

Integrating Clinical Research Sites in Mergers and Acquisitions

By Sandra Albritton and Rhonda J. Paz

When two healthcare organizations combine in a merger or acquisition, their clinical research operations typically combine, as well. Potential benefits include the following:

- More internal clinical research expertise
- Relationships with a broader range of study sponsors
- Larger patient populations for potential enrollment
- Access to clinical studies across a broader range of therapeutic areas
- More facilities, locations and capabilities to offer potential study sponsors
- Less competition between studies for the same patients
- Expanded career-path opportunities
- More study opportunities for investigators
- More opportunities for non-investigator physicians to become principal investigators or sub-investigators
- A more robust research opportunity for new-hire physicians
- More efficiency by integrating systems, adopting the better solutions, and eliminating redundancies
- More resources to support new capabilities, e.g., in training, regulatory compliance, quality assurance, and technology
- Better access to clinical studies that can improve patient care
- A stronger research story for marketing purposes

Challenges

Merging two organizations is challenging. Even if the two organizations are roughly the same size, they will each have their own policies, processes, culture, etc. If one organization is much larger than the other, the burden of change will probably be on the smaller group. Nevertheless, even a small group can probably contribute new ideas.

To achieve the benefits discussed above, numerous challenges must be addressed.

- When a small organization gains access to resources like finance, legal, compliance, quality assurance, and human resource departments, it also loses its autonomy and ability to interact efficiently as a small team and act quickly. It will have to work with more bureaucracy and more complex reporting structures.
- Personnel must be integrated into a single management structure, with consistent responsibilities, authority, job titles, and processes. Former owners might become employees and "directors" might become "managers," with an actual or just perceived loss of prestige. Physicians, in particular, value the prestige they have worked so hard to earn.
- Top management might have unrealistic expectations of potential cost savings, especially during the work-intensive transition period.
- "Efficiency" and "synergy" can be code words for "layoffs." In addition to the impact on the individuals, knowledge and relationships are lost, and the balance of power

can be affected. Small organizations that rely on informal systems and what is in people's heads are especially vulnerable.

- Centralized services might be overwhelmed by increased volume, especially as a bolus of ongoing studies enters the system.
- Consistent clinical research standard operating policies and procedures must be followed.
- Technology systems are probably different, requiring migration of data and training.
- Conflicting policies on personnel matters, such as job descriptions, salary levels, overtime and investigator compensation, must be handled.
- Direct costs and prices for clinical research services are likely inconsistent. Price increases might disrupt relationships with study sponsors.
- Accounting for indirect costs must be adjusted for new patterns of work. Overhead charges can be radically different in small vs. large organizations.
- Actual costs might increase. For example, a hospital might require that study drug be dispensed by the pharmacy.
- Awareness of risk and attitudes toward risk management are likely inconsistent.
- The combination might create issues with the Stark Law, the anti-kickback statute, or state law.
- Transitional activities can easily distract personnel from performing their primary responsibilities, cutting into productivity. Substantial time will be required for training and it might be necessary to develop new training programs.
- If one of the organizations is absorbed into the other, the affected personnel might feel anxious, insecure and mournful of the death of their former organization. Similarly, personnel of the absorbing organization might feel threatened by the "interlopers" who are disrupting their lives.
- Small organizations may lose the ability to work with independent institutional review boards (IRBs).

Tasks

Clinical research is a tiny fraction of most healthcare organizations, so it is natural for top management to focus on clinical care functions during a busy transition. Nevertheless, clinical research is vitally important to the clinical researchers and, in proportion, to the organization overall. It thus falls on the leaders of the clinical research "department" to ensure a smooth transition, possibly with minimal support— or interference — from top management.

As soon as possible, a transition team that includes clinical research leaders from both organizations should start the planning process, focusing on the benefits and challenges described above, subject to the particulars of the situation. Every process will require its own transition plan. The transition team should engage all personnel in the planning process to obtain not just their perspectives, but also their willing cooperation. If they have no voice in the matter, passive resistance is more likely. This is not to say that everyone should have a voice in everything, just the matters that involve them directly and, especially, those for which they are responsible.

Given all the work required during a merger or acquisition, it seems like the worst time to perform financial, regulatory, personnel, technology and operational audits, but plans will be thwarted if assumptions prove untrue. A "profitable" clinical research operation might be "profitable" only because it is not charged for overhead. Study records might be in disarray. The clinical trial management system might be used for only limited purposes. Subject

injury and indemnification clauses in clinical trial agreements might be askew. The accounting department might not be reconciling work performed to payments received from study sponsors. Key personnel might be planning to leave for personal reasons. On the other hand, there might be underutilized talent, strong relationships with study sponsors, or an exceptional database of potential study participants.

Cultural integration might pose the greatest challenges, so it requires special attention. Seemingly petty issues might not be trivial to the person affected. Certain people make it their business to keep the pulse of their coworkers, so they are particularly useful in detecting potential problems and solutions.

A variety of contracts will need to be examined and, potentially, created, modified or terminated:

- Facility agreements might be required, depending on where the research is conducted and which central services are involved.
- Physician agreements might be required, depending on which entity employs them.
- Business Associate agreements might be required so study personnel can access patient records, e.g., for recruiting purposes.
- Clinical trial agreements might have to be assigned to the surviving entity. It might be necessary to revise certain terms. For example, the principal investigator might be a "party" to the old agreement but not the new one. The location of the study might change or expand. The new organization might want to renegotiate the budget and other terms that it deems deficient if it is to continue enrolling study participants.

The transition team should estimate the extra workload that will be required during the transition period. Temporary personnel or external services might be required during the transition period. Productivity should be monitored closely.

The transition team should prepare a package of tools and information for use in future mergers and acquisitions.

Conclusion

Mergers and acquisitions can be challenging, especially given the additional workload during the transition process. However, proper planning and management can reduce the pain and efficiently deliver the benefits. As Henry Ford said, "Coming together is a beginning; keeping together is progress; working together is success."

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