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# Pharmacovigilance: The Role Of Pharmaceutical Companies To Protect Patients From Adverse Drug Reactions

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Pharmacovigilance: The Role Of Pharmaceutical Companies To Protect Patients From Adverse  
Drug Reactions

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## 1.0 Abstract

### Objective:

Health Care Professionals (HCPs) play a vital role in the early detection, assessment and reporting of Adverse Drug Reactions (ADRs) to the Regulatory Health Authority or Pharmaceutical Manufacturer. It's always important that HCPs should improve continuously about their knowledge, attitude and their practice towards Pharmacovigilance and ADR reporting. The main goal of the research study is to evaluate whether if pharmacovigilance

training provided by the Pharmaceutical Company will improve the HCP's knowledge, their attitude and practice improves towards Pharmacovigilance and ADR reporting (Alan, Melike, Sule , Burcu, & Yusuf , 2013). The training is provided through the electronic learning management system. The learning management system (LMS) will be implemented using the Waterfall Methodology (Foreman, 2013).

## 2.0 Introduction

In developing countries, the safe use of the medicines and safeguard of the patients are given most priority. The introduction of new medications has changed the path in which diseases are overseen and controlled, and much of the time this has been a significantly useful for better evolution (Alan, Melike, Sule , Burcu, & Yusuf , 2013). Though there are controlled processes in place, there is a need to share the risks and associated benefits of the safe use of the medicines. However, recent statistics per shows there are considerable increase number of adverse drugs reaction to medicines and yet need to have proper process in place to prevent them from cause of illness, disability and even death. ADRs are one of the major drug related problems associated with pharmacotherapy causing high incidence of mortality and morbidity around the world. It has been become a major health problem around the globe. According to the Institute of Medicine in the United States (2000) reported that reported that between 44,000

and 98,000 deaths occur annually from medical errors. Out of which is 7000 deaths mainly due to the ADRs. Even in developed countries, this has been significant problem (Koh, 2014). The ADRs has made burden on the healthcare systems and the community as well.

The epidemic diseases such as Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome and Tuberculosis and malnutrition that are more predominant in the African countries, is largely chance of risks of certain ADRs in patients (Mehta, M Dheda, & Steel, 2014). The other reason for the increase of the ADRs due to misuse of the medication self-medication of the Over the Counter medicines and medication errors that are the most common underlying reasons in underdeveloped countries.

The ADRs, is causing become major problem in the health care system that needs to be addressed immediately at different levels of the health care system. The common factors that are contributing for this problem is the lack of awareness among health care providers about the risks associated with drugs and misclassification of the ADRs as other diseases or the causal conditions (Shamim, Sharib, Mahi, & Raza, 2016). However, the half of the ADRs that occur in the patients could be preventable with improved prescribing, administration, monitoring and conformance.

Consequently, need to have proper process in place to reduce the occurrence of ADRs that in turn improves the public health. It is a well-established fact, however, that in the clinical trials pharmaceutical companies do not have the statistical power to detect rare ADR's nor do they have significant follow-up to identify delayed adverse drug reactions or effects from long-term exposure (Sharrar & Dieck, 2013). In view of this, pharmacovigilance plays a prominent role in establishing the safety profile of marketed drugs, as pre-marketing clinical trials are often not.

The success or failure of the Pharmacovigilance systems would be mainly depending upon on the reporting process of the ADRs and evaluation of ADRs. For pharmaceutical

products, a proper ADR reporting process should be in place and it should be the integral part of the Pharmacovigilance program which is the efficient process of obtaining information especially new and serious ADRs (Foreman, 2013). For this information, pharmaceutical companies more rely on the HCPs to identify and report the Suspected ADRs to the competent health authorities. Therefore, most companies considered them as the main contributor for the ADR reports and believe them as genuine sources. Thus, the HCP are the contributor of spontaneous ADR reports and important roles for following

- Identification
- Assessment
- Spontaneous reporting.

Per the survey conducted by various researchers shows that the ADR could be avoided only when the HCPs have great knowledge and awareness of the pharmacovigilance and ADR reporting process (Mehta, M Dheda, & Steel, 2014). In the undeveloped countries shows pharmacovigilance training by the companies is very minimal and that's the risk associated to the products in those countries is very high and had been huge impacted on the patient population.

