



Pharmacovigilance Services Section Home

History

The history of pharmacovigilance dates back to the mid-20th century when a few tragic incidents, such as the thalidomide disaster, highlighted the imperative to monitor drug safety post-approval. Thalidomide, prescribed to pregnant women, led to severe birth defects. In response, pharmacovigilance systems were initiated globally to prevent similar tragedies. The World Health Organization (WHO) established the International Drug Monitoring Program in 1968, which laid the foundation for systematic reporting and analysis of adverse events associated with drugs. Since then, pharmacovigilance has evolved to include advanced technologies, international collaborations, and comprehensive regulatory frameworks.

William McBride

His advocacy in exposing the thalidomide tragedy emphasized the importance of drug safety surveillance.

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Ralph Edwards

A prominent figure in international pharmacovigilance efforts, Edwards played a key role in the WHO program.

Industrial Applications

1.

Signal Detection

Identifying potential safety concerns through data analysis and statistical methods.

3.

Post-Marketing Surveillance

Monitoring drugs once they are on the market to identify rare or delayed adverse events.

5.

Drug Withdrawals

Detecting serious safety issues that may warrant the withdrawal of a drug from the market.
7.

Vaccine Safety Monitoring

Assessing the safety profile of vaccines through surveillance systems.
9.

Pregnancy and Lactation Safety

Evaluating the risks and benefits of medication use during pregnancy and breastfeeding.
11.

Global Pharmacovigilance Networks

Collaborating across countries to share safety information.
13.

Pharmacovigilance in Clinical Trials

Monitoring safety data during drug development.
15.

Real-World Evidence Generation

Using post-market data to inform regulatory decisions.
17.

Patient Engagement

Incorporating patient perspectives in pharmacovigilance activities.
19.

Pharmacovigilance Education

Raising awareness and training healthcare professionals on reporting ADRs.

Big Data and AI

Harnessing artificial intelligence for more efficient signal detection and analysis.
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Digital Health Platforms

Leveraging electronic health records and wearable devices for safety monitoring.

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Pharmacovigilance in Developing Countries

Strengthening pharmacovigilance systems globally.

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Multi-Drug Interactions

Studying interactions between multiple drugs and their safety implications.

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Real-World Evidence Integration

Incorporating real-world data to inform regulatory decisions.

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Social Media Monitoring

Expanding the use of social media data for safety signal detection.

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Advanced Analytics

Applying advanced statistical and machine learning techniques for signal detection.

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Drug Repurposing

Using pharmacovigilance data to identify new therapeutic uses for existing drugs.

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Rare Events Detection

Developing methods to detect rare adverse events more effectively.

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Education and Training

Enhancing pharmacovigilance education for healthcare professionals and the public.

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