RAPTAR®

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

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PharSafer®

PharSafer®

Introducing R.A.P.T.A.R®

the Rapid, Automated, Processing and Tracking of Adverse Reactions

Brought to you by

PharSafer®

Your Leading Partner in Drug Safety

RAPTAR®

Founded in 2003 by Dr Graeme Ladds, PharSafer® is a specialist Contract Research Organisation (CRO) in Global Clinical and Post Marketing Drug Safety, and Medical Services, with a wealth of experience in Pharmacovigilance, Auditing and Medical Affairs – and the various, numerous and extensive legal safety/medical obligations for licence holders to comply with – as well as Regulatory Strategy for the best methods for obtaining scientific advice concerning licence submissions and approvals.

Together with our sister company which focuses on Training: SaPhar, PharSafer® continuously seeks new and innovative ways to provide added value for our global clients – going above and beyond expectations and optimising processes and procedures involved with clinical and post marketing drug safety and licencing approach.

Our ability to offer first-class services in Pharmacovigilance, Regulatory Affairs, Training, Auditing, Medical Affairs and IT Informatics means that, for many clients, we operate as their Pharmacovigilance and Medical Departments – guiding them through the labyrinth of drug safety and medical legislation, all in the interests of ensuring patient safety and client compliance.

DR GRAEME LADDS

With a first degree in Biochemistry and Pharmacology, and a Ph.D. focusing on drug metabolism and Pharmacokinetics, Graeme has worked in the areas of Drug Safety and Medical services for over 30 years.

Having worked as a Head of Global Pharmacovigilance for a multi-national innovator Company and EU QP PV for several of the top ten Pharma Companies, large generic and smaller innovative Pharma, Graeme is the CEO and Owner of PharSafer® – a position held for the last 20 years – and has taken many products from bench to clinical to post-marketing in many global markets; helping many small start-up Companies (Biotech, Advanced Therapy, Medical Device, Biologic, Generics, Herbal, OTC) in their planning and growth, due-diligence activities for product in-licensing and marketing, and development strategies with partner and distributor Companies.

Graeme has also been involved in many global audits (conducted) and inspections (taken part in) for clients and also database designs and development.

RAPTAR®

- **R** RAPID
- **A** AUTOMATED
- **P** PROCESSING and
- **T** TRACKING of
- **A** ADVERSE
- **R** REACTIONS

RAPTAR®

With many factors associated with manual case safety reporting continuing to be cited in regulatory inspection findings, the need for the improved, accurate reporting of adverse reactions, for both clinical and post marketing safety reports, has never been greater!

Whether it be clinical or post marketing drug safety, R.A.P.T.A.R® provides an automated solution for companies seeking to address concerns with rising spontaneous reporting demands increasing year-on-year; increasing costs of recruitment and training on the rise; human errors continuing to occur; lack of timely and consistent follow-up; late case submissions; literature searching demands increasing and more!

R.A.P.T.A.R®, and the wider concept of automated case intake and processing, is the natural, next step in the evolution of safety intake for the pharmaceutical industry.

Don't just elevate your safety – transform it with R.A.P.T.A.R®!

CURRENT INDUSTRY SITUATION

1 Reports on Rise

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

2 Exponential Growth

Emerging markets, such as the cosmetics, medical devices, advanced therapies and vaccines industries, have grown exponentially – bringing new and additional legislation into the world of clinical and post marketing drug safety

3 Demands on Resource

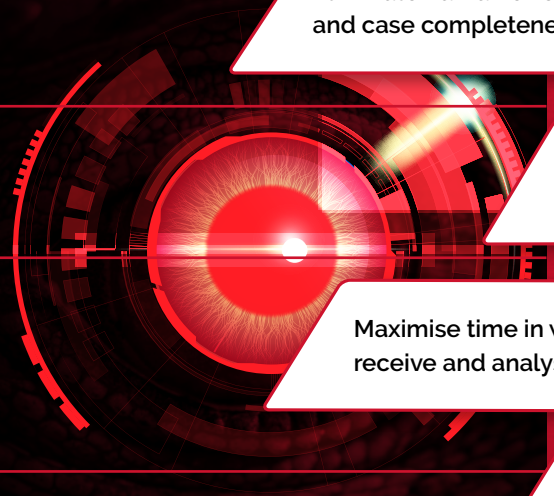
These legislative changes have increased the demand for safety reporting and analysis, resulting in the need for greater staff numbers, increasing costs for such resources and time for processing and follow up

