

December 2024 Release Notes

Role-based access control for users

There are three default roles:

- Admin - add and manage users, configure org settings, and more.
- Contributor - generate and edit content, submit for Review or QC, and more.
- Viewer - view content, comment, and export; they cannot edit content.

Organization Settings		
Users	Roles	+ Create a new role
Name	Description	
Contributor	Generate and edit all content, review, QC, and more	...
Viewer	View all content, comment, export	...
Admin	Add and manage users, configure org settings	...
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Managing roles and permissions as an Admin

Admins have exclusive rights to set roles and permissions for their organization and manage organization members. They have two dimensions of control in role- setting:

1. **Role type** - select from Admin, Contributor, or Viewer roles as described above.
2. **Dossier visibility** - specify the parts of the IND a user can access; this can be set at module, section, or document levels.

To create a new role:

1. From the home page, go to **Manage Organization**, and select the **Roles** tab
2. Click the **Create a new role** button
3. Enter a **Role name** and an optional **Description**, then select a **Role type** and adjust the **Dossier** visibility accordingly

ORG SETTINGS

Create role

Role name

Enter name 0 / 50

Description (optional)

Enter description 0 / 80

Role type

Admin Contributor Viewer

Contributors can generate and edit content, submit for Review or QC, and more.
[See more detail about permissions.](#)

Dossier visibility

<input checked="" type="checkbox"/>	Name
<input checked="" type="checkbox"/>	Module 1 Administrative information
<input checked="" type="checkbox"/>	Module 2 Summaries
<input checked="" type="checkbox"/>	Module 3 Quality
<input checked="" type="checkbox"/>	Module 4 Nonclinical Study Reports

Cancel Save

To edit or delete a role, click the three dots to the right of each role.

Note that role types cannot be changed once set; to assign a different role type, create a new role. Each organization must have at least one Admin role.

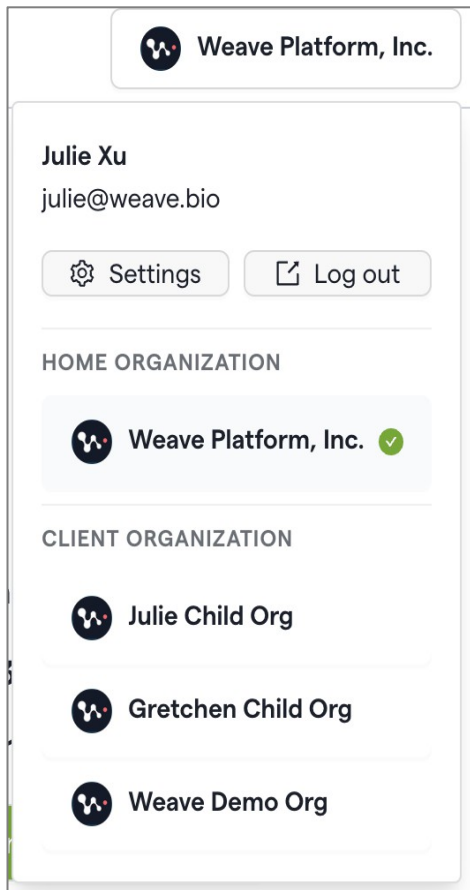
To assign a role to a user:

1. From the home page, go to **Manage Organization**, then the **Users** tab
2. Click the three dots to the right of each user, then **Assign Role**
3. Select from the list of **Roles** and click **Save**

Each organization must have at least one user assigned to an Admin role.

Access and switch between multiple organizations

For Weave customers who want to work with their multiple clients using different instances of AutoIND, Client Organizations can be linked to a Home Organization to provide cross-organization access and maintain consistent branding. Users with access to multiple organizations can easily switch between them via their profile in the top-right corner of the app.



Granular Version History and Restore

It's now even easier to dive into what changes were made to a document and, if necessary, revert those changes to a previous version. Every change to a doc now creates an individual numbered version that can be previewed or restored.

