

Phase I Workshop



03-04 December 2007, Ahmedabad

Workshop Highlights

- Regulatory submission for the EU.
- Preparation of a regulatory dossier.
- Preparing a deficiency report.
- Cardiovascular toxicity studies.
- The role of preclinical studies.
- The thorough QT study.
- Preparing a cardiovascular portfolio of a drug.
- Evaluation of drugs for diabetology.
- Glucose clamp studies.
- Regulatory issues relating to new insulin forms.
- Biomarkers in drug development.
- Preclinical DMPK to Identify an IND Track Compound.

Who Should Attend

Senior Managers and Clinical Research Heads of R&D companies in India, Safety Officers and Scientists working in the area of Metabolic Disorders.

Why Should You Attend

We are aware that India is becoming the hub of clinical research activities. Veeda CR has an excellent Phase I facility with a highly experienced team which can provide guidance and training on Phase I studies. This workshop will provide a good knowledge on very specific Phase I studies

Presenters



Dr. Maurice Cross, Group Medical Director, Veeda



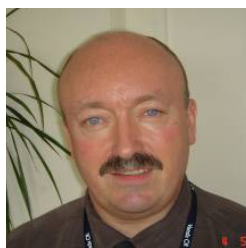
Richard Taylor, Head Regulatory Affairs, Veeda



Dr. Sanjay Sharma, Head Clinical Pharmacology, Veeda



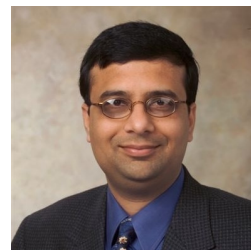
Dr. Vikram Ramanathan Director, Advinus



John Allinson Director, Veeda



Dr. Jinesh Shah, Principal Investigator, Veeda



Dr. Nimish Vachharajani Vice President, Advinus

Sponsors



imagination at work



Click on the photograph for more information on the presenter

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The "How to" in Phase I Clinical Trials

Session 1

Session leader **Dr Richard Taylor**

How toprepare for a clinical trial in the EU and US markets.

- **How to** prepare a CTA for the MHRA for trials conducted in the EU.
- **How to** prepare for a drug master file and the subsequent preparation of a deficiency report.
- **How to** analyse and prepare a deficiency report.

Session 3

Session leader **Dr Sanjay Sharma**

How to..... evaluate an Anti-Diabetic Drug.

- Licensing anti-diabetic products with the EMEA and FDA; Presentation highlights: necessity for clamp studies, the importance of immunogenicity and a pharmacovigilance plan
- Glucose clamping - a technical introduction; Theoretical basis of the glucose clamp, the measurements which should be made and present problems in performing the clamp.

Session 2

Session leader **Dr Maurice Cross**

How to..... evaluate Cardiovascular Toxicity in a drug.

- **Laboratory studies of cardiac toxicity.** hERG, Isolated myocyte, Langendorff and Telemetered species.
- **Essentials of cardiovascular toxicity** in the clinic.
- Establishing a Cardiovascular Toxicity portfolio for a drug.
- The Thorough QT study.
- Demonstration: Latest advances in electrocardiography for clinical trials; The dedicated MAC1200 and the Digital Holter (Speaker from GE Medical).

Practical Demonstration

- Glucose clamp study
- Practicalities of the QT study
- Practical measurement of Cardiac Intervals
- The latest in cardiovascular technology – demonstration
- Poster /demonstration Micro-vascular studies in normals and diabetics
- A device for the bench estimation of insulin resistance in clinical trials

Special Sessions

Biomarkers in Drug Development
by **John Allinson**

Preclinical DMPK to Identify an IND Track Compound
by **Dr Vikram Ramanathan**

The Agenda

Monday December 03

8.30 Workshop Registration

9.15 Welcome note by *Dr Kiran Marthak*

9.45 - 10.45

The Regulatory Submission *Dr Richard Taylor*

Preparation of the Clinical Trial Authorisation (CTA) application for the EU and the Investigational New Drug (IND) application for the US. Preparation of the Drug Masterfile (DMF)

Tea Break for 15 minutes

11.00 - 11.45

Preclinical DMPK to Identify an IND Track Compound *Dr Vikram Ramanathan*

11.45 - 13.00

The Regulatory Process *Dr Richard Taylor*

Making a submission to the Regulatory Authority, the review process and timelines. Pre-submission meetings with Regulatory Authorities. Comparison of the Regulatory Process in EU & US.

