



Vienna School of Clinical Research

in collaboration with



Introduction to Good Clinical Practice

AGENDA

Ankara, 12 – 13 December 2011

Course Director:

Zafer GUNEY

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Operational Council Member,
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Faculty Members:

Canan ULUOĞLU

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Hilal İLBARS

Turkish Ministry of Health

Training Coordinator:

Neelam KAUL

Vienna School of Clinical Research, Austria



DAY 1 – Monday, 12 December 2011

09:00 – 09:45	1. Welcome and Introduction	<i>Zafer GUNEY</i> <i>Neelam KAUL</i>
09:45 – 10:30	2. Lecture Historical Perspective of the Regulations and Guidelines for Clinical Research	<i>Sherry ARMSTRONG-WILKINSON</i>
10:30 – 10:45	<i>Coffee Break</i>	
10:45 – 11:45	3. Lecture The Responsibilities of the Sponsor	<i>Sherry ARMSTRONG-WILKINSON</i>
11:45 – 12:30	4. Lecture The Role of the Investigative Site Staff	<i>Zafer GUNEY</i>
12:30 – 13:30	<i>Lunch Break</i>	
13:30 – 14:45	Workshop The Role of the Investigative Site Staff	<i>Zafer GUNEY</i>
14:45 – 15:00	<i>Coffee Break</i>	
15:00 – 16:30	5. Lecture Essential Safety Definitions <i>including Workshop</i>	<i>Sherry ARMSTRONG-WILKINSON</i>
16:30 – 17:15	6. Lecture Protecting Clinical Trial Subjects	<i>Canan ULUOĞLU</i>
18:00 – 21:00	Group Dinner	



DAY 2 – Tuesday, 13 December 2011

09:00 – 09:45	Workshop Protecting Clinical Trial Subjects	<i>Canan ULUOĞLU</i>
09:45 – 10:00	<i>Coffee Break</i>	
10:00 – 11:45	7. Lecture Essential Documents <i>including Workshop</i>	<i>Sherry ARMSTRONG-WILKINSON</i>
11:45 – 12:00	Learning Check Point	<i>Sherry ARMSTRONG-WILKINSON</i>
12:00 – 12:15	<i>Coffee Break</i>	
12:15 – 13:15	Examination	
13:15 – 14:15	<i>Lunch Break</i>	
14:15 – 14:45	8. Lecture Observational Studies in Turkey	<i>Seçil ÖZKAN</i>
14:45 – 15:15	9. Lecture Legal Aspects of Clinical Research in Turkey	<i>Hilal İLBARS</i>
15:15 – 15:45	Wrap-up & Graduation	