INdIAN MEDICAL ADVISORS SUnMIT

Know Medical, Know Business!
No Medical, No Business!

8:00 AM - 5:00 PM, 22nd February, 2014
The Lalit Mumbai
Sahar Airport Road, Andheri (East), Mumbai 400 059, India
Most pharmaceutical companies have a rhythmic unison of three cross functional teams namely research and development (R & D), medical affairs and marketing. While R & D defines the scientific direction and early stage development, medical affairs creates value and competitive advantage by engaging providers and managed care, and expanding development. It provides scientific support for late stage development and post market support for drugs and devices.

No doubt that the Indian pharmaceutical industry has undergone a paradigm shift since last decade and so has the role of a Medical advisor, which has absolutely become critical and of paramount importance at this point of time. With the changing dynamics in the regulatory framework, both in the Indian pharmaceutical as well as neutraceutical context, along with the maturity of concepts like pharmacovigilance, medical liaisoning, being a regional medical advisor or working for emerging markets, the role of the medical advisor is evolving continuously and is further likely to evolve in years to come in areas like health economics and outcomes research, public private partnerships and strategic planning.

It has been seen that currently Medical Affairs functions in the pharmaceutical industry often lack defined goals, cross-functional communication, and measurable return on investment because of various reasons such as limited resources, personnel turnover, and a rigorous regulatory environment.

This led to the inception of INMAS or Indian Medical Advisors Summit, a first of its kind initiative has been undertaken in India for the cause of Medical Affairs personnel to interact, learn, share new ideas, best practices, and case studies amongst this evolving community. It holds the following key objectives:

- To understand and learn the art of balancing science with marketing
- To understand what it means to be a business manager first and then a medical advisor
- To demonstrate the value of Medical Affairs to the business especially in external expert engagements
- To understand that the future is Field Medical and External Medical Affairs
- To get the understanding of changing dynamics in the regulatory scenario in India
- To co-conceptualize brand plans with local clinical development projects and medical research to plug gaps and meet unmet medical needs of the market

The summit was held at “The Lalit”, Mumbai on 22nd Feb 2014 and was attended by over 100 delegates from Indian as well as global MNC pharmaceutical companies and post graduate students of pharmacology from across the country. It was seen as a highly appreciated move in the field of Medical Affairs in India.

We bring this souvenir to provide you with the key highlights of the summit and thank all the committee members of INMAS, who took time off to share their domain knowledge and made this event a great success.
## INMAS Agenda and Speakers: 2014

### Registration and breakfast - 08:00 a.m. - 09.00 a.m.

**Program Moderator - Anup Soans** - Editor, MedicinMan

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<th>Topic</th>
<th>Time</th>
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<td><strong>Key Note Session</strong></td>
<td>09.00 - Duration 20 min</td>
<td><strong>Dr. Viraj Suvarna</strong> - Medical Director, Boehringer Ingelheim India Private Limited</td>
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<tr>
<td><strong>Utilizing Social Media in Medical Marketing</strong></td>
<td>09.30 - Duration 20 min</td>
<td><strong>Dr. Amit Garg</strong> - Head Emerging Markets, Dr. Reddy's Laboratories</td>
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<td><strong>Stakeholder Management: Internal and External</strong></td>
<td>10.00 - Duration 20 min</td>
<td><strong>Dr. Ganesh Kadhe</strong> - AVP - Medical Affairs &amp; Clinical Operations (India &amp;EM), Wockhardt Ltd.</td>
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### Networking break - 10.30 a.m. Duration 30 min

| How to Make Credible Scientific Presentations?    | 11.00 - Duration 20 min | **Dr. Prashant Desai** - Director - Medical Affairs, Janssen Pharmaceuticals, Johnson & Johnson Limited |
| The Role of Regional Medical Advisor (Field Medical) | 11.30 - Duration 20 min | **Dr. Aju Abraham Varghese** - Sr. Medical Manager Regional Medical Affairs, Pfizer India |
| What Medical Advisor Needs to Know About Regulatory Expertise and NDAC Expectations | 12.00 - Duration 20 min | **Dr. Rohit Arora** - Director- Marketing (Pediatrics), Sanofi Pasteur India |

