

# 2<sup>ND</sup> ANNUAL CONFERENCE

CLINICAL RESEARCH IN INDIA -- TRANSLATING RHETORIC TO REALITY

TAJ LANDS END, MUMBAI

10 - 13 JANUARY, 2009

---

**Pre-Conference Workshop - 10 January, 2009 ( Saturday )**

**“Study Data Tabulation Model (SDTM) from CDISC”**

## **Scope of the workshop:**

Study Data Tabulation Model (SDTM) workshop is intended for those who wish to have a practical introduction to SDTM standard of CDISC. It will be useful for those working in clinical data management and statistical programming domain and are involved in or planning SDTM implementation activities.

**Coordinator :** Mandar Oak

**Faculty :** Anil Kumar Thukkamattathil (Novartis)  
Sandeep Haldankar (Pharmanet)  
Tushar Sakpal (Pharmanet)

**Programme :** See below

Pre-Conference Workshop - 10 January, 2009 ( Saturday )

“Study Data Tabulation Model (SDTM) from CDISC”

**PROGRAMME**

Time	Sub Topic	Deatiled Time	Details
09:00 - 09:40	Overview of SDTM	09:00 - 09:40	This discussion should cover 1) Traditional vs. SDTM 2) SDTM Classes (Interventions etc..) 3) SDTM Domains (DM, CM, AE etc) 4) Variables (Topic, Time, Qualifer etc) 5) Special purpose domains
09:40 - 10:00	<b>Tea Break</b>		
10:00 - 10:30	Trial Design Domain	10:00 - 10:30	1) Detail discussion on Trial design domain 2) Example on subject visits and trial visits
10:30 - 11:00	Special Purpose Domain	10:30 - 11:00	1) Detail discussion on DM domain 2) Mapping dummy DM CRF module along with students
11:00 - 13:00	Intervention Observation Class	11:00 - 11:30	1) Detail discussion on Intervention domains 2) Mapping dummy CM CRF module along with students
		11:30 - 12:15	1) Case Study on "Exposure" domain
		12:15 - 13:00	1) Presentation by groups and discussion
13:00 - 14:00	<b>Lunch</b>		
14:00 - 16:00	Events Observation Class	14:00 - 14:30	1) Detail discussion on Events domain 2) Mapping dummy AE CRF module along with students
		14:30 - 15:15	1) Case Study on "Disposition" domain
		15:15 - 16:00	1) Presentation by groups and discussion
16:00 - 16:15	<b>Tea Break</b>		
16:15 - 18:00	Findings Observation Class	16:15 - 16:45	1) Detail discussion on Findings domain 2) Mapping dummy Lab CRF module along with students
		16:45 - 17:30	1) Case Study on "Vital Signs" domain
		17:30 - 18:00	1) Presentation by groups and discussion