Workshop on

Overcoming Challenges for Conducting Clinical Trials in Sri Lanka

Organized by the Clinical Trials Group, Human Genetics Unit, Faculty of Medicine, University of Colombo and the Drugs Committee, Sri Lanka Medical Association

Faculty of Medicine, University of Colombo
January 12, 2011
Background and Objectives

Sri Lanka is looking at rapid economic growth as it emerges from three decades of war. As part of its economic rejuvenation programme, the government of Sri Lanka established a Sri Lanka Clinical Trials Initiative aimed at promoting Clinical Trials in Sri Lanka.

Clinical Trials may bring economic benefit to the country and create new avenues of employment for doctors as well as graduates of newly established Bachelors courses in Pharmacy in many Sri Lankan Universities. It may also create opportunities for local molecules and chemical entities including herbal compounds to be tested in a formal research setting to gain scientific acceptance.

More importantly, Clinical Trials are a vehicle through which modern medicine could be made available to many people in Sri Lanka, and they also hold the potential to improve the clinical research culture in Sri Lanka.

Industry Sponsored Clinical Trials however is a multibillion dollar industry. It is also one of the most regulated industries in the world with drug regulatory agencies and ethics review committees playing a pivotal role. Such an industry therefore has complexities which we must understand and negotiate carefully if Sri Lanka is to reap the economic and other benefits envisaged when embarking on clinical trials as a national initiative.

The objective of this workshop therefore is to share the experience of the Clinical Trials Group of the Human Genetics Unit of the Faculty of Medicine, University of Colombo which has been in the forefront of conducting Industry Sponsored Clinical Trials in Sri Lanka.
Resource Persons

Dr. Vajira H. W. Dissanayake MBBS (Colombo), PhD (Nottingham)
Vajira is a Senior Lecturer and Head of the Department of Anatomy and Medical Geneticist, Human Genetics Unit, Faculty of Medicine, University of Colombo. Vajira has had postgraduate training in the UK and experience in the USA. Since returning to Sri Lankan in 2004 he has contributed to the development of the regulatory framework for ethics oversight of clinical research in Sri Lanka. He has been involved in running clinical trials in Sri Lanka since 2008. He has knowledge of the research and development landscape, including development and regulatory requirements. He was responsible for setting up the first fully fledged clinical trials team in Colombo which ran the first industry sponsored Phase II clinical trial in Sri Lanka to ICH/GCP standards. He is also a steering committee member of the Forum for Ethics Review Committees in Asia and the Western Pacific which is working towards improving ethics oversight of clinical trials in the region and a member of the Sri Lanka Clinical Trials Registry Committee of the Sri Lanka Medical Association where he is also the President-Elect for 2012. E-mail: vajirahwd@hotmail.com

Dr. Priyadarshani Galappatthy MBBS (Colombo), MD (Colombo), MRCP (UK), Dip Med Tox (Cardiff)
Priyadarshani is a Consultant Physician, Senior Lecturer in Pharmacology, and member of the Ethics Review Committee of the Faculty of Medicine, University of Colombo. She has wide ranging experience in Clinical Trials both locally and abroad and has been the Principal Investigator in Industry Sponsored Clinical Trials run to ICH/GCP standards in Colombo. In 2009/10 she worked as a Specialist Doctor in Clinical Research at the Highlands Clinical Research Facility which is a joint National Health Service, UK and University of Highlands and Islands resource established to promote Clinical Research in Scotland. E-mail: priyadarshani1232000@yahoo.com

Dr. Manthinda Hettiarachchi PhD (Monash)
Manthinda was born in Sri Lanka and has been involved in drug development since 1985 (pre-clinical and clinical research). As a clinical researcher he has more than 35 publications and presentations in peer reviewed journals and international and local conferences. He joined the pharmaceutical industry in Australia 15 years ago as a Clinical Research Associate and has held various positions including Project management and business development in major Clinical Research Organisations and Biotech companies (Parexel, PPD, Novotech, Arana Therapeutics). He has conducted/managed more than 40 multinational multicentre Phase I-IV trials and has experience in all aspects of a study from protocol writing to study close out to final report preparation. Manthinda has particular experience in conducting multinational multicentre studies in Europe, Australia, New Zealand and Asia (China, Hong Kong, Singapore, India and Sri Lanka). He has also conducted QA audits in the US, Australia, China and India. Manthinda is currently based in Sydney Australia. He is currently
coordinating a large international multi centre clinical trial involving centres in Eastern Europe, India and China which is recruiting 3000 patients. E-mail: mhettiar@gmail.com

