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One Day National Seminar
On
"Clinical Research – Current Status and Future Prospectus"

12 November, 2022

Organized by

Swami Vivekanand College of Pharmacy

Vivekanand Knowledge City, Khandwa Road,
Indore 452020 (M.P.) - India
Phone: 07324405000, 405027
Email: info@svcp.ac.in

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Programme Schedule

Time	Events
10:00 am-11:00 am	Inauguration
11:00 am-12:00 pm	Plenary Lecture I
12:00 pm-1:00 pm	Plenary Lecture II
1:00 pm-2:00 pm	Lunch
2:00 pm-3:00 pm	Plenary Lecture III
2:30 pm- 3:30 pm	Poster session
3:00 pm-4:00 pm	Valedictory Function

Chief Patron Message…….

It is a matter of pleasure that the Swami Vivekanand College of Pharmacy is organizing National seminar on the theme "Clinical Research- Current Status and Future Prospectus" on 12 November, 2022.

This seminar is a unique forum for exchange of innovative ideas, technical expertise for technological advancements in this evergreen field. It includes keynote address from Academicians and poster presentation by research scholars and students.

It is a matter of joy for us to welcome the participants to this seminar. I am confident that the national seminar will create the awareness among the all the stockholder. I hope that this national seminar will dwell upon issues related to clinical research.

I congratulate the Institute in organizing the national seminar and wish them a grand success.

Mr. Anoop Mishra
Chairman

Patron Message……..

It gives me an immense pleasure that Swami Vivekanand College of Pharmacy is organizing the National seminar on the theme "Clinical Research- Current Status and Future Prospectus" on 12 November, 2022.

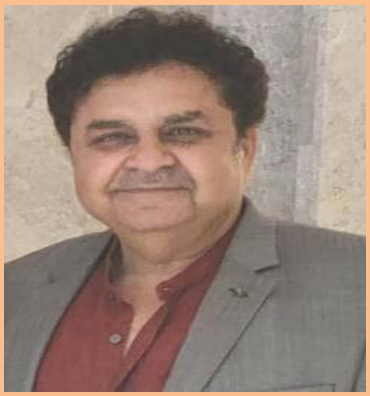
The discipline of clinical research has become highly specialized and contributed positively to the practice of Clinical Research.

The main objective of the seminar is to provide platform to the students, faculties and industrialists of profession involved in the direction of academic development & scientific research to understand the recent research and development in the field of Clinical Research.

I extent my warm welcome to young researchers, Pharmacy professionals, speakers, eminent scientists, guests, faculties, and industrialists in this splendid seminar and wish the seminar a great success.

Mr. Ashwini Mishra

Secretary



Co-Patron Message……

It gives me immense pleasure to be a part of this hosting team of theme "Clinical Research- Current Status and Future Prospectus" on 12 November, 2022.The Seminar intends to bring together academician, practitioners from medical disciplines, research scholar and students to discuss clinical research related issues.

I take this opportunity to welcome all the delegates of the conference.

I would like to express my appreciation to the organizing committee for their dedicated efforts to materialize the seminar. I hope all the participants will have a fruitful and beneficial experience.

My best wishes to all participants of the seminar to make the most out of this event by learning about clinical research.

Mr. Sachin Mishra

Director

Principal Message……

It gives me great pleasure that Swami Vivekanand College of Pharmacy is organizing One day National seminar on the topic "Clinical Research- Current Status and Future Prospectus" on 12 November, 2022.

Pharmacy profession is a Nobel profession and is emerging day by day with development of innovative techniques and trends which will certainly beneficial our society. This seminar would provide opportunities to the delegates to exchanges their ideas and about the clinical research.

I hope this seminar will provide an excellent opportunity for the delegates to enrich their knowledge in today's fast changing scenario and come out with new Prospects of Clinical Research and Pharmacovigilance.

I extent my profound wish for the seminar a grand success.

Dr. P. K. Dubey
Principal

Organizing Secretary Message……

It brings me great pleasure to announce that Swami Vivekanand College of Pharmacy, Indore, is hosting a National Seminar on "Clinical Research-Current Status and Future Prospects" on Saturday 12th November 2022.

It is a real honor and privilege to serve as the Organizing Secretary of the seminar. The seminar will provide a chance for meeting of Young Researchers, Educators, Masters Students, and Specialists in the various research and development fields and from various disciplines.

The occasion will provide an open environment to freely exchange their views and ideas with others.

I would like to extend my best wishes for the success of the seminar in achieving its objectives.

Mr. Anant Kumar Patel
Organizing Secretary

Chief Guest Message……

I am pleased to learn that the SVCP, Indore is going to organize one day national seminar on Clinical research- Current status and future prospectus on 12 November 2022.

Clinical research is an important constituent of our health care system and has several paradigm shifts in the last century.

As such, there is a constant need to equip personnel with multiple skills of clinical trial with e- technology and engineering, for the welfare of the society.

The SVCP, Indore has emerged as one of those institutes in central India that have kept pace with the development in pharmaceutical research and academician profession. I am pleased to note that the SVCP, Indore has taken a lead in exploring clinical research development in collaboration with TCS.

I am sure the SVCP would continue to provide skilled and specialized professionals to the industry besides engaging in cutting edge research and development activity. I wish the SVCP, Indore all the best for their endeavours.

Dr. Shirish Sherlekar

Ex- Global Head, Life Sciences Practice, Tata Consultancy Services, Mumbai

Guest of Honor Message……

SVCP, Indore always thrive its best to the field of education. I am glad to know that SVCP Indore is bringing out national seminar on Clinical research- Current status and future prospectus on 12 November 2022.

I am sure that the interaction of participants will go a long way in knowledge sharing to help academia, industry and society to grow.

I would like to express my appreciation to the organizing committee for their dedicated efforts to materialize the seminar. I hope all the participants will have a fruitful and beneficial experience.

Finally, I congratulate college faculty, student representatives and participant for their efforts in organizing and participating in this seminar and wish the seminar all the success.

Dr. Deependra Singh

Chairman, ERC

Pharmacy Council of India and Vice President (Central) APTI, IPGA

Speaker Message……

It gives me immense pleasure to write a message for the national seminar on the topic- Clinical research- Current status and future prospectus on 12 November 2022. Aim of this seminar is to educate on clinical research and enhance skills. I take this opportunity to congratulate the young and dynamic faculty, student, industrial person of the college particularly those who are providing excellent services in newer areas like clinical research, pharmacovigilance for allopathic as well as natural products, skill development etc. Such ventures add value to create ripple in young minds.

I am sure the entire audience and its constituent institute SVCP Under the leadership of Dr. P. K. Dubey and its distinguished faculty will make every effort to make this seminar Successful. I wish good luck to this national seminar.

Dr. Seema Gurbani

Associate Vice- President, Medical Writing, Tata Consultancy Services, Mumbai

Speaker Message……..

It gives me immense pleasure to note that SVCP, Indore is bringing out national seminar on the Clinical research- Current status and future prospectus on 12 November 2022.

I am happy to note that SVCP, Indore has established links with various organizations which will further enhance the research in various areas of health professional and clinical trials. This will be an excellent opportunity for both students and faculty to interact and established state of art research on many fronts.

The progress of the institute for past 18 years has been excellent both in academic and social fronts. I am also happy to note that group director, faculty members and students have been publishing their research work in international journal of pharmacy and life sciences.

I extend my best wishes to the director, faculty members and students and staff members for the success in their career and for achieving the goals for which the institute has been established.

Mr. Vaibhav Tyagi

Corporate Trainer (Clinical Trials), NIIT Ltd. Gurgaon, H. R.

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Phytotherapeutic potential of Traditional Herbal medicine for the treatment of Gynecological disorders among tribes of Malwa Region of Madhya Pradesh, India

Sumeet Dwivedi

University Institute of Pharmacy, Oriental University, Indore (M.P.) - India

Abstract

Gynecological disorders (vulvodynia, vaginitis, pelvic pain and menstrual disorders) are very prone among females and it's because of several factors which may include weaker immunity, imbalance in body hormones, more sugar intake in food, regular or frequent use of antibiotics, inappropriate hygiene, physical/mental stress, some microbial infection viz., bacteria, and yeast causing fungal or other major infections of fragile female genital organ. The sign and symptoms of the same are very uncommon and tedious. A regular use of pain killer and antibiotics become necessary to the female if they want to get the rid from the same. But at the same time, one should avoid these medications by increasing the immune system. Malwa region of Madhya Pradesh have diversified plant diversity and the tribal women present in the region use traditional herbal medicine for the treatment of gynecological disorders. Also, tribal women are not in condition to take these allopathic medicines all time so they prefer herbal medications. Modern synthetic drugs do not have any cure from the root. However, herbal drugs have a good solution for all these kind of diseases. In the present paper author(s) has collected and enumerated traditional claims of 25 herbs used by the tribal womens of Malwa region of Madhya Pradesh for the treatment of gynecological disorders. The botanical name, local name, part used, method of preparation, dose and duration as claimed by tribes were reported in present communication. The herbs viz., *Asparagus racemosus* Willd., *Achyranthes aspera* L. *Carica papaya* L., *Ipomoea paniculata* (L.) R.Br., *Hibiscus rosa-sinensis* L., *Clitoria ternatea* Linn., *Ipomea cairica* Linn. *Plumeria pudica* Jacq. etc. which are extensively used by the tribal women's to treat the gynecological disorders were discussed.

Keywords: Tribal Women's, Madhya Pradesh, Gynecological disorders, Traditional Herbal Medicine, Malwa region

***Corresponding Author**
Dr. Sumeet Dwivedi
Professor & Principal
University Institute of Pharmacy, Oriental University, Indore (M.P.)
E.mail: sumeet_dwivedi2002@yahoo.com, sumeetdwivedi@orientaluniversity.in
Mob.+91-9893478497

Formulation and Evaluation of Antifungal Powder

Nishant Tiwari[1], Satyaendra Shrivastava[2], Suman Gehlot[3] and Nripen Prakash Khare[4]

Parijat College of Pharmacy, Indore, (M.P.) - India

Abstract

Antifungal powder was formulated to give antifungal effect. The powder was prepared by using the API (clotrimazole), apart from that menthol, zinc oxide; boric acid and salicylic acid were utilized as a excipients.Talc powder was utilized as a base. The powder was prepared by homogeneous mixing of all the excipients. We have developed single batch of our powder. Powder was evaluated for different parameters like appearance, organoleptic properties, powder flow properties like (tapped density, bulk density, angle of repose, carr's index and Hausner's ratio), moisture content and hygroscopy. Powder ingredients showed significant results in evaluation parameters. Based on the results, we can suggest stable product and it is safely stable at room temperature.

Keywords: Clotrimazole, Salicylic acid, Antifungal Powder.

***Corresponding Author**

A story from Thalidomide tragedy to existence of reporting Adverse Events in India

Rupesh Sharma*, Souravh Bais and Nirmal Dongre

Institute of Pharmaceutical Science, SAGE University, Indore, Madhya Pradesh, India

Abstract

Disaster of adverse drug reactions (DDRs), including the 1960s German thalidomide tragedy. Regulatory agencies in line with the pharmaceutical industries for ADRs worldwide. The reporting of adverse drug reactions in India, like "Who will bell the Cat" in context to that a group of regulatory bodies try to make flag program in working Clinical research organization (CROs) to Report ADR. Since COVID-19 pandemic affected the life of worldwide population so it also affected outsourcing of clinical data. This work mainly focus on current scenario of ADRs reporting in India and provide a future perspective for clinical trials in India.

***Corresponding Author**
Email-rupeshsharma5567@gmail.com

Review on Good Pharmacovigilance Practice -Risk Management Plan.

Manocha Nimita *; Dr P. K. Dubey

Swami Vivekanand College of Pharmacy, Indore, (M.P.) - India

Abstract

As per Regulatory norms in European Union (EU) and USA, a Risk Management Plan (RMP) is submitted as part of the dossier for initial marketing authorization of a medicinal product. Pharmacovigilance (PV) is undergoing continuous transformation with respect to evolving processes, technology, legislation, and guidelines to ensure enhanced patient safety and improved monitoring of the safety profile of medicinal products.

Implementation of ICH E2E Guidelines in 2004 has resulted in proactive risk management strategies in the PV domain – like the Risk Minimization Action Plans (RiskMAPs) implemented by USFDA and later the Risk Evaluation and Mitigation Strategies (REMS), replacing RiskMAPs, enforced in 2007.

A comprehensive revision of the EU Guideline on Good Pharmacovigilance Practices (GVP) Module V—Risk Management Systems (Revision 2), adopted in 2017, provides a framework for developing more focused, actionable, and risk-proportionate RMPs.

