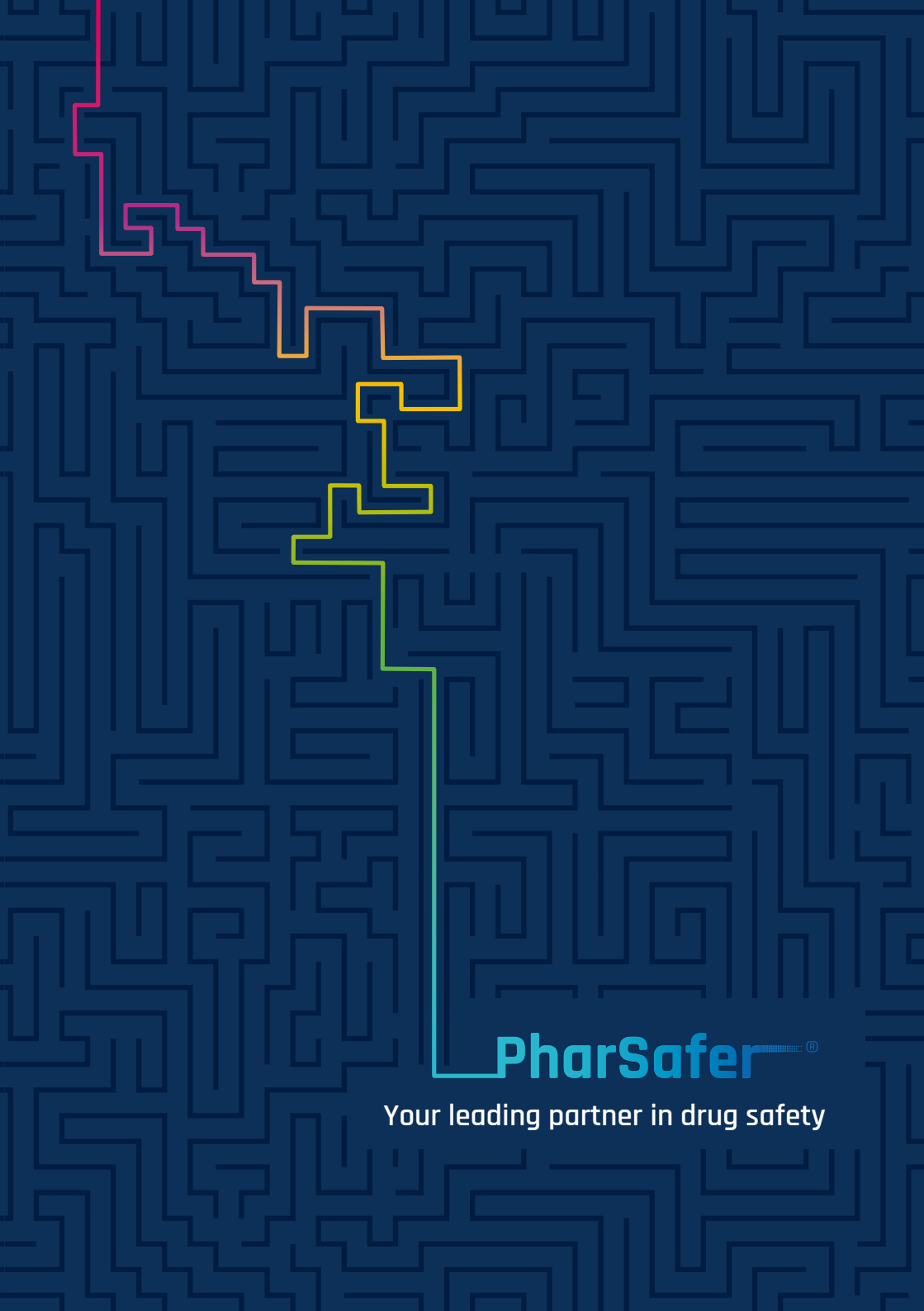

PharSafer®
Your leading partner in drug safety

PharSafer®

We love what we do.
We love finding solutions.
Quite simply, we are by far...

