

A Business Approach to Integrating Clinical Research Sites in Mergers & Acquisitions

*Rhonda J. Paz, Ph.D., CRCP
Sr. Vice President of Clinical Trial Operations
GuideStar Clinical Trials Management*

Introduction

Mergers and acquisitions have become a progressively widespread strategy for achieving hospital growth and expansion. From hospitals to physician practices, the paradigm of merging for purposes of leveraging capital to strengthen competitiveness continues to gain popularity.(1) In many cases of healthcare mergers, clinical research programs are part and parcel to the deal. With this comes the necessity of putting in place post-merger implementation plans in order to gain cost effectiveness, achieve synergies and increase market and productivity power.

Considerations

There are many benefits to mergers and acquisitions that include clinical research programs such as increased market share through gaining a wider patient base, increased competitiveness in vying for available trials in sponsor pipelines, improved profitability from increased trial procurement and patient enrollment, and operational cost savings by way of combined resources and infrastructural components. Another benefit presented is in the form of assuming qualified, specialized staff resulting in the ability to handle higher volumes which equates to greater revenue. (2)

While there are many benefits to acquisitions and mergers, these transactions may pose transitional and management challenges. Understanding the key factors to contemplate is critical for ensuring success. Transitional leaders will need to consider and address adequate agreements and effectively integrate culture and organizational structures, operating systems, standard operating procedures, and finally measure financial impact.

Beginning with the actual purchase agreement, a fair purchase price will need to be established. It is recommended that a business valuation is performed to establish the purchase price. Not only is this a good business practice, it also provides ample documentation of establishing fair market value in the event Stark Laws come into play. Beyond the purchase agreement, determination as to whether facility and physician service agreements will be needed is necessary. Facility Agreements may be required if research services and activities will take place outside of the merged or acquired facilities, and Physician Agreements will be necessary if physicians are not employed by the entity contracted as the research site. This will guarantee that physicians are appropriately paid for their time and effort on the trial. Business Associate agreements should also be considered, as one may be required to access protected health information from various clinical sites, and adequate and safe data storage methods will need to be failsafe.

Once appropriate agreements are in place, transformational leadership members need to pay close attention to the human integration aspect of an acquisition and merger. A lack of focus on the human amalgamation may block successful task consolidation. This can be a time wrought with staff insecurities and emotion. They may feel uncertain about their future, job security or feel a loss of autonomy. A possible result is for the acquired staff to suffer from “merger syndrome” in which employees “mourn a corporate death” as the company with which they have been employed will no longer exist. (3)

Financial considerations specific to the research program unification involve evaluating staff titles and salaries to determine if there is a need for any to be aligned and/or adjusted when warranted to guarantee pay and workload equality. Additionally, space and equipment rentals or leases need to be reviewed to determine if they should remain intact or need to be revised – or at a minimum to revise the “parties” in the contractual relationship. This same exercise should take place with all study sponsor contracts as well. It is important to review the clinical trial agreements and budgets for each trial to ensure they remain financial viable under the new operational structure, and to amend the agreement to state the correct parties as a result of any name changes the merger and acquisition produced.

Internally, sponsor fund distribution should be clearly addressed, especially when more than one facility is providing services. It is important that the payments are transparent and follow through to the point of services, so that the facility or service expending the resources to perform sponsor paid study services receives the funds to offset the expenditure.

Case Study

GuideStar Clinical Trials Management was engaged by a hospital system to aid in the acquisition and merger of a large physician practice-based clinical research program. This four hospital system acquired a local, competing physician practice of 70 physicians in 9 specialties. The first steps in the engagement were to perform a comprehensive site evaluation focused on compliance, operating systems, standard operation procedures, staffing structure and workload measures. Additionally, a business valuation was performed to establish the purchase price and provide proper documentation for Stark Law compliance. With the end results favorable to proceed, the hospital system acquired the practice and reaped many benefits an acquisition and merger can bring.

By expanding the research program into a wide variety of specialties with ample numbers of physician investigators, new industry sponsor relationships were forged. And by eliminating the competition for the same patient population, the organization became more attractive to

sponsors for trial placement. Value and efficiencies were gained through integrating infrastructures and eliminating redundancy in systems and resources resulting in a significant cost savings. The culminating consequence was increased market share and greater profitability.

Conclusions

A well-planned merger can reap many rewards as long as consideration of differences between facilities are taken into account and addressed early on. Further integrating standard operating procedures and retraining staff on new methods will go a long way in managing staff, ensuring retention and compliance, as well as avoiding redundancy.

Beyond the human side, it is important to evaluate and integrate operating systems and perform thorough data migrations. Developing clear service agreements such as business associate agreements, individual physician agreements and facility agreements will go a long way in establishing transparent financial practices to track the overall measurement of the mergers success – increased market share and profitability.

References

(1)

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