Vendor Selection and Management

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Abstract

Vendors provide services that are critical to the successful outcome of a clinical study, yet sponsors retain the ultimate responsibility for activities that are outsourced. If a sponsor is willing to give control of some study activities to a vendor, the sponsor should take measures to ensure the vendor is delivering products or services of acceptable and repeatable quality. This chapter provides recommendations for evaluating, selecting, and providing oversight of vendors to determine whether their services adequately meet quality expectations and regulatory standards.

Introduction

Vendors are used in all aspects of clinical studies and have particular relevance in clinical data management (CDM) processes. Some examples of vendors relevant to CDM include contract research organizations (CROs), case report form (CRF) design and printing companies, electronic patient reporting tool providers, clinical laboratories, central readers, imaging, interactive voice response system (IVRS) providers, electronic data capture (EDC) and other software suppliers, and off-site storage and data hosting facilities. Before a vendor is selected, the end product or result desired from the vendor should be clearly defined and described.

International Conference on Harmonization (ICH) E6 states "Ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor."[1] Therefore, the sponsor must manage vendors in a fashion that ensures quality, integrity and reliability. Not only is this ICH statement relevant to the sponsor, it should also be important to all vendors having an impact on final data quality. Documented processes should be followed to ensure that quality data are received from vendors, as well as to consistently evaluate vendor services.

Scope

The scope of vendor services differs widely across the industry, ranging from CRF printing to assistance with a regulatory submission. This chapter examines the communication of clear expectations between the vendor and the sponsor and some strategies for clearly documenting various areas of vendor oversight. The chapter also includes considerations for vendor qualification and the appropriate level of oversight needed, depending on the vendor's scope of work. Details and discussions regarding relationship management are beyond the scope of this chapter.

Some of the tasks described in this chapter may be joint responsibilities between different groups, just as there may be different groups involved in the implementation of various tasks. However, clinical data managers need to be conscious of whether or not these tasks have been performed in a satisfactory manner.

Minimum Standards

- Document the sponsor's process and support functions that are needed to evaluate the use of vendor services.
- Evaluate and qualify (e.g., capacity, qualifications, experience, regulatory compliance, company stability, etc.) vendors *prior* to contracting for their services or products.
- Obtain a confidentiality agreement with the vendor prior to exchange of proprietary information.
- Create a contacts list that is centrally accessible to study team members.
- Determine and document whether the sponsor's or vendor's standard operating procedures (SOPs) (or a combination of procedures) are to be followed.
- Clearly define expectations, deliverables and responsibilities. Both the sponsor and the vendor must participate in establishing definitions of their roles.
- Conduct ongoing management of vendor activities. Communicate and assess the vendor's performance throughout the study.

Best Practices

- Where feasible, evaluate from a CDM perspective the risk of utilizing or not utilizing vendor services related to the conduct and outcome of the study.

- Maintain an internally approved vendor list with regular evaluations (e.g., preferred vendor list or prequalified vendor list).

- Establish a cross-functional vendor auditing program based on established services, which should include plans to re-audit the vendor within a stated amount of time, if applicable.

- Oversee vendors by utilizing subject matter experts within a centralized organizational team to provide input into the processes of vendor evaluation, vendor audits, and issue resolution and escalation.

- Define and document a detailed statement of work and project plans that detail who is responsible for each task; who is responsible for reviewing and approving various documents; details of project reporting; or a checklist of tools, processes, and services to be performed by the sponsor and vendor at each phase of the study.

- Define and document detailed sponsor/vendor communication plans that clearly address the expected communication tools and frequency, as well as establish who is responsible for communications and how to escalate issues when deemed necessary.

- Identify other possible vendors or options as part of a contingency plan in case the vendor relationship is deemed unsatisfactory at any point during the course of the study.

- Establish a collaborative relationship based on partnership, trust and co-ownership of the project.

- If the vendor is providing services that involve computerized systems, ensure system support documentation is in place, such as a service level agreement (SLA), that describes in detail how much time it will take the vendor to respond to support inquiries, how long it will take to get a

database back online in case of a system failure, and other details related to supporting the sponsor's business requirements.

