

Value Messages: Developing, Incorporating, and Making Use of a Core Strategic Tool

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Presentation Agenda

- Creating Product Value Messages
 - Stephanie Barrows
- Building Outcomes Research Strategy Plans Around Value Messages
 - Jennifer Whiteley
- Developing Global Value Dossiers
 - Amy Barrett
- Creating Product Value Messages: Hypothetical Example
 - Kati Copley-Merriman

Creating Product Value Messages

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What are Value Messages?

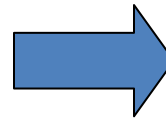
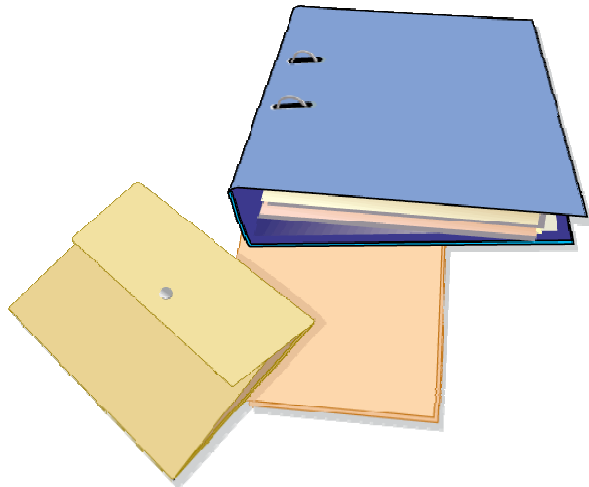
- Statements about the value the product offers to the stakeholders
- Provide concise description of a product based on added value/differentiation from existing products
- Usually include perspectives of various potential audiences (payer/physician/patient/regulatory authority)

Value Messages

- Developed in collaboration with clinical, marketing, commercial (the Product Team)
- May include primary research with payers, physicians, and patients to test the messages

Which comes first – the Value Message or the data?

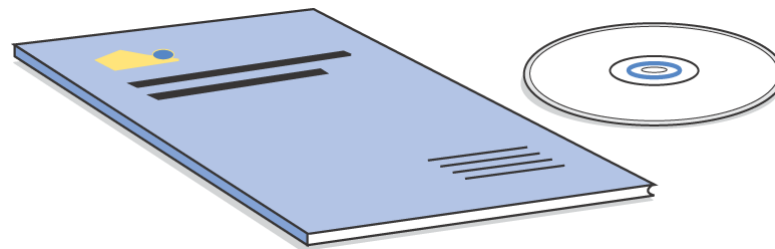
Value Hypotheses



Clinical Data



Strong and Simple Value Messages



Sample Value Messages

Patients	<ul style="list-style-type: none">• Increases length of life within the first 9 months of treatment compared with normal care• Side effects are tolerable• Has been shown to improve functioning, such as ability to perform daily activities
Prescribing Physicians	<ul style="list-style-type: none">• Provides 15% reduction in 28-day all-cause mortality compared with standard care• Provides an acceptable benefit-risk profile with no bleeding complications• Improves cognition and neurological functioning from day 28

Sample Value Messages

Regulatory Authorities	<ul style="list-style-type: none">• Provides statistically significant and clinically relevant reduction in 28-day all-cause mortality compared with standard care in an acceptable benefit-risk profile
Pricing and Reimbursement (P&R) Authorities	<ul style="list-style-type: none">• Provides cost-effective benefits based on cost per life-year gained (cost/LYG) and cost per quality-adjusted life-year (cost/QALY)

Purpose of a Value Message Evidence Table

- Foundation of outcomes research (OR) plan
- Assists in prospectively planning for the OR strategy
- Provides the team with a visual of how the Value Messages will be attained and the likelihood of success
- Creates alignment among team members as to the product strategy
- Start with Value Message and decide how to reach it

Sample Value Message Evidence Table

Value Statement	Target Audience	Evidence	Source of Evidence	Strength of Evidence	Probability of Success	Comments
Drug improves patient functioning	Physicians Patients	Phase 3 trials 001 and 002	Patient-reported outcome (PRO) endpoint data gathered with validated questionnaires	Medium	Medium	Link between drug mechanism and improved functioning not strong

