Concentrics Research
Client Centered Strategies

Switch Challenges and Suggested Solutions
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Overview

- Current Switch research
  - Context
  - Goals
  - Similarities and Differences
- 4 Common Challenges
- 4 Solutions for Consideration

Context of Consumer Research

In clinical research, we are understanding how the drug reacts physiologically in the person.

In consumer research, we are understanding how the person reacts behaviorally with the drug.

Goals of Consumer Research

- Label Comprehension (Focus=label)
  - Communicates product **use**, **directions**, **warnings**.
- Self-Selection (Focus=consumer judgment)
  - Judgment about whether it is appropriate to use the drug based on:
    - The **product label**
    - **Consumer's medical history**.
- Actual Use (Focus=consumer behavior)
  - **Safety** in an unsupervised OTC environment and
    - **Self-selection** and **compliance with label**
  - Obtain a **health benefit** that exceeds the risk.

CHPA Roundtable, February 2005

Consumer Studies are Rigorous

Study Procedures	Clinical Trial	Label Comp	Actual Use
Protocol	Yes	Yes	Yes
IRB	Yes	N/A	Yes
Select Sites	Yes	Yes	Yes
Screen subjects	Yes	Minimal, except special pops	Minimal, except special pops
Informed Consent	Yes	Confidentiality	Yes
Medical History or procedures	Yes	Minimal	Minimal
Enroll subjects	Yes	Yes	Based on Self-Selection and risk
Use drug/device at home	Yes	No	Yes
Diary or usage data collected	Yes	1-day interview	Yes
Follow-up visits/procedures	Yes	N/A	Minimal
Collect paperwork	Yes	Yes	Yes
Collect drug	Yes	N/A	Yes
Post-approval studies	Phase IV	N/A	Phase IV rarely used

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Actual Use Trials Simulate "real-life"

Study Procedures	Real-Life	Actual Use
Awareness & Education	Advertising/ Friends/Family (Product)	No
Motivation to seek the product	Product	Product in context of study
Read label/evaluate	Yes	Yes
Decision: Is it right for me?	Yes	Yes
Decision: Do I want to purchase it?	Yes	Yes
Decision: Do I want to use it?	Yes	Yes
Decision: Will I choose to comply with the label?	Yes	Yes
Protocol, Informed Consent, data collection, drug and diary collection	No	Yes

There must be a balance between simulating the "real-life" experience and gathering useful data.

4 Common Challenges

1. Lack of consensus on what to measure or how to judge success.
2. Evaluating self-selection (right/wrong vs. *risk* of the response or behavior).
3. Balancing the need for naturalistic approaches with the need to collect useful data.
4. Minimal use of post-approval research to answer long-term questions.

Solution1:
Judging "Success"

- Simplify and Target:
  - Label messaging needs to be simplified, consumer-friendly, not overly technical.
  - Agree on targeted and reasonable success criteria upfront with the agency.

- Incorporate Learnings into iterative testing
  - Adjust the label and program based on learnings
  - Re-test
  - Re-evaluate

- Evaluate from a risk perspective
  - Evaluate research results based on ***risk, not on 100%***

Solution 2: Evaluating Self-Selection

- "Ask a doctor or pharmacist" is an acceptable and reasonable self-selection response:
  - Infers caution by consumers
  - Currently, less information in a study, than in the "real-world"
  - Very common in new categories
- Two common reasons for incorrect self-selection:
  - Comprehension (did not see/understand)
  - Over-ride (previous experience, strong motivation)
- Need to understand:
  - How many got it incorrect?
  - WHY did they get it incorrect?
  - What is the ***risk*** of their getting it incorrect?
  - Do the benefits exceed the risks?

Solution 3:
Balancing Controlled vs. Uncontrolled

- "Naturalistic" is in eye of the beholder
  - There is a limit to what can reasonably be incorporated into a study.
  - The true naturalistic setting is "at home" when the consumer is unsupervised.
- Goal of Actual Use Studies
  - Safety in the OTC environment
  - Benefit outweighs risk
- Design Considerations
  - Recruiting and/or enrollment should incorporate intended advertising and education messages
  - Some structure is needed to assure collection of useful data
    - Follow-up phone calls (minimal)
    - Scheduled final visit

Solution 4:
Shift Long-term Endpoints to Phase IV

- Cannot incorporate/learn everything in actual use trial
- Limitations to "naturalistic" study designs
- Long-term trends/patterns of use should be measured in post-approval trials.
  - Similar to Rx research

SUMMARY

- Research goals and endpoints:
  - Simplify, target and agree on reasonable research expectations upfront with a focus on ***risk***.
- Self-Selection:
  - "Ask a doctor, pharmacist, healthcare provider" is an acceptable response in self-selection.
  - Understanding the reasons ("the whys") behind incorrect responses/behaviors and the associated ***risk*** is the key.
- Actual Use:
  - Set realistic expectations for what is "naturalistic."
  - The key naturalistic element in an actual use study is the consumer's "use at home unsupervised."
- Post-approval research:
  - Shift long-term endpoints to post-approval.

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