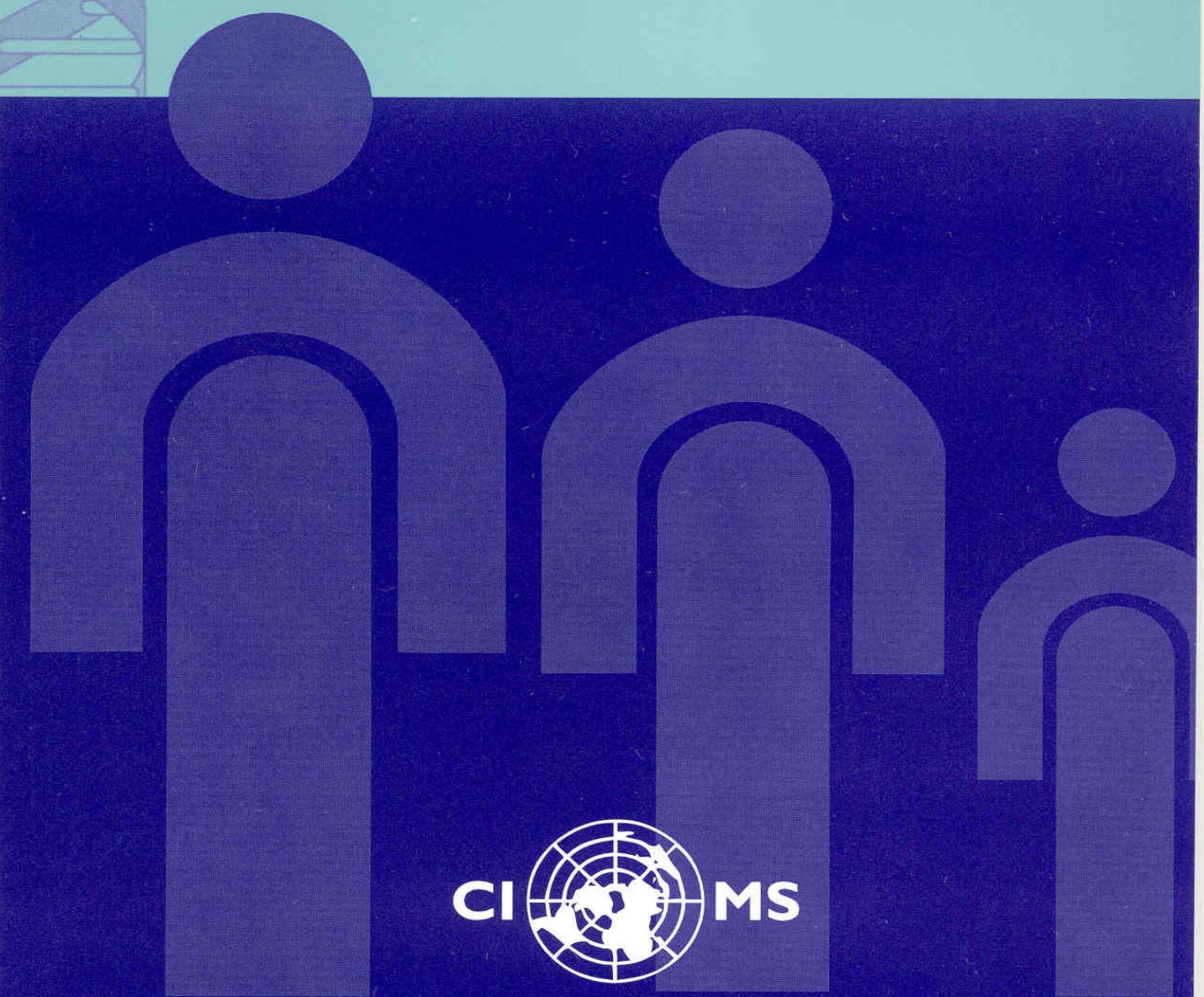
Pharmacogenetics

Towards improving treatment with medicines



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Annex 8

Pharmacogenetics and Pharmacogenomics in the Republic of Korea

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1. Guidelines

1. Bioethics and Biosafety Law (to be effective in January 2005)
   1.1 A National Bioethics and Biosafety Review Committee will be established under direct control of President by the law. The guideline will request institutional bioethics review board be established in each institution dealing with embryo, gene bank and gene therapy, etc. (article 6 and article 10)
   1.2 Facilities testing genetic information should receive quality accreditation by minister of Ministry of Health and Welfare. Genetic tests of scientific ambiguity that may mislead test subjects are prohibited. Genetic testing of embryo or foetus is allowed only for the diagnosis of heredity disease that Presidential decree decides. (Article 24 and article 25)
   1.3 Genetic information must not be used to differentiate individual in social activities such as education, employment, promotion, or insurance. The genetic test or the submission of the test result must not be forced. The director or employee of facilities performing genetic test must not release the genetic information of a person to another without proper justification or must not use the information for improper purpose. (Article 31 and article 35).
2. Research Guideline for Functional Analysis of Human Genome
   http://www.elsikorea.org/, http://www.koreabioethics.net/ (June 2002)
   The essential contents of the guideline are focused on several issues. (1) Specimens from human beings can be used in human genome research. (2) Another issue is autonomy or the right of self-determination of the potential subjects. When researchers select the human subject, they must respect his/her autonomy. To protect the potential subject's autonomy, researchers must get the informed consent. (3) The third issue is to protect the individual's genetic privacy. To protect the individual's genetic privacy, the genetic information must not be linked with the individual's medical record. And the disclosure of individual's genetic information must be banned. (4) The IRB (Institutional Review Board) can be a responsible

body to control the scientific quality of research and the ethical and/or legal problems of research. (5) And researchers can use the genetic counsellor system to assist in getting informed consent, resolving the conflicts between researchers and subjects, and so on.

