International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 6 Nov - Dec 2025, pp: 940-959 www.ijprajournal.com ISSN: 2456-4494

Pharmacovigilance Ensuring the Safe Use of Medicines

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Date of Submission: 05-12-2025 Date of Acceptance: 12-12-2025

ABSTRACT:-
Pharmacovigilance is an essential part of the health-care system focused on maintaining the safety and effectiveness of pharmaceutical products.
It deals with continuous observing, evaluation and prevention of harmful effects of the drugs to protect patients and improve therapeutic outcomes. The field encompasses cooperation within medical practitioner, supervisor authorities, pharmaceutical industries, as well as patients to maintain public trust on drug risk management.
As a part India, the establishment of the Programme of pharmacovigilance in India and adherence to ICH guidelines have strengthened the nation's regulatory framework for drug safety. Moreover, the integration of high-tech solutions such as Machine Learning (ML), Artificial Intelligence (AI),and Natural Language Processing (NLP) has transformed pharmacovigilance by boosting the correctness, speed, plus potency of signal detection and data analysis.
Overall, pharmacovigilance not only minimizes the risk associated with drug therapy but also contributes significantly to public health protection by promoting rational and evidence-based use of medicines. Its advancement represents a critical step toward a safer and more reliable healthcare system.
Keywords: Medication safety surveillance, toxic effects of drugs , medicinal product safety, Artificial Intelligence, Pharmacovigilance Programme Of India, ICH

I. INTRODUCTION TO PHARMACOVIGILANCE

Pharmacovigilance means:
1 Pharmakon = Drug
2. Vigilia= to observe [1]

It addresses the investigation about unpleasant effect , side effects, along with medication associated issues. The discipline and tasks associated with the identification, evaluation, comprehension, and mitigation of the harmful effects of medicines or any additional potential medication-related issues."Represent the WHO definition of the PV . [2] Inside order to diagnose and treat diseases and other health issues, healthcare professionals must "study, advise on, or provide preventive, curative, rehabilitative, and promotional health services based on an extensive body of theoretical and factual knowledge." [3] Adverse drug reactions are unpleasant, unintended reactions that happen during amounts of medication generally administered to humans for the prevention, identification, or management of diseases, or for modifying bodily functions.[4] Pharmacovigilance is study regarding of gathering, watching, analyzing, along with assessing data taken by person togather with medical care professionals about negative effects of drugs, blood along with biotherapeutic agents , natural, sera, immunizing agent, health devices with adjunct and alternative drugs in order to detect new information about medication hazards and prevent patient harm. This entails ongoing observation, evaluation, and comprehension regarding possible harmful effects and any problems associated with drugs. Pharmacovigilance has significantly improved with the use of information technology by evaluating the benefits and risks of particular drugs, enabling improved observation and strengthening patient safety measures. Patient safety may be improved in this way. This constitutes a key component for guaranteeing the protection, effectiveness, and economic efficiency of drugs across it's life span, from development to post-approval monitoring The difficulties in preserving public trust and optimizing drug safety have grow in number. In addition to monitoring, complex pharmaceutical companies also need to proactively estimate and manage medication risk at every stage of a product's lifecycle, from development to post-market drug safety monitoring, it is crucial part for high quality medical care and the efficient use of medications. It could potentially boost self-esteem

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and gives patients and medical professionals hope in medications and helps to improve the standard of medical care. Healthcare professionals can effectively utilize their patients' treatment experiences, both positive and negative, to help medical science as well as to a better comprehension of illnesses and medications.

Role of Pharmacovigilance:

ADRs are the specific focus of pharmacovigilance. Continuous observation of the drug's effects, adverse effects, and contraindications and overt negative consequences that could lead to a severe level of morbidity and in certain situations, even death, are crucial to minimize risks and optimize benefits. Because of the drug regulatory bodies, it is necessary to have a solid . Medication risk management system to tracking undesirable effects throughout a life about a marketed product, starting with the drug development phase and to the final product.

History And Development Of Pharmacovigilance :[5,6]

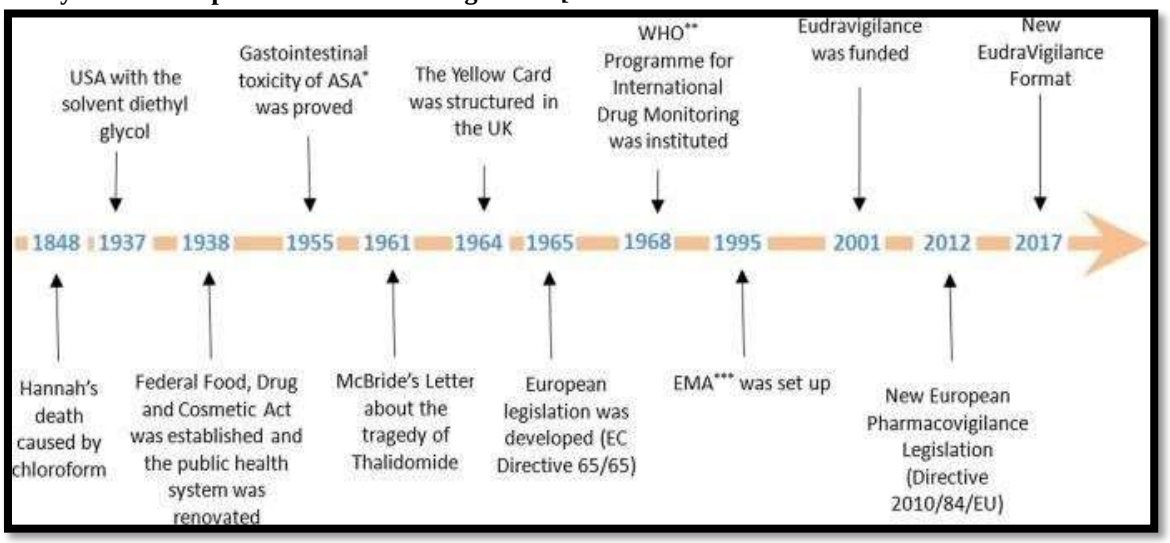

Figure 1: History And Development Of Pharmacovigilance

YEAR	EVENT
1848	First recorded drug-related death (Hannah's case linked to chloroform)
1937	Toxic reaction in the U.S. caused by administration of diethylene glycol as a diluent
1938	Introduction of the Drugs and Cosmetic Act ,U.S. Federal Food, which modernized a society wellbeing .
1955	Evidence confirmed that acetylsalicylic acid (aspirin) can cause gastrointestinal damage
1961	McBride published findings highlighting the birth defects associated with thalidomide
1964	Launch of the Yellow Card scheme for unintended drug effects informing within the UK
1965	Development regarding European pharmaceutical legislation

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1968	WHO found International Drug Monitoring Programme
1995	European Medicines Agency (EMA) officially created
2001	Funding provided for the EudraVigilance system (EU drug safety database)
2012	Updated European Union pharmacovigilance rules introduced (Directive 2010/84/EU)
2017	Implementation of a revised format for EudraVigilance reporting

Table 1 : History And Develpoment Of Pharmacovigilance

MEDICATION RELATED ADVERSE DRUG REACTIONS :

In pharmacovigilance, an medication related adverse events is termed as a harmful or unpleasant pharmacovigilance, which goal to analyse, estimate, figure out and avoid side effects of medicament.

