

# Orientation Training Program

on  
“Research Methodology and Bio-Statistics”  
relevant for researchers in Ayurveda

24<sup>th</sup> to 27<sup>th</sup> March 2010



ANOVA, Logistic Regression

t-test, F-test

$$t = \frac{(\bar{X}_1 - \bar{X}_2)}{\sqrt{S_1^2/n_1 + S_2^2/n_2}}$$

Clinical Research  
Methods

Chi-Square,

Hypothesis Testing

Variance

$$t = \frac{(\bar{X}_1 - \bar{X}_2)}{\sqrt{S_1^2/n_1 + S_2^2/n_2}}$$

Organized by



**Institute of Ayurveda and Integrative Medicine**

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An initiative under the CAPTURED program at IAIM-FRLHT





## ABOUT US

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The **Institute of Ayurveda and Integrative Medicine (IAIM)** is a multi-disciplinary research, education and outreach arm of the Foundation for Revitalization of Local Health Traditions (FRLHT). FRLHT was founded in 1993 by Mr. Sam Pitroda and Darshan Shankar with a vision to **“To revitalize Indian Medical Heritage”**.

The multidisciplinary achievements and growth of FRLHT-IAIM in the last 17 years demonstrates out of the box thinking and is evidence of dedication, hard work, perseverance and efficiency.

Our mission is to demonstrate the contemporary relevance of Indian Medical Heritage by designing and implementing innovative programs, on a size and scale that will have a societal impact.

## BACKGROUND

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Ayurveda is an evidence based health science which has evolved and matured over the last two millennia. The fields of knowledge in Ayurveda like Dravyaguna Shastra (Pharmacology), Bhasajya Kalpana (Pharmaceutics), Nidana (Diagnosis) and Chikitsa (Management principles) are based on validated knowledge. This though does not rule out scope for any further research in Ayurveda, research should certainly be done to enable global acceptance and usage, to attain competence in solving contemporary health care problems and to build upon the already existing knowledge base. However, it is imperative that for such a research to be meaningful and productive, the understanding of differences in the world views and epistemology of Ayurveda from that of Western Biomedicine must always inform and guide that process.

In the past, the design of clinical trials for Ayurvedic interventions mostly abandoned its multi-component, holistic approach and instead has blindly emulated the relatively simple, single drug-single disease oriented, intervention models, used in western bio-medicine. It is now widely accepted that western models of research are insufficient to test holistic systems of medicine like Ayurveda and that new models of clinical research need to be developed for this purpose. We must however ensure that the rigor that usually characterizes scientific research in western biomedicine is imbibed into clinical research in Ayurveda. Such a rigor is characterized by clearly stated objectives, identification of the correct methodology, involving statistically significant trial subjects, adequate documentation and proper reporting.

The way forward is to approach research with sincerity, objectivity and rigor, use the tools and methods provided by current scientific advances but with a thorough understanding of the scope and limitations of such exercises.

IAIM through various training programs, short term courses, doctoral programs, workshops and seminars intends to contribute to capacity building among researchers in making research in Ayurveda more productive, meaningful and beneficial.

## ABOUT THE PROGRAM

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This OTP is specifically aimed at introducing the participant to the fundamentals of Research Methodology and Bio-Statistics that is relevant for doing Clinical Research in Ayurveda. The program would be delivered by extremely competent researchers with hands on experience in clinical research along with a few of the country's top bio-statisticians.



## PROGRAM HIGHLIGHTS

- Faculty with an excellent track record in conducting Clinical Research.
- Precise focus on Research Methodology relevant for Ayurveda.
- A well-compiled reading material and lecture notes for every session.
- Hands on training in Protocol writing.
- Focused classes on Bio-statistics by country's top Bio-statisticians.
- A special session on CONSORT guidelines and Publication of Research Study.

