouped on the right hand side of the toolbar. (6) We'll explore specific buttons in the toolbar in greater detail a little later in this course. First, let's start entering text into our document.</p>
Programming Note	<p>Synch audio to text on screen.</p> <div data-bbox="381 1402 1458 1564"></div> <p>As user hovers over each area (1-4) blow up that area of the toolbar with names of each of the buttons displayed.</p> <p>See Toolbar button for zoom ins.doc for list of all buttons.</p>
Reviewer Name	
Reviewer Note	

eLearning Storyboard

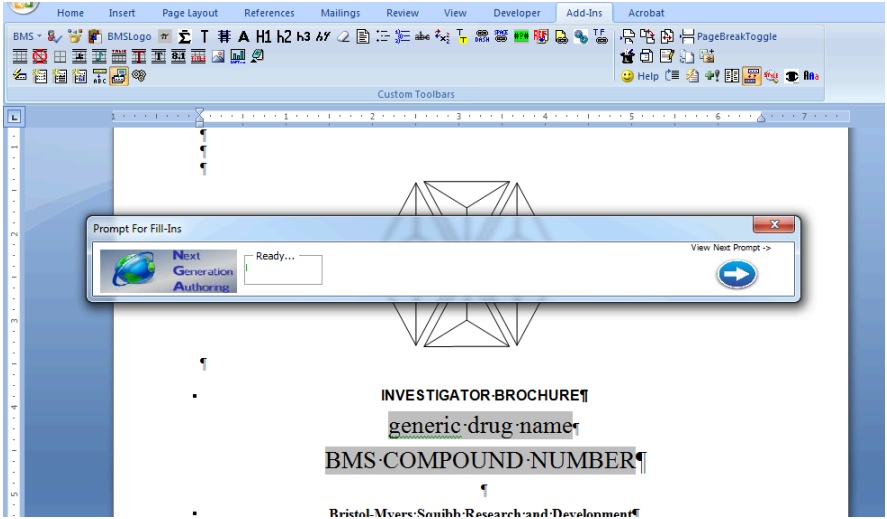
eLearning Storyboard

Module 2: Authoring a Model Document	
Slide	
Screen Title	Working with Text
Screen Text	<p>There are four ways in which text can be entered into a Model Document.</p> <ul style="list-style-type: none">• Prompt for Fill-Ins• “Click here” Fields• Copy and Paste• Typing <p>Click Next to Continue.</p>
Narration	<p>There are four basic ways in which information is entered into a document. Use (1) Prompt for Fill-Ins to enter information, words or phrases that are used repeatedly and that are unique to the type of document being authored. (2) “Click here” fields are used for information that appears in one location. A third method is to (3) copy and paste text directly from a source document into the current document. Finally you can simply (4) type directly into the document being authored. We’ll cover each of these in the next few screens.</p>
Programming Note	
Reviewer Name	
Reviewer Note	

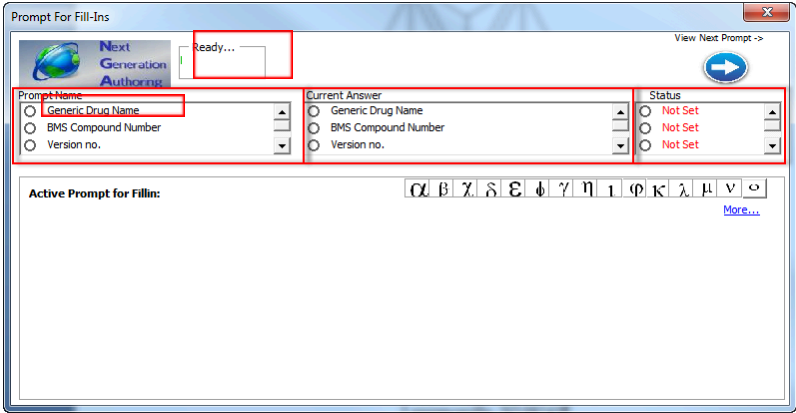
eLearning Storyboard

Module 2: Authoring a Model Document (try it demo)	
Slide	
Screen Title	Prompt for Fill In
Screen Text	 <p>First, let's explore the Prompts for Fill Ins dialog box.</p> <p>Prompt for Fill Ins:</p> <ul style="list-style-type: none"> • Are custom fields unique to the document being authored • Prompt for information words or phrases used repeatedly i.e. BMS Compound Number, Generic Drug Name, Study Number, and Report Date • Saves time and effort <p>Click the Prompt for Fill Ins button to Continue.</p>
Narration	Let's explore the Prompts for Fill Ins dialog box. (1) After opening a document and locating the CoreTemplate Toolbar the first thing that should be done is to run Prompts for Fill Ins. As stated earlier (2) these are fields which are customized based on the type of document being authored. (3) You are prompted to enter words or phrases that are used repeatedly in your document such as BMS Compound Number, Generic Drug Name, Study Number, or Report Date. This (3) saves time and effort by filling in repeated items wherever it appears in the document.
Programming Note	Synch text to audio. Slides 4-12 try it demo. Clicking on Prompt for fill ins button advances slide.
Reviewer Name	
Reviewer Note	

