PRESS RELEASE
For Immediate Publication

Department of Academics and Research Fortis Health Care hosts "Workshop on compensation issues in Clinical Trial Industry- Harmonization and Solutions"

- *Current regulations in clinical research by the regulatory authority*
- *New guidelines to make clinical research more transparent and ethical*

April 30th, 2015, New Delhi: A **"Workshop on compensation issues in Clinical Trial Industry- Harmonization and Solutions"** is being held in India International Center. The workshop is headed by **Prof Dr. Upendra Kaul, Executive Director & Dean – Cardiology, Fortis Flt. Lt. Rajan Dhall Hospital** and is being organized by the Department of Academics and Research Fortis Health Care.

The agenda of the workshop is to track and discuss the current regulations in clinical research instituted by the regulatory authorities over the last few years. The new guidelines were made to make clinical research more transparent, ethical and meaningful. The issues of proper consenting process and regulations for compensations for the subjects participating in clinical trials evaluating drugs or devices have also been incorporated as new rules. However, many of these guidelines and rules do not have clarity and various stakeholders involved in clinical research hesitate to commence new Research projects.

This workshop is driven by the initiative to provide a common platform and bringing all key stakeholders under a most open and conducive environment and to let the policy makers realize the progress made in executing new trials. This will also be a move to address some of the issues which remain a matter of concern and clarifications are provided.

The stakeholders at the workshop comprise of the Regulatory bodies such as the Drug Controller General of India, Sponsors of Clinical trials (Pharma industry and Device Industry), Clinical Research Organizations (CRO's), Insurance Companies, Clinicians who are principal investigators and lastly, but not the least, the subjects whose interests are to be guarded.

The **clinical aspects** will be brought to light by **Dr Vinod Raina, Director & HOD, Medical Oncology & Haematology, Fortis Medical Research Institute, Dr Shamsher Dwivedi, Director & HOD, Neorology, Fortis Medical Research Institute** and **Prof Upendra Kaul, Executive Director & Dean, Cardiology & Academics and Research, Fortis Escorts Heart Institute & Fortis Hospital** from Fortis Healthcare. Other prominent personalities in the field of Clinical trial will also participate in the workshop - **Prof Ranjit Roy Choudhary, Chairman - Task Force for Research, Apollo Hospitals Educational and Research Foundation (AHERF)** and **Dr S K Gupta, Professor**

Emeritus, DIPSAR & National Advisor, Pharmacovigilance Program of India, MOHFW and Legal personalities like **Dr B T Kaul, Chairman, Delhi Judicial Academy and Professor of Law, Delhi University**.

The other eminent speakers would include senior members from the **DCGI office**, **Sponsors** of Clinical Trials like Astra Zeneca, Boehringer Ingelheim, Medtronics, Boston Scientific, Biotronik, St Jude etc., representatives from **CROs** like Quintiles, Max Neemman etc and representatives from **Insurance Companies** like ICICI Lombard, New India Insurance, and Oriental Insurance etc.

The workshop is also targeted to instill greater confidence in various stakeholders on the strides made following the amended guidelines to get India back on the global map as a safe, logical and efficient clinical trials hub and as one of the leaders in this field. The workshop is also being supported by, JK Risk Managers and Insurance Brokers Limited.

Mr. Abrar Ali Dalal, Facilities Director, Fortis Hospital, Vasant Kunj said, "It is a great step towards an open, transparent and ethical level of clinical trials. This will also be a step forward in raising the levels of quality in medical care."

Recent developments in this field show that The **Central Drugs Standard Control Organization** (**CDSCO**) has undertaken the process of registering ECs in India in 2013. It is now mandatory to seek approval from an EC which is registered with CDSCO, before starting any clinical study in India. This is a milestone in the evolution of clinical research in the country. More than 500 ECs have been registered as of today. Since all hospitals may not have the financial and operational capabilities to form and operate an EC, they shall have the option of approaching a registered institutional EC from their locality for review of their research documents. The formation of national and regional ethics committees under the wings of CDSCO could play a supervisory role in guiding the institutional ECs and also review documents for independent researchers. This would serve to make the existing ECs uniform and resourceful and may pave way to the harmonization of the EC review process, which would benefit the research industry as a whole.

About Fortis Healthcare Limited

Fortis Healthcare Limited is a leading integrated healthcare delivery service provider in India. The healthcare verticals of the company primarily comprise hospitals, diagnostics and day care specialty facilities. Currently, the company operates its healthcare delivery services in India, Singapore, Dubai, Mauritius and Sri Lanka with 55 healthcare facilities (including projects under development), approximately 10,000 potential beds and 270 diagnostic centres. In a global study of the 30 most technologically advanced hospitals in the world, its flagship, the Fortis Memorial Research Institute' (FMRI), was ranked No.2, by 'topmastersinhealthcare.com, and placed ahead of many other outstanding medical institutions in the world.

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