I work in a Pharmaceutical Industry has a Pharmacovigilance Compliance Project Manager. As part of my job responsibilities, the Adverse drugs reaction related to our product received from the different sources such as Patient, Health Care professional or from Regulatory authorities are entered the drug safety data base as per the company's policies and procedures. The information received are identified, assessed and evaluated whether the adverse event whether it's known or unknown risks. If the AE has been resulted in the death of the patient, then as Pharmaceutical Company we have an obligation to report the Regulatory Authorities within 15 days of the receipt of the information and if the event is less are severe we are expected to report this information to the health authority within 90 day of the receipt.

As part of my job responsibility, while reviewing ADRs that we receive from the healthcare professionals (HCPs), don't adhere to the Pharmacovigilance reporting requirements (Shamim, Sharib, Mahi, & Raza, 2016). HCPs play an important role in detection, assessment and spontaneous reporting of the adverse event reactions. Pharmaceuticals companies play a vital role in educating the HCPs and their practice regarding ADR reporting and Pharmacovigilance. We often see that the HCPs don't adhere the pharmacovigilance requirement, provide insufficient data to the ADR's and don't have knowledge where to report information. It's mainly due to lack of knowledge and consider ADR reporting as a time consuming process. So, that's motivated to choose this topic if the pharmacovigilance training provided to the HCPs whether or not would improve their knowledge, attitudes towards the ADR reporting. This will help the Pharmaceutical Company to see whether benefit risk profile of the drug is changed when compare to the pre clinical setting and whether new risks were been identified through and ensure that companies have enough risk minimization measures in situation such as as updating the label of the product or educating HCPs or care givers about new risks associated of the product (Maeda, Katashima, Ishizawa, & Yanagawa, 2015) (Mehta, M Dheda, & Steel, 2014).

Laws govern the pharmaceutical companies and regulations to ensure the companies have proper processes and procedures in place and to ensure the safety of the product (Foreman, 2013). It is mandatory for some of the employees working in the company are subjected to training. In the most of the pharmaceutical companies the training is provided through the paper-based system. But when the organization grows geographically it would pose a challenging problem to the company. So its always better if the company switch to the computer based system to maintain productivity. For computer based learning, electronic learning management system is required and FDA has mandated that system have to be in compliance with 21 CFR part 11 Code of Federal Regulations (Foreman, 2013). This regulation specifies the FDA guidelines on electronic records and electronic signatures in the United

States. Part 11, as it is commonly called, defines the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable and equivalent to paper records. In order to develop such complex systems would require lot of planning, inputs from end users, cross functional departments and resources. So to develop the electronic LMS, traditional waterfall methodology approach has been the most successful. For the implementation of Learning Management system consists of following steps.



### 3.0 Problem Statement and Justification

The literature review shows that that ADR is causing significant impact on the global health system, which needs to be, addressed around the globe and as well the different levels of the health care system. The main reason behind this is due to the lack of awareness among HCPs and Caregivers and impact of the problem. Also, misclassification of the ADRs as other non-drug- related diseases or symptoms of the underlying condition. (Mehta, M Dheda, & Steel, 2014)

Even regulatory authorities around the global have implement certain methods and important of Pharmacovigilance problems required to be addressed. Per (Mehta, M Dheda, & Steel, 2014) half of the ADRs could be preventable occurring in the patients with improved prescribing, monitoring and adherence to the Pharmacovigilance requirements. Improving knowledge and awareness among at different level of health care system professionals would benefits the Pharmacovigilance and address the current scenario and helps to prevent occurring the ADRs among patients. The literature indicates shows that Pharmacovigilance ADR reporting would help the companies to propose the risk minimization to prevent occurring of same AEs or ADRs related to the product and protects the patients from untoward harmful risks of the drug. The spontaneous and voluntary reporting of ADRs information is relatively new and for Serious ADR reporting, company rely on the HCPs to identify and report the suspect ADRs to Regulatory authorities or to the manufacturer of the medicine. HCPs are the primary



contributors of ADR reports and would play crucial role in identification, detection and assessment reporting of ADRs.