Generally, the objective of both concepts for risk management (REMS and RMP) is to prevent the known or potential serious risks associated with a medicinal product to ensure that the benefits outweigh risks. Each REMS is designed to address a specific serious safety concern, including information required and the activities to be undertaken by healthcare providers, pharmacists and patients. REMS is required by the FDA, depending on the size of population likely to use the medicine, the seriousness of the disease, expected duration of treatment, expected benefits of the drug, and seriousness of known or potential risks.

The revised RMP format enables product teams to develop an actionable RMP using an evaluative, scientific approach that considers all available evidence, thus providing a simpler, focused (on only those safety concerns that required further characterization or specific risk minimization), and scientifically justified vision for risk management, as well as saving companies' time through a more concise, less repetitive approach.

Keywords: Risk Management Plan, Risk Evaluation and Mitigation Strategies,

Recent Trends in Clinical Research

Anant Kumar Patel*, Kanchan Mona Patel

Swami Vivekanand College of Pharmacy, Indore

Abstract- The global COVID-19 epidemic has fuelled the change of the clinical trial and research industries. Understandably, discovering vaccinations and therapies for COVID-19 has been a major focus of the science and healthcare industries in recent years. The pandemic, on the other hand, has hastened certain developments, such as the use of technology in clinical trials. These growing trends in clinical research point to a change away from an efficiency-focused strategy and toward a more broad-based effectiveness-oriented approach. This shift is motivated by a clear desire to improve on the present partnership and interdependence strategy by implementing an integrated approach that strives to harmonize the interests and roles of diverse stakeholders in clinical research operations. Clinical trials are changing, both in terms of protocols and data collection. Technology has aided in trial process advancements by providing more holistic management across geographically distant clinics and participants. One of the most significant changes in clinical trials is the digitization of communications. Producers can keep more consistency in communication strategies with clinics and participants. They can also discover and include more optimum subjects, resulting in more accurate and meaningful trial results. With genetics and artificial intelligence (AI), modern technology allows for a more customized approach to medication, allowing therapies to be adjusted to each patient. Individual genome mapping has resulted in novel effective therapies for illnesses such as cancer and Alzheimer's disease. Finally, as the COVID-19 pandemic continues future years will see an increase in the number of decentralized and hybrid clinical trials. AI, genomics, and augmented reality (AR) advances will result in new effective treatment options for major diseases such as cancer, diabetes, and Alzheimer's disease.

Key Words: -. Clinical Research, Clinical Trial, Recent Trends, Human Studies.

Emergance of PvPi in India

1 Archana Dubey, 2 Antim Prajapat

Swami vivekanand college of Pharmacy, Indore (452020)

Abstract-Pharmacovigilance starts from pre-marketing of new drugs continuous through the post marketing of drugs. In India to collect the adverse drug reactions (ADRs) from patients, ADR monitoring centers (AMCs) are setup of under national coordinating centers (NCC) the rationale for setting up the AMCs is to make it possible to identify rare ADRs that could not be found through clinical trials programs. The Spontaneous reporting of ADRs is considered us the foundation of post marketing surveillance of drug safety. In future pharmacy institute may be enrolled in pharmacovigilance program of India (PvPi) to enhance ADRs reporting NCC is co ordinate with nearby pharmacy institute in reporting of ADRs. National coordination center, IPC has included Heamovigilance, Biovigilance and Materioviginance in Pharmacovigilance program.

Key words- PvPi, IPC, NCC, AMCs, ADRs.

Role of Technology in Advancement on Clinical Trial

Sunita Patidar*

Swami Vivekanand College of Pharmacy, Indore (M.P)

Abstract- Novel technologies are disrupting multiple sectors of industry, including drug development and healthcare. Innovations in several technological fields can confer huge benefits for clinical trial design and efficiency in several ways. Clinical trials are designed to ensure the safe and effective clinical outcome of treatment for general use. Setting up a trial is a complex procedure that requires a well-planned project management strategy. Anticipating the challenges of a trial ensures its smooth operation. Technology supply has increased in recent years, and regulations governing the use of breakthrough innovations have eased. Technological innovations have offered to improve productivity and efficiency via the use of increased patient engagement, novel outcomes, decreased patient burden, and improved management of the clinical trials. The technology has enabled any clinical trial awareness among the patients. The protection of participants' data privacy and confidentiality has been an ongoing topic of concern. Therefore, it is essential to ensure that proper informed consent procedures are being followed with electronic materials and privacy/confidentiality of participants is being protected when using digital technology in clinical research. Also, artificial intelligence (AI) is being used for remote patient monitoring in clinical trials. An added layer can be used in machine learning for interpreting patient data and integrating them with home monitoring devices. Additionally, the wearable devices backed with AI offer the recruiter and the remote physicians and researchers the opportunity to monitor the physiological changes in the patient in real-time. This eventually

Reduces the difficulty of on-site check-ups and is also cost-effective.

Key words – Efficiency, Technological innovations, Artificial intelligence, Confidentiality.

Review and Comparison of Various Reportng System of Adverse Drug Reaction

Antim Prajapat*, Archana Tiwari, Dr. P. K. Dubey

Swami Vivekanand College of Pharmacy, Indore

Abstract- Adverse drug reactions have been reported to be among leading cause of morbidity and mortality. The spontaneous reporting of ADRs is considered as the foundation of post marketing surveillance of drug safety. The main function of spontaneous reporting is the early detection of signals of new, rare and serious ADRs . Adverse drug reaction impact significantly on a nation's healthcare costs. Voluntary reporting by health professionals is currently considered the cornerstone to the detection and management of ADRs and makes a valuable contribution to the safe use of medicines. ADR reporting systems are managed by national ADR or Pharmacovigilance reporting centers, and differ internationally. Different forms and online tools are available in different countries for spontaneous reporting, one of the most widely used methods of Pharmacovigilance. Capturing sufficient information and adequate compatibility of online systems with respective reporting form is highly desirable for appropriate reporting of adverse drug reactions (ADRs). This study was aimed to compare various online reporting systems (US, UK, WHO and India) of the world and also to check their compatibility with the respective ADR reporting form. Most of international reporting systems for ADRs are either hospital based, or physician based. The opportunity therefore exists to further develop reporting systems that are accessible by community pharmacists, as they are in an ideal situation to detect and report ADRs through contact with patients.

Keywords: Adverse Drug Reaction, Spontaneous Reporting System, Pharmacovigilance, Medwatch.

Responsibility of Industry and Academia in Pharmacovigilance

Pandey Rupesh Kumar *, Gupta Dishant#

* **Kharvel Subharti College of Pharmacy, Swami Vivekanand Subharti University, Meerut (U.P.)**

 # Swami Vivekanand College of Pharmacy, Indore (M.P.)

Abstract- The growing adverse drug reactions with current medication are a global concern. The time to provide the treatment with least toxicities to the patient .The clinical research programme is increasing day by day the need is to strengthen the programme through industry academia interactions. Pharmacy Council of India has introduced the Pharmacovigilance subject in the curriculum of B.Pharm and M.Pharm courses now need is to provide the rigorous training to students as well as academicians in various clinical research organizations across India. The institution as well as clinical research industry will be benefited through knowledgeable candidates who can explore in future. In recent years pharmacy education increased exponentially, the need of the hour is to add much industry academia interaction which can provide outcome based education; this will strengthen the carrier of students and also improve the quality of students. The patient awareness programme should be disseminated among the society because patient is not aware about how to report the adverse drug reactions.

Key Words: Pharmacovigilance, Adverse Drug reactions, Industry, Academia.

Pharmacovigilance & Clinical Trial: A Review

Sunita Sonartiya*Archana Dubey, Dr.P.K.Dubey

Swami Vivekanand College of Pharmacy, Indore, (M.P.) – India

Abstract- Pharmacovigilance is defined by the world health organisation as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem plays a key role in ensuring that patients receive safe drugs. Our knowledge of a drug & adverse reactions can be increased by various means, including spontaneous reporting, intensive monitoring and database studies. New processes, both at a regulatory and a scientific level, are being developed with the aim of strengthening pharmacovigilance. On a regulatory level, these include conditional approval and risk management plans; on a scientific level, transparency and increased patient involvement are two important elements. A clinical trial is a research study in human volunteers to answer specific health questions. Investigational trials determine whether experimental treatment or new ways of using known therapies are safe and effective under controlled environment. Observational trials address health issues in large groups of people or population in natural settings. Clinical trials aim to measure therapeutic effectiveness and constitute an important and highly specialized form of biological assay. In phase I pharmacokinetics, safety, gross effects are studied on human volunteers, by clinical pharmacologists. If the drug passes the test, it enters phase ii testing, where pharmacokinetics, safety, therapeutic efficiency are studied on selected patients by clinical pharmacologist, if passes hundreds of selected patients are now studied, primarily for safety and therapeutic effectiveness by clinical investigators in phase III . If this is passed the drug is now approved and marketed. Even after marketing, physicians from various hospitals and clinics send their opinion about the drug, regarding ADR, Efficacy in Phase IV. Keywords: Pharmacovigilance, Clinical Trials, Preclinical Studies, Clinical studies.

Keywords: Pharmacovigilance, Clinical Trials, Preclinical Studies, Clinical studies

Ongoing and Future COVID-19 Vaccine Clinical Trials: Challenges and Opportunities

Ekta Yadav
Swami Vivekanand College of Pharmacy, Indore (M.P.) India

Abstract-Large-scale deployment of COVID-19 vaccines will seriously affect the ongoing phases 2 and 3 randomized placebo-controlled trials assessing SARS-CoV-2 vaccine candidates. The effect will be particularly acute in high-income countries where the entire adult or older population could be vaccinated by late 2021. Regrettably, only a small proportion of the population in many low-income and middle-income countries will have access to available vaccines. Sponsors of COVID-19 vaccine candidates currently in phase 2 or initiating phase 3 trials in 2021 should consider continuing the research in countries with limited affordability and availability of COVID-19 vaccines. Several ethical principles must be implemented to ensure the equitable, non-exploitative, and respectful conduct of trials in resource-poor settings. Once sufficient knowledge on the immunogenicity response to COVID-19 vaccines is acquired, non-inferiority immunogenicity trials comparing the immune response of a vaccine candidate to that of an authorized vaccine would probably be the most common trial design. Until then, placebo-controlled, double-blind, crossover trials will continue to play a role in the development of new vaccine candidates. WHO or the Council for International Organizations of Medical Sciences should define an ethical framework for the requirements and benefits for trial participants and host communities in resource-poor settings that should require commitment from all vaccine candidate sponsors from high-income countries

Keywords: COVID-19, SARS-CoV-2 vaccine, clinical trials- Phase 2 & Phase 3.

MonkeyPox : A Clinical Update for Pediatrician

Radhika Reddy, Shweta Choudhary, Dr. P. K. Dubey

Swami Vivekanand College of Pharmacy, Indore

Abstract- Monkeypox is a viral Zoonotic disease,caused by monkeypox virus,recognized as the most important orthopoxvirus infection after the eradication of smallpox. Monkeypox usually occur in forested rural areas in Central and West Africa.Monkeypox is caused by monkeypox virus, a member of orthopoxvirus genus in the family Poxviridae.Monkeypox virus was first isolated in late 1958 in Copenhagen during two outbreaks of a small pox-like disease in a colony of cynomolgus monkey.Monkeypox is usually a self-limited disease with the symptoms lasting from 2 to 4 weeks. Severe cases can occur. In recent times, the case fatality ratio has been around 3–6%. The clinical presentation of monkeypox resembles that of smallpox, a related orthopoxvirus infection which was declared eradicated worldwide in 1980. Monkeypox is less contagious than smallpox and causes less severe illness.Monkeypox typically presents clinically with fever, rash and swollen lymph nodes and may lead to a range of medical complications.The Centers for Disease Control and Prevention (CDC) monitors cases that have been reported in countries that don't often have monkeypox, such as the United States. In the 2022 monkeypox outbreak, the CDC is monitoring many cases of monkeypox throughout the world, including Europe and the United States.There is no specific treatment approved for monkeypox. Health care providers may treat monkeypox with some antiviral drugs used to treat smallpox, such as tecovirimat (TPOXX) or brincidofovir (Tembexa). For those unlikely to respond to the vaccine, care providers may offer vaccinia immune globulin, which has antibodies from people who have been given the smallpox vaccine.

Keywords- Pox, Pediatrics, Trial, Vaccine.

Future Prospects of Adverse Drug Reaction Monitoring in India

Gour Rekha*, Patel Anant K.

