



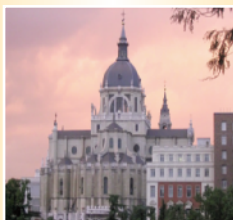
JOINT DIA/ESAME/AMIFE WORKSHOP ON INNOVATIVE MEDICINES WHEN IS A NEW DRUG A THERAPEUTIC INNOVATION?

(This workshop will be held in Spanish)

WEDNESDAY, OCTOBER 17, 2007 AUDITORIUM HOTEL, MADRID, SPAIN



THIS EVENT IS PART OF THE
CLINICAL FORUM 2007
OCTOBER 15 - 19, 2007
AUDITORIUM MADRID HOTEL, MADRID, SPAIN



**Flexibility and Networking Highlight
This One-of-A-Kind Event!**

The Clinical Forum was developed to maximise the synergies between the various areas of expertise, enhance cross-functional teamwork and allow delegates excellent multi-disciplinary networking opportunities.

The Forum will feature a total of eleven conferences, workshops and training courses, covering the areas of Clinical Data Management, eClinical, Clinical Research and Development, Clinical Trial Management, Information Technology, Pharmacovigilance, Statistics, Knowledge Management, Medical Writing, Medical Information & Communications and Therapeutic Innovation.

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Register now for the most comprehensive and best value clinical conference in Europe this year, with rates including VAT from:

1	Day	EUR	749.00
2-3	Days	EUR	1' 284.00
4	Days	EUR	1' 599.65
5	Days	EUR	1' 915.30

For further information on the DIA Clinical Forum 2007, please contact the DIA Europe Customer Services Department +41 61 225 51 51; email: diaeuropa@diaeuropa.org; or visit the DIA website www.diahome.org.

Chairpersons

Xavier Carné

Head of Clinical Pharmacology Department,
Hospital Clínic, Barcelona

Jorge González-Esteban

President,
AMIFE – Asociación Española de Médicos de la Industria Farmacéutica

Organised by

Drug Information Association (DIA), ESAME Foundation & AMIFE

In collaboration with



Key topics

- Innovation
- Innovative Medicines
- Clinical Development of Innovative Medicines
- Pricing & Reimbursement of Innovative Medicines

Who should attend

Professionals in medical affairs, clinical research, drug development, regulatory affairs, outcomes research, pharmacovigilance, clinical research operations, quality assurance, clinical data management, biostatistics, pricing & reimbursement, marketing, study sites.

To register online, please visit www.esame.org
or contact ESAME on +34 918 06 21 26, Fax: +34 918 04 53 35

If you would like to combine this workshop with other meetings, workshops or training (in English) that form part of the DIA Clinical Forum (October 15-19) and take advantage of significant cost savings as a result, please visit the DIA website at www.diahome.org and click on the Clinical Forum icon, or contact DIA Europe on Telephone +41 61 225 51 51; Fax: +41 61 225 51 52; Email: diaeuropa@diaeuropa.org

WEDNESDAY, OCTOBER 17, 2007

09:00 REGISTRATION

Opening Session

09:30 **DIA, ESAME Foundation & AMIFE Welcome and Opening**
Brigitte Franke-Bray

Director DIA Europe, Switzerland

Gonzalo Hernández

Director ESAME Foundation & Scientific Director Health LEIA, Spain

Jorge González-Esteban

President AMIFE, Asoc. Española Médicos Industria Farmacéutica, Spain

SESSION 1

THE DEVELOPMENT OF INNOVATIVE MEDICINES

09:45 Session Chair:

Xavier Carné

Head of Clinical Pharmacology Department, Hospital Clinic, Barcelona

10:00 **What is Innovation in Biomedicine?**

What does Therapeutic Innovation Mean in Medical Practice?

Agustín Gómez de la Cámara
Head of Clinical Epidemiology Department,
Hospital 12 Octubre, Madrid

10:40 **Coffee-Break**

11:10 **Life Cycle Plan for Registration of Innovative Medicines**

What Sort of Clinical Development Plan should be Planned for the Registration of an Innovative Drug?

José María Giménez Arnau
Chief Scientific Officer, Novartis Spain

11:50 **Therapeutic Innovation**

When a new Drug or a New Indication is Considered a Therapeutic Innovation?

Dolores Montero
Agencia Española del Medicamento y Productos Sanitarios

12:30 **Debate - Discussion**

13:30 **Lunch**

SESSION 2

THE PRICING & REIMBURSEMENT OF INNOVATIVE MEDICINES

15:00 Session Chair:

Jorge González-Esteban

President AMIFE (Asociación Española de Médicos de la Industria Farmacéutica)

15:10 **Health Outcomes Research Plan for P&R of Innovative Medicines**

What Sort of Health Outcomes Research and Pharmacoeconomics Plan should be Planned for an Innovative Drug?

Javier Soto
Head of Health Outcomes Research and Pharmacoeconomics Department, Pfizer

15:40 **Pricing & Reimbursement of Innovative Medicines**
When should an Innovative Therapy be Funded by Health Authorities?

