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# Internet Based Communication Strategies to Support Linezolid Bridging Programs During Global Drug Development

Thaddeus Grasela, PharmD, PhD[1], Edward Antal, PhD[2], Jon Bruss, MD[2], Tamie Bergstrom, PhD[2], Ellick Wong, PhD[3]
[1]Cognigen Corporation; [2]Pharmacia Corporation, USA; [3]Pharmacia Pte Ltd, Singapore

## ABSTRACT

**Objectives:** To describe an Internet based communication strategy to facilitate scientific collaboration during the linezolid global drug development program.

**Methods:** Population PK/PD analyses to support a bridging strategy for the approval of linezolid in Japan were captured using the PERSPECTIVE Hypertext Data Analysis Mapping software. These maps were posted to a secure, password-protected website to facilitate global collaboration on data analysis and assembly of regulatory documents.

**Results:** A series of maps were created to summarize the various steps of the bridging strategy including the comparison of pharmacokinetic and safety results from Phase I studies using healthy Japan/Asia Pacific and US/EU volunteers, PK/PD analysis of efficacy and safety outcomes from Phase II clinical trials, and simulations performed to develop dosing recommendations for Japan/Asia Pacific patient populations. Each map provides an overview of the analysis plan and provides access to datasets, graphs, programs, and executive summaries with hypertext links to supportive documentation and materials. The maps provide a central location for sharing information across a multinational corporation and the collaborative development of the analysis process and documentation.

**Conclusions:** The Internet based strategy for communication provided a mechanism for collaboration among geographically distributed scientists and greatly facilitated the performance of complicated analyses and the assembly of a concise document used to support the regulatory submission for linezolid to Japan/Asia Pacific regulatory authorities. Future use of this approach may facilitate collaborations between regulators and scientists to speed regulatory review.

## INTRODUCTION

The successful implementation of global drug development and registration programs demands a new approach to multinational collaboration. We describe an Internet-based strategy that was implemented during the global development program for linezolid.

## METHODS

### Perspective – Hypertext Data Analysis Mapping Tool

- A hypertext data analysis mapping tool for organizing and presenting results of analyses
- A real-time analysis documentation tool which facilitates information retrieval from detailed hypertext analysis documentation
- Perspective served as a basis for an Internet-based strategy for multi-national collaboration during the linezolid bridging program

### Knowledge Portal

- Secure, password-protected web site
- Provided the ability to organize, summarize, synthesize and communicate PERSPECTIVE maps
  - Data and graphics
  - Results and conclusions
  - Questions and action plans

## CONCLUSIONS

- **This Internet based strategy for communication had important benefits for the Linezolid global development program:**
  - **It provided a mechanism for collaboration among geographically distributed scientists**
  - **It facilitated performance of complicated analyses and assembly of documents for regulatory submissions**
- **Future applications may strengthen collaborations between scientists and regulators**

## RESULTS