

SLACOM - GECO - ESMO CLINICAL TRIALS WORKSHOP

REPORT, SURVEY AND GALLERY

24 - 26 OCTOBER 2016
LIMA - PERU

ESMO GOOD SCIENCE
BETTER MEDICINE
BEST PRACTICE

SLACOM

Organized by:

GECOPERU



SLACOM - GECO - ESMO CLINICAL TRIALS WORKSHOP

24 - 26 OCTOBER 2016
LIMA - PERU

ORGANIZED BY



IN COLLABORATION



Speakers

Carlos Vallejos Sologuren
PERU



Dr. Carlos Vallejos Sologuren is principal member of AUNA, one of the most important private healthcare services in Perú, founded in 2009 as a result of the combined strenghts of Health and Investment professionals, based in the values and principles of Oncosalud. In 1996, he founded the Sociedad Peruana de Oncología Médica, being its first President until 1997. By the same time, he took the Presidency of the Chair of Oncocenter, and he was incorporated as Associate Academic of the "Academia Nacional de Medicina". In 1998, he was reelected as President of the Sociedad Peruana de Oncología Médica, and the next year he took responsibility of the functions of consultant doctor of Medical Oncology in "Hospital Central de la Policía Nacional", and he was regional delegate of the "Federation Latinoamericana de Sociedades de Cancerología". In 1999, he created ONCOSALUD, the main private initiative that gives oncological services to Perú. One year later, he was elected Principal Investigator of Eastern Cooperative Oncology Group (ECOG), one of the most important scientific organizations in the World, being at this time the only Latin-American Member with authorized voice. From December 2002 to July 2006, he got the role of General Head of INEN, starting a new approach to fight cancer and the deconcentration and decentralization process for oncological services in Perú. On July 2003, he was chosen as Regional Representative of the "European Society for Medical Oncology" (ESMO) for South America, and since that same year, he became part of the Editorial Committee of the Journal of Oncology. He is the author of the thesis "Mieloma Múltiple" (1968); and "Leucemia Aguda" (1987); He participated in more than 169 researches related to oncology and as result of this he published more than 60 scientific and academic articles and almost 118 abstracts in several books and magazines. Besides being researcher, he is coordinator of projects related to cancer treatment, working as speaker for multiple scientific and academic contests in this country and abroad. Afterward, he was Minister of Health of Perú, from July 2006 to December 2007, whose accomplishments were detailed in his book entitled: "De Pronóstico Favorable". In November 2006, he received an award as the "Best former student 2006" from The University of Texas M.D. Anderson Cancer Center, Texas, United States, one of the best cancer hospitals in that country. He was received more than 46 awards and recongnitions. In Geneva, during his last session on 2008, he was chosen Vice-President of the Executive Committee of the World Health Organization until 2009. In 2010, he has been named Director Member of the International Affair Committee of the American Society of Clinical Oncology – ASCO and in November that same year, he became member of International Education Council of Molecular Targeted Therapy of Cancer (MTTC) as chair under ESMO's sponsorship. He return the role of Institutional Head of the Instituto Nacional de Enfermedades Neoplásicas (INEN), from February 2008 to January 2012, during this period he was manager and leader of the first National Program for Prevention and Early Detection of Cancer, which was implemented in Peru, in 2011. In 2011 he has been named President of the Latin American & Caribbean Society of Medical Oncology (SLACOM). In May 2012 he was named as Visiting Professor at the Universidad del Salvador in Argentina.



Christoph Zielinski
AUSTRIA

Professor Zielinski is Director of the Clinical Division of Oncology and Chairman of the Department of Medicine I at Medical University Vienna, Austria. He serves as Coordinator of the Comprehensive Cancer Center at Medical University Vienna and the General Hospital in Vienna, Austria, and is President of the Central European Cooperative Oncology Group. Professor Zielinski completed his medical training at the University Hospital Vienna and began his career with a position as a research fellow at the Cancer Research Center at Tufts University, Boston, USA. His recent clinical research activities cover a wide range of cancer therapies, with particular focus on clinical trials, breast and lung cancer research and treatment and development of targeted drugs. He has published env. 450 original papers and reviews in peer-review journals and many books including the "State of Oncology 2013" published together with Peter Boyle et al. by IPRI. He is member of the editorial board of numerous peer review journals. In 2013, Professor Zielinski received a "Dr. h.c." degree from Titu Maiorescu University in Bucharest. Professor Zielinski is a member of the American Society of Clinical Oncology (ASCO), the American Association for Cancer Research (AACR) and the European Society for Medical Oncology (ESMO). Prof. Zielinski serves on a series of committees of the European Society of Medical Oncology (ESMO) including its Executive Committee in which he is a member for 2014. He was also Local Officer for the ESMO Congress 2012 in Vienna, Austria.

