

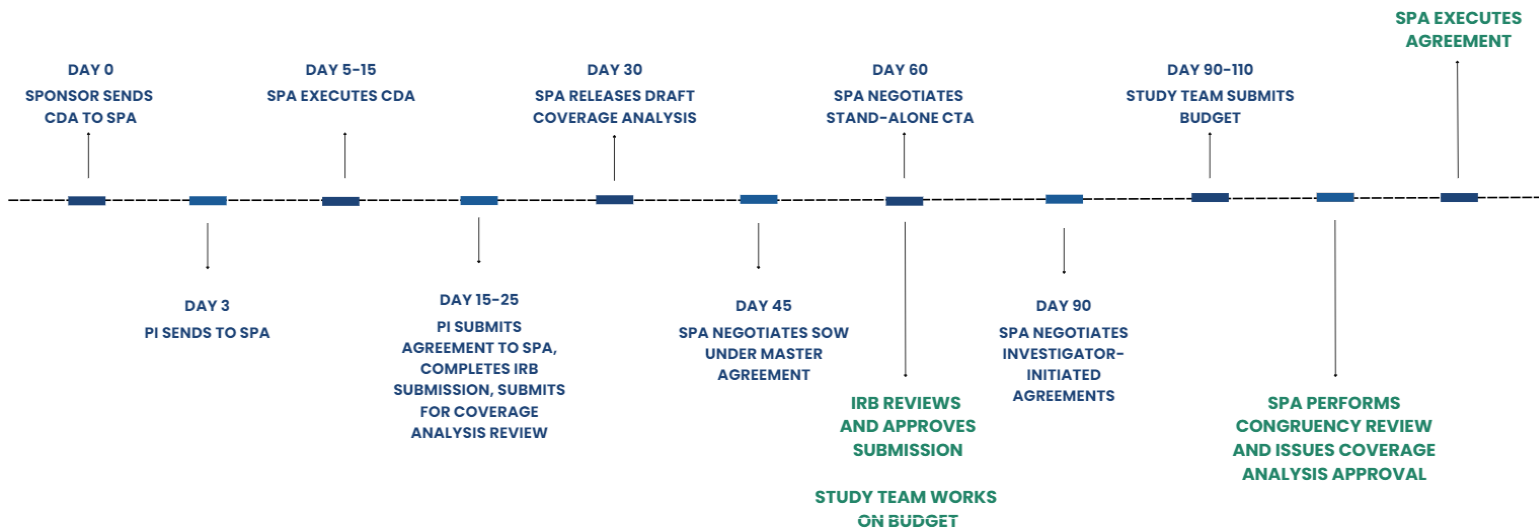
Q4. What is the timeline of a clinical research study? What is the order of the steps and what steps can be taken concurrently?

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.

The screenshot displays the UTSW Sponsored Programs website. On the left, a flowchart titled 'Clinical Research Contract Execution Timeline' details the process from SPA/Department through IRB Submission, SPA registration, and CA/Budget Submission. On the right, the 'Review Study' page is visible, featuring a 'Summary' section and a 'Required UTSW IRB Review' box. A green box highlights the 'Estimated Duration' section, which notes that the duration varies based on sponsor, agreement, or contract type, and includes a 'View Clinical Research Timeline' button.

- 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.

ESTIMATED CLINICAL RESEARCH TIMELINE



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

The screenshot shows the UT Southwestern Medical Center website. The top navigation bar includes links for About Us, Administration, Departments & Centers, Education, Hospital & Clinics, Human Resources, **Research**, Services, and Tools. A green box highlights the 'Research' link, with a green arrow pointing down to the 'Research' page below. The 'Research' page features a dark blue header and a list of links including: Animal Resource Center (ARC), Clinical Laboratory Services Research (CLSR), Core Facilities, Conflict of Interest (COI), Departing Researchers, Export Control, Human Research Protection Program (HRPP)/IRB, iLabs, Institutional Animal Care and Use Committee (IACUC), NIH Data Management and Sharing Policy, Office of Clinical Research, Office of Research Integrity, Office of Research Support and Regulatory Management, Office of Technology Development (OTD), Pure (Influent) Research Portal, Research Lab Directory, Research Security, **Sponsored Programs Administration (SPA)**, and Stem Cell Research Oversight (SCRO).

