

LEADING CLINICAL TRIALS FOR CANCER

A conversation with **JIE HE, M.D. & PH.D.**, Director, National Cancer Center; President, Cancer Hospital, Chinese Academy of Medical Sciences



Cancer is the focus of countless researchers and drug developers. In China, a leader in cancer clinical trials is the Cancer Hospital, Chinese Academy of Medical Sciences (CHCAMS). Housing the National Cancer Center (NCC), its Clinical Trials Center is one of China's first for anti-cancer drugs. Here, the president of CHCAMS, and NCC director, Jie He, discusses CHCAMS's role in standardizing China's cancer clinical trials.

How is China progressing in anti-cancer drug research?

Cancer is a leading cause of death in China. According to the latest data from NCC, there are an estimated 3.93 million new cancer cases, and nearly 2.34 million cancer deaths nationally each year. A series of policies have been issued to align China's cancer drug review, approval, and regulation systems with international standards. China's joining the ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) marks a milestone in this effort, demonstrating the country's commitment to transforming its pharmaceutical regulatory bodies, ensuring safe and effective drugs. This has led to rapid progress, and clinical trials are thriving in China.

What role does CHCAMS play in leading clinical trials on cancer drugs?

As China's top-ranked cancer hospital, our history of clinical research on cancer tracks the development of trials in China. We initiated our first clinical trial in 1960, on N-formylsarcosylsin for seminoma, which was China's first cancer trial. Since then, we have conducted more than 2,600 clinical trials, leading nationally. We've seen 126 cancer drugs approved for the market, benefiting cancer patients in China and beyond.

What is the goal for CHCAMS to establish the Clinical Trials Center?

We established the Clinical Trials Center to promote research on anti-cancer drugs, technologies and treatment approaches. The goal is to improve cancer prevention and treatment capabilities, better serving population health.

We established China's first ethics committee for cancer clinical trials, led China's first international multicentre trial of anti-cancer drugs, set technical standards for clinical studies, and cultivated many professionals for cancer trials. Aiming to become a world-class clinical research institution, our centre has established a centralized management system for cancer clinical trials, enabling one-stop service. As a result, quality and efficiency of clinical trials have been improved, and CHCAMS is ranked as China's best clinical trial institution of 2019 in a review organized by the journal, *Progress in Pharmaceutical Sciences*.

How do you strengthen international collaboration in clinical trials?

We have collaborated with pharmaceutical companies around the world since the 1990s. As China's first hospital to conduct international multicentre trials, we have led clinical trials for Bristol-Myers Squibb, Sanofi, Pfizer, Roche, and AstraZeneca on their

products, which have provided high-quality treatment options for Chinese cancer patients.

Since joining ICH in 2017, China has officially become part of an internationally recognized drug regulatory system, and enhanced its drug regulatory and clinical study capabilities. As more multinational companies are moving their R&D operations to China, we are taking the opportunity to enhance collaborations. By fully adopting ICH technical guidelines and quality control systems for clinical trials, we have accelerated trials and improved quality. We have become the preferred strategic partner for multinational companies to organize clinical trials on cancer drugs. In the past three years, we have conducted 82 international multicentre trials, including leading two phase-III and three phase-I trials globally.

What are the measures to enhance team-building for clinical trials?

A professional research team is essential for ensuring the quality of clinical trials. By piloting new models of team management, we are among the first in China to build a multidisciplinary, high-quality, professional team for cancer clinical trials, comprising physicians, pharmacists, nurses and statisticians. They work on every aspect of clinical trials, from design, implementation, patient management, and data collection, to quality

control. Meanwhile, CHCAMS has established a continuing education system for clinical trial professionals, offering training for researchers, clinical research associates/coordinators, and other clinical trial practitioners on guidelines, protocols and other basic knowledge to improve their clinical research capabilities. Our efforts have ensured the supply of quality clinical research professionals for China.

How does CHCAMS promote translational research?

Focusing on the balanced development of medical research, education, services and disease prevention, CHCAMS emphasizes effective translation of basic research into clinical practice, and has established a system with multiple platforms in support of translational research. For common cancers such as lung cancer and esophageal cancer, we have set a complete system of disease prevention and treatment, linking R&D and clinical application. From epidemiological studies and investigations on the biological mechanisms of cancer etiology and progression, to clinical studies on the effects of new drugs or intervention technologies, we are exploring a holistic approach to cancer prediction, prevention and treatment, which is specifically suitable for the Chinese population.



Leading the battle against cancer

Cancer Hospital, Chinese Academy of Medical Sciences (CHCAMS)



#1 cancer hospital in China

- China's **first hospital** specializing in Oncology
- Ranked **1st** for Oncology and Thoracic Surgery for 10 years on China's Best Hospitals' Leaderboard
- Serving largest number of patients annually: **1.02** million outpatients, **76,000** inpatients, **32,000** operations
- Total funding: **>400** million yuan for scientific research during the 13th five-year plan (2016-2020)
- Annual publication: **771** papers in 2019

A leader in cancer clinical trials

- Cancer clinical trials conducted since 1996: **1221**
- Cancer clinical trials led since 2013: **312**
- Anti-tumour drugs approved to go on market through its clinical trials: **136**
- Cancer drugs approved in China through its clinical trials: **82%**
- Principal investigators leading cancer clinical trials: **193**

A national pioneer in cancer clinical trials

Housing the National Cancer Center, with **four** dedicated national platforms

- National Cancer Registration Center
- National Clinical Research Center for Cancer
- National Center for Quality Control of Cancer Diagnosis & Treatment
- National Clinical Trials Center for New Drugs



Milestones of Clinical Trial Center

1960	1983	1996	1997	2017
Initiated the first anti-cancer drug research (N-formylsarcosylsin)	Established the first clinical pharmacological institute on anti-cancer drugs	Established the first ethics committee for clinical trials on anti-cancer drugs	Approved as the first batch of national clinical research centre for anti-cancer new drugs	Implemented a centralized management system of clinical trials