

Shifting from Network Marketing to Evidence Based Medicine in China

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A decade ago, with the unification of Eastern and Western Europe and the birth of EURO, it also came new problems in health care: 1) Inter-country and intra-country differences in medical practice, 2) Medical guidelines not adhered or not reflective of local practice, 3) Lack of knowledge on epidemiology and influencing factors of major diseases across the region, 4) Lack of evidence of long term clinical outcomes under various health care environments ⁽¹⁾.

Evidently, China is currently facing many similar issues. Over the last decade or so, there has been tremendous amount of enhancement of medical research in China, some of which are reflected in the increasing number of global and local clinical trials conducted in China (Fig 1.1). However, according to www.clinicaltrials.gov, most of the clinical trials conducted in China were investigational or interventional, small in sample size, and relatively short in follow up period (Fig 1.2).

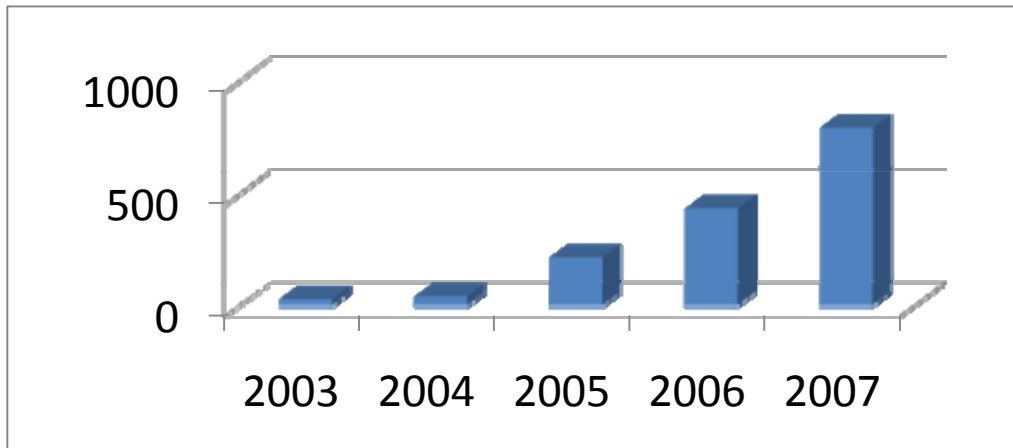


Fig 1.1 Number of clinical trials conducted in China (www.clinicaltrials.gov)

As a result, though almost the same pace of submission of new drug and new device applications to SFDA as to FDA and EMEA, in China, there is a lack of understanding of long-term clinical outcomes in Chinese patients; lack of understanding of how new diagnostics and therapeutics and dynamic life styles have influenced the incidence and prevalence of major diseases; lack of understanding of how western-influenced medical guidelines are adhered and supported by real-life settings, lack of understanding of what are unique unmet medical needs and opportunities.

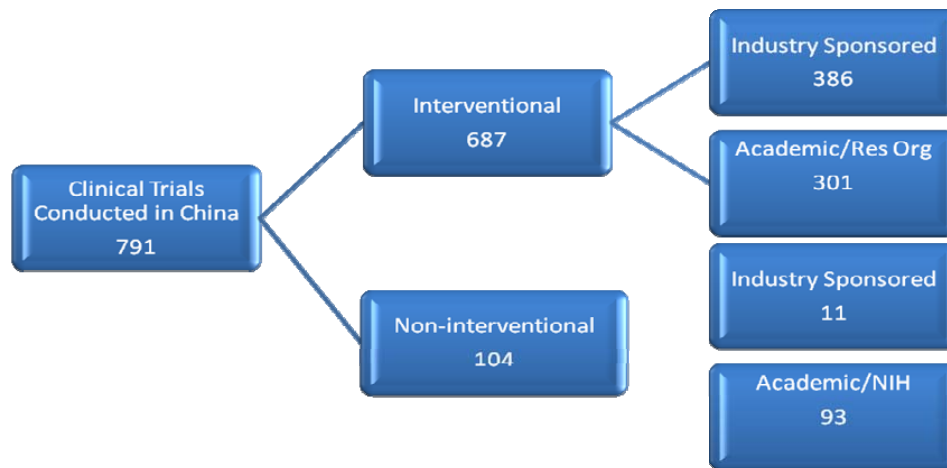


Fig 1.2 Type of clinical trials conducted in China in 2007 (www.clinicaltrials.gov)

How European and American Addressed Their Issues

To address its post-European Union syndrome, European Society of Cardiology (ESC), one of the largest medical societies in Europe decided to conduct a thorough survey across all cardiovascular and metabolic disease, and designed a program called Euro Heart Survey. This is a research program that has touched almost every major global pharmaceutical and medical device companies who had interests in the areas, all major European healthcare related government bodies and institutions, and physicians and patients in more than 28 European countries. Ten years later, this program has produced over a dozen of landmark clinical cohort studies, such as GRACE, ENACT, etc, hundreds of publications in peer reviewed journals, most importantly enhanced evidence based medical guidelines, and reduced the gaps between the guidelines and real-life practice⁽²⁾. The data generated in these studies provided each sponsoring company tremendously valuable information and guidance as to what are unmet medical needs and what are the most effective strategy to address these needs, which otherwise was unimaginable to acquire by a single sponsor.

