

Performance of Electronic Diaries in Diabetes Clinical Trials Measured Through Overall Satisfaction of Site Coordinators

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Abstract

Background:

Clinical trials are increasingly being designed to collect data directly from patients through the use of paper diaries or electronic diaries (e-diaries). E-diaries can be advantageous over paper diaries, but actual benefits may depend on the particular features of a given e-diary. The objective of this study was to determine which e-diary system features are most important to consider when selecting such a tool.

Methods:

A 42-question survey was distributed to 295 site coordinators participating in four diabetes clinical trials, using e-diary systems provided by three different vendors. The survey gathered information about the site coordinators' experience with the e-diary system used. Analyses included a comparison of global satisfaction rating scores and individual survey item responses among the different e-diaries utilized and correlation of individual survey items with the global satisfaction rating for each system.

Results:

The survey was completed by 131 site coordinators (44% response rate). Mean global satisfaction rating scores varied from 3.4 to 7.2 ($p < 0.0001$). Individual survey items such as technical problems that cannot be resolved easily, the ability of the help line to fully address problems, and organization and user-friendliness of the e-diary's data management Web site were most closely correlated with the global satisfaction rating. The site coordinators' prior e-diary experience and years of job experience did not significantly correlate with the global satisfaction rating.

Conclusions:

This survey highlights features of e-diaries for sponsors to consider in clinical trials, including the importance of minimizing technical problems, assessing vendors' help line capabilities, and choosing an e-diary system with an efficient and user-friendly data-management Web site.

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Abbreviations: (e-diary) electronic diary, (PDA) personal digital assistant

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