DEVELOPMENT OF A CLINICAL TRIALS REGISTRY IN JAPAN

Kiichiro Tsutani1, Takahiro Kiuchi2, Yasuo Ohashi3, Eiji Uchida4, Hisako Matsuba1
1) Department of Pharmacoconomics, Graduate School of Pharmaceutical Sciences, the University of Tokyo
2) University hospital Medical Information Network (UMIN) Center, the University of Tokyo
3) Department of Biostatistics/Epidemiology and Preventive Health Sciences, School of Health Sciences and Nursing, the University of Tokyo
4) Clinical Trial Support Center of Showa University Hospital

BACKGROUND
The needs of the clinical trials registry (CTR) have been discussed, and several projects have started since the 1990s, although they have not been quite satisfactory. After the anti-depressant scandal in New York in June 2004, awareness has rapidly grown and global discussion of the topic as well as a new CTR project was initiated by concerned groups. Presently, however, the situation is still fluid and somewhat chaotic. This study aims to review the global status of CTR and introduce the UMIN-CTR, which is the first attempt to develop the CTR system in Japan using public funds.

METHODS
Literature search, internet search, meetings, and interviews with relevant key persons.

RESULTS (JAPAN)
In Japan, a Working Group on CTR was established in October 2004 to develop policy and discuss technical issues on UMIN-CTR. A symposium on CTR to introduce an alpha version of it and to have public comments was held on 2 February 2005. The system is currently under revision [http://www.umin.ac.jp/ctr/index-j.htm]. Full implementation is scheduled to start in April 2005. Fig.1 shows the “what is UMIN-CTR?” page on the web. Table2 shows characteristic of UMIN-CTR, compared with various major CTR systems. Fig. 1 UMIN-CTR website

http://www.umin.ac.jp/ctr/index-j.htm

Table 2 characteristics of UMIN-CTR and other CTR systems

<table>
<thead>
<tr>
<th>Feature</th>
<th>UMIN-CTR</th>
<th>...</th>
</tr>
</thead>
<tbody>
<tr>
<td>...</td>
<td>...</td>
<td>...</td>
</tr>
</tbody>
</table>

CONCLUSIONS
Close collaboration with international agencies, including WHO, as well as internal collaboration within Japan is strongly recommended for more comprehensive and user-friendly system development. A wide range of opinion was observed both globally and domestically. Ethics, ensuring compliance, and the role of government were among the hot topics.