### Lunch break - 12.30 p.m. Duration 45 min

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<th>Defining Performance Indicators for Medical Advisors - Panel Discussion</th>
<th>01.15 - Duration 45 min</th>
<th><strong>Dr. Salil P Shinde</strong> - Senior Manager, Cardiovascular and Critical Care at Pfizer India Ltd.</th>
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<td><strong>Dr. Sanish Davis</strong> - Medical Director, Covance India Pharmaceutical Services Pvt. Ltd.</td>
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<td><strong>Dr. Viraj Suvarna</strong> - Medical Director, Boehringer Ingelheim India Private Limited</td>
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<td><strong>Dr. Prashant Desai</strong> - Director - Medical Affairs, Janssen Pharmaceuticals, Johnson &amp; Johnson Limited</td>
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<td><strong>Dr. K. Karunakar Reddy</strong> - Head - Medical Affairs, India Business, Dr Reddys Laboratories</td>
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<td><strong>Panel Moderator</strong></td>
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<td>Dr Qayum Mukaddam - Director- Medical Services, Abbott Healthcare Pvt Ltd.</td>
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<td>GPP Introduction and “Marketing or Science”: What should be Medical Advisor's Priority?</td>
<td>02.00 - Duration 20 min</td>
<td><strong>Dr. Santosh Jha</strong> - Director - Medical Regulatory, Takeda Pharmaceuticals</td>
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<tr>
<td>On-label Use and Marketing</td>
<td>02.30 - Duration 20 min</td>
<td><strong>Dr. K. Karunakar Reddy</strong> - Head - Medical Affairs, India Business, Dr Reddys Laboratories</td>
</tr>
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### Networking break - 03.00 p.m. Duration 30 min

| Nutrition Industry- Broadening Lens from a Medical/Scientific Advisor's Perspective | 03.30 - Duration 20 min | **Dr. Vinita Satyavrat** - Head - Scientific & Medical Affairs, Abbott Nutrition International - India |
| What Industry Expects from the Medical Fraternity                       | 04.00 - Duration 20 min | **Mr. Sharad Tyagi** - Managing Director, Boehringer Ingelheim India Pvt. Ltd. |
| Summit Summary + Future Career Options for Medical Advisors in India and Abroad | 04.30 - Duration 20 min | **Dr. Qayum Mukaddam** - Director - Medical Services, Abbott Healthcare Pvt. Ltd. |

### Closing remark - 05.00 p.m.
Dr. Amit Garg
Head, Emerging Markets, Dr. Reddy's Laboratories

Key Points:
- Social Media – A powerful tool!
- Role of Social Media in clinical studies
- Late-phase studies (LPS) & its limitations

Synopsis:
Dr. Garg started off by lending support to social media platforms as an intriguing & an excellent platform to explore & lead, be it marketing or sales, or interactions with external experts. Social media has several advantages over conventional platforms, viz. the ability to interact with different people and support groups, good amalgamation between text & videos, lower patient attrition rates, the ability to recruit a large number of subjects, possibility of multiple generation follow-up studies, and evaluation of patient outcomes. Dr. Garg also opined that social media has the power to change the process of how we operate as well as the current belief system. He concluded by quoting Victor Hugo: “Nothing is more powerful than an idea whose time has come!”