An medication related adverse drug events is "any response to a drug which is noxious and unintended," as per the WHO [7].And which takes place at drug regime utilized by persons for treatment disease diagnosis, prevention, and for the alteration of biological process".Item to be used whether internal or external of the selling authorization, may result in adverse reactions or from exposure at work.The main reasons of illness and rate of death is thought to be adverse drug reactions Death.[8] Toxic drug reaction research can focus on the field of pharmacovigilance .The Adverse drug reactions represent a significant clinical issue. The following are some of the effects of an adverse drug reaction..

- Negative effect on the quality life of the patient
- Admission to medical facilities
- The price of medical care goes up.
- Hospital stay duration increases.
- Patients may become less trusting of their physician [9]

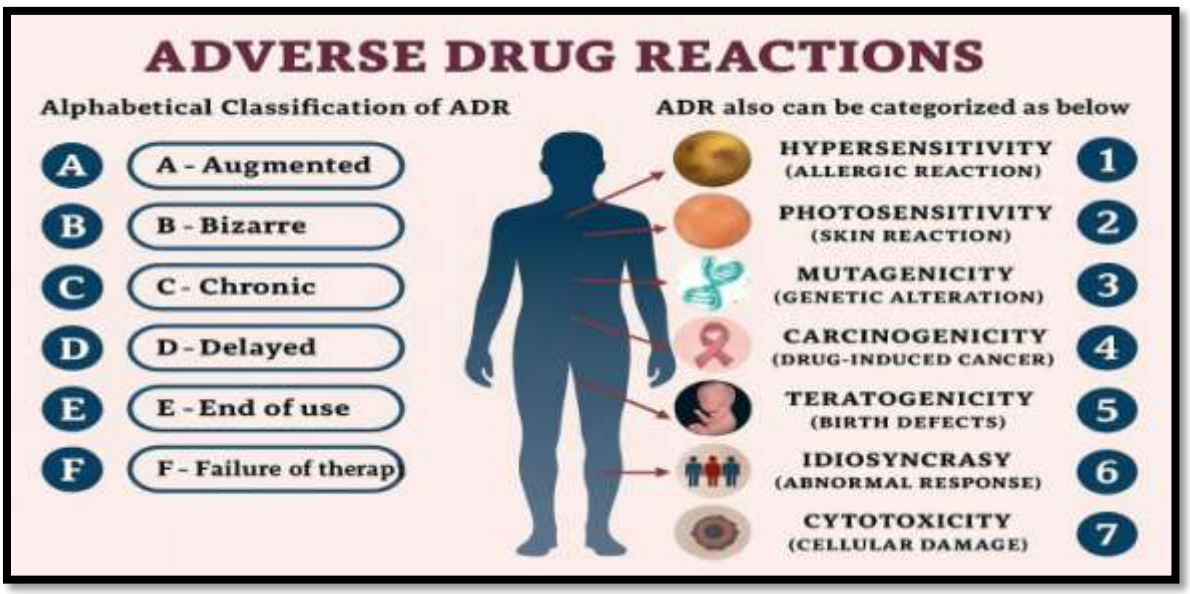

Figure 2: Classification of ADR

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Classification of Adverse Drug Reaction:[10]

Serial number	Class	Characteristics	Cases
1	A Type (Enhanced)	Fairly frequent Therapeutically expected Dose-dependent Resolves If drug is stopped	Reduced blood glucose associated with oral hypoglycemic agents Insulin induced hypoglycemia Reduced heart rate
2	B Type (Unusual)	Not dose-related, unpredictable, often allergic or idiosyncratic	Anaphylaxis from penicillin
3	C Type (Long term)	Related to prolonged administration	Involuntary movement disorder caused by antipsychotics
4	D Type (Late onset)	Occurs after some time, even after stopping the drug	Cancer from immunosuppression
5	E Type (Withdrawal)	Appears on withdrawal of medicament	seizures after Stopping benzodiazepines
6	F Type (Therapeutic Failure)	Drug fails to produce the intended effect (often due to interactions)	Antibiotic resistance due to misuse
7	G Type (Genetic)	•Produce permanent genetic harm	Birth defect causing drugs including thalidomide causes fetal genetic harm
8	H Type (Allergic)	Needs immune system involvement,	Drug induced skin allergy from antibiotics
9	U Type (Unknown mechanism)	Cause is unknown	Simvastatin use causes taste disturbance Nausea and vomiting with gaseous anesthetic

Table 2 :Classification Of ADR

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CLINICAL RESEARCH

To give precise responses about the efficacy and safety of pharmaceuticals,Clinical studies are being conducted on immunogen, complementry therapies and either creative method to utilizes current therapy conducted on volunteers. A specific research protocol developed by the producer, investigator,or researcher is monitored throughout clinical trials. Prior to the start of patient based research.The IND process is a requirement for developers, and they will when they organize the clinical research, considering its aims for all of the various stages of patient based research. Researchers formulate research questions and goals by examining the medication's current data before to the beginning of a human investigation .[11] Next, they Choose:

- Participant selection criteria
- Study time
- Dosage and dosage form administration method

Preclinical Trials:

Preclinical describes FIH studies carried Evaluation of the parameters 6. Information gathering and evaluation .

Phases Of Clinical Trials:

Out with Food And Drug Administration guidelines. Preclinical trials are additionally described as low dose human administration studies. Entail giving 10–15 volunteers individual sub therapeutic doses to obtain pharmacokinetic information or help visualize particular objectives excluding using bioactivity. Pharmaceutical companies carry out preclinical studies to ascertain from their potential drugs possesses the best ADME properties in patient.[12]

Stage 1: Risk prevention and therapeutic dose

The first drug studies with fewer healthy human subjects are called phase I trials. Stage Usually, twenty to eighty unaffected participants with the disorder or state are involved. Clients are frequently used medication's action shows that physically fit won't put up with it. However, Phase 1 trials are conducted by researchers on people with that kind of diabetes if a novel drug is recommended for those individuals. Phase 1 studies collect information on pharmacodynamics in the human body while keeping a close eye on things. To ascertain how much of a medication the body can withstand and what are its immediate adverse effects, researchers adjust the dosage schedule in light of information gleaned creature origin research. IN form of stage first study goes on, researcher gain extra knowledge regarding the efficiency and negative consequences of growing dosage as well as the mode of action. The structure of a stage second study requires this. Approximately seventy percent of medicine of drugs proceed towards subsequent stage.[13]

Stage 2: Effectiveness and adverse effects

Stage second studies involve more patient groups approximately few hundred which are designed for test those medication's effectiveness along with passing stage first security tests. To ascertain whether the .These studies are insufficient to determine whether medication will be therapeutic. Researchers can get additional safety data from studies in phase two. Researchers utilize these data to produce develop research methodologies, enhance research topics, and implement new phase 3 study procedures. About one out of third drugs move toward next stage. The most important stage second clinical studies' contribution is the identification of therapeutic dosages for the comprehensive Phase III study.[14]

Stage 3: Efficacy and adverse drug reactions monitoring :

Researchers design stage three analyses intended to show whether a if a product delivers a specific action positive outcomes for a to a specific individual. Among these studies are 300–3,000pivotal studies, as they are sometimes called. Most of the safety information supplied by phase 3 studies. It's possible that less common negative effects were overlooked in the prior trial. But because phase 3 research is more extensive and includes more volunteers, the results show a great tendancy to disclosure uncommon in place of persistent undesirable effects. Concerning In clinical trials, twenty five to thirty percentage of drugs move on to the next phase. The sector can submit a request to market a drug if a pharmaceutical company offers proof evidence from preclinical, clinical, and earlier studies that the drug is secure and efficient for its intended application. Following across a examination related to all these information submitted through the drug, the food and drug administrative review team determines if it should be approved.[15]]