Swami Vivekanand College of Pharmacy, Indore

Abstract- According to the World Health Organization, adverse medication responses are undesirable and undesired consequences caused by the medicine. Pharmacovigilance (PV) is critical in the monitoring of adverse drug reactions (ADRs) caused by medications used to treat disorders. According to the findings, ADRs account for between 0.2-24% of hospitalisation cases, with 3.7% of patients suffering from deadly ADRs. The reasons include the quantity of prescribed medications, the rise of new medications on the market, the inadequate PV system for ADRs monitoring, and the absence of information on ADR reporting. Severe ADRs raise the likelihood of mortality, lengthen hospital stays, and increase the cost of care.As a result, reporting ADRs from the onset is critical to avoiding subsequent negative effects of the prescription medications. Due to a lack of awareness about PV and ADR monitoring among healthcare practitioners and patients, the rate of ADR reporting in India is less than 1%, while it is 5% globally. Evidence demonstrated that ADR reporting procedures implemented in India resulted in underreporting of ADR, increasing the population's risk. As a result, raising PV and ADR reporting awareness among healthcare professionals and patients, as well as telecommunication, telemedicine, the use of social media and electronic medical records, and artificial intelligence, are potential avenues for ADR prevention, monitoring, and reporting in India.The Drugs Controller General of India (DCGI) should move quickly to improve PV by incorporating Good Pharmacovigilance Practice (GPP) into processes and procedures to improve regulatory compliance, clinical trial safety, and postmarketing monitoring. Based on feasibility, the Pharmacovigilance Programme of India (PvPI) may be expanded to include veterinary pharmaceuticals, herbal medications, and cosmetics. As a result, a well-functioning PV system is critical in India.

Key Words: - Pharmacovigilance, ADRs, Drug safety,India, PvPI.

Using e-Technologies in Clinical Trials

Urmila Kotwal

Swami Vivekanand College of Pharmacy, Indore

Abstract: Clinical trials have been slow to incorporate e-technology (digital & electronic technology that utilizes mobile devices or the Internet) into the design and execution of studies. In the meantime, individuals and corporations are depending more on electronic platforms and most have incorporated such technology into their daily lives. This paper provides a general overview of the use of e-technologies in clinical trials research, specifically within the last decade, marketed by rapid growth of mobile and Internet-based tools. Benefits of and challenges to the use of e-technologies in data collection, recruitment and retention, delivery of interventions, and dissemination are provided, as well as a description of the current status of regulatory oversight of e-technologies in clinical trials research. As an example of ways in which e-technologies can be used for intervention delivery, a summary of e-technologies for treatment of substance use disorders is presented. Using e-technologies to design and implement clinical trials has the potential to reach a wide audience, making trials more efficient while also reducing cost; however, researchers should be cautious when adopting these tools given the many challenges in using new technologies, as well as threats to participants privacy/confidentiality. The role of web and smartphone- based appications is expanding, and the increasing use of those platforms by scientists and the public alike make them tools that cannot be ignored.

Keywords: Clinical trial, e-technology, Internet-based tools.

Role of Community Pharmacist in Pharmacovigilance

Jahnvi Sharma

Swami Vivekanand College of pharmacy

Abstract: Pharmacovigilance is important for safe and effective usage of drug. Pharmacovigilance is not just an indicator it is a discipline for detection and reporting of adverse drug reaction. Pre marketing clinical trial do not give the sufficient knowledge about ADR because the minimum number of population is included in these and exposure time of targeted drug is also short. The professional responsibility of community pharmacist is far more than just preparing and dispensing medicine. As a part of healthcare team, the pharmacist has a crucial role in serving as a source of information early detection and monitoring of ADR. Community pharmacist can Report the ADRs based on clinical experience and by counseling the patient at community pharmacy. Community pharmacist can act as bridge between the physician and patient to ensure drug safety and efficacy. They can educate and counsel patient in order to reduce the medication error. Thus, in such a scenario, the pharmacovigilance system, managed by pharmacist, can easily identify ADRs, and drug regulatory authority and other government bodies can improve the ADR monitoring system by providing necessary resources. The role and contribution of Community pharmacist differ from country to country. However, medicine safety issues remain the same.

Key words – Adverse drug reaction, Patient counseling, and Monitoring system.

Role of Pharmacovigilance on Vaccine Control

Ayushi Patwari

Swami Vivekanand College of Pharmacy, Indore

Abstract: - The pharmacovigilance of vaccine is defined as the science and activities relating to the detection, assessment, understanding, prevention and communication of adverse events of Immunization, and another vaccine, or issues related with immunization. The strengthening of pharmacovigilance is very important in every country because it helps professional healthcare workers to avoid problems with immunization, protect the health of people from adverse events during immunization. The success of the immunization system is reducing morbidity and mortality related to the vaccine. The vaccine is biological products used to prevent infectious disease but some time the vaccine can cause some AEFI (Adverse Event Following Immunization). The detection of adverse event following correct immunization is one very important step for prevention of problems in the immunization system. The vaccines are injected into infant body on the day of their birth and safety of this products is vital. The strengthening of pharmacovigilance is necessary, because this will help to identify the risk and risk factors, and to avoid or minimize the harms.

Keywords: - Vaccine, AEFI, Immunization.

A Primer on Clinical Trial

Shweta Choudhary, Radhika Reddy, Dr. P. K. Dubey

Swami Vivekanand College of Pharmacy, Indore

Abstract- Until 1962 drugs had to be shown "Safe" to be marketed, but there were no requirements to show their effectiveness. The structure of modern clinical trials is designed to protect patient safety while generating safety and efficacy data. Safety is the primary concern, and United States regulations are shaped by a series of responses to incidents, including notable safety lapses and unethical trials. Clinical trials are especially powerful study design that often guides health care policy and clinical practice. Clinical trials are experiments that are conducted in human and are designed to test the effects of a treatment or prevention strategy on pre-specified outcomes. The types of treatments that can be tested are vast and include drugs, procedures, levels of risk factor modification, lifestyle intervention, and dietary modification, health education, clinical trials have special importance because appropriately designed and rigorously conducted trials influence health care policy and provider recommendations. The purpose of a clinical trial can be one of two – either interventional as observational. An interventional study is investigating a device, a drug or a behavior – such as diet. The study may be introducing a new drug and comparing it to an established one or comparing the new drug to no treatment at all. An observational study is doing just that, observing a specific patient population or disease to see perhaps what lifestyle choices contribute to or prevent a certain health condition. The greatest level of evidence in support of a difference in outcome is associated with randomized, controlled clinical trials, particularly when combined with other randomized trials in a systematic fashion. The conduct of such research is characterized by numerous design, methodology and logistic issues. An understanding of these issues is useful for practitioners as they interpret the result of published research and consider the applicability of trial findings to their patients.

Key words- Phases, Clinical Trial, Pharmacovigilance.

Current Trends in Pharmacovigilance

Neelam Patel*, Sunita patidar, Rajat pawar

Swami Vivekanand College of Pharmacy, Indore (M.P)

Abstract: The rapid and continuous progress of medical and pharmaceutical sciences has resulted in the availability of modern medicines that can efficiently prevent, control and/or manage disease states. Despite a plethora of benefits, adverse reactions to medicines are not uncommon and are associated with most newly developed drugs. The adverse effects range from milder side-effects to severe hypersensitivities and often result in new illness, disabilities and death. Adverse drug reactions of medicines have increased in prevalence over the years; and in many countries they rank among the major causes of mortalities. It is thus imperative to have a well-organized system to continuously monitor and assess the safety of medicines. Pharmacovigilance is such a system. The concept of pharmacovigilance is not new and its origins date back over 50 years. The thalidomide tragedy of 1961 drew attention to the importance of the assessment of the adverse effects of drugs. Between 1965 and 1970, after several meetings and resolutions, the International Drug Monitoring Program was formed by the World Health Assembly. Pharmacovigilance is defined by the World Health Organization (WHO) as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems".

Keywords: adverse drug reaction, Pharmacovigilance.

Current Status and Future Prospects of Pharmacovigilance In India

Rajat Pawar*, Apurva Pagare, Rekha Gour

Swami Vivekanand College of Pharmacy, Indore (M.P.)

Abstract: Countries all around the globe are working to establish robust pharmacovigilance systems. Whereas the majority of the developed countries have established well-organized pharmacovigilance systems, the developing countries still lack the basic infrastructure to establish such systems. This commentary focuses on the need of pharmacovigilance and its current status and future trends in India.

Keywords: India, Pharmacovigilance, Adverse drug reaction, DRAP.

R: Key requirement in Drug Discovery & Clinical Research

Priya Jain*, Dinesh Kumar Mishra

Indore Institute of Pharmacy, Indore

Abstract- The introduction of novel molecule to market involves the collective effort of hundreds of quantitative scientists, with incredibly diverse data along with training, tools and work flows. The present abstract focuses on the diverse ways in which R can be used in different stages of the pharma lifecycle, spanning research and drug discovery. R is freely available and open-source integrated suite of software facilities for data manipulation, calculation and graphical display. R is ideally suited for all types of data generated by clinical laboratories either structured or raw. Clinical laboratories can perform laboratory data processing tasks, from generating turnaround time reports to looking at global distributions of results by assay more easily. R is also heavily utilized in high dimensional data analyses, common to 'omics, because of its comprehensive and cutting-edge package library of statistical methods. R integrates seamlessly with many other popular data science technologies (e.g., Python, Spark, TensorFlow, Microsoft PowerBI, GitHub, etc.). Thus, learning R provides a foundation for creating a wide variety of tools that can be scaled anywhere from an individual user to system-wide clinical deployment of a complete data science pipeline. There is growing interest in applying artificial intelligence approaches to laboratory data in order to predict disease. R packages provide access to every major approach in this area, from straightforward logistic regression to random forests and even deep learning.For example, R was used successfully by Roche Diagnostics to analyze hematologyanalyzer results and builds a random forest model that flags samples from patients with myelodysplastic syndrome. R is rewarding and demanding at the same time. It provides reliable calculations and almost immeasurable data processing capabilities, but requires at least basic knowledge of the statistical methods used. In the end, we conclude that learning R will have immense benefits that will provide you with the right tools to deal with data on a large scale.

Keywords- E- Technology, GMP.

Pharmacovigilance Program of India: Recent Developments and Future Perspectives

Bhakti Patil, Dr. PK Dubey

Swami Vivekanand College of Pharmacy, Indore

Abstract- Promoting safe use of medicines is a priority of Indian Pharmacopoeia Commission that functions as the National Coordination Center (NCC) for Pharmacovigilance Programme of India (PvPI). One hundred and seventy-nine adverse drug reactions (ADRs) monitoring centers currently report ADRs to NCC. Current India contribution to global safety database reaches 3% and the completeness score is 0.93 out of 1. NCC is taking several measures to enhance patient safety including capacity building for monitoring, surveillance, collaboration with national health programs and other organizations to increase ADR reporting and to ensure that PvPI is a vital knowledge database for Indian regulators. The Central Drugs Standard Control Organization has notified important safety label changes on drugs such as carbamazepine and piperacillin + tazobactam in the year 2015; other drugs are under monitoring for regulatory interventions.

Pharmacovigilance & drug safety in India: Challenges, current scenarios, advancement and role of health workers or public in PV

Shashikant Mahajan , Dr.P.K Dubey, Radhika Reddy, Shweta Joshi

Swami Vivekanand College of Pharmacy Indore

Abstract- Pharmacovigilance (defined by the World Health Organization, WHO as "The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem") continues to play a crucial role in meeting the challenges posed by the ever-increasing range and potency of medicines, all of which carry an inevitable and some- times unpredictable potential for harm. Present review described Pharmacovigilance and drug safety in India. Challenges related to Pharmacovigilance programme,current scenarios of pharmacovigilance in India, roles of physicians/health professionals as well as role of public/patients for successful monitoring are discussed herewith as nowadays, in India a safety of medicines is one of the key parameters along with therapeutic efficacy for success of any drug as ever-increasing range and potency of medicines. A successful Pharmacovigilance programme related to drug safety should be able to answer the key questions. How quickly has the case been identified? As well as what proportion of patient has successfully monitored collectively by doctor, Pharmacist/health professionals. Advancement of pharmacovigilance, The National Coordination Centre for Pharmacovigilance Program of India, Indian Pharmacopoeia Commission has released a mobile application (app) called "ADR PvPI" to mitigate some of these issues and both standardize and enhance the reporting of ADRs. This is in line with global focus on patient-reported outcomes and real-world data in pharmacovigilance. However, this approach has many implementation challenges including lack of awareness about mobile app, the use of English language in app, low smartphone adoption among the elderly, and in rural areas.

