Workshop

on

Designing Clinical Trials and Value Propositions

On

February 03, 2020 (Monday)

At

New Presentation Hall

International Institute for Population Sciences

Govandi Station Road, Deonar, Mumbai Maharashtra 400 088, India

❖ Objective of the workshop

- This one-day workshop is to provide insights on dealing with the problems and to develop further the ability to interpret and utilise studies from clinical trials. Interactive participation in this programme shall enable practitioners and professionals to demand from those producing the studies the information that is needed by them. The topics of the seminar are also of interest to those who require an understanding of therapeutic value propositions, such as scientific officers in government and in industry, and medical journalists as well.
- The academic aim of this workshop is to advance a range of transferable specialty-specific expertise invigorated by research. The students shall have the practical aspects needed for planning and conducting more advanced studies in the field.

➢ Session I. Design and analysis of randomized clinical trials.
➢ Session II. Evaluate the critical elements of trial design and analysis.
➢ Session III. Issues in the design and analysis of randomized clinical trials.

❖ Topics coverage

A. Design and analysis of randomised clinical trials

1. Challenges in conducting clinical trials.
2. The journey from invention to consumption (milestones for evaluation and verification).
3. Phases of the stages of clinical trials and their features.
4. The “types” of research: superiority (comparing a new treatment with an old one in regard to a better result), non-inferiority (comparing a new treatment with an old one in regard to no inferior result) and bioequivalence (generics, the difference should lie within a certain range of efficacy).
5. Regulation and documentation of clinical trials.
6. Processes of clinical trial:
   - Protocol, DM flow, SAP (E9), Report (E3).
7. Current Trends in Clinical Research: ‘innovative’ designs; modeling and simulations, biomarkers and surrogate endpoints, quantitative decision making, dealing with missing data – MMRM and multiple imputation methods.

B. Evaluate the critical elements of trial design and analysis [specific to the target population]

- Primary and secondary objectives,
- Primary and secondary end points,
- Primary and secondary variables.

Study design:

- Parallel group designs,
- Crossover designs,
- Group sequential designs.

Discussion shall also include "Current trends in study design" i.e. Adaptive Design: Allocation Rules; Sampling rules; Stopping rules; Decision rules.

C. Issues in the design and analysis of randomized clinical trials

- Uncertainty and probability
- Bias and variability
- Confounding and interaction
- Descriptive and inferential statistics
- Hypothesis testing and p-values
- Clinical significance and clinical equivalence
- Reproducibility and generalizability.

❖ Who would be the participants....

- ✓ Academia responsible for providing thought leadership in the specialty and related disciplines;
- ✓ Pharmaceutical and Medical technology companies of India and South Asia and Central Asia;
- ✓ Clinical trial organisation;
- ✓ Market access specialists;
- ✓ Regional and local governments;
- ✓ Regulatory authorities from local geography.

Program		
09:30 - 09:45 hours	Inaugural Talk	Prof. K.S. James Director, IIPS
09:45 - 10:00 hours	About IIPS courses and objective of the workshop	Prof. Sayeed Unisa
Session 1		
10:00 - 10:10 hours	International Collaboration	Dr. Pavitra Paul
10:10 – 10:45 hours	Clinical Trials in India	Dr. Nilima A. Kshrisagar
10:45 - 11:00 hours	Coffee Break	
Session 2		
11:00 - 13:00 hours	Design and analysis of randomised clinical trials	Prof. Natalia Kovtun Ms. Marija Oniščuka
13:00 - 14:00 hours	Lunch break	
Session 3		
14:00 – 15:00 hours	Evaluate the critical elements of trial design and analysis	Prof. Natalia Kovtun Ms. Marija Oniščuka
15:00 - 15:15 hours	Coffee Break	
Session 4		
15:15 - 17:00 hours	Issues in the design and analysis of randomized clinical trials	Prof. Natalia Kovtun Ms. Marija Oniščuka
17:00 - 17:30 hours	Discussion and Way Forward Vote of Thanks	Resource Persons Dr Laxmikant Dwivedi

