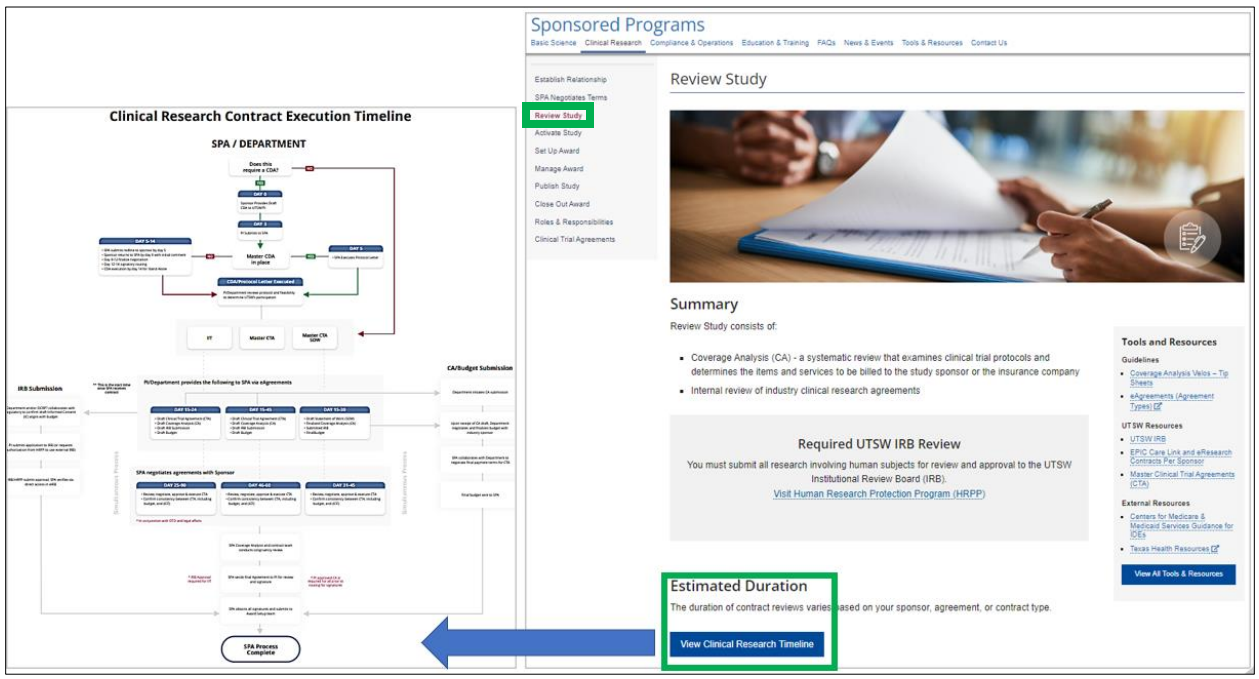
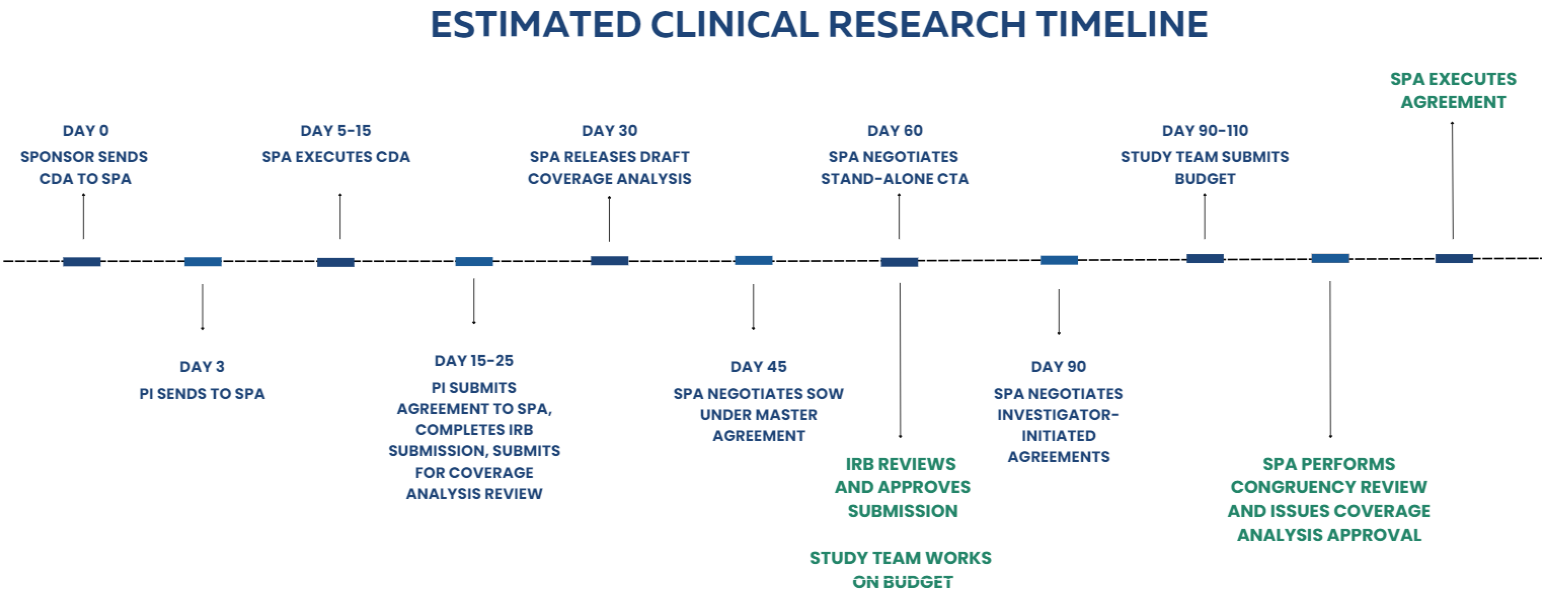
Q4. What is the timeline of a clinical research study? What is the order of the steps and what steps can be taken concurrently?

