

Weave Platform

June 2025 Release Notes

Advancing the Regulatory Lifecycle: Evolution of the Weave Platform
Insert Auto-Extracted Figures

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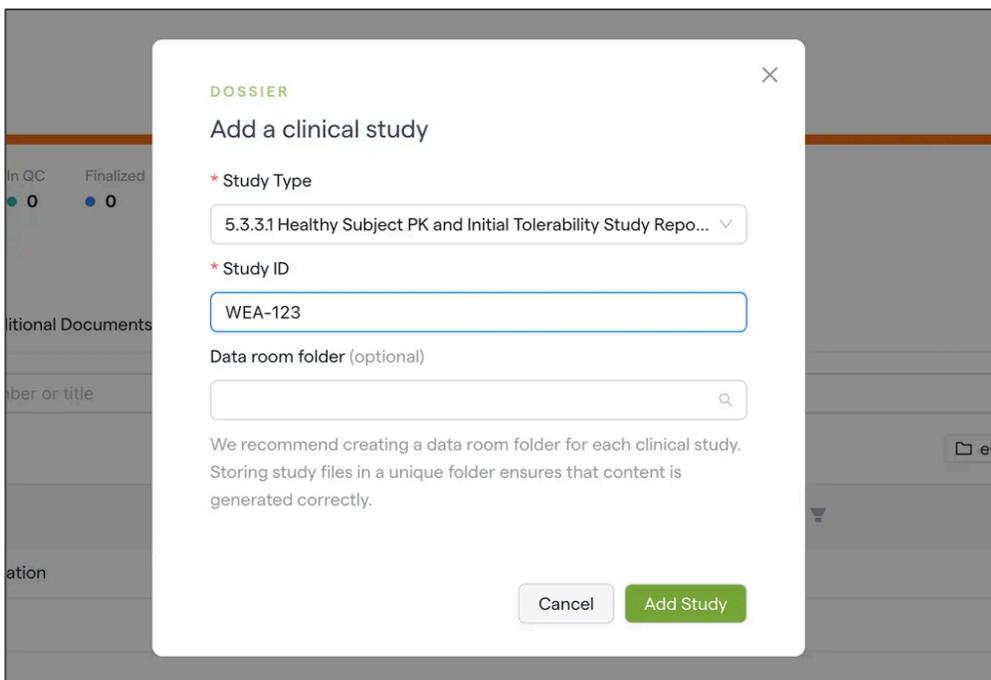
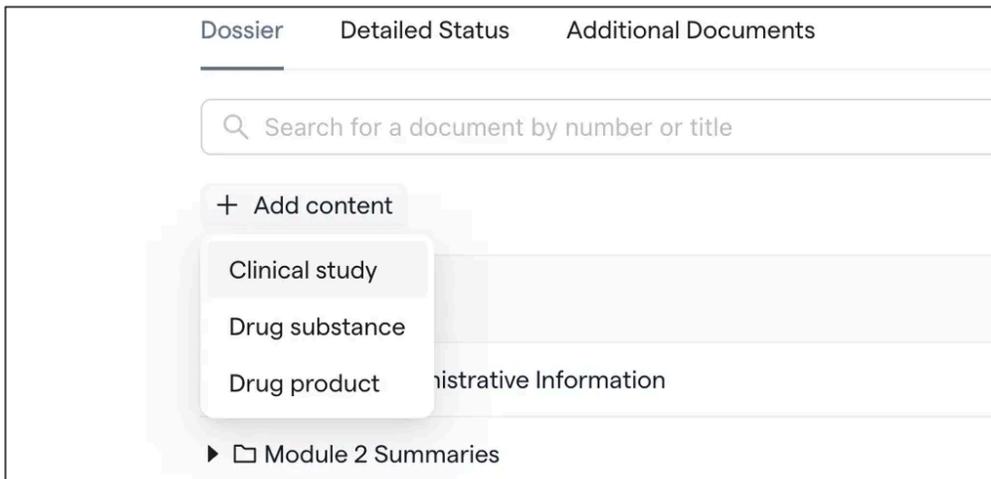
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Advancing the regulatory lifecycle: Evolution of the Weave Platform

To support regulatory document authoring during the clinical phase of development, the Weave Platform now includes the ability to generate clinical documents. Users can now upload clinical study source documents in various formats, create clinical study dossier folders, and use AI Templates to draft clinical study reports, clinical protocols, and all kinds of clinical documents included in Module 5. [View the video overview of this feature.](#)

Create clinical study dossier sections and documents

A clinical study dossier section can be added, which automatically creates a full set of clinical study documents with their corresponding AI templates.