Lunch Break for 30 minutes

13.30 - 14.30

The Ethical Review Process *Dr Richard Taylor*

14.30 - 15.15

What is Cardiovascular Toxicity and how do we measure it *Dr Maurice Cross*

15.15 - 16.00

Essentials of cardiovascular toxicity in the clinic *Dr Jinesh Shah*

Tea Break for 15 minutes

Proceed to Veeda for practical session

16.30 - 18.30

Establishing a Cardiovascular Toxicity portfolio for a drug *Dr Maurice Cross*

The Thorough QT study *Dr Maurice Cross*

Demonstration by GE Medical

Latest advances in electrocardiography for clinical trials. The dedicated MAC1200 and the Digital Holter.

Tuesday December 04

9.30 - 10.30

Biomarkers in Drug Development

John Allinson

An introduction to their use, Issues to be considered from the Laboratory perspective, Latest regulatory and consensus guidelines and Case Studies.

Tea Break for 15 minutes

10.45 - 11.30

Anti-diabetic products evaluation with the EMEA and FDA *Dr Nimish Vachharajani*

Necessity for clamp studies, the importance of immunogenicity and also the importance of a pharmacovigilance plan.

11.30 - 12.15

Cold Chain Management *World Courier*

12.15 - 13.00

Microvascular studies in diabetic subjects; studies of diabetic blood flow *Dr Jinesh Shah*

Lunch Break for 30 minutes

13.30 - 14.15

Glucose clamping - a technical introduction *Dr Sanjay Sharma*

Theoretical basis of the glucose clamp, the measurements which should be made and present problems in performing the clamp.

Tea Break for 15 minutes

Proceed to Veeda for practical session

14.45 - 16.15

Practical Demonstrations *Dr Sanjay Sharma*

Glucose clamp study.

Poster /demonstration Microvascular studies in normals and diabetics.

A device for the bench estimation of insulin resistance in clinical trials.

Vote of Thanks by *Apurva Shah, MD Veeda.*

Presenter Information

Dr Maurice Cross

- He founded Veeda Clinical Research-UK (formerly Phase I Clinical Trials Unit) in 1987.
- Graduated in Medicine from Aberdeen University in 1972.
- Has about 30 years of experience in early drug development and a number of scientific publications to his credit.

Back

Dr Richard Taylor

- He is a recipient of a Medical Research Council Scholarship at The Institute of Psychiatry and Kings College Hospital Medical School, London, UK, and holder of the first UK College of Pharmacy Practice Research Fellowship.
- Richard Taylor is a member of the Executive Committee of a UK National Health Service Primary Care Trust and an assessor for The Royal College of General Practitioners Primary Care Research Team, which assists UK physicians' practices gain accreditation to conduct clinical studies.
- Dr. Richard Taylor is a partner with The Medical and Regulatory Partnership Ltd., a professional services company specialising in global regulatory, clinical and medical marketing solutions.

Back

Dr Vikram Ramanathan

- He is currently Director, Drug Metabolism and Pharmacokinetics and Clinical Pharmacology at Advinus Therapeutics.
- He obtained his PhD at the University of California, San Francisco and completed a postdoctoral fellowship at the National Institutes of Health in Bethesda.
- Dr Ramanathan has previously worked in DMPK to support drug discovery and development at Ranbaxy in Gurgaon, and at GlaxoSmithKline/SmithKline Beecham in Philadelphia.
- He has several international publications and presentations in the area.

Back

Dr Jinesh Shah

- He is an MD in medicine by qualification and was a practicing physician prior to joining Veeda.
- Currently he is working as a Principal Investigator at Veeda CR and is actively involved in Glucose clamp and Experimental studies.

Back

Presenter Information

Dr Sanjay Sharma

- Sanjay is MD (Medicine) from Maulana Azad Medical College (MAMC) & associated Lok Nayak (LN) and Govind Ballabh Pant (GB Pant) hospitals, Delhi.
- With 6 years of experience in Clinical Medicine Sanjay joined the Medical Affairs and Clinical Research Department of Ranbaxy Research Laboratories, India in 2001. He played a pivotal role in conducting Phase I studies on New Chemical Entities and moved on to become the Head-Clinical Pharmacology Unit in 2004.
- He is also actively involved in academic activities.

