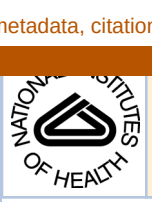



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# The Business Case for Provider Participation in Clinical Trials Research: An Application to the National Cancer Institute's Community Clinical Oncology Program

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## Abstract

**Background—**Provider-based research networks (PBRNs) make clinical trials available in community-based practice settings, where most people receive their care, but provider participation requires both financial and in-kind contributions.

**Purpose—**This study explores whether providers believe there is a business case for participating in PBRNs and what factors contribute to the business case.

**Methodology/Approach—**We use a multiple case study methodology approach to examine the National Cancer Institute's Community Clinical Oncology Program, a longstanding federally funded PBRN. Interviews with 41 key informants across five sites, selected on the basis of organizational maturity, were conducted using a semi-structured interview guide. We analyzed interview transcripts using an iterative, deductive process to identify themes and subthemes in the data.

**Findings—**We found that a business case for provider participation in PBRNs may exist if both direct and indirect financial benefits are identified and included in the analysis, and if the time horizon is long enough to allow those benefits to be realized. We identified specific direct and

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indirect financial benefits that were perceived as important contributors to the business case and the perceived length of time required for a positive return to accrue.

**Practice Implications—**As the lack of a business case may result in provider reluctance to participate in PBRNs, knowledge of the benefits we identified may be crucial to encouraging and sustaining participation, thereby preserving patient access to innovative community-based treatments. The results are also relevant to federally-funded PBRNs outside of oncology or to providers considering participation in any clinical trials research.

### Keywords

clinical trials; provider-based research network; oncology; return on investment; business case

## INTRODUCTION

Clinical trials are research studies that test cutting-edge therapies developed to prevent, detect, and treat diseases (National Cancer Institute 2011). With new discoveries in basic science, it has become increasingly important for clinical trials to be conducted not only in academic medical centers, but also in community-based hospitals and physician practices where most people receive their care (Minasian et al. 2010). Provider-based research networks (PBRNs) -- collaborative partnerships between community-based providers and research institutions -- provide a promising model for increasing community-based provider participation in clinical trials research, and may therefore be a critical component of expanding access to clinical trials and the latest innovations in medical care.

However, participation in clinical trials research can require substantial investments of time and money by community-based providers (Ryan et al. 2011; Holler, Forgione, Baisden, Abramson & Calhoon, 2011). If providers are faced with resource constraints, clinical and quality-improvement programs without a clearly identifiable business case, or financial return on investment, are at risk of either not gaining or not retaining organizational support (Leatherman, et al., 2003; Institute of Medicine, 2008). Thus, the lack of an established business case may result in provider reluctance to participate in clinical trials, or in broader research innovations such as PBRNs.

Currently little is known about whether, or under what conditions, a business case for PBRN participation exists. To fill this gap, this study sought to learn: (1) whether providers believe there is a business case for participating in a PBRN; (2) if so, what factors contribute to the business case; and (3) whether or not providers believe it is important to establish a business case to generate organizational support for initiating or sustaining PBRN participation. To answer these questions, we conducted a multi-site case study of the National Cancer Institute's (NCI) Community Clinical Oncology Program (CCOP).

Our study contributes to the existing business case literature that has investigated investments in clinical or quality-improvement initiatives in health care by being the first to explore whether and under what conditions a business case exists for provider participation in clinical trials through a PBRN. Further, this study identifies specific direct and indirect financial benefits of provider participation in clinical trials research through an established PBRN, and the perceived time frame required for these benefits to accrue. Since the CCOP may serve as a model for future PBRNs, findings from this study can inform decisions at both the organization and policy levels, and help encourage expansion and sustainability of clinical trials research in community-based settings.

## NCI's Community Clinical Oncology Program

The CCOP is a federally-funded PBRN that plays an essential role in the National Cancer Institute's (NCI's) effort to increase enrollment in cancer clinical trials. There are currently 47 funded CCOP organizations (i.e., local networks of hospitals and oncologists), and 16 funded Minority-based CCOP organizations throughout the United States, collectively representing 400 hospitals and 3,520 physicians (National Cancer Institute, 2011). These CCOP organizations provide the research infrastructure and support to make NCI-sponsored clinical trials available in community-based practice settings. The NCI's CCOP model is regarded as a highly successful example of a federally-funded PBRN, with community-based CCOP organizations generating approximately one-third of the total patient enrollments to NCI-sponsored clinical trials (National Cancer Institute, 2011b; Cobau, 1994; Minasian et al., 2010). Because of its success, the NCI's CCOP program has already served as a model for other federally-funded PBRNs such as the National Institute on Drug Abuse's Clinical Trials Network and the National Institute of Allergy and Infectious Disease's Community Program for Clinical Research on AIDS, and may continue to serve as a model for future PBRNs (Lamb, Greenlick & McCarty 1998).