Generating Value Messages

- Review data of key competition and identify Value Messages
 - Literature review
 - Product label review
 - Product Web site review
 - Promotional materials
- Understand how a new treatment could impact the disease or differentiate from the competition based on its product attributes (note: for early-stage OR plans, this may be a bit hypothetical)
 - Clinical, economic, and/or health care delivery advantages

Generating Value Messages

- Strategize with the product team on what they think the product could show
- Draft the messages by stakeholder and develop the evidence table
- Optional: test the messages with key stakeholders

Timing of Value Message Development

- Value hypotheses drafted in early development to help guide the clinical development plan and selection of trial endpoints
- Draft messages developed after the burden of illness and competitive overview sections of Global Value Dossier (GVD) or OR Strategy Plan are written
- Final messages written after the clinical data are available

Building Outcomes Research Strategy Plans Around Value Messages

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Global Health Outcomes and Strategic Pricing
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Outcomes Research Strategy Plan

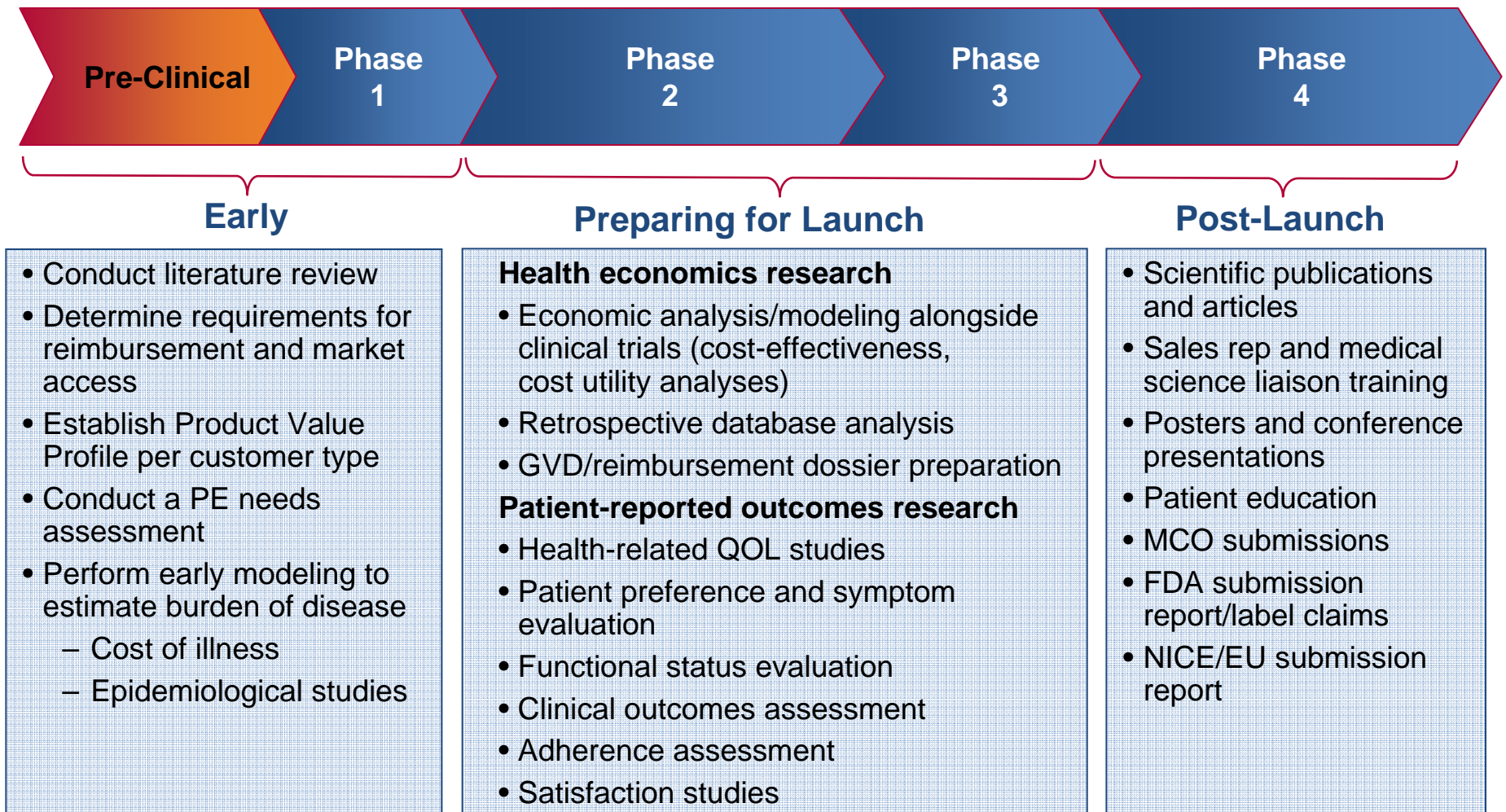
Objective

To develop a plan based around the product's Value Messages to effectively demonstrate and communicate the **value** of products through innovative research, evidence-based tools, and information to relevant stakeholders to support optimal health care decision-making and help people live healthier lives

When should an OR plan be developed?

- As early as possible (e.g., phase 2)
 - May depend on resources
- Build around product Value Messages
- Needs to be flexible and adaptable to account for the changing environment

Outcomes Research Strategy Plans Deliver Across the Lifecycle



Who needs to be involved in the development of an OR Strategy Plan?

- Clinical Team
- Medical Affairs
- Marketing Team
- Health Economics and Outcomes Research
- Others?

What goes into the development of an OR Strategy Plan?

- Understand the current and future market and competitor products
- Understand the value of your product
 - What is the value to the patient, physician, and payer?
 - Does the value differ by different patient subgroups or stakeholders?
- What type of research and tools are needed to effectively demonstrate the value?
 - Are there certain PROs that need to be included early in the clinical trials?
 - What type of economic evidence will be needed to secure access and reimbursement?
- How can the value be optimally communicated to each stakeholder?
 - Can you involve the stakeholders early in the development process to ensure that the product is valuable to them?

