Avoiding Disaster: Manager's Guide on How to Rescue a Failing Outsourced Project

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ABSTRACT

Outsourcing has become a large part of the business model for many pharmaceutical companies. It allows the sponsor to focus on its core competencies, keep their workforce lean and scale up when needed. However, an unfortunate by-product of this growing trend is occasional failure of the outsourced vendor to meet the timelines and/or quality of the deliverable. The failure to meet agreed objectives on a deliverable result in loss of time, money, resources, morale and strains the relationship between sponsor and the vendor. Furthermore, such failures in studies/projects that are critical to the organization end up severely hurting the chances of regulatory approval and affect time to market. In this paper, I will present a tested, step-by-step pragmatic approach from the perspective of the sponsor in identifying a failed outsourced project and provide a mechanism to rescue and/or salvage the work. I will also discuss ways to prevent such failures in the futures and increase the chances of success on outsourcing of critical studies/projects.

INTRODUCTION

The purpose of this paper is to equip the biostatistics manager at the sponsor with a framework that helps navigate the scenario of an outsourced project failure and provide insights into a rescue mechanism. The paper limits its scope to biostatistics deliverables such as SDTM, ADaM, tables/listings/figures (TLF) and submission deliverables such as define.xml and reviewer guides for clinical trials and integrated analyses. Upon reading this paper, you will gain an understanding of how to protect your organization's outsourced project by uncovering its failure before it is too late and give you a range of scenario-based options that help you strategically navigate the process of putting the project back on its path to success. Lastly, it also provides you with takeaways of making process improvements to avoid such outsourcing crisis and achieve predictability of results from your outsourcing arrangements.

IDENTIFYING A FAILING PROJECT

Every sponsor expects the project to be completed with quality and within timelines when outsourced to a vendor. The vendor is expected to follow their SOPs, highlight important gaps in the requirements, communicate items for discussion well in advance, maintain consistency in their approach, output and documentation and deliver the project on time with quality. The only way to find out whether expectations are being met is to look under the hood and make an objective assessment of the quality and the likelihood for the project's success.

CONDUCT DUE DILIGENCE

Every sponsor has their own ways of conducting due diligence on outsourced work. However, the frequency, timing, and the degree of effort varies with each organization. A popular approach to evaluate outsourced deliverables is to conduct dry-runs prior to the final delivery.

The purpose of the dry run(s) is to ensure that the vendor exhibits capability to produce the full scope of deliverables on agreed timelines. A sponsor-led thorough and structured quality assurance review of the inventory of deliverables, SDTM/ADaM compliance, ADaM derivations and adherence of tables, listings and figures to the SAP/mockups is crucial in establishing quality and predict the likelihood for success.

Optimal number of dry-runs

What is the optimal number of dry runs? The answer may vary depending on the type of project that is being outsourced and the importance of the project to the sponsor. Let's take a common phase 2/3 study. It is customary to have between one to three dry runs delivered to the sponsor for review prior to the final deliverable.

A minimum of 1 dry run with the full scope of deliverables should be conducted by the sponsor. This might also be the only choice for short studies that doesn't give the sponsor and vendor the time to make multiple dry runs and reviews. Keep in mind that every dry run cost the sponsor, therefore the strategy for multiple dry runs must pass a cost/benefit analysis commensurate to the risk of failure. Pivotal studies that are key to the success of the sponsor should be baked in with multiple dry runs at the onset. New outsourcing relationships warrants multiple dry runs to account for the increased interactions that are needed for the vendor to learn the sponsor's standards and preferences. When trying to decide how many dry runs are needed for your project, consider the questions below for increased objectivity to your decision-making process. The more times you answer 'yes' to the questions below, your need to have multiple dry runs is substantiated.

- Is this a pivotal study for the sponsor? Do the results of this study make/break your compound?

- Is the final deliverable time-sensitive for your submission or decision making? Can you not afford delays to the final deliverable in lieu of increasing quality?

- Does the study have novel data collection/analysis/endpoints, or in a therapeutic area/indication not previously encountered by the sponsor? Would you benefit from seeing draft packages to confirm they are going in the right direction?