Dr. Viraj Suvarna
Keynote Speaker, Medical Director, Boehringer Ingelheim India Private Limited

Key Points:
- Communication with doctors
- Respect should always be commanded, never demanded
- Ways of marketing & credibility
- 4 P’s: Predictive, Preventive, Pharmionic and Personalized
- Medical Affairs: A part of business; not apart from business

Synopsis:
Dr. Suvarna pointed out that although medical advisors have to walk a thin dividing line, with what the business wants on one hand, and ethics on the other, it is a matter of striking an adequate balance between the two. He also stressed that having knowledge is not enough – its successful application is what makes the difference. One may be professionally qualified, but that does not necessarily make one a qualified professional. He went on to enumerate the responsibilities and duties of a medical advisor in bridging the gap between the doctor and the industry. He concluded with the quote “We believe it is our people with all their differences that actually make the difference!”

“Make music, not noise!”
“Go & Fish, where the fish are!”
Dr. Aju Abraham Varghese  
Sr. Medical Manager Regional Medical Affairs, Pfizer India  

Key Points:
- Evolution & History of the Regional Medical Advisor (RMA)
- Role of RMA & his team  
- Key activities & performance metrics of the RMA team  
- Emerging trends & Challenges faced  

Synopsis:
Dr. Varghese spoke at length about the role of medical affairs team and mentioned that it bridges the gap between the clinical research and commercial fields in a pharmaceutical company, in addition to development of brand strategies, response to drug queries, health economics, medical communications & relationship management with the customer. He stressed on the importance of being unbiased and establishing trust & credibility with customers & healthcare providers.

“It is important to provide updated, unbiased, accurate & complete information to the healthcare professional”

Dr. Prashant Desai  
Director - Medical Affairs, Janssen Pharmaceuticals, Johnson & Johnson Limited  

Key Points:
- 6 I's of Credibility: Ideation, Information, Influence, Integrity, Impact and Ignition  
- Importance of relevant stories/anecdotes  
- Higher the level of evidence, more is the credibility  
- One's credibility depends upon – personal credibility, expertise and audience judgement  

Synopsis:
Dr. Desai emphasized upon the need for a medical advisor to make his/her presentations more relevant and credible to the audience. The key to a good presentation, according to Dr. Desai, is to establish one's area of expertise, have in-depth knowledge with regards to the topic of discussion, establish facts, avoid hidden agendas, be enthusiastic and to firmly stand by one's beliefs. A piece of information should always be backed with reliable evidence for the same, he added.

“A good science is always good business, but a good business is not always good science”

Dr. Santosh Jha  
Director, Medical Regulatory, Takeda Pharmaceuticals  

Key Points:
- Medical affairs: Data generation, packaging & dissemination  
- Promotion of products – the need to share information  
- Key principles of Good Promotional Practice (GPP)  
- Foremost priority – To improve quality of life of the patient  
- Marketing versus Science  

Synopsis:
Dr. Jha focussed his talk upon the ideology of Good Promotional Practice, namely the well being of patients as regards to quality, efficacy and safety of the product. The central theme of his talk revolved around the principles of autonomy, beneficence and non-maleficence. He stressed that the role of a doctor as a medical advisor is to take decisions in favour of the patients. He further stated that it is the duty of a medical advisor to ensure that all research done with regards to a product or disease should ultimately enhance knowledge, benefit patients and contribute to the advancement of science & medicine.

“Credibility, like beauty, is in the eye of the beholder”
Dr. Rohit Arora
Director, Marketing (Paediatrics), Sanofi Pasteur India

Key Points:
- The Indian Drug Regulatory System
- Regulations & Ethics – ICMR, Schedule Y, Indian GCP
- Drugs & Cosmetics Act
- New Drug Advisory Committee (NDAC)

Synopsis:
Dr. Arora shed light upon the expectations and guidelines of various drug regulatory authorities in India, with a greater emphasis on the Drugs & Cosmetics Act and its amendments. He also touched upon the important role played by State Licensing authorities in grant of drug approvals and product licences. He also warned the audience to be adequately prepared while facing an NDAC with regards to technical details of the product, specifics of the clinical study, evaluations for special populations and the need to be crisp & precise in replying to the above queries.

