

Release Notes

May 2026

Import Dossier Documents

Flexible Dossier

HAQ Manager

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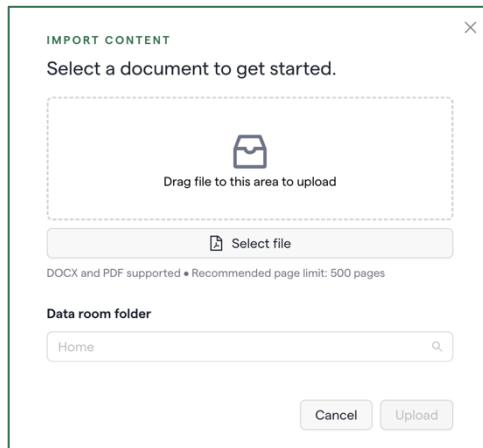
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Import Dossier Documents

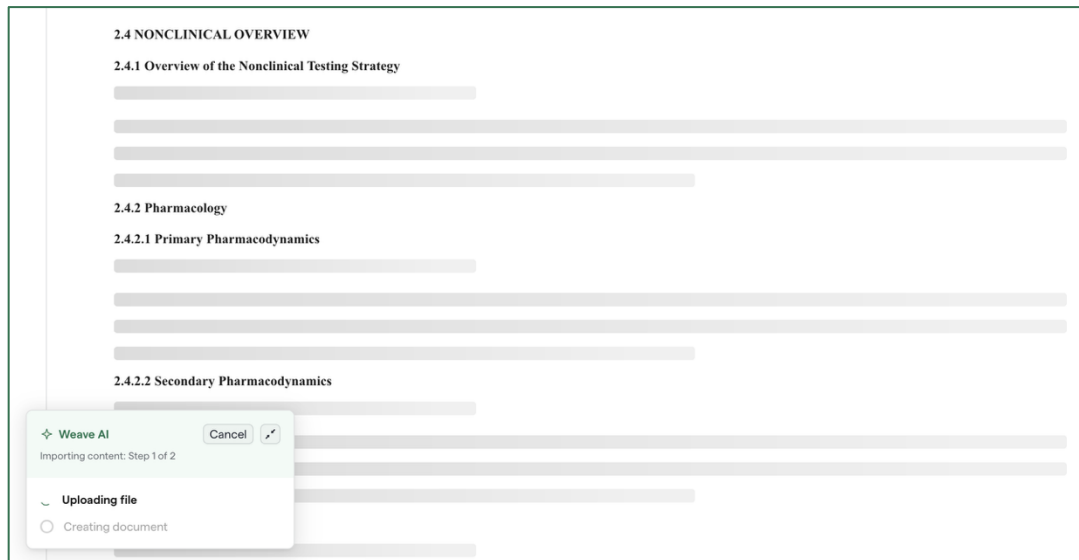
Import existing dossier documents into Weave to continue authoring. Bring in externally authored dossier documents into the Weave Platform, preserving the authored content while enabling continuation of drafting and reviewing in Weave.

Import a file into a dossier document

To copy the contents of an external file into Weave, select “Import” on a dossier document to upload a .docx or .pdf file.



While the import is processing, a progress card will appear on the bottom left of the screen to provide additional transparency on importing steps, including file upload vs. document creation, as well as completion. Imported text, tables, and figures have recall and precision of ~1.0.



2.4 NONCLINICAL OVERVIEW

2.4.1 Overview of the Nonclinical Testing Strategy

13F-SFA (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl acrylate; CAS 17527-29-6) is a colorless, transparent liquid with a reported purity of 99.7%. The mechanism of action and intended clinical use of 13F-SFA are not specified in the provided source content.

A comprehensive nonclinical testing strategy was implemented to evaluate the safety profile of 13F-SFA and its monomer. The nonclinical program encompassed acute and repeated-dose toxicity studies, as well as genotoxicity assessments, in accordance with Good Laboratory Practice (GLP) and relevant OECD guidelines.

The acute oral toxicity of 13F-SFA-Monomer was assessed in female Sprague-Dawley CD (CrI: CDR (SD) IGS BR) rats using the fixed dose method. The objective was to determine the single-dose toxicity and estimate the median lethal dose (LD₅₀). Endpoints included mortality, clinical signs of toxicity, body weight changes, and gross pathological findings at necropsy.

