# Exsys Case Study

## Automating Complex Interviews for Clinical Trial Protocols

*Customized Improvement Strategies*

Clinical trials are a key part of the development and testing of new drugs. Setting up a clinical trial involves consideration and a complex balancing of many, often conflicting factors. This required extensive face-to-face interviews with a top pharmaceutical expert. Using Exsys Corvid®, Customized Improvement Strategies (CIS) has created an online "smart questionnaire" knowledge automation system that emulates this interview process to provide expert advice on the best clinical trial protocol for specific tests.

A Clinical Trial Protocol is a document that describes the objectives, design, methodology, statistical considerations, and organization of a clinical trial. The protocol contains a study plan on which the clinical trial is based. The plan is designed to safeguard the health of the participants as well as answer specific research questions. The protocol commonly considers what types of people may participate in the trial, the schedule of tests, procedures, medications, and dosages; and the length of the study during enrollment.

The details of the protocol strongly influence the number of participants that are likely to be willing to participate in the trial. Clinical trial participation forecasts tend to be too optimistic or the ranges much too small. Events often may be ignored that have a low probability of occurring but could significantly affect performance. CIS has extensive experience and well developed methodologies to produce accurate predictions of participation, and optimize trial protocols to achieve participation goals. However, implementation of their methodology was very human resource intensive, requiring long face-to-face interviews. CIS used Exsys Corvid and Exsys Inc. consulting services to build an online knowledge automation system that implements their interview methodology to accurately emulate the interaction with human experts.

The online, interactive system is internationally accessible 24/7 by pharmaceutical companies; and sessions can be run when convenient for participants. Using proprietary logic that is a result of over ten years of CIS clinical interview experience, system users are asked an automated series of relevant questions, which replicate the same query process that previously was administered in person. The system asks the user to complete the entire interview in a single session, but also "saves state" allowing them to leave and resume later on, automatically saving the input they already provided.

Prior to the development of the online interview, researchers would have to travel to each location to administer the 3-hour question session. By implementing the online system considerable time and costs are avoided. And by providing immediate results, enrollment is improved due to protocol optimization. The expert system also provides any feedback about the protocol and what might make it difficult to enroll participants.

David S. Zuckerman, the leader on this project, is one of the world's foremost experts in the area of pharmaceutical R&D metrics, and lectures internationally on pharmaceutical metrics and balanced scorecards.

**http://www.rx-business.com/**