Stage 4 :**Post-marketing surveillance**

Following FDA approval, phase 4 trials are carried out with thousands of participants to

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evaluate long-term safety, efficacy, and detection of possible negative effects. [16]

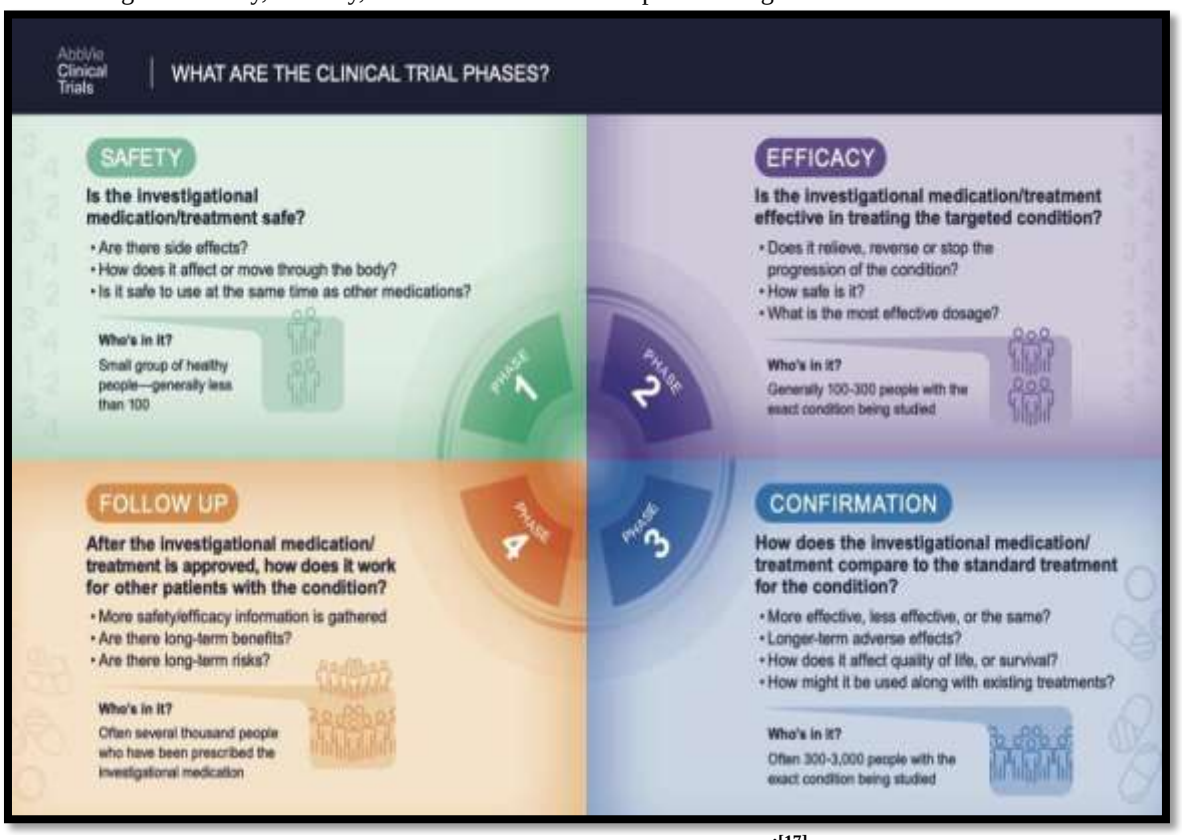

Figure 3: Phases Of Clinical Trials:[17]

The function of the Drug Controller General Of India [18]

DCGI is in charge of upholding quality and operational standards in the production, distribution, importation, and sale of pharmaceuticals in India.

1. Upholding the national reference standard is the program's goal.
2. Train drug analysts to examine cosmetic samples from CDSCO and enforce the Drugs & Cosmetics Act consistently.
3. DCGI authorizes drug licenses and establishes guidelines for pharmaceutical production, distribution, importation, and sale in India.
4. The DCGI authorizes drug licenses and establishes guidelines for the production, distribution, importation, and sale of blood, vaccines, intravenous fluids, and serum in India.

Duties of Central Drug Standard Control Organization :[19]

The Drug and Cosmetic Act controls pharmaceutical organisation selling as well as dispensing together with State government agency mainly accountable Central organisation harmful licensing of newly developed drugs, human studies, pharmaceutical specification, procure internationally product testing along with collaboration. The regulatory drug authorities grant license regarding specific categories of medicine. He acts as health administrator of Central drug regulatory authority .

1. Central drug regulatory authority grant newly formulated drug and human studies.
2. Assessment of novel pharmaceutical.
3. Entry of goods , recordation and permit.
4. Restriction of drug and personal care products .
5. Granting of testing permit, individual certification .
6. Revision of Drug and Cosmetic Act and rules .

Categories of regulatory submission for investigational new drug application: The investigational new drug application can be categorized as follows:

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A .New Drug Application

The FDA approval request is supported by an IND request for human management of a biologic or experimental medication, typically based on clinical data, safety ,efficacy, and need to have been filed earlier. The item is currently being developed and has been submitted for expanded approval to the FDA.

Pre-clinical Testing

Animal pharmacology and toxicology studies are part of pre-clinical testing to ascertain the drug's safety for human testing, taking into account prior drug experiences in humans.

Manufacturing Record

Medicinal components , production units coupled with monitoring that are applied to guarantee reliable manufacturing along with delivery related to the medication.

Experimental Result

The suitability of physicians to conduct clinical trials on research participants is assessed. Verify their eligibility to participate during patient studies.

The patient study evaluation procedure serves as foundation for investigational new drug application along with offers comprehensive guidelines related research for assess participant safety concern.

B. New Drug Application

An FDA uses the NDA as key file to evaluate manufacturing process.Quality control methods for new medications include determining their strength, quality, and purity. Drug sponsors submit a new pharmaceutical form to the food and drug administrative through the New Drug Application process approval, with thirty percent of the original applicant finishing the lengthy development process.[20]

C: ANDA

The new drug authority is an application for the common medication in the United States that is sent to data exploration department of common drugs for evaluation and acceptance. Since 2008, the number of electronic submissions has increased by 70%; however, the section IV challenge prevents new invention of drugs. The effects of pharmaceutical products are identical to those of licensed goods in conditions of medication quantity, potency, utilisation technique, efficacy, properties, efficiency, as well as use planning. It represents the use of new drugs because Although clinical trials and data are not necessary, bioequivalence must be proven by timing. To get to the blood vessel, it's time to take medication. A information filiing to the food and drug administrative for the evaluation and sanction of common medications is known as an ANDA. These medications are comparable to name-brand medications in dosage form. These medications are comparable to name-brand medications in dosage form. They have to carry out research before they can get FDA approval to demonstrate that their item efficient and "bioequivalent" to the novel medication,along with the basis medication mandatory provide the equal outcome to the capillaries of the patient.[21]

Process for Drug Approval in India:

Step	Process	Responsible Authority	Outcome / Result
1	Submission of application	Applicant → Institutional Ethics Committee (IEC)	Ethical review completed (typically within 12 weeks)
2	Filing of IND (Investigational New Drug) application	Applicant → CDSCO Headquarters	Regulatory review initiated

