

Congruency Review FAQs

What is a Congruency review?

The SPA Clinical Research Services groups, Central Coverage Analysis Group (CCAG), as well as the Industry Agreements team, are responsible for ensuring that the information present in the finalized contract (including budget), is in line with the final coverage analysis (CA), contract language and consent form (ICF) language. This review is divided between these two groups who are trained to make the appropriate determinations.

Is this a new process?

No. The process, relative to contract negotiations and coverage analysis process, will remain unchanged. Starting **August 1, 2020**, CCAG team will utilize new Study Statuses in Velos to document the review.

What will change?

Once the coverage analysis draft is created, it will be loaded as an excel spreadsheet into Velos, under the Documents tab. The CCAG team will document this as “Coverage Analysis - Final Budget Requested,” and the study team will receive an email notification, and will be able to view the draft budget in the system.

How will the CCAG team access my budget?

Budgets should continue to be loaded into eAgreements, as per the current process. Once the budget is finalized, the study team will log into the Velos Study and select status, “Study - Final Budget Complete.” The CCAG team will review the draft CA against the final budget and ICF; specifically, the section that refers to financial coverage, and adjust CA to match:

- If all items match, the CCAG team will send out the final CA via DocuSign.
- If adjustments have to be made to either the ICF or budget, the CCAG team will send the CA back to the study team via Velos with specific instructions, using study status, “Coverage Analysis - Congruency Corrections Pending.”

Will the CCAG team be responsible for reaching out to IRB to request changes?

No, it is the responsibility of the study team. Upon making the requested changes, the study team will log into the Velos Study and select status, “Study - Final Budget Complete.”

A MOD to my study is needed in eIRB, will this cause delays?

As long the CCAG team is able to confirm that the requested changes have been submitted to the IRB office, final MOD approval will not be needed, as this would be considered an administrative change that would be aligning study documents with contract terms. However, IRB may request additional information from the study team.