- **Pharmaceutical Industry**
Javier Urzay
Director Department Service to the Associated Platform of Innovative Medicines Farmaindustria
- **Expert in Health Services Research**
Pablo Lázaro y de Mercado
Director TAISS – Advanced Technologies of Research in Health Services, Madrid
- **Comunidad Autónoma**
Antonio Torres
Director General de Calidad, Investigación y Gestión del Conocimiento, Consejería de Salud, Junta de Andalucía, Sevilla

17:30 **Debate - Discussion**

18:30 **Closing Remarks**

09:00 INSCRIPCIÓN

09:30 Sesión de apertura

09:30 Apertura y Bienvenida a cargo de DIA, Fundación ESAME

y AMIFE

Brigitte Franke-Bray

Directora DIA Europa, Suiza

Gonzalo Hernández

Director Fundación ESAME y Director Científico LEIA Salud,

España

Jorge González-Esteban

Presidente AMIFE, Asoc. Española Médicos Industria

Farmacéutica, España

SESIÓN 1

EL DESARROLLO DE MEDICAMENTOS INNOVADORES

09:45 Sesión presidida por:

Xavier Carre.

Jefe del Servicio de Farmacología Clínica, Hospital Clinic,

Barcelona

10:00

¿Qué es innovación en Biomedicina?

¿Qué innovaciones científicas son consideradas como las

en la Práctica Médica?

¿Qué relevantes y ¿Qué significa innovación Terapéutica

Agustín Gómez de la Cámara

Jefe del Servicio de Epidemiología Clínica,

Hospital 12 Octubre, Madrid

10:40

Café

11:10 Plan de Ciclo de Vida para el Registro de Medicamentos

Innovadores

¿Cómo debe ser el Plan de Ciclo de Vida para el Registro

de un Medicamento Innovador?

José María Giménez Arnau

Chief Scientific Officer, Novartis Spain

11:50

Innovación Terapéutica

¿Cuándo se considera una Innovación Terapéutica a un

Nuevo Medicamento o a una Nueva Indicación?

Dolores Montero

Agencia Española del Medicamento y Productos Sanitarios

12:30

Debate

13:30 Almuerzo

SESIÓN 2

PRECIO Y REEMBOLSO DE MEDICAMENTOS INNOVADORES

15:00

Sesión presidida por:

Jorge González-Esteban

Presidente AMIFE (Asociación Española de Médicos de la

Industria Farmacéutica)

15:10

Plan de Investigación de Resultados en Salud y

Farmacoeconomía de los Medicamentos Innovadores

¿Cómo debe ser el Plan de IRS y de Farmacoeconomía de

un Medicamento Innovador?

Javier Soto

Jefe del Departamento de Investigación de Resultados en

Salud y Farmacoeconomía, Pfizer

15:40

Precio y Reembolso de Medicamentos Innovadores

¿Cómo debería ser la Evaluación del Valor Terapéutico y

Farmacoeconómico de un Medicamento Innovador?

¿Cuál podría ser el Precio de un Medicamento Innovador

en función del Grado de Innovación y de su Valor

Médico-Terapéutico, Social y/o Farmacoeconómico?

¿Cuándo una Innovación Terapéutica debería ser

financiada?

Industria Farmacéutica

Javier Urzay

Director Departamento Servicio al Asociado

Plataforma de Medicamentos Innovadores

Farmaindustria

Experto en Investigación en Servicios de Salud

Pablo Lázaro y de Mercado

Director, Técnicas Avanzadas de Investigación en

Servicios de Salud - TAISS, Madrid

Comunidad Autónoma

Antonio Torres

Director General de Calidad, Investigación y Gestión

del Conocimiento, Consejería de Salud, Junta de

Andalucía, Sevilla

17:30

Debate

18:30

Clausura

Workshop organizado por la DIA, ESAME y AMIFE sobre MEDICAMENTOS INNOVADORES

¿Cuándo un Nuevo Medicamento es una Innovación Terapéutica?

(ESTE TALLER SE CELEBRARÁ EN CASTELLANO)

MIÉRCOLES, 17 DE OCTUBRE DE 2007, EN EL HOTEL AUDITORIUM DE MADRID, ESPAÑA



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Destinatarios

Profesionales de los departamentos médicos, registros, I+D, investigación clínica, investigación de resultados en salud y farmacoeconomía, precio y reembolso, relaciones institucionales, marketing, y farmacovigilancia.

- Innovación en Biomedicina
- Medicamentos Innovadores
- Desarrollo Clínico de Medicamentos Innovadores
- Precio y Reembolso de Medicamentos Innovadores

Temas principales

En colaboración con

Organizado por

AMIFE (Asociación de Medicina de la Industria Farmacéutica en España) y AMIFE Drug Information Association (DIA), La Fundación ESAME y AMIFE

Presidentes

Xavier Carné
Jefe del Servicio de Farmacología Clínica,
Hospital Clinic, Barcelona

Presidente de

Jorge González Esteban
Presidente de AMIFE (Asociación de Medicina de la Industria Farmacéutica en España)

Para inscribirse visite www.esame.org o contacte

con Fundación ESAME en el número de teléfono +34 918 06 21 26

o enviando un fax al número +34 918 04 53 35.