



INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

Technology And Ai-Driven ADR Monitoring In Herbal Medicines

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Abstract – With the increasing global use of herbal medicines, monitoring adverse drug reactions (ADRs) has become critical to ensuring patient safety and therapeutic efficacy. However, the unique and complex nature of herbal products presents distinct challenges in pharmacovigilance, including variability in composition, multi-component formulations, and limited reporting systems tailored to herbal medicines. This review highlights the role of advanced technologies and artificial intelligence (AI) in addressing these challenges by enhancing ADR detection, analysis, and reporting within the herbal medicine sector. The integration of AI algorithms with digital databases and specialized software facilitates efficient data mining, pattern recognition, and early signal detection, improving the accuracy and speed of ADR identification. Moreover, AI-driven tools offer scalable solutions for real time data processing and predictive analytics, which contribute significantly to preempting potential adverse reactions and optimizing patient outcomes. We explore current technologies, including machine learning, natural language processing, and mobile application, as they pertain to herbal pharmacovigilance. This paper aims to provide insights into how the synergy between AI, technology and regulatory databases can establish more robust frameworks for ADR monitoring in herbal medicines, ultimately advancing patient safety standards.

KEYWORDS – ADRs, Herbals, AI and Technologies, Patient Safety.

INTRODUCTION: - Since antiquated times, herbs have been broadly utilized for the avoidance and treatment of different infections. As of late, there has been a noteworthy increment within the worldwide propensity to utilize herbal drugs as an elective frame of treatment. Herbal medications, also known as phytomedicines or phytotherapeutic arrangements, are characterized as “medicinal items containing as dynamic substances only herbal solutions or herbal medicate preparations” [1]. The utilization of conventional herbal drugs is predominant over numerous nations, not as it were for treating and avoiding infections but moreover for advancing common wellbeing and well-being [2]. Conventional pharmaceutical frameworks incorporate Ayurvedic pharmaceutical (Indian subcontinent), te rongoa – Maori – (New Zealand), conventional Chinese pharmaceuticals (China), Native medication (Australia), and numerous more.[3] Herbal medications are frequently prescribed by healthcare suppliers due to their potential restorative impacts and comparatively negligible side impacts when differentiated with routine solutions [4, 5]. The utilize of conventional drugs for helpful and preventative reasons may be a long-standing hone all over the world that makes a difference individuals remain upbeat and healthy[6]. The World Health Organization (WHO) characterizes conventional medication as a assortment of wellbeing hones, procedures, information, and convictions that envelop manual, otherworldly, and work out treatments that can be utilized to protect wellbeing as well as to treat, recognize, or remedy diseases.[7] Numerous individuals expect that normal items are continuously secure. This misinterpretation leads to a tall utilization of herbal items within the EU. Unfortunately, this increment has moreover driven to a critical rise within the number of detailed unfavorable responses caused by these items. [8] Pharmacovigilance has been characterized as “the study of the security of showcased drugs beneath the viable conditions of clinical utilization in expansive communities”. [9] It includes checking drug security and recognizing adverse drug responses (ADRs) in people, surveying dangers and benefits, and reacting to and communicating sedate security concerns as of late, it has been proposed that there may be more accentuation on expanding information of security instead of centering on illustrating harm.[10] Pharmacovigilance program focuses to accumulate data relating to the occasion of ADR and to recognize and degree the danger related with the utilize of drugs. Such data is utilized to reach at derivations to endorse taught authoritative trade and communicating threats to wellbeing care specialists and the open. [11] As the afterward growing of counterfeit insights (AI) made a tremendous influence in data science, it highlights a tremendous scope for its utilization inside the field of pharmacovigilance (PV) which is in require of substitute procedures to adjust up with the extending stack of medicate security data collected as a result of changes in unconstrained declaration systems and utilization of social media as a source of pharmacovigilance. [12] AI and machine learning have appeared critical parts in pharmacovigilance by progressing the location, checking, and examination of adverse drug responses (ADRs). The machine learning has moreover appeared a few noteworthy parts in pharmacovigilance.[13] Here's how:

- Early Discovery of ADRs in pharmacovigilance
- Flag Discovery and Prioritization for pharmacovigilance needs
- Information Integration over pharmacovigilance databases
- Design Acknowledgment for ADR patterns
- Real-Time Checking to back pharmacovigilance exercises [13]

