Understanding Site Preferences With eCOA Technologies Used to Increase the Reliability of Clinical Assessments: A Multi-National Survey

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Abstract

Introduction: As technology continues to grow, so does its use within the clinical trial industry. In particular, tablet and computer-based eSource/e-Clinical Outcome Assessments (eCOA) solutions are being used more and more as tools to increase the reliability of clinical assessments. While research indicate these technologies improve the efficiency and quality of rater administered and patient reported outcome assessments compared to paper assessments (Tiplady, 2014; Williams et al., 2015), little empirical exploration has been conducted examining the experiences of those who use these technologies within trials on a daily basis. The current study investigates study coordinator and raters' perceptions on their use of a variety of technologies being applied within the industry. **Method:** Site coordinators and raters were anonymously surveyed from US and ROW sites. The sites designated to receive the survey had previously participated in numerous psychiatric and neurocognitive studies. The site staff were queried about their experiences using these technologies as well as various demographic information. **Conclusion:** Obtaining the experiential realities of site staff who utilize assessment technologies is critical to increasing the use and acceptance of the technologies. The goal of this investigation is to better understand site perceptions regarding these technologies in an effort to address potential shortcomings, leading to their greater usage that will enhance the overall quality of rater assessments.

Background

eSource/e-Clinical Outcome Assessments (eCOA) are increasingly utilized in the collection of patient data as part of clinical trials. Laptop/tablet programs, smartphone/web-based applications and interactive voice systems (IVRS) are among the most commonly used today. Tiplady et al., (2014) demonstrated that developed technologies have shown to be effective in reduction of study costs and increase the reliability of outcome data and inclusion of appropriate subjects. However, there has been limited focus on site perceptions regarding these technologies. The authors of the current study sought to investigate site preferences in using the newer technology of eSource/eCOA, as there has been an increase in its usage for conducting clinical assessments.

Design

Approximately 1500 web-based surveys were designed and distributed by Worldwide Clinical Trials via email in order to inform the utilization of paper-based versus electronic-based data acquisition platforms. All data are proprietary to WCT. Responses were limited to one per computer.

The focus of the questionnaire was to compare differences between eCOA technologies and traditional paper assessments through five questions that were presented in English via SurveyMonkey. The first four questions focused on background information: study role, location, years of clinical trial experience, and number of previous studies using eCOA solutions. Respondents were allowed to choose "Rater" and/or "Coordinator" to define their role. Respondents who indicated both roles were excluded to more clearly compare perceptions based on different roles.

The fifth question focused on preference of various eCOA technologies based on a 5-point Likert scale (Strongly Dislike, Dislike, Neutral, Prefer and Strongly Prefer). For analysis, "Strongly Dislike" and "Dislike" responses were combined into an overall "Dislike" category; "Strongly Prefer" and "Prefer" responses were also combined into one category. The overall percent of respondents that preferred a technology (Strongly Preferred and Preferred) was subtracted from the overall percent of respondents that Disliked (Strongly Disliked and Disliked) the technology. The difference was defined as a Preference Ratio and is represented in the difference of the percentages in overall basis points; positive numbers indicate stronger preferences whereas negative numbers indicate stronger "dislike" partialities.

A final question was open for respondents to provide free text comments on their preferred method for conducting assessments.

On some analyses as defined below, we combined the testing methods of tablet with stylus, tablet with keyboard, and laptop as single eCOA category; the digital pen was kept as a separate eCOA category.

For analysis purposes, responses were transformed from categorical ranges (years of experience, number of studies using eCOA, etc.) to the average of the available range. For example, if the range for years of experience was 1-5, 6-10, etc. these answers were converted to the average of the range to be 3 or 8 years of experience, respectively.

Chi square distribution and ANOVA testing of the results were included as described below, which occasionally included multiple comparisons of a single dataset. Because there were no prior assumptions about the expected pattern of outcomes, a decision was made to control for multiple comparisons using the Bonferonni correction (dividing p value by the number of multiple comparisons).

Results

A total of 319 respondents completed the survey with over half of the respondents from North America (51%), followed by Western Europe, Asia-Pac, Eastern EU, and Russia/Ukraine as depicted in the table 1 below.