Pharmaceutical companies have obligation to continuous monitor the ADRs raised post marketing experience whether the ADRs impacting the benefit risk profile of the drug and implement risk minimization measures like educating the HCPs on the new risks associated with the product. However, it's always been a challenging problem for the Pharmaceutical companies because of the lack of knowledge of ADRs reporting among HCPs and reporting incomplete information to the Pharmaceutical companies that doesn't help them to propose steps to prevent the ADRs. Current knowledge and awareness among the HCPs has to be addressed (Alan, Melike, Sule , Burcu, & Yusuf , 2013). As most of the ADRs occurrence can be preventable with proper prescribing, administration, adherence and monitoring. The proper knowledge and training around pharmacovigilance reporting could bring awareness among HCPs and their perception towards ADR reporting. Pharmacovigilance is the best approach in preventing the occurrence of ADRs and AEs to protect patient well being safety and drug safety. An experimental has been proposed to determine whether or not the pharmacovigilance training provided to the HCPs would improve their knowledge and awareness among HCPs regarding the ADR reporting. The training will be provided through the electronic learning management system. The other objectives of of the study that pharmaceutical company can play an important role in increasing the knowledge of the HCPs, their attitudes towards ADR reporting and benefits of the ADR reporting which will the people from untoward occurrence of ADRs and well being of patient and product. Other underlying reasons are socio-economic concerns from ADRs, and the clear need of involvement of HCPs in the well structured program for monitoring ADRs (Maeda, Katashima, Ishizawa, & Yanagawa, 2015).

The literature review indicates, for the successful implementation of the electronic LMS traditional waterfall methodology is the right choice. The questionnaire and training will be provided through the electronic LMS. Before actual study a pilot, project will be conducted to test overall adequacy of the questionnaire and to understand what problems could be raised. So,

that the problems could be prevented in the actual study (Mehta, M Dheda, & Steel, 2014) (kc, Tragulpiankit, Gorsanan, & Edwards, 2013).

#### 4.0 Literature Review

In current world, the new medicine has changed the way the disease perspective and has been controlled. However, there should be common process in places in minimizing the event of adverse reactions to medicines such as disability, prolonged hospitalization and in the event of death (Mehta, M Dheda, & Steel, 2014).

A best example for this is the Thalidomide tragedy that occurred in the 1960's that led to the congenital abnormality in the newborn neonates to the mother who used the product Thalidomide to treat morning sickness during pregnancy. Due to proper lack of timely reporting events led to the linkage between the effects of product and which is resulted in the congenital abnormality and delayed responsible for the conclusion of Thalidomide introductions. Though this could have been prevented if proper reporting channels would have been in place by informing the patients to know about the adverse events associated with use of the medicines (Jha, Rathore, & Ravi Shankar, 2014).

Due to this major break out this had become the modern starting point of science focused on the patient problems caused by the use of the products in the market. This new branch of science and activities related with it is known as "Pharmacovigilance".

According WHO definition the Pharmacovigilance is defined as the science and activities related

- Detection

- Assessment

- Understanding and prevention of AEs or any other drug related problem (EMA, 2012).

The objective of the Pharmacovigilance to improve the patient care and patient safety in related to use of the medicines and to support the patient through the patient programmes by providing benefit risk profile of the products to the patients (EMA, 2012). The main priorities of any Pharmaceutical companies is to safe guard the patients and safe use of the medicines. The main objective of Regulatory agency and Pharmaceutical Company is to ensure the quality, efficacy and safety of the all the products available in the market. They do based on the two criteria through the data received from the in vitro studies through by ensuring the compliance of the standards and data received from animal preclinical and clinical studies in the humans (EMA, 2012).

Though the products in clinical settings but doesn't have a power a to detect all rare ADRs. Since because in the premarket clinical trials doesn't give full safety profile of the drug and so in this view Pharmacovigilance plays an important role in establishing the safety profile of the marketed drugs (European, 2014). In order to improve the Pharmacovigilance process the drug safety regulations laid by the health regulatory agency is often gets updated in order to improve patient safety and to prevent or minimizing the prevalence of the ADRs. Nonetheless, its remains problem if there is lack of reporting and knowledge about the Pharmacovigilance (European, 2014).

