Tri-party Clinical Initiatives and Its Prospective

MULTI-REGIONAL CLINICAL TRIALS SEOUL WORKSHOP, Inaugural Workshop of the APEC Harmonization center.

Ding Jianhua
State Food And Drug Administration
April 15, 2009, Seoul
Past Activities

• 2005, MOU between three Health Ministers of Korea, China and Japan in Seoul. Established the milestone for clinical trial cooperation within that region, in considering the possibility that its population differences might be very small.

• 2007, the first Tri-party meeting with public symposium on clinical trial followed in Tokyo.

• Some academic actions taken placed on some disease, initiated by Japan
2009 activities

- Working group need to be established
- Working group meeting should be held as soon
- Second Symposium on clinical trials could be held in China after working group meeting.
MOU of KFDA-SFDA

- Signed April 27, Beijing, SFDA office by Yun, YeoPuo, KFDA commissioner, and Shao Mingli, SFDA commissioner
- Effective in Korean, Chinese and English
- Cover area: food (health food), drug (nature product), medical device, cosmetics
- Mechanism: high-level annual meeting rotating by country
- Workgroup: 4 groups, food, drug, medical device, cosmetics, working-level meeting annually on rotation base, industry and third party could be invited upon consent
Cooperation Area - KFDA-SFDA MOU

- Exchange of information: regime, legislation, regulatory approval, other relevant policy.
- Mutual exchange of product safety information: imported and exported pharmaceutical products concerned
- Inspection support: for safety problem, facilitate inspections to each other
- Joint Symposium
- Joint Training course
- Promoting exchange of information on exported products
Yun, Yeopuo, KFDA Commissioner, and Shao Mingli, SFDA Commissioner, photo after MOU signature ceremony in Beijing April 27, 2009
Group photo of KFDA and SFDA after signature ceremony in April 27, 2009
MOU of MHLW-SFDA

- Signed March, by fax signature, between SFDA Commissioner and MHLW vice-Minister
- Effective in Chinese and Japanese
- Cover area: drug, medical device, cosmetics
- Mechanism: annual meeting rotating by country,
- Workgroup: 2 groups, drug, medical device. More working group could be set up. Qualified association could be invited to attend working group meeting upon consent of two sides.
Cooperation Area - MHLW-SFDA MOU

• Achieve and maintain safe and health for the people of both country, by establish bilateral understanding and trust of each other.

• Constructive discussion on laws, regulation and other related regulatory issues, including the current status, and the development in relation to its administrative measure and implementation.

• Respect international responsibilities of each other in the area of drug and medical device.

• Contribute to a health development of China-Japan relationship by drug and medical device cooperation activities.
MOU Conclusion

• Mainly focus on information exchange, communication, understanding, cooperation
• Annual meeting, working groups as mechanism
• Third party could be invited as agreed by two side
• However, no specific objective related to CLINICAL TRIAL.
• A Tri-party MOU could be very useful to cover specifically on regional CT
Something for Tri-party in CT?

- **Objectives:** need to be more clarified and indentified.
- **Organizational structure:** some structure need to be established based on objectives. Such as working group composition, decision making group and its structure, the participation of regulatory body and industry representatives. (ICH a model)
- **Plan:** activities better to be planed in advance
- **Openness:** third party participation and support, such as ICH, APEC LSIF, WHO, general public, to keep transparent.
- **Importance:** legal base need to be early established if there is any result coming out in future
- **Minority population diversification:** China along has 56 minorities.
Cooperative with ICH?

- **A goal of ICH?** (if ICH taking this regional efforts as its guideline implementation input?)
- **A result of ICH?** (If ICH guidelines E5, workable during procedure?)
- **Any support from ICH?** (whether issues considered by ICH and the role of issue within ICH?)
- **Any further influence on ICH?** (whether its result can make some effect on ICH output?)
Conjunction with Ideas as Simultaneous Development?

**Simultaneous Development**: good idea for early availability of treatment of patients with great health needs.

- How this regional effort will be seen by Europe, US as valuable to its R&D?
- How this regional effort will be seen by Regulatory body of Europe, US when CT data produced by the region is used for submission?
- How this regional effort will be seen by pharmaceutical company as influential factor to its multi-center clinical trials strategy globally?
Suggestions

- APEC LISF, ICH, industry, third party, could be invited to listen to, or observe the progress.
- ICH should pay good attention on this issue.
- The issue could be taken more formally under the framework of APEC LISF.
- Priorities should be decided on disease three parties felt important.
- A new MOU between KFDA, SFDA, and WHLW should be early established to stimulate the progress.
- Academic conclusion should be worked out for some area of indication as technical basis to facilitate decision making.
Thank you for your attention!

Email: Dingjh@sfda.gov.cn