Types of Vendor Services

Each clinical study may require a variety of vendor services, depending on the needs of the study and resources already available within the organization. The following list contains some of the types of vendors most often utilized during the course of a clinical study:

- Data management CRO—An enormous range of services may be provided by data management CROs. Some CROs conduct all aspects of data management, while others may only perform select activities. Some of the types of specific services that may be encompassed by data management CROs include: project management; CRF creation; CRF guidelines creation; data management plan creation; database design and programming; edit check specifications development and programming; CRF tracking; data entry; data review and cleaning; data coding; serious adverse event (SAE) reconciliation; external data transfers; quality control audits; database lock(s); and database transfers.

- CRF/document printer—Not all printing companies have the equipment and expertise needed to print CRFs or other documents needed for a clinical study. Paper CRFs are typically printed in triplicate on carbonless copy paper. Ensure that the vendor used for printing these documents is capable of providing the end product needed for the study.

- Translation services—For studies requiring CRFs in multiple languages, accurate and reliable translation of the CRFs is crucial to collecting data that are consistently accurate and equivalent.

- External data providers—For vendors providing external data such as lab data or imaging and diagnostic data (e.g., ECG, MRI, CT), vendor evaluation should ensure vendors provide data that consistently meet quality standards defined for the study.

- Software and hardware providers—The technological needs of clinical studies have been increasing steadily over recent years. The advent of tools such as EDC and ePRO (electronic patient reported outcomes)

necessitate careful evaluation of vendors providing validated software, hardware, or database hosting services.

- Server or network providers—Whether servers and networks are hosted in-house or outsourced, an in-depth evaluation should be made to ensure servers and networks are stable, secure, and accessible only to authorized users. A disaster recovery plan should be available for inspection to help with evaluation of the provider.

- Coding services—Vendors providing coding services or licensing should be carefully evaluated to verify the appropriate training and experience of coding resources to ensure coding is performed accurately and consistently, and that all relevant licenses and documentation are maintained and up to date and the versioning frequency is assessed.

Business Model Impact on CDM

The business model followed by a vendor can significantly impact the relationship of the vendor with CDM personnel. The following are some of the more frequently encountered business models that may affect CDM personnel.

Transactional Model

The transactional model could be considered the traditional outsourcing model for clinical studies, in which a sponsor contracts vendors on a per project or per study basis. Transactional relationships may be more likely than other models to "…perform out-of-scope activities, resulting in cost overruns."[2]

Strategic Partnerships

Strategic partnerships may be formed between companies with complementary resources and expertise, so as to increase efficiencies and lower overall costs. Strategic partnerships could be between a sponsor and a biotechnology company providing EDC or other electronic tools for clinical studies, or may be between a sponsor and a full-service CRO. Strategic partnerships may also be formed to gain location-specific resources needed for studies that span multiple countries or regions. Before forming a strategic partnership, carefully evaluate the potential partner to ensure there are no

significant differences between corporate cultures, philosophies or SOPs that could potentially lead to conflicts. Although strategic alliances may "…not result in lowest-bid providers, the long-term efficiencies, minimization of out-of-scope costs, and performance improvements theoretically surpass short-term cost savings."[2]

Functional Service Provider (FSP) Models

In contrast to outsourcing all data management aspects of a study to a single CRO, an FSP model may involve outsourcing only select activities. "Because project ownership remains in-house, companies that use functional outsourcing may experience higher levels of quality control yet have access to specific services at a lower overall cost. Sponsor companies benefit from being able to ramp up and draw down resources relative to their development activity levels without affecting their internal head count."[3] Using an FSP model allows the sponsor to focus on their core competencies and outsource certain activities (such as CRF design or system validation) to niche vendors, rather than needing to hire additional personnel or provide additional training to existing personnel.

Application Service Provider (ASP) Models

An ASP is a vendor that leases a software application to clients, and can involve contracts that are for the duration of a study, for a set amount of time, or on a per use (e.g., per user, per study, per CRF, etc.) basis. Using an ASP can shift much of the responsibility to the vendor for implementing, hosting, validating, maintaining, upgrading and supporting the software. However, because sponsors are ultimately responsible for data integrity and quality, a risk-based approach should be used to determine the scope and depth of any additional software testing and validation that may need to be performed.

