



Digital Exhibitor Directory

Pharmacovigilance and Risk Management Strategies Conference

January 23-25, 2017 | Mandarin Oriental Washington DC | Washington, DC

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Adis Pharmacovigilance

The Warehouse Way
Northcote, Auckland 0627
New Zealand



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Adis Pharmacovigilance – The expert solution for regulatory literature monitoring.

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ArisGlobal LLC

Ponce De Leon Boulevard
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ArisGlobal's cloud-based solutions facilitate global drug development and regulatory compliance within the life sciences and healthcare industries. Its cloud platform supports the entire product life cycle including clinical development, regulatory affairs, pharmacovigilance and medical communications. Hundreds of drug and device manufacturers, CROs and regulatory agencies leverage ArisGlobal's advanced technology solutions to make better and more informed decisions, facilitate compliance, reduce risk, and improve operational efficiency.



Commonwealth Informatics

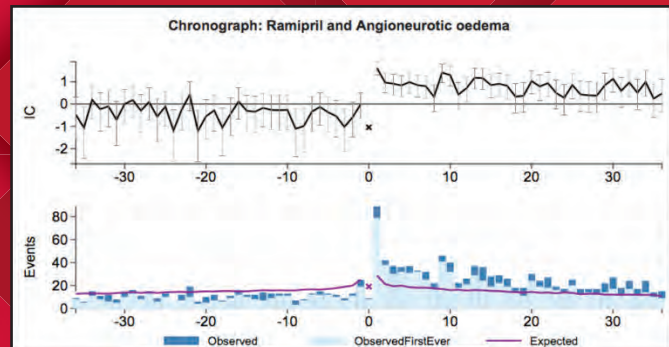
260 Charles Street, Suite 401
Waltham, MA 02453

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Commonwealth Informatics is a global provider of cloud-based analytics products and services for the life sciences industry. Medical product developers, healthcare providers and government agencies use Commonwealth analytics to answer complex clinical and safety questions quickly and accurately.

Transforming Complex Data into Insights for Life Sciences



THE EXPERIENCED COMMONWEALTH TEAM is a trusted collaborator with regulators, academia, life sciences companies and government agencies to improve the way clinical data is analyzed. Contact us at info@commoninf.com to learn more about the innovative clinical and safety analytics products and services that are helping to improve the speed and accuracy of clinical data analysis.



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Mapi

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At Mapi, we know that research centered on people is crucial to improving world health. Our unrivaled four decades of operational expertise in generating, synthesizing, and analyzing Real World Evidence and Health Economics Outcomes Research has established Mapi Group as the industry leader and recognized innovator of Outcomes Research methodologies and sciences. Mapi's research solutions bridge the distance between life science companies and patients, enabling market access and navigating the complex global regulatory environment.

One of Mapi's many offerings is a flexible, global pharmacovigilance service that fully supports regulatory compliance and management of patient safety issues. We offer a full suite of pre- and post-marketing solutions throughout the product lifecycle from phase I-III clinical trials to observational studies and all aspects of the post-marketing environment. Our experienced pharmacovigilance professionals are located in Europe and North America and are accustomed to working across the global regulatory environment. Mapi's pharmacovigilance group is supported by the wider further Mapi community, giving access to a broad range of regulatory experts, epidemiology experts and Late Phase study experts. This unique arrangement provides the opportunity for pharmacovigilance activities to be taken to the next level as regulatory agency demands increase to ever more challenging levels.

