Adverse Drug Event Reporting in U.S. PLAGUED BY INCOMPLETENESS AND INACCURACY

Trending now: A high proportion of healthcare professionals have no ADE reporting experience.

VOLUNTARY ADVERSE DRUG EVENT (ADE) reporting in the United States is incomplete, inaccurate, and inefficient, which could deny or limit patient access to safe and effective treatments, according to recent studies completed by the Tufts Center for the Study of Drug Development.


Ken Getz

"While ADE reporting aims to ensure and enhance patient safety, a high proportion — nearly 40% — of healthcare professionals have never reported an ADE," says Ken Getz, associate professor and director of sponsored research at Tufts CSDD. "Inaccurate reporting, in particular, is problematic, as it may mislead drug safety professionals to draw incorrect conclusions, cause manufacturers to wrongly suspend and withdraw medical interventions, lead health professionals to mistakenly alter their clinical practices, and deny or limit patient access to safe and effective treatments."

Other findings include:

- Pharmacists are more aggressive about ADE reporting, compared with nurses and physicians.
- ADE reports submitted by patients tend to be more complete than reports submitted by healthcare professionals.
- Completeness and accuracy of ADE reports vary by therapeutic area, with those for CNS drugs posting the highest drug name accuracy and some of the lowest lot number completion rates.

Medical Affairs Budgets Expected to Increase


Natalie DeMasi

Medical affairs is increasingly critical to operations at life-sciences companies. While many medical affairs subfunctions must deal with static resources, medical communications teams — medical education, medical information, and medical publications — are receiving budget increases at some companies. This growth in budget reflects how medical communications teams are adapting to technology's impact on the dissemination of medical information, according to a recent study by pharmaceutical intelligence provider Cutting Edge Information.

About 61% of surveyed teams have modified their existing medical operations in response to the challenges resulting from the Internet and social media. In tandem, 21% of global teams expect to increase their medical information budgets between 2015 and 2016.

"According to interviewed executives, the biggest challenge for patients and caregivers is often differentiating between valuable and non-valuable online medical information," says Natalie DeMasi, senior analyst at Cutting Edge Information. "The availability of easily accessible online information may also dissuade physicians from seeking company expertise."

Orphan Drug Market Expected to See Continued Growth

With 2020 worldwide sales forecast at $178 billion, the orphan drug market is expected to grow by 11.7% per year from 2015 to 2020, nearly doubling the yearly growth of the overall prescription drug market. Moreover, worldwide orphan drug sales will account for 20.2% of worldwide prescription sales by 2020, according to EvaluatePharma's Orphan Drug Report 2015.

"Up until now, orphan drug developers have managed to defend the cost of these life-changing drugs but with the increasing scrutiny over drug costs and the growing number of designations awarded, orphan drug developers will have to continue to innovate and demonstrate how their products can help reduce the overall healthcare budget," says Andreas Hadjivasiliou, report author and EvaluatePharma analyst.

Other findings include:

- Median cost per patient is 13.8 times higher for orphan drugs compared with non-orphan; Advate delivers highest revenue per patient for an orphan drug in the United States.
- Celgene overtakes Novartis and climbs to the No. 1 position in orphan drug sales by 2020 thanks to top selling Revlimid.
- Phase III orphan drug development costs are half that of non-orphan development costs but Phase III drug development is no quicker for orphan than non-orphan drugs.
- Return on investment of Phase III/ filed orphan drugs is 1.14 times greater than the ROI for non-orphan drugs.
- 2014 was a record year for orphan drug designations with the FDA awarding 291, Europe awarding 201, and Japan awarding 32 designations.
- Opdivo ranks as the most promising new orphan drug approved in the United States in 2014 while Obeticholic Acid ranks as the most valuable R&D product.

Watch for the February issue of PharmaVOICE for an update on the orphan drug market.

Life-Sciences Companies Lack Automated Processes for Study Startup


Sujay Jadhav

Preliminary findings from the goBalto 2015 Global Study Startup Survey uncovered significant gaps in the industry's ability to efficiently manage document workflows and activities associated with starting clinical trials.

The survey found that industry leaders were continuing to adopt best-of-breed cloud-based eClinical solutions, such as clinical trial management systems (CTMS), electronic data capture (EDC), and electronic trial master file (eTMF).