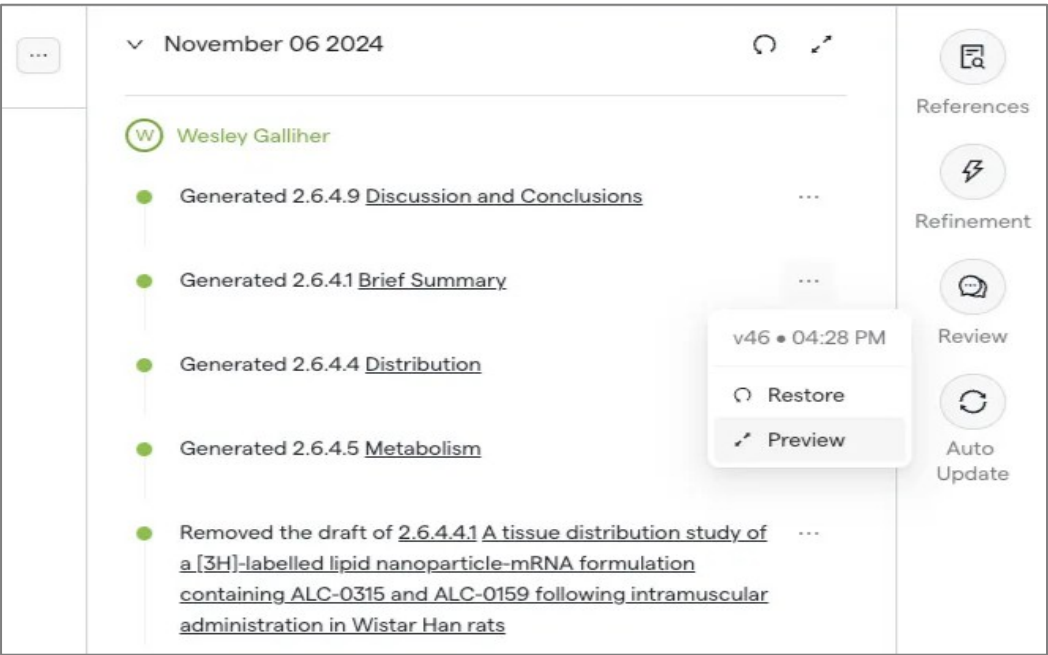


Table References

In addition to viewing fine-grained references for each sentence in generated content, now every cell in a table will show references to the source file(s) contributing to the data in that cell.

2.6.4 Pharmacokinetic written summary Saved Submit for review

Table 2: Overview of Pharmacokinetic Studies

Type of Study	Study Title	Test System	Testing Method	Testing Facility	Study Number	GLP
Distribution	A SINGLE DOSE PHARMOKINETICS STUDY OF ALC-0315 AND ALC-0159	Rat (Wistar Han)	In vivo (IV)	Pfizer, San Diego, CA, USA	PF-07302048 06Jul20 072424	Non-GLP
Metabolism	In Vitro Metabolic Stability of ALC-0315 in CD-1/ICR Mouse, Sprague Dawley Rat, Wistar Han Rat, Cynomolgus Monkey, and Human Liver Microsomes	CD-1/ICR Mouse, Sprague Dawley Rat, Wistar Han Rat, Cynomolgus Monkey, Human	In vitro	Medicilon Preclinical Research, Shanghai, China	01049-20008	Non-GLP

The study aimed to evaluate the in vitro metabolic stability of ALC-0315 in liver microsomes from various species, including CD-1/ICR mouse, Sprague Dawley rat, Wistar Han rat, cynomolgus monkey, and human. The study was conducted by Medicilon Preclinical Research (Shanghai) LLC under non-GLP conditions, following approved protocols and standard operating procedures.

References

REFERENCES FOR SELECTED
126742_S1_M4_4.2.2.4-01049-20008.pdf
Last refreshed 2min ago

100% MATCH

PAGE 3

Inspect source

RESULTS A summary of the % remaining parent compound, CL_{int} and half-life of ALC-0315 obtained from a 2-hour incubation of ALC-0315 with liver microsomes from CD-1/ICR mouse, Sprague Dawley rat, Wistar Han rat, cynomolgus monkey, and human is presented in Table 2.

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PAGE 6

Q

*Medicilon Medicilon Preclinical Research (Shanghai) LLC Test Article: ALC-0315 Study No.: 01049-20008 The following pooled liver microsomes of CD-1/ICR mouse, Sprague Dawley rat, Wistar Han rat, cynomolgus monkey, and human were stored in a -70°C ultra low temperature freezer p... more

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PAGE 1

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See table 'In Vitro Metabolic Stability of ALC-0315 in CD-1/ICR Mouse, Sprague Dawley Rat, Wistar Han Rat, Cynomolgus Monkey, and Human Liver Microsomes' on Page 1.

