

Day 1 – Thursday 27 Jan 2011

07:15 **Registration**

08:15 **Welcome notes**
SEMCO & ASCO Faculty

ASCO Faculty,
J. Harford, Sh. Omar,
H. Khaled, A. Elzawawy

08:30 Introduction

Ahmed Elzawawy

08:45 **Global Overview – Need for International Clinical Trials**

1. Background information
2. Disparity of research available for ethnic groups
3. Global review of clinical research
4. Public Health. Differing objectives and positions of industry-oriented trials

09:15 **Overview of Cancer Issues**

1. Patterns of cancer
2. Cancer registries and epidemiology

09:30 3. Regional concerns of clinical researchers

4. Reasons for regional cooperative groups to conduct research

09:45 **Discussion**

10:00 **Coffee Break**

10:30 **Perspectives of Sponsors**

1. Academic perspective
2. Government perspective
3. Cooperative group perspective
4. Industry perspective

11:30 **Panel Discussion**

12:00 **Lunch**

13:00 **Ethical Considerations**

1. Tenets of Good Clinical Practice (GCP) – ICH.E6 document
2. Declaration of Helsinki

Role and responsibility of Ethics Committee/IRB

3. International standards for informed consent
4. Availability of drugs before and after the trial

13:45 **Egyptian Experience of IRB**

14:00 **Break**

14:15 **Role of the Oncology Research Team**

1. Principal investigator as Team Leader
2. Clinical Research Associate / Research Nurse
3. Data Manager /Data Entry Clerk
4. Nurse / Resident
5. Pharmacist
6. Support staff (administrative)
7. Support specialists (imager, surgeons, etc.)
8. Trial Participant, according to GCP

14:45 **Coffee Break**

15:15 **Clinical Trial Design and Methodology**

1. The Protocol Document: a reflection of trial design
 - 1.a. Formulating a research hypothesis
 - 1.b. Stating the objectives and selection of endpoints (incorporating biomarkers, molecular targets, correlative signs, etc.)
 - 1.c. Design elements of a successful clinical trial
 - 1.d. Example of a successful clinical trial design
2. Phase 0 to Phase IV. What is right for you?

16:00 **Discussion**

16:15 **Planning and surviving a formal audit**

1. Clarification of sponsor role, CRO
2. Importance of staff training before, during and after each trial as protocols evolve
3. Coordination of regulatory compliance

16:45 **Discussion**

17:00 **HIGHLIGHTS**

17:15 **Satellite symposium**

Day 2 – Friday 28 Jan 2011

09:00 **Regulatory Issues – International perspective**

1. International considerations for multi-site trials
2. Generally accepted standards for clinical trial approval
3. Safety and surveillance reporting for adverse events, coding, etc.
4. International insurance requirements for patients
5. Patient protections in Europe – Directive 2001/20/EC

09:30 **Regulatory Issues – Regional Perspective**

1. Reporting requirements of local regulatory bodies
2. Approval process for use/importation of drugs and required endpoints (FWAs, trial approval, shipping of drugs, etc.)
3. Legal aspects of clinical trials (patients, investigators, sponsor)

10:00 **Discussion**

10:15 **Selecting a multi-site Clinical Trial to activate**

1. Financial feasibility
 - 1.a. Elements of a budget – required human/physical resources
 - 1.b. Sources of funding (government, charity, academic/institutional)
 - 1.c. Planning for costs not covered by study sponsors
 - 1.d. Responsibility of patient care costs
2. Define patient population for the study
3. Implementation feasibility – consider resources, staff and technological requirements, available patient population, etc.
4. What is being done to standardize procedures and data across sites?

11:30 **Coffee break & Prayer time**

13:00 Implementation of Science in Cancer Control

13:30 **Enrollment Methodology**

1. Pre-screening patients
2. Accrual Strategies

13:45 **Promoting a Clinical Trial**

Developing tools for referrals and recruitment to trials, including best practices in working with referring physicians

14:30 Satellite symposium