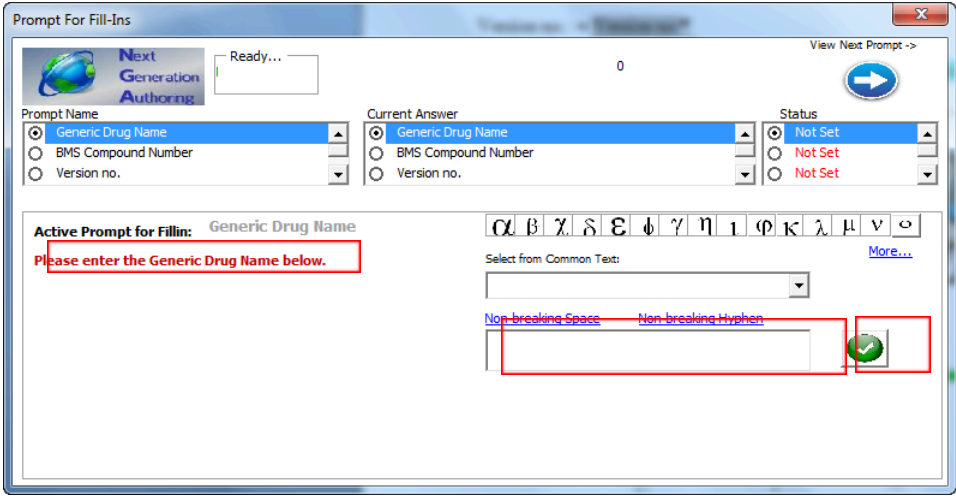
eLearning Storyboard

Module 2: Authoring a Model Document (try it demo)	
Slide	
Screen Title	Prompt for Fill In
Screen Text	 <p>The following window will briefly appear.</p>
Narration	The following window will briefly appear.
Programming Note	
Reviewer Name	
Reviewer Note	

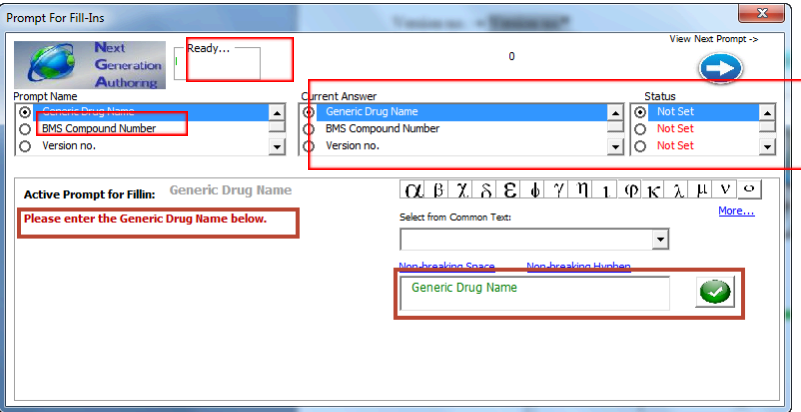
eLearning Storyboard

Module 2: Authoring a Model Document (try it demo)	
Slide	
Screen Title	Prompt for Fill Ins
Screen Text	<p>The Prompt for Fill Ins dialog box opens.</p>  <p>There are four fields.</p> <ul style="list-style-type: none"> • Ready area • Prompt Name • Current Answer • Status <p>Click the Generic Drug Name prompt.</p>
Narration	<p>The Prompt for Fill Ins dialog box opens. You will notice four fields. (1) Prompt Name indicates the type of information required for that field and will vary depending on the document being edited. (2) Current Answer shows the current text for that field. It will either show the default entry or the currently entered text. (3) Status indicates whether or not the sample text has been edited. Not Set means no changes have been made and set indicates a change has been made. (4) Finally, the Ready Area indicates the progress of actions being taken when the user clicks the OK button which will be displayed once a prompt has been selected.</p>
Programming Note	Synch text to audio. Slides 4-12 try it demo. Clicking Generic Drug prompt advances slide.
Reviewer Name	
Reviewer Note	

