WHITEPAPER:
Patient Engagement

Increasing Patient Engagement and Helping Clinical Trials Reach Full Potential with the Clinical Research As a Care Option Model

Only 3% of People With Cancer Participate In Clinical Trials

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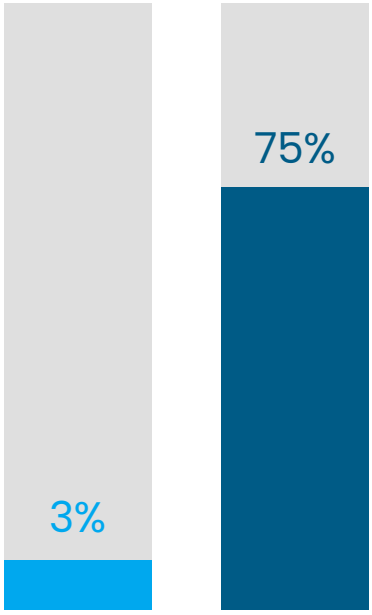
It is estimated that as little as 3% of adults with cancer participate in clinical trials1. At the same time, recent surveys have shown that up to 75% of patients say they are willing to participate in a clinical research study[2], indicating that many more people would take part in studies if given the opportunity.

A similar gap in research participation exists among physicians. American Medical Association surveys of nearly a million physicians in the US reveal that only 1.5% consider research to be their primary focus.[3] Multiple analyses have shown that there is also an extremely high rate of turnover among principal investigators — more than 50% are "one-and-done" investigators who stop research participation after a single clinical trial.[4,5]

These statistics suggest that the entire clinical trials enterprise is operating far below its full potential. It is hard to overstate the magnitude of lost opportunity represented by this gap in trial participation. Drug development remains an immensely costly and high-risk undertaking, plagued by logistical issues and delays. When cutting-edge treatments take longer to get to the clinic (or don't get there at all), the people who are ultimately hurt most are patients.

Clinical research as a care option, also known to the clinical trial industry as the CRAACO concept, offers a solution to the participation and awareness gap. In this paradigm, clinical trial participation is seen as another viable option of medical care for all patients who qualify. By seamlessly integrating clinical research with medical care, more patients and physicians will be able to contribute to the development of new treatments.



CRAACO seamlessly integrates clinical research with medical care, so more patients and physicians are able to contribute to the development of new treatments.

However, the current healthcare ecosystem is not built for a seamless integration between research and care imagined by the CRAACO paradigm. Traditional models of healthcare provision and drug development consider research and care as inherently separate, and existing systems for data collection and research participation act as a barrier to CRAACO.

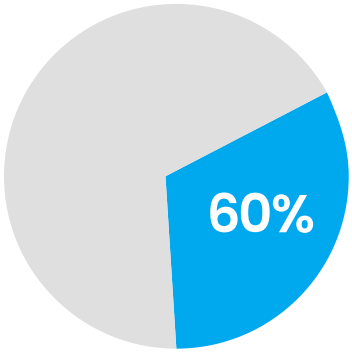
This article explores the benefits of CRAACO for all stakeholders in healthcare, and outlines some of the steps necessary to turn this option into reality.

Benefits of CRAACO

We can already see the benefits of integrating clinical research and medical care in the case of childhood cancers in the United States.[6] Thanks to the efforts of the Children's Oncology Group, more than 60% of children with cancer are enrolled in clinical trials through hospitals affiliated with their network. The results on health have been dramatic — in 1975 just over 50% of children diagnosed with cancer survived for at least 5 years. In 2007-2013, the survival rate had increased to 83%, thanks to the exemplary levels of physician and patient participation in the clinical research process for this therapy area.

Participating in clinical research offers many benefits for patients. In addition to helping advance medical research for the good of society, eligible patients gain access to the most cutting-edge treatments in a setting where safety is carefully overseen by highly-skilled medical staff, IRBs and regulatory bodies.[7]

There is also evidence that participation in clinical studies can result in a higher standard of care as patients are closely monitored by involved teams. One study found that metastatic prostate cancer patients receiving docetaxel in a trial setting showed significantly longer overall survival compared to non-participants receiving the same treatment[8]. However, it is important to emphasize that CRAACO does not envision a world where all patients take part in studies, but rather that they are given the opportunity to voluntarily participate only when it is a suitable option of care.



