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The Benefits of Incorporating Clinical Research Into Physician Practices

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The Benefits of Incorporating Clinical Research Into Physician Practices

The separation of clinical research and patient care has deep roots, but with the health care industry's increased focus on decreasing cost and improving quality, both sides are "reaching across the aisle" for the benefit of patients and the overall health care ecosystem. Collaborating to increase participation in clinical research is a strategy that can help reduce costs and improve outcomes for all health care stakeholders (patients and providers). Increasing both the volume of patients participating in clinical research studies (also referred to as "trials" within this article) and the diversity of participant demographics can have a positive impact on the cost, speed, and quality of trials as well, thereby bringing effective treatments to market faster.

Physicians in the non-academic community setting have not typically been involved in clinical research, both because of their own time and resource constraints and the pharmaceutical industry's lack of understanding of and access to community-based practices. However, clinical research in community physician practices may be just what the doctor ordered to help cure what ails our systems of care.

Current Landscape

Providers may be entering a world of value-based care that focuses on quality outcomes, but for now, most are still compensated in a volume-based model. Merely having the time to learn what the reimbursement model is, what the eligibility criteria are, and what clinical research studies are available is a challenge, never mind the time to complete the training and tasks of a principal or sub-investigator.

The administrative and regulatory requirements of clinical research are overwhelming for practices without the time and resources to support these challenges. Even referring patients to existing research studies administered outside their practice can be challenging for physicians. With respect to the engagement of practicing physicians as facilitators, a 2015 Tufts study indicated that "more than half of physicians (54%) said they lacked access to information and about one-third said they didn't have enough time to learn about studies or discuss them with their patients."¹ In addition, providers often feel that clinical research gets in the way of their ability to effectively manage their patient panel because they do not receive adequate clinical information regarding their patient from the trial investigator.

Finally, the upfront and recurring costs to create and maintain a compliant, fully functioning research department is significant (up to millions of dollars) with uncertain return on investments.² Historically, the pharmaceutical clinical research industry has avoided non-academic, community physicians as they lack training, resources, and a desire to follow the highly regulated requirements of a clinical trial.³

While all these can be valid issues, there are ways to build operational and communication processes to minimize disruption and maximize benefits for physicians and patients who wish to participate in clinical research. According to Mary Jo Lamberti, PhD, with the Tufts Center for the Study of Drug Development, despite the disconnect of the past, "the pharmaceutical industry recognizes the importance of the patient/physician relationship and now understands that, when it comes to participation in clinical trials, the way to a patient is through his or her own physician, and the likelihood of a patient being referred into a trial increases if the physician has had previous experience as a clinical investigator." The advancement of medicine is imperative, so this age-old disconnect between clinical research and community physicians must be resolved.

Value of Clinical Research to All Stakeholders

First and foremost, safe and effective treatments help everyone; there is no denying that. For patients with diabetes, the life expectancy and quality of life have improved dramatically in the past few decades. We owe that in part to the patients who have participated in trials and the physicians who supported their participation. Secondly, with cost of care skyrocketing and more patients and physicians having “skin in the game,” clinical trials can offset the cost of patient care for some of the most expensive disease categories. As more patients participate in clinical research, significant improvements have been demonstrated in both the cost and quality measures of Accountable Care Organizations (ACOs) or other value-based contracts. Finally, patients want access to cutting-edge treatments. Patients want to feel that their health care team will turn over every stone to help them.

Innovative approaches now exist that allow practicing physicians to conduct research within their practice, without the burden of the training and documentation tasks of a formal principal investigator. These centralized models have benefits to both patients and providers with regard to cost, quality, and satisfaction.

The Patient

A 2015 survey conducted by the Center for Information & Study on Clinical Research Participation (CISCRP) found that 80% of patients are willing to participate in clinical research, but the location of the research center is a deciding factor in whether the patients actually participate.⁴ Enabling patients to participate in clinical trials with their own physician, in their hometown, removes the largest barrier to research participation. It provides patients with a care option they may not otherwise have access to, from a physician they trust. Studies have found that patients who participate in clinical research have higher patient satisfaction scores than non-trial participants, both overall and within the same clinical cohort. Ninety-five percent of these patients reported improved quality of care, and 100% reported reduced cost of care and improved engagement.⁵

Other benefits from research include improved quality of care and patient satisfaction. Receiving trial-related care by their own physician ensures ease and accuracy of clinical communication about patients’ study outcomes, and therefore supports improved care management

by the primary physician. Faith Holmes, MD, a family medicine physician for over 30 years and now the Medical Director for Elligo Health Research®, supports the integration of research into a clinical practice for a number of reasons. Removing the barrier of distance is one of them and providing access to valuable tests and treatments that uninsured or underinsured patients would not otherwise be able to afford is another. “A personal physician is often the professional best suited to communicate with patients about the reasons for considering research, as these are patients that are known to the doctor and their physician can discuss the benefits in terms specific to that individual,” Dr. Holmes says.