2. Challenges in Herbal Medicines Safety and Adverse Reactions:

The Pharmacovigilance of herbal medications shows specific challenges since such arrangements are accessible from a wide extend of outlets regularly where there's no healthcare proficiently accessible, most buys are in conventional OTC environment.[14]

1. Lack of Standarization in Herbal Medicines

Standardization of herbal arrangements is the strategy of supporting a set of rules or unavoidable characteristics, relentless parameters, conclusive subjective and quantitative values that carry a confirmation of quality, adequacy, security and reproducibility. There's no successful apparatus to direct manufacturing practices and quality guidelines. Buyers can purchase herbal items without a prescription and might not recognize the potential

dangers in a second rate item. A few issues not appropriate to manufactured drugs frequently impact the quality of herbal drugs. For occurrence:[15]

- Herbal drugs are, usually blends of numerous constituents.
- The active principle(s) is (are), in most cases obscure.
- Specific explanatory methods or reference compounds may not be accessible commercially.
- Plant materials are chemically and actually variable.
- The source and quality of the crude fabric are variable.[15]

2. Quality Control Issues and Adulteration

The quality of the source materials utilized inside the era of home grown medicines chooses to a huge degree the security and amplex of these home grown cures. For the foremost portion, the quality of source Materials are subordinate, not as in case they were on inborn (innate) factors, but besides on outward factors like characteristic conditions, great agrarian, and great collection hones (GACP) for remedial plants, tallying plant assurance and cultivation.[16] In show disdain toward of the truth that, the assessment of the security of home grown drugs has finished up an basic issue for buyers, authoritative masters, and healthcare specialists, examination of unfavorable events related to the utilize of these things is much more complex than inside the case of schedule pharmaceuticals[17,18]. The issues related with unregulated herbal items highlight the major public wellbeing issues that can emerge when their herbal fixings have not been verified correctly.[15] There are occurrences when herbal cures have been tainted with other plant fabric and routine medicines.[15] This practice is most common within the case of unstable oil-containing materials, where the dried exhausted material takes after the initial medicate but is free of the fundamental oils.[20]

3. Inconsistent Dosage and Potency Level

Herbal items frequently have conflicting strength due to common inconstancy and a need of exact dosing benchmarks, which can lead to antagonistic impacts or reduced adequacy[19,20] A couple of afterward considers approximately have filed definitely particular levels of suspected energetic fixings in home grown things. For outline, a afterward examination of 25 open ginseng things found a 15- to 200-fold assortment inside the concentration of 2 fixings acknowledged to have organic development: ginsenosides and eleutherosides. [21] In this way, it may be troublesome for patients to discover out with certainty the precise substance of the things they may be inquisitive approximately taking.[19]

4. Limited Regulatory Frameworks

In numerous nations, herbal solutions need comprehensive administrative systems that guarantee security and adequacy, clearing out consumers defenseless to unconfirmed products. [22,23]

In the event that exchange in a specific herbal item is made between nations where diverse administrative status is given, renaming of the administrative status within the bringing in nation depends not on the nature or characteristics (therapeutic or helpful esteem) of the item itself, but on the administrative system of the bringing in nation. [23, WHO]

An administrative system for herbal drugs can give more noteworthy affirmation to consumers. In any case, the direction and determination of herbal medications shift altogether diverse countries.[24]

5. Herb-Drug Interaction and Adverse Reaction

All herbal medications are complex blends of more than one dynamic fixing. Large number of dynamic fixings will increment the conceivable outcomes of interactions between herbal solutions and conventional drugs. Besides, users of therapeutic herbs are ordinarily enduring from constant conditions for which they are likely to require endorsed drugs concomitantly. This, in turn, assist increments the potential of herb-drug interaction. [24,

25] The think around of herb-drug shrewdly is help anticipated by the nature of home grown solutions. Always (and by definition) these are not drugs with because it were one pharmacologically energetic constituent. Commonly, we are overseeing with complex mixes of modest bunches of conceivably energetic guidelines. It shows up self-evident that this renders examinations of herb-drug intuitive more complex than drug-drug intuitive. [19] The common acknowledgment that home grown cures or drugs are uncommonly secure and down and out of unfavorable impacts isn't because it were unfaithful, but in addition deceiving. Herbs have been showed up to be able of making a wide expand of undesirable or opposing reactions, some of which are competent of causing veritable wounds, life-threatening conditions, and without a doubt passing. [16]

