



Assessing the Effectiveness of Drug Safety Communications

August 17, 2015 • Confidential

BioTrak

Presentation

- About BioTrak
- Summary of REMS assessment experience
- Examples of services and tools

BioTrak Fact Sheet

- Founded in 1999 to provide commercial support and new product planning consulting services to the pharmaceutical and medical device industry. Based in Dallas, TX and San Diego, CA
- Leadership from the pharmaceutical industry including researchers, pharmacists, regulatory, and biostatistics experts.
- Chosen by the best - 6 of the top 10 and 12 of the top 20 global pharmas have selected BioTrak for pharmaceutical risk management programs.
- Over 400 total research studies and more than 200 web-based questionnaire survey studies completed with patients, health care providers, and pharmacists.

BioTrak REMS Expertise

- A recognized leader and innovator in REMS assessment best practices
 - Selected to participate in FDA workshop on REMS assessment standardization
 - Frequent speaker and subject matter expert of REMS assessment
 - Experience with over 40 REMS and 80 assessment reports
- Proprietary and novel analytical toolbox for assessments (ASSESS, PharmaTrak Viewer, other)
- Complete Quality program
 - SOPs and policies covering Quality and Good Clinical Practice (GCP)
 - Good Documentation Practice (GDP)
 - Ethics, privacy, security, and data server safeguards

BioTrak REMS Expertise

A RECOGNIZED LEADER AND INNOVATOR IN REMS ASSESSMENT BEST PRACTICES

“BioTrak is the research organization that we have used for many of our REMS Knowledge surveys (aka, KAB). In fact, Larry is very well connected with FDA REMS leaders and has been instrumental in developing standard protocol approaches for this research that FDA has embraced.”

- Director of REMS, Top 5 Global Pharma

BioTrak REMS Expertise

PROPRIETARY TOOLS AND KNOW HOW IN MEASURING THE EFFECTIVENESS OF DRUG SAFETY COMMUNICATIONS

“Our benchmarking tools like ASSESS and whitepapers on stakeholder performance with REMS surveys provide an informative database and insight into the variables influencing effectiveness of a REMS.”