The newly created study folder populates the correct M5 dossier section based on the selected study type. A study report, study protocol, and a full set of appendices documents are automatically added to the folder.



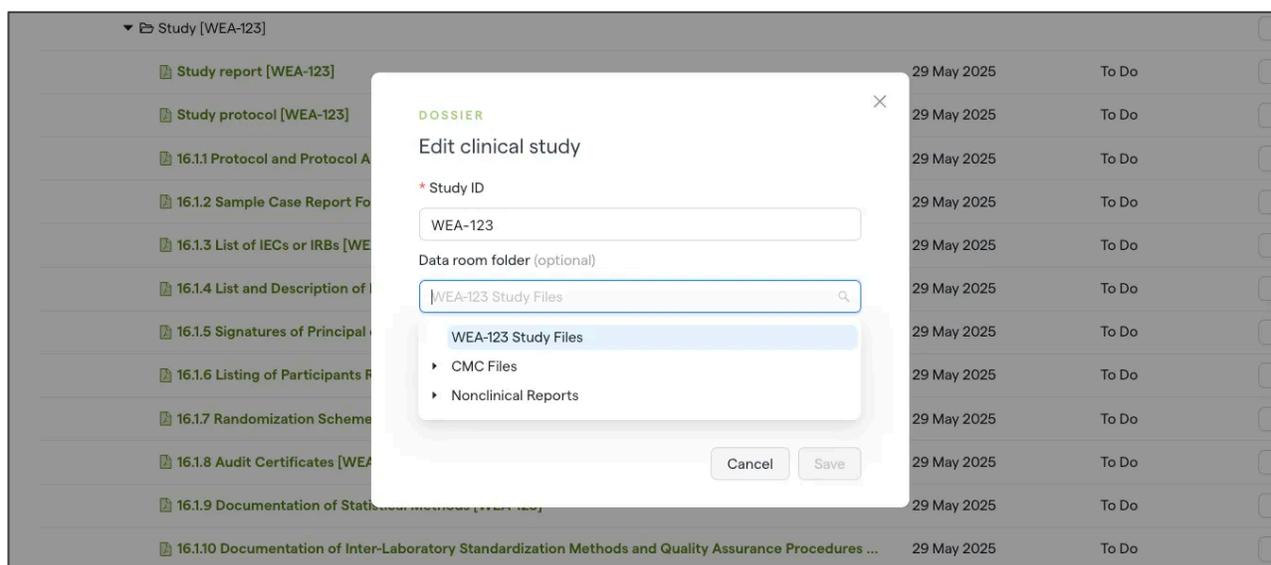
5.3.3 Reports of Human Pharmacokinetic (PK) Studies			
5.3.3.1 Healthy Subject PK and Initial Tolerability Study Reports			
Study [WEA-123]			
Study report [WEA-123]	29 May 2025	To Do	View ...
Study protocol [WEA-123]	29 May 2025	To Do	View ...
16.1.1 Protocol and Protocol Amendments [WEA-123]	29 May 2025	To Do	View ...
16.1.2 Sample Case Report Form [WEA-123]	29 May 2025	To Do	View ...

Important Notes:

1. When drafting a clinical protocol, make sure to add an additional **@protocol-source-material** data tag to any source document that will be used (e.g. a previous protocol, protocol synopsis, or investigator's brochure)
2. The default templates for the clinical study report and clinical protocol are based off of the [TransCelerate templates](#) and are compatible with the [ICH E3 guideline](#).

Connect & use only the source documents in specific Data Room folders

To ensure only the correct protocol, statistical analysis plan, or other clinical docs are used for generation of study documents, a data room folder can be optionally connected to each clinical study.