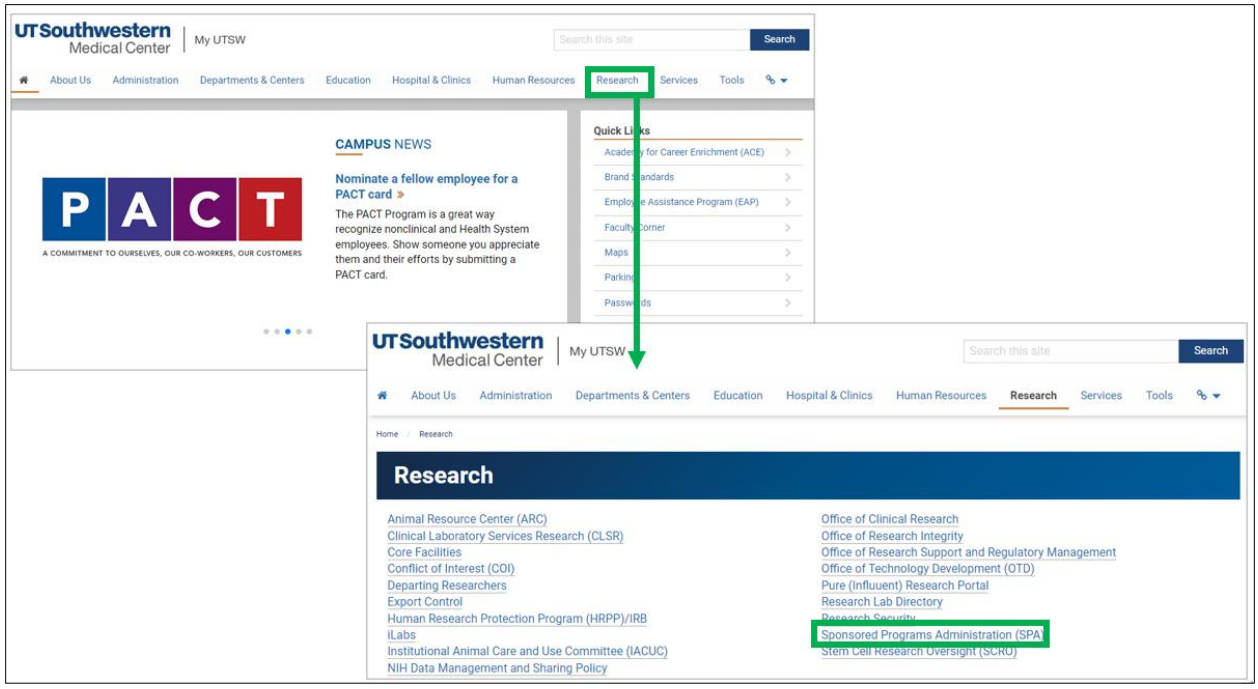
The timeline below represents an **overview** of clinical research. The **full version** is available on the Sponsored Programs website. The link is included in the resources section below.



