PharmaVOICE @INDUSTRY EVENTS

ORLANDO SCDM 2017
ANNUAL CONFERENCE
SEPTEMBER 24-27

SCDM Meets in Orlando

The Society for Clinical Data Management (SCDM), a non-profit, international organization of 2,200-plus members, which is dedicated to advancing the discipline of clinical data management, held its annual meeting in Orlando in September. Professionals were able to take advantage of dozens of workshops addressing topical issues impacting data managers, including international clinical trials, ePRO, EDC/CTMS, real-time monitoring, and more.

Save the date for next year's conference: September 23-26, 2018, Seattle

SCRS Annual Global Site Solutions Summit

INC Research/inVentiv Health was awarded the 2017 Society for Clinical Research Sites (SCRS) Eagle Award in the CRO category during the SCRS Annual Global Site Solutions Summit. The meeting was held October 6-8 in Boca Raton, Fla. The award recognizes the CRO that best exemplifies outstanding leadership, professionalism, integrity, passion and dedication to advancing the clinical research profession through strong site partnerships. To select this year's finalists, SCRS members — almost 9,000 research sites in 45 countries — were invited to nominate the CRO they believe best demonstrates a strong commitment to site partnership. All sites, regardless of SCRS membership, were able to select a winner for announcement at the Summit.

Save the date for next year's Summit: Oct 12-14, 2018, Waldorf -Astoria, Boca Raton, Fl.

Pfizer Service Provides SOCIAL WORKERS FOR PATIENTS

Pfizer Oncology Together provides dedicated social workers for people taking Pfizer Oncology medicines.

Pfizer Oncology Together is a first-of-its-kind offering for patients taking Pfizer Oncology medicines. The program offers dedicated social workers called "Care Champions" to help navigate the complexities that accompany treatment, such as identifying resources to help find emotional support, and workplace transition, transportation, and financial assistance.

Pfizer has also launched This is Living with Cancer, a program that provides tools and resources to support those who have been affected by cancer.

The Pfizer program also includes a mobile app LivingWith, which is designed to help manage some of the daily challenges faced by people living with cancer.

Vertex Announces CORPORATE GIVING COMMITMENT

Vertex Pharmaceuticals has launched a 10-year, $500 million corporate giving commitment focused on providing patient and caregiver support including access to its medicines; expanding our commitment to science, technology, engineering, arts and math education; developing young physicians and scientists; and investing in its communities. $50 million of this giving will be dedicated to STEAM education, particularly for underserved students and young women.

As part of this commitment, the company will establish The Vertex Foundation, a long-term source of charitable giving, with an initial contribution of $10 million.

Jeffrey Leiden, CEO of Vertex, says the company's commitment will provide many more opportunities for Vertex and its employees to make a difference in the lives of people with serious diseases.

Survey Highlights PHARMA'S WORRIES

Nearly all (98%) of life-sciences companies are concerned with FDA regulatory approvals, obligations, and compliance, including limitations on approved products, compared with 97% last year and 94% in 2013, according to the 2017 BDO Life Sciences RiskFactor Report. The report analyzes risk factors listed in the most recent 10-K filings of the largest 100 publicly traded life-sciences companies on the NASDAQ Biotechnology Index.

Other findings:

- Most (84%) cite pressure on pricing and margins, and cost-cutting, down slightly from last year's 89% but compared with 79% in 2015, 68% in 2014 and 66% in 2013.
- 90% mention delays or unfavorable results from preclinical and clinical trials, in line with last year's 91% but up from 87% in 2014 and 80% in 2013.
- Concerns around changes in healthcare laws and regulations, including the ACA, are at an all-time high of 89%, compared with 86% last year and 78% in 2013. 71% mention tax liabilities as a significant business risk.
- Almost half (47%) are worried about compliance with differing tax laws in domestic and foreign jurisdictions.

