

MHRD scheme on Global Initiative of Academic Network (GIAN)
CLINICAL TRIALS: ASIA PACIFIC ADVANCEMENTS AND CHALLENGES

1.0 OVERVIEW

Clinical trials and research is a component of medical and health research that focuses on acquiring knowledge that can be used to improve the understanding of human disease to aid in the prevention and treatment of illness and for promoting good health. Asia-Pacific region is in the forefront of conducting clinical trial and is a preferred outsourcing destination. The current course proposal aims to provide a professional and structured clinical research training program for future health professionals, with an emphasis on applying research within a clinical context. There have been important updates to the regulations governing clinical trials in several of the Asian countries in recent years.

The clinical trial business faced a major setback in 2015 in India wherein the number of trials were reduced by 80%. The unpredictable and uncertain regulatory environment in India posed a significant challenge to an otherwise thriving healthcare business. This was further impacted by lack of quality training and education in regard to recent clinical trial advancement from Western world. Data integrity has been a critical issue with number of pharmaceutical companies submitting inaccurate data. Data fabrication and inaccuracy has been reported. The US Food and Drug Administration (FDA) revisited number of trial sites and reconsidered outsourcing of clinical trials to India. The last two years has been challenging with announcement of new reform policies for the clinical trial process. To this end, number of initiatives such as understanding of cultural competence while conducting clinical trials, advanced informed consent process, patient compensation requirements and amendments to ethics regulations are emphasized.

The present course is aimed in addressing these recently highlighted amendments and will be facilitated through comparison with Western system of clinical trial training and education. With Asia-Pacific region having the world's largest and fastest growing medical device and pharmaceutical markets in the world, India is at the forefront. The need of the hour is to train our budding future healthcare professionals in this area of research, practice and entrepreneurship.

Clinical Trials: Asia-Pacific Advancement and Challenges course is aimed to build research capacity through a formal training and improve the quality of the conduct of clinical trials. Leading to employment opportunities in clinical trials research, this course is designed to equip graduates and post graduates with the skills necessary to lead and design clinical trials both nationally and internationally

2.0 OBJECTIVES

The aim of this course is to develop participant's skills and knowledge in the arena of clinical trials and research. The course integrates participant's theoretical knowledge with clinical approach and lay the basic foundation in understanding of global clinical trials.

The primary objectives of the course are as follows:

- Demonstrate an understanding of principles of clinical trials and research through ICH-Good Clinical Practice (GCP) guidelines.
- Understanding the study design in conduction of clinical trials and being familiar with the applied clinical statistics including quality of life outcome measures (e.g. quality adjusted life years in oncology trials).
- Appreciate the cultural diversity and informed consent process involved in clinical research on a global scale.
- Be able to critique published biomedical evidence/medical information (e.g. critical appraisal of published clinical trials, systematic review/meta-analysis and observational studies)
- Understand medication safety issues (pharmacovigilance); clinical trial study designs (pharmacoepidemiology – health economics) and clinical trials in special population.

3.0 TEACHING FACULTY AND ALLOTMENT OF LECTURES AND TUTORIALS

1. Dr. Sohil Khan (SK): 10 hrs lectures and 10 hrs tutorials
2. Dr. Sanjay Deshmukh (SD): 1 hrs lectures and 1 hrs tutorials

4.0 COURSE DETAILS

4.1 Duration: June 17 – June 21, 2019 (5 days): 11 hrs lectures and 11 hrs tutorials.

4.2 Lecture Schedule:

Day 1

Lecture 1 : 1 hrs: SK

Principles of Clinical Research and Clinical Trials: Introduction to ICH-GCP guidelines and clinical research worldwide

Lecture 2: 1 hrs: SK

Phases and study designing in clinical trials, types of designs and understanding of applied statistics.

Tutorial 1: 2 hrs: SK

Problem based learning and hands on training in applied statistics and interpreting results of clinical trials.

Day 2

Lecture 3: 1 hrs: SK

Understanding the roles and responsibilities of professionals in clinical trials in accordance with global guidelines

Lecture 4: 1 hrs: SK

Asia Pacific clinical trial outsourcing and understanding of cultural diversity in clinical research along with informed consent process

Tutorial 2: 2 hrs: SK

Informed consent process and understanding of various phases of clinical trials

Day 3

Lecture 5: 1 hrs: SD

Clinical research update from India

Lecture 6: 1 hrs: SK

Critical appraisal of biomedical literature

Tutorial 3: 1 hrs: SD

Clinical trial outsourcing: Destination India / Critical appraisal of biomedical literature - 1 (SK)

Day 4

Lecture 7: 1 hrs: SK

Drug safety in clinical trials (pharmacovigilance)

Lecture 8: 1 hrs: SK

Clinical trials in special population

Lecture 9: 1 hrs: SK

Compensation of subjects in clinical trials: Preventing exploitation

Tutorial 4: 2 hrs: SK

Pharmacovigilance: Case based learning and Case study of clinical trial in special population

