FREQUENTLY ASKED QUESTIONS IN PHARMACOVIGILANCE INTERVIEWS & Its PREPARATIONS

Pristyn
Way to Success

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What is Pharmacovigilance?

According to **W.H.O-C.C.I.D.M** The science and activities relating to the detection, assessment, understanding , prevention & Reporting of adverse effects or any other drug- related problem.

What is the minimum criterion required for a valid case according to WHO?

a. An identifiable reporter

b. An identifiable patient

c. A suspect product

d. An adverse drug event

What is an Adverse Drug Event (ADE)?

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.

When do you consider an event to be serious?

If an event is associated with any one of the following, it is considered to be serious

a. Death

b. Life threatening

c. Hospitalization or prolongation of hospitalization.

d. Congenital anomaly

e. Disability

f. Medically significant

Name the regulatory bodies in USA, UK, Japan and India?

USA: United States Food and drug administration (USFDA).

UK: European Medicines Agency (EMEA).

Japan: Ministry of Health, Labour and Welfare (MHLW).

India: IDA Indian Drug Administration previously known as **Central Drugs Standard Control Organization (CDSCO)**

What is Volume 9A?

Volume 9A brings together general guidance on the requirements, procedures, roles and activities in the field of pharmacovigilance, for both Marketing Authorisation Holders (MAH) and Competent Authorities of medicinal products for human use; it incorporates international agreements reached within the framework of the International Conference on Harmonisation (ICH).

Volume 9A is presented in four parts:

Part I deals with Guidelines for Marketing Authorisation Holders;

Part II deals with Guidelines for Competent Authorities and the Agency;

Part III provides the Guidelines for the electronic exchange of pharmacovigilance in the EU

Part IV provides Guidelines on pharmacovigilance communication.

When do you consider a case to be medically confirmed?

A case is considered to be medically confirmed if it contains at least one event confirmed or reported by an HCP (Health Care Professional)

Note: HCP can be a physician, nurse, pharmacist, coroner or psychologist (only in Germany).

What do you mean by causality?

Causality is the relationship between a set of factors. In Pharmacovigilance, causality is the relationship between the suspect product and the adverse drug event.

- Is there a convincing relationship between the drug and the event?
- Did the drug actually cause the event?

Name some data elements in ICSR?

Patient demographics: Age, gender and race.

Suspect product details: Drug, dose, dosage form, therapy dates, therapy duration and indication. Adverse event details: Event, event onset date, seriousness criterion, event end date and latency.

(For practical work on software and other systems for ICSR also for internship in P.V join our short –term training)

What should a narrative consist of?

A narrative should consist of precise and concise information about the source of report, patient demographics, patient's medical history, concomitant medications, suspect product details and adverse event details in an orderly manner.

(For practical work on software and other systems on Narrative also for internship in P.V join our short –term training)

Explain the hierarchy in MedDRA.

System Organ Class (SOC)

High Level Group Term (HLGT)

High Level Term (HLT)

Preferred Term (PT)

Lower Level Term (LLT)

What do you know about E2a, E2b and E2c guidelines?

E2a: E2a guidelines give standard definitions and terminology for key aspects of clinical safety reporting. It also gives guidance on mechanisms for handling expedited (rapid) reporting of adverse drug reactions in the investigational phase of drug development.

E2b: E2b guidelines for the maintenance of clinical safety data management and information about the data elements for transmission of Individual Case Safety Reports.

E2c: E2b guidelines for the maintenance of clinical safety data management and information about the Periodic Safety Update Reports for marketed drugs. (For Guideline soft copy contact us)

State the benefits of Pharmacovigilance program.

This program will increase the knowledge and importance of Pharmacovigilance in drug discovery process and Clinical Research, Pharmacovigilance is becoming an important part of drug development as it deals with the patients' safety & efficacy of drug resulted into new job avenues. The participants after the completion of this would have new economic pursuits as Pharmacovigilance potential opportunities & growth prospects are huge.

Pharmacovigilance programme of India **(PVPI)** - launched in July 2010.

Goal

"To ensure the benefits of use of medicine. safeguard the health of the Indian population"

Role of Drug Safety Associate:

Manage and relay d rug safety information, maintain current knowledge of global drug safety regulations, summaries clinical safety data, participate in meetings with potential and actual study sponsors, write narratives with medical input from a physician, report SADRs to the Regulatory Authorities, participate in the training of operational staff on drug safety issues, quality control work o f other staff in the department, take on any other task as assigned by the manager or Medical Director within the capabilities of the Drug Safety Associate.

What are the objectives in Pharmacovigilance?

Evidence - medicine-related problems

- Public confidence
- Identification of risk factors
- Quantifying risks
- Understanding the concepts of ADR, Medical Errors, Public Health Significance, Regulatory Interventions, ADR Monitoring schemes.

The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems.

What are the types of Pharmacovigilance (PV)?

A. Two types. 1. Active PV and 2.Passive PV

Active PV: Active (or proactive) safety surveillance means that active measures are taken to detect adverse events. This is managed by active follow-up after treatment and the events may be detected by asking patients directly or screening patient records. The most comprehensive method is cohort event monitoring (CEM)

Passive PV: Passive surveillance means that no active measures are taken to look for adverse effects other than the encouragement of health professionals and others to report safety concerns. Reporting is dependent on the initiative and motivation of the potential reporters. This is the most common form of pharmacovigilance. It is commonly referred to as “spontaneous” or “voluntary” reporting.

What are the due dates for safety reporting?

A. Safety reporting due dates are 7days for IND Reporting and 15 days for NDA Reporting

What are Data assessments in Pharmacovigilance?

Data assessments are:

Individual case report assessment

Aggregated assessment and interpretation

Signal detection

Interactions and risk factors

Serial study

Frequency

Estimation

Aim of pharmacovigilance:

- rapid identification of events that are likely to affect adherence to treatment and determination of their rates, and identification of the risk factors that make these events more likely, with the aim of reducing their occurrence;
- identification of signals (i.e., possible causal relationships between an adverse event and a medicine; see Glossary) of ADRs of concern following the introduction of a new drug or drug combination;

• assessment of signals to evaluate causality, clinical relevance, frequency and distribution of ADRs in particular population groups;

calculation of rates of events so that:

— risk can be measured;

— the safety of different medicines can be compared and informed choices made;

— risk factors can be clearly identified;

• contribution to the assessment of benefit, harm, effectiveness and risk of medicines, leading to the prevention of harm and maximization of benefit;

• appropriate response or action in terms of drug registration, drug use and/or training and education for health professionals and the public;

• measurement and evaluation of the outcome of the response or of action taken (e.g. reduction in risk, improved medicine use, or improved outcome for patients experiencing a particular ADR);

• timely communication with and recommendations to authorities and the public; and

• feedback to the clinicians who provided the information.

