Engaging Key Opinion Leaders (KOLs)
Identifying and Leveraging New KOL Groups to Drive Medical Marketing Strategy
GBI Research Report Guidance

- Chapter three investigates the emerging trend to externalize research and establish productive relationships with academic laboratories and principal investigators.

- Chapter four looks at the landscape for the traditional KOL – the healthcare professional – detailing changes to Codes of Practice guiding the pharmaceutical industry’s interactions with these individuals, trends in KOL management, and issues of relevance to emerging markets.

- Finally, Chapter five examines the role of patients and their advocates in providing insights that should drive drug discovery and development in the future.
Executive Summary

Key Opinion Leaders (KOLs) play important roles in drug discovery and development as well as in the marketing of new medicines. Traditionally, KOLs have been healthcare professionals with senior positions in the medical community of interest. They advise companies as to where unmet medical needs lie, choose drug targets, help to define potential product profiles and shape clinical programs, run clinical trials, and may be involved in a drug’s regulatory or reimbursement review process. KOLs from the academic science community are often involved in company-funded research projects, but may also provide scientific advice.

Once a drug has reached the market, a wider group of KOLs may be required to drive the uptake of a new medicine and gain market share.

Engaging Key Opinion Leaders, Key Opinion Leader Activities During Drug Development, 2012

- Identify areas of unmet medical need
- Identify areas of scientific interest (e.g. drug targets, discovery platforms)
- Undertake company funded research
- Provide Scientific advice
- Brief regulators or payers on behalf of a company
- Build product awareness
- Influence prescribing decisions
- Access competitive products (current and future)

This report describes these established KOL roles in more detail and the consequences of the changing healthcare environment on how the industry identifies and works with new groups of KOLs.

New Roles for Key Opinion Leaders are Emerging

The pharmaceutical industry is facing a number of challenges that will influence the way it works with KOLs. Clinical development programs are longer and more complex than in the past and this is increasing costs of R&D while sales revenues are falling. Companies have cut their internal workforces and are now looking externally for new products. The pressure on healthcare budgets from growing and aging populations and the rise in non-communicable diseases, such as cardiovascular disease and different cancers, as well as the increasing costs of some medicines, have led healthcare providers to pay much greater attention to the cost-effectiveness of new products as a condition of reimbursement. As a consequence, the focus on marketing medicines in emerging economies has also increased.

The definition of KOLs as professors of medicine within specialized areas is, therefore, changing. Indeed, Professor Brian Smith, Visiting Research Fellow at the Open University Business School in the UK, comments in an interview with GBI Research that “as the critical issues facing the pharmaceutical industry in developing a strategy are now much broader than clinical issues, so too must the definition of KOL broaden”. Academic scientists, individuals with responsibility for market access, and other groups of thought leaders including patients, representatives of patient advocacy groups, health economists, those involved in the evolution of healthcare systems and the development of new business models are all considered more influential to the future of the industry.
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2 Introduction

2.1 Key Opinion Leaders: A History

Gabriel Tarde first introduced the ideas of innovation and imitation to explain “buyer behavior” at the end of the 19th century, but his work was ignored for a long period and only revisited recently (Wärneryd, 2008). In the mid-20th century, the current idea of the Key Opinion Leader (KOL) was introduced following research into the influence of media on mass audiences. It was presumed, until that point, that media such as press, radio and television influenced consumers directly. However, research on behaviors during the 1944 US presidential election led to the proposal of two-step flow models of influence, in which media influences opinion leaders who then influence their network of contacts (Figure 1).

Figure 1: Engaging Key Opinion Leaders, Introducing the Key Opinion Leader: The Two-Step Flow Model, 2012

Source: Adapted from Katz & Lazarsfeld (1955)

The 1962 publication from Everett Rogers, including his now famous Diffusion of Innovation adoption curve, described factors that affect the speed of innovation, listed below (Rogers, 1962):

- Relative advantage compared with products or ideas already available
- Compatibility with current activity
- Complexity and ease of use
- Trialability, or the ease with which a product can be assessed
- Observability, or the visibility of others using new ideas or products, explaining how adoption of new ideas/innovations spreads and is influenced by usage and endorsement from opinion leaders.

