Digital Exhibitor Directory

Pharmacovigilance and Risk Management Strategies

January 28-30, 2019

Omni Shoreham Hotel | Washington, DC

DIA

ArisGlobal

3119 Ponce De Leon Blvd
Coral Gables, Fl 33134

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ArisGlobal
We Bring the Future to Life™

ArisGlobal is a visionary technology company that's transforming the way today's most successful life sciences companies develop breakthroughs and bring new products to market. Its innovative pharmacovigilance software and drug safety platform, transcends all traditional safety data management and reporting processes, and its 30+ years safety experience provides clients with the expertise they need to respond to a heightened regulatory focus on signal detection and risk management and address adverse event reporting.

The LifeSphere® Safety Difference:
- Delivers mission-critical benefits for multiple safety processes
- Serves more than 200 multi-tenant cloud customers through a comprehensive platform, including 9 global Regulatory Authorities
- Lowers cost of ownership through multi-tenancy, cloud-based computing that eliminates the need for time-consuming, costly upgrades
- Supports full spectrum of safety case needs, including individual case safety reporting (ICSR)
- Enhances collection, assessment and evaluation of safety data
- Enables seamless integration with any case management in pharmacovigilance processing system through open architecture

LifeSphere® MultiVigilance, ArisGlobal's next-generation platform for individual case safety report intake, is developed on a completely new, cutting-edge technology architecture designed for the cloud with the latest robotic automation and cognitive computing technologies including natural language processing (NLP) and machine learning to transform all pharmacovigilance (PV) activities.

Also available in Chinese and Japanese, LifeSphere MultiVigilance is the first and only unified platform fully integrated with product quality complaints and medical information management, delivering a new dimension on compliance with seamless exchange of safety cases between these critical functions.

UP TO **40%** COST SAVINGS

SUPPORTS NLP AND ML, TRANSFORMING ALL PV PROCESSES

1st AND ONLY UNIFIED PLATFORM

DELIVERING A NEW DIMENSION ON COMPLIANCE WITH SEAMLESS INTEGRATION

$0 FOR ALL FUTURE UPGRADES

OFFERS RAPID IMPLEMENTATION ON A MULTI-TENANT CLOUD

9 REGULATORY AUTHORITIES

SELECTED BY TOP REGULATORY AGENCIES, SUCH AS FDA, NOMA, AND CFDA

ArisGlobal

For more information, contact us at: Booth #2 | www.arisglobal.com | info@arisglobal.com

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Deloitte.

A new paradigm for pharmacovigilance is required to address the operational and compliance challenges experienced today. Deloitte has collaborated with several industry partners and regulators to develop ConvergeHEALTH Safety, an evidence-based platform for safety intelligence to enable an outcomes-based, patient-centric care model.

Deloitte.

ConvergeHEALTH™ Safety™

Transform safety processes. Address pharmacovigilance needs and challenges.

DIA 2019
Pharmacovigilance and
Risk Management Strategies Conference

January 28 – 30, 2019 | Washington, D.C.

Meet our team at the expo hall

Deloitte is excited to be back as a sponsor of the 2019 DIA Pharmacovigilance and Risk Management Strategies Conference. Join our industry experts as we explore the evolving safety landscape and the shift from the traditional transactional and risk–based safety approach, to an end–to–end integrated and evidence–based model for safety intelligence.

https://tinyurl.com/ybz72hgq

@DeloittePltfrms | @DeloitteHealth

IQVIA

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IMS Health & Quintiles are now IQVIA™

IQVIA (NYSE:IQV) is a leading global provider of information, innovative technology solutions and contract research services dedicated to using analytics and science to help healthcare stakeholders find better solutions for their patients. Solutions are powered by the IQVIA CORE™, which combines big data, advanced technology, analytics and extensive industry knowledge. Formed through the merger of IMS Health and Quintiles, IQVIA has approximately 55,000 employees worldwide. Learn more at iqvia.com.