Pharmacovigilance centre (PvC)

The PvC of an individual country is responsible for meeting the requirements for pharmacovigilance of all medicines. It is a centre of expertise for the art and science of monitoring and analysis of ADRs, and in use of the information analysed for the benefit of patients. National and regional PvCs should be set up with the approval or involvement of the authority responsible for the regulation of medicines ("regulatory authority"). The centre may function within the regulatory authority, a hospital, an academic institution or as an independent facility such as a trust or foundation.

What is Spontaneous reporting?

Spontaneous (or voluntary) reporting means that no active measures are taken to look for adverse effects other than the encouragement of health professionals and others to report safety concerns. Reporting is entirely dependent on the initiative and motivation of the potential reporters. This is the most common form of pharmacovigilance, sometimes termed passive reporting. In some countries this form of reporting is mandatory. Clinicians, pharmacists and community members should be trained on how, when, what and where to report.

Suitable methods of reporting:

Telephone

Fax

E-mail

Internet

What is WHO ART, WHO DD and MedDRA and the difference between them?

The WHO Drug dictionary (DD), MedDRA and the WHO Adverse reactions terminology (WHO-ART).

WHODD= used for drug coding

MedDRA, WHO-ART = coding of events.

What is Cemflow?

CemFlow is a tool maintained by the UMC for database management in cohort event monitoring (CEM). It is web based and the fields match the data elements on the questionnaires. There are screens for patient demographics, treatment initiation, treatment review and assessment of events. CemFlow as a tool for data entry into an online database maintained by the UMC (Uppsala Monitoring Centre) for CEM. CemFlow provides for entry of cohort data as well as the events.

What to report in PV?

Patient details (Name, Address:, Sex, Date of birth, Weight and height).

Patient medical history of significance.

Details of medicines (this may be the brand or generic name, preferably brand) and formulation, mode of administration (e.g. oral, rectal, or injection), Indication(s) for use, dose).

Reaction details (Date of onset, outcome: resolved, resolving, no change, disabling, worsening, death (with date), or congenital anomaly, Effect of rechallenge).

Reporter details

Date and place of report

Seriousness criteria based on intensity?

not severe, mild, moderate, severe

Synonyms for relatedness (causality-related)?

Related: Certain, possible, probable, likely

Synonyms for relatedness (causality- unrelated)?

Not related: Unlikely, Unclassified (or conditional), Unassessable.

Odd scenarios in PV?

Pregnancy.

Overdose (>MTD)

Off label use

Medication error

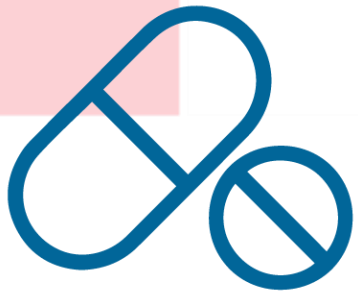
Lack of efficacy.

What is Co-morbid conditions?

Patients may be more susceptible to particular ADRs if they also have other health problems, either because of the concomitant condition or from the interaction of the medicines being used to treat the other condition(s).

What is a signal?

Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. The publication of a signal usually implies the need for some kind of review or action.



DRUG

SIGNAL

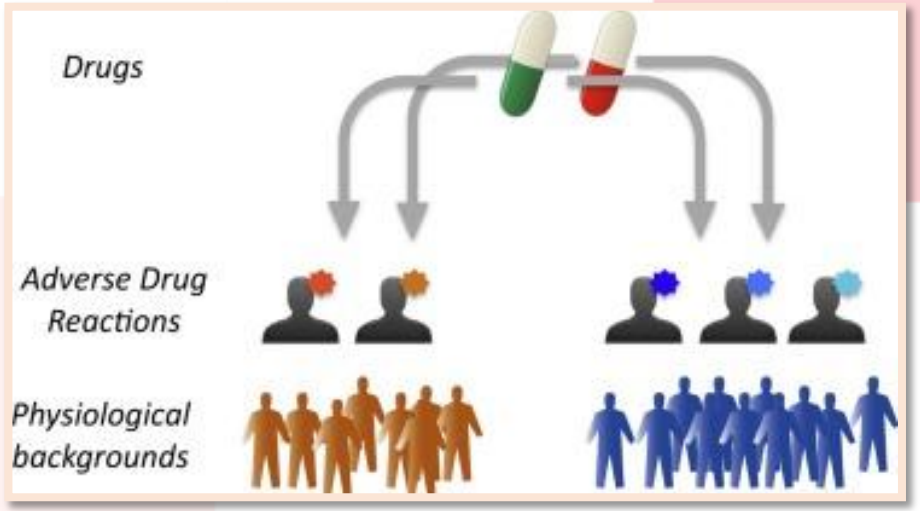
AE

Methods of signal detection?

Methods of signal identification

There are four methods for identifying signals:

1. Clinical assessment of individual events
2. Clinical review of collated events
3. Record linkage
4. Automated signal detection.



Full form of PV terms?

ADRs adverse reactions to medicines (adverse drug reactions)

ART antiretroviral therapy

ARV antiretroviral

ATC Anatomic Therapeutic Chemical (Classification for medicines)

BCPNN Bayesian Confidence Propagating Neural Network

CEM cohort event monitoring

CemFlow Cohort Event Monitoring data entry and analytical tool

DD (WHO) Drug dictionary

ICD 10 WHO International classification of diseases version 10

IMAI integrated management of adolescent and adult illness

ICSR individual case safety report(s)

MedDRA Medical dictionary for drug regulatory activities

OI opportunistic infection

IMMP (The New Zealand) Intensive Medicines Monitoring Programme

PEM prescription event monitoring

PvC Pharmacovigilance Centre

VigiBase WHO database of individual case safety (ADR) reports (ICSR)

VigiFlow spontaneous reporting data entry and analytical tool

VigiMine data mining tool available as part of VigiSearch

VigiSearch search tool for searching the VigiBase database

WHO World Health Organization

WHO-ART WHO adverse reactions terminology.