PharmaVOICE 100 Executive Moves

INCEPTION COMPANIES HIRES AGENCY VET MATT GIEGERICH


Matt Giegerich

The Inception Companies has appointed Matt Giegerich, longtime CEO of WPP's Ogilvy CommonHealth, to serve as CEO for its two largest business units: Inception Digital, a virtual meetings technology company that reduces in-person meeting and travel costs by delivering interactive video broadcasts and webcast platforms, as well as Kampfire, a video production company that creates compelling brand content to influence consumer behavior.

"I could not be more thrilled to join the Inception Companies," Mr. Giegerich. "There are new and exciting capabilities on the way, including a game-changing innovation in virtual meeting technology that I can't wait to unveil."

Mr. Giegerich was named a PharmaVOICE 100 honoree in 2005.

LYNN O'CONNOR VOS TO LEAD THE MDA


Lynn O'Connor Vos

The Muscular Dystrophy Association (MDA) has appointed Lynn O'Connor Vos as president and CEO. Ms. O'Connor Vos previously was global CEO of Greyhealth Group (ghg), a health care communications agency and part of the global WPP Group. She succeeds interim president and CEO Kristine Welker.

"It truly feels as if my entire career path has been leading me to this role," Ms. O'Connor Vos says. "I am excited to bring my passion for patient care and advocacy, as well as my success using new technology to build new, innovative communication approaches, to lead MDA in the fast-changing world of research and patient care."

Ms. O'Connor Vos was named a PharmaVOICE 100 honoree in 2005 and 2017.

CARDINAL HEALTH NAMES MIKE KAUFFMAN CEO


Mike Kauffman

Cardinal Health has named Mike Kauffman, 54, its current chief financial officer, to serve as the company's next CEO and join the board, effective Jan. 1, 2018. Mr. Kaufmann succeeds George Barrett, Cardinal Health's chairman and CEO since 2009. Mr. Kauffman is a 27-year veteran of Cardinal Health with responsibility for all of the company's financial activities in addition to overseeing global sourcing for both the pharmaceutical and medical segments.

Mr. Kauffman was named a PharmaVOICE 100 honoree in 2016.

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PODCAST:

» **How to Navigate Specialty Logistics for Cell and Gene Therapies**
Sponsored by: AmerisourceBergen

WEBINARS:

» **Improving Time-to-Market and Clinical Quality of Studies with Video EEG Protocol**
December 14
Sponsored by: Lifelines Neurodiagnostic Systems

» **Discover the Megatrends Remapping the Pharmaceutical Market (On Demand)**
Sponsored by: Manatt Health

» **Digitizing Clinical Research Processes - The New Frontier (On Demand)**
Sponsored by: DocuSign

WHITE PAPERS:

» **Commercializing Cell and Gene Therapies**
Provided by: AmerisourceBergen

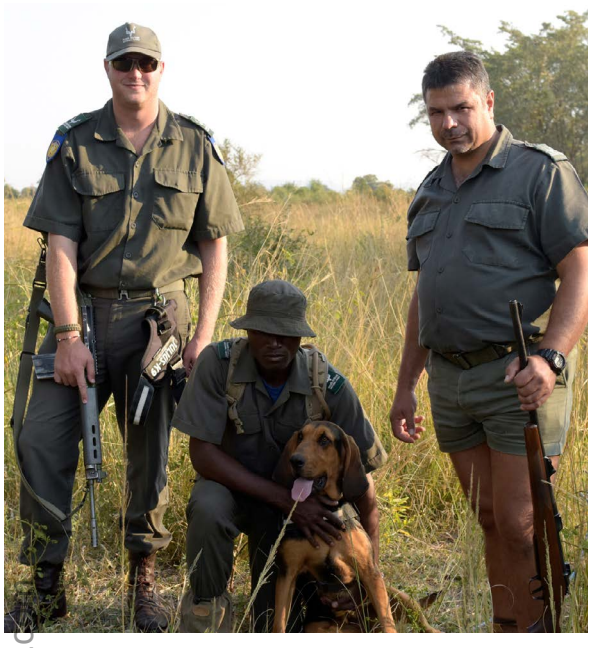
» **Patient Centricity Works**
Provided by: eyeforpharma

» **Data-Driven Patient Outreach**
Provided by: TrialCard

» **Locating Patients with Rare Diseases**
Provided by: TrialCard

Study Examines USE AND COST OF ORPHAN DRUGS

Orphan drugs accounted for only 7.9% of the $460 billion spent on drugs in the United States in 2016, according to a study issued by the QuintilesIMS Institute. The study was commissioned by the National Organization for Rare Disorders (NORD) and analyzed the role of the Orphan Drug Act and orphan drug usage and costs.