SafetyCall International

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SafetyCall International is the recognized leader in Adverse Event Management, Regulatory Reporting and Post-Market Surveillance Services to industry.

SafetyCall professionals are nationally recognized experts in the collection and interpretation of spontaneously reported incident data reported directly to the manufacturer. By providing innovative, high-value services to industry and government, the professional staff of SafetyCall has been actively enhancing product safety for over 30 years. During this time, our staff has managed over 2 million product incident cases, positively impacting the safety of products worldwide.

We operate a 24/7/365 call center staffed with clinical, medical, and veterinary toxicologists, pharmacists, nurses, veterinarians and certified veterinary technicians, physicians, poison information providers and basic science toxicologists. Our highly-credentialed senior health care professionals have over 30 years of product safety experience.

We are also recognized experts in the clinical, academic and research environments, and maintain academic affiliation with the University of Minnesota in multiple collegiate units.

SafetyCall is licensed with the Boards of Medicine, Veterinary Medicine and Pharmacy as a health care practice focused on providing adverse event management and post-market surveillance services on your behalf. By meeting the licensing requirements of these Boards, you can be assured that SafetyCall and its clinicians meet all applicable practice standards which mean added protection for you and your customers.

UBC

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UBC is a leader in the market in providing customizable, integrated, comprehensive clinical, safety, and commercialization services. Our organization is comprised of deep domain experts, committed to partnering with pharmaceutical and biotech organizations to effectively navigate the product lifecycle and make medicine and medical products safer and more accessible while demonstrating product value.

You can count on UBC to be your champion in patient safety and regulatory compliance.

Our extensive medical and regulatory knowledge can help you characterize safety events, identify possible signals, and understand their context throughout the product's lifecycle.

CASE PROCESSING | LITERATURE REVIEW | QPPV & ADVISORY | SAFETY ANALYTICS & REPORTING
SIGNAL DETECTION & REFINEMENT | SIGNAL INVESTIGATION | AGGREGATE REPORTS

Learn More About our Services & Experience, Visit: **www.ubc.com**

PATIENTS FIRST | POWERED BY EVIDENCE

WIRB-Copernicus Group

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The pioneer of independent ethical review, WCG continues to drive ingenuity in the clinical research space. Today, WCG's solutions are built upon the foundation of ethical review, but have grown to include a suite of complementary services and technologies that expand the capabilities of the modern research professional. WCG delivers transformational solutions that stimulate growth, foster compliance, and maximize efficiency for those who perform clinical trials.

WCG is proud to serve the individuals on the frontlines of science and medicine, and the organizations that strive to develop new products and therapies to improve the quality of human health. It is our role to empower them to accelerate advancement, while ensuring that the risks of progress never outweigh the value of human life.

DIA

Pharmacovigilance and Risk Management Strategies Conference

Exhibitor Directory

AB Cube — Table 26

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Since 2006 AB Cube is a pioneer in pharamacovigilance databases delivered as a SaaS.

AB Cube offers a quick, easy, fully validated solution for entry, import, tracking, signal detection and electronic submission of adverse events. Our solution is implemented in less than two weeks, always compliant with the lataest regulations, and delivered at a fair price with no hidden costs.

Adis Pharmacovigilance — Table 1

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Adis Pharmacovigilance, part of Springer Nature, are experts in structured literature monitoring and assessment. By working in partnership with us, you can free up your time and have peace of mind that your processes will continue to run smoothly.

Our literature monitoring services include:

- ICSR monitoring
- special situation ICSRs
- ongoing safety monitoring
- signal monitoring
- local literature monitoring
- customized source coverage
- periodic safety update reports and annual reports

Advera Health Analytics, Inc. — Table 12

Contact: Jim Davis
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Advera Health Analytics provides drug safety data, analytics, and software to access, analyze, and track drug safety issues.

Evidex® is a cloud-based, software-as-a-service drug safety data, analytics, and signal detection platform that provides powerful insights using Advera Health curated data, ICSR databases, and alternative safety data such as claims, EHR, and social media.

