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Key Elements for Implementing Clinical Research as a Care Option

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The concept of *Clinical Research as a Care Option* (CRAACO) has been gaining traction over the past several years. While many healthcare institutions and practices have physicians who participate in clinical research to some extent, ensuring that clinical trials are offered as viable care options by all physicians within the healthcare institution requires three elements: (a) clinical research infrastructure, (b) healthcare practice administration buy-in, and (c) engaged physicians.

Research Infrastructure

Many clinical research departments operate with minimal staff, who are thinly spread across patient recruitment, consenting, visits, study feasibility analysis, regulatory paperwork, and sometimes also standard patient care. These responsibilities leave little time to engage with physicians, nurses, lab managers, and other healthcare providers.

Many physicians are willing to consider conducting clinical research as principal or sub-investigators only if they are reasonably confident that it will benefit their patients without imposing additional burdens on the physician, such as overloading daily schedules, which might already pose challenges.

Core functions essential to supporting the successful integration of clinical research will include the following:

- **Dedicated Resources.** Study coordinators should be dedicated to clinical research, well-trained, and available to support physicians. They should have their own offices or dedicated space, their own commonly used equipment, their own storage spaces for drugs, visit kits, study equipment, and study records, as well as dedicated areas for monitoring. In a large medical center, there should be an appropriate balance between centralized and distributed facilities.
- **Business Development**. The clinical research department must generate a steady flow of new studies that appeal to physician/investigators and patients.
- **Administrative and Start-up Functions.** There must be well-trained personnel for regulatory document coordination and submission, contract and budget negotiations, finance and other functions that physicians do not perform. These administrative (non-clinical) personnel can operate centrally when supporting multiple locations, or within the healthcare practice setting, in which case cross-training on other clinical research duties will give the site more flexibility to handle workload fluctuations.
- **Patient Recruitment**. In theory, physicians often "have the patients," but they might not be able to identify all of them, or be prepared to explain a clinical trial to them during the course of a busy day. The clinical research department can train physicians, provide both provider- and patient-facing study materials, find study candidates in the electronic health records (EHR) system, promote the study to clinic patients and the general community, perform phone screens, and manage the patient recruitment process.

Administrative Buy-In

The value of CRAACO is often overlooked by healthcare organizations. In many practices, research is conducted by only a few physicians, rather than being an integrated part of the organizations' strategy for patient care and population health management.

They may not be aware that properly integrating clinical research into the clinical care continuum has been proven to deliver the following benefits[1]:

- **Better Outcomes**. Some clinical trials may provide real healthcare benefits to patients in the short term. However, other patients will benefit from the higher level of attention they receive in a clinical study, including incidental findings. And, in the long term, many people will benefit from the resulting medical progress.[2]
- **Higher Patient Satisfaction.** Not all patients are interested in joining a clinical study, but those who do appreciate the increased attention and "VIP" treatment (more frequent visits, more in-depth health assessments, etc.) they receive in a clinical study. Many more appreciate the healthcare institution's efforts to find new treatments that might benefit them and their family members. They feel more confident that their regular medical care is provided by experts who are up to date on the best treatments available.
- **Reduced Costs for Patients and Payers**. When a pharmaceutical or medical device company conducts a study, it assumes some or all of the cost of treating the patients, so the patients, providers and payers do not need to cover those costs (in most non-oncology clinical studies). This benefit is most pronounced for under-insured and uninsured patients, as it allows them access to medications and supplies they would not be able to afford on their own.

These benefits align with the "triple aim" of Accountable Care Organizations (ACOs) to (a) improve the patient experience of care (including quality and satisfaction), (b) improve the health of populations, and (c) reduce the per-capita cost of healthcare.

Engaged Physicians

Engaging physicians requires an ongoing outreach program to communicate the above benefits, especially from the physicians' perspectives. However, outreach is not enough. The key factor is to actually deliver the benefits with minimal burden on the physicians. The benefits and burdens will vary across different institutions, therapeutic specialties, roles (e.g., physician vs. nurse), and individual physicians. Their attitudes will also vary, especially based on previous experiences and word-of-mouth. The good news is that effective engagement with a few physicians will make it easier to bring more into the fold. It is therefore best to start slowly, address any issues quickly, and let the momentum build naturally.

There are a multitude of reasons why most institutions will never achieve 100% participation from physicians, nor should that need to be the goal. Some providers will be highly active, some will be less active, some will be more comfortable in a supporting role, and some will not want to or be able to be involved at all. Therefore, maximizing the research "champions" and leveraging those who are able to participate as committed referral sources cannot be overestimated in the broad integration of CRAACO into a healthcare institution's strategy of care.

