EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

Session Three: Stakeholder ADR data quality activities in Europe

EMA Multi-stakeholder workshop on data quality framework for Adverse Drug Reaction reporting, 1st March 2024

James Nickas - Group Vice President, Pharmacovigilance & Clinical Medical Writing at BioMarin Pharmaceutical Inc.

Stakeholder ADR data quality activities in Europe

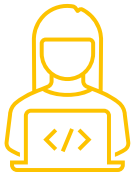
Main actors involved

Patients

Regulators

Healthcare Professionals

Researchers



Medical Coders

Drug Safety Committees

Pharmaceutical Companies

Stakeholder ADR data quality activities in Europe

EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

Current Practices to Improve ADR Data Quality

- Pharmacovigilance systems and processes
- Guidelines and standards
- Training and education
- Collaboration among stakeholders
- Emerging technologies

Challenges in measuring and improving ADR data quality

- Underreporting and reporting biases
- Incomplete and inconsistent data
- Variations across data sources
- Signal detection challenges
- Evolving data standards and practices

Stakeholder ADR data quality activities in Europe

Overview of ADR Reporting Routes and Data Quality Challenges

Spontaneous Reporting Systems
- Underreporting and reporting biases
- Incomplete information
- Duplicate reporting

Patient Support Programs
- Patient self-reporting
- Overreporting
- Incomplete information

Electronic Health Records and Claims Data
- Coding inaccuracies
- Missing data
- Confounding factors

Clinical Trials and Post-Marketing Studies
- Limited generalizability
- Limited follow-up
- Reporting biases