Third party laboratory data management: Perspective with respect to clinical data management

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Abstract

Third party lab vendor provides support for laboratory, biological samples analytics data, collected during the clinical trial. Third party laboratory data is considered to be very significant for the clinical trial data management process. Although outsourcing these services is considered to be advantageous for clinical trials, there are some risks involved. Hence, pharmaceutical companies proactively select, track and evaluate third party vendors on a regular basis before, during and after the completion of the contract. The data manager has a significant role to play in effective management of third party vendor data.

Key words: TPV, laboratory, management

INTRODUCTION

Clinical trials enable pharmaceutical companies to develop and launch a new drug in the market. It takes about 10 years and an average cost of 1 billion dollars to develop a new drug.[1] In the current scenario, clinical trials cost is seeing an average increase of 2.4% annually. Pharmaceutical companies have come up with many measures to reduce the cost and increase the operational efficiency. Outsourcing some of the functions and services to different vendors is a common measure to efficiently monitor and lower cost while maintaining good quality and to use the expertise of vendors in their field.[2]

Different types of vendors are managed by pharmaceutical companies before, during and after the clinical trial. Third party vendors - laboratories (TPVLs) are significant partners in clinical trials since laboratory results play a vital role in evaluating new drugs determining the safety and efficacy of the drug in patients.[3]

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Following factors influence preference of TPVL for clinical trials:

- Advanced technology
- Well-trained and skilled resources
- Logistical support for collection and transport of biological samples
- On-time processing of samples
- Online delivery of results
- Rapid trouble shooting
- In-house mechanism for quality assurance and compliance
- Good laboratory practices (GLP) certification/ accreditation

Sponsors (pharmaceutical companies accountable for the clinical trial) can leverage the services of vendors to benefit both parties. However, managing third party vendors can be challenging. This article explores the management and

relationship between customers and TPVL within the data management process.

TPVL

TPVL manage pharmacokinetic/pharmacodynamic, serology, stool and blood analysis data during the clinical trials.[4] They provide different forms of services to their customers, based largely upon on the specific therapeutic area. For example, serology data is important for vaccine trials.

TPVL data processing involves many steps [Figure 1]. All the process steps are very important in TPVL data because one step will affect all the other steps through a sequential or cascading effect.

TPVL SELECTION

Selection of a TPVL is a cumbersome process and risks are very high because it involves biological samples for analysis. TPVL are selected based on the specific requirements of the clinical trial and sponsor expectation.[5,6] The key points that need to be considered while selecting third party vendor are:

- Evaluate the risk of utilizing or not utilizing vendor
- Evaluate vendors prior to contracting
- Define expectations, deliverables and responsibilities
- Confidentiality agreement
- Identify other possible vendors as part of a backup plan TPVL.

TPVL operates in different geographical locations and hence standard laboratory practices should be maintained in both central and local laboratories.

Some key factors for selection of laboratory vendors for clinical trials include [Figure 2]:

- The testing procedures should follow GLP throughout the operations in the laboratory and they should comply with national and international regulatory standards[7]
- Laboratory accreditations provide a clear picture of laboratory proficiency in techniques and staff[8]
- Laboratory personnel should be well-trained in standard operating procedures, in the operating systems and techniques. Skilled resources should be available for advance technologies and implementation of validated automation will reduce the cost and time of the process[8]
- Laboratories should maintain consistency in logistics, processing, reporting and troubleshooting. Laboratories should have access to couriers or overnight deliveries for receiving the biological samples. They should process the samples on time irrespective of the day and time and results should be available on time unless limitations of the test.

TPVL SETUP AND MANAGEMENT

TPVL management is very important for maintaining turn-around-time of deliverables, reasonable cost and good relationship to improve further in business. After selecting the TPVL through a request for proposal process, it is good to assess the requirements and specifications, risk, implementation planning and scheduling for data transfer. Once the clinical protocol is approved, sponsors engage in discussions with TPVL regarding the data transfer agreement (DTA), file format specifications and data cleaning plan. Implementing the procedures for

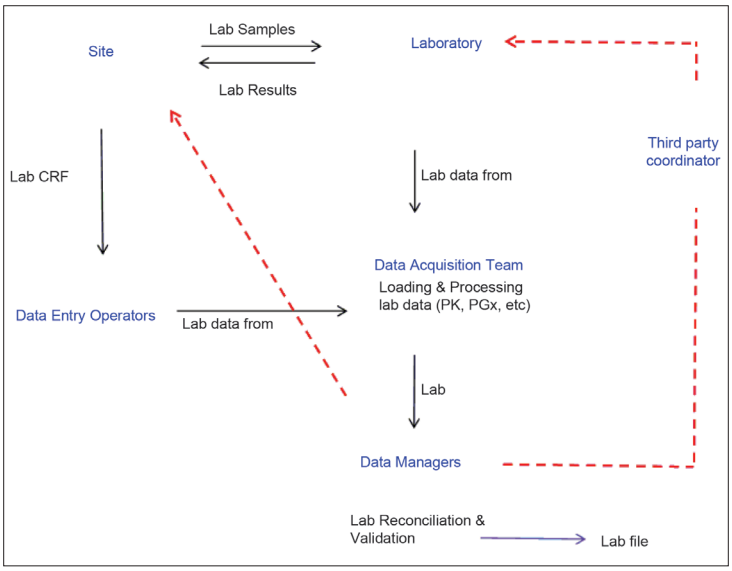

Figure 1: Third party laboratory data process

collecting, transferring, loading and validating and editing external laboratory data document is crucial for clinical data management [Figure 3].[4]

Laboratory data is reconciled with site data during study conduct and any discrepancies are resolved with the laboratory vendor.