DOSSIER

Edit clinical study

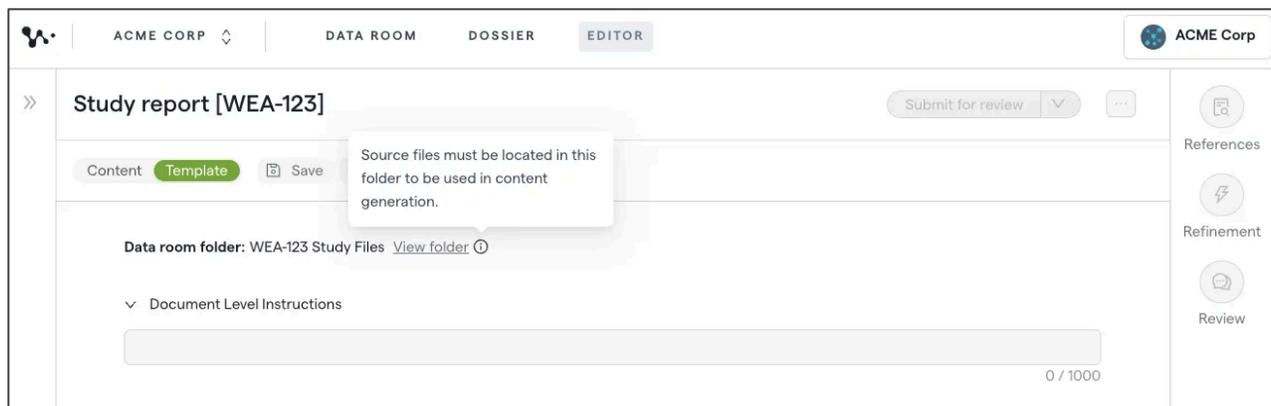
* Study ID

Data room folder (optional)

- WEA-123 Study Files
 - CMC Files
 - Nonclinical Reports

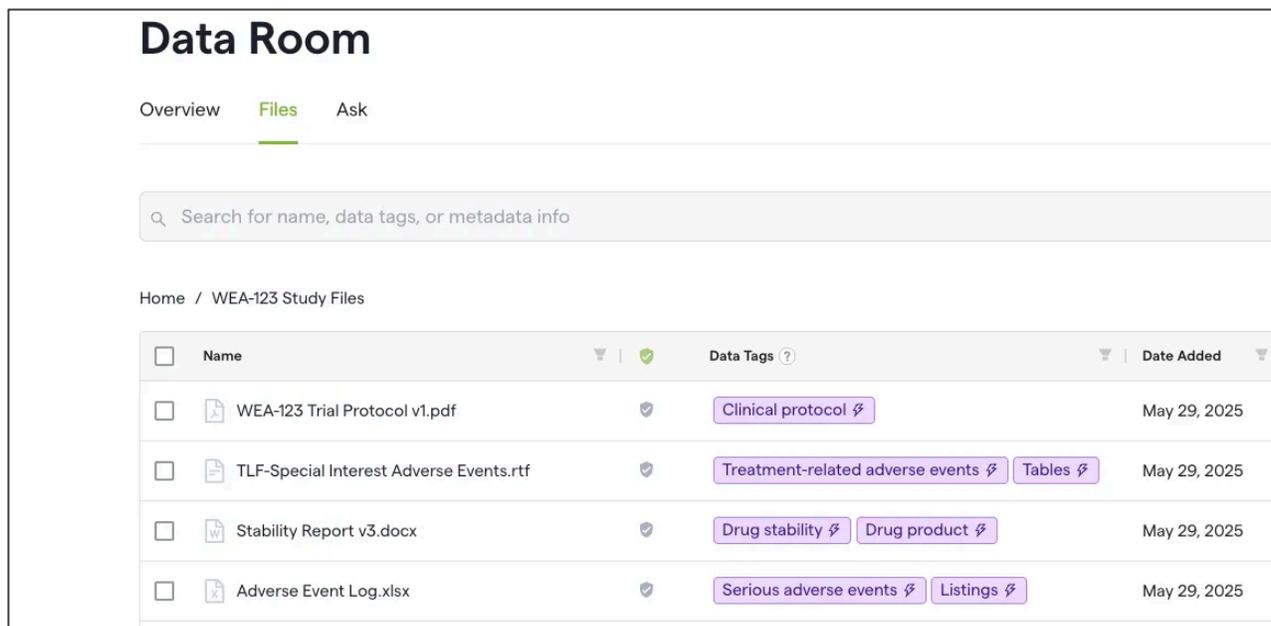
Cancel Save

When connected, only source files contained in that data room folder will be used in content generation. A link directly to the folder is available at the top of the document template and in each ungenerated content block in the Editor.