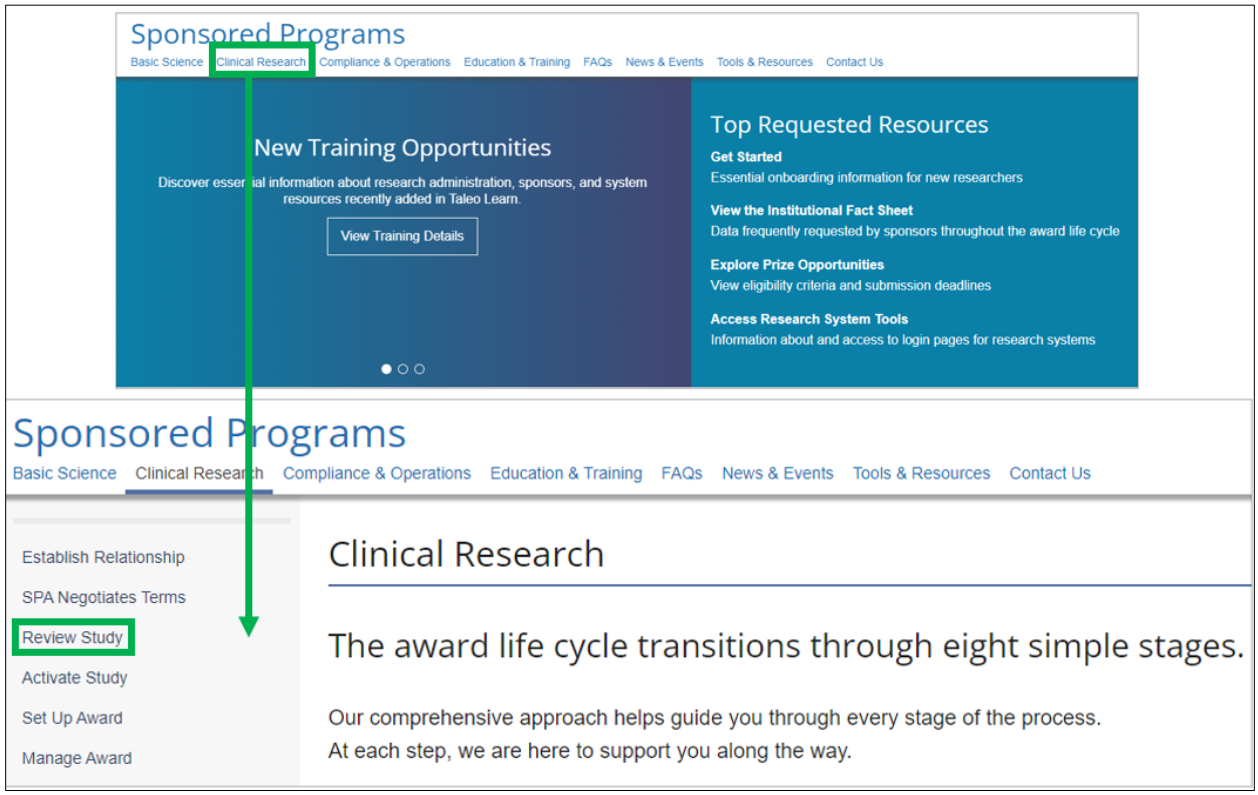
- Please note, the **overview** timeline below is for internal use only and not intended for sharing with external stakeholders. The timeline is based upon time estimates, but specific items may take a longer or shorter duration of time.



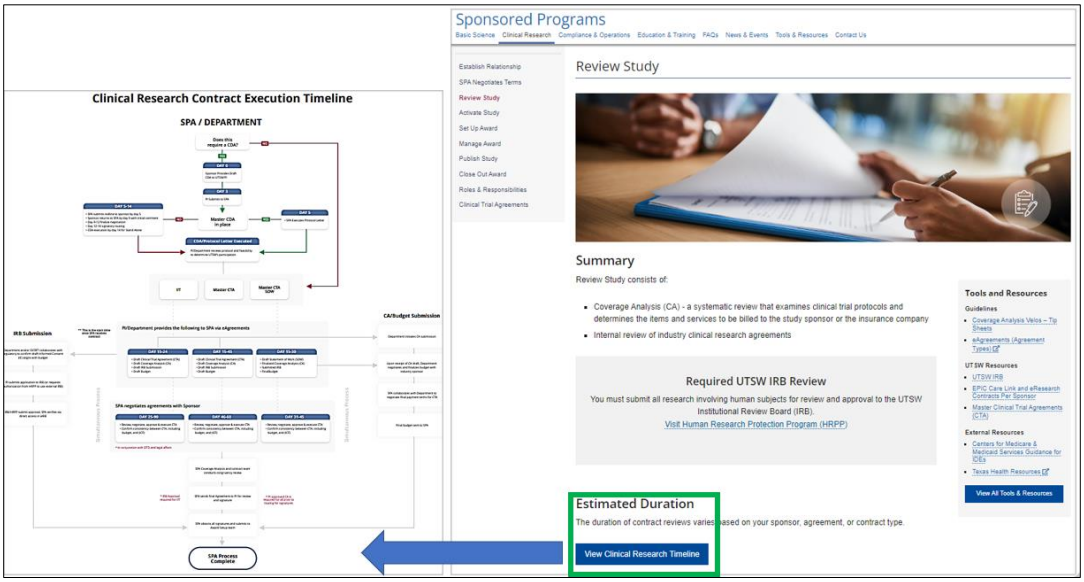
To locate the **full version** timeline, click the **Research** tab on the UTSW website, then select **Sponsored Programs Administration**.