## PARTICIPANT PROFILE



- Faculty in PG Centers & Universities
- Post Graduate Students
- Doctoral Scholars
- Clinical researchers
- Researchers from Pharma Industry

## PROGRAM SCHEDULE

Sl no.	Topic	Time	Date	Faculty
1.	Basic considerations for Research in Ayurveda	Day 1 Session 1	24 <sup>th</sup> March	Dr. G G Gangadharan / Dr. Rangesh Paramesh
2.	CONSORT Statement and Clinical Research in Ayurveda	Day 1 Session 2	24 <sup>th</sup> March	Dr. Narahari
3.	Clinical Research Methods and Whole System Trials	Day 1 Session 3	24 <sup>th</sup> March	Dr. Girish Tillu / Dr. Shantala Priyadarshini
4.	Study Designs and Hypothesis Testing	Day 1 Session 4	24 <sup>th</sup> March	Dr. Alex Hankey / Dr. Vivek Sanker
5.	Design of Experiments and Sample Size	Day 2 Session 1	25 <sup>th</sup> March	Dr. Mahesh
6.	Introduction to Bio-Statistics – ANOVA, t-test, F-test	Day 2 Session 2	25 <sup>th</sup> March	Mr. Vinay
7.	Binary and Multinomial Data – Chi-square, Logistic Regression, Count Data	Day 2 Session 3	25 <sup>th</sup> March	Dr. Mahesh
8.	Regression and Correlation and other Modeling	Day 2 Session 4	25 <sup>th</sup> March	Mr. Vinay
9.	Non-Parametric Methods – Rank Based Method	Day 3 Session 1	26 <sup>th</sup> March	Dr. Ashwini Mathur
10.	Survival Analyses	Day 3 Session 2	26 <sup>th</sup> March	Dr. Mahesh
11.	Bayesian Methods - I	Day 3 Session 3	26 <sup>th</sup> March	Dr. Pulak
12.	Bayesian Methods - II	Day 3 Session 4	26 <sup>th</sup> March	Dr. Pulak
13.	Protocol Writing – Hands on training (group work)	Day 4 Session 1	27 <sup>th</sup> March	Dr. Ashwini Mathur / Dr. Mahesh
14.	Protocol Writing – Hands on training (group work)	Day 4 Session 2	27 <sup>th</sup> March	Dr. Ashwini Mathur / Dr. Mahesh
15.	Protocol Writing - Discussion on Group Work	Day 4 Session 3	27 <sup>th</sup> March	Dr. Ashwini Mathur / Dr. Mahesh
16.	Publication of Research Study	Day 4 Session 4	27 <sup>th</sup> March	Dr. Ashwini Mathur / Dr. Mahesh



## PROGRAM DETAILS

<b>Last date for Registration</b>	20 <sup>th</sup> March 2010  <b>No Spot Registration</b>
<b>Venue</b>	Training Hall, Nagarjuna Block Institute of Ayurveda and Integrative Medicine, FRLHT CAMPUS, Bangalore
<b>Vacancies</b>	15  <b>to be given on a first come first serve basis</b>
<b>Date</b>	24 <sup>th</sup> to 27 <sup>th</sup> March 2010
<b>Registration Fees</b>	Rs. 5000/- Inclusive of Boarding (on twin sharing basis) Rs. 4000/- Excluding Boarding The fee includes charges for: ➤ Access to all scientific sessions ➤ Seminar kit, reading materials and lecture notes ➤ Food for all the four days
<b>Mode of Fees Payment</b>	Payment can be made in the form of Cheque/DD/Pay Order/Money Transfer in favour of <div style="border: 1px solid black; padding: 5px; text-align: center;"><b>Foundation for Revitalization of Local Health Traditions (Canara Bank Ac no. 0425101045572 )</b></div> Duly filled registration forms along with Draft/Cheque/Transaction receipt can be sent or scanned and emailed to the following address: <div style="border: 1px solid black; padding: 5px;"><p>Dr. R C Bharadwaj, Institute of Ayurveda and Integrative Medicine, FRLHT, 74/2, Jarakabande Kaval, Attur Post, Yelahanka, Bangalore – 560106 Ph: <b>(080) 28568000-03 Ext 228</b> Dir: <b>(080) 28565895</b> Email: <b>dr.rcbharadwaj@frlht.org</b></p></div>