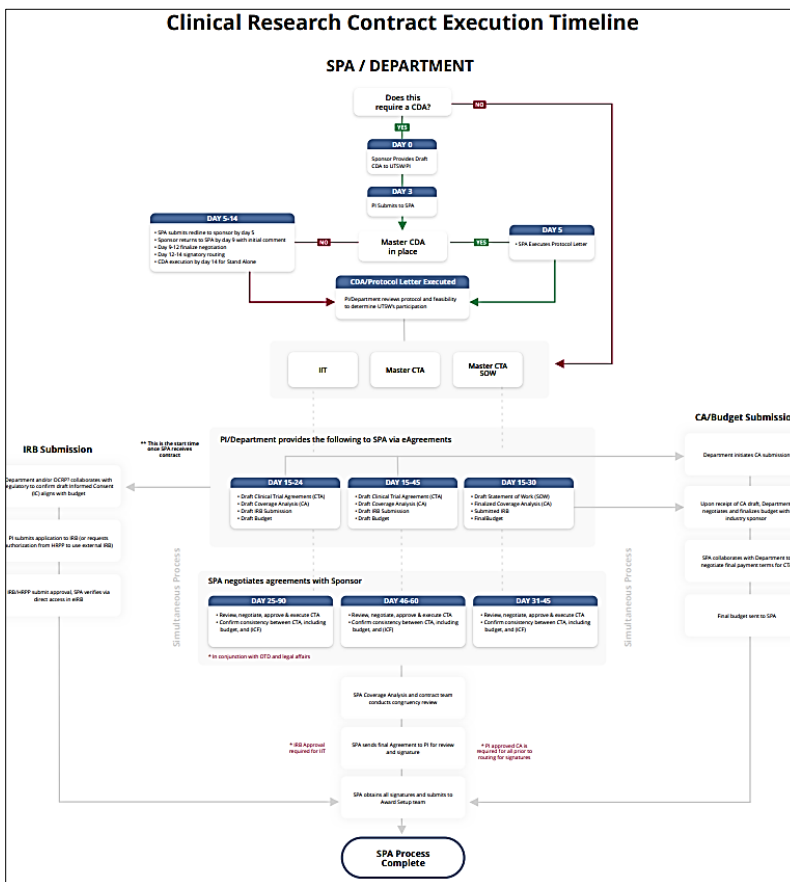
Choose the tab for **Clinical Research**, then **Review Study**.

The screenshot shows the 'Sponsored Programs' website. The top navigation bar includes links for Basic Science, **Clinical Research**, Compliance & Operations, Education & Training, FAQs, News & Events, Tools & Resources, and Contact Us. A green box highlights the 'Clinical Research' link, with a green arrow pointing down to the 'Clinical Research' page below. The 'Clinical Research' page features a dark blue header and a list of links including: Establish Relationship, SPA Negotiates Terms, **Review Study**, Activate Study, Set Up Award, and Manage Award. The main content area includes a section titled 'New Training Opportunities' with a 'View Training Details' button, and a section titled 'Top Requested Resources' with links for 'Get Started', 'View the Institutional Fact Sheet', 'Explore Prize Opportunities', and 'Access Research System Tools'. The main heading 'Clinical Research' is followed by the text: 'The award life cycle transitions through eight simple stages. Our comprehensive approach helps guide you through every stage of the process. At each step, we are here to support you along the way.'

