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

*Barsdorf AI[1], McQuarrie K[2], Vallow S[3], Crescioni M[4], Eremenco S[4]*
*[1]Pfizer Inc., New York, USA, [2]Janssen Global Services, LLC, Horsham, PA, USA,*
*[3]MedAvante-ProPhase, Hamilton, NJ, USA, [4]Critical Path Institute, Tucson, AZ, USA*

## INTRODUCTION

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

These include:

- More accurate measurement of the concept
- Date 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 supporting 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 Patient-Reported Outcome (PRO) Consortium's ePRO Subcommittee with input from ePRO Consortium member firm representatives
- The draft questionnaire was piloted among personnel from 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 member 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 screens presented to survey respondents included an introduction to the survey and a list of definitions of frequently used terms (e.g., COA, PRO, eCOA, BYOD [Bring Your Own Device])

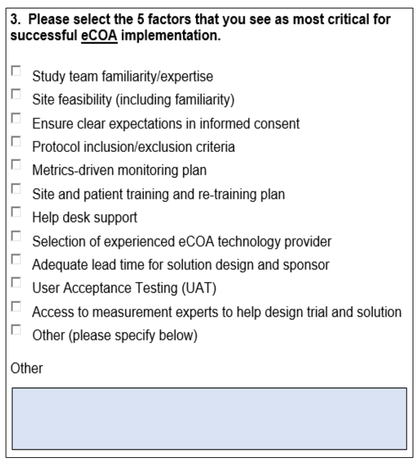
### *QUESTIONNAIRE CONTENT/FORMAT* **(Continued)**

- The final questionnaire included 12 items:
  - Items 1 through 6 elicited preference for mode of data collection and rationale for selection and items to identify real and perceived barriers and reasons for adoption of eCOA data collection
  - Items 7 through 12 characterized respondents' background
- Item content included:
  - Preferred mode of COA data collection (paper or electronic) and free text to describe why
  - Top five factors:
    - Most important when determining the COA data collection mode to use in a study
    - Most critical for successful eCOA implementation (Figure 1)
    - Most critical when choosing an eCOA company
  - To what extent each of the listed considerations is important when selecting a mode of COA data collection
  - Reason(s) preventing you from using eCOA in studies
  - Free text - Any additional comments regarding a challenging experience you may have had or that you heard of related to eCOA implementation

### *DATA ANALYSIS*

- Descriptive statistics were calculated for questionnaire data and text fields were qualitatively analyzed for themes.

### *Figure 1. Screenshot of Item 3*




## RESULTS

### *QUESTIONNAIRE RESPONDENTS (N=152)* (Figures 2 and 3)

***DEMOGRAPHICS***

- Over half of the respondents (n=62/118, 52.5%) had > 15 years of experience in the pharmaceutical industry (Figure 2)
- Over half of the respondents (n=66/117, 56.4%) had involvement with >15 studies in the past 10 years (Figure 3)

**Figure 2. Number of Years Worked in Pharmaceutical Industry OVERALL**

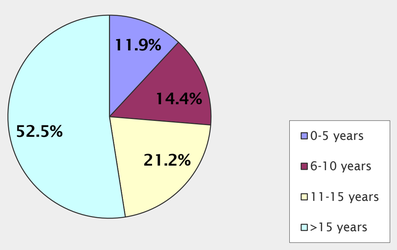
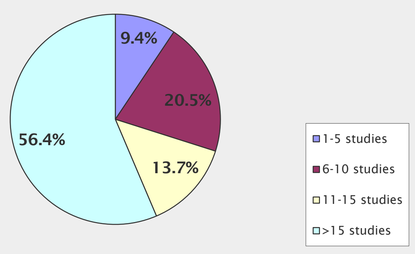



**Figure 3. Number of Studies Overall Involved with During the PAST 10 YEARS**




***CURRENT PRIMARY FUNCTIONAL ROLE (n=116)***

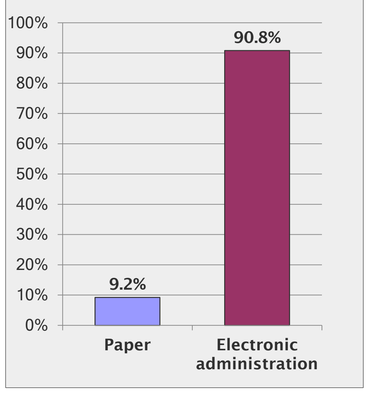
- Greatest number of respondents were clinical/medical scientists (27.6%), clinical trial operations (14.7%), and health outcomes/outcomes research (19%)
- Limited response from regulatory, programming, procurement, and study monitors

