GALBRAITH WIGHT Re:thinking Market Access

Building, Embedding & Optimizing Market Access Capabilities – From Strategy to Execution

Symposium, ISPOR, Dublin, Ireland – 4th November 2013

Symposium Objectives

1. To explore reasons why & consequences of lack of full integration of market access into Pharma company development & commercialisation processes

2. To explore via case studies & discuss ideas for improving methods to embed market access into Pharma company development & commercialisation processes

Symposium Agenda

	Session	speaker
7.30am	Objectives & Introduction	**Colin Wight**, CEO GalbraithWight
	Case Study 1: **Global R&D Clinical Development Process** - Building & Embedding Market Access Requirements into R&D	**Jackie Briggs**, Principal Consultant, GalbraithWight
	Case Study 2: **European Regional Market Access team** - Building Market Access Processes & Capabilities across the team	**Tanea Neville**, Principal Consultant, GalbraithWight
	Case Study 3: **New Products Planning at Country Level** - Embedding Market Access into NPP and Launch Excellence	**Janet Waters**, Principal Consultant, GalbraithWight
	Case Study 4: **Automating Market Access planning for Launch** - Optimising Launch Excellence planning in a web-based tool	**Debbie Thompson**, Principal Consultant, GalbraithWight
	Case Study 5: **Strategic Brand Planning** - Embedding Market Access into Strategic Brand Planning Process	**Mark Boyden**, Principal Consultant, GalbraithWight
	Case Study 6: **Building a Market Access Centric internal organisation** - Building, Embedding & Communicating a market-access based philosophy across an international organisation	**Emma Rawlins**, Principal Consultant, GalbraithWight
	Panel Discussion	**Keith Tolley**, Economic Assessor, Scottish Medicines Consortium **Colin Wight**, CEO GalbraithWight
	Conclusions	
8.30am	Close	

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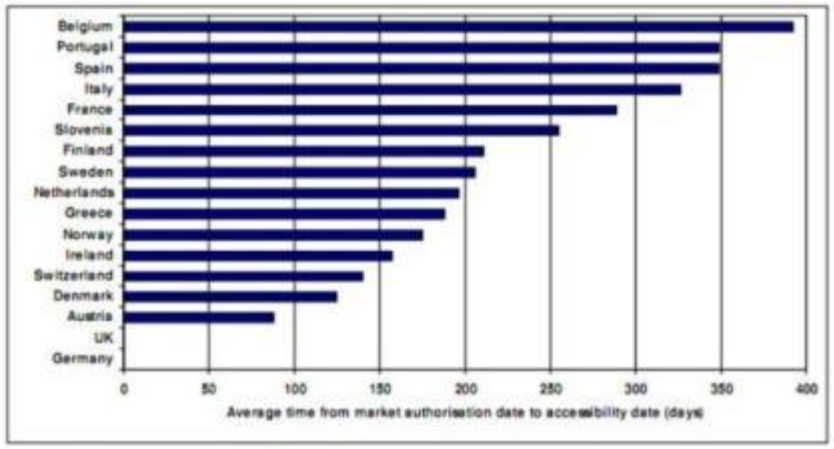
Pharma industry now takes Market Access seriously

We actively **measure** it

Figure 9: Average time from EU market authorisation to accessibility date for medicines with first EU marketing authorisation in the period 2007-09



Source: Patients WAIT Indicator 2010, EFPIA

We talk & **listen to Payer** customers

"Perception of value drives the willingness to pay, and those perceptions vary from country to country," "We need to do a much better job communicating value to payers" *Adam Woodrow, Vice President , Specialty Business Unit, Pfizer September 2011*

We've created **Market Access teams** & hired HEOR experts – in house & agencies

There are good examples of **best practice**

Herceptin trastuzumab

GARDASIL Humaan Papillomavirusvaccin typen 6,11,16,18

HUMIRA adalimumab

Pradaxa dabigatran etexilate

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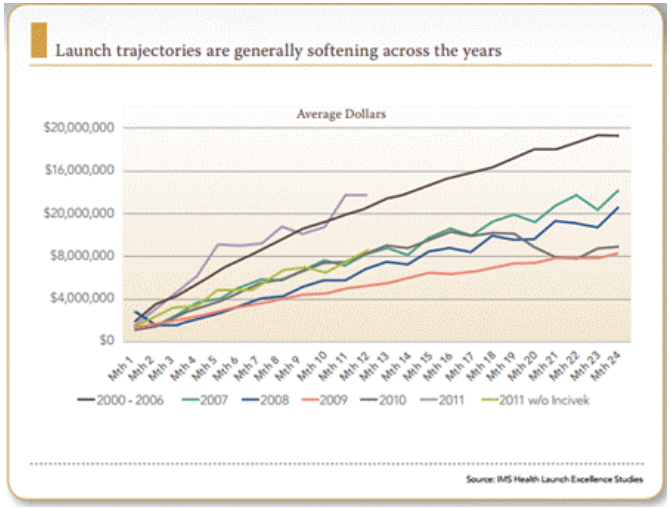
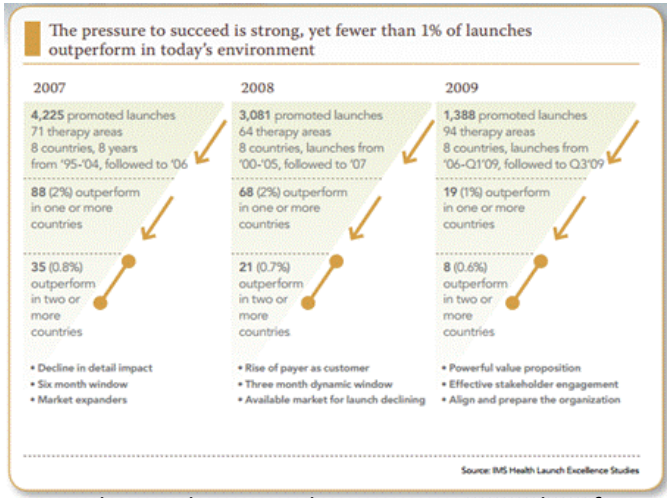
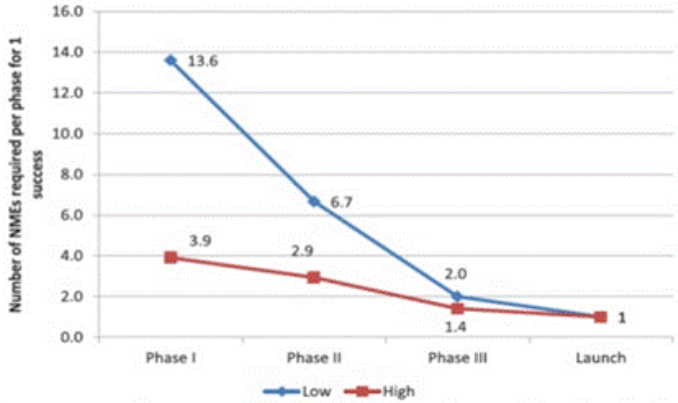
But…Pharma performance in launching new products is declining





Success Rates

Figure 2.6. Number of NMEs required per phase for one successful NME, based on recent estimates for probability of success (high and low estimates)



