By Denise Myshko

Soft Metrics Uncover

Medical Publications' True Value

TRENDING NOW: Despite medical publications' importance in communicating clinical data to the medical community, drug and device companies often track only volume-based metrics, leading to potentially missed opportunities to gauge publication teams' true impact and gain sufficient resource support.

Data from the Cutting Edge Information report Strategic Medical Publications Management: Plan Development and Resource Benchmarks, find that 44% of surveyed companies do not track medical publications performance measures at all. Soft metrics, however, help 48% of companies uncover publications teams' true success and impact.


Ryan McGuire

Some of the soft metrics that underscore medical publications groups' value, according to the report, include physician feedback and message uptake, as well as other anecdotal evidence that publications teams can gather. While they may be more difficult to track, these medical publications performance measures provide insight into whether treatment approaches have changed as a direct result of a journal article.

"It's an uphill climb trying to prove medical publications' value to upper management, especially since companies don't tie publications to prescription rates," notes Ryan McGuire, research team leader at Cutting Edge Information. "Yet performance measurement, combined with a commitment from senior management to the publications teams, is vital to managing effective teams."

For more information, visit cuttingedgeinfo.com.

Use of Efficacy and Effectiveness MAY SKEW REIMBURSEMENT DECISIONS


Dr. Yin Ho

A recent global analysis of product evaluations for health technology assessments (HTAs), which are often influential in decision making for approving and/or providing reimbursement for pharmaceuticals and other medical technology, found that the use of the words "efficacy" and "effectiveness" proved misleading in the context of reimbursement decisions.

The survey, by Context Matters, suggests that while agencies state they are evaluating efficacy and effectiveness a similar number of times, their evaluations are generally for efficacy. Although reimbursement decisions are based on HTAs, the study demonstrated that the term effectiveness is often used when the evidence presented for consideration is often based on clinical trial scenarios rather than real-world circumstances.

"These two terms have been used interchangeably for quite some time," says Yin Ho, M.D., CEO of Context Matters, and co-author of the study. "But the difference between them is a vital one to understand when making reimbursement decisions."

For more information, visit contextmattersinc.com.

Extraneous Data Collected in CLINICAL TRIALS COST DRUG DEVELOPERS

One out of every five procedures performed during later stage clinical trials collects extraneous data and costs drug developers more than $1 million per trial, a new study by the Tufts Center for the Study of Drug Development has found. About 18% of a typical clinical trial budget, or $1.1 million, is spent on direct costs to administer procedures for supplementary endpoints. The study also found:

- An average of 22.3% of all trial procedures are considered to be non-core, including 17.7% of Phase II and 24.7% of Phase III procedures.
- Half of all procedures — 54.3% of Phase II procedures and 47.9% of Phase III — support primary and key secondary endpoints.
- The typical clinical trial protocol has an average of 13 endpoints, with the number of less essential endpoints per protocol almost doubling.

For more information, visit csdd.tufts.edu.

Leading Biosimilar Companies EXPECTED TO REALIZE GROWTH

Sandoz retained its position as the global leader in the biosimilar drugs market in 2012. Its three follow-on biologics were expected to achieve $308 million in revenue, according to a report by Visiongain.

The analysis indicates that the top 10 biosimilar manufacturers accounted for 54.8% of the market in 2011. Global generics manufacturers occupied three of the top four places. Many of the top biosimilar manufacturers have a base in the market, having marketed products for the past five to 10 years.

For more information, visit visiongain.com.

Five Clinical Areas Most Likely To BENEFIT FROM DNA SEQUENCING

Next-generation DNA sequencers are expected to see use in at least five clinical areas over the next several years, according to Kalorama Information. But unpredictable variables will affect the timing for each application, including science, regulation, and economics, and the strengths and weaknesses of different DNA sequencing technologies.

These areas include: cancer diagnostics and treatment; HLA/MHC typing; neonatal and prenatal testing; pathogen detection; and pharmacogenetics.

For more information, visit kaloramainformation.com.

Russia Shows Sustained MARKET EXPANSION

For companies to capitalize on Russia's skyrocketing growth projections, they must expertly navigate a new law, which regionalizes the regulatory decision-making process and significantly limits interactions between physicians and pharmaceutical sales representatives.

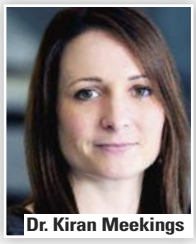
Understanding and adapting to this new regulation are essential to achieving increased value and capitalizing on the country's emergent opportunities.

The Cegedim Relationship Management report, Russia 2012: The Pharmaceutical Market & New Legislation — Building for Growth in a Fast Changing Marketplace, notes that as BRIC economies now deliver between 20% to 30% of pharmaceutical industry revenue, it is not surprising that Russia's market value is forecast to almost triple by 2020. Further, lucrative high-innovation therapies account for 30% of the overall market.