Clinical Trial and Its Importance

Sanjay Tharwani Radhika Reddy Shweta Joshi Antim Prajapat Dr P.K Dubey

Swami Vivekanand College Of Pharmacy, Indore

Abstract- Clinical Trial: - A clinical trial is a systematic investigation in human subjects for evaluating the safety and efficacy of new drug.The clinical research process includes: • Pre-clinical testing • Investigational New Drug Application (IND) • Phase I (assess safety) • Phase II (test for effectiveness) • Phase III (large-scale testing) • Licensing (approval to use) • Approval (available for prescription) • Post-marketing studies (special studies and long-term effectiveness/use) Research is important because: • Clinical trials test how well new approaches and interventions work in people • These approaches can be medical, behavioral, or management Each study helps scientists prevent, screen for, diagnose, manage, and treat a disease . People who take part in clinical trials contribute to the knowledge of how a disease progresses. A clinical trial is a research study that tests a new medical treatment or a new way of using an existing treatment to see if it will be a better way to prevent and screen for diagnose or treat a disease. Phase 0 clinical trial The Phase 0 clinical trial is the latest designation for the exploratory, First-In-Humans trials conducted according to the FDA 2006 Guidance on exploratory Investigational New Drug (IND) studies. Phase 1 clinical trial • Phase I trials are the first stage of testing in human subjects. Normally, a small (20-80) group of healthy volunteers will be selected. • This phase includes trials designed to assess the safety (pharmacovigilance), tolerability, pharmacokinetics, and pharmacodynamics of a drug. Phase 2 trials gives a successful design for phase 3 trials which carried out in multiple centres Phase 2 trials divided into • Phase 2a (how drug should be given and how often) • Phase 2b (how well drug works at prescribed doses) Clinical trial basically used to determine the weather of new drug clinical trial is scientific study of drug.

Clinical Trial Consideration in Neuro-oncology

Kritika jain 1, Dr. Sanjay Jain 2, Dr. Mousumi Kar Pillai 3, Ms. Khushboo Arora

Faculty of Pharmacy Medicaps University Indore (M.P)

Abstract- Critical trial plays a critical role in discovering new treatment and provide a new way to prevent and treat diseases and in this way, they help to improve public health and treatment in future clinical trials are now putting efforts to increase efficiency and interpretability of clinical trials within the neuro oncology community which mainly deals with the treatment of brain and spine tumors. So, with the help of clinical trials we had given consideration in unified resources for multidisciplinary clinicians and researchers in neuro-oncology which is a special topical issue. Which with its global expect has addressed with current challenges.

Key words: Neuro oncology, clinical trial, global expects clinical research.

Melanoma Clinical Trials and Research

Kumkum Patil[1], Dr. Sanjay Jain[2], Dr. Mousami Kar Pillai[3], Mrs. Khusboo Arora[4]

Faculty of Pharmacy, Medi-Caps University, Indore (M.P)

Abstract- Researchers around the world are looking at the causes, diagnosis and treatment of melanoma. When found early, melanoma can often be cured with surgery. However, melanoma is one of the most serious forms of skin cancer. It can grow deep into the skin; this is called invasive melanoma. It can also invade blood vessels and spread to lymph nodes and distant parts of the body; this is called metastatic melanoma. This section explains the types of treatments, also known as therapies that are the standard of care for melanoma. "Standard of care" means the best treatments known. When making treatment plan decisions, you are encouraged to discuss with your doctor whether clinical trials are an option. A clinical trial is a research study that tests a new approach to treatment. Doctors learn through clinical trials whether a new treatment is safe, effective, and possibly better than the standard treatment. Clinical trials can test a new drug, a new combination of standard treatments, or new doses of standard drugs or other treatments. Despite many years of research, melanoma still remains a big challenge for modern medicine. The purpose of this article is to review publicly available clinical trials to find trends regarding the number of trials, their location, and interventions including the most frequently studied drugs and their combinations. (2) We surveyed clinical trials registered in the International Clinical Trials Registry Platform (ICTRP), one of the largest databases on clinical trials. The search was performed on 30 November 2018 using the term "melanoma". Data have been supplemented with the information obtained from publicly available data repositories including PubMed, World Health Organization, National Cancer Institute, Centers for Disease Control and Prevention, European Cancer Information System, and many others to bring the historical context of this study. (3) Among the total of 2563 clinical trials included in the analysis, most have been registered in the USA (1487), which is 58% of the total. The most commonly studied drug in clinical trials was ipilimumab, described as applied intervention in 251 trials. (4) An increase in the number of melanoma clinical trials using immunomodulating monoclonal antibody therapies, small molecule-targeted therapies (inhibitors of BRAF, MEK, CDK4/6), and combination therapies is recognized. This illustrates the tendency towards precision medicine.

Key words: Melanoma, Clinical trials, Melanoma therapy, Melanoma Drugs.

How COVID-19 Has Fundamentally Changed Clinical Research in Global Health

Kamakshi Sharma, Dr P.K. Dubey

Swami Vivekananda College Of Pharmacy, Indore

Abstract- COVID-19 has had negative repercussions on the entire global population. Despite there being a common goal that should have unified resources and efforts, there have been an overwhelmingly large number of clinical trials that have been registered that are of questionable methodological quality. As the final paper of this Series, we discuss how the medical research community has responded to COVID-19. We recognize the incredible pressure that this pandemic has put on researchers, regulators, and policy makers, all of whom were doing their best to move quickly but safely in a time of tremendous uncertainty. However, the research community's response to the COVID-19 pandemic has prominently highlighted many fundamental issues that exist in clinical trial research under the current system and its incentive structures. The COVID-19 pandemic has not only re-emphasised the importance of well-designed randomised clinical trials but also highlighted the need for large-scale clinical trials structured according to a master protocol in a coordinated and collaborative manner. There is also a need for structures and incentives to enable faster data sharing of anonymised datasets, and a need to provide similar opportunities to those in high-income countries for clinical trial research in low-resource regions where clinical trial research receives considerably less research funding.

Pharmacovigilance

Rahul Sarwa, Radhika Reddy Shweta Joshi Antim Prajapat Dr P.K Dubey

Swami Vivekanand College of Pharmacy, Indore

Abstract- Pharmacovigilance began as a reaction to a major and unfortunate oversight in the testing of a popular pharmaceutical drug. In 1961, thousands of infants were born deformed due to in utero exposure to an unsafe medicine (World Health Organization, 2002). This medicine — thalidomide — was tested on animals and found to be safe; however, the tests did not examine the effects of the drug during pregnancy (Thalidomine). This pharmaceutical disaster led to the first organized efforts to address drug safety issues after its release to the general population. In 1963, the Sixteenth World Health Assembly adopted a resolution that reaffirmed the need for early action regarding reporting adverse drug reactions. This assembly ultimately led to the creation of the World Health Organization (WHO) Pilot Research Project for International Drug Monitoring (World Health Organization, 2002). From these efforts emerged pharmacovigilance. Systems were developed throughout the world to collect and evaluate individual cases of ADRs, creating an international database of ADR reports. It was decided that special attention would be paid to new drugs, and special reference centers would be required to provide data regarding drug safety issues (World Health Organization, 2002). The practice of pharmacovigilance has gained significant momentum since its beginnings in the 1960s. By the end of 2010, the World Health Organization Pharmacovigilance Program listed 134 countries.

Role of Clinical Trials in Biosimilar Drug Development

Aastha Patidar*, Jyoti Medatwal, Archana Dubey Tiwari

SWAMI VIVEKANAND COLLEGE OF PHARMACY

Abstract- As most of the drugs have known structure and are chemically synthesized, the biological drugs are derived from living organism and their products. Biologicals have more complex structure and unique from the molecules that are chemically synthesized due to their large size and knotty manufacturing process. Biologics are mainly protein and are used to treat many susceptible acute and chronic diseases such as cancer, diabetes. Biosimilars are intended to offer comparable safety and efficacy from the remarked biologics as they are not identical but are similar to the original compound. Given their structural complexity, multifaceted manufacturing process and risk for immunogenicity, biosimilars require class specific regulatory approval pathway for which, in the era of biosimilar drug development we took an overview of clinical trials. The European Medicines Agency has approved a number of biosimilars and the recent approval of biosimilars infliximab monoclonal antibody is as another regulatory milestone. Lastly, because it may not be possible to fully characterize a biosimilar in relation to its reference biologic, robust pharmacovigilance strategies are utilized to ensure that any matters in regard to safety can be monitored. Other topics including regulatory guidelines for evaluation of biosimilars, clinical trials design considerations, and whether data submitted for the approval of a biosimilar for one indication can be extrapolated to other indications for which the reference biologics is approved.

Key Words:-Pharmacovigilance, Clinical trials, Efficacy, Safety, Biologics, Biosimilar.

A New Era of Pharmacovigilance: Challenges and Opportunities in future therapies

Neha Patidar *, Vikas Singh Chouhan , Mahavir Chhajed , Atika Chhajed ,

Vidyasagar College of Pharmacy, Indore, (MP)-452016 India

Abstract:

Medicines and vaccines are designed to prevent and treatment of diseases and with their benefits they have side effects some are unexpected. Pharmacovigilance ensures the rigorous testing of clinical drugs to improve patient and reduce the risk of negative side effects, PV certifies whether a drug works and it is safe to use. In 1994 more than 100,000 deaths occurred because of ADR, after the introduction of PV the rate of morbidity drastically decreased. Thousands of drugs are life threatening at their clinical trials, but after the introduction of PV mortality rate decreased. And some future impact of PV Making medicine safer to the world, command on technology Main tool of PV is data analytics. PV focuses on data processing instead of data analysis and treating science as a heart of PV, self acting to inventive.

Key words: Adverse drug reaction, electronic health record, Medical information, Electronic medical record.

Drug Safety Monitoring Program in India

Esha Roy Andsakshi Sharma

Swami Vivekanand College Of Pharmacy(Indore)

Abstract-Pharmacovigilance is useful in assuring the safety of medicines and protecting the consumers from their harmful effects. A number of single drugs as well as fixed dose combinations have been banned from manufacturing, marketing and distribution in India. An important issue about the availability of banned drugs over the counter in India is that sufficient adverse drug reactions data about these drugs have not been reported. The most common categories of drugs withdrawn in the last decade were nonsteroidal antiinflammatory drugs (28%), antidiabetics (14.28%), antiobesity (14.28%), antihistamines (14.28%), gastroprokinetic drugs (7.14%), breast cancer and infertility drugs (7.14%), irritable bowel syndrome and constipation drugs (7.14%) and antibiotics (7.14%). Drug withdrawals from market were made mainly due to safety issues involving cardiovascular events (57.14%) and liver damage (14.28%). Majority of drugs have been banned since 3-5 years in other countries but are still available for sale in India. The present study compares the drug safety monitoring systems in the developed countries such as the USA and UK and provides implications for developing a system that can ensure the safety and efficacy of drugs in India. Absence of a gold standard for a drug safety surveillance system, variations in culture and clinical practice across countries makes it difficult for India to completely adopt another country's practices. There should be a multidisciplinary approach towards drug safety that should be implemented throughout the entire duration spanning from drug discovery to usage by consumers.To support ongoing drug safety, biopharmaceutical manufacturers must report adverse drug events (ADEs) to regulatory agencies, such as US Food and Drug Administration (FDA) in the United States and European Medicines Agency (EMA) in the EU.

Keyword- Adverse drug reaction, banned drugs, drug safety, pharmacovigilance.

Drug Discovery Research in India

Gautam Parihar, Satyam Patel

Swami Vivekanand College of Pharmacy (Indore)

Abstract

Indian civilization developed a strong system of traditional medicine and was one of the first nations to develop a synthetic drug. In the post independence era, Indian pharmaceutical industry developed a strong base for production of generic drugs. Challenges for the future are to give its traditional medicine a strong scientific base and develop research and clinical capability to consistently produce new drugs based on advances in modern biological sciences. Indian civilization is one of the few in the world that developed a full-fledged system of traditional medicine. The approach of Indian traditional medicine, e.g., the ayurvedic system, is herbal based in general and is more effective for chronic diseases and prevention. Although modern medicine has found its own niche in India, traditional formulations are still widely used, and more and more scientifically validated formulations are appearing in the market. In recent times, many plants used in Indian system of medicine have been analyzed by modern analytical methods and active components have been isolated. Significant amount of medicinal chemistry efforts are going on around these molecules in an attempt to develop more potent leads. These include curcumin from turmeric, 1 Bacosides from Brahmi (Bacopa monnieri), 2 and Forskolin from Coleus forskohlii. The first modern synthetic drug to be developed in India was Urea Stibamine in 1922 by UN Brahmachari against visceral leishmaniasis. 3 Visceral leishmaniasis was a severe health burden during the early part of the 20th century, and it was a life saving drug for a large section of the population. Historically, it was the second drug developed against an infectious disease after Salversan (against Syphillis) and well before penicillin or sulfa drugs.