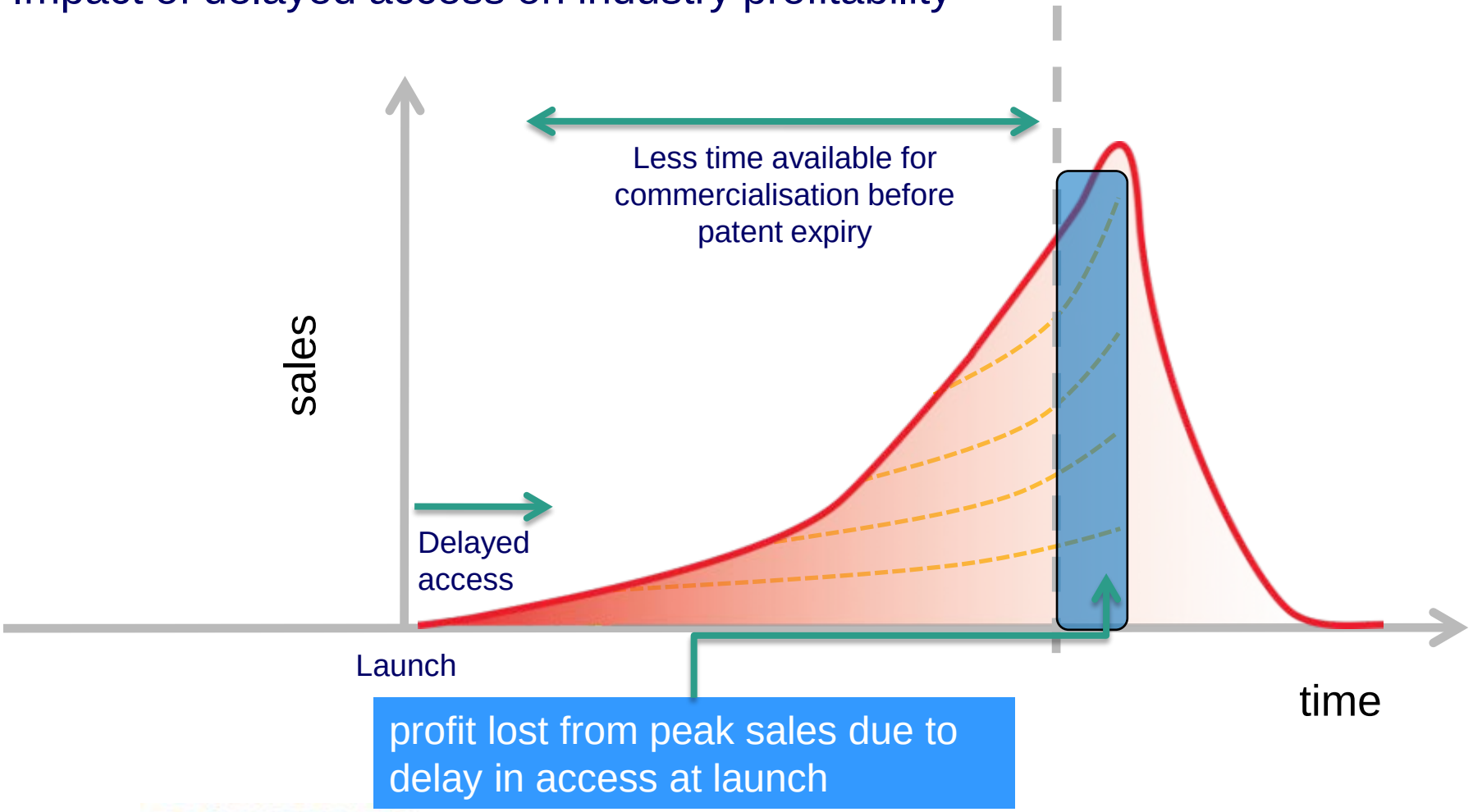
Source: Mestre-Ferrandiz, J., Sussex, J. and Towse, A. (2012) *The R&D Cost of a New Medicine*. London: Office of Health Economics.

OHE concluded that overall, cumulative clinical success rates appear to have decreased over time.

According to data provider IMS, commercial performance of Pharma launches is declining.

The financial risk not launching brands successfully is huge – through delayed access

Impact of delayed access on industry profitability



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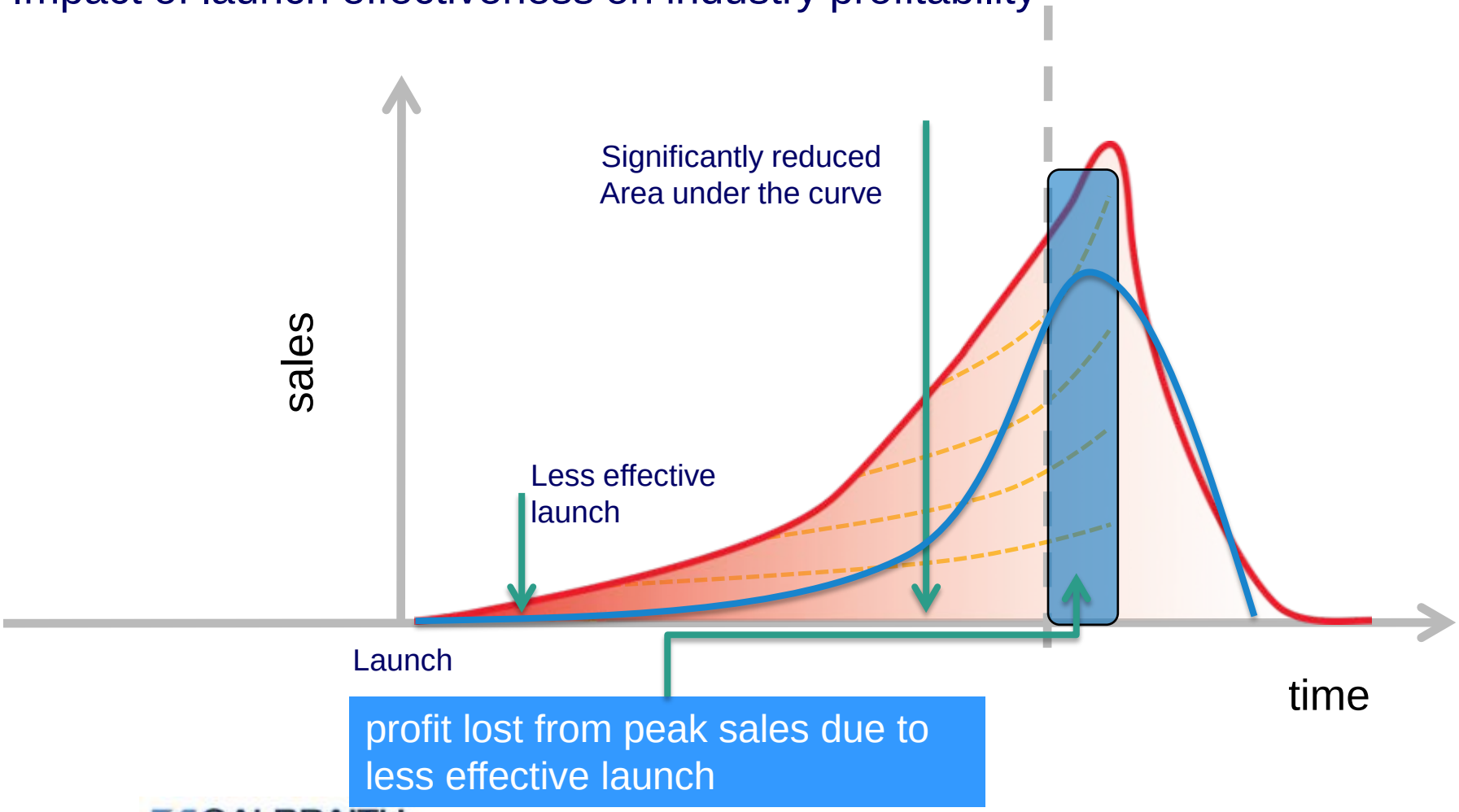
The financial risk not launching brands successfully is huge – through poor launch panning & implementation

Impact of launch effectiveness on industry profitability



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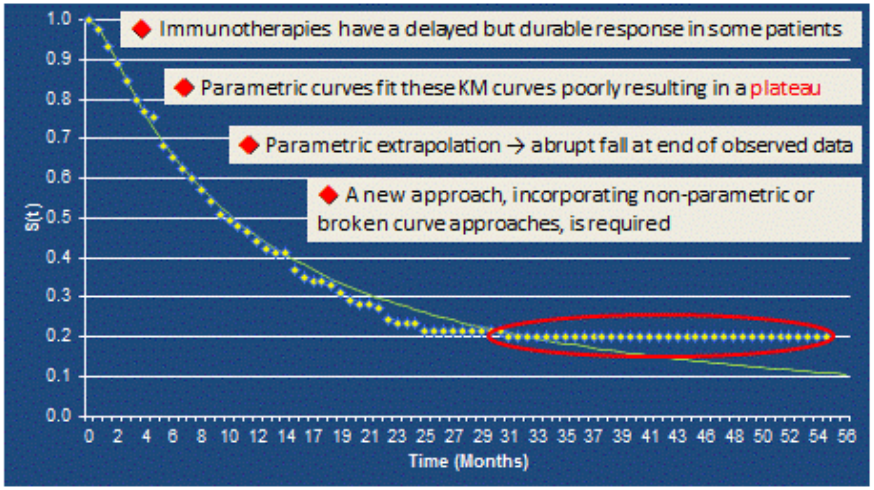
Industry needs to do a much better job in the debate around measuring & rewarding 'value' for innovation

Given the importance of relative benefit in showing innovation, different measures may be needed (2)



Source: Annemans L, Asukai Y, Barzey V, et al. 2011. Extrapolation in Oncology Modelling: Novel Methods for Novel Compounds. Presented at the ISPOR 14th Annual European Congress, Madrid, 5-7 November.