These factors also include a specific reference to the influence of opinion leaders and this, in turn, has encouraged their use in marketing by a wide range of industries.
3 Building Relationships for External Innovation

3.1 Introduction

Pharmaceutical companies have, over the past few years, stated their increasing interest in products conceived externally to fuel company pipelines. New business models are emerging to support this goal, many of which involve closer ties between industry and academia. Some of the key changes are discussed in the following sections including:

- Moving company R&D operations to hubs or clusters renowned for their academic expertise
- Entering specific partnerships with academic groups for drug discovery
- Developing new funding models for innovative start-up businesses

3.2 Growth Close to Hubs and Clusters

Thus, despite the catalogue of workforce reduction and site closures that have occurred in recent years, some of the largest companies are constructing new buildings at these locations:

- Pfizer and the Massachusetts Institute of Technology (MIT) broke ground on a new 180,000ft² development in Cambridge, MA, that will house Pfizer’s Cardiovascular, Metabolic and Endocrine Diseases (CVMED) and neuroscience research units. The building, which is likely to be completed by the end of 2013, will be leased to Pfizer by MIT for a 10-year period.
- In June 2012, Pfizer announced a further project to establish a laboratory in the same building as Harvard University’s Beth Israel Deaconess Medical Center and Boston Children’s Hospital. The company will invest $100m.
- Novartis will start construction of two new buildings and one renovation totaling 550,000ft² square feet in Cambridge, MA.
- Biogen Idec’s new headquarters are in the Alexandria Center, Kendall Square, Boston. The new development will cost $500m and Biogen Idec will be the first of a number of companies located at the Alexandria Center.
- Bayer Healthcare opened a new research facility in San Francisco, close to University of California San Francisco buildings.
5 Building Relationships with Patients

5.1 Introduction

The pharmaceutical industry’s goal has always been to improve outcomes for patients through the development of truly valuable new medicines to meet currently unmet medical needs.

Patients and patient advocacy groups can play a number of different roles in drug development:

- Inspiring drug development by identifying areas of unmet need
- Matching patients with clinical trials
- Paying for research
- Lobbying governments and regulators to speed drug research

This chapter looks in more detail at the roles that patients and their advocacy organizations may have in the research process and how the industry can find and build effective relationships that will improve outcomes for both parties.

5.2 Patients’ Roles in Drug Development

An EU-based virtual network – the European Network of Patients Partnering in Clinical Research (ENCPR) – empowers, enables and mobilizes European patient organizations to interact with other European and international stakeholders in clinical trials. The ENCPR has developed a guide for sponsors and researchers that looks in detail at how to build effective partnerships. The guide highlights the fact that patients and their representatives are able to offer a unique perspective based on their own or collective experiential knowledge; knowledge acquired through dealing with the effects of their condition on a daily basis.

The ENCPR guide for sponsors and researchers discusses the different points at which patients and their representatives could be involved. The experiences and perspective of the pharmaceutical industry on patient involvement in clinical trials and research was surveyed as part of the project, and responses from XX individuals from 19 companies are reported below.

Patients are an increasingly influential group as drug reimbursement becomes more challenging and patients themselves participate more in healthcare decisions.
6 Appendix

