Study Advisor: Accelerating your Data Review Plan

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Thank you for joining. We will be starting shortly.

Agenda

1. Introduction to Study Advisor
2. Create a New Study from a Protocol
3. Review / Integrate suggested Review Objectives
4. Questions

Questions



Study Advisor

Study Advisor is…

Your single repository for all study documents – powering elluminate study intelligence across the platform.

Study Advisor

AI-powered Study Advisor uses the Study Protocol to streamline study set up and review planning by centralizing study documents, extracted study detail, and Review Objective recommendations.

It can:

- Create a study from an uploaded **Study Protocol** (PDF/DOCX)
- Extract key configuration fields and push them into Study Configuration
- Manage protocol documents and versions
- Suggest and manage Review Objectives for review planning
- Feed context to Data Advisor for smarter analyses

Study Advisor helps teams move from

Protocol to **Configured Study** to **Actionable Review Plans**

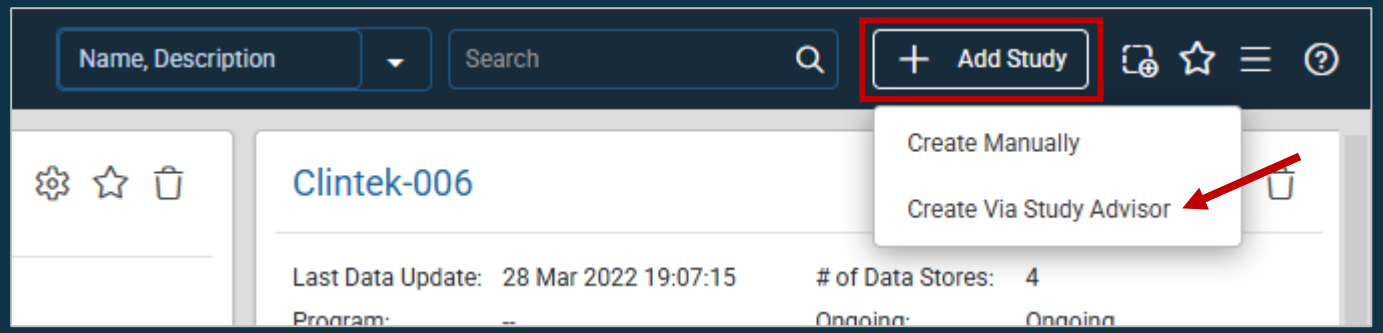
with less manual effort, while maintaining **human review** and **control** throughout the process.