– Larry Risen, President, BioTrak

BioTrak REMS Expertise

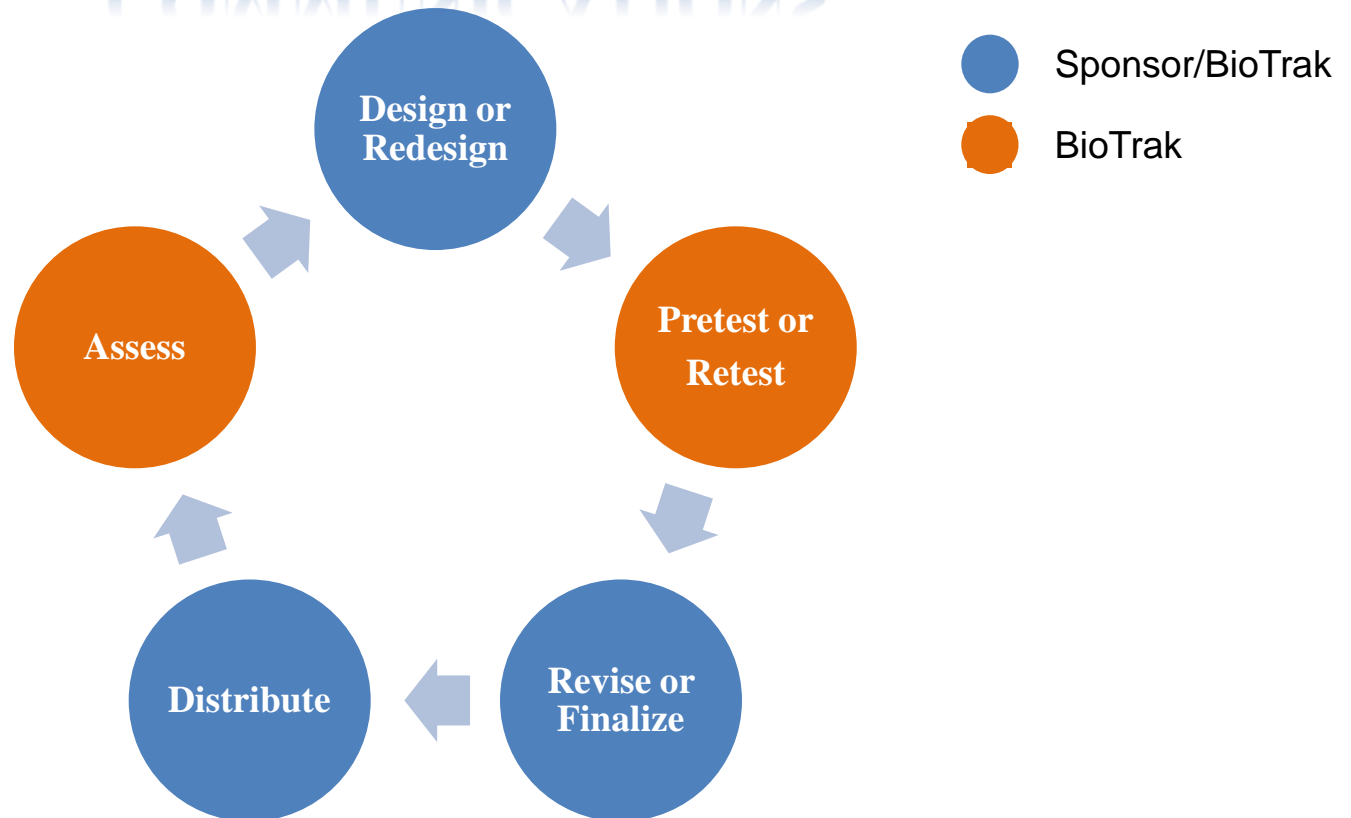
COMPLETE QUALITY PROGRAM

“I am pleased to share that BioTrak has successfully completed numerous pharma quality audits with great success. Our quality practices assure both regulatory compliance and reliability in the results we report.”

– Elaine Welty, Sr. Project Manager & Head of QA, BioTrak

BioTrak as a REMS Partner

EFFECTIVE RISK/BENEFIT COMMUNICATIONS



Complete Range of REMS Assessment Services

**HCP Survey
& Protocol
Development**

**Survey pre-
testing &
validation**

**Patient and
prescriber
recruitment**

**Data
management
& analysis**

**Data
reporting**

REMS BEST PRACTICES

ESTABLISHING INDUSTRY BEST PRACTICES IN REMS ASSESSMENTS

- Proprietary web survey portal providing easy but well controlled online survey access at www.treatmentsurvey.com
- Real-time assessment reporting through “PharmaTrak Viewer”
- ASSESS, the first of its kind analytical tool and registry guiding Clients with selection of appropriate REMS assessment performance metrics, interpretation of results, and determination of corrective actions

REMS BEST PRACTICES



TreatmentSurvey.com
Sponsored by BioTrak Market Intelligence, Inc.

About FAQ's Contact/Support Clients Home

Welcome to TreatmentSurvey.com

Please enter your survey code here:

Please note: You will be asked to re-enter your survey code when you return to the survey you will be participating in.

To complete the survey by telephone, or for telephone assistance, call the toll free number: 866-866-5856 ext 2 between the hours of 9am and 5pm EST.

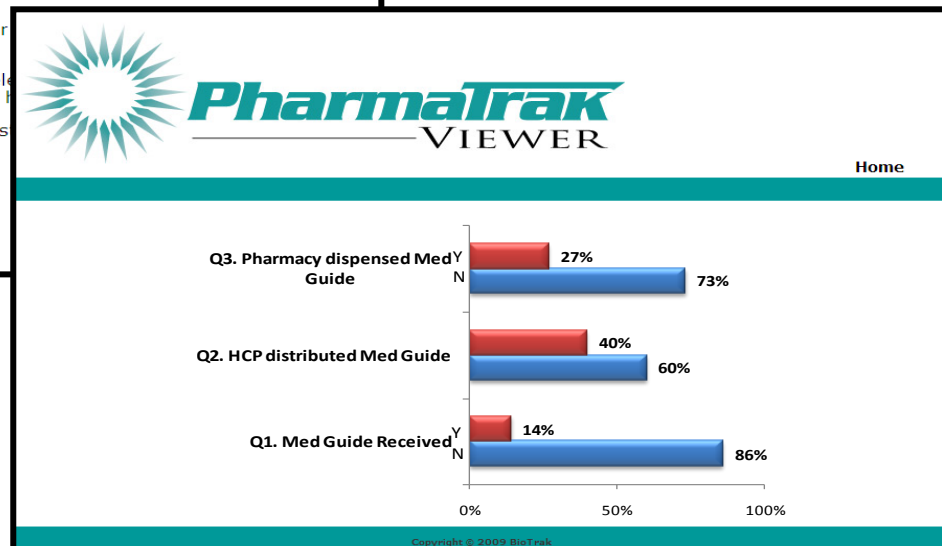
Para ayuda en Español por favor llame a nuestro número de teléfono gratuito 866-866-5856 extensión 2.