Bayer Animal Health supports the work of this anti-poaching unit by providing parasiticides for the dogs.

Bayer Extends Support for RHINO ANTIPOACHING IN SOUTH AFRICA

Bayer Animal Health South Africa is collaborating with South African National Parks' efforts to combat rhino poaching by sponsoring parasiticides for the dogs used to combat poaching.

Clint Austin, veterinarian and head of clinical development & regulatory affairs for Bayer Animal Health South Africa, says "These highly trained and very expensive dogs work in very remote and sometimes extremely inhospitable terrain in a part of the world that is rife with often fatal tick borne disease like Ehrlichiosis or Babesiosis."

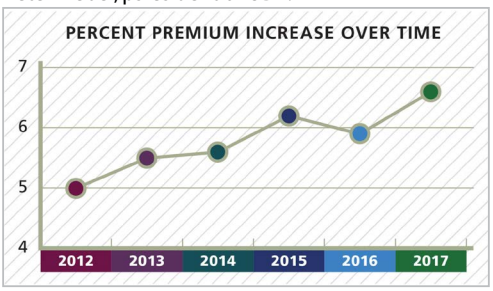
Employer Premiums RISE 7% IN 2017

Premium renewal rates for employer sponsored health insurance rose an average of 6.6%, a significant increase from the five-year average increase of 5.6%, according to the 2017 United Benefit Advisors (UBA) Health Plan Survey.

Two states saw record premium increases: Connecticut saw a 24% increase in premiums in 2017, up to $655 from $530; New York also saw a large increase of 14%, up to $712 in 2017 over $624 in 2016.

For a second year, prescription drug plans with four or more tiers are exceeding the number of plans with one to three tiers. Almost three-quarters (72.6%) of prescription drug plans have four or more tiers, while 27.4% have three or fewer tiers. Even more surprising is that the number of six-tier plans has surged, accounting for 32% of all plans, when only 2% of plans were using this design only a year ago.

"While employers chose to hold contributions, copays and in-network benefits steady, they dramatically shifted prescription drug costs to employees. By increasing tiering and adding coinsurance (vs. copays), employers were able to contain costs," says Peter Weber, psresident of UBA.



Global Genes Hosts 6TH ANNUAL RARE PATIENT ADVOCACY SUMMIT

Global Genes Chair Wendy White addresses more than 700 attendees at this year's RARE Patient Advocacy Summit.

More than 700 rare disease stakeholders from around the globe gathered in Irvine, Calif., for the 6th Annual Global Genes RARE Patient Advocacy Summit. The annual event brings together patients, caregivers, advocates, and rare disease stakeholders, to learn, connect, share, and partner. The RARE Patient Advocacy Summit is a source of motivation and activation for families whose lives have been affected by rare disease. Annually, corporate stakeholders attend the event and become immersed in rare disease advocacy and gain valuable knowledge on patient and caregiver perspectives.

Global Genes is a rare disease patient advocacy organization with worldwide reach that serves and promotes the needs of patients and families touched by rare and genetic diseases. Since 2009, under the unifying symbol of HOPE and the Blue Denim Genes Ribbons, Global Genes has been building awareness, developing patient-focused education and advocacy tools, and funding patient care programs and early investigative research.

QuintilesIMS is now

IQVIA™

QuintilesIMS has changed its name to IQVIA. The company provides customized solutions for clients leveraging IQVIA CORE, a curated healthcare information source that includes advanced analytics and industry knowledge across diseases, geographies, and scientific methods.