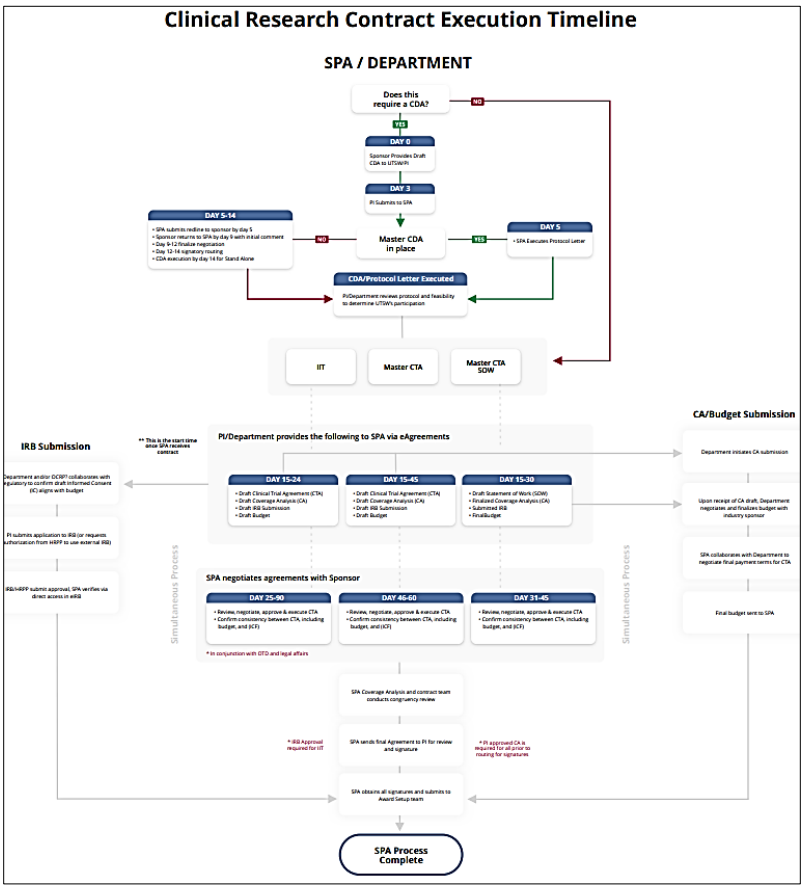
Choose the tab for **Clinical Research,** then **Review Study**.



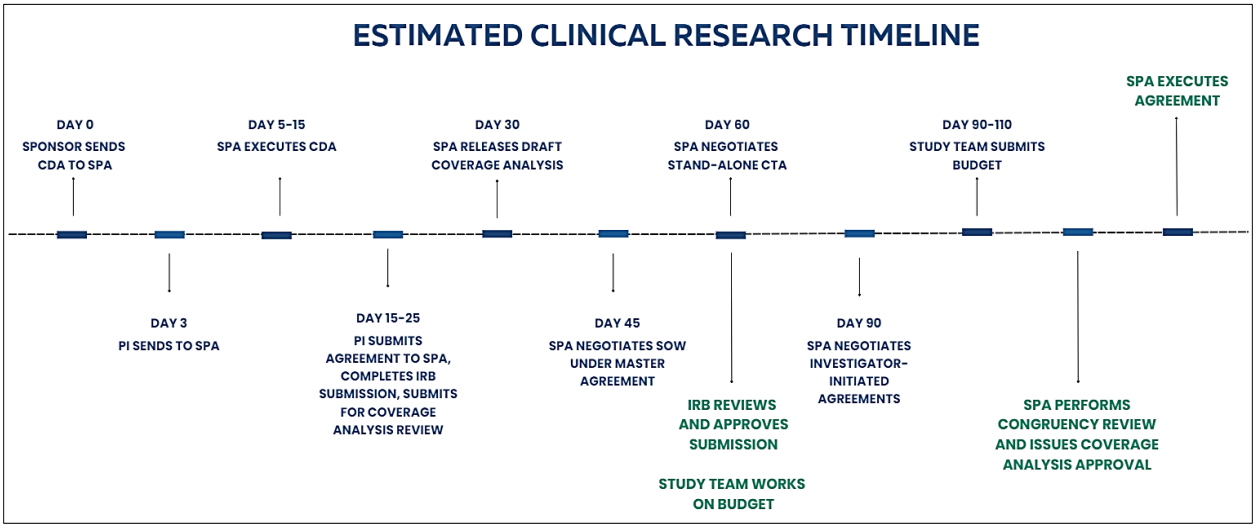
Scroll to the middle of the page and select **View Clinical Research Timeline**.



