

PHARSIGHT® Drug Model Explorer® 1.6

BENEFITS

Flexible 'What-If' Analysis on Drug Behavior and Positioning

- Answers questions on-the-spot in team meetings and with senior stakeholders
- Generates statistics on treatments, competitors and go/no-go criteria

Lower Technical Barriers to Understanding and Using Model-Based Results

- Facilitates direct interaction with and acceptance of model-based results
- Supports FDA "Critical Path" opportunity for use of model-based approaches

Knowledge Management Within and Across Development Programs

- Results are easily updated when new information becomes available
- Standard visual presentation structure and data can be leveraged across drug programs

Advanced Technology, Scalability and Ease of Deployment

- Web client is easily accessed, data are centrally managed
- Architecture and components are compatible with industry standards

HIGHLIGHTS

- Web-based client interface to compare likely product profiles and uncertainty
- Plot and table output are easily copied or downloaded to Windows-based applications
- Quick reference links to model documentation for efficient team interaction
- Desktop publishing tools prepare and upload data to secure server
- Flexibility to build models and run simulations using industry-standard software
- Browser-based tools manage system users and project data
- Support for Oracle® database
- Deployed on corporate networks and over the Internet using standard technologies

PRODUCT PROFILE VISUALIZATION TO SUPPORT MODEL-BASED DECISION MAKING

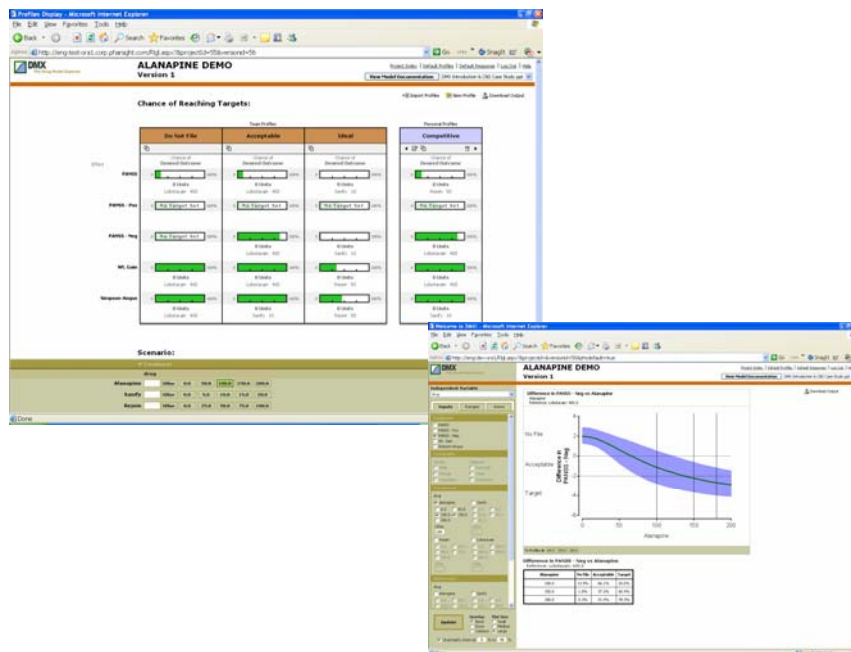
Quantitative modeling and simulation provides drug development professionals with powerful approaches to understand a compound's behavior and expected performance relative to its competitors. However, effective communication of model-based drug attributes and uncertainty is challenging and often limits a development team's ability to reach consensus on key development questions and share results with senior decision-makers.

Pharsight's drug attribute visualization software, called Drug Model Explorer (DMX®) Web Server, is a communication tool to interactively explore model-based product profiles. Through the DMX interface development team members can compare probabilistic outcomes for different endpoints, treatment strategies, patient populations, and competing products based on underlying models of clinical effect.

Pharsight believes that with DMX, companies can continue to capitalize on model-based drug development to accelerate clinical development timelines and cut development costs by making program decisions earlier and with greater confidence.

Web-Based Input Controls and Output Display

DMX provides ready access to a database of pre-simulated responses that are defined and prepared as part of the model-building process. Point-and-click controls on the DMX web client interface allow development team members to easily query this database and to specify an uncertainty (confidence) interval for a given set of input assumptions. Available inputs based on the underlying models include continuous or categorical endpoints, covariates, drug-dose selections for the compound under development and competing therapies. Use the input controls to plot your compound's expected performance versus the competition on an absolute (side-by-side) or relative (first difference) basis. DMX profiles functionality lets you directly examine the likelihood that your compound will meet its target product profile, based on specific performance criteria you set for one or more endpoints.



DMX presents results as dose-response plots and tables, and as visual summaries of predicted profile "success", that can be quickly updated based on new underlying data and simulated outcomes. Plot overlay controls support the ability to simultaneously view multiple inputs of interest, such as dose-response for a safety and efficacy endpoint and their associated covariates. DMX output are easily copied or downloaded into compatible Windows-based applications, such as Microsoft® Word and PowerPoint.