Vendor Qualification, Evaluation and Selection

Before a vendor is selected, an evaluation of the vendor should take place. The sponsor and the vendor must understand specifically what services will be provided, and whether the data in the clinical study could be directly or indirectly affected by these services. Both parties should have a clear task ownership matrix defining who is responsible, accountable, consulted or informed with each specific task. However, before evaluating vendors,

qualification should be performed to ensure resources are not spent evaluating vendors that do not meet the needs of the sponsor. Vendor qualification should be determined by internally evaluating what services will be required, and defining desired attributes for the vendor that will eventually be contracted. For example, a sponsor may determine that they only wish to consider vendors of a certain company size or location, or they may have a preference of a full service CRO or a niche vendor.

The vendor evaluation should provide assurance that the vendor has sufficient staff to perform the contracted services under SOP requirements, and that staff are adequately qualified and trained to perform the regulated activities. A request for information (RFI) should be developed and sent to the vendor for precertification (see Appendix A for a sample RFI form). A full vendor evaluation should examine information provided in an RFI, and may include an on-site vendor visit to interview vendor personnel and review vendor processes and systems. A formal presentation at the sponsor site could also be conducted by the vendor as a response to the RFI, which may include the following:

- Company information, such as a historical overview of the organization, length of time in the industry, financial stability of the organization, and an explanation of the organizational structure
- Products and services
- Experience and areas of expertise (e.g., oncology, adaptive design, Phase 1, etc.)
- Product demonstration
- Computerized systems
- Results of previous regulatory inspections, as permitted

Sponsor staff or delegates who are subject matter experts in the activities being outsourced (e.g., clinical, biostatistics, medical monitors, or data management) should participate in vendor evaluation. The primary goals of vendor evaluation are to determine that adequate quality and sufficient resources are available to provide the defined services in compliance with regulatory expectations and defined quality standards. If a vendor is found to

have deficiencies, they may not necessarily need to be eliminated as a viable option. Deficiencies may be addressed by determining if actions can be taken to correct the deficiencies, or by determining what extent of controls need to be exercised over the vendor. An example of corrective action may be to implement process improvement or remediation. However, the remediation that will be required of the vendor should be defined and evaluated prior to entering into a contract. This remediation may take the form of SOP provisions, data management support, quality assurance (QA) or quality control (QC) advice, or documentation and system validation guidance.

The results of a vendor evaluation should be tailored to the services being provided. For example, CROs providing full service would require extensive evaluation, whereas a vendor that only provides printing for query binders may require a less comprehensive evaluation. From a business perspective, it is most advantageous to thoroughly qualify vendors *before* contracting with them for their services. Qualification prior to contracting can help avoid the need to have work redone due to the original work being of insufficient quality or in a system that is not compliant with relevant regulations. Redoing work or even an entire study can significantly lengthen project timelines and overall costs. See Appendix B for an example of topics that may be examined in an EDC vendor review.

Considerations when evaluating a vendor may include the following (not in order of priority):

- Financial stability of the vendor
- Mergers or acquisitions in the recent past and the impact on SOPs
- The vendor's experience with different business models
- The vendor's geographic capabilities
- The number of sponsors or studies currently supported by the available vendor staff
- References from previous customers
- Outcomes of previous regulatory inspections, as permitted

- Review of required accreditation in the vendor's field of work (e.g., lab certifications)
- Availability of documentation to regulatory authorities
- Review of the vendor's SOPs and work instructions to ensure soundness of processes and proof of regulatory and industry standards compliance
- Vendor's ability to adapt to sponsor's SOPs, if required
- Documentation of vendor's change control processes
- The vendor's quality system (e.g. computer systems, CDMS, databases, etc.) and proof of compliance to their quality requirements
- Evaluation of the vendor's QC/QA processes
- Sufficient staffing, including documented adherence to training and retraining plans
- Personnel qualification (through a review of curriculum vitae (CVs) of company personnel, job descriptions, organizational charts, training plans and documentation, etc.)
- Evidence of clearly defined project-specific training plans for new team members, and adequate transition processes to address staffing changes that occur during a study
- Documentation of system validation for regulated processes
- Data transfer processes
- Security of physical locations where services are provided (controlled facility access, server rooms, file rooms, independent backup procedures, etc.)
- Physical conditions of server and file rooms (limited access, fireproof, temperature and humidity controlled, etc.)
- Disaster/contingency plan(s) to protect business operations

- Evaluation of subcontractors and the vendor's management processes for those subcontractors, if applicable

After the vendor evaluation process is completed, a vendor is selected and is typically presented with an award letter providing notification of the vendor's selection. Larger organizations usually have law and procurement departments that handle award letters and final vendor selection activities, but CDM personnel may be involved in these processes at some organizations.