Evidex® Signal Management is a full integrated module that provides audit ready, GVP IX compliant signal tracking.

APCER Life Sciences — Table 4

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APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory, and technology resources to ensure that patients receive the safest, most effective therapies possible. Learn more about our high-quality, cost-effective solutions at www.apcerls.com.

ArisGlobal — Table 2

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ArisGlobal is a visionary technology company that's transforming the way today's most successful life sciences companies develop breakthroughs and bring new products to market. The ArisGlobal LifeSphere® cognitive technology platform integrates machine-learning capabilities to automate the core functions of the product lifecycle. Our cognitive platform delivers actionable insights, boosts efficiency, ensures compliance, and lowers total cost of ownership through multi-tenancy.

Ashfield — Table 13

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Ashfield Pharmacovigilance is a dedicated full suite pharmacovigilance services provider. We provide global safety solutions for both clinical and post-market products that allow pharmaceutical companies and contract research organizations to meet all safety regulatory requirements. Our services are scalable and available on an as-needed basis.

C3i Solutions — Table 10

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C3i Solutions, An HCL Technologies Company, is a multi-channel customer engagement services provider with a 35-year history of handling complex and sensitive interactions in the life sciences industry. From basic medical inquiries to complex adverse event intake, case processing and aggregate reporting, C3i Solutions provides an end-to-end solution for all of your PV needs including product safety, MI and regulatory compliance. www.c3isolutions.com

Commonwealth Informatics — Table 25

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Commonwealth Informatics, a Genpact Company, is a global provider of cloud-based analytics products and services for medical research and healthcare delivery. Pharmaceutical and biotech companies, government regulatory agencies, academic and government medical research groups use Commonwealth products and services to deliver innovative data analysis solutions to their teams. Commonwealth has experience in data analysis solutions for pharmacovigilance, clinical development and healthcare delivery.

Deloitte Consulting, LLP — Table 17

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A new paradigm for pharmacovigilance is required to address the operational and compliance challenges experienced today. Deloitte has collaborated with several industry partners and regulators to develop ConvergeHEALTH Safety, an evidence-based platform for safety intelligence to enable an outcomes-based, patient-centric care model.

Ennov — Table 18

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Ennov provides the most comprehensive, user-friendly and cost-effective content and data management solutions built specifically for the life sciences industry. Our Quality, Regulatory, Clinical and Pharmacovigilance solutions are based on our highly configurable unified compliance platform which includes business process management, document management, data/forms management, learning management and business intelligence. Over 150 Life Sciences companies around the world use Ennov software.

EVERSANA — Table 11

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EVERSANA is the leading independent provider of global services to the life science industry.

From industry-leading patient service and adherence support to global pricing and revenue management, EVERSANA paves the way to commercial success and creates value across the life cycle for patients, prescribers, channel partners and payers. To learn more about EVERSANA, visit eversana.com.

Evidence Partners — Table 29

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Evidence Partners is the creator of DistillerSR, the world's most widely used literature review software. DistillerSR is a fully compliant, transparent, and audit-ready solution that automates many of the manual tasks involved in the preparation of pharmacovigilance literature reviews. Manage your literature workflows and full text documents in DistillerSR's cloud-based environment so you can easily update your living product safety dossiers. For more information, visit www.evidencepartners.com.

Genpact

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Genpact (NYSE: G) is a global professional services firm that makes business transformation real, driving digital-led innovation and digitally-enabled intelligent operations for our clients. Our Cora PharmacoVigilance solution transforms drug safety through AI ensuring smarter case processing for safer drugs. Learn more at genpact.com/pvai.

GRALC LLC — Table 10

(Global Regulatory Affairs, Labeling & Compliance Services LLC)

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GRALC LLC - GLOBAL EXPERTISE IN PHARMACOVIGILANCE & REMS AUDITS AND LABELING

GRALC offers world-wide PV Audit Services. Our global PV auditing experience expands to small, mid and big size pharma, medical device companies and distributors. GRALC auditors have extensive experience with FDA REMS audits.

