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**Health Economics Outcomes Research:
“Managed Care Applications In Pharmaceutical Brand Management”**

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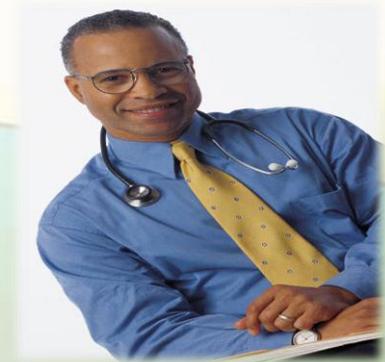
Health Economics and Outcomes Research



Managed Care Applications in
Pharmaceutical Brand Management

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Purpose

- Derive meaningful results with wide utility for your brand and organization
- Gain multi-dimensional care and cost insights to patients, physicians, treatment regimens and managed care
- Demonstrate the brand's combined care/cost performance to clinical and financial thought leaders and decision makers



	+2.000
	+5.000
	+1.500
	+1.125
	+1.062



Purpose

- Establish new positions for the brand based on care/cost performance where it has been unrecognized or under-supported
- Fortify the brand's position against new or established competitors
- Develop a high level of brand HEOR competency for fluid application as the marketplace evolves with additional requirements



Planning

- Align research to generate results to benefit the brand through patient, physician, managed care customer and product applications
- Avoid designing research according to ideal expectations of the brand, this may temporarily position your brand to an advantage but neglect market variables which may shorten/negate relevancy of your results
- Harvest data from recognized industry standard sources to assure a high degree of market representation and acceptance by stakeholders
- Demonstrate meaningful results and introduce new data by avoiding the duplication of earlier HEOR studies



Planning

- Based on brand needs, application of results and organizational resources, determine the scope your HEOR initiative will encompass based on how the results will be used by the brand and your company:
 - Brand marketing
 - Clinical research
 - Industry data tools
 - Market research
 - Post-approval surveillance support
 - Product development
 - Publications
- Cultivate data specifically relevant to central purpose of initiative
 - An overabundance of queries/results may not contribute materially to results and could dilute key findings



Planning

- Consider partnering with outside research companies to conduct HEOR, particularly if the intent is to publish results and/or develop modeling tools for managed care customers:
 - Additional dimension
 - Credibility
 - Logic & methodology experience
 - Objectivity
 - Quickness
 - Tool development competence



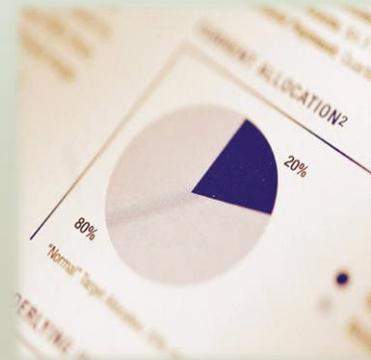
Stakeholders

- Input of provider/managed care stakeholders should be a constant thread in development/execution of an HEOR initiative:
 - It is necessary to combine their brand experience with their disease management and treatment standards
 - Reinforces development of methodology and analysis leading to more definitive outcomes of value to the brand and the marketplace
- Physicians/Managed Care Stakeholders
 - Physicians
 - Employer Medical Directors
 - Managed Care Medical Directors
 - Pharmacy Directors
 - Risk Management



Stakeholders

- Additional external stakeholders:
 - Patient and provider advocate organizations
 - Academia and research institutions
 - Government agencies
 - Employee benefit consultants
 - Global healthcare, entities in other nations
- Internal stakeholders of the pharmaceutical manufacturer:
 - Brand Marketing
 - Managed Markets
 - Product Development
 - Clinical Research
 - Market Research
 - Sales



Internal Brand Assessment

- Develop a high level HEOR brand position through encapsulating latest data (1-3 years) and even further (5 year previous or longer) if you want to illustrate earlier care/cost trends:
 - Existing HEOR (published and internal) on the brand and competitors
 - Marketing/sales (share, volume, average length/cost of therapy, etc.)
 - Current medical, pharmacy and managed care treatment standards
 - Managed care formularies/coverage rules
 - Government statistics (CDC, CMS, NIH, etc.)
 - Syndicated reports
- Based on this detailed brand position, what specific HEOR information is unclear or missing?
- In what areas has the brand not been given an opportunity to demonstrate further care/cost value?