6.1 Abbreviations

ABPI: Association of the British Pharmaceutical Industry
ALS: Amyotrophic Lateral Sclerosis
CALIBR: California Institute for Biomedical Research
CME: Continuing Medical Education
CMS: Centers for Medicare & Medicaid Services
CTI: Centers for Therapeutic Innovation
CTSA: Clinical Translation Science Award
EFPiA: European Federation of Pharmaceutical Industries and Associations
EMA: European Medicines Agency
ENCPR: European Network of Patients Partnering in Clinical Research
FDA: Food and Drug Administration
GNF: Genomics Institute of the Novartis Research Foundation
HTA: Health Technology Assessment
HCP: Healthcare Professionals
IFPMA: International Federation of Pharmaceutical Manufacturers Association
I-SPY2: Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging and Molecular Analysis 2
KOL: Key Opinion Leader
MIT: Massachusetts Institute of Technology
NHS: National Health Service
NICE: National Institute for Health and Clinical Excellence
OIG: Office of Inspector General
PhRMA: Pharmaceutical Research and Manufacturers Association
PRO: Patient Reported Outcome

6.2 References


Appendix


Appendix

- Royal College of Physicians (2009). Innovating for health: patients, physicians, the pharmaceutical industry and the NHS. Available from: [http://bookshop.rcplondon.ac.uk/contents/76673804-76c5-4ab3-89a0-92d44e45edc3.pdf](http://bookshop.rcplondon.ac.uk/contents/76673804-76c5-4ab3-89a0-92d44e45edc3.pdf) [Accessed June 19, 2012]
Appendix


6.3 Research Methodology

GBI Research’s dedicated research and analysis teams consist of experienced professionals with a pedigree in marketing, market research, consulting backgrounds in the medical devices industry, and advanced statistical expertise.

GBI Research adheres to the codes of practice of the Market Research Society (www.mrs.org.uk) and the Strategic and Competitive Intelligence Professionals (www.scip.org).

All GBI Research databases are continuously updated and revised. The following research methodology is followed for all databases and reports.

6.3.1 Coverage

The objective of updating GBI Research’s coverage is to ensure that it represents the most up-to-date vision of the industry possible.

Changes to the industry taxonomy are built on the basis of extensive research of company, association and competitor sources.

GBI Research aims to cover all major news events and deals in the medical industry, updated on a daily basis.

The coverage is further streamlined and strengthened with additional inputs from GBI Research’s expert panel (see below).

6.3.2 Secondary Research

Secondary research was carried out on internal and external sources to obtain qualitative and quantitative information in the report.

The secondary research sources that are referred to in this report include but are not limited to:

- Company websites, annual reports, financial reports, investor presentations and SEC Securities and Exchanges Commission filings.
- Industry trade journals, scientific journals and other technical literature.
- Relevant patent and regulatory databases.
- National government documents, statistical databases and market reports.
- News articles, press releases and webcasts specific to the companies operating in the market.
6.3.3 Primary Research

GBI Research conducts hundreds of primary interviews each year with industry participants and commentators in order to validate its data and analysis. A typical research interview fulfills the following functions:

- It provides first-hand information on the market size, market trends, growth trends, competitive landscape, future outlook, etc.
- Helps in validating and strengthening the secondary research findings; and
- Further develops the analysis team’s expertise and market understanding.
- Primary research involves email correspondence and telephone interviews, as well as face-to-face interviews for each market, category, segment and sub-segment across geographies.

The participants who typically take part in such a process include, but are not limited to:

- Industry participants: CEOs, VPs, marketing/product managers, market intelligence managers and national sales managers;
- Hospital stores, laboratories, pharmacies, distributors and paramedics;
- Outside experts: investment bankers, valuation experts, research analysts specializing in specific medical equipment markets; and
- Key Opinion Leaders: physicians and surgeons specializing in different therapeutic areas corresponding to different kinds of pharmaceutical drugs.

6.3.4 Expert Panel Validation

GBI Research uses a panel of experts to cross-verify its databases and forecasts.

GBI Research’s expert panel comprises marketing managers, product specialists, international sales managers from medical device companies, academics from research universities, KOLs from hospitals, consultants from venture capital funds and distributors/suppliers of medical equipment and supplies.

Historic data and forecasts are relayed to GBI Research’s expert panel for feedback, and adjusted in accordance with their feedback.

6.5 Disclaimer

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