Greetings…!!

Adaptis is established in August 2020, headquartered at Panaji, Goa, India and operational office at Pune, Maharashtra, India. We offer customizable and professional cost-effective global pharmacovigilance services to generic industries as listed below.

Global Pharmacovigilance Services:

Adaptis provides comprehensive global pharmacovigilance services including:

1. Consultancy, Project Management and SOP Development
2. Individual Case Safety Report (ICSR)
3. Safety Data Management and Global Safety Database
4. Medical Literature Monitoring (MLM)
5. Aggregate Reports (PADER/PSUR/PBRER/DSUR/ACO)
6. Signal Detection and Evaluation
7. EudraVigilance/USFDA SRP Management
8. Risk Management Plan (RMP)
9. Pharmacovigilance Site Master File (PSMF)
10. Safety Data Exchange Agreement (SDEA)
11. Qualified Person for Pharmacovigilance (QPPV)
12. Medical Information Call Center (MICC)
13. Pharmacovigilance System Audits

Clinical Trial Pharmacovigilance:

Adaptis provides comprehensive pharmacovigilance services for clinical trials, including:

1. **Adverse Event Reporting:** Systematic collection, assessment, and reporting of adverse events
2. **Risk Management**: Identifying, evaluating, and mitigating risks associated with clinical trials
3. **Regulatory Compliance:** Ensuring all activities comply with relevant regulatory guidelines and requirements
4. **Safety Monitoring:** Continuous monitoring and assessment of patient safety throughout the trial
5. **Data Analysis**: Analysing safety data to detect potential safety signals

Post Authorization/ Marketed Product:

Adaptis provides comprehensive post-authorization pharmacovigilance services, including:

1. **Adverse Event Reporting**: Collection, assessment, and reporting of adverse events from healthcare professionals and consumers
2. **Risk Management Plans (RMPs)**: Development and implementation of strategies to identify, evaluate, and mitigate risks associated with marketed products
3. **Periodic Safety Update Reports (PSURs)**: Regular reporting of safety data to regulatory authorities to maintain compliance
4. **Signal Detection and Management**: Continuous monitoring of safety data to detect and manage potential safety signals
5. **Regulatory Compliance**: Ensuring all pharmacovigilance activities comply with global regulatory requirements
6. **Global Literature Monitoring:** Weekly/Bi-weekly Literature Monitoring for potential adverse events
7. **Medical Information Call Centre (MICC):** Accepting call via Toll free number, Call Triaging and passing information to respective departments

If you are interested to discuss your business need and our service portfolio, please feel free to reach out Adaptis.

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