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3	IND examination	New Drug Division (CDSCO)	Initial assessment of submitted documentation
4	In-depth review	Subject Expert Committee (SEC/IND Committee)	Evaluation of safety and efficacy data
5	Recommendation	IND Committee → DCGI	Recommendation sent to the Drug Controller
6	Approval of IND application	DCGI	Authorization granted to commence clinical trials
7	Conducting clinical trials (Phase I–IV)	Applicant under IEC and CDSCO supervision	Collection of safety, efficacy, and dosage information
8	New drug registration	Applicant → CDSCO	Submission for marketing approval
9	Final assessment	DCGI	Comprehensive review of all trial data
10	Licensing decision	DCGI	Complete application → License granted / Incomplete → License denied

Table3: Process for Drug Approval in India

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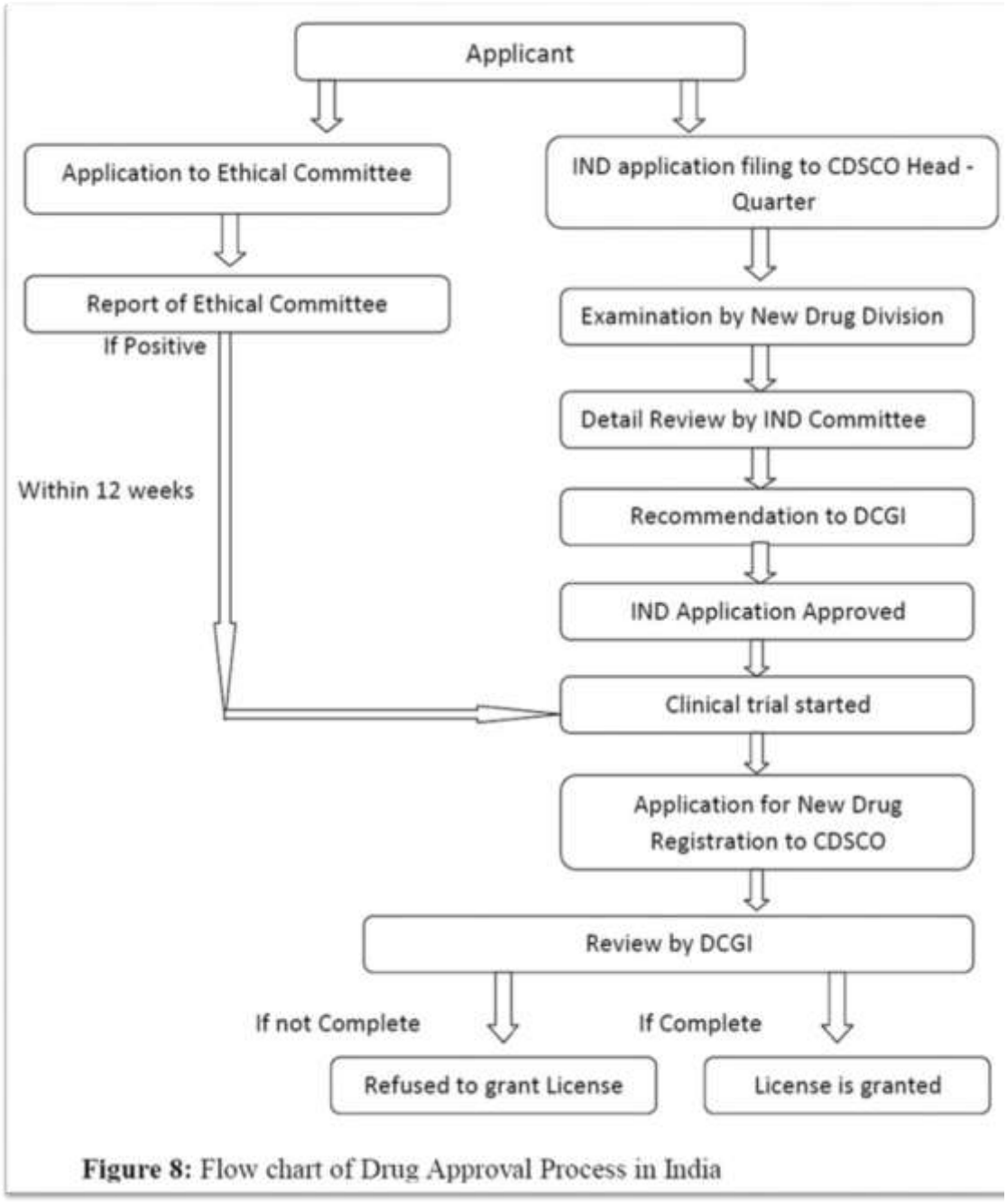

Figure 4: Flow Chart Of Drug Approval Process In India

APPLICATIONS OF PHARMACOVIGILANCE :

Adverse Drug Reaction (ADR) detection

Pharmacovigilance systems aid in the detection of uncommon, severe, or unexpected adverse drug reactions (ADRs) that might not have been noticed during clinical trials. [22]

Monitoring After Marketing

Pharmacovigilance tracks a medication's safety and efficacy in the real world across a wide range of populations after it is put on the market.

Risk assessment and signal detection

Pharmacovigilance assesses benefit-risk profiles and finds safety signals by examining

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clinical trial data, spontaneous reports, and electronic medical records.[23]

Enhancing Patient Security: offers proof for safer prescription practices that avoid drug interactions and dose modifications. .[22]

Making Regulatory Decisions

Findings from pharmacovigilance are used by regulatory agencies to amend drug labels, issue warnings, limit usage, or remove dangerous medications.

Monitoring of Special Populations

Pharmacovigilance aids in the analysis of clinical safety monitoring in groups that are frequently underrepresented in patient studies, including , prenatal women, youngsters, and the old people.

Monitoring of Vaccine Safety

Is essential for evaluating adverse events linked to vaccines, fostering public confidence, and assisting with immunization campaigns.[24]

Integration of Public Health

Pharmacovigilance supports national health initiatives, policy-making, and the prudent use of medications in public health.[22]

Using AI and Technology in Safety Monitoring

Artificial intelligence, big data, and machine learning are used in modern pharmacovigilance to detect ADRs more quickly and accurately.[23]

INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES: [25]

Many nations around the world have developed it's specific drug safety monitoring procedures in an effort to maintain methodical risk management reporting procedure. Six international conference on harmonization guideline protocol cover different facets of drug safety:

E2A	Information Handling for Medical Risk Prevention: Protocols and Clarifications for Expedited Notification.
E2B	Control of medical safety Data: Records components with respect sending safety reports for specific cases
E2C	Management of patient safety information:Regular risk prevention record regarding sold medications
E2D	Safety related record After Approval Organisation: Terminologies along with guidelines concerning quick documentation
E2E	Designing for pharmacovigilance
E2F	Progress report on Development Safety

Table 4:ICH Guidelines For Pharmacovigilance

ICH E2A

Focus: Describes the definition of serious adverse events (SAEs), their frequency, and the deadlines for prompt reporting in clinical trials.

Important Points:

Typical definitions of serious undesirable drug effects and negative incidents

Indicates when significant unexpected reactions must be reported, such as within seven or fifteen days.

Encourages international standardization for the management of clinical safety data.

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ICH E2B (R3) :
Focus: The main goal is to standardize the structure and format for electronically reporting ICSRs to regulatory bodies.
Important Points:
Specifies the data elements (such as patient information, suspect medication, and reaction) needed for ICSRs.
Makes use of XML-based formats for international electronic communication.
Improves the efficiency and accuracy of safety data submission.

