Media Release

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European and Chinese scientists, regulators and ethicists meet to address ethics of clinical trials

BIONET's third International Workshop on International Clinical Drug Trials in Xi'an took place from 9th to 12th September 2008.

BIONET, the European-Chinese consortium on the ethical governance of biomedical research, has concluded its third international workshop in Xi'an, PRC. The focus of this workshop was on clinical trials for drugs and other treatments for diseases, and the role of clinical research organizations. Since the mid 20th century, clinical trials (especially randomized controlled trials) have emerged as the gold standard for evaluating the efficacy of a drug or treatment, and as an 'obligatory point of passage' in translation work from bench to bedside. There are an estimated 50,000 clinical trials being run worldwide today. In recent years, pharmaceutical companies have increasingly contracted clinical research organisations (CROs), which specialise in carrying out clinical trials, to carry out the bulk of their clinical trials. These CROs, which are often based in America or Europe, increasingly 'offshore' trials to Eastern Europe, Latin America and Asia. The reasons for such offshoring can range from an economic drive to rationalise and save costs, the growing difficulty of finding 'treatment naïve' populations in western countries, and a perception that ethical standards are lower in some countries. The value of the worldwide clinical trial industry has been estimated at $50 billion, and China has now overtaken India in the number of trials conducted, not least because it is forecast to be the world's fifth-largest pharmaceuticals market by 2010.

Such a situation raises numerous ethical and regulatory issues: not simply the scientific standards for the conduct of such trials and the integrity of the data produced, but also the nature and meaning of informed consent of subjects, especially when drugs are trialled on vulnerable populations; conflicts of interest between researchers and clinicians; benefit-sharing, and the need to avoid developing country populations becoming 'human guinea pigs' for those who are more well-off; and the direction of flow of economic benefits of the drugs or treatments developed as a result of such trials. At the same time it is clear that, if appropriately conducted and regulated, clinical trials can work to improve the scientific infrastructure, regulatory oversight, and treatment availability in China as well as to stimulate the process of drug discovery.

It is with these ethical and regulatory challenges in mind, that 50 Chinese and European experts met in the ancient city of Xi'an, 9-12 September, to exchange views and develop proposals for the ethical oversight and governance of clinical trials in China- Europe collaborations. The workshop heard presentations from industry, researchers, clinicians and regulators from the Chinese State Food and Drug Authority, the Ministry of Health and the

Ministry of Science and Technology and gathered a unique body of information on the historical and current situation in China, the regulatory problems and developments, and future prospects in this vital area. A valuable comparative perspective was added by presentations from Eastern Europe and India, where similar problems for regulation are arising. The results of the workshop will soon be available on the BIONET website at www.bionet-china.org

Short description of BIONET

BIONET is a network of European and Chinese social scientists, lawyers, bioethicists and biomedical researchers from 20 institutions across Europe and China, which organizes research, training, workshops and conferences on the ethical governance of research in the life sciences and biomedicine within and between China and European countries. BIONET commenced its work in October 2006 and has held workshops in China on assisted reproductive technologies, and on stem cells, and one international conference on reproductive medicine and stem cells in research and treatment. Following the Xi'an workshop, there will be one further workshop in China on genomic research and biobanking in April 2009, and a final Conference will be held in September 2009. A key outcome of BIONET will be a set of recommendations on standards and guidelines for best practice in the Ethical Governance of EU-China Research collaboration in the Life Sciences and Biomedicine.

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More details of BIONET, and copies of publications, can be obtained from:
www.bionet-china.org

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