Over the past decade, the NCI has provided approximately $90 million annually to CCOP organizations and research bases through a competitive grant process. In 2010, the average annual grant awarded by the NCI to a CCOP organization was $890,000 (National Cancer Institute, 2011). While this federal support covers a substantial portion of direct costs associated with participating in the CCOP, the grant is not intended to cover all of the costs needed to conduct NCI-sponsored trials (Minasian et al., 2010). Instead, CCOP organization-affiliated hospitals and/or physician practices (henceforth referred to as “CCOP-affiliated providers”) are expected to contribute both financially and in-kind to support the research infrastructure. Thus, for many community-based providers, participation in a CCOP organization requires substantial financial investment, far greater than the level of federal grant funding. In return for their investment, CCOP-affiliated providers have the potential to realize both clinical and financial benefits from CCOP participation.

Clinical benefits of CCOP participation include access to the most novel and innovative cancer treatment therapies. Two recent studies have demonstrated that CCOP-affiliated hospitals and providers more rapidly adopted evidence-based cancer therapies than did non-CCOP affiliated providers. Specifically, Carpenter et al. (2011) observed that hospitals affiliated with NCI's clinical cooperative groups, a cohort that includes CCOP-affiliated hospitals, more rapidly adopted sentinel lymph node biopsy (an innovation in early-stage breast cancer treatment) than did hospitals with no such affiliation (Carpenter, Reeder-Hayes, Bainbridge, Meyer, Amos, Weiner, Godley 2012). In another study, Carpenter and colleagues observed that Stage III colon cancer patients seen by CCOP providers were more likely to receive the innovative therapy oxaliplatin and guideline-concordant care than were similar patients receiving care from other community providers (Carpenter, Meyer, Wu, Qaqish, Sanoff, Goldberg, Weiner 2012). Yet while the clinical return on investment has been well established, the financial return on investment, or business case, is less clear.

## CCOP Organizations and CCOP-Affiliated Provider Relationships

To be a CCOP is to be funded through a Cooperative Agreement with the NCI for the purpose of accruing patients onto cancer treatment and prevention clinical trials. A CCOP organization may be structured as a single community organization, or as a consortium of community-based hospitals and physician practices (National Cancer Institute, 2011). As a result, the organizational structure and financial relationships between providers and CCOP organizations are varied. CCOP organizations are often housed within one of their CCOP-

affiliated providers (typically the CCOP-affiliated hospital or health system); however, they may also exist independent of a specific provider.

CCOP organizations are led by a physician Principal Investigator (PI) who provides local program leadership. CCOP staff members typically include an associate PI, a program administrator, research nurses or clinical research associates, data managers, and regulatory specialists. These staff members coordinate the review and selection of new clinical trial protocols for CCOP participation, disseminate protocol updates to the participating physicians, and collect and submit study data. CCOP-affiliated physicians accrue or refer participants to clinical trials, and typically include medical, surgical and radiation oncologists, general surgeons, urologists, gastroenterologists, and primary care physicians. CCOP-affiliated physicians, through their membership in CCOP research bases, also participate in the development of clinical trials by proposing study ideas, providing input on study design, and occasionally, serving in the role of PI or co-PI for a clinical trial.

To help support participation in research, NCI trials are deliberately designed to comply with standards of care; as a result, reimbursement for the direct costs of cancer treatment can often be obtained from private insurers and Medicare. Insurers and third-party payers do not, however, reimburse for the costs of research infrastructure (e.g., research nurses, clinical research associates, data managers, etc.). To help support the infrastructure costs, NCI grants funds are provided “up-front” to CCOP organizations, prior to enrolling patient in clinical trials, with the expectation that CCOP organizations will meet certain accrual goals. Although there are rules about the types of costs that can be covered, CCOP organizations have flexibility to allocate the grant funds to support different configurations. The grants do not, however, nor are they intended to fully fund these research costs. Rather, the NCI expects the participating institutions to share in the support of the research activity. For example, a CCOP organization may require a membership fee from affiliated CCOP-providers to participate in the CCOP or, more commonly, hospitals that house CCOP organizations may cover a portion of the CCOP costs.