Development of Contract and Scope of Work (SOW)

Once potential vendors have been evaluated and vendor selections have been made, a contract and statement of the scope of work must be prepared and agreed upon by the sponsor and the vendor. Many large companies have separate departments that handle these details, but CDM personnel may be involved with these processes in some organizations.

Considerations for Sponsors, Vendors, and Data Managers

The type of outsourcing business model used is the most important consideration in preparing the contract and the scope of work. Because numerous variations can exist between outsourcing relationships even when following the same outsourcing business model, the contract and the scope of work for each vendor relationship may also have unique variations.

When using models that involve more organizational integration, such as strategic partnerships or an FSP relationship, both organizations should commit to several levels of oversight (executive committees, operational committees, etc.) that focus on strategy and implementation to ensure that the partnership is successful. Each level of oversight should also be associated with a clear escalation path in case issues are unable to be resolved at a particular level. Governance models should ensure long-term senior management commitment from both sides.

For organizations using a transactional outsourcing business model, costs and scope of work are typically based on certain assumptions. Because some of these assumptions may be incorrect or based on changing information, the contract and scope of work should include provisions detailing how changes will be handled. These provisions should include a description of how changes

to underlying assumptions may result in change orders, as well as mitigation plans to resolve situations where the scope of work slowly evolves over time (i.e., scope creep).

Although typically the responsibility of a legal department, CDM personnel should be aware that contracts may include special clauses such as penalty clauses or bonus clauses. These clauses are intended to give vendors incentives for exceeding expectations, or disincentives for not meeting expectations.

Task Ownership Matrix

A task ownership matrix identifies all tasks that may arise during execution of a clinical study. The matrix is intended to ensure all tasks are accounted for and to reduce the potential for duplication of effort. Not developing a task ownership matrix or developing one poorly can defeat the anticipated benefits that drove the parties to enter into an agreement in the first place. For example, if both parties duplicate efforts with a task because responsibility for the task is not clearly defined, duplicate costs are incurred and the desired monetary savings of the relationship may never be realized. The matrix should clearly identify four ownership responsibilities that occur with any task or document:

- Who is *responsible* for this task or document (e.g., creation, revision, approval)
- Who is *accountable* for this task or document
- Who is *consulted* for this task or document
- Who is *informed* for this task or document

The end result of a well-documented task ownership matrix, also known as a RACI (responsible, accountable, consulted, informed) table, will be a better relationship between the sponsor and vendor, as well as provide clear one-party accountability for success or remediation of various tasks. The task ownership matrix should be mutually agreed upon by both parties prior to study startup.

Bid Grid

A bid grid (sometimes referred to as a roles and responsibilities or R&R matrix) is typically maintained by the sponsor procurement or vendor management office, although assignment of this responsibility may vary between organizations. A bid grid serves two primary purposes:

- A bid grid captures the sponsor's predefined study-specific cost drivers.
- A bid grid allows the outsourced partner to assign prices to specific tasks associated with cost drivers.

For all CDM cost drivers, a bid grid should include definitions of units, cost per unit, the estimated number of units expected, and total anticipated costs for each row. Columns may also capture which party is responsible for each activity and which party is accountable for each activity (the bid grid and task ownership matrix may be combined in some cases). The structure of a bid grid should be clearly aligned with the text portion of the SOW, and all tasks and units should be clearly defined, meaningful and measurable. In addition to specific CDM cost drivers, a bid grid may also include more high-level categories, such as CRF design or data cleaning.

Some high-level categories for pricing consideration include:

- CRF design
- Database development (including edit check specifications)
- Data management plan development
- Data cleaning
- Management of local lab reference ranges
- Data encoding (including panels to be encoded, dictionaries and versioning)
- Management of external data
- SAE reconciliation
- Quality control audit(s)

- Data transfers
- Database finalization/lock

Some examples of CDM cost drivers include:

- Number of unique CRFs (paper or electronic)
- Number of total CRF pages (paper or electronic)
- Number of subjects to be enrolled
- Number of cleanup listings
- Number of external data sources (e.g., central labs, electronic diaries, etc.)
- Number of local labs
- Number of queries expected
- Number of terms to be encoded
- Number of SAEs to be reconciled
- Number of data review rounds
- Number/types of data transfers
- Number of unique status reports
- Frequency of status reports
- Frequency of teleconferences
- Number of interim database locks