Speakers

Christian Rolfo **BELGIUM**



Prof. Dr. Christian Rolfo, MD, PhD, MBAH (Cordoba, Argentina), is board certified oncologist by University of Milan, Italy; and has obtained his PhD in Clinical and Experimental Oncology with a thesis on EGFR in NSCLC. He has worked in the Spanish Group for Lung Cancer, under the direction of Prof. Rafael Rosell, actively involved in studies of molecular biology and clinical research in lung cancer. He has completed his training in Phase I program at MD Anderson, Texas, USA with Prof. David Hong. In February 2011, has been appointed “visiting professor” in Medical Oncology by the Molecular and Clinical Genetic Oncology Unit at the Interdepartmental Centre of Research in Clinical Oncology, School of Medicine, University of Palermo (Italy). From 2012 is Associate Professor in Oncology and Senior Staff Member, in the Department of Oncology at the University Hospital Antwerp (Belgium), headed by Prof. Marc Peeters. Currently, Prof. Rolfo, is Head of Phase I - Early Clinical Trials Unit Director of Clinical Trials Management Program in Oncology and Director of “Investigational Cancer Therapeutics Fellowship and Drug Development: Clinical and Experimental” at Antwerp University Hospital in Belgium. Prof. Rolfo is focus on Clinical Research, Drug Development and Resistance. He is also busily working on Research Program of Liquid Biopsies in Lung Cancer, more specifically in exosomes isolation and circulating tumor DNA. He is the author of numerous papers published in worldwide prestigious journals including New England Journal of Medicine, Lancet Oncology, Translational Oncology, Lung Cancer, among others. Prof. Rolfo is a speaker at national and international forums in Lung Cancer and Drug Development; From 2013 is part of the membership Board of IALSC (International Association for the Study of Lung Cancer) and member of prestigious Societies including AACR, BACR, EACR, ESMO and ASCO.



Urania Dafni **GREECE**

Urania Dafni is Professor of Biostatistics, University of Athens; Director, Frontier Science Foundation – Hellas. She holds a Science Doctorate from the Department of Biostatistics, *Harvard School of Public Health*. She has been one of the founding members of the *Eastern Mediterranean Region of the International Biometric Society (EMR-IBS; 2001-present)* and President of *EMR-IBS (2005-2007)*. In 2008, she received a Recognition Award from the *International Biometric Society (IBS)* for Outstanding Dedication and Exemplary Service as Biometric Bulletin Editor, 2005-2008, and she is currently a member of the Executive Committee of *IBS (2007-2010)*. She has served as the scientific director of the *National Syndromic Surveillance program* for the Athens 2004 Olympic games and currently participates in the European Community Grant on Syndromic Surveillance (Triple S-AGE). She is an Associate Editor of the on line journal *Advances in Disease Surveillance*, and reviewer of several scientific journals. She is a member of the BoD of the *National Network for the Prevention of Accidents and Violence*. She has been a member of the organizing and/or scientific committee of international conferences (XXIIIrd IBS International Conference, 2006; International Society for Clinical Biostatistics - ISCB28, 2007) and chair of the 3rd EMR-IBS conference (2005). She has published over 90 papers in high impact peer-reviewed international journals (including *Biometrics*, *JASA*, *NEJM*, *JCO*, *MMWR*, *J Intern Med*, *Arthritis Rheum*, *Control Clin Trials*). She has participated in numerous Clinical Trials mainly in Cancer, AIDS, and auto-immune diseases and her research interests include surrogate markers, multivariate count data, adaptive study design and methods accounting for crossover.

David Hong **Houston , USA**



Is a Associate Professor Associate Professor and Deputy Chair, Department of Investigational Cancer Therapeutics, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX. His research interests are: Phase I studies, Drug development, The molecular basis of cancer and clinical Trials Design.

He is an recognized international expert in this field. Prof. Hong is author of several publications in high impact factor journals and awarded several accolades and research grants.