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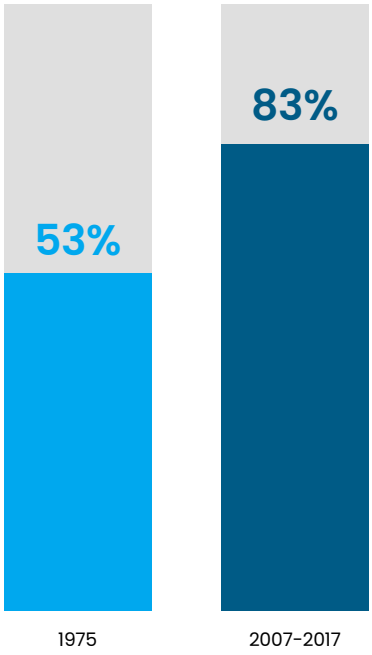

The 5-year survival rate for pediatric cancer has increased thanks to an increase in physician and patient participation in the clinical research process.

CRAACO also offers clear benefits to study sponsors. It is a well-established fact that that lack of physician and patient participation threatens the continued viability of the clinical trials enterprise.[9] Increased participation will reduce costs and delays associated with recruitment, retention and adherence, ultimately increasing the rate of new drug approvals for the entire biopharmaceutical industry.

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Integrating medical care with clinical research will also help to streamline increasingly complex trial protocols,[10] allowing for pragmatic trial designs that can take full advantage of real-world evidence sources like registry databases and electronic medical records (EMR).[11] A notable example is the TASTE trial in Sweden, a randomized, registry-based trial that measured the comparative effectiveness of routine thrombus aspiration in cardiac patients undergoing primary percutaneous coronary intervention.[12] By utilizing pre-existing registry databases, the study was able to greatly simplify enrollment and achieved high rates of follow-up. The final cost of the TASTE trial was about US$2 million, just 1% of what such a conventional randomized trial would cost.

CRAACO has the potential to help payers and healthcare providers as well. As healthcare systems continue to transition to a model of value-based care[13] where payment is tied to patient outcomes and population health, it will become increasingly important for providers to ensure that they are delivering the highest standard of evidence-based care.

It has been shown that integrating clinical research with health care drives important outcomes for the health system from a value-based care perspective. In a survey-based study conducted in type II diabetes, study participation led to improvements in the cost of care, patient outcomes and patient satisfaction.[14] Accountable care organizations use these metrics to document the quality of care for payers, in order to deliver the best possible revenues for the health system. Ultimately, CRAACO can contribute to the development of a learning health system that is able to fully leverage health information systems, reducing the gap between bleeding-edge biomedical discoveries and routine clinical practice.[15]

Turning Vision Into Reality

The CRAACO paradigm offers clear advantages for all relevant stakeholders in healthcare and clinical research, but there are many barriers to wider implementation. Platforms for multi-stakeholder engagement are needed to fully understand the main obstacles for physician and patient participation in clinical research. Broad cultural shifts need to be engineered across the healthcare system, to break down the walls that traditionally separate medical practice from clinical research.[9]

Technology will be a vital part of implementing CRAACO[16]. Digitalization will simplify workflows for clinical trial operations, connecting eligible patients with sites and investigators on a scale that was previously unimaginable. Wearable sensors and user-friendly apps will reduce the burden of trial participation for patients, and enable seamless collection of clinical outcomes. Artificial intelligence and natural laguage processing will revolutionize clinical trials operations by automating complex but tedious tasks like screening medical records or monitoring protocol adherence, greatly reducing the work burden for investigators and site staff.

Digital innovation will play a critical enabling role in breaking the walls between clinical research and medical care, but technology on its own can never be a simple magic bullet in such a complex undertaking. Healthcare IT vendors must be prepared to engage in meaningful multi-stakeholder dialogue about these issues, and carefully understand the needs of disparate groups.

The challenge of bridging the gap between integrating medical practice with clinical research is simultaneously cultural and technological. Ultimately, healthcare will be carried forward by organizations that can effectively grapple with both dimensions of the problem.

For more information or to schedule a demo, email us at solutions@trialbee.com or visit us at trialbee.com.

Citations

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