PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

CASE STUDY:
Assessment of Risk Management Plan Impact on Physician, Pharmacist and Patient Knowledge

CLIENT SIZE	Large pharmaceutical	GEOGRAPHY	US
THERAPEUTIC AREA	Cardiovascular		

CLIENT NEED

- The client was a large pharmaceutical company with offices worldwide
- The company was launching a new phosphodiesterase type 5 (PDE-5) inhibitor for treatment of erectile dysfunction
- The drug class was previously associated with adverse events when used concomitantly with anti-hypertensives
- PharmaLex was contracted to develop methodology and assess the effectiveness of the drug risk management plan, in years preceding issuance of FDA REMS guidances

Timelines

- Drug utilization study – one year after product launch (14 months)
- Pre-Label Change survey (25 months)
- Post Label Change survey (21 months)

OUR SOLUTION

- Analyzed pharmacy-based data to establish baseline prevalence and stakeholder profiles relevant to suspected risk
- Obtained IRB approval for human subjects research
- Organized and conducted stakeholder focus groups
- Developed survey instruments, identified target survey populations and conducted stakeholder surveys
- Analyzed and reported individual and comparative survey findings

PHARMALEX VALUE TO CLIENT

- Comprehensive oversight from baseline profile to assessment of risk management effectiveness
- Familiarity with data sources and strategic partnership with survey experts facilitated obtaining targeted information
- Developed and implemented effective methodology for comprehensive assessment of risk management impact prior to issuance of FDA REMS guidances

DISCOVERY / NON-CLINICAL > CLINICAL DEVELOPMENT > APPROVAL / AUTHORIZATION > PRODUCT MAINTENANCE