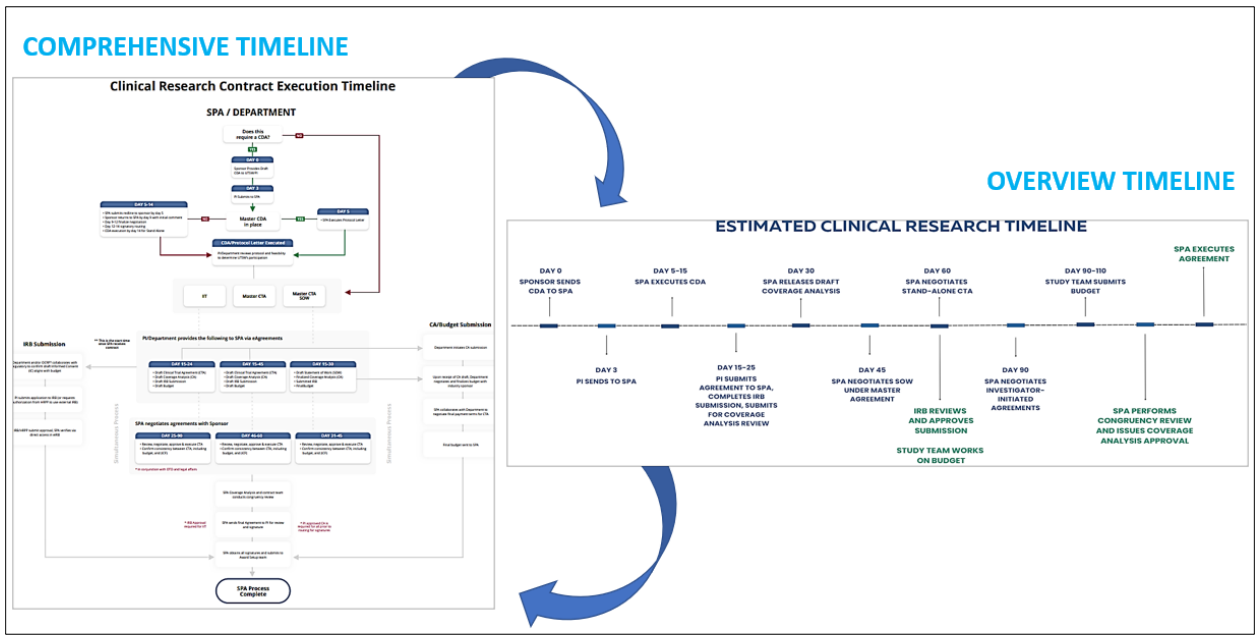
The published timeline is very detailed for those who are new to clinical research administration.



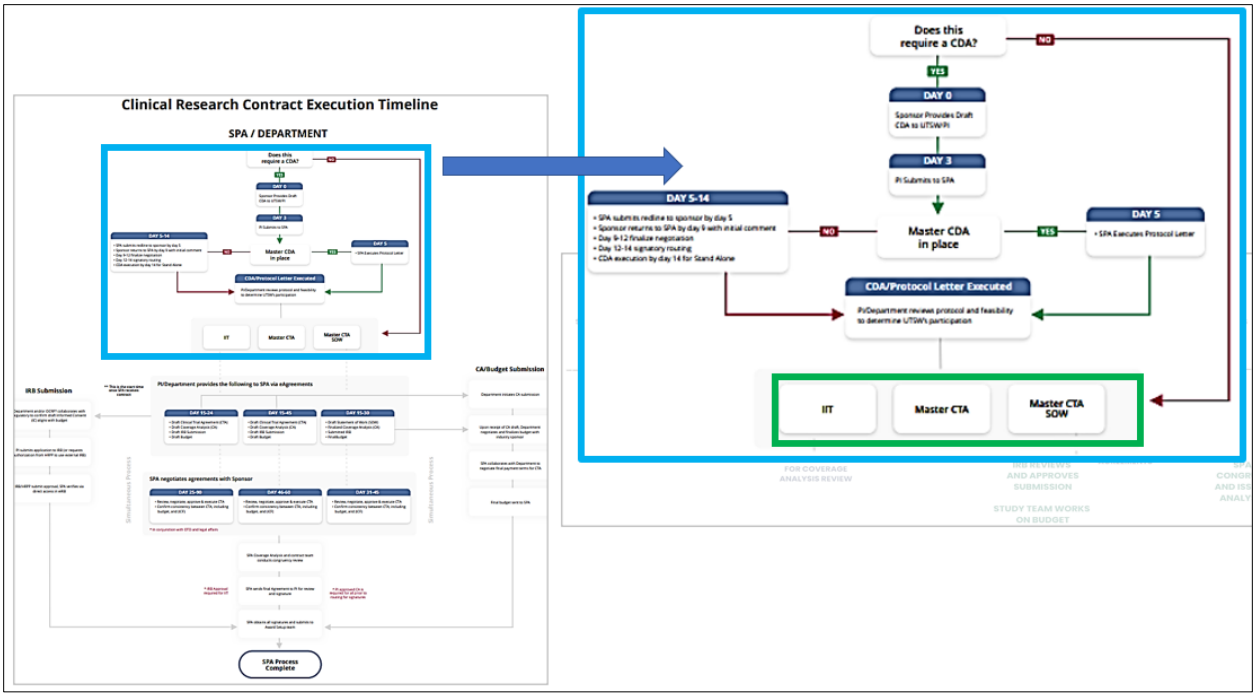
Once you become more familiar with the process, you might refer to a reduced overview.