Study Advisor

Required Privileges

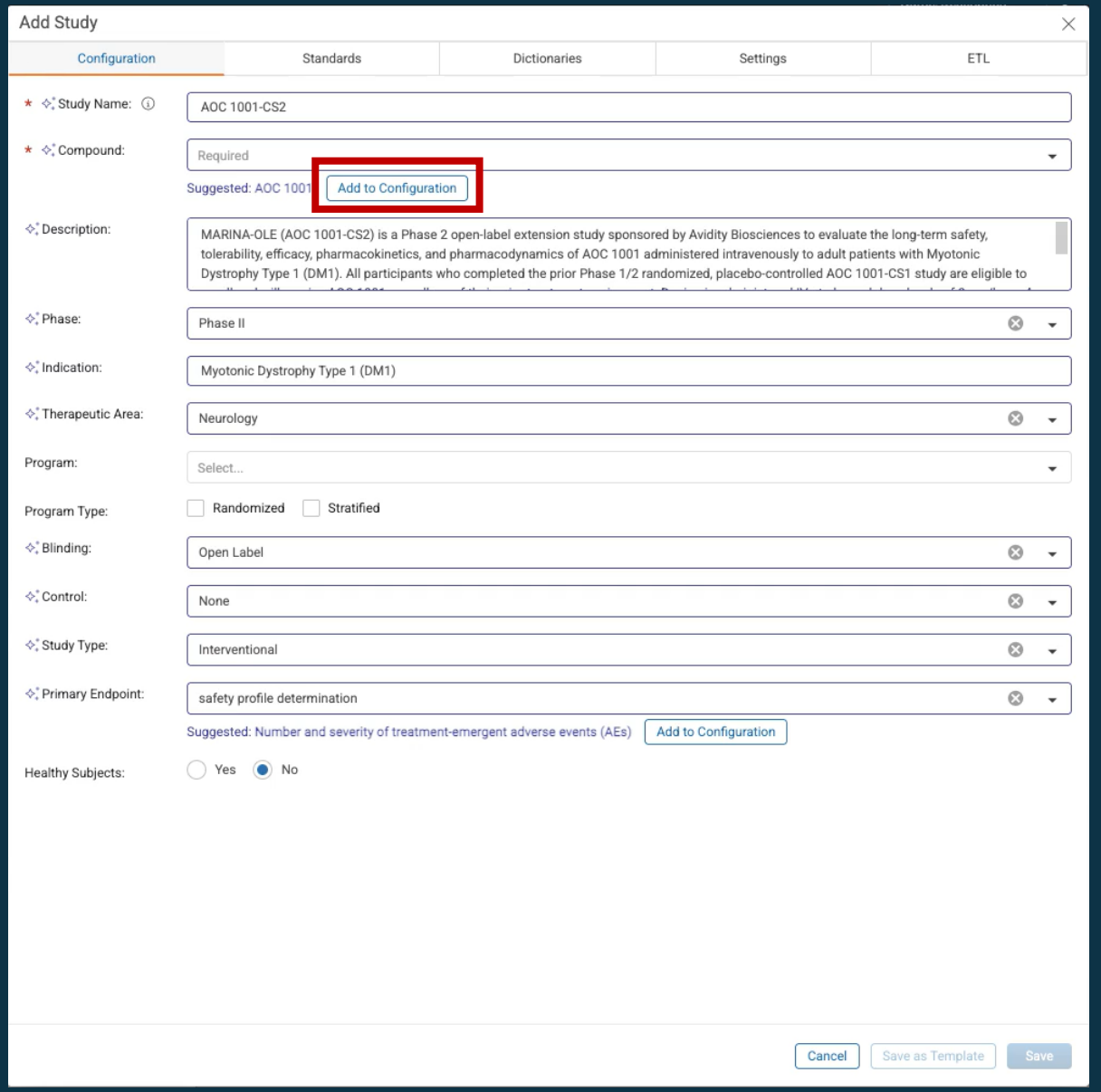
for new study creation

Administer or Study Configure



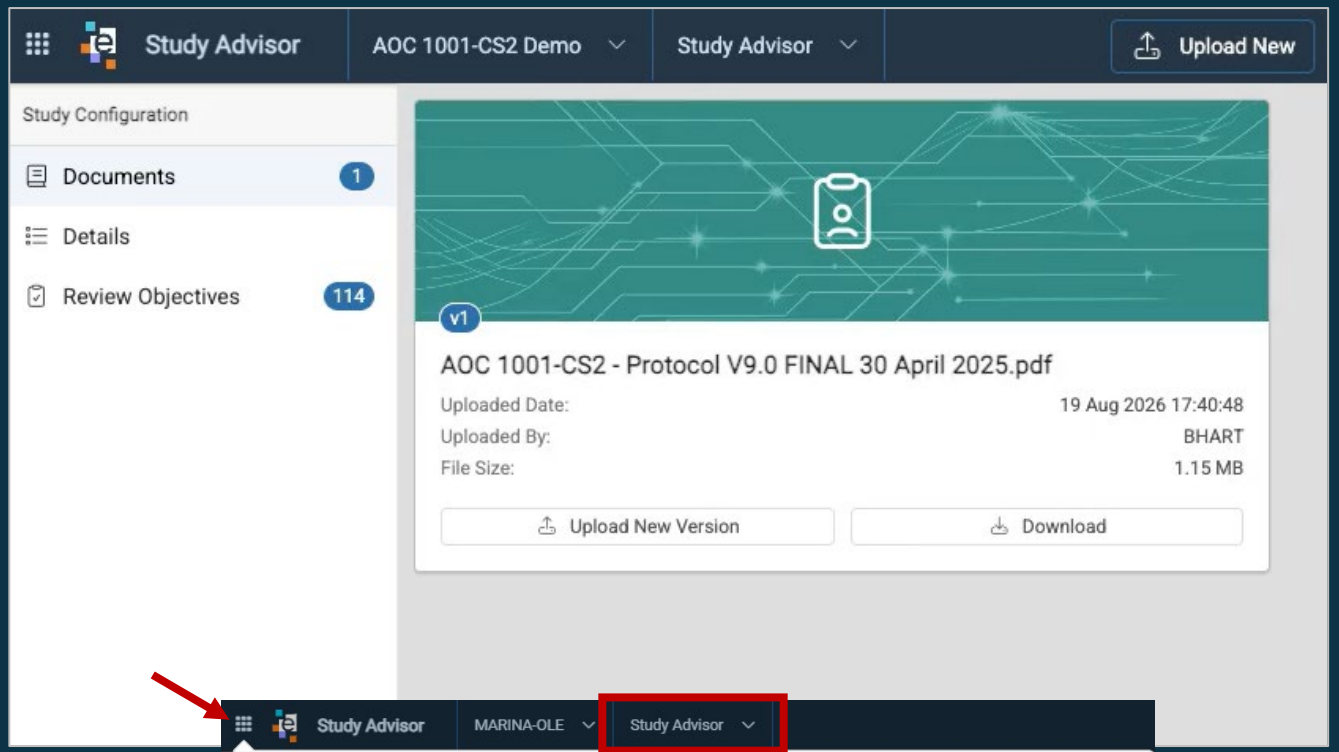
Study Advisor