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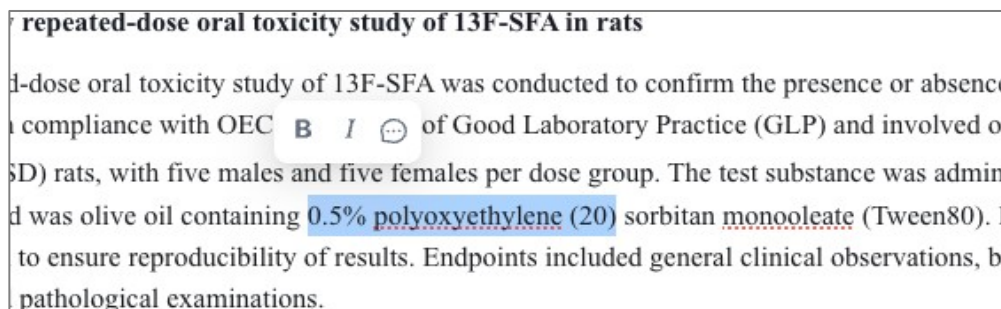
PAGE 3

Q

*Medicilon Medicilon Preclinical Research (Shanghai) LLC Test Article: ALC-0315 Study No.: 01049-20008 SUMMARY This study evaluated the in vitro metabolic stability of ALC-0315 in liver microsomes of CD-1/ICR mouse, Sprague Dawley rat, Wistar Han rat, cynomolgus monkey, a... more

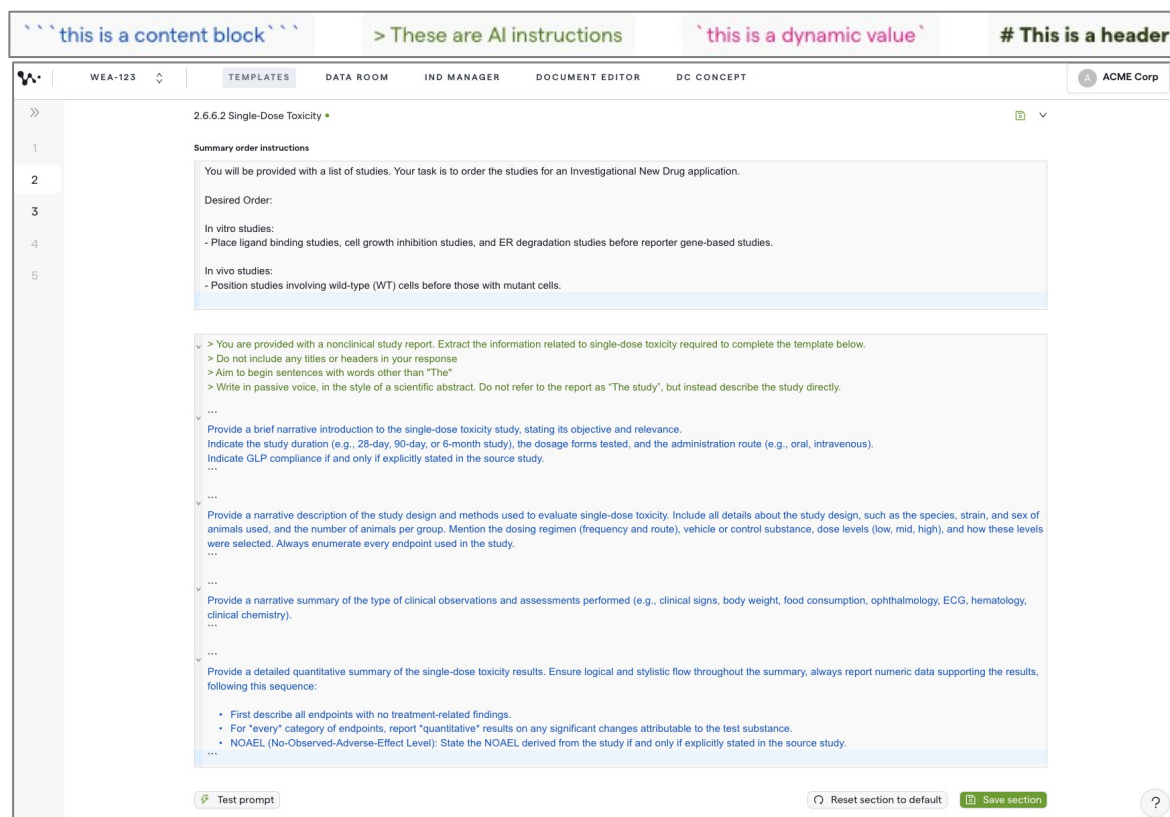
Add Comments While Drafting

All users are now able to add comments to document text throughout the drafting process, not just when in Review mode.



