# AutoIND April 2025 Release Notes

New Template Engine Enhanced Data Room

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# **New Template Engine**

Working with templates to craft regulatory documents is now faster, easier, & more flexible!

Previously, the workflow to get from editing an AI Template to the generated content output was lengthy and disconnected. Now the platform includes a unified Editor with a convenient toggle between the Content view and the Template view. Any edits to the AI Template can be immediately used to generate content in targeted sections of a document and rapidly iterated on. You are now given the option to generate new content that either *replaces* or gets *inserted below* existing content.

#### **Combined Template and Document Editing**

It is now even easier to see and control the connection between the template prompts, source inputs, and the content that will be generated from them. The Editor page conveniently includes buttons to toggle between the Template view and the Content view. Changes made to the template, once saved, will be automatically reflected in the Content view.



Additionally, instead of separate templates for each section (e.g. Section 2.6.6.2 Single-Dose Toxicity) now every document across the eCTD (e.g. Section 2.6.6) has a single template, which ensures a consistent experience across the dossier.

Note: Within any individual program, the main navigational elements are now Data Room, Dossier, and Editor.

#### Generate Documents in Entirety, or Just Individual Parts

Users now have greater control over which parts of a document are generated, with both initial and subsequent generations. Generation of documents can be initiated in multiple places:

1. On the Dossier page, any document that can be generated will have a "Generate" button that will initiate generation of all document sections that have requisite source data.

CME CORP 👌 DATA ROOM DOSSIER EDITOR				🚯 АСМЕ С
Name 🐨	Updated	Status 🕕 🍷	Actions	
Module 1 Administrative Information				
▼ 🖻 Module 2 Summaries				
2.2 Introduction to Summary	05 May 2025	To Do	View ···	
2.3 Quality Overall Summary	05 May 2025	To Do	View ···	
2.4 Nonclinical Overview	05 May 2025	To Do	Generate ····	
2.5 Clinical overview	05 May 2025	To Do	Generate	

2. When viewing a document on the Content tab in the Editor, clicking "D Generate all content" will initiate generation of all sections of the document that can be generated.



3. When viewing a document's Template tab in the Editor, clicking the icon next to any prompt block will open a popup containing the source files that will be used to generate just that section of the document.



Note: In addition to files automatically included in the generation popup based on data tags, any file in the data room can be used for generation of individual prompt blocks.

#### Either Replace or Add Beneath Existing Content

After initially drafting content, users can now choose to incorporate additional generated content in different ways. Generation output can *replace* content that already exists in that content block, or users can choose to *add* the new generated content beneath the existing content.

GENERATE		$\times$
2.6.6 Toxicology written summary		
Source content		
The content below will be used to generate this content block.		
$\fbox{13F-SFA\_single\_tox.pdf}$ $\times$ <code>Search</code> files, data tags, and sections		
For this section, you may need content with the following data tags: single-dose-toxicity		
Regeneration settings		
For content that has already been generated:		
Replace existing content     Add new content beneath existing content		
Go to Data Room	Close Generate	

#### AI Template Prompts Applied to All Files or Each File Individually

For each prompt block in Al Templates, the specific prompts can be applied to all source files included in the generation popup or, by adding **\$each-file** to the top of the prompt block will apply the prompts to each file *individually*. This gives users control as to which studies they want to summarize collectively vs those for which they want to summarize separately.



# General Purpose Document for Making any Document from a Template

In addition to drafting documents within the eCTD structure, the platform now includes a general purpose document with its own template that can be used to create and generate any structured document from a template. This document uses data from the source files already in the Data Room, and is a great opportunity to experience the power of AI Template-driven document creation.

Dossier Detailed Status Additional Documents				
Name 📱	Updated	Status 🕕 🍷	Actions	
🖹 x.x.x General Purpose Document		To Do	Generate	
				C Open Template

# **<u>Click to watch "Working with Templates" video</u>**

### **Enhanced Data Room**

Got questions about your data? Can't find that file you know you have? Data Room now supports question and answer workflows to quickly search and find the relevant files, as well as generate a response. For example, Health Authority Questions can be addressed in a timely and accurate manner along with a draft response created. Additionally, folders can now be selected for batch upload of all contained files while reflecting the same folder structure.

#### Folder uploads

Folders can now be directly uploaded into the Data Room! All PDF files and folders within the selected folder will be automatically uploaded and any folder structures will be maintained. Users can now quickly batch upload multiple folders and files, keeping their Data Room organized with no additional manual work.

UPLOAD	×
Select files or folders to g	get started.
/	
6~	ì
Drag files or folders to	this area to upload.
Select files	Select folders
Supported file	types: PDF
Recommended individua	l file limit: 1,500 pages
Folder structures w	ill be maintained
	Cancel Upload

#### Searching files in the Data Room

Introducing a search bar at the top of the Files tab! Users can easily find their files and folders of interest via two different search methods - keyword search or Deep search.