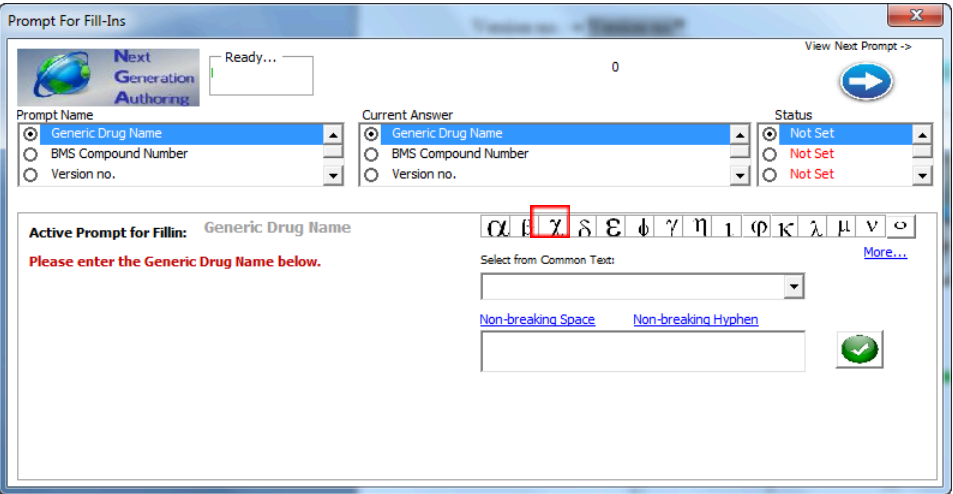
eLearning Storyboard

Module 2: Authoring a Model Document (try it demo)	
Slide	
Screen Title	Prompt for Fill Ins
Screen Text	 <ul style="list-style-type: none"> Type the requested information in the text field <p>Click the next prompt to Continue.</p>
Narration	<p>After Selecting a (1) prompt (2) a text field will appear. You'll also see (3) red text on the left of the dialog box. This text provides guidance as to what should be entered into the text field. Use the Non-breaking Space and Non-breaking Hyphen links directly above the text box to keep text together on one line. After entering the requested text, in this case "Good4U", click the (3) green OK button.</p>
Programming Note	<p>Synch text to audio. Good4u text will be entered without user input. Slides 4-12 try it demo.</p>
Reviewer Name	
Reviewer Note	

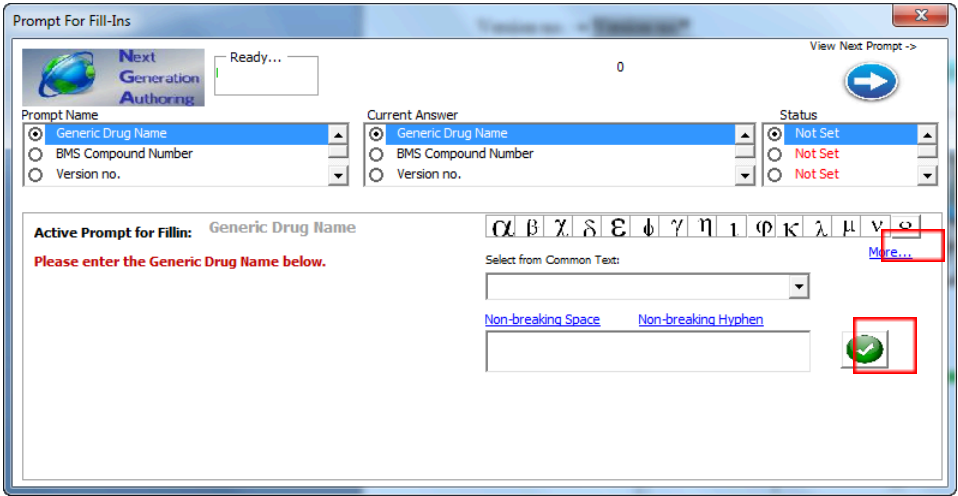
eLearning Storyboard

Module 2: Authoring a Model Document (try it demo)	
Slide	
Screen Title	Prompt for Fill Ins
Screen Text	 <p>After clicking the OK button the CoreTemplate will:</p> <ul style="list-style-type: none"> • Add text to the appropriate fields • The Current Answer column and the Status columns update • Next prompt is selected <p>Click the BMS Compound Number prompt to Continue.</p>
Narration	<p>After clicking the OK button the CoreTemplate will (1) add the entered text into all the appropriate fields in the document. The text in the (2) Current answer column changes to show the entered text and the Status column changes from Not Set, to Set to show that the default text has been changed. The (3) next prompt is also automatically selected. Finally in the (4) Ready area you will see a progress indicator showing the progress of the changes being made.</p>
Programming Note	Synch text to audio. Slides 4-12 try it demo.
Reviewer Name	
Reviewer Note	

