QUALITY SYSTEMS IN HEALTH RESEARCH, MONGOIA

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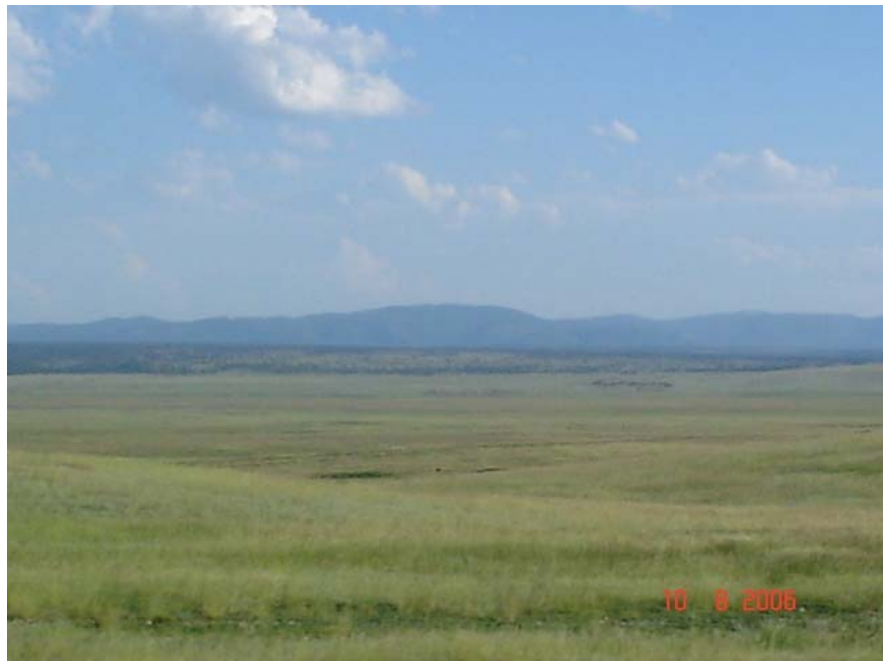
Mongolia at glance

Mountains (North)

Steppe (central)



Mongolian gobi features (south)

Mongolia at glance

- **Location.** Completely landlocked between two large neighbors - Russian Federation and China.
- **Administrative subdivisions.** 21 aimags (provinces), the capital city (Ulaanbaatar). The aimags are subdivided into soums, or district of which there are around 350.
- **Population.** The population of Mongolia is at present 2,5 mil. people. 51% live in urban areas, 1.5 per sq km.

Initiatives have been undertaken to ensure quality systems in research. GCP principles implementation.

- Since 1998 in Mongolia have started much more activities to improve of ethical review in health research and health professional.
- Health professional ethical review committee by the MOH was established in 1999 and approved its regulation and ethics norms of health professionals.
- The committee had 2 main functions: ethical review related to health professional activities in relation to health care and health research ethical review.

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- This committee reestablished in 2002 and renewed the regulation and norms.
- Since 2002 ethical review committee meetings were conducted regularly. But we have some weakness to conducting ethical review of health research projects.
- Since 2000 have translated main health research ethical review guidelines of WHO and CIOMS and used to biomedical ethical review in our country.

Initiatives have been undertaken to ensure quality systems in research. GCP principles implementation

- MOH conducted number of trainings and workshops on biomedical ethical review with the financial and technical support of WHO and FERCAP. As its result health research communities have an enough understanding on biomedical ethics and are using it for improvement of health research quality.
- Currently, 2 ethics committee are functioning at the MOH:
  - Ethics committee on health professional activity and
  - Ethics review committee on health research.

GCP principles implementation

- For implementing of GCP in health practice, MOH had initiative to translate it into Mongolian and it was translated and used to health research practice.
- Main principles of GCP included in “Regulation of new drug registration in Mongolia” and approved by Health Minister’s order #86 in 2004.
- Nowadays, the regulation is used to investigating, producing and importing of new drugs, preparations and vaccines in Mongolia.

Public agencies/government organizations and ensuring quality health research

- Health Law on Mongolia is revised and approved in 2006. According to the initiative of MOH had added some new articles to the Law, which are improved legislative environment of bioethics in our country. These are:
  - Article 23.3. Ethics review committee will be established at the MOH. SOP and ethics norms or principles are approved by Member of Government, who responsible of health related matters (unofficial translation).
  - Article 34.2. Doing complicated diagnosis and surgery, involving of human subject to health research is need a writing and informed consent of patient and participant; parents and legal representative of children under 18 year old and patients with psychological disorders (unofficial translation).

Public agencies/government organizations and ensuring quality health research

- Article 42. Testing and Introduction of New Methods of Diagnosis, Treatment and Prevention (unofficial translation).
  - 42.1. Testing and Introduction of new methods of diagnostics, treatment and prevention shall be done with the permission of the State Central Administrative Body handling health matters (unofficial translation).
  - 42.2. New methods and technology of diagnostics, treatment and prevention shall be introduced for medical practice after clinical trials are completed (unofficial translation).
  - 42.3. Regulation on taking and using of blood and blood productions samples, biological liquids, tissue and organ on purpose to conducting of clinical trials and health research shall be defined and approved by the State Central Administrative Body handling health matters (unofficial translation).

Ethical review structure and practice.

- Biomedical Ethics Review Committee established at the MOH in 2007 and its structure and SOP approved by the Order of Heath Minister, #223.
- Biomedical ethical review committee chaired by Vice-Minister and Chairman of Science and Technology Council of MOH.
- ERC has 13 members including health research organization representatives, health researcher, pharmacologist, ethicist, lay person, nurse, NGO and lawyer.
- ERC meeting was held 4 times and discussed health research projects with domestic and external financial support and approved.
- Recent months we are planning to establish subcommittees as IRB.

Facilitating factors, barriers and gaps to quality systems in ethical review

- Facilitating factors are support of Mongolian Parliament and Government (MOH) WHO, FERCAP. Understanding and supporting of health research organizations and health researchers are other main facilitating factors.
- Main barriers for improving health research quality system is weakness of training and support of attending researchers to foreign good quality and intensive trainings on ethics review.

National registry system of clinical trials

- Conducting of clinical trial is regulating according to the Health Law and regulatory document as, I mentioned above (Health Law and Order of Health Minister #86, 2004).
- Currently, there is no official registration of clinical trial.
- But all health research projects implemented and implementing in our country have listed at the MOH and Ministry of Education, Culture and Science.
- Also, we can use ERC meeting agenda and discussed materials.

THANK YOU