DIA

Global Pharmacovigilance and Risk Management Strategies Conference

Short Course January 25, Virtual | Short Course February 1, Virtual
Short Course February 5, In-Person | Conference February 6-8

Overview

DIA's Global Pharmacovigilance and Risk Management Strategies Conference is a neutral event developed by regulators and industry experts discussing the updates, opportunities, and challenges alongside fresh problem-solving strategies that matter most to safety professionals.

Event Goals and Offerings

- Important safety and pharmacovigilance regulatory updates from U.S, U.K, Europe, Japan, and China regions
- Information on the new internationally harmonized guidance on a selective approach to safety data collection in specific late-stage pre-approval or post-approval clinical trials
- Technology and data heavy sessions discussing how new technology, artificial intelligence, machine learning, and visualization tools are advancing pharmacovigilance practices
- Discussions on the impact of regulatory differences on global risk management organizations and the design and implementation of risk minimization materials
- Panel discussion on key concerns smaller companies have encountered with the FDA Final Rule and FDA's perspective regarding the concerns of smaller pharma companies
- Interactive round table session to discuss safety updates and challenges with transgender population, underrepresented population, cell and gene therapy, and rare disease
- Presentation by the DIA Clinical Safety and Pharmacovigilance Community chair

Breaks on day one of the Conference are sponsored by

EVERSANA™

PROGRAM COMMITTEE CHAIRS

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President
Covilance LLC

Annette S. Williams, MBA, RPh
Vice President, Pharmacovigilance
IQVIA

PROGRAM COMMITTEE

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FDA

Cheryl Campbell, MS
Associate Director of Executive Operations/ Outreach and Communications, OSE, CDER
FDA

Why You Can't Miss It

- Network with like-minded professionals focused on safety and pharmacovigilance to discuss best practices and lessons learned
- Participate in interactive sessions with speakers and other attendees discussing safety considerations for special populations
- Evaluate the application of technology, visualization tools, machine learning, and artificial intelligence to advance safety practices
- Gain insights from global regulatory speakers to stay current with the latest safety and pharmacovigilance updates in Europe, Asia, and United States

Who Should Attend

Professionals involved in:

- Drug Safety
- Pharmacovigilance
- Risk Management
- Benefit-risk Assessment and Communication
- Medical Product Safety Assessment
- Post-Market Studies
- Real-World Evidence Generation
- Regulatory Affairs
- Clinical Research
- Data Safety Monitoring and Analysis
- Pharmacoepidemiology
- Medical Information
- Medical Communications
- Medical Affairs
- Health Outcomes
- Patient Engagement

All times listed are Eastern Time

VIRTUAL SHORT COURSE | WEDNESDAY, JANUARY 25

10:00AM-2:00PM	**Short Course: Aggregate Safety Assessment Planning**	

VIRTUAL SHORT COURSE | WEDNESDAY, FEBRUARY 1

10:00AM-2:00PM	**Short Course: Good Pharmacovigilance Practice (GVP) Operations Development - From Clinical Trial to Post Marketing**	

IN-PERSON SHORT COURSE | SUNDAY, FEBRUARY 5

9:00AM-5:00PM	**Short Course: Pharmacovigilance and Risk Management Planning**	**White Oak**

DAY ONE | MONDAY, FEBRUARY 6

7:00AM-5:35PM	**Conference Registration**	**Ballroom Foyer (Upper Level)**
7:00-8:00AM	**Networking Breakfast in the Exhibit Hall**	**Ballroom A-D**
8:00-8:15AM	**Welcome and Opening Remarks**	**Ballroom E-H**
8:15-9:00AM	 **Keynote Address:** Research Integrity in the Quest for Therapies for Alzheimer's Disease by **Matthew Schrag, MD, PhD**, Assistant Professor of Neurology & Director, Cerebral Amyloid Angiopathy Clinic Vanderbilt University Medical Center	**Ballroom E-H**
9:05-10:20AM	**Session 1:** Global Safety Regulatory Updates: Japan and China Regions	**Ballroom E-H**
10:20-10:50AM	**Refreshment, Exhibits, and Networking Break Sponsored by Eversana**	**Ballroom A-D**
10:20-10:50AM	**SPONSORED SESSION:** Case Study Spotlight hosted by PharSafer® Case Processing – The Most Important Part of Pharmacovigilance? Or Rubbish in, Rubbish Out! *Please note that this is an exhibitor sponsored event and is not eligible for CE credit.*	**White Oak**
10:50-11:50AM	**Session 2:** Europe and United Kingdom Safety Regulatory Updates	**Ballroom E-H**
11:50AM-1:00PM	**Luncheon, Exhibits, and Networking Break**	**Ballroom A-D**