4 Unsustainable Process

As a result, this increased staffing, paired with the continuous updates in legislation, has led to the significant, ever-rising cost of training for personnel, and has amplified demands on reporting accuracy and meeting compliance obligations

WHY WE'VE DEVELOPED R.A.P.T.A.R®

- Following the Covid-19 pandemic, regulatory authorities have reported significant rises in adverse reaction reports for all products, not just for Covid vaccines, each year
- Additional burden is being placed on companies who require greater global reporting for their safety obligations, placing increased pressure on manual processes **where employees require adequate time to rest, go on holiday, take sick leave, have time off at weekends)**
- The top 20-Pharma Companies process 15,000,000 adverse reaction reports per year (not including devices; cosmetics; clinical trial reaction reports or veterinary)
- This demand has also led to more mistakes being made within data capture, processing and review – with human error and late case submissions, due to lack of timely follow-up, continuously cited amongst leading reasons for regulatory inspection findings
- Leading regulatory authorities have outlined the need for greater automation in case processing, in order to stay on top of the increasing numbers of reports, with case reports continuing to be cited during inspections as inaccurate and of poor quality
- Delays in the processing of cases with incomplete (lack of follow up) or inaccurate information will delay the identification of real signals, meaning patient safety is compromised



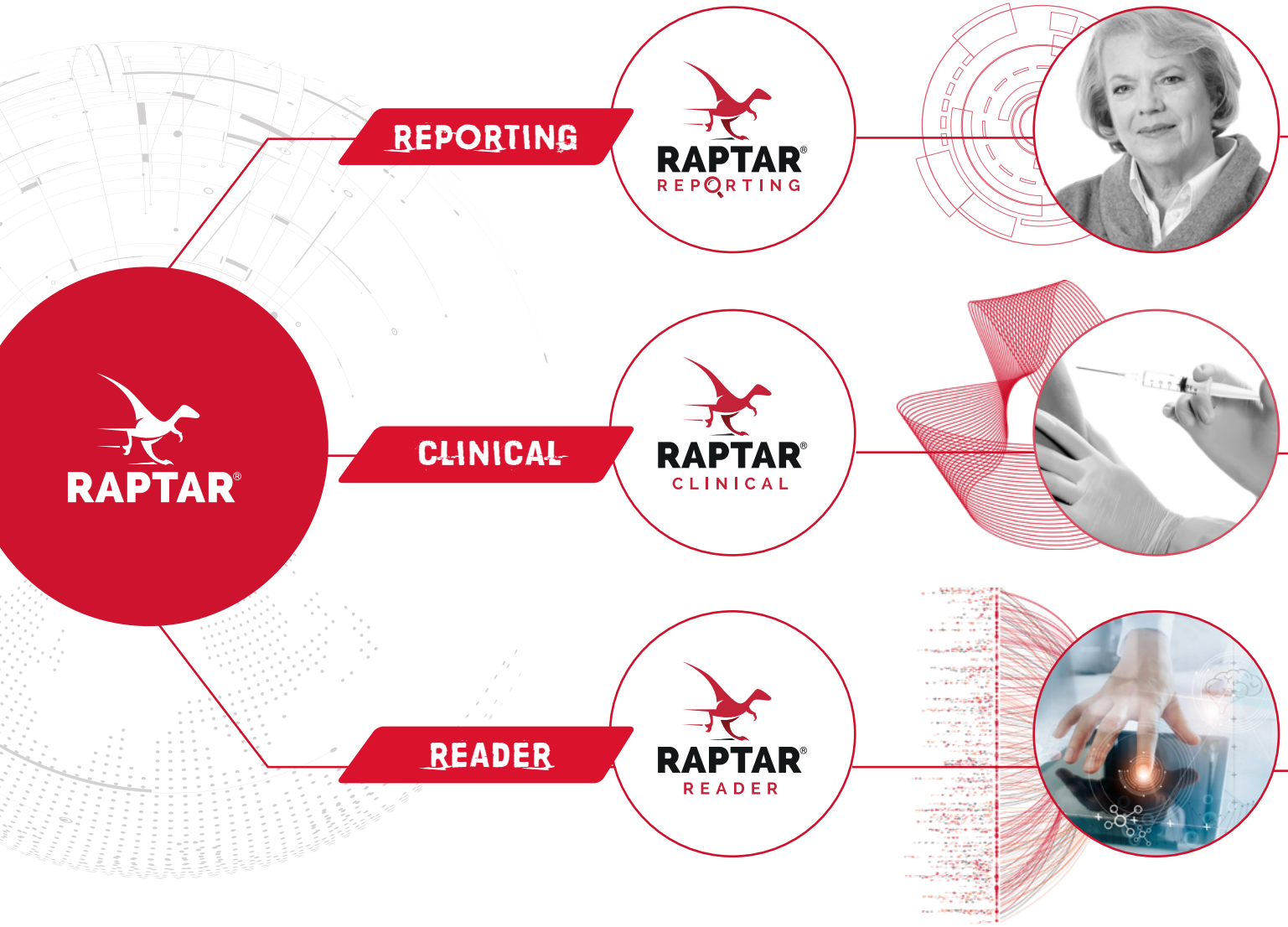
BENEFITS

BENEFITS OF R.A.P.T.A.R®

- Facilitate the industry's movement towards greater automation by replacing and repositioning where the 'human' element of laborious manual reporting fits
- Free up professionals to better concentrate their time and energy into the analysis of data rather than the processing of data
- Eliminate human errors from the reporting phase whilst increasing data accuracy and case completeness for causality assessment and signal identification
- Improve employee morale through reforming the repetitious procedure of data entry
- Maximise time in which companies can receive and analyse safety information
