

WORKSHOP

“HUMAN APPLICATIONS AND CLINICAL TRIALS DESIGN”

Toledo, 28th and 29th June 2011

PALACIO DE BENACAZÓN
CALLE DE RECOLETOS Nº 1

The workshop on clinical trials and human applications is designed both as an introduction to the field for basic science scientists and to illustrate key concepts in clinical trial design, interpretation and current controversial topics for clinical investigators. The speakers will cover topics including choosing the right control group and endpoints; demystifying superiority, equivalence, and non-inferiority trials; and evaluating *p* values, power, and subgroup analyses to understand unexpected trial results. Since the clinical trial represents a significant part of the total cost of the development of a new drug, the regulation by international agencies and a primer on the logistics and costs involved will also be covered. These lectures will use examples from recent HIV treatment and will include time for Q&A.

Confirmed Speakers

Carlos M. Martínez. *Janssen-Cilag (Toledo, Spain)*

Agustín Gómez de la Cámara. *CAIBER-Spanish Platform of Clinical Trials. Hospital Universitario 12 de Octubre (Madrid, Spain)*

José R. Arribas. *HIV Unit. Hospital Universitario La Paz (Madrid, Spain)*

Federico Pulido. *HIV Unit. Hospital Universitario 12 de Octubre (Madrid Spain)*

Ruth Diazaraque. *Director Medical Affairs. International Gilead Sciences (Uxbridge, UK)*

Arantxa Sancho. *Clinical Pharmacology. Hospital Universitario Puerta de Hierro (Majadahonda, Spain)*

Esther Cabrero. *Director of Research in Virology. Abbot Laboratories (Madrid, Spain)*

Organizing committee:
Rafael Delgado
Javier Rojo

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*“Carbohydrated Multivalent Systems as
Tools to Study Pathogen Interactions
with DC-SIGN”*

www.carmusys.iiq.csic.es

Tuesday 28th June 2011

14:00 Registration

Chairperson: Oliviana Calin. MPI (Berlin, Germany)

15:00 Carlos M. Martínez. *Janssen-Cilag (Toledo, Spain)*

“Discovery of New Drugs and Preclinical Development”

16:00 Agustín Gómez de la Cámara. *Universita' CAIBER-Spanish Platform of Clinical Trials. Hospital Universitario 12 de Octubre (Madrid, Spain)*

“The Clinical Trial as a Research Tool (General Concepts, History, Perspective)”

17:00 *Coffee break*

Chairperson: Maurizio Perdicchio. VUmc (Amsterdam, Netherlands)

17:30 José R. Arribas. *HIV Unit. Hospital Universitario La Paz (Madrid, Spain)*

“Clinical development: The Example of Highly Active Antiretroviral Treatment”

18:30 *Guided Visit to Toledo*

21:00 *Special Workshop Dinner*

Wednesday 29th June 2011

9:00 Federico Pulido. *HIV Unit. Hospital Universitario 12 de Octubre (Madrid, Spain)*

“Trick or treat in Clinical trials: Superiority, Equivalence or Non-Inferiority: Which is better?”

10:00 Ruth Diazaraque. *Director Medical Affairs. International Gilead Sciences (Uxbridge, UK)*

“Clinical trials and clinical practice. Can we bridge the gap?”

11:00 *Coffee break*

Chairperson: Rasika Ramdasi. INSERM (Paris, France)

11:30 Arantxa Sancho. *Clinical Pharmacology. Hospital Universitario Puerta de Hierro (Majadahonda, Spain)*

“Regulatory Gods: The EMEA and the FDA”

12: 30 Esther Cabrero. *Director of Research in Virology. Abbot Laboratories (Madrid, Spain)*

“Clinical Trial Logistics and Pharmacoeconomics.”

13:30 Concluding remarks (Javier Rojo)

14:00 *Lunch*



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Registration Form

- Number of participant is limited
- Fellowships available

First name: Name:

Age: Nationality: Organization:

Date of Birth: Place of Birth:

Address:.....

Postal code: Location: Country:

E-mail:

Tel:

Fax:

Include with the application the following documents:

- Short curriculum vitae
- A letter of interest for the workshop

This form and the corresponding documents should be sent via e-mail before June 1st to:

David J. Parras Guijarro (IIQ-CSIC): david.parras@iiq.csic.es