12:00-1:00PM	**Sponsored Lunch and Learn Hosted by IQVIA (Invite Only)**	**White Oak**
1:00-2:30PM	**Session 3:** FDA Safety Regulatory Updates	**Ballroom E-H**
2:30-3:15PM	**Refreshment, Exhibits, and Networking Break Sponsored by Eversana**	**Ballroom A-D**
2:45-3:15PM	**SPONSORED SESSION:** Case Study Spotlight hosted by Veeva Systems, Inc. Beyond Compliance to Collaboration with Modern Content Management Safety Solutions *Please note that this is an exhibitor sponsored event and is not eligible for CE credit.*	**White Oak**
3:15-4:15PM	**Session 4:** FDA Technical Specification for Implementing E2B R3	**Ballroom E-H**
4:20-5:35PM	**Session 5:** Divergences, Harmonization, and Patient Perspective in Risk Minimization	**Ballroom E-H**
5:35-6:35PM	**Networking Reception and Exhibits**	**Ballroom A-D**

DAY TWO | TUESDAY, FEBRUARY 7

7:00AM-4:35PM	**Conference Registration**	**Ballroom Foyer (Upper Level)**
7:00-8:00AM	**Networking Breakfast in the Exhibit Hall**	**Ballroom A-D**
8:00-8:25AM	**Welcome to Day 2 and DIA PV Community Update**	**Ballroom E-H**
8:30-9:45AM	**Session 6:** Signal Detection	**Ballroom E-H**
9:50-10:50AM	**Session 7:** Optimizing Literature Surveillance: A Critical Element in the Pharmacovigilance Arsenal	**Ballroom E-H**
10:50-11:20AM	**Refreshment, Exhibits, and Networking Break**	**Ballroom A-D**
10:50-11:20AM	**SPONSORED SESSION:** Case Study Spotlight hosted by IQVIA The Effectiveness of Automation Technology in Identifying Potential Adverse Events in Common Safety Data Sources *Please note that this is an exhibitor sponsored event and is not eligible for CE credit.*	**White Oak**

11:20AM-12:35PM	**Session 8:** Artificial Intelligence and Machine Learning Use in Patient Safety	**Ballroom E-H**
12:35-1:35PM	**Luncheon, Exhibits and Networking Break**	**Ballroom A-D**
1:35-2:50PM	**Session 9:** Real-World Evidence Support of Clinical Development Programs	**Ballroom E-H**
2:50-3:20PM	**Refreshment, Exhibits, and Networking Break**	**Ballroom A-D**
3:20-4:35PM	**Session 10:** Epidemiology in Post-Approval	**Ballroom E-H**

DAY THREE | WEDNESDAY, FEBRUARY 8

7:00AM-12:00PM	**Conference Registration**	**Ballroom Foyer (Upper Level)**
7:00-8:00AM	**Networking Breakfast in the Exhibit Hall**	**Ballroom A-D**
8:00-9:30AM	**Session 11:** Pregnancy & Lactation: How Are we Going to Get Useful Data?	**Ballroom E-H**
9:30-11:00AM	**Round Table Discussion - Special Topics and Considerations: Can We Have an Inclusive Approach to Clinical Trials and Pharmacovigilance?**	**Ballroom E-H**
11:00-11:30AM	**Refreshment, Exhibits, and Networking Break**	**Ballroom A-D**
11:30AM–12:45PM	**Panel Discussion:** Safety Practices in Small Pharmaceutical Company Settings	**Ballroom E-H**
12:45-12:55PM	**Closing Remarks**	

Learning Objectives

At the conclusion of this conference, participants should be able to:

- Describe the new internationally harmonized guidance on a selective approach to safety data collection in specific late-stage pre-approval or post-approval clinical trials
- Discuss safety regulatory updates in the U.S, U.K, Europe, Japan, and China
- Recognize MHRA's progress on updating clinical trial regulations in the UK and its impact on pharmacovigilance activities
- Define FDA draft guidance on the Benefit-Risk Assessment for New Drug and Biological Products for Industry
- Identify new signal detection tools and reinforce the FMQ method and analysis
- Evaluate how regulatory differences impact global risk management organizations and design/implementation of risk minimization materials
- Describe challenges to establishing global approaches to risk minimization and identify risk analysis approaches to developing risk minimization materials
- Analyze recent advances in the use of AI/ML with respect to safety surveillance
- Identify the latest strategies for managing literature requirements at local and global level
- Examine various ways RWE/RWD are utilized in regulatory interactions during clinical development and its role in the evaluation of safety signals arising from clinical trial data
- Explain safety updates and challenges in special population including pregnancy and lactation and transgender population
- Discuss challenges with reaching the minority population and barriers for enrollment in clinical trials and recognize the need for a more inclusive approach within the drug development lifecycle
- Identify potential approaches to address safety challenges in cell and gene therapy and rare disease
- Recognize key concerns smaller companies have encountered with the FDA Final Rule and discuss FDA's perspective regarding the concerns of smaller pharma companies

