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EDITORIAL

Creating a clinical trials community by moving from human subjects to patient partners: 3 questions every trialist should ask

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SUMMARY
The COVID-19 pandemic has exposed an area of public health impacting the livelihoods, safety, and health of each and every one of us. As everyday Americans volunteered to be first to receive placebo or novel therapeutics in the quest to end a global outbreak, suddenly we as a community were also informed of clinical trials, vaccine safety and development, and research design. As engagement spreads and the opportunity becomes ripe to build a community of researchers, patients, and clinicians and transform what has historically been termed "human subjects" in clinical research, we encourage this drive to strengthen the clinical research ecosystem with a primary focus on patient involvement in all phases of codeveloping clinical research design.

Key Words
Clinical trials; Human subjects research; Patient engagement; Patient partnership

INTRODUCTION

COVID-19 has impacted the world and changed many things in health care that we used to take for granted. The pandemic also has helped the world become aware of what a randomised control trial (RCT) is. As we learned from multiple media sources, scientists helped us all understand how the COVID-19 vaccines were studied to assure they were safe and effective and how hundreds of thousands of patient partners signed up to partner with researchers to learn together. For the uninitiated who did not know how medical scientists learn answers to challenging medical questions, this is an important time. As more and more people understand trials, we have an opportunity to move from the idea that participants are simply "human subjects" to becoming authentic, co-equal members of the clinical trials community.

Where We Have Been, Where We Are Now, and Where We Might Go

To truly examine the role of patient partners in research, we appreciate the historical context of clinical trials evolving from foundations of ethical principles of human research; advancement of the 1979 Belmont Report with processes of informed consent; assessment of risk and benefits; and confidentiality among other key considerations. As recently as 1991, we observed the use of language around "Protection of Human Subjects" as we see this common lexicon play a role in trial design of "human subject research."[1,2] While we have come a long way in clinical research and design, and as clinical trials in the 21st century expand, we see creative ideas reach engaged participants maximising value and patient personalisation through telehealth and other remote

models. The research landscape has shaped and shifted as we observe language such as "study participant" incorporated into new study aims.[3] Today, the healthcare industry innovates with real-world evidence (RWE) and population health studies through ongoing research and a public health network of invested stakeholders. We start to obtain input from key stakeholders affected by the implementation of trials and focus on ways to minimise the burden of participation for patients, their caregivers, and at study sites.[4] Through the Clinical Trials Transformative Initiative, we align with the vision of collaborating to promote Transforming Trials 2030 with the aims of creating clinical trials that are

- Patient-centred and easily accessible;
- Fully integrated into health processes;
- Designed with a Quality approach;
- Maximal, leveraging all available data; and
- Improving population health.[5]

While trial design from the researcher, sponsor, and healthcare industry perspective has evolved incrementally, in this editorial we focus on the patient, family, and caregiver perspectives. Because patients are active participants in clinical trials, clinical researchers have the opportunity to engage in the patients' "lived experience" in a way that can transform research. Patients have always been thanked for their participation in research, but until recently they were not full members of the research teams. We envision a research ecosystem where the patient is central at the start of every clinical trial, and every clinical trial is built within a community that engages all stakeholders as equal partners and includes diverse patient perspectives in every single trial.

To expand our lens to develop authentic "patient partners," rather than simply "human subjects," we propose three questions for all trialists to ask before starting their next clinical trial.

1) How Might We Create an Authentic Clinical Trials Community?

If we really care about the future of research and learning from clinical trials, how might we assure that those participating and those researching are an authentic and fully invested community hoping to advance science, potentially improve health for those living with disease/illness, or try to understand the impact of medicine or compare medicines?

We don't come at this work from the perspective of those readers who are currently, or plan to be investigators, where they have trained or are in training to be experts at how to do trials, where to get funding, and why this matters to their academic/hospital or commercial employer. Rather, we come at this work as patient partners hoping to influence the future of trials by working **together** to build a community of colleagues and experts that change the future of every trial. We're aiming to create what we like to call "Patient-Partnered Research: The Future of Clinical Trials."

2) What Might be a Potential Model to Build such a Community?

As the **ultimate** stakeholder, the patient partner cares deeply about the question being investigated. The patient partner wants to cocreate the question to be investigated, the process to

find funding, the process to find patients to enrol, the process for completing the trial, the ways to disseminate the results, and the first to learn of results. As members of the study team, patient partners and researchers will hope to maintain relationships (friendships), work on new projects together, and continue to advance the role of patient-partnered research.

As an example, the Adaptable trial developed a community of patient partners (called adaptors) that transformed how we might create a large multi-site pragmatic trial.[6–8]

3) How Might I Get Started in Building a Clinical Trial Community?

If you are trialist or member of a research team, you can begin by asking the funders of research the following questions:

1. How might we ask, offer, and compensate patient partners so they are authentic members of our study team at the very beginning of the research?
2. How can we infuse the lived experience/expertise with the experiences of other members of our team (informatician, statistician, program managers, PIs, etc)?
3. How might we create an orientation to assure that language and style of communication doesn't create artificial boundaries amongst our team?
4. How might we assure that all participants (not simply the patient partners on the team) are fully invested and understand our gratitude and help in answering this important research question? In other words, how do we build a community?

If you are a patient or caregiver, you can begin by asking your clinician about opportunities to be involved in clinical trials that are in the "thinking/planning stages" (and have not been funded yet) based on your or your family member's illness, disease, or treatment. Once connected to a trialist, you can ask the following questions:

1. How might my lived experience be most helpful in advancing questions you are considering for research?
2. What ideas do you have to bring together the community of participants (patient partners) and assure they know we care deeply about them and for them?
3. How might my lack of knowledge in how research works be leveraged by the team to ask new questions that challenge the status quo of how research is always done?
4. In addition to advancing the topic in scientific journals, how might we assure that what we discover in this trial reaches millions of patients, caregivers, and clinicians who will care deeply and personally about this question?

Consider Patient-Partnered Research as Your Opportunity to Start a Movement: Role of the First Follower

Derek Sivers, the American writer and programmer, says, "The first follower is what transforms a 'lone nut' into a leader."[9,10] Moving toward patient-partnered research requires everyone to rethink roles, consider opportunities for change, and allow for power dynamics to diminish amongst our community. We can learn to listen with open hearts and teach each other (researchers and patients) new ways to partner together and align incentives for the greater good.

Solving a question like overcoming a pandemic by creating safe and effective vaccines has led to incredible advances in not only medical innovation but also in what it takes as a community to build forward after a pandemic. Let's be sure it also can lead to an even brighter future where **every** clinical trial starts with patients/families as co-equal members of the study teams and clinical trials comprise communities where we are all seen, heard, listened to, cared for, and loved.

Additional Questions for Consideration

We present additional questions for consideration:

1. What if trials (starting with your next one) were named after a patient or family member whose life will be transformed if the science is proven to be beneficial to their condition?
2. What if a member participant in the trial becomes the name of the trial?
3. How can we have the community be more than "subjects"—rather they are co-authors/creators of the study/trial?
4. How can we care about the person who leaves the study as much as the person who completes all tasks and is "counted" for the study?

Actively partnering in the future can help facilitate understanding. Two reasons for joining a study are to help science and maybe help myself or my loved one.

As we include diverse patient perspectives in every single trial, imagine building on the progress that has already been made across the clinical transformation ecosystems[11] and engaging all stakeholders as equal partners. The process of change involves patient engagement, inquiring within and among stakeholders, recruiting differently, disseminating results, and implementing where patients can be reached as a collective community. At the heart of our community's shared goals is the patient – the patient as a partner aligned with our collective community's scientific goals.

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