Costs that are not directly offset by the CCOP grant funds often include indirect costs, such as information technology support, physical space, regulatory or compliance support, and financial management support. These activities are not revenue-generating, and therefore must be offset by other financial benefits for a business case to exist. In the past, financial slack allowed providers to direct funds to non-revenue generating activities and still remain financially viable; however, with the changing financial climate for medical care, the existence of a business case may be increasingly relevant to CCOP-affiliated providers who must make the decision to invest in the CCOP organization. Therefore, our study focuses on the business case, or financial return on investment of CCOP participation, from the perspective of the CCOP-affiliated providers and not the CCOP organization.

## CONCEPTUAL FRAMEWORK

In the standard finance literature, the identification of a business case, or financial return on investment (ROI), is a primary decision criterion for any type of investment. The capital budgeting process systematizes the analysis and ranking of projects subject to financing constraints. Most projects are subjected, at a minimum, to a discounted cash flow analysis that shows the contribution of the project to the overall value of the organization. Although projects without a positive financial return may be undertaken, in total, the portfolio of projects must at least break-even for the organization to remain financially viable (Wheeler and Clement 1998, Cleverly 1995). Over time, reimbursement has failed to keep pace with rising health care costs, straining the profitability of many health care organizations (Speilman 2012) and limiting the capital available for investment. As capital is constrained,

projects that might once have been undertaken for their contribution to the organization's mission are likely to be held to more stringent standards for financial return.

The application of a return-on-investment criterion to potential investments in clinical or quality-improvement programs in health care becomes challenging as many of these programs generate little to no revenue that can be directly attributed to the initiative. Indeed, the health care literature has established that a business case for clinical or quality-improvement related initiatives such as electronic health record implementation or the introduction of high-performance workforce management practices in health care is largely driven by the consideration of indirect financial benefits, or benefits that occur incidental to the initiative but that cannot be directly traced to the program (Bailet & Dyer 2003; Song, Robbins, Garman, & McAlearney, 2011b; Song, McAlearney, Robbins, & McCullough, 2011).

Recognizing this, we use the operational definition of the “business case” for health improvement interventions defined by Leatherman and colleagues to frame our study design and analysis. Leatherman et al. state that “a business case for a health care improvement intervention exists if the entity that invests in the intervention realizes a financial return on its investment in a reasonable time frame, using a reasonable rate of discounting. This may be realized as `bankable dollars' (profit), a reduction in the losses for a given program or population, or avoided costs.” Leatherman and colleagues further add that “a business case may exist if the investing entity believes that a positive indirect effect on the organization function and sustainability will accrue within a reasonable time frame” (Leatherman, et al. 2003, p. 18).

Using this definition, we sought to identify and classify both the direct financial benefits of participation in clinical trials through a PBRN, as well as the indirect financial benefits, from the provider's perspective. We define direct financial benefits as those that involve actual cash transfers between parties that are directly attributable to the CCOP organization (e.g., NCI grant funding). In contrast, indirect financial benefits are those that accrue to providers as a result of their affiliation with the CCOP organization, but that are less easy to monetize because they are not characterized by circumscribed cash transfers or are not directly linked with CCOP activities that generate cost (e.g., benefits described as “non-financial” benefits).

## METHODS & ANALYSIS

We investigated the business case for provider participation in the CCOP as a key component of a larger exploratory study of motives for CCOP participation among CCOP-affiliated providers. Our study was conducted using a multi-site case study methodology (Maxwell, 2005; Yin, 2008) and used key informant interviews as the basis for our qualitative data collection (Yin, 2008; Edmonson & McManus, 2007).

### Case Study Site Selection

Sites were selected as part of a two-stage process. The first stage focused on an assessment of CCOP variability in terms of size, organizational structure and organizational maturity. Based on this first stage assessment and the business case objectives of our study, we determined that organizational maturity and willingness to participate in our research study would serve as the primary criteria for the second stage site selection. Thus, we specifically selected sites that represented nascent to very mature CCOP organizations. Selection based on differences in organizational maturity ensured variation in perspectives with respect to initial investment costs, and ongoing costs and returns associated with starting and sustaining a CCOP organization. Thus, our final study sample included five sites, two of

which had been operating as CCOP organizations for over 10 years, two of which had been operating as CCOP organizations between 5 and 10 years, and one of which was an organization that had recently applied to the NCI, but had not yet become a CCOP organization. Because the NCI requires CCOP applicants to demonstrate their ability to conduct clinical trials research, all of the sites in our study report accruals to NCI-sponsored clinical trials.

## Data Collection

Key informant interviews were the primary source of data for these analyses. We developed a list of targeted key informants based on job title or role within the CCOP or provider organization. We then worked with the CCOP organization administrator at each study site to identify potential participants based on this list. We conducted interviews with 41 key informants across the five study sites. Our key informants included CCOP organization administrators, principal investigators, physicians, nurses, and hospital accounting and finance personnel. Detailed information on the study sites, labeled A-E to maintain confidentiality, is presented in Table 1.

