

Are you ready for REMS?

Don't wait for the FDA to mandate a REMS program for your new product.

*Be pro-active. Be prepared.
Start researching and planning now.*

Start with

SZF REMS[©]

Custom studies for companies planning Risk Evaluation and Mitigation Strategies research under FDA Title IX regulations.

SZF REMS[©] supports your pre-launch preparations and post-launch REMS monitoring.

Pre-Launch Research

Beginning as early as Phase II we work with your commercialization team to identify critical safety and communications issues that your future REMS program must address and resolve.

As your new product moves towards market, we work with your team to develop and test your Medication Guide, Patient Package Insert and other ETASU materials to ensure that they are clear, concise and accessible to Physicians, Pharmacists, Patients and other stakeholders targeted by your REMS Communications Plan.

This pre-launch research is conducted through a series of focus groups followed by qualitative in-depth interviews with each target audience.

Post-Launch Research

Once your new product has been introduced, we work with your Pharmaco-vigilance team to track awareness, familiarity, use and understanding of REMS materials among your various audiences at 18, 36 and 84 months post-launch as mandated by the FDA.

This REMS tracking is conducted through a series of Internet or phone-based surveys.

We also offer follow-up qualitative research to examine in greater depth and detail areas where communications goals have not been met and REMS safety and administration materials have been found wanting.

Our standard **SZF REMS**[©] research package starts at just \$335,000 and includes:

- Six pre-launch focus groups with Physicians, Pharmacists and Patients designed to identify critical safety and communications issues within each stakeholder segment
- Thirty IDI's with Physicians, Pharmacists and Patients designed to evaluate and, if needed, help revise your professional and patient REMS materials prior to launch
- Three post-launch surveys with 100 Physicians, 100 Pharmacists and 200 Patients designed to track awareness, familiarity, use and understanding of REMS materials among these three key audiences
- Six post-survey focus groups with Physicians, Pharmacists and Patients designed to examine in greater depth and detail areas where communications goals have not been met and REMS safety and administration materials have been found wanting and generate possible remedies and solutions to these problems
 - All necessary Market Data and Sample purchases will be billed at cost
 - All Honoraria, Travel, Food and Lodging will be billed as out-of-pocket expenses

For more information about our **SZF REMS**[©] contact Steve Finestone at 215-886-8290 or Steve@szfassociates.com