- To what degree would the clinicians and medical writers benefit from seeing the package in draft? Are the medical writers gaining efficiencies for the CSR with draft/near-final deliveries?

- Does your organization have data/output standards that need to be strictly adhered to regardless of the accuracy of the output?

- Are you working with a new vendor for your outsourced project or with a brand-new team within an existing vendor relationship?

MAKE AN OBJECTIVE ASSESSMENT

Prepare and follow an objective quality assurance plan to evaluate dry run deliverables. At the end of the quality assurance review period, consolidate the findings and communicate it to the vendor. Offer explanations to findings and clarify expectations with the vendor, allowing them a fair chance to correct findings in a reasonable timeframe. At the end of the cycle, use the following measures as a guide to determine quality and likelihood for success.

Measures for quality

1. Compliance of SDTM/ADaM standards through the Pinnacle 21 reports and the explanations for errors/warnings.
2. Proficiency in handling CDISC SDTM/ADaM guidelines in domain mappings, sponsor defined domain creation, SDTM to ADaM traceability, and enabling one proc away analysis for the TLF.
3. Consistency between documentation (aCRF, specifications, define.xml, xDRG, mockups) and deliverables (SDTM/ADaM datasets, TLF)
4. Algorithm correctness per SAP for derived endpoints
5. Consistency in algorithms across data sets (baseline flags, relative day, epoch, analysis visit windowing.
6. Consistency and accuracy of titles/footnotes, study population counts, presentation of TLF.
7. Prevalence of burst errors (ex. Population counts are wrong in a few tables) and systemic errors (ex. the same wrong footnote used throughout the deliverables)

Measures for likelihood of success

1. The inventory of deliverables during of dry run matches the expected list of deliverables. Any gaps are attributed to legitimate reasons. For example, excluding a PK parameter summary table since the

non-compartmental analysis will not be performed until after database lock.

2. The delivery is made on time per previously agreed timelines.

3. The vendor proactively communicates grey areas of SAP or algorithms during implementation and seeks sponsor guidance or keeps sponsor in the loop of decisions made.

4. Upon reviewing sponsor's dry run comments, the vendor exhibits concern for the quality and willingness to correct them.

5. Upon reviewing sponsor's dry run comments, the vendor has a clear/reasonable estimate for correction and re-delivery.

6. Vendor implements all dry run comments and findings in subsequent deliveries.

7. Escalations made by the sponsor to the vendor's management team are promptly and satisfactorily addressed.

SET CRITERIA FOR FAILURE

Quality issues in outsourced deliverables is not always quantifiable into a score that you can use as a cut-off for determining whether the engagement has failed. Therefore, it is important to establish your own criteria for failure ahead of each project so that there is a level of objectivity when it comes to decision making. Consider the measures of quality and likelihood of success and rate your vendor's performance. You might also want to assign these measure different weights to account for your priorities.

ACCEPT THE OUTSOURCING HAS FAILED

The first step of fixing something is to acknowledge it is broken. If the outsourcing has met your criteria for failure, act immediately by escalating it to your management team. The more you wait and hope that things will correct itself, the fewer your options will be to rescue the project.

GATHER THE FACTS

With a failed outsourced project, the emotions usually run high and people tend to start using hyperboles such as "everything is wrong", "none of the work can be reused", "we have to start from scratch" etc. Resist the temptation to resound such hyperboles and spend some time to gather the facts of the project that will be crucial for your rescue attempt.

ASSESS SCOPE OF WORK

1. What deliverables were completed and delivered?

2. What are the ongoing pieces?

3. What items have not been started?

4. What is the % completion of SDTM? ADaM? TLF? Define.xml/xDRG?

5. What is the time remaining for the final deliverable?

IDENTIFY SOURCE OF ISSUES

1. Did vendor have qualified resources (ex. CDISC expertise, TA expertise, experienced lead)?

2. Did vendor miss timelines due to inadequate resourcing?

3. Did vendor miss timelines/quality due to being spread thin on other projects or multitasking?

4. Did vendor grossly misinterpret the SAP during their implementation?

5. Do vendor's quality issues point to errors in specifications or errors in implementing the specifications or both?

6. Did vendor fail to communicate questions on grey areas during implementation which is leading to

considerable rework?

