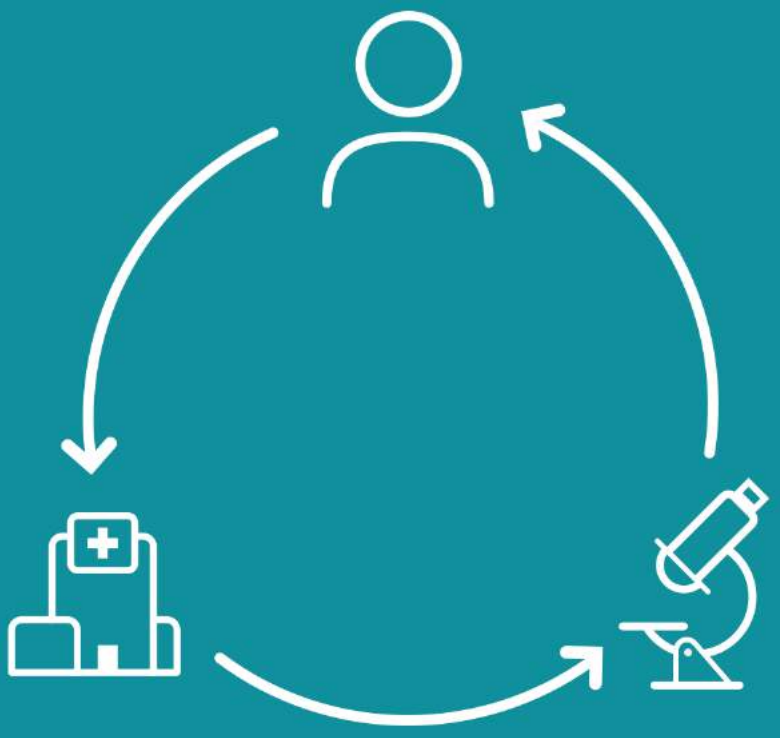
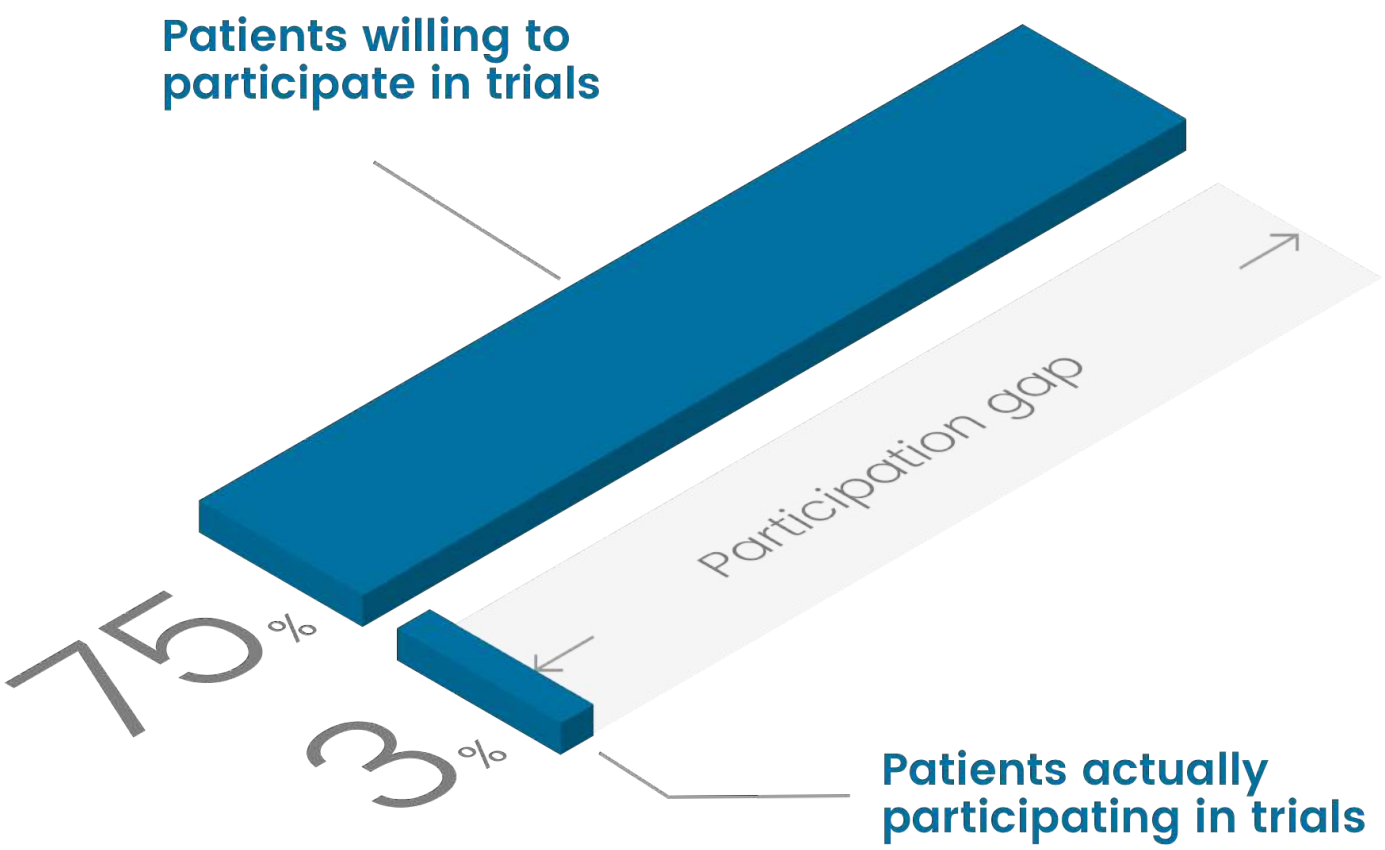
trialbee