Understand the Value Messages the OR Strategy is Built Around

- Where did the Value Messages come from?
 - Are they hypothetical?
 - What evidence is available to support the messages?
 - Were they tested through market research or expert opinions?
- What is the value the stakeholders (i.e., patient, provider, and payer) place on the messages?
- What messages are most important to the stakeholders in each of the key markets/countries?
- What is the likelihood that the compound is capable of delivering on each of these messages?
- What is the impact on potential sales from delivering or failing to deliver on these messages?

Supporting the OR Strategy

Burden of Illness

Patient-Reported Outcomes

Economics

Outcomes Research Communication Strategy

Burden of Illness

- What is the unmet medical need?
- Is the burden of illness well established and understood by key stakeholders (i.e., patient, provider, and payer)?

Patient-Reported Outcomes

- What do we know about PROs in this indication?
- What measures have competitors used in labeling, advertising, publications?
- Is development of a new PRO necessary to support a label claim or commercial message?
- What is the likelihood that the measures proposed will show a significant and clinically meaningful improvement over the comparator?
 - Is there evidence that this difference has relevance to patients, providers, payers?

Economic Evaluation

- What are the key economic drivers in this indication?
- What metrics (e.g., cost-effectiveness/cost utility) have competitors used in formulary or reimbursement submissions, advertising, and publication strategies?
- What are the key economic thresholds this compound will have to achieve?
- What are the appropriate comparators?
- What is the plan for collecting data to document economic value of the compound?
 - What is the likelihood that the compound will be able to demonstrate economic value relative to key comparators?

Outcomes Research Communication Strategy

- How does the OR strategy fit within the overall commercial strategy for the compound?
- Does the OR strategy support the Global Access and Reimbursement Plan?
 - Does it support the needs of the individual countries/key markets?
- What is the plan for communicating the key Value Messages?

Key Considerations in Developing an OR Strategy Plan

- Build around the Value Messages of the product
- Ensure alignment with commercial strategy
- Flexible and adaptable to support across the lifecycle
- Seek country input early on to understand:
 - What is needed?
 - By when is it needed?
 - Are you able to meet all or select country needs?
 - What is the best method to deliver the information?
- Understand the type of internal resources available
 - Large health outcomes department available to meet all needs, or is it a small company that may seek external consultant involvement early on?

