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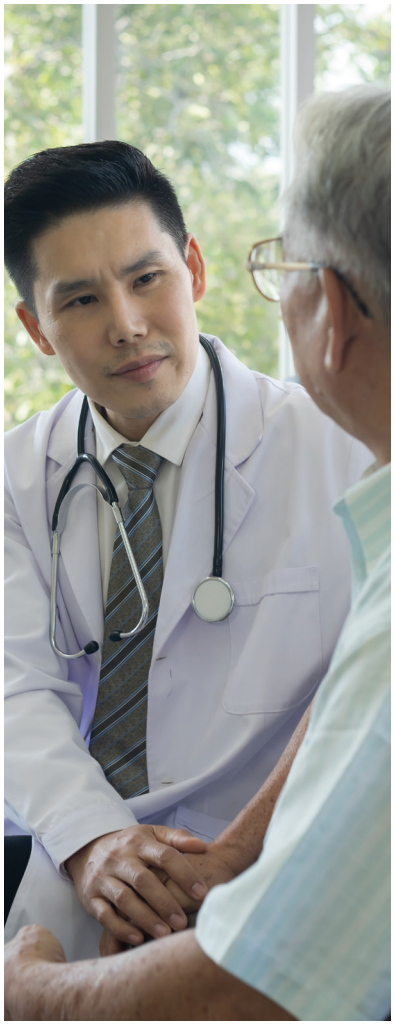

Clinical Research as a Care Option:

Addressing Obstacles to Study Participation and Collaborating for the Greater Good

Clinical Research as a Care Option (CRAACO) is a method of connecting patients with clinical trials as part of their ongoing health care programs. The ultimate aim of the CRAACO movement is to introduce patients to suitable clinical trials to bring about improved outcomes, while establishing stronger relationships between health care systems and research providers.

There are currently two common routes into clinical study participation. The first is through physician care: the traditional model of a doctor recommending that a patient become involved in a study to give them access to innovative compounds, where treatment options might otherwise be limited.

The second route, and one that has become more commonplace in recent years, is that of the informed individual patient or care provider who looks to social media, online research, and advocacy communities (both online and locally) to understand their condition and learn about opportunities for better (and potentially cost-effective) care. This patient persona will often actively discuss their condition with others across various forums, seek out research studies and assess whether the latter are appropriate for their condition.

Diversity and Inclusion

Historical inequality in health care provision has meant that access to clinical trials may have been limited for certain populations, particularly where general health care coverage is inadequate -- an issue that remains to be fully resolved. However, the search for a COVID-19 vaccine brought the need for fair representation in clinical research to the world stage, and caused a seismic shift in the way society engages with health care systems. The expedited adoption of patient-facing technologies; the raised profile of clinical studies as scientists raced to ensure safe and effective vaccines for all; and the patients forced to navigate alternative routes to required treatments as many health care networks globally were overburdened – all contributed to a situation in which patients are now more open to exploring CRAACO.

As they have become more aware of the societal benefit of clinical trials, and the requirement for representation of people from all backgrounds to ensure drug development meets the greatest need, patients are perhaps now more likely than ever to engage with clinical research opportunities when presented with them. This is supported in the findings of a recent survey conducted by Accelerated Enrollment Solutions (AES) involving 270+ patients worldwide, in which 90% of healthy volunteer respondents (e.g., those taking part in vaccine studies) were motivated to join a clinical trial to contribute to the advancement of medical science.

"It was fairly simple to do and certainly made me feel good to have helped in developing a COVID vaccine." – AES patient survey participant, 2021.

After receiving a diagnosis, a patient's first action will often be to carry out online research in which they seek to understand their prognosis and the most effective treatment options available to them. It is at this point that the CRAACO concept can be explored by the patient. In the aforementioned AES survey, it was found that 100% of respondents participating in patient trials (treating an active condition, as opposed to joining as a healthy volunteer) did so either to manage and better understand their own condition, or to help others with the same condition.

"The trial gave me good information about my condition and how to control it." – AES patient survey participant, 2021.

Patient Experience and Barriers to Participation

Clinical research providers can look to understand patient needs through technologies such as social listening, a practice in which discussion of medical conditions or research participation is monitored across social media platforms and analyzed to understand and improve patient experience.