ICH E2C (R2)
Focus: Offers content along with structure for recurring reporting on the profit exposure rate of distributed medications.
Important Points:
PSUR has been replaced.
incorporates risk and benefit data.
promotes ongoing post-marketing safety data evaluation.

ICH E2D :
Focus: Offers recommendations for managing safety data following marketing authorization.
Important Points:
Specifies the requirements for reporting adverse events after marketing.
Describes when to report severe and unanticipated adverse reactions.
Standardizes post-marketing safety reporting procedures worldwide.

ICH E2E – Pharmacovigilance Planning (PVP)
Focus: Provides standards for pharmacovigilance plans both during and after product development.
Important Points:
Introduces RMPs, or risk management plans.
Aids in identifying safety issues and risk-reduction tactics.
Promotes proactive planning and monitoring for safety.

ICH E2F :
Focus: Compiles yearly risk assessment reports while a drug is being developed clinically.
Important Points:
Creates a single report by combining data from several trials.
Considers clinical development when assessing new safety data.
Complies with International Birth Date (IBD) reporting.

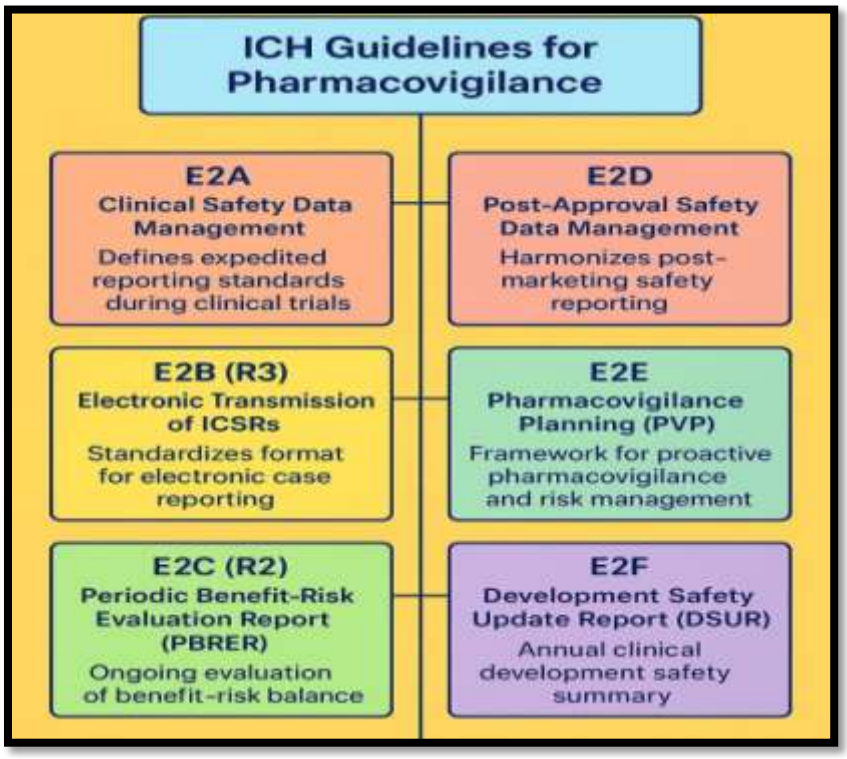

Figure 5:ICH Guidelines for Pharmacovigilance

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PHARMACOVISILANCE PROGRAMME OF INDIA (PvPI)

Experimental studies are used to assess a therapeutic safety as well as effectiveness before this is authorized for use and sold in a nation .The goal of trials is consistently negative responses .Some important reactions, such as those that occur gradually or that take time to manifest, may be missed by clinical trials rarely.Because clinical trials are carried out under close observation, they might not always be indicative of actual global usage. For a drug to be considered safe, its anticipated advantages must exceed any potential risks of negative responses. Pharmacovigilance, for instance, is essential. Pharmacovigilance screens for drug safety using information from multiple sources. It contains a technique for reporting adverse drug reactions (ADRs); internationally published medical literature; and regulatory bodies' activities in foreign countries.Significant social and financial consequences may result from adverse drug reactions, so using appropriate risk .A favorable return on investment is possible for management. The purpose of the PvPI is to collect, process, and analyze data in order to make inferences that can be utilized to recommend regulatory reactions in addition to alerting the public and medical professionals to risks. [26]

Implementation Of PvPI

The IPC assumed that in order to enhance patient safety, the nearby hospital-based centers needed to be based all over the nation .To find out any fresh details about the drugs' safety profile, it was crucial to keep an eye on both side effects that were previously known and those that were not. A consistent plus efficient post market safety monitoring was crucial designed for the With a population over 1.2 billion, India is a huge country with a wide range of ethnic groups,patterns of disease prevalence, the use of various medication systems, and socioeconomic backgrounds. [26]

Short-term goals

- Primarily, all Medical council of India sanction hospital facilities serving all over the India will be enrolled in the program westward.
- To create and execute a pharmacovigilance system in India.
- To require medical practitioners to document any adverse reactions to medications, vaccines, or treatment devices biological products as well as patients.
- To gather case studies and statistics [26]

Long lasting goals

- For extend the adverse events reporting program for every private healthcare , public health program sites, and
- Indian government hospitals.
- To design and put into place an electronic reporting system (e-reporting)
- To mandate that healthcare professionals report adverse drug reactions;
- To encourage a reporting culture among medical personnel [26]

AI IN PHARMACOVIGILANCE :

AI servers as the capacity related to computer systems to carry out tasks that usually need human thinking including training, logical thinking ,judging and language comprehension [27]. The field officially emerged in 1956 with John McCarthy's Dartmouth Conference, which is considered to be the first academic event in the history of artificial intelligence [28]. In his groundbreaking work, Alan Turing first proposed the human like evaluation test as way to obtain whether the device could replicate human intelligence [29]. Over time, artificial intilligence (AI) has evolved from rule-based systems (expert and symbolic AI) to data-driven tactics powered by ML and DL .The specific capacity regarding big records and advanced computational resources has allowed these techniques to achieve human-level or even superhuman performance in certain domains [30].

In the fields of drug safety, genomics, diagnostic imaging, also prospective analytics, AI is becoming more prevalent in certain healthcare industry. While it offers opportunities to improve accuracy, efficiency, and scalability, problems like algorithm transparency, data privacy, and ethical governance remain significant barriers [31,32].

Advantages Of Artificial intelligence (AI)

1. Enhanced Productivity & Efficiency: AI can continuously complete monotonous tasks, resulting in faster and more accurate results [33].
2. Improved judgement: Artificial Intelligence technique analyze large amount of data to idepattern and assist during making well-informed choices [33].
3. Long-Term Cost Savings: AI lowers errors and streamlines procedures, which results in long-term cost savings, despite the high initial costs [34].
4. Innovation & New Capabilities: AI makes it possible for innovations like medical

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diagnostics, smart assistants, and driverless cars [35].

5. Service Personalization: AI personalizes entertainment, shopping, and education [36].
6. Risk Reduction in Dangerous activities: Artificial Intelligence can capable to work in risky place, such as mines or disaster areas [33].

