Driving the brand journey with anonymised patient level data

Declining R&D productivity and a tougher healthcare environment have made the search for ‘blockbuster’ brands more challenging than ever. Informed and successful development and marketing decisions require a deeper understanding of patient/doctor interactions, stakeholder needs and incentives based on real world dynamics. Chris Thomson and Kate Perry explain why anonymised, longitudinal patient level data can be pharma’s key to the insights that count…

In a world increasingly dominated by the quest for improved return on investment, brand teams are under more pressure than ever to build development programmes that yield optimal labels, clear proof of brand value and strong competitive differentiation. A major challenge in itself. But with it now comes the additional pressure of achieving these goals against the clock to maximise effective patent life and improve net present value. Success is contingent on faultless launch planning and the development of impactful marketing and lifecycle strategies that demonstrate real prescriber, payor and patient benefits.

At the same time, a saturated primary care sector, growing regulatory hurdles and increasingly demanding

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reimbursement constraints are driving a more challenging and complex market and shifting the decision-making power across multiple stakeholder groups.

Traditionally, brand teams have relied on a variety of sources to reach a better understanding of market dynamics, physician behaviour and areas of unmet need. Such standard ‘tools’ include market research, sales information, advisory boards and prescription trends supplemented by medical data. As a snapshot of real world physician behaviour, these measures are invaluable but at best serve only as a proxy for the everyday exchanges and outcomes of a doctor/patient consultation. Competing effectively in the complexity of today’s dynamic markets requires more granular insights on the complex needs, interactions and incentives operating between patients, payors and prescribers at the regional and national level.

The possibility of observing real world physician/patient interactions and tracking patient progress over time has long been held as an ideal but somewhat unrealistic goal in understanding the simultaneous behaviours of stakeholder groups. However, increasing technology and the ability to retrieve and analyse large volumes of complex patient information (eg, electronic medical records and health claims databases) has now made it possible to do just that, as well as follow through on long-term outcomes of treatment. In some countries this ability is already well established – in the UK such information has been available since 1989 – but only now is its true value being harnessed across the industry in support of improved brand performance.

A TOTAL MARKET PERSPECTIVE

Anonymised patient level data (APLD) provides longitudinally linked patient records that give an evidence-based view of most healthcare interventions in primary care, including rich details on diagnosis, testing, medical procedures and pharmaceutical therapy – for millions of de-identified patients. From this panorama of medical practice based on real world observation, it is possible to investigate patient types, treatment practices and health outcomes which inform many of the key activities required to bring a new product to launch – including assessments of market size, patient and physician segmentation, pricing and market access decisions and message development and delivery.

Furthermore, real world observational data is increasingly being recognised by regulatory bodies such as the European Medicines Agency and the National Institute for Health and Clinical Excellence (NICE) in England and Wales, as being instrumental in identifying how new therapies are used in a real world situation as opposed to a carefully selected and often atypical group of patients in the setting of a clinical trial. It is unique in its ability to surface real world outcomes that drive more effective product differentiation and proven demonstration of value, and key to providing the healthcare context for a total perspective on the market, offering powerful insights for optimal decision making across the spectrum of development and commercialisation.

EXTENSIVE APPLICATIONS

The journey of a new molecule is fraught with hurdles in both the pre and post launch environment and many
different disciplines are involved in its progression to a successful licensing conclusion. All share one key common denominator – the need for better information.

The array of applications for APLD is extensive – from simple analyses of such things as climatic changes on prescriptions for nasal antihistamines, behavioural trends in the use of nicotine replacement products, to the effect of NICE guidelines on anti-obesity products and more complex comparisons of drug costs and persistence rates across markets. Its ability to read and interpret the real world market provides critical support to the gamut of launch and brand activities including R&D, regulatory, pharmacovigilance, outcomes research, post-patent expiration strategies and guiding marketing strategy and implementation.

**INFORMING R&D**
Research and development, clinical trial planning and regulatory submissions require detailed, robust and transparent information for statistical modeling and analytics to:
- Model recruitment for clinical trials
- Inform clinical development decisions
- Measure impact of compliance programmes
- Support regulatory submissions including cost of care modeling
- Inform the development of health economics endpoints

**CLINICAL TRIAL PLANNING**
Recruiting patients for clinical trials is one of the biggest hurdles faced by pharmaceutical companies. APLD can provide insight into the total target population available in a given country and opens up the opportunity to model the inclusion and exclusion criteria required for the proposed clinical trial, thus informing the planning process and ensuring realistic and achievable goals in the time frame allowed.