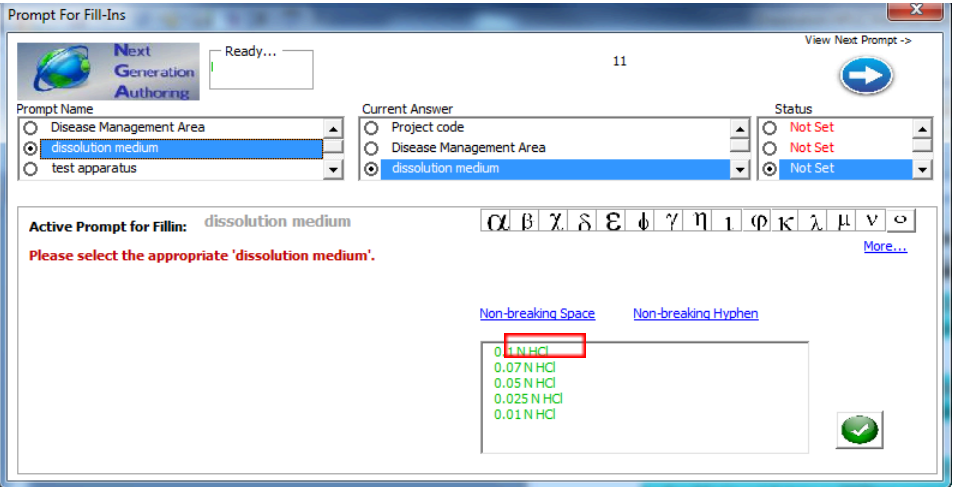
eLearning Storyboard

Module 2: Authoring a Model Document (try it demo)	
Slide	
Screen Title	Prompt for Fill Ins
Screen Text	 <p>To add symbols</p> <ul style="list-style-type: none"> • Click in the text box • Enter text • Click a symbol <p>Click the β symbol to Continue.</p>
Narration	There will be occasions when you will need to add a symbol to a Prompt for Fill_Ins field. After entering your text into the text box select the desired symbol. In this case the beta symbol. The symbol code will automatically be filled in. Later during the authoring process these symbol codes will have to be converted from codes to symbols. This will be discussed in the last module. Click the β symbol to Continue.
Programming Note	Synch text to audio. Slides 4-12 try it demo.
Reviewer Name	
Reviewer Note	

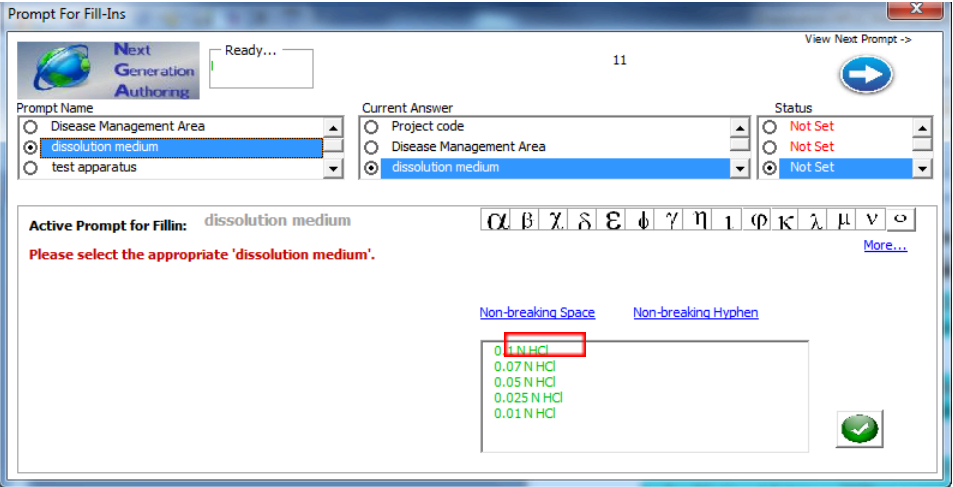
eLearning Storyboard

Module 2: Authoring a Model Document (try it demo)	
Slide	
Screen Title	Prompt for Fill Ins
Screen Text	 <p>Click the More... link for additional symbols.</p> <p>Click Next to Continue.</p>
Narration	If the symbols currently shown don't meet your needs, click the More... link for additional symbols options. Not all prompts involve you typing text into a text field. Sometimes you'll need to select a choice from multiple options.
Programming Note	Synch text to audio. Slides 4-12 try it demo.
Reviewer Name	
Reviewer Note	

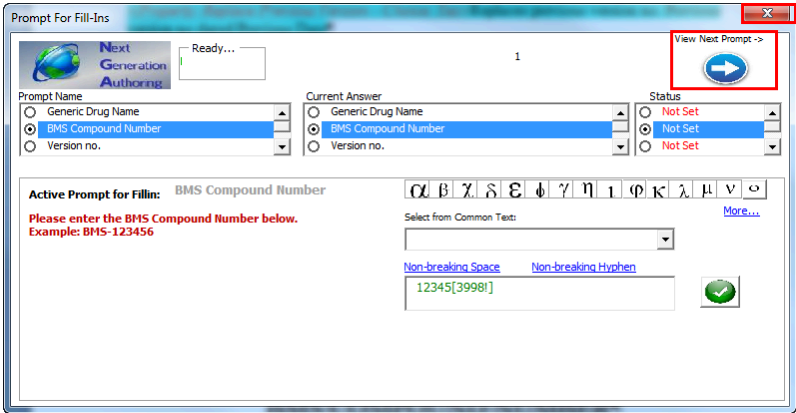
eLearning Storyboard

Module 2: Authoring a Model Document (try it demo)	
Slide	
Screen Title	Prompt for Fill Ins
Screen Text	 <p>Some prompts require selecting a choice from multiple options.</p> <p>Select 0.1 N HCl.</p>
Narration	As mentioned earlier some prompts require you select a choice from multiple options. Select 0.1 NHI from the selection menu.
Programming Note	Synch text to audio. Slides 4-12 try it demo.
Reviewer Name	
Reviewer Note	