SUSAR Suspected Unexpected Serious Adverse Reaction

SAE Serious Adverse Event

CIOMS Council for International Organizations of Medical Sciences

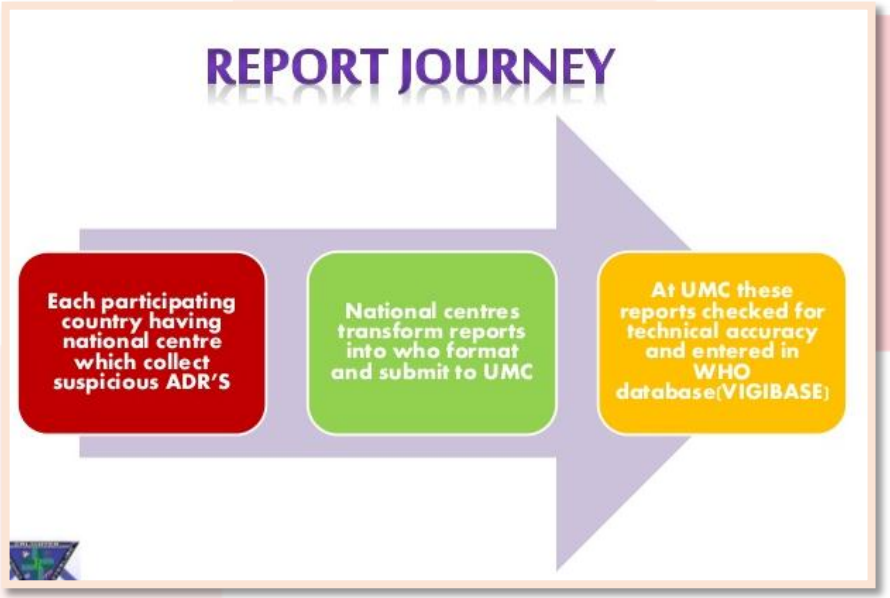
ADE Adverse Drug Event

SSAR Suspected Serious Adverse Reaction

SOC system organ class

SOP standard operating procedure

UMC the Uppsala Monitoring Centre



ADR Adverse Drug Reaction

ICSR Individual Case Safety Report

PSUR Periodic Safety Update Report

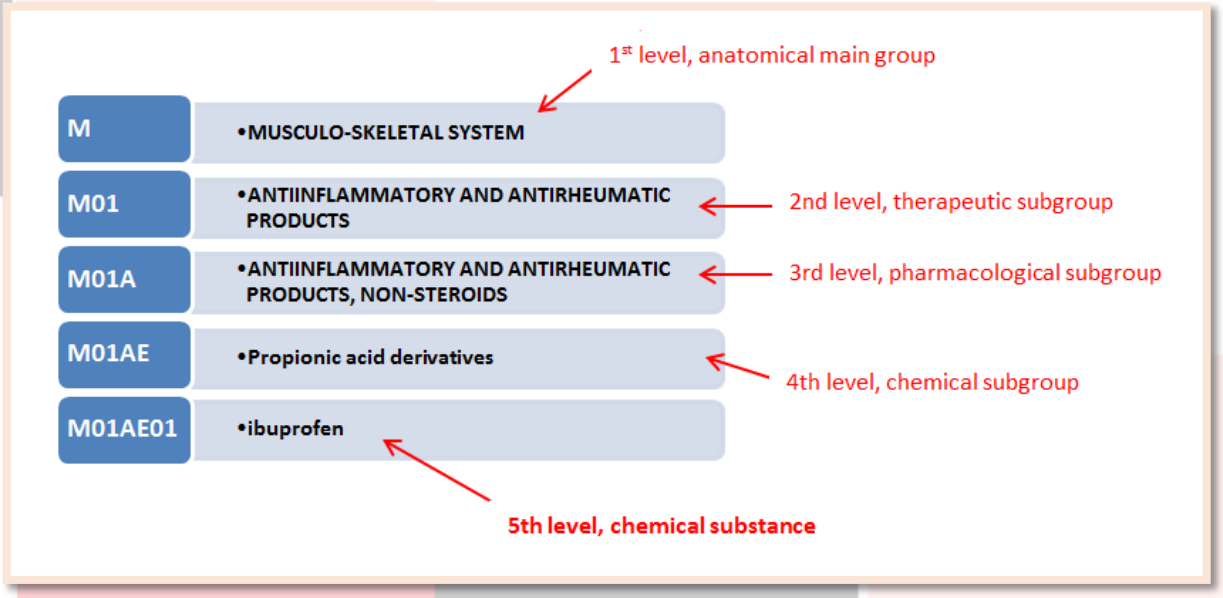
ICH The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

HIPAA Health Insurance Portability and Accountability Act

ESTRI Electronic Standards for the Transfer of Regulatory Information

IBD International Birth Date

ATC Anatomical Therapeutic Chemical (ATC) Classification



Outcome of the event

The types of outcome to be recorded are as follows, along with codes that can be used to simplify recording:

R1 resolved;

R2 resolving;

RS resolved with sequelae;

NR not resolved;

Re-challenge

The point at which a drug is again given to a patient after its previous withdrawal - also see de-challenge.

De-challenge

The withdrawal of a drug from a patient; the point at which the continuity, reduction or disappearance of adverse effects may be observed.

International Society of Pharmacovigilance (ISOP)

This is an important international society. Their web site gives information about meetings and training courses.

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Definations you should know before applying for PV?

Absolute risk

Risk in a population of exposed persons; the probability of an event affecting members of a particular population (e.g. 1 in 1,000). Absolute risk can be measured over time (incidence) or at a given time (prevalence).

Adverse Event (AE)

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.

Adverse (Drug) Reaction (ADR)

A response which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function. (WHO, 1972).

"A response to a medicinal product which is noxious and unintended."

Allopathy

Non-traditional, western scientific therapy, usually using synthesised ingredients, but may also contain a purified active ingredient extracted from a plant or other natural source, usually in opposition to the disease.

Association

Events associated in time but not necessarily linked as cause and effect.

Attributable risk

Difference between the risk in an exposed population (absolute risk) and the risk in an unexposed population (reference risk). Attributable risk is the result of an absolute comparison between outcome frequency measurements, such as incidence.

Biological products

Medical products prepared from biological material of human, animal or microbiologic

Causal relationship

A relationship between one phenomenon or event (A) and another (B) in which A precedes and causes

B. In pharmacovigilance; a medicine causing an adverse reaction.

Causality assessment

1. The evaluation of the likelihood that a medicine was the causative agent of an observed
2. adverse reaction. Causality assessment is usually made according established algorithms.

Caveat document

The formal advisory warning accompanying data release from the WHO Global ICSR, Database: it specifies the conditions and reservations applying to interpretations and use of the data.

Cem-Flow

Software developed by UMC for collection and analysis of data in Cohort Event Monitoring.

Clinical trial

A systematic study on pharmaceutical products in human subjects (including patients and other volunteers) in order to discover or verify the effects of and/or identify any adverse reaction to investigational products, and/or to study the absorption, distribution, metabolism and excretion (ADME) of the products with the objective of ascertaining their efficacy and safety.

Cohort Event Monitoring

Cohort Event Monitoring (CEM) is a prospective, observational study of events that occur during the use of medicines, for intensified follow-up of selected medicinal products phase. Patients are monitored from the time they begin treatment, and for a defined period of time.