## RESOURCES PERSONS



**Dr. Ashwini Mathur**  
Head CIS, Novartis, Hyderabad

Dr. Ashwini Mathur is currently India Operations Head, TS and NSO Franchise, IISO Novartis Health care Pvt. Ltd. based in Hyderabad heading a team of close to 100 programmers, statisticians, data managers, medical writing and scientists reporting Novartis global clinical trials.

Previously he worked as Head, BDSI, GSK based in Bangalore and Assistant Director, Clinical Pharmacology Statistics Group for GSK based in Philadelphia. Prior to this, Ashwini worked as an Adjunct Professor, Department of Radiology, University of California, Berkeley. Ashwini has a PhD in Biostatistics from University of California, Berkeley, USA. He has several publications on collaborative medical research, book chapters and invited presentations. He is Secretary for International Biometrics Society and a member of DIA and ISCR. He is Adjunct Faculty at Institute of Applied Biology and Bioinformatics, Bangalore and Institute of Ayurveda and Integrative Medicine, Bangalore.

He is one of the founding members of the “Indian Association for Statistics in Clinical Trials” and currently is its president.



**Dr. Alex Hankey**  
Dean-Academics, IAIM-FRLHT, Bangalore

Dr Alex Hankey is Dean, Academic Studies at IAIM. He is the Executive Editor of IAIM's new Journal of Ayurveda and Integrative Medicine, which has just released its first issue [www.jaim.in/currentissue.asp](http://www.jaim.in/currentissue.asp)

He was a Scholar of Trinity College, Cambridge University, from 1965 to 1968, and obtained his M.A. in Natural Sciences. He obtained his PhD in theoretical physics from M.I.T. in Cambridge, Massachusetts; his advisor's were Nobel Laureate Steven Weinberg, and Professor H. Eugene Stanley. After a year as Lindemann Foundation Post-Doctoral Fellow at the Stanford Linear Accelerator Centre, he joined Maharishi International University, rising to be Professor of Physics in 1980. In 1977, he gained a Masters in the Science of Creative Intelligence (MSCI) for research on the Consciousness as a Field of All Possibilities, involving investigation into the Samyama program of Maharishi Patanjali, Yoga Sutras Pada 3. Dr Hankey has lectured extensively on the relationship between Vedic Science and Modern Science in Eastern and Western Europe, North America, and India since 1973.

He has been concerned with Ayurveda, conducting research on its fundamental concepts since 1988. Since 2007 he has lived and worked in Bangalore, associated with Manipal Universal Learning, Swami Vivekananda Yoga Anusandhana Samsthana, where he still directs research as Professor of Yoga and Physical Science. His most recent work includes both “The Physics of Sankhya”, and “Decoding Ayurveda”.



**Dr. Pulak Ghosh**  
Professor of Statistics, IIM Bangalore

Prof. Pulak Ghosh is currently associate professor of Statistics at Indian Institute of Management, Bangalore.

Previously he was a tenured faculty at Georgia state university and Emory University. He was also an associate director in the Statistical Methodology group of Novartis Pharmaceuticals, USA.

He has strong research interest in Biostatistics and also serves in the editorial board of five statistical journals including Journal of the American Statistical Association.



## RESOURCES PERSONS



### **Dr. GG Gangadharan**

Joint Director, IAIM-FRLHT, Bangalore

Dr. GG is presently working in IAIM as its Joint Director, heading the Ayurveda Hospital, Training and Clinical Research Units. He heads a group of around 50 physicians, researchers, Sanskrit scholars and service staff engaged in clinical services, research and educational activities.