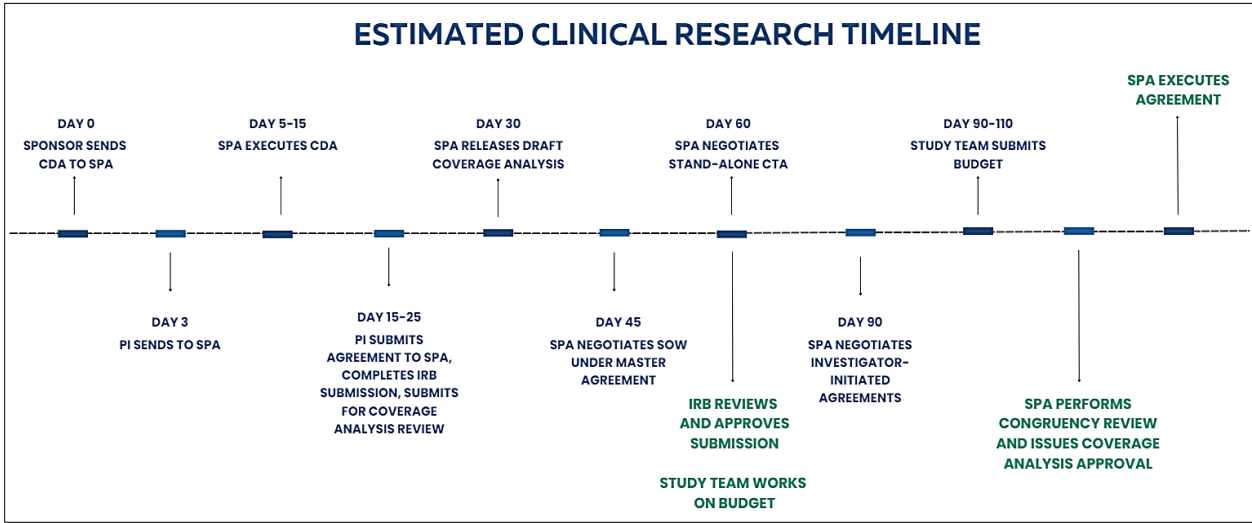
Scroll to the middle of the page and select **View Clinical Research Timeline**.

The screenshot shows a web interface with a main diagram on the left and a sidebar on the right. The diagram is titled 'Clinical Research Contract Execution Timeline' and details the 'SPA / DEPARTMENT' process. It includes stages like 'IRB Submission', 'SPA negotiates agreements with Sponsor', and 'CA/Budget Submission'. The sidebar, titled 'Sponsored Programs', has a 'Review Study' section with a 'Summary' and 'Tools and Resources'. A blue arrow points from the diagram to a button labeled 'View Clinical Research Timeline' in the sidebar.

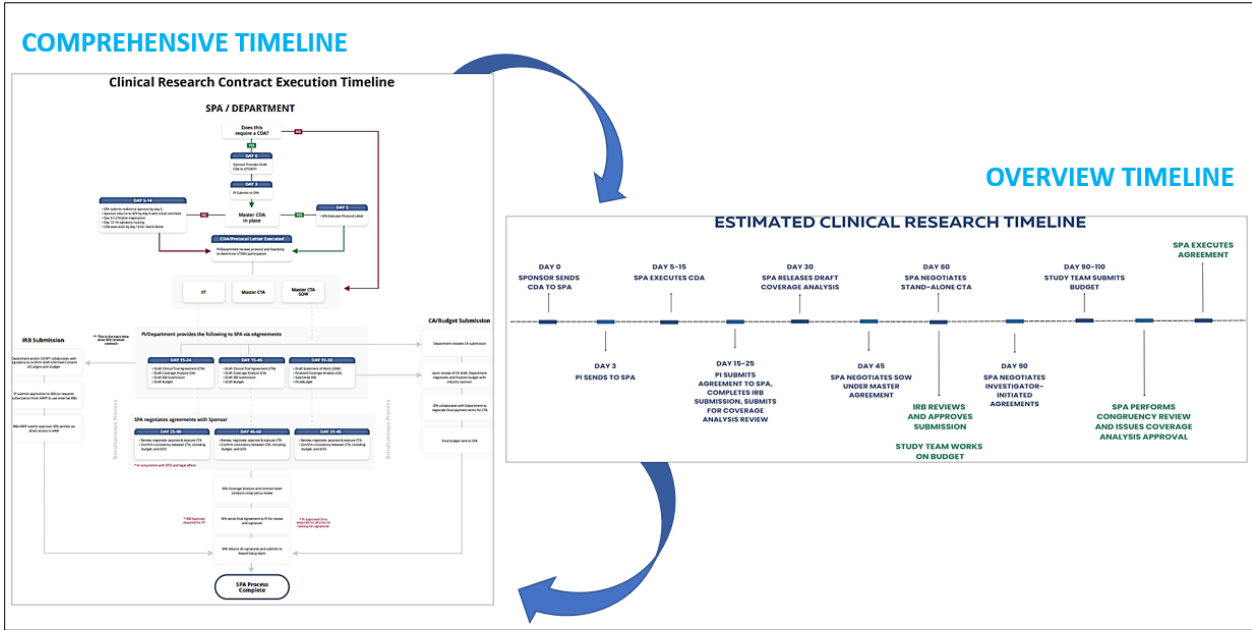
The published timeline is very detailed for those who are new to clinical research administration.