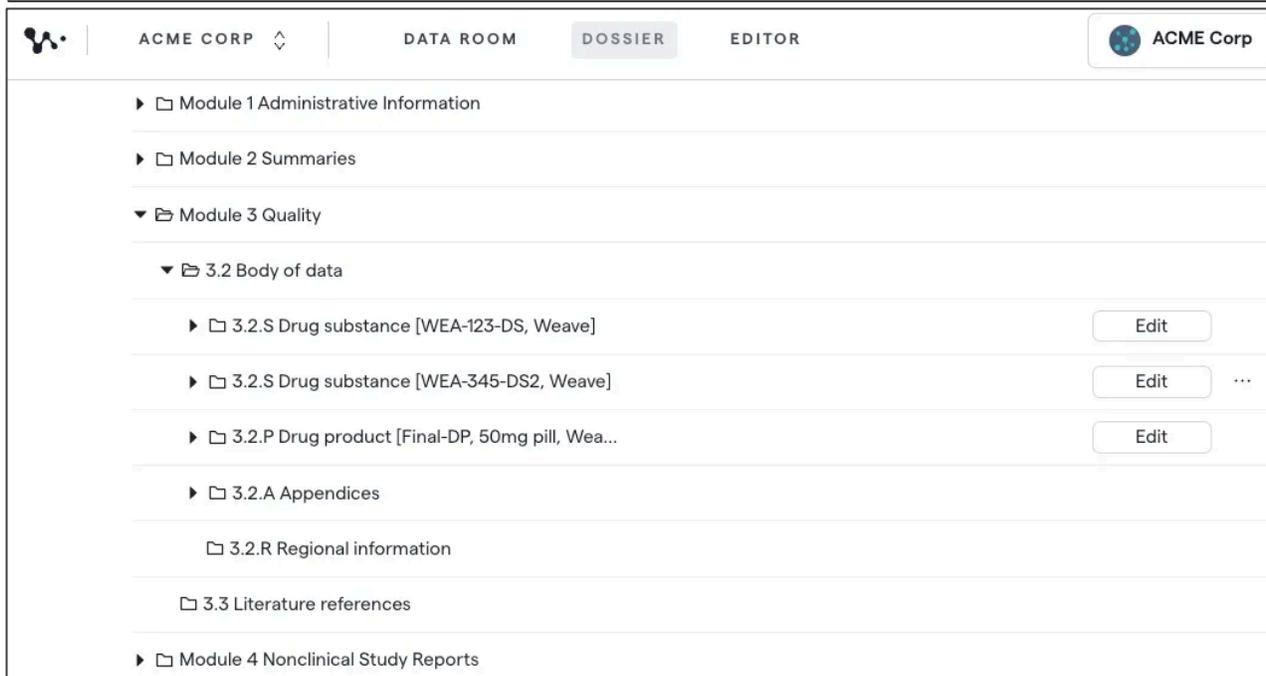
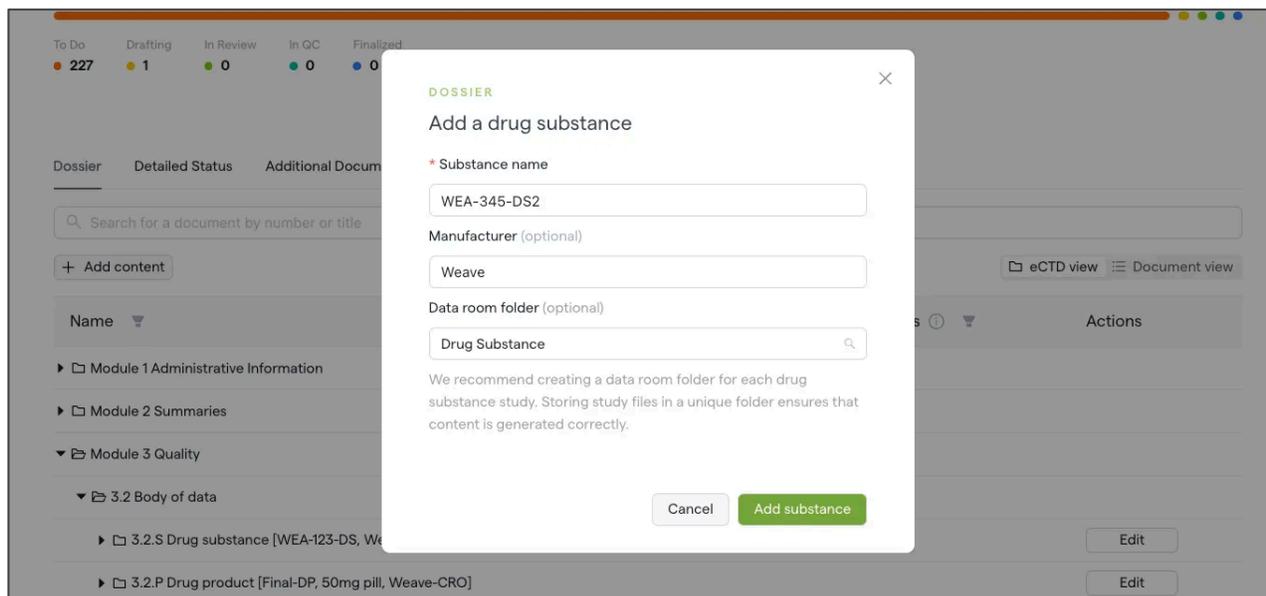
Support for clinical file types, including .rtf, .docx, and .xlsx