Prior to joining FRLHT, he was with The Arya Vaidya Pharmacy (Coimbatore) Ltd., as the Sr. Vice President, serving for them 18 years in various leadership roles. He has delivered lectures on various aspects of "Ayurveda" in a number of national as well as International seminars and published few books on Ayurveda. He has traveled widely in the US, Europe, China, Africa and South East Asia.

He is a member of State Medicinal Plant Board, Ex-member of Ayurveda Siddha Unani Technical Advisory Board of Govt. of India apart from being a member of several National committee of Ayush Department of Govt. of India. He is a member of the Scientific Advisory Committee of the CCRAS and a designated GURU (Mentor) of the Rashtriya Ayurveda Vidyapeeth, New Delhi. He is a recipient of the Vaidyaraj Datar memorial award for proficiency in clinical application of Ayurveda.



### **Dr. Shantala Priyadarshini**

Asst. Professor, GAMC, Mysore

Dr. Shantala Priyadarshini is currently working as Assistant Professor at Government Ayurveda Medical College, Mysore and is the chief consultant at Dr. Vijay's Ayurveda research and treatment center - a holistic in patient facility for prevention and promotion of health and management of diseases.

She is a member of the committee formed by the University of Health Sciences to revise and review the syllabus for Graduate and Post-Graduate studies in Shalakya. She is a guide for post graduate studies in Ayurveda, did her post graduation in Ayurveda (Shalakya) and also in Sanskrit and has been invited by universities abroad to design study modules for Ayurveda courses. (Thames Valley university UK and Ayurveda holistic center Long Island USA) She has been invited as an Ayurveda expert to universities in Netherlands, Australia and Thailand. She has been teaching Ayurveda to students from Germany, Japan and UK at the Sri Sachidananda International Charitable Trust, Mysore.

She has keen interest in both clinical and theoretical research in Ayurveda with special reference to Shalakya (eye, ear, nose, throat, neurological disorders) disorders and management of chronic ailments like Diabetic complications, Multiple Sclerosis, AD by Panchakarma.



## RESOURCES PERSONS



### **Dr. Rangesh Parmesh**

Himalaya Drug Company Ltd, Bangalore

Dr. Rangesh is currently the Head of new product initiatives at Himalaya Drug Company Limited and is involved in developing novel actives from nature for personal and health care products and providing advices in the regulatory matters of product registration and technical support for domestic as well as international markets.

He was responsible for developing actives derived from Ayurveda, for a wide range of Himalaya's personal care range of products including baby care range and especially for a set of organic products, besides facilitating to develop effective pharmaceutical products in the area of Gastrointestinal, Urinary, Dermatological and Immunological systems. Beginning his career as a university lecturer in Karnataka Government Ayurveda Medical Colleges in Bangalore and Mysore, after teaching in the field of Ayurvedic pharmacology and pharmaceutics as well as a research guide to post graduate studies for 15 years.

Dr. Rangesh joined R & D Center of The Himalaya Drug Company as a Medical Advisor, rose to senior level and currently the Head of new product initiatives serving the company for over a decade. Dr. Rangesh was conferred Fellowship Of Royal Asiatic Society, London in 1993, 'PURNA SVASTHYA AWARD', from the World Federation of Societies of Holistic Medicine, Italy, in 1991, 'HAMSA PURASKARA AWARD' from Hamsajyothi, Bangalore, in 1999, and 'VOCATIONAL EXCELLENCE AWARD' from Rotary Club Bangalore Orchards for high ethical standards, excellence & integrity in Ayurveda medical practice, in 2006.



### **Dr. Narahari**

Director, Institute of Applied Dermatology, Kasargod

Dr. Narahari, is a dermatologist of international repute, who pioneered the use of an integrated approach in the management of chronic skin disease like filariasis. He is the director and head of the Institute of Applied Dermatology based at Kasargod Kerala.