On the other hand, cross the Atlantic, American College of Cardiology (ACC) also initiated a program about 10 years ago called National Cardiovascular Data Registry, which was to help participating hospitals in the United States to monitor the disease progression and the quality of care for cardiovascular patients.

What Chinese Medical Community Eager To Do

As an initial effort to enhance the understanding of clinical outcomes in Chinese cardiovascular and metabolic patients, several studies including China Heart Survey, DaQing Survey, etc were conducted⁽³⁾⁻⁽⁴⁾. These studies though individually designed and executed, concluded with a couple of important message: 1) different life styles from Westerners and unique combination of Western and Chinese traditional medicine may require modified therapeutic or disease management approach, 2) real-life experience is needed in order to better implement and follow medical guidelines. These studies further demonstrated that there are significant needs of nation-wide, cross sectional or longitudinal database in China that could enable the medical community to better monitor clinical outcomes of various therapeutics in real life settings and to detect trends and opportunities that may improve quality of patient care.

Based on these findings and building on the successful experience of ESC and ACC, Chinese College of Cardiovascular Physicians (CCCP), Chinese Endocrinologists Association (CEA), and VitalStrategic Research Institute (VSRI) have decided to collaboratively design and conduct China Cardiometabolic Registries (CCMR), which is consisted of a series of cohort studies in most common cardiovascular and metabolic diseases, that are individually designed but centrally coordinated. Since its inception one month ago, CCMR has received strong support from medical associations, Ministry of Health, as well as international experts. Several global pharmaceutical companies have already begun to consider participating in this program and providing sponsorship. There is no doubt that CCMR will increasingly gain both domestic and international attention.

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CCMR program may last for years. However, its impact to Chinese pharmaceutical market will begin to be seen soon after its initiation. It will most likely influence the mind set among cardiologists and endocrinologists on using all clinical evidence, real-life and investigational, to make informed medical decisions. This need arisen from the medical community for more real-life clinical data may lead to a resource shift within global pharmaceutical companies in China. Such a change may subsequently lead to a shift of paradigm from network marketing to evidence based medicine. This shift of paradigm has occurred in the US market a few years ago and may transform the China market to a more sophisticated pharmaceutical market.

Turning Evidence into Values

CCMR is aimed to not only generate large amount of long term clinical evidence but more importantly to turn evidence into values benefiting all parties, including patients, physicians, industry and government. The organizer encourages sponsorship from all sources, industry, government, private funding, etc. A sponsor would not only be recognized as the leader in

cardiovascular and metabolic disease areas, but also have opportunities to provide input in design of a study focused on a specific disease, such as heart failure, diabetes, atrial fibrillation, etc., receive study reports, receive study datasets, and have access to retrospective and meta-analyses across several individual studies. These invaluable data will help industry to better determine their development and business strategy, help physicians to make informed medical choices, and ultimately help improve the quality of patient care.

In order to help public understand better how CCMR would be valuable to each of their business and interests, CCMR advisory board has organized an open symposium, “Cardiometabolic Risk Factors and Clinical Outcomes in Chinese Patients – Introducing CCMR”. This symposium will take place on October 16, 2008, 4 – 9 pm, at Traders Hotel in Beijing. Online registration is available at www.CCMRegistry.org.

Reference:

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- (4) Li G, Hu Y, Pan X. Prevalence and incidence of NIDDM in Daqing City. *Chin Med J (Engl)*. 1996 Aug;109(8):599-602.

Dr. Danyi Zhang founded VitalStrategic Research Institute (VSRI) in 2007 after a successful career as an executive in global medical affairs and clinical R&D of major pharmaceutical companies including Bristol-Myers Squibb, Wyeth, and Astra Merck. She received her medical education from Shanghai Medical School of Fu Dan University, postgraduate training from MIT and Harvard Medical School. Her research experience has included cardiovascular diseases, diabetes, thrombotic conditions, and laser medicine. VSRI designs, executes, and reports interventional and non-interventional evidence based outcomes research to better define unmet medical needs, thereby to potentially enhance values of medical innovations, improve quality of healthcare service, and strengthen effectiveness of health care policies. She can be reached at dzhang@vitalstrategic.com.