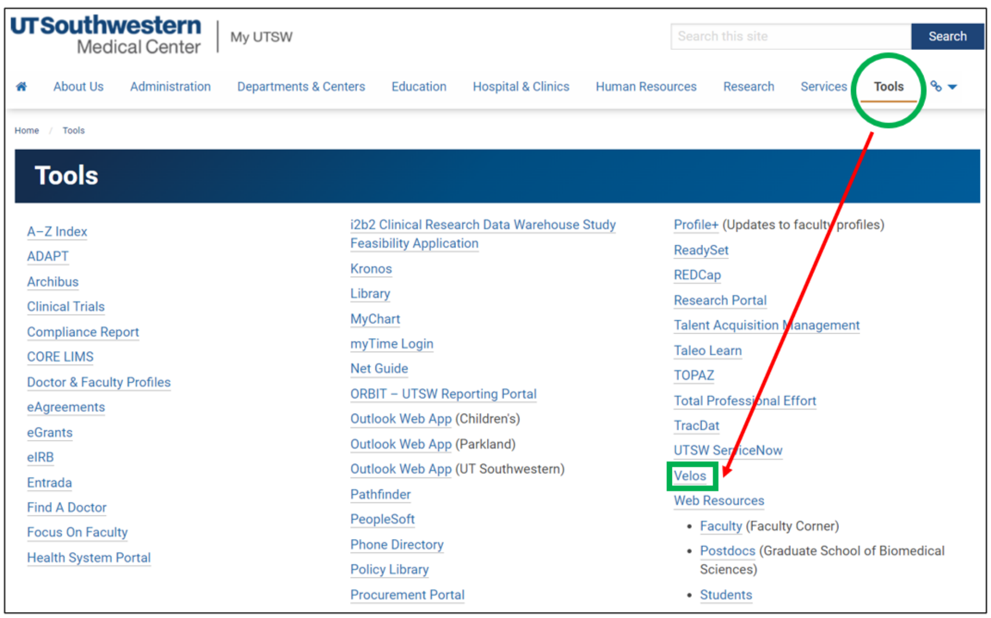
Q2. How do I request a coverage analysis?

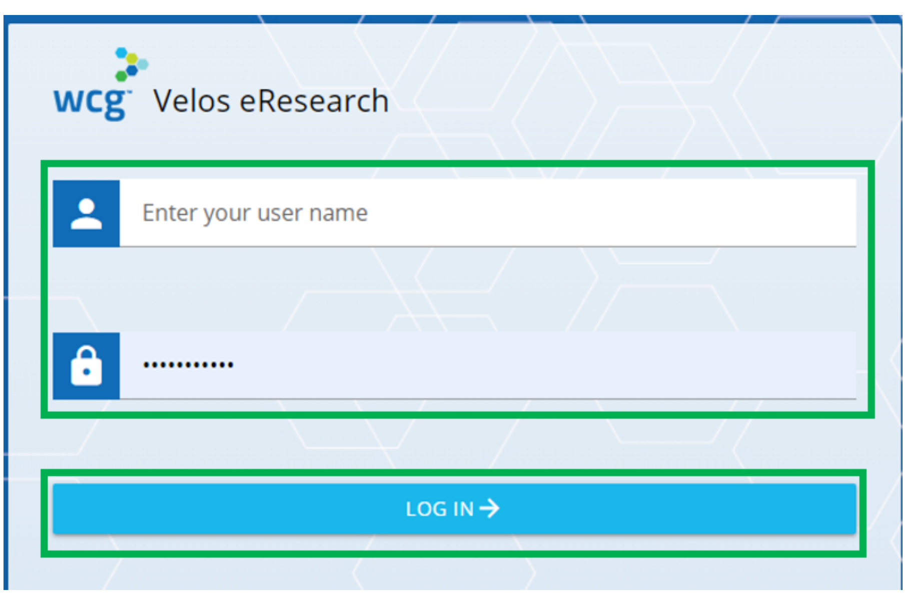
The process begins by determining whether your study requires a coverage analysis by the SPA Clinical Research Services team. UT Southwestern utilizes Velos, a CTMS (Clinical Trial Management System), to manage the coverage analysis process. To request a coverage analysis review, please adhere to the following steps. These tasks may be completed in parallel when appropriate.

- Manage all updates and results on clinicaltrials.gov. Refer to tip sheet under Resources for more information.
- Request access to Velos and eIRB by completing the eResearch Access Request Form.
- Register your study in Velos. Refer to tip sheet under Resources for more information.
- Register your study with IRB. Refer to tip sheet under Resources for more information.
- Request a Coverage Analysis from SPA's Coverage Analysis Team. You can submit your Coverage Analysis (CA) documents through the Velos system once your IRB application is complete or in draft. Refer to tip sheet under Resources for more information.