Clinical trial conducted by Dr. Narahari on patients suffering from 'Shleepada' (Stone foot) or LF, hitherto considered as a neglected disease, have showed a drastic reduction in those with thickened skin, the research had also shown a drastic reduction in the intake of antibiotic. The unique methodology, (Shleepada-IAD-Ryan Regime) was developed by the IAD after incorporating three branches of medicine -- Allopathy, Ayurveda and Homeopathy -- following a pilot study using "reverse pharmacology" design under the patronage of Global Alliance to Eliminate Lymphatic Filariasis (GAELF).

He has received numerous award and accolades; the golden coin for this presentation from the Principal Secretary Health of Andra Pradesh Government. a president's award for the work of his institute on this project at the September 2005 International Congress of Lymphology in Brazil. The study conducted by him and team on filariasis is recognized as the new medical development of India by Indian Council for Medical Research, New Delhi. Apart from that, Dr. S.R. Narahari has conducted various awareness programme on HIV/AIDS.



### **Dr Girish Tillu**

Group Leader, C-DAC, Pune

Dr Girish Tillu is M.D. in Ayurveda. He worked as senior research fellow in Interdisciplinary School of Health Sciences under CSIR - New Millennium Indian Technology Leadership Initiative program for Ayurveda based drug development for Arthritis.

Girish is associated with Center for Rheumatic Disease s, Pune and Institute for Ayurveda and Integrative Medicine for development of research methods and reporting standards suitable for Ayurveda. He is Group Leader in Center for Development of Advanced Computing, (CDAC) Pune and working on R&D projects in 'Informatics and Integrative Medicine' domain.



### **Mr. Vinay Mahajan**

Novartis, Hyderabad

Vinay Mahajan is currently working with Oncology Biometrics and Data management (BDM) group Novartis Health care Pvt. Ltd. based in Hyderabad leading a team of 10 programmers reporting in the clinical pharmacology and dose escalation trials for Novartis global clinical trials.

Before joining the Oncology team he has worked in various other therapeutic areas. He has worked for Novartis for close to 9 years. He has an MSc in statistics from University of Mumbai and Executive MBA from Welingkar Institute Mumbai and is a certified SAS programmer.



### **Dr. Mahesh Iyer**

Group Head, Oncology Bio-metrics, Novartis, Hyderabad

Dr. Vishwanath (Mahesh) Iyer has a Ph. D. in Statistics from Temple University, Philadelphia. Mahesh has been involved in analyzing and reporting clinical trial data since 1998 with companies like Boehringer-Ingelheim and Bristol Myers Squibb, and specifically for Oncology studies since 2000.

In addition, Mahesh has also been active in the statistical research community with a primary focus on multiple comparison procedures. Currently, he heads the Oncology Biostatistics and Statistical Reporting group for Novartis in India. Mahesh is actively involved in teaching at multiple institutes in India, serves on the Advisory Council of India for the DIA and is the co-editor for a pharmaceutical journal.

**Institute of Ayurveda and Integrative Medicine  
FRLHT, Bangalore**

**Orientation Training Program - REGISTRATION FORM**

Topic : **Research Methodology and Bio-Statistics**

Date : **24<sup>th</sup> to 27<sup>th</sup> March 2010**

**Name:**

**Dr./Mr./Ms.** .....

**Name required on badge**.....

**Date of birth:** ..... **Sex: Male/Female.**

**Designation:**.....

**Institute/Organization:**.....

**Full Address:**

**1. Home:**

.....  
.....  
.....

**2. Office:** .....

.....  
.....

**Phone No: Off:** ..... **Mob:** .....

**Fax:** ..... **E-mail:** .....

**Mode of travel and details (Flight / Train / Bus):** .....

**Date and Time of Arrival at Airport / Railway station / Bus Station** :

**Pick-up required (on payment basis)** : Yes/No

**Boarding required** : Yes/No

**Station:**

**Signature**

Organized by



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