Continuing Education Credit

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for up to 31.75 contact hours or 3.175 continuing education units (CEU's). Type of Activity: Knowledge

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, MARCH 10, 2023

DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system. **All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity.** If ACPE credit is not requested by **Friday, March 10, 2023**, the CEU request will not be transmitted through to the CPE Monitor. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit **www.cpemonitor.net**

- **January 25, 2023** - Short Course #1 Aggregate Safety Assessment Planning (Virtual): 3.75 contact hours or .375 CEUs Type of Activity: Knowledge, 0286-0000-23-001-L04-P
- **February 1, 2023** - Short Course #2 Good Pharmacovigilance Practice (GVP) Operations Development - From Clinical Trial to Post Marketing (Virtual): 3.75 contact hours or .375 CEUs Type of Activity: Knowledge, 0286-0000-23-006-L04-P
- **February 5, 2023** - Short Course #3 Pharmacovigilance and Risk Management Planning: 7 contact hours or .7 CEUs Type of Activity: Knowledge, 0286-0000-23-002-L04-P
- **February 6, 2023** - Pharmacovigilance and Risk Management Strategies Conference – Day 1: 6.75 contact hours or .675 CEUs Type of Activity: Knowledge, 0286-0000-23-003-L04-P
- **February 7, 2023** - Pharmacovigilance and Risk Management Strategies Conference – Day 2: 6 contact hours or .6 CEUs Type of Activity: Knowledge, 0286-0000-23-004-L04-P
- **February 8, 2023** - Pharmacovigilance and Risk Management Strategies Conference – Day 3: 4.5 contact hours or .45 CEUs Type of Activity: Knowledge, 0286-0000-23-005-L04-P

Continuing Education Credit and My Transcript

If you would like to receive a statement of credit for the days you attend the conference, you must attend one or all three days of the conference, (in their entirety) sign in at the DIA registration desk each day, and request CE credit online through My Transcript (see instructions below). Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning **Wednesday, February 22, 2023**.

Drug Information Association (DIA) is accredited by the International Association for Continuing Education and Training (IACET) and is authorized to issue the IACET CEU.

As an IACET Accredited Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer the up to .8* CEUs for this program.

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***IACET CEUs are only available for the virtual Short Course(s).**

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If you are claiming CE credit for the conference, you must:

1. Attend one or all three days of the conference, (in their entirety)
2. Sign in at the DIA registration desk each day, upon arrival
3. Access your DIA account and select My Transcript to claim your CE credit, available on **Wednesday, February 22, 2023**

DIA Disclosure Policy

It is DIA policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any relevant financial relationships related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Disclosures will be included in the handout materials.

This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the DIA or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices.

Disclosure statements are included with each speaker's biographical sketch.

Planning Committee

DIA staff members have no relevant financial relationships to disclose.

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- Agenda at your fingertips
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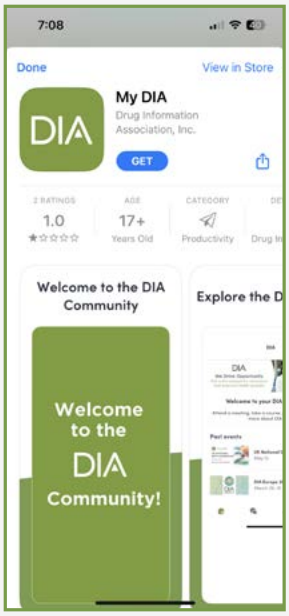

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swapcard

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You will be directed to login to our My DIA Account in order to access the mobile app.

Follow the instructions on screen, or please see the registration desk/contact NAEvents@diaglobal.org if you need additional assistance.

Exhibitor Directory

Global Pharmacovigilance and Risk Management Strategies Conference

February 06-08, 2023

Bethesda North Marriott Hotel and Conference Center | North Bethesda, MD

DIA

Insife

Booth 211
Automatikvej 1, 3. Floor
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Insife is dedicated to making the best PV technology readily available and taking away the complications of setting it up by providing solutions that work together. HALOPV is a comprehensive PV solution with 18 modules that can cover all of your PV needs including ICSR processing & reporting (including medicines, devices & combinations), PSMF, PVAs, signals, risks, and more. Modular in nature by design, HALOPV eliminates the need for the "big bang" approach and can help transform your business.

