Med COMMUNICATIONS
The Right Partner. The Right Resource.

With over 20 years of medical affairs experience in the pharmaceutical, biotech, and medical device industries, Med Communications has emerged as a leading medical affairs service provider.

https://medcommunications.com/
info@medcomminc.com
877-477-0977

PHARMACOVIGILANCE CONSULTANCY

- Assist in building client PV department
- Advise client with data migration and oversight
- Help with data migration tasks and oversight
- Provide guidance & supports in development of PV SOP's
- Onsite or remote regulatory inspection support
- Support on safety database including due diligence, setup, configuration, validation, data, migration and activities

CASE MANAGEMENT

Case Intake
- Manage intake and documentation of source information

Case Triage
- Conduct assessment of case specifics
- Perform duplicate case checks
- Perform medical assessment if needed
- Perform additional triage per client request

Case Reconciliation
- Capture PC investigation results and reconcile AE/PC cases
- Reconcile cases from call center
- Reconcile cases sent by any other means (business partner, E2B, EDC)

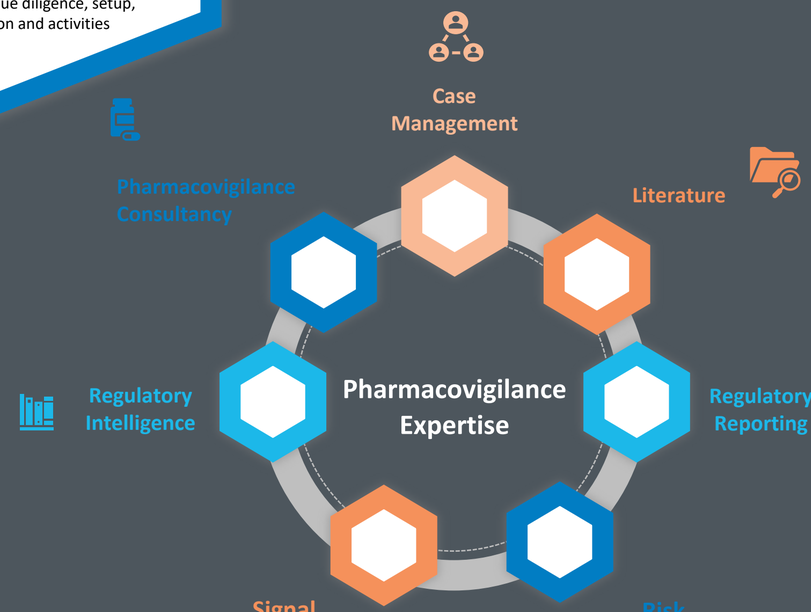
Case Processing
- Perform case entry (enter case data)
- Assess events for listedness/ labelness, and coding of patient history, product, and event information
- Write narratives
- Perform case coding activities (MedDRA, WHO Drug)
- Prepare and conduct follow-up on cases as needed
- Perform quality check and quality assurance activities on cases
- Provide medical review to fully support medical assessment
- Write periodic report case comments
- Route case per workflow

LITERATURE

- Provide a validated literature database
- Prepare literature strategy
- Validate literature review parameters
- Complete literature review
- Monitor EMA medical literature
- Identify terms
- Monitor global medical literature
- Identify terms of special interest

REGULATORY INTELLIGENCE

- **Regulations/Guidance**
  - Monitor via Pink Sheet (weekly)
  - Monitor via Safety Observer (monthly)
  - Monitor RSS feeds from regulators
  - Monitor regulatory websites
  - Attend PV-related conferences/meetings
- **Database**
  - Attend user group meetings to learn of new features and updates
  - Participate in testing and validation of new features and updates
  - Provide feedback on data tests, requirements, design specifications, new features to software developers



REGULATORY REPORTING

- PADER
- DSUR
- PSUR / PBRER
- IND Annual Report
- Canadian PBRER
- Non-expedited submissions
- Routine safety listings
- Expedited reporting
  - Marketed product
  - Clinical trials
- Aggregate reporting

SIGNAL MANAGEMENT

- Aid in signal detection
- Aid in investigation activities
- Run reports to support signal detection activities
- Track and document each signal or potential signal identified in client signal tracking tool
- Provide evaluation and prioritization of confirmed signals
- Prepare benefit-risk analysis and recommended action plan for the identified signal with input from PV physician and client personnel
- Conduct routine safety surveillance meetings with client personnel
- Assist client in determining appropriate communication plans as necessary for the identified signal and provide support for the communication plan
- Coordinate and document periodic safety surveillance meetings by PV Specialist
- Provide medical expertise and lead safety surveillance meeting activities by PV Physician

RISK MANAGEMENT

- Aid in risk evaluation and mitigation strategies documentation
- Provide guidance in REMS and RMPs and facilitate the elements of each document
- Regulatory communications
- Healthcare communications
- Respond to ad hoc requests
- Monitor effectiveness of safety mitigation measures

With years of experience delivering regulatory support for our clients' pharmacovigilance needs, our highly qualified team of safety professionals adheres to good pharmacovigilance practices with timely regulatory screening and reporting of adverse events and product complaints.

Is your PV department ready for an inspection by the FDA, EMA, or other regulatory bodies? With over 20 years of experience, our PV experts can help you identify potential areas of concern and suggest a plan for improvement. Let us help you perform your audit to verify you are ready for inspection! If you want more information on our pharmacovigilance services, contact us: 877-477-0977 or info@medcomminc.com.

Legend:
AE, adverse event; DSUR, Development Safety Update Report; EDC, electronic data capture; EMA, European Medicines Agency; FDA, Food and Drug Administration; IND, Investigational New Drug; PADER, Periodic Adverse Drug Experience Reports; PBRER, Periodic Benefit Risk Evaluation Report; PC, product complaint; PSUR, Periodic Safety Update Report; PV, pharmacovigilance; REMS, Risk Evaluation and Mitigation Strategies; RMP, Risk Management Plan; SOP, standard operating procedures.