6. Challenges in Pharmacovigilance and Reporting

The underreporting of negative events can be one of the major issues in herbal medication as there are no strong surveillance systems in place. This hampers effective monitoring and management of the safety profiles of herbal products, hence, effective adverse event reporting is hampered. [23, 26]

7. Variability in Active Compounds

Herbal drugs frequently contain a extend of dynamic compounds, which can shift due to plant hereditary qualities, developing conditions, and collecting practices. This inconstancy complicates adequacy and security appraisals, as each group may vary in restorative impacts and potential antagonistic responses. [27]

3. Systems for Monitoring and Reporting ADRs

Monitoring and reporting adverse drug reactions (ADRs) makes a considerable contribution toward ensuring medication safety. These components comprise a nationwide and worldwide registry, mobile individual report applications, and connection to electronic health records, which allows for active data collection and evaluation.

1. Global and National ADR Monitoring System-

WHO Programme for International Drug Monitoring (PIDM), established by the world health organization in 1968. As part of the WHO Programme for International Drug Monitoring, every government in charge designates one national center for ADR reporting among several. These centers collect reports describing all adverse drug reactions encountered by healthcare practitioners in their patients. Monitoring and assessing these spontaneous reports, national centers add their share of the databases that are aimed to ensure the drug safety at the global level. This particular system is dependent upon the perspectives from health professionals whereby it allows for a global perspective of substance abuse safety.[28]

VigiBase, by July 2023 VigiBase had accumulated over thirty-five million anonymized reports of adverse drug reaction events from patients all over the world.[29] This platform is under the auspices of the World Health Organization and acts as a central database on medicine safety issues across the globe. VigiBase systems management is relational database management system (RDMS) that communicates in SQL language, utilizes open database connectivity (ODBC) and can be used from client-server or web-based applications.[30]

In the VigiBase core there are several databases that form a network, such as:

- Individual Case Safety Report (ICSR): This is the primary set of data concerning the adverse reaction cases.
- Medicinal products database: It contains lists of Articles of pharmaceutical origin.
- WHO Drug Dictionary (WHO-DD): It serves as the primary source of drug information.
- Medical terminology classifications: WHO-ART, ICD, and MedDRA are the classifications which aim to provide uniformity of many medical concepts to facilitate the reporting process.[29,30]

Regional Pharmacovigilance Centers, as much as ADRs are their main concern, other variables come into play such as the FDA Regional Centre in the US and MHRA in the UK that help in determining and spotting issues within those drugs through their respective data sources. These agencies contribute structured data in VigiBase for the purposes of these assessments which is aimed at improving the detection of signals and the safety of the population in comparison to each other. The centers' databases enable the regions to be able to deal with safety concerns in the areas quickly which ensures that all major safety concerns are eventually looked into which further strengthens the pharmacovigilance approach of the WHO. [30,31]

2. Key ADR Databases-

Key ADR databases are principal for large-scale information investigation and announcing of ADRs. **VigiBase** is the biggest universal database for ADRs, accepting millions of ADR entries every year from WHO part nations. This database employs information mining and factual investigation tools to identify developing security issues over distinctive locales and drug categories. [30,32]

Within the **United States**, the **FDA Adverse Event Reporting System (FAERS)** empowers healthcare experts, patients, and producers to report ADRs. For example, FAERS was instrumental in revealing antagonistic cardiovascular occasions related with the herbal supplement ephedra, which driven to a nationwide boycott within the U.S. [33]

EudraVigilance is a highly important system for pharmacovigilance as it acts as the primary source for signal detection and is seen as assisting regulators in their decisions. The system is also accessible to a range of stakeholders, ranging from healthcare professionals, pharmaceutical companies, and academia; however, in varying depths. EudraVigilance is the European Medicines Agency's (EMA) platform for the collection and analysis of data related to suspected adverse drug reactions (ADRs). It serves as a comprehensive database for ADRs reported during both clinical trials and the post-authorization phase across the European Economic Area (EEA).[34]