IQVIA

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Twitter: *https://twitter.com/InsifeHalo*

As one of the world's leading pharmacovigilance organizations, IQVIA brings extensive domain expertise and deep regulatory knowledge to every program. Our safety teams leverage automation, AI and machine learning to design, build and execute end-to-end safety solutions. Powered by IQVIA Connected Intelligence – integrated, scalable technologies combined with global data, advanced analytics, and deep domain expertise – our innovative Safety solutions help PV organizations do more with less.

IQVIA Vigilance Platform

Safety technology developed by Safety experts

With IQVIA Vigilance Platform, you can automate and simplify manual, highly repetitive activities.

- **Automate** intake and streamline case processing
- **Establish** a single source of truth for global and local teams
- **Simplify** expected and periodic reporting without compromise
- **Leverage** real-time insights and analytics, including signal and risk-management

IQVIA's integrated, pharmacovigilance platform reimagines drug and product safety to *enable delivery of safer, more effective drugs and devices – faster.*

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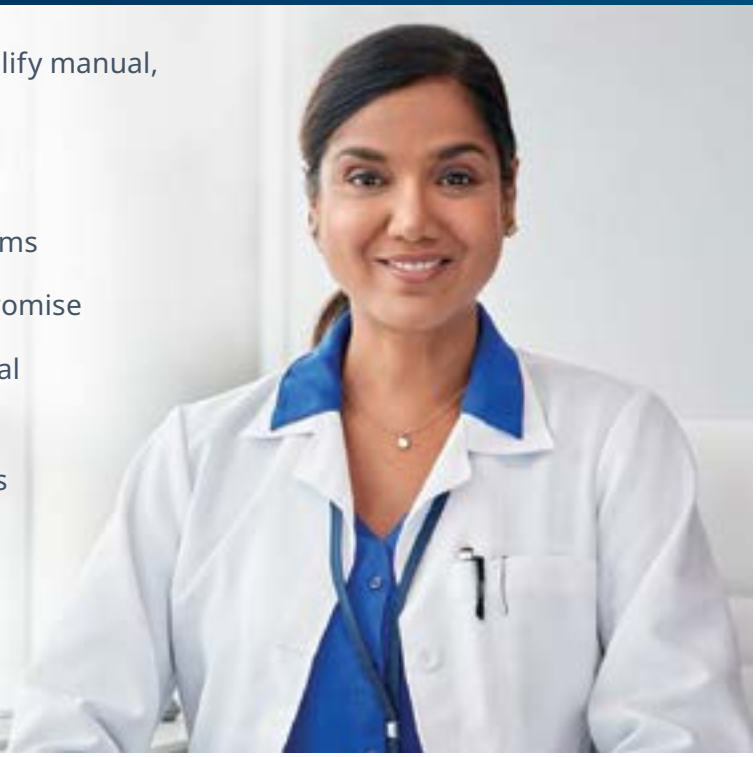

Nextrove

Booth 201

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Nextrove is a global professional services firm focused exclusively on serving Pharmaceutical and Biotech organizations. We take pride in being the only niche consulting firm to assist clients with Pharmacovigilance, Hosting, eTMF, RIM, Regulatory Affairs and Clinical Operations, Medical Information, Artificial Intelligence, Salesforce, and Integration services. Our mission is to deliver preeminent and innovative solutions that enable the global Health Science industry to improve public and patient safety.

Nextrove has a global team with established offices in New Jersey, Milan, Tokyo, Shanghai, Bangalore, Noida, and Chennai. With over 20+ years' experience, we help our clients meet their global digitalization strategy, maintain regulatory compliance, and drastically reduce the total cost of ownership in a variety of engagements.

The combination of our business knowledge and technical skill set allows us to bridge the gap between business needs and technology to meet and exceed the expectations of our clients.

PharSafer Associates Ltd

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PharSafer® is a specialist Contract Research Organisation in Global Clinical and Post Marketing Drug Safety, and Medical Services, with a wealth of experience in Pharmacovigilance, Signal Detection and Medical Affairs – and the various, numerous and extensive legal safety/medical obligations for licence holders to comply with - assisting with audit preparedness and running industry training courses for industry professionals - ranging from introductory, through to intermediate and advanced.

TriNetX

Booth 208

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TriNetX is a global network of healthcare organizations and life sciences companies driving real-world research to accelerate the development of new therapies. Through its self-service, HIPAA, GDPR, and LGPD-compliant platform of federated EHR, datasets, and consulting partnerships, TriNetX puts the power of real-world data into the hands of its worldwide community to improve protocol design, streamline trial operations, refine safety signals, and enrich real-world evidence generation.