After relevant cost drivers have been shared with the vendor, the sponsor and vendor should discuss variables that could impact pricing prior to the vendor completing an initial bid. This discussion should include determination of which organization's SOPs will be followed. If the sponsor's SOPs are to be followed, training requirements will need to be determined for the vendor. Both parties should also consider which systems will be used and if any standards or efficiencies can be applied to the project(s). During this phase of

the relationship, clear expectations should be agreed upon and documented. Expectations to be discussed and documented should include:

- Communications (project status updates, escalation path, etc.)
- Quality (documents and data)
- Timelines and turnaround times
- Final deliverables

When working with a CRO, the final bid grid should be shared with the CRO parties in charge of managing the study and study deliverables. Both parties (sponsor and CRO) should review each task on the bid grid, line by line, to confirm understanding of the task and confirm the responsibility and accountability (responsible party, approving party, etc.). Each task should be explained to the CRO in sufficient detail prior to completion of the bid so that both parties fully understand what is to be included and priced. See Appendix C for an abbreviated sample bid grid.

Vendor Oversight

The vendor's responsibilities should be specified in detail and all deliverables in the contract should be clearly defined. The vendor should have frequent quality reviews to ensure compliance with contracted processes and deliverables. Continuous oversight of the vendor must occur throughout the study and until all final deliverables from the vendor have been accepted. A sponsor's quality management plan should include information regarding vendor oversight, and should be comprehensive enough to include processes and expectations.

Milestones should be based on defined deliverables that are mutually agreed upon throughout the study. These milestones are monitored through regular communication and status updates that are documented and provided to the sponsor. Out-of-scope or unexpected contractual issues should be discussed and handled as they occur, which will help ensure that misunderstandings and problems are minimized. All deficiencies should be analyzed to determine the appropriate preventive or corrective actions.

Governance Documents

Every clinical study should include governance documents that explicitly describe how various processes will be carried out. These governance documents should relate directly to the data management plan (DMP) and be referenced within the DMP. The following are some of the governance documents that may be used within a clinical study, although some of these documents may be consolidated within other study documents (such as within the DMP itself).

- Training and on boarding plans
- Transition plans to cover staffing changes
- Key milestones on study timeline
- Performance metrics definitions
- Communication plan (to include roles and responsibilities)
- Escalation plan

Monitoring adherence to study governance documents may involve formal governance teams, depending on the size, value, or risks of the project or study.

Resource Management

Resource management is a key component of providing sufficient vendor oversight. The sponsor must ensure that the resources needed to provide effective oversight are available. Similarly, both sponsor and vendor must ensure that they continue to possess the resources needed to fulfill their respective contractual obligations. In addition to physical resources (hardware, software, physical space, etc.), resource management should include personnel qualifications and availability, as well as the vendor's ability to ramp resources up or down as needed to fulfill contractual obligations.

Study Startup Oversight

Vendor oversight may vary during different phases of a clinical study. The following are areas requiring vendor oversight that occur during the startup phase of a study.

- Depending on the business model selected, training on sponsor's systems and SOPs, if appropriate—The sponsor must ensure that the vendor's team is thoroughly trained on the sponsor's systems and SOPs where applicable.

- Project-specific training—Although this training should occur for both sponsor and vendor personnel prior to the start of the study, it is not intended to train personnel on the fundamental aspects of a therapeutic area or clinical research in general. The vendor evaluation process should have already demonstrated that vendor personnel have the level of knowledge and experience needed to perform their respective functions. Because both sponsor and vendor personnel should already have expertise in clinical research and the study's therapeutic area, project-specific training should focus on those aspects of the study that make it unique. Project-specific training should follow the Pareto principle, commonly known as the 80/20 rule, meaning that 80% of the training should focus on the 20% of study parameters and processes that are unique to the individual study.

    - Retraining—Retraining study-specific processes and parameters should be carefully considered. Retraining necessitated by personnel changes (or other reasons) may occur for both the sponsor and the vendor during the course of the study, and it is crucial that responsibilities for project-specific retraining are determined at study startup. Although not always the case, each party (sponsor and vendor) typically assumes responsibility for retraining their own personnel when staffing changes occur.

