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## 가교시험 현황

장 정 윤

식약청 기관용의약품팀

The concept of the bridging will be introduced with the ethnic factor. The bridging data based on the recent data is that waiver of BD was 44%, bridging data obtained by PK, PD-dose response and confirmatory study was 50%. Each category of bridging waiver is the orphan drugs, drugs for the life-threatening disease or AIDS, diagnostic topical drugs and drugs that have demonstrated no ethnic difference. The product name in each category will be deal with under our experience.

The PK study for bridging is accepted if the drug has similarity of ethnic extrinsic factor, wide safety range and PK-PD and dose response relationship well established. Up to now, about 70% of bridging is performed by confirmatory study. The example of dose adjustment is Actos tablet, Crestor Tab, Morniflu Tab. The reason of the dose adjustment will be shown.

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**Education and Working Background**

May 2004 ~ August 2005	Postdoctor in Cornell Biomedical engineering July.
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Mar 1998 ~ Aug 2002	Ph.D. in Pharmacy, Seoul National University, Seoul, Korea
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**Publications**

1. Jung Yun Chang, Yu-kuoung Oh, Hak Soo Kong, Eun Jung Kim, Dong Deuk Jang, Ki Taek Nam and Chong-kook Kim, "Prolonged antifungal effects of clotrimazole-containing mucoadhesive thermosensitive gels on vaginitis," *J. Controlled Release*, Vol. 82, (2002) 39-50.
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5. Chong-kook Kim, Jung Yun Chang and Woon Yong Na, "Efficacy test of compound digestive enzyme product containing antacid, digestive and herbal medicine (II)-Digestive activity" *J. Kor. Pharm. Sci.*, Vol. 20, (1990) 209-215.
6. Chong-kook Kim, Eun Ju Jeong and Jung Yun Chang, "Effect of lymphatic uptake of hepatitis B surface antigen on the production of hepatitis B antibody," *Proc. Mol. Biol. & Genet.*, Vol. 5, (1990) 331-334.