

# GECO-OLA-ESMO Clinical Trials Workshop

Lima, Peru - 25 Oct - 27 Oct 2017

## Wednesday 25 October 2017

8:30 - 9:00	Registration
9:00 - 9:25	Welcome (Chairs: <i>C. Vallejos, C. Rolfo</i> ) Personal presentations
9.25-9.45	Knowing OLA: introduction, history, work and future perspectives H Gomez - C. Rolfo
9.45 11:00	Statistics (Urania Dafni) <ul style="list-style-type: none"><li>• Phase I design</li><li>• Phase II designs:<ul style="list-style-type: none"><li>○ Single arm design:</li><li>○ One and two-stage designs (Simon's)</li><li>○ Randomised designs</li><li>○ Adaptive designs</li></ul></li></ul>
11.00 - 11:30	Coffee Break
11:30 - 12:45	<ul style="list-style-type: none"><li>• Variability and Bias</li><li>• Descriptive statistics Common plots: Kaplan Meier, Waterfall, Forest plot</li></ul>
12:45-13.45	Lunch - Meet Professor Urania Dafni
14.00 16:00	Good Clinical Practice. speaker TBC
16.00-16.30	Coffee Break
16:30 – 17.30	GCP (Good Clinical Practice) speaker TBC Test for certificate in GCP

17:30 – 18.30	Exercise (SWOT Analysis Clinical Research in Latam)
19:00 21.00	Dinner with all participants & faculty

## Thursday 26 October 2017

08.00 - 09.00	<p>How to write an abstract/publication – C. Rolfo</p> <ul style="list-style-type: none"> <li>• What makes a great paper?</li> <li>• Tips to get your research published in high impact journals</li> <li>• What high impact journals are interested to publish?</li> </ul>
9.00- 10.45	<p>Statistics (Randomised Trials): (<i>Urania Dafni</i>)</p> <ul style="list-style-type: none"> <li>• Non-inferiority and Superiority Trials</li> <li>• Hypothesis Testing <ul style="list-style-type: none"> <li>○ Sample size, Power, Clinical Significance vs Statistical significance</li> </ul> </li> <li>• Estimating sample size parameters</li> <li>• Endpoints <ul style="list-style-type: none"> <li>○ Surrogate &amp; Composite Endpoints</li> </ul> </li> </ul>
10.45-11.00	Coffee Break
11.00-12.00	Exercise: Statistics
12.00-12.45	<p>Statistics (Results): <i>Urania Dafni</i></p> <ul style="list-style-type: none"> <li>• Multiple Testing</li> <li>• Interim analysis</li> <li>• Subgroup Analyses</li> </ul> <p>Meta-analysis</p> <p>Statistics Common Errors – <i>Urania Dafni</i></p>
12:45 - 13:30	Lunch - Meet Christian Rolfo - Career development
13.30- 14:30	<p>Regulation in Clinical Trials</p> <ul style="list-style-type: none"> <li>• FDA (Luis Raez )</li> <li>• EMA (Christian Rolfo)</li> <li>• LOCALS : Brasil and Peru: Different approaches in legislation in the same geographic area (Gustavo Werutsky –Denisse Bretel-)</li> </ul>
14:30 - 15:00	Reading Literature With A Critical Eye: Peter Van Dam
15:00 16.15	Exercise: publications review
16.15-16.30	Coffee Break

16:30 – 17:15	Writing a clinical trial protocol: C. Rolfo
17:15 – 17:45	Clinical Cancer Research Concepts <ul style="list-style-type: none"><li>• Introduction Phase I trials (C Rolfo)</li><li>• Single Arm Phase II (L Ruez)</li><li>• Randomized trials Phase II and Phase III (H Gomez)</li><li>• Phase IV (Luis Ruez)</li></ul>
17:45 18.30	Exercise: Design a Clinical Trial (groups) & discussion

## Friday 27 October 2017

08.00-9.45	<p>Knowing ESMO: introduction, history, work and future perspectives</p> <p>C. Zielinski</p> <p>Clinical Cancer research Worldwide – (C. Zielinski)</p> <p>Clinical Research in Latin-American (H Gomez)</p>
9.45 – 11.15	<p>Funding and Implementations -</p> <ul style="list-style-type: none"> <li>• Industry and CROs &amp; Grants</li> <li>• Academic Groups – Luis Ruez</li> </ul>
11.15-11.30	Coffee Break
11.30 – 12.15	<p>Clinical Trial Design: Hypothesis IIT(the answer is the question)</p> <p>Urania Dafni</p>
12.15 – 12.45	<ul style="list-style-type: none"> <li>• Research network: Cooperative groups</li> <li>• C.Zielinski</li> </ul>
12.45-13.15	Exercise: Design a Clinical Trial (groups) & discussion corrections
13.15 – 14.00	Lunch with the expert: C. Zielinski
14.00 - 16:15	<p>Survey of the event</p> <p>Closing Ceremony– Awarding of Certificates and closing remarks</p>