Keywords: - Indian civilization, traditional medicine, synthetic drug, generic drug, medicinal chemistry.

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COVID-19 and Clinical Trials: Past, Present, and Future

Sohan Thakur* Radhika Bhagat, mayank varma, Rekha Gour

Swami Vivekananda College of Pharmacy Indore

Abstract

The COVID-19 pandemic, declared by the World Health Organization in March 2020, has had a significant impact on clinical trials. An analysis by Medidata1 based on cross-industry data from 5,222 studies and 198,120 study-sites shows a notable decline in new patients entering trials at study sites compared to pre-COVID baselines, and the recovery has differed based on geography (country-by-country) and therapeutic area (TA, by varying impact of the respective diseases). China experienced the initial outbreak of SARS-Cov-2, and new patient flow in clinical trials has since recovered almost back to levels prior to the pandemic. In contrast the pandemic in the United Kingdom and India impacted the flow of new patients entering clinical trial study-sites at the outset, and India has not gained much ground back. In Japan, new patient flow in June, July, and August was higher than pre-COVID-19 levels, likely due to pent-up demand. Among therapeutic areas, oncology saw the least impact in new patients entering study-sites and has shown the best recovery. Cardiovascular trials saw the largest drop at the outset of the pandemic but have since recovered tremendously.

Keywords: Psychometrics, Clinimetrics, Pandemic clinical trials.

Clinical Development: Novel Drug Radiotherapy

Gresi Patidar*, Jyoti Medatwal, Apurva pagare

Swami Vivekanand College of Pharmacy

Abstract-Radiotherapy is an elementary component of treatment for the majority of patients with cancer. In recent decades, technological proceeding has enabled patients to receive more targeted doses of radiation to the tumour, with sparing of adjacent normal tissues. Combining chemotherapy and radiotherapy has resulted in significant clinical improvements in many different tumour types. There had been the hope that era of precision medicine would enhance the combination of radiotherapy with targeted anticancer drugs; however this intention remains to be realized. Novel approaches including immune onchology or DNA repair inhibitor agents combined with radiotherapy should be prioritized. Radiotherapy can provide enormous benefit to patient with cancer. However, apart from the combination of traditional cytotoxic chemotherapy with radiotherapy, little progress have been made in identifying and defining optimal targeted therapy and radiotherapy combinations to improve the efficacy of cancer treatment. Their s an unmet need for intelligent and rational approaches to drug radiotherapy combinations on the basis of our molecular understanding of radiobiology and increased ability to develop agents that can be combined with radiotherapy in preclinical models.

Key words: Chemotherapy, Radiotherapy, Onchology, Efficacy, Cytotoxic, Targeted therapy. Radiobiology, preclinical models.

The Impacts of Covid-19 on Global Health Clinical Research

Akanksha Pathak

Swami Vivekanand College of Pharmacy Indore, MP

Abstract- The COVID-19 pandemic and the research community's response to it have brought to light a number of basic flaws with clinical trial research that are present in the existing system and its incentive structures. The COVID-19 pandemic has highlighted the need for large-scale clinical studies structured in accordance with a master protocol in a coordinated and collaborative manner in addition to reiterating the need of well-designed randomized clinical trials. People who take part in clinical trials frequently expect to benefit from novel therapeutic procedures, but they may also put themselves at danger. Risks to participants may not be avoided given the experimental character of clinical research. Clinical trial participants expect and desire that their data will be appropriately used to promote research, even when the value of clinical trials for society is different from the advantages that clinical trial interventions have on specific study participants. Collaboration is necessary for the development of knowledge and the improvement of public health outcomes, and this entails publishing all data, regardless of the findings, and making them available to the research community. Significant takeaways from COVID-19 have demonstrated the necessity for pre-existing trial sites, capacity, and It will be crucial to make the research ecosystem more resilient and dynamic not only for the COVID-19 pandemic but also for future pandemics and other diseases with significant unmet medical needs that are challenging to treat.

Key words: COVID-19; Clinical trials; clinical trial participants.

Clinical Trials in Cancer on "Chemotherapy"

Kavya Sharma * Sukdeev Mandal

Swami Vivekanand College Of Pharmacy Indore

Abstract-The success of cancer chemotherapy has increased greatly the potential areas for its inclusion in clinical trials and therefore has made the experimental design considerations more complex in these trials. New drugs which are launchedyet go through the three classic phases of clinical study beginning with clinical pharmacology (Phase I), efficacy screening (Phase 2) and role delineation (Phase 3). The Phase 2 and 3 trials now need to be considered within the overall therapeutic strategies which are required for each of the many diseases which are called cancer. Drugs consumed in chemotherapy, such as cytarabine, work in different ways to stop the growth of cancer cells, either by killing the cells or stopping them from increase exponentially. may stop the growth of cancer cells by blocking some of the enzymes needed for cell growth. It is not yet known whether cytarabine is more effective in treating acute myeloid leukemia. The motive of this study is to assess the efficacious and eternal side effects of using combined tretinoin and arsenic trioxide in treating patients with newly detection of acute promyelocytic leukemia. Chemotherapy was identical, except for the addition of DTIC (300 mg/m2) for each course. A new drug may have required a lot of Phase 2 and 3 trials in a variety of tumors before it can be considered appropriately estimated. Essential aspects of valid clinical trials include an adequate protocol which details the study which is viable not for the current status but also for the future aspects.

Key Words: chemotherapy, 0ncology, phase 1, phase 2, leukemia.

Impact of Covid-19 on Clinical Trials

Mohammad Abrar*, Megha Chouhan

Swami Vivekanand College Of Pharmacy, Indore

Abstract- Coronavirus infection 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), has affected tens of millions of people worldwide, since it was declared a pandemic by the World Health Organization (WHO) on March 11, 2020. There is an urgent need for safe and effective inhibitory vaccines to cure this pandemic. A increased amount of related research has been published. This study aimed to provide the current status of COVID-19 vaccine using bibliometric analysis. Various strategies have been designed to contain the COVID-19 pandemic. Among them, vaccine development is main agenda in spite of the unknown duration of the protection time. Various vaccines have been under clinical trials have been developing with promising results in different countries. The protective effectiveness and the short-term and long-term side effects of the vaccines are one of the major concerns. Therefore, comparing the protective efficacy and risks of vaccination is needed for the worldwide control of COVID-19 through herd immunity. Overall, all COVID-19 vaccines had a high effectiveness against the original strain and the variants of concern, and were well tolerated. BNT162b2, mRNA-1273 and Sputnik V after two doses had the highest efficacy (>90%) in preventing symptomatic cases in phase III trials. mRNA vaccines, AZD1222, and CoronaVac were effective in preventing symptomatic COVID-19 and severe infections against Alpha, Beta, Gamma or Delta variants. Regarding observational real-life data, full immunization with mRNA vaccines and AZD1222 seems to effectively prevent SARS-CoV-2 infection against the original strain and Alpha and Beta variants but with less effectiveness against the Delta strain. A decline in infection protection was observed at 6 months for BNT162b2 and AZD1222. Serious adverse event rates were rare for mRNA vaccines—anaphylaxis 2.5–4.7 cases per million doses, myocarditis 3.5 cases per million doses—and were similarly rare for all other vaccines. There are subtle differences in the mechanism by which the different vaccine products introduced within host cells to persuade immunity. Many successful vaccines of the 20 century utilized the target proteins directly such as the tetanus and pertussis vaccine.

Keywords: - Pandemic, bibliometric analysis, vaccine, immunization

Decentralised clinical trials: The future of clinical trials

Dr. Prerna Chaturvedi

Acropolis Institute of Pharmaceutical Education and Research

Abstract-In response to the Covid-19 pandemic, the life sciences industry had little option but to accelerate its adoption of cloud-based and end-to-end technology solutions and implement virtual digital trial models that would enable clinical trial processes to continue in the face of global lockdowns. Since then, decentralised clinical trials (DCTs) have continued to transform thinking where the discipline of clinical trials is concerned. Conducted remotely or through local healthcare providers, decentralised trials deliver wider access to more diverse patient populations, streamline trial processes, support a more patient-centric approach, and enable the continuous collection of richer data sets. As regulatory authorities continue to clarify their remote and hybrid trial monitoring procedures, the evolution of decentralised clinical trials looks set to continue as study teams look to take advantage of the enhanced flexibility offered by DCTs. However, as promising as decentralised clinical trials are, there are some key things the industry will need to reckon with before it can scale successfully across therapeutic indications or global regions. That includes ensuring they have the right technology foundations and protocols in place to ensure consistent collaboration between partners and full compliance with standard operating procedures (SOPs), as well as increased data transparency and quality.

Keywords: Clinical trials, DCT, patient-centric approach.

COVID-19 Phase 4 Vaccine Candidates, Effectiveness on SARS-CoV-2 Variants, Neutralizing Antibody, Rare Side Effects, Traditional and Nano-Based Vaccine Platforms: A Review

Saini Deeksha

B.Pharmacy College of Rampura, Kakanpur Godhra, Gujarat (M.P.) India

Abstract- The COVID-19 pandemic has endangered world health and the economy. As the number of cases is increasing, different companies have started developing potential vaccines using both traditional and nano-based platforms to overcome the pandemic. Several countries have approved a few vaccine candidates for emergency use authorization (EUA), showing significant effectiveness and inducing a robust immune response. Oxford-AstraZeneca, Pfizer-BioNTech's BNT162, Moderna's mRNA-1273, Sinovac's CoronaVac, Johnson & Johnson, Sputnik-V, and Sinopharm's vaccine candidates are leading the race. However, the SARS-CoV-2 is constantly mutating, making the vaccines less effective, possibly by escaping immune response for some variants. Besides, some EUA vaccines have been reported to induce rare side effects such as blood clots, cardiac injury, anaphylaxis, and some neurological effects. Although the COVID-19 vaccine candidates promise to overcome the pandemic, a more significant and clear understanding is needed. In this review, we brief about the clinical trial of some leading candidates, their effectiveness, and their neutralizing effect on SARS-CoV-2 variants. Further, we have discussed the rare side effects, different traditional and nano-based platforms to understand the scope of future development.

Keywords: Covid-19, Neutralizing antibody, rare side effects, Vaccine platforms, Variants.

Clinical Trials in Onchology

Jyoti Medatwal, Aastha Patidar, Sunita Sonartiya

Swami Vivekanad College of Pharmacy

Abstract- Advancement in biomedical researches has produced significant opportunities to improve cancer prevention, detection, and treatment. Insights about the genomic and molecular mechanism of disease have enabled basic scientist to identify new therapeutic targets and develop new agents that are changing the paradigm of cancer research from nonspecific, broadly toxic chemotherapies to highly targeted combination of therapies. However, the ability to translate biomedical discoveries into advances in care for patients with cancer remains dependent on the clinical trial system. Clinical trials provide an essential link between scientific discovery and clinical practice. These trials are crucial to the translation of new knowledge into tangible benefits for patients and the knowledge gained in clinical trials can also inform and guide further research into the biology of disease. These research and development efforts entail enormous costs and are critical to progress in cancer treatment. Publicly funded clinical trials also play a vital role and are complimentary to clinical trials in advancing science and patient care, particularly by addressing questions that are important to patients but are less likely to be top priorities of industry. For ex, companies may have less incentives to conduct clinical trials to compare the effectiveness of different treatment options that are already approved for clinical use, combine novel therapies develop by different sponsors, develop therapies for rare diseases, determine optimal duration and dose of treatment with drugs in clinical use, test multimodality therapies, such as radiant therapy, surgery or devices in combination with drugs, study screening and prevention strategies, or focus on rehabilitation and quality of life following therapies.

Key words: Chemotherapy, Paradigm, Therapeutic, Biomedical, Genomic, clinical trials.
Genomic, clinical trials.

Medical Coding, Billing Error and Its Regulation

Aman Sharma*, Jyoti Medatwal, Dr. Dishant Gupta

Swami Vivekanand College Of Pharmacy

Abstract- Medical coding is the conversion of procedures, healthcare diagnoses, medical services, and equipment into medical alphanumeric codes. International Classification of Diseases (ICD) codes represent a patient's injury or sickness. Current Procedure Terminology (CPT) codes, which relate to functions and services the healthcare provider performed on or for the patient. HCPCS level II are used to code health care equipment & supplies. Every code has its own set of rules and instructions. Code should be placed in a particular order. Medical biller will bill for service provided on the basis of the codes report. Making even a mistake of no account lead to significant time lost chase down the source of mistakes, and serious delays in payments. Data generated in all clinical trial are recorded on the data collection instrument Case report Form / Electronic Case Report Form by investigators located at various sites in various countries. In multicentric clinical trials since different investigator or medically qualified experts are from different recording the medical term(s) consistently is a big provocation. Medical coders from clinical data management team process these terms and perform medical coding. Medical coding is performed to categorize the medical terms reported appropriately so that they can be reviewed. It is expected to help medical coders to understand the process of medical coding in clinical data management.

