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A REVIEW ARTICLE ON SAFETY DATA GENERATION

Sharuti Chaudhary*, Ajeet Thakur, Rahul, Uday Singh, Himanshu Thakur, Associate Prof. Kavita Pathania, Asst. Prof. Neha

Dreamz College of Pharmacy Khilra, Sundernagar.

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***Corresponding Author: Sharuti Chaudhary**
Dreamz College of Pharmacy Khilra, Sundernagar.
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ABSTRACT

Safety data generation is an important part of making sure medicines are safe for people. It includes collecting, studying, and understanding information about side effects and risks of drugs. This article explains how safety data is developed and how it has improved over time, along with the rules that guide it. It also describes different stages of drug development, such as laboratory testing, clinical trials on humans, and monitoring after the drug is available in the market. Important processes like Investigational New Drug (IND) and New Drug Application (NDA) are also discussed. The article highlights the role of doctors, researchers, pharmaceutical companies, and regulatory authorities in keeping medicines safe. Overall, it shows that continuous monitoring of drug safety is necessary to protect patients and improve treatment outcomes.

KEYWORD: Safety data generation, Pharmacovigilance, ADRs, Clinical trials, IND, NDA, Drug safety.

1. INTRODUCTIOIN

Starting in 1938, the FDA made it necessary for drug companies to prove that their medicines were safe before selling them. This rule came after a serious incident involving a product called Elixir Sulfanilamide, which contained a toxic substance and caused many deaths. Later, in 1962, another major change was introduced after the Thalidomide tragedy in Western Europe.[1,2] The Kefauver-Harris Amendment required that medicines must not only be safe, but also proven to work effectively for the condition they are meant to treat. Pharmacovigilance (PV) is a field that focuses on keeping medicines safe. It studies and tracks any side effects or problems that people may experience after using medicines. According to the World Health Organization (WHO), pharmacovigilance is about finding, understanding, checking, and preventing side effects or any other issues related to medicines. In simple words, pharmacovigilance works like a safety system for medicines. It keeps an eye on drugs after they are used by people, so that they help patients instead of causing harm.[3,4,5]

2. Importance of Safety Data Generation

Safety data is important because it helps keep patients safe and follows health rules. It helps find side effects of medicines early and shows whether a drug's benefits are greater than its risks.[6,7,8] Good safety information helps doctors, researchers, and health authorities make better decisions. Regular monitoring also improves the quality of medicines and reduces the chances of serious or rare side effects. It helps people use medicines safely and leads to better health results.[9,10,11]

3. Historical Background

According to the European Commission, means continuously checking the safety of medicines and taking steps to reduce risks and improve benefits.[12,13]

The idea of medicine safety started long ago. In 1848, a girl named Hannah Greener died after using chloroform during a small surgery. This raised concerns about drug safety. Later, James Young Simpson introduced chloroform in medical use, but such incidents showed the need for careful monitoring.[14,15,16] In the United States, drug safety laws improved after tragedies. In 1937, many people died from a medicine called Sulfanilamide because it contained a toxic chemical. This led to stricter laws in 1938 to ensure medicines are tested for safety before being sold.Another example is Aspirin, which was later found to cause stomach problems, so its use is limited in some patients.[17] A major turning point came in 1961 with the Thalidomide disaster, when a medicine caused serious birth defects. This was highlighted by William McBride. After this, strict monitoring systems for drug side effects were introduced worldwide.Overall, these events helped build today's pharmacovigilance system, which ensures medicines are safe even after they reach the market.[18]

4. DRUG DEVELOPMENT PHASES

It is divided into three phases:-

1. **Pre –clinical phases**

i. This phase happens before the drug is given to people to make sure it is safe.

ii. The drug is tested in test tubes or cells (in vitro) to see how it reacts.

iii. It is also tested on animals like rats or mice to check its effects on a living body.

iv. Scientists study if the drug causes any harmful or toxic effects.

v. How the drug works in the body**[19,20]**

✓ how the drug is:

- Absorbed
- Distributed
- Broken down
- Removed from the body**.**

vi. If the drug is found safe and effective**,** it is allowed to move to human testing (clinical trials).[21]

2. Clinical Trials

i. Clinical phases start when the drug is tested on people instead of animals.

ii. Divided into 4 phases :

Phase I – Safety check

- Done on a small group of healthy people to find safe dose and side effects.

