Piecing together a high-stakes puzzle:

Integrating an acquired biotech's systems and data

The successful integration of a biotech hinges on an acquirer's ability to piece together a complex puzzle of systems and data. An acquirer will require visibility into the acquired clinical trial pipeline for investor materials, regulatory disclosures and a variety of operational reasons.

Key Data Inputs

- Subject Data
- Center Data
- Project Milestones
- Study Data

Key Systems/Repositories

- Clinical Database
- CTMS
- RTSM
- Project Management
- Safety Database
- Trial Master File

Key Outputs

- Investor Materials
- Regulatory Disclosures
- Progress Monitoring
- Operational Support

However, the flow of clinical trial data required for visibility relies on a network of tightly interlinked systems (e.g. EDC, CTMS, RTSM, etc.) that may need to straddle both organizations until the trials are complete.

While IT should facilitate a deliberate plan, broad input from numerous disparate functions will be needed that must be triaged in order to avoid value-destroying risks.

What's at risk?

Regulatory authorities may refuse to review a submission that lacks data integrity which could require re-running the trials[1]

Compromised Day 1 cutover

Failure to link operational systems with external partners such as CROs/CMOs (including inbound and outbound data flows) can compromise the ability of a trial to continue to operate on Day 1

Misalignment of integration approaches

The approach taken by individual functions for their own systems can result in unanticipated downstream impacts. For example: Data Management's approach to the EDC can impact the RTSM functionality envisioned by Clinical Supply

Unanticipated IT spend

Not achieving system integration timelines can force teams to maintain legacy systems longer than anticipated resulting in additional licensing costs (that can be measured in millions of dollars)

Invalidation of the acquired studies

Inadvertent unblinding of studies (based on RTSM data) or exposing of patient data (from the EDC) could result in significant regulatory issues or worse invalidate the studies entirely

Inability to make well-informed portfolio decisions

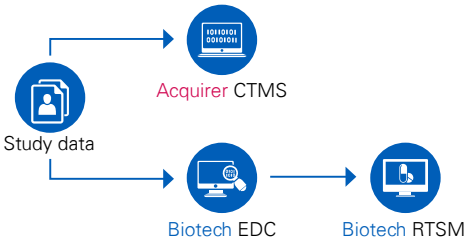
Leadership will need visibility of study progress as well as to make portfolio decisions between existing and legacy studies

Delayed regulatory filings

Outdated data repositories (such as TMFs) can compromise a timely regulatory submission as teams will need to scramble to locate the required data

Where do you start?

1. Baseline current systems and data location(s) of acquisition
2. Determine Day 1 combined clinical system plan (see figure on right)
3. Align functions (e.g. Clinical Operations, Data Management, Stats, Clinical Supply, etc.) on assumptions and create detailed plan



! *The EDC may not be able to be migrated requiring new interfaces or re-programming which will play a major role in the formulation of a systems plan*

How KPMG can help

Deal Planning

- Organize & launch the program office
- Develop stand-alone / integrated objectives, & guiding principles
- Develop high level integration roadmap

Day 1 Execution

- Identify mission critical / Day 1 requirements to ensure business control
- Finalize and begin execution of detailed integration plans

Evaluation of Value Creation

- Implement, track and monitor integration plan and value capture initiatives
- Execute Day 2 growth initiatives across integrated organization

[1] Notice to sponsors on validation and qualification of computerised systems used in clinical trials (europa.eu)

Case Study: Big pharma acquisition of a biotech

Challenge:

Our client, a large pharmaceutical company, announced the multi-billion-dollar acquisition of a target with one marketed product and several promising assets (including a biologic) in their development pipeline for the maintenance treatment of several forms of cancer. Maintaining the development pipeline and ensuring regulatory filings during the integration was critical to realize the transaction value.

What KPMG did:

- Created a methodology to drive the transition of 18 clinical trials (including multiple cohort studies) being run by four separate CRO partners with approximately 3,500 subjects enrolled across 25+ countries
- Led efforts to map and document deviations for 100+ R&D standard operating procedures (SOPs) to minimize regulatory compliance risks
- Conducted detailed walkthroughs of the entire clinical supply chain from raw material to site distribution, aligning Finance, IT, Trade Compliance and Supply Chain objectives
- Supported the integration management office, including prioritization of integration versus key regulatory submissions

Results:

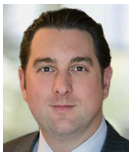
- 10+ filings submitted globally supporting an sNDA expanding the original indication
- New BLA and MAA filed for a pipeline asset (biologic)
- Development pipeline migrated: In-flight clinical trials transitioned to our client's ways of working (with deviations documented)
- 25+ alliances covering research, supply, collaboration and development transitioned to client

Why KPMG?

We Have Unparalleled Experience

Our teams have worked with clients across major therapeutic areas and emerging precision medicine technology, which means we bring deep experience and insights to each project.

Contact us



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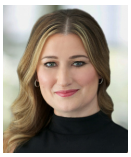

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