### **Adverse Drug Reactions:**

The main objective of the Pharmacovigilance is mainly related with the reporting of the ADRs. As per the definition of the WHO ADR is defined as a response to medicine in humans or animals, which is unintended and noxious including the lack of efficacy that occurs at any dosage and can also be due to misuse, overdose and abuse. Adverse event (AE) is any undesirable experience associated with the use of the medicinal product in human (kc,

Tragulpiankit, Gorsanan, & Edwards, 2013). Per the literature review ADR and AEs are common problems due to the pharmacotherapy and which are main reason for the congenital anomaly, morbidity and mortality around the world. In some countries ADRs are categorized as a top ten for the leading causes of the mortality. Per the research studies conducted at various parts of the world containing 41900 patients and identified that approximately 6.7% of all the hospitalization were due to ADRs (Mehta, M Dheda, & Steel, 2014). Below are the statistics from the countries were AEs accounted for hospitalization (Mehta, M Dheda, & Steel, 2014)

- 3.2 % in France
- 6.7% in the USA
- 12% in Sweden
- 6.5% in the UK

The studies conducted by Metha (2014) showed for managing ADRs it causing significant burden on the Health care. Per the literature review, some countries are spending 15% of their budget to manage drug related issues. So, due to ADRs pose more burden on the health care system as they lead to prolonged hospital stays and increase cost of the treatment.

### **ADR reporting:**

The success of the Pharmacovigilance depends upon the suspected ADR reporting process. The ADR reporting process can be done by two methods

- Voluntary
- Spontaneous reporting

Spontaneous reporting is considered as the most common method and the keystone for any Pharmacovigilance system (European, 2014).

The two reporting system are considered as the essential components of the drug safety surveillance system and are the most effective methods of collecting ADRs especially in case of the new and serious ADRs. This type of reporting lies within in the HCPs identify and report

suspected ADRs to the respective health authorities or the pharmaceutical companies that own marketing authorization for the product.

Though the process is considered as vital role for the reporting but under reporting is the most outcome for the spontaneous reporting system (European, 2014). The underreporting system will impact majorly on the safety profile of the product which delays in identifying the ADRs and can increase risks of drugs related morbidity and mortality rate. Overall, under reporting of the ADRs is common and significant problem for developing effective drug safety surveillance programs for products.

### **Under –reporting by HCPs**

Per the several studies in the literature shows that HCPs play a vital in role in the identifying, assessment and spontaneous reporting of the ADRs. To understand the reasons for the under reporting there were number global conducted to assess their attitude and behavior towards the regulatory program and their ADR reporting program with aim of recognizing reason of underreporting and the steps to evaluating the steps to improve the increase reporting rates (Peter , Hervé , Yola , & Conti, 2016). Based on the studies conducted and here are the summarize of the various studies due lack of resources for drug safety surveillance and reporting, Labor intensive and time consuming for reporting processes, ambiguity in interpreting whether the AE is in relationship to the product, ignored about the official procedures, ADRs are mistakenly considered significant to report, no reward and motivation to report and lack of knowledge to differentiate between ADRs and minor ones.

Based on the several studies to assess the knowledge, attitude and practice between HCP and results show that their knowledge regarding reporting procedures is inadequate. The only way to improve their knowledge is to provide continuous training about the products and make them familiar to the ADR reporting process and change their attitudes and beliefs (Alan, Melike, Sule , Burcu, & Yusuf , 2013).

### **Improving HCP's pharmacovigilance awareness:**

Health Authorities, Pharmaceutical Companies and HCP play a vital role in protecting the patients from the harmful effects of the medicines. This would be the shared responsibility by each of them to understand the risks associated with the medicines and have proper process in places in minimizing or managing the risks associated with use of the products.

Raising awareness of the important risk associated with the medicines directly or indirectly and gives brief information about the benefits related to the product will help addressing the drug-induced diseases. Lack of maintaining such vigilance system would impact more and even sometime fatal consequences as well. The HCPs should know about benefits and risks associated to the medicines (Peter , Hervé , Yola , & Conti, 2016). The HCPs should inform to the patients about the benefit and risks profile of the medicines and give clear instruction about the use of the medicines. HCPs should also broader knowledge about the pharmacovigilance and ADR reporting process to effectively minimize the drug related reactions (Bowers, 2011). HCPs need to know their role and responsibility for the following

- Detection
- Management
- Documentation
- ADR reporting process

### **The role of Pharmaceutical companies to educate HCPs Pharmacovigilance awareness:**

Drug safety system is now considered as the integral part of the pharmaceutical companies. The current regulatory framework shows the Pharmacovigilance is considered as the crucial and categorized them as the organizational obligation. Improving the knowledge about the benefits of the pharmacovigilance could change the perception and considered it as the fundamental position (European, 2014). Pharmaceutical should have generalized process and standards about the awareness of the pharmacovigilance among companywide employees by creating certain norms and training all employees on the process and procedures. The companies should have

proper pharmacovigilance system that makes awareness around the benefits of those systems, which may help HCPs effectively maintain patient's safety and ensuring that patients are free from the harmful effects of the medicines.