"Companies must fully reconfigure both market access and physician engagement strategies in Russia to capture new value in a market set to grow exponentially," explains Stefan Janssens, president EMEA of Cegedim Relationship Management. "The new imperative for companies operating in Russia consists of developing initiatives that regionalize market access campaigns, increase understanding of existing KOLs, and develop a more educational approach to HCP interaction."

For more information, visit cegedim.com/rm.

Orphan Drugs PROVE ECONOMICALLY VIABLE


Dr. Kiran Meekings

Life-sciences researchers found that developmental drivers such as government incentives, shorter clinical trials, and high rates of regulatory success make top orphan drugs as economically viable as non-orphan therapies, even though the number of patients benefiting from them is significantly smaller than those benefiting from non-orphan medicines, according to Thomson Reuters in a report The Economic Power of Orphan Drugs.

"These new data give economic validity to the importance of targeting rare diseases in the global pharmaceutical market," observes Kiran Meekings, Ph.D., life-sciences consultant at Thomson Reuters and co-author of the report. "Not only does such focus help those affected by rare diseases, of which there are 25 million people in the United States alone, it also furthers the aim of precision medicine and substantiates the envisioned high returns on the R&D investment, particularly for drugs with multiple orphan disease approvals."

The Thomson Reuters report provides extensive evidence that orphan drug development is an important component of biopharmaceutical R&D strategy, and that a number of orphan drug therapies are already achieving blockbuster status. For example, the compound annual growth rate for the orphan drug market between 2001 and 2010 came in at about 25.8%, compared with 20.1% for non-orphan drugs. More specifically, the orphan drug Rituxan, approved for several rare conditions, has an estimated lifetime revenue potential of $154 billion, second only to Pfizer's blockbuster Lipitor, with lifetime revenue potential of $197 billion.

For more information, visit thomsonreuters.com.

Broad-based Technology Platforms TO ADDRESS DRUG DELIVERY EFFICIENCY

The popularity of medicines and devices with improved, easy-to-use dosing schedules present both an opportunity for pharma companies to create new innovative products and improve patient adherence to prescribed medications.

But proof will also be needed to back up claims that new drug delivery methods are not a waste of valuable R&D funding, according to GBI Research. For instance, the link between convenience and adherence with medication schedules will come under closer scrutiny in the future, as reimbursement companies will demand clinical data to support the superiority of less frequent dosing regimens.

The global drug delivery market was estimated to be worth $101 billion in 2009 and set to rise to $199 billion in 2016 at a CAGR of 10.32%. Individual blockbuster products may earn more than $1 billion as a single product.

For more information, visit gbiresearch.com.

Global Proteomics Market to GROW BY 14%

The global proteomics market is estimated to grow at a CAGR of 14.2% to reach $17.2 billion by 2017, according to MarketsandMarkets. The key players in the market are Thermo Fisher Scientific, Agilent Technologies, Life Technologies, Sigma-Aldrich, Danaher Corp., Waters Corp., Roche, Bio-Rad, and Luminex.

Proteomics, over the last decade, has gained importance in the field of diagnosis and drug research and development and is poised to grow at a healthy pace mainly due to increasing innovations and developments in the field of proteomics instrumentation, availability of funds from various organizations, and increasing research and development expenditure.

But the economic slowdown and lower adoption rate due to expensive tools and instruments will restrict the growth of this market to some extent.

For more information, visit marketsandmarkets.com.

Pharmaceutical Anti-counterfeiting TECHNOLOGIES MARKET TO INCREASE

The world market for pharmaceutical anti-counterfeiting technologies will reach $1.2 billion in 2015, according to Visiongain. The study predicts that the pharmaceutical anti-counterfeiting market will

grow strongly from 2012 to 2022. The illicit trade in counterfeit drugs costs the pharmaceutical industry billions of dollars every year. Also, the consumption of counterfeit drugs poses a serious threat to public health. Visiongain believes drug counterfeiting is one of the most pressing challenges facing the pharmaceutical industry. The more widespread use of anti-counterfeiting technologies will help to defeat counterfeiting activities.

Visiongain's Dr. Peter Williamson says growth of the market will be stimulated by the introduction of industrywide standards and mandatory supply chain track-and-trace technologies.

For more information, visit visiongain.com.

Next EMR Opportunity May Be IN EUROPE

Europe may provide opportunity for EMR software companies as European healthcare systems update their systems, according to Kalorama Information. European electronic medical records (EMR) market reached revenue of $6.8 billion in 2012. An established market in some countries and implementation issues in other countries have kept revenue growth at a modest rate of 3%, but that's expected to double in the coming years.