3. Korean Association of Institutional Review Boards (KAIRB's): comprehensive guideline for IRB Standard Operating Procedures (February 2003) was published as a monograph by KAIRB.

2. Projects to establish a foundation for Pharmacogenomic research

1. Korean Pharmacogenomics Research Network (KPRN)
   - 1.1 Schedule: FY2003- FY2011 (9-year term)
   - 1.2 Budget: 21 million USD for 9 years
   - 1.3 Aim: Discovery of polymorphisms related to drug safety and efficacy in Korean population and clinical application of pharmacogenomics information.
   - 1.4 Scope: 5 specific pharmacogenomic research centers focused on adverse drug reaction, drug metabolism, drug transporter, respiratory drug, and CNS drug pharmacogenomics.
   - 1.5 Project Leader: Professor Sang-Goo Shin (Seoul National University)
2. National Research Laboratory for Pharmacogenomics
   - 2.1 Schedule: FY2003- FY2007 (5-year term)
   - 2.2 Budget: 3.3 million USD for 5 years
   - 2.3 Aim: Application of pharmacogenomics to clinical practice.
   - 2.4 Scope: Relations of pharmacokinetics and pharmacogenomics.
   - 2.5 Project Leaders: Professor Jae-Gook Shin (Inje University) and Hyong Doo Shin (SNP Genetics Inc.)
3. Hap Map Project
   - 3.1 Schedule: FY2003-2008 (5-year term)
   - 3.2 Budget: 9 million USD for 5 years
   - 3.3 Participant: JE Lee (DNA Link, Inc.), JJ Hwang (Samsung), KY Song (Ulsan Univ), JM Yang (Seongkyunkwan Univ.), and CB Kim (NIH bioinformatics)
   - 3.4 Aim: Haplotype and LD mapping (Chromosome based + gene based approach) of Korean genome
   - 3.5 Scope: As a start, chromosome 22 is targeted (about one million genotyping/year, about 10,000 SNP/year)
   - 3.6 Project Leader: Kyuyoung Song (Ulsan University)
4. The Center for Functional Analysis of Human Genome
   - 4.1 Schedule: FY1999-FY2009 (10-year term)
   - 4.2 Budget: 90 million USD for 10 years
   - 4.3 Aim: Large-scale isolation of genes and proteins associated with diseases most characteristic of Korean populations. Identification of candidate target genes from in-depth functional analysis. Development of novel, genome-based diagnostics and therapeutics. Establishment of tech-

nological basis on which to build the national competitiveness in bio-industry and by which to contribute to the improvement of human welfare
   4.4 Scope: genomic research on gastric and liver cancers, etc.
   4.5 Project leader: Hyang-Sook Yoo (KRIBB)
5. Disease and Pathogenic Microbe Genomics
   5.1 Schedule: FY2001 – FY2011 (10-year term)
   5.2 Budget: 62 million USD for 10 years
   5.3 Aim: Disease and pathogen related functional genomics
   5.4 Scope: 11 disease specific genomics centers and 3 pathogenic microbe specific genomic centers
   5.5 Project management: Ministry of Health and Welfare, National Institute of Health
   5.6 Project coordinator: Professor Yangsoo Jang (Yonsei University)

3. Activities

1. Ministry of Health and Welfare; funding the Korean pharmacogenomics research network, disease genomics, pathogenic microbe genomics, proteomics research center.
2. KFDA (Korean Food and Drug Administration); preparing guideline for application of pharmacogenomics in drug regulation
3. Ministry of Science and Technology; funding National Research Laboratory for Pharmacogenomics, planning to fund the research in the toxicogenomics in non-clinical field
4. Academia
   4.1 Pharmacogenomics Research Study Group was established in June 2001 with over 100 members working at universities and drug industries. Regular research seminar and symposia are arranged by the network.
   4.2. PharmacoGenomics Research Center (PGRC) was established in January 2003 in Inje University, Busan.
   4.3 International symposia:
      4.2.1 Yonsei Biomedical Symposium: February, 2003, Seoul
      4.2.2 Pharmacogenomics: Impact on clinical trial – October, 2003, Seoul
      4.2.3 Pharmacogenomics: A step toward personalised pharmacotherapy – February 2004, Busan, organized by KPRN and PGRC.

4. Pharmaceutical Industry

Many drug discovery and genotyping bio-ventures are investing in this field. Several bio-ventures are applying the genotype to clinical practice. Multinational pharmaceutical companies are sponsoring several clinical trials searching any relation between drug efficacy/adverse effect and specific genotypes. A global pharmaceutical company sponsored a genotype-phenotype association study of CYP enzymes using probe drugs as cocktail administration. The study was done in Caucasian, Japanese and Korean, simultaneously. Pharmacogenetics/genomics is becoming an important issue in new drug approval especially related to the ethnic sensitivity of a drug by ICH E5 foreign clinical data acceptance guidance.



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