Compliance:

Faithful adherence by the patient to the prescriber's instructions.

Control group:

The comparison group in drug-trials not being given the studied drug.

Critical terms

Some of the terms in WHO-ART are marked as 'Critical Terms'. These terms either refer to or might be indicative of serious disease states, and warrant special attention, because of their possible association with the risk of serious illness which may lead to more decisive action than reports on other terms.

Data mining:

A general term for computerised extraction of potentially interesting patterns from large data sets often based on statistical algorithms. A related term with essentially the same meaning is 'pattern discovery'. In pharmacovigilance, the commonest application of data mining is so called disproportionality analysis, for example using the Information component (IC).

De-challenge

The withdrawal of a drug from a patient; the point at which the continuity, reduction or disappearance of adverse effects may be observed.

Disproportionality analysis:

Screening of ICSR databases for reporting rates which are higher than expected. For drug- ADR pairs, common measures of disproportionality are the Proportional Reporting Ratio (PRR), the Reporting Odds Ratio (ROR), The Information Component (IC), and the Empirical Bayes Geometrical Mean (EBGM). There are also disproportionality measures for drug-drug-ADR triplets, such as Omega (Ω).

Effectiveness/risk

The balance between the rates of effectiveness of a medicine versus the risk of harm is a quantitative assessment of the merit of a medicine used in routine clinical practice. Comparative information between therapies is most useful. This is more useful than the efficacy and hazard predictions from pre-marketing information that is limited and based on selected subjects.

Efficacy:

The ability of a drug to produce the intended effect as determined by scientific methods, for example in pre-clinical research conditions (opposite of hazard).

Epidemiology:

The science concerned with the study of the factors determining and influencing the frequency and distribution of disease, injury and other health-related events and their causes in a defined human population for the purpose of establishing programs to prevent and control their development and spread.

Essential medicines

Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness.

Excipients

All materials included to make a pharmaceutical formulation (e.g. a tablet) except the active drug substance(s).

Formulary

A listing of medicinal drugs with their uses, methods of administration, available dose, dosage forms, side effects, etc, sometimes including their formulas and methods of preparation.

Harm

The nature and extent of actual damage that could be caused by a drug. Not to be confused with risk.

Frequency of ADRs:

In giving an estimate of the frequency of ADRs the following standard categories are recommended:

Very common* > 10%

Common (frequent) >1% and <10%

Uncommon (infrequent) >0.1% and < 1%

Rare >0.01% and <0.1%

Very rare* <0.01%

* Optional categories

Generic (multisource product)

The term ‘generic product’ has somewhat different meanings in different jurisdictions. Generic products may be marketed either under the non-proprietary approved name or under a new brand (proprietary) name. They are usually intended to be interchangeable with the innovator product, which is usually manufactured without a license from the innovator company and marketed after the expiry of patent or other exclusivity rights.

Herbal medicine

Includes herbs, herbal materials, herbal preparations and finished herbal products.

Homeopathy

Homeopathy is a therapeutic system which works on the principle that ‘like treats like’. An illness is treated with a medicine which could produce similar symptoms in a healthy person. The active ingredients are given in highly diluted form to avoid toxicity. Homeopathic remedies are virtually 100% safe.

Information component (IC)

The Information component (IC) measures the disproportionality in the reporting of a drug- ADR pair in an ICSR database, relative to the reporting expected based on the overall reporting of the drug and the ADR. Positive IC values indicate higher reporting than expected. The IC has also been implemented on electronic health records, to detect interesting temporal relationships between drug prescriptions and medical events.

Incidence

Number of new cases of an outcome which develop over a defined time period in a defined population at risk.

Individual Case Safety Report (ICSR)

A report that contains ‘information describing a suspected adverse drug reaction related to the administration of one or more medicinal products to an individual patient’.

MedDRA

MedDRA is the Medical Dictionary for Regulatory Activities. WHO-ART, the WHO Adverse Reactions Terminology, is now mapped to MedDRA.

Medical error

“An unintended act (either of omission or commission) or one that does not achieve its intended outcomes.”

Member countries

Countries which comply with the criteria for, and have joined the WHO Programme for International Drug Monitoring.

National Pharmacovigilance centres

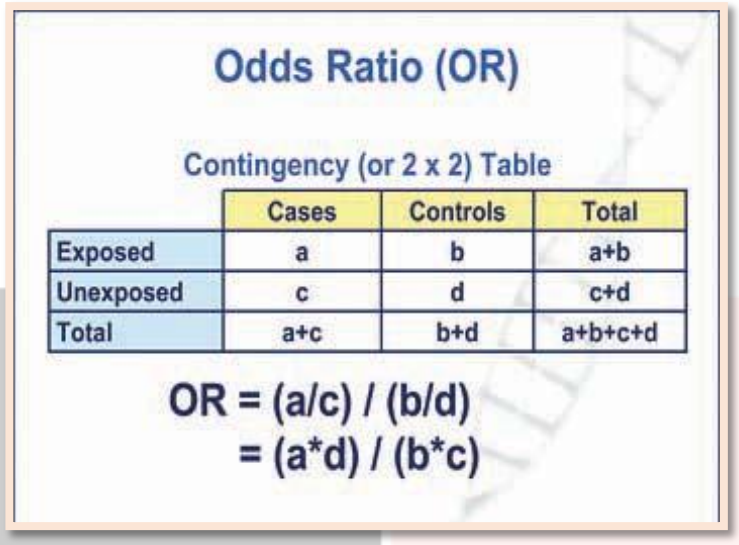
Organisations recognised by governments to represent their country in the WHO Programme (usually the drug regulatory agency). A single, governmentally recognized centre (or integrated system) within a country with the clinical and scientific expertise to collect, collate, analyse and give advice on all information related to drug safety.

Odds

Probability of an occurrence p divided by the probability of its non-ocurrence (1 - p).

Odds ratio

Ratio of the Odds in a given population and the Odds in another population.



Omega (Ω)

A measure of disproportionate reporting for drug-drug-ADR triplets in ICSR databases, designed to highlight potential signals of drug- drug interactions. Just like the more established disproportionality measures for drug-ADR pairs, Ω is based on a contrast between the observed and expected number of reports. A positive Ω indicates higher reporting than expected.

OTC (Over the Counter) medicine

Medicinal product available to the public without prescription.

Pani-Flow

Software developed by UMC for collection and analysis of data in relation to vaccinations in a pandemic situation.

Periodic Safety Update Report (PSUR)

A systematic review of the global safety data which became available to the manufacturer of a marketed drug during a specific time period. Produced in an internationally agreed format.

