

# Release Notes

## November 2025

HAQ Manager

Suggested Changes Functionality

Complex Tables from Examples

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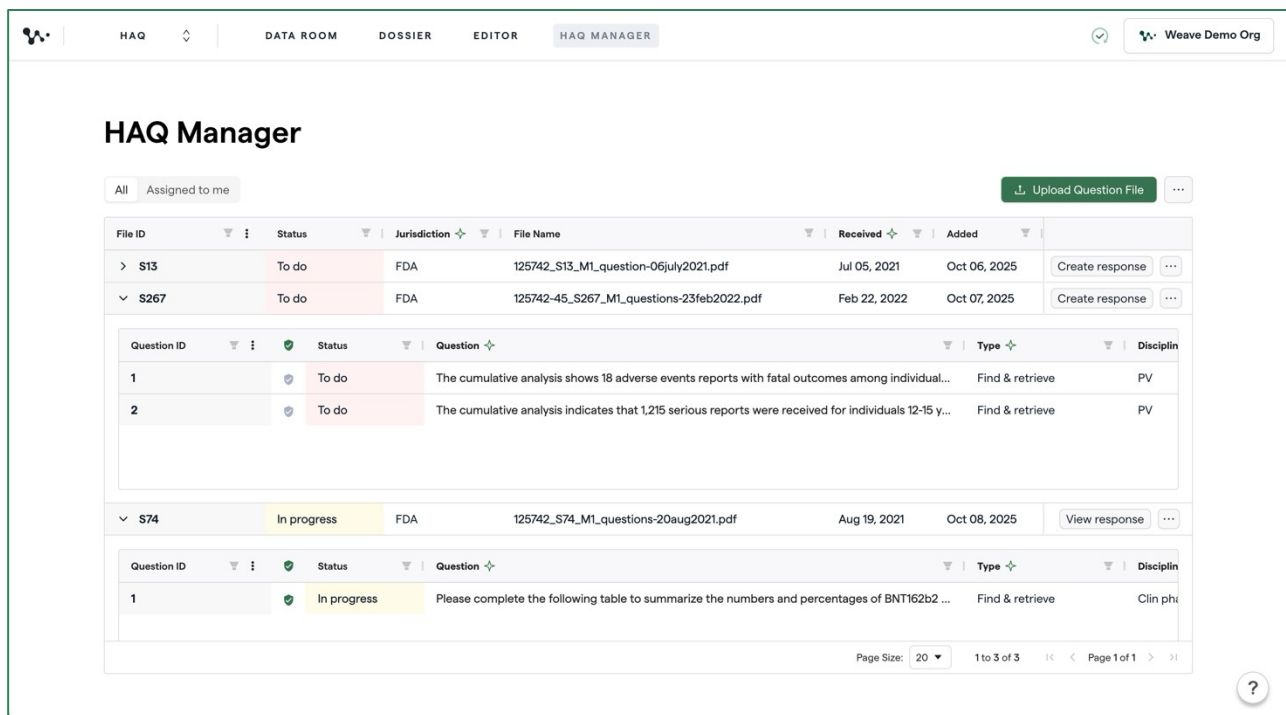
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# HAQ Manager: Respond Quickly and Confidently

A typical program can receive hundreds of HAQs, some arriving unexpectedly, and with response times as fast as just 24 hours. Weave’s HAQ Manager automates and simplifies question management as well as generates a draft response in a matter of minutes.