Speakers / Resource Persons

Prof. Natalia Kovtun, *D.Sc., Professor in the Department of Statistics and Demography, Taras Shevchenko National University of Kyiv, Ukraine*

Prof. Kovtun is a statistician specialising in Biostatistics, Population demography and Clinical trials. Prof. Kovtun also works in the private sector. At present, she is advising to EDETEK and COVANCE. Her recent work informs surgical intervention outcome of breast cancer and determining the volume of optimal surgical excision for breast cancer. She conducts workshops/seminars at regular intervals at Rīga Stradiņš University, Riga, Latvia. Prof. Kovtun is credited with publications in high impact journals, http://www.researcherid.com/rid/M-6596-2017, and is serving as an opponent in doctoral dissertations' defence. She is a member of the (1) methodological committee on improving methodology and statistical documentation of the State Statistics Service of Ukraine, and (2) expert commissions on licensing and accreditation of universities expertise to conduct educational activities for training in "Applied statistics". Prof. Kovtun was a consultant of World Bank in the year 2005 for "Improving Efficiency in Management of Reforming the Social Protection System in Ukraine"; and in 2011, for "Designing the State Statistical System of Monitoring the Social and Economic Transformation in Ukraine".

Ms. Marija Oniščuka, MPH

Ms. Oniščuka is a specialist in public health and epidemiology with a Master's degree in Health Sciences from Riga Stradiņš University, Latvia. Till recently, she was the project manager in the Statistics Unit of Faculty of Medicine, Riga Stradiņš University where amongst other things she conducted clinical trials data management and statistical analysis for top Latvian pharmaceutical companies like Olainfarm and Silvanols. She was also involved in the training of "Good Clinical Practice" for trial design. Now, she works for Latvian National Cancer Registry, the Centre for Disease Prevention and Control, Government of Latvia as the Public Health Analyst with the specialist role of oncological data synthesis, data quality improvement and analysis.

Dr. Nilima A. Kshrisagar, *National Chair Clinical Pharmacology, Indian Council of Medical Research, Ministry of Health & Family Welfare, Government of India*

Dr Kshirsagar is currently National Chair of Clinical Pharmacology, ICMR, New Delhi, President, South Asian chapter of American college of clinical Pharmacology, Member of WHO Committees on Product development, Drug statistics Methodology, Member DTAB (Drug technical Advisory Board), Chairman core training Panel PvPI Govt.

of India, Fellow of Royal College of Physicians, Faculty of Pharmaceutical Medicine UK and Fellow of American College of Clinical Pharmacology, USA.

Dr Kshirsagar was former acting Vice-Chancellor at the State Health Science University, and also Dean Director of medical education and research, and Prof. Head Clinical Pharmacology G.S. Medical College KEM Hospital, Parel, Mumbai and at T. N. Medical College Mumbai, President of the Indian Pharmacology Society and Infectious Disease Society, India, Chairman Academic Committee AIIMS. Govt. of India, Delhi. Dr Kshirsagar as produced over 200 publications featuring in the Lancet, Lancet Global Health, Lancet infectious diseases, etc.

Dr. Pavitra Paul, PhD.

Dr. PAUL Pavitra, PhD. is a health economist. His research streams are (1) evaluating public policy, and equity in health policies and healthcare services, (2) choice modelling for healthcare service/s consumption and welfare measures, and (3) measuring health systems' performance. At present, he is working on "Revisiting the choice of a sustainable environment: an understanding of subjective health". Pavitra is also spearheading the ongoing project of "Examining Health Systems' efficiency" under the auspices of the International Health Economics Association. Dr. PAUL was an "Academy of Finland" scholar in 2018 for his study, "the welfare effect of choice in a compulsory insurance-based health system in the Russian Federation". He is a member in the scientific review panel (s) of (1) Applied Economics; (2) International Journal for Equity in Health; and (3) International Journal of Health Economics and Management.