DIA
Global Pharmacovigilance and Risk Management Strategies Conference
Exhibitor Directory

February 06-08, 2023

Bethesda North Marriott Hotel and Conference Center | North Bethesda, MD

Adis — Booth 202

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AdisInsight Safety gives you the tools to stay on top of your in-house PV literature monitoring. With AdisInsight Safety you can monitor individual case safety reports (ICSRs) for both adverse events and special situations. You can keep up to date with important drug safety news. And what's more important, AdisInsight Safety covers all pharmaceutical products.

Stop by our booth to get a live demo!

APCER Life Sciences — Booth 204

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APCER Life Sciences provides comprehensive drug safety/ pharmacovigilance, medical information, medical writing, regulatory services, quality assurance and risk management programs to pharmaceutical and biotech companies globally. Our focus on Patient Safety and Risk Profile Management makes us the leading pharmacovigilance services partner for biopharma companies who are looking for pre /post marketing compliance.

AWINSA Life Sciences — Booth 210

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LinkedIn*: https://www.linkedin.com/company/awinsa-life-sciences*
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Planning for a paradigm shift in the delivery of PV services, AWINSA provides end to end PV services including in its ambit both CT and postmarketing services. Manned by people with discernment and an eye for quality, we at AWINSA ensure astute analysis of safety reports so that clinical scenarios emerge in perspicuity. Intricate and deep-rooted knowledge of the subject and the global regulations will ensure that you are delivered services of the highest order within the stringent timelines.

Axian Consulting Ltd. — Booth 110

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Axian is a technology-enabled service provider delivering end-to-end solutions to support patient safety. We work with pharma, biotech, and medtech companies across the globe, providing a comprehensive range of safety consulting, patient risk management and technology based services that span the entire product lifecycle. We apply benefit-risk analyses and structured design thinking to help our clients optimise patient outcomes.

biologit — Booth 108

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biologit MLM-AI is a scientific literature monitoring platform for active safety surveillance that is simple to use, fully web-enabled and powered by AI. Our validated and compliant platform offers true productivity gains and is ready for pharmacovigilance and safety screening for medical devices, cosmetics or veterinary products.

Commonwealth Informatics — Booth 207

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At Commonwealth Informatics, a Qinecsa Company, we are providing cloud-based analytics products and services for medical research and healthcare delivery. Our company is led by the pioneers of signal detection and signal management software with over 30 years of experience. Pharmaceutical and biotechnology companies, government regulatory agencies, academic and government medical research groups use Commonwealth products and services to deliver innovative data analysis solutions to their teams.

Elite Safety Sciences — Booth 206

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Elite Safety Sciences (ESS) is a Pharmacovigilance (PV) service provider that provides excellent compliance & quality deliverables. ESS provides end to end pharmacovigilance services in both clinical and post marketing phases of medicinal product development from ICSRs to aggregate reports to safety signal & risk management. ESS builds a custom service model tailoring to products, people & processes to perform high quality pharmacovigilance services that meets the organization/business demand.

IQVIA — Booth 102

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LinkedIn*: https://www.linkedin.com/showcase/iqvia-global-compliance*

As one of the world's leading pharmacovigilance organizations, IQVIA brings extensive domain expertise and deep regulatory knowledge to every program. Our safety teams leverage automation, AI and machine learning to design, build and execute end-to-end safety solutions. Powered by IQVIA Connected Intelligence – integrated, scalable technologies combined with global data, advanced analytics, and deep domain expertise – our innovative Safety solutions help PV organizations do more with less.

Insife — Booth 211

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Insife is dedicated to making the best PV technology readily available and taking away the complications of setting it up by providing solutions that work together. HALOPV is a comprehensive PV solution with 18 modules that can cover all of your PV needs including ICSR processing & reporting (including medicines, devices & combinations), PSMF, PVAs, signals, risks, and more. Modular in nature by design, HALOPV eliminates the need for the "big bang" approach and can help transform your business.

Insuvia — Booth 106

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iVigee Services, a.s. — Booth 209

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iVigee is passionate about building and operating advanced, simple, and beautiful pharmacovigilance systems. We are a group of trustworthy approachable professionals enabling innovation and sustainable solutions. We combine people and technology to always be 2 steps ahead.

Nextrove — Booth 201

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Nextrove is a global professional services firm focused exclusively on serving Pharmaceutical and Biotech organizations. We take pride in being the only niche consulting firm to assist clients with Pharmacovigilance, Hosting, eTMF, RIM, Regulatory Affairs and Clinical Operations, Medical Information, Artificial Intelligence, Salesforce, and Integration services. Our mission is to deliver preeminent and innovative solutions that enable the global Health Science industry to improve public and patient safety.

