

Pharmacovigilance and Risk Management Strategies

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Adis Pharmacovigilance (part of Springer Nature)



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ADIS PHARMACOVIGILANCE - THE EXPERT SOLUTION FOR REGULATORY LITERATURE MONITORING

With more than 30 years' experience of delivering pharmacovigilance content and solutions, Adis is the unrivalled industry leader. More than 6,000 customers globally purchase drug safety information and pharmacovigilance solutions from Adis.

By outsourcing some of your pharmacovigilance work to us, you can free up your internal resources and have peace of mind that you are securing a reliable and cost-effective service for your organization.

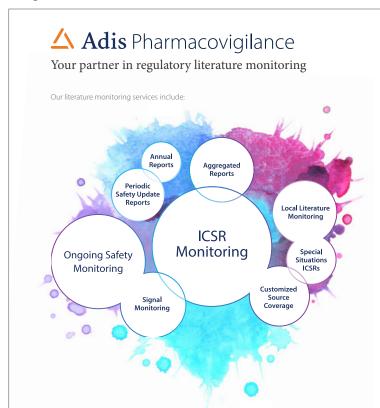
Our literature monitoring services include:

ICSR monitoring

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

Together we will review your current processes and determine how we can best support you. We work with your team throughout the whole process, from designing the right solution to helping you prepare for audits. We understand that your business needs can change during the course of the year, as can regulatory requirements, so we meet with you on a regular basis to ensure that we are always delivering the best possible service to your organization.

If you are ready to take the first step and would like to explore the possibility of working in partnership with Adis Pharmacovigilance, please get in touch.



Regulatory literature monitoring puts many pressures on your pharmacovigilance department – from the time and specific expertise required, to constantly battling to meet deadlines.

Adis Pharmacovigilance 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.

"It would be difficult for us to replicate the expertise and automation that an external vendor such as Adis can offer. The beauty of working with them is that we no longer have to worry about literature monitoring as this part of our pharmacovigilance process is taken care of. We can present our workflows during inspections and audits and be confident that we are complying with regulations".

A testimonial from one of our existing customers.

Take the first step towards a better way of working and get in touch. Email **pharmacovigilance@adis.com** or visit **adis.com/pharmacovigilance** for further details.

ArisGlobal LLC

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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. Designed with deep expertise and a long-term perspective that spans more than 30 years, our cognitive platform delivers actionable insights, boosts efficiency, ensures compliance, and lowers total cost of ownership through multi-tenancy.

Headquartered in the United States, ArisGlobal has regional offices in Europe, India and Japan. For more information, visit arisglobal.com or follow ArisGlobal on LinkedIn and Twitter.



Deloitte Consulting, LLP

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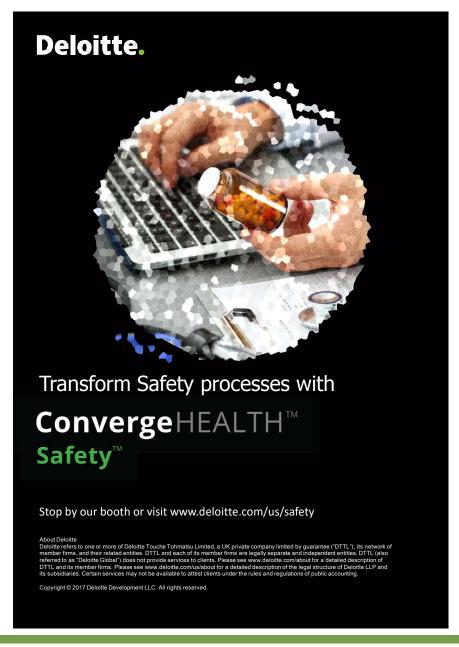
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A new paradigm for pharmacovigilance is required to address the operational and compliance challenges experienced today. Deloitte has collaborated with several industry partners and regulators to develop ConvergeHEALTH Safety, an evidence-based platform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