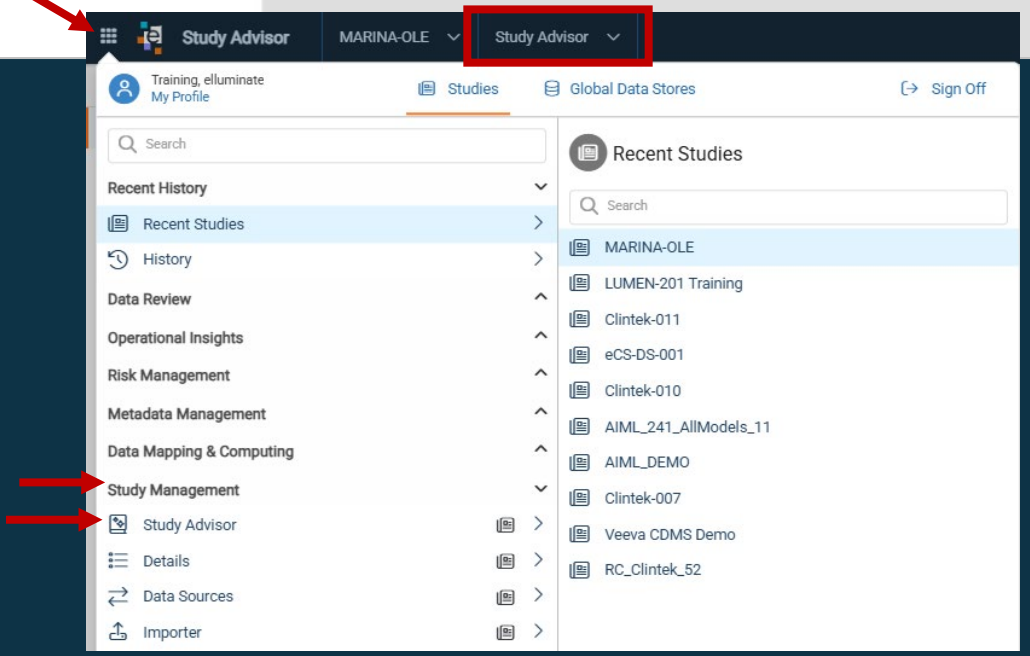
- Extracts key information to populate the Configuration tab.
- Any configuration items not already defined within elluminate can easily be added.
- Review, edit, confirm / save.