**Firoz Nilam CBiol, MSB (Lond)**

Firoz was born in Sri Lanka and has worked in the pharmaceutical and biotechnology industries for over 37 years in the USA and Europe (England and Switzerland) in varied capacities which included research, medical information, pharmaceutical sales, clinical operations, contract management, regulatory and clinical quality assurance. He has worked at Glaxo SmithKline, Eli Lilly, Hoffmann La-Roche, Lundbeck, Elan, Parexel and Pfizer. Senior positions held included being the Global Head of Clinical Quality Assurance and Vice President for Pfizer, Elan and Roche and as a Vice President of Quality for Parexel International. He has published several papers and has chaired and presented at domestic and International Conferences. He is currently based in San Diego, California, USA and works as a consultant to the pharmaceutical, biotechnology and device industries. He did his undergraduate and post-graduate studies in England in Chemistry and Biochemistry respectively. E-mail: firnil8@aol.com

**Mrs. Therese R Perera PC**

President’s Counsel Mrs. Therese R. Perera created legal history when she became the first woman to be appointed to the office of Legal Draftsman of Sri Lanka. Mrs. Perera was also the first woman to be appointed as a President’s Counsel from the Official Bar. She entered the legal profession in 1974, having taken her oaths as an Attorney – at – Law in December 1974. She has an association of almost 32 years with the legal profession, out of which 31 years has been with the Legal Draftsman’s Department. She graduated from the University of Ceylon with a Degree of Bachelor of Laws in 1972. She joined the Legal Draftsman’s Department as an Assistant Legal Draftsman in June 1975. E-mail: lddsl@sltnet.lk

**Tony Singarayar MBA (Univ. of Texas, Austin), ACA, ACMA**

Tony was born in Sri Lanka. He spent 20 years at Johnson & Johnson in a variety of global roles in Over The Counter (OTC) medicine and Personal Healthcare, with responsibility for New Category Development, Business Development, Marketing, Finance, Process Reengineering, and Business Model Design. He led a team that reduced the clinical research processes at a Fortune 100 company by two years from study initiation to FDA submission. He currently is Founder of Analogy partners, a firm based in USA providing advisory services to senior management and brand teams in multinationals and start-ups in the Pharmaceutical (Rx and OTC), Consumer products, and Food/Beverage industries; Managing Director of Ceylon Business Appliances Ltd, Sri Lanka; COO of Smart Brain Technologies a firm based in USA which has an exclusive license to use National Aeronautics and Space Administration (NASA) neurofeedback technology to help people develop better concentration skills. E-mail: tonys@analogypartners.com
Programme

08.00 – 8.30 a.m.  Arrival of Invitees

08.30 – 10.00 a.m.  Inauguration

Welcome address by Prof. Rohan W Jayasekara, Director, Human Genetics Unit
Address by Prof. Gita Fernando, Chairperson, Drugs Committee, Sri Lanka Medical Association
Address by the Guest of Honour, Prof. Kshanika Hirimburegama, Vice Chancellor, University of Colombo
Address by the Chief Guest, Dr. Ravindra Ruberu, Secretary, Ministry of Health
Overview of Challenges for Clinical Trials in Sri Lanka
Dr. Vajira H. W. Dissanayake

10.00 – 10.30 a.m.  Tea

10.30 a.m.  Proposed Legislation for Clinical Trials in Sri Lanka
Mrs. Therese R Perera

11.00 a.m.  Enhancing the Benefits to Research Subjects and Ensuring their Safety
Dr. Priyadarshani Galappatthy

11.30 a.m. onwards:  The resource persons will make brief presentations, which will be followed by open discussion. These presentations will be in the following areas:

- **Clinical Trial Conduct**
  - Clinical trial protocol
  - Informed consent and patient recruitment
  - Data collection, Source documents and case report forms
  - Drug accountability, movement and documentation
  - Laboratory requirements and Clinical Trial documents
  - Safety reporting

- **Regulation and EC oversight**
  - Regulatory inspections: What are regulatory authorities looking for?
  - Fraud and Misconduct in Clinical Trials
  - Ethics oversight of Clinical Trials
  - Conflicts of Interest

- **Test tube to approval**
  - Legal issues
  - Clinical Trial Contracts, Indemnity/Insurance
  - Business and Financial issues

There will be a lunch break between 12.30 p.m. and 1.15 p.m.

02.15 p.m.  Summing Up and Recommendations

03.15 pm  Close followed by Tea
Invitees

Ministry of Health Officials

Drug Regulatory Authority Officials

Members of the SLMA Medical Drugs Committee


Members of Clinical Trial Groups in Sri Lanka

Academics

Clinicians

Hospital Administrators

Pharmaceutical Industry Representatives

Other Stakeholders in Clinical Trials
Clinical Trials Group, Human Genetics Unit, Faculty of Medicine, University of Colombo

Prof. Rohan W Jayasekara MBBS (Ceylon), PhD (Newcastle), CBiol, MSB (Lond) – Chair and Senior Professor of Anatomy; Director and Medical Geneticist, Human Genetics Unit

Dr. Vajira H. W. Dissanayake MBBS (Colombo), PhD (Nottingham) – Senior Lecturer and Head of Department of Anatomy, Medical Geneticist and Co-coordinator of the Clinical Trials Group

Dr. Jagathie Fonseka MBBS (Colombo) – Medical Coordinator

Ms. Sandamali Senanayake BSc (Pharmacy) (Colombo) – Ethics and Regulatory Affairs Coordinator

Ms. Janaki Niranjala BSc (Pharmacy) (Colombo) – Pharmacy and Laboratory Coordinator

Collaborators

Dr. Priyadarshani Galappatthy MBBS (Colombo), MD (Colombo), MRCP(UK), Dip Med Tox (Cardiff) – Consultant Physician and Senior Lecturer in Pharmacology, Department of Pharmacology, Faculty of Medicine, University of Colombo.

Ms. Dinesha Samararatne LL.B. (Colombo), LL.M. (Harvard), Attorney-at-Law – Lecturer, Department of Public and International Law, Faculty of Law, University of Colombo.

Honorary Advisors

Tony Singarayar MBA (Univ. of Texas, Austin), ACA, ACMA

Firoz Nilam CBiol, MSB (Lond)

Dr. Manthinda Hettiarachchi PhD (Monash)

Ethics oversight of clinical trials conducted by the group is provided by the Ethics Review Committee, Faculty of Medicine, University of Colombo which is the only committee recognized under the SIDCER programme of the World Health Organisation by the Forum for Ethics Review Committees in Asia and the Western Pacific Region.
Recent Industry Sponsored Clinical Trials Conducted to ICH/GCP Standards Conducted Jointly by the Faculty of Medicine, University of Colombo and the National Hospital of Sri Lanka

2007/2008: Study of LJP 394 in Lupus Patients with History of Renal Disease (ASPEN)
ClinicalTrials.gov Identifier: NCT00089804
SLCTR Registration Number: SLCTR/2008/006
Investigators: Dr. Priyadarshani Galappatthy, Prof. Rezvi Sheriff
Sponsor: La Jolla Pharmaceutical Company. San Diego, California, USA

ClinicalTrials.gov Identifier: NCT00854685
Investigators: Dr. Lalith Wijeyarathne, Dr. Lilani Weerasekara, Dr. Priyadarshani Galappatthy, Dr. Vajira H. W. Dissanayake
Sponsor: Arana Therapeutics Ltd. Australia

Details of these trials are available at the http://www.clinicaltrials.gov (the United States Clinical Trials database) and http://www.slctr.lk (the Sri Lankan Clinical Trials Registry database).

Currently two trials are awaiting ethics and regulatory approval.