Repeat-dose toxicity was evaluated in a 28-day oral gavage study in CrI:CD(SD) rats of both sexes. The objective was to characterize the toxicity profile following repeated administration. Endpoints included clinical observations, body weight, food consumption, blood chemistry, and pathology (gross necropsy, organ weights, and histopathology of liver and kidneys).

Genotoxicity was assessed using two in vitro assays. The bacterial reverse mutation (Ames) test utilized Salmonella typhimurium strains TA100, TA1535, TA98, TA1537, and Escherichia coli strain WP2uvrA to evaluate mutagenic potential, both with and without metabolic activation. The in vitro chromosomal aberration test employed Chinese hamster lung fibroblasts (CHL/IU cells) to assess the potential for induction of structural and numerical chromosomal aberrations under both short-term and continuous exposure conditions, with and without metabolic activation.

The nonclinical testing strategy is summarized in the following table.

Table 1: Summary of Nonclinical Testing Approaches for 13F-SFA

Study Type	Objective	Assay/Model	Species/Cell Line	Key Endpoints
Acute Oral Toxicity	Evaluate single-dose toxicity and estimate LD ₅₀	Fixed Dose Method (OECD 420)	Female Sprague-Dawley CD rats	Mortality, clinical signs, body weight, necropsy
Repeat-Dose Toxicity	Assess toxicity profile after	28-Day Oral Gavage	CrI:CD(SD) rats (male and	Clinical signs, body weight,

Any comments in the imported .docx file will live in the Comments panel!

3.2.S.5 Reference standards or materials

storage, and re-qualification protocols in compliance with cGMP requirements.

No interim standards are described or utilized within the provided documentation. The following sections detail the characteristics, generation, qualification, and storage of both the Primary Reference Standard and the Secondary (Working) Reference Standard.

Primary Reference Standard (PRS)

The Primary Reference Standard (PRS) for Albiglutide Drug Substance is derived from a single, highly purified cGMP batch selected for its representative quality profile. The PRS undergoes an exhaustive characterization program to confirm its identity, purity, potency, and structure. Analytical procedures include amino acid analysis, peptide mapping, disulfide bridge analysis, far-UV circular dichroism (CD),

Comments

Julie Xu
[Imported comment by Julie Xu, 2026-06-01] Double-check this

No interim standards are described or utilized within the provided documentation.

Matching template with reverse-engineered prompts

Besides copying in the content, Weave will also automatically create matching template prompts for the imported content. This enables continued authoring in Weave, especially if the imported file is still a draft.

2.4.4 Toxicology

2.4.4.1 Brief Summary

Provide a comprehensive summary of the single-dose toxicity study in rats, organized into the following components:

- Begin with a brief introductory paragraph identifying the test substance, species and strain, study design framework (OECD guideline, GLP compliance), and primary objective.
- Describe the experimental design: acclimatization period, animal characteristics (age range, sex, reproductive status), group size, dosing regimen (sighting test followed by main study), dose level(s) tested, vehicle (if any), dose volume calculation, and absence of control group if applicable.
- Summarize the endpoints and observation schedule: clinical observation timepoints, body weight measurement schedule, mortality monitoring frequency, and necropsy procedures.
- Present the quantitative and qualitative results: mortality, clinical signs, body weight changes (provide numeric ranges for weight gain by week if available), and gross pathology findings at necropsy.
- Conclude with an integrative analysis: interpretation of findings, estimated LD₅₀ value and classification under the Globally Harmonised System (GHS), statement regarding NOAEL if applicable or explanation of why it was not determined, and overall acute toxicity profile.

2.4.4.2 Repeat-dose Toxicity

2.4.4.2.1 Studies in Rats

Provide a comprehensive summary of the repeat-dose toxicity study in rats, organized into the following components:

Begin with an introductory paragraph identifying the test substance, species and strain, study duration and route of administration, and primary objective. Include rationale for

Reverse-engineered prompts are optimized for regeneration using the imported file as the source (similarity of 0.99), but other source files can be used as well along with additional template customizations.

Continue using Editor workflows after import

After importing, continue drafting and collaborating using familiar workflows in Weave, as if the content was originally created in Weave. Sources will indicate that content came from an imported document.