#### Keyword search

The default search method, keyword search matches on words or phrases entered against file names, folder names, data tags, and metadata fields of all files in the Data Room.

\$∿∙	WEAVE-123 🗘	DATA ROOM DOSSIER EDITOR	🐼 Weave Platform, Inc.				
	Data Room						
	Overview Files Ask		New folder				
	Q Search for name, data tags, or metadata info Deep search						
	Home						
	Name	🗑   🥏 🛛 Data Tags	T Date Added T Status T Actions				
	🗋 🗋 m1		Mar 26, 2025 Ready Open				
	🗋 🗋 m2		Mar 26, 2025 Ready Open				
	🗌 🗋 m3	-	Mar 26, 2025 Ready Open				
	🗆 🗅 m4		Mar 26, 2025 Ready Open				

Once a search query is entered and submitted, keyword search results will populate with matching words or phrases in the Name and Data Tags column in bold.

WEAVE-123 🗘 DATA ROOM DOSSIE	R EDITOR		🐼 Weave I
Data Room			New folder
Q product			8 Deep search   >
Search results			
□ Name	Tags	Location	T Actions
product		i forms	Open
125742_S2_M2_drug- <b>product</b> -description-com.	Dosage and administration & Drug <b>product</b> &	• 🗅 m2	Preview
125742_S2_M2_drug- <b>product</b> -stability.pdf	Drug stability Ø Drug composition +1	🗋 m2	Preview
125742_S55_M2_drug- <b>product</b> -stability.pdf	Drug stability & Drug <b>product</b> &	🗋 m2	Preview
125742_S2_M2_drug- <b>product</b> -reference-stand-	Analytical method +2	🗋 m2	Preview
125742_S2_M2_introduction.pdf	Local tolerance Drug <b>product</b>	🗀 m2	Preview
125742_S55_M2_introduction.pdf	Drug stability & Drug <b>product</b> &	🗋 m2	Preview
□ [} 125742_S11_M3_32r_fc3184-coa.pdf	Batch analysis Ø Drug <b>product</b> Ø	🗋 m3	Preview

#### **Deep search**

When a search query is more complex or keyword search isn't providing relevant results, Deep search becomes the preferred method. With the Deep search toggle on, all the files in the Data Room will be searched semantically - understand the meaning and intent behind a user's query, rather than matching on words.

•	WEAVE-123 🗘 DAT.	A ROOM DOSSIER EDITOR	Weave Platform
	Data Room		
	Overview Files Ask		New folder
	Q Search for name, data tag	gs, or metadata info	Deep search 🕥 🍥
	Home		
	Name Name	🐨 🛛 🥏 🛛 Data Tags	The Added The Status The Actions
	🗋 🗋 m1	-	Mar 26, 2025 Ready Open
	🗋 🗋 m2	**	Mar 26, 2025 Ready Open
	🗋 🗋 m3		Mar 26, 2025 Ready Open

Deep search results contain a Relevance column generated by AI that shows the percent match as well as an explanation for why each search result is relevant to the search query.

WEAV	VE-123 🗘	DATA ROOM	DOSSIER EDITOR		🐼 Weave
D	ata Roor	n			
Ove	rview Files A	Ask		New folder	上 Upload
Q	information reques	sts from the FDA re	lated to manufacturing		
Cle	ear search			Deeps	search 🂽 🔶
Sear	ch results				
	Name	Ξ	Relevance (generated with Al)	Location T	Actions
	125742_S53_N	/1_response-13au	75% match: Contains information about FDA information requests related t	responses	Inspect
	125742_S7_M1	I_response-08jun	69% match: Contains responses to FDA requests for information	responses	Inspect
	125742_S9_M	1_response-29jun	69% match: Contains responses to FDA requests for information	responses	Inspect
	125742_S16_M	11_response-15jul	69% match: Contains responses to FDA requests for information	responses	Inspect
	3125742_S10_M	11_response-25ju	69% match: Contains responses to FDA requests for information	responses	Inspect
	125742_S13_M	11_response-06ju	69% match: Contains responses to FDA requests for information	responses	Inspect

Clicking "Inspect" or the Relevance explanation will open an adjustable sidebar preview of the file, automatically scrolled to the relevant page, so users can quickly preview and decide whether that is the file they're searching for.