Study Advisor

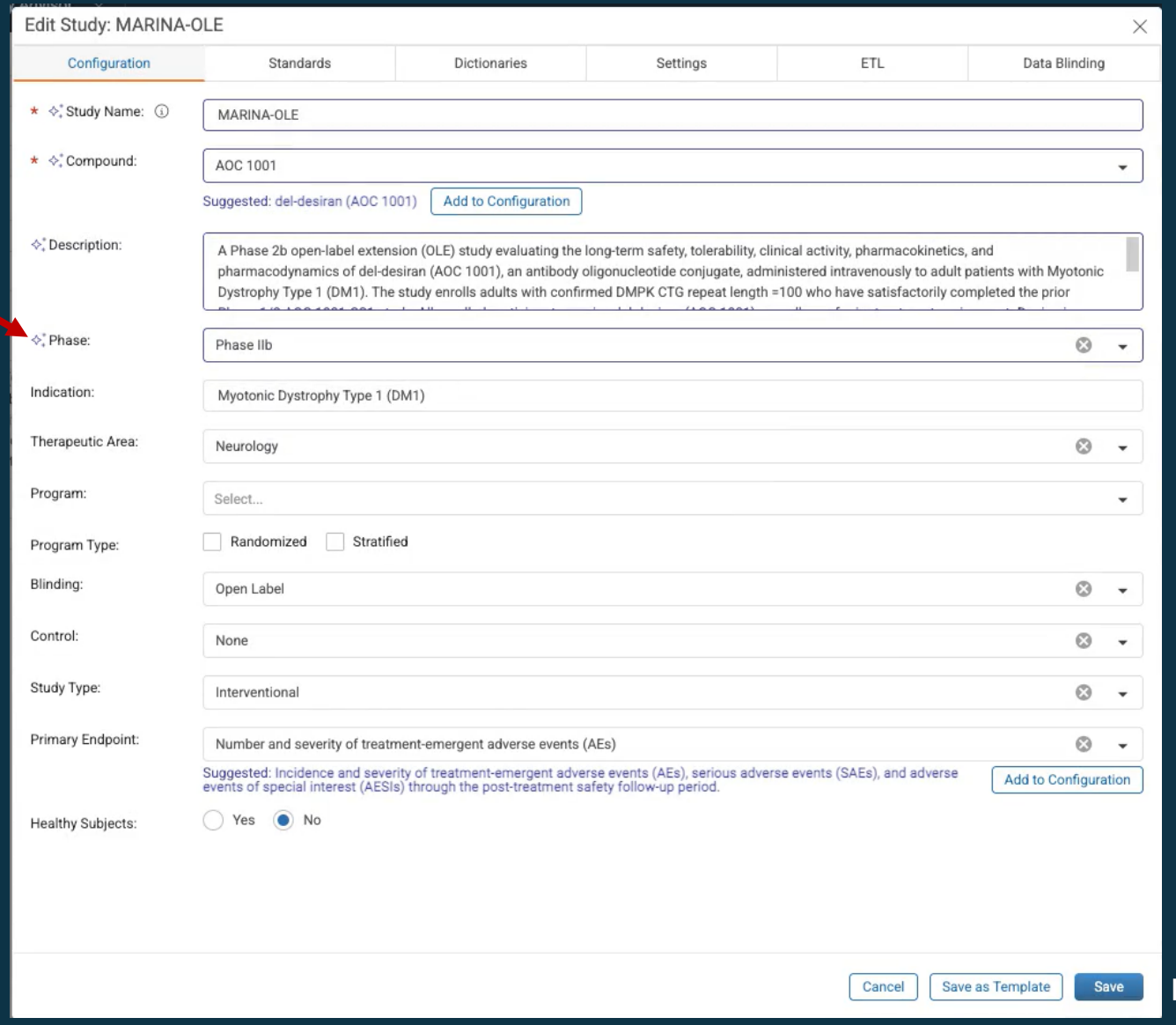
- Document management is handled from the Study Advisor section of elluminate.
- Users with the following privileges can upload new versions of the protocol as well as other study documents:
  - Administer
  - Study Configure
  - eDrive Read Write