## Manage global HAQs in one central place

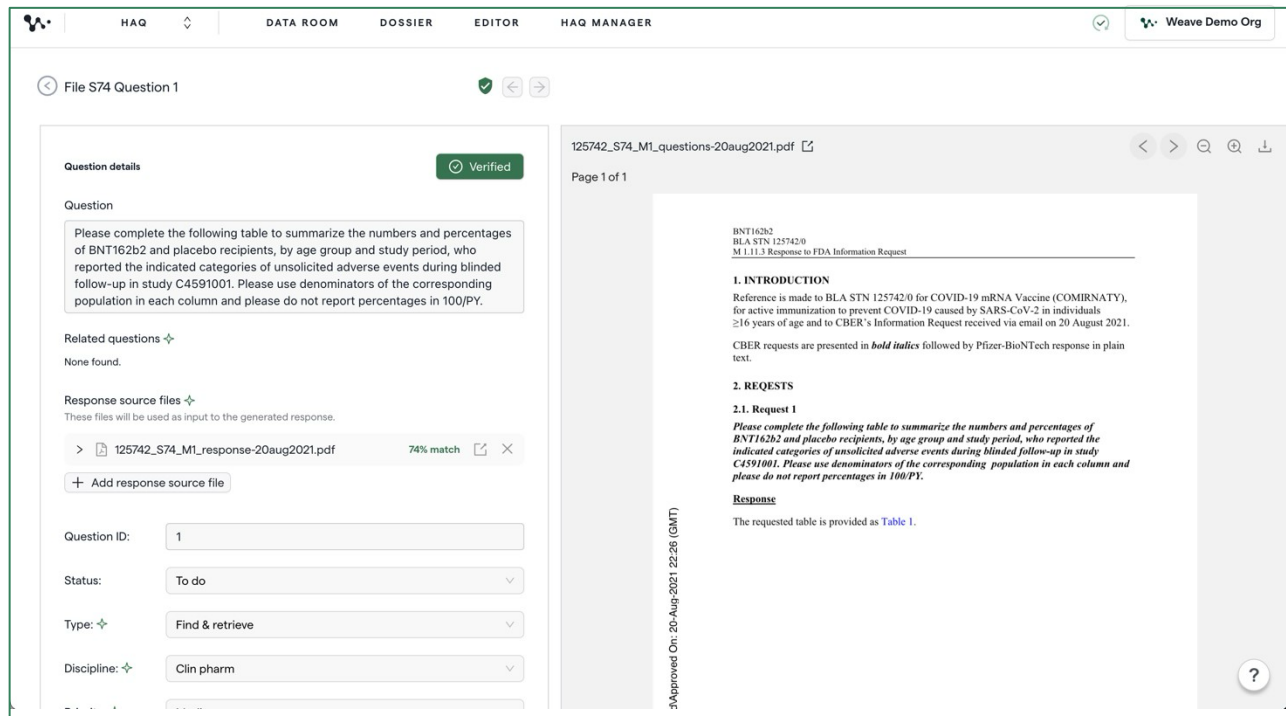
After uploading the question file from the health authority (in either .pdf or .docx format), Weave AI will auto-populate HAQ Manager with individually extracted questions as well as categorized metadata. This not only saves time from traditional copy and paste into a spreadsheet but prevents manual errors.



Weave AI has been shown to extract questions at 96% precision and 97% recall when tested across example question files from FDA and EMA.

## Verify and collaborate across teams

The expanded preview enables easy and fast side-by-side comparison of question details to the original question file, including any related questions. HAQ Manager automatically finds any relevant source files from the Data Room that could be used to answer each question. Team members can then be assigned to each question so the correct SMEs can already get a head start on the responses!



## Draft a response in the matter of minutes

A structured response document is created in Weave in section 1.11 where each question is repeated verbatim with a corresponding response block below. Weave AI can generate a first draft response to each question in seconds, whether it’s narrative, tabular or other structured content.

**Response to S74** Submit for review

Content Template Generate all content Fill variables

**RESPONSE TO S74**

**1 Question #1**

Please complete the following table to summarize the numbers and percentages of BNT162b2 and placebo recipients, by age group and study period, who reported the indicated categories of unsolicited adverse events during blinded follow-up in study C4591001. Please use denominators of the corresponding population in each column and please do not report percentages in 100/PY.