- Reduce both time and costs involved with recruitment, staffing and training
- R.A.P.T.A.R® integrates with any safety database
- Minimal and efficient onboarding process and operates globally

R.A.P.T.A.R® FAMILY

As R.A.P.T.A.R® has evolved, so has the level and breadth of services available. In addition to enabling clients to fulfil their post marketing requirements, through automating spontaneous capture and reporting of adverse reactions across multiple product types, R.A.P.T.A.R® also provides clients with the ability to monitor and process reactions found during the clinical phase, in addition to assisting and automating literature searching activities, for their products.



R.A.P.T.A.R® Reporting: The new, unique, validated and automated case data capture and processing tool, designed to connect with any safety database and overcome the many issues associated with manual data capture and case processing for drugs/cosmetics/devices/vaccines and more!

R.A.P.T.A.R® Clinical: A movement away from the traditional, outdated, paper-heavy processes associated with Clinical Trial adverse event reporting, R.A.P.T.A.R® Clinical reduces the time taken to report incoming safety information; improve report quality through identifying errors in real time and enable rapid patient safety reporting on behalf of Sponsors!

R.A.P.T.A.R® Reader: Moving beyond simplistic abstract review, R.A.P.T.A.R® Reader assists with full-text article review that goes far beyond existing practice, providing Companies with an optimised approach to sourcing and sorting adverse event data – and much more!

With R.A.P.T.A.R®, companies now have direct access to a complete, all-encompassing solution for not only meeting but exceeding regulatory expectations!

REPORTING

R.A.P.T.A.R® REPORTING OVERVIEW

Designed with over 150+ years combined PV experience, our R.A.P.T.A.R® case data capture and processing system simply captures safety data globally, identifies and targets inaccurate data; chases follow-up; eliminates errors, and integrates with any safety database to help automate your case processing and overcome increased reporting demands of adverse reactions for drugs, cosmetics, devices, vaccines, pregnancy cases and much more!