"The Committee acknowledged that few advances had been made in the treatment of advanced melanoma in recent years and ipilimumab could be considered a significant innovation for a disease with a high unmet clinical need"

NICE FAD November 2012

http://www.nice.org.uk/nicemedia/live/12092/61322/61322.pdf

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Value delivered by the same medicine varies by disease

- Bevacizumab in combination with a taxane for the first-line treatment of **metastatic breast cancer** - ICER for bevacizumab plus paclitaxel versus weekly paclitaxel was between £110,000 and £259,000 per QALY gained
- Bevacizumab in combination with oxaliplatin-containing regimens as a second-line treatment for **metastatic colorectal cancer** the ICER was £103,000 per QALY gained.
- Bevacizumab in combination with paclitaxel and carboplatin for first-line treatment of **advanced ovarian cancer** gave a range of ICERs from £128,000 to £161,000 per QALY gained.

- Etanercept for **active polyarticular-course juvenile idiopathic arthritis** whose condition has not responded adequately to, or who have proved intolerant of, methotrexate the ICER is in the region of £15–30,000 per QALY
- Etanercept for **first-line treatment for early RA**, the estimated ICER with methotrexate is £78,100 per QALY
- Etanercept in **adults with active psoriatic arthritis**, the ICER was £12,480 per QALY gained when compared with best supportive care.

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Source: www.nice.org.uk

The value of innovative medicines is delivered over decades, with the majority of benefit delivered by generic use post patent expiry

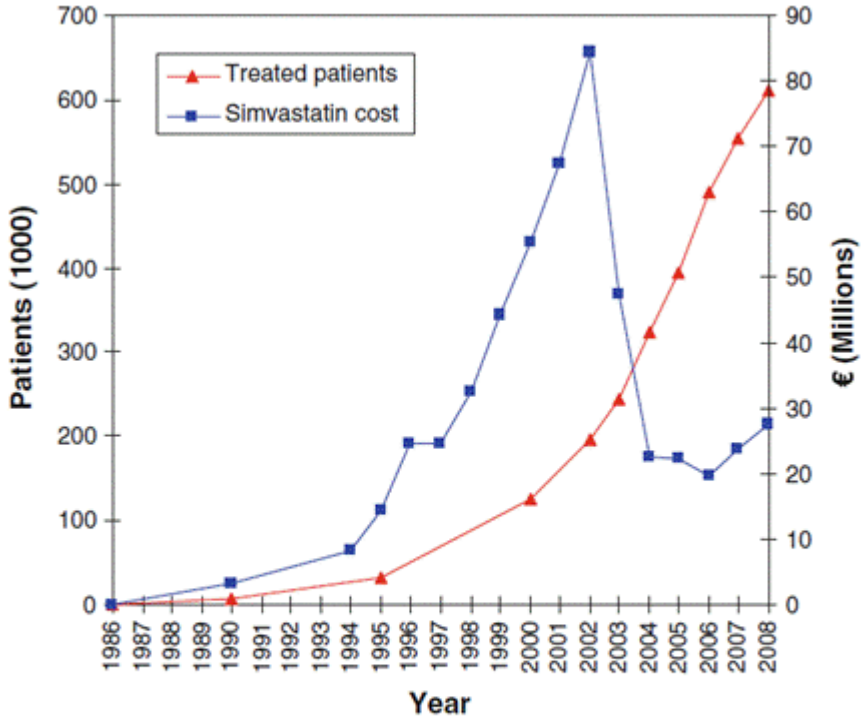

Fig. 1 The total cost of simvastatin prescriptions and the number of patients treated in Sweden 1987–2008. Source: National board of Health and Welfare [21], sales data from MSD Sweden AB and Apoteksbolaget AB (data on file)

"The fact that such a large proportion of the social surplus being appropriated by others than the innovator highlights the relevance of a societal perspective in economic evaluation. It may also make a case for considering looking a dynamic cost–effectiveness when assessing the introduction of new therapies."

Source: Cost–effectiveness of statins revisited: lessons learned about the value of innovation. Peter Lindgren, Bengt Jönsson. Eur J Health Econ (2012) 13:445–450

There are some perverse internal incentives around market access

Industry has tended to build functional or therapeutic **silos** in Pharma, & market access is the latest version.

There is sometimes an apparent **complicity** between many Marketers that market access is **'too complicated'** with HEOR technical experts happy to agree with them to protect their own value to the company.

The result? No joined up thinking, planning & action across the brand teams at global, region & country level – so **no overall company capability** in market access

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All functions need to closely align to work together to effectively satisfy the requirements of all Market Access stakeholders

No functional group on their own has the answer!

Market Access needs to be a **company-wide capability**

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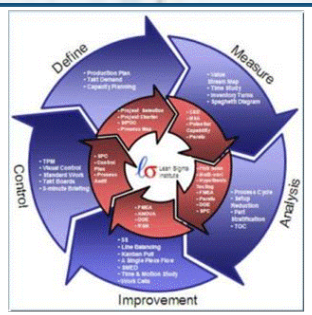
Great! Another new corporate initiative!

Many initiatives are started as **stand alone** projects so they do not get ‘too complicated’ – in particular initiatives which are ‘Big Consultancy led’ tend to be **designed as stand alone** deliverables

What companies & teams really need is **integrated processes** which promote **joined up thinking** & **cross-functional working**

Market Access, New Product Planning, Launch Excellence & Brand Planning are all elements of a **continuum**



LAUNCH EXCELLENCE

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Case Study 1:

Building & Embedding Market Access Requirements into the global R&D Clinical Development Process

Jackie Briggs – Principal Consultant, GalbraithWight

What was the challenge?

The client :

- Global Market Access Director of a medium-sized Pharma

The challenge:

- Market Access not yet fully embraced, particularly within R&D where focus on requirements for first Marketing Authorisation Approval
- Company ethos entrepreneurial, not limited by structures and processes, allowing people freedom to make their own decisions
- A need to demonstrate to executive team causes of Market Access issues as well as drivers of Market Access so they could address them in a more systematic way
- Possible lack of training and understanding about Market Access in global brand teams, no formal structure or process for new products planning & inconsistency in interpretation for terms 'Target Product Profile' and 'Minimal Acceptable Product Profile' between teams

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Methods & Outcomes

- Conducted interviews with Senior Management team - *What did Market Access mean to them ? How should it be addressed?*
- Identified key findings & conducted Gap Analysis to identify how, where, when and what MA tools and processes needed
- Sought senior management buy-in to proposals
- Conducted interactive workshops with global teams to share key findings, train and seek feedback on proposed educational tools and processes
- Finalised a first ever set of MA tools and processes for the company to address MA needs across the product lifecycle – from project initiation to patent expiry

