UNIFYING SCIENTIFIC ASSETS TO CREATE A SHARED BRAND STORY:

BUILDING A CROSS-TEAM "PLAYBOOK" TO SUPPORT LAUNCH SUCCESS

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Today's pharmaceutical marketplace poses a growing array of complex challenges. Gone are the days of blockbuster drugs achieving fast uptake, fueled by sales-driven markets. Today, we operate in an outcomes-focused, evidence-based world of relatively slow product adoption and few new drug approvals. The new drugs that are making it to market are not compensating for the large-scale patent expirations hitting the industry. In addition, shrinking windows of exclusivity are giving companies limited time to earn the full return on their R&D investments.

With the Affordable Care Act (ACA) about to take hold, we are entering a new era of healthcare reform—one that brings an increasingly regulated environment that pressures pharma both to contain costs and to demonstrate treatment value. Payers face greater accountability for drug pricing and co-pay decisions, putting stricter demands on pharma to deliver real-world evidence that new products truly provide substantially improved health and economic outcomes.

All of these forces are converging at a time when pharma is particularly unprepared to deal with them. Massive re-organizations, consolidations and down-sizing around the world have weakened many teams, leaving them with less experienced members. While teams have been scaled down, however, the demands on them have not. Teams still need to produce the full set of deliverables to support a coordinated and effective launch.

It's important to remember that, even in a payer-dominated market, providers continue to play a key role. While payers drive approvals, physicians drive acceptance. Fast acceptance is important, because companies have only a short time to establish themselves in the market. IMS studies reveal that products that do well in their first six months have a much better chance of long-term success—and less than 20% could make significant improvements between six and eighteen months.

ACHIEVING CROSS-DISCIPLINARY COOPERATION

How can companies best meet the challenges they face today—and ensure they optimize approval and acceptance of their new brands? The key lies in cross-disciplinary collaboration—tapping into experts from multiple departments, including medical affairs, market access, market research, HEOR, marketing strategy, scientific communications and R&D.

To succeed in today's volatile market, companies must bring all relevant teams together to coordinate activities across departments—and focus everyone on the shared goals of uncovering adoption drivers, identifying market needs and improving patient outcomes.

This cross-collaboration should start early in the process, so it can inform pre-clinical and clinical planning, as well as the ultimate economic and outcomes requirements.

All functions must collaborate to develop two types of powerful value stories in tandem. The first is the clinical story that demonstrates safety and efficacy. The second is the economic story that fuels approval, access and usage. To avoid playing catch up down the road—perhaps too late in the process to change things—teams should begin developing their value stories as soon as a product appears to be commercially viable. Effective value stories should address how the drug meets unmet needs, how its effectiveness compares with other therapies and how it impacts budgets and other real-world factors.

Finally, to keep all team members on the same page as they build their brand stories, it's essential to have a central repository of scientific information that supports consistent and aligned language and claims—and an integrated message strategy and execution—across every function. A detailed Scientific Platform meets that need, providing a comprehensive, uniform reference for all departments—from medical affairs to the commercial team to public relations.

WHAT IS A SCIENTIFIC PLATFORM?

A Scientific Platform is the foundation of a clear, empirically-driven, rigorous scientific story. Providing direct links from each claim to its supporting abstracts, it is a complete resource of all the scientific assets around a brand, including uniform referencing. In short, it puts all the best evidence a company needs to tell its story in one place:

- **An in-depth look at the disease state,** including incidence, burden, current treatments and unmet needs
- **A platform for the brand,** including how it works, pre-clinical evidence, pharmacodynamics, phase 2 and 3 results, pharmacoeconomics and the value proposition
- **A uniform reference library,** linking directly to relevant abstracts

In addition to supporting consistent messaging, a well-constructed Scientific Platform identifies the need for further areas of study and new publications, as well as uncovers opportunities to create novel data. It also forms a framework for evidence-based discussions with Key Opinion Leaders (KOLs) and for medical education programs.

UNDERSTANDING THE SCIENTIFIC PLATFORM STRUCTURE

Scientific Platforms include planks, sub-planks and reference-supported statements, each linked to a citation. Put simply, the planks are the "headline" statements. Reading the planks alone can provide the story "summary"—the key points and messages around the brand. The sub-planks flow organically from the planks and are, in essence, the subheads—the next-level of detail underscoring each plank. Finally the reference-support statements are the citations that provide the evidence behind each statement.

Consider the example below. (See figure 1.) The statement at the top is the plank, setting up the overall topic: The use of stents has improved outcomes for coronary artery disease patients. Under that "headline statement," we have our first supporting sub-plank: Bare metal stents reduce re-occlusion of coronary arteries following angioplasty. Below the sub-plank, we see our list of reference-supported statements—basically, all of the factual "proofs," hyperlinked to their source documents.

