
Your leading partner
in drug safety
PharSafer®

WHO ARE PHARSAFER?

PharSafer

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

Founded in **2003** by Dr Graeme Ladds, PharSafer® is a specialist Global Contract Research Organisation (CRO) in Global Clinical and Post Marketing Drug Safety, and Medical Services, with a wealth of experience in Pharmacovigilance, Medical Affairs and Medical Information – and the various, numerous and extensive legal safety/medical obligations for licence holders to comply with.

Where are PharSafer?

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

Colleagues around the globe

- 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.

VETERINARY VIGILANCE

Veterinary Activities

- Veterinary Regulations are constantly evolving, like human medicine regulations:

The Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6) updated the rules on the authorisation and use of veterinary medicines in the European Union (EU) when it became applicable on 28 January 2022. The European Medicines Agency (EMA) works with the European Commission and other EU partners in implementing the Regulation.

Regulation (EU) 2019/5 amended the EU pharmaceutical legal framework set out by Regulation (EU) 726/2004 and created a legal framework specific to veterinary products. The new provisions apply from 28 January 2022, when Regulation (EU) 2019/6 replaced Directive 2001/82/EC.

The European Parliament and European Council adopted the Regulation in December 2018. It took effect on 28 January 2022.

Veterinary Activities

All of which are underpinned with:

- Quality Assurance
- Increased Compliance
- Training requirements
- New SOPs
- And more!

Veterinary Safety Requirements

There are many areas to consider when it comes to Veterinary Safety Requirements:

- Veterinary medicines have their own set of stringent regulations similar to humans.
- These regulations must be followed to ensure animals are provided with the best medicines, providing maximum benefit and minimum risk.
- The wide variety of different species means animals may react very differently to the same medicine.
- Even when addressing the same species, understanding different dosages and different weights for animals, together with pharmacokinetics, age and gender, brings its own challenges.

Veterinary Qualified Person Requirements

Of these areas, the Veterinary Qualified Person must ensure compliance for the following:

- Adverse reaction case processing;
- Answering veterinary enquiries into the product usage (veterinary information);
- Understanding the varied legislation;
- Providing aggregate data assessments (safety reviews);
- Periodic Safety Update Report (PSUR) writing;
- Provision of a Veterinary Qualified Person for Pharmacovigilance;
- Helping to keep labelling up to date;
- Literature searching for possible adverse reactions;
- Attendance for possible Regulatory Inspections and more!

Clinical Trials Requirements

Veterinary medicines must be rigorously tested, prior to license submission and approval, in order to get approval for sale.

- Assessing the safety aspects from such clinical studies and reporting;
- Comply with the requirements for license approval; this included:
- Accurate case reporting to understand drug related (S)ADRs
- Perform any post-marketing safety commitments/studies in line with the terms of license approval
- Perform rigorous signal detection for new risks

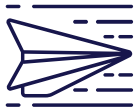
License Agreements & Regulatory Inspections Requirements

When it comes to license agreements and regulatory inspections:

- Setting up of any license agreements for marketing partners, to ensure the transfer of both Medical Enquiries and Pharmacovigilance reports;
- Carrying out any due diligence activities in the acquisition of products or companies involved with animal medicines, to ensure a smooth transition to your own company;
- Handling of all of the Pharmacovigilance activities and medical services and more!

THE PROBLEM

The Veterinary Vigilance Problem



SPEED

For most companies, case processing remains a slow, manual process

INCREASING VOLUMES

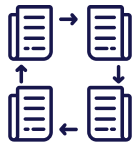
Emerging markets have grown exponentially, bringing new and additional legislation

REPORTING TIMELINES

This increases the demand and results in issues for staffing and reporting timelines

DATA INNACURACIES

The resultant impact leads to increasing levels of human error



POOR/LACK OF FOLLOW-UP

Obtaining follow-up can be difficult for both timing and resource

EXAMINING DATA FOR POTENTIAL NEW SIGNALS

All of which lead to problems with regulatory compliance, data analysis and review.

The Veterinary Vigilance Problem

Speed

The timelines for reporting adverse reactions to be compliant are challenged because of:

Increasing Volumes

Volumes of reports are increasing because of new country regulations requiring reporting; more new products; increased reporting from product users and healthcare professionals

Reporting Timelines

More regulations from more countries expanding the number of reports requiring submission to the various Regulatory Authorities

The Veterinary Vigilance Problem

Data Inaccuracies

This can occur for many reasons:

- Incorrect data; processing; lack of follow up; poor data provision

Poor/Lack of Follow-up

This reduces the opportunity for good quality information which allows for accurate causality assessments signal detection and risk determination

Examining Data New Signals

Good quality cases improve the determination of new signals by allowing accurate signal detection.

