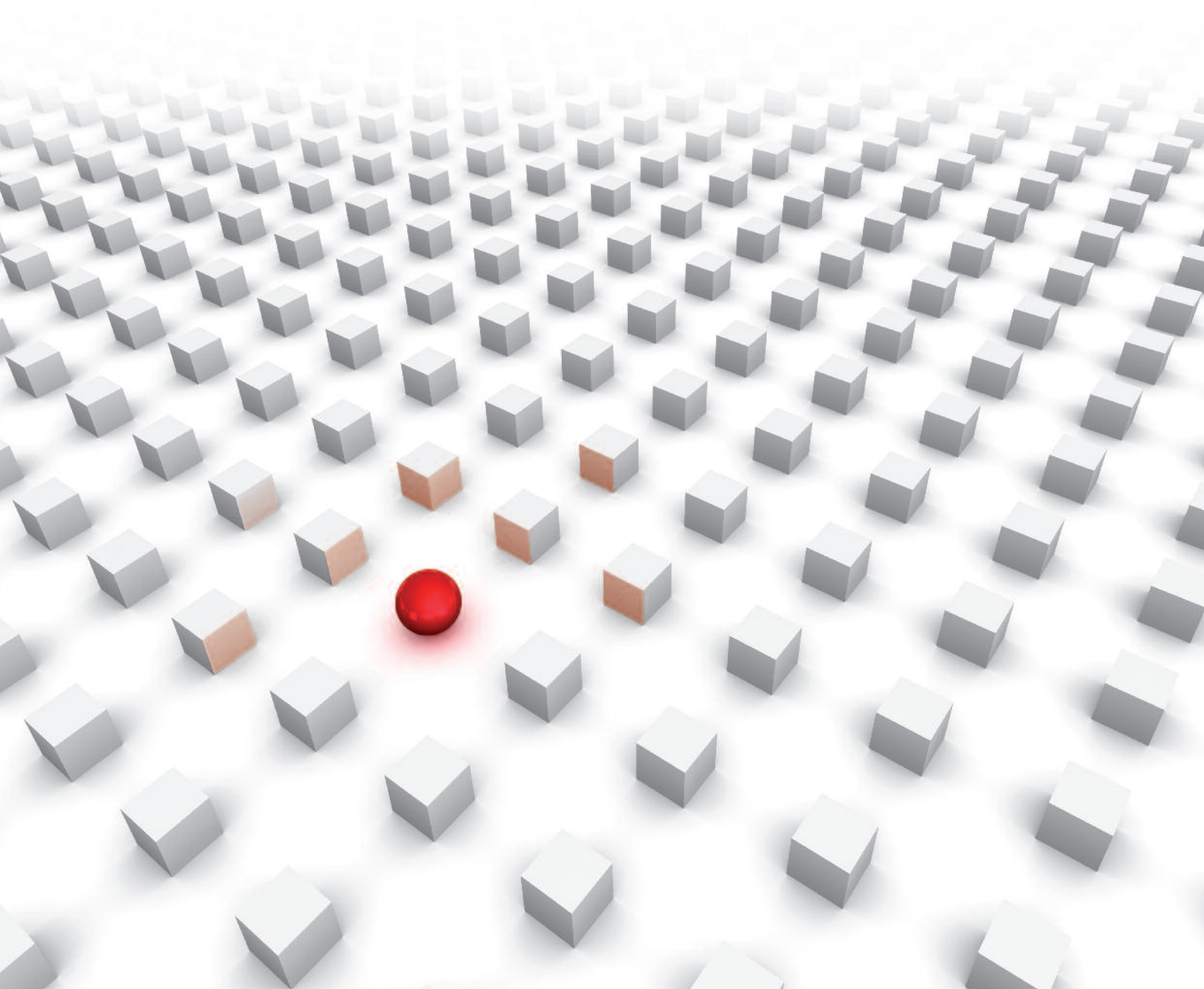




PIERREL RESEARCH

# Drug Safety Solutions



## Our Solution for the safety of your project

The safety of medicines is an essential part of patient safety. The rapidly increasing scrutiny on drug safety issues, and an increasing number of regulations and risk management commitments have led to increased safety data collection, analysis and regulatory surveillance, which in turn have increased costs.