SYSTEM REQUIREMENTS

Database Server

- Oracle® 9i (Solaris 9, HP-UX) or 10g (Solaris 10, HP-UX)

Web Server

- Windows® Server 2003
- Internet Information Services (IIS) 6.0
- MDAC 2.8
- Member of Active Directory®
- Baseline server specifications: 2GHz Pentium® 4 with 1 GB RAM (2 GB RAM recommended)

Desktop Applications

- MS Windows® 2000 (SP1, 2, 3, 4) or Windows® XP (SP1, 2)
- MS .NET™ Framework version 1.1
- Internet Explorer version 5.5, 6.0 or 7.0
- Adobe Acrobat® Reader
- 256 MB RAM, 512 MB disk space (512 MB RAM recommended)
- 1024 x 768 resolution, 16-bit high color graphics display

Web Client

- MS Windows® 2000 (SP1, 2, 3, 4) or Windows® XP (SP1, 2)
- Internet Explorer version 5.5, 6.0 or 7.0 (Windows Host Script 5.6 required)
- Adobe Acrobat® Reader



For additional information

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This information applies to DMX version 1.6

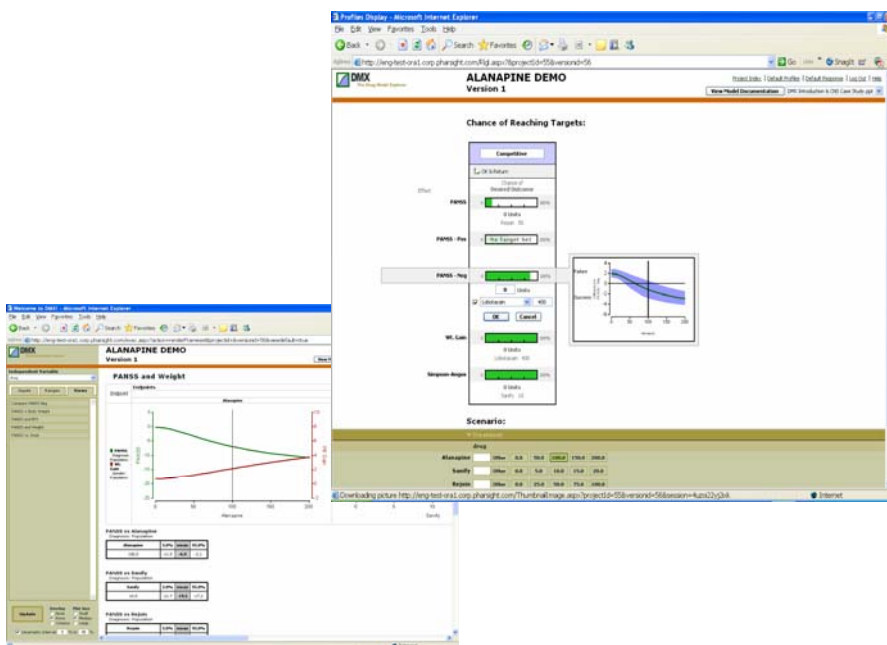
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Creation and Management of Response Views

DMX includes the ability to create and share specific "response views" - pre-defined combinations of dose-response plots and tables - that summarize important findings or provide rationale for team recommendations. DMX response views also provide a historical record of team discussion and progress.

Creation and Management of Profiles

Profiles represent a collection of success criteria defined for one or all modeled endpoints, and display the probability that a drug will meet desired targets. This functionality allows project team members to define endpoint performance targets on an absolute or relative basis (e.g., versus a competitive reference treatment), and to assemble them in the context of a product profile. The profile view presents a compact summary of the relationship between desired targets and modeled endpoints, and displays the chance that the drug effect will meet the defined target for a given set of input or treatment "scenario" assumptions. There are two types of profiles displayed by the web client: team and personal. Team profiles are created by modelers and published to the web server on a read-only basis for team review. Personal profiles are created and managed by individual web client users, either as copies of team profiles or as newly defined profiles.



Links to Model Assumptions and Documentation

The DMX web interface offers a reference link to supporting drug model documentation that can be viewed as Adobe® Portable Document Format (PDF) files or in other Windows-supported application formats. Review model assumptions, equations, and validate source data without ever leaving the DMX software. This helps provide you with increased confidence in DMX results.

Desktop Publishing Tools

Desktop publishing tools provide the essential link between simulated drug attribute data and the visual presentation of that data in the DMX web interface. These easy-to-use desktop tools convert simulation data files into a format that is loaded, interpreted and displayed by the DMX web client. Prepared files are uploaded to the server for use by the team via the web client. Users can edit model metadata (endpoint names, data labels) for clear communication with those who were not involved in the technical aspects of running the simulations prior to publishing. DMX offers flexibility to perform drug modeling and source simulations using industry standard tools such as NONMEM®, S-PLUS® or SAS®. DMX requires that simulation results be converted to S-PLUS® or SAS® format prior to publishing.

Project and Version-Based System Management

Browser-based administrative tools manage projects, permissions and users. DMX data are organized as a series of projects and corresponding project versions. Only drug development team members with explicitly assigned permissions can view projects, publish to the server, or perform other system management tasks.