External Brand Assessment

- Engage physician and managed care stakeholders via email surveys to determine:
 - Relative to the brand and treatment protocols, what are primary care/cost issues, how are they changing?
 - What care/cost attributes of the brand are they currently satisfied or dissatisfied with?
 - Are there any significant misconceptions pertaining to the brand and its care/cost performance?
- Based on the input they provide, what primary care/cost information would benefit them the most?
- Align the results of the internal and external assessment of the brand then determine initial applications of measurement and evaluation for a pilot analysis

Pilot Analysis

- The pilot analysis combines high level internal and external assessments then converts them into a statistical measurement application
- While internal and external assessments provide initial input, they do not have enough uniformity/structure to design/orchestrate an in-depth HEOR analysis through
- The pilot queries are to be conducted from a robust database of managed care claims to generate results across a high number of patients/claims data from a variety of plans
- Initial variables may include:
 - Brand indications/formulations/strengths/dosing
 - Disease(s)/associated treatment paths
 - Medical diagnosis/procedure codes/associated costs
 - Patient characteristics/age/sex/co-morbidities
 - Medical claims/associated costs
 - Pharmacy claims history/associated costs

Pilot Analysis

- For uniformity purposes, pilot queries should be from the same database to be used for the full-scale HEOR analysis, this will also ease the path for analysts when conducting the full-scale HEOR study
- A core set of measurements/objectives needs to be established through which methodology and queries will be developed towards
 - The core set of measurements/objectives is adjusted upon completion of the pilot analysis and centrally featured in the large scale analysis
- The pilot analysis is critical, it provides the initial managed care claims data to assess the brand's position/performance in the marketplace in relation to the input from the internal and external stakeholder's assessments

Pilot Analysis

- The results of the pilot analysis can be assessed internally and then with external shareholders via electronic survey and/or within the context of other brand and managed care research focus groups
- It is important to explain how the pilot was developed and its results are strictly preliminary so external shareholders can better evaluate it and offer input/recommendations
- The pilot analysis also serves as a proving ground in the event results fall far short of expectations and have minimal potential to prove themselves in a full scale HEOR application
 - Internal/external assessment and pilot analysis data should be retained following the discontinuance of an HEOR initiative after a pilot analysis as a brand resource

Pilot Analysis

- Key considerations of the pilot analysis is to cultivate input from external stakeholders:
 - What deviates from their experience with the brand?
 - What deviates from their disease management/treatment standards?
 - What pharmacy costs are of primary interest?
 - How may brand performance impact formulary/member costs?
 - What medical costs are of primary interest?
 - How may the brand directly/indirectly impact medical costs?
 - How may the brand's performance impact the medical loss ratio?
 - What aspects of the patient sample are of primary interest?
 - What aspects of the database and claims data are of primary interest?
 - Do they agree/disagree with methodology, sample, interpretation, etc.?
 - What is necessary to migrate the pilot to a full scale HEOR analysis?
 - How does their input compare to the initial stakeholder assessments?