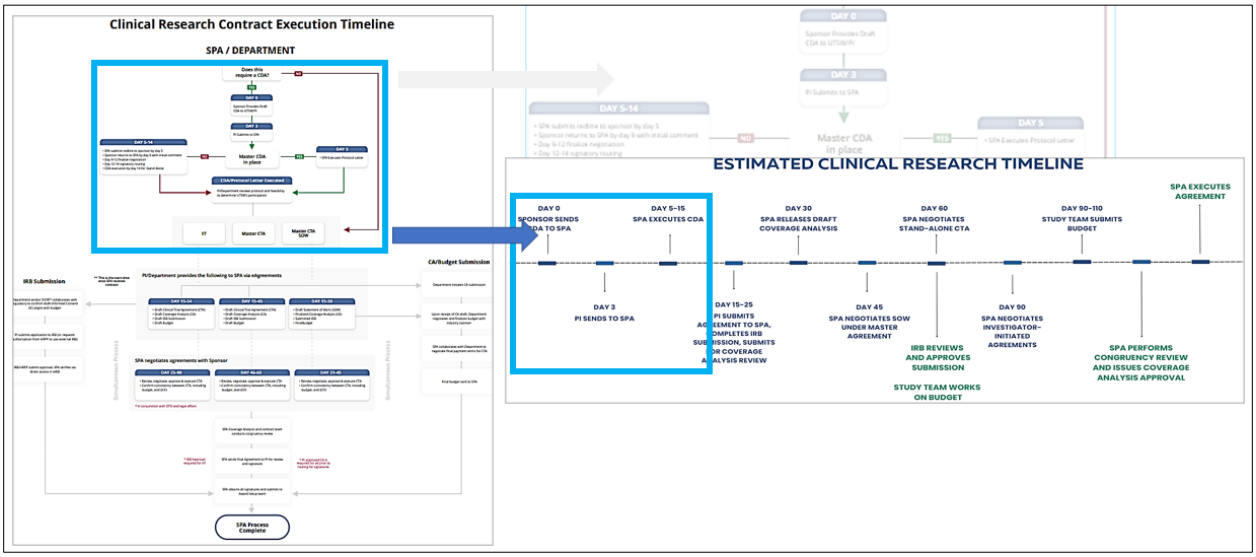
Now we will compare the two timelines and drill down to identify what can be done ahead of time and what can be done concurrently.



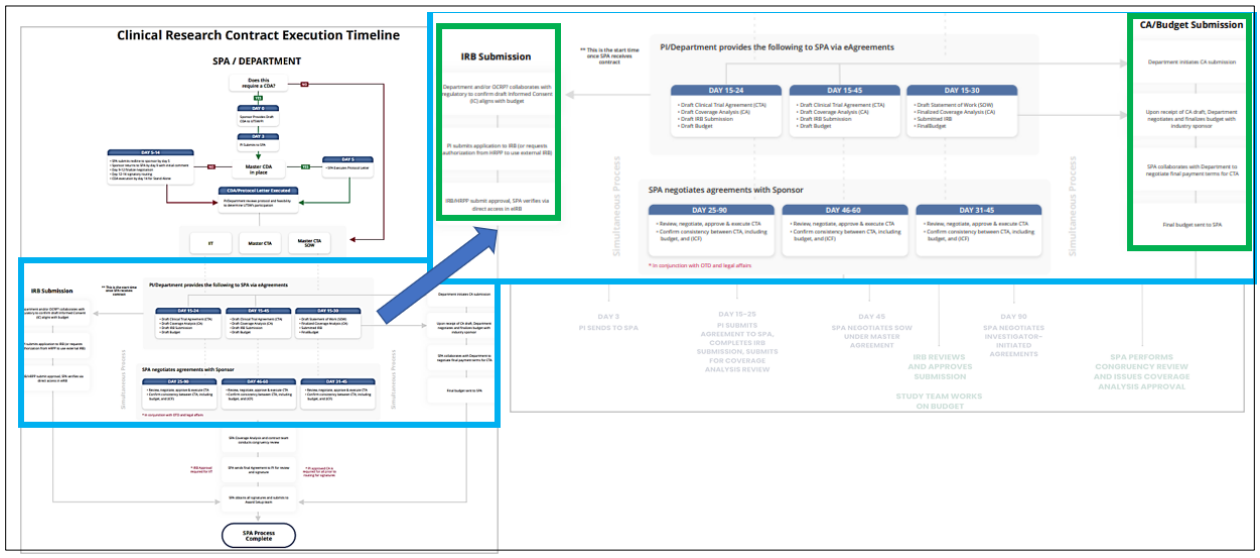
The top portion of the detailed timeline begins with the Confidential Disclosure Agreement process. This is the time to get the CDA in place before continuing the steps, based on whether it is investigator-initiated trial, master clinical trial agreement, or master clinical trial agreement statement of work.