Case Quality and Data Accuracy

- Capture of 4 key criteria
- Required and Important Fields
- Limited free text fields
- MedDRA Patient Friendly & HCP Terms & definitions
- Accessible for easy use by Partner Companies/Affiliates/ Distributors in Various Countries
- Pregnancy Form and baby ADR form built in
- Built with ICH E2B Fields and complies with EDQM enabled profiles
- Each version of a report can be exported in R3 XML and PDF
- Analytics

Follow-up

- Client can determine which fields require follow-up
- Configurable frequency of follow-up and timescales
- Includes long-term follow-up and R.A.P.T.A.R® intelligent decisions for follow up
- Each submission is recorded as new version
- Auto-closure once all follow-up attempts have been reached

Speed

- Speeding up single case processing over 80%
- 24/7 access
- Seamless QR code –Website link access
- No account required
- Dynamic, linear form process – Can be completed in 5 minutes
- Expedited E2B XML R3, PDF Report
- Instant confirmation email/text
- Drag-and-drop import into safety database

What Our User Testers Thought

- 100% positive response rate
- 90% would actively use an automated tool
- 80% strongly agreed/agreed that there is a demand for greater patient involvement for reporting adverse reactions
- PV professionals rated 4.3/5 stars
- 100% agreed the pharmaceutical industry would benefit from greater integration of automation

RAPTAR® REPORTING

REPORTING FEATURES

RAPID	QR code access, Linear Form Build, Dropdown Fields
AUTOMATED	Required Fields, Absent/Nonsense Data Checks, MedDRA Patient Friendly and Healthcare Professional (HCP) Terminology Configurable Follow-up
PROCESSING	Individually Submitted Reports, Multi-Device and Multi-Browser Compatible, Data Capture per page, Case Closure
TRACKING	Exportable as XML, PV Reviewable, Full Audit Trail, Tailored KPIs and Analytics
ADVERSE REACTIONS	Caters for all variations of ADRs Across all Report Types (Drugs; Cosmetics; Devices; Vaccines and Pregnancy), Captures 4 Minimum Criteria (Reporter; Reaction; Patient and Product), Supportive Document and Imagery Upload

REPORTING

R.A.P.T.A.R® REPORTING PACK

R.A.P.T.A.R® has the ability to report a variety of adverse reactions, for a multitude of products, and for both post marketing and clinical – with both maternal and paternal pregnancy exposure enabled for all report types – including a baby ADR form.

DRUGS

RAPTAR® REPORTING

REPORTING PACK

COSMETICS

RAPTAR® REPORTING

DEVICES

RAPTAR® REPORTING

VACCINES

RAPTAR® REPORTING

PREGNANCY

RAPTAR® REPORTING

VETERINARY

RAPTAR® REPORTING

ADVANCED THERAPY ADR

RAPTAR® REPORTING

REPORTING PACK FEATURES

Drug and Medicinal ADR reporting made accurate with R.A.P.T.A.R®

Specialised data fields for not only capturing four minimum criteria, but also additional important data fields with nonsense checks for accuracy and much more...

Cosmetic AE reporting made quicker with R.A.P.T.A.R®

Unique cosmetic data fields, relevant to the cosmetic, which include site of undersirable effect, product picture capability, easier customer engagement with consumer friendly data fields and much more...

Medical Device ADR reporting made simple with R.A.P.T.A.R®

Specialised data fields for lot number, photo upload, model and serial #, including combination (drug-device) products and much more...

Vaccine ADR reporting made easier with R.A.P.T.A.R®

(specialised data fields for batch #, boosters, units, pregnancy exposures and much more...)

Pregnancy ADR reporting made possible with R.A.P.T.A.R®

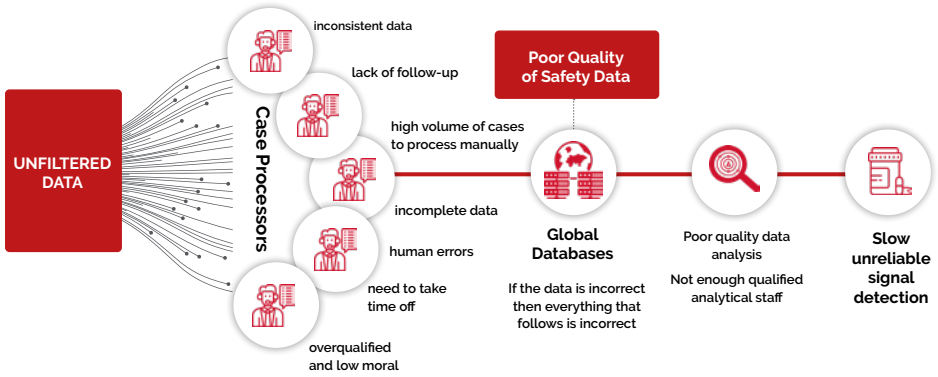
Specialised data fields for Maternal and Paternal pregnancy exposure and outcome, with baby ADR form and much more...