Our PV, Regulatory and Compliance experience enables us to prepare companies for upcoming audits.

GRALC offers fully integrated RSI and Labeling services to ensure compliant global and local labels.

IQVIA — Tables 30 & 31
IQVIA, Inc. AETracker

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IQVIA (NYSE:IQV) is a leading global provider of information, innovative technology solutions and contract research services dedicated to using analytics and science to help healthcare stakeholders find better solutions for their patients. Solutions are powered by the IQVIA CORE™, which combines big data, advanced technology, analytics and extensive industry knowledge. Formed through the merger of IMS Health and Quintiles, IQVIA has approximately 55,000 employees worldwide. Learn more iqvia.com.

Med Communications — Table 15

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Med Communications' team members have years of experience delivering support for our clients' PV needs. Our highly qualified safety professionals adhere to GVPs with timely adverse event reports & product complaints, signal detection activities & benefit risk analyses to exceed your safety necessities while meeting the highest quality standards.

MyMeds&Me Limited — Table 34

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www.reportum.com

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MyMeds&Me, the company behind Reportum, specialises in simplifying adverse event and product quality data capture across the product lifecycle, streamlining processes and improving downstream benefit-risk analysis. Reportum is a multi lingual, multi-platform intake solution for adverse event and product complaints.

Oracle Health Sciences — Table 20

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Oracle Health Sciences Safety drives innovation and unifies safety in the cloud, standardizing and automating processes to detect risks early, respond quickly, and increase compliance, while addressing increasing data sources and volumes.

Oracle Health Sciences is trusted by 29 of the top 30 pharma, 10 of the top 10 biotech, and 10 of the top 10 CROs for clinical trial and safety management around the globe.

Orbit — Table 19

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www.workinorbit.com

Orbit is your one-stop-shop for Regulatory, Pharmacovigilance and Safety process tracking.

From simple data capture through complex workflows and access rights, Orbit promises to change the way your company approaches workflow management for their regulated processes.

- Aggregate Report Scheduling and Authoring
- RMP, REMS and aRMMs Tracking
- Signal Management
- End-to-End Label Tracking

PrimeVigilance — Table 23

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PrimeVigilance is a long standing global services company, established and run by former regulators, providing competent life-cycle management in pharmacovigilance, medical information, regulatory science, pharmacoepidemiology and real world evidence with over 500 highly qualified professionals providing expert consulting services, and competitive offshoring and nearshoring solutions, which have been successfully inspected on multiple occasions. Our Mission is a world with safer drugs.

ProPharma Group — Table 22

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At ProPharma Group, we understand the criticality of having a compliant and comprehensive pharmacovigilance program to meet regulatory and patient safety requirements.

ProPharma Group is a global provider of clinical and postmarketing PV services, including case processing, aggregate reporting, literature screening, European and local Qualified Persons, and signal detection. Our expert staff and robust infrastructure ensures a compliant program you can trust.

Prudentia Group — Table 14

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Prudentia is a Global Team providing Coding and PV Consulting & Managed services to the Life Sciences industry. We advise companies on Processes & Technologies in support of Clinical & Post-Market Safety & Surveillance, and combined with our suite of Innovative Products, we have the ability to provide the full gamut of Coding and Drug Safety Consulting support.

Services

- Coding
- Consulting
- Managed

Proprietary Products

- MedCodr
- E2B R2/R3 Bridge
- PVTrend

Quartica, Inc. — Table 16

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Quartica is a life sciences solutions provider that offers solutions by blending automation technologies with life sciences domain expertise. Quartica's MARS platform provides the unique capability of Automated Content Management (ACM) which transforms, extends and enhances the capabilities of your existing systems with the aid of intelligent machine computing. Example areas of usage include Aggregate Reports, Clinical Safety Reports, Signal, Risk Management, PRAC, SRT and other areas.