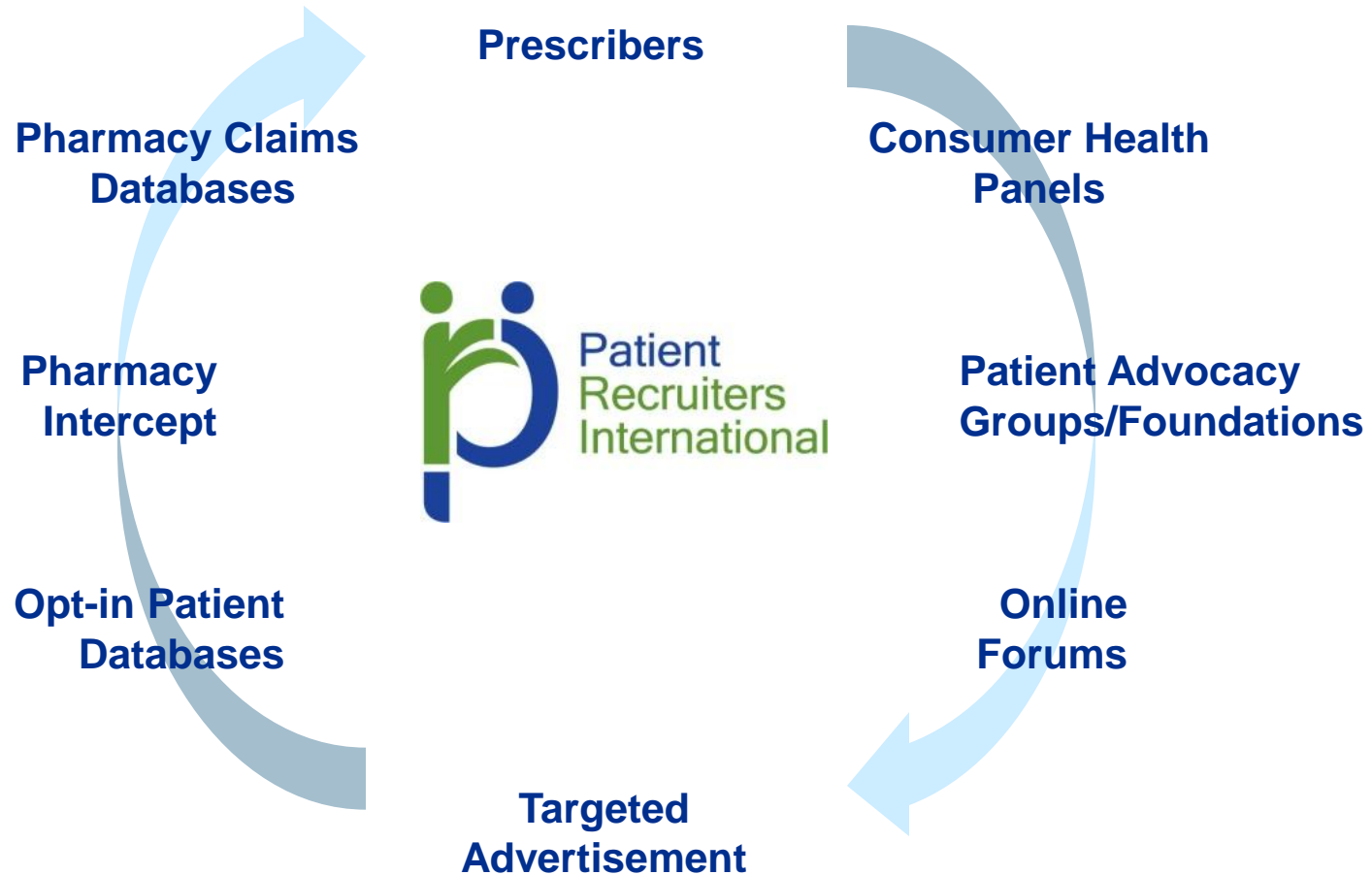
Centralized assessment portal for easy stakeholder and client access

Unique client specific dashboard for real-time assessment reporting

Proprietary web coding and database system verifies survey code authorization, and directs to appropriate survey