Dr. Ganesh Kadhe,
AVP, Medical Affairs & Clinical Operations (India & EMI), Wockhardt Ltd.

Key Points:
- Good Medical Affairs Practices (GMAP)
- Stakeholders – external & internal

Synopsis:
Dr. Kadhe imparted a brief insight into various stakeholders, their mindsets, expectations, their strengths & weaknesses, and the different ways to handle them. The key to manage stakeholders, according to Dr. Kadhe is to successfully manage oneself first. He advised the audience to change their thought processes from project management to people management, from an operational mindset to a strategic mindset with operational awareness, and of becoming a business leader from a scientific one. He also stressed upon the need to develop an emotional quotient, as this would go a long way in helping manage various stakeholders.

Dr. K. Karunakar Reddy
Head - Medical Affairs, India Business, Dr Reddys Laboratories

Key Points:
- Need to share information – both good & bad
- Off-label drug use & its magnitude
- Relevance of off-label drug use
- Legal issues concerning off-label drug use

Synopsis:
Dr. Reddy pointed out that it takes about 14 years and close to a billion dollars when a drug undertakes the journey from discovery to marketing. He opined that the decision to prescribe a drug for off-label indications should be based on the emerging signs and clinical evidence in support of such use. He went on to say that though it is legal for a clinician to prescribe a drug for an off-label indication, it's marketing for such use by a pharmaceutical company is illegal, and should be avoided. He urged to audience to learn from past experiences and to always do the right thing.

“Selling is a practice that in most industries means just giving the good news & leaving out the bad”

“The (im)perfect excuse: Not in my scope of practice”

“Life is easier to take than you’d think; all that is necessary is to accept the impossible, do without the indispensable, and bear the intolerable”
Mr. Sharad Tyagi
Managing Director, Boehringer Ingelheim India Pvt. Ltd.

Key Points:
- Medical Advisors in the business environment
- Role of Medical Affairs –
  - The Most Integrated Function
  - Guide To Business
  - Bridge between Science & Business

Synopsis:
Dr. Tyagi underscored the importance of medical affairs as a means to engage several stakeholders by creating value and competitive advantage. He went on to enumerate the roles played by medical affairs in attending to the unmet medical needs for R&D, defining the benefits of a product, and providing a direction to the business with regards to its potential in the market. He also mentioned that Medical Affairs also plays a key role in engaging with key stakeholders to communicate & discuss the science behind the product.

“Good ethics are good for the business. Bad ethics will have only short term benefits”

Dr. Vinita Satyavrat
Head - Scientific & Medical Affairs, Abbott Nutrition International – India

Key Points:
- Leading players in the Indian Nutraceutical Market
- Shift in focus from curative to preventive approach
- Driving forces – preventive approach, increase in incomes, increase in lifestyle diseases, growth of pharmacy & wellness-related chains
- Challenges – lack of standardization, poor consumer awareness, high pricing, product promotion & differentiation, raw material imports, regulatory guidelines
- Shift towards ‘functional foods’ as the future of nutrition

“Know your science – Every word matters”

Dr. Qayum Mukaddam
Director, Medical Services, Abbott Healthcare Pvt. Ltd.

Key Points:
- What we learnt today
- The Need to ‘Make your mark’
- Dare to be different
- Do some Research, not re-search

Synopsis:
Dr. Mukaddam succinctly summarized the day’s proceedings for the benefit of the audience. He counselled the audience on the importance of applying knowledge - a product may have multiple positive features, but if it doesn't translate into patient benefits, it is of no use. He also advised the audience to develop good communication skills, which are the crux in sharing of vital information, leading to patient benefit. He went on to enumerate the numerous options opening up within the industry for the medical professional.

