**PND36**

**OBSERVED DIFFERENCES BETWEEN DAILY DIARY AND WEEKLY REPORT OF CYSTIC FIBROSIS SYMPTOMS**

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**OBJECTIVE:** Recent reviews of human memory processes in cognitive psychology suggest that shorter recall periods in patient-reported outcome (PRO) measures capture daily experience more accurately. Few empirical studies quantify patient symptom reporting by length of the recall period. This study compares 7-day recall of symptoms during the past week with 24-hour recall in a daily diary to determine whether the recall period yields significant differences in measures of patient-reported symptom occurrence and severity. **METHODS:** The Cystic Fibrosis Respiratory Diary (CFRD) is a recently developed PRO including 13 symptoms (e.g., cough, tiredness, frustration) in which patients record the occurrence and severity of symptoms for six consecutive days using a 24-hour recall period and on the seventh day using a 7-day recall period. Cystic fibrosis patients age 2 and older (parents for children age 11 or younger), completed two diaries while clinically stable period and on the seventh day using a 24-hour recall period. The objective of this analysis was to evaluate how training affects PRO study results. Further, the FDA asserts that implementation of standardized interviewer training can optimize study quality by minimizing inconsistencies in trial conduct. Presently, there is no standard PRO interviewer training method, and many registration trials neglect this important aspect of ensuring quality data. To test the effectiveness of such training, United BioSource Corporation (UBC) analyzed outcomes of PRO interviewer training in a global clinical trial. **RESULTS:** A total of 506 (97.5%) demonstrated scale knowledge performance was not affected by nationality, clinical experience, or prior experience with the instrument. A total of 519 potential interviewers live (70%) at 4 separate investigator meetings (Nashville, Geneva, Kuala Lumpur, Buenos Aires), or via the internet for those unable to attend an IM (30%). Following training, interviewer knowledge was independently assessed using an exam specifically created for that purpose. **RESULTS:** A total of 519 interviewers completed the training. Seventy-four percent of interviewers had no previous instrument specific experience. A total of 506 (97.5%) demonstrated scale knowledge mastery (80% or greater). As shown by one-way ANOVAs, performance was not affected by nationality, clinical experience, clinical trials experience, or prior experience with the instrument (all F ratios < 1). **CONCLUSION:** We report the global delivery of a comprehensive PRO interviewer training package consistent with FDA goals. The study suggests that comprehensive PRO interviewer training is feasible in multinational trials, is effective in live or remote delivery platforms, and results in high levels of demonstrable scale knowledge across a wide range of clinical and research experience levels.

**PND37**

**REDUCTIONS IN FREQUENCY AND INTENSITY OF PAIN WITH BOTULINUM TOXIN TYPE A FOR THE TREATMENT OF CERVICAL DYSTONIA**

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**OBJECTIVE:** The objective of this study was to assess reductions in pain frequency and intensity in cervical dystonia patients treated with botulinum toxin (BoNT-A). **METHODS:** A total of 170 patients were randomized to receive (BoNT-A) or placebo as part of a 10-week, double-blind study. Patients assessed their pain frequency on a scale from 0 (never) to 4 (constant) and their pain intensity on a scale from 0 (none) to 4 (very severe). Pain frequency and intensity were measured at follow-up visits at weeks 2, 4, 6, 8, and 10. **RESULTS:** The mean baseline pain frequency scores were 1.79 for the BoNT-A group and 1.91 for the placebo group. The reduction in mean change of pain frequency ranged from –0.19 to –0.37 in the BoNT-A group and from –0.01 to –0.20 in the placebo group. A greater reduction in the mean change in pain frequency was seen at all timepoints in the botulinum toxin group; the difference was statistically significant at week 6 (–0.31 vs –0.01; P = 0.018). The mean baseline pain intensity scores were 1.78 in the BoNT-A group and 1.80 in the placebo group. The reduction in the mean change of pain intensity ranged from –0.20 to –0.47 in the BoNT-A group, while the placebo group had an increase in pain intensity at week 6, no change from baseline at week 10, and reductions ranging from –0.06 to –0.18 at other timepoints. The mean change in pain intensity showed a greater reduction at all timepoints in the BoNT-A group compared to placebo, with the difference being statistically significant at week 2 (–0.39 vs –0.07; P = 0.026) and week 6 (–0.36 vs 0.06; P = 0.001). Adverse events rates were nearly equivalent between groups (59.1% BoNT-A vs. 58.5% placebo group). **CONCLUSION:** Treatment with BoNT-A lowered frequency and intensity of patient-assessed pain as compared to placebo.

**PND38**

**EVALUATION OF INTERVIEWER TRAINING FOR AN INTERVIEWER ADMINISTERED PATIENT-REPORTED OUTCOME IN A GLOBAL CLINICAL TRIAL**

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**OBJECTIVE:** Patient reported outcomes (PROs) play an increasingly important role in pharmaceutical clinical trials. The Food and Drug Administration (FDA) recognizes that interviewer training affects PRO study results. Further, the FDA asserts that implementation of standardized interviewer training can optimize study quality by minimizing inconsistencies in trial conduct. Presently, there is no standard PRO interviewer training method, and many registration trials neglect this important aspect of ensuring quality data. To test the effectiveness of such training, United BioSource Corporation (UBC) analyzed outcomes of PRO interviewer training in a global clinical trial. **RESULTS:** United BioSource Corporation worked in conjunction with a pharmaceutical sponsor to develop a training program for an interviewer administered PRO designed to assess symptom severity and resultant distress to patients. Custom training on instrument content, format and administration guidelines was provided to 519 potential interviewers live (70%) at 4 separate investigator meetings (Nashville, Geneva, Kuala Lumpur, Buenos Aires), or via the internet for those unable to attend an IM (30%). Following training, interviewer knowledge was independently assessed using an exam specifically created for that purpose. **RESULTS:** A total of 519 interviewers completed the training. Seventy-four percent of interviewers had no previous instrument specific experience. A total of 506 (97.5%) demonstrated scale knowledge mastery (80% or greater). As shown by one-way ANOVAs, performance was not affected by nationality, clinical experience, clinical trials experience, or prior experience with the instrument (all F ratios < 1). **CONCLUSION:** We report the global delivery of a comprehensive PRO interviewer training package consistent with FDA goals. The study suggests that comprehensive PRO interviewer training is feasible in multinational trials, is effective in live or remote delivery platforms, and results in high levels of demonstrable scale knowledge across a wide range of clinical and research experience levels.

**PND39**

**PATIENT- AND PHYSICIAN-ASSESSED FUNCTIONAL DISABILITY IN PATIENTS TREATED WITH BOTULINUM TOXIN TYPE A FOR CERVICAL DYSTONIA**

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**OBJECTIVE:** The objective of this analysis was to evaluate functional disability in patients with cervical dystonia. **METHODS:** The study consisted of a 10-week, non-randomized, open-label...