C3i SOLUTIONS

An HCL Technologies Company

# Pharmacovigilance & Medical Information

## Transforming Patient Safety & Inquiry Management through Innovative and Integrated Services

Our significant PV and Medical Information expertise, operational excellence and global scale put us in a unique position to accommodate all of your product safety needs from intake to regulatory reporting, in all geographies and in multiple regulatory environments, whether human or animal health, PV, inquiry management around cosmetics or other, we have the expertise. C3i Solutions has a 30+ year history of handling complex and sensitive interactions in the life sciences industry, backed by the acquisitions of Sentrx Safety Solutions and C3i.

## Medical Information Services

### Medical Information Contact Center

**Global, multi-channel, multi-lingual operations providing best-in-class medical inquiry management**

C3i Solutions effectively and empathetically delivers medical information to consumers and healthcare professionals, while helping our clients better understand their target market, control costs and compete strategically.

- 150+ Healthcare Professionals on Staff
- Primary Intake for Adverse Events and Product Quality Complaints

### Medical Writing

**At C3i Solutions we leverage our vast experience with many life stages and disease state documentation to deliver complaint and on time collateral.**

- Frequently Asked Question creation
- Standard Response letter creation

# Pharmacovigilance Services

## Safety Medical Writing

### Experienced Medical Writing staff with healthcare degrees and pharmacovigilance experience ensures that PV documents are thoughtfully authored to meet regulatory and PV specifications.

By crafting content, documenting and formatting regulatory reports to meet country specific regulations, C3i Solutions ensures pharmaceutical, biotech and medical device companies unrivaled safety medical writing documentation.

- Serious Adverse Event Narratives
- Drug Safety Update Reports (DSUR)
- Periodic Safety Update Reports (PSUR)/PBRER format
- Periodic Adverse Drug Experience Reports (PADERs)
- Benefit Risk Assessments
- Risk Management Plans
- Informed Consent Forms (ICFs), Subject Information Sheets (SISs) Quality checks for all documents

## Global Adverse Event Case Processing / Regulatory Support

### Our PV Staff consists of experienced healthcare professionals who are empowered to use their clinical and PV knowledge base when assessing and processing safety information

The flow of safety information is based on a collaborative model, whereby our safety scientists immediately triage each case and enter the data into the safety database in accordance with governing data entry conventions while performing necessary follow-ups prior to submission.

## Safety Database Systems Hosting and Managed Services

### We Focus on the Technology While you Focus on your Core Services

- Hosting services for Oracle Argus Safety systems
- Oracle Argus Safety System Management and Administrative services

**Low cost of ownership**

**No internal validation effort**

**Audit Readiness**

**Low burden on internal IT resources**

**Reduced time/case**

**Superior quality up-time for high performance safety processing**

## Partner with C3i Solutions for significant Pharmacovigilance and Medical Information expertise on a global scale.

### Contact C3i Solutions

**C3i Solutions, an HCL Technologies company, is a multichannel customer engagement services provider, specializing in global, high-touch consumer, patient and end user engagement. www.c3isolutions.com**