



GECO - OLA - ESMO CLINICAL TRIALS WORKSHOP

GECO-OLA-ESMO CLINICAL TRIALS WORKSHOP FINAL PROGRAMME

Thursday 4th October 2018

8:30 - 9:00	REGISTRATION
9:00 - 9:25	WELCOME (Chairs Welcome: <i>C. Vallejos, C.Rolfo</i>) (Personal presentations)
9.25-10:00	Knowing ESMO: introduction, history, work and future perspectives ESMO : <i>C. Zielinski</i>
10:00- 11:00	Introduction: Clinical Cancer research Worldwide - (<i>C. Zielinski</i>) Clinical Research in Latin-American (<i>H Gomez</i>)
11.00 - 11:30	Coffee Break
11:30 - 12:45	Clinical Cancer Research Concepts <ul style="list-style-type: none"> • Introduction Phase I trials (<i>Christian Rolfo</i>) • Single Arm Phase II (<i>Andres Cardona</i>) • Randomised trials Phase II and Phase III (<i>C. Zielinski</i>)
12:45- 13.45	Lunch meet the expert: <i>Christian Rolfo</i>
14.00 - 16:00	Statistics (<i>Urania Dafni</i>) <ul style="list-style-type: none"> • Phase I design • Phase II designs:

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	<ul style="list-style-type: none"> ○ Single arm design: ○ One and two-stage designs (Simon's) ○ Randomised designs ○ Adaptive designs ● Variability and Bias ● Descriptive statistics ● Common plots: Kaplan Meier, Waterfall, Forest plot
16:00 - 16:15	Coffee Break
16:15 - 16:45	Clinical Trial Design: Hypothesis IIT(the answer is the question) (<i>Jacob Sands</i>)
16:45 - 19:45	GCP (Good Clinical Practice): Pfizer speaker
20:00- 21:00	Dinner meet the expert Christoph Zielinski

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Friday 5 th October 2018	
07:30 - 08:00	Ethics Principles <ul style="list-style-type: none"> History (Nuremberg, Belmont, Helsinki) (Carlos Vallejos)
08:00 - 09:00	Regulatory in Clinical Trials <ul style="list-style-type: none"> FDA (Luis Raez) EMA (Christian Rolfo) LOCALS : Chile and Peru: different approaches in legislation in the same geographic area (Christian Caglevic-Henry Gomez- Denisse Bretel)
09:00 - 10:30	Inform Consent Form (ICF) (Denisse Bretel) <ul style="list-style-type: none"> Description Parts Exercise (review different ICF, explain and talk with a patient) Christian Caglevic, Luis Raez, Denisse Bretel
10.30 10.45	Coffee Break
10:45 - 12:45	Statistics (Randomized Trials): (<i>Urania Dafni</i>) <ul style="list-style-type: none"> Non-inferiority and Superiority Trials Hypothesis Testing <ul style="list-style-type: none"> Sample size, Power, Clinical Significance vs Statistical significance Estimating sample size parameters Endpoints <ul style="list-style-type: none"> Surrogate & Composite Endpoints
12:45 - 13:45	Lunch (Meet Professor, Career development): <i>Luis Raez</i>
14:00 - 14:30	Phase IV trials and Observational Trials Design -Luis Raez <ul style="list-style-type: none"> Cohort Case Control
14:30 - 15:00	Statistics Common Errors - Urania Dafni

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15:00 16.15	Execericise: Statistics
16:15 - 16:30	Coffee Break
16:30 - 17:00	Writing a protocol: Jacob Sands
17:00 - 17:30	Reading the Literature With Critical Eye (Andres Cardona)
17:30 19.00	Exercise: Design a Clinical Trial (groups) & discussion Luis Raez, Denisse Bretel, Christian Caglevic , Jacob Sands, Discussion: Urania Dafni & Christian Rolfo

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Saturday, October 6th 2018	
08:00 - 09:00	Funding and Implementations - <ul style="list-style-type: none"> • Industry and CROs - Christian Rolfo • Academic Groups -Zielinski • Grants: Luis Raez
9:00 - 10:15	Statistics (Results): Urania Dafni <ul style="list-style-type: none"> • Multiple Testing • Interim analysis • Subgroup Analyses • Meta-analysis
10:15 - 10:30	Coffee Break
10:30 - 11:00	HOW TO WRITE AN ABSTRACT/PUBLICATION - Christian Rolfo - Luis Raez <ul style="list-style-type: none"> • What makes a great paper? • Tips to get your research published in high impact journals • What high impact journals are interested to publish?
11:00 - 12:30	Exercises : Luis Raez, Denisse Bretel, Christian Caglevic, Christian Rolfo Review Publications and comments per groups
12:30 - 13:45	Lunch & Closing Ceremony- Awarding of Certificates and closing remarks