

Integrating the Clinical Research Activities of Physician Groups into Healthcare Systems

By Marti Gardner and Rhonda Hoffman

When a Healthcare System acquires a Physician Group, it is probably much more interested in the group's clinical practice than its clinical research activities. Nevertheless, integrating the Physicians' clinical research activities into those of the system is a challenge that cannot be overlooked. This article will focus on this process as it relates to the Physician/Investigator.

Successful integration typically requires the following fundamental understandings:

- Integration is a team process that requires open communication.
- The System recognizes that the Physician's research is important.
- The System's policies and procedures are necessarily more complex and time-consuming, with more oversight, than those the Physician has been using.
- The Physician will benefit from more clinical research opportunities, more support staff and internal expertise, less regulatory risk, and more sophisticated technologies.
- It is much more likely that the Physician will change his or her practices than that the System will change its practices.
- The integration process might identify problems with the Physician's current clinical studies, which will have to be addressed.
- The integration process will be time-consuming and, at times, frustrating, but it will pay off in the end.

The integration process should start before the System, Group and Physician sign contracts to join forces. If all parties do not have clear expectations upfront, there is sure to be confusion, wasted effort, and maybe hard feelings later. The System's research office needs to know about the Physician's current studies and plans for the future. The Physician needs information about his or her future research environment. A packet of information regarding research infrastructure and contact information can provide a guide during the transition.

The research office needs to know what commitments senior management is planning to make to the Physician to ensure they are realistic and consistent with system practices, on topics like the following:

- Research support the System will provide to the Physician
- Industry-sponsored vs. investigator-sponsored (i.e., System-funded) research
- Travel allowances
- Protected time
- RVU credits
- Physician authority (or lack thereof) to select studies, sign clinical trial agreements and confidentiality agreements, and accept payments from study sponsors.

It takes at least a year to fully integrate research from an acquired Physician Group into a hospital system. The following actions must be completed:

- Facilitate Physician interactions with support resources and potential research collaborators.

- Train the Physician on general and clinical research policies, procedures, management structures, System culture, etc.
- Train the Physician on the clinical trial management system (CTMS), electronic medical record (EMR), and other technology.
- Align reporting relationships, job descriptions, and pay grades for the Physician's clinical research staff.
- Review the design of the Physician's current studies for questions like feasibility and standard-of-care, and address any issues.
- Expose the Physician to potential study sponsors.
- Inform the Physician's current study sponsors and CROs of the acquisition, and amend the contracts accordingly.
- Review and address any conflicts of interest with study sponsors.
- Review outstanding receivables and incorporate them into the System's payment system.
- Amend regulatory documents to include the System.
- Build a trusting relationship between the Physician and the System's research office.

Provided both parties understand the challenges and systematically move through the process, while emphasizing trust and open communications, integration should be successful, to the benefit of all concerned.

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