eLearning Storyboard

Module 2: Authoring a Model Document (try it demo)	
Slide	
Screen Title	Prompt for Fill Ins
Screen Text	 <ul style="list-style-type: none"> • Add text to the appropriate fields • The Current Answer column and the Status columns update • Next prompt is selected • Hide linked text of the unselected choices which will appear in the document as <i><choice placeholder></i>. <p>Click Next to Continue.</p>
Narration	When the OK is button is clicked, the CoreTemplate will (1) add the selection to the appropriate fields, (2) update the Current Answer and Status columns and (3) select the next prompt. In addition the CoreTemplate will (4) hide linked text of the unselected choices which will appear in the document as <i><choice placeholder></i> .
Programming Note	Synch text to audio. Slides 4-12 try it demo.
Reviewer Name	
Reviewer Note	

eLearning Storyboard

Module 2: Authoring a Model Document (try it demo)	
Slide	
Screen Title	Prompt for Fill Ins
Screen Text	 <ul style="list-style-type: none"> • Click the blue View Next Prompt button to skip a prompt • To complete skipped prompts Re-run the Prompt for Fill-Ins dialog. <p>Click the x in the upper right corner to Continue.</p>
Narration	<p>If you need to skip a prompt, for example you don't have the required information, (1) click the blue View Next Prompt button to move onto the next prompt without entering any text. (2) Skipped prompts can be entered later by re-running the Prompt for Fill-Ins dialog. (3) To close the Prompt for Fill-Ins dialog box click the x in the upper right corner.</p>
Programming Note	<p>Synch text to audio. Slides 4-12 try it demo. At (1) highlight the blue View Next Prompt button. At (4) blink or highlight the x button so users know to click that to continue.</p>
Reviewer Name	
Reviewer Note	

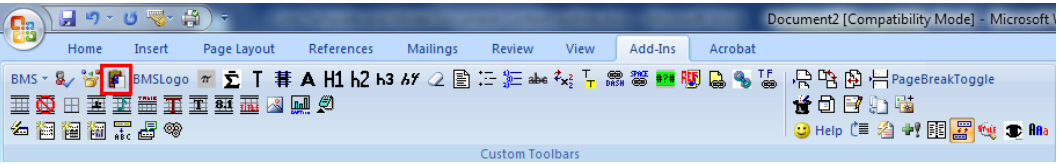
eLearning Storyboard

Module 2: Authoring a Model Document	
Slide	
Screen Title	“Click Here” Fields
Screen Text	<p>Clinical investigation of good4u has been underway in the US and other countries since [Click here to enter text]. Over [Click here to enter number of subjects] subjects has participated in clinical trials, with [Click here to enter #] subjects exposed to good4u.</p> <p>Next let's explore “Click Here” fields.</p> <ul style="list-style-type: none"> • Specific information • Uses existing boilerplate text • Appear as shaded areas with brackets surrounding the shading. <p>To edit a “Click here” field:</p> <ul style="list-style-type: none"> • Click <u>once</u> in the gray area and start typing. • The gray highlighting will be replaced with the newly typed text <p>Click Next to Continue.</p>
Narration	<p>Next let's explore “Click Here” fields. (1) “Click Here” fields are used for specific information that are used for information that appears in one or two locations within a document. (2) They enable an author to enter information into existing boilerplate text. These (3) fields appear as shaded areas with brackets surrounding the shading. Inside the shading are instructions to “Click here to enter” or “Click here”. The instructions will vary and in some cases only the brackets and shading are used based on space limitations.</p> <p>(4) To edit a “Click here” field (5) Click once in the gray area and start typing. If you do double click, close the dialog box that opens. Click the field again and begin typing. (6) Once you begin typing the gray highlighting will disappear and be replaced with the newly typed text.</p>
Programming Note	Synch audio to text.
Reviewer Name	
Reviewer Note	

eLearning Storyboard

Module 2: Authoring a Model Document (demo)	
Slide	
Screen Title	“Click Here” Fields
Screen Text	<p>Let’s watch a demonstration of the “Click here” field.</p> <div><p>Clinical investigation of good4u has been underway in the US and other countries since [Click here to enter text]. Over [Click here to enter number of subjects] subjects has participated in clinical trials, with [Click here to enter #] subjects exposed to good4u.</p></div>
Narration	<p>(1) Let’s watch a demonstration of the “Click here” field. (2) Click in the highlighted field. (3) Type the requested text, in this case the number of subjects which is 15. Notice that the (4) gray highlighting is replaced with the newly typed text.</p>
Programming Note	Demonstration.
Reviewer Name	
Reviewer Note	

