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Real World Evidence

Learning to live with the RWE future

Retrospective Studies

Real world data, real world applications

Outcomes Data

Why it's critical for all oncology stakeholders

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Get Real: Preparing for the RWE Future

Joakim Söderberg explains why Real World Evidence (RWE) is here to stay, and what you need to do to integrate it into your business strategy as painlessly as possible.

People that used be Key Account Managers or Business Development Managers now turn up to conferences as “Manager RWE”...

We are all familiar with the traditional life cycle of pharmaceuticals. The tradition has also formed its own logic regarding research and data collection.

There are however signs that this paradigm is fundamentally changing. Over the past year, Real World Evidence (RWE) has gathered more pace as a buzz term. People that used be Key Account Managers or Business Development Managers now turn up to conferences as “Manager RWE” and “Adherence Manager”.

The background for this is as simple as it is terrifying: the old business model doesn’t work any more.

We used to be able to market blockbuster products to physicians who individually had the right to make a

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decision on what drug should be used. This we did using our traditional tools, reps and advertising.

And we tolerated the spill that we always knew was there —the drug not being used to its full potential, patients stopping therapy to early, patient being non adherent to healthcare's recommendation, etc.

This we did because we knew that the real battle was not in the usage of the drugs, but in getting access to the physicians. Filling the sink with prescriptions in a tempo that allowed us to ignore the hole in the bottom, where potential profits and patient well-being flowed out.

Well, the battleground has moved and the leakages can no longer be ignored.

Cost awareness has led to more control from, and a power shift to, the payers. Potential blockbuster drugs, most notably Vioxx and Acomplia, have been withdrawn from the market due to side effects in small subset populations, and a lot of NCEs with high potential have failed, quite often as late as in late-Phase III.

This has led to an increased focus in what we might call the "Aftermarket", everything that happens after that a drug has been prescribed. In the IT world we would use terms like "support market", "customer retention activities", "returning customer". It is not a coincidence that we do not have terms like these to describe the relationship between Big Pharma and patients on the Rx market.

Using Real World Evidence

In its simplest form RWE involves collecting and analyzing data on how a drug is actually used in the real world, as opposed to what happens in a ordered clinical research setting with protocols and highly motivated physicians.

The tools used are registries and the data collection is done as part of everyday healthcare.

Not surprisingly, battle cries of "source data verification"

and “data control” are being called by the defenders of the old clinical research paradigm. But when confronted with the important question, “How well have the old methods predicted actual use and effects of drugs in real life?” these defenders are usually without answer.

The new model will not come through by breaking down the old paradigm. It will have to evolve from the way we have worked over the past 30–40 years.

Nevertheless, the new model will not come through by breaking down the old paradigm. It will have to evolve from the way we have worked over the past 30–40 years.

Adaptive licensing

We are already seeing movement in this direction from the regulatory agencies. There’s growing attention, for example, to a concept called “adaptive licensing”

The agencies are taking models used in the orphan drug market and applying them on a broader basis. It is by default almost impossible to get adequate Phase III data on orphan drugs since the patient material is too small, so regulatory departments on both sides of the fence have been forced to accept that these drugs have been released for general use in spite of not having enough Phase III evidence.

To compensate, the drugs are followed and studied extensively during their first years on the market — in “real life”. Adaptive licensing is simply doing the same thing for drugs that have a broader potential. They are released to the market earlier than they would normally be, but to a small subset of

patients, who are followed in much more detail, using registries, electronic medical records and other everyday clinical tools. It's RWE instead of late-Phase III.

Some regulatory commentators are speculating that this will lead to different kinds of approvals that will affect pricing and reimbursement decisions. There is no consensus on the exact models that should be used, but pilot projects are already being planned. It is clear that this will increase the focus even more on RWE.

RWE and pharma

So how will all this affect pharma as we know it? Well, to the roots. And when something is torned up by its roots, it tends to be painful. There'll be skepticism and a degree of protectionism, both from the industry and the regulatory agencies. But this is not about changing the game, it is about playing a new one — with rules that are not yet written.

Ten to 15 years down the line, RWE and adaptive licensing will be cornerstones of the pharma market. Ahead of this, by way of practical advice, I suggest that you take note of the following.

Control over data is power. Traditionally pharma companies have supported researchers and payer organizations financially to help them set up registries and follow up programs and then given them full control over the usage of data. This will have to change. Transparent agreements regarding mutual rights to follow up data will need be set up.