“Good ethics are good for the business. Bad ethics will have only short term benefits”
The panel discussed at length on the different ways of evaluating the performance of medical affairs personnel. They were unanimous in their opinion that, in contradiction to the current scenario, such an assessment should not be judged on the basis of sales alone. That being said, the panel agreed that it is extremely difficult to dissociate one's self from product performance. There is a need to be ethical in promoting a product, and the effectiveness of a particular programme should be judged, as it can provide an insight into the success or failure of a product. In the words of a leading pharmaco-economist – “healthcare is economic growth with finite supply where the basic human right is an infinite demand’. The role of a medical advisor lies in guiding the sales colleagues to achieve effective & ethical communication with respect to the target population regarding a product – the business of pharmaceutical selling is the business of communication. There is a need to accept greater social responsibility by the healthcare industry, need for medical advisors to respect the doctor-patient relationship and to ideally do the right thing despite being linked to sales numbers. Patient benefit is the utmost priority, & there is a need for CMEs to be more disease-centric, as opposed to being product-centric. The panel opined that, on occasion one might be required to take a business decisions which seem to go against the organisation – however, as long as they are in favour of patients towards which you are primarily responsible to, one needn't feel guilty about it.
Testimonials

Attendees/ Delegates

“Good Work”
- Dr. Deepak Bachani
Senior Medical Advisor-Metabolics at Bristol-Myers Squibb India Pvt.Ltd.

“Good initiative. Should be continued”
- Dr. Archana Toppo Panda
Medical Advisor, Dr. Reddy’s Laboratories

“Overall INMAS 2014 was really good. Being a student in MD Pharmacology, it was good to know about various career prospects in the industry”
- Dr. Abhinay Paunikar
M.D. Pharmacology, MGM Medical College

“Amazing platform to interact with industry pioneers and seniors in the pharma world to learn and plan carrier development”
- Dr. Ahsan Shoeb
Medical Advisor - Emerging Markets
Dr. Reddy’s Laboratories

“Found it very interesting and wonderful to attend INMAS. There has to be such events in near future”
- Dr. Dhammdeep Dabhade
Senior Manager - Medical Affairs at Venus Remedies Limited

“Excellent with insightful talks by all speakers”
- Dr. Madhura Naik
M.D. Pharmacology, TNMC Medical College and Nair hospital

“This was a good initiative, much needed, well organised. Should use this to convert into an annual meeting perhaps an association. Well Done! Keep it Up!”
- Dr. Aamir Shaikh
Founder Assensa, Health Care Consultant

“It was a brilliant effort and especially helpful for someone who is an aspirant, coming from an academic background, where we do not get necessarily get to understand the industry expectations”
- Dr. Richeek Pradhan
MD Pharmacology student at IPGME&R, Kolkata

“Incited us towards medical affairs part of industry. Brought "industry touch" to an otherwise academic industry curriculum”
- Dr. Poorwa Wandalkar,
MD Pharmacology resident, B. J. Government Medical College

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Straight from the horse's mouth

Dr. Viraj Suvarna
Medical Director, Boehringer Ingelheim India Private Limited
This particular initiative, the first Indian Medical Advisors Summit, is long-awaited & an extremely crucial initiative that has been organized by Geronimo Healthcare, in particular Dr. Amit Dang. The reason I am saying this is because if you look at different functions in the medical department, medical affairs is the one that is closest to business, & is arguably the toughest, because on one hand you have business needs & on the other SOPs, compliance, applicable regulatory requirements; and sometimes it is extremely difficult for medical affairs to walk that thin dividing line. So it is increasingly important for medical affairs personnel from different companies to come to such a forum.

Dr. Amit Garg
Head Emerging Markets, Dr. Reddy’s Laboratories
It is a very good initiative, it’s the first of its kind and the first time in India that all of us have gathered together, & it needs to gather momentum. I think the beauty is that we have a very cross-cultured diverse background encompassing people working in clinical operations, regulatory affairs & medical affairs, in India as well as emerging markets.