To support the various file formats typical of clinical source files, the platform now supports .rtf (Rich Text File), .docx (Word), and .xlsx (Excel) file types. Icons on uploaded files will match the file type.



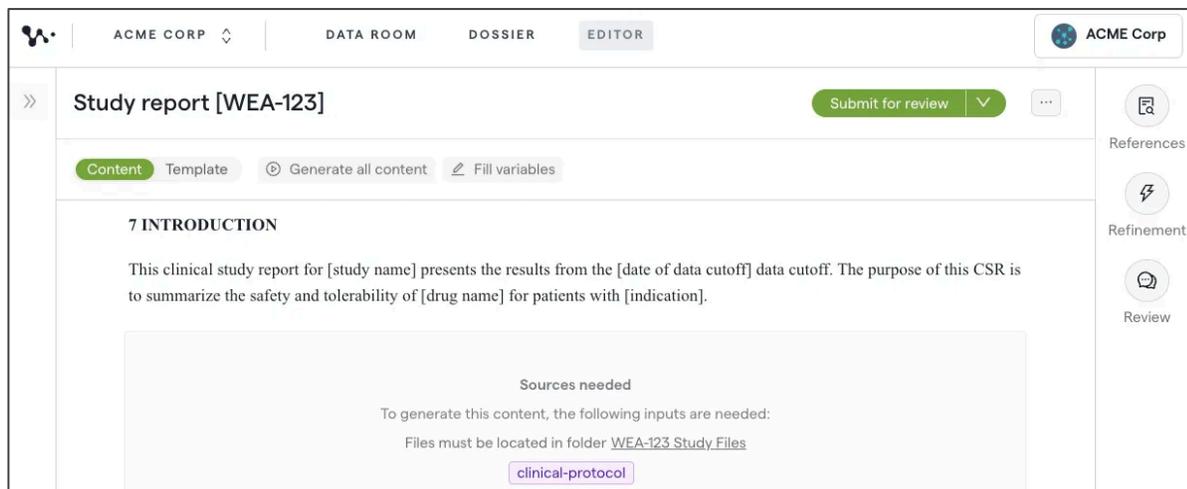
Create additional drug substance (3.2.S) or drug product (3.2.P) folders

The dossier for each program in the platform is even more flexible in Module 3, now supporting the creation of additional drug substance (3.2.S) or drug product (3.2.P) dossier folders. Editable fields for drug substances and products include the name, manufacturer, and dosage form. Additionally, a data room folder can be optionally connected to each drug substance or drug product folder to use only the files in that folder for content generation.