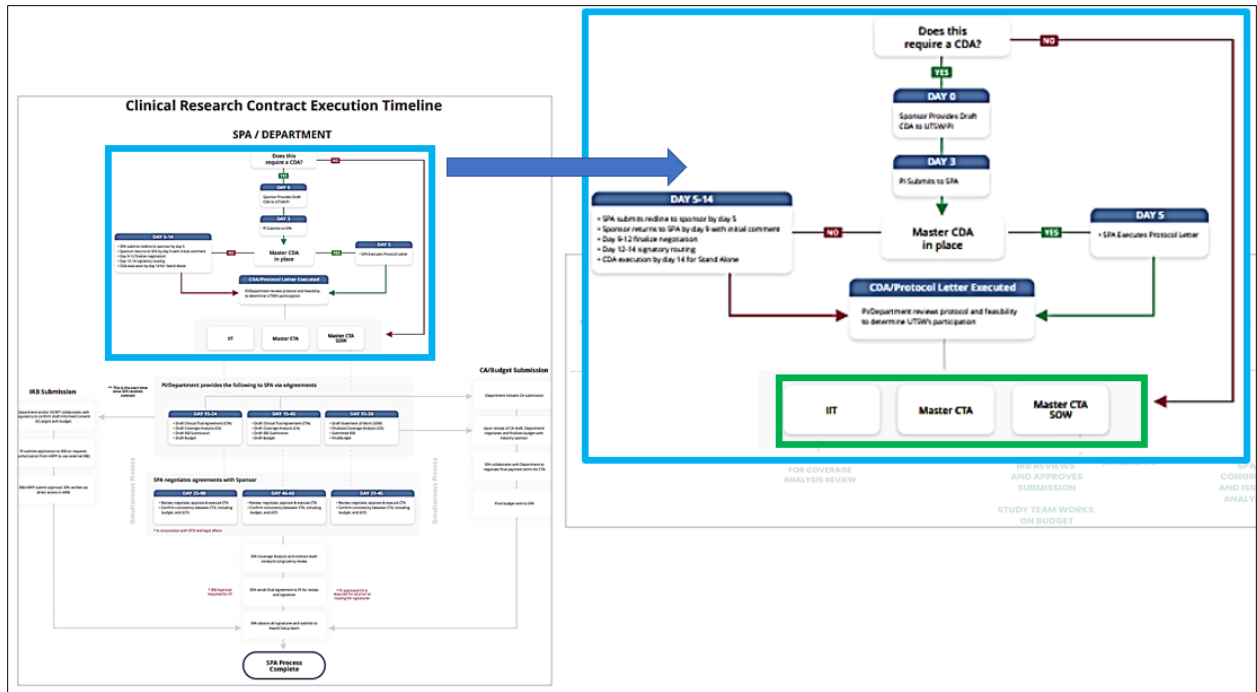
Once you become more familiar with the process, you might refer to a reduced overview.