Therapeutic trax

Autoimmune Conditions

The market for RA disease-modifying therapeutics is expected to increase from $56.6 billion in 2013 to $80.7 billion in 2020 at a CAGR of 5.2%. First-line DMARDs are expected to remain stagnant, as the late-stage pipeline predominantly constitutes second-line therapies. In the EU market, the patent expiration of blockbuster drugs as early as 2015 is expected to cause a strong uptake of biosimilars. But uncertainty over the regulatory guidelines that govern the approval pathway of biosimilars into the US, the largest RA market across the eight key territories, may not measurably affect the pricing of the currently marketed drugs.

Source: GBI Research

The value of the multiple sclerosis therapeutics market will rise slowly from $17.2 billion in 2014 to about $20 billion by 2024, at a CAGR of 1.5%. this growth, which will occur across the 10 major markets of the US, France, Germany, Italy, Spain, the UK, Japan, Canada, China, and India will be driven by the continued uptake of premium products and an increase in treatment rates as a result of the availability of novel alternatives.

Source: GlobalData

Cardiovascular Conditions

In the 2014 base year, the peripheral artery disease (PAD) market was worth $543.4 million, including both branded and generic drugs, across eight major markets (US, France, Germany, Italy, Spain, UK, Japan, and urban China). By 2024, it is expected that the global PAD market will experience significant expansion, partly attributable to the launch of several PAD drugs currently in late-stage pipeline development.

Source: GlobalData

CNS Conditions

The attention-deficit hyperactivity disorder (ADHD) therapeutics market value will rise from $6.9 billion in 2013 to $9.9 billion by 2020, with broadening diagnostic criteria a key driver of growth. This increase, which represents a CAGR of 5.3% and relates to eight major markets (the US, the UK, France, Germany, Spain, Italy, Japan and Canada), will occur fastest in Japan, due to its high ADHD prevalence. Despite the stigma attached to mental health conditions, this country will witness a more impressive ADHD treatment market CAGR of 15.7%.

Source: GlobalData

Diabetes

The global market for type 2 diabetes mellitus therapeutics will rise in value from $23.5 billion in 2014 to an estimated $39 billion by 2021, driven primarily by rising disease prevalence and the continued uptake of recently approved and emerging branded treatments. This increase, which will occur across the eight major markets of the US, Canada, France, Germany, Italy, Spain, the UK, and Japan, represents a CAGR of 7.5%.

Source: GBI Research

Infections

The global therapeutics and prophylactics market for Clostridium difficile infections (CDIs) will expand more than fourfold from $356.3 million in 2014 to over $1.5 billion by 2024, representing a CAGR of 15.8%. This will be driven by the modest uptake of patent-protected, CDI-specific antibiotics and the arrival of novel non-antibiotic approaches to treat and prevent recurrent CDI.

Source: GlobalData

But even the latest releases of these applications fell short in addressing one of the most inefficient and costly bottlenecks of clinical trial conduct — study startup (SSU).

The process of initiating clinical trials continues to remain cumbersome, challenging, and often behind schedule, making study startup one of the poorest performing aspects of clinical trials.

"Excel is still the mainstay in managing clinical trials, and while a few have tried to use existing eClinical or document management systems for study startup, they have fallen short," says Sujay Jadhav, goBalto's CEO.

"Only a purpose-build study startup solution capable of handling complex regulatory/SOP workflows is able to tackle the complexities associated with starting clinical trials, providing true efficiencies via cycle time reductions."

More than two-thirds of sponsors and contract research organizations use Excel for site selection and evaluation, with the majority of sponsors (93%) and contract research organizations (80%) using Excel for site feasibility.

EHR Market Expected to Grow

The global electronic health record (EHR) systems market was valued at $20.96 billion in 2014 and it is expected to grow at a CAGR of 6.2% during the period 2015 to 2020, according to a new study by P&S Market Research.

With the increase in chronic disease cases, the need for better healthcare facilities is increasing, which is resulting in increased demand for EHR systems. Increasing government initiatives, need for advanced healthcare information system and growing investment by healthcare IT players are further encouraging the growth of the global EHR systems market.

Note: See the February issue of PharmaVOICE for an update on the EHR market.