**REGULATORY ADHERENCE**
With over two-thirds of children currently receiving therapies that are unlicensed in this age group and only 20 per cent of new medicines being tested in children, it is perhaps not surprising that paediatric medicines are coming under increasing focus from European regulatory authorities. In line with changes from the US FDA, which aims to increase the information available on the use of medicines in children, the European Medicines Agency has amended paediatric regulations surrounding...
the availability of data. Effective in January 2007, this essentially obliges manufacturers of new adult medicines to conduct trials in children (mostly dosing safety and efficacy studies), but without slowing down the market access process of the innovative product. An inventory of other specific needs in paediatric medicine must also now be met. For all molecules that appear on this list, a Paediatric Investigation Plan must be submitted at renewal of market authorisation (every five years).

Anonymised patient level information is crucial in helping companies get ahead with this new legislation, with its ability to determine current usage in children and facilitate an understanding of where, how and why these medicines are being used to help inform and plan prerequisite clinical trials.

**PHARMACOVIGILANCE**

Clinical trials are often powered for efficacy and not safety, in relatively small, ‘clean’ populations. Once a drug is launched there is a rapid increase in the exposed population, which is often comprised of very different patient types from the group tested in clinical trial settings. Pharmacovigilance is an increasingly important part of a new drug application, to bridge the knowledge gap this creates.

The use of patient level data in pharmacovigilance is now gaining increasing focus and momentum for its use by government agencies, regulatory bodies and pharmaceutical companies alike. It allows practical and ethical measurements of drug use, reveals user characteristics and enables estimates of relative and absolute risk, often in comparison with alternatives. By placing drug safety in a ‘real world’ context, APLD facilitates a clear assessment of the on-going risk benefit balance in the target population, defining patients who may be at high risk and thus enabling proactive, targeted measures. All of these aspects are vital for our knowledge and understanding of the use and benefits of medicines once they are available in mainstream clinical practice, helping governments in their effort to be more effective in protecting public health. Going forward there is a clear role for APLD to measure the effect of regulatory actions or guidelines.

**INFORMING THE UNEXPECTED**

Things don’t always go to plan in the pharmaceutical industry. In addition to the more expected shake-ups in the market, such as new competitor launches, patent expiries and shifts in product status, are the occasional, high-profile unexpected events – a drug withdrawal, recall, label warning or media scandal – which cause

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**Informing clinical trial planning with APLD**

<table>
<thead>
<tr>
<th>Exclusion factors</th>
<th>Number of patients</th>
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</thead>
<tbody>
<tr>
<td>Asthma in current year</td>
<td>3,538,920</td>
</tr>
<tr>
<td>Ages under 12 and over 17 years</td>
<td>3,148,740</td>
</tr>
<tr>
<td>Irreversible airways obstruction</td>
<td>0</td>
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<tr>
<td>COPD (optional exclusion in lieu of FEV1 results)</td>
<td>9,660</td>
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<tr>
<td>Oral parenteral or rectal steroids in last 1m</td>
<td>5,100</td>
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<tr>
<td>Atopic asthma in last 2mo, not for 4mo prior</td>
<td>7,560</td>
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<tr>
<td>Respiratory antibiotics last 1 month</td>
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<tr>
<td>Severe illness cvs (broad definition)</td>
<td>22,680</td>
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<tr>
<td>Beta blocker</td>
<td>2,340</td>
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<tr>
<td>Pregnant first mention in last year</td>
<td>5,880</td>
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<tr>
<td>Alcohol drug abuse</td>
<td>1,560</td>
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<tr>
<td>Remaining patients for clinical trials</td>
<td>325,740</td>
</tr>
</tbody>
</table>