Using social listening, clinical research providers can identify patient concerns and apply those learnings to their day-to-day interactions, actively joining with the patient over their preferred communication channels to overcome hurdles, and in some cases, even using the patient's unique insights to shape protocol development.

In today's clinical world, especially when seeking to ensure underrepresented demographics are actively involved in research, it is vital to understand barriers to study participation. Besides not hearing about a study in the first place, the AES Patients survey uncovered other reasons that a patient may decline to participate: e.g., fears of receiving a placebo treatment (over 30% of respondents expressed this concern), or simply feeling that a study would not fit into their busy lifestyle. They may have concerns about demands on their time, conflicts with work schedules or childcare commitments, or issues with travel (over 21% of AES survey participants identified a time or lifestyle issue as a challenge to their participation). Travel in particular was a key concern for many in recent patient interviews also conducted by AES, and it was found that proactively offering solutions to transport patients to the research site resulted in better overall engagement with the study.

"While I was talking about getting there, they offered to arrange a taxi for me. That was so simple...any stress about finding the place went away." – AES patient interview, 2021.

Removing Physician Burden

To ensure patients are aware of their options to participate in clinical trials, clinical research providers should also consider ways to bridge the gap between physicians and themselves. In a May 2021 interview with industry publication Outsourcing Pharma, acting U.S. Food and Drug Administration (FDA) Commissioner Janet Woodcock remarked, "Too often there is a disconnect between health care professionals looking to provide care for a specific condition and the trial system working on a novel therapy for that condition."

In the past, many physicians who actively engaged in clinical research, particularly those taking on the role of Principal Investigator (PI), felt increased pressure due to the associated administrative burdens. Lessening those burdens and encouraging more practitioners to get involved in clinical trials will require ensuring centralized administrative processes, utilizing innovative technologies and communication routes, and offering different levels of involvement (from only referring patients through to PI). These methods can support the physician in considering and offering all open avenues of care and allowing them to focus entirely on the patient. Many public bodies globally are currently looking at cross-sector policies to establish better and more consistent interaction and infrastructure to create a digitally enabled, innovative and patient-centric research environment in which CRAACO is a feasible option for all.

The AES Difference

AES is uniquely positioned to overcome barriers to study participation, making clinical research a realistic care option for patients globally. Our AES Patients offering utilizes a patient-first approach, with data gleaned from past performance giving us the confidence to predict future results. Our database, composed of over 100 million households and more than 20 million identified, pre-screened, and consented individuals with an interest in joining a clinical study, helps us ensure more diverse clinical trials consistent with the target disease population, and allows us to identify and engage patients most likely to participate within specific demographics. We also carry out targeted direct-to-patient recruiting efforts both online and in the community, continually seeking new patients in the places where they are learning more about their health issues, and gauging their interest in clinical trial participation.

Furthermore, a centralized platform for initial patient evaluation is utilized globally, and rapid follow-up and referral processes drive timely patient randomizations, meaning AES clients benefit from a recruitment rate that is twice the industry average, and pay-for-performance pricing models that demonstrate our commitment to delivering patients.

To address physician and site burden issues and deliver consistency, the AES Sites and Patients solution builds upon our AES Patients model by recruiting patients directly to AES-owned and partnered research sites that are purpose-built to support large volumes of patients, and staffed by experienced teams dedicated exclusively to clinical research. In contrast to the traditional model of combining disparate physicians' practices and sites, our centrally managed research site solution uses a single contract and standardized processes designed specifically for clinical research to drive uniform site conduct across more than 160 sites in 16 countries, meaning those staffing our sites can do what they do best – take care of patients. We also have relationships with a vast network of independent physicians globally who work alongside AES to provide patient referrals – meaning their patients can still consider CRAACO while maintaining relationships with their usual practice, bridging the gap between the health care system and research sponsor.

References:

[1] Outsourcing Pharma May 2021 FDA leader discusses breaking barriers in clinical care (outsourcing-pharma.com)

[2] Examples, EUPATI European Patient Academy for Therapeutic Innovation (EUPATI) - BASG, UK The Future of UK Clinical Research Delivery: 2021 to 2022 implementation plan - GOV.UK (www.gov.uk) Australia Clinical Trials Activity initiative | Australian Government Department of Health US/China New Collaboration Will Accelerate US-China Clinical Trials | Memorial Sloan Kettering Cancer Center (mskcc.org)