TRANSFORMING HEALTH

CLINICAL RESEARCH AS A CARE OPTION





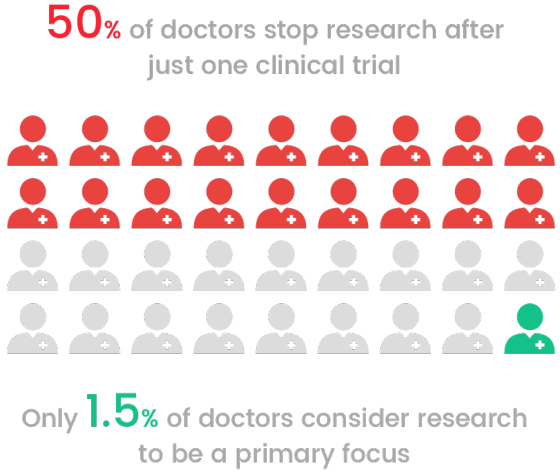
Only 3 percent of patients participate in clinical trials

It is estimated that as little as 3% of adults with cancer participate in clinical trials[1]. 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].

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. Ultimately the people hurt most are patients, as cutting-edge treatments take longer to reach the clinic.

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



However, the current healthcare ecosystem is not conducive to the seamless integration between research and care imagined by the CRAACO paradigm. Traditional models of healthcare provision and drug development see 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 vision into reality.