### **Role and responsibility of Pharmaceutical Companies.**

The main objective of the Pharmaceutical companies is to ensure the marketed products are safe and effective use for the human. The Pharmaceutical companies should proper risk management systems to evaluate continuously about safety -risk profile of the products. This could be achieved only when proper pharmacovigilance systems are in places. Pharma companies have obligation to continuously monitor their product use and AEs received from the resources and to detect, assess and evaluate the ADRs to understand the and prevent the ADRs by having better risk management systems. In order to achieve this regulatory agency have developed certain framework for Pharmacovigilance standards the company should have to established such as

- 1) Having a responsible contact person for the product in the European area and will acting as liaison between the Pharmaceutical Company and Regulatory agency.
- 2) Immediate actions should be taken when the serious ADRs identified related to the product
- 3) Benefit -risk profiles ratio of the product should be continuously informed to the regulatory agency.

The Companies should have to work together with other stakeholders such HCPs; Patient Support Programmes to make sure the safety of patient is compromised using the medicines (European, 2014).

### **A strong Pharmacovigilance System:**

Companies should have strong pharmacovigilance system to identify and assess the ADRs received from the different resources and have proper process in place for addressing them.

In developing countries and poor countries, Pharmacovigilance systems are not well established with in the companies and often seen to detect the ADRs related to the products. The Pharmacovigilance system should include the following

- Should continuous monitor the risks and benefits of the drug
- Give proper information to the patient about the safe use of the drug and associated risks related to drug (Bowers, 2011).
- Need to have proper process for training to the HCPs and their effective communication with the patients on the use of the medicines.
- Ensuring the nurses and health care professionals are aware about the Pharmacovigilance reporting process.

The companies should motivate the HCPs to more vigilant while prescribing the drugs to the patients and monitor them continuous about the use of medicines. A strong Pharmacovigilance system helps in identifying the AEs that have not been seen in the clinical setting and evaluating the effectiveness of the product. This system will help in decreasing the incidence of the morbidity and mortality. The Pharmacovigilance is considered as effective only when the ADRs related to the products are managed appropriately and the safety profile of the drug remained same from pre-clinical setting to the clinical setting.

### **Implementation of Electronic Learning Management System:**

Upon literature review, the successful implementation of Learning Management System Traditional waterfall methodology has been proven and widely used methodology in the pharmaceutical companies. For the implementation of Learning management system requires following are key essential steps for selecting right product (Foreman, 2013).



For the selecting the right product for the company, requires inputs from cross-functional stakeholders and the inputs from the management team. This requires a proper planning and



inputs from the current paper based training groups about the requirements. The requirements gathering should do properly before the selection of the product. For successful implementation of the LMS right resources are selected which is the crucial step Organizations that lack appropriate planning and resources risk a string of unwanted surprises, extensive delays, and problems that are likely to result in unhappy users. Once resources are identified, through traditional waterfall methodology following steps should be followed (Foreman, 2013).



The further literature review will be conducted to understand what possible timelines for the implementation of LMS.

## 5.0 Methodology

Per the available literature and results shown that ADR has been significant problem that is accounting for the hospitalization in some of the countries and also causing significant burden on the healthcare system. As the problem has been arising only due to lack of awareness about the effects and severity of the problem (Koh, 2014).

The Pharmaceutical more rely on the ADR reporting process and HCPs plays an important role in the detection, assessment and evaluating the ADRs. The only thing is to improve their knowledge, attitude and perception in reporting the information and towards and Pharmacovigilance.

The research design that have chosen for this research proposal is to evaluate whether the training provided to the HCPs would improve their knowledge, attitude towards reporting of the ADRs. A quantitative research study design methodology will be used for evaluating the results. A traditional waterfall methodology will be used for the implementation of the electronic LMS (Foreman, 2013). Upon literature review shown that, waterfall methodology has been successful method for the implementation of LMS.