Phase II – Check if it works

- Tested on patients to see if the drug actually treats the disease.

Phase III – Large testing

- Given to many patients to confirm effectiveness and compare with other medicines.

Phase IV – After approval

- Done after the drug is sold in the market to monitor long-term safety and rare side effects.[22]

3. Post marketing surveillance

i. After the drug is sold:- This phase starts after the medicine is available in the market.
ii. Monitoring real patients:- The drug is used by many people, and doctors observe its reallife effects.
iii. Detect rare side effects:- Some side effects are not seen earlier, so this phase helps to find rare or long-term problems.
iv. Ensure long-term safety:- Continuous checking is done to make sure the drug is safe over a long time.
v. Collect feedback:- Information is collected from doctors, patients, and hospitals about the drug's performance.
vi. Take action if needed:- If any serious issue is found, the drug may be restricted, updated, or even removed from the market.[23]

5. INVESTIGATIONAL NEW DRUG APPLICATION

An Investigational New Drug (IND) application is an official request made by a pharmaceutical company or researcher to a regulatory authority (like the U.S. Food and Drug Administration) to get permission to test a new drug in humans.[24,25,26]

The IND application contains all important information about the drug, such as:

- How the drug is made?
- Results from laboratory and animal studies.
- Plans for testing the drug in humans (clinical trials).
- Safety measures to protect participants.

After reviewing the IND, the regulatory authority decides whether the drug can be tested in humans. If approved, the drug moves to clinical trials.[27]

Drug Discovery
↓
Preclinical Studies
(Lab + Animal Testing)
↓
IND Application Submission
(to U.S. Food and Drug Administration)
↓

FDA Review of IND

↓

Clinical Trials Start

↓ ↓ ↓

Phase 1 Phase 2 Phase 3

(Safety) (Effect) (Confirmation)

↓

Data Collection & Analysis

↓

NDA Application Submission

↓

FDA Review of NDA

↓

Approval / Rejection

↓

If Approved → Drug Marketed

↓

Post-Marketing Surveillance[28,29]

6. STAKEHOLDER IN SAFETY DATA GENERATION

Stakeholders are the people and groups involved in making sure medicines are safe. They help in collecting and checking information about side effects and risks of a drug.[30,31]

When a new medicine is developed and used, many stakeholders work together to keep patients safe.

➢ **Main Stakeholders**

- **Pharmaceutical companies** – They make the medicine and collect safety data
- **Doctors, nurses, and pharmacists** – They see how the medicine works and report side effects
- **Patients** – They take the medicine and share their experience
- **Regulatory authorities like the U.S. Food and Drug Administration** – They check the data and approve drugs
- **Researchers** – They test the drug in clinical trials.[32,33,34]

7. CONCLUSION

Pharmacovigilance is an important system that helps make sure medicines are safe for people. Over time, serious incidents like the Thalidomide tragedy and the Elixir Sulfanilamide case led to stronger rules by authorities such as the U.S. Food and Drug Administration. These rules made it necessary to test medicines properly for both safety and effectiveness. Safety data generation plays a key role at every stage of drug development, from laboratory testing to use in real patients. It helps in identifying side effects, comparing risks and benefits, and improving the quality of medicines. Continuous monitoring, especially after the drug is marketed, ensures that even rare or long-term side effects are detected and managed. The involvement of different stakeholders like pharmaceutical companies, healthcare professionals, patients, researchers, and organizations such as the World Health Organization helps create a strong

safety system. In simple words, pharmacovigilance ensures that medicines remain helpful and do not cause harm, leading to safer treatment and better health for everyone.

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