Benefits of CRAACO

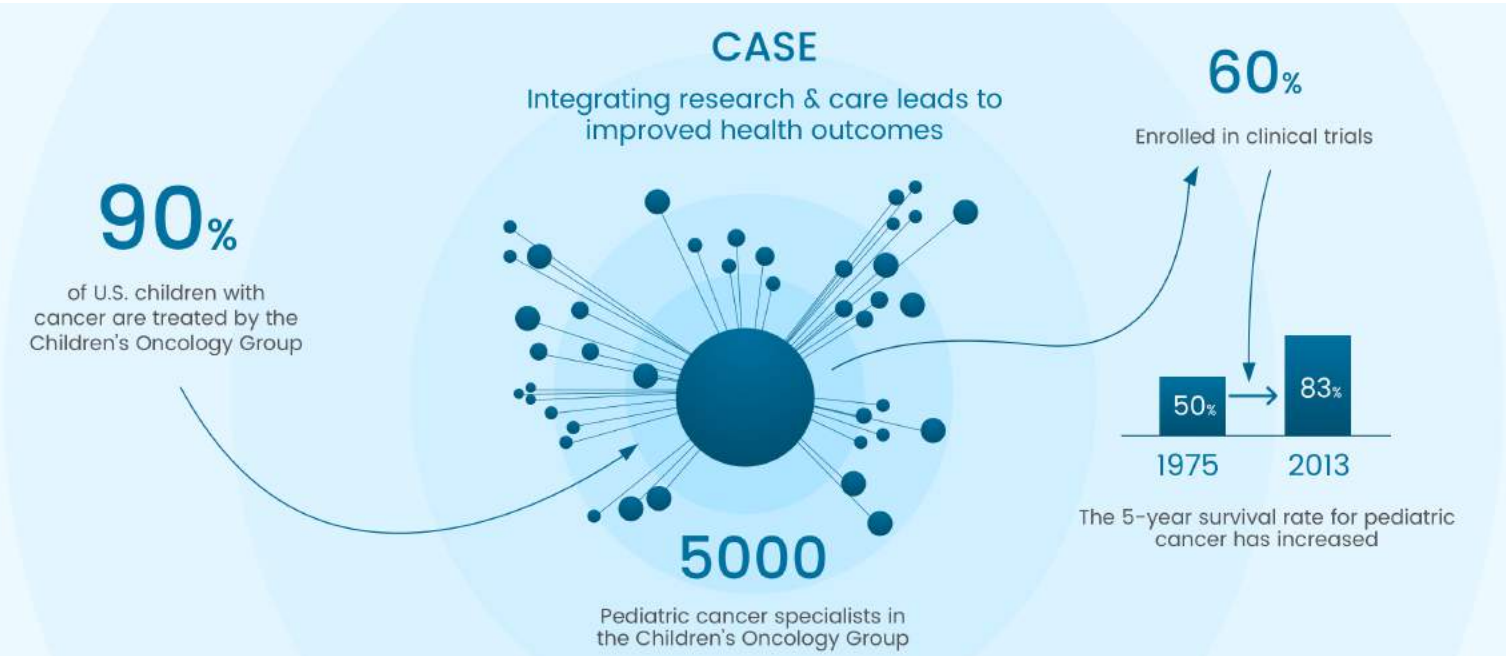
We can already see the benefits of integrating clinical research and medical care in the case of childhood cancers in the United States[6]. Thanks to the efforts of the Children's Oncology Group, more than 60% of children with cancer are enrolled in clinical trials through hospitals affiliated with their 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 benefit of society and contributing to a public good, 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 participating in clinical studies can result in a higher standard of care as patients are closely monitored by expert 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 are given the opportunity to voluntarily participate only when it is a suitable option of care.

CRAACO also offers clear benefits for study sponsors. It is well-established 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.

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



DIGITALIZATION IS KEY TO INTEGRATING MEDICAL CARE WITH CLINICAL RESEARCH

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.

There are also clear benefits for payers and healthcare providers. 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 lead 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 many barriers remain to its 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 the workflow for clinical trial operations, connecting eligible patients with sites and investigators on a scale that was unimaginable in the past. 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 language 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 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.

Citations

1. "A National Cancer Clinical Trials System for the 21st Century." *Institute of Medicine Committee on Cancer Clinical Trials and the NCI Cooperative Group* 2010
2. "Perception & Insights Study: General Perceptions and Knowledge on Clinical Research." *Center for Information & Study on Clinical Research Participation* 2017
3. Milewicz DM et al. Rescuing the physician-scientist workforce: the time for action is now. *The Journal of Clinical Investigation* 2015
4. Corneli A et al. One and done: Reasons principal investigators conduct only one FDA-regulated drug trial. *Contemporary Clinical Trials Communications* 2017
5. "High Turnover, Protocol Noncompliance, Plague the Global Site Landscape." *Tufts Center for the Study of Drug Development Impact Report* 2015
6. Gelijns AC and Gabriel SE. Looking beyond Translation – Integrating Clinical Research with Medical Practice. *The New England Journal of Medicine* 2012
7. Schaefer GO et al. The obligation to participate in biomedical research. JAMA 2009.
8. Goyal J et al. The effect of clinical trial participation versus non-participation on overall survival in men receiving first-line docetaxel-containing chemotherapy for metastatic castration-resistant prostate cancer. *BJU International* 2012
9. Eapen ZJ et al. Rescuing clinical trials in the United States and beyond: A call for action. *American Heart Journal* 2013
10. Getz K. Trends in clinical trial design complexity. *Nature Reviews Drug Discovery* 2017
11. Ford I and Norrie J. Pragmatic Trials. *The New England Journal of Medicine* 2016
12. Fröbert O et al. Thrombus Aspiration during ST-Segment Elevation Myocardial Infarction. *The New England Journal of Medicine* 2013
13. Burwell SM. Setting Value-Based Payment Goals — HHS Efforts to Improve U.S. Health Care. *The New England Journal of Medicine* 2015
14. Shen J et al. Clinical research participation as a care option: Driving patient experience and satisfaction. *PMG Research White Paper* 2015
15. Friedman CP et al. Achieving a Nationwide Learning Health System. *Science Translational Medicine* 2010
16. El Fadly A et al. Integrating clinical research with the Healthcare Enterprise: from the RE-USE project to the EHR4CR platform. *Journal of Biomedical Informatics* 2011