Content Templates Updates

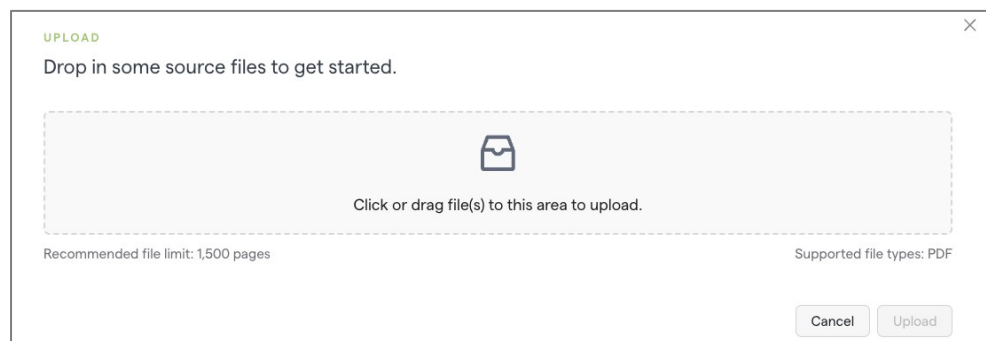
The content templates that are used to generate key nonclinical documents (Sections 2.2, 2.4, and 2.6) have been updated to support the new template syntax. This allows for creation of separate content blocks, distinct AI instructions for the section, use of dynamic values, and structuring the section with content headers.



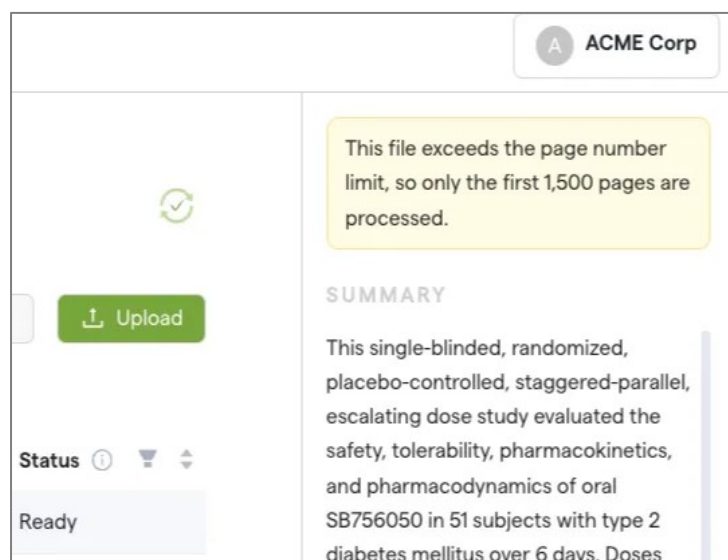
Additionally, the underlying system-level prompts have been simplified to minimize any potential prompt instruction conflicts with user-configurable content templates.

Data Room Improvements

Uploads of large PDF documents containing more than 1,500 pages are now supported. The upload modal displays the supported file types (PDF only) and recommended file page limit (1,500 pages).



If a file exceeding that page number limit is uploaded, only the first 1,500 pages will be processed and the preview panel in the data room will display an indicator noting that.



New, Improved, Fixed

New

- Default roles and role types of Admin, Contributor, Viewer
 - Each role type has pre-set permissions reflected accordingly across AutoIND
- Ability for an Admin user to create, edit, assign and delete roles based on role type and dossier visibility
- Creation of client organizations that are associated with home organizations
- Ability for a user to have access to multiple organizations and switch between them
- Every change to a document creates an individual version that can be previewed
- Document can be restored to the state in which it existed in a previous version
- Comments can be added by any user while the document is being drafted
- Source references can be viewed for table cells
- Data room document previews will indicate if pages beyond the 1,500 page limit were not processed

Improved

- Ability to optionally select a Role when inviting a new member
- Source files with more than 1500 pages no longer fail, but only the first 1500 pages will be processed
- Templates for sections 2.2, 2.4, & 2.6 now support creation of content blocks, AI instructions, dynamic values, and headers

Fixed

- Fixed issue where certain tables were not included in the exported Docx files
- Fixed multiple issues with comment highlighting when a doc is in review mode
- Fixed issue where section “2.4.3 Pharmacokinetics ” could not be generated when only “2.6.4.8 Other Pharmacokinetic Studies ” had been summarized
- Improved the display & formatting of document content with References panel open

