From Silos to Centralization: A Seven Year Experience

Leslie Baga RN, MSCRA, CCRC
Lehigh Valley Health Network, Leslie.Baga@lvhn.org

Eric Mueller MSA, MBA
Lehigh Valley Health Network, Eric_M.Mueller@lvhn.org

Published In/Presented At

Baga, L. Mueller, E. (2018, September 27). *From Silos to Centralization: A Seven Year Experience*. Poster Presented at: Society of Clinical Research Associates, New Orleans, LA.

From Silos to Centralization: A Seven Year Experience

Leslie Baga, RN, MSCRA, CCRC Eric Mueller, MSA, MBA
Lehigh Valley Health Network, Allentown, Pa.

BACKGROUND

Traditionally, frameworks upon which clinical site research programs have been built have consisted of decentralized silos working independently with a similar focus. Trends in health care and increased regulatory oversight have resulted in the emersion of "centralized" research models. There are varying levels of centralization, ranging from efforts to centralize single entities (e.g., business office activities, grant processes, staff resources) to complete centralization of all research activities across a site. At any level, the path to centralization requires forethought and a unified team possessing attributes of resiliency, innovative thinking and excellent interpersonal skills.

METHODS

Seven years after the initiation of a centralized model, a clinical site evaluates its process and progress

Year one – the most challenging of all.
Bringing individual silos together requires strong leadership, persistence and adaptability. Key points during this first year include evaluating existing independent departments, hiring staff, making financial determinations regarding historical funds, choosing the leaders, naming the department, and establishing operational processes.

Year two – the dust has settled; now what?
Key points during the second year include administering a needs assessment to researchers, developing staff, creating standard operating procedures for research, establishing research review committees, building a centralized business office, re-establishing industry contacts, and providing resources for investigator-initiated studies.

Year three – the ground is becoming solid.
Begin setting the stage for new opportunities to grow and further develop the program. Key points include evaluating and refining processes; retention of high-performing staff; assuring compliance through continued education and partnering with compliance services; understanding the site's portfolio of research and setting future trends and goals; partnering with sponsors; and expanding services.

Year four – busier than ever; what happened?
Year four is the time when sponsors are recognizing the site as a desirable, high-functioning site. Key activities during year four include triaging trials to staff in an era of lean management, complex trials, and increased training requirements; assuring compliance while accepting more projects; continuing development and education for staff and new investigators; and determining where strengths and challenges lie within the various clinical specialties.

Year five and beyond – a more sophisticated model. The centralized office is recognized by all within the network. Expansion of research is being initiated at satellite sites and partnerships within the oncology research arena are being developed and fostered. Most important, the foundation of quality and education serves as a pillar, continuously supporting the research infrastructure.

CONCLUSION

Setting the stage for a truly centralized research model at a clinical site requires commitment from the highest levels of an institution. Even with this support, many challenges persist, e.g., issues with staffing, facilities, electronic systems, training, budget and contract negotiations; maintaining good customer service; and promoting a positive workplace. Although these challenges may be onerous at times, they can be overcome by having a vision of future directions and a strong team to transform the vision into reality. A centralized model can be a lasting investment in quality and, ultimately, financially and administratively lucrative for a clinical site.

Lehigh Valley Health Network
LVHN.org