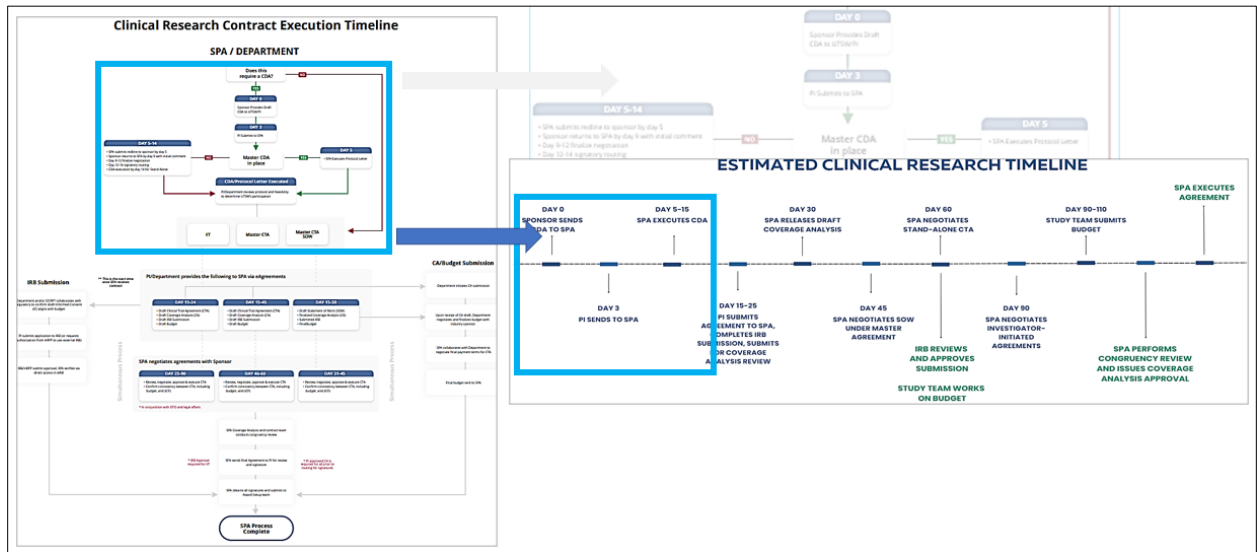
Now we will compare the two timelines and drill down to identify what can be done ahead of time and what can be done concurrently.



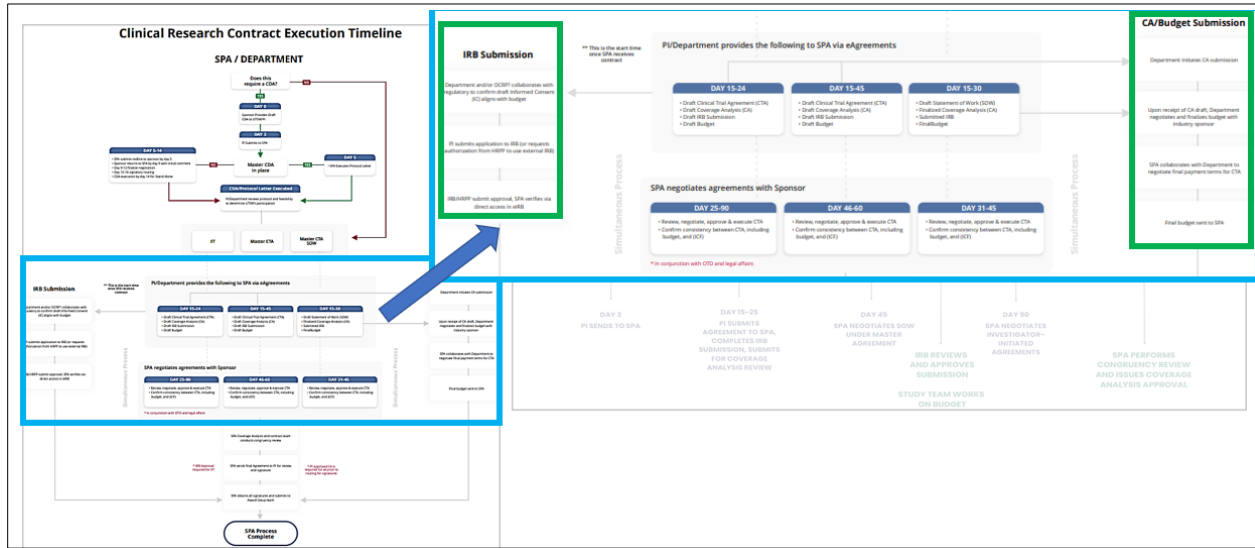
The top portion of the detailed timeline begins with the Confidential Disclosure Agreement process. This is the time to get the CDA in place before continuing the steps, based on whether it is investigator-initiated trial, master clinical trial agreement, or master clinical trial agreement statement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