The pharma companies' responsibility includes setting the stage. There is little competence within pharma today on things like electronic medical records, data quality in everyday care and information standards. This also needs to change. If pharma companies want to have access to qualitative data on their drugs, they will have to be involved in the mechanisms that actually generate these data.

Open up for internal discussions and changes. A paradigm shift of this magnitude requires more than simply changing titles on name tags. Regulatory and clinical research departments will need to evolve. The new business models will not work with old organizations.

RWE is not a new trend or a concept; it is, rather, an important symptom of a fundamental change in the global pharma market. As such it cannot be ignored.

About the author

Joakim Söderberg (joakim.soderberg@healthsolutions.se) is a Swedish pharmacist and entrepreneur who founded Health Solutions in 2000. Health Solutions, says Söderberg, has worked with real world evidence "since before the term existed, and is today extremely excited to be in the middle of the changing pharma environment".

The Value of Retrospective Studies

Saray Ray outlines the multi-purpose versatility and real-world applications of retrospective studies.

"If a product is already on the market, retrospective studies may bolster sales by highlighting the drug's efficacy ."

The value of retrospective studies cannot be overstated. They affect many healthcare sectors, including the pharmaceutical industry and general public health. Applying these studies provides clear advantages at different points of the product lifecycle.

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During drug development, retrospective studies may help clinical teams propose adaptations or even a companion diagnostic tests to identify the patient populations most likely to bene fit from a company's experimental treatment. This early work may lead to shorter trials and faster approval rates.

If a product is already on the market, retrospective studies may bolster sales by highlighting the drug's efficacy or by identifying its potential

for use in other indications. Beyond pharma, retrospective studies may also help global health organizations such as the World Health Organization (WHO) in their efforts to promote and support public health policies.

Clinical trial outcomes through a retrospectivel lens

Retrospective studies can prove instrumental for pharma, research organizations and other institutions conducting clinical trials. During the drug development process, dedicated teams may leverage retrospective studies to help them design robust late-stage clinical trials.

For example, Genentech designed and implemented a companion diagnostic for its Phase 3 onartuzumab (MetMAb) trial based on retrospective analysis of its Phase 2 findings. In its Phase 2 trials, MetMAb extended the progression-free survival period for patients with high levels of the MET protein receptor from 1.5 months to 2.9 months.

Consequently, Genentech bolstered the efficacy of its ongoing Phase 3 trials by exclusively targeting patients with high MET levels — the individuals who are most likely to benefit from MetMAb.

Clinical teams may also use retrospective studies to identify additional applications for drugs already approved for at least one indication. In such instances, retrospective studies are especially useful given a company's risk of failure in early- and late-stage trials.

Bernstein analyst Tim Anderson estimates that companies' Phase 2 success rates have declined from 34% (2003–2007) to 22% (2007–2011). He also estimates that Phase 3 rates have decreased from 70% to 65% during the same period.

In the wake of patent expiries — and the risks associated with traditional clinical trials — many companies are pitting the merits of traditional blockbuster drugs and niche products against each other.

Outside of these models, companies may also shift their focus from targeting symptoms attributable to a specific disease state to addressing the disease pathway. In this manner, retrospective studies may help researchers identify multiple disease states that, based on similar mechanisms of action, a single type of medication can target.

Retrospective analyses also have public health implications outside of the immediate pharmaceutical world.

Tracking real-world data

Retrospective analyses also have public health implications outside of the immediate pharmaceutical world. Recent studies following outbreaks of the Middle East Respiratory Syndrome (MERS) coronavirus in Saudi Arabia emphasize the value of retrospective studies from a public health perspective.

One study, published in The Lancet, shows that some experts are using statistics from the severe acute respiratory syndrome (SARS) virus to gauge the probable effects of MERS.

Within the study, researchers calculated and compared the basic reproduction rate figures for SARS and MERS. These basic reproduction numbers depict how quickly a virus is transmitted from person to person. The higher the reproduction number, the more easily a disease spreads. At the height of its prevalence, SARS had a reproductive number of 3.0.

To compare MERS to SARS, researchers examined data from the early stages of both diseases. So far, researchers estimate MERS' reproductive number to fall between 0.60 and 0.69. By

comparison, data from the early stages of SARS showed a reproductive number of 0.80.

MERS and SARS may have similar profiles. However, the rapid spread of SARS compared to the slower rate currently observed with MERS may have been promoted by crowded populations. In response to the MERS health concern, public health officials are working to identify and track the source of the MERS coronavirus before it mutates or rises to the notoriety of SARS.