3. Online Reporting Portals-

MedWatch: The Food and Drug Administration (FDA) propelled the Medical Items Detailing program (MedWatch) in 1993[MedWatch started as a paper-based framework utilizing mail and fax to yield antagonistic occasion reports. The FDA propelled its site in 1998 to create detailing more helpful and more rapid.[35] Nowadays, the FDA gets more than half a million intentional, postmarketing antagonistic occasion reports on chemical substances, biologics, immunizations, and gadgets yearly MedWatch was “developed with the eager back of the therapeutic community, to meet 4 primary objectives:

- (1) To create it simpler for health care suppliers to report genuine unfavorable occasions.
- (2) To form clear to doctors and other wellbeing professionals the particular antagonistic occasion data that the FDA wishes to get.
- (3) To extend the perceivability of FDA's activities that have come about from antagonistic occasion detailing.
- (4) To extend doctor and other wellbeing proficient understanding and mindfulness of medicate- and device induced disease.[35,36]

Yellow Card: The Yellow Card plot is run by the Medicines and Healthcare Items Regulatory Agency (MHRA), which shields solutions, immunizations, restorative gadgets, blood items, and e-cigarettes quality and viability within the United Kingdom. Through the Yellow Card conspire, the MHRA collects and screens data on suspected security concerns, including healthcare items like side effects caused by a medication or antagonistic occurrences, including therapeutic gadgets.

4. Data Analysis and Signal Detection Systems

Signal Detection in VigiBase: VigiBase utilizes information mining and flag location calculations to recognize potential security signals. By analyzing endless amounts of ADR reports, it has recognized a few security concerns in herbal items, such as hepatotoxicity related with conventional Chinese herbs like radix Polygoni multiflori. This has driven to more noteworthy administrative examination and rules to guarantee more secure utilization. [33]

AI and Machine Learning: Artificial intelligence (AI) and machine learning are progressively utilized to improve ADR observing, especially for herbal items, where complex fixings complicate security evaluations. For illustration, AI-driven calculations can analyze persistent information from electronic wellbeing records (EWRs) to distinguish designs characteristic of ADRs. Administrative organizations just like the FDA and EMA have started coordination AI for real-time signal discovery, permitting for speedier, recognizable proof of adverse responses and made strides patient security. [38,39]

Role of Technology in Pharmacovigilance: Utilizing Databases and Software for Adverse Event Reporting

➤ Key Technologies in Pharmacovigilance

1. Databases for Adverse Event Reporting

1.1. Databases are at the core of modern pharmacovigilance. These centralized systems allow the collection, storage, and retrieval of vast amounts of Adverse event data from various sources, including healthcare providers, patients, pharmaceutical companies, and regulatory agencies.

1.2. **FDA Adverse Event Reporting System (FAERS):** One of the largest PV databases, FAERS is a publicly accessible repository maintained by the U.S. Food and Drug Administration. It contains millions of AE reports submitted by healthcare professionals and consumers. FAERS allows for the analysis of drug-related risks through signal detection algorithms [1].

1.3. **EudraVigilance :** Overseen by the European Medications Office (EMA), EudraVigilance may be a framework for overseeing and analyzing information on suspected ADRs to medications authorized within the European Financial Zone (EEA). It underpins the early location of safety signals, risk-benefit assessment, and administrative decision-making [2].

2. Vigi Tools

VigiFlow- VigiFlow may be a web-based person case security report (ICSR) administration framework that's accessible for utilize by national pharmacovigilance centers of the WHO Program for Universal Sedate Observing.[8]

➤ **Vigilyze** is an online database and analytical tool developed by the World Health Organization's Uppsala Monitoring Centre (UMC). It is part of the global pharmacovigilance effort to monitor and improve drug safety. The tool allows authorized users, such as healthcare professionals and regulatory authorities, to access and analyse data from the WHO Global Individual Case Safety Reports (ICSR) database, also known as Vigi Base.[10]

➤ **VigiBase** the WHO worldwide ICSR database; it comprises of reports of antagonistic responses gotten from part nations since 1968. VigiBase database framework incorporates connected databases containing therapeutic and medicate classification: WHO- Craftsmanship/ MedDRA, WHO ICD and WHO-DD. It can be a computerized pharmacovigilance system, in which information is recorded in a organized, different

leveled outline to allow for straightforward and versatile recuperation and examination of the data. Its reason is to supply the prove from which potential medication security dangers may be identified. [7]