Speakers

Denisse Bretel Morales **PERÚ**



Dr. Denisse Bretel is a breast surgeon trained at National Cancer Center in Lima, Peru. Is the director of Peruvian Oncology Cooperative Oncology Group, A excellence group in Clinical Research in Latin America. Dr. Bretel have an extensive expertise in clinical trial management across several Latin American countries. Is also member of several oncology societies, including ESMO, EORTC SLACOM. She is in charge of organization of several educational events in clinical research and participate in international cooperation for clinical trials with countries like Belgium, Spain, USA, Switzerland.



Christian Caglevic **CHILE**

Christian Caglevic is a Medical Oncologist graduated at Universidad de Chile, Postgrade in Molecular Oncology and Targeted Therapies at Universidad del Salvador, Buenos Aires, Argentina. Currently, he is Medical Oncologist at Fundación Arturo López Pérez of Santiago, Chile and Head of the Early Development of Drugs Unit at the same institution. Dr. Caglevic has been principal investigator and sub investigator in several clinical trials in solid tumors. He has several publications in solid tumors treatment but also in basic sciences. He participates in ASCO as collaborative member and is also member of ESMO, ILOGI, Sociedad Médica de Chile, IASLC, SIOG, Sociedad Chilena de Oncología Médica, Grupo Latinoamericano de Tumores Gastrointestinales. Dr Caglevic is Board Member of Ecancer Medical Science and recently reviewer of several journals as Oncotarget and Revista Médica de Chile.

Henry Gomez Moreno **PERÚ**



Henry L. Gómez, MD is graduated from the School of Medicine of the Universidad San Agustín (Arequipa – Peru), obtaining his speciality in Medical Oncology from the Universidad Peruana Cayetano Heredia (Lima – Peru) and the Medical Residence in the Instituto Nacional de Enfermedades Neoplásicas (INEN, Lima – Peru). He has a Post graduate Fellowship at the Hospital 12 de Octubre (Madrid-Spain) in the Service of Medical Oncology. Dr. Gómez earned a Master degree in Molecular Oncology from the Centro Nacional de Investigaciones Oncológicas (CNIO, Spain) and a Doctoral Degree in Medicine from the Universidad Peruana Cayetano Heredia (Lima – Perú). Currently, Dr. Gomez is the Director of the Division of Medicine of the INEN and Associate member of the Peruvian Academy of Medicine. Dr. Gomez´s major interest is clinic and translational research of Breast Cancer.



Edgardo S. Santos

Dr. Santos is a board certified oncologist with the Center for Hematology-Oncology, the Lynn Cancer Institute, and the Lynn Cancer Institute at Boca Raton, where he is Director of Cancer Research. Dr. Santos graduated from the University of Panama School of Medicine, and completed his internship and residency at Jackson Memorial Hospital in Miami, Florida. He is a member of the International Association for the Study of Lung Cancer, and he has a fellowship from the American College of Physicians, among other professional organizations.

Speakers

Ana Oton **Denver , USA**



Dr. Ana B. Oton is an Associate Professor of Medical Oncology at the University of Colorado Denver and Denver Health Medical Center. She completed her fellowship training in Hematology-Oncology at the University of Pittsburgh. In 2007, she joined the University of Colorado Denver, Division of Medical Oncology in a dual appointment with Denver Health Medical Center as medical Oncologist and Hematologist. She devotes her time between clinical, teaching and research activities. She is currently the Director of the Clinical Trials Program at the Division of Hematology-Oncology at Denver Health Medical Center and the principal investigator of several therapeutic clinical trials in both institutions. Her research interests are new drug development in the field of thoracic malignancies and palliative care.



Luis E. Raez **Miami, USA**

Luis E. Raez, MD, FACP, FCCP, is the Medical Director of Memorial Cancer Institute, he is also the Oncology Research Director of Memorial Health Care System and Director of the Thoracic Oncology Program. He is also Clinical Associate Professor of Medicine at Florida International University and Visiting Professor of Medicine at Cayetano Heredia University in Peru. He was an Associate Professor of Medicine, Epidemiology and Public Health, and a Co-Director of Thoracic Oncology at Sylvester Cancer Center/University of Miami for 10 years (2001-2011). He has expertise in medical oncology in the areas of lung cancer, and head and neck cancer. He designs phase I-III clinical trials with new chemotherapeutic agents and combinations. Dr. Raez does translational research in the areas of cancer vaccines. He has been funded by NCI and the pharma industry. He has given oral presentations and lectures in national and international meetings in the US, Europe, Latin-America and Asia. He is American Board Certified in: Internal Medicine, Medical Oncology and Geriatric Medicine. He is Board Eligible in Hematology. He is a member of AACR, ESMO, ASCO, IASLC, ALLIANCE, NCCTG, ACCP, ACP, ACSG, FLASCO among other institutions.

