



**Complete !**  
**Correct !**  
**Consistent !**  
**Compliant !**

**Your Responsibility Our Passion**



**Consulting**  
**Onsite Services**  
**Off-site Services**  
**Support**  
**Training**

**Simplifying Pharmacovigilance and Regulatory Services**  
**4C is ISO 9001:2008 Certified**

**CASE PROCESSING**  
**LITERATURE SEARCH**  
**MEDICAL INFORMATION**  
**PERIODIC REPORTS**  
**SIGNAL DETECTION**

**REGULATORY SUBMISSION**  
**RISK MANAGEMENT**  
**LABELLING UPDATES**  
**MEDICAL WRITING**  
**TRANSLATION SERVICES**

# Seamless expertise and technology at work

Your **Responsibility** Our **Passion**

## COMPLETE

We provide comprehensive Pharmacovigilance and Regulatory services



## COMPREHENSIVE SAFETY SERVICES WE PROVIDE

- ▶ Collection of Safety reports through Call Center, Fax, Email
- ▶ Case Registration and Triage
- ▶ Full Data Entry
- ▶ MedDRA and WHO-DD Coding
- ▶ Narrative Preparation
- ▶ Quality Control
- ▶ Case Follow-up and Tracking
- ▶ Medical Review
- ▶ Literature Monitoring
- ▶ Expedited and Periodic Reporting
- ▶ Compliance Tracking
- ▶ Signal Management
- ▶ Risk Management Plans
- ▶ Training on Argus, ARISg

## CORRECT

We perform correct actions necessary to provide best quality of services

## CONSISTENT

We enhance quality and speed of services with consistent results



## KEY BENEFITS WITH 4C PHARMA SOLUTIONS

- ▶ Reduce the burden of in-house Pharmacovigilance to focus on R&D
- ▶ Owned and Managed by expert Pharmacovigilance professionals
- ▶ Cost-efficient, turnkey solutions
- ▶ Prevalidated **Argus** safety database for case processing
- ▶ Comply with FDA mandate for electronic submissions with **Axway**
- ▶ Leverage **ISO certified** 4C processes to improve quality
- ▶ Support across time zones for enhanced patient care
- ▶ Trained team for rapid start-up and ramp up of operations
- ▶ Enhance quality, consistency and speed of case processing
- ▶ Increase operational efficiency while reducing costs
- ▶ Improve compliance and adherence to global regulations
- ▶ Flexibility to adapt rapidly to fluctuating volumes of cases
- ▶ Handle regulatory inspections effortlessly with confidence



## COMPLIANT

We adhere to regulations and service level agreements to improve compliance



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