

**CHALLENGES IN CONDUCTING MULTICENTER CLINICAL TRIALS IN FEMALE SEXUAL DYSFUNCTION.** Jules T. Mitchel, MBA, Ph.D. and Joyce Hays, MS, Target Health Inc., 305 Madison Ave. 25th Floor, NY, NY 10165; Ralph D'Agostino, Jr., Ph.D. Target Health Inc. and Wake Forest University School of Medicine, Winston-Salem, North Carolina 27157-1063; and Raymond Rosen, Ph.D., Center for Sexual and Marital Health, UMDNJ-Robert Wood Johnson Medical School, 675 Hoes Lane, Piscataway, New Jersey 08502

Female Sexual Dysfunction presents several challenges in the design and interpretation of multicenter clinical trials. The challenges are in part due to difficulties in characterizing the clinical diagnosis; possible non-independence of the variables of desire, arousal, orgasm and pain; relationship and partner issues; individual perceptions of the nature of the disease; regional and societal norms; and time of measurements. Each of these variables must be accounted for in any statistical analysis. In particular, variable reduction techniques such as factor analysis can be useful in creating a more coherent picture of the relationship among the variables of interest. In addition, multivariate techniques may be employed to adjust for the influences of potentially confounding variables such as those described above. While validated questionnaires will be critical in evaluating inclusion criteria and clinical improvement, validation of psychophysiological measures such as photoplethysmography and ultrasound measurements must also be carried out. There is also a need for more normative data on female sexual function against which evaluation of the usefulness of questionnaires or physiological assessment procedures can be made.

While using statistical analyses to determine the validity of these instruments, care must be taken to assess the influence of the different sources of variability. For example, accurate measures of inter- and intra-subject variability are needed to determine reliability. In addition, estimation of the possible impact of measurement error needs to be addressed for instruments using techniques such as ultrasonography. Lastly, validation studies must be performed to evaluate clinical endpoints of sexual activity and to correlate these endpoints with overall patient satisfaction with treatment. Since relationship issues will be involved in most studies, there should be assurances in the inclusion criteria that the population under study includes partners with healthy relationships, partners with a history of sexual activity and a current desire by both partners for improved sexual activity.

**Key words:** Female Sexual Dysfunction; Clinical Trials; FSAD; Female Sexual Arousal Disorder