Key words: Medical coding, clinical data management, Medical alphanumeric codes, Medical biller.

Adverse Events Reported From COVID-19 Vaccine Trials: A Systematic Review

Tahir Nizami, Vishakha Chauhan, Danish Hasan*, Hritik Jain

Smriti College of Pharmaceutical Education, Indore, MP.

Abstract- COVID-19 infection originated in Wuhan, China in December 2019 and crippled human health globally in no time. The public health emergency required urgent efforts to develop and test the efficacy and safety of vaccines to combat the COVID-19 pandemic. The emergency use approval has been granted to COVID-19 vaccines before the completion of conventional phases of clinical trials. This study aims to systematically review and synthesize the evidence on the safety data from the published COVID-19 vaccine trials. This study followed PRISMA guidelines. We searched three major electronic databases (PubMed, Embase, and Google Scholar) for published studies between Dec 2019 and 2020. Eligible study designs were randomized trials and pre-and post-intervention evaluations. Descriptive findings of included studies were reported stratified by target population, setting, outcomes, and overall results. The systemic reactions included fever, fatigue, myalgia, and headache. Some trials also reported laboratory derangements like decreased haemoglobin, increased bilirubin, altered SGOT and SGPT. None of these alterations were clinically manifested and were self-limiting. However, long-term post-marketing surveillance data, particularly in high-risk vulnerable populations (elderly and those with co-morbidities, pregnant women, and children) is warranted to ensure the safety of COVID-19 vaccines.

Keywords: COVID-19, COVID-19 vaccine, Clinical trials, adverse effect following immunization, adverse drug reactions, Vaccination.

Review on Post Marketing Surveilence

Aayush Sardar*, Sunita Patidar

Compfeeders Aisect College of Professional Studies,Pharmacy College , Indore (M.P)

Abstract- Postmarketing drug surveillance refers to the monitoring of drugs once they reach the market after clinical trials. It evaluates drugs taken by individuals under a wide range of circumstances over an extended period of time. Such surveillance is much more likely to detect previously unrecognized positive or negative effects that may be associated with a drug. The majority of post marketing surveillance concern adverse drug reactions (ADRs) monitoring and evaluation. Other important post marketing surveillance components include unapproved or off-label drug use, problems with orphan drugs, and lack of pediatric formulations, as well as issues concerning international clinical trials in pediatric population. The process of evaluating and improving the safety of medicines used in pediatric practice is referred to as pediatric pharmacovigilance. It requires special attention. Childhood diseases and disorders may be qualitatively and quantitatively different from their adult equivalents. This may affect either benefit or risk of therapies (or both), with a resulting impact on the risk/benefit balance. In addition, chronic conditions may require chronic treatment and susceptibility to ADRs may change throughout the patient's lifetime according to age and stage of growth and development. Therefore, pediatric pharmacovigillance aspects need to be tailored to a number of variables based on heterogeneity of paediatric population. This chapter will summarize and discuss the key issues.

Key words - Drug Surveillance, Pediatric Pharmacovigilance , ADRs , heterogeneity of paediatric Population

Registering A Clinical Trials

Sachin Jat*, Jyoti Medatwal, Antim Prajapat

Swami Vivekanand College Of Pharmacy

Abstract- Trial registration creates a public record of all clinical trials that researchers are planning and what they intend to do. Trial registration makes the research process more transparent. Registering clinical trials helps make sure that researchers try to publish all research that is carried out, even if the outcome was non-significant or 'negative'. This helps to prevent publication bias and means that those making clinical decisions to make them based on all of the evidence. The registration of all interventional trials is considered to be a scientific, ethical and moral responsibility because: There is a need to ensure that decisions about health care are informed by all of the available evidence. Registering and publishing clinical trials can demonstrate that ethical obligations towards participants and the research community have been fulfilled, and that publication and outcome reporting biases are absent. The importance of public disclosure of clinical trials not only applies to patients but also to other groups, including clinicians and the research community. It is important to register and publish data from clinical trials at the beginning of the study, during the conduct of the study to update the clinical community about the research progress, and at the end of the investigation to present the results and conclusion.

Key words: Clinical trials, Registry, Ethical, Evidence, Clinicians, Interventional.

Evolution of Drug Safety System (Pharmacovigilance)

Singh H*, Raghuwanshi V, Saraogi G.K.

Sri Aurobindo Institute of Pharmacy, Indore, M.P.

Abstract- According to the World health organization, pharmacovigilance helps to strengthen or implement patient care and public safety regarding the use of medicines. To support public health programs through solid provisions of reliable, cost-effective, encouragement of drug safety system. The objective of the study is to determine the availability of pharmacovigilance systems employed strategically in the regulation and monitoring of medicines, minimizing adverse drug reactions, and assessing the under events. Pharmacovigilance is a field of pharmaceutical science that includes various activities like data collection, detection, research, development and prevention. It also aspires to highlight the importance of pharmacovigilance or post-effect surveillance of drugs to emphasize the requirement of a dynamic approach toward drug safety. India had its drug safety program since 14th July 2010 but there is certain insufficiency in the framework of the drug safety system with respect to reporting adverse drug reactions (ADRs).Toa greater extent, it not only affects Pharma industry, and Health care professionals but also the general public. This entails the demand for effective regulations of drug approval, assessing the results, and vigilance of post effects mainly reporting undesired results. Analyzing ADR with the framed regulatory easily accessible system helps in diagnosis and disease management. Pharmacovigilance helps the public and patients with critical illness effectively to get the optimal or ideal results. Minimizing undesired events, avoiding illness, and providing a healthy life is the main goal of pharmaceutical industries, clinicians, and healthcare workers.

Keywords: Pharmacovigilance, ADR, Drug safety system, Drug regulation.

Antifungal Drugs to High Prevalence of Tinea Infections.

Dr. Kashish Sindhwani

Abstract- Introduction - Skin is the largest organ and represents about 8% of body weight. The skin disorders are mostly ignored by the patients till it increases in severity and have serious detrimental effect on the quality of life. It increases the chances of irrational prescribing and results in polypharmacy which leads to economic burden on the patients. Prescription pattern analysis helps to improve the quality of prescription, reduces adverse drug effects and promotes rational use of drugs.

Methodology – a cross sectional observational study was conducted at dermatology OPD of MYH hospital, Indore, Madhya Pradesh, India after receiving permission from Institutional ethics committee. The study was conducted from November 2021 till January 2022 over a period of 3 months. A total of 206 prescriptions were analysed including both male and female patients.

Results – in this study a total of 206 prescriptions were analysed and the number of female patients were 115(55.8%) and male patients were 91(44.17%). The most common dermatological disorder found were tinea infections (21.35%) followed by acne vulgaris (14%) and scabies (11.65%).The total number of drugs prescribed in 206 prescriptions were 640. Out of 640 drugs, 365 (57%) drugs were topical and 275(43%) were oral drugs. Most commonly prescribed drugs were antimicrobials. Among antimicrobials, antifungal drugs were maximally prescribed.

Conclusion – We found that antifungal drugs were most commonly prescribed owing to high prevalence of tinea infections. Polypharmacy and antimicrobial prescribing were found to be more in our study. Antimicrobials should be prescribed according to the sensitivity pattern to avoid emergence of resistance. There is a scope of improvement and need to encourage dermatologists to promote more prescribing from NLEM. Rational and cost-effective use of medicines can contribute to raise standard of medical treatment.

Keywords – Drug utilisation, Prescription pattern, Dermatology OPD.

Isolation of Amylase Producing Bacteria from Soil and Its Optimization of Production Parameters by Shake Flask Culture Method

Vikas Singh Chouhan[1*], Neha Patidar[1], Mahavir Chhajed[1], Atika Chhajed[1], A. G. Hariharan[2], Sumeet Dwivedi[3]

[1]Department of Pharmaceutical Chemistry, Vidyasagar College of Pharmacy, Hingonia, Near Kanadiya, Indore, (MP)

[2]Department of Pharmaceutical Biotechnology, Ultra College of Pharmacy, Madurai (TN)

[3]Department of Pharmacognosy, University Institute of Pharmacy, Oriental University, Sanwer Road, Jakhya, Opp. Revati Range, Indore, (MP)

Abstract: The effects of various production parameters such as pH, temperature, incubation time and sources of carbon were tested in submerged fermentation process by shake flask culture method in production of amylase by bacteria isolated from groundnut field soil. The production medium with provision of glucose as carbon source, yeast extract as nitrogen source incubated for 48 h, maintained with pH of 6.5 at 39°C, was found optimal for production of amylase.

Key words: amylase, shake flask culture, starch agar plate, fermentation.

A Review on Antacid Clinical Pharmacology and Their Therapeutic Use

Sayyed Md Raza

Sri Aurobindo Institute of Pharmacy, Indore, M.P.

Abstract- Antacids are commonly used self-prescribed medications. They consist of calcium carbonate and magnesium and aluminum salts in various compounds or combinations. The effect of antacids on the stomach is due to partial neutralisation of gastric hydrochloric acid and inhibition of the proteolytic enzyme, pepsin. Each cation salt has its own pharmacological characteristics that are important for determination of which product can be used for certain indications. Antacids have been used for duodenal and gastric ulcers, stress gastritis, gastro-oesophageal reflux disease, pancreatic insufficiency, non-ulcer dyspepsia, bile acid mediated diarrhoea, biliary reflux, constipation, osteoporosis, urinary alkalinisation and chronic renal failure as a dietary phosphate binder. The development of histamine H2-receptor antagonists and proton pump inhibitors has significantly reduced usage for duodenal and gastric ulcers and gastro-oesophageal reflux disease. However, antacids can still be useful for stress gastritis and non-ulcer dyspepsia. The recent release of proprietary H2 antagonists has likely further reduced antacid use for non-ulcer dyspepsia. Other indications are still valid but represent minor uses. Antacid drug interactions are well noted, but can be avoided by rescheduling medication administration times. This can be inconvenient and discourage compliance with other medications. All antacids can produce drug interactions by changing gastric pH, thus altering drug dissolution of dosage forms, reduction of gastric acid hydrolysis of drugs, or alter drug elimination by changing urinary pH. However, when large doses are taken for long periods of time, significant adverse effects may occur especially patients with underlying diseases such as chronic renal failure. These adverse effects can be reduced by monitoring of electrolyte status and avoiding aluminum-containing antacids to bind dietary phosphate in chronic renal failure. Antacids, although effective for discussed indications of duodenal and gastric ulcer and gastro-oesophageal reflux disease, have been replaced by newer, more effective agents that are more palatable to patients. Antacids are likely to continue to be used for non-ulcer dyspepsia, minor episodes of heartburn (gastro-oesophageal reflux disease) and other clear indications. Although their wide-spread use may decline, these drugs will still be used, and clinicians should be aware of their potential drug interactions and adverse effects.

Molecular structure, Drug Likeness, Toxicity prediction and Docking study of Chalcone derivatives as anticancer agents

Sen Jayant*, Mandloi Nilesh

GRY, Institute of Pharmacy, Vidhya Vihar Borawan

Abstract- Cancer is a multifunctional disease that arises when cells are dividing at an uncontrollable rate. it has been depicted by the presence of mutation,independent cell proliferation of mitogen,high genetic instability and invasion of other tissues.In present study we used computational tools like Molinspiration, to predict pharmacokinetic study. We also performed between designed chalcone derivatives andPDB "1jx1" using Molegro software to check the binding affinity.Compound c13 showed highest mol dock score-139.57while compounds c12,c14,c15 showed maximum hydrogen bond and steric interactions with amino acidsAsn113,His117,Ser120,Glu189,Thr190,His195,Val197.