Tutorial 5: 1 hrs: SK

Critical appraisal of biomedical literature -2

Day 5

Lecture 10: 1 hrs: SK

Health economics in clinical trials – principles and practices

Lecture 11: 1 hrs: SD

Course review and revision

Tutorial 6: 2 hrs: SK

Clinical trials in traditional system of medicine; Adaptive clinical trials and future of clinical research

Tutorial 7: 1 hrs: SK

Case based problem solving: Healthcare outcome research (Australia and India perspective)

5.0 WHO CAN ATTEND

- Graduates and postgraduates from healthcare and biological science disciplines (Medicine, Pharmacology, Pharmacy, Nursing, Dentistry, Biotechnology and allied health disciplines)
- PhD and research candidates
- Healthcare professionals involved in clinical research

Fee Structure:

DD to be drawn in the name of Finance and Accounts officer, University of Mumbai

PhD Students: INR 2,000/-

Post Docs: INR 3,000/-

Faculty Members: INR 5,000/-

Participants from Industry/ private sector: INR 7,000/-

The above fee include all instructional materials, computer use for tutorials and assignments, 24 hr free internet facility. The participants will be provided with accommodation on payment basis. Mode of payment: Demand draft in favour of "Finance & Accounts Officer, University of Mumbai" payable at Mumbai. The demand draft is to be sent to the Course Coordinator at the address given below.

Overseas applicants should contact the course coordinator for information about the mode of payment.

6.0 DETAILED CV OF EXPERTS

6.1 CV OF DR. SOHIL KHAN

Career Summary: Dr. Khan is a Senior Faculty with Menzies Health Institute Queensland – Griffith University, School of Pharmacy, Gold Coast; Research Fellow and Honorary Faculty with the Mater Research Institute – The University of Queensland, Brisbane and Adjunct Professor overseas healthcare University from South India. He holds a PhD in evidence based paediatric clinical research from The University of Queensland and completed postgraduate specialty qualifications in Clinical Pharmacology and Master of Business Administration (MBA) in Healthcare. Dr. Khan has extensive experience as an evidence based translational researcher within Australia and overseas (India and Thailand). His research and practice experience has predominantly been in: evidence based mental health management in adolescent and youth; development of guidelines, protocol and systematic reviews/meta-analysis in paediatric developmental disorders; public health and policy making in the area of infectious disease management and addressing barriers while providing pharmaceutical care in high risk groups (patients with limited English proficiency and indigenous population). He was awarded the best clinical project under paediatric research by the Mater Research Institute – The University of Queensland and has won numerous awards and recognition (n=5) in learning and teaching evidence University (Faculty of the year – Early Career and inclusion in top 3% faculty of the year for the past three consecutive years). He is currently an associate editor of a PubMed Central indexed journal and regularly peer reviews for journals such as British Journal of Clinical Pharmacology.

Research Track and Contribution to Clinical trials: Dr. Khan has extensive experience as a translational researcher in paediatric and youth mental healthcare and has been able to secure external funding for multiple projects in excess of \$ 1.5 M. He has received early career research funding for project grants by the Department of Education and Training, Australia and Thailand.

Dr. Khan demonstrates a strong commitment to disseminating the result of his research by regularly publishing his work in relevant Australian and international journals with 38 peer reviewed publication, 10 of which have been published in the last 5 years. He has received numerous awards for his research including the **Best Clinical Paper** from the University of Queensland, Pharmacy research; **Best Research Project (Clinical)** from the Mater Medical Research Institute. Dr. Khan regularly share his expertise in translational research at national and international conferences and has chaired three prestigious international conference session in the area of clinical research at the Drug Information Association (DIA), USA and the Association for Regulatory and Clinical Scientists (ARCS), Australia.

Collaborations: Dr. Khan's expertise is in conducting mixed methods studies, many of which are designed to promote the uptake of evidence in practice. He is a member of Mater Research Institute

– The University of Queensland in the area of paediatric and youth research. Dr. Khan leads the evidence based practice learning and teaching team at the School of Pharmacy, Griffith University. He conducts knowledge translation and evidence based practice research at international level and has been offered the adjunct professional position with a prestigious university from India. Dr. Khan's research has specific outcomes targeted towards active consumer engagement in both the practitioner and patient/family contexts. As an early career researcher, Dr. Khan has supervised 3 higher degree by research students in the past 5 years. His active collaborators belong to diverse geographical location that include: Cochrane Developmental, Psychosocial and Learning Problems Group, UK; Manipal University and PES University, India; Thammasat University, Thailand and he works closely with the Trade and Investment Queensland (TIQ) for internationalisation of translational research in Asia-Pacific Region. Dr. Khan has successfully supervised the student exchange research program with Griffith University and Manipal University, India between 2016-February 2017.

Community engagement and participation: While Dr. Khan's current role is predominantly research and teaching related, he has demonstrated a strong interdisciplinary approach to his professional practice and is currently the chief investigator for a project in provision of pharmaceutical care and quality use of medicines in patients with limited English proficiency from community set-up in rural and urban region of South East Queensland. Dr. Khan has actively collaborated with community educators in promoting sleep hygiene among children with developmental disorders and visual impairment. His community engagement and participation is further strengthened with active research partners from India (evidence based paediatric and infectious disease management) and Thailand (preventive strategies against malaria and dengue among frequent travellers).