7. Did vendor fail to get sponsor endorsement on their incorrect decisions?

8. Did vendor seem to have internal handoff issues, as exhibited by lack of cohesiveness of SDTM, ADaM and TLFs?

9. Does the trial/project have a high degree of complexity when it comes to study design, database structures, derived endpoints?

10. Did the requirements (protocol/SAP/mockups) shift considerably during vendor's implementation of work?

11. Were the agreed upon timelines reasonable and accounted for any shift in requirements?

12. Was the sponsor closely involved in the progress of work and available to answer questions?

MAKE THE TOUGH DECISION

You know what this project means to your organization. You know the scope of work. You know where the quality issues are. You see signs of competence/commitment in the vendor or the lack thereof. You have also looked inward to identify potential shortcomings of your own organization. You have all the facts in front of you. Let's make the tough decision.

Here is a decision guide matrix to help you visualize your project facts and options for decision-making.

Project Facts	Missing timelines		Simple systemic errors		High complexity of trial/data/endpoints	
	Incomplete delivery		Honest misinterpretation of requirements (SAP/Mockups)		Lack of sponsor oversight/availability	
	Poor communication		Lack of consistency		Shift in requirements	
	Blame-game		Willingness to make corrections and achieve quality		Unrealistic timelines	
	Failure to fix findings		Has qualified resources			
	Indifference to escalation					
Project time sensitivity	High	Low	High	Low	High	Low
Decision guide	Fire the vendor	Fire the vendor	Keep the vendor	Keep the vendor	Bring it in house	Keep the vendor
Next Steps	Bring it in house	Outsource again or Bring it in house	Increase sponsor involvement		Tighten up scope, Gain control over details	Increase sponsor involvement

Figure 1. Decision Guide Matrix

FIRE THE VENDOR

Regardless of the severity of quality measures, if the vendor shows very few signs of likelihood for success, it is safe to end that relationship as soon as you can. Missing delivery timelines, not delivering to scope, poor communication, playing the blame-game, failure to fix dry run findings, and indifference to escalations are all warning signs that will result in project failure. Moreover, these signs are indicative of the culture and management of the vendor and therefore cannot be expected to rectify overnight. Respectfully convey your decision to the vendor, request a full delivery of all work performed (outputs,

codes, specifications) that you are entitled to per contract, and keep the lines of communication open for future questions down the line.

WORK WITH THE VENDOR

Errors in implementing the correct specifications, prevalence of systemic errors that need a simple change to fix, logical misinterpretation of the SAP that is not incorrect yet not intended by the sponsor, inadequate resourcing to achieve timeline, lack of consistency between outputs and documentation while one of them is right, and the willingness to fix dry run findings in reasonable timeframes are all signs of hope to continue the relationship with the vendor and get them back on track for a quality and timely delivery. I have experienced the very capable vendor teams not deliver quality work for the dry run due to de-prioritization of our project and being spread too thin. Escalate your concerns to the vendor's management, clarify your expectations against the quality findings, ringfence the vendor team until a quality product is achieved, negotiate a realistic timeline to receive corrected delivery, and increase supervision by ensuring frequent communication with the vendor's lead to assess progress. To err is human, but if the vendor shows signs of competence, willingness to work with the sponsor for the common goal and receptive to change, you are better off working to salvage the relationship than pursue any other rescue option.

It is not uncommon to have parts of the delivery and the vendor's team exhibit competence while other parts are substandard. This can be attributed to the nature of compartmentalizing work across the lines of SDTM, ADaM/TFL generation and case report tabulation documents such as define.xml and xDRGs. These silos of work are sometimes taken over by different teams at the vendor, often geographically distributed. In your evaluation of quality and likelihood for success, consider these silos to evaluate whether you can continue to work with the vendor for parts of the projects that show promise of success.