Pierrel Research offers a comprehensive portfolio of services for the active management of product safety and patient health during the entire lifecycle of a product, helping you manage your pre- and post-marketed product safety program.

Our global reach, quality system approach, leading technology for SAE and AE cases management and reporting, combined with a multi-disciplinary safety expertise offers true value and key benefits to pharma, biotech and device companies.

Pierrel Research is your strategic partner with specific product safety expertise who can minimize your current cost pressure while unlocking value and maintaining compliance.



## Pharmacovigilance Services

- Adverse event (AE) and serious adverse event (SAE) data collection, logging , tracking , coding and case processing
- MedDRA and WHO-DD coding
- Web-based SAE reporting tool, **Hyper-eSAE®** for immediate SAE notification from clinical trials
- AE and SAE evaluations
- SAE narrative writing
- Physician medical review and signal detection
- Literature reviews and summaries
- Generation of CIOMS I /MedWatch 3500A forms
- Preparation of Annual Safety Reports from clinical trials
- Expedited reporting to competent authorities, ethics committees and investigators
- Electronic expedited reporting via EVWEB, provision of Responsible Person for EudraVigilance and certified users for EVWEB
- Electronic expedited reporting of Individual Case Safety Reports
- Preparation and submission of PSURs
- Development of Risk Management Plans
- Set-up of the pharmacovigilance system of MAH/applicant for marketing authorization
- EU QPPV/deputy QPPV
- Web-based, ICH E2B- compliant safety database, HyperVigilance®, validated in-line with GAMP 5 and 21 CFR 11

## Medical Monitoring

Medical monitoring is provided by licensed physicians who have extensive experience in clinical development and review of SAE and AE cases.

- Assessing subject eligibility
- Evaluating study protocols and informed consents
- Analyzing and reporting serious adverse events (SAEs)
- Tracking participants' safety throughout the trial
- Assessing the benefits and risks on an ongoing basis
- Identifying safety signals and safety trends

## Medical Writing

Regardless of your product study phase, our highly skilled medical writers can save you time and costs by clearly and accurately writing the medical documents your development program requires. We will provide you with thoughtful, cohesive medical documents that will stand up to regulatory and industry scrutiny. Below are examples of the various medical documents we routinely write:

- Trial synopses, protocols and amendments
- Patient information sheets & informed consent forms
- Case report form (CRF) design
- Patient questionnaires & diaries
- Investigator Brochures
- Standard operating procedures (SOPs)
- Summary of clinical safety/ISS
- Integrated summary of efficacy (ISE) reports
- Non-clinical pharmacology and toxicology
- Benefit-risk analyses
- Integrated clinical trial reports (ICH E3) / interim reports
- Common Technical Documents (eCTDs)
- Patient narratives (for safety reporting)
- Periodic safety update reports (PSURs)
- Periodic adverse drug experience reports
- SAE narratives
- Regulatory reports
- Responses to deficiency letters
- Workshop presentations, abstracts, and posters
- Newsletters, advertisements for clinical studies
- Systemic literature search
- Publications for medical journals
- Review & editing of manuscripts in terms of language/ grammar, scientific content, journal instructions, revision towards the view of journal editors and suggestions of reviewers

## Medical Consulting

Our medical experts will help you develop effective strategies to making accurate safety assessments to ensuring regulatory compliance in your medical reports. Together with the regulatory team, they will help you design appropriate clinical trials and ensure an efficient regulatory submission strategy to expedite your product approval and commercialization. Our medical consulting services include:

- Strategic planning throughout the registration process
- Strategic planning in the designing of efficacy and safety clinical trials
- Assessing regulatory compliance of the product development plan
- Identifying safety signals and determining significance
- Developing Pre-registration meeting packages
- Providing medical review of your safety data
- Providing benefit-risk assessments

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