IBM Watson Health

IBM Watson Health

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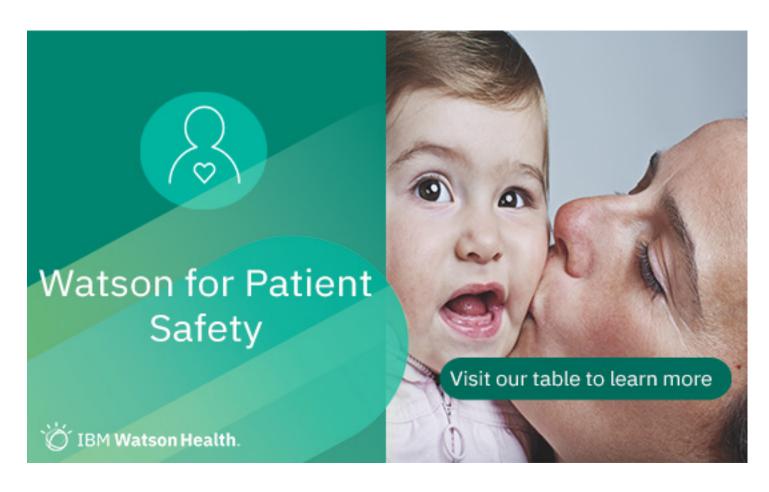
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IBM Watson Health - Empowering PV professionals, Transforming Pharmacovigilance

IBM Watson Health aspires to improve lives and give hope by delivering innovation, through data and cognitive insights, to address the world's most pressing health challenges.

Watson for Patient Safety is a cognitive end-to-end SaaS based solution designed to help PV professionals discover relevant safety information and make decisions.

- Consistency Watson for Patient Safety can offer consistency in case evaluation and intake.
- **Confidence** Safety issues may be detected earlier by applying predictive analytics to detect early trends.
- Speed Accelerate and scale intake workflows with cloud and cognitive technologies



IQVIA

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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 at <u>igvia.com</u>.



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Oracle Safety drives innovation and unifies safety in the cloud. Our market-leading, cloud-based safety suite is built for the market and by the market, leveraging standard industry best practices and artificial intelligence to automate processes, allowing you to detect risks early, respond quickly, and increase compliance, while addressing growing data sources and volumes.



PharmaLex

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PharmaLex is one of the largest providers for Development Consulting, Regulatory Affairs, Quality Management & Compliance and Pharmacovigilance, Epidemiology & Risk Management worldwide. We are involved in the advancements of Artificial Intelligence initiatives discovering the benefits AI brings to Pharmacovigilance and particularly adverse event monitoring in the future.

Meet our experts and find out how PharmaLex can support your Pharmacovigilance activities.

An overview of our capabilities



ACTIVITY	PHASE 1 TO PHASE 3	MARKETING AUTHORIZATION DOSSIERS	APPROVAL TO 5 YEARS POST-APPROVAL	MATURE PRODUCTS
Literature searching		✓	✓	~
ICSR processing	*	✓	~	~
Signal detection and evaluation	~	~	~	~
Aggregate / Periodic Safety Reports (DSUR/ PSUR/PBRER/PADER)	~	✓	~	~
Risk Management Plans (Writing, Strategy, Execution, Effectiveness)	~	✓	~	~
Pharmacoepidemiology		✓	✓	*
Full Pharmacovigilance services	*	✓	✓	~
EEA Qualified Person for Pharmacovigilance			✓	✓
Pharmacovigilance System Master File		✓	✓	~
Post-Authorization Safety and Efficacy Studies		✓	~	~

Sciformix Corporation

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Sciformix Corporation is a leading Scientific Process Organization (SPO) that provides comprehensive Safety and Risk Management process, technology and consulting services, including Safety Database Support and Hosting, Medical Contact Center, Case Processing, Medical Review, Aggregate Reporting, Safety Surveillance and QPPV services.

sciformiz

Global Locations: US | EU | India | Philippines



TConneX, Inc

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innovPV supports Pharmacovigilance needs. This product is a user friendly innovative post-market drug safety analytic tool that generates proactive and strategic drug safety intelligence information. Through its advanced data analytics, signal detection algorithms, and cutting-edge data visualizations of data mining outputs, innovPV streamlines the post-market safety process by discovering, analyzing, classifying and aggregating, emerging drug safety information from spontaneous sources and literature in MEDLINE in graphical and statistical outputs.

TConneX, Inc. is a certified 8(a), Capability Maturity Model Integration (CMMI)[®] Level III, Information Technology (IT) management consulting firm located in McLean, Virginia. TConneX provides clients the independent and objective insight necessary to solve their most critical management, organizational, and technical challenges.



