Case Study

External Stage-Gate Review
The gold standard for providing a second opinion before making costly Phase III investment

YourEncore developed an external stage gate review process that is utilized by top pharma companies to assist in making the GO / NO-GO decisions for assets poised to transition into Phase III.

90% of the $1.0 B drug development costs market are spent in Phase III.
Source: Manhattan Institute for Policy Research, 2012

With the average Phase III program costing $80-100 MM, the Phase III GO / NO-GO decision is critical to ensuring the best utilization of limited company resources. A second opinion at this critical juncture can be a competitive advantage for companies that leverage external perspectives.

As companies build impressive early-stage pipelines, they recognize the huge investment of money, personnel, and time for Phase III programs. Making crisp, objective decisions on which assets to progress to Phase III is critical to turn the promise of the Phase II portfolio into reality.

Increasingly, Phase III “post-mortems” disclose signals that could have been helpful, or gaps in data that could have been closed before making such a large investment, were it not for the strong “ownership bias,” “investment bias” and “optimism bias.”

Companies are finding that external perspectives can remove these biases and can help make the Phase III GO / NO-GO decision as objective as possible.

OPPORTUNITY: ELIMINATE BIAS FOR CRITICAL DECISIONS

A Top 5 global pharmaceutical company wanted to improve Phase III GO/NO-GO decisions with perspectives from non-vested experts.

The company’s portfolio decision committee (senior leaders of R&D and commercial) recognized their internal biases, as well as the limited capacity for leaders to review assets in-depth and seek external perspectives.

your encore®

© 2015 YourEncore, Inc. All rights reserved.

APPROACH

A team of clinical, regulatory, commercial and market access functions conducted an independent assessment of the client's asset approaching the Phase III GO/NO-GO decision point.

These experts were provided the client's strategies and associated materials for a particular asset (e.g., data from the latest development studies, market research, and regulatory feedback). They then critiqued the strategies and provided an independent assessment of the decisions, relevant information and assumptions. The purpose was to provide an independent voice on development options so a robust GO / NO-GO decision can be made.

YourEncore has completed external stage-gate reviews across multiple therapeutic areas, including:

- Inflammation
- Pain
- Oncology
- Osteoarthritis
- Neuropathy

THERAPEUTIC-AREA CUSTOMIZED TEAMS

Based on the asset being considered, YourEncore customized the team to include the four requisite functional areas, but selected experts for each functional area that had the specific disease- or therapeutic-area expertise for the asset under review. This ensured a peer relationship with the internal client project team.

your encore®

OUTCOMES

This process was piloted in 2012 for a key asset approaching Phase III. The pilot was so successful that YourEncore external stage-gate reviews have been required by the portfolio review committee for all key assets entering Phase III since mid-2012.

The external stage-gate reviews have become an embedded part of the Phase III GO / NO-GO decision point, required for all key assets.

20%

- For 20% of the reviews, the YourEncore team recommended a NO-GO decision, disagreeing with the internal team's conclusion.
- In every instance, senior management accepted the recommendation and discontinued the program.

80%

- For 80% of the reviews, YourEncore recommended a GO decision, agreeing with the internal team's conclusions. In each case, they also recommended improvements to the Phase III program, including:
  - **Proposed an expanded clinical development plan** to address a scope that was too limited to gain the desired clinical benefit
  - **Suggested that market access levels** were too optimistic in EU.
  - **Recommended a different qualitative market research forecast** after the YourEncore team determined the forecast was too high.
  - **Recommended adding a special protocol assessment** (potentially delaying the start of Phase III, but with benefits outweighing the potential risk).
  - **Recommended a special diagnostic test** to mitigate changes in the diagnostic landscape and increase line-of-sight throughout trial.
  - **Re-evaluated the identified pricing and payer strategy** given the clinical scenarios.
  - **Suggested a revised clinical plan to take to FDA** due to the low patient target and because the internal teams plan was not sufficient.

THE INDUSTRY STANDARD FOR PROGRESSING ASSETS

YourEncore's clients who leverage the external stage-gate review process have a competitive advantage over their competitors for four key reasons:

- **A proven methodology** that has been tested and refined over time, providing a consistent output
- **Credible functional expertise** that can draw upon the rich pool of talent within the YourEncore expert network of 8000+ experts, spanning all therapeutic areas and most disease areas
- **Proven outcomes** based on experience in this space
- **Unbiased**, **non-vested**, multi-dimensional perspective that challenges and critiques assumptions

your encore®

Deployed Expert Team: Pain Indication

Development Expert

- MD, Pulmonary Diseases and Critical Care Fellowship; BA, Government
- Expert with significant clinical research experience; career began at the NIH, followed by 20 years in the pharmaceutical industry.
- Expert held senior leadership roles while at Pfizer, Inc.
- Former FDA Pulmonary and Allergy Advisory Committee member (Pharmaceutical Industry Representative) from 2008-2011.

(Expert #14419)

Regulatory Expert

- MD; BA
- Industry-recognized Pharmaceutical executive physician with demonstrated success in top Fortune companies in United States and International settings. Relationships of trust with key regulators, US and International.
- Former Group Vice President and Head, Global Regulatory Affairs, Schering-Plough, expert was responsible for all Regulatory Affairs activities

(Expert #14402)

Market Access Expert

- BS; Graduate Diploma in Epidemiology
- Currently president of a consultancy service specializing in market access, health economics, pricing and reimbursement in Asia Pacific, Japan, Europe and USA.
- Has over 20 years of experience in the pharmaceutical industry in the areas of health economics, reimbursement and pricing and business development.

(Expert #12536)

Commercial Expert

- BA; Marketing and Entrepreneurship
- Expert with 23 years of work experience including 10 years of management consulting experience and 13 years of experience as a commercial operations executive (marketing, sales, and business development).
- The vast majority of work has been in the life sciences with a particular focus on the commercialization of specialty therapeutics (e.g. oncology, rheumatology, multiple sclerosis, etc.).

(Expert #13730)

your encore®

Deployed Expert Team: Osteoarthritis Indication

Development Expert

- MD; PhD, Physiology; BA, Chemistry
- Former Group Vice President: Arthritis, Cardiovascular and Oncology Clinical Development, Pharmacia. Conducted Global clinical research for compounds designed to treat the signs and symptoms of rheumatoid arthritis, osteoarthritis and for the management of pain.
- Provided compound development strategy with a focus on clinical strategy, study designs and implementation.

(Expert # 13084)

Regulatory Expert

- Expert with 31 years of pharmaceutical industry experience, including 17 years in Regulatory Affairs.
- Worked closely with FDA including clinical team leaders in the Division of Anesthesia, Analgesia, and Rheumatology Products.
- Extensive regulatory experience with drugs/biologics that are disease modifying therapies for rheumatoid arthritis and related disorders.

(Expert # 7787)

Market Access Expert

- Experienced pharmaceutical executive, with a background and specialty in the pricing and reimbursement of new medicines.
- Has 18 years of strategic and operational experience at the local (Australia and New Zealand), regional (Asia-Pacific) and international level and a sound track record in achieving favorable pricing and reimbursement outcomes for new medicines in many therapeutic areas.

(Expert # 12535)

Commercial Expert

- Expert with over 27 years' commercial experience in the pharmaceutical and biotechnology industry.
- Has extensive Global Marketing experience, specifically with Metabolic/Endocrinology and Infectious Diseases including HIV. Developed strategic marketing plans for U.S. and International operations; and was involved in developing sales, production, business unit and promotional forecasts.
- Expert has conducted market research within the RA and OA space,

(Expert # 11884)

your encore®