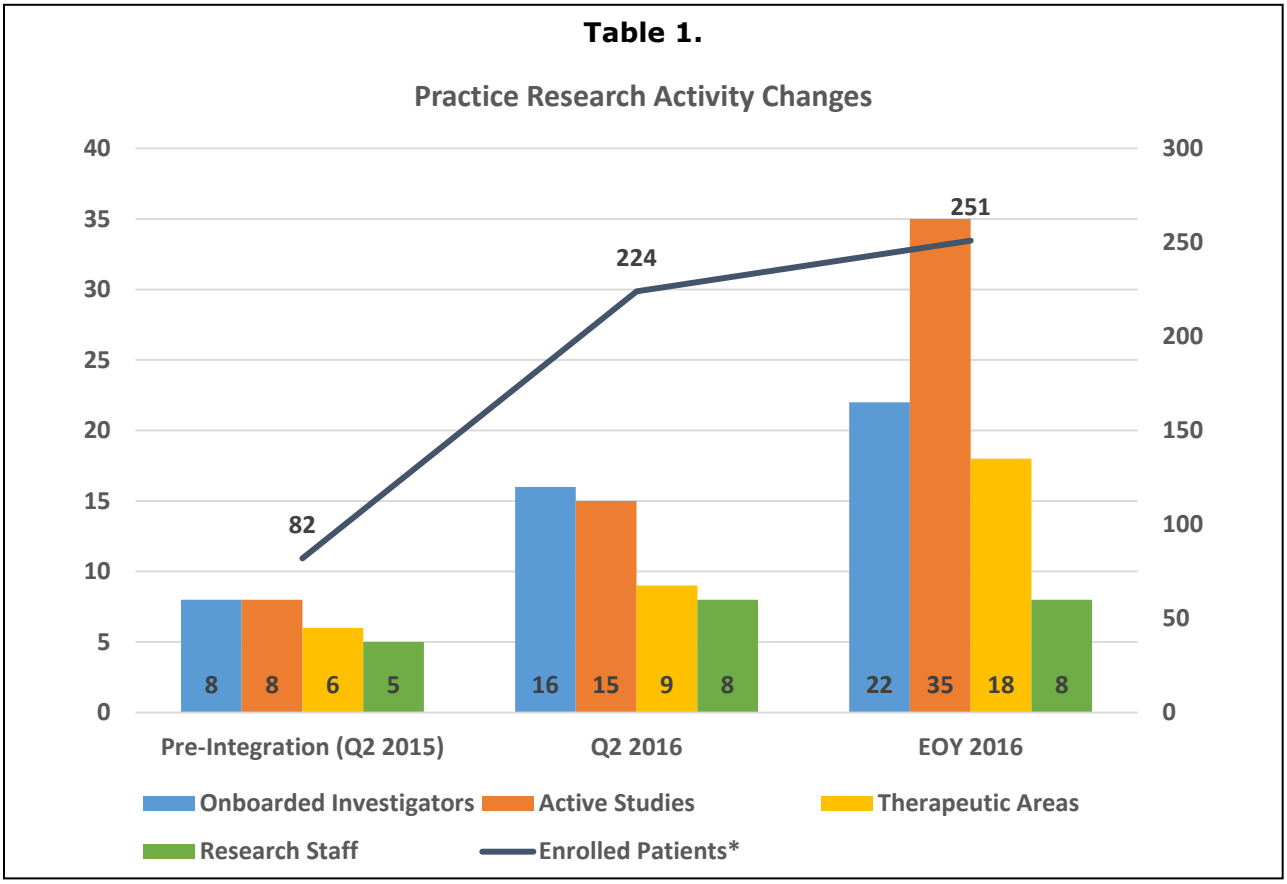
Case Study

It may not take a large increase in personnel to achieve the benefits of implementing CRAACO. While additional resources might be needed, it is just as important to deploy them correctly.

In a recent example, a 120-provider multi-specialty group practice participating in an ACO program implemented CRAACO in collaboration with an integrated site network. As shown in Table 1, over the course of 18 months:

- Participating investigators increased by 175%
- Departments/specialties participating in research increased by 200%
- Active studies increased by 337%
- Enrolled patients increased by 206%
- Research staff increased by only 60%

Table 1.



Metrics that more directly measure the integration of clinical research into an organization's strategy for patient care and population health management are under development.

References

1. Case Study Illustrating the Value of Integrating Clinical Research into Patient Care within Multi-Specialty Healthcare Institutions. PMG Research and Wilmington Health. The Avoca Group Quality Consortium Summit, May 2015.

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