Disadvantage Of Artificial intelligence (AI)

1. Job Displacement: Routine and low-skilled jobs are at risk from automation [37].
2. High Initial Costs: AI necessitates costly training, data, and infrastructure [38].
3. Privacy and ethical problems: The implementation of large data collection raises questions regarding consent and surveillance [39].
4. Discrimination & Bias: AI that has been trained on biased data may generate unfair results [40].
5. Insufficient clarity: Since numerous Artificial Intelligence models works as "black boxes," accountability is restricted [37].
6. Over-reliance on AI: Excessive reliance on AI may hinder human creativity and problem-solving abilities [41].
7. Security Risks & Misuse: AI systems are susceptible to deep fakes and cyber attacks [42].
8. Ecological effects: Big AI models consume a large amount of energy during training [43].
9. Lack of Creativity & Emotional Intelligence: AI is devoid of ethics, empathy, and true creativity [41].

Applying AI In Pharmacovigilance

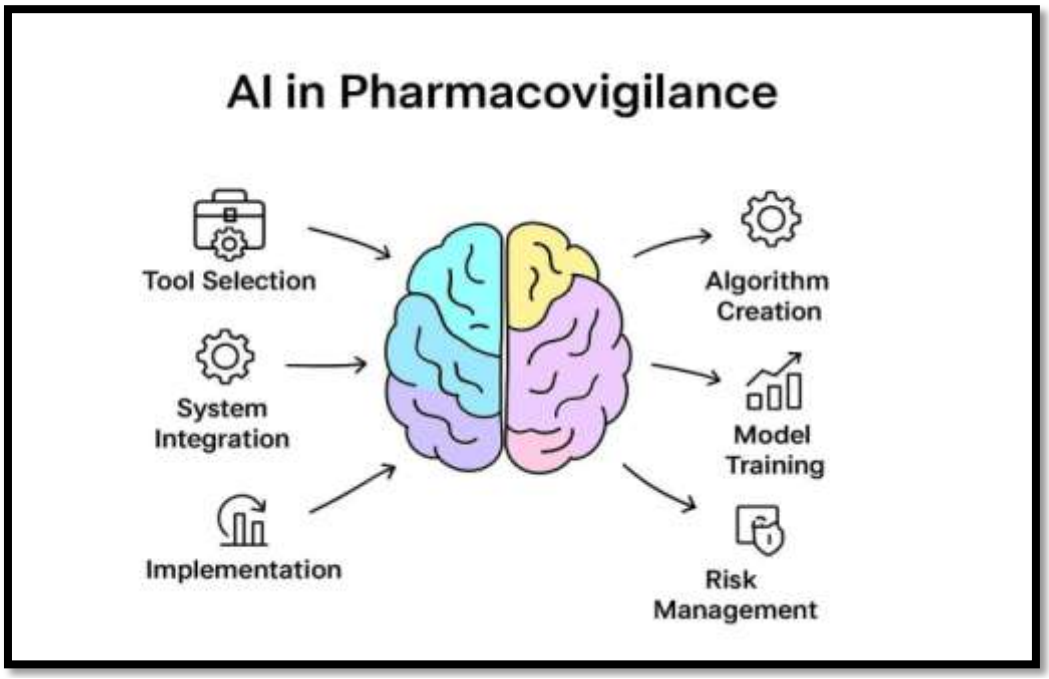

Figure 6: Artificial Intelligence In Pharmacovigilance

Integrating AI into PV incorporating computational intelligence technical system inside current pharmacovigilance systems and workflows. The following is a comprehensive advisor 0:

Enumerate particular pharmacovigilance objectives and problems that AI may help [44]. For digital intelligence combination, examining the standard, structure also origin of information which is accessible. Create the correct choices regarding artificial intelligence software and methods. Create AI algorithms or alter existing ones for safety surveillance functions. Connect smart tools along with preparation to the knowledge store, software as well as study design used in pharmacovigilance today. To train AI models and assess their efficacy, use historical data. Use AI-powered pharmacovigilance solutions while monitoring their effectiveness. These factors are very important, sensitive data sources, and require careful consideration because human lives

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are at stake. AI can be helpful in this exact situation. AI models can assist in identifying new possible signals and indications of likely contributory relationship among any medication togather with negative incidents from large databases. According to Meyer (2020),[45] these models can identify patterns that traditional statistical methods might miss. Furthermore,hazard control, self – operating report analysis, data mining, expectative assessment are recording combined with experimental studies controlling are all areas in which digital intilligence is capable of perform vital role .

Functions Of AI In PV

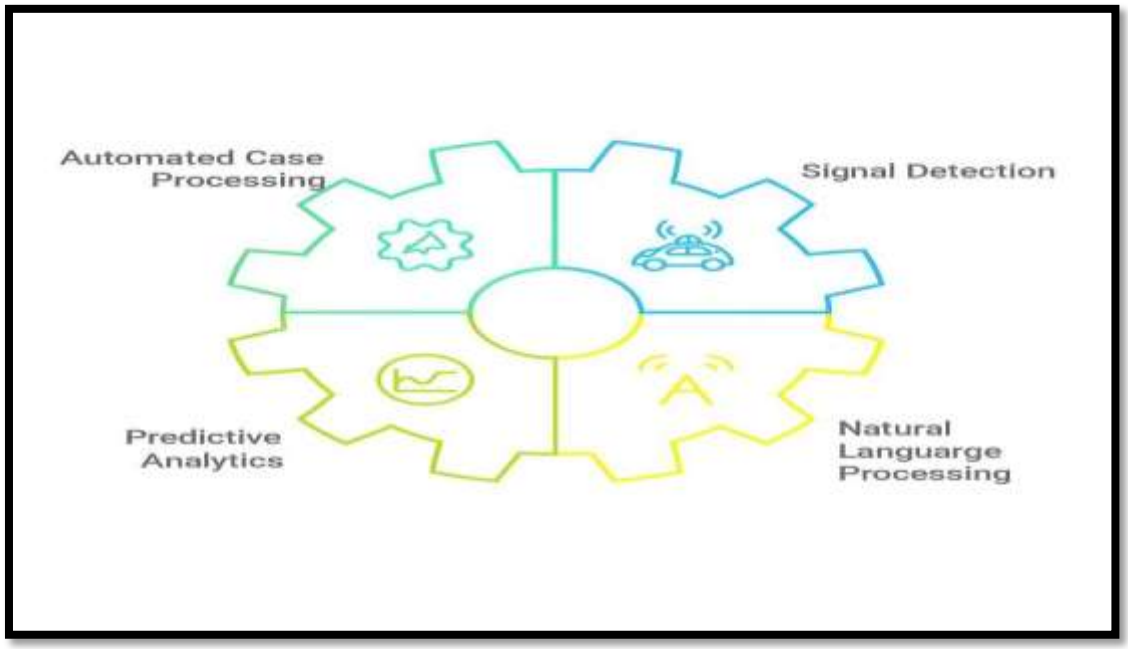

Figure 7: Functions Of AI In PV

Inside the PV, AI are applied to evaluate vast count of drug details in order to recognize hidden patterns, calculate possible risks, and ultimately improve drug efficacy. Pharmacovigilance guarantees the success and quality of a pharmaceutical product throughout its various stages. Current methods for tracking ADR are materials-intensive are also frequently lead for ADR understating .One area of pharmacovigilance assessment that is currently expanding is AI with adverse reaction reporting interfaces. The purpose of this section was to examine the different advantages of AI in PV One area of pharmacovigilance assessment that is currently expanding is AI with adverse reaction reporting interfaces. The purpose of this section was to examine the different advantages of AI in PV. [46] AI deep learning and NLP devices may demonstrate the ability into automate pharmacovigilance data, such as signal detection, risk assessment, and regulatory compliance requirements. Because it makes pharmaceutical safety control procedures successful, artificial intelligence is crucial to pharmacovigilance (Figure 7).