**Response:**

**Table 1: Summary of Unsolicited Adverse Events Reported by BNT162b2 and Placebo Recipients by Age Group and Study Period (Study C4591001, Blinded Follow-up)**

Adverse Event Category	BNT162b2 (30 µg) ≥16-55 Years (N=12,995) n (%)	BNT162b2 (30 µg) >55 Years (N=8,931) n (%)	BNT162b2 (30 µg) Total (N=21,926) n (%)	Placebo ≥16-55 Years (N=13,026) n (%)	Placebo >55 Years (N=8,895) n (%)	Placebo Total (N=21,921) n (%)
<b>From Dose 1 through 1 Month after Dose 2</b>						
Any unsolicited adverse event	4,233 (32.6)	2,384 (26.7)	6,617 (30.2)	1,871 (14.4)	1,177 (13.2)	3,048 (13.9)
Unsolicited non-serious adverse events	4,207 (32.4)	2,350 (26.3)	6,557 (29.9)	1,855 (14.2)	1,141 (12.8)	2,996 (13.7)
Serious adverse events	52 (0.4)	75 (0.8)	127 (0.6)	49 (0.4)	67 (0.8)	116 (0.5)
Withdrawal due to	19 (0.1)	13 (0.1)	32 (0.1)	20 (0.2)	16 (0.2)	36 (0.2)

From here, various tools exist to quickly iterate and finalize responses:

- Trace every answer to its source using Sources
- Refine the first draft with AI’s help in Refinement or Templates
- Add comments or run auto-data verification
- Export to .docx for final submission

# Suggested Changes Functionality

Suggesting Mode gives you full visibility into every text change. Review, track, and act on team suggestions with complete transparency.

## Suggest edits in redline format

Redlined edits give you instant visibility, with every suggestion captured in the Suggestions panel.

### 2.6.6 Toxicology written summary 🗨 Suggesting

**Content** | Template | Generate all content | Fill variables

#### 2.6.6.2 Single-Dose Toxicity

##### 2.6.6.2.1 13F-SFA-MONOMER: Acute Oral Toxicity in the Rat – Fixed Dose Method

Acute oral toxicity of 13F-SFA-MONOMER was evaluated in female Sprague-Dawley CD (CrI : CD® (SD) IGS BR) rats over a 14-day period. The study was conducted in compliance with Good Laboratory Practice (GLP) standards. **Ten**Five nulliparous, non-pregnant female rats were administered a single oral dose of undiluted 13F-SFA-MONOMER at 2000 mg/kg bodyweight via gavage. The specific gravity of the test material was 1.549, resulting in a dose volume of 1.3 ml/kg. The dose level was selected based on available toxicity information and in accordance with OECD Guideline 420 (Fixed Dose Method). No vehicle or control group was included, as the test material was administered as supplied.

Clinical observations were performed at 0.5, 1, 2, and 4 hours post-dosing and then daily for 14 days. Morbidity and mortality checks were conducted twice daily. Body weights were recorded on the day of dosing (Day 0), Day 7, and Day 14. At the end of the observation period, all animals were euthanized and subjected to gross necropsy, including external and internal examination for macroscopic abnormalities.

No mortality occurred at any time point. No clinical signs of systemic toxicity were observed in any animal throughout the 14-day observation period. All animals exhibited expected gains in body weight. Individual body weight data demonstrated increases from Day 0 to Day 14, with gains during the first week ranging from 10 g to 41 g and during the second week from 22 g to 30 g. At necropsy, no macroscopic abnormalities were detected in any animal.

The acute oral median lethal dose (LD<sub>50</sub>) of 13F-SFA-MONOMER in female Sprague-Dawley rats was estimated to be greater than 2000 mg/kg bodyweight. **According to the Globally Harmonised Classification System (GHS), 13F-SFA-MONOMER is categorized as 'Unclassified' for acute oral toxicity under these test conditions:** No NOAEL was explicitly stated in the study.