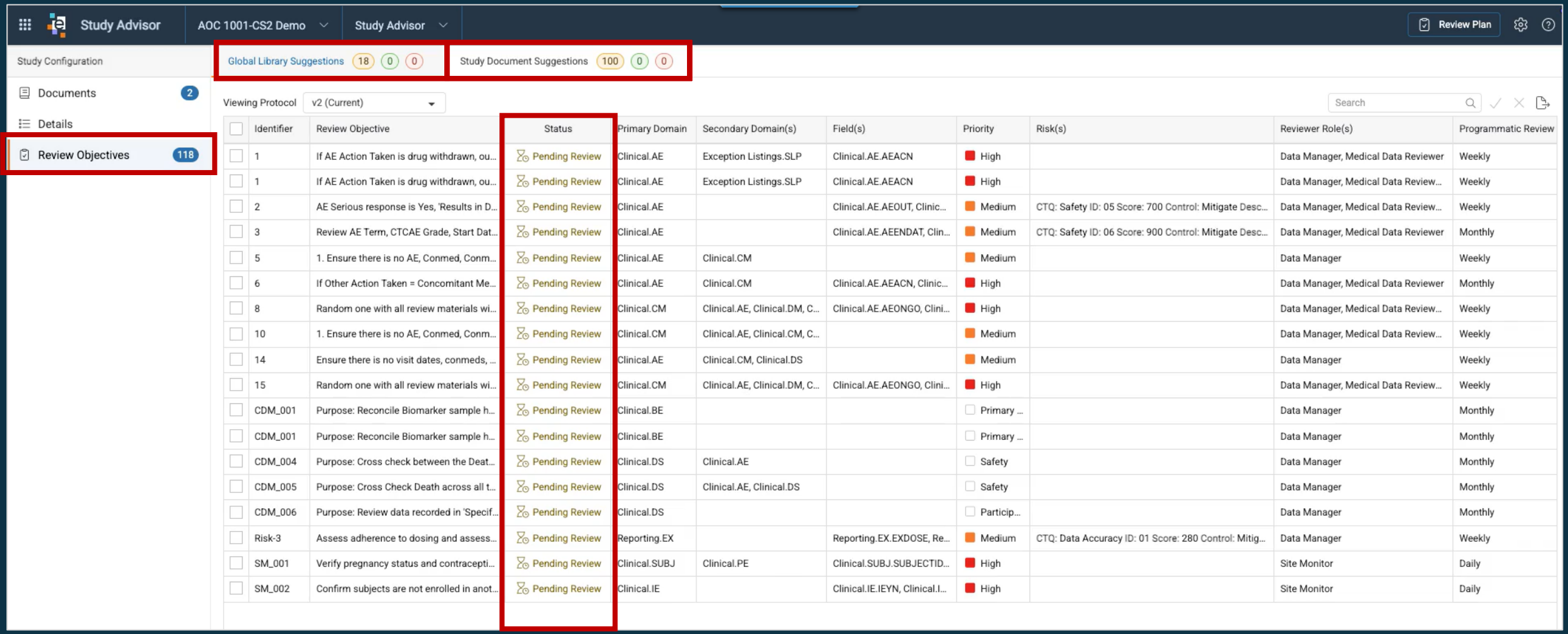


Study Advisor

- When a new version of the protocol is uploaded, you can push the extracted information to study configuration – any new information is identified by a sparkle icon.
- Review and edit as needed and then save.