These are a few of the main objectives of pharmacovigilance that artificial intelligence serves. Automated Case Management: Artificial Intelligence systems might be able for swiftly examine big numbers of notifications of unfavorable events, and they may also be able to identify situations and gather valuable data. These automated systems reduce delays and the amount of manual labor needed. Signal Recognition: Machine learning techniques may be utilized to analyze big quantity of details from multiple sources to identify recent advancements in acceptable safety signals that may indicate a drug-related risk. This abrupt goal of discovery made it simple to find and react quickly. Predictive analytics: Using historical data to train AI models may be useful in predicting the likelihood of undesirable outcomes based on specific individuals or problems. Risk assessment and management

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strategies are supported by such an aggressive approach. Processing Natural Languages Artificial intelligence AI-based NLP systems are capable of interpreting unstructured data, such as social media posts or incident reports, and can extract critical safety information that might otherwise be difficult to obtain through traditional approaches. By integrating artificial intelligence (AI) with pharmacovigilance, the pharmaceutical industry can enhance its ability to detect safety risks and accelerate response times, ultimately improving patient outcomes and ensuring regulatory compliance.

How Adverse Drug Reactions (ADRs) Are Identified by AI[47],[48],[49]

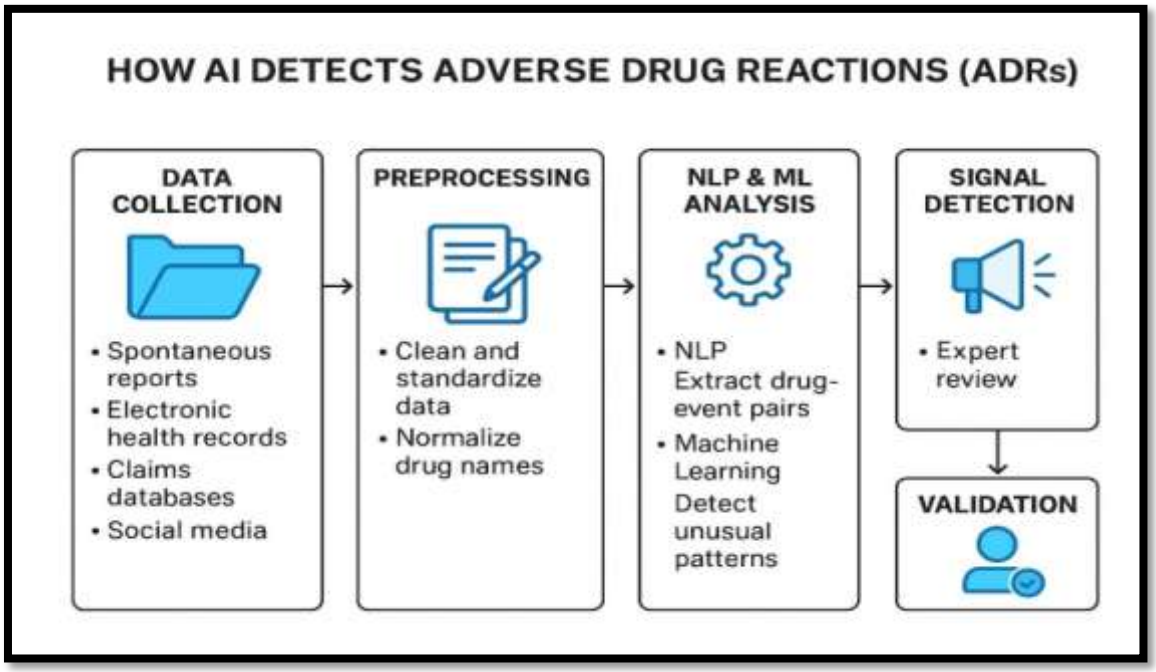

Figure 8: Detection of ADR By Using AI

Data Collection

AI first collects unprocessed data from various sources in this step:

Reports about side effects that patients, physicians, or pharmacists voluntarily submit are known as spontaneous reports.

Electronic health records (EHRs): Digitally stored patient medical records that can show trends in drug reactions.

Claims databases: Information on drug use and related health problems can be found in insurance and pharmacy claims.

Social media: Patient posts or conversations regarding their drug-related experiences.

Goal: Gathering a variety of data guarantees AI has sufficient knowledge to identify even uncommon or uncommon ADRs.

Preprocessing (Getting ready)

Data must be cleaned and standardized before AI can analyze it:

Data should be cleaned and standardized by eliminating mistakes, duplicates, and unnecessary information.

Normalize drug names: Standardization guarantees consistency even though different sources may use different names or abbreviations for the same drug.

Goal: Enhances dependability by ensuring AI algorithms operate on consistent, accurate data.

Analysis of NLP and ML

AI employs sophisticated methods to identify possible ADRs:

The NLP is the technique of detecting connections between medications and side effects in unstructured text, such as social media posts or clinical notes.

Machine Learning (ML): By examining past data, ML finds odd trends and forecasts possible ADRs.

Goal: Automates the identification of indicators that could point to a novel or uncommon adverse drug reaction.

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Signal Detection
After AI detects possible ADR patterns, professionals examine them:
Expert review: Physicians or pharmacologists confirm if the signals found are clinically meaningful.
Goal: Reduces false positives by fusing human knowledge with AI efficiency.

Verification/Validation
Verifying the ADR is the last step:
Before reporting or taking regulatory action, validation makes sure the identified ADR is authentic, trustworthy, and actionable.

Goal: Preserves patient safety and guarantees accurate reporting.

Detecting Drug-Drug Interactions (DDIs) with Artificial Intelligence (AI)

AI is developing into a potent tool for detecting drug-drug interactions (DDIs), which are circumstances in which two or more medications interact and may result in negative side effects or decreased efficacy. Conventional approaches depend on post-marketing reports and clinical studies, which can be laborious and lacking. On the other hand, AI can more effectively identify known and unknown Drug- Drug Interaction by quickly analyzing vast amounts of biomedical data.

How Artificial Intelligence (AI)is used to detect Drug–Drug Interactions (DDIs): [50],[51],[52]

Step No.	Step Name	Description	AI Techniques Used
1	Data Collection	Gather comprehensive datasets from varied sources including electronic health records (EHRs), clinical studies, biomedical literature, chemical and pharmacological databases (e.g., Drug Bank, PubChem), and online social platforms.	Data mining, Web scraping
2	Data Preprocessing	Prepare the collected data by eliminating redundancies, standardizing drug nomenclature, and addressing missing or inconsistent values to ensure data quality for AI modeling.	Data cleaning algorithms, NLP-based preprocessing
3	Feature Extraction	Identify and isolate key drug-related attributes such as molecular structures, target proteins, adverse effects, and pharmacokinetic parameters.	Natural Language Processing (NLP), Feature engineering
4	Model Training	Utilize curated datasets of known interactions to train AI models, enabling them to learn hidden patterns and associations among different drug pairs.	Machine Learning (ML) models — Random Forest, SVM, Deep Learning, Graph Neural Networks (GNNs)
5	Interaction Prediction	Apply trained AI models to forecast possible interactions between novel or existing drug combinations based on the relationships learned during training.	Predictive modeling, Deep Learning (CNN, RNN, GNN)
6	Validation and Evaluation	Assess the performance and reliability of AI predictions using benchmark datasets or	Cross-validation, ROC analysis, Precision–Recall metrics
		laboratory results through statistical validation techniques.	
7	Interpretation and Visualization	Analyze the model's predictions to understand interaction mechanisms or severity levels and present them using visual tools such as interaction maps or	Explainable AI (XAI), Network analysis techniques