The key informant interviews lasted 30–60 minutes, with nearly all of the interviews held via telephone with at least two study investigators. To ensure consistency in the data collection process, key informant interviews were conducted using a semi-structured interview guide. We pilot tested a draft interview guide to ensure that interview questions were salient and lacked ambiguity. After pilot testing, we revised the interview guide prior to use in our study.

Our final interview guide included specific questions about business case considerations such as “What, if any, sources of revenue are associated with CCOP participation?”; “Do you think there is, or could be, a positive business case for your organization's participation in the CCOP?”; and, “How has your organization benefitted from CCOP participation?” Depending on the respondent's level of business case knowledge and expertise, we probed further and asked more in-depth questions such as “What kind of impact has the CCOP had on your organization? Is this impact measureable?” All interviews were recorded and transcribed verbatim, and then reviewed and verified by the study investigators.

## Analyses

We analyzed interview data iteratively using the constant comparative method (Miles & Huberman, 1994; Strauss & Corbin, 1998). Data were coded initially based on questions posed in the interview guide, with additional codes introduced as themes and patterns emerged in the data. A team consisting of a study investigator and two coders trained in qualitative methods met regularly to review, redefine, and create additional codes as themes and patterns emerged in the data. We used Atlas.ti, Version 6, to support our coding and qualitative analyses (Scientific Software Development, 2009).

We analyzed a subset of the data that specifically addressed business case considerations for provider participation in the CCOP. This included data that reflected both direct responses to the business case questions as well as unprompted comments related to the business case. The research team categorized the themes that we found in the answers associated with the business case through an iterative process. We defined themes and sub-themes that emerged from these responses when we found confirmation across at least three study sites, and agreement among the members of the analysis team. A concurrent review of the literature helped us to compare, validate, and extend our findings where appropriate (Glaser & Strauss, 1967).

## FINDINGS

While none of the informants in our study explicitly reported financial returns as a primary motive for CCOP participation, we found there was a widespread belief that a business case could exist for provider participation in the CCOP. We identified two main themes related to the potential existence of a business case: 1) the existence of a business case depended on the relevant time frame under consideration, and 2) the business case depended on the consideration of both direct and indirect financial benefits to the CCOP-affiliated provider. Within the second theme we also identified sub-themes involving the direct and indirect financial returns to CCOP participation.

### The Business Case and Relevant Time Frame

Most informants reported the belief that a positive business case would be unlikely in the short-term, defined as less than five years, but that it could exist over the long run. One research nurse in a mature CCOP organization explained, “Well, I know that in reality we have to make a long-term commitment because you're not going to see too much in the short term. You really have to be committed to the CCOP for the long term to be able to see a return.” Consistent with this sentiment, informants at the site that recently applied to become a CCOP organization expected their investment would yield returns over the long-term. A senior administrator at this site explained, “You mean a net positive return? Yeah, I think so -- over time. It's not anything we're looking to turn around in the next three years or so, but my hope would be that if in the next five years, if we haven't broken neutral, maybe we've gotten to the point where we're doing things more efficiently and reducing our costs and having a higher accrual rate so we're drawing in more revenue.” Additional representative quotes supporting this theme are presented in Table 2.

A minority of informants reported that they believed there was a positive business case in the short-term, and cited the grant funding provided by NCI along with reimbursement from health insurers, which are obligated to pay for standard-of-care treatments, as sufficient drivers of the short-term business case. Receipt of the grant funds “up-front” was viewed as advantageous in terms of planning and strategic management practices. An administrator at one site stated, “I think that having that money handed to you at the beginning of the process would certainly enable you to make some other choices or to be able to cover some of the expenses that you may have to be shifting around throughout the process while you're waiting for that reimbursement later on.” Similarly, another administrator stated, “We don't do Phase 1 trials, and so the Phase 2 and Phase 3 trials that we have are standard of care. So the majority of it can be billed to the person's insurance. And so I do think that if we manage things well we could at least, yeah, I do think we could have a positive [ROI].”

### Direct and Indirect Financial Benefits

The second theme that emerged around establishing the business case was the importance of both direct and indirect financial returns from CCOP participation. Informants across the study sites believed a business case for CCOP participation existed if both direct and indirect financial benefits were considered. As one administrator explained, “Yes, I think so…I think [affiliated hospital] is aware that there is a positive outcome—both financially and non-financially—for having the CCOP here. I'm not sure that everybody in this facility is knowing of that, but we have the right people that know.” Similarly, another administrator agreed that a business case existed, but conceded, “It's a difficult one [ROI] to measure in direct terms… I certainly think it brings a lot of positive, un-measurable [sic] positive benefits to our organization.” However, as we further explored this theme of direct and indirect financial benefits' contributions to the business case, several subthemes also emerged, as we describe next.