Your leading partner in drug safety

SCAN ME

SCAN ME

About us

We are passionate about protecting patients by identifying and, where possible, minimising any potential risks. We want to provide confidence for prescribers in having fully up-to-date product information, in order to use the product in the best way for their patients.

Dr Graeme Ladds
B.Sc (Hons); PhD; MTOPRA; DIA; RQA; IOD; PIPA; MAPS
Director

Founded in 2003 by Dr Graeme Ladds, PharSafer® has a wealth of experience in Pharmacovigilance (Clinical and Post Marketing) and Medical Services (Medical Affairs and Medical Information).

Notably, these areas have numerous and extensive legal safety/medical obligations for sponsors and licence holders to comply with and Dr Graeme Ladds' 30+ years' industry experience, including Global Head positions and Senior Pharmacovigilance positions (EU QP PV) within top ten Pharma Companies, ensures all our clients, and their patients, are in safe hands.

His personal ethos is one of proactivity and is the core driving force behind our successful team.

The journey to Regulatory compliance can be a tricky one, with constantly changing regulations and different global legislation.

Having the required systems and personnel in place that can adapt to these multiple requirements is essential for ensuring your product meets its safety obligations and complies with any and all updates made to domestic, regional and worldwide demands.

PharSafer® has a highly experienced and well-trained team which comprises of Physicians; PhDs; MSc scientists and Pharmacists, with many years' experience in pharmacovigilance and medical services at a global level.

Our focus is to keep each and every one of our clients compliant – as the global environment evolves – leading them through the labyrinthine rules that involve drug safety, with exceptional knowledge gained over many years of practical problem solving; and quality of service and commitment to patient safety.

We are passionate about protecting patients and keeping every one of our clients compliant

Quality and excellence

PharSafer® works with each of our clients as if they were our only client; not only working for them but with them, as partners, to meet their regulatory obligations. We build long-term relationships, with the majority of our clients being with us for 10+ years and we have taken many of these successfully through a number of regulatory inspections.

Patient safety is our priority

Above all else, PharSafer® prioritises patient safety and considers this to be the company's fundamental value, and it is this that our processes and procedures are based upon.

Our flexible approach

We recognise that each client has different needs and, as a specialist provider, we are able to tailor solutions according to client requirements through our 'One-Stop-Shop'.

We care for your reputation as much as our own

We have an exemplary record for case accuracy and compliance, repeatedly achieving 97-99% on all cases, as well as completing over 300,000 submissions by 2012, and more than 750,000 submissions to date in 2022.

We want to be different

We provide clients with all information and proactively suggest any improvements we can see as necessary, and outlining advice and recommendations on future programmes, to keep them compliant and at the forefront of the industry.

We train our people to be the best

As part of our ongoing commitment to excellence, PharSafer® has utilised the training from its sister company SaPhar, which serves as the training platform for all PharSafer's employees, for industry training as well as training our clients on any pharmacovigilance and clinical aspects.

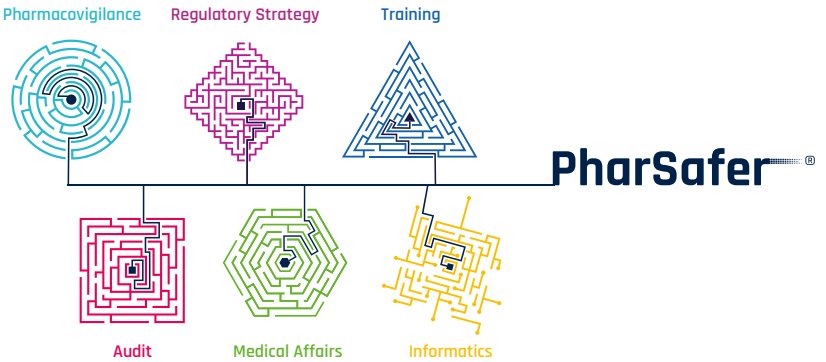
Size doesn't matter

All our clients receive the same level of professional expertise, no matter the size or location of the business or how many of our services are used.