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		network graphs.	
8	Integration into Pharmacovigilance Systems	Incorporate the developed DDI prediction models into clinical or pharmacovigilance systems for continuous monitoring and real-time alert generation.	Clinical Decision Support Systems (CDSS), API integration

Table 5: AI-Driven Process for Detecting Drug–Drug Interactions

Figure 9 illustrates the workflow of how Artificial Intelligence (AI) is used to detect Drug–Drug Interactions (DDIs) in healthcare and pharmacovigilance. It presents a stepwise process, beginning from data collection to validation of AI-generated results. Here's a detailed explanation of each step:[52]

Gathering Information from Various Sources :Gathering large and varied datasets collected from numerous sources such as pharmacy databases, clinical trial reports, scientific literature, Clinical data from EHRs alongside social media information is a first step. AI-based on the useful information about medications, dosages, side effects, and patient experiences that can be found in these data .

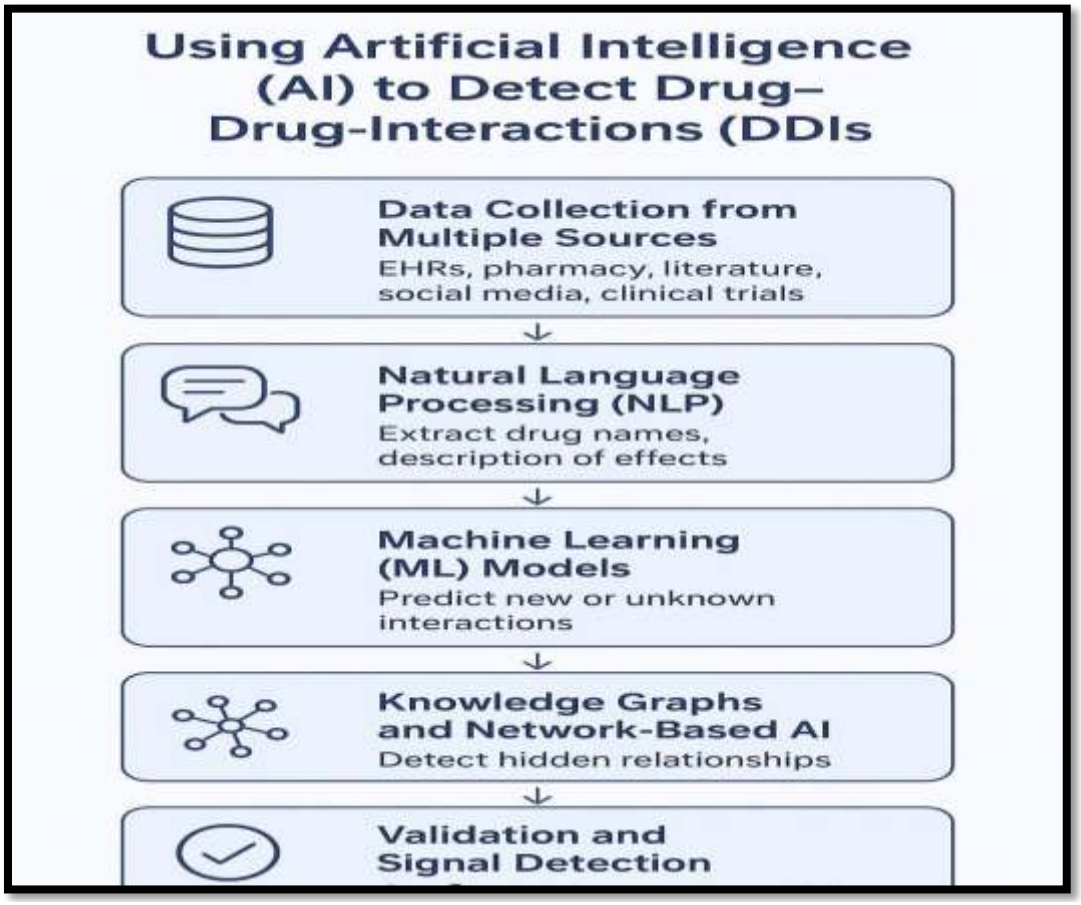

Figure 9: Detection Of Drug -Drug Interaction By Using AI

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NLP, or natural language processing

Following data collection, unstructured text, such as research papers or clinical notes, is analyzed using NLP techniques. NLP facilitates the removal of medication names, dosage material, adverse effects, and interaction descriptions. In this step, unstructured text data is transformed into information that AI models can understand.

Models for Machine Learning (ML)

This step involves training machine learning algorithms with data on known drug interactions. These models pick up on trends and connections between various drug combinations. They can anticipate novel or unidentified interactions once they are trained, which aids researchers and medical professionals in spotting possible hazards early.

Network-Based AI and Knowledge Graphs

Here, artificial intelligence creates knowledge graphs, which are visual networks that link medications, targets, proteins, and adverse effects. These networks make it possible for network-based artificial intelligence algorithms to identify indirect or hidden relationships that conventional analysis might miss. Finding intricate multi-drug interactions requires this step.

Signal detection and validation

Lastly, to guarantee accuracy, the predictions generated by AI models are verified using benchmark datasets or clinical evidence. Through signal detection, the system finds statistically significant correlations between medications that could point to actual interactions. Pharmacovigilance systems can then incorporate this verified data for ongoing observation.

Advantages of AI in Drug Interaction Detection

1. Identifies drug interactions that were previously unknown.
2. Facilitates real-time drug safety monitoring
3. Cuts down on human bias and manual review time
4. Combines clinical, biological, and chemical information
5. Predicts risks unique to each patient, supporting personalized medicine.

Difficulties

1. Heterogeneity of data (various formats and sources)
2. Deep learning models' inability to be interpreted ("black box" problem)
3. Issues with ethics and regulatory validation.

II. CONCLUSION

Pharmacovigilance, which continuously tracking , examines, evaluates, and avoid medication reactions throughout a medication's life cycle, is the cornerstone of drug safety and people wellbeing security. By ensuring that the advantages of pharmaceutical products continuously outweigh the risks, it protects patient welfare and upholds public confidence in healthcare systems. The implementation of ICH guidelines and the creation of organized programs like the PvPI have improved regulatory frameworks and encouraged international standardization of drug safety procedures. The combination of AI,ML, and NLP has further transformed pharmacovigilance by facilitating quicker information analysis, accurate alert detection as well as effective hazard analysis. These tools improve drug regulation decision-making and enable the early detection of possible safety issues. IN conclusion, cooperation between patients, pharmaceutical companies, regulatory bodies, and healthcare professionals is necessary for effective pharmacovigilance. The responsible use of cutting-edge technologies, open communication, and ongoing education will guarantee safer therapeutic outcomes, reduce drug-related risks, and eventually enhance patients' quality of life everywhere.

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[5]. Figure 1. Timeline of key milestones in pharmacovigilance (1848–2017), adapted from Safety Drugs (2024), with events sourced from [SafetyDrugs (2024);

SciencePharma (n.d.); WHO, EMA, and other regulatory histories].

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