BRING IT ALL INHOUSE

When an outsourcing fails, this option is often the natural knee jerk reaction. It might be the only option if the timelines are too short to engage another vendor, relationship with the existing vendor is strained to a point of no return, the requirements of the project are still in constant flux (multiple modifications to the SAP), or if the complexity of the trial, endpoint and underlying data are far too great. It is also a sensible option if part of the previous outsourcing can be salvaged. For example, it is common to have the vendor continue with SDTM, while the sponsor takes ADaM/TLF in-house. The two most important aspects prior to choosing this option is to confirm management support for such a decision and the availability of an internal lead resource who can be dedicated throughout the project.

Once the sponsor estimates the resource needs to pull the work in-house, you can consider filling them through multiple avenues. You can choose to pull internal resources who are available or working on other lower priority projects, you can hire a contractor team to supplement the rest, or you can choose to hire a functional service provider (FSP) team to take over the work. The FSP model is well suited for such a rescue attempt, since most providers are able to ramp up an FSP team relatively quick, you get an FSP lead who will be your single point of contact and lead the rest of the FSP team, you can get the FSP team to work with your systems/SOP increasing visibility, you free yourself up from onboarding activities, and you reduce the day-to-day delegation and supervising chore which frees you up to focus on the critical components of the project.

Whatever the resource model may be, ensure to have a dedicated lead from the sponsor's end and strive to collocate key members of the team to improve communications and handoffs and foster a sense of urgency and importance to the project.

OUTSOURCE TO NEW VENDOR

If the decision is made to fire the existing vendor at a time that enables you to start it all over again with another vendor, or if the timelines for completion of the project are flexible, then the option to outsource it again to someone else is on the table. Before choosing to do so, pay special attention to the following factors. Ensure that the failed outsourcing was not a result of you own organization's shortcomings, as that would tend to repeat itself no matter whom you choose to outsource to. Ensure the new vendor understands this is a rescue attempt and share the quality issues you faced previously so that it remains

as their internal checklist not to repeat those again. Since you cannot afford to fail a second time, work with a vendor's team with whom you have had or currently have a positive experience. Since you will have less time for the rework, ensure that the vendor can provide a dedicated ringfenced team for your work. Never outsource to a new vendor without fully understanding why the original vendor failed.

SEE IT THROUGH

FULL DISCLOSURE TO STAKEHOLDERS

It is extremely important for your stakeholders (clinicians, medical writers, upper management) to be aware of what happened to the outsourced project, why it failed, and what the recommendation is to turn it around. Have them participate in the decision-making process and gain their endorsement. It is important to point out to them that there might be difficulties down the road but assure them that the team is capable and committed to see it through. Keep the stakeholders informed of the progress and especially any issues that are leading to a slowdown. Also, if the original timelines were not realistic, or if the rescue attempt will take longer than the plan for the outsourced delivery date, renegotiate an achievable timeline with the stakeholders to set the expectations clear.

TIGHTEN UP SCOPE

Get stakeholder support to work on reducing the scope to keep it strictly to what's important. If everything is important, then prioritize the scope. Often the stakeholders only care to see the topline results soon after database lock and can wait a few weeks to see the rest. Take advantage of any reduction or reprioritization in scope. Work backwards from the important analysis and fin the related TLF, ADaM, SDTM datasets that need to be prioritized. This allows the team to increase focus on what's important and possible allow them to work in a phased approach which boil down to a manageable and achievable daily/weekly goal.

Avoid scope creep at all costs and escalate all scope creeps to an adjudication team that curates the requests. It is important to highlight that with limited time and set number of resources, any new work will have to replace existing work and that carries inherent risk of unintended failure.

DIVE INTO DETAILS

It is often said that the devil is in the details. Most projects that have quality issues boil down to an underlying lack of attention to detail. Thoroughly read each section of the SAP pertaining to derived endpoints, proofread the specification to ensure the algorithms are per SAP, discuss with the team about high risk derivations and possibility of corner cases, verify the ADaM datasets/variables are adequate for all specified analyses, reduce elaborate programming/derivations in TLFs by making ADaMs more 'one proc away', identify algorithms that affect multiple analysis and centralize their execution (macros), and centralize artifacts that are commonly used across multiple outputs such as titles/footnotes and population counts.