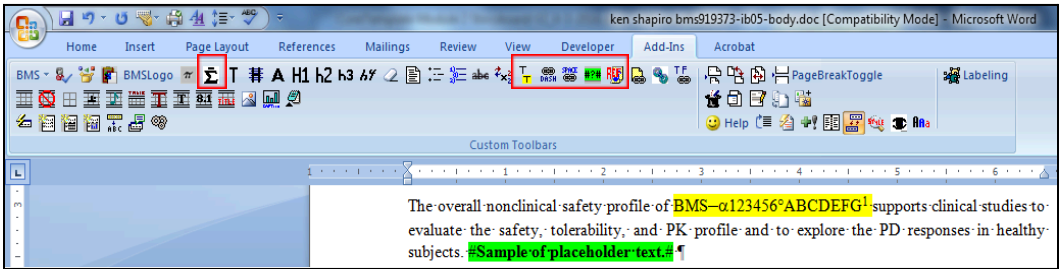
eLearning Storyboard

Module 2: Authoring a Model Document	
Slide	
Screen Title	Copy and Paste
Screen Text	 <p>The third method is copy and paste.</p> <p>The Paste Special Unformatted Text button</p> <ul style="list-style-type: none"> • Deletes unnecessary background coding • Cannot be used with Tables • References and cross references must be recreated <p>NOTE: Always quality check text pasted into Model Document to make sure appropriate styles, formatting and symbols are used.</p> <p>Click here to see a comparison of text copied from a source document into a Model Document.</p> <p>Click Next to Continue.</p>
Narration	<p>The third method we'll explore is to copy and paste text from another document and paste it into your working document. Select your text from a separate document and use the Paste Special Unformatted Text button to paste that text into your working document. (1) Use of this button will delete unnecessary background information from the source document. (2) The unnecessary background information can cause CoreTemplate documents to fail during publishing or submission. (4) This tool cannot copy tables or references. There is a separate tool for tables. (5) References and cross references also cannot be copied and must be recreated in the working document.</p> <p>(6) NOTE: Always quality check text pasted into Model Document to make sure appropriate styles, formatting and symbols are used.</p>
Programming Note	<p>Synch audio to text.</p> <p>Create an optional pop up to allow users to see original text next to copied text using the Paste Special Unformatted button.</p>
Reviewer Name	
Reviewer Note	

eLearning Storyboard

Module 2: Authoring a Model Document (pop-up)							
Slide							
Screen Title	Side by Side comparison (Optional)						
Screen Text	<p>Source text</p> <div> <p>Lorem ipsum dolor sit amet, consectetur adipiscing elit. Maecenas porttitor congue massa. Fusce posuere, magna sed pulvinar ultricies, purus lectus malesuada libero, sit amet commodo magna eros quis urna.ⁱ</p> <p>Nunc viverra imperdiet enim. Fusce est. Vivamus a tellus.</p> <p>Pellentesque habitant morbi tristique senectus et netus et malesuada fames ac turpis egestas. Proin pharetra nonummy pede. Mauris et orci.ⁱⁱ</p> <p>ⁱsample endnote</p> <p>ⁱⁱsample endnote</p> </div> <p>Copied into Model Document</p> <table> <tr> <td>BMS Body Text</td><td>Lorem ipsum dolor sit amet, consectetur adipiscing elit. Maecenas porttitor congue massa. Fusce posuere, magna sed pulvinar ultricies, purus lectus malesuada libero, sit amet commodo magna eros quis urna. ¶</td></tr> <tr> <td>BMS Body Text</td><td>Nunc viverra imperdiet enim. Fusce est. Vivamus a tellus. ¶</td></tr> <tr> <td>BMS Body Text</td><td>Pellentesque habitant morbi tristique senectus et netus et malesuada fames ac turpis egestas. Proin pharetra nonummy pede. Mauris et orci. ¶</td></tr> </table>	BMS Body Text	Lorem ipsum dolor sit amet, consectetur adipiscing elit. Maecenas porttitor congue massa. Fusce posuere, magna sed pulvinar ultricies, purus lectus malesuada libero, sit amet commodo magna eros quis urna. ¶	BMS Body Text	Nunc viverra imperdiet enim. Fusce est. Vivamus a tellus. ¶	BMS Body Text	Pellentesque habitant morbi tristique senectus et netus et malesuada fames ac turpis egestas. Proin pharetra nonummy pede. Mauris et orci. ¶
BMS Body Text	Lorem ipsum dolor sit amet, consectetur adipiscing elit. Maecenas porttitor congue massa. Fusce posuere, magna sed pulvinar ultricies, purus lectus malesuada libero, sit amet commodo magna eros quis urna. ¶						
BMS Body Text	Nunc viverra imperdiet enim. Fusce est. Vivamus a tellus. ¶						
BMS Body Text	Pellentesque habitant morbi tristique senectus et netus et malesuada fames ac turpis egestas. Proin pharetra nonummy pede. Mauris et orci. ¶						
Narration							
Programming Note	Optional Pop up window						
Reviewer Name							
Reviewer Note							

