# WORKING AGENDA

## INTERNATIONAL CLINICAL TRIAL WORKSHOP

September 11-13 2014
Hotel Sheraton……, Córdoba, Argentina
Chairs: Lucia Delgado, Guadalupe Pallota, Eduardo Richardet

## Day 1

**07:30** **Registration**

**08:00** **Welcome and Introduction**
FLASCA: Eduardo Richardet
ASCO: Suanna Bruinooge
NCI:
ONS: Barb Ljubeko

**08:30** **Overview of Cancer Issues in Latin America**
*Coordinators:* (FLASCA)

1. Epidemiological patterns of cancer and cancer registries in Latin America (LA) (FLASCA) – 15 min
2. The importance of epidemiological studies (FLASCA)- 15 min
3. Translational cancer research - 15 min
4. Current situation of clinical cancer research (FLASCA) – 15 min

**9:30** **Academic clinical trials in Latin America. Importance and main challenges**
Coordinator:
1. Academic perspective (FLASCA) (15 min)
2. Government view (FLASCA) (15 min)

**10:00** **Coffee Break**

**10:15** **Funding sources & Perspective sponsors**
*Coordinators:*

1. Overview of Funding Sources (10 min)
2. Academic perspective (5 min)
3. Government perspective
    a. USA (5 min)
    b. LA- INC Argentina (5 min)
4. Cooperative group perspective
    a. NCI (5 min)
    b. FLASCA (5 min)
5. Industry perspective (5 min)
6. **Discussion Panel** - All (30 min)

## Day 1 *(continued)*

**11:25** **Role of the oncology research team**
Coordinators:
1. Principal investigator as Team leader and support specialists (e.g., imagers, surgeons, etc.) (10 min) – Gail Eckhardt
2. Biostatistician and Bioinformatics (NCI) (10 min)
3. Clinical Research Associate/Research nurse/nurse/resident pharmacist/supportive staff (administrative)/data Manager/Data Entry/Trial participant according to GCP (ONS) (20 min) – Carmen Jacobs
3. **Question & Answer** (15 min)

**12:25** **Lunch**

**14:00** **Ethical Considerations**
*Coordinators*
1. Tenets of Good Clinical Practice 10min
2. International standards for informed consent 10min
3. Availability of drugs before and after the trial (NCI) 10min
4. Conflict of interests relevant to clinical research (FLASCA- Eduardo Cuestas) 15 min
5. Role and responsibility of Ethics Committee/IRB and ethical considerations about biologic samples in clinical studies (NCI) 10min
6. **Discussion Panel** – All 20 min

**15:15** **Reading the literature on clinical trials with a critical eye: recognizing and learning from the mistakes of others** (Ian Tannock)

**15:45** **Coffee break**

**16:00** **Clinical Research Design and Methodology (I)**
Coordinators:
1. Developing a hypothesis from a clinical observation – Ian Tannock
2. Developing a protocol design.
   a) Phase I trials – Gail Eckhardt
   b) Phase II trials – Gail Eckhardt
   c) Phase III trials – Ian Tannock
3. Defining the population and eligibility criteria. Primary and secondary endpoints. RECIST criteria. Evaluation and recording of toxicity. – Ian Tannock
4. Patient reported outcomes and quality of life – Ian Tannock
5. Writing the protocol to satisfy IRB requirements – same as Ethics speaker – NCI
6. ***Question & Answer***

**Interactive breakout session**
**17:30** Group discussions of protocols phase I, II and III
Main facilitators: Gail, Ian, Lucia, NCI
Co-facilitators:

**Opening Ceremony & Welcome Reception**
**19:00**

## Day 2

**08:00** **Clinical Research Design and Methodology (II)**

Coordinators:

1. Sample size. Type I and type II errors. Survival analysis. – 15 mins – NCI
2. Systematic review and meta-analysis– 15 mins – Eduardo Cuestas
3. Defining roles and responsibilities of each party in co-sponsored or collaborative studies. – 15 mins – Gail Eckhardt
4. Standardizing procedures – creating SOPs. Incorporating quality control and quality assurance. – 15 mins – Carmen Jacobs
5. Prognostic & observational studies – 15 mins – Ian Tannock
6. How to measure the cost effectiveness of research – 15 mins – Ian Tannock
7. ***Question & Answer***

**Interactive breakout groups – need local co-facilitators**

**10:00** Group 1: Developing a viable early phase research proposal. Deciding the project, objectives, draft writing, systematic review. – Gail Eckhardt

Group 2: Implementation of the project: Site selection, the multidisciplinary team, Training. – NCI speaker?