Table 1: Regional Demographics of Responders

Answer Options	Response Percent	Response Count
Asian-PAC	15.7%	50
Eastern EU	7.5%	24
North America	50.8%	162
Russia / Ukraine	1.6%	5
Western EU	21.9%	70
Total Responses		**319**

Years of clinical trial experience was skewed, with 60% of respondents indicating 10 or less. Nearly 25% of respondents had over 16 years of clinical trial experience as shown in Table 2. There was a good representation and range of experience with eCOA solutions from the responders as depicted in Table 3.

Table 2: Number of Years of Experience of Responders

| Answer Options	Response Percent	Response Count
1-5 Years of Experience	32.6%	104
6-10 Years of Experience	27.9%	89
11-15 Years of Experience	15.7%	50
16-20 Years of Experience	8.5%	27
> 20 Years of Experience	15.4%	49
Total Responses		**319**

Table 3: Number of studies you have used a tablet / electronic device to conduct assessments?

Answer Options	Response Percent	Response Count
0	14.7%	47
1-3	33.5%	107
4-6	22.9%	73
7-9	7.2%	23
> 9	20.7%	66
N/A	0.9%	3
Total Responses		**319**

Surprisingly, sites based in CEE averaged the most number of studies using eCOA, followed by sites based in North America as depicted in the Figure 1 below. An ANOVA across all data indicated a significant difference among regions regarding the rater experience with eCOA solutions (p<0.00000). No difference between North America and Eastern EU was indicated (p=0.29) and significant differences between North American and Western EU (p<0.0000) and Asia Pac (p<0.0000) were identified.

Figure 1: Average Number of eCOA Studies by Region
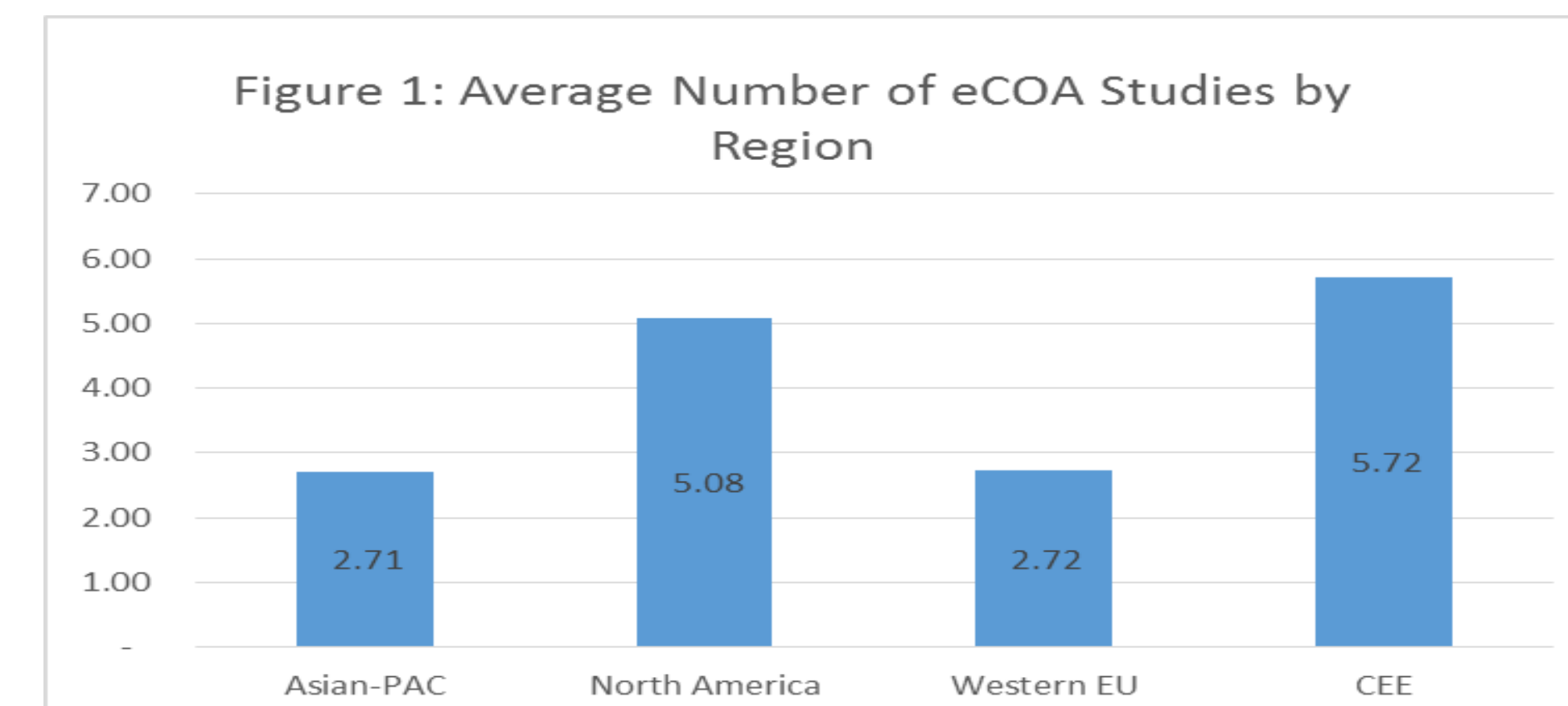
Not surprising, a rater or coordinator with overall less experience was shown to also have overall less experience with eCOA, but surprisingly there was not a stronger trend (Figure 2). There was a slight trend for more eCOA experience with more years of experience with an R value of 0.765, but the trend was not significant.

