Dealing with Treatment ~~Compliance~~ Adherence in Clinical Trials on Inherently Low-~~Compliant~~Adherent Populations: What to Do at the Design, Monitoring and Analysis Stages

33nd Annual Meeting of the Society for Clinical Trials

Invited Session 30

23 May 2012

Miami, Florida, USA

Outline

(1) How best to design a study to maximize medication or psychosocial treatment compliance? What are successful (and unsuccessful) trial design strategies for improving compliance? Are clinical trials where compliance is so low worth doing? At what compliance level does a trial become useless?

Lawrence Friedman, MD

Lawrence M. Friedman

Consultant to the National Institutes of Health

Rockville, Maryland, USA

l.m.friedman@verizon.net

Outline

(2) What are participants telling us on the barriers that affect compliance?

Viviana Horigian, MD

Viviana Horigian

Research Assistant Professor

Center for Family Studies

Miller School of Medicine

Department of Epidemiology & Public Health

University of Miami

Miami, Florida, USA

vhorigian@med.miami.edu

Outline

(3) What are available technologies and methods to maximize compliance?
How best to monitor to ensure compliance?

Michele Straus, MS, RPh

Michele Straus

Clinical Trials Program Specialist

Center for the Clinical Trials Network

National Institute on Drug Abuse, NIH

Rockville, Maryland, USA

mstraus@nida.nih.gov

Outline

(4) How best to analyze the data in the presence of less-than-perfect treatment compliance? Which should be the primary analysis: intent-to-treat, “completers”, or something else? What are the pros and cons?

James Rochon, PhD

James Rochon

Senior Statistical Scientist

Rho Inc.

Chapel Hill, North Carolina, USA

james_rochon@rhoworld.com

Paul Wakim

Senior Mathematical Statistician

Center for the Clinical Trials Network

National Institute on Drug Abuse, NIH

Rockville, Maryland, USA

pwakim@nida.nih.gov