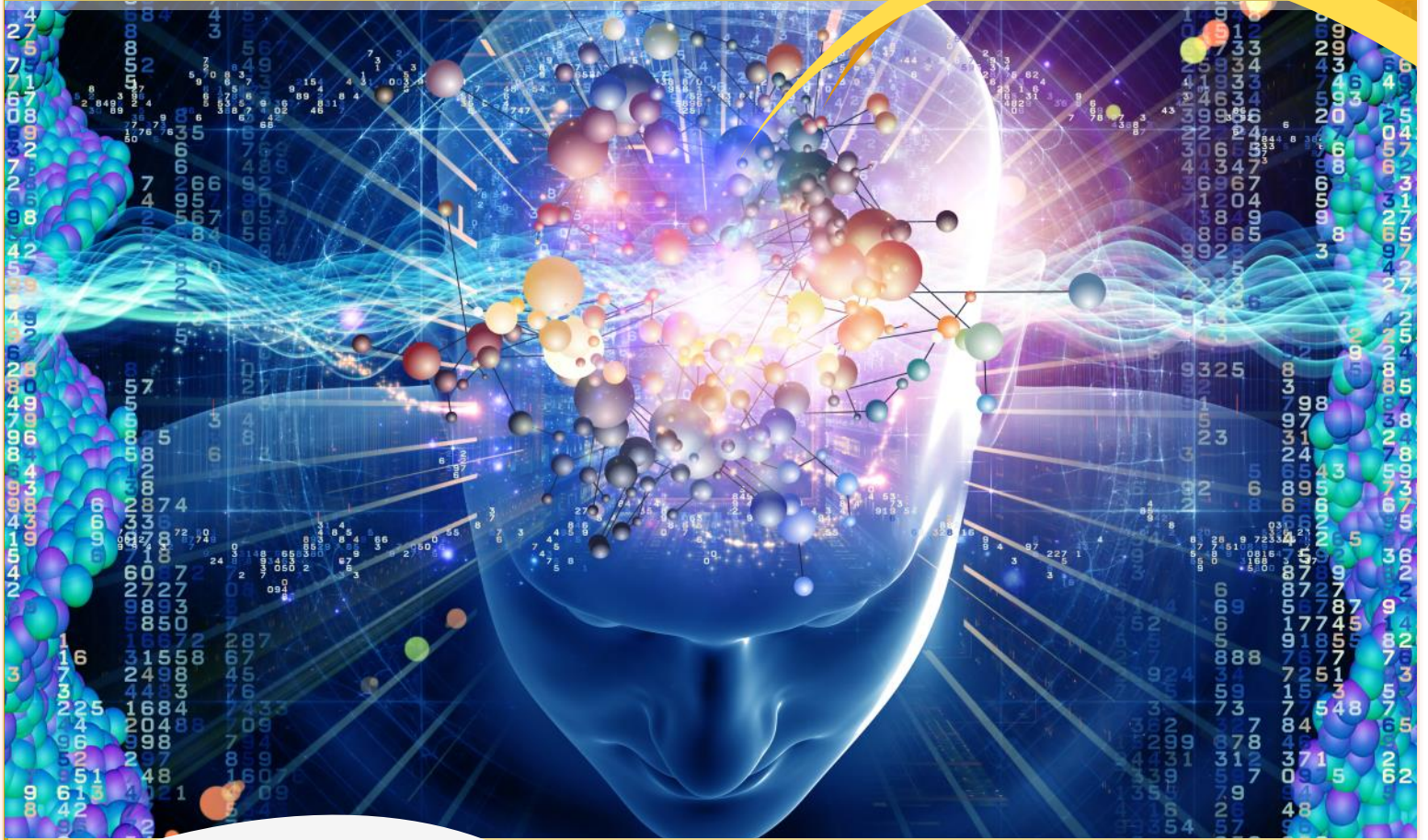


# DRUG SAFETY SERVICES



Case Processing  
Aggregate Reporting  
Risk Management  
Signal Management  
Literature Search  
Drug Safety System Set-up & Support



