

## TN MEDICAL COLLEGE AND BYL NAIR CHARITABLE HOSPITAL RESEARCH SOCIETY

### Symposium on Clinical Research Methodology – 14<sup>th</sup> August 2013

#### Report

The TN Medical College and BYL Nair Charitable Hospital Research Society organized and conducted the **Symposium on Clinical Research Methodology** on Wednesday 14<sup>th</sup> August 2013 at the Nair Hospital Auditorium, TN Medical College and BYL Nair Hospital, Mumbai. The main objective of the program was to disseminate knowledge regarding various aspects of clinical research and Good Clinical Practice. It was attended by **147 delegates** from our own as well as other institutes.

- The Symposium consisted of presentations by experts in the field drawn from academic and corporate fields. At the short inaugural program, **Dr. Girish Rajadhyaksha**, Joint Hon. Secretary of the Society **welcomed** the delegates. The Symposium was inaugurated by the Dean and the President of the Society, **Dr. Ramesh Bharmal**, with the traditional lighting of the lamp. In his **Inaugural Address**, Dr. Bharmal welcomed the idea of Research Society organizing such programs and stated that the delegates will benefit from the Symposium and interaction with the faculty.
- The Scientific program began with the presentation by **Dr. CS Pramesh**, Professor of Thoracic Surgery, Tata Memorial Hospital and Medical Research Center, Mumbai. He discussed the issue of **'Formulating Research Question'** and discussed the need to have a hypothesis and a definitive research question before initiating any research project. He stated that the research question could be related to determining etiology, mechanisms, pre-disposing factors, diagnostics, therapeutics, prognostication, prevention quality of life, cost-effectiveness or service delivery. He emphasized the **FINER Criteria** (Feasibility, Innovation, Novel, Interesting to the researcher, Ethical and Relevant to the community's health needs) for a good research question and stated that the research question should have participant, intervention, comparator and outcome (**PICO**) as the minimum components.
- **Dr. Vasumathi Sriganesh**, Founder Director of QMed Knowledge Foundation spoke on **'Literature Search'**. She emphasized the importance of good literature search for the

purpose of finding out what is published in the world and for building evidence. The key is to have all the relevant literature published till that point in time and being able to manage the list of references generated. **PubMed** being the commonest online source for most researchers, Dr. Vasumathi provided clues to the delegates regarding using this tool effectively and efficiently. She also gave tips regarding **searching the Cochrane Library**.

- This was followed by two presentations by **Dr. Samik Banerjee**, Medical Advisor, Pfizer on **Protocol Writing** and **Study Designs**. He stated that Protocol Development and writing are two crucial steps in the conduct of a research study. He emphasized that protocol is a written document that describes the objectives, design, methodology, statistical methods and organization of a trial. It also gives the background and rationale for the trial and is required to protect the study participants, standardize all study procedures and assure that the study meets regulatory requirements. He also discussed the various components of the protocol. His whole talk can be summarized on the basis of one of his slides that stated: **A good protocol does not guarantee good results if executed badly; but a bad protocol ensures bad results even if executed in the right manner**. In the presentation on 'Study Designs'; he **highlighted the importance of selecting the appropriate study design** depending upon various factors such as the research question, feasibility (in terms of availability of adequate number of participants, time and money) and stated that selecting the appropriate design is important to ensure that the research question is answered properly. Then he went on to describe the utility and statistical highlights of various observational and interventional study designs.
- **Dr. Urmila Thatte**, Professor and Head, Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai then discussed the **ethical issues related to clinical trials**. After describing the differences between the doctor-patient relationship in practice and that in research, she went on to elucidate upon the **responsibilities of investigators and ethics committees** when it comes to clinical research. A lively discussion and interaction followed her talk.

- The post-lunch session started with the talk by **Dr. Sridharan Kannan**, Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital on '**Appropriate Use of Statistical tests**'. Several researchers find 'Biostatistics' as the greatest challenge in research. Dr. Kannan through his lucid talk dispelled the apprehensions of most delegates. He dealt upon issues such as descriptive statistics, inferential statistics, sample size calculations, appropriate statistical tests and reporting of statistics in a manuscript. The talk generated great interest and was followed by interaction.
- It was followed by two talks delivered by **Ms. Swapnali Raut** of Pfizer Ltd., who provided an overview of **Good Clinical Practices (GCP)** and **Safety Reporting**. She emphasized on the fact that participant safety is paramount and explained the various Guidelines and Regulatory requirements.
- **Dr. Sandeep B. Bavdekar**, Vice-President of the Society provided a **succinct summary of the various presentations** and described how the speakers covered all the aspects related to the design and conduct of research and analysis of data and reporting of results. The Symposium was anchored by **Dr. Lona Dash**, Joint Hon. Secretary. **Dr. Shailesh Mohite**, Executive member of the Research Society proposed the **Vote of Thanks** and the program ended with the National Anthem.