A quasi-experimental research method will be used to evaluate the HCPs knowledge. A total of 40 HCPs, which includes General Physician or Research Nurse, will be the participants in the study. All the participants are divided in two groups. Each group will have equal number of participants in the study. The experimental group gets the Pharmaceutical Pharmacovigilance training interventional and control group will not receive the training. To assess the knowledge of the HCPs each group will receive the questionnaire before and after the pharmaceutical pharmacovigilance training intervention. At the end of the study the results will be analyzed to determine the pharmacovigilance training provided to the experimental group whether or not improved their knowledge, attitude towards Pharmacovigilance ADR reporting.

### **Objectives of the Research Study:**

The Main aim of the research study is to evaluate whether or not training provided by the companies would increase the HCPs knowledge towards ADR reporting. Also, determines the significant role of the companies can play in improving the knowledge of HCPs around the importance of ADR reporting and safety of the medicines.

To determine the training provided would help in changing attitudes of the HCPs towards the pharmacovigilance reporting and increase their knowledge towards the pharmacovigilance system (Patidar, Rajput, Nirmal, & Savitri, 2013). The initial experimental design has three phases

### **Experimental Design:**

In order to evaluate if the Global Pharmacovigilance product and patient safety would bring the awareness in the HCPs regarding the ADR reporting and their attitudes a qualification test will be done pre-and post-test design.

Here are the following phases would be included.

- Observation Point 1(also known pretest)
- Intervention- Pharmacovigilance training
- Observation Point 2(Post test)

If a difference in the results pre-test and post-test, then one would expect it would be the intervention of the Pharmacovigilance training provided by the Pharmaceutical company.

Though this approach good idea but need to have a control groups because we cannot come to conclusion the results are due to Pharmacovigilance training may arise from memory bias. So, a control group is included and utilizes a quasi-experimental research design (Mehta, M Dheda, & Steel, 2014).

- Non-random experiment group
- observation study point 1
- Intervention
- Observation study point 2
- Nonrandom control group
- Observation study point 1
- No intervention
- Observation study point 2

So, the groups are divided into two and both are required to complete an initial questionnaire in the LMS which has set of ADR reporting and Pharmacovigilance questions to complete. Once the observational point 1 is finished then the non-random experimental groups got Pharmacovigilance training and other hand control group did not receive any training. After the two weeks, then at the post step or observational study point 2 the groups were to take again the same pharmacovigilance questionnaire.

## The Questionnaire Design

The HCP knowledge and their attitudes towards ADR reporting and Pharmacovigilance among all the research participants are assessed and participants completed the questionnaire by using pen and paper. The questionnaires are used at different phases of the study discussed in the section 4.3 (kc, Tragulpiankit, Gorsanan, & Edwards, 2013).

The Questionnaire consists of following sections.

- Demographic information of the HCP
- Question related to Pharmacovigilance
- HCP practice
- Prior experience in the ADR reporting process
- Specialization of the HCP
- Reasons for encourage or discourage ADR reporting
- Problem faced while reporting ADR process.

The following questionnaires are designed based on the literature reviewed, current job experience and the common issues identified in the underdeveloped and developed countries. A total 25 questions were framed to collect the information of the demographics, Knowledge and their attitudes regarding ADR reporting, prior experiences and issues they commonly face.

Most of the questions are framed most of the different aspects of Pharmacovigilance and ADR reporting process. The questions are more centric to HCP viewpoint and their experience of ADR reporting (kc, Tragulpiankit, Gorsanan, & Edwards, 2013). The responses were most of them are measured on the Likert scale and consist of

- Strongly disagree (=1)
- Disagree (=2)
- Neutral (=3)
- Agree (=4)

- Strong Disagree(=5)

The questionnaire is reviewed by SMEs of the different companies and changes are made appropriate. The informed consent of the all the participants will be taken and confidentiality is ensured.

### **Pilot Study**

A pilot study is conducted to test adequacy of the questionnaire. The questionnaire is will be complete to similar audience volunteer were to participate in the study. Based on the issues faced from the underlying pilot study can help to make necessary changes in the questionnaire and improved the overall study. The participants participated in the study are not participated in the actual study (Mehta, M Dheda, & Steel, 2014). The only four questions included for this study. Based on the results some of the questions were modified and were reassessed again. The pilot study results were given boost to study.

### **Pharmacovigilance training.**

Pharmacovigilance and HCP training a play pivotal role in this research study.