Pharmacoepidemiology: Study of the use and effects of drugs in large populations.

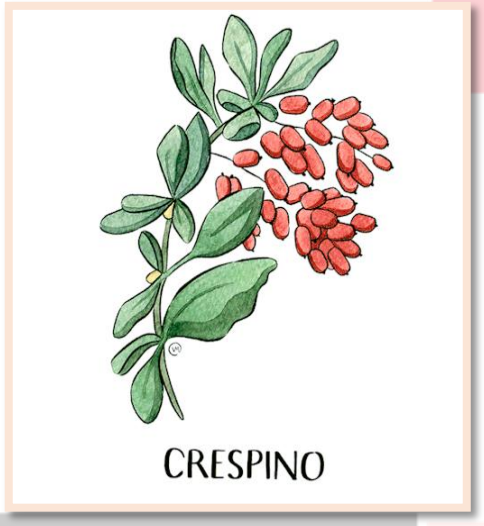
Pharmacology: Study of the uses, effects and modes of action of drugs.

Phocomelia

Characteristic deformity caused by exposure to thalidomide in the womb, also very rarely occurring spontaneously. Meaning: limbs like a seal.

Phytotherapy

Western-style, scientific treatment using plant extracts or materials.



Placebo

An inactive substance (often called a sugar pill) given to a group being studied to compare results with the effects of the active drug.

Polypharmacy

The concomitant use of more than one drug, sometimes prescribed by different practitioners.

Post-marketing

The stage when a drug is generally available on the market.

Predisposing factors

Any aspect of the patient's history (other than the drug) which might explain reported adverse events (genetic factors, diet, alcohol consumption, disease history, polypharmacy or use of herbal medicines, for example).

Prescription Event Monitoring (PEM)

System created to monitor adverse drug events in a population. Prescribers are requested to report all events, regardless of whether they are suspected adverse events, for identified patients receiving a specified drug. Also more accurately named Cohort Event Monitoring.

Prescription Only Medicine (POM)

Medicinal product available to the public only on prescription.

Prevalence

Number of existing cases of an outcome in a defined population at a given point in time.

Prophylaxis

Prevention or protection.

Rational drug use

An ideal of therapeutic practice in which drugs are prescribed and used in exact accordance with the best understanding of their appropriateness for the indication and the particular patient, and of their benefit, harm effectiveness and risk.

Pre-marketing

The stage before a drug is available for prescription or sale to the public.

Record linkage

Method of assembling information contained in two or more records, e.g. In different sets of medical charts, and in vital records such as birth and death certificates. This makes it possible to relate significant health events that are remote from one another in time and place.

Reference risk

Risk in a population of unexposed persons; also called baseline risk. Reference risk can be measured over time (incidence) or at a given time (prevalence). The unexposed population refers to a reference population, as closely comparable to the exposed population as possible, apart from the exposure.

Regulatory authority

The legal authority in any country with the responsibility of regulating all matters relating to drugs.

Relative risk

Ratio of the risk in an exposed population (absolute risk) and the risk in an unexposed population (reference risk). Relative risk is the result of a relative comparison between outcome frequency measurements, e.g. incidences.

Risk

The probability of harm being caused; the probability (chance, odds) of an occurrence.

Serious Adverse Event or Reaction

A serious adverse event or reaction is any untoward medical occurrence that at any dose:

results in death

requires inpatient hospitalization or prolongation of existing hospitalization

results in persistent or significant disability/incapacity

is life-threatening

Side effect

Any unintended effect of a pharmaceutical product occurring at normal dosage which is related to the pharmacological properties of the drug.

Signal

Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. The publication of a signal usually implies the need for some kind of review or action.

Summary of Product Characteristics (SPC)

A regulatory document attached to the marketing authorization which forms the basis of the product information made available to prescribers and patients.

Spontaneous reporting

System whereby case reports of adverse drug events are voluntarily submitted from health professionals and pharmaceutical manufacturers to the national regulatory authority.

Thalidomide

Drug prescribed in the 1950s as a mild sleeping pill and remedy for morning-sickness for pregnant women. Led to serious birth defects and the start of modern pharmacovigilance. Returning to favour in treatment of serious diseases such as cancer and leprosy.

Traditional medicines

Traditional medicine is the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.

Unexpected adverse reaction

An adverse reaction, the nature or severity of which is not consistent with domestic labelling or market authorization, or expected from characteristics of the drug.

Vigi-Base

The name of the WHO Global ICSR Database.

Vigi-Flow

Vigi-Flow is a complete ICSR management system created and maintained by the UMC. It is web-based and built to adhere to the ICH-E2B standard. It can be used as the national database for countries in the WHO Programme as it incorporates tools for report analysis, and facilitates sending reports to Vigi-Base.

Vigi-med

Share point based conferencing facility, exclusive to member countries of the WHO Programme for International Drug Monitoring for fast communication of topical pharmacovigilance issues.

Vigi-Mine

A statistical tool within Vigi-Search with vast statistical material calculated for all Drug- ADR pairs (combinations) available in Vigi-Base. The main features include the disproportionality measure (IC value) stratified in different ways and useful filter capabilities.

Vigi-Search

A search service for accessing ICSRs stored in the Vigi-Base database offered by the UMC to national pharmacovigilance centres and other third-party inquirers.

WHO-ART

Terminology for coding clinical information in relation to drug therapy. WHO-ART is maintained by UMC.

WHO Drug Dictionary (WHO DD)

The WHO Drug Dictionary is an international classification of drugs providing proprietary and non-proprietary names of medicinal products used in different countries, together with all active ingredients.

WHO-UMC Causality assessment scale

Causality term Assessment criteria*

Certain

Event or laboratory test abnormality, with plausible time relationship to drug intake

Cannot be explained by disease or other drugs

Response to withdrawal plausible (pharmacologically, pathologically)

Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognized pharmacological phenomenon)

Rechallenge satisfactory, if necessary

Probable/ Likely

Event or laboratory test abnormality, with reasonable time relationship to drug intake

Unlikely to be attributed to disease or other drugs

Response to withdrawal clinically reasonable

Rechallenge not required

Possible

Event or laboratory test abnormality, with reasonable time relationship to drug intake

Could also be explained by disease or other drugs

Information on drug withdrawal may be lacking or unclear

Unlikely

Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible)

Disease or other drugs provide plausible explanations

Conditional/Unclassified

Event or laboratory test abnormality

More data for proper assessment needed, or

Additional data under examination

Unassessable/ Unclassifiable

Report suggesting an adverse reaction

Cannot be judged because information is insufficient or contradictory

Data cannot be supplemented or verified

What is SUSAR:

SUSAR: An unexpected adverse reaction (UAR) is an adverse reaction that is not consistent with the product information in the SPC.