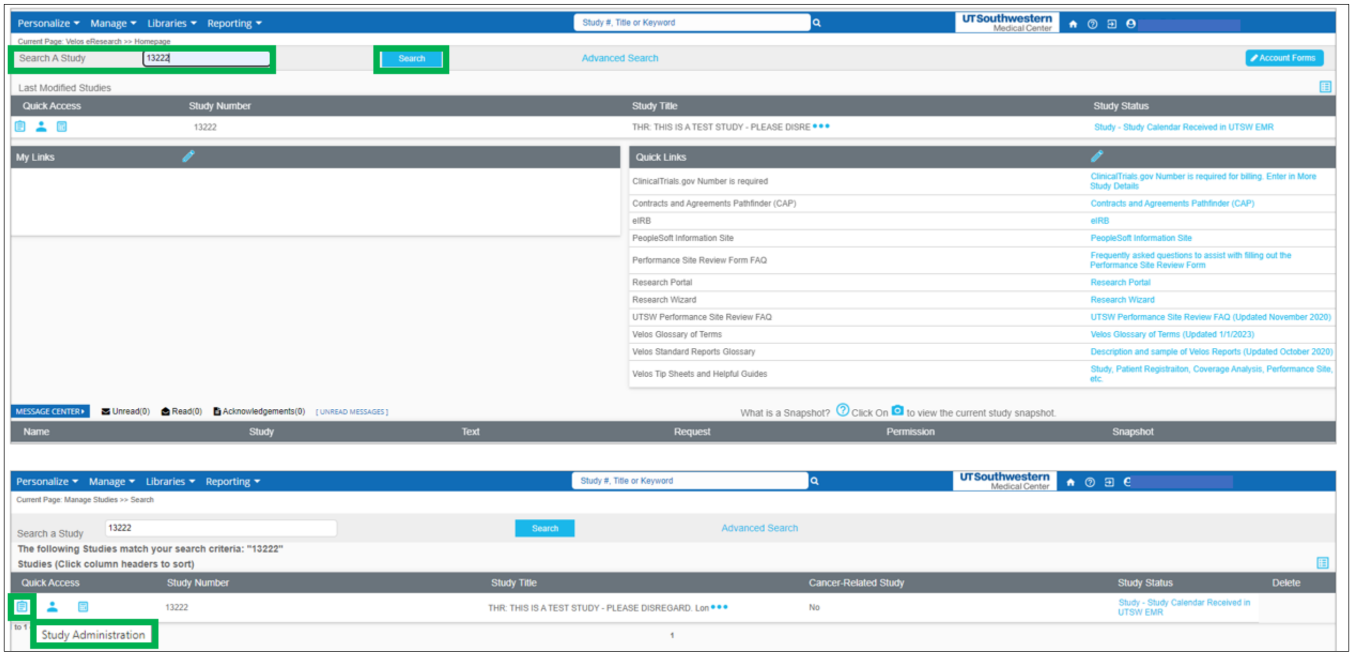
To request a coverage analysis, login to **Velos** from the **Tools** page on the UTSW website.



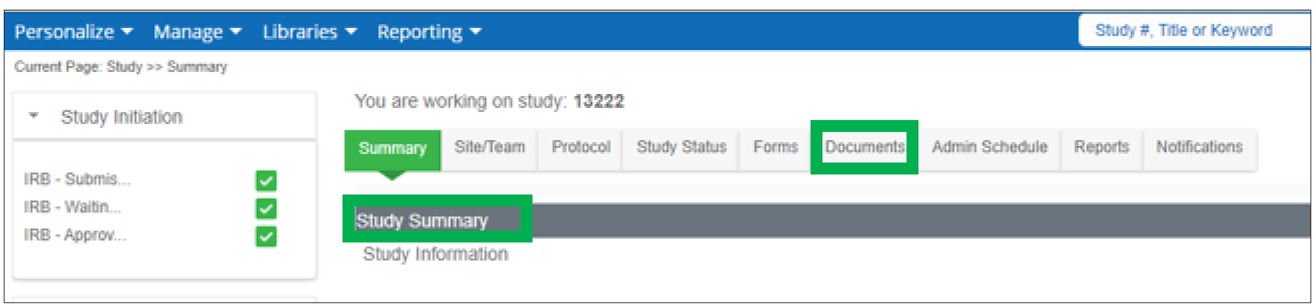
Enter your UTSW username and password to login.