Opioid Painkiller Users Unaware They Are Taking Addictive Drugs

According to a National Safety Council survey, 45% of Americans who use opioid prescription painkillers do not realize they are taking an opioid. In fact, opioid painkillers and heroin have nearly identical chemical makeups and produce the same effects. Drug overdoses, largely from opioid painkillers, are a leading cause of unintentional death.

"Americans should not be fooled: an opioid painkiller is the equivalent of legal heroin," says Deborah Hersman, president and CEO of the National Safety Council. "The drugs in our medicine cabinets can be just as addictive as illicit ones."

Other council survey findings exposed additional disconnects in education and behaviors around opioid painkiller use. The survey found almost 9 in 10 opioid painkiller users are not concerned about addiction, despite 67% saying they believe the drugs are more addictive than other types of prescriptions.

The survey also showed many people are not familiar with formulary names. Just 29% of survey respondents said they had taken an opioid painkiller, but that increased to 42% when they saw common opioid brand names such as Vicodin, Percocet, and Oxycontin.

Oncology Corner...

As a continuation of the popular oncology series of articles PharmaVOICE initiated in 2015, we will continue to cover breaking news and updates around cancer-related R&D, products, services, and trends expected to impact the industry in the coming months and years.

ORIC Pharmaceuticals Announces $53 Million Series B Financing to Support Discovery and Development of Novel Therapies for Treatment-Resistant Cancers

ORIC Pharmaceuticals, a cancer therapy company focused on the discovery and development of small-molecule drugs that target treatment-resistant cancers, announced a $53 million Series B financing. The funds will be used to support advancement of the company's first drug candidate into initial clinical trials and to further develop the company's pipeline.

ORIC was founded by two world-class oncology experts, Charles Sawyers, M.D., and Scott Lowe, Ph.D., who are on the faculty at Memorial Sloan Kettering Cancer Center. Drs. Sawyers and Lowe have been involved with groundbreaking work in cancer-treatment resistance, which resulted in the discovery and development of several novel therapeutics. Dr. Sawyers was instrumental in the discovery and development of leading drugs, including imatinib for chronic myelogenous leukemia and enzalutamide and ARN-509 for castration-resistant prostate cancer. Dr. Lowe identified BRD4 as a therapeutic target in acute myeloid leukemia, with drugs for this target currently in clinical trials.

In addition to these academic co-founders, Valeria Fantin, Ph.D., recently joined ORIC as the company's chief scientific officer (CSO). Dr. Fantin is a biopharmaceutical executive with deep expertise in oncology drug discovery and development.

The company is initially focusing on drugs targeting resistance mechanisms associated with androgen receptor (AR) therapies in advanced (i.e., castration-resistant) prostate cancer.

ORIC's first drug candidate will focus on the glucocorticoid receptor (GR) as a target for AR resistance. Research has shown that the GR may replace the AR to drive prostate cancer growth and metastasis in settings of androgen deprivation.

Mathematical Modeling Can Help Predict Impact of Surgery on Cancer Metastasis

The size of a surgically removed tumor is generally thought to relate to the risk of the cancer spreading to other regions of the body. But because tumor cells may metastasize at different times and the rate of spread is difficult to assess, the relationship between tumor size and the relative risk of recurrence after surgery is challenging to calculate.

Writing in the journal Cancer Research, scientists at Roswell Park Cancer Institute (RPCI) and Inria, the French National Institute for computer science and applied mathematics in Bordeaux, France, demonstrate that mathematical models can provide useful clues about the impact of surgery on metastasis and may help to predict the risk of cancer spread.

The scientists generated a mathematical model using the key parameters of primary tumor size and metastatic spread based on data generated from laboratory models designed to mimic cancer's progression in humans. They used tumor cells engineered to express a luminescent marker, allowing for the tracking and quantification of these otherwise-undetectable cancer cells.

The mathematical modeling confirmed a strong dependence between presurgical primary tumor size and postsurgical metastatic growth and survival. However, some surprising developments were noted.

"We found that this relationship was not simply dependent on size," says the study's corresponding author, Sebastien Benzekry, Ph.D., a research scientist on the Modeling in ONCology team at the Inria Bordeaux Research Center, which is affiliated with the Institute of Mathematics of Bordeaux (University of Bordeaux). "The models indicate that in the case of tumors that are either very large or very small, tumor size does not significantly impact on survival, and therefore loses its predictive value. This, in turn, could impact how treatment decisions, such as the optimal time to start and stop therapy, are made."