- Timeline planning and review—Prior to the official start of the study, study timelines should be reviewed and mutually agreed upon by both sponsor and vendor. Any timeline changes should be agreed upon by both parties and communicated as soon as possible.

- Project milestone tracking tools/metrics—A set of predefined tracking tools and metrics should be established prior to the start of the study. The definition and expected use of these tools and metrics should be mutually agreed upon by the sponsor and vendor. The study's communication plan should establish how often and through which medium the tools or metrics will be shared. Milestone tracking tools and metrics give better direction to sponsors in determining the correct level of oversight, while also helping vendors measure their own success, which may ultimately relate to bonus payments if stipulated in the contract.

Study Conduct Oversight

After a study has begun, vendor oversight is needed to ensure the vendor continues to provide contracted services in accordance with agreements and timelines established during study startup.

- Timeline management—Both sponsors and vendors benefit from effective oversight and management of study timelines. Ultimately, timeline management should ensure the vendor is meeting sponsor needs and prescribed milestones, but effective timeline management will benefit the vendor as well by providing an assessment of vendor performance throughout the study. Timelines should be clearly documented from study startup until after study closeout, and should specify both major and minor study milestones. Any midstudy adjustments to study timelines should be mutually agreed upon, documented, and version controlled.

- Scope management—Throughout the course of a study, periodic evaluations should reexamine the scope of work being performed by the vendor. Although not always readily apparent, a slowly changing scope of work being performed by the vendor can result in unexpected cost overruns. Periodic scope of work reevaluations can benefit the vendor by ensuring all parties are aware of the amount of work that is being performed, as well as associated costs.

- Key performance indicators—Although established during the study startup phase, key performance indicators should be monitored throughout the study. Meeting or beating performance indicators may have an impact on the level of data quality oversight needed. Performance indicators may also be used to reward or penalize a vendor if such clauses exist within the

contract. For example, if a CRO achieved final database lock ahead of schedule, a monetary bonus may result. Conversely, if a vendor did not complete a data-entry system build by the date specified in the timeline, the sponsor may be entitled to a predetermined discount.

- ☐ Determination of meeting or beating performance indicators can be very subjective if not clearly defined. In the event of a discrepancy between achieving and not achieving a key performance indicator, an arbitration may occur between predetermined representatives from both sponsor and vendor organizations. In these situations, best practice is to use arbitration representatives who are separate from the day-to-day operations of the study.

- Data quality oversight—Because of the variations that may exist between quality requirements of different types of data, data quality oversight may be highly individualized for each vendor, and may be individualized within different parts of a single vendor's scope of work. Data quality oversight may (and probably will) change during the course of a study. Different levels of oversight may be needed for different data elements in a study. For example, more data quality oversight may be needed for primary efficacy and safety variables than for a subject's routine vital signs.

- Compliance—Sponsors should ensure regulatory compliance is consistently documented, complete, and timely, as compliance records may be audited at any time. Sponsors should also monitor and document strict adherence to all SOPs and ICH guidelines.

- Relationship Governance - It is advisable to have a face-to-face meeting between the sponsor and the vendor at least annually to evaluate the progress of the relationship and to determine the future shared vision.

Study Closeout Oversight

The last stage of the vendor management relationship is the project closeout phase. During study closeout, the sponsor should conduct and document rigorous oversight of all closeout activities and processes. Some of the primary goals of the project closeout phase are to ensure all contractual obligations have been met, finalize the study's objectives, conduct meetings to discuss lessons learned, complete and archive study records, and celebrate

successes. In terms of CDM, the specific activities associated with project closeout may include the following:

- Conduct database finalization activities (e.g., database lock, decommissioning sites, unblinding, preparing final analysis datasets).
- Conduct lessons learned meeting with all stakeholders to identify successes and challenges to be mindful of for future projects.
- Finalize and archive all relevant communications and data management documents according to applicable SOPs.
- Recognize the team for their contribution.

Continuous vendor oversight throughout the course of a study helps to ensure that study objectives are met effectively and efficiently, and that the vendor is fully aware of expectations. A successful sponsor–vendor relationship is one in which both parties' business needs are met, and one where both parties would be willing to enter into a similar agreement with each other in the future.

Recommended Standard Operating Procedures

- Vendor Qualification and Selection
- Specifications for Outsourced Deliverables
- Ongoing Vendor Management
- Vendor Auditing Specific to Types of Vendors
- Vendor Relationship Termination

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Further Reading

Terms used in this chapter may be found in the *Good Clinical Data Management Practices* Glossary.