RxLogix Corporation — Table 7 & 8

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RxLogix is a Global PV Solutions company specializing in innovative software and expert consulting services. Our team of business and technology innovators work with PV and Risk Management Professionals to increase the compliance, productivity and quality for the entire Drug Safety value chain. Headquartered in Princeton, NJ with offices in Europe, US, and Japan.

SafetyCall International — Table 3

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SafetyCall ®operates the world's largest 24/7 human and animal adverse event call center, providing clients and their customers with immediate access to trusted health, safety and medical information. As a multidisciplinary health care practice we provide manufacturers with adverse event management, regulatory reporting and post-market surveillance services. We have managed more than 3 million product incident cases. For more information, visit http://safetycall.com

Sciformix, A Covance Company — Table 24

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Sciformix, A Covance Company, constitutes the drug safety business of Covance®. We provide process, technology and consulting drug safety services to clients in the life sciences industry that accelerates business, drives higher levels of performance and fosters innovation. As part of the world's most comprehensive drug development company, we are dedicated to advancing healthcare through a Designed Around You® experience and delivering Solutions Made Real®.

www.covance.com/marketaccess

Sophos IT Services LLC — Table 32

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Sophos is a global professional services company in the area of Drug Safety and Pharmacovigilance. Focused exclusively on clinical and post-marketing drug safety, surveillance and risk management; Sophos' expertise in Pharmacovigilance solutions includes Oracle® Argus Safety™ Suite, ArisGlobal® ARISg, Oracle® AERS and other commercial drug safety systems. Sophos deliver precise, timely and cost-effective solutions, helping our clients manage risk and achieve lower operational costs.

Techsol Corporation — Table 6

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Techsol Corporation specializes in offering cloud-based information technology services and innovative software solutions to global pharmaceutical, life sciences and healthcare companies. Techsol is a market leader in providing highly configurable process-oriented technology solutions for digitally transforming pharmaceutical business operations across Medical Affairs, Drug Safety and Clinical Development. As an Oracle Gold partner we delivered over 100 projects to global Pharma companies.

Trilogy Writing & Consulting — Table 5

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Trilogy Writing is a medical writing consultancy focused specifically on clinical regulatory and safety documentation. We proactively plan, coordinate and write clinical documents to meet timelines, with a readability that reduces the time for review and approval. Beside regulatory submission documents, we also write DSURs, PADERs, PSURs, PBRERs, REMS and RMPs, including Part VI. Trilogy currently has more than 50 writers, who are located in Trilogy's 4 offices: Germany, UK and US (NC and IN).

UBC — Table 21

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UBC is a leader in the market in providing customizable, integrated, comprehensive clinical, safety, and commercialization services. Our organization is comprised of deep domain experts, committed to partnering with pharmaceutical and biotech organizations to effectively navigate the product lifecycle and make medicine and medical products safer and more accessible while demonstrating product value.

Uppsala Monitoring Centre — Table 27

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Uppsala Monitoring Centre (UMC) is an independent non-profit foundation and centre for international service and scientific research. Our vision is a world where all patients and health professionals make wise therapeutic decisions in their use of medicines. Our mission is to support and promote patient safety through effective global pharmacovigilance practice. We provide scientific leadership and operational support to the WHO Programme for International Drug Monitoring.

Vitrana — Table 28

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Vitrana has a vision to drive major advances in the quality, efficiency and cost of clinical research, development and patient care through Vitrana's integrated healthcare and life sciences IT platform and comprehensive integration services across the enterprise. Vitrana believes that clinical research, development and patient care can be significantly improved through the adoption of key technology, leveraging information assets for improved insights and service quality.

WCG — Table 33

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The pioneer of independent ethical review, WCG continues to drive ingenuity in the clinical research space. Today, WCG's solutions are built upon the foundation of ethical review, but have grown to include a suite of complementary services and technologies that expand the capabilities of the modern research professional. WCG delivers transformational solutions that stimulate growth, foster compliance, and maximize efficiency for those who perform clinical trials.

DIA

Pharmacovigilance and Risk Management Strategies Conference

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