## Accept and reject changes for total control

Review all suggestions in one place in the Suggestions panel. Suggestions can be accepted or rejected individually, or all at once with Accept all and Reject all.

### 2.6.6 Toxicology written summary 🗨 Suggesting 📝 Suggestions

**Content** | Template | Generate all content | Fill variables

Body weights were recorded on the day of dosing (Day 0), Day 7, and Day 14. At the end of the observation period, all animals were euthanized and subjected to gross necropsy, including external and internal examination for macroscopic abnormalities.

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Accept | Reject | < | >

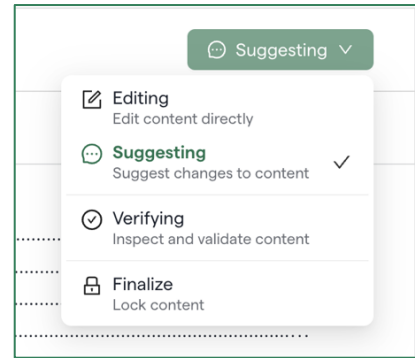
**Julie Xu**  
Add: Ten...

**Julie Xu** · 11/3/25 · 9:14 PM ✓ ✕  
Add: At the end of the observation period, all animals were euthanized and subjected to gross necropsy, including external and internal examination for macroscopic abnormalities.

**Julie Xu**  
Delete: According to the Globally Harmonised Classification System...

## Switch between document modes seamlessly

Toggle between Editing, Suggesting, Verifying and Finalized modes during the different phases of writing a regulatory document.



## Complex Tables from Examples

Have a preferred table structure with lots of merged cells? Paste an example table structure from Word or Excel into the AI Table prompt block and AI will recreate the table structure using the new source data. Even example tables populated with previous data will work.

## Copy/paste table structures into Weave AI Templates

Tables inside AI Templates can be easily built from example tables rather than simply listing the columns or rows. Copy a simple or complex table structure from Word or Excel, and paste it directly into a Weave AI Template. Simply add instructions for the AI to use the table as an example and optionally add any additional instructions as needed, such as how to populate rows or columns, how to format table footnotes, etc.

**2.6.7.7 Repeat-Dose Toxicity: Pivotal Studies**

Create a table with the following structure. Populate the cells with square brackets based on their row and column header, using data from the source document. Include a list and definitions of any abbreviations used in the table caption. Title the table with this pattern: "Report Title: [report title]"

Report Title:			Study Number:			
Species/Strain:	Duration of Dosing:		Test Article:			
Initial Age:	Duration of Postdose:		Location in CTD:			
Date of First Dose:	Method of Administration:		GLP Compliance:			
Vehicle:						
Special Features:						
No Observed Adverse Effect Level:						
Group Number:	1	2	3	4		
Group Name:	Vehicle Control		[test article] Low	[test article] Mid	[test article] High	
[test article] (mg/kg/day):	0		20	60	150	
	M	F	M	F	M	F
Number of Animals (Total)						
Main						
Number Examined Terminal Sacrifice - Day 29						
Toxicokinetic						
Recovery						
Number Examined Recovery Sacrifice - Day 43						

Note: any text formatting, such as bold or italics, in the template table will not automatically be applied in the output table.

## Easily & quickly format your in-text tables

Once a table has been generated, there are many different actions to adjust the format of the table structure and cell text.

### Table structure actions

- Select multiple cells and click the merge icon to quickly **merge** them
- Select a previously merged cell and click the un-merge icon to quickly **split** the cells
- **Drag any column or row border** to change the width or height, respectively
- Make a mistake? Type CTRL-Z (or CMD-Z on a Mac) to **quickly undo** 1 or more actions

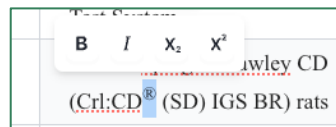
Treatment Duration		Testing Facility
14 days	Oral	<u>Safepharma</u> Laboratories Limited
28 days	Oral (gavage)	Chemicals Evaluation and Research Institute, Japan, <u>Hita</u> (CERI <u>Hita</u> )
6 h (short-term), 24 h (continuous)	In vitro	Hita Laboratory Chemicals Evaluation and Research Institute, Japan

### Table content actions

Drag across multiple cells or entire rows/columns to select them and format in **bold** or *italics*.