**DDReg**

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drug safety expertise & services”*



## ***“Drug Safety Services that make the difference”***

### **MAKE YOUR BUSINESS DRUG SAFETY COMPLAINT FOR GLOBAL OPERATIONS**

The need to fully understand the risks and benefits of drug products through all phases of their lifecycle is ever increasing. Therefore, for a pharmaceutical organization it is important to rely upon a Drug Safety system that efficiently captures and processes risks as well as benefits, reports them in a time bound manner to ensure regulatory compliance. DDRReg delivers on all of these expectations.

DDRReg’s comprehensive set of services across all phases of the product lifecycle are based on latest global Drug Safety/ Pharmacovigilance Regulations. DDRReg team is involved in drug safety services, collates, processes and compiles relevant safety information from all sources, including individual cases, published literature and clinical studies to facilitate client organizations to take decisions related to drug safety, that are logical and evidence-based.

There are many good reasons for global pharmaceutical organizations to prefer DDRReg as its partner. Key ones are:

#### **Functional Expertise**

- Standard Operating Procedures & Working Guidelines that define global Drug Safety standards
- Consistent monitoring & tracking of global Drug Safety/ PV Regulations/Guidelines

#### **Operational Excellence**

- Strong Quality Management System
- Process Consistency, Robust Templates, Proven Project Management

#### **Compliance to Global Drug Safety Requirements**

- Processes developed in line with requirements of Global agencies e.g US FDA & EMA
- Strong Reference base of various agency requirements, WHO, ICH, US FDA & EMA Drug Safety Practices

### **CASE PROCESSING**

- Spontaneous, Clinical Trial, Literature, Regulatory
- Triaging
- Data Entry (E2B fields)
- MedDRA Coding
- Quality Checks
- Narrative Writing
- Medical Reviews
- Follow Ups
- Agency Reporting via Electronic Submission Gateway (ESG)

### **RISK MANAGEMENT**

- Risk Evaluation and Mitigation Strategy (REMS)/ Risk Management Plans
- Signal Detection, evaluation and Reporting

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## AGGREGATE REPORTING

Authoring and compilation of

- Aggregate Reports – PADERS, / PBRERS/PSURS
- Annual Safety Reports
- eSubmission of PADERS

## DRUG SAFETY SYSTEM SET UP

- Development of Standard Operating Procedures (SoPs) and Working Guidelines (WGs)
- Process Flows and reporting templates
- Safety Data Exchange Agreements
- Trainings on SOPs/WGs, Regulations and Stakeholder Obligations
- QPPV Services
- Literature Surveillance
- Legacy Data Migration
- MedDRA Maintenance
- Pharmacovigilance Safety Master File
- Compliance Audits
- 24 X 7 Call Intake



## DDREG TEAM

- Led by Experts with combined experience of ~ 60 years in handling global Drug Safety & Medical writing work
- Efficient Drug Safety Structure with experienced groups handling each stage of safety management
- Extensive trainings on all critical aspects of Drug Safety Management (e.g GVP, ICH, US FDA, MedDRA, Signals)

## DATABASE & IT INFRASTRUCTURE

- Inhouse expertise in all major safety databases that include Argus® , ArisGlobal® and PcVmanager™.
- On-site commissioned PcVmanager™ - fully validated, in compliance to 21 CFR Part 11 and E2B(R3) standards.
- Cloud access on Argus® provided by client.
- Consultant Partner to Extedo, Germany
- Efficient procedures for Data security and disaster management along with in-house developed e-processes and secure FTP servers.



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## Quality Driven by Passion @DDReg

We stand committed to high QUALITY of services for global markets in cost efficient manner. By QUALITY we mean more than just services meeting our own specifications. It means meeting customers' requirements and ensuring QUALITY at all levels of dealing with our customers.

When we think of QUALITY, our aim is therefore to continuously meet and exceed the quality levels expected by our customers in everything we do!



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