For further information and innovPV demo registration, please visit the website https://pvaicloud.com. Phone: 703-382-8228 Email: support@pvaicloud.com

Innovative Pharmacovigilance Analytics and Intelligence

innovPV is an innovative post-market drug safety analytic tool that generates drug safety intelligence proactively and strategically with advanced data analytics, signal detection algorithms, and cutting-edge data visualizations of data mining outputs from spontaneous data sources and literature.

Facilitating Risk Benefit Analysis

Datamining adverse events reported in spontaneous data sources and MEDLINE side by side to gain insights into drugs' safety information

Strategizing Drug Safety Management

Utilizing statistical datamining techniques to quantify all possible drug-event combinations and drug-druginteractions and visualize through interactive graphs for rapid analysis

Safety Signal Management

End to end tracking and managing signals, providing audit trail and receive alert notifications when data is refreshed or updated

Literature

Literature articles can be investigated as overall events associated with the selected product.

WIRB-Copernicus Group

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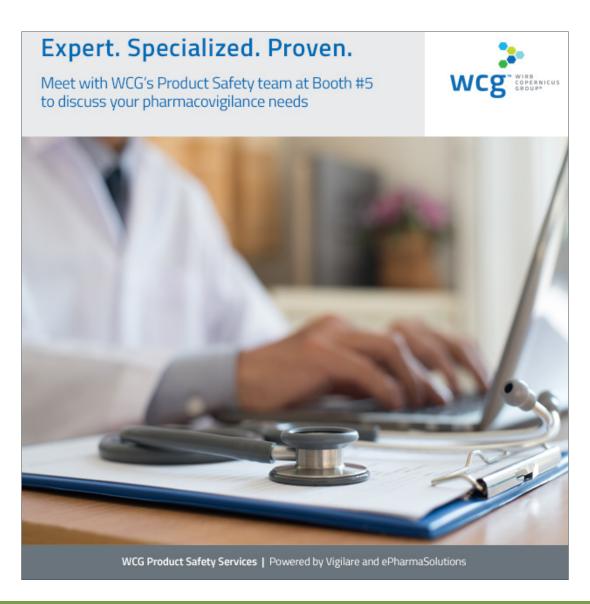
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WIRB-Copernicus Group (WCG) is the world's leading provider of solutions that measurably improve the quality and efficiency of clinical research. WCG enables biopharmaceutical companies, CROs, and institutions to accelerate the delivery of new treatments and therapies to patients, while maintaining the highest standards of human subject protection.





AB Cube Table 11

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AB Cube provides the international healthcare industry with evolutive cloudbased vigilance software solutions for management of adverse events. AB Cube is expert of multivigilance and provides dedicated solutions for pharmacovigilance, medical devices vigilance, cosmetovigilance.

AB Cube's pharmacovigilance software is fully E2B (R3) native.

Adis Pharmacovigilance

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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

Advera Health Analytics

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Advera Health Analytics is a global leader in pharmacovigilance software, analytics, and data at the leading edge of drug safety science. We mitigate client risk by improving the transparency and actionability of drug safety data through the curation and aggregation of large disparate datasets and the application of propietary analytics.

Table 21 **AgilePV**

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Born from customer need, AgilePV provides intuitive, secure, and validated PV, Safety and Regulatory solutions that help organizations mitigate risk and enhance visibility within patient safety processes. We have new tools, so stop by!

APCER Life Sciences

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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.

Ashfield Pharmacovigilance

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Ashfield Pharmacovigilance is a dedicated full suite pharmacovigilance services provider. We provide global safety solutions for both clinical and postmarket 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.

Author-it Software Corporation

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Author-it Software Corporation (ASC) is a world leader in component authoring for Life Sciences. Our Docuvera solution spans departmental silos, bringing structure, visibility and reuse to regulated information. This enables your teams to efficiently create, collaborate and deliver content to multiple-channels from one solution.

Table 32 **Bioclinica**

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Bioclinica is a global life sciences solution provider that utilizes science and technology to bring clarity to clinical trials - helping companies to develop new life-improving therapies more efficiently and safely.

C3i Solutions Table 13 Genpact Table 34

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C3i Solutions: BPO with 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.

Commonwealth Informatics

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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.

Deloitte Consulting, LLP

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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.

Table 31 **Ennov**

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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).

Evidence Partners Table 7

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Evidence Partners is the creator of DistillerSR, the world's most widely used literature review software. DistillerSR is a a fully compliant, transparent and audit-ready solution that automates many of the manual tasks involved in the preparation of pharmacovigilance literature reviews.

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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.