Activity	Phase 1 to Phase 3	Marketing Authorisation Dossiers	Approval to 5 years post approval	Mature Products
Full Pharmacovigilance Services	✓	✓	✓	✓
E2B Submissions	✓	✓	✓	✓
SOPs and Pharmacovigilance System Development	✓	✓	✓	✓
Safety Database	✓	✓	✓	✓
Individual Case Safety Reports	✓	✓	✓	✓
Aggregate/Periodic Safety Reports (DSUR/ PSUR/ PBRER/ PADER)	✓	✓	✓	✓
Risk Management Plans (Writing, Strategy, Execution, Effectiveness)	✓	✓	✓	✓
Pharmacovigilance System Audits	✓	✓	✓	✓
Signal detection and evaluation	✓	✓	✓	✓
Literature Searching	✓	✓	✓	✓
Medical Information Services			✓	✓
EEA Qualified Person for Pharmacovigilance			✓	✓
Pharmacovigilance System Master File		✓	✓	✓
Post-Authorisation Safety and Efficacy Studies		✓	✓	✓

Medical Vigilance Solutions

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Cincinnati, OH 45229

Contact Person: Mike Davis | Director, Business Operations
Phone: +1.513.803.6772
Email: michael.davis@cchmc.org
Website: www.medicalvigilance.org

medical **vigilance**
solutions

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Medical Vigilance Solutions (MVS), a business unit of Cincinnati Children's Hospital, is a global provider of Pharmacovigilance, Medical Communications, and 24/7 Contract Center services. Our team is committed to help you meet regulatory and compliance requirements to ensure successful execution of your objectives. Our experienced staff comprised of doctors, pharmacists, registered nurses, and allied health care professionals are prepared to deliver on your expectations and build a long term partnership.

P: 855.752.3742 | Contact Mike Davis | michael.davis@cchmc.org



The graphic features a dark background with colorful dots (blue, green, orange) scattered across it. The 'medical vigilance solutions' logo is in the top right. Below the logo are three circular icons: a document with a checkmark, a telephone handset, and an hourglass. At the bottom, there are three overlapping colored shapes (blue, green, orange) containing text.

medical **vigilance**
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Visit us at **Booth #2** to learn more about our comprehensive pharmacovigilance services.

- **AE Management**
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 - Conducting follow up ensuring due diligence
 - AE reconciliation with contact center
- **Medical literature surveillance**
- **Global AE expedited reporting to regulatory authorities**
- **Aggregate report preparation**
 - PADERS, PBRERs, and PSURs
- **Safety Database**
 - In-house validated ARISg™ database – Database set up, implementation, and maintenance
 - Electronic expedited AE submissions
 - Experience with multiple Clients safety database platforms (e.g. Argus)

QuintilesIMS

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QuintilesIMS is a leading global healthcare provider of integrated information and technology-enabled services. QI is dedicated to helping its clients improve their clinical, scientific and commercial results. Formed through the merger of Quintiles and IMS Health, QuintilesIMS's approximately 50,000 employees conduct operations in more than 100 countries. QuintilesIMS develops and implements solutions to help its clients maximize innovation and drive healthcare forward.

To learn more, visit www.QuintilesIMS.com.



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AB Cube

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AB Cube, an 11 years old publisher, provides the international healthcare industry with multivigilance software (Pharmacovigilance, Medical device vigilance, Cosmetovigilance,...) managing safety data, in compliance with European and worldwide regulatory requirements. All AB Cube software are validated according to GAMP5 and FDA 21CFR part 11.

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Adis Pharmacovigilance – The expert solution for regulatory literature monitoring. Free up your internal resources and gain peace of mind with Adis, the industry leader. We offer a wide range of services with personal support every step of the way. Speak to us at the event or visit adis.com/pharmacovigilance to discover more.

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AgilePV

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Born from customer need, AgilePV is an intuitive, secure, and validated pharmacovigilance solution that helps organizations mitigate risk and enhance visibility within patient safety processes.

Facebook: www.facebook.com/agilepv

Table 18

APCER Life Sciences

Contact: Jill Notte
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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.

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ArisGlobal LLC

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ArisGlobal's cloud-based solutions facilitate global drug development and regulatory compliance within the life sciences and healthcare industries. Its cloud platform supports the entire product life cycle including clinical development, regulatory affairs, pharmacovigilance and medical communications. Hundreds of drug and device manufacturers, CROs and regulatory agencies leverage ArisGlobal's advanced technology solutions to make better and more informed decisions, facilitate compliance, reduce risk, and improve operational efficiency.