Orbit by Feith Systems — Booth 101

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PharSafer Associates Ltd — Booth 105

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Website: *https://www.pharsafer.com/*
Twitter: https://twitter.com/Pharsafer
LinkedIn: *https://www.linkedin.com/company/pharsafer/*

PharSafer® is a specialist Contract Research Organisation in Global Clinical and Post Marketing Drug Safety, and Medical Services, with a wealth of experience in Pharmacovigilance, Signal Detection and Medical Affairs – and the various, numerous and extensive legal safety/medical obligations for licence holders to comply with - assisting with audit preparedness and running industry training courses for industry professionals - ranging from introductory, through to intermediate and advanced.

PPD, part of Thermo Fisher Scientific Booth 111

Contact: Duane Tester
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Email: Duane.Tester@ppd.com
Website: https://www.ppd.com/
Twitter: *https://twitter.com/ppdcro*
Facebook: *https://www.facebook.com/PPDCRO*
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PPD, part of Thermo Fisher Scientific, provides clinical development and analytical services that enhance customer innovation and productivity. Utilizing patient-centered strategies and data analytics, we cover multiple therapeutic areas and include early development, all phases of clinical development, peri- and post-approval, patient recruitment, investigator sites and comprehensive laboratory services.

PrimeVigilance Ltd — Booth 100

Contact: Florence Denance Habek
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LinkedIn: *https://www.linkedin.com/company/primevigilance-ltd*
Facebook: *https://www.facebook.com/Primevigilance*

PrimeVigilance has become the leading Pharmacovigilance specialist company, delivering global solutions for clinical safety and post-marketing pharmacovigilance and medical information from our operational hubs in the USA, Europe, and Japan. Our extensive experience enables us to offer comprehensive, top-quality, cost-effective, and innovative safety solutions to over 300 clients worldwide with a partnership model and tailor-made approach.

Prudentia Group, LLC — Booth 205

Contact: Vineet Singh
Phone: Email: vsingh@prudentia-grp.com

RxLogix Corporation — Booth 109

Contact: Shalini Modi
Email: shalini.modi@rxlogix.com

Soterius, Inc. — Booth 103

Contact: Kanak Soni
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Website: https:// www.soterius.com
Twitter: *https://twitter.com/wearesoterius*
Facebook: *https://www.facebook.com/wearesoterius*
LinkedIn: *https://www.linkedin.com/company/soterius/*

Soterius provides comprehensive clinical and post marketed safety services, that include aggregate report writing, signal detection and management, global literature surveillance, risk management, case processing and reporting.

Our Technology Solutions use state-of-the-art technologies to solve complex safety operations problems, be it case processing, intake, site reporting for clinical trials, or literature search and management.

Techsol Corporation — Booth 200

Contact: Satya Sagi
Email: sagi@techsollifesciences.com

TriNetX — Booth 208

Contact: TriNetX
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Email: join@trinetx.com
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LinkedIn*: https://www.linkedin.com/company/trinetx*

TriNetX is a global network of healthcare organizations and life sciences companies driving real-world research to accelerate the development of new therapies. Through its self-service, HIPAA, GDPR, and LGPD-compliant platform of federated EHR, datasets, and consulting partnerships, TriNetX puts the power of real-world data into the hands of its worldwide community to improve protocol design, streamline trial operations, refine safety signals, and enrich real-world evidence generation.

Veeva Systems, Inc. — Booth 107

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LinkedIn: *https://www.linkedin.com/company/veeva-systems*

Veeva is the global leader in cloud software for the life sciences industry. Committed to innovation, product excellence, and customer success, Veeva serves more than 1,000 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. As a Public Benefit Corporation, Veeva is committed to balancing the interests of all stakeholders, including customers, employees, shareholders, and the industries it serves. For more information, visit veeva.com.