**Direct Financial Benefits—**We characterized two subthemes involving direct financial benefits contributing to the business case for provider participation in the CCOP organization: 1) grant funding from NCI, and 2) access to additional revenues from pharmaceutical industry trials.

**1) Grant Funding from NCI:** The most obvious direct financial benefit from CCOP participation was the grant funding received from the NCI. CCOP organizations are awarded grant funds based on expected annual patient accruals to clinical trials. The current funding is approximately $2,000 per patient enrolled in a clinical trial. As discussed earlier, these funds are not intended to cover the full costs of conducting clinical trials, and informants in our study consistently acknowledged that the current reimbursement provided by NCI was insufficient to cover the costs of CCOP participation. As one stated, “Everybody knows that basically the per-case reimbursement that you get for putting people on cooperative group [NCI-sponsored] trials probably isn't going to quite pay for the pay lines.” However, among the CCOP organizations included in our study, there was considerable variability with respect to how much of the total CCOP operating costs could be covered by the grant. One site reported that the NCI grant covered as much as 90% of the total CCOP organization costs. In contrast, another site reported that the NCI grant covered “46–48% of our budget, and the remainder is made up by [the CCOP-affiliated hospital].” Despite this variation, interviewees across all sites consistently noted that NCI grant funds provided a level of financial stability and predictability to the CCOP-affiliated provider's research infrastructure that was valued.

**2) Access to Pharmaceutical Industry Trial Revenues:** The ability to participate in pharmaceutical industry-sponsored trials was also identified as a direct financial benefit associated with CCOP participation. Pharmaceutical industry-sponsored trials tend to be more lucrative than NCI-sponsored trials because providers have flexibility to negotiate reimbursement rates that will cover all of their costs, including start-up costs associated with starting a new clinical trial (e.g., internal review board approval, other regulatory processes, etc.). In contrast, the reimbursement rate for NCI-sponsored trials is a fixed amount per patient enrollment. Providers suggested that being affiliated with a CCOP organization made them more competitive with respect to their abilities to participate in industry trials. Specifically, they cited that they could leverage the existing CCOP infrastructure and demonstrated success with conducting federally-sponsored clinical trials when negotiating with pharmaceutical companies to thus make themselves more competitive and more attractive participants for the more lucrative pharmacy industry-sponsored clinical trials.

The financial contribution of industry trials was noted as an important benefit in four of the study sites. As one senior oncology administrator explained, “Since we have such a huge volume of patients, we do drug-sponsored clinical trials where the reimbursement covers the patient's costs, maybe a hair more, and can offset the rest of the infrastructure.” Another CCOP administrator was more specific about the contribution of industry trials to the CCOP-affiliated provider: “For example, this year we overspent the [CCOP] grant by $240,000, meaning it did not cover all of our basic costs that we needed to be covered under the grant. But in pharmaceutical, we made $600,000 in revenue. So that $600,000 in revenue makes up for us losing on the other side, and that what's really helped us with the institution.” This administrator went on to explain how the CCOP-affiliated providers' management went from the sentiment of “oh gosh, you know research is just a drain on the finances and we can't afford to continue to support this” to “Great! You know we are going to make revenue from research.”

In addition to financial considerations, providers reported that they participated in pharmaceutical industry-sponsored clinical trials because it clinically “made sense” given

their patient populations and given their existing clinical trial portfolios. Thus, participation in industry-sponsored trials was a strategic decision based on overall fit in the CCOP-affiliated providers' clinical trial portfolio, and as a means to support the research infrastructure for these providers. It is important to note that since federal funds cannot be used to directly support industry-sponsored trials, separate accounting practices and proper oversight must be maintained to ensure compliance. This was the primary reason why one of the sites in our study decided to discontinue participation in industry-sponsored trials.

**Indirect Financial Benefits—**The second key consideration for the business case is the indirect financial benefits, or returns incidental to participation that do not generate direct, circumscribed cash flows to the CCOP-affiliated provider. Four sub-themes emerged as we probed to identify, specifically, what CCOP-affiliated providers characterized as indirect financial benefits of CCOP participation.

