Review of bridging data generation studies

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For the approval of drugs developed in foreign countries, KFDA adopted bridging concept of ICH E5 in Dec 1999. From July 2001, all the NDA should be compliant to bridging concept, that is the sponsor should submit a request for waver for bridging data on the basis of ethnic insensitivity of ICH E5 or submit NDA package with at least one clinical trial data intended for bridging. Now under the IND system, the sponsor can do practically any clinical trial in Korea to generate bridging data.

Until now, more than 8 products were waived of any local clinical data on the basis of bridging concept. Four of them belonged to orphan drug category, one was diagnostic, one was topical, and one was drug for life threatening disease. Among them one antibiotic was waived of clinical data on the basis of ethnic insensitivity and in vitro microbiological sensitivity test of local clinical isolates.

Three products were approved with single clinical trial data. All of them were pharmacokinetic (PK) studies and one was done in other country. Currently, 3 more sponsors finished PK studies and preparing for study report and/or bridging study exemption request. More than 4 sponsors are planning to do PK based bridging data generation and submitted clinical trial protocols.

Currently more than 12 local clinical trials are underway for bridging data generation as phase 3 design in Korea. Korean investigators are participating in more than 24 multinational phase 3 and phase 2 (2 trials of the 24) trials (19 products). Many of those 24 multinational trial data will be submitted as a bridging data in the future.

Until now only four products have been approved under the genuine bridging concept of ICH E5. But many new drugs will be approved in the very near future as such. For there are many clinical trials undergoing to generate bridging data. One interesting finding is that there are no dose-finding or dose-response studies done or planned in Korea for bridging data generation.