Vitrana — Booth 203

Contact: Sean Pfifer
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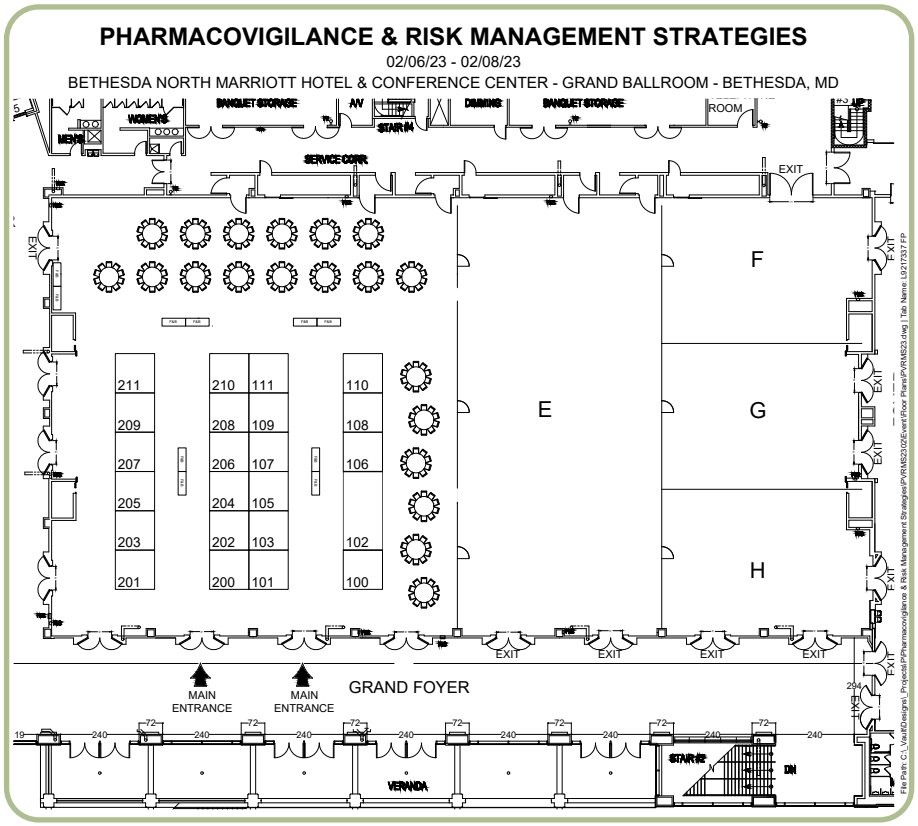
Facebook: https://www.facebook.com/cloudvitrana
Twitter: https://twitter.com/cloudvitrana
LinkedIn*: https://www.linkedin.com/company/vitrana-private-limited*

Vitrana is a market leading Drug Safety/Pharmacovigilance technology solution and services provider. Vitrana's market leading PV solution platform (HiLIT PV) has been utilized by leading life sciences organizations since 2016. HiLIT PV is used by our clients for global intake, data quality, medical review, reporting compliance and analysis, regional submission and compliance, and provides integrated security and privacy with safety systems. Vitrana also provides Consulting and Managed Services.

Exhibiting Companies

100	PrimeVigilance Ltd.
101	Orbit by Feith
102	IQVIA
103	Soterius, Inc.
105	PharSafer Associated Ltd
106	Insuvia UAB
107	Veeva Systems, Inc.
108	biologit
109	RxLogix Corporation
110	Axian Consulting Ltd.
111	PPD, part of Thermo Fisher Scientific
200	Techsol Life Sciences
201	Nextrove LLC
202	Adis
203	Vitrana
204	APCER Life Sciences
205	Prudentia Group LLC
206	Elite Safety Services
207	Commonwealth Informatics
208	TriNetX
209	iVigee Services a.s.
210	AWINSA Life Sciences
211	Insife

Floorplan



Exhibitors by Services

ADE Evaluation/Drug Safety Assessment

Adis Booth 202
APCER Life Sciences Booth 204
AWINSA Life Sciences Booth 210
Commonwealth Informatics Booth 207
Elite Safety Sciences Booth 206
PharSafer Associates Ltd Booth 105
Soterius, Inc. Booth 103

Adverse Event Management/Software

APCER Life Sciences Booth 204
AWINSA Life Sciences Booth 210
Commonwealth Informatics Booth 207
Insife Booth 211
IQVIA Booth 102
PharSafer Associates Ltd Booth 105
PrimeVigilance Ltd. Booth 100
Soterius, Inc. Booth 103
TriNetX Booth 208
Veeva Systems, Inc. Booth 107
Vitrana Booth 203

Case Report Forms

Vitrana Booth 203

Change Management/Implementation

Elite Safety Sciences Booth 206
Insife Booth 211
Nextrove Booth 201
PrimeVigilance Ltd. Booth 100
Soterius, Inc. Booth 103

Claims Support Studies/Safety and Efficacy Studies

TriNetX Booth 208

Clinical R&D

TriNetX Booth 208

Client/Server Database Development and Migration

IQVIA Booth 102
Nextrove Booth 201
Vitrana Booth 203

Clinical Pharmacology

Adis Booth 202

Clinical Study Reports

AWINSA Life Sciences Booth 210

Clinical Trial Monitoring

Adis Booth 202

Comprehensive Drug and Biologic Development

TriNetX Booth 208

Computer System Validation

Veeva Systems, Inc. Booth 107
Vitrana Booth 203

Consulting

APCER Life Sciences Booth 204
Axian Consulting Ltd. Booth 110
Commonwealth Informatics Booth 207
Elite Safety Sciences Booth 206
Insife Booth 211
IQVIA Booth 102
Nextrove Booth 201
PrimeVigilance Ltd. Booth 100
Soterius, Inc. Booth 103
Veeva Systems, Inc. Booth 107
Vitrana Booth 203