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Table 12

Arriello Group

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A truly experienced provider of Consulting, Medical Writing, Regulatory Affairs, Translation and Pharmacovigilance services. Our Mission is to enable life science companies to market their products. Our Vision is to become a leading global service provider for the Life Science industry.

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Table 9

Ashfield Pharmacovigilance

Table 7

Contact: Trent Wadford
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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.

Bioclinica

Table 22

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Bioclinica is fully dedicated to the interests of Pharmacovigilance and Risk Management professionals across the globe. Our specialists team at booth 22 can highlight our distinctive Pharmacovigilance as a service model (PVaaS), and our newly launched suite of tools to help with Literature Review (LitTRACE), Signal Detection (SigTRACE) and Regulatory.

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C3i Healthcare Connections

Table 6

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C3i Healthcare Connections is a leading BPO specializing in the engagement of patients & HCPs via a network of global contact centers. We set the standard for drug safety services by putting best practice processes into action including a fully validated, cloud-based solution for adverse event intake, medical inquiry management and quality complaints.

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Commonwealth Informatics

Table 15

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Commonwealth Informatics is a global provider of cloud-based analytics products and services for the life sciences industry. Medical product developers, healthcare providers and government agencies use Commonwealth analytics to answer complex clinical and safety questions quickly and accurately.

LinkedIn: www.linkedin.com/company/commonwealth-informatics-inc

Deloitte Consulting

Table 24

Website: www2.deloitte.com/us/en/pages/consulting/solutions/pharmacovigilance-drug-safety.html

Deloitte helps organizations grow their businesses and enhance value by identifying actionable insights. More than 23,000 professionals provide a broad range of capabilities across human capital, strategy and operations, innovation and technology that are aligned to the particular needs of specific sectors, businesses and organizations. Deloitte provides clients with leading business insights that can help generate a tangible and measurable impact.

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Ennov

Table 27

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Ennov is a content management software vendor. On top of a generic EDMS/BPMS platform, we propose 4 solutions for the Life Sciences market (over 150 customers): Quality Management (documents, processes, training), Regulatory Compliance (eCTD, RIM, IDMP), Clinical Trial Management (EDC, CTMS), Pharmacovigilance (PV database, statistical analysis).

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Gilead Sciences, Inc.

Table 26

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For more than 25 years Gilead has been revolutionizing healthcare by bringing urgently needed medicines to millions of patients in the areas of HIV/AIDS, liver diseases, hematology and oncology, inflammation and respiratory diseases and cardiovascular conditions.

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Global Pharma Tek LLC

Table 17

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We are a fast growing CRO providing outsourced DS/PV services to the industry globally. Together with an excellent consulting/staffing division, we offer a wide range of hybrid services to suit all client needs in the ever-demanding world of Patient Safety. Stop by our table #17 and review our excellent testimonials from current satisfied partners.

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Language Scientific

Table 10

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Language Scientific is a US-based translation and localization services company. Our network of Industry Expert linguists holding advanced degrees provide medical, scientific and technical translation services in all major European, Asian, Middle Eastern, African and American languages. We adhere to ISO 9001 and EN 15038 quality standards.

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Mapi

Table 13

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At Mapi, we know that research centered on people is crucial to improving world health. Our unrivaled four decades of operational expertise in generating, synthesizing, and analyzing Real World Evidence and Health Economics Outcomes Research has established Mapi Group as the industry leader and recognized innovator of Outcomes Research methodologies and sciences.

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Med Communications, Inc

Table 14

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Website: www.medcommunications.com

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 and product complaints, signal detection activities & benefit risk analyses to exceed your safety necessities while meeting the highest quality standards.

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Medical Vigilance Solutions

Table 2

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Medical Vigilance Solutions is a global provider of Pharmacovigilance, Medical Communications, and 24/7 Contact Center services. Expertise in full AE case management, medical affairs, and 24/7 med info, AE and quality complaint collection and documentation. P: 855.752.3742 | Contact Mike Davis | michael.davis@cchmc.org

MyMeds&Me

Table 25

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MyMeds&Me is a leading SaaS provider of web-based adverse event and product quality capture solutions for life sciences. Client companies see efficiency and effectiveness benefits by rapidly accessing more complete safety data for the earliest detection of safety or quality issues. Learn more about our web-based Reportum® solution today.