MicroRNA Signature as Biomarkers and Therapeutic Target for CNS Embryonal Tumors: The Pros and the cons

Mayank Verma*, Tanisha Tamboli, Megha Chouhan

Swami Vivekanand College of Pharmacy, Indore

Abstract- Embryonal tumors of the central nervous system represent a heterogeneous group of childhood cancers with an unknown pathogenesis;diagnosis,on the basis of histological appearance alone, is controversial and patients' response to therapy is difficult to predict. They encompass medulloblastoma, atypical teratoid /rhabdoid tumors and a group of primitive neuroectodermal tumors. All are aggressive tumors with the tendency to disseminate throughout the central nervous system.The large amount of genomic and molecular data generated over the last 5-10 years encourages optimism that new molecular targets will soon improve outcomes. Recent neurological studies have uncovered the key role of microRNAs (miRNAs) in embryonal tumors biology and their potential use as biomarkers is increasingly being recognized tumors biology and their potential use as biomarkers is increasingly being recognized and investigated. However the successful use of microRNA as reliable biomarkers for the detection and management of pediatric brain tumors represent a substasnial challenge. This review debates the importance of miRNAs in the biology of central nervous systemembryonal tumors focusing on medulloblastoma and atypical teratoid/rhadoid tumors and highlights the advantages as well as the limitations of their prospective application as biomarkers and candidates for molecular therapeutic targets.

Keywords: central nervous system (CNS) embryonal tumors; medulloblastoma; atypical teratoid /rhabdoid tumors; microRNAs (miRNA); biomarkers.

Conducting Clinical Research during the COVID-19 Pandemic: Investigator and Participant Perspectives

Keshavendra Singh Chouhan *, Tanisha Tamboli, Saloni Rathore

Swami Vivekananda College of pharmacy Indore

Abstract- As the medical landscape changes daily with the coronavirus disease (COVID-19) pandemic, clinical researchers are caught off-guard and are forced to make decisions on research visits in their ongoing clinical trials. Although there is some guidance from local and national organizations, the principal investigator (PI) is ultimately responsible for determining the risk-benefit ratio of conducting, rescheduling, or cancelling each research visit. The PI should take into consideration the ethical principles of research, local/national guidance, the community risk of the pandemic in their locale, staffing strain, and the risk involved to each participant, to ultimately decide on the course of action. While balancing the rights and protection of the human subject, we seldom examine patients' views and opinions about their scheduled research visit(s). This article discusses the ethical principles of beneficence and autonomy in helping the decision-making process. We discuss ways to weigh-in local and national guidance, staffing strain, and institutional support into the decision-making process and outline potential changes needed for regulatory bodies depending on the decision. Further, we discuss the need to weigh-in the individual risk-benefit ratio for each participant and present a decision tree to navigate this complex process. Finally, we examine participant and caregiver perspectives on their fears, sense of preparedness, and factors that they consider before deciding whether to keep or postpone the research appointments. This entry also provides PIs ways to support their research participants in both scenarios, including provision of psychological support.

Keywords: Clinical research, COVID-19, Pandemic, Outbreak, Infectious disease.

How COVID-19 Has Fundamentally Changed Clinical Research in Global Health

Saloni Rathore *, Sohan Thakur, Keshavendra Singh Chouhan

Swami Vivekananda College of pharmacy Indore

Abstract- COVID-19 has had negative repercussions on the entire global population. Despite there being a common goal that should have unified resources and efforts, there have been an overwhelmingly large number of clinical trials that have been registered that are of questionable methodological quality. As the final paper of this Series, we discuss how the medical research community has responded to COVID-19. We recognize the incredible pressure that this pandemic has put on researchers, regulators, and policy makers, all of whom were doing their best to move quickly but safely in a time of tremendous uncertainty. However, the research community's response to the COVID-19 pandemic has prominently highlighted many fundamental issues that exist in clinical trial research under the current system and its incentive structures. The COVID-19 pandemic has not only re-emphasised the importance of well designed randomised clinical trials but also highlighted the need for large-scale clinical trials structured according to a master protocol in a coordinated and collaborative manner. There is also a need for structures and incentives to enable faster data sharing of anonymised datasets, and a need to provide similar opportunities to those in high-income countries for clinical trial research in low-resource regions where clinical trial research receives considerably less research funding.

Keywords: COVID-19, Clinical trials, Global health.

Adverse Drug Reaction and Pharmacovigilance of Herbal Medicines in India

Dhanshree Chaudhari, Dr P.K. Dubey

Swami Vivekananda College of Pharmacy, Indore

Abstract- The use of Ayurvedic medicines is popular in India and in recent times has become accepted in other countries.Pharmacovigilance encompasses the science and practice related to the detection, assessment, understandingand prevention of adverse effects of drugs or any other possible drug-related problems. Recently, its purviewhas been widened to include herbal, traditional and complementary medicines, with the goal to comprehensivelydetect, assess, understand with the unanimous goal of preventing occurrence of adverse effects in those individualsundergoing therapy. This paper discusses, in brief, the Ayurvedic concepts of adverse reactions to medicines, theneed for pharmacovigilance of Ayurvedic medicines, challenges in introducing pharmacovigilance in Ayurveda, andsome recommendations to successfully implementing these activities. The objective of the present article is to reviewthe recent trends and challenges posed in the practice of pharmacovigilance of herbal drugs, especially in the Indiancontext and to shed light on the importance of pharmacovigilance practice in establishing and maintenance of rationaluse of these drugs. Proper reporting of suspected adverse drug reactions to herbal medicines is currently the mainmethod of detection. However, there is under-reporting for herbal medicines, since users do not seek professionaladvice about their use of such products, or report adverse effects. The promotion of the systematic and rational use ofdrugs requires the reporting of adverse events possibly caused by herbal and traditional medicines also.

A Review on Abrocitinib Drug Clinical Study

Satish Chouhan* Manish Meena

Swami Vivekanand College of Pharmacy, Indore

Abstract:-The JAK-STAT pathway is involved in pathophysiology of various immune-mediated inflammatory skin diseases, including vitiligo, psoriasis atopic dermatitis (AD).Since JAK inhibitors have a mechanism of action that impacts signaling of several cytokines compared to specific blockade of their monoclonal antibody-based counterparts, JAK inhibitors demonstrate broad immune-suppressing effects.JAK inhibitors intracellular signalling pathway where many pro inflammatory pathways converge. Currently no complete treatment for atopic dermatitis is available for patients. Abrocitinib (PF-04965842) is an oral Janus kinase 1 selective inhibitor, developed by Pfizer under investigation for the treatment of atopic dermatitis. Clinical phase I trial was only conducted on men. Clinical phase II trial was conducted on 267 participant patient adverse events were observed in 184 of 267 patients. The most frequently reported adverse events were upper respiratory tract infection, dermatitis atopic, headache, nausea, and diarrhea. Dose-dependent decreases in platelet count were observed. Clinical phase III trial was conducted on 387 patients enrolled, 156 were assigned to abrocitinib 100 mg, 154 to abrocitinib 200 mg, and 77 to placebo. All enrolled patients were given one dose of study treatment and thus were under evaluation for 12-week efficacy. Elimination of Abrocitinib is primarily by metabolism involving cytochrome P450 (CYP) enzymes. Pharmacologic activity of Abrocitinib is attributed by unbound concentrations of the parent molecule and 2 active metabolites, which are substrates of organic anion transporter 3 (OAT3). A small amount of abrocitinib parent drug is excreted unchanged in the urine, indicating that majority of the drug undergoes hepatic metabolism. In vitro and in vivo studies have manifested that abrocitinib is a substrate of cytochrome P450 (CYP) 2C19. (53% of abrocitinib metabolism).

Key words:- JAK STAT pathway, Atopic Dermatitis, Eczema, Cytochrome P450,Organic Anion Transporter, Metabolism, Cytokines.

"Review on the clinical trials on hypertension"

Bhawsar Ashutosh*, Dr. Gupta Dishant

Abstract- Hypertension onset age, night time blood pressure levels and a riser pattern are relevant for the prognosis of future cardiovascular disease. The risk of coronary heart disease appears to increase linearly with increasing exercise systolic blood pressure. Renin- angiotensin system blockers are not associated with an increased risk for a serve cource of COVID-19. In elderly patients, a risk – benefit assessment of intensified blood pressure controle should be individually evaluated. Salt restriction and lifestyle modification remain effective options in treating hypertensive patients at low cardiovascular risk. Sodium glucose co- transport 2 inhibitors and glucagon like peptide-1 receptor agonist show BP-lowering effects. Renal denervation should be considered as an additional or alternative treatment option in selected patients with uncontrolled hypertension. The National Heart, Lung, and Blood Institue assembled an ad hoc working group to evaluate opportunities for new major clinical trials in the field of Hypertension. The mandate of this working group was to consider the possible designs of major randomized clinical trials focused on clinical outcomes the might merit significant investment by National Institue of Health. Subjects would be randomizes to a target of systolic blood pressure <130 versus 130 to 15 mm Hg for adequate separation of means. Initial treatment with thiazide diuretic would be followed by randomization to angiotensin converting enzyme inhibitor or angiotensin receptor blocker, beta blocker , calcium channel blocker , or aldosterone Antagonist. A third drug could be added according to a protocol. New knowledge of prevention And treatment for cardiovascular disease, coupled with a better understanding of implementation strategies for therapy has reduced its age- specific mortality and morbidity rated . The digonis and the treatment of hypertention have been a significant part of this success story. Nevertheless, we have fallen far short of our potentional to improve longwvity and functionality by more effectively managing hypertension.

Key words: cardiovascular risk, exercises- include hypertension, COVID-19, renal denervation, systolic blood pressure.

Current scenario on phamacovigilence

Pravin chawda, Dr. Pk dubey

Swami Vivekananda College Of Pharmacy Indore

Abstract- Pharmacovigilance in India was initiated way back in 1986 with a formal adverse drug reaction (ADR) monitoring system, under supervision of the drug controller of India. India joined the World Health Organization (WHO) Programme for International Drug Monitoring in 1998, but was not successful. Later, the National Programme of Pharmacovigilance was launched in 2005, and was renamed as the Pharmacovigilance Programme of India (PvPI) in 2010. In consideration of having a robust pharmacovigilance system in India, steps were taken. The National Coordination Centre was shifted from New Delhi to the Indian Pharmacopoeia Commission (IPC) in Ghaziabad. The PvPI works to safeguard the health of the Indian population by ensuring that the benefit of medicines outweighs the risks associated with their use.

Pharmacovigilance and Clinical Trial

Roshni Kushwaha, Dr P.K. Dubey

Swami Vivekananda College Of Pharmacy

Abstract- Medicines and vaccines have transformed the prevention and treatment of diseases. In addition to their benefits, medicinal products may also have side effects, some of them which may undesirable and unexpected. Pharmacovigilance started 169 years ago on Jan 29, 1848 when a young girl (Hannah Greener) from the north of England died after receiving chloroform Anaesthetic before removal of an infected toenail. The European medicines Agency developed the good pharmacovigilance practise (GVP) guideline In India launched by the MOHEW Govt of India in the year 2010 at AIIMS New Delhi as National Coordinating Centre (NCC). Clinical trial is conducted to examine the clinical questions of practising physicians. Clinical trial Produtcs in relating small number of selected individuals for a period of time. James Lind is considered the first physician to have conducted a controlled Clinical trial of the modern era. In fact the clinical trial is the medical Invention that has contribuitated to nearly all of the lifesaving medicines we know today.

History, Current Status and Future Aspects of Clinical Trial in India

Kuldeep Vinchurkar, Dinesh K Mishra

Indore Institute of Pharmacy, Indore, M.P.

Abstract- Clinical trial is defined by the World Health Organization (WHO) as "Clinical trials are a type of research that studies new tests and treatments and evaluates their effects on human health outcomes. People volunteer to take part in clinical trials to test medical interventions including drugs, cells and other biological products, radiological procedures, devices, behavioural treatments and preventive care. Clinical trials in India have been a buzzing topic in the pharmaceutical industry for decades.

In 1994, India acceded to TRIPS to provide minimum protection to intellectual property which resulted in a "product patent regime." This resulted in an influx of pharmaceutical companies into India and the Government realizing the potential of clinical research for new therapies, amended Schedule Y in 2005. Parallelly, the Indian Council for Medical Research ("ICMR") - India's apex regulatory body for biomedical research, along with Schedule Y of the DCR framed the clinical trial regulatory framework in India.

In 2005, when the Agreement on Trade Related Aspects of Intellectual Properties ("TRIPS") became operational, it was guaranteed for India to become a global hub of pharmaceuticals. The passage of the New Drugs and Clinical Trial Rules, 2019 ("CT Rules") transformed the clinical trials ecosystem in India. It provides for a precise and predictable system of clinical trial regulations which are beneficial to all stakeholders.

India is currently a desirable clinical testing location for to be launched drug entities. The clinical trial activity is regulated in India through the Central Drug Standard Control Organization (CDSCO). India accounts for 18% of the world's population but is home to just 1.4% of the global clinical trials. Although, the Indian clinical trial market size is expected to grow at an unprecedented rate of 8.2% from 2022 to 2030. This article summarized introduction, history, current status and future aspects of clinical trial in India.