Retrospective studies may contribute to an expansion both in the numbers and types of drug therapies available in the future.

To prevent MERS from escalating, the WHO, the Centers for Disease Control and Prevention (CDC) and Saudi Arabia's Ministry of Health maintain a proactive stance. The WHO is tracking the ways individuals become infected. The CDC has issued precautions for travelers visiting areas of known outbreaks. In preparation for both this month's Umrah and November's Hajj, Saudi Arabia's Ministry of Health has established a medical surveillance system that will screen visitors for symptoms.

Moving forward

Ultimately, retrospective studies serve a multitude of purposes.

Studies that use previous disease data as benchmarks may help public health officials target and contain new viruses earlier. When applied by companies' research and development teams, they may help companies refine their trial specifications and decrease the duration of their clinical trials.

Equally important, leveraging retrospective analyses may enhance research organizations' and pharmaceutical companies' efforts to identify and target similar pathways across multiple disease states.

In doing so, retrospective studies may contribute to an expansion both in the numbers and types of drug therapies that will be available in the future.

About the author

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Getting ROI on Your HEOR

Real-world pharmacoeconomic data should be central to the overall brand strategy of any oncology product, write Debra Patt and Claude Bergeron.

Today, all stakeholders throughout the US healthcare arena are making greater use of HEOR...

While clinical trial data is critically important to advancing the science of oncology, there is an important need for additional clinical insights to guide treatment decisions.

Steve Cole/Getty Images

Comparative prospective trials can bring valuable information into therapeutic superiority, and health economic outcomes research (HEOR) generally can provide insight into the determinants of a treatment and an outcome, sequencing strategies, and relative effectiveness between competitors within a given indication.

Today, all stakeholders throughout the US healthcare arena are making greater use of HEOR, which involves using a variety of mechanisms to gather and assess true clinical benefits and cost effectiveness

in real-world settings. The goal, from the standpoint of the pharmaceutical and biotech companies, is to augment the clinical data package in order to clearly articulate the product's full value proposition. Such mechanisms include:

- Clinical-effectiveness studies to find out how a product performs in real-world settings.
- Comparative-effectiveness studies to compare Drug A and Drug B, based on a specific set of criteria.
- Patient-reported outcomes data to capture the patient's experience in taking a particular drug, including ease of administration, quality of life, ability to function and so on.
- Cost-effectiveness studies to help determine how Drug A compares to Drug B when you account for efficacy, safety and costs.

Traditionally, Phase IIII clinical trials, which are conducted in accordance with specific protocols with clear inclusion/exclusion criteria, are meant to demonstrate the drug's impact on specific safety and efficacy endpoints relative to a control agent. By comparison, HEOR data can provide a more-realistic picture of how specific therapeutic options perform under non-ideal conditions, in real-world settings. Notably, HEOR trials often represent treatment patterns outside of major academic centers, which can be very relevant as 80% of oncology in the US is practiced in the community setting. It's only by combining clinical trials and HEOR studies that the different stakeholders can begin to understand the benefits and limitations of the treatments available.

Moving HEOR to the forefront

Once considered largely a support function, the need for, and use of, HEOR data is now being recognized as a central component to the overall brand strategy of any biopharmaceutical product (Figure 1). Today, all stakeholders in the healthcare arena — ranging from patients and physicians, to drug developers, regulators and payers — are able to make treatment decisions and improve patient care through the use of HEOR data.

Prospective comparative effectiveness data can greatly guide the treatment decision process

Payers

The insurance community's desire to identify the most cost-effective treatment options is more important than ever, as US healthcare costs have continued to rise in the face of numerous drivers, such as:

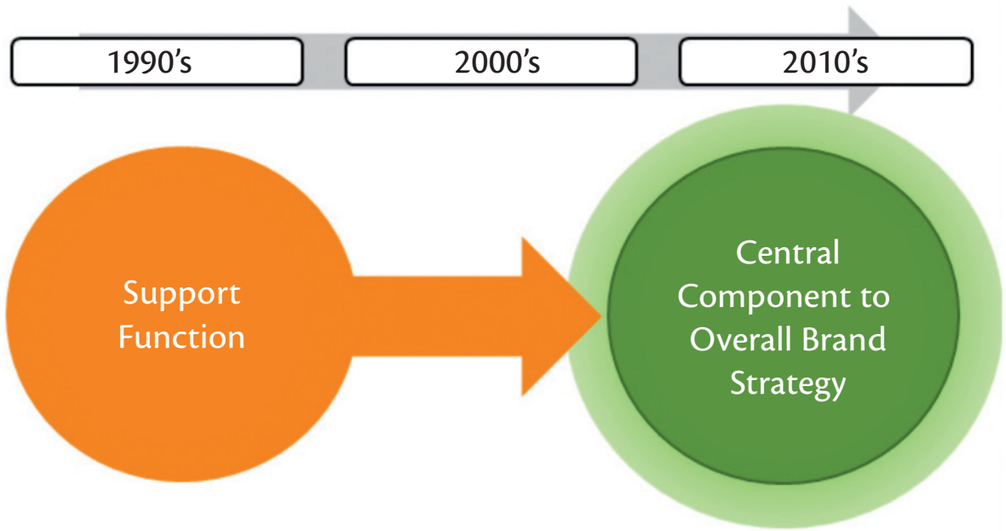
- Over-reliance on hospitals and emergency room settings rather than lower-cost practice environments for routine healthcare
- The need for physicians to adapt to new technologies and costly laboratory tests
- Growing administrative costs associated with the healthcare plans
- Varying treatment strategies when no prospective comparative data exists

Payers are demanding HEOR data that can provide evidence that a drug is "worth paying for." This is especially important in therapeutic categories for which there are numerous competing treatment options, and where costs need to be controlled. More often than not, payers rely on cost-effectiveness data to help justify reimbursement and formulary-designation decisions, to cut costs and reduce inappropriate medication use.

Physicians

In recent years, across many disease states, the sheer

Figure 1: HEOR Transition from Support to Central Function



number of drug options in a given therapeutic category has increased dramatically. While this proliferation of options is promising on many levels, it can also create considerable challenges for prescribers.

Prospective (and retrospective in the absence of prospective) comparative effectiveness data can greatly guide the treatment decision process. Data on optimal therapy sequencing can be of particular value as well, and patient reported outcomes (PRO) data help physicians

factor in the patient experience with regards to varying treatment choices, including meaningful health-related quality of life indicators.

Across a variety of disease states, US physicians and payers have been placing growing emphasis on the use of formalized treatment guidelines or clinical pathways to help guide treatment decisions and increase standardization. Such treatment protocols are typically developed, published and updated by independent committees comprised of physicians, pharmacists and other experts — such as the National Cancer Care Network (NCCN), The US Oncology Network, and many others. As both payers and physicians are increasingly cost-sensitive when it comes to treatment decisions, some pathways reflect not only the evidence of efficacy and safety, but also include treatment costs as criteria for recommendations.

Armed with such information, prescribers are able to evaluate competing options more critically, favoring those that demonstrate the best balance among key considerations of safety, efficacy and cost.

Patients

Today's patients face higher-than-ever out-of-pocket costs for healthcare, in terms of higher plan premiums, higher co-payments and co-insurance requirements and plan limits. And thanks

In recent years, US regulators have been putting increased emphasis on PRO data...

to increased overall longevity in many disease states, many patients will require longer durations of therapy to manage chronic conditions. As educated consumers, many of today's patients are becoming increasingly vested in getting more value out of their healthcare delivery system.

Regulators

HEOR data can also support the regulatory-approval process for prescription therapies. In recent years, US regulators have been putting increased emphasis on PRO data to make sure that the clinical benefits delivered by a specific drug are both demonstrable and meaningful to patients in real-world settings.

For instance, in its "Guidance for Industry" document around PROs, the US Food and Drug Administration (FDA) states that "findings measured by a well-defined and reliable PRO instrument in appropriately designed investigation(s) can be used to support a claim in medical product labeling if the claim is consistent with the instrument's documented measurement capability." The FDA goes on to say that the "use of a PRO instrument is advised when measuring a concept best known by the patient or best measured from the patient perspective." 1

To date, several prescription drugs have received FDA approval for labeling claims based on PRO, including oncology drugs. The FDA has stated that for product-approval decisions in oncology, the agency will focus on "endpoints that demonstrate a longer life or a better life or a favorable effect on an established surrogate for a longer life or a better life."

Putting HEOR to work

As demand for HEOR data grows among all stakeholders in the US healthcare arena, the onus is on drug developers to develop a complete, cogent HEOR strategy for each product that can demonstrate safety and clinical effectiveness, as well as economic performance in a real-world setting. The availability of robust, outcomes-related data can both assist with favorable coverage and formulary decisions from private and government payers, and encourage the most-appropriate prescribing practices among physicians and product acceptance among patients. To get started, drug companies should consider the following questions:

- How robust and comprehensive is your overall HEOR strategy?
- Is your HEOR strategy integrated and complementary to your R&D, reimbursement and commercialization strategies?