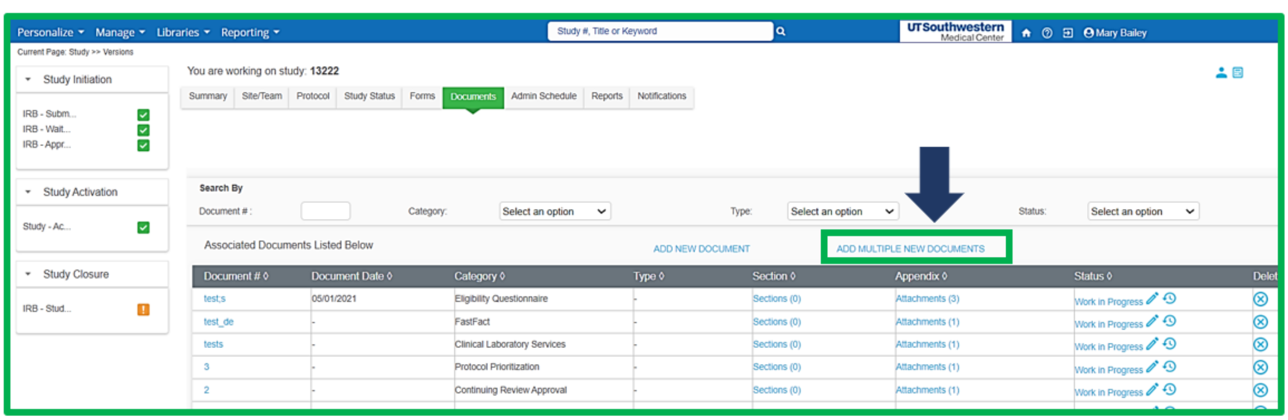
In the **Search a Study** field, enter the study number, then click **Search**. Next, click the **Study Administration** icon to pull up the study summary.



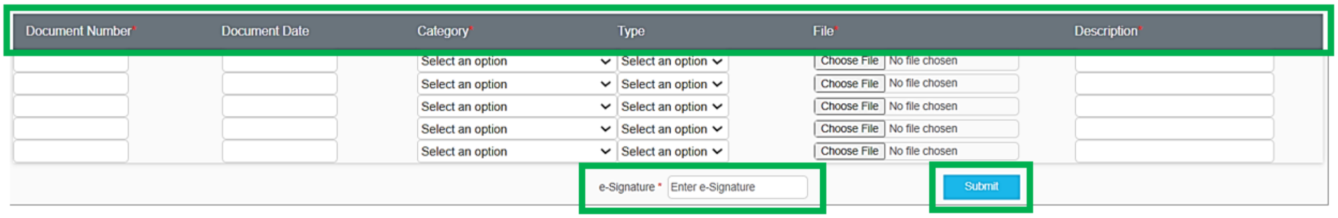
From the **Study Summary** page, click the **Documents** tab.



After clicking the **Documents** tab, a new screen appears. Select **Add Multiple New Documents**.



This will direct you to a second screen where you will upload all required documents (see **Documents to Upload** under **items 1 through 8** below):



Documents to upload:

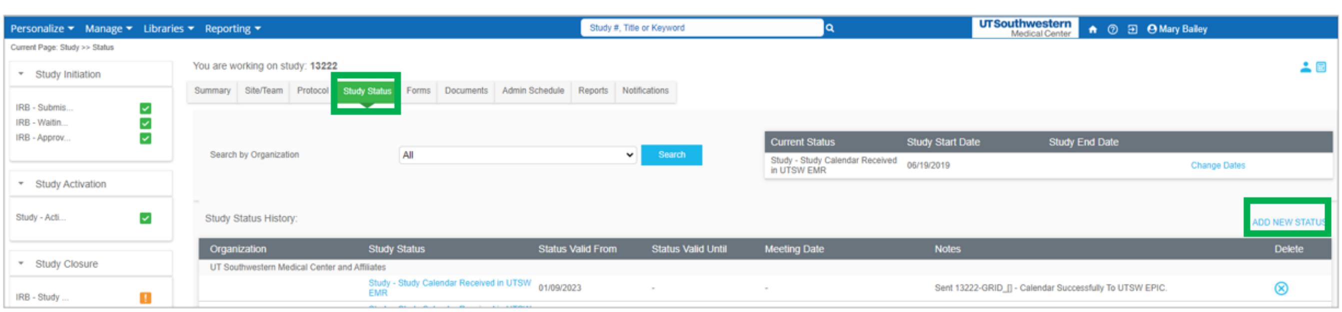
1. Protocol
2. Consent draft
3. Budget draft, if available
4. Investigational New Drug (IND) letter, if applicable
5. Investigational Device Exemption IDE letter, if applicable
6. Centers for Medicare & Medicaid Services (CMS) IDE approval letter, if billing to Medicare will be done on a research device
7. ClinicalTrials.gov Registration Number (NCT) number
8. IRB application draft

In the remaining columns in the screenshot above, enter the following document information for each document:

9. Document Number
10. Document Date
11. Category
12. Type
13. File
14. Description

Enter e-Signature, then click Submit.