Pharmacovigilance training would help in improving their attitude and their knowledge. The pharmacovigilance system is backbone for the pharmaceutical company to promote and understand the product knowledge that is on the market and under development.

The pharmacovigilance trainings included the following sections (kc, Tragulpiankit, Gorsanan, & Edwards, 2013)

- 1) ADR reporting timelines
- 2) Importance of Pharmacovigilance
- 3) History of Pharmacovigilance
- 4) International Pharmacovigilance
- 5) FDA regulatory guidelines
- 6) Role of the Pharmaceutical Company

- 7) Companies Pharmacovigilance system
- 8) Role of HCPs
- 9) Examples of Safety related and POCs.

### **Study Participants:**

The participants in the study were among the general physicians or working in hospitals. The total participants in the study are 20 and they will be divided into two groups, 10 in experimental group who received Pharmacovigilance training and other group 10 in control group who did not received pharmacovigilance training. Experimental groups received the Company named Y Pharmacovigilance training and training will be provided. (Peter , Hervé , Yola , & Conti, 2016). Before doing the training, take questionnaire will be asked to complete the questionnaire by both groups. A quasi-experimental research method will be used to evaluate the HCPs knowledge. All the participants are divided in two groups. Each group will have equal number of participants in the study. The experimental group gets the Pharmaceutical Pharmacovigilance training interventional and control group will not receive the training. To assess the knowledge of the HCPs each group will receive the questionnaire before and after the pharmaceutical pharmacovigilance training intervention. At the end of the study the results will be analyzed to determine the pharmacovigilance training provided to the experimental group whether or not improved their knowledge, attitude towards Pharmacovigilance ADR reporting.

### **Statistical analysis:**

The results obtained from this research were analyzed after the end of the training. The effect of the pharmacovigilance training would be analyzed based on the pre test and posttest between the two groups. The data would be analyzed to understand the difference in pharmacovigilance knowledge after the end of the study.

### **Questionnaire Examples:**

- 1) Please specify your gender
  - a) Yes
  - b) No
  
- 2) Please provide your age
  - a) 20-25
  - b) 35-40
  - c) 50-60
  - d) 50-67
  
- 3) Qualification details
  - a) Doctor
  - b) Pharmacist
  
- 4) How many years of experience in your field
  - a) 4
  - b) 5
  - c) 7
  - d) 8
  
- 5) Do you do browsing in Internet?

- a) Yes
  - b) No
- 6) Do you aware of Pharmacovigilance
- a) Yes
  - b) No
- 7) Have you ever reported ADR?
- a) Yes
  - b) No
- 8) Have ever trained on Pharmacovigilance training by any company?
- a) Yes
  - b) No
- 9) ADR reporting can only be done by
- a) HCPs
  - b) Pharmacists
  - c) Both
- 10) Please indicate your gender:
- a. Male
  - b. Female
- 11) Please provide your age in years: a.
- a. 24 - 30
  - b. 31 - 40
  - c. 41 - 50
  - d. 51 - 60
  - e. Above 60



12 Professional qualification

- a. Doctor
- b. Pharmacist
- c. Nurses

13 Please state your years of experience in your field

- a. 1 – 5
- b. 6 – 10
- c. 11 – 15
- d. 16 – 20
- e. Above 20

14 Do you have internet access

- a. Yes
- b. No

15 Are you aware of the term Pharmacovigilance?

- a. Yes
- b. No

16 What do you think Pharmacovigilance is?

- a. Detection and reporting of any unintended effect of a pharmaceutical product occurring at normal dosage which is related to the pharmacological properties of the drug
- b. Reporting of any unintended effect resulting from the use of a pharmaceutical product to the Pharmaceutical Company that manufactures the pharmaceutical product.
- c. The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

17 What do you think pharmacovigilance aims to assess?

- a. Safety over efficacy
- b. Efficacy over safety

18 An Adverse drug reaction is defined as: any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment( WHO)

- a. True
- b. False

19 ADR reporting can be done by

- a. Healthcare Professionals
- b. Patients
- c. Both

20 Which of the following defines a serious adverse event?

- a. Life threatening
- b. Disability
- c. Death
- d. Hospitalization
- e. All

21 With regards to ADR reporting, please mark the statement that best describes your reporting experience:

- a. I have never reported an ADR before
- b. I have reported the ADR to the Hospital Institution where I work
- c. I have reported the ADR to the Pharmaceutical Company
- d. I have reported the FDA
- e. I have reported to other Health Care Professionals