The onus is on drug developers to develop a complete, cogent HEOR strategy...

- Does your strategy address the unique needs of all key stakeholder groups?

It is important for drug developers to recognize that the strategic use of HEOR data is essential during all phases of the product lifecycle:

- During drug development. PROs should be included in the pivotal clinical trial design to create compelling support for regulatory approval.

- At product launch. Comparative-effectiveness studies, cost-effectiveness studies and a solid value dossier that can demonstrate not just the required safety and efficacy profile, but clinical effectiveness or financial advantage as well, are important as US payers are assigning products to formularies and making reimbursement decisions.

- During product adoption. At this point in the product lifecycle, real-world effectiveness studies of the product in use, and comparative-analysis studies of competing products in the same disease class, can influence prescribing habits in a way that drives appropriate product use and increases market share.

As the needs and demands for HEOR data among US stakeholders has increased steadily over the past years, We have seen its volume of HEOR studies and publications growing by 10-fold between the early 2000's to the early 2010's. Combining the expertise of outcomes researchers and physicians with unique data assets that contain deep clinical and

financial information can bring significant payback.

Armed with such information, pharma and biotech companies are better positioned to hone their marketing outreach efforts, justify their drug pricing, inform reimbursement and drug formulary designations among private and government payers, and support better-informed prescribing practices.

It is important for drug developers to recognize that the strategic use of HEOR data is essential during all phases of the product lifecycle.

All of these outcomes will provide critical strategic insight, drive clinical improvements, and cost savings throughout the US healthcare arena.

Reference

1. FDA Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims, December 2009.

About the authors

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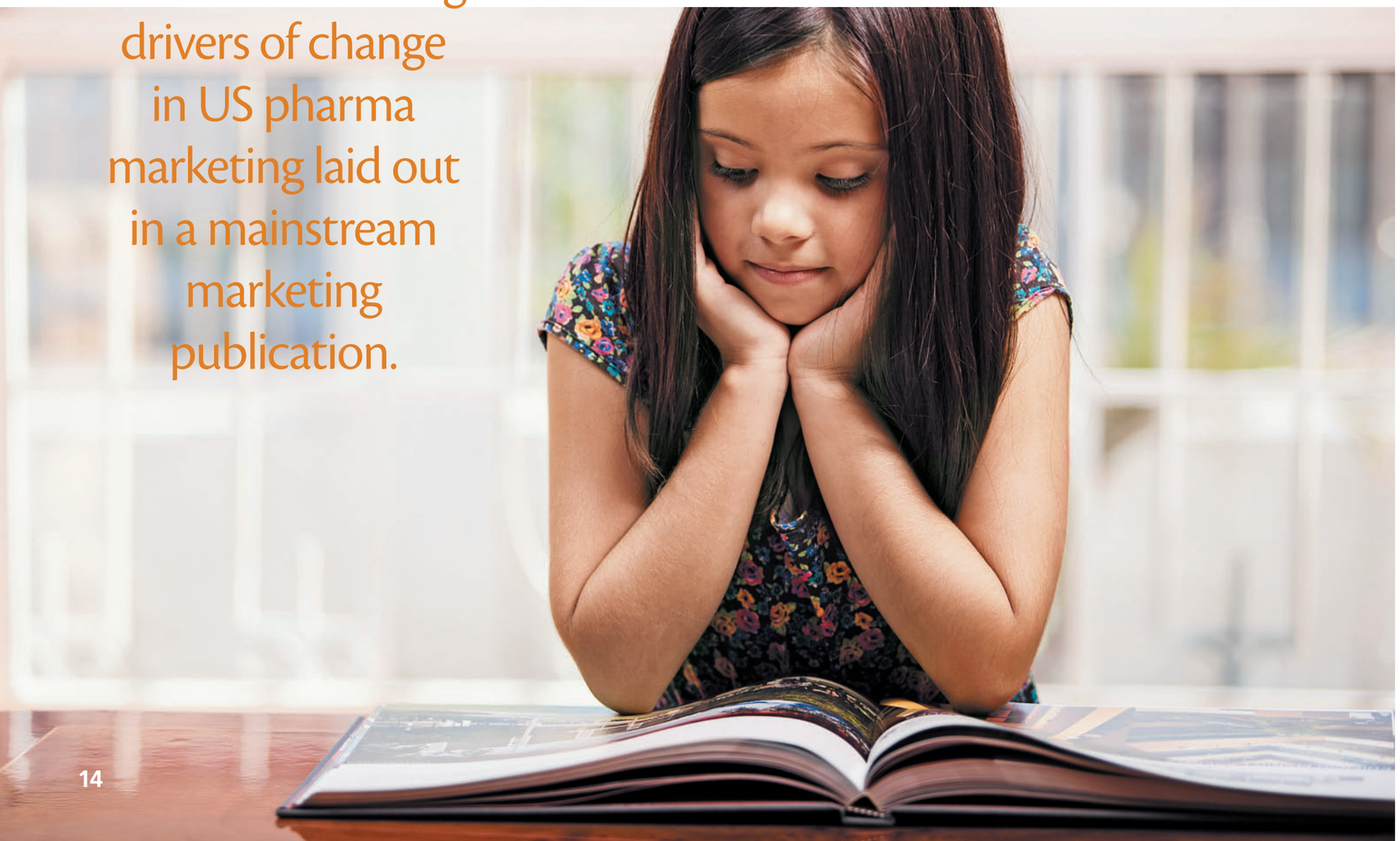
Storytelling Partnerships: the New Face of Pharma Marketing