Dr. Ganesh Kadhe
AVP, Medical Affairs & Clinical Operations (India & EMI), Wockhardt Ltd.
First of all, I would like to thank Geronimo for arranging this summit – I think it was required from a long time – it happens abroad in Asia-Pacific & the western world, but this was the first time it was happening in India, & was definitely required for all of us. It will not only help students who are doing their post-graduation to understand their roles & responsibilities in the future, understand career opportunities, but also those who are right now in their job in a pharmaceutical industry as medical advisors to understand the scope of their job & what the expectations are from them by the various stakeholders.

Dr. Aju Abraham Varghese
Sr. Medical Manager Regional Medical Affairs, Pfizer India
First of all, I would like to thank Geronimo for organising this event, & it was a very successful one, with over 100 participants here. I am personally glad to be here as there was a new topic given to me – Regional Medical Affairs & introduction of its team members. I could see the drive of the people present here, their passion! So I would request Geronimo to conduct this more often (even every year), & we should together take this journey forward.
Dr. Prashant Desai
Director - Medical Affairs, Janssen Pharmaceuticals, Johnson & Johnson Limited

I think the idea of Indian Medical Advisors Summit was a brilliant one. Such a forum & such a meeting were long overdue. It should make a lot of difference to the people who participated. It was also an opportunity for fraternising, intermingling and mixing with people. It was a wonderful forum as the topics were diverse, the role of a Medical Advisor itself involves a lot of diversity in terms of subjects that one is involved in, & a lot of interesting points came up during the day. So I think, on the whole, it was a wonderful event.

Dr. Santosh Jha
Director, Medical Regulatory, Takeda Pharmaceuticals

I hope that you all enjoyed attending this Indian Medical Advisors Summit & I believe this is a great & fantastic initiative in which all medical folks from industry come together & share their experiences & understanding, so that people can develop their opinions based on what others have been doing & then decide how it is useful. It’s been a great opportunity for all of us & I think there should be more similar meetings organised, with more local chapters opened up, & they should now take up full-fledged face of an association for medical advisors of India. I am thankful to Dr. Amit for organising this fantastic summit.

Dr. Rohit Arora
Director, Marketing (Paediatrics), Sanofi Pasteur India

I think this INMAS summits is one of the unique initiatives that has been organized by Geronimo Healthcare to bring together professionals from the industry, from a medical advisor perspective. & I think the attendance is tremendous – we have a lot of doctors who are attending, the sessions since morning have been really exciting and we have talked about the relevant issues facing the industry.

Dr. Salil Shinde
Senior Manager, Cardiovascular & Critical Care, Pfizer India Ltd

I would like to congratulate the organisers for this fantastic summit. I think it brought together the best brains in the industry - in the medical division you had some very senior people imparting pearls of wisdom, which I am sure have benefitted the young medical advisors a lot. The best part was the clarity of thought that they had regarding goals that a medical advisor should have, & what should be his day-to-day job. This is a very good initiative & I hope we can continue it & take it forward. In particular I would like to quote one of the lines mentioned today – ‘you should be a part of business, not apart from business;’ & I believe that is the very essence of medical function & what a medical advisor does in the pharmaceutical industry.
Dr. K. Karunakar Reddy
Head - Medical Affairs, India Business, Dr Reddys Laboratories

I think it was a great meeting today – I wish the organisers the best, & I hope to see this initiative on a yearly basis, & I hope we have a publication for Indian businesses to do this service to future generations of medical advisors coming into the pharmaceutical industry.

Dr. Qayum Mukaddam
Director, Medical Services, Abbott Healthcare Pvt. Ltd.

This is an exciting initiative – not only the first of its kind, but also one of its kind in India, & I am sure that it has given a good platform for medical advisors to exchange ideas, to learn from experts – we have experts from various companies that have come in & given their feedback - & this will tremendously help our new medical advisors to learn and to understand their roles, & to really put in a lot of effort, so that they can add value to marketing teams. I must really thank Geronimo for thinking of this, conceptualising & more importantly, executing this initiative. I hope that it will go on & become an annual feature, & I'm urging in my personal capacity each & every individual to become a part of this particular movement, to become active members, participate, give suggestions & criticisms, so that we can improvise & have a much better platform in the coming years which will benefit not only the medical advisors, but also the pharmaceutical industry at large.