Back

John Allinson

- John Allinson, is a Fellow of the Institute of Biomedical Sciences (FIBMS) and, having spent 23 years in diagnostic laboratories in the UK National Health Service, has experience in all major fields of clinical pathology.
- John's experience in method and equipment validation in regulated environments covers over 150 methods on 30 different types of analytical platforms used in drug development today.
- John is a respected speaker in a number of conferences addressing the topic of biomarkers, regulatory issues, and the synergies with traditional bioanalytical laboratories.
- He is a member of the Biomarker Committee of the AAPS Ligand Binding Assay Bioanalytical Focus Group (LBABFG) whose aims are to produce recommendations for the industry for biomarker assays and their validation.

Back

Dr Nimish Vachharajani

- Dr. Vachharajani, has over 13 years of drug development experience with a large pharmaceutical company in the US and has published over 40 scientific and review articles in various peer-reviewed journals.
- Prior to joining Advinus, he was with Bristol-Myers Squibb in Princeton, NJ, USA. During his tenure with Bristol-Myers Squibb, he worked in many therapeutic areas including metabolic diseases, neuroscience, and cardiovascular.
- Dr. Vachharajani, also led the Diabetes Early Development Team at Bristol-Myers Squibb and was responsible for developing strategies and plans for the pre-clinical and early clinical development (up to Phase IIB) of the entire portfolio of drug candidates for the diabetes franchise.

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Phase I Workshop



03 - 04 Dec, 2007 by Veeda Clinical Research and IDMA

Delegate Registration Form

Participant Fees: Rs. 25,000 per person

Participant Fees for *students: Rs. 15,000 per person

Venue: Ahmedabad Management Association (AMA),
Opp. Indian Institute of Management (IIM), Ahmedabad.

**Practical sessions will be held at Veeda's Phase I unit
at:** Shivalik Plaza-A, Opp. AMA, Near IIM, Ahmedabad.

Yes, please register me for the workshop.

Mr. Ms. Mrs. Dr.

Name: _____

Company/University: _____

Job Title: _____

Email: _____

Contact No: _____

Registration Contact (If different from above) :

Mr. Ms. Mrs. Dr.

Name: _____

Job Title: _____

Email: _____

Contact No: _____ Direct /Extn: _____

**I am unable to attend but please put me in your
mailing list for future workshops.**

For further details please contact:

Ms. Priyanka Shah

Cell: +919879068886, Email: priyanka.shah@veedacr.com

Board Line: +91 79 30013000 Ext. 285

Fax: +91 79 30013010

General Rules:

- Delegate fees are non-refundable, however changes in nominations are accepted.
- Fees are inclusive of service tax.
- Payments have to be made via Demand Draft drawn in favour of 'Veeda Clinical Research Pvt. Ltd'.
- Pre-registration and pre-payment is necessary.
- The registration forms should reach us by 20 Nov 2007.
- Program and speakers are subject to change.
- *Students are required to submit a letter from their Head of Department/Dean/Principal along with the application.

Hotels in Ahmedabad

Delegates are requested to make their own arrangements for accommodation and travel.

The Pride Hotel www.pridehotel.com

Judges Bungalow Rd, Off. S.G. Rd, Bodakdev.
Rate (Deluxe): **Rs. 6000/- (incl. of breakfast & airport transfers, taxes extra)
Contact: Mr. Darshan Shah
Cell: 9898507824 Tel: 079-30115555
Distance from Veeda: 4 kms.

The Grand Bhagwati www.thegrandbhagwati.com

S.G. Road, Bodakdev.
Rate (Standard Deluxe): **Rs. 5200/- (incl. of breakfast & airport transfers, taxes extra)
Contact: Ms. Tanushree or Mr. Kavina
Tel: 079-26840741, 26841000
Distance from Veeda: 5 kms.

The Fortune Landmark

www.fortunelandmark.com

Usmanpura Cross Roads, Ashram Road.
Rate (Deluxe): **Rs. 5760/- (incl. of breakfast & airport transfers, taxes extra)
Contact: Mr. Raja
Cell: 9825879790
Distance from Veeda: 5 kms.

****These are special rates for Veeda CR, so kindly mention the same while booking a room.**

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