Your complete service department

PharSafer® can act as your complete Pharmacovigilance & Medical Services department, performing all of the activities expected of your own team. This includes compliance with the necessary and varied global legislation and the ability to provide accurate information to Healthcare professionals and patients, ensuring that your business achieves consistently high regulatory performance.

To deliver this first-class service, we have refined the structure of our business to provide a wider range of services and solutions that we offer our current and new business partners.



We're with you at every step of the journey

From the outset, you will receive a truly tailored approach. We have devised a fully comprehensive PharSafer® Shopping List for you to select the services you require. We provide a session with one of our highly experienced consultants to establish any gaps that appear in your portfolio and work with you to develop a service offering that will meet any regulatory compliance expectations.

Our aim is to uphold and nurture both your reputation and our own.

PharSafer® locations

PharSafer has a truly global reach, enabling us to offer support to clients anywhere, at any time.

Ripley, UK

HQ located in Ripley, UK

Quality center for our global brand

Outputs to Regulatory Agencies and clientele

Technical and administration staff

Facilitating both day and nigh, operating 24/5

Global reach

Global offices strategically placed in India and Spain

Local expertise and highly-skilled international workforce

Provide a complete 24/7-365-day service operation

Perform the volume of work necessary for safety assessments, case processing, literature searching and literature assessments, and achieving our business development goals.

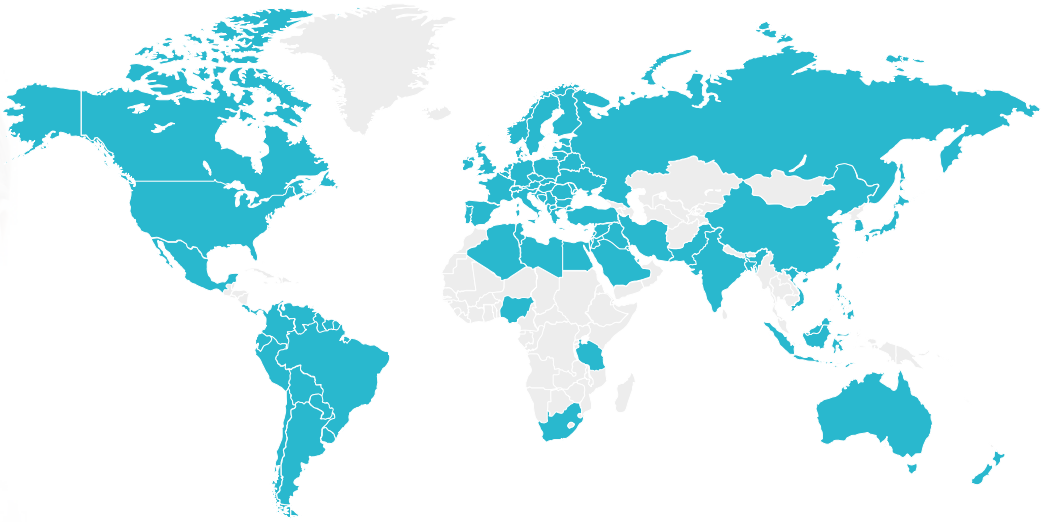
PharSafer® clientele

Our clients are global and national, with large product portfolios in multiple countries; through to national companies with few products.

We are a truly global organisation with approximately 70% of our clients from outside the UK, based in the USA; Canada; Europe; SE Asia; Australia and Africa.

PharSafer® have procedures in place and are ready to meet safety reporting regulations (clinical and post marketing) in over 130 countries.

We often help set up Safety Data Exchange Agreements (SDEAs) with clients on a global scale and help them to maintain and monitor compliance with them.