Formulation and Evaluation of medicated chewing gum

Toufique Khan Pathan

Modern institute of pharmaceutical sciences

Abstract- The objective of the present study was formulation and evaluation of new medicated chewing gum for the treatment of nausea and vomiting induced by motion sickness, chemotherapy, radiation therapy, and post-operative conditions in cancer using ginger extract and fennel volatile oil as drug candidate.

Keywords: Ginger extracts Fennel volatile oil, nausea and vomiting.

Formulation and Evaluation of Herbal Anti Arthritic Gel

Dr. Raju Choukse, Ms. Sonu Prajapati, Ms. Sonam Thakur, Mr. Mohd.Faarooq Khan

R.D. Memorial College of Pharmacy & Research, Khandwa Road, Indore (M.P.)

Abstract-In Indian systems of medicine majority of herbal products are made by using crude plant or portion of plant parts and their extracts. Herbal medications are considered safer than allopathic medicines as allopathic medicines are associated with the side effects. One of the methods for its survival is preparation of extract and their formulations for better absorption and penetration of the active moiety into the systemic circulation. The leaves extract of Datura stramonium, Vitex - negundo, was taken for this present study and formulated for the topical gel and its properties. The gel prepared using Datura stramonium, Vitex - negundo, leaf extract and Caster oil, Eucalyptus oil was found to be good gel characteristics with respect to homogeneity, spredability, pH, viscosity, anti-inflammatory, antiarthrities, and antimicrobial activity. Herbal gel formulation containing leaf extract of Datura stramonium, Vitex - negundo, Caster oil, and Eucalyptus oil was successfully prepared with carbopol 940 as a gelling agent. The contents of developed herbal extract based gel were propylene glycol as plastisizer, methyl and propyl paraben as preservative and double distilled water and carbopol 940 as gelling agent. The extract of Datura stramonium, Vitex - negundo, Caster oil, and Eucalyptus oil exhibited strong anti-inflammatory, antiarthrities activity. The results of different chemical and physical tests of gel showed that the formation could be used topically in order to Treatment of anti-inflammatory, antiarthrities disorder. Thus it can be concluded that there is a growing demand for herbal formulation in the world market and they are invaluable gift of nature.

Keywords- Datura Stramonium,Anti-Inflammatory, Antiarthrities, Herbal.

Development and Characterization: Proniosomes of Ketoconazole For The Management of Candidiasis

Dr. Raju Choukse, Ms. Sonu Prajapati, Mr. Mohd. Faarooq Khan, Ms. Rashmi Mishra

R.D. Memorial College of Pharmacy & Research, Khandwa Road, Indore (M.P.)

Abstract-A successful attempt was made to develop proniosomal gel for topical delivery of ketoconazole using different ratio of span and cholesterol concentration and evaluated for different in-vitro and skin irritancy test. From the results obtained it can be concluded that –In stability studies $L_3S_1D_1$ is observed in storage stability studies suggested keeping the proniosmal gel in the refrigeration condition. Proniosomes are dry formulations of surfactant-coated carrier, which can be measured out as needed and rehydrated by brief agitation in hot water. These "proniosomes" minimize problems of niosomes physical stability such as aggregation, fusion and leaking while providing additional convenience in transportation, distribution, storage and dosing. Proniosome derived niosomes are superior to conventional niosomes in convenience of storage, transport and dosing. Stability of dry proniosomes is expected to be more stable than enhanced as compared to pre-manufactured niosomal formulation. Proniosomes gel of ketoconazole for the attainment of better therapeutics in candidiasis. The drug is 99% protein bound moreover, it is hepatotoxic hence a cutaneous/topical delivery is more beneficial for the attainment of better therapeutic results.

Keywords- Proniosome, Ketoconazole, Candidiasis.

Evalution of Anti-Inflammatory Effect of Ethanolic Extract of *Balanitesa Egyptiaca*

Dr. Raju Choukse, Ms. Sonu Prajapati, Ms. RoshniKhan, Ms. Sandhay Mourya

R.D. Memorial College of Pharmacy & Research, Khandwa Road, Indore (M.P.)

Abstract- The result of the present investigation revealed that the parts of plants used possess a moderate anti-inflammatory effect that was evidenced by the significant reduction in paw edema and hot plate, tail flick methods. Carrageenan is a sulphated polysaccharide obtained from seaweed (Rhodophyceae) which is commonly used to induce acute inflammation and is believed to be biphasic. The first phase is due to release of histamine and serotonin. The second phase is caused by the release of bradykinin, protease, prostaglandin and lysosome. It has been reported that the second phase of the edema is sensitive to most clinically effective anti-inflammatory drugs, which has frequently to access the anti-edematous effect of natural products. Prostaglandins play a major role in the development of the second phase of the reaction, which is measured at around 3 hours time. The carrageenan-induced paw edema model in rats is known to be sensitive to cyclo-oxygenase (COX) inhibitors and has been used to evaluate the effects of non-steroidal anti-inflammatory agents against which primarily inhibits the enzyme COX involved in prostaglandin synthesis. Based on the results, it can be inferred that the inhibitory effect of extracts on carrageenan-induced inflammation in rats may be due to the inhibition of enzyme cyclo-oxygenase. The present results suggest that Ethanolic extract of *Balanitesa egyptiaca* suppresses the first phase of carrageenan-induced paw edema, thus, confirming an NSAID-like property.

Keywords-Cyclo-Oxygenase,*Balanitesa Egyptiaca*, Anti-Inflammatory, NSAIDS.

Development and Optimization Niosomalgel of Newly Approvedanti-Fungalazole Derivativeluliconazole

Dr. Raju Choukse, Ms. Sonu Prajapati, Mr. Jaydeep S. Baghel, Ms. Sonam Thakur

R.D. Memorial College of Pharmacy& Research, Khandwa Road, Indore (M.P.)

Abstract

We started our research work in a conventiontoformulateandevaluatetheniosomalgelof newly approved anti-fungalazole derivative Luliconazole. In this study, an attempt was made to entrap the drug insidetheniosomesandtoenhancethedrugreleaseofdrugfromniosomes.Thedifferentdrugsolutions werepreparedalongwithaselectedconcentrationofpermeationenhancerwithwhichfurtherstudiesw erecarriedout.Morphologicalstudiesrevealedthatalltheformulationswereshericalinshapeandexi stedasseparateparticles.FTIRspectrashowedthatthereisnointeractionbetweenthesampledruganex cipientsinphysicalaswellasmixtureform.Drugcontentwashigherenoughtoincorporaterequireddos eofdruginminimumpossibleconcentratedniosomalgel.Thereleaseofdrugfromniosomewascontrol ledby diffusionfora prolonged period of time. Picinthecamera. Finally,itwasconcludedconfidentlythatLuliconazoleisasuitableantifungaltobegivenviaTDDS.Th iswillhaveenormousadvantageandifinfuture,thedevelopmenttakesplaceforthismolecule,itmayit mayrevolutionariestheprophylactictreatmentforfungalinfections.

Key Words- Luliconazole, Niosome, Anti-fungal, Gel.

Pharmacokinetic study with computational tools and Molecular Docking study of some new designed 4-Aminoquinoline derivatives as Antimalarial agents

Mahajan Vaishnavi*, Mandloi Nilesh*

GRY, Institute of Pharmacy Vidhya Vihar Borawan – 451228

Abstract-Molecular study has become an increasingly important tool for drug discovery. In this work we used some computational tools for molecular study and performed docking. In this we used some important methods like, "Lipinski'sRule of Five to evaluate drug likeness or determine if a chemical compound with a certain pharmacological or biological activity has properties that would make it a likely orally active drug."Molinspiration" offers broad range of cheminformatics software tools supporting molecule manipulation and processing, including SMILES. "ADMET" the molecular properties which describes Adsorption Distribution, Metabolism, Excretion and Toxicity (ADMET) were predicted using the online software PreADMET. We performed docking on Molegro software using PDB "6UKJ". Five compounds were of good dock score and showed hydrogen bond and steric interaction with the binding site of protein.

In-Silico Docking study of Phenylhydrazone derivatives as Antimalarial agents

Chouhan Meenakshi *Deshmukh Nitin*

***GRY Isntitute of Pharmacy Vidhya vihar borawan**

Abstract- Malaria is the most prevalent mosquito-transmitted infectious disease worldwide affecting humans. It is caused by *Plasmodium* parasites, namely five species infecting humans (*P. falciparum, P. vivax, P. ovale, P. malariae, P. knowlesi*) Among them, the most threatening for human health is *P. falciparum.* In 2019, the number of malaria cases is reported to have exceeded 220 million causing 400,000 deaths, mostly in Africa Therefore, the development of novel antimalarial drugs targeting essential and alternative biological pathways is an urgent need to control malaria worldwide and to reduce the risk of cross-resistance.In present study we used In present study we used computational tools like Lipinski rule of five , Molinspiration, to predict bioactivity and calculate properties , PreADMET analysis , and docking study between designed phenylhydrazone derivatives and PDB(6LHI) using Molegro software to check binding affinity.

Pharmacokinetic study with computational tools and molecular docking study of some new designed Formazan derivatives as anticancer agents.

TomarPrinci*, Mandloi Nilesh*

GRY, Institute of Pharmacy Vidhya viharborawan – 451228

Abstract- Cancer is a multifictional disease that arises when cells are dividing at an uncontrollable rate. it has been depicted by presence of mutations , independent cell proliferation of mitogen, high genetic instability and invasion of other tissues. Targeted therapy targets the tissue which is in any way responsible for the growth and survival of the cancer cell. in our studies docking was performed for reported compound on PARP target ie.XTT or 2 ,3-bis(2-methoxy-4- nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide compound P2 has show highest dock score ie.-137.354 while compound P15 and P12 have shown maximum interaction (P15) Thr195 ,Pro264 , Asp136 , Lys138 , Lys102 , Asn104 ,lle266 ,lle292 , Arg294 Gln269 ,Phe107 (P12) Thr195 ,Pro264 , Asp23 , Lys138 ,lle266 ,lle292 ,Gln269 , Gly293 ,Ala295 ,Ala268 ,Arg294 ,Asn196, when docked against 3S9Y.The newly designed compounds again docked against the PDB and compound P7 show the best dock score:-149.209 and H- bond interactions: Glu490 ,Thr489 ,Val473, Ala443, Lys445 ,lle492 against 3SXR.These compound can be further synthesized and evaluated for different cell lines of cancer which may prove to be potent.

Keywords:-cancer, targeted therapy, docking, binding affinity.

Recent Advancement and Clinical Research on Cancer Immunotherapy

Gourav Mishra, Dr.PK Dubey

Swami Vivekanand College of Pharmacy, Indore

Abstract- Cancer is a disease that begins as a renegade human cell over which the body has lost control. In order for the body and its organs to function properly, cell growth needs to be strictly regulated. Cancer cells, however, continue to divide and multiply at their own speed, forming abnormal lumps, or tumors. An estimated 6.7 million people currently die from cancer every year. Recent progress in cancer immunotherapy has resulted in complete responses in patients refractory to current standard cancer therapies. However, due to tumor heterogeneity and inter-individual variations in anti-tumor immunity, only subsets of patients experience clinical benefit. This review highlights the implementation of a personalized approach to enhance treatment efficacy and reduce side effects, including the identification of tumor-specific antigens for cancer vaccination and adoptive T cell therapies.

Key words: immunotherapy, oncology, mortality rate, gene therapy.

Types and Phases of Clinical Trial

Kamlesh Chouhan, Radhika Reddy, Shweta Joshi, Antim Prajapat, Dr P.K Dubey

Swami Vivekanand College of Pharmacy, Indore

Abstract- Clinical trials are studies to test new drugs, already approved drugs, devices, or other forms of treatments. Many clinical trials look at new ways to detect, diagnose, or measure the extent of disease. Some even look at ways to prevent diseases from happening. Researchers still use human volunteers to test these methods, and the same rules apply. Doctors use clinical trials to learn whether a new drug, treatment, or combination works and is safe to use for people. Clinical trials are important in developing new treatments for serious diseases like cancer. All new treatments must go through clinical trials before being approved by the Food and Drug Administration (FDA). Cancer clinical trials can take years to complete. It can take months, if not years, to see if a cancer treatment does what it is meant to do. There are 3 main phases of clinical trials – phases 1 to 3. Phase 1 trials are the earliest phase trials and phases 3 are later phase trials. Some trials have an earlier stage called phase 0, and there are some phase 4 trials done after a drug has been licensed.

Key words:-Clinical phase trials, Earliest phase trials, later phase trials.

Swami Vivekanand College of Pharmacy

Vivekanand Knowledge City, Khandwa Road,
Indore 452020 (M.P.) - India
Phone: 07324405000, 405027
Email: info@svcp.ac.in