PETER HOUSTON

Doing deals with storytellers could be as important for pharma as collaborating with research scientists, writes Peter Houston.

It was interesting to see three of the big drivers of change in US pharma marketing laid out in a mainstream marketing publication.



Leading advertising trade publication Ad Week ran an interesting feature on the 'New Face of Big Pharma Marketing' recently. The piece outlines the changes that Obamacare combined with public distrust of pharma is forcing on marketers, noting that the era of pushing the 'magic pill' is gone.

It was interesting to see three of the big drivers of change in US pharma marketing laid out in a mainstream marketing publication like Ad Week

First, the Affordable Care Act (ACA) is expected to bring millions of people into the system. Second, the ACA's

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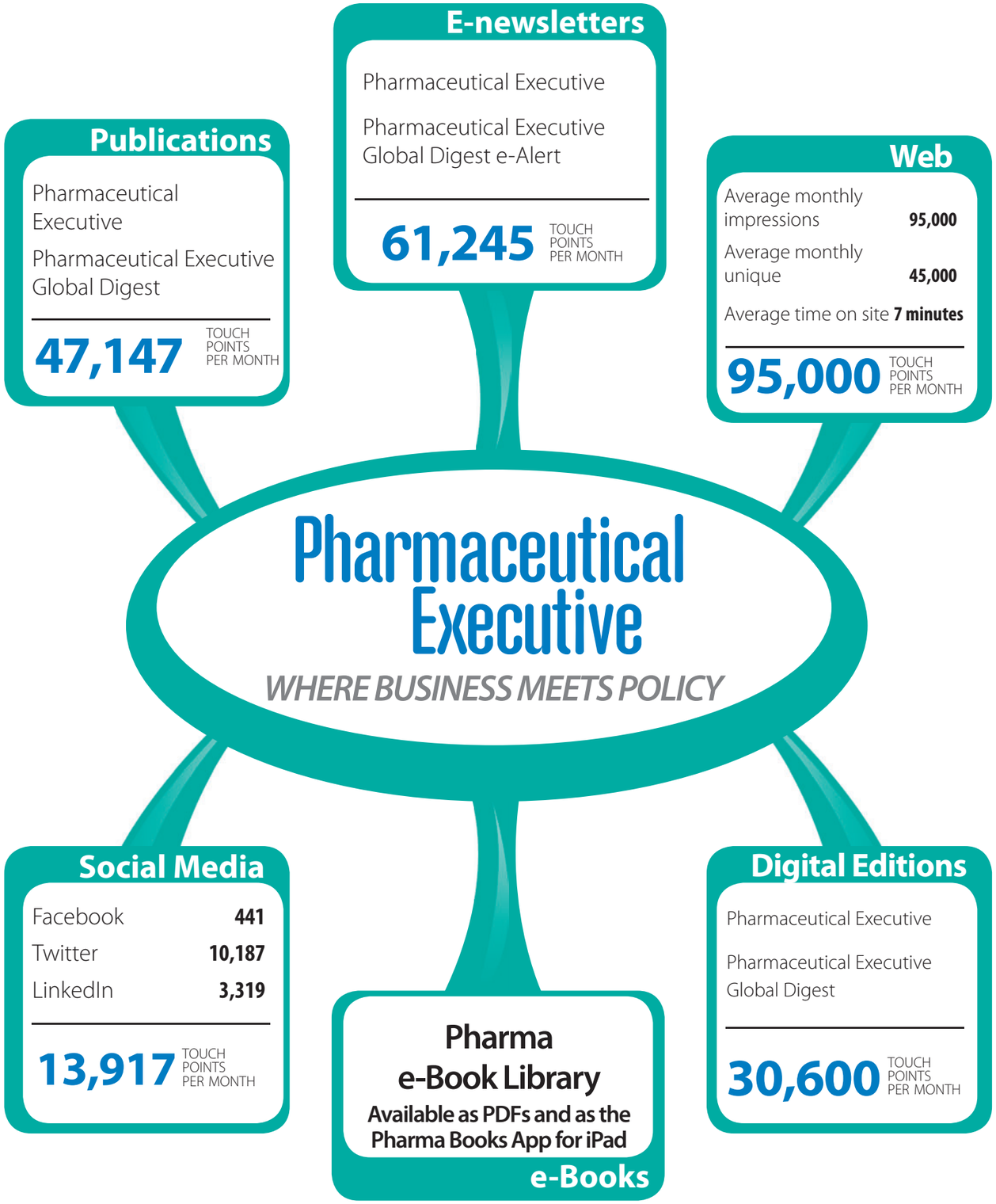