Client company types include:

- Biologics
- Vaccines
- Devices
- Generics
- Cosmetics
- OTC
- Advanced Therapy
- Innovative

The therapeutic areas covered by our client's portfolios include:

- Nervous system
- Gastro-intestinal
- Respiratory
- Oncology
- Metabolic
- Infectives
- Musculo-skeletal
- Immunological
- Skin
- Ocular
- Cardiovascular

The products owned by our clients are equally diverse and range from your everyday pharmaceutical products, to rare disease (Orphan and Ultra-Orphan); generic; Drug/Device; OTC; generic; innovator and advanced therapy, including gene therapy and stem cell therapies, and many more.

DRUG SAFETY & PHARMACOVIGILANCE

The science relating to the detection, assessment and prevention of adverse reactions to drugs

Involvement in 1st Covid Vaccine Development Programme

750,000+
Cases Processed

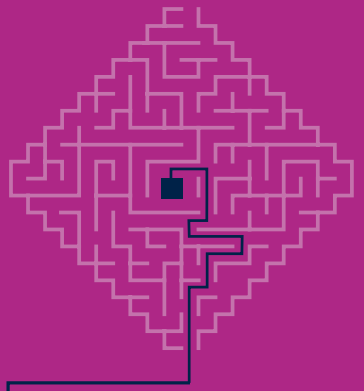
6,000+
PSURs/DSURs/PBRERs and RMPs Written/Processed

As specialists in global clinical and post marketing drug safety, we consider Safety to be the centrepiece of our services and the foundation of our business.

From routine pharmacovigilance services, such as the individual case processing of adverse reactions (ICSRs); comprehensive literature searching; signal detection; periodic report writing; risk management/minimisation and medical device safety, all the way through to more bespoke service offerings, such as vaccines; biologics; cosmetics; advanced therapy products; drug-device combinations and many other consultancy services, PharSafer® will advise and guide you on your way to meeting your regulatory compliance obligations.

KEY PHARMACOVIGILANCE SERVICES OFFERED

- Full Manual Case Processing of Adverse Reactions (ICSRs);
- Pharmacovigilance Project Management;
- Comprehensive Literature Searching;
- EU QPPV PV, Local QPs;
- Signal Detection, Analysis, Benefit-Risk determinations;
- Risk Management Plans (RMPs)/Risk Evaluation and Mitigation Strategies –Design and Maintenance;
- Periodic Report Writing (PBRERs, DSURs, PADERSs);
- Clinical Trial Safety Documentation (IBs, CRFs, Protocol reviews, DCSI etc...);
- Medical Device Safety;
- Global Expedited Reporting submission and supervision;
- Safety Labelling Management (DCSI/CCSI/Local labelling updates);
- Up to date EU PSMF & Local PSMFs;
- Covering Vaccines, Cosmetics, Advanced Therapies, Drug-Device Combinations and more.



REGULATORY STRATEGY

Taking your clinical data into license submissions and approval

Determining the Regulatory strategy to use for product licence submission can mean the difference between approval or delays

50%+

Over 50% of our clients have needed Regulatory Strategy advice to enable a successful licence submission and approval

Global regulation differences means that licence submission requirements differ even for the same product and our advice prevents licence delays

To help clients effectively navigate the complex regulatory landscape and meet their regulatory compliance obligations, PharSafer® support clients by preparing and submitting the varied regulatory filings world-wide, utilising scientific advice in development programmes for filing strategy; monitoring regulatory changes, and understanding the various mechanisms for obtaining licences for different product types e.g., herbal; traditional; generic; OTC; innovator.

Whether it be performing comprehensive regulatory compliance assessments, developing and maintaining the Global Product Labelling and Core Data Sheets or undertaking activities such as Licence extensions in new territories with new indications and formulations, our team has many years' expertise to ensure our clients receive a first-class service.

KEY REGULATORY STRATEGY SERVICES OFFERED

- Regulatory Strategy for Licence Construction, Scientific Advice & Submissions;
- Global Licence Submissions;
- Licence Variations;
- Licence Renewals/Extensions;
- Due Diligence for Licence Acquisitions;
- SOP Writing;
- Scientific Advice;
- Core Safety Implementation;
- Urgent Safety Restrictions;
- XEVMPD updates;
- Licence Renewals;
- Product licence extensions.