Dr. Holmes practiced in a small town for most of her career and says, “Offering advanced care options all under one roof is what patients want and, as physicians, it’s what we strive to deliver.” Patients who participate in clinical research also exhibit improved adherence and decreased mortality rates.⁶ Participation in a clinical trial significantly increases adherence to both trial-related and non-trial-related treatment, suggesting that participants in a trial are more involved with their conditions and treatments. Medication adherence has also been shown to persist for a long period after trial participation ends.⁷ We can likely conclude that when the trial visits are conducted by the patient’s own physician, the longevity of adherence will persist far beyond that of traditional off-site research participation. Stephanie Abbott, PharmD, is the Research Director for Western Washington Medical Group, an independent multispecialty group, where clinical research is an integral part of the care team. She poignantly states, “It often takes a village or a multidisciplinary team to support a patient. Everyone has an impact and the patient feels empowered to take control of their disease state.”

With the rise in health care consumerism, patients are not only seeking to make more informed decisions by scouring publicly available patient satisfaction data when selecting a provider, they are seeking providers who deliver more than the standard office visit. Clinical research offerings are a way for physician practices to differentiate themselves in the market and deliver a message of being at the forefront of medicine. In fact, 42% of physicians and 43% of nurses indicate that their patients are inquiring about clinical trials more frequently than they did a few years ago.⁸

The Physician

The direct benefits of clinical research to practices and their individual physicians are beginning to come to light. Western Washington Medical Group, for instance, has integrated clinical research into its practice model. The physicians and providers believe that clinical research can differentiate the group in the market by offering a diversification of revenue, additional patient support services, and facilitation of enhanced care management that allows physicians to focus on the delivery of optimized care for their patients.

Other physician groups have been able to demonstrate sound results that support these assertions as well. In early 2016, Wilmington Health, a large multispecialty group that is one of the country's top performing ACOs, wanted to refine the process to engage physicians and patients in clinical research. The group had already demonstrated improved patient experience ratings, better A1C results (Figure 1), and lower cost per beneficiary (Figure 2) in diabetic patients who participated in a trial, as compared to both diabetics not in a trial and the entire non-diabetic population. The improvements in cost of care and quality have direct impact on ACO performance and can result in financial return from many commercial-value-based contracts. The group's goal was to expand these positive effects throughout its patient population by increasing participation in research. In a survey of Wilmington Health's physicians, it was found that they reap a number of benefits from clinical research in their practice, as shown in Figure 3.

Additionally, physicians reported that clinical research was not only a way to diversify revenue but also to enhance credibility in a way that was unmatched by other strategies. Christy Capet, MD, an Austin, TX, based physician who participates in clinical research alongside her practice and specializes in gynecology, views clinical research as rewarding, saying, "I now have more options for frustrated patients that have seen physician after physician, only to be told there aren't any alternatives." Dr. Capet says that many patients are looking for nontraditional options. A patient, who recently participated in a urinary incontinence study, was extremely pleased with the outcome, stating, "Nothing else had worked, and I am so grateful." Dr. Capet added that an unanticipated benefit of a clinical research team is the positive working relationships she has with her