IBM Watson Health

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IBM Watson Health aspires to improve lives and give hope by delivering innovation, through data and cognitive insights, to address the world's most pressing health challenges. The organization aims to provide life sciences with the technology and expertise needed to power thriving organizations and support vibrant communities.

Ideagen Plc. Table 4

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Ideagen's solutions for document collaboration and control make reviewing and making changes to documents more effective and efficient. Together, PleaseReview and Q-Pulse standardise and automate the document control process from a request for change, through review, acceptance or rejection of changes, approval, distribution and acknowledgement.

IQVIA Table 28

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IQVIA (formed through the merger of IMS Health and Quintiles) 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.

Med Communications. Inc.

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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.

Medical Vigilance Solutions

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Medical Vigilance Solutions (MVS) is a distinct and specialized business unit of Cincinnati Children's Hospital Medical Center (CCHMC). Although our name is new, MVS has provided safety, medical communications, and contact center services to the pharmaceutical, biotech, and consumer health products industries for over 30 years.

MvMeds&Me Table 29

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MyMeds&Me is a leading SaaS provider of Adverse Event and Product Quality Capture solutions for life sciences. Organisations see efficiency & effectiveness benefits throughout the end-to-end PV process by rapidly accessing more complete and standardised safety data with fewer manual touchpoints and hand-

Oracle Health Sciences

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Oracle Safety drives innovation and unifies safety in the cloud. Our market-leading, cloud-based safety suite is built for the market and by the market, leveraging standard industry best practices and artificial intelligence to automate processes. allowing you to detect risks early, respond quickly, and increase compliance, while addressing growing data sources and volumes.

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PharmaLex is one of the largest providers for Development Consulting, Regulatory Affairs, Quality Management & Compliance and Pharmacovigilance, Epidemiology & Risk Management worldwide. We are involved in the advancements of Artificial Intelligence initiatives discovering the benefits AI brings to Pharmacovigilance and particularly adverse event monitoring in the future.

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Huron & Pope Woodhead provide life science companies with deep market/ industry experience & end-to-end solutions. Our strength in drug safety, regulatory & access combined with Huron's commercial expertise provides an integrated & agile partner: Benefit/Risk Management | Digital Enablement | Real World Evidence | Commercial & Market Access | Org Development

PPD

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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.

PrimeVigilance

Table 20

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PrimeVigilance is a dedicated pharmacovigilance & medical information fully comprehensive service provider with 500+ in-house employees, supporting pharma, biotech and generics companies in managing their products' global drug safety from clinical development through to full post-marketing activities within their US, EU & international markets.

ProPharma Group

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ProPharma Group is an industry leader in providing a comprehensive suite of pharmacovigilance services, including case processing, aggregate reporting, and signal detection. Our staff is dedicated to providing consistent support, utilizing established processes to ensure regulatory compliance from a partner you can trust.

Prudentia Group LLC

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Prudentia provides pharmacovigilance management and technology consulting services to the pharmaceutical industry. We advise companies on processes and technologies in support of clinical and post marketing safety and surveillance. We provide technology solutions to enhance Safety.

RxLogix Corporation

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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

Table 24

UBC

Table 22

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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 & Post-Approval Support Services, Regulatory Affairs & Regulatory Operations, and Technology Services. Locations: US|UK|India|Manila

TConneX Inc Table 17

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TConneX, Inc. is a certified 8(a), Capability Maturity Model Integration (CMMI)® Level III, Information Technology (IT) management consulting firm located in McLean, Virginia. TConneX provides clients the independent and objective insight necessary to solve their most critical management, organizational, and technical challenges.

Techsol Corporation

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Techsol Corporation is a leading global software product and solution provider for Pharmaceutical and Life Sciences organizations. Techsol primarily focuses in the area of Medical Affairs, Drug Safety, Clinical Development, LAB, MES and Quality. Techsol helps you adopt digital technology to achieve patient safety and regulatory compliance.

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United BioSource Corporation (UBC) is a best in class clinical and commercial services provider delivering patient-centric, platform-enabled solutions focused on product safety and value and minimizing barrier to study participation and product access.

Uppsala Monitoring Centre

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Uppsala Monitoring Centre is an independent non-profit foundation and centre for international service and scientific research. Vision: A world where all patients and health professionals make wise therapeutic decisions in their use of medicines. Mission: To support and promote patient safety through effective global pharmacovigilance practice.

WIRB-Copernicus Group

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