**1) Downstream Revenue:** Downstream revenue is not the revenue earned at the initial encounter, but the revenue that arises from providing additional services at a later time throughout the organization (Petersen, 2007). For CCOP-affiliated providers, downstream revenue is the revenue earned from providing services to patients enrolled in clinical trials (primarily ancillary services) that are either directly or indirectly related to, but not covered by, the clinical trial protocol. Across all study sites, downstream revenue was consistently cited as a primary indirect financial benefit of CCOP participation. Only one study site reported conducting a formal study of downstream revenue; as described by an administrator at this site, “We actually did a data sort and came up with all the patients that had been enrolled; registry studies and everything. And we provided that to financial affairs and said, `please do a downstream revenue project for us.' And so they did. That downstream revenue project kind of catapulted us forward. As sort of the leader of the oncology service line, [the CCOP organization] became a major player.” Although CCOP-affiliated providers at the remaining four sites had not conducted any formal analyses of downstream revenues, there was a consistent perception that downstream revenue was a significant factor. One physician conceded, “It [downstream revenue] is hard to measure and track, but it's there. We wouldn't be able to be in this business if it weren't.”

**2) Market Share:** A second sub-theme related to the indirect financial benefits of CCOP participation was the impact on the CCOP-affiliated provider's market share. Informants described how CCOP participation contributed to the market share for the CCOP-affiliated provider by both attracting new patients and keeping patients in the local market. Informants across all study sites perceived that the ability to offer clinical trials through the local CCOP organization brought new patients into the system that may have otherwise sought care elsewhere. A physician summarized this explaining, “I think it [CCOP organization] makes the practice stronger and it keeps people coming to the center. And so you get a lot of indirect [benefits] from it, but nothing direct. I think that when you're competing against major cancer centers and patients have the ability to get on the Internet and to look around at other places, it allows you to say, `well, you can go to [major cancer center], but they have the same trial that we have'… It evens that playing field. So it helps to obtain patients.” Having access to clinical trials through the CCOP also allows physicians to treat existing patients in the local market. As one informant explained, “we retain patients here. They kind of walk them through every step of the way throughout their care.” The importance of market share benefits for the business case was best described by one informant who stated, “I think about the ability [of the CCOP organization] to add more patients and getting through the doors, [and] that helps that positive bottom line.”

**3) Philanthropic Support:** The third sub-theme that emerged was the role of CCOP participation in attracting support from the philanthropic community. While oncology services, relative to other services, are traditionally well-supported by the philanthropic community, informants across the study sites believed that being part of a CCOP organization further enhanced the CCOP-affiliated providers' abilities to attract donations. One senior administrator described this relationship: “We have a long tradition of being well-supported by the philanthropic community in cancer treatment. Cancer care is one of the areas that people like to support, and we've benefitted from that. We think the CCOP has helped us -- it's helped us as an underpinning to the overall stability of the program.” These donations can benefit the CCOP-affiliated providers generally, or can be directed by the donor for a specific purpose, such as oncology research. When directed toward the latter, donations can be used to subsidize CCOP organization operations. In fact, two of the CCOP-affiliated providers reported being able to draw on these donated funds directly to balance any shortfalls in the program.

**4) Other Revenues:** While downstream revenue, market share, and philanthropy were predominant sub-themes, there were several other important indirect financial benefits cited by our informants. For example, one study site suggested performance-based payments for improved cancer care quality could be attributable to CCOP participation. Similarly, avoided costs associated with improved efficiency and quality gains in cancer care were also suggested as indirect financial benefits of CCOP participation. Finally, several informants mentioned avoided turnover costs due to higher employee satisfaction among physicians and nursing staff working with the CCOP, and noted that this was an important indirect benefit of CCOP participation.

## The Need for A Business Case

The final question we explored in this study was about the importance of a business case to generate or sustain executive leadership support for the CCOP organization within the CCOP-affiliated provider's organization. Across all sites, informants perceived the business case as increasingly important, particularly given the strained economic climate existent during the study period. CCOP-affiliated providers did not view research as a “way to make money,” but at the same time suggested that, at a minimum, the CCOP organization would need to break-even or demonstrate a slightly positive ROI, inclusive of direct and indirect benefits, to maintain organizational support from the CCOP-affiliated provider. The importance of a business case was particularly acute for the site that had recently applied to become a CCOP organization. A senior administrator at this site said, “Oh, it [a business case] would absolutely be imperative. There would be no way that we would go down this path without a sound financial business plan for doing clinical research and expected ROI. And you know, at one, three, five years out from there.” Another administrator at the same site echoed this sentiment: “I think that, again, in this economy, that approval of anything without showing that you're either going to have positive revenue, or at least not a loss, is going to be critical.” Similarly, informants in mature CCOP organizations recognized the growing importance of a business case. A physician affiliated with one mature CCOP organization explained, “I think it's [the business case] going to be needed. I mean, the hospital's had to undergo so many cost cuts to stay solvent. We're no way going to be immune to that unless we can justify our position with the downstream revenue.”