Kalorama finds several factors are driving the European EMR market, including a growing elderly population, rapid development of medical technology, and cost. There is a strong drive to reduce avoidable medical errors, thus improving overall quality of care and facilitating the sharing of patient data.

But there are also challenges that the report identifies. Key barriers to the adoption of EMRs in Europe include lack of funds, time, and cooperation of users, complexity of the systems and evaluation of need. These barriers differ from country to country but do create stumbling blocks for implementation.

For more information, visit kaloramainformation.com.

Contract Support and Technical Service Providers Expected to PLAY A GROWING ROLE

Drug sponsors and their contract service providers are using more sophisticated, integrated, and coordinated relationship structures to deliver greater speed and efficiency, a trend that is expected to accelerate, according to a panel of leaders convened by the Tufts Center for the Study of Drug Development.

Sponsors are adopting relationships with their technical and support service providers much the same way they have established strategic, integrated alliances with contract clinical research service providers. The adoption of these relationships is due in part to the growing numbers of increasingly complex, global clinical trials that require drug development sponsors to manage ever-more diverse combinations of contract technical and support services, such as clinical supplies, testing, and cardiac safety assessments.

For more information, csdd.tufts.edu.

Patient Centricity Key to PATIENT ADHERENCE


Michelle Vitko

Pharmaceutical companies must shift their perspective from looking at patients as statistics and embracing patient needs and goals, according to a recent study by Cutting Edge Information.

The study found that generating a long-term impact on patient outcomes requires a cultural and philosophical shift within pharmaceutical organizations. The industry currently loses $290 billion annually because of patient nonadherence. Specifically, improving patient adherence requires an overhaul of the current system in which caregivers instruct patients and provide them with medical plans, expecting them to follow that course of treatment flawlessly.

Industry experts advise going beyond the scope of delivering medical information. Patient-centricity is a growing factor in shaping company adherence strategies.

Many pharmaceutical companies have developed patient programs geared to individual patient groups. One profiled company's program provides breakfast to patients' children, for example. By initiating such activities, pharmaceutical companies emphasize building relationships with consumers to establish a real sense of their goals and needs.

"Ultimately, to realize success, companies must move beyond cookie-cutter adherence tactics," says project leader Michelle Vitko. "Organizations that embrace patient-centric thinking better position themselves to reach their program goals by treating consumers as critical customers and responding to their unique needs."

For more information, visit cuttingedgeinfo.com.

Market for NANOPARTICLES TO GROW

The global market for nanoparticles in biotechnology, drug development, and drug delivery was valued at $17.5 billion in 2011 and should reach almost $21.6 billion in 2012, according to BCC Research. Total market value is expected to reach $53.5 billion in 2017 after increasing at a five-year CAGR of 19.9%.

The market for nanoparticles in biotechnology and pharmaceuticals can be broken down into four segments: biotechnology applications, drug development and formulation, drug delivery systems, and diagnostic imaging and testing.

Biotechnology applications are expected to increase from $388 million in 2012 to more than $1 billion in 2017, a CAGR of 21%. Drug development and formulation should total almost $9.4 billion in 2012 and $20.5 billion in 2017, a CAGR of 16.9%. Drug delivery systems are expected to increase from $11.3 billion in 2012 to $30.9 billion in 2017, a CAGR of 22.2%. Diagnostic imaging and testing should increase from $466 million in 2012 to $1.1 billion in 2017, a CAGR of 19.6%.

In the last decade, the science of nanoparticles has made major advances in particle type production and in nanoparticle application in all areas of the life sciences.

The most rapid advances have been made in the application of nanoparticles in drug research and development, drug product formulation, and development of novel drug delivery systems using nanoparticle carriers.

The development of nanoparticles and their rapid incorporation into the research and development, formulation, and production of drug products has given rise to the need for rapid and accurate analytical instrumentation that is necessary for determining the size and characteristics of particle materials in the nanometer size range.

For more information, visit bccresearch.com.

Global Market for Nanoparticles in Biotechnology and Pharmaceuticals ($ in millions)

	2010	2011	2012	2017	CAGR%
Drug delivery systems	$7,878	$9,454	$11,345	$30,905	22.2%
Drug development and formulation	$5,472	$7,387	$9,382	$20,490	16.9%
Diagnostic imaging, diagnostic testing*	$330	$389	$466	$1,140	19.6%
Biotechnology applications	$236	$318	$388	$1,006	21.0%
Total	$13,916	$17,548	$21,581	$53,541	19.9%

*Revenue in this category does not include the cost of imaging instruments or fees paid to physicians, clinics or hospitals for imaging and analysis.
Source: BCC Research

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