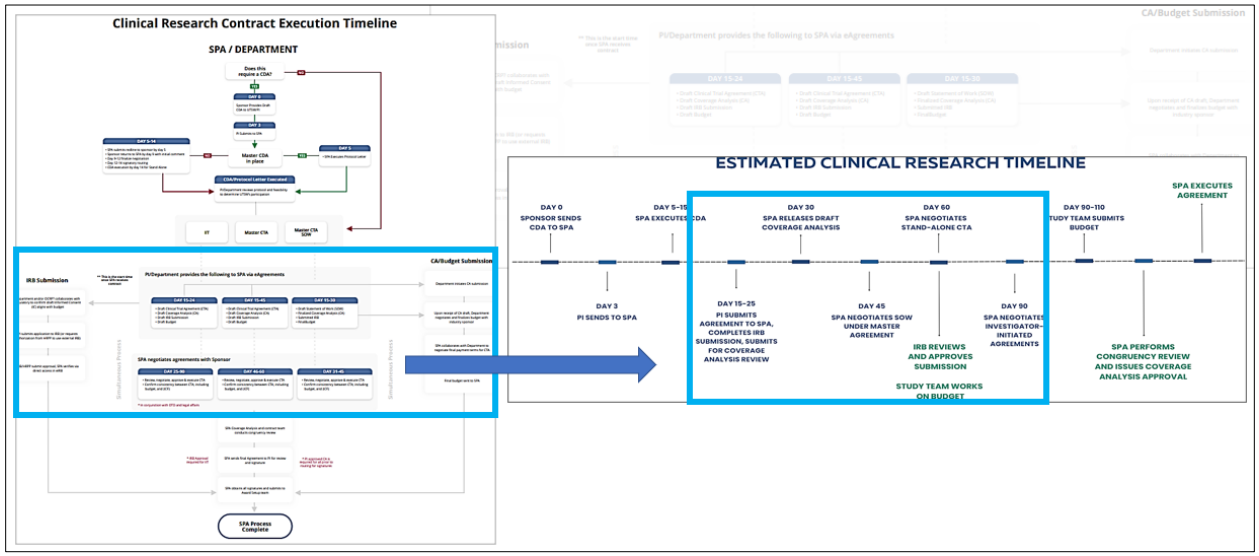
The top portion of the detailed timeline is identified in the overview timeline as Day 0 through Day 15.



