

A CALL TO ACTION

Clinical Trials for Breast Cancer Research

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Breast cancer detection and survivorship have improved greatly in 20 years, and biomedical science is poised to usher in a new and previously unimaginable era of progress.

However, continued advancements are thwarted by factors beyond the challenges of science itself. Currently, the two most salient impediments to scientific progress are funding and patient participation in clinical trials. All breakthroughs to date have ultimately depended on the altruism, willingness, and enthusiastic support of the patients who participated in the trials that led to today's best standard treatments.

Lumpectomy, or breast-conserving surgery, which today most women with breast cancer choose to undergo

as their surgical treatment of choice, could not be safely offered if it weren't for the women who participated in the once-groundbreaking randomized trials where patients either underwent mastectomy or lumpectomy. From those important trials, we now know that both approaches offer equivalent survival rates.

While some patients do personally benefit from trial participation, the overall advantage is to push our knowledge forward so we can continuously improve care for all patients. Despite this tremendous benefit, a relatively small number of adult patients with cancer currently enroll in clinical trials. At this pivotal moment, patient access to, and participation in, clinical trials must be expanded. This could be achieved by expanding patient advocacy and outreach efforts and improved—rather than decreased—funding.

Furthermore, a cautious reduction of overreaching and prohibitively onerous regulatory restrictions would fast-track trials to opening, thus making it easier for a greater number of candidates to enroll. In addition, academic medicine, the pharmaceutical industry, and

government must also introduce high-level collaboration, and an equitable realignment of the burdens and benefits of drug and other therapeutic development, in order to develop and prioritize new therapeutics. This synthesis could flourish within a restructured drug-approval process, one that requires post-approval funding from the pharmaceutical and insurance industries so clinical and comparative research could be conducted.

Enlightened changes such as these would give scientists and physician researchers the support they need to realize even greater improvements in breast cancer prediction, detection, and treatment.

Already radiologic screening and diagnostic tools have dramatically improved our early detection of breast

cancer. We can also identify individuals who may be at higher risk of developing breast cancer, and from there we can provide options to manage that risk.

Now, molecular and genetic sciences have put us at the cusp of a major paradigm shift. Expansion of gene sequencing in individual breast cancers, together with the ongoing revolution in bioinformatics, will better position us to rapidly develop more rational therapeutics and individualized treatment and prevention strategies. Development of additional molecular profiling tools could also advance efforts to determine optimal, personalized treatment choices based on rational therapeutic targets.

Improved access to clinical trials and expanded research funding would help us build even more rapidly on past achievements—as well as today's promise. We owe this much to our patients and to all the women in our lives.

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