Dynamic replacement of variables

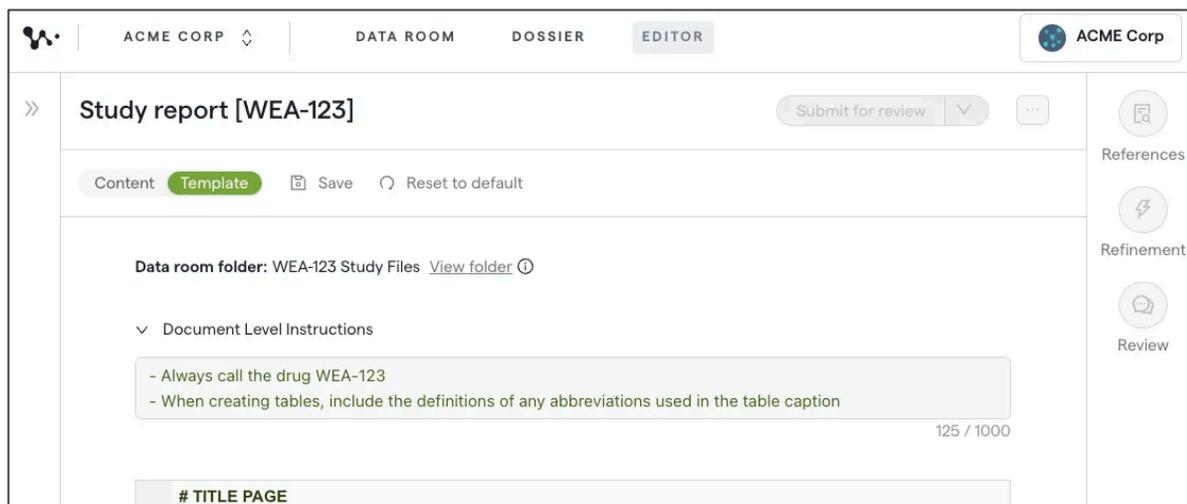
AI Templates support the inclusion of `[variables]` in headings and boilerplate text that can be dynamically replaced using data contained in the source files used for generation of the document. Clicking “Fill variables” at the top of the Content view in the Editor will replace each of the variables in the draft, avoiding the need to manually incorporate these data elements.



Note: Any changes to the template structure, outline, or static content (e.g. boilerplate text, headings, etc.) will cause any variables to return to their unfilled state, so it is recommended to do variable replacement later in the drafting process.

Document-level prompt instructions

Any AI instructions that apply to the entire document (rather than individual sections of the document) can be added at the top of the AI Template. These prompts will be sent to the AI whenever content is generated for that document, either from the Template view or the Content view.



Insert auto-extracted figures

Any figures in uploaded source files are now automatically extracted and available to be directly inserted into any document! Based on customer feedback, we've drastically improved this previously manual process of uploading an image file from a user's local computer to an intuitive search and select of any figure from source files already in the Data Room. [View the video overview of this feature.](#)

Find in Data Room

The entry point for inserting figures remains the same - in the Content view of the Editor, click the "+" button to the left of the preceding block and hover over "Figure." There is now a new "Find in Data Room" option where users can select from a list of figures that have been automatically extracted from uploaded source files.

The screenshot displays the Weave Editor interface. At the top, there are three tabs: 'DATA ROOM', 'DOSSIER', and 'EDITOR'. Below the tabs is a document title '2.6.6 Toxicology written summary'. Underneath the title are four buttons: 'Content' (highlighted in green), 'Template', 'Generate all content', and 'Fill variables'. The main content area shows a text block starting with 'The experimental designs of the toxicological studies conducted on 13...'. A '+' icon is visible to the left of the text. A context menu is open over the text, listing options: 'Insert block below', 'Text', 'Table', 'Figure', and 'Delete'. The 'Figure' option is selected, and a sub-menu is open over it, showing 'Find in Data Room' and 'Upload from computer'.

Note that the "Upload from computer" option remains in the cases where the figure users want to insert does not come from a source file in the Data Room.

Recommended figures

“Find in Data Room” opens a new “Figures” right panel that will automatically be populated with a “Recommended figures” list to start. This Recommended list contains the top five matching figures related to the preceding text block. Each figure is shown with a title, the percent match, the source file name, and the page number in the source file. Note that in the cases where the title could not be properly extracted, it will show as Untitled.

2.6.6 Toxicology written summary Submit for review

2.6.6.3 Repeat-Dose Toxicity

2.6.6.3.1 Twenty-Eight-Day Repeated-Dose Oral Toxicity Study of 13F-SFA in Rats

A twenty-eight-day repeated-dose oral toxicity study was conducted to evaluate the toxicity of 13F-SFA in rats. The study adhered to the OECD Principles of Good Laboratory Practice (GLP) and was performed at the Chemicals Evaluation and Research Institute, Japan (CERI Hita). The test substance, 13F-SFA, was administered orally by gavage to CrI:CD(SD) rats. The study included three groups: a vehicle control group (olive oil containing 0.5% Tween80) and two test substance groups receiving doses of 30 mg/kg/day and 120 mg/kg/day. Each group consisted of five males and five females. Dose levels were selected based on a prior study, with the aim of confirming toxic effects at 30 mg/kg/day and assessing reproducibility.