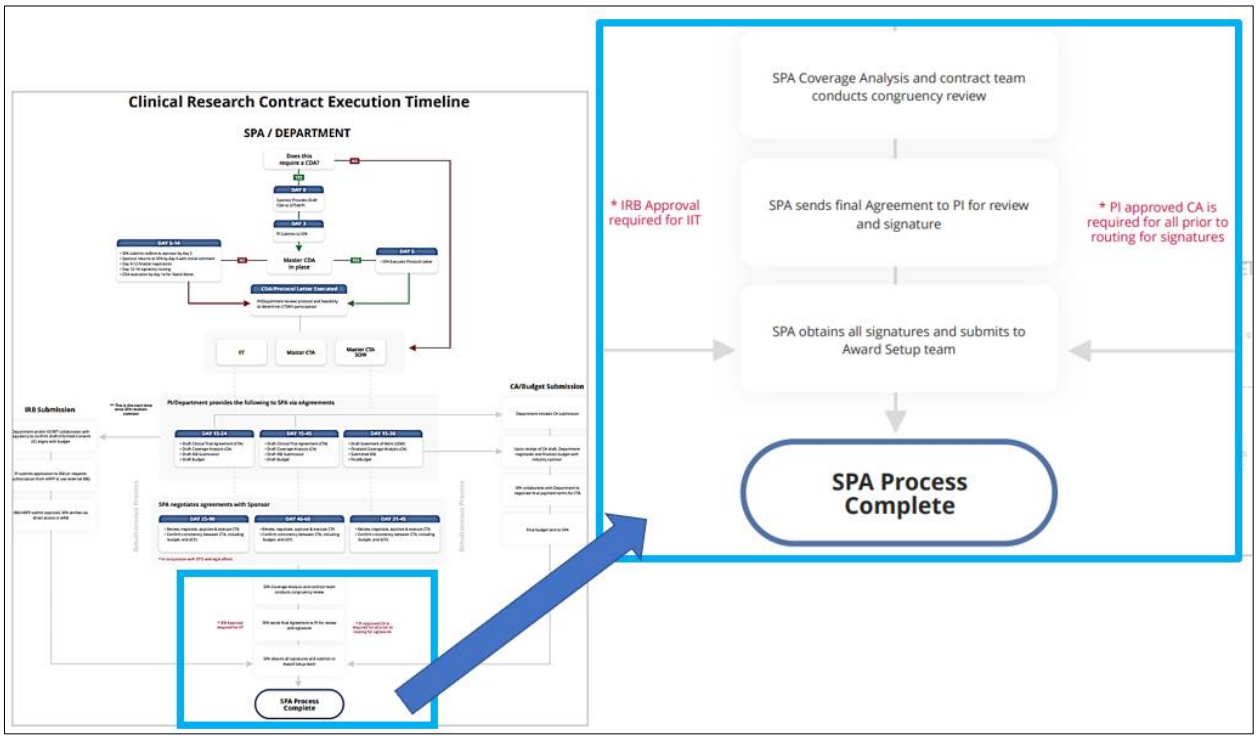
Referring now to the middle section, while you are working on your contract execution, there are some concurrent IRB protocol and coverage analysis budget items.



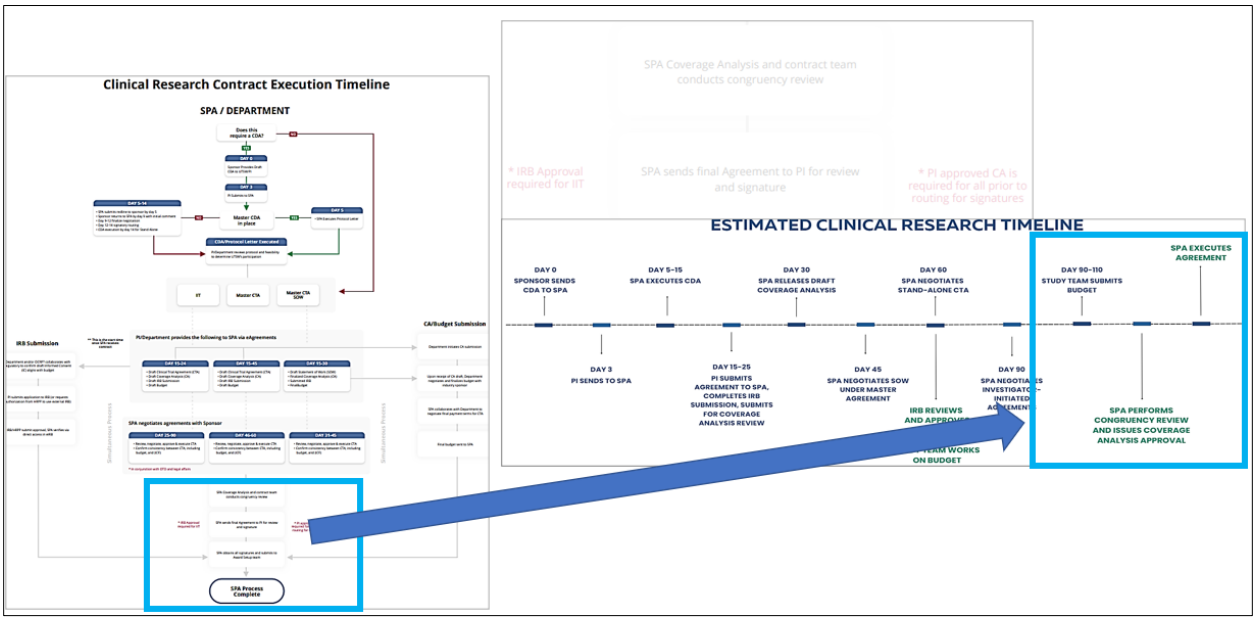
The middle portion of the detailed timeline is identified in the overview timeline as Day 15 through Day 90.



And finally, the bottom portion shows that the SPA process concludes with congruency review and final execution of signatures before submitting to the SPA award setup team.



The bottom portion is identified in the overview timeline beginning with Day 90.



For additional information, see the Clinical Research Services Overview module in Taleo.

Resources

Clinical Research Contract Execution Timeline

SPA Clinical Research Review Study Webpage

Clinical Research Services Overview Taleo Module