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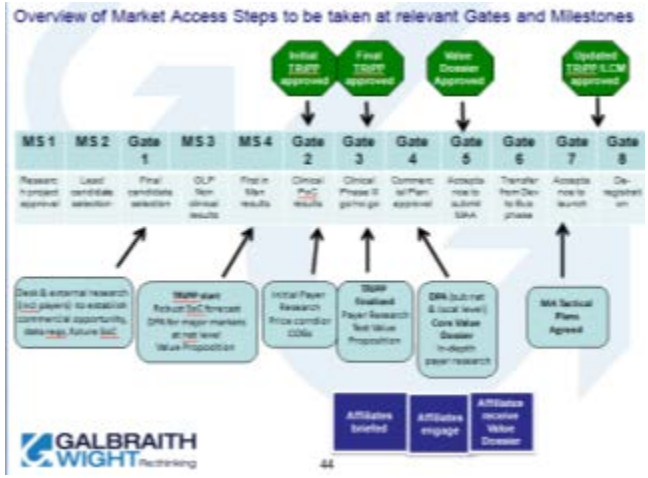
Results

An agreed new process for what Market Access activities are required when, embedded into the organisation's existing process for R&D Gates and Milestones, rolled out to all teams across the organisation

- Full senior management support for the need for MA to be integral to all stages of product development
- Market Access tools bringing consistency in timing, format and standard of all MA activities, assessments & deliverables

Market Access at the core of the organisation in a way that was practical and straightforward for the company to adopt



'We have to elevate the awareness of this company to what market access means, from the standpoint of the different players – manufacturing, R&D, QA, commercial etc. They have to understand that there is one place where everything's got to come together and it's called Market Access.'

Company President

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Case Study 2

Building Market Access Processes & Capabilities for a new Market Access European Regional team

Tanea Neville – Principal Consultant GalbraithWight

What was the challenge?

The client :

- Director of Market Access at the European Headquarters of a medium-sized fast growing Pharma company

The challenge:

- To really understand what is needed to achieve and maintain access and to determine what is required of an organisation to deliver Market Access success -across pipeline, launch and in-line brands

- To be understood in terms of:-
  - Processes, frameworks and tools
  - Competencies and skill sets required
  - Organisational Design
  - 'Ways of Working' across functions at regional headquarters and between European HQ and countries

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Methods & Outcomes

Insights from Research & Analysis

- Large number of in-depth internal stakeholder interviews across functions at EHQ
- Internal Interviews across a large number of lead market countries
- External Environment reporting
- Global Company Benchmarking assessment
- Internal pipeline and portfolio analysis

Engagement Approach

- Interactive workshops with project specific task force representing a wide range of departments and functions
- Formation of and communication with Market Access Leadership team and Market Access Council (of nations)
- Development of an external network of experts for on-going consultation with across Europe

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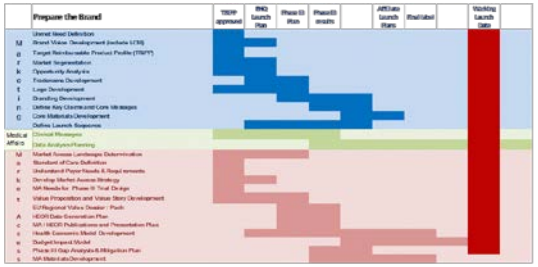
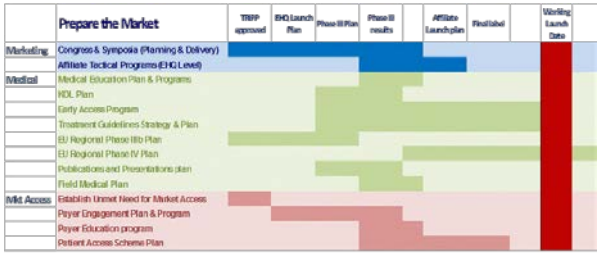
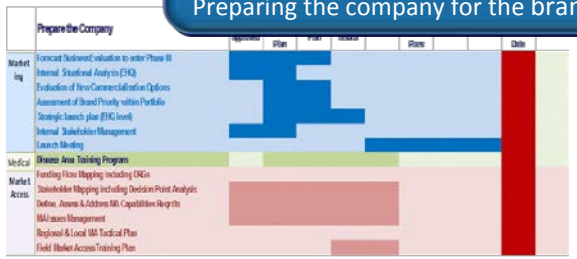
What was Delivered

- Market Access Planning Timeline
  - A structured process with milestones & deliverables to achieve and maintain access
  - Spanning pipeline, launch and in-line brands
  - Dovetailing with Launch Excellence process

Launch Excellence
Preparing the brand for the market
Preparing the market for the brand
Preparing the company for the brand







- Strategic & Tactical market Access Plan
  - Comprehensive objectives and priorities
  - Linking regional headquarter planning to country affiliate planning

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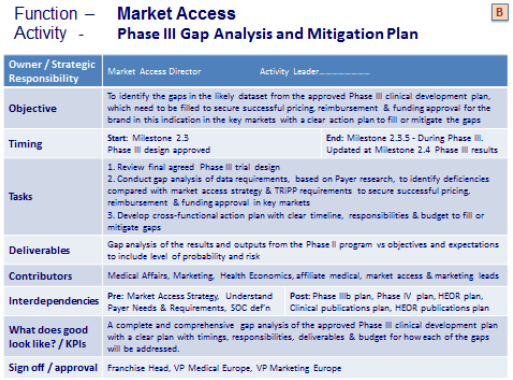
What was Delivered

- Market Access Activity Templates
  - Activity by function with objectives, roles & responsibilities and quality standards



- 1O Step Competency Framework
  - Linked to a training curriculum to develop priority skill sets

- Recommendations for Market Access resourcing aligned to current and near future organisational demands

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Results

A mind-set shift in understanding the complex requirements to achieve & maintain successful Market Access for pipeline, launch brands and in-line brands

- Clearer roles & responsibilities against defined activities across departments with accountability and quality standards built in
- Recognition that greater inputs from commercial development & marketing are required earlier in an asset's development process
- A structured process with milestones & deliverables to achieve and maintain access
- Clarity around regional headquarter requirements & in-country market access challenges; leading to redeployment of & realignment of resource to meet access demands
- Market Access tools & templates that 'bring to life' and prioritise the timing, format and standard of all MA activities, assessments & deliverables
- Insight into the skills required and existing levels of knowledge and competencies across several functions of the organisation

"…key measures to demonstrate value and build the Value Proposition need to be included in early clinical studies" ***Regional Head of Marketing***

Successful Market Access cannot be the responsibility of a single department or function……."everyone should own and be accountable" ***Oncology Business Unit Director"***

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Case Study 3

Embedding Market Access within New Products Planning & Launch Excellence Process at Country level

Janet Waters – Principal Consultant, GalbraithWight

What was the challenge?

The client :

- New Products Planning Manager in a country affiliate of large Pharma

The challenge:

- Suboptimal Market Access planning likely to compromise launch performance

- No process to enable early enough or rigorous enough engagement to influence
  - Target Reimbursable Product Profile
  - comparators and outcomes to be included in Ph III
  - Potentially unready for timely implementation of MA activity at country level

- Country level resources are focussed on achieving this year/next year plan.
  - Limited country-level resource allocated for pipeline products

- New Products function confined to being reactive to Global/Regional requests (e.g. forecasts) rather than enabling an informed country level evaluation