"IMS Health and Quintiles came together because our clients were asking for better, faster ways to bring innovations to patients and capture the improvements the industry has been pursuing for years," says IQVIA Chairman and CEO Ari Bousbib. "Since the merger, we've worked to integrate our capabilities in advanced analytics, leading technologies and therapeutic expertise into powerful, differentiated offerings."

SPEAKout

Provided by: Worldwide Clinical Trials

Innovations in Alzheimer's Clinical Trial Operations Promise to Smooth Transitions

by Allison House, Neuroscience Strategy Lead, and Natalia Drosopoulou, Senior Director, Global Project Management, Neuroscience, Worldwide Clinical Trials

The global impact of Alzheimer's disease continues to increase. By 2050, the Alzheimer's Association expects the number of people diagnosed with dementia to increase to 131.5 million, and currently, Alzheimer's is a direct cause of dementia in an estimated 60%-80% of the 46.8 million people living with degenerative brain disease[1,2]. Despite more than a decade of frustration in finding effective disease-modifying therapies, there are new opportunities to reduce the time and risk of AD drug development through improvements in trial operations[3].

For example, there has been an effort led by the innovative Alzheimer's disease researchers of Worldwide Clinical Trials and others to ensure a seamless transition from single to multiple dose cohorts of patients (SAD-MAD) within a single study often consisting of up to 10–12 cohorts across as many sites. Of note, some sites may be engaged early on in the enrollment process while others are activated in a staggered approach.

Unlike studies seeking to enroll healthy volunteers at a single site, the majority of early-phase cohort studies in patient populations are conducted across multiple sites, with the number of sites being dependent upon sample size, length and complexity of the study, and the recruitment potential of the indication of interest.

"Virtual waiting room" enables proactive management of early-phase Alzheimer's study tasks

In an effort to increase the predictability of timelines, stabilize enrollment fluctuations, master the timing and unpredictability of complex cohort designs, fight recruitment fatigue, and ensure that all eligible patients who can be randomized actually are randomized, Worldwide's researchers created a technology-assisted "virtual patient waiting room" in partnership with the study sponsor [4].

This virtual waiting room permits investigators in Alzheimer's disease research to recruit patients on an ongoing, rolling basis with a "next-in-line" approach that permits multiple sites to simultaneously enroll patients into a single cohort, while continuing to recruit for the upcoming cohorts. Recruited patients who meet eligibility criteria when randomization is closed for a specific cohort are simply placed in the virtual patient waiting room while screening activities continue for the subsequent cohorts. This simple maneuver stabilizes recruitment efforts and patterns so that sites do not have to be shut down and restarted multiple times.

Technology ensures all eligible patients are enrolled and there is no over-enrollment

By utilizing this strategy, the appropriate enrollment of each individual cohort can be more easily managed simply by proper programming of the interactive response technology (IRT) to ensure that all eligible patients are randomized, that there is no over-enrollment within the cohort and that the time between cohorts is minimized. Importantly, forecasting important metrics such as the last patient visit in each cohort can be easily achieved.

Conclusion

In summary, the technology-assisted cohort optimization strategy outlined above results in faster progression through cohorts in Alzheimer's disease research while preserving study data integrity in early-phase multi-center studies, which saves both time and money.

To learn more about Worldwide's early phase clinical research services, please contact Worldwide Clinical Trials at +1 (610) 964-2000 or visit www.worldwide.com.

References

1. 2016 Alzheimer's Disease Facts and Figures. Alzheimer's & Dementia 2016;12(4).

2. World Alzheimer Report 2016. Alzheimer's Disease International

3. Cummings J, et al. "Drug Development in Alzheimer's Disease: The Path to 2025." Alzheimer's Research & Therapy 2016 8:39.

4. House A, Drosopoulou NE, Riordan HJ. "Technology-assisted Cohort Optimisation of Early-phase Multi-centre Patient Studies." International Pharmaceutical Industry, July 27, 2017.

WORLDWIDE CLINICAL TRIALS