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Cost Effectiveness of a Query Management System

INTERNET-BASED CLINICAL TRIALS

THE NEW PARADIGM IN DRUG DEVELOPMENT

ABSTRACT

Objectives: The objective of this study was to evaluate the economics of performing Internet-based clinical trials, looking specifically at query management.

Methods: Three identical clinical trials, with a total of 349 patients at 31 centers, were performed in the area of Infertility to support two NDA submissions. Study 1 was performed with traditional paper CRF's and a Data Clarification System. Study 2 utilized the Target e*CRF™ Internet-based data collection with no edit or logic check functions. Study 3 utilized the Target e*CRF™ with full edit and logic check functions. For each study, the total number of queries and queries generated by page were calculated.

Results: For Study 1, the data entry group generated 1,109 queries consisting primarily of missing and illegible data. The monitoring group generated an additional 1,826 queries, about half of which were acknowledgment that the data were truly missing and or correct. For Study 2, there was a similar number of queries generated by the monitoring group, but since data entry occurred at the study site with no edit or logic checks, the data entry group generated no queries. For Study 3, there was a 65.5% reduction in all-cause queries generated by the monitoring and a 63% decrease in queries at the time of data entry, compared to the all-paper CRF program.

Conclusion: As we enter the 21st century, a new paradigm in drug and device clinical research is rapidly evolving towards web-based data collection, retrieval and management. Implementing web-based solutions offers a convenient, cost effective medium to streamline areas such as patient enrollment, data entry, query management, communication and project management. By increasing data quality as well as the time to database lock, companies can expedite time-to-market with reduced costs. Based on the current study, it is concluded that query management in Internet-based clinical trials is cost effective and markedly reduces the number of generated queries.

INTRODUCTION

There are many stakeholders involved in the process of converting from paper to web-based systems, including sponsors, independent clinical study sites, site maintenance organizations (SMO's), contract research organizations (CRO's) and the FDA.

Costs

1. Hiring a team of programmers to write source code
2. Assigning clinical and data management experts to interface with the programming group
3. Setting up internal computer systems

Benefits

1. More rapid access to trial data and trial progress
2. Higher-quality data entry due to edit and logic checks
3. Elimination of double-key entry
4. Elimination of commercial paper case report forms (CRF)
5. Alerts to safety and enrollment issues
6. Faster time to data lock
7. Seamless integration with electronic NDA submissions

Table 1. Paper-Based Versus Internet-Based Trials: Various Tasks

Task	Paper-Based Trial	Internet-Based Trial
Paper Case Report Forms	YES	NO
Printing of Case Report Forms	YES	NO
Data Entry	Double-Key by Sponsor	Entered by Site Once
Edit and Logic Checks	SAS Program	Time of Data Entry
Query Management	Paper Forms	Electronic Record
Data Management	Paper Forms	Instantaneous Audit Trail
Data Quality Assurance	After In-House Data Entry	Monitoring Function
Monitoring	All Done in Field	Combination Field and Office
	Problems Identified at Site	Many Problems Identified in Advance
	Problem Resolution After Site Visit	Problem Resolution Prior to Site Visit

Table 2. Summary of the Minimum Estimated Cost Savings of a Multicenter Study

Number of Centers	40		
Number of Patients	1,000		
CRF Pages	100		
Tasks	Paper	Electronic	Net Savings
Printing of CRF's (\$100/Book)	\$ 100,000	0	\$ - 100,000
Double-Key Data Entry (\$3/Page x 2)	\$ 600,000	0	- 600,000
Data QA (\$3/Page)	\$ 300,000	0	- 300,000
Query Management (\$50/Query)	\$ 150,000	\$ 50,000	- 100,000
Monitoring (One Trip, \$3,000/Trip)	\$ 120,000	0	- 120,000
TOTALS	\$ 1,270,000	\$ 50,000	\$ - 1,120,000

FEATURES OF TARGET e*CRF™

Description	Key Features
100% developed and managed by TARGET HEALTH INC.	Comes with either the sponsor's or a customized database
Is a customized application with a web user interface	Comes with data warehousing
Requires NO software installation and NO high speed Internet connections	Runs on all computer systems
Runs off regular modem phone lines	Has customized pages and data entry screens
Is housed at a secure website and utilizes secure encrypted communication	Can provide pre-assigned patient and pin numbers
Provides unique websites and domain names	Has built-in encryption
Is fully compatible with SAS system	Has a sophisticated, thorough, user-friendly, query management system
Benefits Include:	Can provide E-mail notifications
1. Real time data availability	Has customized edit/logic checks
2. Elimination of traditional paper CRF's	Has customized range checks
3. Less transcription and logic errors	Has a friendly customized navigation system
	Can deliver customized management reports

AN INTERNET-BASED TRIAL CASE STUDY

Methods

1. Study 1 was performed with traditional paper CRF's and a data clarification system.
2. Study 2 utilized the Target e*CRF™ Internet-based data collection with no edit or logic check functions.
3. Study 3 utilized the Target e*CRF™ Internet-based data collection tool with full edit and logic check functions.

Results

Table 3. Metrics of Paper Versus Electronic Systems

Study	N (Patients)	Pages Reviewed	Queries All Causes	Queries/ Page	Queries at Data Entry	Queries/ Page
1. Traditional Paper	192	11,130	2,935	0.264	1,109	0.100
2. Internet Based - No Edit or Logic Checks	66	2,475	900	0.364	0	0
3. Internet Based - With Edit or Logic Checks	191	7,908	937	0.118	612	0.037*

*At the time of this analysis, 16,494 pages were entered into the database and 7,908 pages were reviewed by the monitoring group.

CONCLUSION

Within two years, in our opinion, most companies will be using Internet-based systems to perform clinical trials. This will occur as: **(1)** the prices for Internet-based systems fall with more competition; **(2)** there is increasing confidence in the use of electronic data; and **(3)** economies of scale develop as studies with similar designs, architectures and business rules are implemented.

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