SaPhar
INDUSTRY TRAINING

Industry training provided by PharSafer's sister company: SaPhar.
Training professionals today, for tomorrow's decisions

23
Training Courses Delivered Annually, Globally

6,000+
Training Courses Delivered Face-to-Face

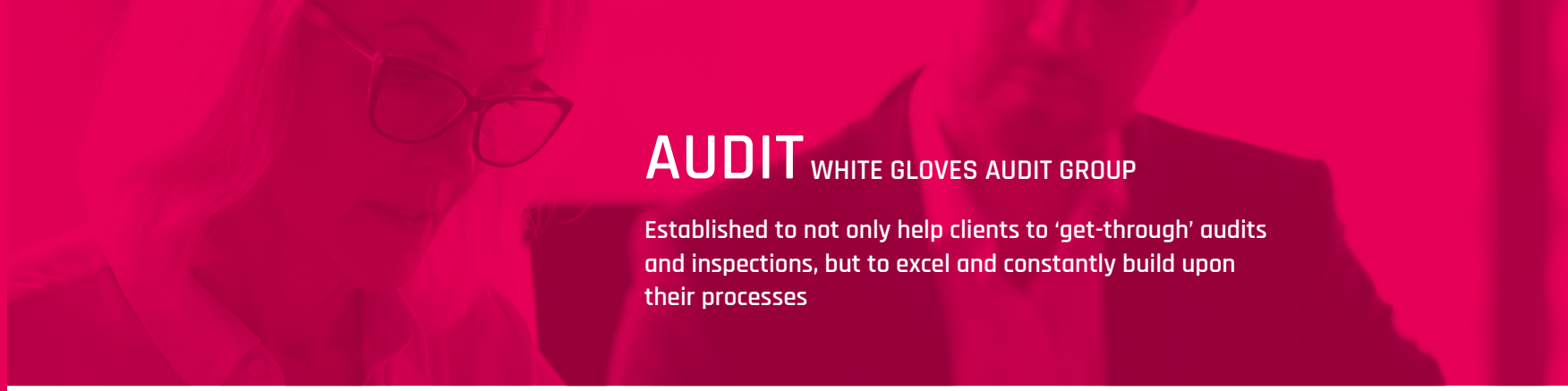
1,000+
Training Courses Delivered Online

As the sister company to PharSafer®, SaPhar Training® provides pharmaceutical professionals with introductory, intermediate and advanced level practical training, in addition to bespoke training courses that are tailored to the specific needs and requirements of a client, covering a wide range of subject areas within global clinical, GCP, signal detection, post marketing drug safety, medical affairs, cosmetovigilance, audits and inspections.

These training programmes can be conducted face-to-face or online and are designed to help equip professionals with the necessary skills and knowledge to effectively navigate the field of pharmacovigilance at various levels of proficiency ready for them to make practical decisions for the future.

KEY SAPHAR INDUSTRY TRAINING SERVICES OFFERED

- Introductory, intermediate and advanced level practical training;
- Both in person and online training;
- Bespoke and Set-Topic driven training courses;
- Designed for all levels of industry professionals – including competitors and regulatory personnel;
- Covering a wide range of subject areas within global clinical and post marketing drug safety;
- Face-to-Face and Webinar training;
- Training for Pharmacovigilance, Medical Device Safety, Cosmetics, Medical Information/ Promotional compliance;
- Bespoke client training courses.



AUDIT WHITE GLOVES AUDIT GROUP

Established to not only help clients to 'get-through' audits and inspections, but to excel and constantly build upon their processes

150+
SOPs/WPDs Written for Clinical and Post Marketing

175+
Audits and Inspections Performed Globally

As well as Inspection Preparation, Due Diligence, Gap Fill Analysis and more!

PharSafer® understand the importance of being compliant and not only passing or 'getting through' audits and inspections but excelling in them; applying a constant quality improvement philosophy through the work of our White Gloves Audit Group, with over 75 years of senior auditor experience performing GCP and GPV audits against multinational legislation requirements, as well as 21 CFR Part 11/GAMP 5 audits on system validations.