***THERAPEUTIC EXPERIENCE (n=115)***

- Greatest number of respondents had experience in the following therapeutic areas in the past 10 years: oncology (48.7%), cardiovascular/metabolism (47.0%), neuroscience (42.6%), rheumatology (38.3%), rare disease (32.2%)
- Well-represented across other therapeutic areas

### *PREFERRED MODE OF COA DATA COLLECTION* (Figure 4)

**Figure 4. Preferred Mode of COA Data Collection**




**Electronic preference**

Main reasons (summarized from text fields) included:

- Data Quality (28/158)
- Data Entry (26/158)
- Monitoring capabilities (13/158)

Other reasons noted included: Advantages of removing the need for transcription and data entry (quality, reduces site burden, etc.), real time data access and monitoring, efficiency, 21 CFR Part 11 compliant, PRO data completed in time window, user friendly, minimizes missing data

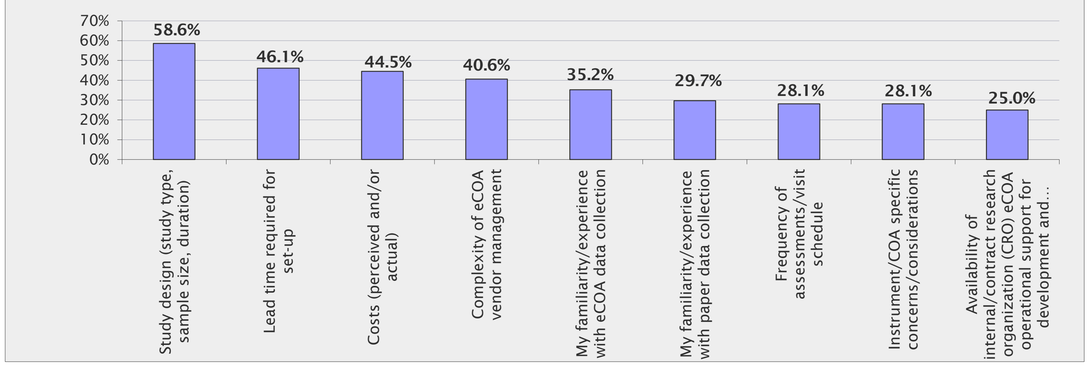
**Paper preference (n=14)**

- Respondents provided minimal descriptions of why (8 of 14)
- Ease of use was reported by 3 of the above 8

### *FIVE MOST IMPORTANT FACTORS FOR CHOOSING COA DATA COLLECTION MODE* (Figure 5)

Study design, lead time for set up, costs, complexity of eCOA vendor management, and familiarity with eCOA data collection were frequently endorsed as most important factors for choosing a mode of data collection.

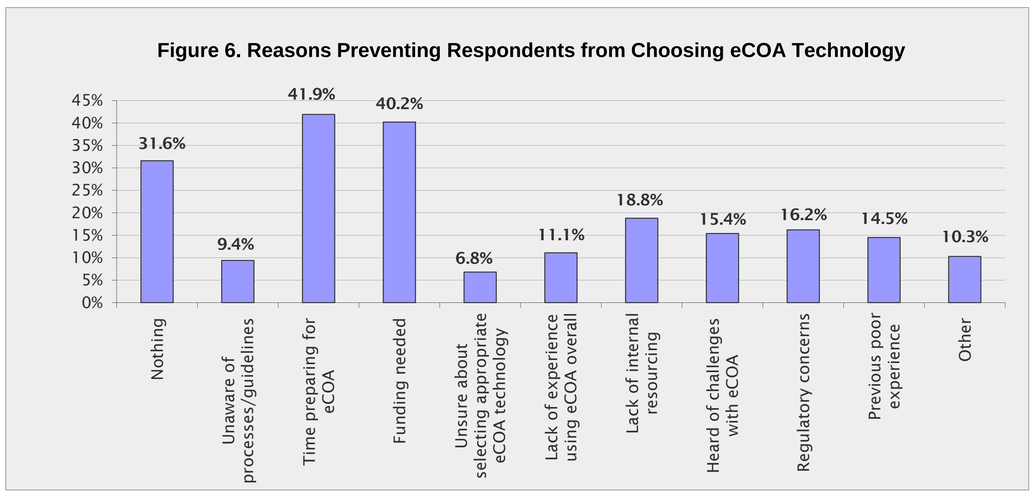
**Figure 5. Most Important Factors for Choosing COA Data Collection Mode**




### *REASONS PREVENTING RESPONDENTS FROM CHOOSING eCOA TECHNOLOGY* (Figure 6)

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.