Mr. Anup Souns
Program moderator and Editor, MedicinMan

I think it is a fantastic effort – it's the first of its kind wherein medical advisors have been brought together, on a platform & we have had some great thought leaders come and share their experiences, their insights and to show how complex medical affairs really is, how important it is to an organisation, & the several of the grey areas as to whether medical advisors should in anyway be influencing sales or are they responsible for sales in anyway – all these kind of issues on which many of them had several thoughts, we had great leaders come and speak about different aspects of medical affairs as also what a business head expects from medical affairs. We also had students come over to understand what the job prospects are for medical advisors. It was a terrific session and I look forward to more such sessions.
Information about Serious ADRs explored by Pharmacovigilance approaches

Authors: Singh J, Mahajan B, Kaushal S, Kaur G
Department of Pharmacology, DMCH, Ludhiana, Punjab

Background: Pharmacovigilance Programme of India (PvPI) has a classification system for the analysis of ADRs which has been suggested based on dose relation, timing, and patient susceptibility. In spite of that, PvPI has not picked up well in India and the subject is in its infancy. Data about serious ADRs is deficient so this study was planned as a preliminary initiative to contribute to PvPI. Objective: To study incidence of serious ADRs at a Tertiary care hospital. Material and Methods: This prospective observational study was carried out on patients admitted in Medical College of North India for the duration of 6 months i.e. from July, 2013 to January, 2014. Data regarding the patient demographics and ADRs were collected by serial patient interviews in the Tertiary care Hospital collaborated by information in respective patient file. No changes in treatment decision, schedule or duration were made as part of study. The incidence rate of each ADR was calculated. Results: A total of 66 serious ADRs were reported during this duration in 60 patients (27 males, 33 females). Mean age of patients was 46.90 years. ADR incidence was found to be 1.11 per patient. The average number of drugs prescribed was 1.64 per patient. The most common drug leading to Serious Adverse Drug Reaction was Phenytoin (13%) followed by Paclitaxel (10%). The most common ADR noted was Rash leading to hospitalization (31.18%) and Steven Johnson Syndrome (31.18%), followed by Fever (16.60%), Anaphylactic Reactions (5%), DRESS (5%) and Toxic epidermal necrolysis (5%). Patients suffering from serious ADRs had presented with diagnosis of seizures (20.75%) followed by ALL (7.73%). Conclusions: Most common serious ADRs reported were Rash and Steven Johnson Syndrome (31.18%).

Comparison of different dosing protocols for Anti-Snake Venom IN Snake-Bite cases

Authors: Daswani BR, Chandanwale AS, Manu HC, Ghorpade V, Ghongane BB, Kadam DB
B.J. Govt. Medical College, & Sassoon General Hospital, Pune

Introduction: Study was conducted to compare the modified low dose ASV protocol with conventional ASV protocol. Objectives: To obtain information on the Anti-Snake Venom (ASV) treatment pattern of inpatients who were prescribed low dose ASV and conventional dose ASV during the study period and to compare them both for cost, side-effect profile and outcome of the patients. Materials and Methods: A Retrospective study was conducted at BJGMC & SGH, Pune.

Poster abstracts
time in the cefixime group was 4.32 ± 1.63 days as compared to 4.68 ±1.52 days in the azithromycin group (p=0.413). Clinical cure was achieved in 23 (92%) patients in the cefixime group and 22 (88%) patients in the azithromycin group (p=0.64). Azithromycin was significantly cheap as compared to Cefixime though there was no significant difference in the cost of treatment. **Conclusion:** Both the drugs cefixime and azithromycin showed comparable efficacy in the clinical cure rate as well as the fever defervescence time. Both were well tolerated. Azithromycin could be a safe and efficacious alternative to the current first line drug cefixime in the management of uncomplicated enteric fever in children.