Developing Global Value Dossiers

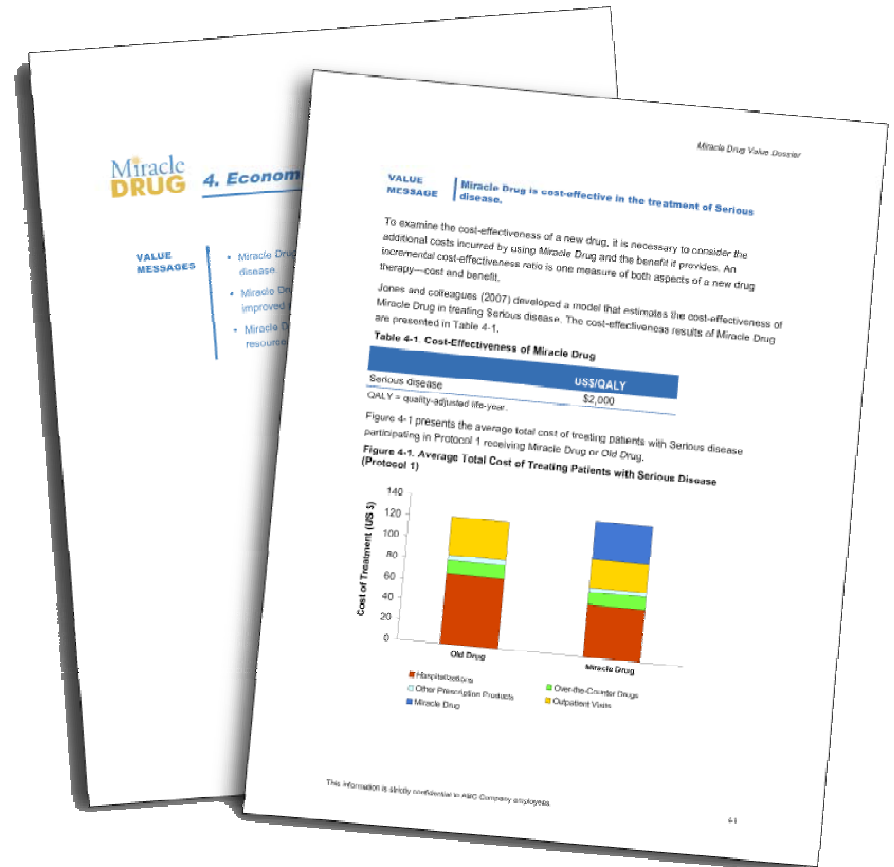
Amy Barrett, MSPH, MA

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What is a GVD?

- Document that summarizes burden of disease (problem) and Value Story of product (solution)
 - Value Story consists of series of Value Messages, each supported by concise and scientifically accurate evidence
- Communication tool developed internally, primarily for internal use
- Serves as basis of country affiliate reimbursement submission dossiers, but not directly transferable



Benefits of Developing a GVD

- Focuses attention on Value Story and Value Messages
 - Drives refinement of Value Messages
 - Builds consensus internally on global product strategy
- Highlights gaps in evidence to be addressed with further research
- Highlights conflicting evidence or counter-evidence
- Helps identify and prioritize OR plan

Benefits of Having a GVD

- Acts as central repository for most current Value Messages and best available evidence
 - Enables dissemination of strategic guidance and coordinated launch strategy across many countries
 - Informs economic modeling efforts
 - Summarizes results of cost-effectiveness and budget-impact analyses in an accessible way
- Supports work of local affiliates
 - Supplemental tools help present arguments
 - PowerPoint slides
 - FAQ for objection handling
- Provides template for Value Messages for subsequent indications