eLearning Storyboard

Module 2: Authoring a Model Document	
Slide	
Screen Title	Typing Text
Screen Text	<p>Typing text</p> <ul style="list-style-type: none"> Place the cursor anywhere in the document Begin typing  <p>The text shown contains examples of:</p> <ul style="list-style-type: none"> Symbol Highlight text toggle Non-Breaking hyphen Non-Breaking space Superscript/Subscript Placeholder <p>Click Next to Continue.</p>
Narration	<p>The fourth and perhaps most basic method is typing text directly into the document. (1) Place your cursor anywhere in the document and begin (2) typing as you would in any MS Word document. The text shown here contains a few examples of tools that allow you to add things other than text to a document. Let's go through each of these elements one at a time. (3) The Symbols button inserts a symbol at the cursor location. Unlike with Prompt for Fill-Ins these symbols do not need to be converted. (4) The Highlight text toggle button toggles a yellow highlight over selected text. Use this if you want to draw attention to a statement during a review. To keep words or phrases together use (5) The Non-Breaking Hyphen, which looks like a long dash or (6) Non-Breaking Spaces which are shown as a hollow super scripted circle. (7) The Superscript/Subscript toggle button switches selected text between super and subscript. (8) The Placeholder button highlights selected text in green to indicate the text is only a placeholder and will be replaced at a later time. You can only highlight up to 50 characters at a time with this tool. (9) For more information please refer to the job aid xxx on the learning center. Now that we've explored entering text and other elements into a document let's discuss the instruction text that authors rely on to know what type of information to enter into a document.</p>
Programming Note	Synch audio to text.
Reviewer Name	
Reviewer Note	

eLearning Storyboard

Module 2: Authoring a Model Document	
Slide	
Screen Title	Understanding Instruction Text
Screen Text	<p>BMS Instruction Text is <i>red, italicized text with a dotted underline</i>.</p> <ul style="list-style-type: none"> Guidelines to what content to add Responsible department or group for a Whether a section is optional Guidance on the most appropriate phrasing <p>Guidance for Instruction Text:</p> <ul style="list-style-type: none"> Can be printed Must be removed before final submission <p>For more information please refer to the job aid</p> <p>Click Next to Continue.</p>
Narration	<p>Instruction Text within Model Documents provides guidance to authors on what information should be entered in the various sections of a model document. (1) BMS Instruction Text appears as <i>red, italicized text with a dotted underline</i>. It provides (2) Guidelines as to the content required for a particular section within a document. Such information includes (3) The department or group that is responsible for documenting a certain topic, (4) Whether a section is optional and help (5) in choosing the most appropriate phrasing. (8) Instruction text can be printed if the correct MS Word options are selected. Finally, it (7) must be removed before final submission using the BMS QA Tools which will be covered in the last module of this course. (9) For more information please refer to the job aid xxx on the learning center.</p>
Programming Note	Synch audio to text
Reviewer Name	
Reviewer Note	

Investigator Signature →

Example tables 4.2.6-1 and 4.2.6-2 may be appropriate for an early development program, while for a program with available clinical pharmacokinetic data, Table 4.2.6-3, including only the most relevant data, may be appropriate. ¶

Table 4.2.6-3: → Summary of Pharmacokinetic Parameters of XXXX in XXXX Species ¶

Species	Route	Dose ^a (mg/kg)	Area ^a (ng·h/mL)	CL ^a (mL/min/kg)	T _{1/2} (h)	CL ^a (mL/min/kg)	T _{1/2} (h)	CL ^a (mL/min/kg)	T _{1/2} (h)
Human	Oral	100	100	100	100	100	100	100	100
Human	Oral	100	100	100	100	100	100	100	100
Human	Oral	100	100	100	100	100	100	100	100

¶

4.3 → Nonclinical Toxicology ¶

Detailed summary tables should not be used in the nonclinical toxicology section. Rather, each section should use text from the appropriate section of the Toxicology Written Summary (TWS). In addition to the text from the TWS, a short summary table should precede the text in Table 4.3-1. Table 4.3-1 is an abbreviated version of Table 2.6-1 from the Toxicology Tabulated Summary. Please see the example introductions text below. The table format in Table 4.3 should NOT be changed. ¶

