ELECTRONIC CAPTURE OF CLINICAL OUTCOME ASSESSMENT DATA: WHY IS IT NOT USED MORE IN CLINICAL STUDIES?

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INTRODUCTION

The collection of clinical outcome assessment (COA) data electronically (i.e., eCOA) has many benefits over paper-based data collection (Crosby et al. 2009). These include:

• More accurate measurement of the concept
• Data and time stamping of data (FDA 2009)
• Support for regulatory compliance (e.g., audit trails, protocol adherence)
• Patient engagement and compliance
• Lower likelihood of missing data
• Possibility for smaller sample sizes
• Potential for reduced operational costs (e.g., data entry, monitoring)

However, the uptake of eCOA data collection by pharmaceutical sponsors has not been as high as expected and there is a disparity in user adoption. Perceived and real barriers to eCOA adoption should be identified and further explored in order to better understand the reason for the slow adoption and imbalance in uptake.

OBJECTIVES

To understand perceptions of and factors considered by various cross-functional pharmaceutical company stakeholders considering clinical trials when choosing a COA data collection mode, the objectives are as follows:

• Characterize and understand preference for paper vs. electronic data collection
• Identify barriers to adoption of electronic data collection for COA tools

METHODS

SURVEY QUESTIONNAIRE DEVELOPMENT

• A questionnaire for pharmaceutical industry representatives was developed by members of the Participant-Reported Outcome (PRO) Consortium’s ePRO Subcommittee with input from ePRO Consortium member firms representatives
• The draft questionnaire was piloted among several PRO Consortium member firms
• Questionnaire items were revised based on early feedback
• An introductory email with a link to the online eCOA-Adoption Survey was distributed to the 26 firm representatives of the PRO Consortium’s Coordinating Committee in order to standardize survey completion and data collection
• Representatives from the PRO Consortium member firms distributed the survey link internally to various stakeholders considering the roles and process related to eCOA development and support
• The questionnaire was completed anonymously by respondents during February 2017

QUESTIONNAIRE CONTENT/FORMAT

• The first screen presented to survey respondents included an introduction to the survey and a list of definitions for frequently used terms (e.g., COA, PRO, eCOA, BYOD [Bring Your Own Device])

RESULTS

DATA ANALYSIS

• Descriptive statistics were calculated for questionnaire data and test fields were qualitatively analyzed for themes.

REASONS PREVENTING RESPONDENTS FROM CHOOSING eCOA TECHNOLOGY

Reasons frequently endorsed for not choosing eCOA included time preparing for and funding needed for eCOA implementation. Lack of internal resources and regulatory concerns were the next most frequently chosen reasons.

Table 1. BARRIERS TO eCOA ADOPTION

Study Limitations

• Not a representative sample of the target population
• Survey data was described for the PRO Consortium member firms
• Majority of respondents had >15 years of experience in the pharmaceutical industry and >15 studies in the past 10 years
• Likely that people who have an interest and experience in COA were more inclined to respond

REFERENCES


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