Presentation

• About BioTrak

• Summary of REMS assessment experience

• Examples of services and tools
• 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
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
“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

Design or Redesign

Assess

Pretest or Retest

Distribute

Revise or Finalize

Sponsor/BioTrak

BioTrak
Complete Range of REMS Assessment Services

- HCP Survey & Protocol Development
- Survey pre-testing & validation
- Patient and prescriber recruitment
- Data management & analysis
- Data reporting
ESTABLISHING INDUSTRY BEST PRACTICES IN REMS ASSESSMENTS

- Proprietary web survey portal providing easy but well controlled online survey access at [www.treatmentsurvey.com](http://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

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

Prescribers

Pharmacy Claims Databases

Pharmacy Intercept

Opt-in Patient Databases

Targeted Advertisement

Consumer Health Panels

Patient Advocacy Groups/Foundations

Online Forums
### Examples of REMS Assessment Projects

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

*BioTrak*
## Examples of Labeling Comprehension Study Experience

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<td>Allergy</td>
<td>Patients and Parent Caregivers</td>
<td>Injectable Drug/Device combination</td>
<td><strong>Observational study pre-market assessment</strong> of usability and attitudes towards a new drug delivery device</td>
<td>One-on-one interviews</td>
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<tr>
<td>Asthma</td>
<td>Patients and Parent Caregivers</td>
<td>Inhaled Drug/Device combination</td>
<td><strong>Observational study and pre-market assessment</strong> on probable use patterns and attitudes towards new inhaler technology</td>
<td>Web-based Survey</td>
</tr>
<tr>
<td>Dermatology</td>
<td>Patients</td>
<td>Injectable Aesthetic</td>
<td><strong>Observational study and pre-testing</strong> of a patient package insert for readability and comprehension</td>
<td>One-on-one interviews</td>
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<tr>
<td>Diabetes</td>
<td>Patients</td>
<td>Injectable Drug/Device combination</td>
<td><strong>Observational periapproval study</strong> on product usability and comprehension of patient package insert</td>
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<td>Epilepsy</td>
<td>Patients and Parent Caregivers</td>
<td>Rectally administered Drug/Device combination</td>
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<td></td>
<td>Pharmacists</td>
<td>Rectally administered Drug/Device combination</td>
<td><strong>Observational periapproval study</strong> on dose preparation and understanding of instructional materials</td>
<td>One-on-one interviews</td>
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<tr>
<td></td>
<td>Patients and Parent Caregivers</td>
<td>Rectally administered Drug/Device combination</td>
<td><strong>Phase IV Patient Registry</strong> to measure pharmacy dispensing performance and patient understanding</td>
<td>Survey</td>
</tr>
<tr>
<td>Gastro-esophageal Reflux (GERD)</td>
<td>Patients</td>
<td>Orally administered Drug capsule</td>
<td><strong>Pre-Market Product Evaluation</strong> for new oral GERD medication including swallow test</td>
<td>One-on-one interviews</td>
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<td>Pain</td>
<td>Patients</td>
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Key Business Assets Owned by BioTrak
We hope you found this summary useful. To learn more or to discuss your program needs, please contact:

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