Whether or not there are issues, organize a series of meetings to elaborate on each endpoint and discuss in detail with the programmers and statisticians the journey of data from CRF all the way to the TLF that pertains to the analysis in question. I have been pleasantly surprised of how misconceptions and misinterpretations can be avoided with a simple end-to-end discussion of a derived endpoint. This is a valuable learning experience for the programmers to understand bigger picture, think with the end in mind, view things with their stakeholder's perspective, and increases their commitment to producing quality code. For the statisticians, it allows them to pick up on corner cases in the algorithms and clarify their stance, generate a list of clarifications for an SAP addendum/update and gives them the confidence that everyone has the right understanding of concepts, especially of complicated analysis.

CELEBRATE SMALL WINS

A rescue attempt often operates at higher visibility, increased costs and tight timelines. While all pieces are in place for success, a key ingredient is positive morale of every working member in the team. Set achievable milestones that marks the forward progression of the team and visibly celebrate the wins. It is important to frequently reinforce the feeling of 'can-do' and to foster the sense of optimism in achieving

the end goal. It is often the people with 'boots on the ground' who do all the heavy lifting. Each small milestone needs a well-deserved victory lap and must energize and hone the attention of the team to achieve the next milestone. Such celebrations are also important for the stakeholders to establish and reinforce confidence on the team's ability to drive the project to success.

LEARN LESSONS

FROM FAILURE

Good decisions are an outcome of great experience. However, great experience is the outcome of bad decisions. Occasional failures of outsourcing are part of our business model in today's landscape. Turn the failure of the outsourcing as an opportunity for process improvement. Analyze the reasons that led to the failure of the project and gain insights on the root cause of each. For each root cause, find a realistic and actionable improvement of systems/processes that can avoid such failure in the future. Share the lessons learned and recommendations to management and have an open discussion on the importance for such changes and its cost in time and resources. Spearhead the effort to improve outcomes for your organization.

FROM SUCCESS

When an outsourcing failure is turned around into a success, there are many valuable lessons to learn from that effort. Success in such cases is only achieved when collaboration, commitment, management support and resources come together in ways that exceed the normal standards of the organization. Right there, it is important to understand the 'magic sauce' that resulted in success. Who spearheaded the effort? What new lines of inter-departmental communications were created? What new meeting patterns emerged? What new tools/systems/platforms were used? What new resourcing model was used? How was the team kept motivated through the project? How was commitment and positive moral maintained through tight timelines and possibly overtime work?

Then ask yourself the most important question of them all. Can the 'magic sauce' be recreated for other projects? Can it be used to fuel process improvements within the organization? How do you incentivize the people who perform at that caliber to stay and grow in your organization? What is the roadmap to increase the operational excellence within your organization to make that 'magic sauce' the standard recipe?

PREPARE FOR AN OUTSOURCING FAILURE

Despite best efforts, some outsourcing arrangements do fail, and the sponsor is forced to investigate rescue options. As a sponsor, you need to have a contingency plan for this outcome in advance and know how to put it in motion. Here are some ways to prepare yourself to tackle possible outsourcing failures.

1. Strategically time the dry run: Consider the duration of your study and speed of enrollment to choose a point in time to conduct a dry run that gives you a full set of deliverables across all endpoints yet gives you ample time to 'pull the plug' on the relationship if the situation turns dire. This enables you to be in the driver seat when considering alternatives for rescue options as opposed to not have options since you are past the point of no return with the vendor.

2. Have a plan B for resourcing a rescue: Evaluate your existing vendor relationships and proactively seek out new relationships that will enable you to have a plan B when the need arises. Perform an assessment on how quick you can hire and onboard a team of statisticians and programmers, given the constraints of your organization (such as time for headcount approval, engaging vendors, reviewing CVs and scheduling interviews, norms of candidate notice periods, IT setup of laptops/access/permissions, ramp up with internal SOPs, etc.). Seek out FSP providers who can produce a fully functioning, self-managed team in relatively short turnaround time. The goal is to have viable options for a rescue plan prior to the need of such rescue, and to maintain such options and understand the ramp up time for each. This will give you great precision and confidence in estimating

the timelines for a rescue effort.

