



NEWS RELEASE

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(For immediate release)

i3 PRESENTATIONS AT NCDEU SHOWCASE CNS SPECIALIZATION *Computerized Cognitive Assessment, Rater Training and Other Methodologies for Achieving Optimal Clinical Trial Results are Featured*

Basking Ridge, N.J., May 27, 2008—Pharmaceutical services company i3 announced today that i3 Research will present five posters at the 48th Annual New Clinical Drug Evaluation Unit meeting (NCDEU), a critical venue for psychopharmacology, to be held May 27-30, 2008 in Phoenix, Ariz. They are:

**1. Reduced Cognitive Impact of a Novel Extended Release Formulation of Topiramate:
Measured by the Computerized Neuropsychological Test Battery (CNTB)**

Although Topamax (topiramate) is an effective anti-seizure medication, many patients discontinue its use due to cognitive side effects. Veroff et al. report on the findings from a study with a two-period, randomized crossover design in which i3's proprietary Computerized Neuropsychological Test Battery (CNTB) was used to measure attention and concentration, verbal and visual memory, and working memory in healthy volunteer subjects administered single doses of the novel extended-release compound and immediate-release Topamax. The CNTB results demonstrated that the extended-release formulation of topiramate was associated with significantly reduced cognitive impairment and were supported by fewer spontaneously reported adverse cognitive events among subjects receiving the extended-release compound.

Poster Session: Wednesday, May 28, 2008, 12:00 p.m. – 2:00 p.m.

**2. A Positive International Adolescent Schizophrenia Clinical Trial: Ensuring Inter-Rater
Reliability**

International clinical trials face clinical and operational challenges in the use of psychiatric scales, but a well executed comprehensive rater training program can manage those challenges and contribute to a positive trial outcome. i3 provided comprehensive rater training services for a global adolescent schizophrenia trial that had a positive outcome. (The study used the Positive and Negative Syndrome Scale: PANSS). There were 347 raters who were trained in 13 countries; 59 percent of the raters were trained at investigators' meetings; 41 percent were trained after the investigators' meetings. Raters were pre-qualified based on experience, trained and certified prior to rating subjects, and during the trial were recalibrated at two time points. Veroff et al., analyzing inter-rater reliability, demonstrated that there was an excellent degree of inter-rater reliability on the PANSS total score across all phases of rater certification and recalibration. Moreover, there were no differences in inter-rater reliability between raters trained at the investigators' meetings and those trained afterwards.

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3. Hamilton-Depression-17 (HAM-D-17) in International Clinical Trials: Culture-Specific Differences in Ratings of Depression Symptoms

Raters from varied cultural backgrounds express and perceive depression differently, which may present a challenge to developing a consistent approach to rating HAM-D-17 items in international trials. Manjon and Fielding followed 161 raters from across the international spectrum who had received standardized, pre-study training on rating the HAM-D-17. The training program, provided by i3's Clinical Training and Assessments group (i3 CTA), consisted of a didactic overview of the rating scale, practice rating of a videotaped HAM-D-17 interview, feedback on appropriate ratings for the practice videotape, and then rating another videotaped HAM-D-17 interview for certification. They found that, although the rater training program achieved acceptable rating consistency across countries for the HAM-D-17 total scores, underlying cultural trends in rating specific depressive symptoms did exist between Western and non-Western raters. Identifying and addressing these factors will become more important as psychiatric trials include even more culturally diverse regions.

Poster Session: Wednesday, May 28, 2008, 12:00 p.m. – 2:00 p.m.

4. Central Monitoring of Hamilton-Anxiety (HAM-A) Scores in a GAD Clinical Trial: An Extension of Rater Training to Ensure Data Accuracy

A few poor clinical raters can substantially affect the outcomes of trials of psychotropic drugs. Brady et al. used a customized Central Monitoring (CM) program to review the HAM-A and (HAM-D) scores of 77 raters evaluating 236 subjects in a trial of an investigative compound for the treatment of generalized anxiety disorder (GAD). By developing and implementing an automated program that flags aberrant rating patterns, i3 CTA was able to identify raters who potentially required additional training on the appropriate use of these clinical rating instruments and, with intervention, improved compliance with rating conventions.

Poster Session: Wednesday, May 28, 2008, 12:00 p.m. – 2:00 p.m.

5. Centralized Scoring: Increasing Clinical Trial Data Quality Obtained from Complex Behavioral Performance Measures

With increasing frequency, CNS clinical trials require assessment of treatment outcomes using complex behavioral performance measures, such as neuropsychological tests and proxy measures of functional capacity simulating community functioning. However, such tests are more difficult to administer and may be more prone to scoring errors than more commonly employed symptomatic measures. Costello et al. evaluated scoring errors on the UCSD Performance-Based Skills Assessment (UPSA-2), a role-play test used in multi-center schizophrenia trials to measure potential changes in functional capacity. It was found that on certain UPSA-2 subtests, as many as 42 percent of raters failed to match a computer-derived standard score when attempting to score the test by hand. The researchers describe a centralized, computerized scoring alternative developed by i3 CTA to eliminate scoring errors in these types of tests and enhance data quality.

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About i3

i3, a global Ingenix company, provides integrated scientific strategies and solutions throughout the pharmaceutical product lifecycle. It is composed of i3 Research, a therapeutically specialized contract research organization; i3 Drug Safety, engaged in pharmacovigilance and epidemiology; i3 Pharma Informatics, a data, science and technology provider of market analytics; i3 Statprobe, a leader in comprehensive data services; i3 Pharma Resourcing, a world-class staffing partner; and i3 Innovus, delivering the science and solutions to achieve marketplace success. i3 helps companies gain sharper insights that lead to better patient care. For more information, visit www.i3global.com.

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