The screenshot displays the Weave Editor interface. On the left, a document titled "2.4 NONCLINICAL OVERVIEW" is shown in "Editing" mode. The document content includes a paragraph about systemic toxicity and a highlighted section of text: "Endpoints assessed encompassed clinical signs, body weight, food consumption, blood chemistry, and detailed pathological evaluation, including gross necropsy, organ weights, and histopathology of liver and kidneys." On the right, a "Sources" panel is visible, showing a list of sources for the selected content. One source is listed as "2.4_document_2026-04-30_001911 (1).docx (Removed)" with a note: "This was an imported document." The interface also features a sidebar with icons for Sources, Refinement, Comments, and Auto Update.

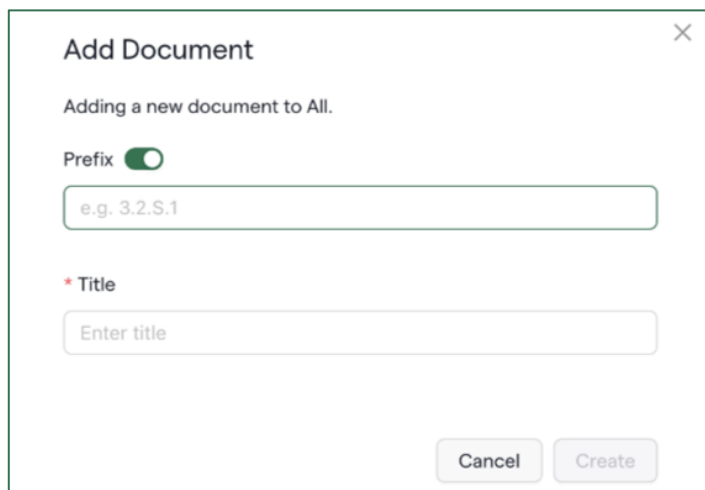
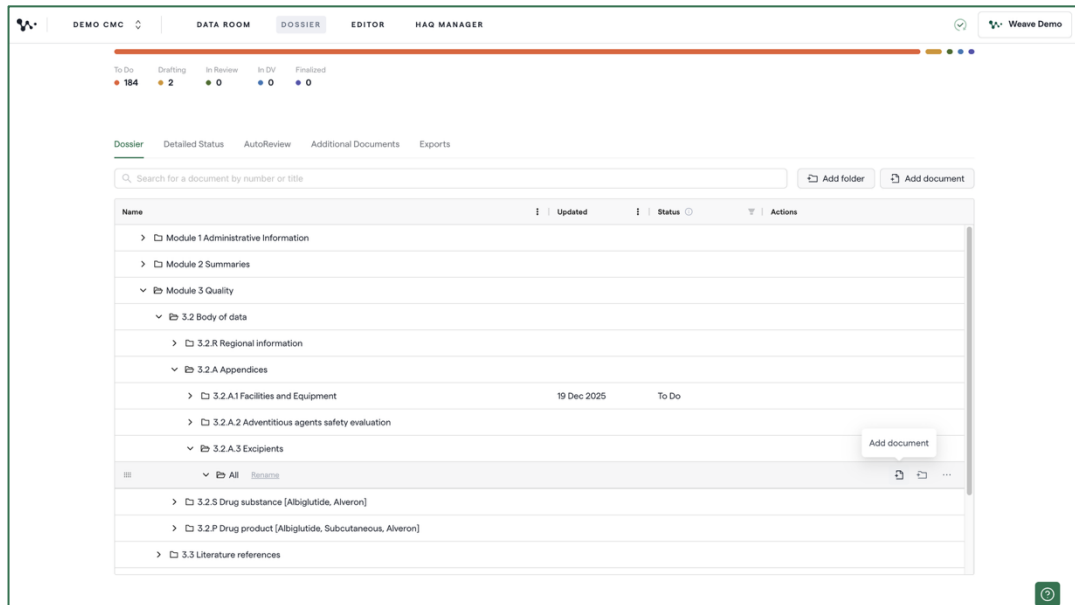
Flexible Dossier