3. Standard doomsday operating procedure: Even though a formal SOP might be a stretch for the purpose, have a clear plan on how to operate when you hit the crisis mode. Assume that the decision to pull the plug on the current vendor is made and outline the next steps in the document. Address the possible candidates for rescue which can include organizations that you can re-outsource to, FSP vendors whom you can ramp up a team with, headhunting vendors who might rapidly fill you with temporary contract staff, and names of leads within your organization who have championed such efforts before and are more likely to bring such a venture to success. If available, link to lessons learned from previous rescue attempts within the organization so the current team can navigate the crisis equipped with more information. Identify key stakeholders who will be the decision makers and outline the flow of events to initiate the rescue.

PREVENTION OF OUTSOUCING FAILURES

As the age-old saying goes, prevention is better than cure. The goal of any sponsor is to have a predictable positive outcome in their outsourced projects and reduce the need for a eleventh hour rescue.

INCREASE CHANCES OF OUTSOURCING SUCCESS

1. Focus on building vendor continuity: Vendors who know their repeat business is at stake tend to prioritize you amongst their projects and make investments in their resources to operate at your expectations. Everyone makes mistakes but understand that a vendor who demonstrates the willing to work with you given the constraints of the project will eventually succeed and replicate the success in future projects. Prioritize long term relationship building than the short-term benefit of cost savings.

2. Achieve optimal supervision: A common misconception of outsourcing is that the vendor will provide a turn-key product at the end of the day with little or no supervision. While such events are possible, little or no supervision more commonly leads to a product that is not per expectations, and eventually a strained relationship with the vendor. Dedicate your resources upfront to provide supervision to the outsourced project. Decide on how frequent vendor touchbases should be, what they should cover as part of the agenda and incorporate informal draft reviews of specifications prior to the official dry run. It is necessary as the sponsor's project lead to want to review how primary/secondary endpoints are being derived, bring up corner cases and clarify how they are being handled, and be involved or appraised of discussions that settle programming/statistical disputes.

3. Get to know your team members: Time and time again, I have experienced that a project's success or failure largely depends on the people in the team doing the work. Everyone does a better job when they understand the importance of their work. Everyone goes a bit farther when they can put a face to the names of their clients. Consider a week of colocation for key team members of the vendor at your site or theirs where they can meet you and the extended team, learn about the importance of the drug/trial they are working on, and build the interpersonal relationship that will be crucial if the project hits a crisis mode. Vendors who operate globally and shuffle their resources as they see fit might not be keen on the idea of providing dedicated personnel with whom you can build such relationship. However, if you are in the business of building a long-term relationship with vendors, it is time to rethink what your priorities are and find synergies with the vendors who offer them.

4. Trust, but verify: it is perfectly OK to trust your vendor to do the right thing, especially if they have demonstrated history of success with you. However, past performance is not a guarantee of future success, neither in the stock market nor in outsourcing relationships. Stick to your internal process of quality assurance that is commensurate to the risk of the project's failure. Having a consistent, objective and structured quality assurance process of vendor deliverables keeps the vendor honest and allows the sponsor to bake that into the cost of outsourcing.

CONCLUSION

Clinical trials and drug development costs are already high, and it makes business sense to prevent or contain such outsourcing failures to restrict the further increase in spending. In the timeline of outsourcing as a business model, the pharmaceutical industry, especially biostatistics, is a late entry to the game. The

prevalence of outsourcing failures that we deal with on a regular basis is unacceptable in the long run. As a manager who is responsible for an outsourced trial, the success of the outsourcing also reflects on your personal success. The mechanism offered in the paper to identify a failing project, objectively analyze the situation, make informed decisions, get the project back on track, learn lessons and prevent such failures in the future are meant to serve as a guide to the next person or team in crisis. Outsourcing work is a business practice that is here to stay. It is up to us to champion it, control the outcome, increase chances of success and add value to our organization and lives of the patients who use our drug.

RECOMMENDED READING

- Faye Yeh, 2015. "Lessons Learned from the QC Process in Outsourcing Model." *Proceedings of the PharmaSUG 2015 – Paper TT11*.

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