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Marketing Communications *(including advertising & PR agencies)*	4,498
TOTAL UNIQUE SUBSCRIBERS	**90,929**

FUNCTION DIMENSION	QTY
Business Development	3,797
Consultant	3,197
Corporate Management	26,711
Finance	1,403
HR	815
IT	1,851
Managed Care	2,920
Market Research	1,218
Marketing	12,913
Media Planning	1,375
Medical Affairs	4,860
QA/QC	7,201
R&D	16,386
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Sales management	7,771
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focus on prevention means anything pharma can do to improve patient adherence will be welcomed. And last, accountable care measures of effectiveness mean the 'price of the pill' is only part of future efficiency equations — behaviour modification, education and tracking all matter now.

As a switched on pharma professional you knew all this, but did you know about the partnership used by Ad Week to illustrate new approaches to pharma marketing?

Think about partnering and pharma and you think pioneering research, drug development or market access. It's all about assets, technologies, novel ideas for collaborations that will bring new drugs to new markets.

Nowhere in that scenario does great storytelling feature, but that is the driver behind Eli Lilly's deal with Disney to deliver an online resource to the parents of children with Type 1 diabetes.

Spoonfull.com is exactly what you would expect from Disney, a website for parents featuring things to do, make and see. Launched in April 2012, Disney created the site to provide parents with resources and a community that inspires fun, memorable parenting.

Of course, Spoonfull.com doesn't look like a pharmaceutical company website. Instead, as Ad Week points out, it features "playful branded stories, games and tips" to make it easier for young diabetic patients and their families to deal with the disease.

> Maybe we'll see more companies adding storytellers to their partnering roster alongside the scientists.

The thinking behind Eli Lilly and Disney's collaboration — integrating specialist health information into a destination and community format already successful with a target audience — resonated with the message in another blog post I read recently.

In "Your brand is not the story, your brand is *in* the story", regional Creative Director at Ogilvy Singapore, Barrie Seppings, raises concerns about too many brands telling their stories rather that the stories of their audience.

Commenting on the 'death' of advertising and the rise of what he calls the 'brand story' juggernaut', Seppings worries that, "the person marketers work so hard to tell the story to, is actually the person they should bet telling the story about."

He says the brand is "… more likely to be a character. Or a location. Or a plot device. Or maybe a chapter. But the real protagonist (the person we care most about in any story) is likely to be the person you've spent years describing as your audience."

He admits this is a subtle distinction, but believes brands would be better served working out 'creative, relevant ways' to be in the stories written by their audiences. With Spoonful's Type 1 site, Eli Lilly have achieved exactly that — the stories on the site are all about the audience, pretty much never about Lilly's diabetes drugs.

The Ad Week article ends with a quote from Stig Albinus, chair of global healthcare at branding consultancy APCO Worldwide. He says pharma brands have an unprecedented opportunity to move up from low-key makers of medications to "champions for change."

If pharma is to accept this challenge, succeed with health care reform and turn around consumer skepticism, maybe we'll see more companies adding storytellers to their partnering roster alongside the scientists.

New Devices and Diagnostics Rules: Shockwaves Imminent?

Reflector reports how the EU's proposed new medical device and diagnostics legislation could shake up the European drug industry.

