Innovations and Expertise in Labeling Comprehension and Human Factors Research Studies

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BioTrak Research Services

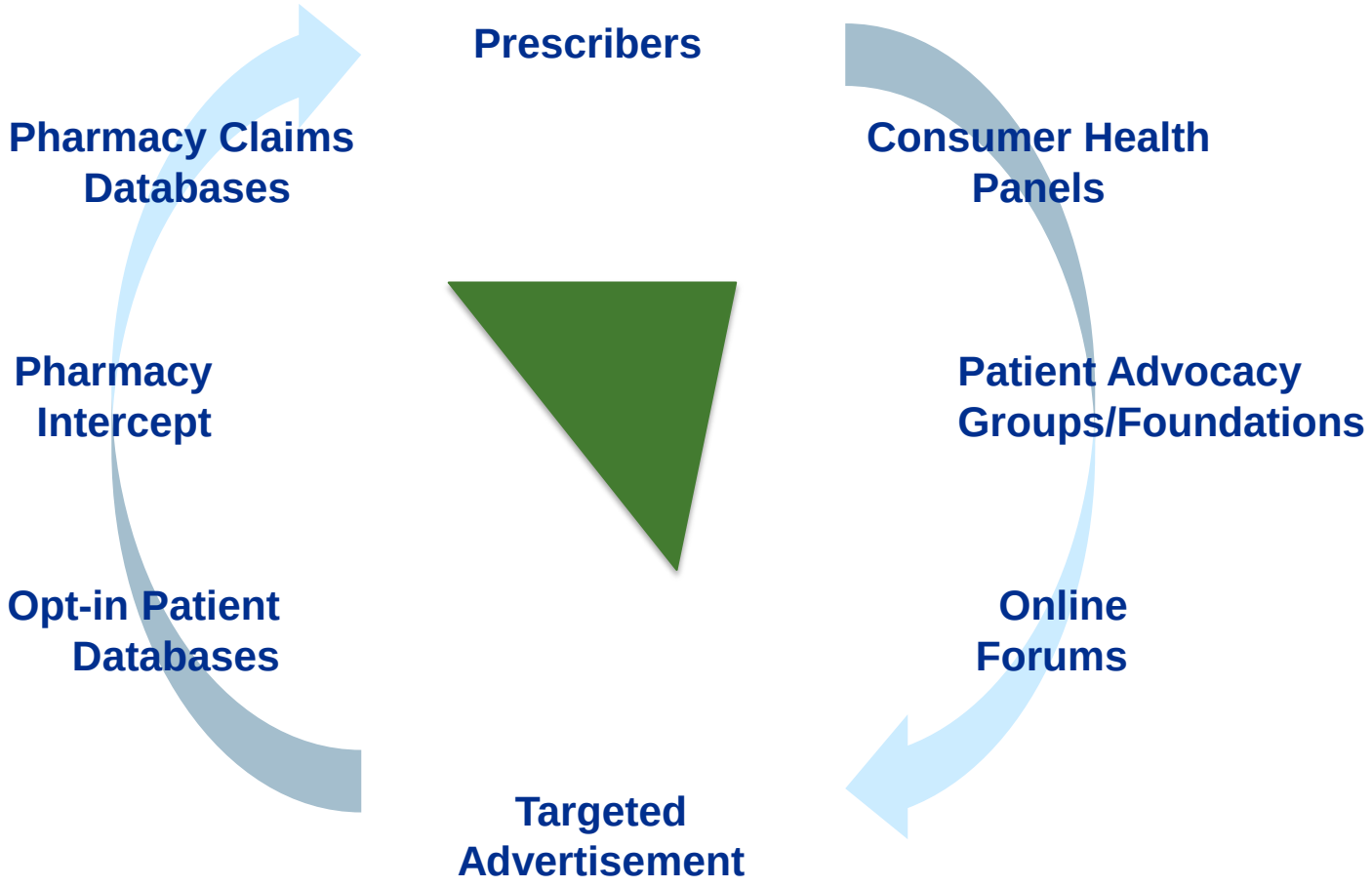
Easy to understand medical information and clear product labeling is critical to the safe use of certain drugs, biologics and medical devices.

- BioTrak offers comprehensive studies to determine the effectiveness of medical product labels, directions, risks, and warnings. These studies evaluate user understanding, user acceptance, performance and human factors with:
  - *Patient instructional aids (ex. IFUs)*
  - *Patient educational information (medication guides, package inserts)*
  - *Self-administration, preparation and/or product user tasks*
  - *Educational information and risk/benefit communications for healthcare professionals*
  - *Instructional information for healthcare professionals*
- Often, these studies are performed with patients and healthcare providers in private observational research settings.

