Transcend Global and Corporate Boundaries During Drug Development

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ABSTRACT

Objectives: We developed an innovative and alternative web-based strategy which combines a hypertext environment with human intelligence and creativity to lead a scientific audience through complex statistical analyses with the goal to enhance decision-making.

Methods: A geographically-dispersed pharmaceutical company and Cognigen were involved with the program. A secure internet portal was used as the entrance for communication and collaboration among the scientists, data managers, and administrators involved. PERSPECTIVE Hypertext Data Analysis Mapping software was used as the differentiating component of this web-based strategy. The lead scientist used the software to document and organize the analysis results for the project. A variety of tools were used to provide passive interactive communication between scientists at their own discretionary time. Lastly, virtual meetings were conducted over the web using a web tour mechanism.

Results: The results of the complex analysis were documented and presented in PERSPECTIVE over the portal and were traversed by the scientists at their own discretion or as part of a guided discussion group. The collaboration of the scientists among the cross functional departments allowed interactions about the analysis to proceed across the traditional barriers within the pharmaceutical industry, provided education to clinicians and scientists not familiar with the analysis techniques, and improved collaborative knowledge creation. As a result, since approval of the analysis was proceeding along with performance, the final conclusions of the program were approved simultaneously. This potentially saved two months to a year of review time over traditional methods of review and approval of final program deliverables.

Conclusion: More information does not necessarily equate to better insight into a thought process. The cognitive engineering approach used by this alternative web-based strategy is possible, successful, and a cost-effective solution that has the potential to optimize product approvability and marketability.

INTRODUCTION

During the course of a complex statistical analysis, numerous graphs, charts, tables, data sets, and technical documents were generated for an interim review at defined intervals during the data collection period.

Traditionally, paper copies of these documents would then be delivered to the key decision makers via the mail system or overnight delivery service. Once reviewed, content of the documents would then be discussed via teleconferences, e-mails, or meetings. Integrating comments back into the documents required further iterations of the paper-based delivery system.

This inefficient method was labor intensive, slow, and lacked the ability to keep up with the rapid changes that occur during most project initiatives. A central location to view other collaborators opinions was unavailable, thus causing duplication of effort among those reviewing the documents and potentially unnecessary iterations of the process.

For this project, the use of an innovative, web-based strategy allowed scientists from around the world to have immediate access to the published documents. Communication and collaboration occurred in real time during drug development, when flexibility still existed for actions to be taken to adjust or change course based on the knowledge provided. Additionally, this strategy provided a resolution to the problems inherent in the paper-based system.

METHODS

Cognitive Engineering

- Human insights and information technologies were combined using a classic model of strategic decision-making during the drug development process resulting in the transformation of information into knowledge.
- Cognitive engineering harnessed intellectual capital to improve business results. It encompassed: people and how they work, access to information, ability to share knowledge, collaboration (internal and external), innovation, and tools that minimize geographic and time constraints.

OODA Decision-Making Model: Observe, Orient, Decide, and Act

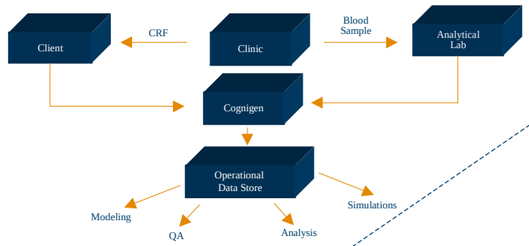
Strategic decision-making model that enables the transformation of information into knowledge and facilitates the communication of that knowledge in real-time to a global team.

- Observe: compile and organize observations; in clinical development, these are the data points.
- Orient: analyze data with respect to previous experience, new environments, and socio, cultural, and genetic factors.
- Decide: collectively apply the knowledge gained to make a decision or propose a hypothesis.
- Act: transform the decision into action. The action leads to new observations, thus completing the loop and starting the OODA process again.

RESULTS

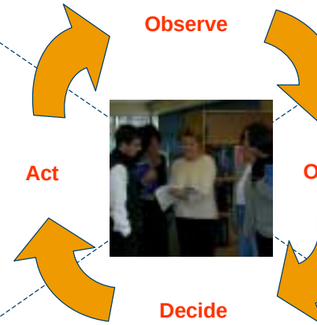
REAL-TIME DATA ASSEMBLY (RTDA)

- RTDA is a structured process for rapid retrieval, assembly, and analysis of data during clinical trials.
- Obtaining data in this manner allowed us to develop programming code to construct datasets, become familiar with the data, identify anomalies, and perform interim analysis prior to database lock.
  - When the locked database was received, we were able to immediately generate the final datasets, analyses, and results.
  - RTDA yielded a comprehensive database for analysis of drug-drug interactions, lab data, adverse events and can provide prompt feedback of drug exposure estimates for dose adjustments during the trial.
    - Interim and final results were communicated to the client via PERSPECTIVE and the Knowledge Portal.
    - RTDA was adopted by the FDA for inclusion in the 1999 Guidance for Population Pharmacokinetic Studies.