A1C Outcomes

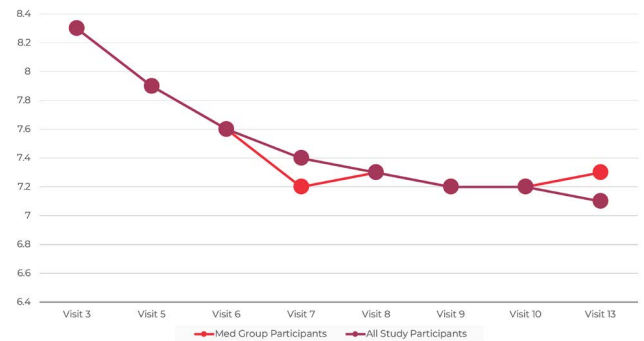


Figure 1

Cost of Care per Beneficiary per Month

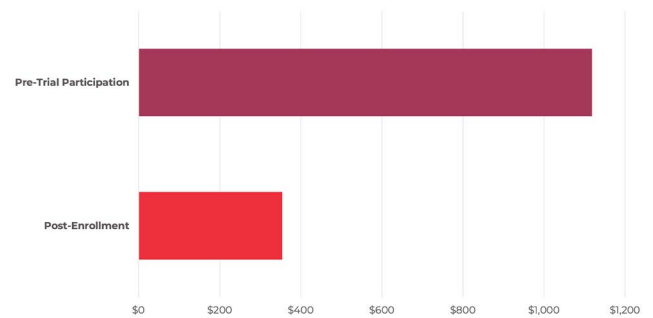


Figure 2

Independent Physicians' Perceptions of Participating in Clinical Research

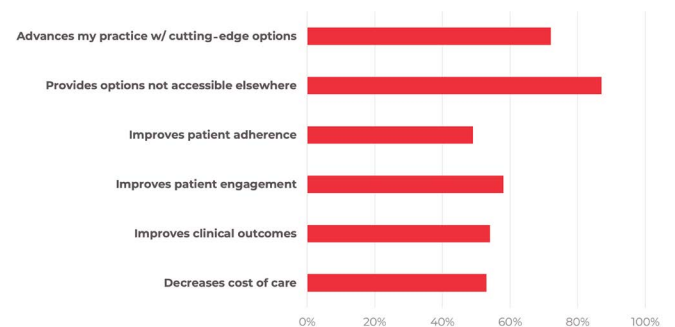


Figure 3

study staff. “We work together throughout the day. If I have a patient who might benefit from a study, I can simply walk her down the hall to talk with the research assistant. We’re able to offer a higher level of care and service without compromising workflow.”

Countering Physician Burnout

The ability to provide a higher level of care and access to more care options can also alleviate physician burnout, a growing epidemic that has become central to the state of health care itself. Clinical research can help bring physicians back to why they went into medicine in the first place. Dr. Holmes reminds us that physicians are drawn to medicine for the high level of intellectual stimulation, but mundane administrative tasks can dilute that. She says that clinical research reignites a physician’s involvement with the advancement of medicine. Nancy Dickey, MD, President Emeritus, Texas A&M Health Science Center and Executive Director, A&M Rural & Community Health Institute, explains that, “Participation in clinical research revives the notion that physicians are contributing something positive to health care at large, not just patient by patient. It can be refreshing to claim back some of the control that many feel has been lost to administrative burden.”

Dr. Dickey, who was also a private practice family medicine physician, explains that physician burnout is driven by three main areas: administrative requirements that have increased and seem to be ever-changing, time demands that compromise personal and family life, and the emotional toll of dealing with diagnostically challenged, chronic, and often life-threatening patient circumstances. Clinical research offers physicians a hopeful alternative for these patients, mitigating at least some of the emotional toll. Dr. Dickey added, “Research within the practice setting also reinforces the advancement of

knowledge during the normal course of patient care, thereby minimizing the time spent reading and studying at the end of the day.”

As a leader in rural health care, Dr. Dickey stresses the importance of access to interchange with other clinical experts for physicians that may not be physically located near academic centers of medical advancement. “The outcomes of clinical trials also benefit by reaching patients in suburban and rural areas to examine possible differences in patients who reside in urban settings,” says Dr. Dickey.

What Clinical Research Means to Health Care – For Everyone

Thanks to the transformation occurring in centralized models of clinical research, barriers to research participation are being overcome. Physicians and patients are reaping benefits beyond the advancement of medicine, – benefits that impact their own day-to-day life. The collaboration between community physicians and clinical research stands to positively impact the health care system overall, and this includes the development of new biopharmaceuticals. According to Michael Ibara, PharmD, Vice President of Data Sciences with Elligo Health Research, clinical research sponsors can benefit from data that represents a more real-world sample of study patients, more accurate identification of qualified patients, and a shorter time to enrollment through community-based research. Over time, it is anticipated that expanding clinical research beyond the academic setting to community physicians will decrease the high cost of patient recruitment and retention. These two elements comprise a significant portion of the cost of drug development.

In essence, we can come full circle, not only benefiting those patients who helped bring new treatments to market, but decreasing the cost and quality of care for all patients.

References

- 1) Korieth, K. "Engaging Healthcare Providers as Research Facilitators." CenterWatch Monthly. Volume 23. Issue 06. June 2016.
- 2) "Research as Care: Bringing Clinical Research Directly to Patients and Physicians." CenterWatch Monthly. July 2018. Volume 25. Issue 7.
- 3) Costello, M., "Within Our Backyard: Finding Solutions to Overcome Research Resistance." BioSpace. November 2, 2017.
- 4) Report on the Decision to Participate. CISCRP. Perceptions & Insights Study. 2015. <https://www.ciscrp.org/download/2015-perceptions-insights-study-decision-to-participate/?wpdmdl=5734>.
- 5) Shen, J., Buechler, A., Byrne, J., Hecht, J., James, J., Pancratz, B. "Clinical research participation as a care option: Driving patient experience and satisfaction." Quintiles.com. 2015.
- 6) Selby, P. and Autier, P. "The impact of clinical research on health service outcomes." Annals of Oncology. 2011(22; vii5-vii9).
- 7) Hein A.W. van Onzenoort et al. "Participation in a clinical trial enhances adherence and persistence to treatment: A retrospective cohort study." Hypertension. 2011(58:573-578). AHA Journal.
- 8) Getz KA. "Examining and Enabling the Role of Health Care Providers as Patient Engagement Facilitators in Clinical Trials." Clinical Therapeutics. Volume 39. Number 11. 2017.

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