CRAFT™: Facilitating Clinical Trial Execution Quality

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Abstract

The number of clinical investigators is declining in the United States¹, so it should come as no surprise that patient recruitment into clinical trials is the primary cause of study delay.² CRAFT™ (Clinical Research Analysis and Feasibility Tool) is a java-based tool that mines the Ingenix claims database to find relevant patient populations and associated health-care providers in order to accelerate clinical trial timelines.

Introduction

In a 2005 survey of investigative sites in the United States, 45% considered patient recruitment to be a major cause of study delay; an increase of 7% over 2003 figures.³ Compounding the challenge of recruiting subjects into investigative programs is finding clinicians who are willing to participate in such trials. Since 2001, there has been a 6% annual decline in the number of clinical investigators; the rate at which principal investigators permanently left the research arena doubled between 1990 and 2000¹.

The ability to find physician-investigators who can provide, from their practice populations, patients who meet clinical trial protocol specifications would significantly decrease the cost of trial conduct and decrease a new drug’s time to market. The purpose of CRAFT™ is to characterize the geographic distribution of patients who meet clinical trial protocol specifications and then to identify investigators for clinical trial participation.

Application Development

We created a java-based application that aggregates disparate databases and permits the evaluation of protocol-specific inclusion and exclusion criteria. Claims data (including ICD-9, CPT, and Rx) from the Ingenix claims database (Research Data Mart, RDM), which captures > 20M lives, are consolidated to provide geographic patient densities that can be extrapolated with Census 2000 data (Figure 1). Cross referencing the Food and Drug Administration’s 1572 database the Bioresearch Monitoring Information System (BMIS) database, facilitates identification of clinical-trial-experienced investigators within RDM, thereby allowing targeted placement of investigative sites based on available patient pools (geographically as well as within the context of the clinicians’ practice) and the clinical trial experience of the clinician.

Leveraging proprietary Ingenix “Ipivot” technology, very large populations can be manipulated in real time. Queries that may otherwise take hours with standard data warehouse structures (e.g., star schema) return in seconds with “Ipivot” methodology.

Conclusion

The rapidity with which patients eligible to participate in approved clinical trials can be identified should dramatically improve the selection of geographic sites at which clinical protocols should be implemented. In addition, the ability of CRAFT to identify those physicians likely to have access to patient populations with specific characteristics further enhances its usefulness and could diminish the time required for traditional telephone-based surveys to determine protocol feasibility.

References