Table 1: Summary of Toxicology Studies

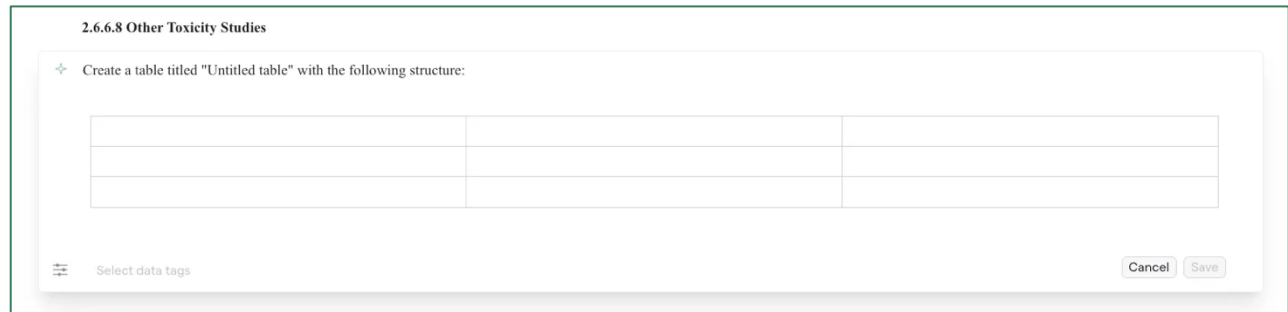
Study Type	Test System	Treatment Duration	Method of Administration	Testing Facility	Study Number	CTD Location
Single-Dose Toxicity	Female Sprague-Dawley CD (CrI:CD <sup>®</sup> (SD) IGS BR) rats	14 days	Oral	<u>Safepharma</u> Laboratories Limited	1458/0061	



Select any text and choose to either superscript or subscript the characters.

## AI Table blocks launch with a ready-to-use blank table for fast setup

Click the (+) menu in any AI Template to insert a new AI Table block. This will open a pre-populated editable block that contains some placeholder text and a blank 3x3 table to get you started quickly.



## AI Table Generation Quality & Metrics

We evaluated both the accuracy of the content in the table cells as well as the structure of the tables using two metrics. Content accuracy measures the percentage of generated table cells that match ground truth content. The structure score measures how well the generated table layout matches the ground truth layout (e.g, number of rows/columns and layout of cells, including row and column spans).

	<b>Previous</b>	<b>With latest improvements</b>
Structure score	~70%	~95%
Content score	~90%	~95%

# New & Improved Functionality

## New

- Automatically extract questions and related information from original question file
- Compare extracted questions and related information to original question file
- Automatically find related questions and relevant source files
- Create response file in 1.11 with first drafts generated by Weave AI
- Manually override or assign field values; manually add missing questions
- View questions only assigned to the user
- Export HAQ Manager table to Excel
- Suggesting mode to suggest changes to content
- Suggestions shown in redline format in Content view
- Suggestions panel
- Accept or reject individual suggestions or all suggestions
- View previously resolved suggestions
- AI Templates support pasted table structures copied from Word or Excel
- Merge and split table cells
- Change column widths or row heights
- Superscript or subscript text
- CTRL-Z (CMD-Z) to undo

## Improved

- Toggle between document modes without forced workflows
- Multiple cells, rows, or columns of a table can now be selected
- Refinement instructions now apply to the table captions & footnotes in addition to the table itself