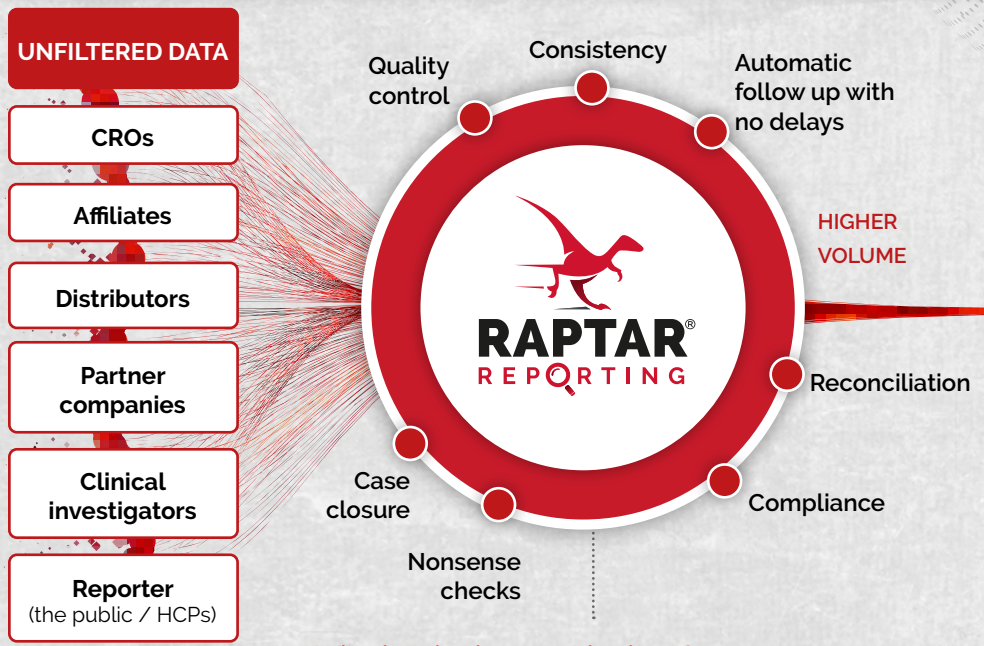
REPORTING

WHERE R.A.P.T.A.R® REPORTING FITS

REPORTING

PROCESS WITHOUT R.A.P.T.A.R®





Structured data and improved quality of Safety Data

What is going into your database?
How complete are your cases?
RAPTAR can answer regulatory authorities questions on quality
MHRA can fine you and your products removed from market
You don't want to be penalised if not done properly

PROCESS WITH R.A.P.T.A.R®

R.A.P.T.A.R® REPORTING PACKAGES

We appreciate all clients are not the same, and require different levels of access and usability of the R.A.P.T.A.R® system.

That is why we have designed various levels, from Diamond to Silver, for our clients depending upon your needs. Migration between levels is simple if your requirements change, giving you flexibility when you need it.

R.A.P.T.A.R® is far more than a system, it is a strategy for your overall Pharmacovigilance approach to Quality and Compliance.

SILVER

GOLD

PLATINUM

DIAMOND

These levels are explained in our demonstration of R.A.P.T.A.R®, so that you get the full picture of all of the options open to you.

BOOK YOUR DEMO TODAY!

REPORTING

AN INNOVATIVE

ONLINE TOOL

RAPTAR®

BOOK YOUR DEMO TODAY!

and find out how R.A.P.T.A.R® can help your business RAPTAR@PHARSAFER.COM

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STAY TUNED

Stay tuned for future developments – R.A.P.T.A.R® will continue to evolve

REMEMBER

Remember – Don't just elevate your Safety – Transform it with R.A.P.T.A.R®

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