Customize the dossier for your submission

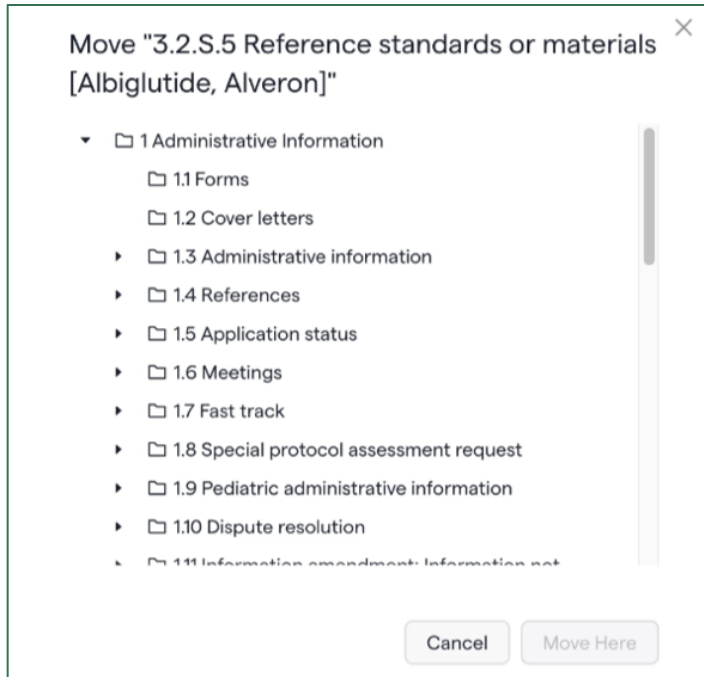
The dossier is now customizable — you can add a document or folder anywhere to include content, split out existing documents into multiple parts, or reorganize content like Module 3 Appendices.

You can add study reports to Module 4, customize document prefixes, split out a Module 3 document into multiple documents, apply new ICH guidance, or just delete documents you don't need.

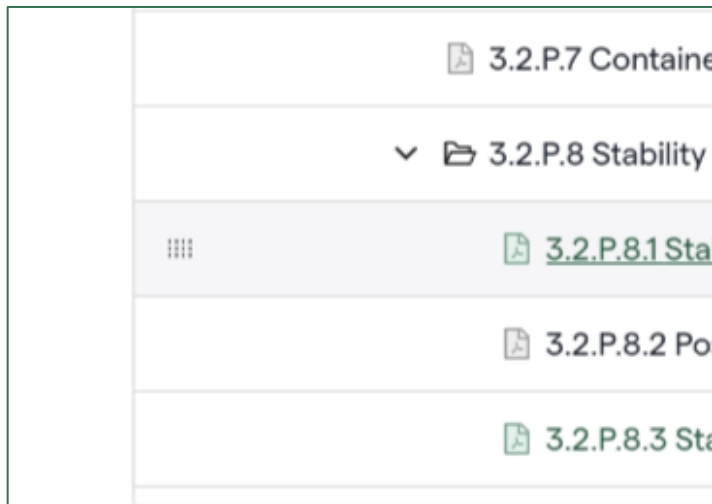
Add a document or folder using the menu within the dossier:



Move content to a precise location by clicking “move into” then selecting a destination:

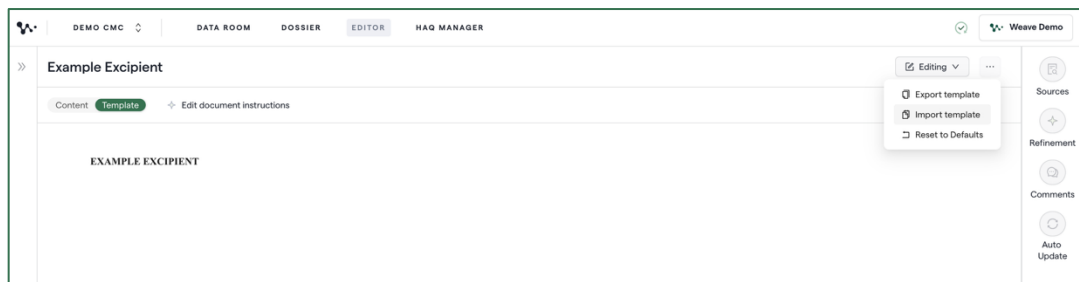
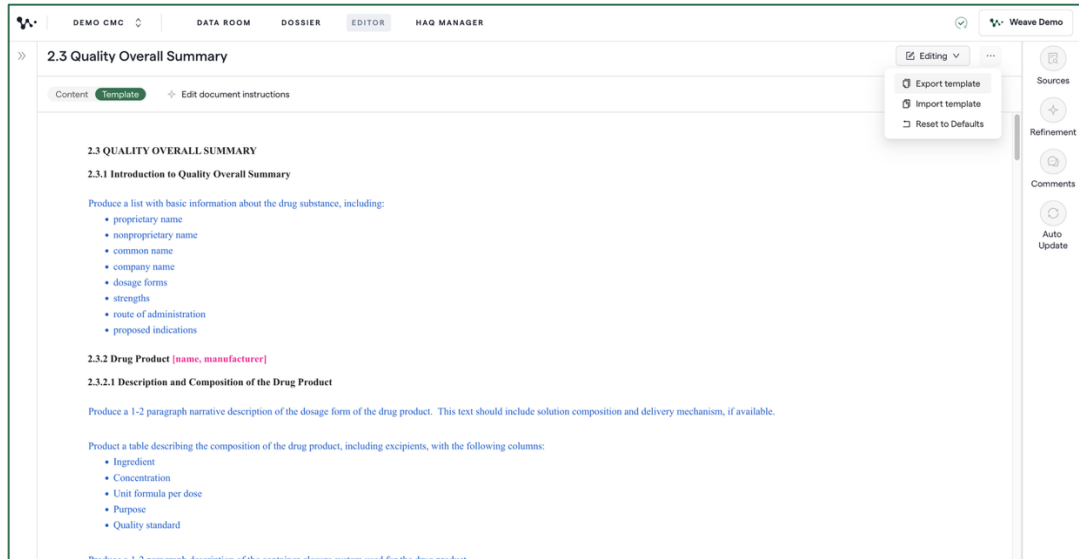


Or simply grab the content and drag to the desired location with the new drag-and-drop functionality. This can also be used to re-order content within the dossier.



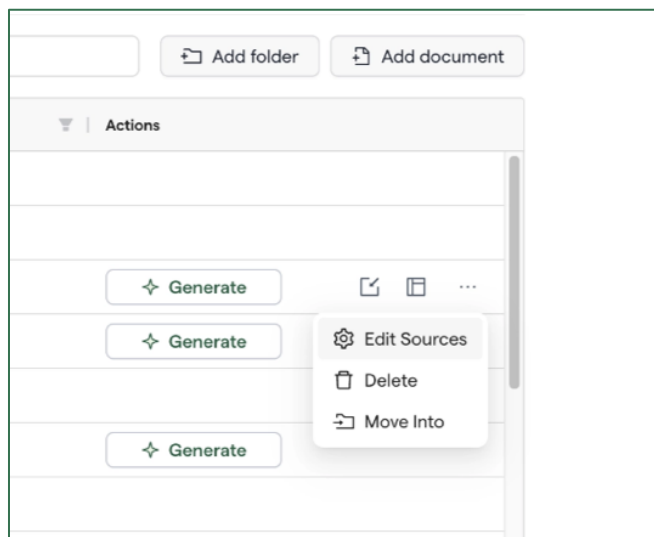
Adapt Weave's existing templates for new documents

Once a document is created, you can start from scratch by adding template blocks or import a template from another document as a starting point to customize.



Assign any document to a data room folder

Working on many CSRs, or a complex product with multiple drug substances or drug products? Now you can constrain any individual document in the dossier to *only* use data from a specific data room folder in initial generation.



HAQ Manager

Improved similar question identification

More similar questions will be returned than before, with the new relevance indicator showing High or Medium or Low for each question.

Similar questions ✨

Responses to these questions may be included in Response source files.

- > File FDA-S18 Question 1 High
- > File S74 Question 1 High
- > File FDA-S74 Question 1 High
- > File BLA STN 125742/0 Question 1 High
- > File S13 Question 1 Medium
- > File FDA-S18 Question 14 Medium
- > File FDA-S18 Question 12 Medium

Data Room folder paths for all files

Files shown under “Response sources files” and “Submitted response files” are now shown with their Data Room folder path to provide additional context besides the file name itself, such as jurisdiction, sequence number, and module.

Response source files ✨

These files will be used as input to the generated response.