BioTrak Overview

- Founded in 1999 by leadership from the pharmaceutical industry, BioTrak has established a legacy of commercial support and new product planning consulting services to the pharmaceutical and medical device industry.
- Our team and comprises a team of researchers, pharmacists, regulatory, biostatistical experts, and support staff.
- Global pharmaceutical and development stage biotech companies have come to trust BioTrak's knowledge of regulatory requirements and FDA expectations, which have resulted in numerous successful FDA approvals.
  - Over 400 research studies completed - interview projects and web-based survey studies with patients, health care providers, and pharmacists
- Complete Quality program
  - *SOPs and policies covering Quality and Good Clinical Practice (GCP)*
  - *Good Documentation Practice (GDP)*
  - *Ethics, privacy, security, and data server safeguards*

Multimodal Recruitment Capabilities



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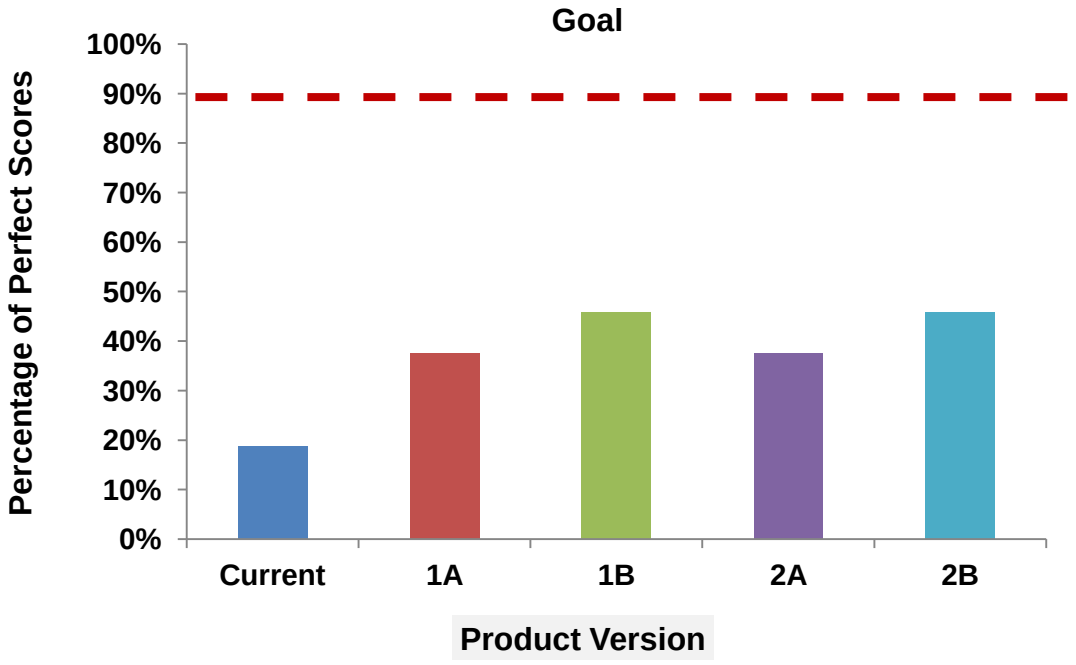
Examples from Labeling Effectiveness and Usability Research Studies

Labeling Effectiveness Testing

- **Rationale & Benefits**
  - Improve product safety, efficacy, and usability
  - Mitigate risks from inappropriate drug or product use
  - Reduce regulatory jeopardy
  - Improve approval timeframe

Labeling Effectiveness Testing
BioTrak Case Example - 1

- **Studies of labeling comprehension, compliance and product usability have revealed surprisingly poor initial labeling performance by patients.**
- Figure 1 below is an example of a caregiver study involving manipulations with a novel drug delivery device. One device represented the currently marketed product; the other four devices tested were replacement prototypes. The study revealed labeling as a major source of end user confusion.
- **Figure 1. Caregivers Ability Properly Perform a Drug-Device Delivery without Error (n=48)**



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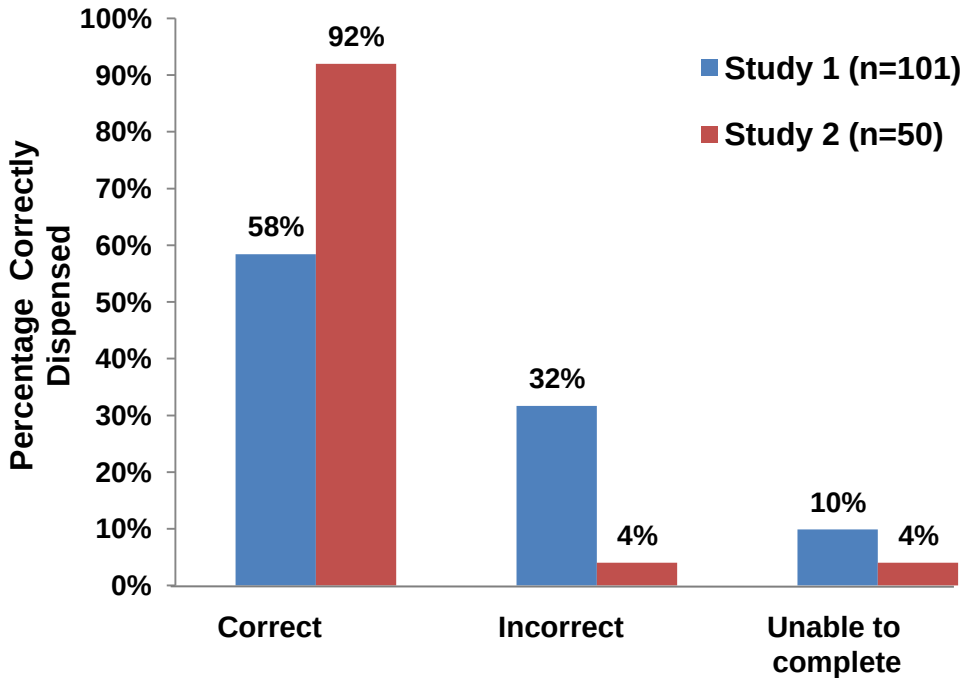
Labeling Effectiveness Testing
BioTrak Case Example - 2