The shockwaves of the current European Union debates are likely to echo through the medicines business over the coming years.

Most pharmaceutical executives breathe a sigh of relief when they hear that the discussions in Brussels on medical devices are becoming ever more complicated. "Thank heavens I don't have to deal with all of that," is a common response, with only a half-sympathetic glance towards their colleagues labouring in one of the junior partners of the healthcare sector.

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Think again! The shockwaves of the current European Union debates are likely to echo through more and more of the medicines business over the coming years. So breathe those sighs of relief while you can.

The story so far...

First, a little about the debates themselves. In September, the European parliament's health

committee was scheduled to reach its view on the two major proposals launched last year by EU officials — one on devices, and one on in vitro diagnostics. In October, the parliament as a whole is due to agree its definitive opinion on the proposals — taking account of the health committee's thinking.

And before the end of the year, the governments of the EU's 28 member states are expected to finalize their position on the proposals too

So in all likelihood, in early 2014, new rules should be signed off that will change the face of EU controls on these products.

Post-PIP measures

Why should anyone other than the manufacturers of hip replacements or home blood-pressure monitors care?

Three good reasons. One is the wide scope of the legislation. Another is the atmosphere in which the new rules are being discussed. And the third is intimately related to the progress of medical science.

The prospects for introducing reasoned and reasonable updates to the EU's earlier legislation, some of which is more than 20 years old, might not have been so delicate if the context had not been so contaminated by the French Poly Implant Prothèse (PIP) breast implant scandal that coincided with the genesis of the new measures.

PIP may have had nothing to do with the world of pharmaceuticals, but it certainly had plenty to do with the rigor that marked the regulatory proposals for devices and diagnostics, and the vigor that characterizes the debates around them.

It is also why the parliament's health committee is having to work its way through 399 proposed amendments on diagnostics, and through 907 amendments on devices.

In his draft report on the proposals on diagnostics, German physician and MEP Peter Liese has also urged particular attention to companion diagnostics, and is insisting that they should comply with the new rules.

Why should anyone other than the manufacturers of hip replacements care?

He is also advocating further toughening up of the rules, because in vitro diagnostics, far from being the poor relations of the medical sector, "may be the parents of all therapies, including pharmaceutical products and surgery".

The clarification Liese is calling for is long awaited — not just in relation to companion diagnostics, but in relation to personalized medicine in general.

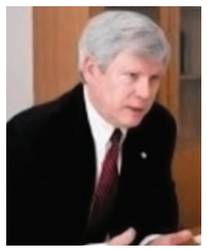
But executives in Europe are still awaiting a crucial paper from the Commission, announced five years ago, but still not finalized. According to the latest draft, in vitro diagnostics represent one of the principal hopes for promoting personalized medicine.

The paper, entitled "The use of '-omics' technologies in the development of personalized medicine", suggests major new opportunities for the treatment of patients in the European Union, with better targeted treatment, fewer medical errors and reduced adverse reactions. And it argues for greater attention to diagnostics, rather than merely focusing on therapies.

Meanwhile, without the benefit of the Commission's final version of its strategy paper, the debates on devices, diagnostics and the future of the drugs industry roll onwards.

And they are likely to start rolling very soon across the paths of many pharma executives.

APPOINTMENTS



Daiichi Sankyo has announced that Dr Glenn Gormley will take on the role of President and Chairman of its US subsidiary when current President and CEO John Gargiulo steps down. Dr Gormley will continue in his existing roles as President, Daiichi Sankyo Pharma Development, Global Head of R&D, and Senior Executive Officer.

inVentiv Health (Burlington, MA, USA) has made two new appointments to lead its business in Europe and Asia. Dan Feldman, who established and led inVentiv's operation in Japan, will take on the new position of President of inVentiv Health Europe. Stephen J. Walter will join the company as Executive Vice President for Asia. Mr Walter formerly served as Managing Director for Merck Sharpe & Dhome in Vietnam and Cambodia.

Merck Serono (Darmstadt, Germany) has promoted Chief Operating Officer Belén Garijo to President and CEO. Ms Garijo will take the place of Stefan Oschmann, who is to focus on a wider group role as a Member of the Board and Head of Pharmaceuticals at Merck.

Recordati (Milan, Italy) has promoted Andrea Recordati to Chief Operating Officer. Mr Recordati will be responsible for all the group's commercial and production activities.

EUSA Pharma founder Bryan Merton has joined the UK's Glide Pharma as Non-Executive Chairman.

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