Multi-Model Recruitment Capabilities



Examples of REMS Assessment Projects

Examples of REMS Assessment Experience

Disease Area	Sample	Product	Type of Research Study	Methodology
<i>Antiviral</i>	Patients	New Rx Medication	REMS Assessment for measuring understanding of the serious medication risks	Web-Based and Call Supported Survey
<i>Cardiovascular</i>	Patients and Prescribers	New Rx Medication	REMS Assessment for measuring understanding of medication risks, appropriate use, and medication guide distribution compliance	Web-Based and Call Supported Survey
<i>Cardiovascular</i>	Patients	Existing Rx Medication	REMS Assessment for measuring understanding of serious risks and medication guide distribution compliance	Web-Based and Call Supported Survey
<i>CNS</i>	Patients and Physicians	New Rx Medication	REMS Assessment for measuring understanding of medication risks, appropriate use, and medication guide distribution compliance	Web-Based and Call Supported Survey
<i>CNS</i>	Patients	New Rx Medication	REMS Assessment for measuring understanding of serious risks and medication guide distribution compliance	Web-Based and Call Supported Survey
<i>Epilepsy</i>	Patients	New Rx Medication	REMS Assessment for measuring understanding of serious risks and medication guide distribution compliance	Web-Based and Call Supported Survey
<i>Epilepsy</i>	Patients	Existing Rx Medication	REMS Assessment for measuring understanding of serious risks and medication guide distribution compliance	Web-Based and Call Supported Survey
<i>Epilepsy</i>	Patients	Existing Rx Medication	REMS Assessment for measuring understanding of serious risks and medication guide distribution compliance	Web-Based and Call Supported Survey
<i>Gastroenterology</i>	Patients	New Rx Medication	REMS Assessment for measuring understanding of serious risks and medication guide distribution compliance	Web-Based and Call Supported Survey
<i>Gastroenterology</i>	Patients	New Rx Medication	REMS Assessment for measuring understanding of serious risks and medication guide distribution compliance	Web-Based and Call Supported Survey
<i>Metabolic</i>	Patients	New Rx Medication	REMS Assessment for measuring understanding of the serious medication risks	Web-Based and Call Supported Survey
<i>Oncology</i>	Patients	New Rx Medication	REMS Assessment for measuring understanding of the serious medication risks	Web-Based and Call Supported Survey
<i>Pain</i>	Patients	New Rx Medication	REMS Assessment for measuring understanding of the serious medication risks	Web-Based and Call Supported Survey
<i>Pain</i>	Patients and Physicians	New Rx Medication	REMS Assessment for measuring understanding of serious risks and medication guide distribution compliance	Web-Based and Call Supported Survey
<i>Surgical/Other</i>	Patients and Physicians	New Rx Medication	REMS Assessment for measuring understanding of medication risks, appropriate use, and medication guide distribution compliance	Web-Based and Call Supported Survey
<i>Transplantation</i>	Patients and Prescribers	New Rx Medication	REMS Assessment for measuring understanding of medication risks, appropriate use, and medication guide distribution compliance	Web-Based and Call Supported Survey
<i>Transplantation</i>	Patients and Prescribers	Existing Rx Medications	Elements to Assure Safe Use Program, Shared REMS. REMS assessment design and implementation for patients and health care providers to measure REMS performance	Web-Based and Call Supported Survey

Examples of Labeling Comprehension Study Experience

Observational Research and Labeling Comprehension Study Experience

Disease Area	Sample	Product	Type of Research Study	Methodology
Allergy	Patients and Parent Caregivers	Injectable Drug/Device combination	Observational study pre-market assessment of usability and attitudes towards a new drug delivery device	One-on-one interviews
Asthma	Patients and Parent Caregivers	Inhaled Drug/Device combination	Observational study and pre-market assessment on probable use patterns and attitudes towards new inhaler technology	Web-based Survey
Dermatology	Patients	Injectable Aesthetic	Observational study and pre-testing of a patient package insert for readability and comprehension	One-on-one interviews
Diabetes	Patients	Injectable Drug/Device combination	Observational periapproval study on product usability and comprehension of patient package insert	One-on-one interviews
Epilepsy	Patients and Parent Caregivers	Rectally administered Drug/Device combination	Observational periapproval study on product usability and comprehension of patient package insert	One-on-one interviews
	Pharmacists	Rectally administered Drug/Device combination	Observational periapproval study on dose preparation and understanding of instructional materials	One-on-one interviews
	Patients and Parent Caregivers	Rectally administered Drug/Device combination	Phase IV Patient Registry to measure pharmacy dispensing performance and patient understanding	Survey
Gastro-esophageal Reflux (GERD)	Patients	Orally administered Drug capsule	Pre-Market Product Evaluation for new oral GERD medication including swallow test	One-on-one interviews
Pain	Patients	Inhaled medication	Observational periapproval study on product usability and comprehension of patient package insert	One-on-one interviews

Key Business Assets Owned by BioTrak



PharmaTrak[®]



**DecisionTool
Optimizer**



Sponsored by BioTrak Research

For More Information

We hope you found this summary useful. To learn more or to discuss your program needs, please contact:

Larry A. Risen

President

BioTrak Research Inc.

760.448.4823

Email: risen@biotrak.com

Web: www.biotrak.com