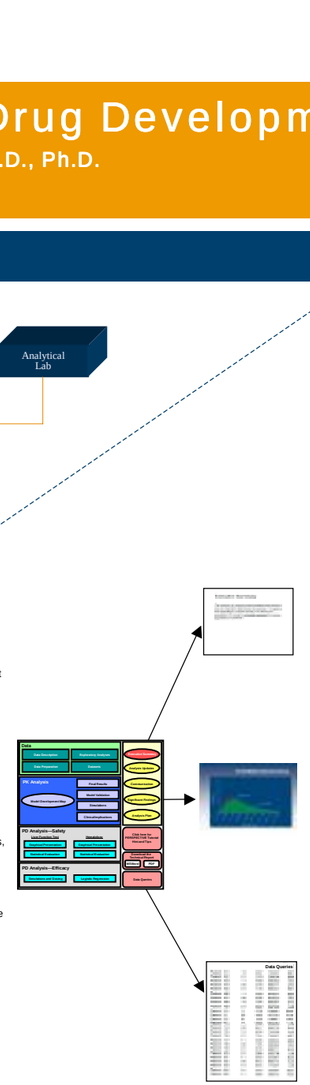
TRANSFORM

- Cognitive engineering is a living, breathing development strategy that continually generates and applies knowledge.
- Based on the transformation of information into knowledge, we were able to make critical decisions early and communicate that knowledge, creating an environment of action and strategy, where bad news was managed quickly, and good news was converted into profit.
- Flexibility was introduced into the clinical development process by adapting, regrouping, and changing course based on decisions made from available information.
- Participants were constantly learning and continually generating and applying knowledge in an effort to streamline processes to gain faster FDA approval.
- Power comes not from knowledge kept, but from knowledge shared, leading to new observations, completing the loop, and starting the process again.



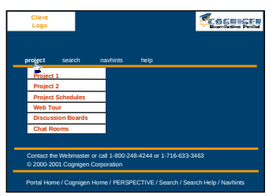
PERSPECTIVE

- As the results of the data management and data analysis activities became available, a PERSPECTIVE map and its supporting layers was built to organize, document, summarize, and house the information.
- The results were documented and organized in real time, capturing thought processes and decision rationale.
- Web enabled, graphically-oriented analysis maps provided direct access to the desired results, datasets, graphs, tables, summaries, etc., without flipping through hundreds of pages of text.
- Scientists from around the world accessed PERSPECTIVE maps via the Knowledge Portal to view the information and continually convert it into knowledge.



KNOWLEDGE PORTAL

- The Knowledge Portal provided a secure web site to enhance communications and facilitate collaborative interactions.
- Project information, analysis results, and collaboration tools were available from a pull-down menu.
- Virtual meetings were held with geographically dispersed attendees, while simultaneously viewing PERSPECTIVE maps and the underlying study-related information and analysis results.
- Attendees were automatically guided to appropriate web pages, eliminating the need to type in a web address.
- Interactive whiteboarding enabled participants to point out relevant findings during the virtual meeting.
- Various chat rooms provided a forum for interactive discussions.
- Discussion boards provided a centralized location to view comments and feedback on information available in the Knowledge Portal.

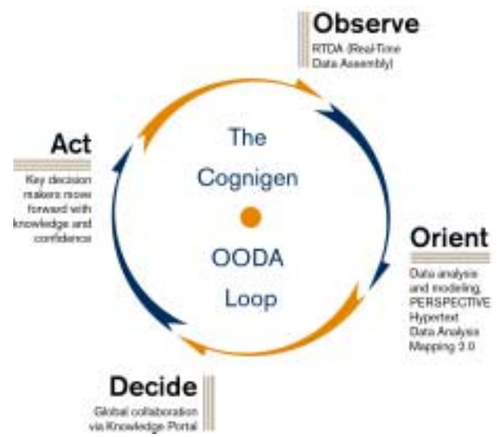


METHODS

Information Technologies

- Real-Time Data Assembly is a quality assurance program designed to gather, analyze, and monitor drug dosing and concentration-time data acquired during clinical trials.
- PERSPECTIVE Hypertext Data Analysis Mapping Software was used as the front-end for documenting and organizing the analysis results.
- The Knowledge Portal provided a secure mechanism to view the analysis results and supporting documentation.

Cognitive Engineering in Action



Human Insights and Interactions

- We formed a network of geographically dispersed people linked by collaborative learning relationships, each sharing their experience and expertise.
- Tapping the knowledge within the company and across global teams, and sharing it with the right people at the right time, enabled decisions that were more informed and timely.

CONCLUSION

- Without human creativity and collaboration, clinical development can never reach its maximum potential.
- Cognigen Corporation utilizes the Cognitive Engineering approach that cultivates the knowledge and creativity of the development teams using today's most cutting-edge technology.
- Turning insight into action, based on superior methods of communication and collaboration, helps optimize product approvability and marketability, and avoid costly mistakes.
- Knowledge accumulated during drug development needs to be readily available for global development teams to make strategic program adjustments and take advantage of the knowledge gained while studies are ongoing.