- **The process of labeling pretesting can yield critical insights into improving successful product use and reducing the potential for medication risk.**
- Figure 2 is a pharmacist study. The first pilot with the labeling (Study 1) demonstrated a 42% rate of dispensing error. Following label revisions and beta testing, a second study (Study 2) was performed with fifty retail pharmacists to measure effect of the labeling changes. The comparative results for study 1 and 2 are shown in Figure 2. The error rate from study 1 to study 2 declined from 42% to 8%.
- **Figure 2. Labeling Comprehension Study with Pharmacists: Results Before and After Label Revisions**



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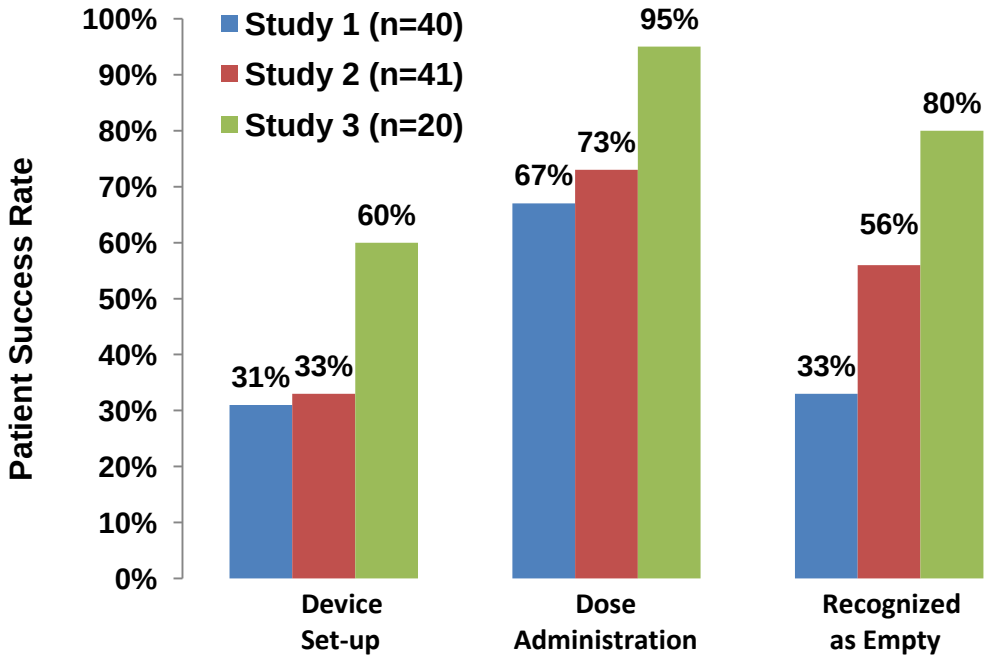
Labeling Effectiveness Testing
BioTrak Case Example - 3

- **Often more than one pilot study is needed to optimize comprehension of patient labeling.**
- Figure 3 provides the comparative results for three sequential studies on patients' ability to properly set a dose, self-administer a medication, and recognize an empty delivery device. Labeling revisions occurred between study 1 and 2, and study 2 and 3. The success rates for each study are given in Figure 3. A dramatic improvement was observed from study 1 to study 3 with overall error reduced in half or more for each key measure, including a 95% success rate with dose administration in the last study.
- **Figure 3. Labeling Comprehension Study with Patients: Results Before and After Two Label Revisions**



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Labeling Comprehension and Human Factors Research Consulting Experience

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Observational Research and Labeling Comprehension Recent 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

Compliance and Quality Assurance

Compliance Statement

- ✓ Ethics policy, training, and designated Ethics Officer
- ✓ Good Clinical Practice (GCP) and Part 11 compliance procedures and training program
- ✓ Privacy and Security compliance procedures and training program and designated Officer
  - 100% of staff NIH certified in human subjects research and privacy
- ✓ Data management safeguards
  - Secure server - Physical and IP security measures (i.e. intrusion detection, encryption security, locked restricted access room)
  - Remote (offsite) backup and disaster recovery plan
  - Offer SSH that is user name/password authenticated
  - SSL on all data collecting websites
- ✓ In compliance with federal, state and local laws – no history of non-compliance

Key BioTrak Assets

DecisionTool Optimizer

Contact to Learn More

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

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