A suspected unexpected serious adverse reaction (SUSAR) is any UAR that at any dose:

a. Results in death;

b. Is life threatening (i.e. the subject was at risk of death at the time of the event)

c. Refer to an event which hypothetically might have caused death if it were more severe

d. Requires hospitalisation or prolongation of existing hospitalisation;

e. Results in persistent or significant disability or incapacity;

f. Is a congenital anomaly or birth defect.

SUSAR is a serious adverse drug reaction (SAR) that is unexpected or for which the development is uncommon (unexpected issue) observed during a clinical trial and for which there is a relationship with the experimental drug, whatever the tested drug or its comparator.

What is Day zero?

Day zero remain as the day that the first information was received.

Or

Day zero should be considered the day on which the minimum criteria for a reportable adverse reaction report becomes available

Medication Errors

Medication errors are mishaps that occur during prescribing, transcribing, dispensing, administering, adherence, or monitoring a drug. Examples of medication errors include misreading or miswriting a prescription. Medication errors that are stopped before harm can occur are sometimes called “near misses” or “close calls” or more formally, a potential adverse drug event. Not all prescribing errors lead to adverse outcomes. Some do not cause harm, while others are caught before harm can occur (“near-misses”).

Medication errors are more common than adverse drug events, but result in harm less than 1% of the time. About 25% of adverse drug events are due to medication errors.

Misuse

This refers to situations where the medicine is intentionally and inappropriately used not in accordance with the authorised PI or the directions for use on the medicine label.

Beneficial effects

The adverse effect of a drug should not be considered without taking account of its beneficial effects.

Process in Pharmacovigilance

Collect and record of AEs / ADRs

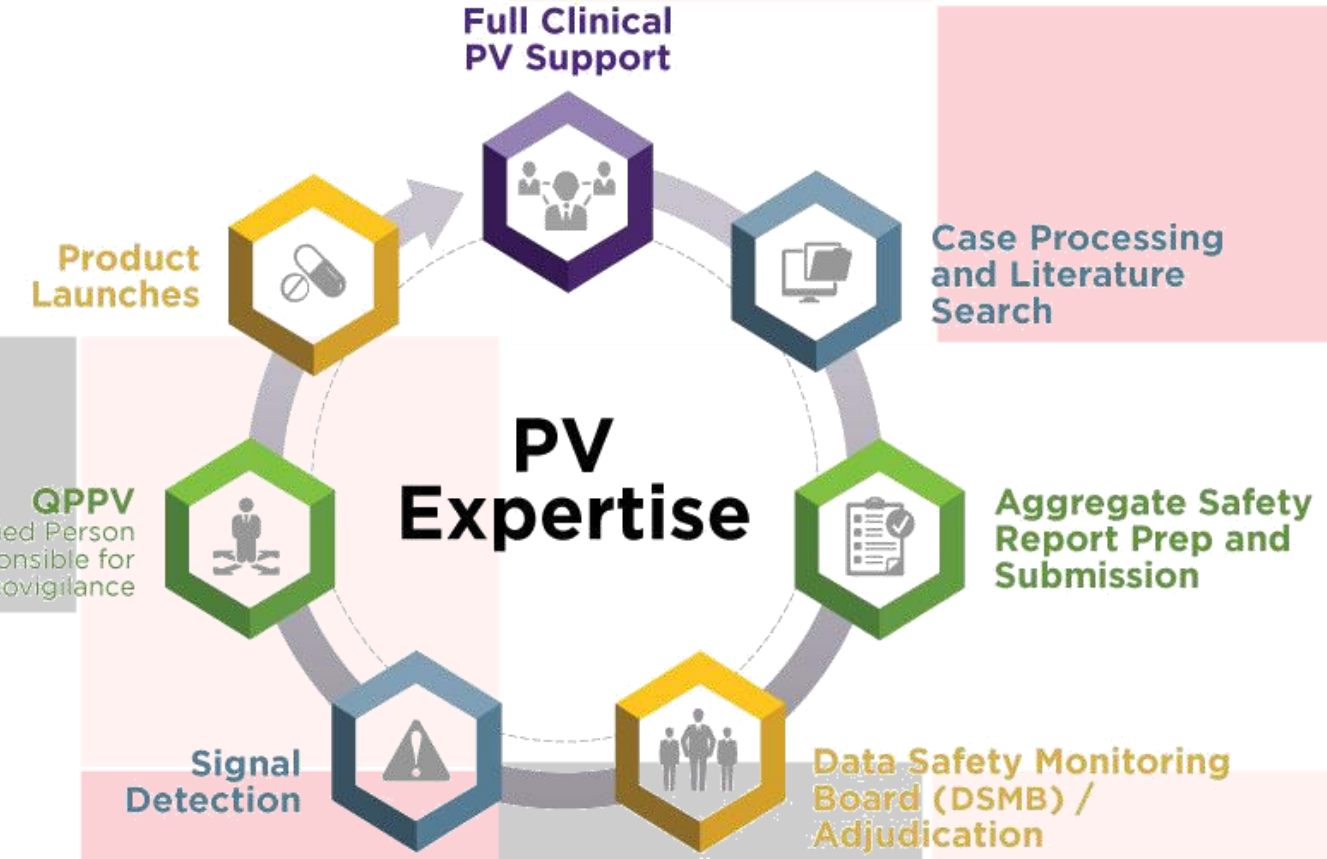
Causality assessment and analysis of ADRs