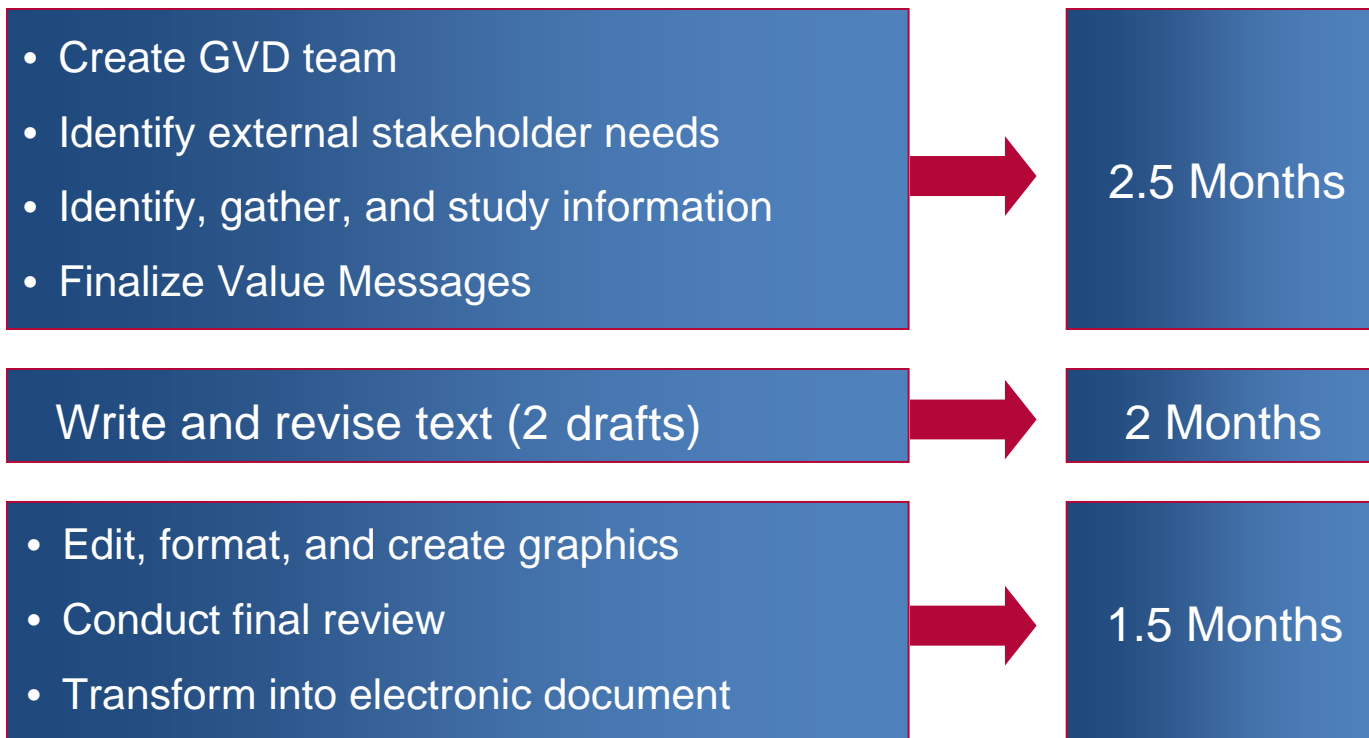
GVD Key Contributors

- Internal team
 - Clinical development
 - P&R
 - Regulatory
 - Marketing
 - Health economics
 - Local affiliates
- External contributors
 - Key opinion leaders
 - Local P&R consultants
 - Vendors

**Interaction of internal, external contributors
managed by internal GVD lead**

Development Timeline for GVD

- Approximately 6-7 months
- Ideally beginning late phase 2/early phase 3



GVD Development Process

- Disease burden sections, particularly disease background, can be developed quite early
 - Peer-reviewed literature
 - Authoritative national/international sources
 - Professional organizations
 - Federally sponsored research organizations

GVD Development Process

- Product value will be based primarily on outcomes of sponsored studies
 - An early start increases likelihood that supporting data will be published, increasing credibility
 - Literature search allows inclusion of independent studies supporting product or counter-evidence that may be refuted or contextualized

Global Component

- Important to seek input from affiliate representatives about their needs/challenges early in GVD development process
 - Simple questionnaire or interview
 - Market access challenges
 - Key comparators, potential differentiation from comparators
 - Potential objections of payers or providers
 - Evidence needs
 - Seek input on aspects of product value that are poorly recognized by payers or providers
 - Request feedback on draft Value Messages, additional potential Value Messages

Global Component

- Content to be explored by country
 - Epidemiology
 - Economic and quality-of-life (QOL) burden
 - Country-specific clinical considerations, including key comparators
 - Country-specific economic considerations, including reference drugs
 - Country-specific Value Message considerations (e.g., value may vary by country related to differences in comparators, treatment guidelines, physician awareness of adverse events)