The test substance was prepared as a solution in the vehicle at concentrations of 0.3% and 1.2% (w/v) and administered daily for 28 days. Animals were observed for clinical signs, body weight changes, and food consumption. Blood samples were collected for clinical chemistry analysis, and necropsy was performed to assess organ weights and histopathological changes.

No treatment-related effects were observed in body weight or food consumption across all groups. Male rats in the 30 mg/kg/day and 120 mg/kg/day groups exhibited transient salivation immediately after dosing, with incidences of 3/5 and 4/5, respectively. Female rats in the 120 mg/kg/day group also showed transient salivation in 3/5 animals. No abnormalities were noted in the 30 mg/kg/day group for either sex.

In clinical chemistry, males in the 120 mg/kg/day group exhibited a significant increase in total bilirubin levels (0.082 ± 0.019 mg/dL) compared to the control group (0.060 ± 0.007 mg/dL). No significant changes were observed in females at any dose level.

Pathological examinations revealed dose-dependent effects on liver weights. In males, absolute liver weights increased significantly in the 120 mg/kg/day group (12.284 ± 1.937 g) compared to controls

Figures

Find figures by description or location

Describe the figure that you're looking for

Select a folder or file

Recommended figures

- Food consumption (g) 25 Fig. 3-2 Twenty-eight-day repeated-dose oral toxicity study in rats Food...**
66% match • 13F-SFA-repeat_tox.pdf • Page 25
- Food consumption (g) Fig. 3-1 Twenty-eight-day repeated-dose oral toxicity study in rats Food consumption: Male**
65% match • 13F-SFA-repeat_tox.pdf • Page 24
- Short-term treatment without S9 mix**
65% match • 13F-SFA_genotox_1.pdf • Page 33
- Short-term treatment with S9 mix**
64% match • 13F-SFA_genotox_1.pdf • Page 33
- 23 Fig. 2-2 Twenty-eight-day repeated-dose oral toxicity**

Search for figures

To look for a particular figure not shown in the Recommended list, use the search feature at the top of the Figures panel. There are multiple search options:

1. Users can enter just a string query and search figures across the Data Room - results will show up to the top 30 matching figures, sorted by descending percent match.
2. Users can select just a file or folder - results will show up to the first 30 figures from that file or files in the folder.
3. Users can enter both a string query as well as select a file/folder to narrow the search - results will show up to the top 30 matching figures, sorted by descending percent match.

The screenshot displays the Weave Platform interface. The top navigation bar includes 'WEAVE-999', 'DATA ROOM', 'DOSSIER', and 'EDITOR'. The main content area is titled '2.6.6 Toxicology written summary' and contains a section '2.6.6.3.1 Twenty-Eight-Day Repeated-Dose Oral Toxicity Study of 13F-SFA in Rats'. The text describes a study conducted to evaluate the toxicity of 13F-SFA in rats, including details on the study design, dosing, and results.

On the right side, the 'Figures' panel is active, showing a search for 'chromosomal aberration' within the file '13F-SFA_genotox_1.pdf'. The search results list several figures with their respective match percentages and page numbers:

- Fig. 4 Results of chromosomal aberration test in continuous treatment of 13F-SFA**: 53% match • 13F-SFA_genotox_1.pdf • Page 36
- Untitled**: 51% match • 13F-SFA_genotox_1.pdf • Page 35
- Photo 3 Structural aberration induced by 13F-SFA 72.9 µg/mL in 24 hours continuous treatment b : chromatid...**: 51% match • 13F-SFA_genotox_1.pdf • Page 40
- Fig. 3 Results of chromosomal aberration test in short-term treatments of 13F-SFA**: 50% match • 13F-SFA_genotox_1.pdf • Page 35
- Photo 2 Structural aberration induced by 13F-SFA 100**: (Match percentage not fully visible)

Figure preview and insertion

Selecting a figure from either the Recommended list or the search results list opens an additional Preview panel. The figure image is enlarged for confirmation, along with additional metadata such as data tags and an AI-generated summary.