When forming a partnership with a client, we agree to see ourselves as an extension of their brand and Company ethos, protecting their reputation as we would our own, as we understand that any failures in compliance may result in significant consequences to their brand and to their product's ability to produce revenue; guaranteeing that all standards of work are upheld to the highest possible standard, both within PharSafer® and in any external audits conducted.

Now with over 75 years of senior auditor experience, our White Glove Audit Group have performed GCP; GPV audits, against multinational legislation requirements, as well as 21 CFR Part 11/GAMP 5 audits on systems validation.

KEY AUDIT SERVICES OFFERED

- Helping Companies establish and strengthen their Quality Management Systems (QMS);
- Helping define Regulatory standards and establish Key Performance Indicators (KPIs);
- Ensuring standards are maintained for regulatory submissions via consistent measurement;
- Writing/review and strengthening SOPs & other Detailed Written Procedures; Performing Pre-Qualification (including risk assessments) and Partner Audits;·
- Performing Good Clinical Practice (GCP) and Good Pharmacovigilance Practice (GPV) audits, in line with multilingual legislation, as well as system validations;
- Providing gap analysis for process improvements;
- Audit for Due Diligence activities for Company or product purchases.

MEDICAL AFFAIRS

A vital role in the communication of effective and proper usage of the Company products

Launch of Validated Medical Information Database

350,000+
Medical Information Queries Answered

As well as FAQ Design, Competitor Analysis, Promotional Sign-off and more!

Whilst we place great emphasis on the importance of pre and post marketing drug safety, we also place absolute value on the importance of peace of mind for both our client and our client's stakeholders – ensuring the products are used properly and information is accurate and up to date to be provided to Healthcare Professionals and patients alike.

To complement our services in clinical and post marketing drug safety, we provide interactive medical services within our Medical Affairs Group that cater to the needs of our client's stakeholders (for medicines; devices; cosmetics; vaccines; radioisotopes) to ensure their brand is supported to the highest possible ethical standard.

All of our clients have the ability to benefit from our front line services in medical affairs, with our Medical Information Department taking on the role of first responders on behalf of our clientele; being the first port-of-call for product enquiries and concerns.

In addition to peace of mind for our client's consumers, we also provide our clientele with up-to-date product/industry information and analysis - providing factual information, through monthly analyses, on the usage of their product.

KEY MEDICAL AFFAIRS SERVICES OFFERED

- Having fully trained medical affairs staff to provide live, multi-national medical, front-line services to Healthcare Professionals (HCPs) and patients;
- Medical Information Department performing as first responders, on behalf of clientele; utilising information contained in the approved product information as well as: - Frequently Asked Questions (FAQs) –Design, Implementation and Maintenance;
- First port-of-call for any product enquiries and concerns (product complaints; adverse reactions);
- Providing clients with up-to-date product/competitor analysis and trends in treatment;
- Reviewing supportive study information for claims;
- Preparation of scientific information for product launches;
- Clinical Paper reviews.

INFORMATICS

Continuously looking to the future for PharSafer® and the improvement of Global patient safety for the industry

SCAN ME

RAPTAR®

Intelligent software to achieve Rapid, Automated, Processing and Tracking of Adverse Reactions for clinical and post marketing drug safety

20
Database Migrations

3
Safety Database Upgrades

8
Global Safety Database Implementations

At PharSafer®, we add value to our first-class service by not only going above and beyond expectations for the task at hand, but by always looking ahead and recognising the need for change before your competition through applying cutting edge technology and our internal expertise and ingenuity.

By continuously evaluating the processes and performance of our business, we constantly seek out opportunities to both expand and improve on the quality, breadth and depth of our services through IT development for practical solutions, in addition to raising the bar for standards across the wider industry.

PharSafer® Informatics is your absolute first choice for efficient process management and integration for pharmacovigilance, medical affairs and regulatory activities.