Good quality individual cases aid both early and continuous signal analysis

CURRENT SITUATION

Since the 1960's the number of adverse reaction reports received by pharmaceutical companies and Regulatory Authorities has risen year after year.

Emerging markets - such as the cosmetics and medical devices industry - have grown exponentially, bringing new and additional legislation into the world of post marketing drug safety.

This increases the demand for case processing and analysis; resulting in increased cost of staffing and time processing.

Resulting in a significant, ever-rising cost of training for personnel, due to continuous updates in legislation, increasing demands on compliance and accuracy.

PROBLEM

Case Processing Errors

Case processing cases are increasing year on year.

Amount of manual work required leads to increased levels of human error.

Human errors in case reporting continue to be reported, highlighting a lack of training and/or insufficient capabilities/resources, to meet regulatory standards.

Incorrect/Missing Data

This increases recruitment and training costs – often at the detriment of quality.

The lack of consistent and methodological follow up of adverse reactions contributes to the errors and lack of compliance.

PROBLEM

Literature Cases

Most literature reports do not specify individual patient details, therefore becoming difficult to differentiate between multiple cases within a given report.

Where more than one patient is involved and authors are from a different country, it becomes difficult to understand which country the patient belongs to.

Significant amount of manual work required when reviewing literature search results for eliminating irrelevant data, as honing the search strategy is not always the solution since the search is deliberately broad to ensure obtaining of all relevant hits.

Translations

Where a translation agency is used, managing time requirements and standards, plus considering issues regarding high cost.

PROBLEM

Processing Time

Ensuring outstanding follow-up requests are undertaken in a timely manner can often prove challenging, with various timescales and limitations involved.

Obtaining relevant follow up information is time-consuming.

In turn, late case reporting continues to be a finding within Inspections.

Follow-up

Obtaining sometimes multiple follow-ups can be difficult for both timing and resource and especially to focus upon the most important reactions first.

PROBLEM

Regulatory Authorities

Duplicates and incomplete information can also be identified after receiving information from the Regulatory Authority, with this information often being difficult to follow-up on, due to a lack of reporter details.

Findings in Regulatory inspections, relating to case processing, continue to be reported; often bringing with them Regulatory findings, fines and/or demand for implementing new processes and following up on historical cases.

Regulatory Authorities continue to find cases that are not followed up on (not meeting deadlines) and therefore fail in Quality and compliance

ULTIMATE

INNACURATE DATA

INCOMPLETENESS

REDUCING QUALITY

Misleading analysis; poor periodic reports; inaccurate benefit-risk determinations