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PleaseTech Ltd.

Table 19

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PleaseTech's flagship product, PleaseReview, is a unique collaborative review, co-authoring and redaction solution for Microsoft Word, PDF and other document types. Used extensively by Life Sciences organizations, it facilitates controlled, simultaneous and secure collaboration for the production of quality compliant documents.

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PPD

Table 3

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PPD is committed to patient safety and is ready to collaborate with clients to meet the increasingly complex regulatory requirements in pharmacovigilance. Our full range of services offer flexible technologies, resourcing solutions, effective governance and continuous process improvement from early clinical development to marketed product support.

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ProPharma Group

Table 8

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ProPharma Group provides Pharmacovigilance and Medical Information services worldwide, including call center support for 30+ languages with native speaking specialists. Our integrated solution provides handling of medical inquiries, adverse events, and product complaints. Other services include expert medical writing and document translations.

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QuintilesIMS helps companies drive healthcare forward by creating novel solutions from the industry's leading data, technology, healthcare and therapeutic expertise. To learn more, visit www.QuintilesIMS.com.

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RxLogix Corporation

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RxLogix is a leading innovator in Drug Safety and Pharmacovigilance. RxLogix will be showcasing Argus Accelerator, the rapid Argus 8.x upgrade solution, RxLogix PV Analytics Suite. World class software products that deliver reporting, analytics and signal detection capability that enhance the Argus software with innovative reporting and visualization.

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Sciformix Corporation

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Sciformix Corporation is a leading scientific knowledge-based organization that provides process, technology and consulting services to the life sciences industry in the areas of Safety & Risk Management, Clinical Research and Post-Approval Support Services, Regulatory Affairs and Regulatory Operations, and Technology Services. Locations: US|UK|India|Manila

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LinkedIn: www.linkedin.com/company/sciformix

Table 23

UBC

Contact: Krista Huck
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Website: www.ubc.com

UBC is a leading provider of pharmaceutical support services, partnering with life science companies to make medicine and medical products safer and more accessible. Our diverse suite of services helps bridge the gap between development and delivery and builds brand loyalty through patient access and adherence.

Twitter: @ubcpharma
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Table 4

Table 5

Vigilare International

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Vigilare International, a private corporation, has 45 years of combined leadership experience, is a safety services organization providing pharmaceutical, biotechnology, and medical device companies with a full range of product safety services located in suburban Philadelphia, PA.

LinkedIn: www.linkedin.com/company/5288036

Table 1

DIA

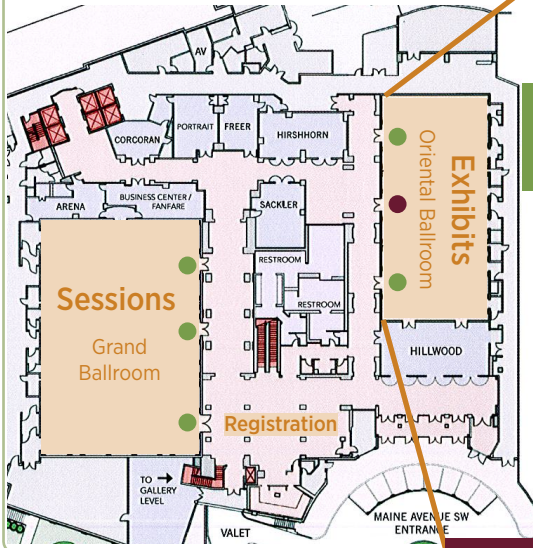
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Conference Floor Overview



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8. ProPharma Group
9. Arriello
10. Language Scientific
11. APCER Life Sciences
12. Agile PV
13. Mapi

Oriental Ballroom

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