Programming Role in In-Licensing Projects

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Background

The pharmaceutical industry has seen many acquisitions/ divestments of products. As a result, the receiving company finds itself inheriting another company's development work. Proper strategic planning is critical to a successful transition. Programming plays a valuable role in ensuring that inherited data is workable/ reusable, and assessing how closely it aligns with CDISC standards to help plan for future deliverables.

Highlighted are some issues & solutions from a programming perspective.

Examples

Two in-licensing projects are:

Project I: Received 70+ reported Phase I – III studies from two separate vendors.

Planning for a submission.

Project II: Received 15+ studies plus integrated data and a completed submission. Done by multiple vendors. Urgent timelines for Reg defense/submission.

Results

Project I:

Issues	Resolutions
➢ **Large file size**	➢ Collaborated with vendor & AZ IT on recommendations for efficient transfer method (encrypted hard drive).
➢ **Understanding what is available**	➢ Met with partner programming team to understand the history of what had been done (ongoing/completed studies DSUR, submissions etc.).
➢ **Inventory**	➢ Created a data inventory sheet outlining what was delivered, e.g., SDTM/ADAM, Reviewer's Guides (RG), and discussed with vendor when any gaps were seen, e.g.: missing data etc.
➢ **CDISC compliance**	➢ Created and maintained a list of discrepancies across studies to ensure transparency and submission readiness.
➢ **Unforeseen risks**	➢ Identified risks with data and algorithms and escalated it to project team, e.g.:, missing SAS programs.

Project II:

Issues	Resolutions
➢ **Limited time for transition**	➢ Collaborated with vendor to set data delivery expectations (e.g., SAS programs, logs, TFL, Validation tracker, validation code, Define, RG's) via a test transfer and planned for batch wise delivery of data packages.
➢ **Received work done by multiple vendors**	➢ Ensured communications directly with vendor and not just partner company.
➢ **Lack of data specifications**	➢ Leveraged Define files as specifications.
➢ **Plan upcoming programming activities**	➢ Prioritized delivery of pivotal studies with partner's vendor and collaborated with IT to load data within programming environment.
➢ **Resourcing**	➢ Forecasted resources prior to delivery so programmers were available to hit the ground running when data arrived.

Conclusion

The clock starts ticking the moment after a compound is acquired, and programming expertise is imperative in ensuring a smooth transition. The examples highlight some of the common issues and resolutions on topics related to various stages of acquisitions that can be followed for in-licensing projects. With advanced planning related to file delivery strategy, open communication related to setting expectations, and strategic foresight related to resourcing and future deliverables, programmers can successfully play the lead role during the data transition process.

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