

Workshop on Recent changes in the Regulatory Scenario of India with respect to Serious Adverse Events, Compensation and Registration of Ethics Committees

April 10, 2013

Jamia Hamdard, New Delhi - 110062



About the Workshop

The recent regulatory changes in Drugs and Cosmetics Act, 1945, applicable to the clinical research processes released by the Ministry of Health and Family Welfare, Govt. of India on 30th January 2013 and 8th February 2013 (Appendix XII, Rule 122DAB, Rule 122DD) have a huge impact on how clinical research is conducted in India.

This workshop is designed with the purpose of having brainstorming discussions on these changes and their impact, through talks by eminent speakers from academia and industry and discussion of case studies for better understanding of changed scenario.

Who Should Attend?

- All the stakeholders in clinical research industry including
- Investigators / Site Study Team / Ethics Committee Members,
- Sponsors, CRO and SMO Representatives,
- Pharmacovigilance Team Members,
- Clinical Research Associates, Clinical Research Trainers,
- Insurance Company Representatives,
- Regulatory Consultants
- UG and PG Students and Research Scholars of Clinical Research and Pharmacy.

Agenda (Tentative)

Time (hr)	Topic	Faculty
9:00 – 11:30	Registration and Inauguration	
11:30 – 11:50	Ethical requirements for conduct of clinical trials in India	Dr Vijay Kumar, Scientist 'F' & HEAD, Basic Medical Scientist Division, ICMR
11:50 – 12:15	Regulatory challenges in upcoming clinical trial process and documentation	Dr. Khalid Khan, Director, Fermish Clinical Technologies Pvt. Ltd. & Regulatory Consultant
12:15 – 13:00	Changes in compensation requirements, SAE reporting timelines, Informed consent requirements, and SAE reporting process	Ms. Shilpa Garg Agrawal, Founder & CEO, SenseCR
13:00 – 13:30	Impact of amended regulations on Pharmacovigilance reporting for sponsors/CROs	Dr. Jamal Anwar, Country Head, Pharmacovigilance, Merck Sharpe and Dohme
13:30 – 14:15	Lunch Break	
14:15 – 14:45	Case Studies	Ms. Shilpa Garg Agrawal
14:45 – 15:30	Changes in the scope, work and responsibilities of Ethics Committees, EC registration process and case studies	Dr. Manoj Karwa, Head, Project Planning and Management, Auriga Research Ltd.
15:30 – 16:00	Impact of regulatory changes on vaccine studies	Dr Shilpi Jain, Senior Manager - Clinical Research, Panacea Biotec Ltd
16:00 – 16:15	Tea Break	
16:15 – 16:45	Impact of amended regulations on Clinical Trial insurance and indemnity	Dr. Banusri Velpandian, Advocate
16:45 – 17:10	Impact of the amendments on research related to traditional system of medicine	Prof. M.A. Jafri, former Director, National Institute of Unani Medicine, Faculty of Medicine (Unani), Jamia Hamdard
17:10 – 17:30	Q&A, Conclusion and valedictory function	All Speakers and Panellists

Organizing Committee

- Dr. S. Raisuddin, Jamia Hamdard
- Dr. Nidhi Agarwal, Jamia Hamdard
- Dr. Manoj Karwa, Head-Project Planning and Management, Auriga Research Ltd.
- Ms. Shilpa Garg Agrawal, Founder & CEO, SenseCR
- Mr. Nishant Singh, Auriga Research Ltd.
- Ms. Hemangi Vanmali, Clinical Research Assistant, SenseCR

Registration

Delegate Fee: INR 3000 for working professionals and INR 2000 for teachers and students from academic institutions.

Spot registration: INR 4000 (all categories)

Registration fee includes training material, lunch, tea/coffee and certificate

Last date of registration: April 5, 2013. Limited seats available.

Special prizes and certificates will be awarded to the winning participants of quiz sessions..

You can collect the registration forms from Dr. Nidhi Agarwal at Jamia Hamdard, or write to us at training@sensecr.com or auriga@aurigaresearch.com for the forms.

Please refer to the registration form for details of payment and submission of duly completed forms. For more detail please visit www.aurigaresearch.com or www.jamiahamdard.edu.

Do not miss this chance to learn, interact & connect!

For more information, contact us at:

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