Nonetheless, not all informants agreed that a business case was an absolute requirement for CCOP participation. As one informant explained this contrasting view, “That's a difficult question to answer because our expectation, especially from the federal funding perspective, is that we don't necessarily have positive. I mean our goal isn't to make a lot of money off of it.” While a majority of interviewees shared the perspective that a business case was indeed

important, there was also collective sentiment that other reasons for participating in a CCOP, such as the multiple indirect benefits of participation described above as well as altruistic reasons, might lessen the strict requirement to demonstrate a financial business case. Additional representative quotes showing these perspectives about the need for a business case are presented in Table 3.

## DISCUSSION AND CONCLUSION

The lack of an established business case may result in provider reluctance to participate in clinical trials research through PBRNs such as the CCOP, particularly when financial resources are constrained. However, results from this study suggest that it may be possible to establish a business case if both direct and indirect financial benefits are identified and included in the analysis, and the time horizon is long enough to allow those benefits to be realized.

Although none of the study sites reported any formal attempt to demonstrate a business case (possibly because many of the CCOP organizations were established during more favorable economic conditions), most conceded that such evidence would be increasingly necessary to maintain financial and in-kind support from the senior leadership of these CCOP-affiliated providers. The need for a demonstrated business case was most acutely recognized by the study site that had recently applied, but not yet become a CCOP. The recent economic downturn, combined with escalating pressure on hospital and provider organizations to manage costs, was perceived as driving the need for CCOP organizations to demonstrate a business case to their affiliated providers. Our findings echo those of previous studies that have shown the need for clinical or quality-improvement health programs to demonstrate a business case to generate or maintain organizational support (Leatherman et al., 2003; Reiter, Kilpatrick, Greene, Lohr, & Leatherman, 2007; Song et al., 2011b), and the importance of including indirect benefits in making the business case.

Our findings should be taken in the context of the study limitations. This study included five CCOP organizations that were selected on the basis of organization maturity in a CCOP organization. Because these organizations were already part of a CCOP organization or had recently applied to become a CCOP organization, it is possible our findings may reflect participants' desire to justify their decision to participate in the CCOP organization despite formal evidence of a business case. However, we did find participants across all sites who reported that a positive financial return was unlikely; even among this group we found consistency about the reported financial benefits of CCOP participation. Also, the potential direct and indirect financial benefits we identified may not apply to all CCOP organizations, potentially limiting the generalizability of our findings to all CCOP organizations. Finally, it is important to recognize that clinical trials are not for everyone, rather patient participation is completely voluntary and physicians need to agree that the question under study is valid to their practice. As such, there should not be an expectation that most patients will participate in clinical trials, nor will most physicians be comfortable with the conduct of all trials. This study was meant to look beyond physician commitment to the clinical benefits that could results from clinical trials participation and explore the incentives for long-term sustainability of provider-based research networks such as the CCOP.

## PRACTICE IMPLICATIONS

Although this study focuses on the business case for provider participation in CCOP organizations, the results are relevant to other federally-funded PBRNs outside of oncology, and salient to those considering participation in any clinical trials research. The costs and benefits described by study participants, for example, salaries of research personnel and downstream revenue, were generally not unique to cancer. Since the CCOP may serve as a

model for other PBRNs, our results, together with the existing literature, can be applied by organization and policy leaders to identify and communicate elements of the business case to encourage expansion and sustainability of provider participation in clinical trials research. Our results can also be applied more generally to clinical and quality-improvement initiatives to develop appropriate and practical strategies for evaluating such programs' business case (Leatherman et al., 2003; Reiter et al., 2007; Song et al., 2011; Song et al., 2011b; Kilpatrick et al., 2005; Bailit & Dyer, 2004). By establishing a business case, providers will be free to move beyond financial hurdles and to realize other benefits of clinical research participation, including the satisfaction that comes with providing effective care to local populations, achieving accrual goals, increasing patient satisfaction, and being recognized as a leader in health care.