AstraZeneca Launches Oncology Patient Site

LVNG With, pronounced "Living With," is both a patient-centric Web site — LVNG.org — and a series of live events across the country, comprising a day of inspiration and encouragement from people who are living with lung cancer. LVNG With was co-developed by AstraZeneca and three leading lung cancer advocacy organizations — Bonnie J. Addario Lung Cancer Foundation, Free to Breathe, and Lung Cancer Alliance.

This program is the only one of its kind for lung cancer and is unique from any unbranded program. More than 100 people with lung cancer and their loved ones contributed to the development of LVNG With by sharing personal stories about their emotional journeys and everyday lives. The stories shared on LVNG.org are authentic insights from patients, for patients. AstraZeneca connected personally with each person who shared a story and was inspired by their generosity and willingness to help support others with lung cancer, whom they did not even know.

SERMO Takes Pulse of Lung Cancer Physician Community

SERMO, a leading global social network exclusively for doctors, took the pulse of the physician community on prevention and treatment of lung cancer, the leading cancer killer. The results showed many doctors wanting to go one step further than the screening recommendations from the U.S. Preventive Task Force and few doctors doing genetic testing that would allow for personalized medicine.

Findings include:

- 43% of doctors polled think low-dose screening should extend low dose CT screening for lung cancer to all patients
- 48% of those doctors think that screening should start at age 50
- 66% of doctors polled think radon testing should be mandated before a person moves into a new property and the results should be shared with the new tenant so the seller or tenant can take measures to reduce radon exposure and prevent lung cancer (Radon is the #1 cause of lung cancer in nonsmokers)
- 23% of doctors polled test for gene mutations in people with lung cancer
- 93% of those doctors change their treatments based on the results

Calendar Alert — World Cancer Day Feb. 4

The first Toulouse Onco Week (TOW) — The World United Against Cancer — will take place Feb. 3-6, 2016, at the Pierre Baudis Congess Center, Toulouse, France. This event will be focused on the international fight against cancer by bringing together stakeholders from around the world and presenting the latest global innovations in oncology.

TOW aims to unite all forces in the fight against cancer: scientists, clinicians, caregivers, industry,

pharmaceutical and biotechnology companies, public authorities, and charities. The event will be part of World Cancer Day 2016 on Feb. 4. This initiative was founded by the Toulouse Center for Cancerology Research (CRCT)* and will be conducted in partnership with the Cancer-Bio-Health cluster, the Toulouse Cancer Health Foundation, Toulouse Métropole, and So Toulouse.

At TOW, six events will be taking place in one venue. The highlights of these will be the 1st International Symposium of CRCT, academic and industrial presentations, Business to Business meetings organized by the Cancer-Bio-Health cluster, public-expert discussion sessions and charitable events arranged by Toulouse Métropole and So Toulouse with profits donated to the Toulouse Cancer Health Foundation.

Oncology Experts Share Essential Actions to Achieve a Positive Impact on Patient Care in the Integrated Healthcare Environment

The U.S. healthcare industry is undergoing unprecedented consolidation and integration that is having an impact on all stakeholders — health systems, hospitals, private practices, providers, payers, and most importantly, patients and their families. Hospital systems are merging, hospitals are purchasing provider practices, and the insurance industry is undergoing what some are calling "merger madness." By 2025, it is likely that the U.S. cancer care delivery system will look completely different as programs and providers find themselves working in new ways with new partners.

To address this trend and to suggest steps toward a future path that ensures improved patient care within this changing environment, the Association of Community Cancer Centers (ACCC) has released a white paper "What Will It Take? Five Essential Actions to Achieve a Positive Impact on Patient Care in the Integrated Healthcare Environment," at its 32nd National Oncology Conference last October.

The five essential actions for achieving a positive impact on patient care are:

1. Aligning stakeholders and requiring accountability
2. Defining quality in a value-based reimbursement system and providing access to quality care
3. Using nontraditional delivery systems (telehealth) and providers (primary care physicians and non-physician providers) to deliver cancer care
4. Integrating the use of big data to drive treatment decisions
5. Moving to patient-directed care in which the patient is at the center of all decisions and systemic change

"Increased integration will impact all aspects of an organization's cancer care delivery — cultural, operational, clinical, and financial," says ACCC President Steven D'Amato. "Our focus in this newly integrated environment is to provide education for hospital systems and physician practices on how to offer the best collaborative oncology care in a seamless way for patients."