Group 3: Project management: How to enhance enrollment, source data collection, data management, SOPs, and follow-up. – Carmen Jacobs

Group 4: Developing a viable late phase research proposal. Deciding the project, objectives, draft writing, systematic review. – Ian Tannock, Lucia Delgado

*(Coffee Break indoors during this session)*

**Breakout Discussion – Group Presentations** (15 mins each)

**12:00**

***Lunch***

**13:00**

**Regulatory Issues**

**14:15**

1. International perspective (20 min) NCI
   - International considerations for multi-site trials
   - Generally accepted standards for clinical trial approval
   - Safety and surveillance reporting for adverse events, coding, etc.
   - International insurance requirements for patients.
2. Regional perspective (20 min) - Mauricio Cuello
   - Legal aspects of clinical trials (patients, investigators, sponsor) and reporting requirements of local regulatory bodies
   - New regulatory laws in Latin America
   - Approval process for use/importation of drugs and approval process for sending human samples abroad
3. **Discussion Panel** – All (30 min)

**15:25** **Coffee Break**

## Day 2 *(continued)*

**15:40** **Planning and Surviving an Audit**. **Sponsors expectations vs academic expectations**
Coordinators:
1. Minimum Standards and Exemplary Attributes of Clinical Trial Sites - (15min) Gail Eckhardt
2. How to plan and survive a formal audit, monitoring visits – (15min) – Carmen Jacobs
    a. Clarification of sponsor role
    b. Adherence to protocol and SOPs
    c. Regulatory compliance
3. **Question & Answer** (15 min)

**16:40** **Selecting a multi-site Clinical Trial to Activate**
*Coordinators:*

1. Financial & Logistical feasibility FLASCA 20min
    a. Elements of a budget – required human/physical resources
    b. Sources of funding (government, charity, academic/institutional)
    c. Planning for costs not covered by study sponsors
    d. Contract negotiation skills
    e. Responsibility of patient care costs
2. Legal feasibility - NCI Faculty: 15min
    a. What is being done to standardize procedures and data across sites?
3. **Discussion Panel** 20 min

**17:35** ***Biomarker Translation (or something similar about translating research)***
Gail Eckhardt

**18:00** **End of day 2**

## Day 3

**08:30** **Public Policies to encourage scientific research (FLASCA)**

**09:00** **Impact of Clinical Trials on Cancer Care in Low- and Middle-Income countries**
*Coordinator:* (FLASCA)
*Speaker:*
20min
**Question & Answer**
*Moderators:* (FLASCA)
20 min

**09:40** **Intellectual Property & Technology Transfer Issues**
Coordinator:
Speaker: (Industry?) (20 min)

**10:00** **Coffee Break**

**10:15** **Publishing Research Findings**
Coordinators:
1. Publishing and presenting your data (20 min) - Ian Tannock
   a . Developing principles for authorship and data sharing in a multi-site trial
   b. How to write a clear and concise scientific abstract and paper

2. How to be successful in publishing your work (20 min) - Eduardo Cuestas
   a. How to select a relevant journal for publishing
   b. How to respond to editorial critiques

**Question & Answers** (20 min)

**11:15** **Opportunities and main challenges faced by clinical researchers in LA. Young oncologist investigator's vision**
*Coordinator:*
*Speakers:* Rachel Riechelmann (Brazil), Mauricio Cuello (Uruguay)
20 mins each

**11:55** **Closing Remarks**

**12:10** **End of the Workshop – Certification**