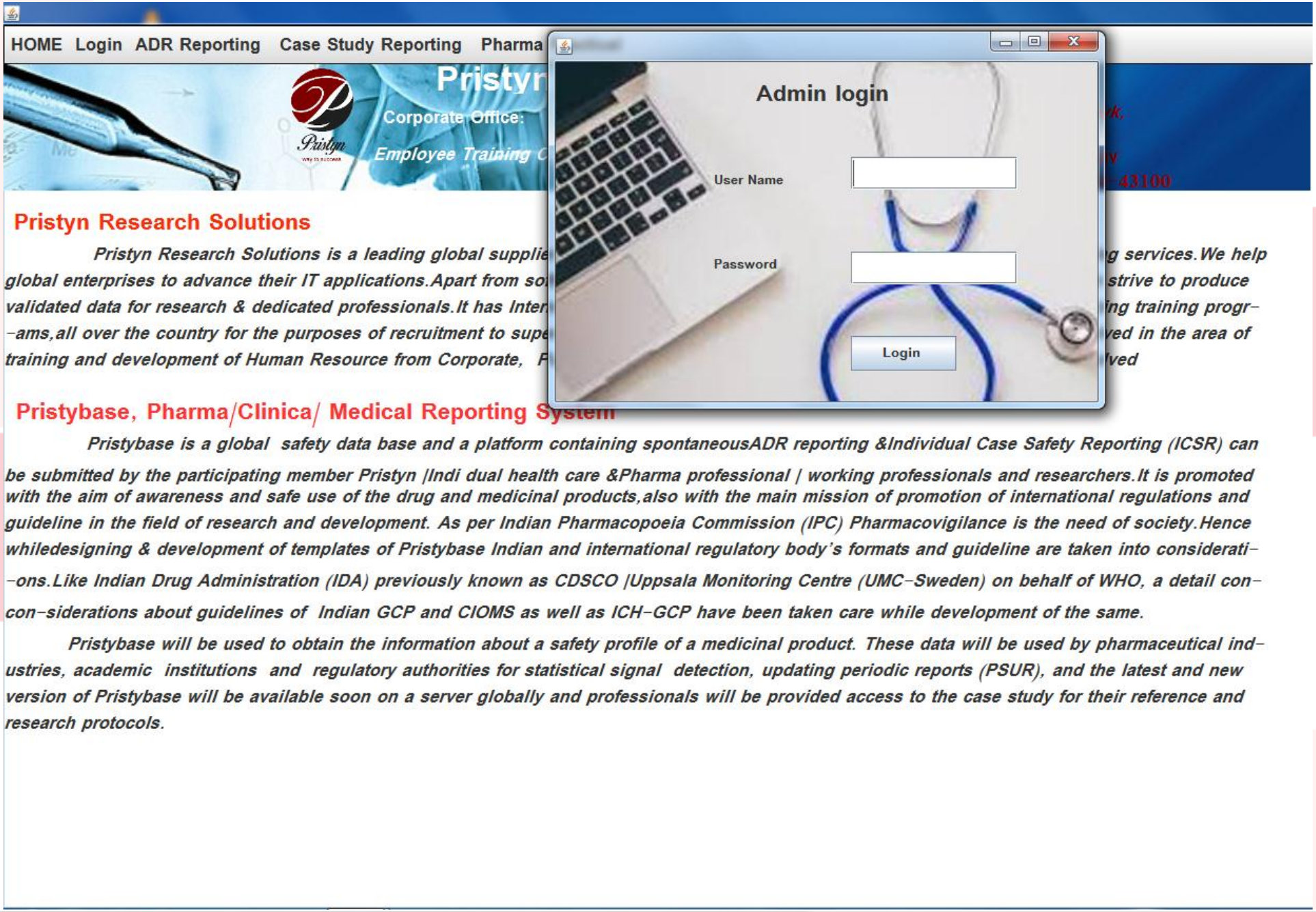
Collate and code in database

Compute risk-benefit and suggest regulatory action

Communicate for safe use of drugs among stakeholders

Practical Demo





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Pristyn Research Solutions

Pristyn Research Solutions is a leading global supplie ...g services.We help global enterprises to advance their IT applications.Apart from so... strive to produce validated data for research & dedicated professionals.It has Inter... ...ing training progr--ams,all over the country for the purposes of recruitment to supe... ...ved in the area of training and development of Human Resource from Corporate, P... ...lved

Pristybase, Pharma/Clinica/ Medical Reporting System

Pristybase is a global safety data base and a platform containing spontaneousADR reporting &Individual Case Safety Reporting (ICSR) can be submitted by the participating member Pristyn |Indi dual health care &Pharma professional | working professionals and researchers.It is promoted with the aim of awareness and safe use of the drug and medicinal products,also with the main mission of promotion of international regulations and guideline in the field of research and development. As per Indian Pharmacopoeia Commission (IPC) Pharmacovigilance is the need of society.Hence whiledesigning & development of templates of Pristybase Indian and international regulatory body's formats and guideline are taken into considerati--ons.Like Indian Drug Administration (IDA) previously known as CDSCO |Uppsala Monitoring Centre (UMC-Sweden) on behalf of WHO, a detail con-con-siderations about guidelines of Indian GCP and CIOMS as well as ICH-GCP have been taken care while development of the same.

Pristybase will be used to obtain the information about a safety profile of a medicinal product. These data will be used by pharmaceutical ind--ustries, academic institutions and regulatory authorities for statistical signal detection, updating periodic reports (PSUR), and the latest and new version of Pristybase will be available soon on a server globally and professionals will be provided access to the case study for their reference and research protocols.

C. SUSPECTED MEDICATION(S)

Report Number
Sr.No
8. Name (Brand/Generic)
Manufacturer (if known)
Batch No. / Lot No.
Exp. Date
Dose used
Route used
Frequency (OD, BD etc.)
Therapy dates strated
Therapy dates stopped
Indication
Causality Assessment
Add

Report Number	S.No	8. Name (Bran...	Manufacturer (...	Batch No. / Lot...	Exp. Date (if k...	Dose used	Route used	Frequency (O...	Therapy dates...	Therapy dates...	Indication	Causality Ass...

9. Action Taken(in Yes or No)

Report Number
S.No as per C: 1
Drug withdrawn: YES
Dose increased: YES
Dose reduced: YES
Dose not changed: YES
Not applicable: YES
Unknown: YES

10. Reaction reappeared after reintroduction (please tick): YES

Effect unknown: YES
Dose (if reintroduced)
Add

Report Number	S.No as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Reaction reappe...	Effect unknown	Dose (if reintrodu...

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

Report Number
Sr.No
Name (Brand/Generic)
Route Used
Frequency (OD, BD, etc.)
Therapy dates started
Therapy dates stopped
Indication
Add

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Current Standard Hiring Process of Companies

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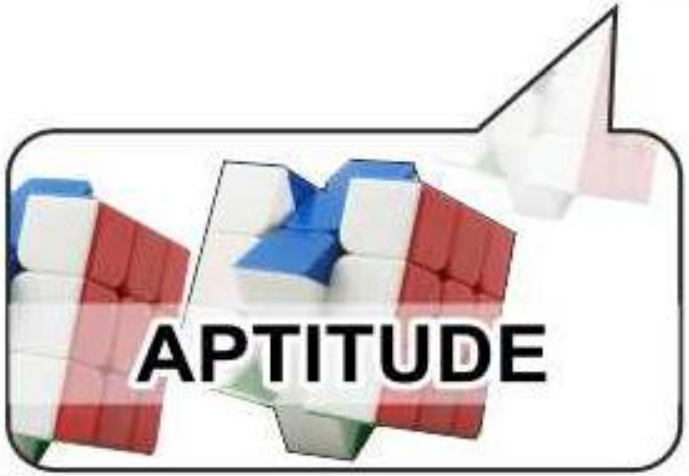

