Concentrics Research
Client Centered Strategies

Design of Consumer Research in Adolescents 12.7.07

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Overview

- Context of Consumer Research
  - Goals
  - Rigor
  - Approaches
- Testing in Adolescents
  - Defining the population
  - Goals in this population
  - Consent and IRB/Ethics ramifications
- Learnings
- Challenges
- Potential Solutions

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.

OTC Development Program

OTC Label

Label Comprehension

- Self-Diagnosis
- Self-Selection

Actual Use

- Self-selection
- Safety
- Compliance

Post-approval

- Safety
- Compliance

Additional clinical studies may be done during this time, if needed.

Note: Not all studies are necessary for every program.

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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	Yes Based on risk
Use drug/device at home	Yes	No	Yes
Diary or usage data collected	Yes	No- 1 d 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)	Limited
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.

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How do we Define this Population?

- FDA Guidance for Industry
  - *E11 Clinical investigation of Medicinal Products in the Pediatric Population:*
    - Children = 2 to11 years of age
    - Adolescents = 12 to 16-18 (depending on region)
    - Adults = 18+

Research Goals in Adolescents

- Risk Minimization
  - Safety
    - Potential for harm under normal conditions
      - Children
      - Adolescents
    - Long term effects
    - Adverse events
    - Risk/benefit ratio in this population
  - Compliance with label directions/warnings
    - Potential for Abuse
    - Potential for Mis-use
  - Usage Patterns – (target market is adults)
    - Amount purchased
    - Frequency of purchases
    - Types of drugs purchased

Is Research Done with Adolescents for OTC Products?

- Yes: Case by case assessment
  - Label Comprehension
    - Focused: ex: a specific warning
    - Full: product use, warnings and directions
      - Ex: Plan B tested in Teens
  - Self-Selection
    - Correctly choose NOT to select the product
      - Ex: Alli tested in teens for a self-selection study
  - Actual Use
    - Studies have been done
      - Alli: limited adolescents
      - Several Switches in development are including adolescents
  - Post-Approval
    - Limited in OTC research

IRB/Ethics Committee

- IRB
  - Members or experts in pediatric population.
  - Review protocol(s), advertising, screening tools, informed consent and assent.
- Recruitment
  - Free of inappropriate inducements (parent or child)

Consenting

- Market Research (interviews/opinions)
  - Types of consumer studies:
    - Label comprehension
    - Self-Selection
  - Consenting
    - MRA Guidelines:
      - Parental permission and informed consent if < 13 years of age
      - Consent signed by individual in simple, straightforward language
      - Can always be more conservative:
        - » Ex: Interview regarding a sensitive topic: birth control, HIV

Consenting

- Clinical/marketing and clinical
  - Types of consumer studies:
    - Self-diagnosis/self-selection with exams or tests or extensive medical history, but no drug use
    - Actual use study: exams or tests and drug use
    - Clinical trials: exams or tests and drug use
  - Consenting
    - E11 Guidance for industry: Parents or guardian to provide consent. “Participants of appropriate intellectual maturity provide assent. Sign and date.
    - AAP: Advocates assent in children and adolescents: Telling patient what he/she can expect in terms of tests and treatments.
      - Assessment of the patient’s understanding
      - Assessing willingness to participate
      - Clarity about voluntary nature and ability to withdra

Our Learnings: *purchase* behaviors in adolescents

- Parent purchases
  - Ages 0-15
- Adolescents begin purchasing occasionally
  - Ages 16-18
  - Rare: kids do not want to spend their money on OTC drugs vs. gas/clothes, entertainment
- Purchases by the adolescent tend to happen when they leave home (college or move out) .
  - Can be ages 16+, but generally 18+
  - Occasional to often: Will purchase if they have to. Do not like spending their money on OTC drugs. More likely to borrow when needed or take from home supplies.

Our Learnings: *usage* behaviors in adolescents

- Parent generally makes a usage decision
  - Ages 0-15
- Adolescents begin making usage decisions
  - Ages 16-18
  - Can often borrow from the household or from friends
  - Usually follow guidelines for usage that they have been taught or observed
- Adolescents make usage decisions (college or move out).
  - Can be ages 16+, but generally 18+
  - Still largely influenced by what they have been taught or observed
  - Increased influence from friends and co-workers

Inherent Research Challenges

- Label
  - Amount of space on the label
  - Drug Facts format
    - Are we clear enough about benefits and consequences?
    - Are the warnings linked to consequences?
- Label and self-selection
  - Verbal answers do not always coincide with behaviors
- Assessing mis-use and abuse in a study
- Observation and peer experience
  - Adolescents are strongly persuaded by peer experiences and suggestions as well as
  - Parental and other adult examples

Potential Solutions: *Start* with the Label

- Clarity and consumer friendly language
  - Chunking of key information
  - Drug purpose and indications
  - Simple, clear instructions
- Clarity about benefits and risks
  - Are we clear enough about benefits and consequences?
- Clarity about warnings:
  - DO NOT USE
  - "Ask a doctor or healthcare provider if…"
  - STOP USE
- Clarity about directions
  - Dosing: amount and frequency

Potential Solutions: *Beyond* the Label

- **Label and Self-Selection Testing**
  - Test in adolescents, when applicable
  - Test literacy in adolescents
  - Consider testing that has behavioral elements (i.e. dosing)
  - Use open-ended scenarios
  - Get the "whys" behind incorrect responses
  - Adjust labeling based on learnings
- **Education**
  - Leverage the adolescent's ability with technology—internet links
  - Educate adults as well as adolescents about the benefits of appropriate use and consequences of inappropriate use —Learn by example
    - PSAs:
    - Programs in schools
    - Increased information on the internet
    - Special patient brochures for adolescents?
- **Mis-Use/Abuse and adverse events**
  - Post-approval studies/surveillance for safety
  - Information about purchase of drugs by adolescents: frequency, types, amounts

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