

Cancer Clinical Trials

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Many of our readers know that the major clinical advances in cancer depend upon clinical trials. Virtually all drugs used have been introduced after a randomized clinical trial, whereby the new drug is tested against the standard regimen or treatment. However, less than 10% of patients in the United States who are eligible for such trials enter them for a variety of reasons.

The clinical trial system as it exists in the U.S. has many deficiencies. It exhausts the investigator by virtue of many bureaucratic roadblocks, utilizes a great deal of research time and is unusually expensive. An article in the May 2009 issue of *Oncology News International* (ONI) emphasized this as did the American Society of Clinical Oncology at its annual meeting in 2009 in Orlando, in a symposium entitled “Global Clinical Trials—Challenges and Solutions”. Going global, as noted in ONI pertains not only to computers and automobiles, but also to clinical trials which are performed more and more overseas, especially in the Asia/Pacific region. Such trials have increased by 50% in 2007 compared to 2004. It is also clear that our European colleagues have far outdistanced us in the United States. For example, there is an organization called the European Breast International Group (BIG) which consists of a network of 44 collaborative groups and

partnerships in Europe, Canada, Latin America and the Asia/Pacific region which can rapidly accrue a large number of patients so that studies can be completed within a reasonable time. Moreover, both European patients and physicians are more responsive to entering clinical trials. For example, in Austria, there is a high enrollment of patients, resulting from the efforts of scientists and physicians working together for more than 20 years. It also reflects a homogeneity of the population and the relatively small size of the country.

In the United States, it takes nearly 2 ½ years to design and open a clinical trial, longer than foreign countries. The pharmaceutical industry has long looked to the U.S. for initial testing of new compounds while European consortiums are now used for comparative drug trials. Can governments influence this clinical trial situation? Absolutely. Japan has experienced a dramatic increase in participation in global clinical trials because of an environment established by the government which is more conducive to them, according to a report cited by Centerwatch, entitled “The Emerging Markets of Clinical Research” cited by ONI in May 2009. This is at least one instance where government intervention can help.