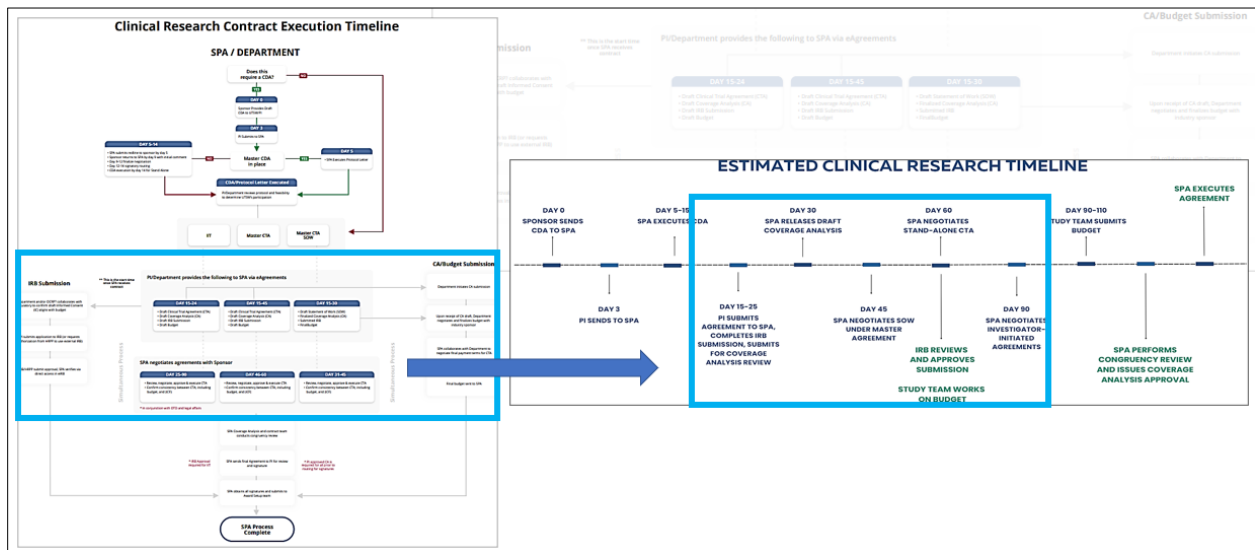
The top portion of the detailed timeline is identified in the overview timeline as Day 0 through Day 15.



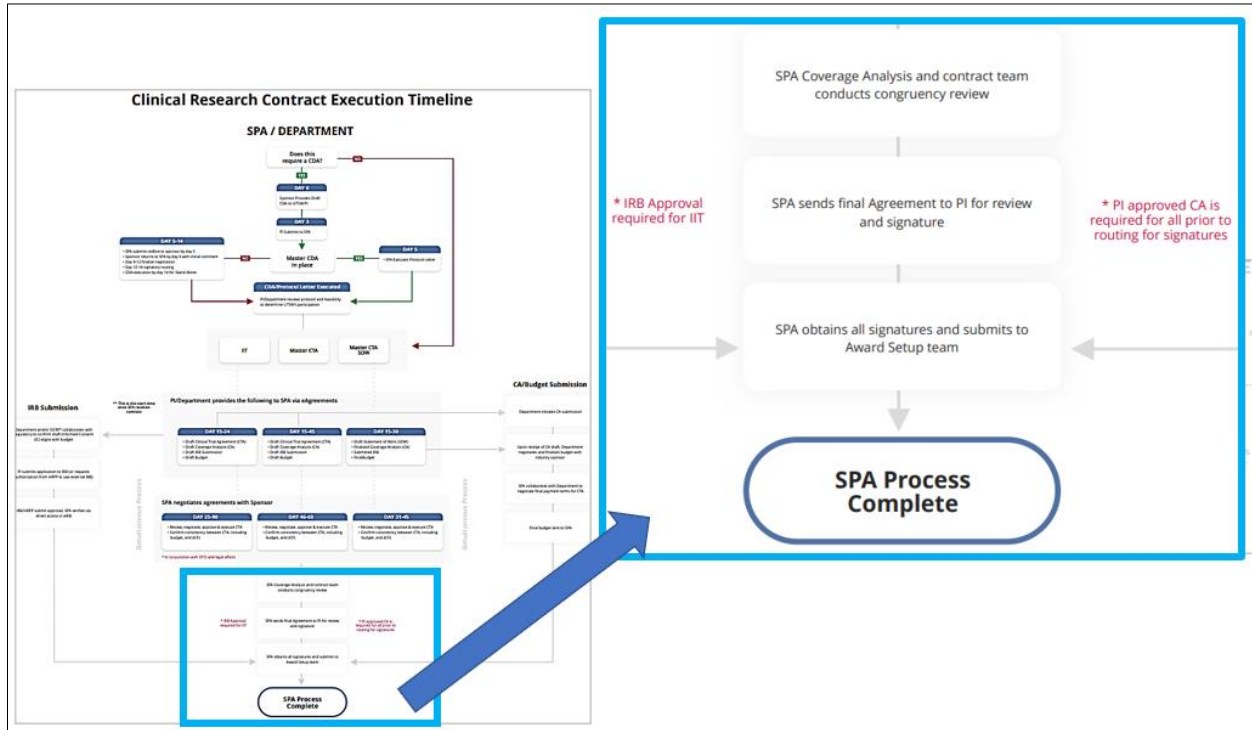
Referring now to the middle section, while you are working on your contract execution, there are some concurrent IRB protocol and coverage analysis budget items.