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**Table 1**

CCOP Case Study Site Characteristics

| CCOP Site | Organizational Maturity (Years in Operation) | Annual Patient Accruals* in NCI/DCP Clinical Trials | Key Informants (n=41) |
|---|---|---|---|
| A | Recently applied for CCOP grant | ~300–500 | Administrators (n=7)<br>Physicians (n=5)<br>Nurses (n=1) |
| B | 5–10 years | ~500–800 | Administrators (n=4)<br>Physicians (n=3)<br>Nurses (n=2) |
| C | 5–10 years | ~250–300 | Administrators (n=2)<br>Physicians (n=1)<br>Nurses (n=0) |
| D | 10+ years | ~ 1000 | Administrators (n=6)<br>Physicians (n=2)<br>Nurses (n=3) |
| E | 10+ years | ~ 500 | Administrators (n=3)<br>Physicians (n=2)<br>Nurses (n=0) |

CCOP= Community Clinical Oncology Program; NCI/DCP = National Cancer Institute Division of Cancer Prevention

*Accruals include patient accruals to all NCI-sponsored clinical trials, not only CCOP trials.

## Table 2

Case Study Sites' Characterizations of the Business Case for Provider Participation in the CCOP

| | **Representative Verbatim Quotes** |
|---|---|
| Short-term versus long-term business case for CCOP participation. | "Absolutely not. No, no, no, no. Short term to me would mean less than a couple of years and it actually has taken us a really long time to come into a positive budget. Probably, I would say eight years."<br><br>"No, I think the financial gain is a long haul sort of thing. I don't know that just putting together some sort of CCOP program and putting patients on trial is going to make you rich in a year or two. But I think that as you establish yourself in the community for providing high quality of care, I think people see that."<br><br>"Yes, absolutely. And I think it's been underestimated. And that's kind of the case I'm trying to make. The fact is, we're meeting with the COO[Chief Operating Officer] to go over that issue that it's underappreciated. And then it needs to be factored in, when they're sitting down. And they should not be looking at this is just a negative on the balance sheet, to support research, the plus thing." |
| Direct and Incidental Financial Benefits for Business Case | "It would be more on the intangible sides that we would probably try to document and look at it there. Because right now, the best thing we can do around clinical trials, it's not just cancer, but different areas, is that if you break even, you are doing pretty good on clinical research."<br><br>"You know, I'd like to think that it's not a money loser and that there truly is some portion of those patient revenues that would not be here if we did not have the CCOP. The prestige it affords the institution, you know? The ability to make those protocols available to the patients who would seek them out. And so I'd like to say that it at least nets a zero."<br><br>"Oh, absolutely. I absolutely believe that. And the reason I do is because I sort of make this analogous to our genetic counseling program. We have a very extensive genetic counseling program… if you look at downstream revenue and you look at tests that were ordered or patients that came to us simply because we have a genetic counseling program, it is certainly a very, very profitable service. And I think the same thing about research." |

CCOP= Community Clinical Oncology Program

## Table 3

Case Study Sites Characterizations of the Need for a Business Case

| | Representative Verbatim Quotes |
|---|---|
| A business necessary | "I just think it's unrealistic to think that the CCOP program is going to continue unless you can say you're at least breaking even. And I don't think there's anything wrong with saying you made a couple extra bucks as long as that money is going back into the CCOP system… So I think you have to be realistic. This has got to start being run like a business. That's the problem with medicine today--it's not run as a business. And the CCOP program is not going to be immune from that." |
| | "…in this economy, that approval of anything without showing that you're either going to have positive revenue, or at least not a loss, is going to be critical." |
| | "If we were starting today, that would be a lot harder because obviously hospitals are struggling to maintain. And in these economic times and with the uncertain economic future and healthcare reimbursement returns coming, so I think that if we were doing that today, it would even be of much greater importance in terms of getting it going." |
| | "Yeah, absolutely. I mean I think as a private, not-for-profit, clearly one thing I've learned at [CCOP-affiliated hospital] is everything has a business plan. And yeah, no, I think clinical trials and certainly the CCOP was part of a business plan. Not a stand-alone plan, but part of a business plan for cancer services in general. The research services." |
| A business case is unnecessary | "I guess from an observer, I don't know that I would say yes. Only because I've seen [affiliated hospital] step up to the plate when there was a potential for loss. So if they were only looking for a positive financial return, it doesn't seem like they'd be putting much effort into cooperative group research at all. But again, that's an observer's perspective." |
| | "You know, I don't know. I think that it's part of the organization's culture: innovation. So the balancing, it's the research participation that is very important. And again, this is intellectually. The research is extremely important, and it's part of our vision and strategy. Then you probably forego investments in other areas because you believe this investment will further your movement towards your vision. So once again, it's a trade-off, if you will." |
| | "So I guess that the question really is, do I think that you have to have a CCOP that needs to make money? I would say no. But I do think it should break even. That sounds like it's not even doing that." |

CCOP= Community Clinical Oncology Program