GVD Outline: Introduction and Burden of Disease

- Introduction to GVD
 - Purpose/how to use GVD
 - Requirements for review before external use
 - Contact information for internal contact/point person (usually internal GVD lead)
- Disease background
- Epidemiology
 - Prevalence/incidence
 - Mortality
- Economic burden
 - Cost of illness
- QOL burden
- Unmet treatment need (competitive differentiation)
 - Current therapies

GVD Outline: Value of Product

- Clinical value
 - Efficacy/effectiveness
 - Safety/tolerability
- Economic value
 - Cost-effectiveness
 - Budget impact
 - Associated decrease in health care resource utilization
- Patient-reported outcomes/QOL value
 - Health-related QOL
 - Functional status
 - Compliance
 - Patient satisfaction
 - Patient preference
 - Caregiver burden

Updating GVD

- Establish process and triggers for updates
 - Publication of additional data
 - Development of economic model
 - Routine annual review
- Examine newly published data carefully to determine if new Value Message is warranted or if data support existing message
- Delete less authoritative versions of the same data (e.g., replace poster presentation citation when study is published in a journal)
- Ideally, the team that develops GVD will be responsible for updates

Key Factors for Successful GVD

- Start early
 - Value hypotheses guide OR plan, resulting in published support for Value Messages
 - Plan to develop at least two draft GVDs before finalization
 - Begin late phase 2, finalize after phase 3 data available
- Solicit feedback from local affiliates and other internal stakeholders
- Provide training when rolling out GVD
- Maintain relevance of GVD through frequent updates

Summary: Value Messages, OR Strategy Plans, and GVDs

- Value Hypotheses guide the clinical development plan and selection of trial endpoints
- Value Messages describe product's value and differentiation from existing products
- OR Strategy Plan establishes research and tools needed to effectively demonstrate the product's value
- GVD communicates Value Story with messages supported by strong, credible evidence

Creating Product Value Messages: Hypothetical Example

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Product Description

- Name: Frightolol
- Indication: “stage fright” or anxiety while public speaking
- Efficacy: reduces anxiety and “fight or flight syndrome”
- Safety issues: lack of alertness, slows reflexes, rarely agitation

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Frightolol Competition

- Benzodiazepines (Xanax, Klonopin, Valium, Ativan)
- Efficacy: relieve anxiety by slowing down the central nervous system for a relaxing and calming effect
- Safety: sleepiness, foggy, uncoordinated, slow reflexes, slurred speech, dizziness, nausea

Generating Value Messages

- Strategize with the product team about what they think the product could show
- Draft the messages by stakeholder and develop the evidence table
- Optional: test the messages with key stakeholders

Frightolol Benefits

- Reduces heart pounding
- Reduces stomach butterflies
- Calming
- Reduces anxiety
- Increases productivity
- No slurred speech, sleepiness, dizziness, nausea

Frightolol Detriments

- Some loss of alertness lasting 30 minutes
- Slows reflexes, should not be taken right before driving
- Agitation only occurs in patients being treated for depression

Timing of Value Message Development

- Value hypotheses drafted in early development to help guide the clinical development plan and selection of trial endpoints
- Draft messages developed after the burden of illness and competitive overview sections of Global Value Dossier (GVD) or OR Strategy Plan are written
- Final messages written after the clinical data are available

Sample Value Messages

Patients	<ul style="list-style-type: none">• Frightolol will calm your nervousness in giving public presentations
Prescribing Physicians	<ul style="list-style-type: none">• Frightolol had a statistically significant improvement in the number of stage fright responders versus valium

Sample Value Messages

Regulatory Authorities	<ul style="list-style-type: none">• Frightolol has a positive benefit compared with the risks for most patients
P&R Authorities	<ul style="list-style-type: none">• Frightolol has low budget impact

Sample Value Message Evidence Table

Value Statement	Target Audience	Evidence	Source of Evidence	Strength of Evidence	Probability of Success	Comments
Frightolol reduces anxiety compared with valium	Physicians Patients	Phase 3 trials 001 and 002	PRO endpoints with validated questionnaires	Medium	Medium	PRO instrument for stage fright would need to be validated in that population