Data Management

IQVIA Booth 102
Nextrove Booth 201
Veeva Systems, Inc. Booth 107

Data Safety Monitoring Board Services

Soterius, Inc. Booth 103

Data Validation

Nextrove Booth 201
Veeva Systems, Inc. Booth 107

Database Conversions

Vitrana Booth 203

Document Management

Nextrove Booth 201
Veeva Systems, Inc. Booth 107

Electronic Data Capture

PharSafer Associates Ltd Booth 105
Vitrana Booth 203

Electronic Submissions

Veeva Systems, Inc. Booth 107

GCP Compliance

APCER Life Sciences Booth 204

Market Research/Product Communication

TriNetX Booth 208

Medical Communications

APCER Life Sciences Booth 204
Soterius, Inc. Booth 103

Medical Devices/Combination Products

APCER Life Sciences Booth 204
Elite Safety Sciences Booth 206

Medical Information

APCER Life Sciences Booth 204
AWINSA Life Sciences Booth 210
PharSafer Associates Ltd Booth 105
PrimeVigilance Ltd. Booth 100
Soterius, Inc. Booth 103

Medical Writing

APCER Life Sciences Booth 204
AWINSA Life Sciences Booth 210
Axian Consulting Ltd. Booth 110
Elite Safety Sciences Booth 206
PharSafer Associates Ltd Booth 105
PrimeVigilance Ltd. Booth 100
Soterius, Inc. Booth 103

Patient Education

Axian Consulting Ltd. Booth 110

Patient Recruitment

TriNetX Booth 208

Pharmacoeconomic/Pharmacoepidemiology Studies

PrimeVigilance Ltd. Booth 100

Pharmacovigilance

Adis Booth 202
APCER Life Sciences Booth 204
AWINSA Life Sciences Booth 210
Axian Consulting Ltd. Booth 110
Commonwealth Informatics Booth 207
Elite Safety Sciences Booth 206
IQVIA Booth 102
iVigee Services, a.s. Booth 209
Nextrove Booth 201
PharSafer Associates Ltd Booth 105
PrimeVigilance Ltd. Booth 100
Soterius, Inc. Booth 103
TriNetX Booth 208
Veeva Systems, Inc. Booth 107

Preclinical Development Services

PharSafer Associates Ltd Booth 105
TriNetX Booth 208

Process Validation

IQVIA Booth 102

Programing (Database, SAS, etc)

Vitrana Booth 203

Project Management

Axian Consulting Ltd. Booth 110

Elite Safety Sciences	Booth 206
Insife	Booth 211
IQVIA	Booth 102
PrimeVigilance Ltd.	Booth 100
Soterius, Inc.	Booth 103

Publications (Books, Journals)

Adis	Booth 202
TriNetX	Booth 208

Quality Assurance/Control

AWINSA Life Sciences	Booth 210
PharSafer Associates Ltd	Booth 105

Regulatory Affairs/Regulatory Strategy

APCER Life Sciences	Booth 204
AWINSA Life Sciences	Booth 210
Axian Consulting Ltd.	Booth 110
PharSafer Associates Ltd	Booth 105
PrimeVigilance Ltd.	Booth 100
TriNetX	Booth 208

Regulatory Document Preparation

AWINSA Life Sciences	Booth 210
Axian Consulting Ltd.	Booth 110

Software Development & Evaluation

Axian Consulting Ltd.	Booth 110
Insife	Booth 211

Standard Operating Procedures

Elite Safety Sciences	Booth 206

Strategic Planning and Implementation

Axian Consulting Ltd.	Booth 110
Elite Safety Sciences	Booth 206
Insife	Booth 211
Nextrove	Booth 201
PrimeVigilance Ltd.	Booth 100

Technology Assessment

Insife	Booth 211
Nextrove	Booth 201
Vitrana	Booth 203

Telephone Support

Nextrove	Booth 201

Training

Elite Safety Sciences	Booth 206
PharSafer Associates Ltd	Booth 105

Trial Management

AWINSA Life Sciences	Booth 210

Workflow Assessment/Re-engineering

Axian Consulting Ltd.	Booth 110
Insife	Booth 211
IQVIA	Booth 102
Vitrana	Booth 203