Navigating Complexities: Integrating Data from Ongoing Studies in Regulatory Submissions

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Integrating data for regulatory submissions requires organizing and consolidating information from multiple studies for a project. The activities could include aligning variables from studies using different versions of CDISC standards and/or creating new variables to support integrated analyses. ***BUT***, what happens when another layer of complexity is added? What if an ISS or ISE will include data from ongoing studies? What are key considerations when dealing with ongoing data?

Data Cleaning

- What key data points are needed for the ISS/ISE? Identify these key fields on the CRF and share with the data management team.

- Establish a data cutoff date. Consider having a data freeze date, then a target date to have data cleaned up to freeze date.

- Focus data cleaning efforts on larger study sites. More clean data, more impact.

- Run/Review Pinnacle 21 reports frequently to identify data pain points.

Maintenance of Blinded Information

- Keep study teams separate when possible. Create separate ISS/ISE team to work with unblinded information.

- Understand what is considered unblinding information for the ongoing studies (ex. treatment codes, specific labs, AEs, PK results, etc.).

- Which team handles creation of eSubmission materials? (ex. Who provides Pinnacle 21 explanations?)

End Goal: Including Ongoing Study Data in Integrated Analyses

Communication between Study Teams

- Work with data management team to establish a process for the data freeze. (ex. Discuss if the data freeze will be based on visit or date?)

- Meet regularly with study teams to share updates such as FDA requests, timelines for when individual studies will lock, etc.

-Work with ISS/ISE programming team to assess priority data fields and ADaM flags needed to support analyses.

Flexibility/ Course Correction

- Create a plan based on the initial information you have.
“If you fail to plan, you are planning to fail.”
~Benjamin Franklin

- Revisit and reassess your plan frequently. Changes are inevitable. You may need to accommodate additional FDA requests, individual study SAP updates, updating ADaM to accommodate many types of deliverables, and the list goes on.