

**One day Workshop on
GCP & Recent Advances in Clinical Trials' Conduct
Organized by**

**Indian Society of Clinical Research
&**

Apollo Research and Innovations, Apollo hospitals, Hyderabad

Final report

The workshop on “**GCP and Recent Advances in Clinical Trials Conduct**” organised by Indian Society for Clinical Research & Apollo Research and Innovations (ARI), Hyderabad, was held on the 23rd Nov 2018 at the Apollo Auditorium. There were 140 delegates from various stakeholders (Doctors/PIs/ coordinators/ethics committee members/PI/SMOs/CROs/ Students) participating in deliberations through the day. Each one of the talks was well appreciated. The group exercise (mentimeter) was the highlight of the day.

The workshop was inaugurated by Ms. Ishita Shively, Vice President, ARI. She welcomed the speakers and spoke on how important it was for organizations like ISCR, the only body for clinical research in India and Apollo Research and Innovation, doing research for the last 18 years, to be hand in hand to not only conduct ethical research but also deliberate in workshops and meetings like these to keep the research society united and updated. This was one of a kind workshop where the target delegate was site and site specific research personnel – the force that mans clinical research on the ground.



Mr. Rakesh, training council member of ISCR, gave a brief introduction of the vision, mission and activities of ISCR. He urged the delegates to come forward and become ISCR members, highlighting the advantages of being a member, like getting the PICR (Perspectives in clinical research journal) and subsidized registration charges. One Principle Investigator and another industry representative has shown interest to take membership.

The first talk was on “**Another Look at Respecting Patients Autonomous Choices**” by Prof. Deen Dayal Reddy, HOD, Bio Medical Ethics, Apollo Institute of Medical Sciences and Research. He beautifully explained the meaning of autonomy and concluded that consent is obtained by not merely the subject signing the form but it is by discussion and in India, it is the family that decides and not the subject alone.

Next speaker was Dr. Ramesh, South Chapter Head for ISCR, presently at Bangalore. He presented the clinical research scenario and current regulatory requirements in India. It was explained well and many questions from the audience were taken.

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Documentation and safety reporting in clinical trials was presented by Dr. Arun Bhatt, senior clinical research consultant from Mumbai. He emphasised on the importance of documentation and safety reporting by the PI and his delegates . His presentation focused on how safety reporting protects the research participants (subjects) from harm and helps in gaining an understanding of the safety profile of the drug.

Need and usefulness of registration and accreditations was the next topic by Dr. Usha rani, Prof and Head, Clinical Pharmacology and Therapeutics, NIMS. She emphasized on the need for accreditations and how it has gained impetus in the recent years.

Dr. Sai Praveen Haranath, Consultant, Apollo hospitals, spoke about the role of PI in clinical trials, need for doing research and the distant future of clinical research. He said research done in today's world by the physicians might get overpowered by artificial intelligence. He reinstated that the 'human touch' of the stakeholders will continue to guide research in the right direction. He said the research was there during his medical college days too, but things have become much more streamlined now. He also emphasized the need to 'hands-on researchers' for better conduct of research and its results.

In these times when regulations are becoming stringent, roles of players in clinical research have changed, including that of the EC secretariat. There is no concept of a pre-defined role anymore, therefore, making it more dynamic. This was discussed by Dr. Mohd. Ziauddin, Pharmacologist and EC member secretary, Apollo hospitals.

Post lunch, there was a session by clinical research coordinators, Ms. Vamshipriya and Dr. Vedaprteek on "CRC: the de facto face for ethical conduct of trials". CRCs play a very important role in the conduct of research. They juggle between the many tasks and also continuously coordinate with the PI, subject, EC, CRA and more. They are truly the backbone of research conduct at the site. CRC responsibilities are multifold which the highlight of the presentation was.

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Then it was time for the quiz session, the highlight of the workshop. Jointly conducted by Mr Praveen (ARI) and Mr Rakesh , it held the audience in rapt attention. A 30 questions quiz was designed and uploaded on Mentimeter . Each delegate was asked to download the app after they registered. Questions were shown on the screen, 30 seconds time given, all the chosen answers popping up on the 4 possible answers as bars and finally the correct answer shown and discussed. This was a good learning session and most liked one too.

Quality – a perspective for all stakeholders was the penultimate topic taken up by Ms. Chandana Pal, Quality and Accreditation Systems Incharge, ARI, the organizing secretary of this workshop. She threw light on the importance of quality, its need, benefits and consequences of poor quality. Quality has to be maintained at all levels of trial conduct and if compromised, the 5 Ms- money, manpower, material, machines and methods all go wasted. Her talk was well appreciated by the audience. She made it crisp, short and easy for everyone to understand.

The workshop concluded with panel discussion. The topic discussed was role of important stakeholders maintaining quality in the trial conduct. Dr Radha Shah (PI), Dr Suseela (EC Member Secretary), Mr Praveen (Site Incharge) and Dr Ramesh. These senior people representing different stakeholders of research had a good interactive session and kept the audience also involved.

Ms. Chandana Pal closed the meeting by proposing vote of thanks.

The feedback from the audience was overwhelming. The content, conduct, presentation was appreciated by one and all. They are looking forward to many more such workshops which would orient them to the present scenario in clinical research.



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Salient take aways from the workshop was:

- ✓ High numbers of registrations including 15 spot registrations
- ✓ Participation from 15+ different organizations
- ✓ Maintaining time discipline among all speakers
- ✓ Timely registrations and certificate disbursement
- ✓ No drop outs in the speakers once the draft was final

Will Look forward to many such events in the future !!

Programme Organising Committee:

1. Ms Chandana Pal (Hyderabad)
2. Dr. Ramesh Jagannathan (Bengaluru)
3. Praveen Kumar (Hyderabad)
4. Rajesh CN. (Hyderabad)
5. Rakesh Dadhania (Hyderabad)