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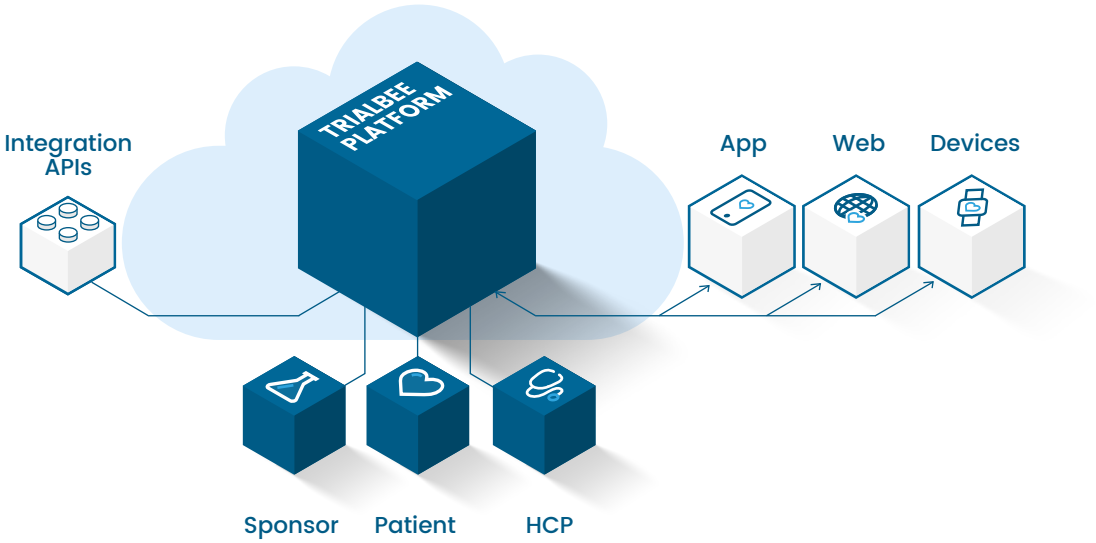
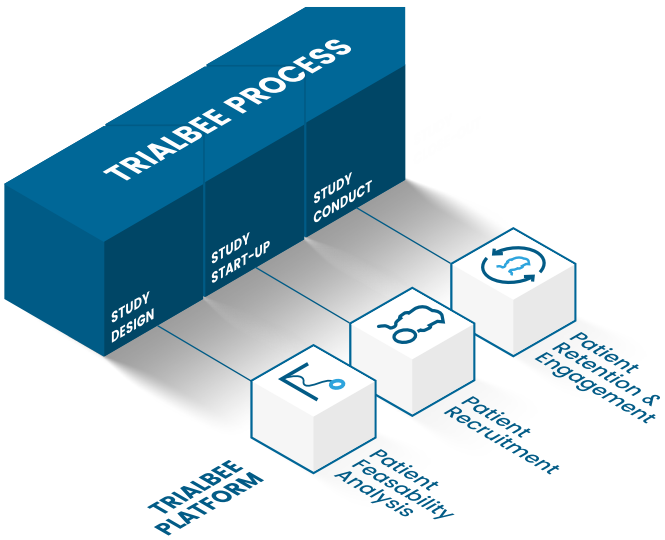
WHAT WE DO

Our platform

The Trialbee product suite is designed to create holistic digitalization of the patient journey in clinical trials. We have developed a cloud-based platform to connect patients, investigators and sponsors and support workflows across the study chain.



Our offerings



Trialbee's end-to-end solution provides patients with easy mobile access to disease communities, trial research & signup, treatment journeys, adherence reminders and outcomes reporting for highest possible engagement.

Simultaneously, investigators gain access to digital outreach campaigns, online screening, patient administration tools and actionable analytics to streamline the workload of clinical sites.

To request a demo, visit us at **www.trialbee.com**
or email us at **solutions@trialbee.com**

ABOUT US

Trialbee is a software solutions company founded in 2010 and based in Malmö, Sweden.

We partner with pharmaceutical companies and CROs to digitally connect and engage stakeholders across the clinical study chain.

We strive to be innovation and thought leaders in the evolution towards clinical research as a care option and virtual trials.

Our vision is to be the key industry provider of end-to-end digital services for the clinical journey.

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