Source: IMS® Disease Analyzer – Medipus UK

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“By placing drug safety in a ‘real world’ context, APLD facilitates a clear assessment of the on-going risk benefit balance in the target population defining patients who may be at high risk”
significant short-term perturbation in market dynamics. It is a fact of pharmaceutical life that in the face of these market disturbances, one manufacturer’s loss may well be a competitor’s gain. And while damage limitation may be necessary for some, others are presented with a potential opportunity to take advantage of the unfolding events. But in order to do so they must be prepared and all too often have precious little time to do so. Standard, routine prescription counts and sales by product, as well as ex-factory ‘own drug’ sales, can serve to demonstrate the immediate repercussions of an event in the market. But their value beyond the broad and general is limited. They cannot, for example, offer any insight into the factors driving doctor and patient responses to a particular market event, the selection of alternative therapy, or the rate, nature and timing of changes in treatment, etc. Thus, potentially significant pointers that could make or break a successful strategic decision remain concealed and unexplored.

As a tool for foresight, APLD makes it possible to not only understand patient and prescription numerics in a number of European countries and the US but also patient demographics as well as information on their sequence of treatment and diagnosis. Any changes can be examined as they arise and in detail, including the proportion of total patients switching therapy, for example, and the clinical and demographic profile of patients affected.

**IMPROVING MARKETING EFFECTIVENESS**

Marketing and brand teams require clear consistent information delivered in a format that, while detailed, is easy to use and analyse on a regular basis for a variety of marketing activities and launch tracking, specifically:

1) **Identifying high value market opportunities**

Because APLD is based on real world prescribing behaviour, brand teams can accurately size and characterise both the treated and untreated market.

2) **Anticipating mid-course opportunities and threats**

In the current dynamic market, with new competitors and indications emerging every day, understanding the detail of brand prescribing that lies behind market share – including new, switch and repeat prescriptions – is essential for identifying new opportunities and flagging potential threats. APLD shines a powerful light on emerging trends and new opportunities with a definitive picture of real world treatment dynamics, allowing brand teams to identify and harness the potential they bring.

3) **Developing successful campaigns**

Fewer than 10 per cent of detailing messages are...
actually remembered by physicians. Accurate patient images, based on evidence-based profiling, are a powerful aid to recall, allowing sales people to hit the mark – instantly – with a visual depiction of patient segmentation that creates lasting brand association. APLD can drive the development of targeted campaigns based on compelling messages that resonate with the target audience.

4) Real world evidence of value
In an increasingly genericised and financially constrained environment, understanding cost of care and outcomes is essential to proving brand value and securing inclusion in best practice protocols of care. APLD provides a thorough understanding of diseases, treatments and their associated costs and outcomes, enabling the development of convincing evidence-based value propositions and more informed market access decisions.

5) Patient guidelines
A view of patient flows for a brand provides important insights on treatment dynamics that inform tactical planning:
• relative size of patient segments
• drivers of progression
• adherence to treatment guidelines
• opportunities to demonstrate improvement
APLD reveals the practical impact of new treatment guidelines to better inform message generation and drive improved positioning and performance.

6) Driving growth with effective licensing decisions
An increasingly complex pharmaceutical market requires creative approaches to mitigate risk. Licensing with the right partner can deliver significant upside but finding high-value candidates that fit a company’s strategic needs calls for rigorous, comprehensive, on-the-ground intelligence – on competitors, market shares, trends, segmentation and indications. APLD enables detailed market profiling from diagnoses to potential gaps and unmet needs in the market as well as market profiling based on actual physician behaviour, for more insightful grounded development decisions that drive stronger portfolio growth.

7) Impacting patient compliance and persistence
Poor compliance with treatment reduces clinical benefit, increases healthcare costs and drains brand revenue. Understanding why and when patient ‘drop-offs’ occur is essential to driving behavioural change and optimal outcomes from treatment. By examining length of therapy it is possible to identify opportunities to maximise product utilisation. By analysing the effect of current adherence trends you can reveal the critical minutiae of current brand use, enabling the development of tailored programmes to improve patient retention that increase marketing ROI and maximise the benefits of treatment.

“As therapy areas reach saturation point, ensuring brand differentiation is imperative. Robust, sustainable claims are key to establishing a clear point of difference between a product and its competing brands”
Successful brand differentiation
As therapy areas reach saturation point, ensuring brand differentiation is imperative. Robust, sustainable claims are key to establishing a clear point of difference between a product and its competing brands. APLD supports the development of compelling arguments – backed by the facts on prescribing behaviour – that cut through the noise to maximise brand performance.