- Need to engage executive team to create change

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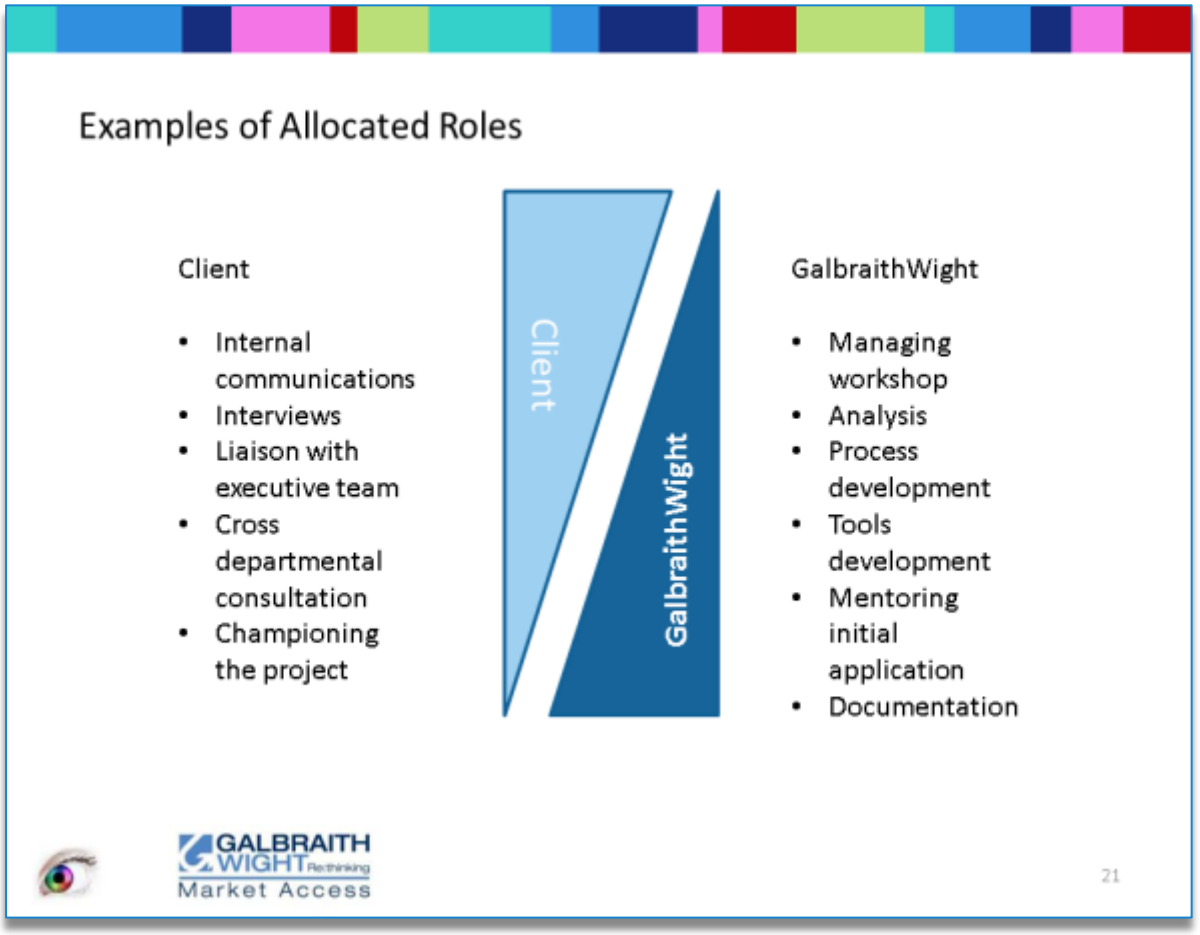
Methods & Outcomes

- Partnered with the New Products Manager

- **Identified gaps in current ways of working**



Methods & Outcomes

- Partnered with the New Products Manager

- Identified gaps in current ways of working,

- **Deduced and mapped on a timeline the critical inputs and actions**
  - ✓ **impact on global plans as well as local**

Example of Guidance for actions by Timepoint

During Ph II	• Prepare local evaluation
End of Ph II	• Give well-informed input to Global • Market Access needs, comparators, trial centers
Start of Ph III	• Assess gaps between Global plan and local requirements • Propose local action plan

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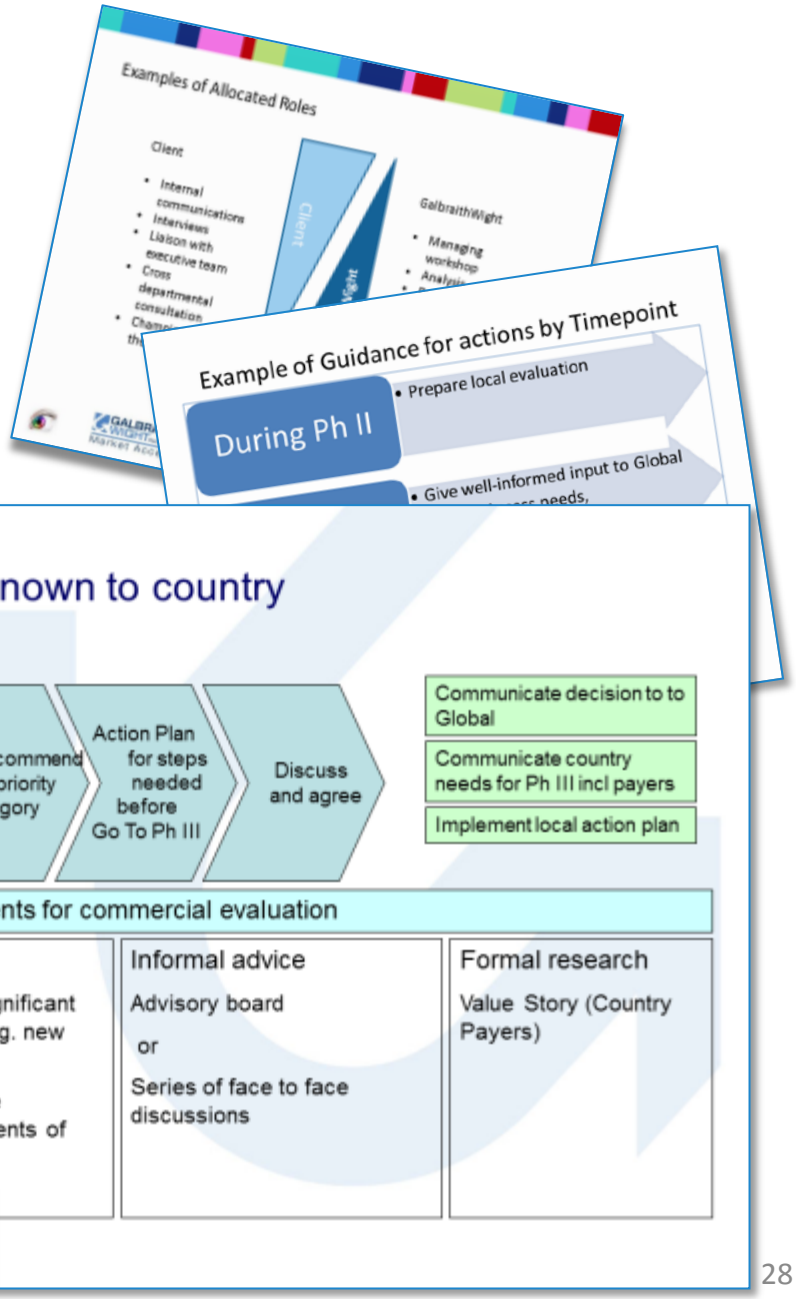
Methods & Outcomes

- Partnered with the New Products Manager

- Identified gaps in current ways of working,

- Deduced and mapped on a timeline the critical inputs and actions
  - ✓ impact on global plans as well as local

- **Created New Product Planning Process aligned with global development stages**



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Methods & Outcomes

- Developed commercial evaluation process for pipeline assets,
  - ✓ Categorisation according to country priorities
  - ✓ Justification for level of investment at country level

- Proposed governance structure
  - ✓ Executive team oversight
  - ✓ Accessing approval & sponsorship of planning resources

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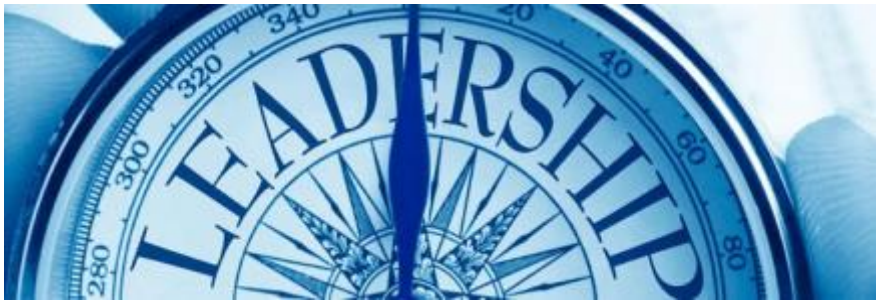
Methods & Outcomes