KEY INFORMATICS SERVICES OFFERED

- Developing in-house and commercially available, validated, innovative IT system solutions;
- Continuously evaluating processes and performance;
- Constantly seeking new opportunities to both expand and improve quality, breadth and depth of services;
- Allocating a large proportion of non-client facing activities, towards business development;
- Acting as first-choice, efficient process management and integrations for Pharmacovigilance, Medical Affairs and Regulatory activities;
- Client onboarding – data transfers from multiple systems and data collation;
- Globally Validated Safety Database Provision, Integrations and Migrations, Upgrades and Assessments;
- Automated Case Processing (R.A.P.T.A.R®).

PharSafer® shopping list

At PharSafer®, we offer a breadth of services for clients around the world.

This page shows an example shopping list available with PharSafer®. However, in any client request, our full, comprehensive shopping list can be provided to cover the following key areas and more:

Pharmacovigilance

- Safety Database
- Case Processing
- Safety Reviews and Signal Detection
- Periodic Reports (DSUR, PBRER, PSUR, PADER, IND ANNUAL)
- Risk Management Minimization Plans (RMPs/REMs)
- Pharmacovigilance System Master File (PSMF) (Production and Maintenance – EU, UK, ROW)
- EU QP PV and Local QPPVs
- Regulatory Intelligence for Safety Reporting Requirements
- Global and Local Literature Searching
- Clinical Trial Safety Activities

Regulatory Strategy

- Global Licence Submissions
- Licence Variations
- Licence Renewals/Extensions
- Due Diligence for Licence Acquisitions
- SOP Writing
- Regulatory Strategy for Licence Construction, Scientific Advice & Submissions
- Scientific Advice
- Core Safety Implementation
- Urgent Safety Restrictions
- XEVMPD updates
- Licence Renewals
- Product licence extensions

Training

- Face-to-Face (F2F)/Online Training
- Webinars
- Bespoke Company Training
- General Staff Training on Safety Reporting
- Investigator Safety Training
- QPPV Mentor Training

Audits

- Risk-assessment Questionnaires for Pharmacovigilance Audits
- Pharmacovigilance Audits
- Good Clinical Practice (GCP) Audits
- Gap-fill Analysis
- Due-diligence Audits
- CAPA Management and Closure
- Quality Management System (QMS) Design and Assessment

Medical Affairs

- Medical Information Services
- Promotional Item Reviews
- Frequently Asked Questions (FAQ) Design and Maintenance
- Product Complaints
- Product Educational Materials
- Competitor Analysis
- Due Diligence Reviews

Informatics

- Database Implementations
- Database Migrations
- Database Validations
- Database Upgrades
- Systems Development
- IT SOPs
- IT Audits
- Data Protection & Privacy
- Back up, disaster recovery & Business Continuity

Our team of experts are on hand to help walk you through which services are right for you!

Contact us for a free consultation session and we will help guide you through the safety activities you require for a fully personal, compliant first-class service.

Your leading partner in drug safety

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Ripley, Surrey GU23 6ND, UK

Phone: **+44 (0)1483 212150**
Email: **enquiries@pharsafer.com**
Website: **www.pharsafer.com**

PharSafer®

PharSafer® is a Global Contract Research Organisation (CRO) specialising in Global Clinical and Post Marketing Drug Safety, and Medical Services.

We offer an extensive range of vigilance services, ranging from Pharmacovigilance; Cosmetovigilance; Materiovigilance; VaccineVigilance; Nutrivigilance; Veterinary Pharmacovigilance; assisting with audit preparedness; performing global medical services and running industry training courses for industry professionals - ranging from introductory, through to intermediate and advanced. Together with our sister company SaPhar, PharSafer® continuously seek new and innovative ways to provide added value for our clients, with the aim of optimising the processes and procedures involved with clinical and post marketing drug safety reporting.

We ensure all of our activities and communications are conducted with full transparency, guiding our clients through the maze of global safety and medical affairs legislation, and in the interest of patient safety.

PharSafer® are more than a provider. Like a family, we care deeply about our customers; our service; our reputation; our customer's reputation and our people.