Figure 2: Average Number of eCOA Studies by Years of Experience
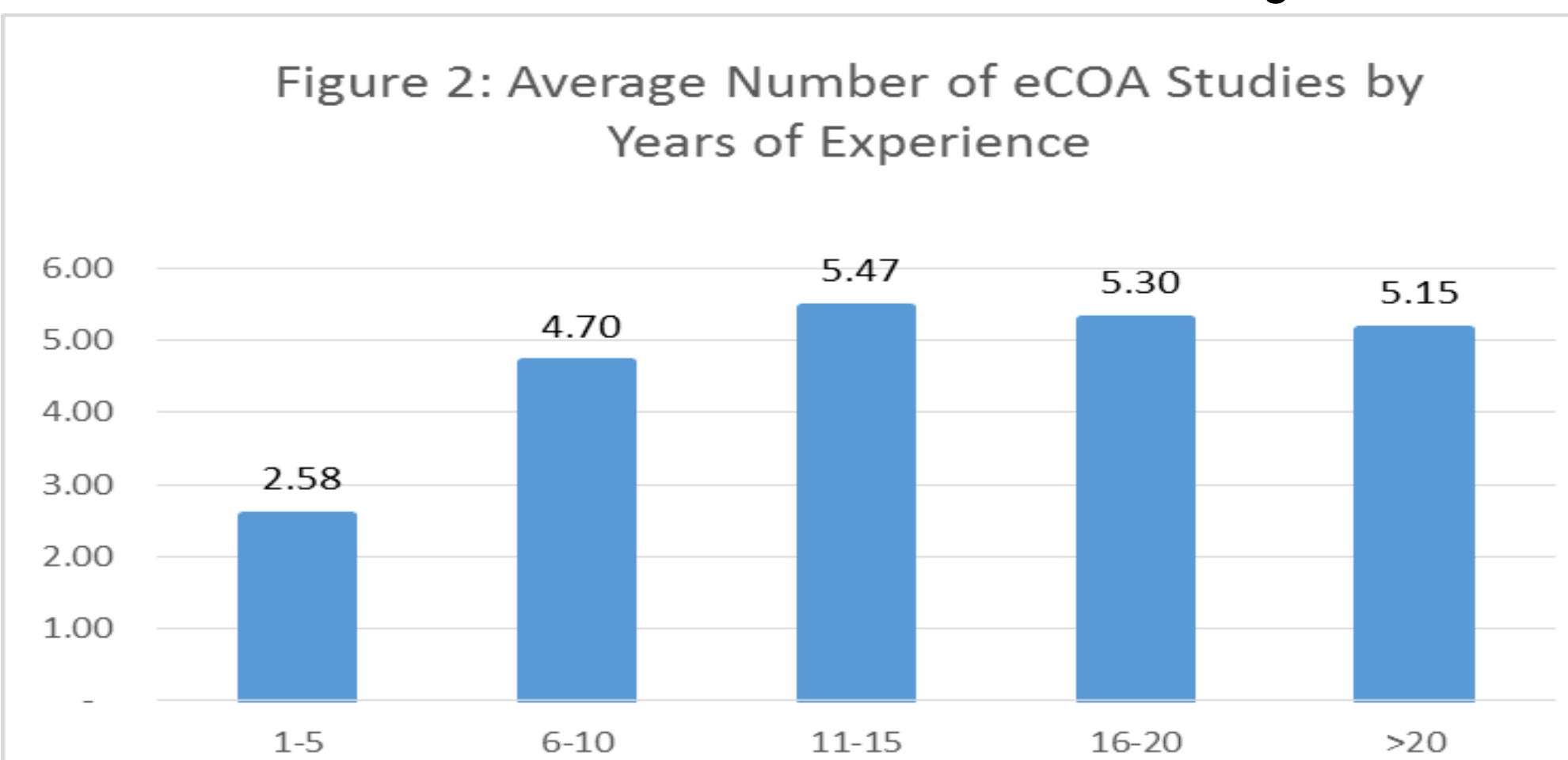
Results (cont.)