- Included senior management at each stage
  - ✓ draft proposals were anticipated



- Bridged from New Products Planning to Launch planning process
  - ✓ appropriate timescale for Market Access activities
  - ✓ joined-up process to transition from New Products to Brand Team

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Results

Robust Commercial Evaluation	Country affiliate enabled to make informed evaluations of pipeline assets for the country market
	Informed discussion with Global about Market Access opportunities, based on a robust case for country needs –
Process Aligned with Global Development Stages	Enhanced understanding of country inputs to Global & time frame of influence
	Greater leverage for country-appropriate health economic and outcome measures to be collected during Ph III
Governance Structure	Highly Informed executive team, better prepared for future portfolio impacts and resourcing requirements
	Improved decision-making about appropriate time frame to hand over to brand team
Joined up with Launch Excellence	Market Access planning and execution as a continuum

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Results

Early results:

- Successful advocacy
- Additional comparator included in Phase III trials
- Appropriate for demonstrated market access opportunities

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Case Study 4

Optimising Launch Excellence Planning with Market Access embedded in a web-based tool

Debbie Thompson – Principal Consultant, GalbraithWight

Launch Excellence Planning – What was the challenge?

1. Maximise the potential of future product launches
2. Strengthen competitive advantage
3. Establish a consistent framework
4. Develop a pragmatic approach

"We are aiming for a new standard and consistently applied approach to Launch Excellence"

Insights uncovered summed up in 4 areas

The need for One Truth

Timing – Start Earlier

Teamwork

Touchpoints

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Methods & Outcomes

Requirements for Launch Excellence	How they were addressed
• All preparatory steps to be taken in a timely fashion.	• looked at how the process could be AUTOMATED
• Commercial evaluation linked to an assessment system to inform strategic decision making	• developed web-based tool to allow people to:
• Set 'review' points through the pre launch process	1. Know what they need to do and when 2. Incorporate inter-dependencies 3. See progress at a glance

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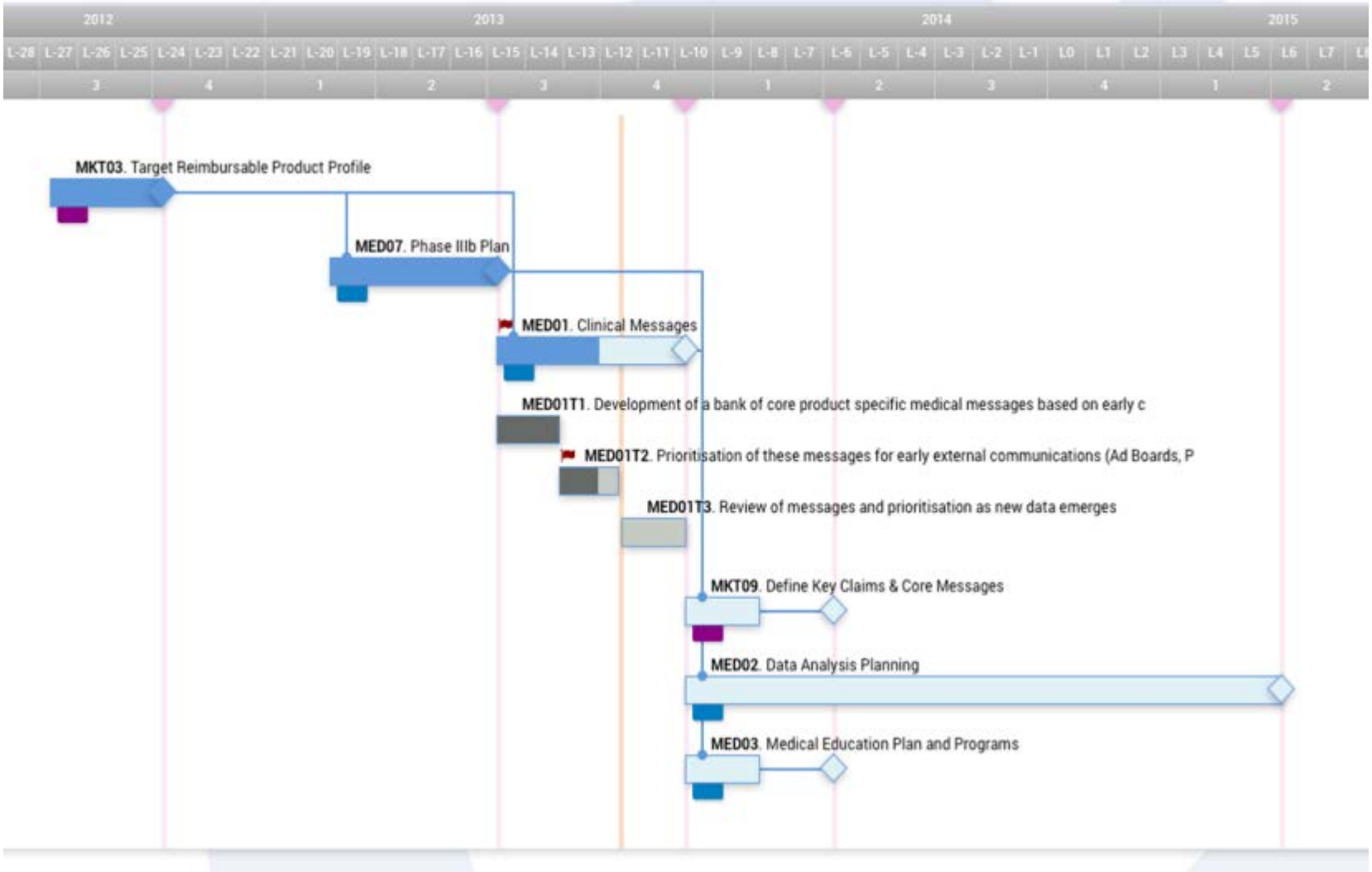
1. Lets people know what they need to do and when...