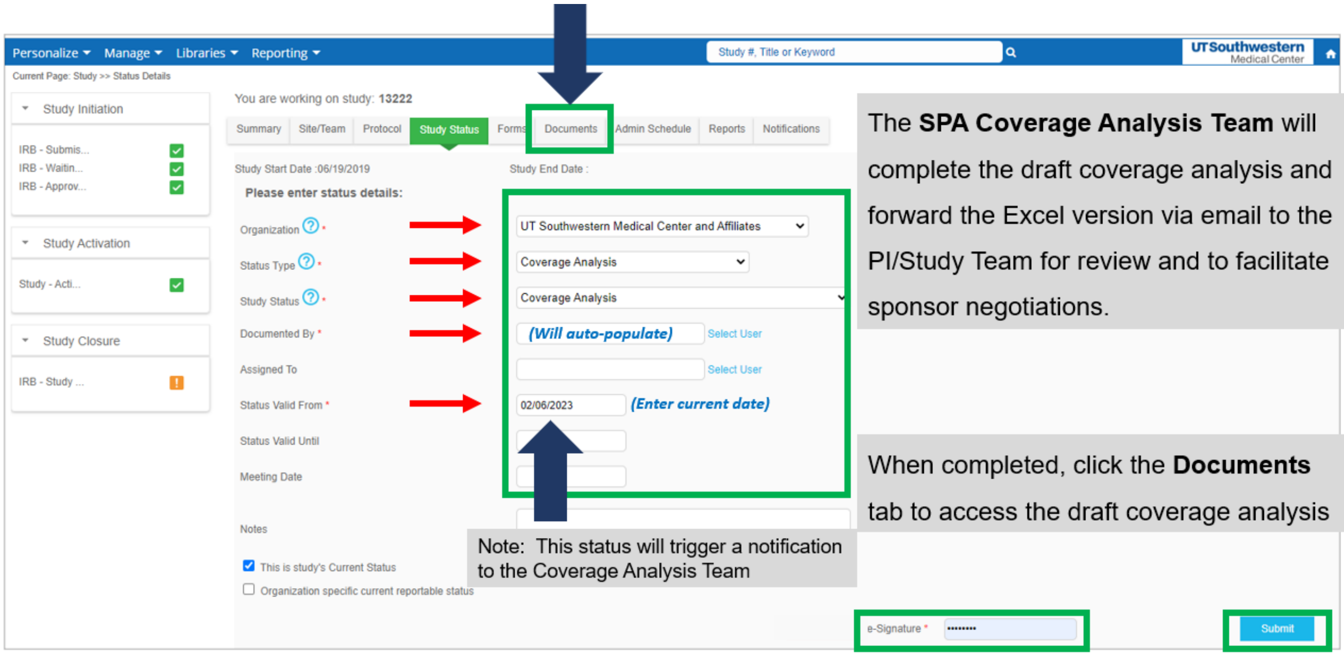
On the next screen, select **Study Status**, then **Add New Status**.



Next, enter these status details (see screenshot below):

- Organization: choose UT Southwestern Medical Center & Affiliates
- For Status Type and Study Status- Select Coverage Analysis
- Documented By- this field will auto-populate

- Status Valid From- ***enter the current date***. Please note that this status will trigger a notification to the Coverage Analysis team.
- Enter e-Signature
- Then click Submit.



The SPA Coverage Analysis Team will complete the draft coverage analysis and forward the Excel version via email to the PI/Study Team for review and to facilitate sponsor negotiations. You may also access the draft coverage analysis once it is completed by clicking the study's **Documents** Tab. The next steps are as follows:

- Negotiate your final budget with sponsor. Refer to SPA Website: SPA Negotiates Terms for more information.
- A copy of the final coverage analysis will be sent as a PDF and includes the Coverage Analysis Billing Grid and Coverage Analysis Form to the PI/Study Team via DocuSign for final approval (upon final sponsor budget/grant).
- PI will approve Coverage Analysis in DocuSign.
- The SPA Coverage Analyst will add the study status of "Coverage Analysis- PI Approved" to the study in Velos and will update the Coverage Analysis Form.
- Review approved Coverage Analysis and request changes if applicable. Refer to the Velos Coverage Analysis Modification tip sheet under **Resources** for more information.

Resources

ClinicalTrials.gov	Coverage Analysis Submission Tip Sheet
Clinical Trials.gov Tip Sheets	Velos Coverage Analysis Modification Tip Sheet
Clinical Trials.gov Submission Guidance	SPA Website: SPA Negotiates Terms
Velos/IRB Study Registration Tip Sheet	SPA Website: Review Study