The key question in the survey asked "Please rate each of the following methods for conducting assessments based on your experience using each of the below technologies." Respondents to this question indicated that paper based assessments were highly favored, with a 62 basis point Favorability Ratio (67% favored paper, 6% did not favor paper) as shown in Table 4. The most disliked method was Digital pen recorder with a -31 point favorability ratio (12% preferred, 43% did not favor). The tablet with stylus was more preferred than tablet with keyboard whereas a laptop was favored over either tablet options.

Table 4: Overall Preference of eCOA Options Compared to Paper Assessments

Answer Options	Strongly Dislike	Dislike	Neutral	Prefer	Strongly Prefer	% Prefer	% Dislike	Preference Ratio
Tablet with Stylus	33	40	91	68	34	32%	23%	9%
Tablet with Keyboard	28	53	93	58	27	27%	26%	1%
Laptop	21	44	102	69	41	35%	21%	14%
Audio/Digital Pen Recorder	65	70	82	29	8	12%	43%	-31%
Paper Assessment	4	14	80	108	105	67%	6%	62%

When this question was analyzed based on the role of the respondent, Coordinators consistently liked eCOA more than the raters as shown in Tables 5 and 6 below. Since the data from "Table with Stylus", "Tablet with Keyboard", and "Laptop" tended to be similar across Tables 4, 5 and 6, we combined this data into one "eCOA" preference ratio; this ratio did not include the responses from "Digital Pen Recorder" as the responses were markedly different from the other eCOA options. The Coordinators had a modest 17 point preference ratio for the combined eCOA solutions, whereas Raters had a 0 basis point preference for eCOA solutions (data not shown in table). Nevertheless, paper assessments were still highly favored in both groups, with Coordinators preferring paper assessments (52 point preference ratio) a little less than Raters (69 point preference ratio).

Table 5: Coordinator Preference of eCOA Options Compared to Paper Assessments

Answer Options	Strongly Dislike	Dislike	Neutral	Prefer	Strongly Prefer	% Prefer	% Dislike	Preference Ratio
Tablet with Stylus	5	12	25	17	13	42%	24%	18%
Tablet with Keyboard	5	10	54	12	11	25%	16%	9%
Laptop	3	11	30	19	14	43%	18%	25%
Audio/Digital Pen Recorder	15	18	23	8	3	16%	49%	-33%
Paper Assessment	2	4	27	29	19	59%	7%	52%