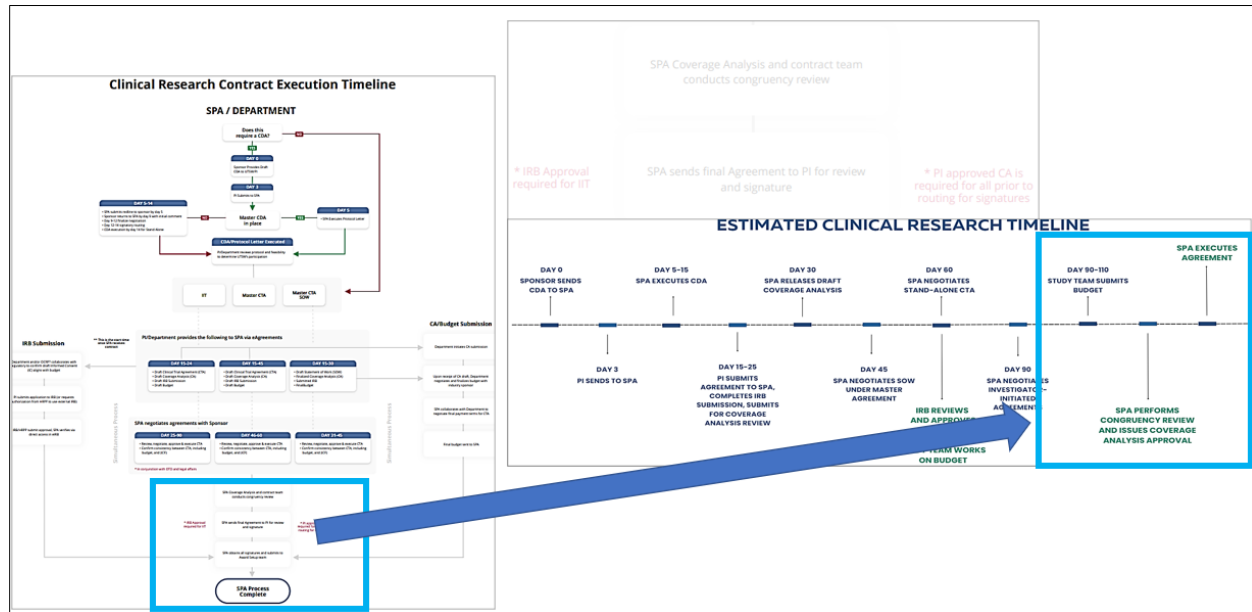
The middle portion of the detailed timeline is identified in the overview timeline as Day 15 through Day 90.



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](#)