VISUAL: FIGURE 1. THE SCIENTIFIC PLATFORM STRUCTURE

The Use of Stents has Improved Outcomes for Coronary Artery Disease Patients			
Bare metal stents (BMS) reduce re-occlusion of coronary arteries following angioplasty			
Coronary artery bare metal stents (BMS) were designed to offset elastic recoil and maintain the diameter of coronary arteries following PCTA procedures		Sigwart et al 1987	Newsome et al 2008
A BMS is a collapsed, cylindrical, metal mesh tube mounted on a balloon catheter and inserted into the narrowed blood vessel during PCI			Newsome et al 2008
BMS expand upon balloon inflation and remain in the artery to maintain vessel diameter following balloon removal, subsequently reducing the occurrence of vessel closure and restenosis			Newsome et al 2008
As of 2000 (prior to DES trials), there were 12 randomized trials comparing BMS to POBA including more than 6,300 patients with de novo lesions showing consistent reductions in reintervention rates of approximately 50%			Al Suwaidi et al 2000
BMS use contributed to a significant decrease in restenosis rates versus the use of PTCA alone at six month follow-up		Serruys et al 1994	Fischman et al 1994
Restenosis rates have varied from 30% to 50% in PTCA	Newsome et al 2008	Doostzadeh et al 2010	Eisenberg 2004
With use of BMS, restenosis rates decreased to 20-25% in most patients, but remained higher in patients with diabetes, complex lesions, or small arterial vessels	Newsome et al 2008	Birkenhauer et al 2004	Doostzadeh et al 2010
Stent thrombosis development was originally a significant complication of BMS, initially occurring in 4-24% of patients before improving to the current rate of approximately 1.2% in the 1990's with improved techniques and adjunctive pharmacology	Kereiakes et al 2004	Topol and Serruys 1998	Wenaweser et al 2005

EXTENDING THE SCIENTIFIC PLATFORM

The Scientific Platform itself provides the technical detail, capturing all of the key concepts around a brand (or a competitive brand) and the supporting references. It establishes the story flow—and the detailed evidence today's strict regulations require—in one central place from which all functions on the team can draw for their specific communication needs. To extend the value of the Platform, three related deliverables are also recommended:

- The brief digest. The brief digest provides the "elevator speech" for key audiences. It delivers the "go to" story in paragraph form, covering the essential points in a concise, one-page narrative.
- The FAQs. The FAQs anticipate and address potential questions. Each question has its own tab providing all related information.
- Training. The developers of the Scientific Platform should provide easy training to help team members understand and use the resources available to support their specific tasks and information requirements. Training can be done live or via WebEx, depending on the location of participants. In addition, it can be adapted to the needs of the commercial team, which can be critical to ensuring compliance.

MAPPING THE SCIENTIFIC PLATFORM PROCESS

Building a complete Scientific Platform that puts all of the brand story elements along with the proof documents behind them in one place is, of course, a massive undertaking requiring deep therapeutic, disease-state, research and scientific knowledge. It is critical to work with a partner who has extensive experience in creating successful Platforms and can bring the full range of skill sets required.

The process starts with a review of all available data and scientific materials related to the category and the brand, including competitive insights and strategies. An exhaustive literature search augments and complements the information gained from internal thought leaders. To further strengthen and enhance the Platform, in-depth workshops are conducted with all key stakeholder groups, identifying key issues, treatment patterns, unmet needs and other critical information.

The team constructing the Scientific Platform uses all of the data and insights it gathers to create the planks and sub-planks—the key evidence-based messages that will be used to tell the brand's story and support its approval, acceptance and usage. The planks and sub-planks will incorporate competitive differentiation across key scientific topics to ensure optimal positioning and message strategies in the market.

SUMMARY

Launching brands into today's market is particularly challenging. Faced with tight regulations and even tighter cost constraints, companies must call on all of their areas of expertise to bring products successfully to market. They must begin planning earlier than ever or risk losing the opportunity—and they must be sure that every phase, right from pre-clinical planning, is guided by the need to develop effective evidence-based clinical and economic value stories.

Key to coordinating smoothly across functions is a tool that ensures consistent focus, language and messaging. (See figure 2.) A comprehensive Scientific Platform fills that role, providing a central, uniform repository of all the scientific assets that support the brand story. In essence, it's the common "playbook" all departments can count on to support alignment across the organization,

The Scientific Platform ensures the brand message meets both regulatory requirements and the market's demand for demonstrating substantial clinical benefits. In today's economic-driven and outcomes-focused world, a Scientific Platform is an essential tool for building value messages that clearly link drugs directly to their impact on patient health.

THE SCIENTIFIC PLATFORM IS A CENTRAL REPOSITORY ALL FUNCTIONS CAN TAP INTO TO SUPPORT CONSISTENT, ALIGNED, EMPIRICALLY-DRIVEN LANGUAGE AND MESSAGING.