- **VigiAccess** is a web-based tool developed by the World Health Organization's Uppsala Monitoring Centre (UMC) that allows public access to information from the WHO Global Individual Case Safety Reports (ICSR) database, known as VigiBase. It is designed to promote transparency and provide the public with insights into reported adverse drug reactions (ADRs) from around the world. [9]

❖ Key features of VigiAccess include:

- ✓ • **Public Access:** Unlike Vigi lyze, which is restricted to authorized users, VigiAccess is available to the general public, allowing anyone to explore global data on drug safety.
- ✓ • **Search Functionality:** Users can search for information on specific drugs, adverse reactions, or therapeutic areas.
- ✓ • **Data Visualization:** The tool provides graphical representations of data, such as the frequency of reported ADRs and the demographics of the affected individuals. 28
- ✓ • **Educational Resource:** VigiAccess serves as an educational resource for patients, healthcare professionals, and researchers, helping them understand the potential risks associated with medications.
- ✓ • **Transparency and Awareness:** By making pharmacovigilance data accessible, VigiAccess aims to raise awareness about drug safety and encourage reporting of ADRs. VigiAccess is part of the broader effort to improve drug safety and PV by leveraging global data and making it accessible to a wider audience.

1.5. These databases utilize advanced query systems and algorithms to detect patterns or signals that may indicate a potential safety issue, thus improving the identification of new and rare ADRs.

3. Automation in Adverse Event Reporting

Automated reporting tools and platforms help healthcare providers and patients submit AE reports more efficiently. Software solutions such as web-based portals and mobile apps simplify the reporting process, increasing the volume and accuracy of data submitted.

Electronic Data Capture (EDC) systems: EDC tools facilitate the collection of AE data during clinical trials. These systems allow for real-time data entry, error detection, and faster reporting of AE occurrences.

Mobile Apps: Various regulatory agencies, including the FDA and EMA, have launched mobile applications that enable patients and healthcare professionals to report AEs directly through their smartphones. These apps often include features like auto-population of drug and patient information, making reporting quicker and reducing data entry errors [1, 2].

4. Signal Detection Algorithms and Artificial Intelligence (AI)

The Concept of Signal Detection

The World Health Organization defines a safety signal as "reported information on a possible causal relationship between an adverse event (AE) and a drug, of which the relationship is unknown or incompletely documented previously". "Signal detection" is a technique usually applied to marketed medications where a safety issue may be novel not identified during the premarketing stages or a new trend of previously identified adverse medication reaction in terms of high risk and severity frequency, subpopulation, and so forth). The detection of signals can be "qualitative." constructed on the basis of evaluating each case safety report separately. Or. "quantitative" by utilizing mine or machine learning techniques with databases of actual data from clinical trials and electronic health records, databases on pharmacology, biomedical literature, etc. [11].

Spontaneous reporting System

The majority of pharmacovigilance nowadays is based on impulsive reporting systems (IRS). The case report and the case sequences are typically regarded as a component of spontaneous reporting framework. In order to identify type B impacts and uncommon consequences of type A. The primary purpose of SRS is the early identification of signs of significant, uncommon, and novel ADRs. Reports are made spontaneously by a medical professional. a Pharmacovigilance center, where the examination of Reports is completed. Among the primary drawbacks of This strategy may result in biased reporting and not reporting enough. In 2015, Visacri et al. revealed the underreporting of negative medication interactions and their effects aberrations observed in Sao Paulo based on unprompted reports, Brazil. According to Hazell and Shakir, almost 94% of all ADRs reported by SRS go undetected. Less understanding among the general public and medical professionals is the primary reason for underreporting. Because of the underreporting of ADRs, there may be a mistaken belief that a danger that is genuinely present is not. This system's selective reporting is another flaw that could provide the false appearance of a risk that doesn't actually exist. Since impulsive reporting is inexpensive, it is not the ideal solution for after marketing drug surveillance; yet, it is undeniable that it was and remains the primary means of identifying early drug safety indicators.

The primary method for identifying early warning signs of medication safety.