Awards/Recognition

- Griffith Excellence: Academic Commendation for the consecutive three years (2014-2017)
- Faculty of the year (Highly Commended – Early Career Category): Griffith University 2014
- Australia-Thailand Early Career Research Mobility Program, 2014-2015
- Best Paper Award : Quality Use of Medicine, The University of Queensland 2012
- Best Research Higher Degree Award (Clinical Category), Mater Research 2011-12
- International Postgraduate Research Scholarship (IPRS), Department of Health, Australia 2000

6.2 CV OF DR. SANJAY DESHMUKH

Dr. Sanjay Deshmukh was the 24th Vice-Chancellor of the 158-year-old University of Mumbai. He was the youngest ever full-time Vice-Chancellor of the University and second youngest after Justice K.T. Telang who in 1892, held the said position in honorary capacity.

Professor Sanjay has been a student of University of Mumbai. He acquired his PhD Degree in Sci-ence at the age of 25, was recognised as PhD Guide at 30 and at 37, he was selected Professor of Life Sciences. Dr. Sanjay is the only faculty of the University to be a recognized PhD Guide in five subjects, i.e., Geography, Botany, Life Sciences, Environmental Sciences and Biotechnology. Dr. Sanjay was trained in China in 1991 under a fellowship from IDRC-Canada, in UK in 1993 under the Colombo Plan Award, and at IIM-Ahmadabad in 1996 under the Fellowship from IIM, in areas of farm forestry, global biodiversity management, and management of CPR (common property re-sources) respectively.

In a career spanning 25 years, Sanjay has generated research grants amounting to INR 15 Crore and 50 Lakh through 32 Research Projects, with total grants of besides, he has generated grants of over INR 2.50 Crore for his Department. His research has taken Dr. Sanjay to 47 different countries. He has to his credit, 169 research publications that include Books, Monographs, Edited Proceedings, Research Papers, and popular Science Articles. Dr. Deshmukh has held several academic and ad-ministrative positions at the University of Mumbai such as (a) Academic and Administrative Head of Ratnagiri Sub-Centre, (b) Head of University Dept of Life Sciences, (c) Member of Senate, BCUD, Academic Council, Faculty of Science, BUTR; and (d) Chairman, Board of Studies in En-vironmental Sciences and also in Life Sciences.

Dr. Deshmukh holds life memberships and elected fellowships of several prestigious Societies and Organisations. He is also the recipient of various prestigious Awards such as Fellow of National Environmental Science Academy (NESA), 2014; Talented Scientist Award, by International Society for research in Medicinal Plants and Herbal Products, Johns Hopkins University, Maryland, USA (2012); Maymar-E-Watan, a Civilian Award of the Sindh Province of Pakistan (2006); LEAD Fellow, LEAD International, UK (2005); Indradhanu Yuvonmesh Puraskar by “Indradhanu” - a premier Cultural Organisation in Maharashtra (2004). Colombo Plan Award, a Technical Co-operation Award of the United Kingdom (1993). Dr. Sanjay was a finalist (among top 5) for INSA Young Scientist Medal, constituted by Indian National Science Academy, New Delhi (2007).

In 2001, Sanjay and his friends established an NGO named KONIM (Konkan Nisarg Manch) to work in Konkan region of Maharashtra. Under Sanjay’s Leadership as President (he was President of KONIM during 2007-12), KONIM has acclaimed wide recognition in the form of prestigious awards such as (a) Best Cluster in India (Western Region) Award: Hon’ble Prime Minister of India Dr. Manmohan Singh handed over this Award which is constituted by the Ministry of Micro, Small and Medium-scale Industries (MSMI), Govt. of India. KONIM achieved Cluster Development (by way of fruit processing) in 30 villages of Sindhudurg District; and (b) Best Village Development Award (through Bamboo plantation) in NGO Category (2010): Hon’ble Chief Minister of Maharashtra State Mr. Prithviraj Chavan handed over the Award, which is constituted by the Ministry of Environment and Forests, Govt. of Maharashtra. KONIM achieved livelihood security through large scale Bamboo plantations in Sindhudurg District.

Dr. Sanjay’s research interests are Climate Change impact on biodiversity, ICT for rural development, conservation and sustainable management of plant genetic resources, Environmental economics, Protected Area Management, Human Genetics, Sleep Sciences, Environmental Planning for Development of Hill Stations, EIA of mega-projects, Management of Research and Administration, Creation of new Organisations, CSR and Ethical management to name a few. He would particularly like to use his professional skills to closely work with corporate leaders and policymakers and influence peoples' representatives to develop a political will for achieving sustainable development.

Course Coordinator:

Sanjay Deshmukh

PhD Mumbai University, DSc (Honoris Causa, RML Avadh Univ., UP) India; FNESA [LEAD Fellow (INDIA) - Cohort 11] Professor Life Sciences; Formerly, Vice-Chancellor (2015-17)

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