

From Publication to Protocol: Increasing Awareness of Nonadherence Working Group Recommendations

Shiovitz TM^{1,2}, McCann DJ³, Oseas RN^{1,2}, Skolnick P³, Alexander RC⁴

Methodological Question Being Addressed: What steps can be taken to implement recommended changes in study design?

Introduction: Nonadherence is a substantial problem in clinical trials and contributes to study failure. This working group has published its recommendations for mitigating the effects of nonadherence in clinical trials. Such recommendations, however, can only be effective if stakeholders are made aware of them in a way that facilitates their implementation.

Methods and Results: Working group members have made several suggestions to promote our nonadherence recommendations. These include promoting the Nonadherence white paper published in *J Clin Pharmacol*, developing a best practices statement to add recommendations to protocols and making themselves available to consult on this process, and discussing nonadherence implementation methods with other societies.

Conclusions: Recommendations alone are not enough to change current practices. Despite the publication of the white paper, the working group should continue to meet for another year with a focus on increasing awareness of working group recommendations.

Disclosures: Robert Alexander is a full-time employee of Pfizer Inc., Thomas Shiovitz is President of CTSdatabase, LLC.