22 Are you aware that you can report ADR's to the FDA?

- a. Yes
- b. No

23 Have you ever reported and ADR or side effect to a Pharmaceutical company?

- a. Yes
- b. No

24 Have you recently come across a side effect that you felt was strange/new/serious and wished to report it to the Pharmaceutical company

- a. Yes
- b. No

Statements	Level of agreement				
	Strongly agree	Agree	Not sure	Disagree	Strongly disagree
Do you know how to report ADR					
Are you aware of any procedure how to report ADR					
Do you think one ADR report will make any difference					
Do you think managing patient reporting more than ADR reporting					
Do you have time to report ADR					
Do you think ADR reporting takes more time					
Do you think Pharmacovigilance is important as already its known ADR					
If I provide training, will you be able to report an ADR.					
Do you aware the benefits of the ADR					
Do think ADR reporting is part of my professional responsibility					
Do you think Pharmacovigilance is overrated system?					
Do you think HCPs need to be provided to training Pharmacovigilance					

	Statements	Level of agreement				
		Strongly agree	Agree	Not sure	Disagree	Strongly disagree
29	Healthcare professionals need to increase ADR reporting to effectively prevent avoidable, harmful drug reactions					
30	Do you think success or failure depends on ADR reporting					
32	Pharmacovigilance won't lead to fewer ADR's					
33	Have you ever received training on the Pharmaceutical company					

### 6.0 PROPOSED WORK PLAN

My plan is to initiate project kick meeting early summer i.e from 21-Jun-2017 and end around 21-Jan-2018. Before starting the activities related to the project I would consider what resources might be needed for the successful implementation of the project. Below are the proposed plan dates for the project.

Activity	Responsible Person	Start Data	End date
Prerequisites Set Kick-Off meeting	PM and Company Stakeholder sponsor	21-Jun-2017	21-Jun-2017
Agree on Objectives	PM and	22-June-2017	22-Jun-2017

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	Company Stakeholder Sponsor		
Initiation- Requirements and Human Resource Planning	PM, HR	26-Jun-2017	28-Jul-2017
Logistic resources like hardware, access to databases ProQuest, company online journal resources	PM and HR and relevant SMEs	01-Aug-2017	01-Sep-2017
Activities related to Literature review	SMEs like SAS programmer, Risk Management Manager, Compliance specialist	02-Sep-2017	06-Nov-2017
Development of Questionnaire	All SMEs and Project Manager	07-Nov-17	18-Dec-17
Pilot Project demo	PM	19-Dec-17	20-Dec-17
Any changes to Pilot Project	PM and SMEs	21-Dec-2017	26-Dec-17
Finalization of Pilot Project Questionnaire	PM and Risk Management Manager	28-Dec-2017	29-Dec-17

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Recruitment of Research Participants	PM and Risk Management Manager	02-Jan-2018	05-Jan-2018
Initiation of Pilot Project	Risk Management Manager	08-Jan-2018	09-Jan-2018
Analyzation of the data generated from test and Results	Risk Management Manager and Statistical Programmer.	10-Jan-2018	12-Jan-2018
To discuss problems of the pilot project and questionnaire changes if applicable	PM and all SMEs	15-Jan-2018	18-Jan-2018
Develop final research questionnaire	SMEs Risk Management Manager and Medical Advisors	19-Jan-2018	28-Feb-2018
Research participant's recruitments for actual research study	PM and all SMEs	28-Feb-2018	16-Mar-2018
Initiation of the actual research	Risk	19-Mar-2018	19-Mar-2018

study	Management Manager & SMEs		
Intervention of Pharmacovigilance training	Risk Management Manager and Medical Advisors	19-Mar-2018	23-Mar-2018
Retest the knowledge of Participants	Risk Management manager	02-Apr-2018	02-Apr-18
Analyse the Research study data	SAS programmer	03-Apr-2018	06-Apr-2018
Results	PM and Risk Management	09-Apr-2018	10-Apr-2018
Results shown to stakeholder or sponsor	PM	16-Apr-2018	16-Apr-2018
Completion of the project	PM	17-Apr-2018	17-Apr-2018



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