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Post-trial responsibilities beyond post-trial access

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What happens at the end of a trial when a patient responds to an investigational medication and benefits considerably? Many people believe that this patient should continue to receive the beneficial drug. This belief underlies the idea of post-trial access—providing investigational interventions post-trial to participants who benefited from them—and was formally introduced by the Declaration of Helsinki in 2000. But even if this patient did not benefit from the investigational medication, doing nothing for them at the end of the trial seems ethically problematic. What, then, should be done for patients after a trial?

The research community's focus on post-trial access overlooks a broader set of post-trial responsibilities to research participants, which we classify as post-trial care or responsible transitioning of participants. Even when commentators refer broadly to post-trial obligations and responsibilities, they often mean access to investigational interventions, leaving the equally important issue of general post-trial care unaddressed.

Although post-trial access refers narrowly to arranging access to an investigational drug or intervention (eg, through extension trials or dedicated funding strategies), post-trial care encompasses a broad array of responsibilities. These responsibilities include helping arrange clinical care or social services after a trial's conclusion, referral to appropriate follow-up care in the health-care sector or to another trial, or provision of alternative interventions to the investigational medication, and other types of support to ensure smooth transition from research to health-care sectors.[1] Post-trial care should be offered to varying degrees at the end of every trial, consistent with the principles of ethical research.[2]

Distinguishing these concepts prevents conflation of post-trial access with broader post-trial responsibilities, and possible omission of these responsibilities. Responsible transitioning might be particularly important for trials that do not provide post-trial access, or provide this access only for a short time, consistent with generally accepted criteria for post-trial access and limitations of research funding. Even when post-trial access is arranged, investigators and sponsors retain duties to inform participants of results, help them transition to appropriate care in the health-care system, or refer them to other trials.

Furthermore, post-trial care safe-guards participants who do not have access to health care outside of research. Although reasonable availability or provision of fair benefits could prevent general exploitation in research, post-trial care is necessary to prevent the exploitation of participants with insufficient access to health care, who have poorer health

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outcomes than people with full access to health care.[3–6] These participants include people from low-income and middle-income countries and people who are uninsured or otherwise lack sufficient access to health care in high-income countries such as the USA.

Before regulatory approval, all participants regardless of access to heatlh care have equal need for an investigational treatment (if indicated), and neither group has post-trial access without external provision. However, these groups' post-trial care needs (and thus investigators' responsibilities to each group) differ substantially. Simply transitioning an insured participant to the extant health-care system might discharge an investigator's obligation, because the participant will probably receive comparable or adequate care; this transition is insufficient for uninsured participants with poor access to health care and disregards their safety. Even with post-trial access, uninsured participants might not have access to continued monitoring, treatment for complications, or existing treatment alternatives. Investigators and sponsors might need to help arrange additional post-trial care, including financial support, medical care, or social services, to bridge this gap. These arrangements ensure adherence to well established principles of ethical research, such as beneficence and respect for study participants, and decreases the temptation to exclude uninsured participants for fear of exploitation, which would further disadvantage people who are already disadvantaged.[2]

In short, to ensure ethical clinical research and to retain public trust, researchers have broader post-trial care responsibilities to individual research participants than arranging access to investigational interventions, including responsible transitioning to needed health care, especially for people with insufficient access to health care.

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