

# The Clinical Trial is Complete. Now What?

By Paula Kim

Dealing firsthand with a disease or illness is as up close and personal as life gets. A serious diagnosis can result in a patient's daily routine, future plans and status quo evaporating along with any modesty they might have had in the hands of modern practitioners. Patients shift their focus to dealing with their diagnosis physically and emotionally, managing their quality of life while attempting to navigate and negotiate their care within a very complicated and sometimes onerous medical system. The uninsured and underserved populations face additional challenges as they often are without health insurance, financial means, and access to high quality health care. It is from this disadvantaged position that the underserved are approached by the medical system for participation in clinical trials. Participation in a clinical trial is a commitment that adds burdens such as coping with greater uncertainty, treatment side effects, extra visits to the hospital for tests and scans, filling out often incomprehensible paperwork, and increased travel.

## Patient participation in clinical trials

Each patient has his or her own personal reasons for participating in a clinical trial. A 2003 Harris Poll Survey reported, "helping to advance science" as the most common reason for patient participation (54%), followed by "helping others with the same disease condition" (46%). Obtaining better treatment, which ranked first (56%) in the original 2001 survey, dropped to fourth (40%) in the 2003 follow up survey.<sup>1</sup>

A smaller study in the UK reported patient desire to be in expert hands as the key influence in clinical trial participation (54%). Helping others (e.g., future patients, cancer research, and researchers) was a close second (52%), while 36% stated that they felt they had no choice but to participate if they wanted to live. An additional 23% felt that they had nothing to lose because they were going to die anyway.<sup>2</sup>

## Disparities and clinical trials

Disparities in clinical trials most often relate to racial, social, geographic, and economic factors. As important as these factors are, inequities can and do exist with respect to age, gender, disease type, and treatment modalities. These inequities can affect public perception of clinical trials including how to take advantage of post-trial benefits. Disparities often exacerbate some of the common negative results of clinical trials and lead us to some important ethical considerations.

"To remedy disparities in clinical trials, we must use a systems-based approach that builds upon grassroots awareness and involvement as well as community leadership working in partnership and harmony with regional and national leadership to collectively make changes in behavior, policy, systems, and attitudes."

For example:

- Should people who participate in a clinical trial continue to receive any type of care after the trial is finished? One incentive for participating in a clinical trial is the secondary health care and monitoring received that are often part of the research protocol. Thus, for an underserved or poor participant, the conclusion of the trial may also represent the cessation of accessible health care.
- Do patients from underserved populations who participate in clinical studies experience more burdens than usual during and after participation? If so, is clinical trial participation a benefit or a drawback for these populations?
- How do we integrate new knowledge from human genome sequencing in clinical trials? Undoubtedly, this pivotal achievement in medical history has left us with both questions and answers regarding the impact of biology, the environment, and socio-cultural factors on the individual response to a given treatment. What we continue to discover in this arena may add to our understanding and beliefs regarding this issue.

## Post-clinical trial benefits and return

Although many of the patients who participate in clinical trials do so for the "greater good," it is important that we look at this statement in the context of who is participating. As previously stated, only 3% of cancer patients participate in clinical trials. Thus, the desire to "further scientific progress" or to "serve the greater good" is only sufficient to attract a very limited segment of the population with a given condition to participate in a clinical trial. Thus, it follows that we should invest our energy in identifying other ways to attract people to clinical trials. We must emphasize the "return on investment" people will gain for participating in a clinical trial to make this a more attractive option.

The impact and nature of benefits and the degree of return for participating in a clinical trial varies depending on a number of circumstances. For example, benefits important to one group of people might be of little or no use to another. In any case, providing culturally and socially appropriate benefit to participants and their communities post-trial should be a constant goal—always tempered with the awareness that the benefits should not be coercive and foreclose the possibility that a patient can say "no." In order to provide meaningful post-trial benefits and return to the participant and the community, the opinions of the community should be solicited and considered in designing post-treatment follow-up. It is also important to consider ethical, social, and cultural aspects of benefits and return.

Examples of post-trial benefits and return could include:

- Direct medical benefit (effective treatment or prevention)
- Access to experimental agent
- Eligibility for follow-up and future related studies
- Long term follow-up and access to health care
- Access to information, support networks, and other patients
- Opportunity for continued interaction with the research team
- Greater awareness and understanding of the health care system may help with future medical care needs
- Opportunity for involvement with related activities and programs (advocates, cancer centers, community, social workers etc)
- Individuals can share information about their experience with their family, peers, and community
- Community could develop increased awareness of the resources, greater trust, and interaction in health care system
- Satisfaction of contributing to science

### Helping the system include benefits and return

Dedicating more time, energy and resources can help address the disparities in clinical trials. This is necessary but not sufficient to solving this challenging problem. Many patients see a very limited return for their participation in a clinical trial. This impacts their decision to take part in a clinical trial and causes low clinical trials accrual and disparities in clinical trial enrollment.

Lessening the impact of disparities and strengthening the benefit and return of participation, requires strategic relationships. To remedy this situation we must use a systems-based approach that builds upon grassroots awareness and involvement and community leadership working in partnership and harmony with regional and national leadership to collectively make changes in behavior, policy, systems, and attitudes.

Potential solutions from such an approach will present a foundation to address the myriad concerns patients may have regarding clinical trial participation. For instance, current research demonstrates that despite their fears of abandonment and requests for clinical trial results by patients, there is little researcher-patient involvement after the trial concludes.<sup>3</sup> Taking an approach which engages participants in problem solving regarding clinical trials may have a two-fold benefit. First, this could be a viable way to keep patients after a study has concluded and could contribute to a positive experience they are more likely to repeat or suggest that friends and family consider. Second, beyond the biological findings from a study, we can learn directly from a patient what benefits and barriers affected their clinical trial participation and use this information in the design of future clinical trials.

Balancing scientific interests with patient-centered needs including post-trial activities should be our notable goal. Achieving the goal will require much progress in our lifetimes so that we can optimize our capability to prevent, detect, treat, and manage diseases while at the same time being responsive to the social and ethical needs of patients for truly personalized medicine—accessible by all. ●



### References

1. Harris Survey, Health Care News Vol 3, Issue 10, June 16, 2003. The Many Reasons Why People Do (and would) Participate in Clinical Trials
2. Enhancing Cancer Clinical Trial Management, Recommendations from a Qualitative Study of Participants' Experiences, Cox K, Psycho-Oncology, 2000