His primary affiliation is with Laboratory for Experimentation in Social Sciences and Behavioral Analysis, Burgundy school of business, France. Dr. PAUL is trained in medicine with his Baccalaureate from North Bengal University, India. He is an alumnus from Tata Institute of Social Sciences, India; The London School of Economics and Political Science (LSE), United Kingdom; Erasmus University, The Netherlands; and University of Eastern Finland, Finland.

Prof. K.S. James, *Director and Senior Professor, International Institute for Population Sciences, Mumbai*

Before joining of IIPS, Dr. James was Professor of Demography, CSRD, JNU, New Delhi. He has also served as Acting Director as well as Professor and Head of Population Research Centre, Institute for Social and Economic Change, Bengaluru. His areas of interest include demographic change, health transition, ageing issues and migration. He has been visiting fellow in many prestigious institutes and universities including Harvard University, USA, London School of Economics, UK, University of Southampton, UK, University of Groningen, The Netherlands and International Institute of Applied System Analysis (IIASA), Austria. He has published numerous research papers in the nation and international journals in the area of demography and health.

Prof. Sayeed Unisa, PhD, *Professor and Head, Department of Mathematical Demography and Statistics, International Institute for Population Sciences, Mumbai*

Prof. Unisa is a Statistician and trained population. Her research interests are nutrition, biostatistics and epidemiology, infertility issues, large-scale surveys and multivariate analysis. She is Principal Investigator of the project on Impact Evaluation of Intervention entitled "SWABHIMAAN Women's Nutrition demonstration Programme in Bihar, Chhattisgarh, and Odisha" Funded by UNICEF. Currently, she is involved in many committees commissioned by national and international agencies as an expert and technical advisor. She has presented papers and chaired the sessions at international conferences on population and health. Prof Unisa has published five books and more than 80 articles in the refereed journals.

She is an alumnus of Osmania University, Hyderabad and London School of Hygiene and Tropical Medicine. She was also Visiting Professor at International Institute of Social Studies, Netherland.

Dr. Laxmi Kant Dwivedi, *Assistant Professor, Department of Mathematical Demography and Statistics, International Institute for Population Sciences, Mumbai*

Dr. Dwivedi is PhD in Population Sciences and has been the principal investigator in the National Family Health Survey, round 4 and round 5 funded by Government of India along with other international organizations. He has been even associated with SWABHIMAAN project and several other national-international projects related to the field of demography. His area of interest includes Demographic Models; Applied Econometrics; Applied Multivariate Analysis; Impact Evaluation; Large-scale Survey Research Methods in the field of Demography and Health among others. He has more than fifty publications in the national and international journal. He has received Post-doctorate fellowship through Erasmus Mundus Europe Asia coordinated by Lund University, Sweden. He has received numerous awards for his research and visited several countries.

PATRON

Prof. K.S. James

Director, IIPS

COORDINATORS

Prof. Pavitra Paul

Prof. Sayeed Unisa

Dr. Laxmikant Dwivedi

ORGANIZED BY

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Note: For any other details, kindly email at clinicaltrialsws@iips.net

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February 03, 2020

REGISTRATION FORM

(Last date for Submission of the Registration Form is January 15, 2020)

1. Name: - Mr./ Ms. / Dr. _____
2. Highest Degree: -_____
3. Designation: - _____
4. Mailing Address:- _____
   _____
5. Organization:_____
   Department: - _____
   Mobile no.:- _____
   Email: - _____

The interested candidates would need to send the details at clinicaltrialsws@iips.net. Must write "**Register for Designing Clinical Trials and Value Propositions"** in the Email Subject.

Note: There is no registration fee for attending the workshop. **Travel allowance and accommodation will not be provided for attending the workshop to any participants. Outstation participants need to make their arrangements for travel and accommodation.**

Snacks, Tea and Lunch will be arranged for all the registered participants of the workshop.