bionet UPDATE
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SIXTH FRAMEWORK PROGRAMME

International clinical trials

Hu Qingli addresses workshop participants

In September 2008, BIONET held its third workshop on ethical issues surrounding the governance of clinical trials, especially in contexts of international collaboration where European companies or institutions carry out such trials in China. A total of 60 speakers and participants gathered in Xi'an for a frank and constructive exchange about some of the many challenges 'on the ground' facing partners who engage in clinical trial collaborations. Participants included clinicians, ethicists, regulators, lawyers, medical company representatives, pharmacologists as well as government officials. Speakers examined the different factors which contributed to making China an attractive place to carry out clinical trials, as well as the kinds of ethical challenges that resource inequalities as well as conflicts of interest between researchers and clinicians gave rise to. Another key issue discussed was that of ethical review and capacity building efforts. While many steps have been taken to build up a national system of ethical review of biomedical research in China, a number of challenges remained, including lack of resources, lack of qualified members of committees as well as what form a national system of ethical review should take (eg, based on institutional review or provincial/national review?). Finally, another key issue discussed was that of data quality as well as capacity for reporting and monitoring, all of which could affect the safety of human subjects.

A comprehensive workshop report is available for download from the BIONET website: **www.bionet-china.org**

Expert Group: Working towards a best practice guide

Co-chairs Qiu Renzong (left) and Christoph Rehmann-Sutter (middle) with Expert Group member Herbert Gottweis speaking to media

The Xi'an workshop in September 2008 provided a host of evidence for the existence of a gap between international ethical guidelines (like the Helsinki declaration or the CIOMS/WHO guidelines) and the reality of human subject research in international clinical trials, which involve European and Chinese partners. The Expert group is working towards recommendations for 'best practice' in ethically governing EU-Chinese research collaborations. The field of clinical trials proves to be one of the hot spots where issues like power imbalance, dependency, legal differences and different availability and levels of medical treatments play a role. On the basis of the results of the previous workshops and conferences, the Expert Group is currently analysing, which will be the most urgent points to consider in improving ethical protection of human subjects under such circumstances.

Consensus about the normative principles that make clinical research 'ethical' is evidently not sufficient for establishing the appropriate institutional and regulatory frameworks on the ground. Much more is needed. The formal adoption of international guidelines does for example not guarantee that local research ethics committees have enough legal power to effectively safeguard the rights, dignity and to protect the health of study participants. Informed consent procedures need to be quality assured in order to meet the local requirements, which may differ according the economic, social and cultural conditions at a trial site. Good follow-up care of clinical trial participants needs to be guaranteed. When international partners collaborate, the legal authority of ethical review procedures needs to be clarified: Where and who should ethically review trials involving international partners? Adequate training of ethics committee members needs to be developed, and the working procedures of these committees need also to be evaluated in order to meet appropriate criteria of procedural fairness in the decision-making process. Additional issues can emerge in situations of power imbalance between multinational pharmaceutical and clinical research industries on the one hand and local clinics and their patients on the other.

These are only a few of the questions the Expert Group is currently working on, in order to develop a set of recommendations for regulators and involved parties on all sides of international studies. Previous workshops have provided information about research in the fields of reproductive medicine and stem cells. The next workshop will add genomics and biobanks. Provisional results shall be presented and discussed at the final BIONET conference in London in September 2009.

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Workshop four on biobanks and genomic research

DNA sequencing at the Beijing Genomics Institute

The European-Chinese research consortium, BIONET (Ethical Governance of Biological and Biomedical Research: Chinese European Co-operation) will hold its fourth workshop from 27-29 April 2009 in Shenzhen.

BIONET is sponsored by the European Commission and the UK's Medical Research Council from 2006 to 2009. With its 21 European and Chinese partners, this collaborative programme is networks between China and Europe, to examine the challenges of the ethical governance of research in the life sciences and biomedicine in collaborative researches between China and the EU. Its focus is on three key areas: reproductive and regenerative medicine, clinical trials and biobanks and the genomics of disease. Three state-of-the-art reports have been made publicly accessible (**www.bionet-china.org/Default.htm**).

The BIONET's workshop in Shenzhen is generously hosted by Professor Yang Huanming (Beijing Genomics Institute – Shenzhen). The theme will be 'Biobanking and Genomics: Challenges and Futures for China-Europe Collaborations'. At this exciting event, we expect participation of approximately 50 delegates from different disciplines and international backgrounds as well as experts from governance, social sciences, bioethics, legal and industry perspectives.

This workshop will organise a platform for state-of-the art discussion of the currently perceived issues, the described challenges and prospective future scenarios in Chinese-European activities in Biobanking and Genomic Research. The results will feed into the network-building and mapping tasks which are the major purpose of BIONET.

At present, there are still a few seats available for participants who wish to attend and contribute to the high-level expert debate. There will be no participation fee. The organisers can help to arrange accommodation on a self-pay-basis. Enquiries about the workshop should be addressed to:

Dr Ole Doering, Senior Research Fellow, GIGA-Institute for Asian Studies (Hamburg), at: **doering@giga-hamburg.de**; and

Su Yeyang, Director's Assistant in Bioethics, Beijing Genomics Institute, at **suyy@genomics.org.cn**; as the co-organisers of this workshop.

Applications should be accompanied by a short CV and a letter that elaborates serious interest!

Deadline for applications is 20 December 2008.

Student exchanges

In BIONET's second year, a further three postgraduate students were awarded BIONET student stipends to help them in carrying out cross-cultural research into social and ethical implications of biological and biomedical research. Chen Haidan from Zhejiang University in Hangzhou travelled to Austria and London to attend events and meet experts to help her with her PhD project 'Regenerating China: Stem Cell Politics in Transition'. Anika Mitzkat of the University of Witten-Herdecke in Germany spent two months in Changsha carrying out interviews and observations for a pilot project on 'Embryo donation for research in China'. And finally, Sui Suli of the Amsterdam School for Social Science Research spent three months in China to learn about genetic testing and counselling practices in the United Kingdom as compared to in China (the latter being the topic of her PhD). In the final year of BIONET, a total of five student stipends have been awarded.

BIONET exchange student stipend recipient Joy Zhang

Final conference in September 2009

The final conference of BIONET will take place 1-4 September 2009 in London. The conference will focus on the findings of the BIONET project by focusing in particular on issues surrounding collaboration between Chinese and European biomedical and biological researchers. Invited speakers and BIONET partners will reflect on questions around 'Why collaborate?', 'Where are collaborations taking place?' as well as 'What are the challenges of collaborating?'. For advance information about this final conference please contact Dr Ayo Wahlberg (**a.j.wahlberg@lse.ac.uk**).