*Program Final**Monday, October 24th, 2016*

8:30 - 9:00	REGISTRATIONS
9:00 - 9:25	WELCOME (Chairs Welcome: C. Vallejos , C. Rolfo) (Personal presentations)
9:25 - 10:00	Knowing ESMO: introduction, history, work and future perspectives ESMO : C. Zielinski
10:00 - 11:00	Introduction: Clinical Cancer research Worldwide (C. Zielinski) Clinical Research in Latin - American (H. Gomez)
11:00 - 11:30	Coffee Break
11:30 - 12:45	Clinical Cancer Research Concepts <ul style="list-style-type: none">• Introduction Phase I trials (David Hong)• Single Arm Phase II (Ana Oton)• Randomized trials Phase II and Phase III (C. Zielinski)
12:45 - 13:45	Lunch meet the expert: Christian Rolfo
14:00 - 16:00	Statistics (Urania Dafni) <ul style="list-style-type: none">• Phase I design• Phase II designs:<ul style="list-style-type: none">◊ Single arm design:◊ One and two-stage designs (Simon's)◊ Randomized designs◊ Adaptive designs• Variability and Bias• Descriptive statistics• Common plots: Kaplan Meier, Waterfall, Forest plot

Program Final*Monday, October 24th, 2016*

16:00 - 16:15	Coffee Break
16:15 - 16:45	Clinical Trial Design Hypothesis IIT (the answer is the question) (David Hong)
16:45 - 19:45	GCP (Good Clinical Practice): PPD CRO speaker
20:00 - 21:00	Dinner meet the expert Christoph Zielinski

Tuesday, October 25th, 2016

07:30 - 08:00	Ethic Principles <ul style="list-style-type: none">◊ History (Nuremberg, Belmont, Helsinki) (C. Vallejos)
08:00 - 09:00	Regulatory in Clinical Trials <ul style="list-style-type: none">◊ FDA (David Hong)◊ EMA (Christian Rolfo)◊ LOCALS: Chile and Peru: different approaches in legislation in the same geographic area (Christian Caglevic - Henry Gomez)
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, Ana Oton, Denisse Bretel
10:30 - 10:45	Coffee Break

*Program Final**Tuesday, October 25th, 2016*

10:45 - 12:45	Statistics (Randomized Trials): (Urania Dafni) <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) : David Hong
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	Statics Common Errors - Urania Dafni
15:00 - 16:15	Exercise: Statistics
16:15 - 16:30	Coffee Break
16:30 - 17:00	Writing a protocol: Edgardo Santos
17:00 - 17:30	Reading the Literature with Critical Eye (Ana Oton)
17:30 - 18:00	Funding and Implementations <ul style="list-style-type: none">• Industry and CROs - Ana Oton
18:00 - 19:00	Exercise: Design a Clinical Trial (groups) & discussion David Hong, Denisse Bretel, Christian Caglevic, Ana Oton Discussion: Urania Dafni & Christian Rolfo

Program Final

Wednesday, October 26th, 2016

08:00 - 09:00	Funding and Implementations <ul style="list-style-type: none">• Academic Groups - Henry Gomez• Grants: Luis Raez
09:00 - 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 AND ANSTRACT/PUBLICATION Christian Rolfo <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 & Closign Ceremony - Awarding of Certificates and closing remakrs

PARTICIPANTS



Peru



Chile



Colombia



Costa Rica



Brasil

- 41 applications in time frame
- 5 applications outside frame time
- 40 accepted
- 30 participants
- 5 nacionalities
- Central and South America



LATIN AMERICAN SPEAKERS



Peru



Chile



Panama

EUROPEAN AND US SPEAKERS



Austria



Belgica



Grecia

USA - Houston



USA - Denver



USA - Miami



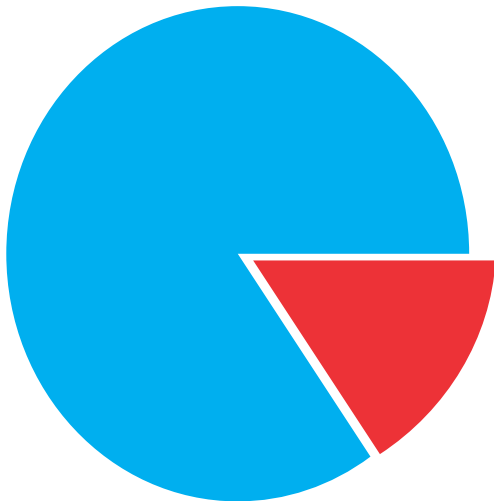
SATISFACTION SURVEY

QUESTION TO ANSWER:

- ★ Organization
- ★ Venue of meeting
- ★ Registration
- ★ How did you hear about this workshop
- ★ Food and Beverage
- ★ Hotel accomodation
- ★ Program
- ★ Interaction with colleagues and speakers
- ★ Possibility to recommend the event
- ★ The event fulfuill your reason to attending
- ★ Main reason for attending

Report

SURVEY ANALYSIS

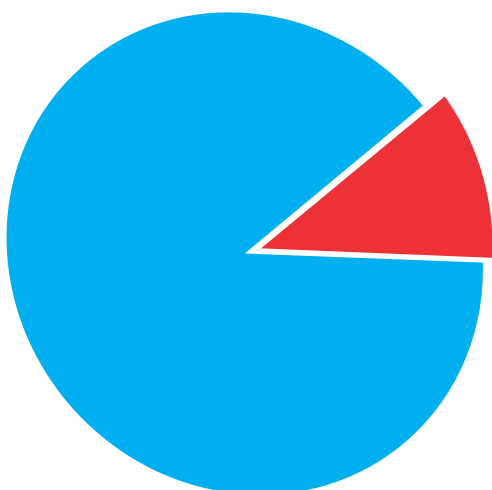


RECOMEND TO OTHERS

- Yes, Absolutely!
- Yes Probably
- No

100% Yes

SURVEY ANALYSIS



CONFERENCE FULFILL YOUR REASON TO ATTENDING

- Yes - Absolutely
- Yes - But not to my full extent
- No

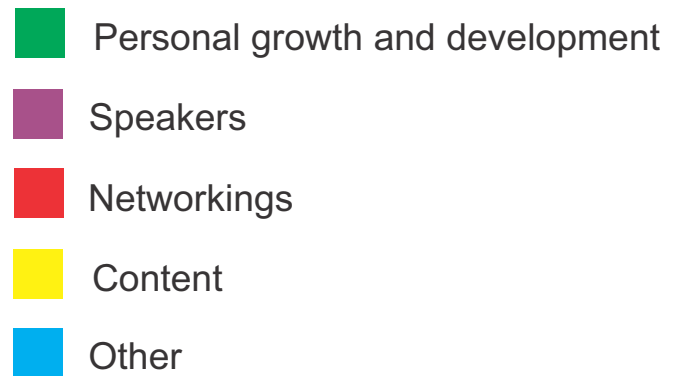
100% Yes

Report

SURVEY ANALYSIS

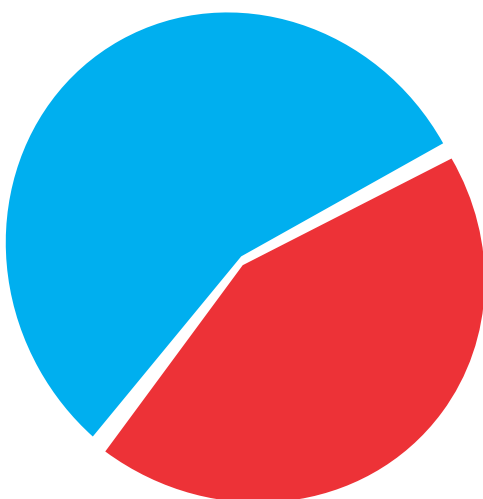


REASON FOR ATTENDING

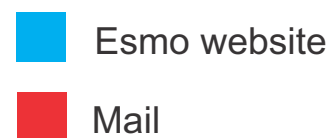


68% Personal growth and development

SURVEY ANALYSIS



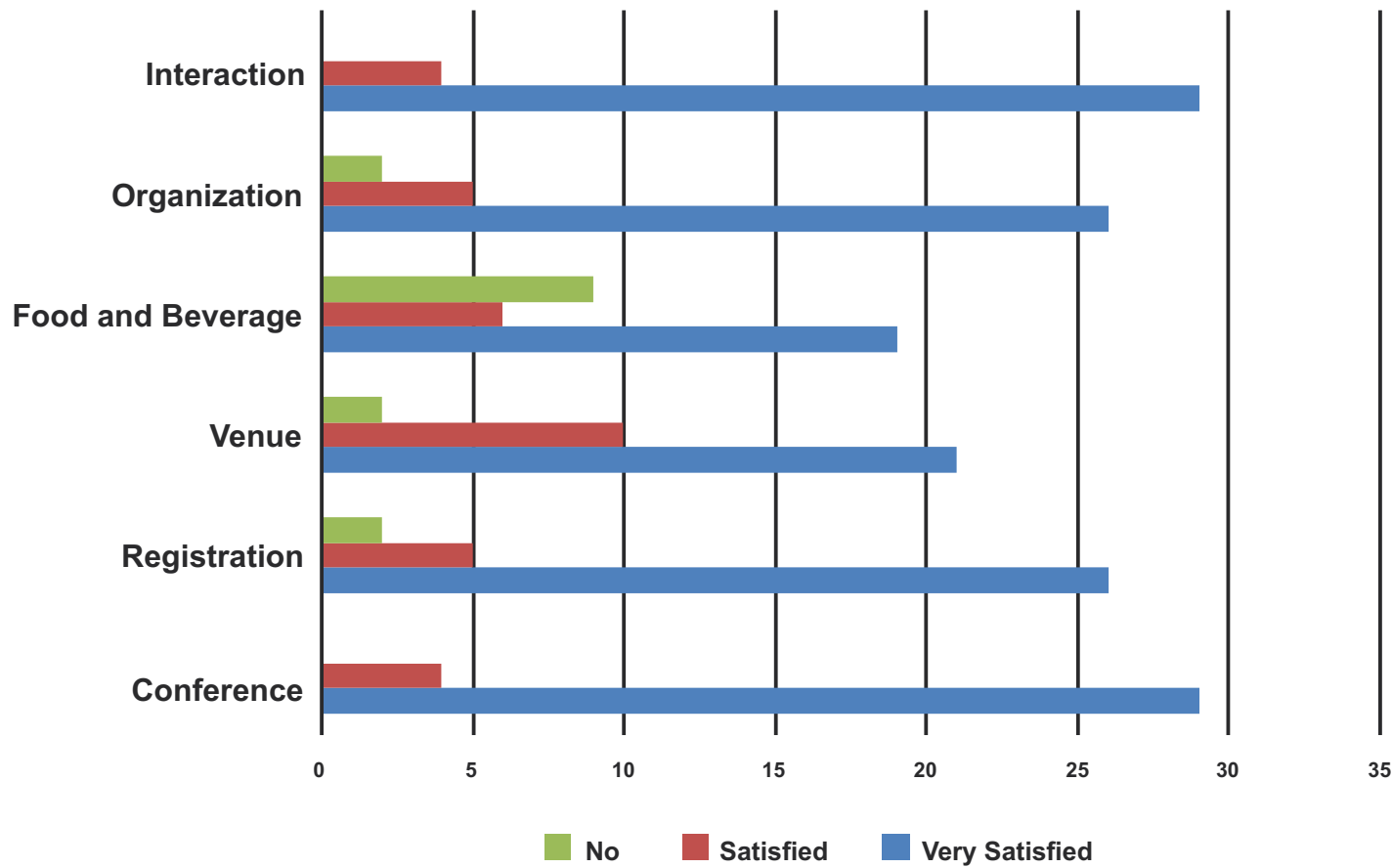
HOW DID YOU HEAR ABOUT THIS?



**58 %Esmo website
42 % Mail**

SURVEY ANALYSIS

SATISFACTION



SURVEY ANALYSIS

WHAT WAS THE MOST BENEFICIAL ASPECT OF THE WORKSHOP?

- Exercises
- Interaction with speakers
- Networking
- Statistics
- Speakers experience
- “Open my mind”
- Quality of presentations
- Industry - academia vision

SUGGESTIONS FOR NEXT EDITION

- | | |
|--------------------------|---|
| - More exercises | - Review our ongoing protocols |
| - Translational research | - Split the statistics and more exercises |
| - Biomarkers | - PK/PD |
| - Collaborative groups | - Cooperative trials |
| - Management of AE | - Immunotherapy |
| - Retrospective trials | |

GALLERY



GALLERY



Presentation Workshop



Statistics with Urania Dafni



Discussion Workshop - David Hong

GALLERY



GALLERY



Review publications and comments per groups



Review publications and comments per groups

Report

GALLERY



GALLERY



Group Interaction



Faculty Dinner