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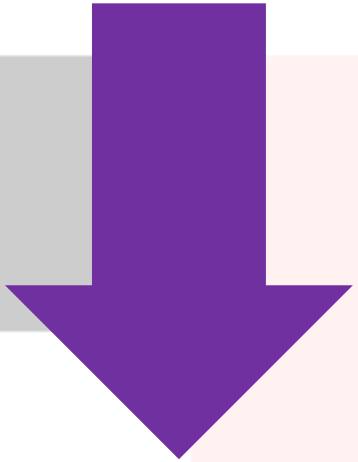

Check

Pharmacovigilance | Clinical Research | Clinical Data Management
Drug Regulatory Affairs | Pharma Q.A / Q.C | Pharma Production
Pharma Digital Marketing | R & D | Medical Coding
Medical Transcription | Medical Writing | Research Publications

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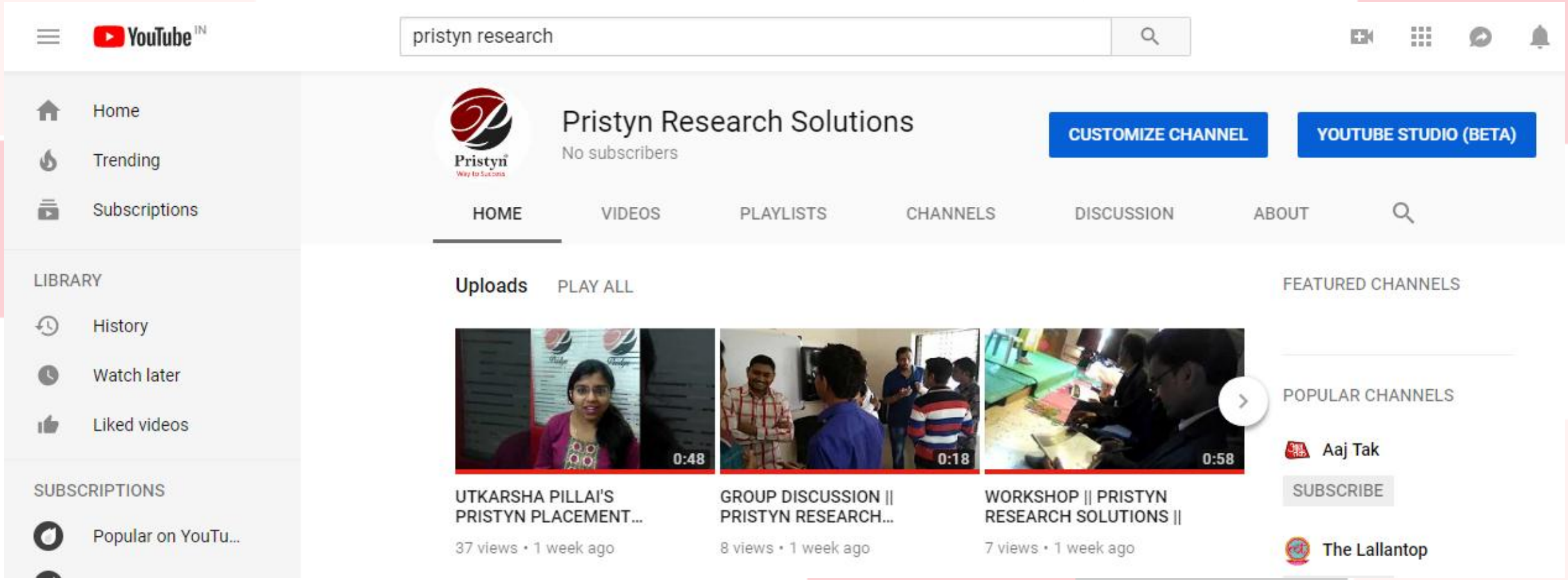

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LAST

Malviya proposed a vote of thanks.

Shivaji College of Pharmacy, Deori

Guests present at the workshop.

A DAYLONG workshop on "Students Industrial Pre-Placement Programme" was organised by Chhatrapati Shivaji College of Pharmacy, Deori in association with MSBTE, Mumbai and Pristyn Research Solution ,Pune. The main objectivebehind organising the workshop is to create awareness among the student about the industrial demand for skilled manpower to have employability. Pristyn Director Pathan Azhar Khan guided on Drug Discovery to Approval process with latest requirements and international regulations. The delegates were acquainted with role and responsibilities, interview techniques and job requirement . Pristyn Counselor Pavitra Shibad and Vinod Nair explains about the importance of having pleasant personality, soft skills and communication skills. In this workshop, Zhamsing B. Yerne, President Krushna Sahypgi Tantra Shikshan Sanstha (Deori) Presided over while Dr. Milind Umekar ,Principal SKB College of Pharmacy, Kamptee and Dr. Dinesh Biyani Associate Prof. were chiefly present alongwith Anil Z. Yerne ,Secretary and Jayshree Yerne. Dr Milind Umekar also spoke on the occasion.Earlier, Upadesh Bhimrao Lade, Principal of Chhatrapati Shivaji College of Pharmacy, Deori delivered inaugural speech. Meenakshi Mhaske conducted the proceedings while Co-ordinator Sandipkumar Agrawal proposed vote of thanks.

Shri Shivaji College, Akola

About Pristyn Research Solutions:

Pristyn Research Solutions is a leading global supplier of I.T, Clinical, Pharmaceutical services and Knowledge processing services. We help global enterprises to advance their IT applications. Apart from software developments and frame-work global services Pristyn provide corporate training in profession and skills development. We strive to produce validated data for research & dedicated professionals. It has International affiliations and regional government approvals for organizing training programs, all over the country - for the purposes of recruitment to superior posts. It has huge associations of individuals and group involved in the area of training and development of Human Resource from Corporate, Public, Private Sector Organization & other Professional Bodies.

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(A) Domain	(B) Domain	(C) Domain
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3. Clinical data Management	3. DRA | Ph-Digital Marketing	3) P.V| Research Publications
4. Drug Regulatory Affairs	4. R & D	4) DRA
Duration= 3 Months	Duration= 3 Months	Duration= 3 Months

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- Group Discussion and Teamwork
- Job Search/Job Applying Tools and Tricks
- Computer & Online literacy required for Job
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- Resume/C.V and Profile Building
- Motivational Lectures by industry Persons
- Career Guidance/ Self-Confidence Boosting
- Brush up-on English language.
- Soft Skills and communication
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(Drug Discovery to Approval)

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2. PHP	2. PYTHON	Development Work for 1 Month

Advanced PGD & Professional Internship Programed (I.T)

Domain	Domain	Duration= 6 Months
1. JAVA	1. .NET	Live Client Project and
2. PHP	2. PYTHON	Development Work for 2 Month

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