<b>%</b> ••	WEAVE-123  C DATA ROOM DOSSIER EDITOR	125742_S53_M1_response- 13aug2021.pdf	< > Q 🕀 ±
		Page 20 of 20	
	Data Room	COVID-19 Vaccine (INT162, 197-67302048) BLA 1257420 Response 13 Aug 2021 FDA quarties – Drug Product (Pfiner P SUPPORTING DOCUMENTATION New or Replaced Supporting Documentation	sury and Kalamazoo)
	Overview Files Ask	None	
	_	Previously submitted supporting documentation Response to FDA 26 July 2021 Information Request R Equipment, Query 15 (STN 125742.0/25 submitted 30	legarding Manufacturing and Jul 2021)
	${\rm Q}_{\rm c}$ information requests from the FDA related to manufacturing	A.1 Cleaning Validation Summary (Puurs)	
	Clear search		
	Search results	(TM	
	□ Name The Relevance (generated with AI)	20:29 (C	
	Image: 125742_S53_M1_response-13a         75% match: Contains responses	ug-2021	
	Image:	4 On: 17-4	
	Image:	Approvec	
	Image:	Approved	
	Image:	7d5b557v	
	125742_S13_M1_response-06j      69% match: Contains responses	0177e19	
	125742_S54_M1_response-16a 69% match: Contains responses	8 PFIZER CONFIDENT Page 20	TAL FDA-CBER-2021-5683-1149637

Users can select any files and choose the "Ask a question" action for additional open-ended exploration, which will automatically populate the file selector in the Ask tab.

<b>%</b> •	WEAVE-123 🗘 DATA ROOM DO	DSSIER	EDITOR			Weave Platform, Inc.
	Data Room					
	Overview Files Ask				New folder	土 Upload
	Q Search for name, data tags, or metadata ir				Deep s	earch 🔘 🛞
	Home / m1 / responses	()	Are you sure you want to send the files to Ask?	ese		
	Name T		Ask feature would use these files to create a	a dded 🐨	Status 📱	Actions
	✓ 125742_S52_M1_response-13aug2021		new question.	6, 2025	Ready	Preview
	2 125742_S25_M1_response-26jul2021		No	es 6, 2025	Ready	Preview
	125742_S77_M1_response-21aug2021	0	Postmarketing data ۶	Mar 26, 2025	Ready	Preview
	125742_S12_M1_13jul2021-response.p	۲	Container closure & +1	Mar 26, 2025	Ready	Preview
	125742_S27_M1_response-29jul2021	۲	Clinical safety Ø	Mar 26, 2025	Ready	Preview
	125742_S11_M1_response-25jun2021	۲	Reference standards Ø +1	Mar 26, 2025	Ready	Preview

₩EAVE-123 û DAT	A ROOM DC	SSIER EDITOR	Weave Platform, Inc.
Data Room			L Upload
ALL QUESTIONS	+	NEW QUESTION	
Q Search		Enter your question here	Revert
Question #3			
Question #2	:		
Question #1		125742_S52_M1_response-13aug2021.pdf ×)         125742_S25_M1_response-26jul2021.pdf ×)         Search files and data tags	
		Response	

#### Ask multiple questions

Previously known as the Explore tab, responses and questions are now automatically saved on the left in the newly-named Ask tab! Users are able to create multiple questions in the Ask tab, as well as go back and pick up where they left off with a previous question by editing and resubmitting.

Data Room								
Overview Files Ask								d I
ALL QUESTIONS	+	QUESTION #3	3					)
Q Search		Question					E	dit question ename questio
Question #3	:	Create a table of all studies, with columns for study number, study type, treatment duration, dose, species, and adverse events Delete						
Question #2	:	Perpense						
Question #1		in a grant a gr						J
		Study Number	Study Type	Treatment Duration	Dose (mg/kg)	Species	Adverse Events	
		1458/0061	Acute Oral Toxicity	14 days	2000	Female Sprague- Dawley Rat	None observed	
		Note: Data extracted from ().						
		References						
		1 13F-SFA_single_tox.pdf						
		7 This have is an experimental feature so responses may be incomplete or contain errors						

Questions can also be renamed or deleted. Responses can be copied to the clipboard (recommended for text) or still exported to Word like before (recommended for tables). References are new and now included with every response, along with the ability to download the referenced source file.

# New, Improved, Fixed

#### New

- Updated platform naming:
  - $\circ$  "IND Manager" page  $\rightarrow$  now called "Dossier"
  - "Document Editor" page  $\rightarrow$  now called "Editor"
  - "INDs" → now called "Programs"
- Folder uploads in the Data Room
  - Folder uploads via drag or select
  - Folder structures are maintained
- Files tab in the Data Room
  - Search bar with toggle between keyword search and Deep search
  - Keyword search results bolded to show matching terms
  - Deep search Al-generated relevance percent and explanation
  - Deep search auto-scroll to the relevant page on inspect
  - o Send any file to auto-populate file selector in the Ask tab
  - Pagination of files
- Ask tab in the Data Room (previously known as Explore)
  - Auto-save of questions and responses
  - Creation of multiple questions
  - Edit, rename, delete existing questions
  - Copy to clipboard for responses
  - Source file references for every response
  - Download source files individually

#### Improved

- Comments indicator on Review panel icon
- "Reset Document" in the Editor ... menu will remove the document content, restoring it back to the default state from the template
- A more distinct and performant table grid in the Files tab
- Move folders with nested folders within maintains folder structure
- Cancel all processing of files and folders in one click

#### Fixed

• Data tag search no longer requires hyphen for multi-word data tags

# Click to watch "Enhanced Data Room" video