Chapter Revision History

Publication Date	Comments
September 2000	**Initial publication.**
May 2007	**Revised for style, grammar, and clarity. Substance of chapter content unchanged.**
July 2008	**Revised for content, style, grammar, and clarity.**
March 2010	**Revised for content, style, grammar, and clarity.**

Appendix A: Sample Request for Information (RFI) Form

Company Information
1. Provide a brief description of the company's history, including length of time in the industry, origins of the company, mission statement and vision.
2. Provide an organizational chart. Include position and number of employees in each department (senior management, technical support, user support, technical and client service managers, sales and marketing, development, recruiting, quality assurance, training, etc.).
3. Describe quality assurance processes and roles. Is the quality assurance organization independent of the operational organization?
4. Describe the current level of company funding.
5. Describe the company's pricing model.
6. Describe the quality management system adopted by the company.
7. Describe the validation/change control processes of the computerized systems.
8. Describe results of prior audits.
9. Describe quality oversight on contractors (if applicable).
10. If applicable, provide the results of previous regulatory inspections.

Products/Services
1. Describe the evolution of your product or service.
2. How many clients are currently using your product or service?
3. Describe your user support services (IT, helpdesk, IVRS, etc.).
4. Describe the company's interpretation of 21 CFR 11 and how your product is in compliance with this regulation.
5. Can your company produce Clinical Data Interchange Standards Consortium (CDISC) compliant data? If so, which model or models?
6. Describe the company's involvement and specific recommendations for user training. Differentiate between clinical studies with a few sites and those with a large number of sites, if appropriate.
7. What other products or services do you offer?

Experience
1. How many studies has your company supported in the past _____ years?
2. What is the largest clinical study completed to date with respect to number of sites, number of subjects? What lessons did you learn?
3. What are some of the qualities of your company from a human resource perspective? (e.g., What is your rate of turnover? What percentage of your employees are contract versus permanent? What are your training procedures?)
3. What user feedback have you solicited or received from study site personnel or clients about your product or services? How was the feedback addressed?
4. Provide references.
5. Provide CVs and training plans for the proposed personnel.

Appendix B: Sample Internal Review—Topics for EDC Vendor

(for more discussion of EDC vendors, please see chapter entitled "EDC—Concepts and Study Start-up")

Investigator Site	Electronic CRF interface Infrastructure Data entry Programmed validation checks – display and resolution Query resolution and workflow CRF status and workflow CRF design
CRA	Source document verification Query management CRF status and workflow Appropriate access to data
Data Management	CDM review of data Automatic query approval Manual query generation Query management Re-run of validation checks Appropriate access to data Security Change control Coding
External Data Integration	Laboratory Data Interactive Voice Response System (IVRS) Pharmacovigilance database (also known as a safety database—this will only be external in certain situations)
IT	Server requirements Client requirements Architecture Database Security measures
Company	EDC experience Funding Size
Helpdesk	24/7 service to support users Multiple languages Users activation and deactivation

Appendix C: Sample Bid Grid

CRO SERVICES	Unit	Cost / Unit	Estimated Number of Units	Item Cost
DATA MANAGEMENT				
Project Management	Month			$0.00
CRF Creation	Per Unique Page			$0.00
CRF Guidelines	Per Unique Page			$0.00
Create Data Management Plan	Plan			$0.00
Design Database	Per Unique Page			$0.00
Program Derived Fields	Per Unique Page			$0.00
Program Data Edit Specifications (to include number of edit checks to be developed)	Per Edit check/Per Unique Page			$0.00
CRF Tracking	Page			$0.00
Double Key Data Entry	Page			$0.00
Query Rate (queries X pages X subjects	Page			$0.00
Line Listing Review (for Safety, Sponsor, etc)	Listing			$0.00
Data Management Review	Page			$0.00
Data Coding	Code			$0.00
Provide Coding Dictionaries	Dictionary			$0.00
SAE Reconciliation	SAE			$0.00
Lab Normal Maintenance	Lab Site			$0.00
External Data Loads	Load			$0.00
QC Audit	Page			$0.00
Database Lock	Lock			$0.00
Database Transfer(s)	Transfer			$0.00
			TOTAL	**$0.00**

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