CASE STUDY – DEVELOPING MORE TARGETED MESSAGING

A brand team was preparing to launch Product X, which in clinical trials had shown superior efficacy as a first-line therapy to treat Syndrome Y. In addition to providing a better treatment outcome in this setting, a market analysis revealed more patients on first-line therapy than subsequent lines, suggesting that the market opportunity decreased with each subsequent line of therapy. The brand team was therefore hoping for physician adoption of the product as a first-line therapy.

As a number of primary market research studies showed that physicians were impressed by Product X's efficacy profile and were keen to use it as a first-line of therapy, the brand team developed messaging stressing its efficacy as a first-line treatment. At launch, the field force relied on deciling based on total prescription and new prescription metrics to identify the types of physicians who would be likely prescribers of the drug. Using these aggregated, top-line metrics alone, the sales force was not able to identify or direct their efforts toward the physicians who saw the greatest number of patients just beginning therapy — the ideal candidates for the drug. So, the marketing strategy began to unravel the minute it was handed over to sales.

In the early days post-launch, the brand team was eager to know:
• How Product X was being used – were physicians adopting the product for new patients only or were they also switching patients to the brand?
• What was the role of office-based specialists in markets such as Germany and the US? Were some more likely to prescribe Product X as first-line therapy than others?
• How effective was the messaging?
• Were reps reaching physicians with the most opportunity to prescribe Product X for new patients?

Since the company was relying solely on standard prescription metrics to evaluate sales performance, it was unable to answer these questions. While dispensed prescriptions are, and will remain, the gold standard for measuring performance, they are not sufficiently granular to reveal details about specific physician prescribing behaviours or the progression of treatment for various patient segments. Thus, they cannot address questions about line-of-therapy use. Similarly, while primary market research could have been used to address some of these questions, the results are difficult to track on a frequent, ongoing basis. In addition, the results of primary market research are based on physicians' recollections of what they did, as opposed to what they actually did, which can lead to potential accuracy issues.

With the benefit of APLD’s insights into physician treatment dynamics, the brand team would have been able to quickly determine whether or not physicians were using Product X as first-line therapy, and refine their strategies and tactics appropriately to drive this behaviour. For example, the team would have seen that even though earlier analyses had revealed that their overall usage of Product X was higher, primary care physicians (PCPs) were using Product X less often as a first-line therapy than were specialists. Knowing this, the brand team could have developed specific messages for PCPs that spoke to the benefits of starting patients new to therapy on Product X. In turn, the sales team could have conveyed these messages to the physicians treating those patients who would benefit most from this particular therapy. The effectiveness of the strategy as executed would have become clear in the new therapy start rates among PCPs. And the progression from assessment to planning to implementation and measurement would have operated as a closed circuit.
CORNERSTONE RESOURCE

APLD is the cornerstone of informed decision making for key pharmaceutical activities today, providing essential support from product inception through development, launch, marketing and sales. Its rich, evidence-based view of complex market dynamics enables companies to understand and respond to usage and treatment trends, identify untreated populations, more accurately reach the right physicians and ensure that brand performance is always on track. Affording the means to seamlessly translate strategy into tangible tactics and business results.

“Marketing and brand teams require clear, consistent information delivered in a format that, while detailed, is easy to use and analyse on a regular basis”

IMS Patient Information covers more than 93 million patient lives in five European countries and the USA, reported monthly and including up to 18 years of back data. IMS Medical Information is collected on an ongoing basis from over 23,000 doctors across 50 countries worldwide. To learn more about the practical applications of APLD, visit www.imshealth.com/medicalandpatient or contact Chris Thomson at cthomsom@uk.imshealth.com or Kate Perry at kperry@uk.imshealth.com

Is your brand being prescribed the way you intended… for the patient groups you targeted?

ASK IMS. We have a point of view. Informed by the world’s richest, most accurate market intelligence – seamlessly integrated and analyzed across prescribers, payors and anonymized patients. We address your toughest business issues. Help you understand and respond to utilization and treatment trends. So you can enhance patient compliance and persistency. Identify untreated populations. Fine-tune educational messages to physicians. And uncover growth opportunities.

Only IMS has the information... analytics... and consulting expertise to master the market.

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