Oncology Leaders Convene

The Economist Event's inaugural War on Cancer 2015, held in London last October, was host to some of the industry's most high-profile leaders in oncology from across the field and around Europe. With a focus on cross-sector collaboration to improve the health and wealth of Europe's nations and people, the program examined leading initiatives in policy and financing, innovation in prevention, treatment and diagnosis, and new methods of community engagement.

War on Cancer was attended by more than 200 people, who included a mix of industry leaders, stakeholders, and national and international media.

Highlights from the event include:

Patrick Soon-Shiong, Chairman and CEO, Chan Soon-Shiong Institute of Molecular Medicine; Founder, Nantworks, says: "We have the opportunity to completely change the paradigm of cancer treatment and, alongside capabilities to extract the precise genomic signature of a patient's cancer, engineer treatments that are personalized for that person's particular cancer.

Elisabeth Prchla, General Manager UK & Ireland, Merck Serono, comments: "Oncology is a key priority for us and we're committed to tackling the war on cancer head on. We're focused on addressing the areas of high unmet need and developing innovative cancer medicines. One of the key challenges in the UK is access to these innovative medicines."

Speakers offered contrasting and thought-provoking commentary on how to deal with the most pressing of sector trends leading to lively debate among the packed room of delegates. Topics covered included how to improve cancer control systems, erasing the human and financial burden by maintaining innovation across the treatment pathway, and the role of society and how to widen the net of cancer stakeholders.

Cancer Trax

The entry of 11 novel therapies into the non-small-cell lung cancer (NSCLC) market will drive the market's growth from $5.4 billion in 2014 to $12.7 billion in 2024. In addition to the recently approved programmed death-1 inhibitors Opdivo (Bristol-Myers Squibb) and Keytruda (Merck & Co.), three more immune checkpoint inhibitors are slated to enter the NSCLC market: atezolizumab (Roche/Genentech), durvalumab (AstraZeneca/MedImmune), and avelumab (Merck KGaA/Pfizer).

Source: Decision Resources

The global prostate cancer (PC) market is expected to increase from $7.6 billion in 2014 to $13.6 billion by 2021. This growth will be driven predominantly by the forecast growth in disease prevalence. PC is a disease of the elderly, with about 70% of cases diagnosed in men above the age of 65. Although expected to have a smaller impact on overall market growth than disease prevalence, the continued uptake of Zytiga and Xtandi for the treatment of chemotherapy-resistant metastatic castration-resistant prostate cancer is also expected to be a key driver throughout the forecast period.

Source: GBI Research

The global treatment market for multiple myeloma will rise in value from $8.9 billion in 2014 to an estimated $22.4 billion by 2023, representing a CAGR of 11.2%. This increase, which will occur across the eight major markets of the US, France, Germany, Italy, Spain, UK, Japan, and urban China, will be boosted by increasing therapeutic options, including the introduction of two monoclonal antibodies (mAbs) with blockbuster potential, namely Empliciti and daratumumab, during the forecast period.

Source: GlobalData

The value of the global acute myeloid leukemia (AML) therapeutics market will increase moderately from $632.6 million in 2013 to $878.6 million by 2020, representing a CAGR of 4.8%. This growth will occur across eight major markets (the US, UK, Canada, Germany, France, Italy, Spain and Japan) and is attributable to rising AML prevalence and the anticipated launches of five premium-priced drugs into a market dominated by generics.

Source: GlobalData

The non-small cell lung cancer (NSCLC) market is forecast to grow substantially over the forecast period, from $6.9 billion in 2014 to $10.9 billion in 2021, following the introduction of a number of premium novel therapies. Growth will be primarily driven by immune-checkpoint inhibitors, such as Opdivo and Keytruda, which are anticipated to capture a significant share of the second-line treatment market. The majority of new therapies will target the second-line treatment of NSCLC in both non-squamous and squamous patient subsets, leading to a crowded treatment algorithm for second-line patients. Ultimately, due to strong clinical performances, immune checkpoint inhibitors will have a greater uptake than other second-line market entrants.

Source: GBI Research PV