Study Advisor



Identifier	Review Objective	Status	Primary Domain	Secondary Domain(s)	Field(s)	Priority	Risk(s)	Reviewer Role(s)	Programmatic Review
1	If AE Action Taken is drug withdrawn, ou...	Pending Review	Clinical.AE	Exception Listings.SLP	Clinical.AE.AEACN	High		Data Manager, Medical Data Reviewer	Weekly
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2	AE Serious response is Yes, 'Results in D...	Pending Review	Clinical.AE		Clinical.AE.AEOUT, Clinic...	Medium	CTQ: Safety ID: 05 Score: 700 Control: Mitigate Desc...	Data Manager, Medical Data Review...	Weekly
3	Review AE Term, CTCAE Grade, Start Dat...	Pending Review	Clinical.AE		Clinical.AE.AEENDAT, Clin...	Medium	CTQ: Safety ID: 06 Score: 900 Control: Mitigate Desc...	Data Manager, Medical Data Reviewer	Monthly
5	1. Ensure there is no AE, Conmed, Conm...	Pending Review	Clinical.AE	Clinical.CM		Medium		Data Manager	Weekly
6	If Other Action Taken = Concomitant Me...	Pending Review	Clinical.AE	Clinical.CM	Clinical.AE.AEACN, Clinic...	High		Data Manager, Medical Data Reviewer	Monthly
8	Random one with all review materials wi...	Pending Review	Clinical.CM	Clinical.AE, Clinical.DM, C...	Clinical.AE.AEONGO, Clini...	High		Data Manager, Medical Data Review...	Weekly
10	1. Ensure there is no AE, Conmed, Conm...	Pending Review	Clinical.CM	Clinical.AE, Clinical.CM, C...		Medium		Data Manager, Medical Data Review...	Weekly
14	Ensure there is no visit dates, conmeds, ...	Pending Review	Clinical.AE	Clinical.CM, Clinical.DS		Medium		Data Manager	Weekly
15	Random one with all review materials wi...	Pending Review	Clinical.CM	Clinical.AE, Clinical.DM, C...	Clinical.AE.AEONGO, Clini...	High		Data Manager, Medical Data Review...	Weekly
CDM_001	Purpose: Reconcile Biomarker sample h...	Pending Review	Clinical.BE			Primary ...		Data Manager	Monthly
CDM_001	Purpose: Reconcile Biomarker sample h...	Pending Review	Clinical.BE			Primary ...		Data Manager	Monthly
CDM_004	Purpose: Cross check between the Deat...	Pending Review	Clinical.DS	Clinical.AE		Safety		Data Manager	Monthly
CDM_005	Purpose: Cross Check Death across all t...	Pending Review	Clinical.DS	Clinical.AE, Clinical.DS		Safety		Data Manager	Monthly
CDM_006	Purpose: Review data recorded in 'Specif...	Pending Review	Clinical.DS			Particip...		Data Manager	Monthly
Risk-3	Assess adherence to dosing and assess...	Pending Review	Reporting.EX		Reporting.EX.EXDOSE, Re...	Medium	CTQ: Data Accuracy ID: 01 Score: 280 Control: Mitig...	Data Manager	Weekly
SM_001	Verify pregnancy status and contracepti...	Pending Review	Clinical.SUBJ	Clinical.PE	Clinical.SUBJ.SUBJECTID...	High		Site Monitor	Daily
SM_002	Confirm subjects are not enrolled in anot...	Pending Review	Clinical.IE		Clinical.IE.IEYN, Clinical.I...	High		Site Monitor	Daily



Study Advisor:

Adding a study

Thank you!