DATA ROOM DOSSIER EDITOR Weave Platform, Inc.

Submit for review

PREVIEW

Source file
13F-SFA_genotox_1.pdf
Genotoxicity In vitro

Page 33

Title
Short-term treatment without S9 mix

Preview

Summary

Title: Results of Cell Growth Inhibition Test of 13F-SFA The graph shows a dose-response curve measuring cell growth rate against increasing concentrations of 13F-SFA. The cell growth rate starts at 100% at the lowest dose and decreases sharply between 10-100 µg/mL, reaching its lowest point around 25% at approximately 100 µg/mL. After this point, the growth rate slightly increases and stabilizes around 35-40% for doses between 1000-10000 µg/mL. The IC50 (half maximal inhibitory concentration) is indicated as 85 µg/mL on

Cancel Insert

Figures

Find figures by description or location

Describe the figure that you're looking for

Select a folder or file

Recommended figures

- Short-term treatment without S9 mix
65% match • 13F-SFA_genotox_1.pdf • Page 33
- Fig. 6 Results of confirmation test in short-term treatment of 13F-SFA
65% match • 13F-SFA_genotox_1.pdf • Page 38
- Fig. 1 Results of cell growth inhibition test of 13F-SFA
64% match • 13F-SFA_genotox_1.pdf • Page 33
- Short-term treatment without S9 mix Fig. 5 Cell growth rate in confirmation test of 13F-SFA
63% match • 13F-SFA_genotox_1.pdf • Page 37

References Refinement Review

Clicking “Insert” will add the selected figure into the Editor with auto-populated figure number and figure title. The title of the figure can be edited, and the figure image itself can be resized.

WEAVE-999 DATA ROOM DOSSIER EDITOR Weave Platform, Inc.

Submit for review

2.6.6 Toxicology written summary

Content Template Generate all content Fill variables

g/100g). In females, absolute liver weights increased significantly in the 120 mg/kg/day group (6.100 ± 1.050 g) compared to controls (6.032 ± 0.509 g), and relative liver weights were similarly elevated (3.954 ± 0.299 g/100g vs. 2.918 ± 0.107 g/100g). Kidney weights were increased in females of the 120 mg/kg/day group, with relative kidney weights at 0.864 ± 0.042 g/100g compared to 0.780 ± 0.058 g/100g in controls. However, no histopathological changes were observed in the kidneys at any dose level.

Histopathological findings in the liver included periportal hypertrophy of hepatocytes in 3/5 males and diffuse hypertrophy in 4/5 females in the 120 mg/kg/day group. Microgranulomas were observed in one male and one female in the 120 mg/kg/day group, but these were considered spontaneous lesions. No histopathological changes were noted in the 30 mg/kg/day group.

The No-Observed-Adverse-Effect Level (NOAEL) for 13F-SFA was determined to be 30 mg/kg/day, as no adverse effects were observed at this dose level.

Figure 1: Short-term treatment without S9 mix

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 - 2.6.6.3.1 Twenty-Eight-Day Rep...
 - 2.6.6.4 Genotoxicity
 - 2.6.6.4.1 Chromosomal Aberrat...
 - 2.6.6.4.2 Mutagenicity Test of 1...
 - 2.6.6.5 Carcinogenicity
 - 2.6.6.6 Reproductive and Develo...
 - 2.6.6.7 Local Tolerance
 - 2.6.6.8 Other Toxicity Studies
 - 2.6.6.9 Discussion and Conclusio...

References Refinement Review

New, Improved

New

- Default templates for clinical study report, clinical protocol, and all the CSR appendices that would be generated (not simply imported from stats software such as SAS).
- Dossier documents in Modules 1 and 5 no longer display the eCTD numbering in the document name; instead, content outlines in those documents begin with the number 1.
- Additional data tags have been added to automatically tag clinical tables, listings, and figures (TLF) files with relevant tags, including those used for the default clinical study report AI template
- Auto-extraction of figures from source files
- Find in Data Room option for inserting Figures in Editor
- Recommended list of figures
- Search figures by text input or file/folder selection or both
- Preview of figures with additional metadata

Improved

- AI Template prompts that include an instruction for creating bulleted or numbered lists are now supported
- A @current-document tag has been added to use the current document's content as source inputs for prompt blocks (e.g. for the Brief Summary or Discussion and Conclusions sections of 2.6 Nonclinical Written Summaries)