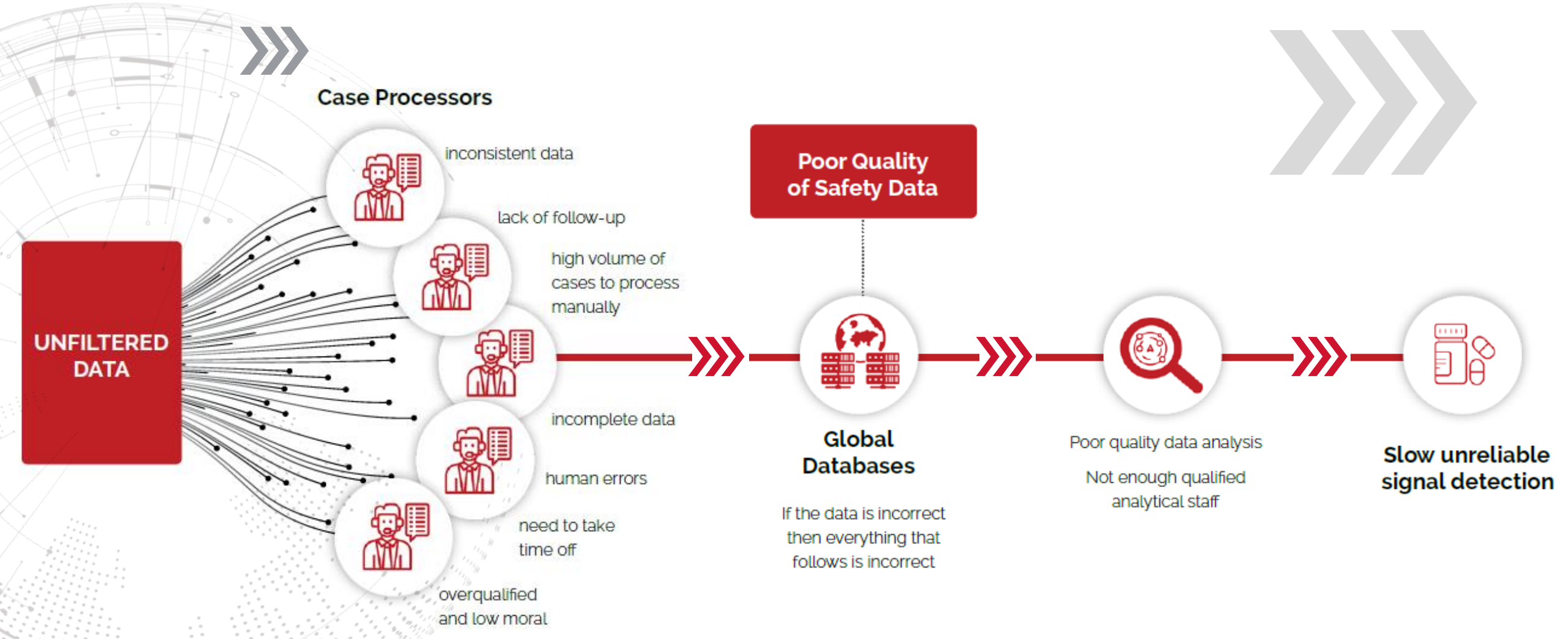
CURRENT INDUSTRY STRUCTURE

CURRENT INDUS STRUCTURE

Number of Staff

Cost of Staff

PROCESS WITHOUT AUTOMATION



SOLUTION

Aim to replace and reposition where the ‘human’ element of case processing (data entry) fits, facilitating the industry’s movement towards an automated process

Free up these professionals to better concentrate their time and energy into the analysis of data rather than the processing of data

Eliminate human errors from the case processing phase while increasing case completeness

Improve employee morale through reforming the repetitious procedure of data entry

Allow to maximise time (R.A.P.T.A.R operating 24/7) where employees would eat, sleep; go on holiday; take sick leave; have time off at weekends, or leave; placing pressure on maintaining compliance

Reduce both time and costs involved with training

Reshaping the Industry

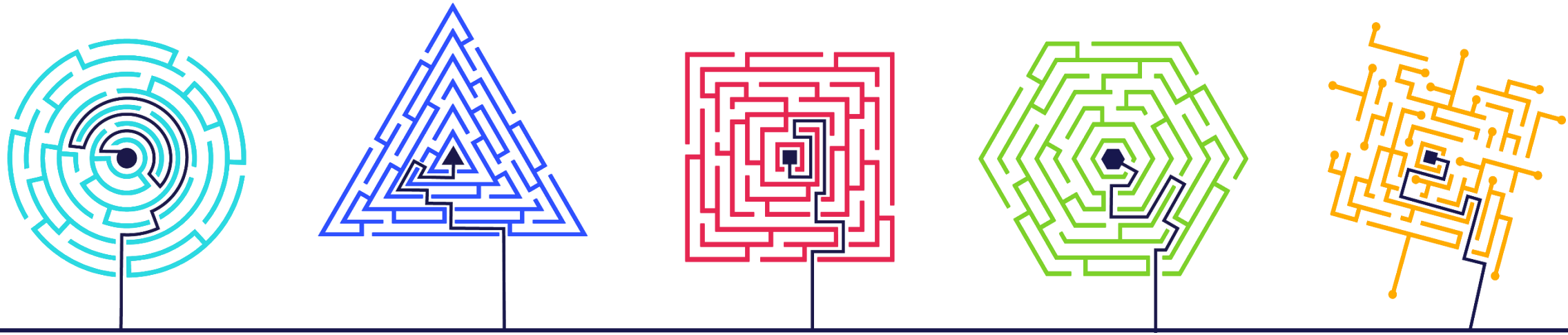
Case processing staff are top heavy, expensive and management intensive for training

We want a bottom heavy environment for greater amount of time reviewing and determining signals

RAPTAR®
REPORTING

Questions
?

PharSafer®



Pharmacovigilance | SaPhar Training | White Gloves Audit | Medical Affairs | Informatics

Questions

RAPTAR® REPORTING

PharSafer®

Guiding you to a clearer, (Phar) Safer future

Head Office: PharSafer House, White Hart Meadows, Ripley, Surrey GU23 6ND, UK

Direct: **+44 (0) 1483 212155** Reception: **+44 (0) 1483 212150**

PharSafer