This format is particularly applicable to initial 1b and early stage 1b studies. The level of detail of this section will evolve during the life of a program, with more study-specific details at the early stage of the compound development and more of a higher-level, integrated summary for late stage studies. ¶ Thus, as the need for a detailed toxicology summary becomes less prominent, the need for Table 4.3-1 will diminish as well. When this occurs, it will have to be made as a one-to-one basis with the team. ¶

A battery of nonclinical studies, including (list type of toxicology studies here, eg, single-dose toxicity, repeat-dose toxicity, genotoxicity, safety pharmacology), have been completed to assess the potential toxicologic profile of Error! Unknown document property: name. The scope of the toxicologic evaluation for Error! Unknown document property: name, as outlined in Table 4.3-1, supports its proposed clinical testing in a Phase I study in humans. ¶

Table 4.3-1: → Toxicology Studies ¶

Type of Study ^a Species and Strain ^a	Method of ^a Administration ^a	Dose ^a (mg/kg/day)	Dose ^a (mg/kg/day)	GLP ^a Compliance ^a	Study No. ^a Duration ^a Concomitant Treatments ^a
Single-dose Toxicity ^a	0	0	0	0	0
Human	Human	Human	Human	Human	Human

→

eLearning Storyboard

Module 2: Authoring a Model Document	
Slide	
Screen Title	Instruction Text
Screen Text	<p>Instruction Text Guidelines</p> <ul style="list-style-type: none"> Do not try to alter the instruction text Keep Paragraph marks turned on Before a document can be submission ready ALL Instruction Text must be deleted Use the Clear Formats button if you have typed text into an area with Instruction Text <p>Next, let's explore styles, formatting and working with tables and figures.</p> <p>Click Next to Continue.</p>
Narration	<p>Some additional guidelines to keep in mind about Instruction text. (1) Do not try to alter the instruction text in any way. It is there to provide guidance to you as an author. Any text added will get deleted when the instruction text is removed from the document at the conclusion of the authoring process. (2) It is recommended that you keep paragraph marks turned on. This will help to make sure you are working outside the Instruction Text boundaries. All instruction text (3) must be deleted before the document can be submission ready. Deleting Instruction Text will be covered in the Document Clean up module. If you do find that you've typed text into an area with instruction text and you don't want to move it, use the Clear Formatting button to clear the current instructional text formatting and replace it with another style. The Clear Formatting button will be demonstrated in the next module. (4) Now that we've learned about entering text into a Model Document the next module will cover styles, formatting, tables, and figures.</p>
Programming Note	
Reviewer Name	
Reviewer Note	

Investigator Section 4.3
Nonclinical Toxicology

Example tables 4.2.6-1 and 4.2.6-2 may be appropriate for an early development program, while for a program with available clinical pharmacokinetic data, Table 4.2.6-3, including only the most relevant data, may be appropriate.

Table 4.2.6-3: Summary of Pharmacokinetic Parameters of XXX in XXX Species

Species	Dose ^a (mg/kg)	C _{max} ^a (ng/mL)	AUC _{0-∞} ^a (h·ng/mL)	T _{1/2} ^a (h)	CL _{CR} ^a (mL/min/kg)	C _{ss} ^a (ng/mL)	Ex ^a (%)
Human	100	100	100	100	100	100	100
Mouse	100	100	100	100	100	100	100
Rat	100	100	100	100	100	100	100

4.3 Nonclinical Toxicology

Detailed summary tables should not be used in the nonclinical toxicology section. Rather, each section should be derived from the appropriate section of the Toxicology Written Summary (TWS). In addition to the nonclinical TWS, a clear summary table should precede the non-clinical Table 4.3-1. Table 4.3-1 is an abbreviated version of Table 2.6.1.1 from the Toxicology Tabulated Summary. Please see the example introductory text below. The table format in Table 4.3-1 should NOT be changed.

This format in particular applies to initial IBs and early stage IB updates. The level of detail of this section will evolve during the life of a program. With more study-specific details on the early stage of the compound development and more of a higher-level integrated summary for later time points. Thus, as the need for a detailed toxicology summary becomes less important, the need for Table 4.3-1 will diminish as well. When this point occurs, it will have to be made on a case-by-case basis with the team.

A battery of nonclinical studies, including [list type of toxicology studies here, eg, single-dose toxicity, repeat-dose toxicity, genotoxicity, safety pharmacology], have been completed to assess the potential toxicologic profile of **XXXXXX**. The scope of the toxicologic evaluation for **XXXXXX**, as outlined in **XXXXXX**, supports its proposed clinical testing in a Phase 1 study in humans.

Table 4.3-1: Toxicology Studies

Type of Study ^a Species and Strain	Method of Admin ^a or Route	Dose ^a (mg/kg/day)	GLP ^a Compliance	Study No. ^a Description/Control Number
Single-dose Toxicity	□	□	□	□
Repeat-dose Toxicity	□	□	□	□