Table 6: Rater Preference of eCOA Options Compared to Paper Assessments

Answer Options	Strongly Dislike	Dislike	Neutral	Prefer	Strongly Prefer	% Prefer	% Dislike	Preference Ratio
Tablet with Stylus	18	19	40	33	14	38%	30%	8%
Tablet with Keyboard	18	32	85	25	9	20%	30%	-9%
Laptop	11	25	50	28	15	33%	28%	5%
Audio/Digital Pen Recorder	32	41	41	14	0	11%	57%	-46%
Paper Assessment	0	5	38	52	59	72%	3%	69%

When the preference data was analyzed based on region, CEE had the strongest preference for paper assessments (82 point preference ratio), followed by North America (70), Asia-PAC (51) and Western EU (50) (Table 7). When tablet and laptop preferences were combined, North America and CEE had the least favorable ratings (-3 preference points), with North America (1), Western EU (13) and Asia-PAC (20) having higher preference ratios for overall eCOA solutions.

Results (cont.)

Table 7: Overall eCOA Preference vs Paper Preference Ratio by Region

Region	Overall eCOA Preference Ratio	Paper Preference Ratio
Asia-PAC	20%	51%
CEE	-3%	82%
North America	1%	70%
Western EU	13%	50%

Those with zero experience with tablet/eCOA solutions had the highest preference for tablet/eCOA based solutions (31 preference points). Those with any experience with eCOA solutions consistently had higher preference for paper as compared to those respondents with no experience with eCOA. (Table 8).

Table 8: Overall eCOA Preference vs Paper Preference Ratio by Number of eCOA Studies

Number of eCOA Studies	eCOA Preference Ratio	Paper Preference Ratio
0	31%	46%
1-3	6%	70%
4-6	11%	57%
>7	-4%	73%

Discussion

It is understood that the industry is clearly moving from paper based solutions to electronic solutions. The transition to eCOA solutions may be slow just as it was for EDC where it took 10+ years for the vast majority of new studies to adopt EDC over double-data entry of paper based CRF forms. Over these years, many of the issues and complications of EDC have been resolved - or accepted as a necessary challenge that is outweighed by the benefits of EDC. It is clear that eCOA solutions will continue to grow in use and acceptability over the coming years as we address some of the challenges and issues with eCOA solutions.

As we analyzed the data, some interesting trends appeared. For example, Study coordinators liked the eCOA technologies more than raters; this may reflect how technology makes the lives of the coordinator easier, whereas raters may be experiencing more difficulty with implementing the technology directly with the patient. Indeed, many of the comments from respondents were concerned that the physical barrier and challenges with the eCOA solution when interviewing the patient may affect the reliability of data derived from eCOA.

Not surprisingly, a rater with overall less experience was also shown to have overall less experience with eCOA, but there was not a stronger trend with more years of experience. The combination of lack of overall experience and lack of eCOA experience within this less experienced group may be reason to question the validity of these perceptions as they may not have a strong experiential history to develop well-formed opinions re paper or eCOA based assessments. For example those with zero experience with tablet/eCOA solutions actually had the highest preference for tablet/eCOA based solutions (31 preference points); a clear demonstration that "grass is greener on the other side of the fence."

One of the primary goals of this survey was to understand sites perceptions of eCOA solutions in order to: 1) potentially address problems, challenges and issues associated with eCOA options, 2) increase the use of tablet-based eCOA solutions, and 3) ultimately increase reliability of outcomes data through greater site acceptance of eCOA technologies. Based on our experience - and free-text entries from the respondents - some of the issues that should be considered when implementing eCOA solutions include: easier interface that is less distracting for the clinician to utilize while interviewing a subject, ensure that the eCOA solution is not developing a barrier between the clinician and the subject, provide easier set up for each subject, ensure font is large enough on eCOA, ensure strong tech support, ensure backup/contingency plans regarding the device are appropriately addressed, ensure training and orientation to the site staff is comprehensive. Throughout the industry, we should continue to ask sites opinions regarding their perceptions and how we can best implement eCOA and other technology solutions. By removing issues and obstacles, we will ultimately increase the reliability of the assessments as well as make the day-to-day life/study activities/work easier at the site. Of course, site, sponsors, vendors and patients all win when the reliability of outcomes data increases in CNS indications, ultimately leading to more drugs being approved to treat the manifold unmet needs of these patient populations.

References provided upon request.