Based on SRS, the majority of pharmaceutical items are taken off the market.

which shows how well it can identify new safety signals.[12]

Monitoring Prescription Events

One method of keeping track of every patient exposed to particular medications is through prescription event monitoring. This type of active surveillance was created in the UK (Prescription Event Monitoring) and New Zealand (Intensive Medicines Monitoring Program). A questionnaire can then be used to contact the patients or their physicians in order to document any or a subset of the incidents. Selection bias is eliminated because this kind of monitoring is not impacted by the kinds of exclusion and selection criteria that define clinical studies. This approach might identify unanticipated therapeutic advantages. Nevertheless, there are several restrictions on this monitoring, such as the unknown percentage of side effects that are not reported to physicians. [12]

Signal detection is the process of identifying new or unknown safety concerns (signals) that emerge from the analysis of AE data. Traditionally, signal detection relied on manual review, but technology has introduced new methods, such as:

Disproportionality Analysis: Algorithms like the Proportional Reporting Ratio (PRR) and the Reporting Odds Ratio (ROR) are used to detect disproportionate reporting of AEs for specific drugs compared to other drugs in the same class. These algorithms can identify potential safety signals by highlighting unusually high AE frequencies.

AI and Machine Learning: AI-powered systems have the potential to revolutionize PV by detecting complex patterns in large datasets that may not be easily discernible to humans. Machine learning algorithms are increasingly being used for signal detection, literature review, and even predictive analysis. These algorithms learn from historical data to forecast potential safety issues before they are reported widely [5].

Natural Language Processing (NLP): NLP tools enable the automatic extraction and interpretation of AE

information from unstructured text sources, such as medical literature, social media, and electronic health records (EHRs). This broadens the scope of data that can be used for PV purposes [6].

5. Data Integration and Interoperability

As AE data comes from diverse sources, interoperability between different data systems is crucial. Technologies such as Application Programming Interfaces (APIs) and data standardization tools facilitate the seamless exchange of information between databases, healthcare systems, and regulatory authorities. **ICH E2B Standards:** The International Council for Harmonization (ICH) has developed the E2B guidelines, which provide standards for the electronic transmission of individual case safety reports (ICSRs). This standardization ensures that data is consistent and can be shared easily across borders [4]. **Cloud-Based PV Systems:** Cloud technology allows for the secure storage and sharing of AE data on a global scale. Cloud-based platforms provide real-time access to PV data and analytical tools, enabling collaboration between regulators, pharmaceutical companies, and healthcare providers. These systems also support compliance with global regulations, including data privacy laws such as GDPR (General Data Protection Regulation).

6. Real World Data (RWD) and Big Data Analytics

Real-world data (RWD) from electronic health records (EHRs), claims databases, and patient registries provide insights into how drugs perform in everyday clinical practice. By integrating RWD with traditional AE reports, PV professionals can gain a more comprehensive understanding of a drug's safety profile.

Big Data Analytics: The sheer volume of RWD makes manual analysis impractical. Big data analytics tools, powered by AI and machine learning, enable the analysis of massive datasets to identify trends, correlations, and safety signals that might be missed in traditional AE reporting systems [6].

Challenges in Implementing Technology in PV

Data Privacy: The collection and sharing of health-related information raise concerns approximately understanding security and information security. PV frameworks must comply with strict information security directions, such as the GDPR in Europe and HIPAA within the U.S.

Integration of Systems: Many pharmaceutical companies and healthcare providers use disparate systems, making data integration difficult. Achieving full interoperability between different PV tools and databases remains a challenge.

Quality of AE Data: Automated reporting systems and data from non-traditional sources (e.g., social media) can sometimes lack the clinical detail required for thorough AE analysis. Ensuring data quality is critical for accurate signal detection.

CONCLUSION - With the growing popularity of herbal medicines worldwide, ensuring their safety and effectiveness is more important than ever. Monitoring adverse drug reactions (ADRs) is a critical step in protecting patients, but the unique nature of herbal products—such as their complex mixtures and inconsistent quality—poses significant challenges. This review explores how advanced technologies, particularly artificial intelligence (AI), are transforming the way we detect, analyze, and report ADRs in the herbal medicine field. AI tools like machine learning and natural language processing make it easier to identify potential safety issues, recognize patterns, and process large amounts of data quickly. By combining these technologies with robust digital databases and user-friendly software, we can create a stronger system for monitoring herbal medicines, improving safety, and ensuring better outcomes for patients.

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