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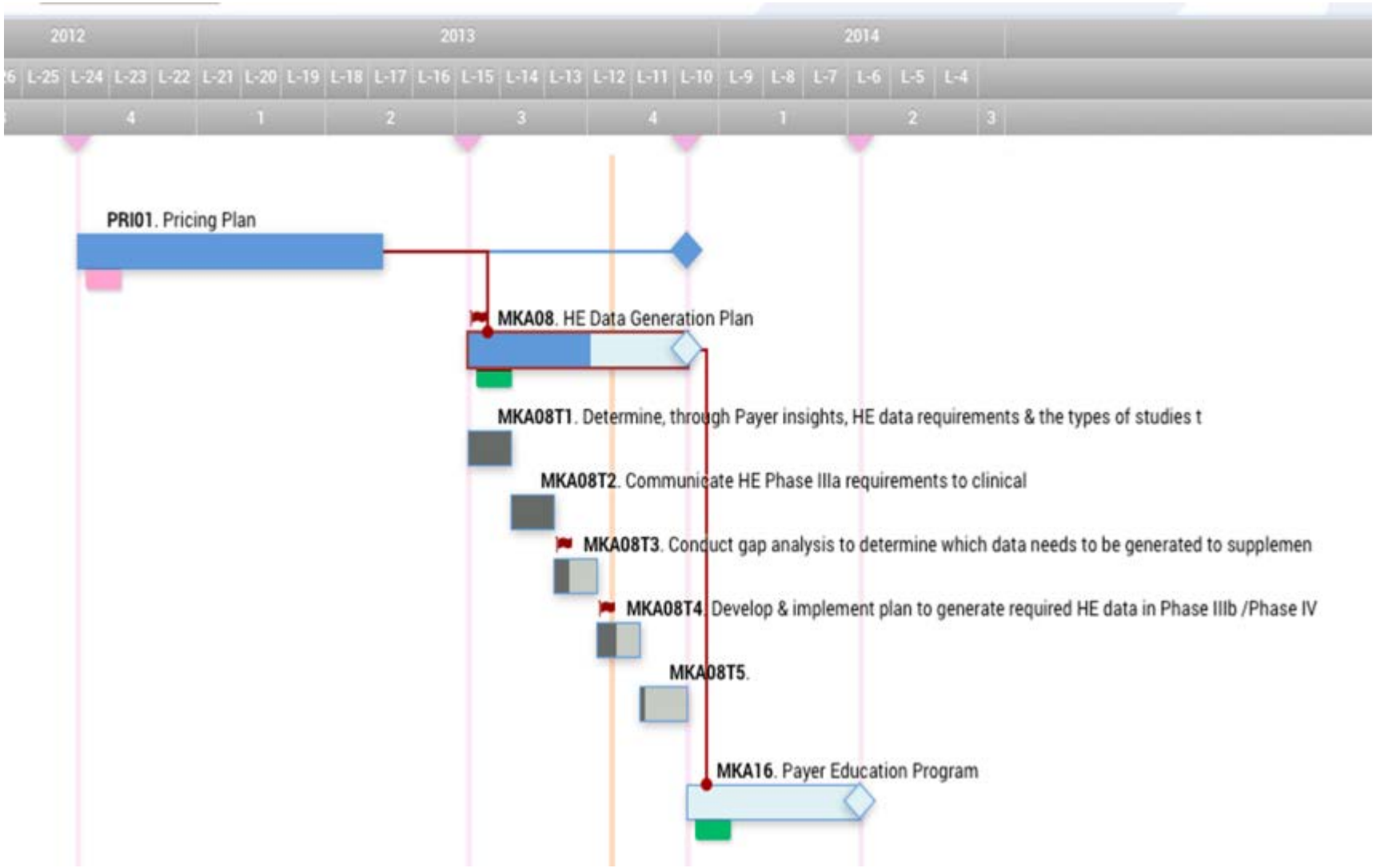
2. Allows automation of interdependencies between functions



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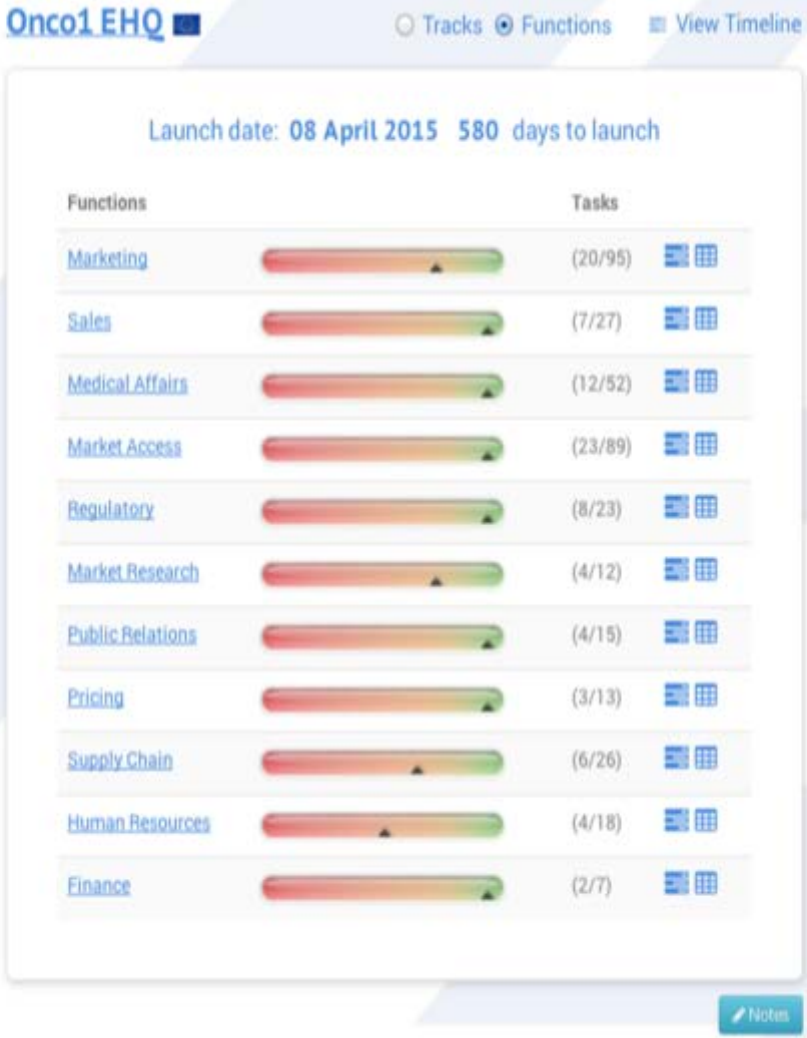
3. Lets people see an overview of how things are going



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Outcome

The client has moved their mind-set from:
"Preparing for Launch" to "Being Brand Ready"

…from "Being Prepared" to being "Ahead of the Game" with everything in place and everyone clear about their responsibilities…

…and an automated tool with **market access embedded** can help to make it happen

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Thank you

Case Study 5

Embedding Market Access into Strategic Brand Planning Process

Mark Boyden – Principal Consultant, GalbraithWight

What was the challenge?

The client :

- European lead for Market Access capability

The challenge:

- Refusals or restrictions on reimbursement
- Sub optimal formulary acceptance
- Weak support at a Regional or local budget holding level resulting in sub optimal brand use even within the patients authorised in formulary guidelines
- Weak use in the private Healthcare system channel

  - ➢ Slow uptake of new brands at launch

Why?

- Still operating with the old 'Blockbuster' model, focused almost exclusively on clinical stakeholders with little or no understanding of payers and policy makers and impact on achieving Market Access

Methods & Outcomes

1. Re-engineered brand planning process to embed MA requirements throughout
2. Ensured common understanding of the nature, scope and requirements for MA
3. Ensured Regional brand plans provided support and guidance to country teams in fully addressing Market Access at local level
4. Ensured full internal stakeholder engagement - vertically and horizontally
5. Mediated delivery through a multi channel programme





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MA LANDSCAPE ANALYSIS: unmet need; SOC; payer drivers; incremental value delivered by competitors today and future.

- Where are the opportunities as well as the barriers?

FUNDS FLOW analysis at target leverage points: how is the money spent today?; who controls it?: DRGs

MARKET ACCESS STRATEGY for each Life Cycle Milestone:

- Unmet need
- SOC
- Position in treatment algorithm
- Source of incremental clinical benefit
- Basis for economic justification
- Pricing strategy: level and approach
- Target leverage points

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Results

BEHAVIOURS:

- Everyone now speaking the same language around brand planning and market access leading to:
  - greater team understanding of the '**real issues',** quickly! (Unmet need, SoC, ICEB)
  - more alignment in cross functional development of **options** to resolve the issues
  - **improved decision making** to identify the best option

- Strategy first, without jumping straight into tactics!

- More active payer engagement at National, Regional and Local level

BUSINESS OUTCOMES:

- Improved rates of brand uptake through faster and wider Market Access through:
  - Faster times for reimbursement approval
  - Increased payer support at local level driving improved formulary placement

Case Study 6

Building, Embedding & Communicating a market-access based philosophy across an international organisation

Emma Rawlins – Principal Consultant, GalbraithWight

What was the challenge?

The Client

- European Headquarters of a large Pharmaceutical Company

The challenge

- How can we ensure that everyone in the commercial organisation considers Market Access to be a part of their role?

- How can we ensure that all of the market access requirements are met without adding significant additional market access resource?