The Deep Dive

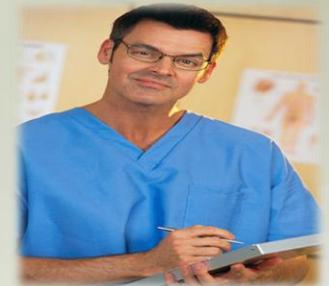
- Based on successful results of the internal/external assessments and pilot analysis, the HEOR initiative is ready to embark on “The Deep Dive”
- The Deep Dive is the full scale analysis combining actuarial, clinical and financial measurements to produce truly representative and statistically sound perspectives
- The core set of measurements, with necessary adjustments, migrate from the pilot to the Deep Dive, representing the central purpose of the HEOR initiative which all queries/results contribute to
- Data should be derived from a large database of managed care claims to generate results across a high number of patients and claims generated from a variety of plans –ideally it is the same database from which the pilot analysis was conducted from

The Deep Dive

- The Deep Dive and the interpretation of its results are the most complex portion of brand HEOR, methodology must be sound and consistently intertwined throughout the overall study
- Well-constructed queries and thorough analysis generate results according to the key measurements which can be more conclusively interpreted
- Interpretation of the results should be exhaustive as care/cost outcomes have significant impact upon the brand and external stakeholders
- Significant corrections/re-direction in the course of executing The Deep Dive results in:
 - Revamping substantial portions of queries
 - Renders much of accumulated data and early results useless
 - Substantially more time and costs

Composite Evaluation

- Results of the Deep Dive should be summarized for discussion and presented in 2-3 advisory boards
- This is necessary to gain external stakeholder insight:
 - Validate interpretations
 - Refine the explanation of methodology
 - Conduct necessary follow-up queries to conclusively quantify results
 - More effectively present the data according to managed care stakeholder's formats and preferences
- If the intent is to publish the HEOR results and/or produce modeling tools for use by external stakeholders, the composite evaluation advisory boards are of critical importance to formally assess results with managed care thoughtleaders



Composite Evaluation

- Request advisory board attendees in advance of the meeting to bring themselves up to date on their own organization's experience so they may be prepared to provide greater insight to results
- It is strongly encouraged one of the data analysts be present at each advisory board to explain the methodology and data collection details to attendees
- What were the primary results of the core measurements for which the HEOR analysis was conducted for and how relative are they to the brand's value proposition?
- In alignment to the brand's attributes, was its care/cost performance strong, intermediate or weak?

Composite Evaluation

- Which areas have strongest care/cost attributes:
 - Therapeutic brand performance
 - Particular indication(s)
 - Patient demographics
 - Medical treatment/cost applications
 - Pharmacy treatment/cost applications
 - Co-morbidities
 - Commercial or Medicare plan considerations
- How can methodology and analysis be more clearly conveyed?
- Are results significant enough to be prepared for publication, what journals or other venues would it be appropriate for?
- What brand applications warrant further HEOR work?



Results

- Based on results of the Composite Evaluation, data can be applied to appropriate applications defined in the Planning phase and others as recommended by internal or external stakeholders
- Cumulative results offer a comprehensive perspective of analysis while segmentation of results can greatly widen its utility through distribution and application of data to specific purposes
- Completed HEOR initiatives provide further utility:
 - Validated chronological information to build brand management and category management resources throughout the product lifecycle
 - Serving an accessory purpose as models to build more advanced applications as marketplace demands evolve

Results

- Meaningful HEOR data can effectively impact:
 - Brand promotion
 - Clinical messaging
 - Commercial & Medicare formulary advantages
 - Market channel positioning



Key Concepts

- Conduct a thorough internal/external assessment of the brand's care/cost attributes prior to beginning an HEO initiative
- Cultivate the input of external stakeholders throughout the process
- Establish core measurements early and maintain close alignment to them throughout the initiative
- Utilize a database which is representative of the marketplace and meets industry/ professional research standards
- Apply sound methodology and validated, exacting queries
- Exercise development during the pilot analysis so the full scale initiative returns the truest results with a minimum of issues

Your Brand

- Each HEOR initiative provides an opportunity to fortify the brand's position in the market by learning more about its care and cost performance
- By directly engaging physician and managed care stakeholders, the brand and your company establishes a stronger identity, while strengthening the approaches and mechanisms of each HEOR initiative you undertake
- As care and cost attributes of pharmaceutical products is increasingly benchmarked and assessed, HEOR continues to widen its role in pharmaceutical brand management



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