

Advanced clinical trials for China

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Clinical trials are the primary means through which new drugs and devices are developed for use in patients. Through a series of studies that aim to demonstrate safety, activity, benefit, and effectiveness, clinical trials provide a rigorous scientific methodology for evaluating questions in clinical medicine and advancing new treatments to the marketplace. Clinical trials are also essential to directly compare the effectiveness of various treatment options and to assess the cost and cost effectiveness of new treatments. Clinical trials also provide a context and infrastructure that enables investigators to prospectively collect biospecimens that can be used to answer important questions about the benefits and harms of therapies in subgroups of patients as well as to develop new prognostic and predictive tests.

Clinical trials are the primary tools that commercial sponsors use to develop new therapies for patients with cancer and that regulatory authorities use to determine whether a new drug is safe and effective in a proposed indication and should, therefore, be made available in general medical practice. Increasingly, national health systems and insurance companies also use the results of clinical trials to develop reimbursement policy that is often based on the value and relative effectiveness of a new treatment compared to prevailing standards.

During the last 60 years, the clinical research community has developed a rigorous methodology for the design and conduct for clinical trials that requires a clear statement of objectives, description of patient inclusion and exclusion criteria, well defined study endpoints, a clearly specified treatment plan and a rigorous statistical analysis plan. Organizing such studies requires a deep understanding of clinical medicine, pharmacology and biostatistics as well as adherence to international standards of human subjects protection and Good Clinical Practices.

Conducting clinical trials requires dedicated and well trained teams of research professionals, rigorous quality control, and modern informatics. Clinical trials used to support drug approval are ideally conducted in the country and with the patient population in which the drug is intended to be used. Thus, while clinical trials conducted in North America and Europe may reveal information that is relevant to the Chinese patient population, it would be far better to conduct such studies in China itself so that genetic variables that might impact treatment effects, cultural sensitivities and local standards of care can be accounted for and used to more readily interpret the impact of the new drug or treatment program. Ideally then clinical trials of new drugs and devices intended for use in the Chinese cancer patient population will be conducted in China by Chinese oncologists who have been well trained and are experienced in the methodology of clinical trials.

With this goal in mind, last year the Chinese Society of Clinical Oncology (CSCO) in partnership with the Society for Translational Oncology convened the first Advanced Clinical Trials Workshop-China (ACT-China) in Shanghai. A distinguished faculty including Professors Shukui Qin, Yi-Long Wu, Jin Li and other leaders of CSCO along with experts in clinical trial design and regulatory affairs from China and North America came together to design and deliver a two and one half day course on the basic elements of clinical trial design and implementation. Course lectures covered a range of topics including ethical considerations in clinical trials; the responsibilities of the principal investigator of a clinical trial; the objectives, design, and operating requirements for phase I clinical trials; design considerations, endpoint selection, and statistical methods for phase II trials; biomarker driven clinical trials; and the design, execution, and monitoring of phase III clinical

trials. In addition to outstanding lectures on these and other topics, a key feature of the course was simultaneous workshops during which the course participants worked together in small groups to design phase I or phase II clinical trials of a fictitious oral multi-kinase inhibitor named “chinitinib” produced by the fictitious company “CHINACIA”. The day following the breakout sessions, a representative of each working group presented a summary of that groups’ clinical trial design to the entire audience for discussion and feedback.

The course participants, all senior clinical investigators and oncology department heads from across China, praised the course content and, in particular, enjoyed the experience of working with an international faculty to design a novel clinical trial. The course was judged a resounding success by the participants and will be repeated again in late 2012 in Guangzhou hosted by Professor Yi-Long Wu, the President-elect of CSCO and Vice President of the Guangdong General Hospital and Guangdong Academy of Medical Sciences.

It has been my great honor to serve as Dean of the Faculty of ACT - China and to work with an outstanding

group of colleagues from China, the United States, Canada and Europe. Given China’s large population and explosive growth, one can expect that a great proportion of the global burden of cancer in the next 20 years will occur in the Chinese population. In view of this high medical need and given China’s growing prosperity and importance in the global marketplace, it is necessary and appropriate that cancer clinical trials be conducted by Chinese oncologists for the benefit of the Chinese people. Doing so will provide Chinese cancer patients with access to state of the art therapies, improve the overall quality of cancer care, and enable Chinese regulatory authorities to have confidence that new cancer drugs are safe and effective when used in the Chinese population. With ACT-China we hope to enable Chinese oncologists to design and conduct the pivotal clinical trials that will improve the survival and quality of life of Chinese people who are living with cancer.

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