**ADR profiles of events related to Anti-Cancer drugs in patients at a Tertiary Care Hospital**

**Authors:** Gupta V, Gupta K, Kaur G, Sekhon JS, Dhiman A, Kaushal S

**Department of Pharmacology, Dayanand Medical College and Hospital, Ludhiana, Punjab**

**Background:** The data about the incidence of adverse drug reactions (ADR) in the Indian set-up is meagre. So there is an unmet need of regular reporting of ADRs in the form of Pharmacovigilance. This is especially important in case of anti-cancer drugs as they are very toxic and have higher incidence of ADRs as compared to other group of drugs. **Objective:** To determine the frequency of ADRs and to establish a causality and severity of these ADRs. **Material and Methods:** This prospective, observational study was carried out in the patients admitted in the Department of Oncology at Dayanand Medical College and Hospital for the duration of seven months i.e. from July 2013 to January 2014. The data regarding the patient demographics and ADRs were collected by patient interviews in the Oncology department, collaborated by the information in the respective patient file. The data so collected was entered in the CDSCO ADR reporting form. Causality was assessed by WHO-UMC causality assessment scale and severity by Modified Hartwig's & Seigel Severity Assessment Scale. No changes in the treatment decision, schedule or duration were made as a part of the study. The decision was made by evaluating oncologist. The incidence rate of each ADR was calculated. **Results:** A total of 299 ADRs were reported during this duration in 136 patients (70 males, 66 females).

Among the total number of patients presenting with ADRs, the most common diagnosis noted was Carcinoma colon (13.24%) followed by Carcinoma breast (10.29%). The most common anti-cancer drug prescribed was 5-Fluorouracil (15.26%) followed by Oxaliplatin (11.04%). The most common ADR noted was Alopecia (13.04%) followed by loss of appetite (10.03%) & weakness (10.03%). The causality assessment by WHO-UMC scale established the relationship between the ADR and the drug. **Conclusions:** Anti-cancer drugs have the highest incidence of ADRs, so they need to be used very cautiously. In view of their narrow risk benefit ratio these ADRs needs to be monitored as well as reported carefully.

**Knowledge and perception of clinical trials among Indian doctors: a pilot study**

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**Background:** Clinical trials are standard tools for translation of any intervention from ‘bench to bedside’. However, the knowledge and perception of Indian doctors on clinical trials is not adequately reported. **Methods:** For this cross-sectional survey based pilot study we developed a questionnaire to test the knowledge and perception of doctors employed in Institute of Post-graduate Medical Education and Research and College of Medicine & Sagore Dutta Hospital, Kolkata. Construct validity of the questionnaire was done by 5 pharmacologists. Items were divided into demographic questions, questions testing the knowledge and questions evaluating the perception of the doctors. **Results:** 56 participants with a median age of 33 years responded. A median score of 12 was obtained in knowledge part with maximum achievable score of 21. Knowledge was specifically lacking in questions pertaining to regulations and logistics of clinical trials. Perception was generally low, with a median score of 16 out of a maximum of 60, as measured on a 5 point likert scale. **Conclusion:** Considerable knowledge gap regarding clinical trials amongst doctors exist with a low positive perception of clinical trials. Training pertaining to the clinical trials can be considered in order to bridge this gap and improve clinical research environment.
About the organizers

GERONIMO is a Med-Com agency based out of Mumbai, the financial capital of INDIA. Currently working for over 20 pharma MNCs under the leadership of Dr. Amit Dang, the recipient of "Indian Leadership Award for Healthcare Excellence" by "All India Achievers Foundation" (2013), the organization aims to provide medico-marketing business solutions to all requirements related to drug development, promotion and its life style extension. To this effect this summit is the first of its kind initiative which enabled the Medical Affairs people to interact and come together under one roof.

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