Best practices during study conduct include automation of checks for data and for reconciliation, streamlining query resolution process and implementation of issue trackers to track issues for future use to update standards and process.

Finally, the third party data is placed in a central repository for further analysis.

CHALLENGES WITH TPVL

There are many reasons for slippage in third party data transfer to data management group (DMG) during the conduct and closeout phase of the study. Of these, delay in receipt and poor quality of data leading to rejection or rework can account for more than 50% of reasons for the delay in database lock due to the laboratory issues. Other causes in delay are normal ranges for laboratory data, especially when local laboratories in use are not available, data entry issues and delays in responses to data queries, errors during data transfer and merger and discrepancies due to poor setup of database.

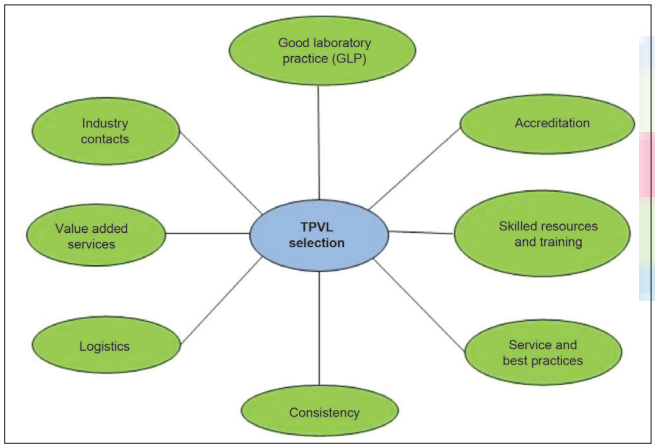

Figure 2: Selection criteria's for third party vendors for laboratories

Quality of deliverables should be continuously monitored using key performance indicators from study start up to closeout. Poor quality in interpretation of results or missing the delivery schedule will affect the timelines of the study, which can cause late submission of clinical study report to regulatory authorities.

Data managers are expected to look for the delay in processing the TPVL data address issues identified during reconciliation, communicate the timelines to the vendor and ensure common understanding between various stakeholders in order to ensure timely inclusion of laboratory data before database lock.

Efficient communication and good relationship with vendor can help in planning the schedules and steps to ensure timeliness of receipt of data. To this effect, the schedules, communication plan and roles and responsibilities should be discussed and agreed during the kick-off meeting. Laboratory data should be reviewed in batches during the conduct of study so that generic issues can be identified and addressed during the course of study conduct.

Best practices to avoid such situations are training, discussing improvement area or issues with the vendor, using reference documents, reconciliation checks and transfer of file according to the DTA, standard test names, quality assurance and quality control of laboratory data

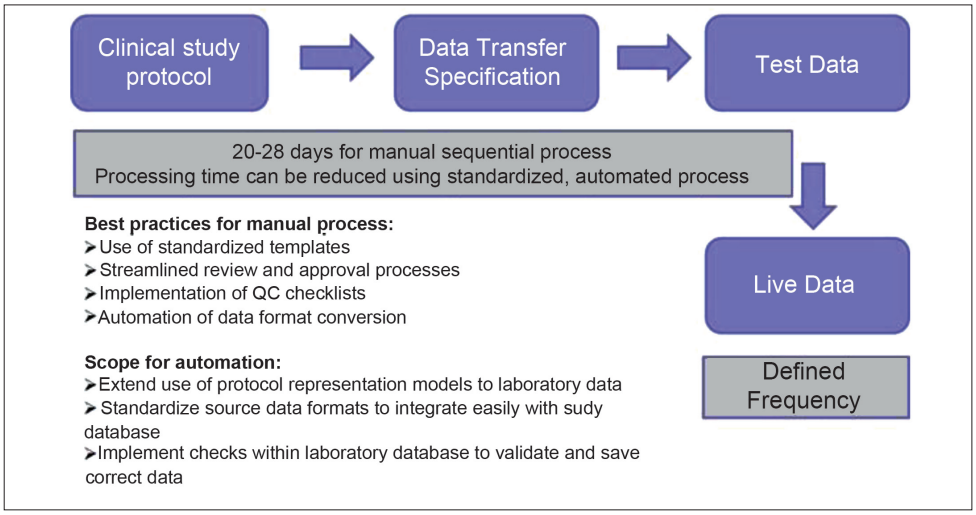

Figure 3: Setup process for collection and transfer of laboratory data

on the on-going basis and verification of reference ranges according to the local regulatory authorities.

TPVL OVERSIGHT

TPVL can be monitored based on the commitment, performance and relationship. All the three components are interlinked to each other and breach in one area will affect other two. Vendor performance should be monitored from signing the contract to database lock.[7] Data managers should set expectations at the contractual level based on the quality and oversight plans to manage TPVL.[4] Areas of concern should be evaluated and shared with TPVL. Communication and escalation plan should be implemented based on the service level agreement and metrics. Gantt chart, resource plans and communication plans directly help in managing the vendors. Performing regular audits internally give significant information to the operational team to identify the areas of slippage, which can be corrected by training. Corrective and preventive action should be reviewed to avoid such issues in the future. Regular assessments with the vendor identify weak and improvement areas, from sample processing to third party data transfer.[7] It also gives an overview of the status of deliverables. Mitigation and escalation plan should be outlined in vendor oversight plan if timelines are expected to be deviated.

CONCLUSION

TPVL management outlines the processes and framework for the data manager and the sponsor to measure the performance and improvement of collection of laboratory data that is analyzed and reported for evaluation of the outcome of the clinical trial. In turn, the DMG should also acknowledge the advantage of this proactive approach for better quality, good relationship and future business. Good management of vendor will achieve a win-win situation for both DMG and the vendor.

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