125742_S74_M1_response-20aug2021.pdf

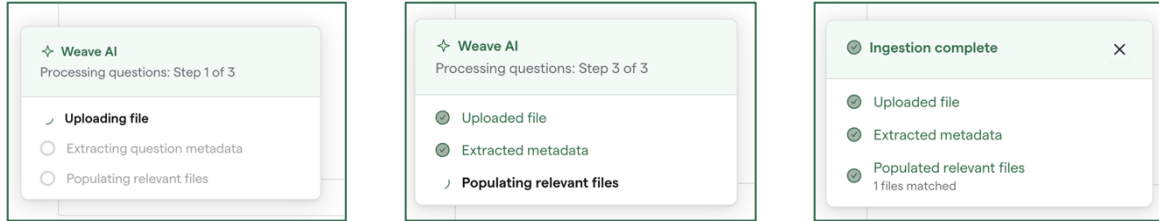
Provides a summary table of numbers and percentages of BNT162b2 and placebo recipients by age group and study period reporting unsolicited adverse events during blinded follow-up in study C4591001

Data room location
us/0001/m1/us/125742_S74_M1_response-20aug2021.pdf

+ Add response source file

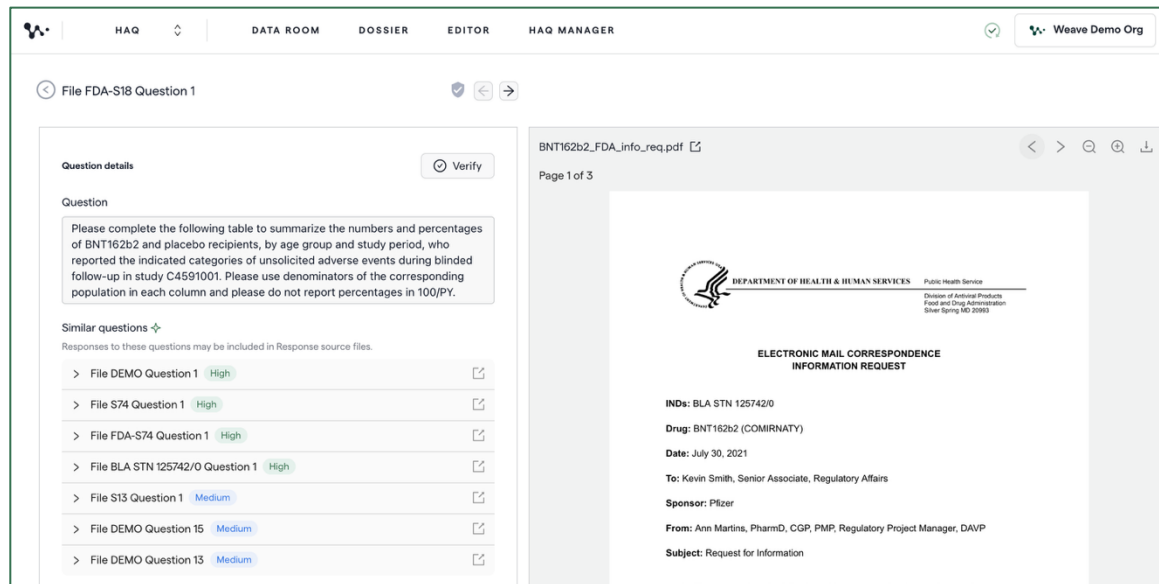
Question file upload progress card

After question file upload, a new progress card appears on the bottom left of the screen to provide additional transparency on processing steps, including file upload vs. extracting metadata vs. finding relevant source response files.



View similar detail questions in a new tab

To look at the details of a similar question, click the box with arrow icon to open that question in its expanded preview in a new tab.



New and Improved Functionality

Submission Builder new:

- Import workflow for a dossier document
- Processing indicators and completion notifications during import
- Matching template prompts reverse-engineered for imported draft documents
- Comments in the imported file imported and shown in the Comments panel
- Ability to continue downstream Editor workflows on imported documents
- Sources indicator on an imported document
- Version History entry for import
- Add, move, delete, and rename documents
- Edit Sources for individual documents

Submission Builder improved:

- Simplified primary action buttons in dossier
- Click directly into a document via its title
- CSR now available in dossier by default

HAQ Manager new:

- Data Room folder paths to all files
- Progress card during question file upload
- Ability to open similar question to the expanded preview
- New Jurisdiction options

HAQ Manager improved:

- Similar questions identification and relevance indicator
- Updated description under Submitted response files