**Figure 6. Reasons Preventing Respondents from Choosing eCOA Technology**




### *FIVE MOST CRITICAL FACTORS FOR SUCCESSFUL eCOA IMPLEMENTATION*

Critical factors for successful eCOA implementation included study team familiarity with it, site feasibility/familiarity with it, ensuring expectations are clear in informed consent and protocol inclusion/exclusion criteria, having metrics-driven monitoring plans for eCOA implementation, training of sites and patients, and adequate help desk support.

### *Table 1. BARRIERS TO eCOA ADOPTION*

| Summary of Key Barriers | |
|---|---|
| **Necessary lead time/time preparing for eCOA for a study** | 62.4% (64% of those who prefer paper) responded that "Adequate lead time for solution design and sponsor" is one of the top 5 most critical factors for successful eCOA implementation<br>41.9% (43% of those who prefer paper) responded that "Time preparing eCOA for a study" is preventing them from using eCOA<br>40.6% (43% of those who prefer paper) responded that "Necessary Lead Time" is one of the top 5 most important considerations when selecting mode |
| **Cost and funding needed to implement eCOA** | • 44.5% (57% of those who prefer paper) responded that "cost (perceived and/or actual)" is one of the top 5 most important considerations when selecting mode<br>• 40.2% (57% of those who prefer paper) responded that "funding needed to implement eCOA" is preventing them from using eCOA |
| **Regulatory concerns** | 16.2% (14% of those who prefer paper) responded that "Regulatory concerns" are preventing the respondent from using eCOA |
| **Site receptivity/burden and site and patient training and re-training plan** | • 80% (71% of those who prefer paper) responded that "Site and Patient Training and Re-Training Plan" is one of the top 5 factors most critical for successful eCOA implementation<br>• 45.6% (28% of those who prefer paper) responded that "Site feasibility (including familiarity)" is one of the top 5 factors most critical for successful eCOA implementation<br>• 28% (21% of those who prefer paper) responded that "Site Receptivity/Burden" is one of the top 5 most important considerations when selecting mode |
| **Patient receptivity or burden and consideration of patient population** | 46.1% (57% of those who prefer paper) responded that "Patient Receptivity or Burden" is one of the top 5 most important considerations when selecting mode<br>29.7% (21% of those who prefer paper) responded that "Consideration of Patient Population" is one of the top 5 most important considerations when selecting mode |
| **Data integrity, device failure, no paper backup** | Security with Paper<br>• "No forgetting to charge the battery, no forgetting the password, no issues with wrong time/date stamp, faster, cheaper"<br>• "Never had missing data issues using paper in my trials with many PRO instruments over 2 years of clinical trial time frame"<br>• "No chance of malfunction of the e-devices"<br><br>Device Failure<br>• "hardware failure leading to missing data"<br>• "device issues, issues with quality data capture and cleaning"<br>• "Even with eCOA, there is still the chance that captured data will be incorrect, and that assumptions made when designing a tool are not accurate"<br>• "Extremely poor experience with device failures" |
| **Lack of internal resourcing and study team familiarity/ experience (e.g., effective UAT)** | 19.5% (28% of those who prefer paper) of the respondents selected "providing a non-paper backup solution in the event of device failure" as one of 5 factors that are most critical when choosing an eCOA company |

### *STUDY LIMITATIONS*

- Not a representative sample of the target population
- Survey site link was distributed only to 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

## CONCLUSIONS

Our findings support the need for:

- Ensuring understanding of the value of eCOA by pharmaceutical company stakeholders, for example:
  - True cost of electronic vs. paper data collection
  - Effective communication with teams on the true value of the investment of time, cost, and staff resources
  - More training and hands-on experience with a recognition that user acceptance testing (UAT) provides this opportunity to the internal team
- Increasing reliance on vendor expertise to help companies ensure thorough and efficient UAT
- Identifying and discussing lessons learned to enable internal process improvements
- Sharing of best practices to increase confidence across therapeutic areas
- Ensuring clear responsibilities across the interdisciplinary team
- Streamlining of eCOA services
- Improving partnerships between sponsor and technology providers

All of the above may enhance eCOA uptake so that the benefits of eCOA data collection may be realized with more studies and by more stakeholders.

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For further information, please contact:
Sue Vallow, svallow@medavante.com

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