- Market access is not just about launch products – but should be considered as part of life cycle management for all the products in our portfolio

Methods & Outcomes

- **Woven into all aspects of European Marketing Excellence Programme**
  - Training Curriculum – including specific market access course
  - Strategic Brand Planning and link to tactical budget allocation
  - E-book to support brand planning
  - Launch Preparation
  - Communications plan
  - Internal website
  - Pan-European awards
  - Strong branding of the programme

- **Bringing it to life**
  - Presentation and discussion session with 'live' payers
  - Video interviews with national and regional payers
  - Debate about the responsibility for market access
  - Range of tools and approaches
    - E.g. Forces and Needs analysis

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Customer Type – Hospital Budget Holder

Forces	Needs	Implication for Value Proposition and Messaging
Favorable public opinion		
Pressure to make quick decisions. Patients and physicians don't want to wait		
To make the best use of the budget they have		
To keep healthcare system functioning - patients and resources moving smoothly		
Keep bureaucracy down (paperwork) for physicians		

Customer Type – Hospital Budget Holder

Forces	Needs	Implication for Value Proposition and Messaging
Favorable public opinion	Be able to demonstrate delivering improved Health Outcomes	
Pressure to make quick decisions. Patients and physicians don't want to wait	Clear, accurate, concise and relevant information for medicines and interventions to enable rapid decision making	
To make the best use of the budget they have	Be able to demonstrate that they have achieved improved health outcomes for the money invested	
To keep healthcare system functioning - patients and resources moving smoothly	Demonstrate / evidence how they have improved efficiency of care pathways / use of HC resources	
Keep bureaucracy down (paperwork) for physicians	Demonstrate delivery of simplified processes for physicians (helping to enable more patient care time)	

Customer Type – Hospital Budget Holder

Forces	Needs	Implication for Value Proposition and Messaging
Favorable public opinion	Be able to demonstrate delivering improved Health Outcomes	Include clear and easily shared outcomes data
Pressure to make quick decisions. Patients and physicians don't want to wait	Clear, accurate, concise and relevant information for medicines and interventions to enable rapid decision making	Rapid access to key data to meet decision making criteria
To make the best use of the budget they have	Be able to demonstrate that they have achieved improved health outcomes for the money invested	Show improved health outcomes which meet the customer needs
To keep healthcare system functioning - patients and resources moving smoothly	Demonstrate / evidence how they have improved efficiency of care pathways / use of HC resources	Resource mapping tool
Keep bureaucracy down (paperwork) for physicians	Demonstrate delivery of simplified processes for physicians (helping to enable more patient care time)	Simple process maps and possibly tools

Customer Type – Hospital Budget Holder

Forces	Needs	Implication for Value Proposition and Messaging
Favorable public opinion	Be able to demonstrate delivering improved Health Outcomes	Include clear and easily shared outcomes data
Pressure to make quick decisions. Patients and physicians don't want to wait	Clear, accurate, concise and relevant information for medicines and interventions to enable rapid decision making	Rapid access to key data to meet decision making criteria
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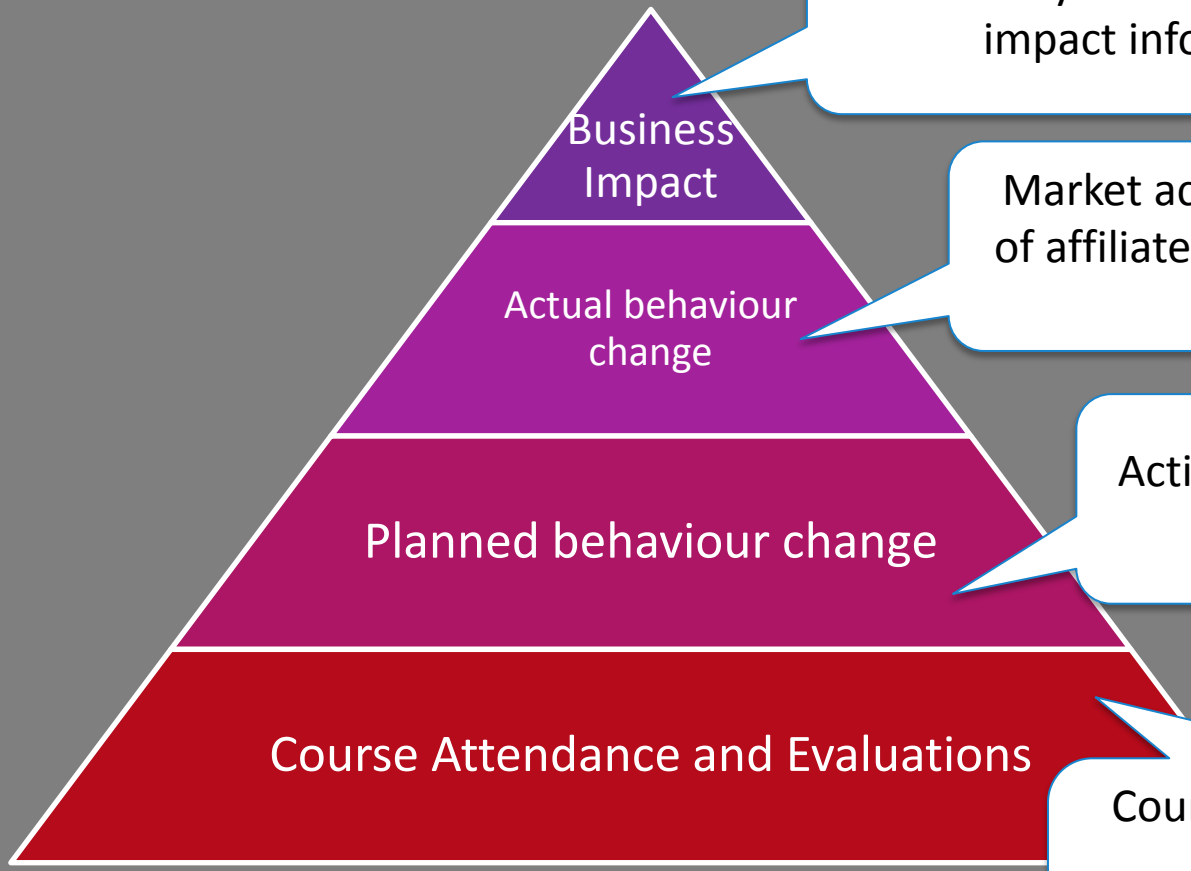
Metrics – what we measure



Currently collecting business impact information

Market access included in 100% of affiliate and head office brand plans

Action plans from over 90% of delegates

Courses attended by 66% of all marketers in Europe
230 course delegates – average score = 9.2 out of 10

Results

Acceptance of responsibility for delivering market access, using current resources, right across the product lifecycle

- Active agreement from all delegates that have engaged with the programme that they share the responsibility for market access – we are seeing **BEHAVIOUR CHANGE**
- All course delegates submitted an action plan to show what steps they will be putting in place, who will be involved and when it will be completed. People are **TAKING RESPONSIBILITY**
- All delegates are currently being followed up 6 months later to see how successful they have been in implementing their action plans and what the actual or anticipated impact on the business will be. Measuring **BUSINESS IMPACT**

Panel Discussion:

Keith Tolley – Economic Assessor, Scottish Medicines Consortium (SMC)

Colin Wight– CEO, GalbraithWight

Summary:

Colin Wight– CEO, GalbraithWight

Summary

1. Patient & healthcare systems are not getting access to innovative life saving or life enhancing medicines quickly enough in some cases because Pharma industry is potentially losing time & money by not fully integrating market access requirements into development & commercialisation processes – depth & breadth

2. Market access needs to be a company-wide capability, across all functions, with leadership from Market Access experts

3. Building market access capability across the organisation is more about hearts minds - not just processes & templates

4. Market access is a critical component of a wide range of Pharma company development & commercialisation processes and needs to be embedded within;
   - Clinical development from early phase
   - Business development/licensing due diligence
   - New product planning
   - Launch excellence/launch readiness
   - Brand planning
   - Marketing/commercial excellence

5. Some of these processes lend themselves to a level of automation to enable companies to do more with less, and improve communication

GALBRAITH WIGHT Re:thinking Market Access

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GALBRAITH WIGHT Re:thinking Market Access

Building, Embedding & Optimizing Market Access Capabilities – From Strategy to Execution

Symposium, ISPOR, Dublin, Ireland – 4th November 2013

ISPOR – International Society for Pharmacoeconomics and Outcomes Research